Australian Government

National Health and Medical Research Council

LITERATURE REVIEW

Infant Feeding Guidelines

2012

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Preface

The first sets of Dietary Guidelines in Australia were developed by the Dietitians Association of Australia (DAA) and another by the Health Department in 1979. The guidelines were very similar guidelines and the Health Department Guidelines were then endorsed by the National Health and Medical Research Council (NHMRC) Nutrition Committee in 1982. It was notable that from the beginning the Guidelines included a guideline for breastfeeding. Subsequently this was worded as "Encourage and Support Breastfeeding" to acknowledge the role of all members of the community in the appropriate nutrition of Australia's next generation. The example of Australia was subsequently followed by other countries, but we are the only country to include breastfeeding in guidelines for children and adults.

The World Health Organization (WHO) International Code of Marketing of Breast milk Substitutes (WHO 1981), was formulated in response to concerns over the effects on infant health of unfettered promotion of infant formula throughout the world. The drive for the code came from recognition of the increased risks of morbidity and mortality in infants who are not breastfed. The Code itself, as approved by the World Health Assembly (WHA), is not legally binding unless individual nations enact legislation making it so.

Australia stated at the WHA:

'in voting for the adoption of this Code, Australia made an international commitment to take action to give effect to its aims and principles and accepted responsibility for their implementation as appropriate to social and legislative frameworks in this country.' (National Health and Medical Research Council, 1985).

In 1984 the NHMRC Working Party issued guidelines for the health care sector for implementing the WHO Code following the establishment of a working party on the implementation of the Code in Australia (National Health and Medical Research Council 1985).

A new, more comprehensive voluntary Code for industry was signed in May 1992 and subsequently the Advisory Panel on Marketing in Australia of Infant Formula (APMAIF) was established. It has been located in a number of different departments including Treasury, Consumers Affairs and Health.

One of the responses of the Australian Government was the development of more detailed guidelines for health workers on the Code and the implementation of the Marketing in Australia of Infant Formula (MAIF) agreement in Australia. The first edition of the Infant Feeding Guidelines were developed by the Infant Nutrition Panel of the NHMRC beginning in Oct 1992, but took several years to finalise and was published in 1996. The impetus to develop the Infant Feeding Guidelines came from two sources. Firstly, the demand from health workers for additional information on infant feeding to supplement the NHMRC Dietary Guidelines (the development of the NHMRC Dietary Guidelines for Children and Adolescents also commenced in 1992). Secondly, as a part of Australia's response to the signing of the World Health Organisation's International Code of Marketing of Breast milk Substitutes (the WHO Code). At a national level the WHO Code is implemented under the Agreement on the Marketing in Australia of Infant Formula for Manufacturers and Importers (the MAIF Agreement) which has some differences from the original WHO Code.

While the WHO Code has never been revised, there have been supplementary resolutions and decisions by the World Health Assembly leading to the publication of a consolidated edition of the Code in 2008. As recently as May 2010 the WHA passed a resolution (Sponsored by

Norway) urging countries to strengthen their commitments to the WHO Code and the companion Baby Friendly Hospital Initiative. This aim was clearly stated in the first edition of the NHMRC Infant Feeding Guidelines: "The guidelines aim to help all health workers understand how the WHO Code and Australian Agreement affect their work in both breastfeeding and using infant formula."

Since the last set of guidelines were published in 2003 there have been developments in infant feeding that require revision, many references need updating and the Australian context has changed. As the first stage of revision of the Guidelines this literature review was undertaken to provide the underlying scientific basis for the revision.

The literature reviews that follow update most of the areas covered in the 2003 edition of the Infant Feeding Guidelines. Generally they are narrative reviews as the evidence base for infant feeding is not always as strong as other areas of nutrition. The issue of definitions of breastfeeding continues to be a major problem in the interpretation of studies. While standard definitions are usually agreed on, they are then operationalised in different ways. Data are sometimes reported as point prevalence and sometimes as period prevalence. Breastfeeding may be assessed using cohort studies of by cross sectional studies with results based only on the previous 24 hours. In some reports monitored for this review, breastfeeding history was assessed retrospectively up to 7 years previously and then related to present morbidity.

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Notes on Methodology Used in this Review

Cultural and environmental factors have a great influence on infant feeding practices. The countries and regions of the birth places of mothers of children born in Australia in 2008 are listed below. This is the most recent year for which data are available

Countries of mothers' births:

Australia NZ	77.8%
United Kingdom	3.3%
India	1.6%
Vietnam	1.6%
China	1.5%
Other	14.2%

Regions of mothers' birth:

Australia NZ	77.8
NW Europe	3.3
N Africa, Mid East	2.7
Sub Saharan Africa	1.7
Total Overseas	22

The 'other countries' group includes more than 100 additional countries.

Limitations on literature searches:

Countries. To ensure relevance of the literature review on factors that effect duration and initiation of breastfeeding the searches will be limited to the above countries. Where issues are not so specifically related to cultural conditions within a country, e.g. the management of mastitis or listing drugs that should not be used during lactation, a wider range of countries will be included.

Language. The literature searches were limited to the English language.

Birth weight restrictions. The literature review will be limited to infants of normal birthweight (ie > 2500 grams). The management of very low birthweight infants requires specialised care until normal birthweight ranges are achieved.

Time Period. Generally the literature will be limited to the time period since the preparation of the literature reviews for the Third Edition of the Infant Feeding Guidelines (2002). The period of this review will generally restricted to the period 2002-2010. However in many cases in order to obtain a satisfactory database the search period was 1990-2010.

Databases

The following databases were searched for relevant articles:

- Pubmed (Medline)
- CINAHL
- Informit
- Science Direct
- Cochrane Reviews
- Web of Knowledge

Search Terms

Breastfeeding, breast-feeding, breast feeding and/or specific terms for each question.

Definitions

The definitions used were taken from the NHMRC Infant Feeding Guidelines, which in turn are consistent with the WHO Code. More specifically breastfeeding is defined:

Exclusive Breastfeeding "the infant has received only breast milk from his/her mother or a wet nurse, or expressed breast milk, and no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines"

Full Breastfeeding "infants who are receiving almost all of their nutrients from breast milk but take some other liquids such as water, water-based drinks, oral rehydration solutions, ritual fluids, and drops or syrups.

Any Breastfeeding. The infant is receiving some breast milk.

Process

The process for the literature review generally followed the procedures outlined in the NHMRC systematic literature review documents and more specifically in the manual prepared for the Dietary Guidelines Systematic Literature Reviews. The procedure involved:

Searching databases listed above

Each Abstract was read and classified as 'relevant' or 'non- relevant' by one or more of the principal investigators

The full text of articles classified as relevant was retrieved

The articles were reviewed for inclusion in the Body of Evidence

In excess of 2700 full text articles were retrieved.

Because of the large number of reviews required and following the decision of the Monitoring Group Meeting in Canberra (18 August 2012), umbrella or narrative reviews have been provided.

For ethical reasons it is not possible to undertake randomised controlled trials with breastfeeding as an intervention. Most studies involving breastfeeding were cohort studies.

Topics of reviews for the Infant Feeding Guidelines:

Reviews previously completed for the Dietary Guidelines Committee

Dairy and lipid profile in infants
Age of introduction of solid foods
Optimising breastfeeding outcomes
Life course
Food selection guides
Food safety including storage of infant formula
Obesity indices
Some authoritative sources of safe food handling advice

Umbrella Reviews (ie using published reviews)

Prelacteal Feeds
Types of feeds
Reasons
Impact on initiation and duration of breastfeeding (see SLR below)
Other impacts (eg GI infection, human microbiome)
Gastro oesophageal reflux, regurgitation, feeding related issues
Developmental Origins of Adult Disease
Early influences on later obesity
Early introduction of solid foods and weight gain
Breastfeeding problems and management
Working mothers and breastfeeding (covered in SLR below)

Expression of breast milk
Methods,
Impact on breastfeeding duration
Storage of breast milk
Infant formula – Preparation, use and storage
Infant feeding in specific conditions eg HIV and other specific conditions listed in old guidelines
Alcohol and tobacco and breastfeeding
Pharmaceutical drugs and breastfeeding
International infant feeding guidelines
Factors associated with increased rates of breastfeeding initiation
Factors associated with increased rates of breastfeeding duration

Data Updates
Breastfeeding rates in Australia and countries of maternal origin (UK, NZ, India, China)
Prelacteal feeding rates in Australia

These reviews were then adapted to the Chapter Headings in the 2003 Infant Feeding Guidelines.

At the request of the NHMRC Dietary Guidelines Working Committee (Meeting 8 – 9 December 2010) the results of previous literature reviews prepared by the Dietitians Association of Australia have been included for completeness. They can be found in the Appendix.

SUMMARY OF FINDINGS RELATED TO THE OBJECTIVES OF THE LITERATURE REVIEW

Using the evidence from the recent literature, what current recommendations on infant feeding are strengthened, weakened or stay the same.

Most areas of the Infant Feeding Guidelines need only minor changes and updating.

Areas needing to be strengthened

Prelacteal Feeds – increasing in prevalence in Australia.

Strengthen the need for informed consent

Breastfeeding immediately after birth

Rationale:

Interference with lactogenesis

Changes to human microbiome

Infection

For these reasons prelacteal feeds have become a major indicator for the Baby Friendly Hospital Initiative (BFHI)

Areas needing to be updated

Use of pharmaceuticals while breastfeeding

Management of difficulties in breastfeeding

Attachment

Introduction of solid foods – order, timing, potential allergens. There is no need to restrict foods until after 6 months. Order and timing do not appear to be important providing the foods are nutrient dense and iron fortified. Food texture and taste (eg hot spicy foods) still need to be considered.

- **The need for any new recommendations**

Infant Formula

Protein levels of infant formula. Following the European Multicentre Trial preference should be given to formula with lower protein levels (Koletzko, von Kries et al. 2009; Koletzko, von Kries et al. 2009).

