The Association Between Pacifier Use and Breastfeeding, SIDS, Infection, and Dental Malocclusion

Systematic Review of the Literature

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The Institute Nurses' Network, Community Health Nurses Western Australia, and The Western Australian Centre for Evidence Based Nursing and Midwifery in collaboration with the Joanna Briggs Institute

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ABSTRACT

Objective

To critically review all literature related to the association between pacifier use and breastfeeding, Sudden Infant Death Syndrome (SIDS), infection, and dental malocclusion.

Background

Knowledge of the health and developmental consequences of pacifier use is important for parents and health professionals. Cursory review of the literature indicates that the use of a pacifier leads to negative outcomes, such as a shortened duration of breastfeeding, infection, and dental malocclusion. Conversely, pacifier use is associated with a reduced incidence of Sudden Infant Death Syndrome (SIDS). A closer examination of the literature reveals important methodological issues that cast doubt on the veracity of some findings. In the absence of a definitive answer, parents need clear information on which they can base child care decisions and health professionals need to be aware of the research evidence upon which they base their practice.

Method

The review comprised published and unpublished research literature. The search was restricted to reports published in English, Spanish, and German. The time period covered research published from January, 1960 to October, 2003. A protocol developed by New Zealand Health Technology Assessment was used to guide the search process. The search comprised bibliographic databases, citation searching, other evidence-based and guidelines sites, government documents, books and reports, professional websites, national associations, hand search, contacting national/international experts, and general internet searching.

Only randomised controlled trials, prospective cohort studies and, in the case of SIDS research, case-control studies were included. Purely descriptive and cross-sectional studies were excluded, as were qualitative studies and all other forms of evidence. Studies that did not meet the requirement of appropriate temporal sequencing of events and studies that did not present an estimate of the strength of association were not included in the final review.

Results

Only one out of a total of ten studies did not report a negative association between pacifier use and breastfeeding duration or exclusivity. Results indicate an increase in risk for a reduced overall duration of breastfeeding from twenty per cent to almost three fold. The data suggest that very infrequent use may not have any overall negative impact on breastfeeding outcomes. With regard to SIDS, all six studies found significantly fewer SIDS cases used a pacifier compared with controls. That is, pacifier use was associated with a reduced incidence of SIDS. These results indicate that the risk of SIDS for infants who did not use a pacifier in the last or reference sleep was at least twice, and possibly five times, that of infants who did use a pacifier. With regard to the association between pacifier use and infection and dental malocclusion it was found that, due to the paucity of epidemiological studies, no meaningful conclusion can be drawn.

Implications for practice

Because breast feeding confers an important advantage on all children and the incidence of SIDS is very low, it is recommended that health professionals generally advise parents against pacifier use, while taking into account individual circumstances.

EXECUTIVE SUMMARY

Objective

To critically review all literature related to pacifier use for full term healthy infants and young children.

The specific review questions addressed are:
What is the evidence of adverse and/or positive outcomes of pacifier use in infancy and childhood in relation to each of the following subtopics:

- breastfeeding;
- Sudden Infant Death Syndrome (SIDS);
- infection;
- dental malocclusion.

Inclusion Criteria

Specific criteria were used to determine which studies would be included in the review: 1) the types of participants; 2) the types of research design; and 3) the types of outcome measures. To be included a study has to meet all criteria.

Types of participants

The participants included in the review were healthy term infants and healthy children up to the age of 16 years. Studies which focused on pre-term infants, and infants and young children with serious illness or congenital malformations were excluded. However, some total population studies did include these children.

Types of research design

It became evident early in the review process that very few randomised controlled trials (RCTs) had been conducted. A decision was made to include observational epidemiological designs, specifically prospective cohort studies and, in the case of SIDS research, case-control studies. Purely descriptive and cross-sectional studies were excluded, as were qualitative studies and all other forms of evidence.

A number of criteria have been proposed to establish causation in the scientific and medical literature. These key criteria were applied in the review process and are described as follows: 1) consistency and unbiasedness of findings; 2) strength of association; 3) temporal sequence; 4) dose-response relationship; 5) specificity; 6) coherence with biological background and previous knowledge; 7) biological plausibility; and 8) experimental evidence.

Studies that did not meet the requirement of appropriate temporal sequencing of events and studies that did not present an estimate of the strength of association were not included in the final review.

Types of outcome measures

Our specific interest was pacifier use related to:

- breastfeeding;
- SIDS;
- infection;
- dental malocclusion.

Studies that examined pacifier use related to procedural pain relief were excluded. Studies that examined the relationship between pacifier use and gastro-oesophageal reflux were also excluded as this information has been recently presented as a systematic review.

Search Strategy

The review comprised published and unpublished research literature. The search was restricted to reports published in English, Spanish, and German. The time period covered research published from January, 1960 to October, 2003. A protocol developed by New Zealand Health Technology Assessment was used to guide the search process. The search comprised bibliographic databases, citation searching, other evidence-based and guidelines sites, government documents, books and reports, professional websites, national associations, hand search, contacting national/international experts, and general internet searching.

Assessment of Quality

All studies identified during the database search were assessed for relevance to the review based on the information provided in the title, abstract and descriptor/MeSH terms, and a full report was retrieved for all studies that met the inclusion criteria. Studies identified from reference list searches were assessed for relevance based on the study title. Keywords included: dummy, dummies, pacifier(s), soother(s), comforter(s), non-nutritive sucking, infant, child, infant care.

Initially, studies were reviewed for inclusion by pairs of Principal Investigators. Authorship of articles was not concealed from the reviewers. Next, the methodological quality of included articles was assessed independently by groups of three or more Principal Investigators and Clinicians using a checklist. All 20 studies that were accepted met minimum set criteria, but few passed without some methodological concern.

Data Extraction

To meet the requirements of the Joanna Briggs Institute, reasons for acceptance and non-acceptance at each phase were clearly documented. An assessment protocol and report form was developed for each of the three phases of review. The first form was created to record Investigators evaluations of studies included in the initial review. Those studies that failed to meet strict inclusion criteria were excluded at this point. A second form was designed to facilitate an indepth critique of epidemiological study methodology. The checklist was pilot tested and adjustments were made before reviewers were trained in its use. When reviewers could not agree on an assessment, it was passed to additional reviewers and discussed until a consensus was reached. At this stage, studies other than cohort, case control, and RCTs were excluded. Issues of clarification were also addressed at this point. The final phase was that of integration. This phase, undertaken by the Principal Investigators, was assisted by the production of data extraction tables. Through a process of trial and error, a framework was formulated that adequately summarised the key elements of the studies. This information was tabulated under the following headings: authors/setting, design, exposure/outcome, confounders controlled, analysis, and main findings.

Results

With regard to the breast feeding outcome, ten studies met the inclusion criteria, comprising two RCTs and eight cohort studies. The research was conducted between 1995 and 2003 in a wide variety of settings involving research participants from diverse socio-economic and cultural backgrounds. Information regarding exposure and outcome status, and potential confounding factors was obtained from: antenatal and postnatal records; interviews prior to discharge from obstetric/midwifery care; post-discharge interviews; and post-discharge postal and telephone suveys. Both the level of contact and the frequency of contact with the informant, the child's mother, differed widely. Pacifier use was defined and measured inconsistently, possibly because few studies were initiated expressly to investigate it's relationship with breastfeeding. Completeness of follow-up was addressed, but missing data were not uniformly identified and explained. When comparisons were made between participants and non-participants there was some evidence of differential loss and a bias toward families in higher socio-economic groups. Multivariate analysis was undertaken in the majority of studies, with some including a large number of socio-demographic, obstetric, and infant covariates and others including just maternal age and education.

As might be expected given the inconsistency of definition and measurement, the relationship between pacifier use and breastfeeding was expressed in many different ways and a meta-analysis was not appropriate. In summary, only one study did not report a negative association between pacifier use and breastfeeding duration or exclusivity. Results indicate an increase in risk for a reduced overall duration of breastfeeding from twenty per cent to almost three fold. The data suggest that very infrequent use may not have any overall negative impact on breastfeeding outcomes.

Six SIDS case-control studies met the criteria for inclusion. The research was conducted with information gathered between 1984 and 1999 in Norway, the UK, New Zealand, the Netherlands and the USA. Exposure information was obtained from a variety of sources including: hospital and antenatal records, death scene investigation, and interview and questionnaire. Information for cases was sought within two days after death, within two to four weeks after dealth, and in one study between three and 11 years after death. Information for controls was sought from as early as four days of a nominated SIDS case, to between one and seven weeks from the case date, and again in one study some three to 11 years later. In the majority of the studies case ascertainment was determined by post-mortem. Pacifier use was again defined and measured somewhat inconsistently. All studies controlled for confounding factors by matching and/or using multivariate analysis. Generally, antenatal and postnal factors, as well as infant care practices, and maternal, family, and socioeconomic issues were considered.

All five studies reporting multivariate results found significantly fewer SIDS cases used a pacifier compared with controls. That is, pacifier use was associated with a reduced incidence of SIDS. These results indicate that the risk of SIDS for infants who did not use a pacifier in the last or reference sleep was at least twice, and possibly five times, that of infants who did use a pacifier.

Three studies reported a moderately sized positive association between pacifier use and a variety of infections. Conversely, one study found no positive association between pacifier use at 15 months of age and a range of infections experienced between the ages of 6 and 18 months. Given the limited number of studies available and the variability of results, no meaningful conclusions could be drawn.

Five cohort studies and one case-control study focused on the relationship between pacifier use and dental malocclusion. Not one of these studies reported a measure of association, such as an estimate of relative risk. It was therefore not possible to include these studies in the final review.

Implications for practice

It is intended that this review be used as the basis of a ‘best practice guideline’, to make health professionals aware of the research evidence concerning these health and developmental consequences of pacifier use, because parents need clear information on which they can base child care decisions. With regard to the association between pacifier use and infection and dental malocclusion it was found that, due to the paucity of epidemiological studies, no meaningful conclusion can be drawn. There is clearly a need for more epidemiological research with regard to these two outcomes. The evidence for a relationship between pacifier use and SIDS is consistent, while the exact mechanism of the effect is not well understood. As to breastfeeding, research evidence shows that pacifier use in infancy is associated with a shorter duration and non-exclusivity. It is plausible that pacifier use causes babies to breast feed less, but a causal relationship has not been irrefutably proven.

Because breastfeeding confers an important advantage on all children and the incidence of SIDS is very low, it is recommended that health professionals generally advise parents against pacifier use, while taking into account individual circumstances.

1 INTRODUCTION

Knowledge of the health and developmental consequences of pacifier use is important for parents and health professionals. Cursory review of the literature indicates that the use of a pacifier leads to negative outcomes, such as a shortened duration of breastfeeding, infection, and dental malocclusion. Conversely, pacifier use is associated with a reduced incidence of Sudden Infant Death Syndrome (SIDS). A closer examination of the literature reveals important methodological issues that cast doubt on the veracity of some findings. In the absence of a definitive answer, parents need clear information on which they can base child care decisions and health professionals need to be aware of the research evidence upon which they base their practice.

A pacifier is defined as “an object that a baby is given to suck so that the baby feels comforted and stays quiet” (1) (p. 222). Pacifiers, colloquially known as “dummies”, “soothers”, and “comforters” in the English speaking world, are used widely to soothe or calm a distressed child. Pacifiers are also used to prevent the sucking of thumbs and other objects, and as an aid to weaning. Pacifier use is frequently associated with “non-nutritive sucking” in the medical literature.

Reports of infants sucking objects appear as early as the late fifteenth century (2). Small linen bags filled with bread, milk and sugar were used for the nourishment and comforting of children in the early nineteenth century (3). The first patent on the India rubber nipple which resembles the present day pacifier was recorded in 1845 (4). According to Winter, “The practice of dipping the dummy into a variety of sweetening agents to make it a more effective pacifier was first described by Pitts in1927” (3) (p. 28).

Currently, pacifiers are made of latex or silicone and they come in several different shapes and sizes. The nipple may be long or short, with a ball shaped or flattened end. A shield is attached to the nipple to prevent swallowing or choking. All pacifiers sold in Australia must conform to the Australian standard (Australian Standards Services Certification AS2432).

The prevalence of pacifier use varies between cultures, societies, and communities. A New Zealand study, for example, reported that the prevalence of dummy use differs between 5% in the South Island compared to 32% in the North Island (5). In the UK, North et al. (6) reported two thirds of infants up to the age of six months had used a pacifier. Similarly, two thirds of infants aged approximately 3 months in Western Australia had used a pacifier at some time (7).

The reasons why carers decide to use a pacifier are many and varied, based on cultural mores, past practice, health care policy and advice, and occasionally substantive research. Webster (8) noted that neonatal nurses identified culture, experience, parental wishes, research, and policy as influencing their practice. An Australian survey of child health nurses and midwives found that as many advised pacifier use as did not (9). It was found that the advice given by these health professionals was not based on a consistent and coherent rationale, but on personal experience, or the belief that it was simply a matter of parental choice.

This paper critically reviews all literature relevant to pacifier use for full term healthy infants and young children. There are four subtopics within the review which relate to specific health and developmental outcomes of pacifier use. The four subtopics are: breastfeeding, SIDS, infection, and dental malocclusion. The research includes randomised controlled trials, longitudinal cohort studies and case-control studies.

2 OBJECTIVE

To critically review all literature related to pacifier use for full term healthy infants and young children.

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- infection;
- dental malocclusion

The synthesis of this critical evaluation will be used to inform professional practice and parental decisions about pacifier use.

3 REVIEW METHOD

Inclusion Criteria

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Types of participants

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Search Strategy

The review comprised published and unpublished research literature. The search was restricted to reports published in English, Spanish, and German. The time period covered research published from January, 1960 to October, 2003. A protocol developed by New Zealand Health Technology Assessment was used to guide the search process (11). The search comprised bibliographic databases, citation searching, other evidence-based and guidelines sites, government documents, books and reports, professional websites, national associations, hand search, contacting national/international experts, and general internet searching.