Correct preparation of formula – high rates of incorrect preparation are reported in the literature.

Revise

Strengthen advice on not to use Soy based formula

Solids – the order and timing of introduction of solids. Less restrictive than recommendations in previous guidelines

- **Literature for health workers regarding the best way to promote optimal infant feeding (0-12months)**

The Australian and the New Zealand Guidelines are as good as any in the world. A list of major reviews and reference works will be provided

- **Practical infant feeding advice for health workers to provide to parents and carers**

This will be the basis of the complete version of the guidelines

- **The appropriate age to introduce solids from all food groups**
  The majority of international and national organisations recommend introduction of solids at six months or around six months. There are many reasons why 'six months or around six months' is the best time to introduce solids (see details in text). There is some evidence that introduction of solids at an earlier time will increase the risk of obesity. There is a discussion in the allergy literature of probable "window of tolerance" in the introduction solid foods of between 4 -7 months (Prescott, Smith et al. 2008). Currently all Australian infants have solids introduced during this period. Given the above there seems to be no reason to change the present Australian recommendation of "around six months and never before 4 months". To avoid any confusion these times should be expressed as weeks.

- **Current international infant feeding guidelines that are relevant to the Australian population.**
  New Zealand is probably the most relevant for Australia. There has been a delay in the publication of the new Singapore Guidelines which would have been of interest to Asian Australians. The new Chinese Infant Feeding Guidelines book is based on the Australian Guidelines and would be useful for Chinese Australian families. Further review and guideline documents are provided in the appendix.

- **Policy related issues around infant feeding**
  This will be discussed in the final infant feeding guidelines document\

- **Definition of health workers**
  The WHO definitions of Health Worker have been included and discussed. A broad inclusive definition is recommended

- **Barriers and enablers for optimal infant feeding**
  Barriers to breastfeeding programs in Australia include:
  1. The lack of adequate monitoring of breastfeeding rates in Australia. Without a longitudinal cohort study there is a lack of information for program planning and monitoring. The best model is the USA Infant Feeding Practices Study II with regular data collection from the third trimester until 12 months. Cross sectional and retrospective studies do not provide sufficient accurate information for breastfeeding programs.
  2. Infant growth reference. The choice for Australia lies between using the CDC reference (in current use) and the new WHO growth reference. Both have serious short comings. The WHO sample was highly selected and probably represents maximum achievable growth which may be different to growth that optimizes health and longevity for the average infant. There is also a lack of transparency about the development of the WHO growth reference, including very high rate of subject attrition and differences in variance between centres. The reasons for the new WHO reference being heavier than the older CDC reference in infancy have not been explained. An equal number of difficulties can be raised about the existing CDC reference. Comparable countries to Australia have arrived at different solutions (see details). Before changing to the new WHO reference in Australia a clinical trial is needed to answer the following questions:
     a. Will the use of a heavier reference in the first six months of infancy result in lower rates of exclusive and/or any breastfeeding?

b. Will the use of a heavier reference during infancy result in higher rates of childhood obesity and later increased rates of chronic adult disease?

If the answer to both these questions is “no” then the WHO reference can be safely introduced into Australia.

- how best to address common barriers to optimal infant feeding
- how the enablers for optimal infant feeding are supported

Factors in breastfeeding initiation, intensity and duration are addressed in the report.

Introduction

Definitions
- from existing Infant Feeding Guidelines

I Encouraging and supporting breastfeeding in the Australian community

Breastfeeding as the physiological norm
– existing data to be updated

Breastfeeding in Australia
– outline of data from Appendix

II Initiating, establishing and maintaining breastfeeding

Antenatal advice and Breastfeeding education for parents
- see Appendix

Physiology of breast milk and breastfeeding
- update existing Infant Feeding Guidelines information.

Time to first feed and breastfeeding

Early breastfeeding (colostrum feeding) is important for the establishment of breastfeeding and infant health. Two Australian cohort studies found no association between breastfeeding duration and initiating breastfeeding within the first 30 minutes of birth, as recommended by the BFHI. However, two other Australian cohort studies which investigated the association with a longer time to first breastfeed (i.e. > 1 hr and >12 hours postpartum) reported a negative association with breastfeeding duration.

What is the relationship between breastfeeding in first hour after delivery and breastfeeding outcomes?		
Draft Evidence statement		Breastfeeding in the first hour after delivery is associated with improved breastfeeding outcomes
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Good	4 cohort studies (3P, 1 O), 2 cross-sectional study (O), 1 RCT (O),
Consistency	Satisfactory	All of the studies using time to first breastfeed of > 1 hr found an effect on breastfeeding outcomes.
Clinical impact	Poor	There was an inconsistent association
Generalisability	Excellent	All studies involved either Australian women or women from relevant population sub-groups
Applicability	Satisfactory	

The studies included in the body of evidence statement are shown in the Table below Additional international reviews that provide evidence include; WHO Evidence for the Ten Steps (WHO/CHD 1998), ABM Protocol (Academy of Breastfeeding Medicine 2008; Philipp 2010).

This is a Millennium Development Goal indicator because of its importance to infant nutrition (UNICEF 2010).

Studies used to make evidence statement for the association of infant time to first feed and breastfeeding

Reference	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta Paediatr 1999;88: 416-421**	**Li L, Scott JA, Binns CW J Hum Lact 2004; 20: 188-195**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**	**Rutishauser IHE & Carlin JB Journal of Epidemiology & Community Health 1992; 46: 559-565.**
Type of study	Prospective cohort study	Cross-sectional (retrospective recall)	Prospective cohort study	Prospective Cohort
Level of evidence	II(aetiology)	IV(aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding duration	Any breastfeeding initiation	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Not defined
Intervention/ comparator	Infant put to breast within 30 minutes of birth vs other	Time to first put to breast (categories not identified)	Infant put to breast within 30 minutes of birth vs other	12 hours to first feed vs <1 hour to first feed (ref)
N	556 (77% of women contacted, 58% of eligible women)	506 (95% of 532 women contacted and 17% of 2925 eligible women aged 23-59 estimated from 2001 Census)	587 (68% of 870 women contacted and 55% of 1068 eligible women)	739 (81%)
Population/study information	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Mandarin speaking Chinese Australia mothers living in Perth 193 gave birth only in home country, 214 only in Australia and 99 gave birth in both countries.	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Geelong, Australia Primiparous women who chose to breastfeed & attended an infant welfare centre in Barwon region of Victoria, Australia
Quality	P	O	P	P
Results	No specified but adjusted for in backwards conditional Cox regression model	*Breastfeeding initiation in home country* Adj OR Not specified but controlled for in multivariate	*Risk of discontinuing any BF* No adjOR reported but non-significant when controlled for in multivariate analysis	Adj HR cessation of breastfeeding 1.37 (95%CI 1.03-1.82)

		logistic regression and non-significant *Breastfeeding initiation in Australia* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant	*Risk of discontinuing full BF* No adjOR reported but non-significant when controlled for in multivariate analysis	
Effect on risk	There was no significant independent association between risk of cessation of breastfeeding and early infant to breast contact (i.e. within 30 minutes)	There was no association between time that infant was first put to the breast and breastfeeding initiation among women delivering in their home country and/or Australia.	There was no association between early infant to breast contact (< 30 minutes) and the duration of full and any breastfeeding.	Mothers who had a longer time to the first breastfeed were more likely to cease breastfeeding
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y (Chinese)	Y	Y
Applicability	Y	Y	Y	Y

Reference	**Carfoot et al. Midwifery (2005) 21, 71–79**	**Chye et al. Journal of Tropical Pediatrics Vol. 43 October 1997**	**James Breastfeeding Review, 2004, 12: 19-27**
Type of study	RCT	Cross-sectional	Prospective cohort (12 mo)
Level of evidence	II (intervention)	IV (aetiology)	II (aetiology)
Definition of breastfeeding	Any (Partial or exclusive) breastfeeding at 4 months	Exclusive BF at 6 weeks (Defined as breastfeeding without any non-human milk supplementation)	Cessation of breastfeeding by 13 weeks
Intervention/ comparator	Skin to Skin contact vs routine delivery care	Delayed first feed (i.e. outside of labour room) vs (early first feed (while in labour ward)	1st feed ≥ 1 hr of birth vs < 1 hr birth (ref)
N	204 mother and baby pairs; 102 randomised to each group.		298
Population/study information	Women delivering in Warrington Hospital in the north of England in 2002. A healthy, pregnant woman was eligible for the trial if she intended to breastfeed, had 'booked' at Warrington Hospital, her healthy fetus was greater than 36 weeks' gestation and she had given informed consent. A woman was ineligible if she requested either skin-to-skin or no skin-to-skin contact after delivery, or had a multiple pregnancy. In the group receiving routine care, babies were quickly dried and wrapped in a towel before being handed to their mother or father. Mother–baby contact was interrupted	Mothers who had returned to the Hospital with their infants for the 6-week post-natal follow-up clinics, from-September to November of 1D95 and dad agreed to the study were interviewed. Mother and infant pairs were randomly selected. Selection criteria were recruited into the study: (a) Malay, Indian and Chinese mothers (the three major ethnic groups) with singleton pregnancies, and (b) normal healthy infants at birth (no major congenital malformations), with gestational ages >35 weeks and birth weights >2kg, and were not admitted into the Neonatal Intensive Care Unit.	Convenience sample of mothers from a range of maternity service across Victoria. Recruited late in pregnancy or in the early postpartum period. Follow-up questions at 3 monthly intervals until 12 mo of age

	for weighing, dressing and measuring the baby, or for suturing the mother's perineum after delivery. The midwife offered assistance with breastfeeding when both mother and baby were ready. In the skin-to-skin care group, the midwife placed the baby naked in a prone position against the mother's skin between the breasts as soon as possible after birth. For the purpose of the study, skin-to-skin contact was limited to mother and baby.		
Quality	P	O	O
Results	The difference in breastfeeding rate at 4 months was 3.3%, 95% CI (–10.3%, 16.7%); χ^2 =0.22; df = 1; P = 0.64.	Univariate OR (95% CI) 0.62 (0.14-2.68)	Univariate analysis **First feed ≥1 hour** **β**= -1.737 (sd) 0.733 crude OR 0.178'
Effect on risk	No significant effect. However, mothers who had skin-to-skin contact enjoyed the experience, and most reported that they would choose to have skin-to skin care in the future.	No effect but only 10% of mothers breastfed in the delivery room.	Mothers who initiated breastfeeding 1 or more hours after birth were less likely to be breastfeeding at 13 weeks
Clinical importance	1	4	4 (univariate)
Clinical relevance	1	1	1
Generalisability	Y	N (Chinese/Malaysian)	Y
Applicability	Y	Y	Y

Study Details	Reason for exclusion			
Author, year, journal	Not a comparison study (e.g. descriptive, prevalence only)	Not a relevant population (country (Specify), pre-term)	Not a relevant outcome (i.e. BF initiation or duration)	Duplicate (Multiple papers on same cohort)
Cantrill, Breastfeeding Reviews 2004,12: 25-35			√ (Knowledge of midwives re early infant feeding)	
Chandrashek et al. Indian J of Pediatrics 1995; 62: 707-712	Descriptive Indian study of mothers knowledge related to infant first feeds			
Chhabra et al, Indian J Pediatrics, 1998: 65 867-872	Descriptive Indian study of mothers knowledge related to infant first feeds			
Cooke et al Breastfeeding review 2003; 11: 5-11	√ descriptive study of textbook recommendations			
Deshpande et al 1996, 50: 4-8	Descriptive Indian study of early infant feeding practices			

Impact of delivery method on breastfeeding outcomes

Search results

Data were extracted from 15 studies, including 12 prospective cohort studies, 1 retrospective cohort study and 2 cross-sectional studies. For obvious ethical reasons there were no randomised controlled trials. Data from 14 publications were used to form the final body of evidence statement, which included 5 studies of Australian women, 7 studies of Chinese women, 1 study from New Zealand and 1 study from the UK. Sufficient evidence was found to make statements on the relationship between delivery method and breastfeeding outcomes. Breastfeeding outcomes investigated included breastfeeding initiation/ at discharge (any or exclusive) and breastfeeding duration (any or exclusive).

What is the effect of delivering by caesarean section on breastfeeding outcomes?		
Draft Evidence statement		Delivery by caesarean section may be negatively associated with the initiation of breastfeeding, particularly exclusive breastfeeding, and to a lesser extent breastfeeding duration.
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Good	13 cohort studies (11P, 2 O), 1 cross-sectional study (O)
Consistency	Poor	Approximately half of the studies found no effect for one or more breastfeeding outcomes, whilst the remainder found no effect
Clinical impact	Poor	There was an inconsistent association
Generalisability	Excellent	All studies involved either Australian women or women from relevant population sub-groups
Applicability	Satisfactory	Studies of Chinese women not directly relevant to the Australian healthcare context

Studies of women from Australia, New Zealand or the UK were considered separate to those of Chinese women. Two studies reported that women who delivered by caesarean section were significantly less likely to have initiated breastfeeding or be breastfeeding at discharge, while another two studies reported that the women who delivered by caesarean section were significantly less likely to be discharged from hospital exclusively breastfeeding. Two studies reported no association between delivery method and (any) breastfeeding at discharge and one study reported no association between delivery method and exclusive breastfeeding at discharge. One study reported that women who delivered by caesarean section were less likely to be fully breastfeeding at 1 month but the negative association did not persist beyond this time. Two other studies reported no association between delivery method and overall breastfeeding duration, with two studies reporting no association with duration of exclusive or full breastfeeding.

Two cohort studies involving Chinese women reported a negative association between caesarean delivery and the initiation of breastfeeding while another two reported no association. A cross-sectional study reported no association with breastfeeding initiation for women who delivered children in either China or Australia. One cohort study reported a negative association with duration of exclusive breastfeeding and two for any breastfeeding. The cross-sectional study reported no association between caesarean section and any breastfeeding duration for Chinese women delivering in their homelands, whereas for

Chinese women delivering in Australia caesarean section was associated with a longer duration.

Overall, approximately half of the studies failed to find an association between caesarean section and breastfeeding outcomes with the remainder of studies finding that women who delivered by caesarean section were less likely to initiate breastfeeding, in particular exclusive breastfeeding. Once established there appeared to be no association between caesarean section and overall duration of breastfeeding among Western women but it did appear to have a negative impact on Chinese women delivering in homeland countries. The inconsistency in findings suggests that the association may be due to a confounding factor not adjusted for in all studies. For instance, in those studies that adjusted for time taken to initiate breastfeeding and/or use of prelacteal feeds, delivery method was not shown to be independently associated with breastfeeding outcomes.

Studies used to make evidence statement for delivery methods and breastfeeding

Reference [1]	**Xu F, Binns C, Zhang H, Yang G & Zhao Y Journal of Human Lactation 2010.**	**Baxter J, Cooklin AR & Smith J Acta Paediatrica 2009; 98: 1274-1277.**	**Qiu L, Binns C, Zhao Y, Lee A & Xie X Asia-Pacific Journal of Public Health 2008; 20: 220-227**
Type of study [2]	Prospective cohort	Data from Longitudinal Study of Australian Children (LSAC) Retrospective cohort study using infant cohort only	Prospective cohort (6 months)
Level of evidence	II (aetiology)	III-2 (aetiology)	II (aetiology)
Breastfeeding definition	Any breastfeeding Exclusive breastfeeding (WHO)	Full breastfeeding Complementary breastfeeding (WHO)	Exclusive BF (WHO) Any breastfeeding
Intervention/ comparator [4]	Caesarean section vs vaginal delivery (ref)	C-section yes vs no	C-section vs vaginal delivery (reference)
N [5]	1256 mothers invited, 1219 agreed (97%) & 1088 fathers agreed (87%) (Analysis undertaken on 1088 couples)	5090 (54% response rate)	1520 of 1551 questionnaires (98% response rate)
Population/study information [6]	Xinjiang, China Mothers interviewed in hospital & 0.5, 1.5, 2.5, 3.5, 4.5 & 6 months after birth Recruited from 5 hospitals in urban & rural areas Smaller hospitals – all mothers recruited Larger hospitals – mothers recruited every 2nd or 3rd day	Australia Random sampling through Medicare database Interview with mothers of infants involved in LSAC Study aged 3-19 months Breastfeeding transitions between birth & 1 month and 1 month and 2 months	City, suburban & rural China Random sample of mothers from hospitals at city, suburban & rural locations. Interview conducted in hospital

Quality [7]	P	P	P
Results [8]	Adj HR (95%CI) any breastfeeding 1.57 (1.01-2.43) Adj HR (95%CI) exclusive breastfeeding 1.17 (0.97-1.41)	Transitions between birth & 1 month, marginal effects Still full breastfeeding: -6% (95% CI -8, -3) (p<0.001) Complementary feeds: 3% (95% CI 1, 4) (p<0.01) Not breastfeeding: 3% (95% CI 1, 5) (p<0.05) Transitions between 1 & 2 months, marginal effects Still full breastfeeding: 1% (95% CI -2, 3) Complementary feeds: 0% (95% CI -2, 1) Not breastfeeding: 0% (95% CI -2, 2) Still complementary feeds: -5 (95% CI -13, 4)	Adjusted OR of initiation during hospital 0.64 (95% CI 0.46-0.88) *Univariate analysis:* Mothers living in city & suburbs who had a c-section less likely to be breastfeeding on discharge than those who had vaginal delivery Effect size 35.8 vs 45 (city) & 59.6 vs 74.4 (suburbs) p<0.05 No effect on any breastfeeding.
Effect on risk	Mothers who delivered via caesarean section more likely to discontinue any breastfeeding before 6 months. No significant effect on exclusive breastfeeding.	For those who were full breastfeeding at birth, women who had c-sections less likely to be full breastfeeding at one month, more likely to be giving complementary feeds and more likely not to be breastfeeding For those who were fully breastfeeding at one month there was no significant association between delivery method and transition at 2 months.	Women who delivered by c-section less likely to initiate exclusive breastfeeding
Clinical	1	1	1

importance			
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Yes	Y (Chinese)
Applicability	Y (Chinese)	Yes	Y (Chinese)

Reference [1]	**Chien L & Tai C Birth 2007; 34: 123-130.**	**Qiu et al *Asia Pac J Clin Nutr 2007;16 (Suppl 1):458-461***	**Scott JA, Binns CW, Graham KI, Oddy WH Birth 2006; 33:37-45**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**
Type of study [2]	Prospective cohort study. Follow-up at 1 & 3 months after delivery	Prospective cohort study	Prospective cohort study	Prospective cohort study
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	II (aetiology)
Breastfeeding definition	Exclusive breastfeeding (water not considered) Partial breastfeeding (breast milk & formula) No breastfeeding	*Any* breastfeeding at discharge	Any breastfeeding at discharge, Exclusive breastfeeding since birth at discharge (WHO)	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)
Intervention/ comparator [4]	Cesarean section vs unassisted vaginal delivery (reference) Assisted vaginal delivery vs unassisted vaginal delivery (reference)	C-Section vs vaginal (Ref)	Vaginal delivery No vs yes (ref)	C-Section vs vaginal (ref)
N [5]	2079 of 3670 questionnaires returned (56.6% response rate) 15 excluded, final n=2064	638	587 (68% of 870 women contacted and 55% of 1068 eligible women)	587 (68% of 870 women contacted and 55% of 1068 eligible women)