Bibliographic databases

The following bibliographic databases were searched:

- Medline
- Cochrane Library
- Embase
- Current Contents
- Pubmed
- DARE
- CINAHL
- Psychinfo
- Best Evidence
- TRIP
- CenterWatch
- Expanded Academic Index
- Australian Medical Index
- ERIC
- Austrom

Citation searching

Starting from relevant articles the Science Citation Index was searched forwards and backwards for other subsequent articles which had cited the original ones.

Other evidence-based and guidelines sites

The following websites were searched:

- Trawling the Net
- Netting the Evidence
- Agency for Health Research Quality

Government documents

Two documents were reviewed: “Eat Well Australia” (12) and “Dietary Guidelines for Children and Adolescents in Australia incorporating the Infant Feeding Guidelines for Health Workers” (13).

Books and reports

Two World Health Organisation Reports were relevent to our review. The Innocenti Declaration: Progress and achievements, Parts I, II and III (14, 15, 16). The Baby-friendly Hospital Initiative. Monitoring and reassessment: Tools to sustain progress (17).

Professional websites

The following websites were searched:

- Australian Breastfeeding Association – Lactation Resource Centre
- La Leche League
- Lactnet
- BMJ - paediatrics
- MD Consult
- American Dental Association

National associations

The Australian Breastfeeding Association, the College of Lactation Consultants, and the International Lactation Consultants Association were informed of the review and its progress.

Hand search

The reference section of every article identified for extensive critique was searched.

National/International experts

Experts were consulted regarding literature relevant to the following sub-topics:

Breastfeeding – Ms Linda Smith, Ms Robyn Noble, and Ms Ann Povey
SIDS – Dr Ed Mitchell
Dental malocclusion – Dr Kate Taylor

General internet searching

Google and Yahoo were used to search the general internet.

Assessment of Quality

All studies identified during the database search were assessed for relevance to the review based on the information provided in the title, abstract and descriptor/MeSH terms, and a full report was retrieved for all studies that met the inclusion criteria. Studies identified from reference list searches were assessed for relevance based on the study title. Keywords included: dummy, dummies, pacifier(s), soother(s), comforter(s), non-nutritive sucking, infant, child, infant care.

Initially, studies were reviewed for inclusion by pairs of Principal Investigators. Authorship of articles was not concealed from the reviewers. Next, the methodological quality of included articles was assessed independently by groups of three or more Principal Investigators and Clinicians using a checklist (see Appendix 1). All 20 studies that were accepted met minimum set criteria, but few passed without some methodological concern.

Data Extraction

The number of studies included in the initial review, the number selected for intensive critique, and the number accepted for inclusion in the final review are presented in Table 3.1.

Table 3.1
Numbers of studies included in the review

Sub-topic	Initial review	Intensive critique	Final review
Breastfeeding	59	32	10
SIDS	74	17	6
Infection	51	18	4
Dental	68	47	0
Total	252	124	20

The studies included in the final review had been published over 10 years from 1993 to 2003. The great majority of literature was published in the 1990s (13), with substantial contributions made since in the breastfeeding literature (5). Twelve studies purported to be of cohort design, six were case-control studies, and two were RCTs. Study populations were widely dispersed with regard to race/ethnicity and sociodemographic profile. The greatest number of studies originated in the USA and the UK (4 each). Also featuring prominantly were Brazil, Finland and New Zealand (2 each),

with researchers in Australia, Canada, Italy, the Netherlands, Norway, and Sweden also making a contribution.

To meet the requirements of the Joanna Briggs Institute, reasons for acceptance and non-acceptance at each phase were clearly documented. An assessment protocol and report form was developed for each of the three phases of review. The first form was created to record Investigators evaluations of studies included in the initial review (Appendix 1). Those studies that failed to meet strict inclusion criteria were excluded at this point. A second form was designed to facilitate an in depth critique of epidemiological study methodology (Appendix 2). The checklist was pilot tested and adjustments were made before reviewers were trained in its use. When reviewers could not agree on an assessment, it was passed to additional reviewers and discussed until a consensus was reached. At this stage, studies other than cohort, case control, and RCTs were excluded. Issues of clarification were also addressed at this point. The final phase was that of integration. This phase, undertaken by the Principal Investigators, was assisted by the production of data extraction tables. Through a process of trial and error, a framework was formulated that adequately summarised the key elements of the studies. This information was tabulated under the following headings: authors/setting, design, exposure/outcome, confounders controlled, analysis, and main findings. The data extraction tables are presented in Appendix 3.

4 REVIEW OF THE LITERATURE

The association between pacifier use and breastfeeding

A comprehensive research literature shows that breastfeeding plays a fundamental role in child health and development. Breastfeeding naturally leads to effective mother-infant bonding and human milk is the most appropriate nutrition for all infants (18). In a recent review, Oddy (19) points out that omega–3 long chain fatty acids in breast milk are particularly important as potential modulators of immune and central nervous system development. According to Oddy (19) breast milk is recognised as one of the most 'natural and best forms of preventive medicine' providing substances which complement the developing abilities of the infant by aiding digestion and providing host defense, functions not provided by formula. As part of the nutritional advantage it confers, human milk protects against infections through a variety of specific and non-specific immunological factors and has long term consequences for metabolism, development and diseases later in life.

It is, therefore, extremely important to identify factors that disrupt breastfeeding, leading to partial rather than exclusive feeding and/or a shorter duration. Pacifier use has been implicated as a barrier to breastfeeding for quite some time. This review focuses on the accumulated evidence for a causal relationship between pacifier use and disrupted breastfeeding behaviour.

Ten studies met the inclusion criteria, comprising two RCTs (20, 21) and eight cohort studies (22-29). Howard et al. (25) purported to be an RCT, but the intervention was not related to pacifier use.

The research was conducted between 1995 and 2003 in a wide variety of settings (Australia, Brazil, Canada, Italy, New Zealand, Sweden, and the USA) involving research participants from diverse socio-economic and cultural backgrounds. Mother-infant pairs (median number 607, range 265 to 1601) were recruited conveniently from hospitals and health clinics, and randomly from selected populations. In addition to excluding unhealthy, preterm, and low birth weight infants, Aarts et al. (24) excluded mothers who intended to use oral contraception and those who had recommenced menstruation following the infant's birth, while Victora et al. (23) excluded mothers with breastfeeding problems. Barros et al. (22) excluded those in higher socio-economic groups. Follow-up time ranged from four weeks until the cessation of breastfeeding which was in one study (25), beyond the first year.

Information regarding exposure and outcome status, and potential confounding factors was obtained from: antenatal and postnatal records; interviews prior to discharge from obstetric/midwifery care; post-discharge interviews; and post-discharge postal and telephone suveys. Both the level of contact and the frequency of contact with the informant, the child's mother, differed widely.

Pacifier use was defined and measured inconsistently, possibly because few studies were initiated expressly to investigate it's relationship with breastfeeding. In some instances detailed information about pacifier use was sought, while in most cases only one or two secondary questions were asked. The most comprehensive surveys asked about: the number of times per day, the length of time of each use, and the time of day at which it was used (day, night, or going to sleep). The least comprehensive simply asked if a pacifier was used: frequently or occasionally. Both exclusivity and duration of breastfeeding were employed as outcome measures, but once again definitions varied considerably. The difference between exclusive breastfeeding (breast milk only source of milk and infrequent supplements of water, juice or other fluids) and partial breastfeeding (a combination of breast milk and other infant or milk formulas with the addition of other supplements of water, juice etc) was not uniformly established.