Population/study information [6]	Taiwan Random, national sample from birth registration records	Mothers in Hangzhou, China were recruited and interviewed while in hospital.	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.
Quality [7]	P	P	P	P
Results [8]	Adjusted OR initiation during hospital stay Cesarean: 1.19 (95%CI 0.995-1.43) Assisted vaginal: 0.88 (95%CI 0.68-1.15) Adjusted OR breastfeeding 1 month after delivery (type not specified) Caesarean: 0.69 (95%CI 0.55-0.89) Assisted vaginal: 0.75 (95%CI 0.53-1.06) Adjusted OR breastfeeding 3 months after delivery (type not specified) Cesarean: 0.70 (95%CI 0.56-0.88) Assisted vaginal: 0.67 (95%CI 0.48-0.93)	*Any breastfeeding at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis	*Any breastfeeding at discharge* Crude OR (95% CI) 0.47 (0.23-0.94) No adjOR reported but non-significant when controlled for in multivariate analysis *Exclusive breastfeeding at discharge* adj OR (95% CI) 0.42 (0.26-0.68)	*Risk of discontinuing any BF* No adjOR reported but non-significant when controlled for in multivariate analysis *Risk of discontinuing full BF* No adjOR reported but non-significant when controlled for in multivariate analysis
Effect on risk	Women who had caesareans less likely to be breastfeeding at 1 and 3 months after delivery than	No association	There was no significant independent association between delivery method and any breastfeeding at	There was no association between delivery method and the duration of full and any breastfeeding.

	those with unassisted vaginal delivery. Women who had assisted vaginal delivery less likely to be breastfeeding at 3 months after delivery than those with unassisted vaginal delivery.		discharge but women who delivered by C-Section were significantly less likely to have breastfeed exclusively between birth and discharge	
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y (Taiwanese women)	Y (Chinese)	Y	Y
Applicability	Y (Taiwanese women)	Y	Y	Y

Reference [1]	**Butler S, Williams M, Tukuitonga C & Paterson J The New Zealand Medical Journal 2004; 117.**	**Li L, Scott JA, Binns CW J Hum Lact 2004; 20: 188-195**	**Binns CW, Gilchrist D, Gracey M et al Public Health Nutr 2004; 7: 857-861**	**Patel RR, Liebling RE & Murphy DJ Birth 2003; 30: 255-260.**
Type of study [2]	Prospective cohort	Cross-sectional (retrospective recall)	Prospective cohort study	Prospective cohort Follow-up at 6 weeks & 1 year after delivery
Level of evidence	II (aetiology)	IV (aetiology)	II (aetiology)	II (aetiology)
Breastfeeding definition	Exclusive breastfeeding – other (includes water) Not breastfeeding exclusively	Breastfeeding initiation Any breastfeeding duration	Any breastfeeding at discharge from hospital	Exclusive breastfeeding (not defined further) Breastfeeding at one year (not defined further)

Intervention/ comparator [4]	Caesarean vs vaginal delivery (reference)	C-section vs other (ref)	Vaginal delivery Yes vs No (Ref)	Caesarean section vs instrumental vaginal delivery (reference)
N [5]	1247	506. 95% of 532 women contacted and 17% of 2925 eligible women aged 23-59 estimated from 2001 Census.	425	393 (100% response rate)
Population/study information [6]	Auckland, New Zealand 1 or more parent Pacific ethnicity Data part of Pacific Islands Families (PIF) Study through interviews with mothers & hospital records	Mandarin speaking Chinese Australia mothers living in Perth 193 gave birth only in home country, 214 only in Australia and 99 gave birth in both countries.	Self-identified Aboriginal women delivering in the major Perth maternity hospital (n=310) and 5 suburban hospitals (n=115). baseline interviews conducted in prior to discharge.	Bristol, UK Women recruited from 2 hospitals, approached after delivery Questionnaires
Quality [7]	P	N	P	P
Results [8]	Adj OR not breastfeeding exclusively at hospital discharge 1.75 (95%CI 1.18-2.60)	*Breastfeeding initiation in home country* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant *Breastfeeding initiation in Australia* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant	*Breastfeeding at discharge* Adj OR 0.30 (95%CI 0.14-0.64)	Adj OR intended breastfeeding predelivery 0.64 (95%CI 0.39-1.07) Adj OR exclusive breastfeeding at discharge 0.84 (95%CI 0.50-1.41) Adj OR exclusive breastfeeding 6 wks 1.15 (95%CI 0.69-1.93) Adj OR exclusive breastfeeding 1 year 1.10 (95%CI 0.61-1.96)

		Breastfeeding duration in home country Not specified but controlled for in multivariate linear regression and non-significant *Breastfeeding duration in Australia* (multivariate linear regression) *β = 0.227 0.0003 – 0.451*		
Effect on risk	Women who delivered via caesarean more likely to not be breastfeeding exclusively at hospital discharge	Women who delivered in Australia by C-section breastfed for longer than women who delivered vaginally.	Women who delivered vaginally were less likely to be breastfeeding at discharge than those who delivered by C-Section	No significant association between breastfeeding and mode of delivery.
Clinical importance	1		1	1
Clinical relevance	1		1	1
Generalisability	Y (Pacific Islanders)	Y/N	Y	Y (English women)
Applicability	Y (Pacific Islanders)	Y/N	Y	Y (English women)

Reference	**Leung GM, Lam T & Ho L Obstetrics & Gynecology 2002; 99: 785-794**	**Rowe-Murray HJ & Fisher JRW Birth 2002; 29: 124-131.**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**
Type of study	Prospective cohort study (9 months)	Prospective cohort (Follow-up at 2 days & 8 months postpartum)	Prospective cohort study

Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	No definition	Not provided	Any breastfeeding at discharge Any breastfeeding duration
Intervention/ comparator	C-section vs normal vaginal delivery (reference) C-section vs forceps or vacuum delivery (reference)	Caesarean delivery vs spontaneous vaginal delivery (reference) Instrumentally assisted vaginal delivery vs spontaneous vaginal delivery (reference)	Vaginal vs C-section (ref)
N	8327 (final cohort) but 7825 followed up 95% response rate, accounting for 88% of births in the period	203 primiparous women (86% response rate)	556 urban, Perth 503 rural, Darling Downs, Queensland
Population/study information	Hong Kong All infants brought to health centre for first health check, across 47 centres	Melbourne, Australia Consecutive women identified from birth registers at 4 study hospitals Interview (2 days postpartum) Postal questionnaire (8 months postpartum)	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .
Quality	P	O	P
Results	*Adj OR never breastfed* Assisted delivery not sig: 1.09 (95% CI 0.95-1.26) Caserean delivery: 1.52 (95% CI 1.34-1.73) *Adj OR breastfed <1 month* Assisted delivery: 1.32 (95% CI 1.04-1.68) Caserean not sig: 0.25 (95% CI 1.00-1.56)	*Time to first breastfeed:* Significant differences between delivery groups, spontaneous vaginal delivery< time than instrumentally assisted delivery< caesarean section (p<0.001) [details not provided] No significant differences between elective & emergency caesarean (p=0.416) [details not provided] *Duration of breastfeeding:* No significant differences between delivery groups at 8 months (p=0.814)	*Breastfeeding at discharge* Crude OR 1.60 (95% CI 1.08-2.38) Adj OR Not specified but controlled for in multivariate logistic regression and non-significant *Risk of cessation of breastfeeding* Not specified but adjusted for in multivariate Cox regression analysis. Not significant

	Adj HR duration Assisted delivery not sig: 1.12 (95% CI 0.99-1.26) Caserean: 1.16 (95% CI 1.04-1.30)	[details not provided]	
Effect on risk	Women who delivered by c-section more likely to have never breastfed, more likely to breastfeed for less than one month and more likely to cease breastfeeding Women who had an assisted vaginal delivery more likely to breastfeed for less than one month.	Mothers who have a caesarean more likely to have a longer time to first breastfeed than spontaneous or instrumentally assisted vaginal delivery. Mothers who have instrumentally assisted vaginal delivery more likely to have a longer time to first breastfeed than spontaneous vaginal delivery. No effect on breastfeeding duration.	There was no significant independent association between delivery method and breastfeeding at discharge or breastfeeding duration
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Y	Y
Applicability	Y (Chinese)	Y	Y

Birth weight and breastfeeding

If the infant is not admitted to NICU, the rate of breastfeeding is not related to birthweight (see evidence Table).

For LBW infants (outside the scope of this review) every effort is now made to facilitate breastfeeding. Expressed breast milk is a factor in reducing the incidence of necrotizing enterocolitis in NICUs (James and Lessen 2009; Renfrew, Craig et al. 2009; Bartick and Reinhold 2010).

Studies used to make evidence statement for birth weight and breastfeeding

Reference	**Leung GM, Lam T & Ho L Obstetrics & Gynecology 2002; 99: 785-794**	**Qiu L, Binns C, Zhao Y, Lee A & Xie X Asia-Pacific Journal of Public Health 2008; 20: 220-227**	**Rajan L Midwifery 1994; 10: 87-103.**
Type of study	Prospective cohort study (9 months)	Prospective cohort (6 months) Cross-sectional analysis of baseline data	Cross-sectional (6 weeks post delivery)
Level of evidence	II (aetiology)	II (aetiology)	IV (aetiology)
Definition of breastfeeding	No definition	Exclusive BF (WHO) Any breastfeeding	Not provided
Intervention/ comparator	<2500g vs 3000-3499g (reference) 2500-2999 vs 3000-3499 3500-3999 vs 3000-3499 >4000 vs 3000-3499	Infant birth weight (details not provided)	Cross-tabulation: below 2500g, 2500-2999g, 3000-3499g, 3500-3999g, over 4000g
N	8327 (final cohort) but 7825 followed up 95% response rate, accounting for 88% of births in the period	1520 of 1551 questionnaires (98% response rate)	1149 (10% of initial survey) via follow-up postal questionnaire
Population/study information	Hong Kong All infants brought to health centre for first health check, across 47 centres	City, suburban & rural China Random sample of mothers from hospitals at city, suburban & rural locations. Interview conducted in hospital	UK women completing National Birthday Trust Fund Pain Relief in Labour survey
Quality	P	P	0
Results	*Adj OR never breastfed* <2500g vs 3000-3499g 1.25 (95% CI 0.96-1.64) 2500-2999 vs 3000-3499 1.05 (95% CI 0.93-1.19)	Adj OR exclusive breastfeeding initiation No significant effect (results not reported)	*Univariate analysis:* Breastfed compared with bottlefed compared with breast and bottle/ other: X^2=11.64, df=8, p=0.07

	3500-3999 vs 3000-3499 1.00 (95% CI 0.87-1.14) >4000 vs 3000-3499 1.11 (95% CI 0.84-1.48) *Adj OR breastfed<1 month* <2500g vs 3000-3499g 0.73 (95% CI 0.43-1.23) 2500-2999 vs 3000-3499 1.16 (95% CI 0.93-1.44) 3500-3999 vs 3000-3499 0.96 (95% CI 0.79-1.22) >4000 vs 3000-3499 1.15 (95% CI 0.68-1.94) *Adj HR duration* <2500g vs 3000-3499g 0.91 (95% CI 0.70-1.18) 2500-2999 vs 3000-3499 1.05 (95% CI 0.94-1.17) 3500-3999 vs 3000-3499 0.99 (95% CI 0.88-1.11) >4000 vs 3000-3499 1.00 (95% CI 0.77-1.32		

Effect on risk	No significant association between birth weight and breastfeeding initiation or duration	No significant association between infant birth weight and initiation of exclusive breastfeeding	No significant association between birth weight and feeding method.
Clinical importance	0	0	0
Clinical relevance	1	1	4
Generalisability	Y (Chinese)	Y (Chinese)	Y (UK)
Applicability	Y (Chinese)	Y (Chinese)	Y (UK)

Reference	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta PAediatr 1999;88: 416-421**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Scott JA, Binns CW, Aroni RA. J Paediatr Child Health 1997;33:305-307**
Type of study	Prospective cohort study	Prospective cohort study	Prospective cohort (Cross-sectional analysis of baseline data)
Level of evidence	II (aetiology)	II (aetiology)	IV (aetiology)
Definition of breastfeeding	Any breastfeeding duration	Any breastfeeding at discharge Any breastfeeding duration	Breastfeeding initiation
Intervention/ comparator	≥2500g vs < 2500g (low birth weight)	≥2500g vs < 2500g (low birth weight)	≥2500g vs < 2500g (ref)
N	556 (77% of women contacted, 58% of eligible women)	556 urban, Perth 503 rural, Darling Downs, Queensland	556 (77% of women contacted, 58% of eligible women)
Population/study information	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals
Quality	P	P	P

Results	No specified but adjusted for in backwards conditional Cox regression model	*Breastfeeding at discharge* Crude OR 2.16 (95% CI 1.13-4.12) *Cessation of breastfeeding* No specified but adjusted for in backwards conditional Cox regression model – non-significant	Adjusted OR for breastfeeding initiation 4.29 (95% CI 1.01 -18.28)
Effect on risk	There was no significant independent association between risk of cessation of breastfeeding and low birth weight	There was no significant independent association between infant low birth weight and breastfeeding at discharge or breastfeeding duration	Women who delivered an infant of ≥ 2500g BWT were significantly more likely to initiate breastfeeding than women who delivered a low BWT (<2500g) baby
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Reference	**Qiu et al *Asia Pac J Clin Nutr 2007;16 (Suppl 1):458-461***	**Clements et al Acta Paediatr, 1997; 86:51-56**	**Xu F, Binns C, Zhang H, Yang G & Zhao Y Journal of Human Lactation 2010.**
Type of study	Cross-sectional analysis at baseline of a prospective cohort study	Prospective cohort study	Prospective cohort
Level of evidence	IV (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	*Any* breastfeeding at discharge	Exclusive BF at discharge Any breastfeeding duration	Any breastfeeding Exclusive breastfeeding (WHO)

Intervention/ comparator	≥2500g vs < 2500g (low birth weight)	< 2500g vs 2500+g (ref)	Birth weight <2500g vs 2500-3999g (ref) ≥4000g vs 2500-3999g (ref)
N	638	700	1256 mothers invited, 1219 agreed (97%) & 1088 fathers agreed (87%) (Analysis undertaken on 1088 couples)
Population/study information	Mothers in Hangzhou, China were recruited and interviewed while in hospital.	Infants from South West Thames (UK) region were randomly selected from all births, except home births. The subjects were randomly allocated an age at which to be interviewed, in such a way as to ensure that they had a similar age distribution to that previously described for **SIDS** cases. The median age was 90 days (range 30-302 days). The study ran from 14 October 1990 to 13 October 1991.	Xinjiang, China Mothers interviewed in hospital & 0.5, 1.5, 2.5, 3.5, 4.5 & 6 months after birth Recruited from 5 hospitals in urban & rural areas Smaller hospitals – all mothers recruited Larger hospitals – mothers recruited every 2nd or 3rd day
Quality	P	P	P
Results	*Any breastfeeding at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis	*Exclusive BF at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis *Any breastfeeding duration* No adjOR reported but non-significant when controlled for in multivariate analysis	*<2500g vs 2500-3999g (ref)* Adj HR (95%CI) any breastfeeding 1.43 (0.53-3.86) Adj HR (95%CI) exclusive breastfeeding 1.87 (1.10-3.18) *≥4000g vs 2500-3999g (ref)* Adj HR (95%CI) any breastfeeding 0.58 (0.26-1.31) Adj HR (95%CI) exclusive

			breastfeeding 0.78 (0.58-1.04)
Effect on risk	No association	No association with exclusive BF at discharge or duration of any breastfeeding	Mothers who gave birth to babies with a birth weight <2500g were more likely to discontinue exclusive breastfeeding before 6 months. No significant association with any breastfeeding.
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Y (English)	Y (Chinese)
Applicability	Y	Y	Y (Chinese)

Impact of Prelacteal Feeds on Breastfeeding Outcomes

Search results
In total 29 papers were retrieved but data were extracted from only 5 papers, 2 Systematic Review and 3 prospective cohort studies. The majority of excluded studies were descriptive studies reporting the incidence of prelacteal feeding amongst Indian, primarily, or Chinese women. One prospective cohort study was an Australian study and two involved Chinese women. Sufficient evidence was found to make statements on the relationship between the use of prelacteal feeds and breastfeeding outcomes. Breastfeeding outcomes investigated included breastfeeding at discharge and breastfeeding duration.

What is the impact of prelacteal feeds on breastfeeding outcomes?		
Draft Evidence statement		There is consistent evidence to support the hypothesis that the use of prelacteal feeds negatively affects breastfeeding duration.
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	2 SLR (RCT 1), 3 cohort studies
Consistency	Poor	The SLR involving 1 RCT found a negative association with breastfeeding duration to 16 weeks and 1 cohort study found a negative association with breastfeeding at discharge. 2 cohort studies found no independent association with breastfeeding duration.
Clinical impact	Good	There was an association between the use of prelacteal feeds and exclusive breastfeeding and duration of any breastfeeding
Generalisability	Excellent	All studies involved either Australian women or women from relevant population sub-groups
Applicability	Satisfactory	Studies of Chinese women not directly relevant to the Australian healthcare context

One systematic literature review of randomised control trials was retrieved; however of the 58 potentially relevant trials investigating the impact of prelacteal feeds or supplements in the early post partum period only 1 met the inclusion criteria for the SLR. This study reported that significantly fewer infants in the experimental group who had received *ad libitum* 5% glucose water in the first 3 day of life were still breastfed at 16 weeks compared with the control group. 1 Chinese cohort study reported that the use of prelacteal feeds was negatively associated with breastfeeding at discharge while 1 Australian cohort study and 1 Chinese cohort study reported no association with the duration of any and exclusive/full breastfeeding when other potential confounders such as time to first feed were adjusted for.

Few studies have studied the effect of early prelacteal feeds and/or in-hospital supplementation on breastfeeding duration. The majority of studies from the USA conducted in the 1990s investigated the relationship of discharge packs containing infant formula on breastfeeding duration. These studies were not considered as the distribution of samples in this way is not permitted in Australia under the MAIF agreement. Overall, there is insufficient evidence to support or refute the hypothesis that the use of prelacteal feeds or the brief exposure of supplements in the early post partum period, negatively affect breastfeeding duration. However, all studies reported either a negative association or no association.

Studies used to make evidence statement for use of prelacteal or supplements in early post partum period

Reference [1]	**Szajewska et al. Acta Paed 2006;95:145-152**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**	**Qui et al J Health Popul Nutr 2010 Apr;28(2):189-198**
Type of study [2]	Systematic review of RCTs	Prospective cohort study	Prospective cohort study
Level of evidence	I (intervention)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding or exclusively breastfeeding at various time points. Exclusive BF not clearly defined	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Any breastfeeding Exclusive breastfeeding (WHO)
Intervention/ comparator [4]	Experimental groups received fluids such as water, water-based drinks, glucose solution, breast milk substitutes during first days of life as prelacteal feeds of supplements. Infants in the control group were exclusively breastfed	Infant's first feed Formula/other vs breast milk/colostrums (ref)	First feed: Breast milk vs other
N [5]	Search yielded 2859 citations of which 2801 were excluded as not relevant to breastfeeding supplementation. Of the 58 potentially relevant trials identified and/or or screened for retrieval only 1 met the inclusion criteria for the systematic review.	587 (68% of 870 women contacted and 55% of 1068 eligible women)	1520 (98% of 1520 invited to participate)
Population/study information [6]	83 in experimental group received 5% glucose *ad lib* after breastfeeds during first 3 d of life. Control group (n=87) exclusively BF.	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Mother were recruited from maternity wards of 3 hospitals in Zhejiang province, China from October 2004 toDecember 2005
Quality [7]	P	P	P