Completeness of follow-up was addressed, but missing data were not uniformly identified and explained. When comparisons were made between participants and non-participants there was some evidence of differential loss and a bias toward families in higher socio-economic groups. Multivariate analysis was undertaken in the majority of studies, with some including a large number of socio-demographic, obstetric, and infant covariates and others including just maternal age and education.

As might be expected given the inconsistency of definition and measurement, the relationship between pacifier use and breastfeeding was expressed in many different ways and a meta-analysis was not appropriate. Results are presented in Appendix 3 and a summary of the main findings for duration and exclusivity, are presented in Table 4.1.

Table 4.1.
The association between pacifier use and breastfeeding duration and exclusivity

Study	**Definition of pacifier use**	**Shorter duration of BF** RR/HR/OR(95%CI)[1]	**Non-exclusivity of BF** RR/HR/OR (95%CI)
Barros, 1995	At one month	Overall[2] 2.87 (1.97-4.19)	
Victora, 1997	Part-time use at one month Full-time use at one month	Overall 1.74 (1.15-2.63) Overall 2.37 (1.40-4.01)	
Aarts, 1999	Occasional Often Frequent	Overall 1.07 (0.79-1.47) Overall 1.62 (1.28-2.07) Overall 2.17 (1.53-3.09)	
Howard, 1999	Daily use up to 6 weeks	Exclusive 1.53 (1.15-2.05) Overall 1.61 (1.19-2.19)	 1.53 (1.15-2.05)
Riva, 1999	Started in first month of life	Partial 1.18 (1.04-1.34) Exclusive 1.35 (1.18-1.55)	
Kramer, 2001	Use vs no use	Overall 1.0 (0.6-1.7)	
Vogel, 2001	Less than daily use Daily use Daily use first month	Overall 1.02 (0.75-1.39) Overall 1.91 (1.45-2.51) Exclusive 1.35 (1.05-1.74)	
Binns, 2002	Before 2 weeks	Overall 2.50 (1.59-4.00)	
Levy, 2002	Before 6 weeks	Overall 1.88 (1.36-2.62)	
Howard, 2003	Before 5 days vs after 4 weeks	Overall 1.22 (1.03-1.44)	

[1] RR - relative risk, HR – hazard ratio, OR – odds ratio, CI – confidence interval, [2] Overall – any breastfeeding

Table 4.1 shows that pacifier use, however defined, was associated with reduced overall duration of breastfeeding in all but three analyses. Statistically significant relative risks, hazard ratios, and odds ratios range from 1.22 to 2.87, indicating an increase in risk for a reduced overall duration of breastfeeding from twenty per cent to almost three fold. Aarts et al. (24) found no statistically significant association between occasional pacifier use and the overall duration of breastfeeding (any breastfeeding) (HR 1.07), but these authors did find a dose-response effect in which the increasing frequency of pacifier use was associated with a decline in overall breastfeeding duration (occasionally used HR 1.07, often used HR 1.62, frequently used HR 2.17). Kramer et al. (20) reported that an intervention to reduce pacifier use was not successful (no reduction of early weaning, RR 1.0). Vogel et al. (27) found no association between less than daily use (OR 1.02) and reduced breastfeeding duration, but a two fold risk of reduced duration when a pacifier was used daily (OR 1.91).

In addition to Aarts et al. (24), two other studies established a dose-response effect. Victora et al. (23) found that compared with those who did not use a pacifier, part-time users had an increased risk (HR 1.74) of stopping breastfeeding between the ages of one and six months and full-time users had an even great risk of stopping (HR 2.37). Barros et al. (22) also found a dose-response effect, but the strength of association was not quantified.

Table 4.1 also shows that pacifier use, however defined, was associated with a shorter duration of partial breastfeeding (OR 1.18) and exclusive breastfeeding (ORs 1.35 to 1.53). Howard et al. (25) identified an association between daily use of a pacifier up to six weeks and the non-exclusivity of breastfeeding. As Table 4.1 shows, the the odds of not exclusively breastfeeding were significantly increased when a pacifier was used (OR 1.53).

In summary, only one study did not report a negative breastfeeding duration or exclusivity outcome associated with pacifier use. The data suggest that very infrequent use may not have any overall negative impact on breastfeeding outcomes. There are two possible explanations for the consistent finding of an association between pacifier use and negative breastfeeding outcomes. First, it is entirely plausible that pacifier use causes babies to breast feed less. The innate sucking reflex of the infant is satisfied by the pacifier, decreasing or eliminating the desire for contact with the nipple and breast. Second, pacifier use does not cause a reduction in breastfeeding, it is simply a marker for

socio-economic, demographic, psychosocial, and cultural factors that determine both pacifier use and breastfeeding. An alternative hypothesis that the cessation of breastfeeding leads to pacifier use has not, to date, been tested in an epidemiological study.

The association between pacifier use and SIDS

SIDS is a diagnosis of exclusion and is defined as "the sudden death of an infant or young child which is unexpected by history, and in which a full post-mortem examination fails to demonstrate an adequate cause of death" (30) (p. 18). Unexpected and sudden deaths in infancy which can be explained are not classified as SIDS and thus are not considered in this review. SIDS is a major classification of mortality in infants between one month and one year of age in Western industralised countries (31).

The aetiology of SIDS is poorly understood, however, epidemiological research has identified a number of factors and modifiable infant care practices which appear to increase or decrease the risk. Key practices found to increase the risk include: prone sleeping, antenatal and postnatal cigarette smoke exposure, and hyperthermia (5). Important practices reported to reduce the risk of SIDS include: breastfeeding (32), room-sharing (33), and pacifier use (5, 34). This review focuses on the evidence for a causal relationship between pacifier use and SIDS.

Six published case-control studies met the criteria for inclusion (5, 34-38). The research was conducted with information gathered between 1984 and 1999 in Norway, the UK, New Zealand, the Netherlands and the USA. Cases were infants who had died of SIDS (median number 214, range 73 to 485). With one exception, case ages ranged from seven to 365 days. L'Hoir et al. (36) included cases up to the age of two years. All controls were drawn from the community at a ratio to cases varying between one-to-one to four-to-one (median number 284, range 146 to 1800). In all but one study, controls were matched to cases on factors such as age, sex, time of birth, and region. Mitchell et al. (5) randomly selected almost four controls for every case.

Exposure information was obtained from a variety of sources including: hospital and antenatal records (5, 34), death scene investigation (38), and interview and questionnaire (5, 34-38). Information for cases was sought within two days after death, within two to four weeks after dealth, and in one study (35) between three and 11 years after death. Information for controls was sought from as early as four days of a nominated SIDS case, to between one and seven weeks from the case date, and again in one study (35) some three to 11 years later.