Results [8]	Intro of formula at 4 wk 34% Exp group and 18% control group ($p<0.05$) Continuation of breastfeeding at 16 wk 43% Exp group and 67% control group ($p<0.01$)	*Risk of discontinuing any BF* No adjOR reported but non-significant when controlled for in multivariate analysis *Risk of discontinuing full BF* No adjOR reported but non-significant when controlled for in multivariate analysis	Univariate Non Sig Any breastfeeding at 6 months Breast milk 77% (95% CI73.1-80.9) Other 71% (95% CI 67.1-74.9) Mean duration of Exclusive breastfeeding Breast milk 51.4d (95% CI 47.2-55.5) Other 40.4d (95% CI 35.0-45.7) Multivariate Cox regression Adj HR not specified but no independent significant association with any or exclusive breastfeeding with adjusted for in a backwards model
Effect on risk	SLR demonstrated lack of adequate RCT evidence to support or refute the hypothesis that brief exposure of breastfed infants to other liquids influences the success and/or duration of future breastfeeding	There was no association between prelacteal feeding and the duration of full and any breastfeeding.	No association
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y (Chinese)
Applicability	Y	Y	Y

Reference [1]	**WHO Review Ten Steps 1998**	**Declercq 2009 AJPH**	**Qiu et al Asia Pac J Clin Nutr 2007;16 (Suppl 1):458-461**

Type of study [2]	Systematic review of literature	National Survey USA	Prospective cohort study
Level of evidence	II (intervention)	III (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding or exclusively breastfeeding at various time points	Any breastfeeding or exclusively breastfeeding at various time points	*Any* breastfeeding at discharge
Intervention/ comparator [4]	Prelacteal feeds given or not	Prelacteal feeds given or not	Prelacteal feeds vs no prelacteal feeds (Ref)
N [5]	4 quasi- experimental studies. 1 RCT, 3 prospective cohort studies	N=1537	638
Population/study information [6]		National sample mothers USA	Mothers in Hangzhou, China were recruited and interviewed while in hospital.
Quality [7]	P	N	P
Results [8]	Evidence for an association between the use of supplements and premature cessation of breastfeeding	Mothers who reported supplemental feedings for their infant were less likely to achieve their intention to exclusively breastfeed: primiparas (adjusted odds ratio [AOR]=4.4; 95% confidence interval [CI]=2.1, 9.3); multiparas (AOR=8.8; 95% CI=4.4, 17.6)	Adj OR 0.12, 95% CI 0.06-0.24.
Effect on risk	Negative. Use of prelacteal feeds reduces breastfeeding duration	Negative. Use of prelacteal feeds reduces breastfeeding duration And exclusive breastfeeding	Prelacteal feeds were negatively associated with any breastfeeding at discharge. Use of prelacteal feeds was positively associated with the infant having been

			admitted to the NICU adj OR17.8 (10.5-30.4) and negatively associated with level of maternal education adj OR0.61 0.18-0.90
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y (Chinese)
Applicability	Y	Y	Y

WHO (WHO/CHD 1998)
For any breastfeeding babies being given food or drink other than breast milk there should be acceptable medical reasons. No promotion for infant foods or drinks other than breast milk should be displayed or distributed to mothers, staff, or the facility. (The Global Criteria for the WHO/UNICEF Baby Friendly Hospital Initiative, 1992).

ABM Protocol (Academy of Breastfeeding Medicine 2009)
Given early opportunities to breastfeed, breastfeeding assistance and instruction, the majority of mothers and babies will successfully establish breastfeeding. Although some infants may not successfully latch and feed during the first day (24 hours) of life, they will successfully establish breastfeeding with time, appropriate evaluation, and minimal intervention. Unfortunately, formula supplementation of healthy newborn infants in hospital is commonplace, despite widespread recommendations to the contrary. The most recent scientific evidence indicates that *exclusive breastfeeding* (only breast milk, no food or water except vitamins and medications) for the first 6 months is associated with the greatest protection against major health problems for both mothers and infants.

1. Healthy infants should be put skin-to-skin with the mother immediately after birth to facilitate breastfeeding because the delay in time between birth and initiation of the first breastfeed is a strong predictor of formula use.
2. Antenatal education and in-hospital support can significantly improve rates of exclusive breastfeeding. Both mothers and healthcare providers should be aware of the risks of unnecessary supplementation.
3. Healthy newborns do not need supplemental feedings for poor feeding for the first 24–48 hours, but babies who are too sick to breastfeed or whose mothers are too sick to allow breastfeeding are likely to require supplemental feedings.
4. Hospitals should strongly consider instituting policy regarding supplemental feedings to require a physician's order when supplements are medically indicated and informed consent of the mother when supplements are not medically indicated. It is the responsibility of the health professional to provide information, document parental decisions, and support the mother after she has made the decision.40 When the decision is not medically indicated, efforts to educate the mother ought to be documented by the nursing and/or medical staff.
5. All supplemental feedings should be documented, including the content, volume, method, and medical indication or reason.
6. If mother–baby separation is unavoidable, established milk supply is poor or questionable, or milk transfer is inadequate, the mother needs instruction and encouragement to pump or manually express her milk to stimulate production and provide expressed breast milk as necessary for the infant.19,30,31,35
7. When supplementary feeding is necessary, the primary goals are to feed the baby and also to optimize the maternal milk supply while determining the cause of poor feeding or inadequate milk transfer.
8. Whenever possible, it is ideal to have the mother and infant room-in 24 hours per day to enhance opportunities for breastfeeding and hence lactogenesis.

Factors protecting against Supplementation (Gagnon, Leduc et al. 2005)
In this study the authors reviewed the factors that protected a cohort of mother/infant pairs being given in hospital supplements.

"The UNICEF/WHO Baby-Friendly Hospital Initiative suggests that breastfeeding activities in hospital are important to later breastfeeding. Understanding reasons for in-hospital

supplementation may help to optimize the successful implementation of this initiative. The objective was to identify predictors of in-hospital initial formula supplementation of healthy, breastfeeding newborns. The authors analysed 564 Canadian mother-infant pairs and interviewed nurses. Half of the study infants (47.9%) received formula in hospital; the median age at first supplementation was 8.4 hours. Risk for supplementation was affected by birth occurring between 7 PM and 9 AM (hazard ratio [HR] varied with time) and high maternal trait anxiety (HR = 1.61, 95% confidence interval [CI] = 1.01, 2.59). The following variables were protective against supplementation: planning to exclusively breastfeed (HR = 0.46, 95% CI = 0.33, 0.64), planning to breastfeed for ≥ 3 months (HR = 0.56, 95% CI = 0.37-0.86), childbirth

education (HR = 0.61, 95% CI = 0.43, 0.86), mother born in Canada (HR = 0.68, 95% CI = 0.53, 0.87), completion of community college (HR = 0.76, 95% CI = 0.59, 0.98), male infant (HR = 0.78, 95% CI = 0.61, 0.99), and breastfeeding at delivery (HR varied with time). Nurses reported breastfeeding problems, infant behaviour, and maternal fatigue as reasons for supplementing. Reassessing patterns of night feeds and encouraging breastfeeding at delivery may decrease supplementation. Trait anxiety reduction and the role of infant gender in supplementation merit further study."

Ethnicity and Breastfeeding

Data were extracted from 7 studies, including 7 prospective cohort studies and 1cross-sectional study. All studies were from Australia with the exception of one New Zealand and one Chinese cohort study. The New Zealand cohort study reported no association between ethnicity and breastfeeding at discharge or at 6 weeks. The Chinese cohort study reported that the ethnic minority groups were less likely to discontinue exclusive breastfeeding before 6 months than the ethnic majority group. One Australian cohort study reported that Australian women were more likely to initiate breastfeeding and second reported they were more likely to be discharged form hospital exclusively breastfeeding than women from other ethnic groups. Three Australian cohort studies reported no association between ethnicity and breastfeeding duration. Only the one Australian cross-sectional study reported that Australian women were less likely to be breastfeeding at the time of the study than women from other ethnic groups.

There is insufficient evidence to make a formal evidence statement on ethnicity and breastfeeding in Australia. There appears to be no association between ethnicity and breastfeeding duration. While Australian women may be more likely to initiate breastfeeding or leave hospital fully breastfeeding, most Australian studies grouped women from all other countries together and compared against Australian born women, making it impossible to identify particular ethnic groups with breastfeeding initiation and duration rates different from Australian women.

Studies reviewed to make evidence statement for ethnicity

Reference	**Butler S, Williams M, Tukuitonga C & Paterson J The New Zealand Medical Journal 2004; 117.**	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta PAediatr 1999;88: 416-421**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Scott JA, Binns CW, Graham KI, Oddy WH Birth 2006; 33:37-45**
Type of study	Prospective cohort	Prospective cohort (6 mo)	Prospective cohort study	Prospective cohort study
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Exclusive breastfeeding – other (includes water) Not breastfeeding exclusively	Any breastfeeding duration (risk of breastfeeding cessation at anytime up to 6 months)	Any breastfeeding at discharge Any breastfeeding duration	Any breastfeeding at discharge, Exclusive breastfeeding since birth at discharge (WHO)
Intervention/ comparator	Ethnicity (details not provided)	Mother's country of birth Australia/NZ (ref) UK/Ireland, Asia, Other	Mother's country of birth Australia/NZ vs other (ref)	UK/Ireland, Other, Aust/NZ (ref)
N	1247	556 (77% of women contacted, 58% of eligible women)	556 urban, Perth 503 rural, Darling Downs, Queensland	587 (68% of 870 women contacted and 55% of 1068 eligible women)
Population/study information	Auckland, New Zealand 1 or more parent Pacific ethnicity Data part of Pacific Islands Families (PIF) Study through interviews with mothers & hospital records	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.
Quality	P	P	P	P
Results	Significance not reached for breastfeeding exclusively at hospital discharge or 6 weeks post birth (results not given)	Not specified but adjusted for in backwards conditional Cox regression analysis	*Breastfeeding at discharge* adjOR 1.98 (95% CI 1.14-2.43) *Risk of cessation of breastfeeding* Not specified but adjusted for in multivariate Cox regression analysis. Not significant	*Any breastfeeding at discharge* Crude OR (95% CI) UK/Ireland 0.67 (0.25-1.82) Other 2.36 (0.70-7.91) Adj OR Not specified but controlled for in multivariate logistic regression and non-significant