In the majority of the studies case ascertainment was determined by post-mortem. L'Hoir et al. (36) acknowledged that 25 of their 73 cases did not undergo postmortem and, therefore, a small proportion of these 25 may have been incorrectly identified as SIDS. Brook et al. (37) did not report case ascertainment in the brief report that was available. Pacifier use was again defined and measured somewhat inconsistently. Five studies referred to pacifier use in the "last" sleep for SIDS cases and an assigned "reference" sleep for the control, matched to the time of the case's death. Arnstad et al. (35) recorded usual use during the day and at night, as "sometimes", "often" or "always".

All studies controlled for confounding factors by matching and/or using multivariate analysis. Generally, antenatal and postnal factors, as well as infant care practices, and maternal, family, and socioeconomic issues were considered. Mitchell et al. (5), Hauck et al. (38), and Flemming et al. (34) also accounted for many of the known SIDS risk factors. The Norwegian study (35) collected data three to 11 years after the infant death, leaving it open to claims of substantial recall bias. While, it is internationally accepted that SIDS may take place between the age of seven days to one year, L'Hoir et al. (36) included children up to the age of two years.

Full results are presented in Appendix 3 and a summary of the main findings are presented in Table 4.2. With regard to pacifier use in the last sleep (case) or reference sleep (control), Table 4.2 shows that all five studies reporting multivariate results found significantly fewer SIDS cases used a pacifier compared with controls. That is, pacifier use was associated with a reduced incidence of

SIDS. Effect sizes following multivariate analysis ranged from 0.43 (0.24-0.78) (5) to 0.19 (0.08-0.46) (36). These results indicate that the risk of SIDS for infants who did not use a pacifier in the last or reference sleep was at least twice, and possibly five times, that of infants who did use a pacifier.

L'Hoir et al. (36) also found significantly fewer cases compared to controls "usually" used a pacifier 0.24 (0.11-0.51). Arnestad et al. (35) reported a series of associations between usual pacifier use, both during the day and at night, and SIDS (see Table 4.2) and again, pacifier use was associated with a reduced risk. Mitchel et al. (5) and Fleming et al. (34) found no statistically significant difference for usual use between cases and controls.

Table 4.2.
The association between pacifier use and SIDS

Study	**Definition of pacifier use**	**Bivariate** (matched) OR[1] (95%CI[2])	**Multivariate** OR (95%CI)
Mitchell, 1993	Last/reference sleep Usually in the past 2 weeks	0.44 (0.26-0.73) [3]	0.43 (0.24-0.78) 0.71 (0.50-1.01)
Arnestad, 1997	Usually: - up to 2 months age at night - up to 2 months age during day - 3 to 4 months age at night - 3 to 4 months age during day None up to 2 months during day	 0.17 (0.08-0.36) 0.36 (0.19-0.69) 0.17 (0.08-0.36) 0.17 (0.08-0.39) 1.83 (1.19-2.80)	
Flemming, 1999	Last/reference sleep Usually day or night	0.62 (0.48-0.83) 1.03 (0.77-1.38)	0.41 (0.22-0.77)
L'Hoir, 1999	Last/reference sleep Usually	0.16 (0.07-0.33) 0.19 (0.09-0.36)	0.19 (0.08-0.46) 0.24 (0.11-0.51)
Brook, 2000	Last/reference sleep		0.33 (0.15-0.77)
Hauck, 2003	Last/reference sleep	0.33 (0.21-0.54)	0.30 (0.17-0.55)

[1] OR – odds ratio, [2] CI – confidence interval, [3] - not matched

Several causal mechanisms have been proposed to explain the finding of a negative association between pacifier use and the risk of SIDS, including the following: the presence of a pacifier may protect the infant's airway (5, 36, 39); pacifer sucking, or just the presence of a pacifier, may lessen the likelihood of apnoea (35); and pacifier use may reduce high risk infant sleep behaviours, such as a prone sleeping position (5, 36). Most researchers and clinicians, however, are reluctant to actively promote the use of pacifiers in the absence of adequate knowledge regarding actual mechanisms related to pacifier use and SIDS.

The association between pacifier use and infection

If it was established that pacifier use caused gastro-intestinal, upper respiratory tract, or lower respiratory tract infection, or dental caries, this would be a serious concern and a powerful argument against the practice. With this in mind, 18 research articles that purported to investigate the relationship between pacifier use and infection were intensively critiqued. Of these 18 articles, only four met the criteria for inclusion in the final phase of the review process (6, 40, 41, 42). The excluded articles were mostly case-series and cross-sectional designs. One cohort study (40) examined the possible association between pacifier use and acute otitis media. Another cohort study (41) looked at the association between pacifier use and dental infection leading to dental caries. Finally, North et al. (6) and North Stone et al. (42) utilised a birth cohort study to investigate the association between pacifier use and a range of outcomes including: respiratory symptoms, ear problems, gastro-intestinal symptoms, and other symptoms of infection. Three studies reported a moderately sized positive association between pacifier use and the outcome, or outcomes of interest (6, 40, 41). Conversely, North Stone et al. (42) found no positive association between pacifier use at 15 months of age and a range of infections experiences between the ages of 6 and 18 months. Given the limited number of studies available and the variability of results, no meaningful conclusions could be drawn.

The association between pacifier use and dental malocclusion

Forty-seven articles were identified that purported to investigate the relationship between pacifier use and dental malocclusion, a subject of great interest to dentists and child health professionals for many years. Of these 47 articles, five were cohort studies (43-47) and one was a case-control study (48). There were no RCTs and the excluded articles were mostly case-series and cross-sectional designs. Not one of the cohort or case-control studies reported a measure of association, such as an estimate of relative risk. It was therefore not possible to include these studies in the final review.

5 DISCUSSION

This review of the literature has presented evidence that pacifier use in infancy is associated with both shorter duration and non-exclusivity of breastfeeding, and a reduction in the incidence of SIDS. To determine the likelihood of a causal relationship between pacifier use and these two outcomes, key criteria, documented in the methods section of the review, were considered: 1) consistency and unbiasedness of findings; 2) strength of association; 3) temporal sequence; 4) dose-response relationship; 5) specificity; 6) coherence with biological background and previous knowledge; 7) biological plausibility; and 8) experimental evidence.

With regard to the first criteria, the evidence for these two effects is strong because a number of studies by different investigators, in different populations, using different methods, 10 in the case of breastfeeding and 6 in the case of SIDS, all have very similar results. Only one study contradicted the finding that pacifier use shortens the duration and exclusivity of breastfeeding, and no study contradicted the finding that infants who use a pacifier are at reduced risk of SIDS. On the other hand, most studies were subject to bias of some kind. For example, missing data was not uniformly identified and explained, and when comparisons were made between participants and non-participants there was some evidence of differential loss and a bias toward families in higher socio-economic groups. Another common problem was the failure of many studies to adequately control for possible confounding. This was especially problematic in breastfeeding studies, because pacifier use is clearly associated with socio-economic status and socio-economic status is clearly related to breastfeeding behaviour.

Second, overall, relative risks, hazard ratios, and odds ratios were all of moderate strength, supporting the claim of a causal relationship between pacifier use and breastfeeding, and pacifier use and SIDS. Only RCTs, cohort studies, and case-control studies were included in the final review so that a temporal relationship between pacifier use and the outcomes of interest could be established. The finding of a quantitative relationship between the factor and the frequency of the disease, a dose-response relationship, adds to the weight of evidence. Four independent studies established a dose-response relationship between pacifier use and shorter duration and exclusivity of breastfeeding. No studies established gradient effect between pacifier use and risk of SIDS. The specificity of pacifer use was not established either for breastfeeding or SIDS. As previously discussed, it is biologically plausible that pacifier use causes disruption to breastfeeding, while at the same time reducing the risk of SIDS. Finally, there is limited experimental evidence (21) that pacifier use causes shorter duration of breastfeeding. It is unlikely that an experimental protocol, even a convincing natural experiment, could ever be applied to the study of SIDS.

6 IMPLICATIONS FOR PRACTICE

It is intended that this review be used as the basis of a ‘best practice guideline’, to make health professionals aware of the research evidence concerning these health and developmental consequences of pacifier use, because parents need clear information on which they can base child care decisions. With regard to the association between pacifier use and infection and dental malocclusion it was found that, due to the paucity of epidemiological studies, no meaningful conclusion can be drawn. There is clearly a need for more epidemiological research with regard to these two outcomes. The evidence for a relationship between pacifier use and SIDS is consistent, while the exact mechanism of the effect is not well understood. As to breastfeeding, research evidence shows that pacifier use in infancy is associated with a shorter duration and non-exclusivity. It is plausible that pacifier use causes babies to breast feed less, but a causal relationship has not been irrefutably proven.

Because breastfeeding confers an important advantage on all children and the incidence of SIDS is very low, it is recommended that health professionals generally advise parents against pacifier use, while taking into account individual circumstances.

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Pacifier Systematic Review

Appendix 1 – Protocol for Initial Review

Author(s) _____ Year _____

Inclusion criteria:

☐ Pacifier use
☐ Age < 16 years

Subgroup:

☐ Breast feeding
☐ SIDS
☐ Infection
☐ Dental malocclusion

Database:

EM	Embase	☐	PL	Psychlit	☐
M	Medline	☐	B	Biol Abst	☐
C	Cinahl	☐	PM	Pubmed	☐
O	Other	☐			

Abstract:

☐ Detailed information
☐ Minimal information
☐ No information

Comments:

_____
_____
_____
_____
_____
_____

MEETS INCLUSION CRITERIA YES ☐ NO ☐

Find article? Yes ☐ No ☐

Possibility for another group? Yes ☐ No ☐ Group _____

Reviewer / month / year _____

Appendix 2 - ASSESSMENT OF EPIDEMIOLOGICAL STUDIES

Title of article: ……

……

Authors: …… **Year:** ……

Sub-topic: BF ☐ Dental ☐ Infect ☐ Sids ☐

Checklist:

	Pass	Fail	Not Stated	Not Sure
Intervention Studies				
Selection of study population				
- experimental population generalisable to reference population?	☐	☐	☐	☐
- differences between participants and nonparticipants?	☐	☐	☐	☐
- sample size sufficiently large – statistical power?	☐	☐	☐	☐
- will participants experience sufficient number of outcomes of interest?	☐	☐	☐	☐
Allocation of study regimes				
- random allocation of treatment?	☐	☐	☐	☐
- participants blinded?	☐	☐	☐	☐
- investigators blinded?	☐	☐	☐	☐
Maintenance, assessment of compliance, and ascertainment of outcome				
- extent of noncompliance?	☐	☐	☐	☐
- extent of loss to follow-up?	☐	☐	☐	☐
- uniform ascertainment of outcome?	☐	☐	☐	☐
Cohort Studies				
Selection of exposed and non-exposed population				
- non-exposed group same as exposed group?	☐	☐	☐	☐
- population generalisable to reference population?	☐	☐	☐	☐
- differences between participants and nonparticipants?	☐	☐	☐	☐
- sample size sufficiently large – statistical power?	☐	☐	☐	☐
- will participants experience sufficient number of outcomes of interest?	☐	☐	☐	☐
Sources of exposure and outcome data				
- exposure information adequate?	☐	☐	☐	☐
- outcome information adequate?	☐	☐	☐	☐
- information equal for exposed and non-exposed individuals?	☐	☐	☐	☐
Completeness of follow-up				
- extent of loss to follow-up?	☐	☐	☐	☐
- difference between those who continue in study and those who withdraw?	☐	☐	☐	☐
Sources of bias				
- selection bias if outcome known in advance?	☐	☐	☐	☐
- non-random misclassification error?	☐	☐	☐	☐
- difference between participants and nonparticipants?	☐	☐	☐	☐
- difference between those who continue in study and those who withdraw?	☐	☐	☐	☐
Case-Control Studies				
Definition and selection of cases				
- certain of diagnosis – strict diagnostic criteria?	☐	☐	☐	☐

Checklist:

	Pass	Fail	Not Stated	Not Sure
Selection of controls - comparable to the source population of the cases?	☐	☐	☐	☐
- controls not cases – strict diagnostic criteria?	☐	☐	☐	☐
- any exclusions or restrictions apply equally to cases and controls?	☐	☐	☐	☐
Selection of cases and controls - experimental population generalisable to reference population?	☐	☐	☐	☐
- differences between participants and nonparticipants?	☐	☐	☐	☐
- sample size sufficiently large – statistical power?	☐	☐	☐	☐
Ascertainment of disease and exposure status - exposure information adequate?	☐	☐	☐	☐
- outcome information adequate?	☐	☐	☐	☐
Sources of bias - hospital/clinic cases/controls?	☐	☐	☐	☐
- prevalent rather than incident cases?	☐	☐	☐	☐
- selection bias?	☐	☐	☐	☐
- observation/information bias?	☐	☐	☐	☐
- recall bias?	☐	☐	☐	☐
- non-random misclassification error?	☐	☐	☐	☐
The Role of Chance Hypothesis Testing - to what degree did chance account for the results?	☐	☐	☐	☐
- was the sample size adequate to determine a statistically significant difference?	☐	☐	☐	☐
Inference - are you able to make a generalisation about a larger group of individuals on the basis of the results for the sample?	☐	☐	☐	☐
The Role of Confounding Have methods been used to control for confounding? - randomisation	☐	☐	☐	☐
- restriction and matching				
- stratified analysis				
- multivariate analysis				
Overall assessment of this study	☐	☐	☐	☐

Comments:

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ASSESSMENT OF EPIDEMIOLOGICAL STUDIES

References from article to follow-up:

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Authors of the article to follow-up:

Name ……

Website ……

Email ……..

Address ……

Contact number ……..