				Exclusive breastfeeding at discharge adj OR (95% CI) UK/Ireland 0.73 (0.32-1.67) Other 0.33 (0.18-0.59)
Effect on risk	No association between ethnicity and exclusive breastfeeding at hospital discharge or at 6 weeks post-birth.	There was no association between mother's country of birth and the risk of breastfeeding cessation	Women born in Australia or NZ were significantly more likely to be breastfeeding at discharge than women from other countries. There was no association with duration.	There was no association between maternal country of birth and any breastfeeding at discharge but women born in countries (other than UK/Ireland) were significantly less likely to be breastfeeding at discharge compared to women born in Australian or NZ.
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y (Pacific Islanders)	Y	Y	Y
Applicability	Y (Pacific Islanders)	Y	Y	Y

Reference	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**	**Xu F, Binns C, Zhang H, Yang G & Zhao Y Journal of Human Lactation 2010.**	**Yeoh BH, Eastwood J, Phung H & Woolfenden S Journal of Paediatrics & Child Health 2007; 43: 249-255.**	**Baghurst P, Pincombe J, Peat B, Henderson A, Reddin E & Antoniou G Midwifery 2007; 23: 382-391.**
Type of study	Prospective cohort study	Prospective cohort	Cross-sectional	Prospective cohort
Level of evidence	II (aetiology)	II (aetiology)	IV (aetiology)	II (aetiology)

Definition of breastfeeding	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Any breastfeeding Exclusive breastfeeding (WHO)	Any current breastfeeding including token, partial, fully & exclusive (other)	Fully breastfeeding (breast milk only) Partly breastfeeding (formula and/ or solids and breast milk)
Intervention/ comparator	UK/Ireland, Other, Aust/NZ (ref)	Ethnicity Uygur vs Han (ref) Kazakh vs Han (ref) Other vs Han (ref)	Country of birth: Other vs Australia (ref)	Maternal country of birth: Other vs Australia/ New Zealand (ref)
N	587 (68% of 870 women contacted and 55% of 1068 eligible women)	1256 mothers invited, 1219 agreed (97%) & 1088 fathers agreed (87%) (Analysis undertaken on 1088 couples)	9618 babies & mothers	317
Population/study information	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Xinjiang, China Mothers interviewed in hospital & 0.5, 1.5, 2.5, 3.5, 4.5 & 6 months after birth Recruited from 5 hospitals in urban & rural areas Smaller hospitals – all mothers recruited Larger hospitals – mothers recruited every 2nd or 3rd day	Sydney, Australia Data from Ingleburn Baby Information Systems Database-IBIS and Obstetrics Package – OBSTET IBIS-data collected at first well-baby clinic after hospital discharge OBSTET-data from hospital birthing units	Primiparous mothers South Australia, Australia Recruited from antenatal clinic at large, teaching hospital (sample not necessarily random) First contact prior to baby's birth, follow-up in hospital post delivery, 1 week, 6 weeks, 3 months & 6 months postpartum
Quality	P	P	P	P
Results	*Risk of discontinuing any BF* Adj HR not specified but controlled for in multivariate logistic regression and non-significant *Risk of discontinuing full BF* Adj HR not specified but	*Uygur vs Han* Adj HR (95%CI) any breastfeeding 1.14 (0.63-2.06) Adj HR (95%CI) exclusive breastfeeding 2.56 (2.00-3.27)	Adj OR (95%CI) risk for not breastfeeding 0.60 (0.53-0.69)	Adj HR for weaning (95%CI) 0.63 (0.31-1.26)

	controlled for in multivariate logistic regression and non-significant	*Kazakh vs Han* Adj HR (95%CI) any breastfeeding 0.72 (0.35-1.52) Adj HR (95%CI) exclusive breastfeeding 0.95 (0.72-1.27) *Other vs Han* Adj HR (95%CI) any breastfeeding 0.42 (0.09-1.84) Adj HR (95%CI) exclusive breastfeeding 0.65 (0.43-0.97)		
Effect on risk	There was no association between maternal country of birth and breastfeeding duration	Mothers with Uygur ethnicity more likely to discontinue exclusive breastfeeding before 6 months. Mothers with 'Other' ethnicity less likely to discontinue exclusive breastfeeding before 6 months. No associations for any breastfeeding.	Mothers who were not born in Australia were more likely to be breastfeeding at the time.	No significant association between weaning from breastfeeding & country of birth
Clinical importance	1	1	1	0
Clinical relevance	1	1	1	1
Generalisability	Y	Y (Chinese)	Y	Y
Applicability	Y	Y (Chinese)	Y	Y

Fathers and Breastfeeding

There is sufficient evidence to make a statement on the role of fathers in supporting the decision to breastfeed. There are supportive studies from Australia and China.
There is an association between breastfeeding and the support of fathers for breastfeeding. Mothers who have the support of the infants father are more likely to initiate breastfeeding and to breastfeed for longer.

Data were extracted from 10 studies, including 8 prospective cohort studies and 2 cross-sectional studies. Data from 10 publications were used to form the final body of evidence statement, which included 6 studies of Australian women, 4studies of Chinese women and one from Vietnam. Breastfeeding outcomes investigated included breastfeeding initiation/ at discharge and breastfeeding duration.

What is the association between fathers supporting the decision to breastfeeding and breastfeeding outcomes?		
Draft Evidence statement		When the infant's father is supportive of breastfeeding, initiation of breastfeeding is more likely and the duration will be longer for any breastfeeding
Draft Grade		**B**
Component	**Rating**	**Notes**
Evidence Base	Good	9 cohort studies, 1 cross-sectional studies ,
Consistency	Good	All except one of the studies found a positive effect. The study by Forster found a univariate effect, but no results given for the multivariate analysis which was reported as not significant.
Clinical impact	Good	Generally consistent association across cultures
Generalisability	Excellent	All studies involved either Australian women or women from relevant population sub-groups
Applicability	Satisfactory	Studies of Chinese women are relevant to the Australian healthcare context

The results of the studies reported are all consistent except for the RCT by Forster. However the RCT by Forster was a trial of an antenatal intervention. There was no specific intervention related to fathers. Hence this should be classified as a cohort study in this context. A RCT just being completed (FIFI Study, Perth WA) which trialled a specific educational intervention for fathers did show a an effect and will be published shortly (Tohotoa, Binns)

Studies used to make evidence statement for the association of fathers attitude/support and breastfeeding

Reference	**Chien L & Tai C Birth 2007; 34: 123-130.**	**Scott JA, Binns CW, Aroni RA. J Paediatr Child Health 1997;33:305-307**	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta Paediatr 1999;88: 416-421**	**Forster DA, McLachlan HL & Lumley J International Breastfeeding Journal 2996; 1.**
Type of study	Prospective cohort study. Follow-up at 1 & 3 months after delivery	Prospective cohort study	Prospective cohort study	RCT (analysed as cohort study)
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Exclusive breastfeeding (water not considered) Partial breastfeeding (breast milk & formula) No breastfeeding	Breastfeeding initiation	Any breastfeeding duration	Any breastfeeding (at 6 months)
Intervention/ comparator	Father's support for breastfeeding vs ? father's non-support (reference not clearly defined)	Father prefers breastfeeding vs father prefers bottle feeding or ambivalent (mother's perception)	Father prefers breastfeeding vs father prefers bottle feeding or ambivalent (mother's perception)	Partner prefers me to breastfeed vs other than prefer breastfeed (ref)
N	2079 of 3670 questionnaires returned (56.6% response rate) 15 excluded, final n=2064	556 (77% of women contacted, 58% of eligible women)	556 (77% of women contacted, 58% of eligible women)	981
Population/study information	Taiwan Random, national sample from birth registration records	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Melbourne, Australia Primiparous women attending a public, tertiary hospital All eligible women approached for participation Data from RCT used investigating effect of 2 pregnancy interventions on breastfeeding initiation & duration Interview in hospital at birth

				& at 6 months over phone
Quality	P	P	P	P
Results	Adjusted OR initiation during hospital stay 1.02 (95% CI 1.01-1.03) Adjusted OR breastfeeding 1 month after delivery (type not specified) 1.03 (95% CI 1.02-1.04) Adjusted OR breastfeeding 3 months after delivery (type not specified) 1.01 (95%CI 0.995-1.02)	Adjusted OR for breastfeeding initiation 10.18 (95%CI 4.42-23.42)	Adjusted HR 1.52 (95% CI 1.04-2.21)	(Univariate analysis) OR any breastfeeding at 6 months 1.52 (95%CI 1.15-2.02) Multivariate analysis – not significant (results not provided)
Effect on risk	When fathers provided breastfeeding support, mothers were more likely to initiate breastfeeding and be breastfeeding 1 month after delivery (weak effect).	Women who perceived their partner to prefer breastfeeding were significantly more likely to initiate breastfeeding than women who perceived their partner to prefer bottle feeding or to be ambivalent about how they fed their infant	Women who perceived their partner to prefer bottle feeding or to be ambivalent about how they fed their infant had a significantly higher risk of stopping breastfeeding than women who perceived their partner to prefer breastfeeding	Women whose partner preferred them to breastfeed were more likely to be feeding any breast milk at 6 months (univariate analysis only)
Clinical importance	1	1	1	4
Clinical relevance	1	1	1	1
Generalisability	Y (Taiwanese women)	Y	Y	Y
Applicability	Y (Taiwanese women)	Y	Y	Y