Possibility for another sub-group: ☐ **Yes** **Group** ……

Reviewer/Month/Year/Group: ……..…

Appendix 3 – Data Extraction - Description of Included Studies – Breast-feeding (PU = pacifier use; BF = breastfeeding; SES = socioeconomic status)					
Author(s)/Setting	**Design**	**Exposure/Outcome**	**Confounders controlled**	**Analysis**	**Main findings** (Odds ratios, relative risks; hazard ratios; 95% confidence limits)
Barros FC, Victora CG, Semer TC, Filho ST, Tomasi E, Weiderpass E (1995) - Guaruja, Sao Paulo, Brazil	Cohort (selected low SES sample) 605 infants. Hospital and home visits – interview / questionnaire.	PU at 1 month (never, partial, frequent). BF duration 1, 4, 6 months, exclusive BF.	SES, demographic characteristics, feeding practices, infant care.	85% follow-up Multivariate (logistic)	PU at 1 month associated with not BF 1-6 months 2.87 (1.97, 4.19).
Victora CG, Behague DP, Barros FC, Olinto MTA, Weiderpass E (1997) - Pelotas, Brazil	Cohort (population sample) 655 infants. Hospital and home interviews, hospital records.	PU at one month (full-time, part-time, none). BF duration to 6 months.	Sociodemographic, environmental, parenting, and reproductive factors.	97% follow-up Multivariate (logistic)	Part-time PU at 1 month associated with shorter overall duration of BF between 1 and 6 months 1.74 (1.15 - 2.63). Full-time PU at 1 month associated with shorter overall duration of BF between 1 and 6 months 2.37 (1.40 - 4.01).
Aarts C, Hornell A, Kylberg E, Hofvander Y, Gebre-Medhin M (1999) - Uppsala, Sweden	Cohort (selected high SES sample) 506 infants. Daily recordings and fortnightly home interview / questionnaire to 26 weeks.	PU every 2 weeks from 2 weeks (never, occas., often, frequently). BF duration, pattern of exclusive BF.	Maternal education and age.	79% follow-up Multivariate (logistic)	PU associated with shorter duration of overall. BF - HR: occas. 1.07 (0.79-1.47); often 1.62 (1.28-2.07); freq. 2.17 (1.53-3.09).
Howard CR, Howard, FM, Lanphear B, deBlieck EA, Eberly S, Lawrence RA (1999) - New York, USA	Cohort (high SES sample from RCT) 265 infants. Hospital records, serial telephone interviews.	Daily PU at 2, 6, 12, 24 weeks. BF duration at 2, 6, 12, 24 weeks, then every 90 days.	Sociodemographic, obstetric, postnatal and infant factors.	Complete follow-up Multivariate (logistic)	PU by 6 weeks associated with shorter duration of exclusive BF 1.53 (1.15, 2.05) and overall BF 1.61 (1.19-2.19).
Riva E, Banderali G, Agostoni C, Silano M, Radaelli G, Giovannini M (1999) – Multi-centre, Italy	Cohort (stratified random sample) 1601 infants. Inteview and telephone questionnaires.	Started PU in the first month of life. Exclusive and partial BF duration.	Sociodemographic, obstetric, postnatal and infant factors.	85% follow-up Multivariate (cox, logistic)	PU associated with shorter duration of: exclusive BF 1.35 (1.18-1.55), partial BF 1.18 (1.04-1.34).
Kramer MS, Barr RG, Dagenais S, Yang H, Jones P, Ciofani L, Jane F (2001) - Montreal, Canada	Randomised controlled trial (double-blind) 281 infants. Intervention and questionnaires.	Intervention - education session to avoid PU. Outcome – BF at 3 months. (intervention successful in reducing PU)	Randomised - stratified by parity and BF history.	92% follow-up Multivariate (logistic)	Education intervention of avoidance of PU had no significant effect in reducing weaning (stopping BF) at 3 months RR 1.0 (0.6-1.7).

Appendix 3 continued- Description of Included Studies – Breast-feeding (PU = pacifier use; BF = breastfeeding; SES = socioeconomic status)					
Author(s)/Setting	**Design**	**Exposure/Outcome**	**Confounders controlled**	**Analysis**	**Main findings** (Odds ratios, relative risks; hazard ratios; 95% confidence limits)
Vogel AM, Hutchison BL, Mitchell EA (2001) - Auckland, NZ	Cohort (convenience sample) 350 infants. Face to face and telephone interviews.	PU at 1, 2, 3, 6, 9, 12 months (days in week and hours in day). Duration of exclusive BF.	Sociodemographic, obstetric, postnatal and infant factors.	94% followed to 1 year Multivariate (logistic)	PU less frequently than daily not associated with shortened duration of overall BF: RR 1.02 (0.75-1.39). Daily PU associated with shorter duration of overall BF: 1.91 (1.45-2.51). Daily PU in first month associated with shorter duration of exclusive BF: RR 1.35 (1.05, 1.74). Timing of pacifier introduction (at ≤2 weeks, 2-6 weeks of >6 weeks) was not assoc. with cessation of overall BF.
Binns CW, Scott JA (2002) - Perth, Australia	Cohort (selected from low SES sample) 610 infants. Questionnaire, telephone interviews.	PU in first: 2 weeks (yes/no); 6 weeks (yes/no). BF at 2,6,10,14,16 and 24 weeks.	Maternal age, education, infant sex.	90% follow-up Multivariate (logistic)	PU before 2 weeks associated with shorter duration of overall BF 2.50 (1.59 - 4.00).
Levy SM, Slager SL, Warren JJ, Levy BT, Nowak AJ (2002) - Iowa City, USA	Cohort (convenience sample) 1387 infants. Mailed questionnaire.	PU in the first 6 weeks (yes/no). BF duration.	Parental age, educ, income, BF plans, smoking, infant antibiotic use, infant sex.	76% follow-up at 6 months Multivariate (cox, logistic)	When modelled with no child care and digit sucking PU associated with shorter duration of BF 1.88 (1.36 - 2.62).
Howard CR, Howard, FM, Lanphear B, Eberly S, deBlieck EA, Oakes D, Lawrence RA (2003) - Rochester,USA	Randomised controlled trial (breastfeeding mothers intending to use a pacifier) (blinding not reported) 700 infants. Intervention, telephone interviews.	Intervention - early PU introduction (first 5 days) cf. later PU introduction (after 4 weeks) Outcome – BF duration up to 52 weeks. (Intervention successful in delaying introduction of PU)	Randomised and maternal: obstetric history, age, race, education, SES; infants postnatal and current supplemental feeding factors controlled for in analysis.	Complete follow-up Multivariate (cox, logistic)	Early PU introduction associated with shorter duration of overall BF 1.22 (1.03-1.44).

Appendix 3 continued - Description of Included Studies – SIDS (PU = pacifier use; BF = breastfeeding; SES = socioeconomic status)					
Author(s)/Setting	**Design**	**Exposure/Outcome**	**Confounders controlled**	**Analysis**	**Main findings** (Odds ratios, relative risks; hazard ratios; 95% confidence limits)
Mitchell EA, Taylor BJ, Ford RPK, Stewart AW, Becroft DMO, Thompson JMD, Scragg R, Hassall IB, Barry DMJ, Allen EM, Roberts AP (1993) - Multicentre, New Zealand.	Case-control (SIDS deaths Nov 1987-Oct 1990). 485 cases and 1800 randomly selected controls. Obstetric records (cases); literview (cases and controls).	PU in last sleep for cases and in nominated/ reference sleep for controls; PU in past two weeks (cases & controls). SIDS cases, postmortem.	Infant age, sex, birth weight, gestational age; Maternal obstetric history, smoking; season, time of death, socio-demographic; SIDS risk factors.	87% full data from cases and controls. Multivariate	Fewer SIDS cases cf to controls used a pacifier at the last/reference sleep 0.43 (0.24-0.78). No difference between SIDS cases cf to controls related PU in past two weeks 0.71 (0.50-1.01).
Arnstad M, Anderson M, Rognum TO (1997) - East/South Norway.	Case-control (SIDS deaths 1984-1992). 167 cases and 307 matched controls (sex, time of birth, region). Hospital records (cases); questionnaire (cases and controls).	PU (always, often, sometimes, seldom) Data collected 3-11 years after case death. Postmortem, Nordic SIDS criteria, health records		Data from 73% cases, and 87% controls. Bivariate	Fewer SIDS cases cf to controls "always" used a pacifier: at night in first 2 months 0.27 (0.14 - 0.51); in the day in first 2 months 0.36 (0.19-0.69); at night between 3-4 months 0.17 (0.08-0.36); in the day between 3-4 months 0.17 (0.08-0.39). More SIDS cases cf to controls never used a dummy during the day in first two months 1.83 (1.19-2.80).
Fleming PJ, Blair PS, Pollard K, Platt MW, Leach C, Smith I, Berry PJ, Golding J (1999) - 5 regions, SW England.	Case-control (SIDS deaths 1993-1996). 325 cases and 1300 matched controls (age). Interview (cases and controls).	PU in last sleep for cases, and in nominated/ reference sleep for controls. Avon scoring system for SIDS, paediatric postmortem.	Infant gestational age, birth weight and breast feeding; Maternal socio-demographic age, parity and smoking. SIDS risk factors.	Full data from 89.5% of cases and controls. Bivariate & Multivariate	Fewer SIDS cases cf. controls used a pacifier at the last/reference sleep 0.41 (0.22 - 0.77) (multivariate analysis). No difference between SIDS cases cf. controls for "usual PU (day or night)" 1.03 (0.77-1.38). No difference between SIDS cases cf. controls for routine pacifier users who did not use a pacifier in the last sleep 1.39 (0.93-2.07) (controlled for SES).
L'Hoir MP, Engelberts AC, van Well GTJ, Damsté PH, Idema NK, Westers P, Mellenbergh GJ, Wolters WHG, Huber J (1999) - Netherlands.	Case-control (SIDS deaths Mar 1995-Sept 1996). 73 cases and 146 matched controls (date of birth and area). Interview (cases and controls).	PU in last sleep for cases, and in nominated/ reference sleep for controls. Usual PU (cases & controls). SIDS cases: 48 with postmortem and interview, and 25 interview only (no postmortem).	Infant age, sex; birth weight; Maternal age, parity, smoking in pregnancy, SES.	Data - different sources for cases (with/ without postmortem). Complete data for controls. Multivariate	Fewer SIDS cases cf controls used pacifier on last/reference sleep 0.19 (0.08-0.46). Fewer SIDS cases cf controls "usually" used a pacifier 0.24 (0.11-0.51).

Appendix 3 continued - Description of Included Studies – SIDS (PU = pacifier use; BF = breastfeeding; SES = socioeconomic status)					
Author(s)/Setting	**Design**	**Exposure/Outcome**	**Confounders controlled**	**Analysis**	**Main findings** (Odds ratios, relative risks; hazard ratios; 95% confidence limits)
Brook H, Tappin DM, Beckett C, Gibson A (2000) - Scotland	Case-control (SIDS deaths 1996-1999). 159 cases and 229 matched controls (age). Home interviews (cases and controls).	PU in last sleep for cases, and in nominated/sleep on night before interfies for controls. SIDS cases, not stated how ascertained.	Infant, birthweight, breast feeding, age; Maternal parity, age, employment, marital status, education, cigarette smoking.	Not stated if complete data. Multivariate	Fewer SIDS cases cf controls used pacifier in the last/reference sleep OR 0.33 (0.15-0.77).
Hauck FR, Herman SM, Donovan M, Iyasu S, Merrick Moore C, Donoghue E, Kirschner R H, & Willinger M (2003) - Chicago, USA.	Case-control (SIDS deaths Nov 1993-April 1996). 260 cases and 260 matched controls (age, race, birth, weight). Medical records (cases), control data - selection method not stated.	PU in last sleep for cases and in nominated/ reference sleep for controls. SIDS death scene investigation, postmortem, medical records.	Maternal education, antenatal care, marital status, age. SIDS risk factors.	Not stated if complete data. Multivariate	Fewer SIDS cases cf to controls used pacifier in the last/reference sleep 0.30 (0.17-0.55).

Appendix 3 continued - Description of Included Studies – Infection (PU = pacifier use; BF = breastfeeding; SES = socioeconomic status)					
Author(s)/Setting	**Design**	**Exposure/Outcome**	**Confounders controlled**	**Analysis**	**Main findings** (Odds ratios, relative risks; hazard ratios; 95% confidence limits)
Niemela M, Uhari M, Mottonen M (1995) - Oulu, Finland	Cohort (convenience sample). 845 children attending 20 day care centres full-time. Parental questionnaire, symptom sheets	PU at start of monitoring, PU duration. Episodes of acute otitis media (AOM) (>3 weeks between episodes), mean moitoring time 10 months.	BF, parental smoking, bottle use, thumb sucking, maternal education, child's age, duration of monitoring	Complete follow-up. Multivariate analysis	PU between 2 and 3 years of age associated with >3 episodes of AOM: 2.9 (1.2-7.3). PU less than 2 years, and between 3 and 4 years of age not associated with >3 episodes of AOM.
Ollila P, Niemela M, Uhari M, Larmas M (1998) - Oulu, Finland	Cohort (convenience sample). 183 children attending day care centres. Questionnaire, annual dental examinations.	PU: never, < 2 years, >= 2 years. Initial and manifest caries at 2 years.	Parental employment	83% follow-up Multivariate analysis	PU for 24 months or more associated with caries 3.5 (1.5–8.2).
North K, Fleming P, Golding J, and ALSPAC Study Team (1999) – Bristol, UK.	Cohort (population sample). 10,950 infants. Postal questionnaire.	PU: day or night, at 4 weeks and at 6 months. Respiratoty symptoms, ear problems, gastro-intestinal symptoms, other symptoms of infection.	Socioeconomic factors, demographic factors, maternal smoking, BF, infant special care admission and sleep position.	Complete follow-up. Multivariate analysis	PU associated with: cough 1.16 (1.04–1.29); wheezing attack 1.23 (1.08-1.42); earache 1.37 (1.14-1.63); diarrhoea/gastroenteritis 1.44 (1.18-1.75); high temperatures 1.23 (1.10-1.37). PU not associated with: ear discharge and reduced hearing after a cold
North Stone K, Fleming P, Golding J, and ALSPAC Study Team (2000) – Bristol, UK.	Cohort (population sample). 10,006 infants. Postal questionnaire.	PU: at 15 months most of the time, sometimes, never. Respiratoty symptoms, ear problems, gastro-intestinal symptoms, other symptoms of infection.	Socioeconomic factors, demographic factors, maternal smoking, infant factors, physical living conditions.	Complete follow-up. Multivariate analysis	PU not associated with: having a cold or wheezing since 6 months, measles, chicken pox, or any other infection.