Reference	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Li L, Scott JA, Binns CW J Hum Lact 2004; 20: 188-195**	**Binns CW, Gilchrist D, Gracey M et al Public Health Nutr 2004; 7: 857-861**
Type of study	Prospective cohort study	Cross-sectional (retrospective recall)	Prospective cohort study
Level of evidence	II (aetiology)	IV (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding at discharge Any breastfeeding duration	Breastfeeding initiation Any breastfeeding duration	Any breastfeeding at discharge from hospital
Intervention/ comparator	Father prefers breastfeeding vs prefer bottle or ambivalent (Ref)	Father prefers breastfeeding Yes *vs* No (ref)	Father prefers breastfeeding vs prefers bottle or ambivalent (Ref)
N	556 urban, Perth 503 rural, Darling Downs, Queensland	506 (95% of 532 women contacted and 17% of 2925 eligible women aged 23-59 estimated from 2001 Census)	425
Population/study information	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Mandarin speaking Chinese Australia mothers living in Perth 193 gave birth only in home country, 214 only in Australia and 99 gave birth in both countries.	Self-identified Aboriginal women delivering in the major Perth maternity hospital (n=310) and 5 suburban hospitals (n=115). baseline interviews conducted in prior to discharge.
Quality	P	P	P
Results	*Breastfeeding at discharge* Adj OR 9.13 (95%CI 4.83-17.26) Adj HR cessation of breastfeeding 0.58 (95%CI 0.45-0.75)	*Breastfeeding initiation in home country* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant *Breastfeeding initiation in Australia* Adj OR 4.96 (95%CI 1.93-12.66) *Breastfeeding duration in home country Australia* Not specified but controlled for in multivariate linear regression and non-significant *Breastfeeding duration in Australia* Not specified but controlled for in	*Breastfeeding at discharge* Adj OR 6.65 (95%CI 2.81-15.74)

		multivariate linear regression and non-significant	
Effect on risk	Women who perceived their partner to prefer breastfeeding were more likely to be breastfeeding at discharge and to breastfeed for longer	There was a independent positive association between father's preference for breastfeeding and breastfeeding initiation among women delivering in Australia but not in their home country. There was no association with breastfeeding duration either for women delivering in Australia or their home country.	There was a independent positive association between father's preference for breastfeeding and breastfeeding at discharge
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y (Chinese)	Y
Applicability	Y	Y	Y

Reference	**Qiu et al *Asia Pac J Clin Nutr 2007;16 (Suppl 1):458-461***	**Xu F, Binns C, Zhang H, Yang G & Zhao Y Journal of Human Lactation 2010.**	**Scott JA, Binns CW, Graham KI, Oddy WH Borth 2006; 33:37-45**
Type of study	Prospective cohort study	Prospective cohort	Prospective cohort study
Level of evidence	IV (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	*Any* breastfeeding at discharge	Any breastfeeding Exclusive breastfeeding (WHO)	Any breastfeeding at discharge, Exclusive breastfeeding since birth at discharge (WHO)
Intervention/ comparator	Father prefers breastfeeding vs father prefers bottle or ambivalent (ref)	Father suggested breastfeeding (further details not provided)	Father prefers breastfeeding vs father prefers bottle or ambivalent (ref)
N	638	1256 mothers invited, 1219 agreed (97%) & 1088 fathers agreed (87%) (Analysis undertaken on 1088 couples)	587 (68% of 870 women contacted and 55% of 1068 eligible women)

Population/study information	Mothers in Hangzhou, China were recruited and interviewed while in hospital.	Xinjiang, China Mothers interviewed in hospital & 0.5, 1.5, 2.5, 3.5, 4.5 & 6 months after birth Recruited from 5 hospitals in urban & rural areas Smaller hospitals – all mothers recruited Larger hospitals – mothers recruited every 2nd or 3rd day	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.
Quality	P	P	P
Results	Adj OR Not specified but controlled for in multivariate logistic regression and non-significant	Not significant (results not provided)	*Any breastfeeding at discharge* adj OR (95% CI) 12.12 (2.00-73.50) *Exclusive breastfeeding at discharge* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant
Effect on risk	No association	No effect of whether the father suggested breastfeeding on the risk of discontinuing any or exclusive breastfeeding before 6 months.	Women who perceived their partner to prefer breastfeeding were significantly more likely to be feeding their infants any breast milk at discharge but were no more likely to be exclusively BF at discharge
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Y (Chinese)	Y
Applicability	Y	Y (Chinese)	Y

Social support (other than fathers) and breastfeeding

There is insufficient evidence to make a statement on the role of maternal grandmothers in supporting the decision to breastfeed.

There are prospective studies from Australia, Vietnam and China which studied the effect of a supportive grandmother on breastfeeding initiation and duration.

However the studies are inconsistent in their results and no conclusion can be drawn.

Studies used to make evidence statement for the association of social support (other than fathers) and breastfeeding

Reference	**Qiu L, Binns C, Zhao Y, Lee A & Xie X** J HEALTH POPUL NUTR 2010 Apr;28(2):189-198	**Forster DA, McLachlan HL & Lumley J International Breastfeeding Journal 2006; 1.**	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta Paediatr 1999;88: 416-421**	**Li L, Scott JA, Binns CW J Hum Lact 2004; 20: 188-195**
Type of study	Prospective cohort (6 months)	RCT (analysed as a cohort study)	Prospective cohort (6 mo)	Cross-sectional (retrospective recall)
Level of evidence	II (aetiology)	II (aetiology)	II(aetiology)	IV(aetiology)
Definition of breastfeeding	Exclusive BF (WHO) Any breastfeeding	Any breastfeeding (at 6 months)	Any breastfeeding duration (risk of breastfeeding cessation at anytime up to 6 months)	Breastfeeding initiation Any breastfeeding duration
Intervention/ comparator	Grandmother supportive of breastfeeding vs not supportives (reference)	Family prefers me to breastfeed vs other than prefer breastfeed (ref)	Maternal grandmother prefers breastfeeding vs prefers bottle feeding or ambivalent (mother's perception)	Maternal grandmother prefers breastfeeding Yes vs No (ref)
N	N=1520 (98% response rate)	981	556 (77% of women contacted, 58% of eligible women)	506 (95% of 532 women contacted and 17% of 2925 eligible women aged 23-59 estimated from 2001 Census)
Population/study information	City, suburban & rural China Random sample of mothers from hospitals at city, suburban & rural locations. Interview conducted in hospital	Melbourne, Australia Primiparous women attending a public, tertiary hospital All eligible women approached for participation Data from RCT used investigating effect of 2 pregnancy interventions on breastfeeding initiation & duration Interview in hospital at birth & at 6 months over phone	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Mandarin speaking Chinese Australia mothers living in Perth 193 gave birth only in home country, 214 only in Australia and 99 gave birth in both countries.
Quality	P	P	P	O

Results	NS effect	(Univariate analysis) OR any breastfeeding at 6 months 1.95 (95%CI 1.49-2.55) Multivariate analysis – not significant (results not provided)	Maternal Grandmother support NS.	*Breastfeeding initiation in home country* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant *Breastfeeding initiation in Australia* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant *Breastfeeding duration in home country* *Australia* Not specified but controlled for in multivariate linear regression and non-significant *Breastfeeding duration in Australia* Not specified but controlled for in multivariate linear regression and non-significant
Effect on risk	Supportive of grandmother not associated with duration od any breastfeeding	Women whose family preferred them to breastfeed were more likely to be feeding any breast milk at 6 months (univariate analysis only)	There was no association between mothers perception of maternal grandmothers feeding preference and the risk of breastfeeding cessation	There was no association between maternal grandmother's preference for breastfeeding and either breastfeeding initiation or duration among women delivering in their home

				country and/or Australia.
Clinical importance	0	4	1	1
Clinical relevance	1	1	1	1
Generalisability	Y (Chinese)	Y	Y	Y (Chinese)
Applicability	Y (Chinese)	Y	Y	Y

Reference	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Binns CW, Gilchrist D, Gracey M et al Public Health Nutr 2004; 7: 857-861**	**Qiu et al *Asia Pac J Clin Nutr 2007;16 (Suppl 1):458-461***
Type of study	Prospective cohort study	Prospective cohort study	Prospective cohort study aetiology)
Level of evidence	II(aetiology)	II(aetiology)	IV (aetiology)
Definition of breastfeeding	Any breastfeeding at discharge Any breastfeeding duration	Any breastfeeding at discharge from hospital	*Any* breastfeeding at discharge
Intervention/ comparator	Maternal grandmother prefers breastfeeding vs prefers bottle or ambivalent (Ref)	Maternal grandmother prefers breastfeeding vs prefers bottle or ambivalent (Ref)	Maternal grandmother prefers breastfeeding vs prefers bottle or ambivalent (Ref)
N	556 urban, Perth 503 rural, Darling Downs, Queensland	425	638
Population/study information	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Self-identified Aboriginal women delivering in the major Perth maternity hospital (n=310) and 5 suburban hospitals (n=115). baseline interviews conducted in prior to discharge.	Mothers in Hangzhou, China were recruited and interviewed while in hospital.
Quality	P	P	P
Results	*Breastfeeding at discharge* Adj OR 2.16 (95%CI 1.15-4.03) *Cessation of breastfeeding* Adj HR not specified but controlled for in backwards conditional multivariate analysis and not significant	*Breastfeeding at discharge* Crude OR 3.19 (95%CI 1.49-6.80) Not significant when controlled for in multivariate analysis	*Any breastfeeding at discharge* Adj OR 3.60 (95% CI 1.43-9.04)
Effect on risk	Women who perceived their mother to prefer breastfeeding were more likely to be breastfeeding at discharge. There was not association with breastfeeding duration	There was no independent association between breastfeeding initiation and maternal grandmother's preference for breastfeeding	Positive association Women who perceived their mother to prefer breastfeeding were more likely to be breastfeeding at discharge.
Clinical importance	1	1	1
Clinical relevance	1	1	1

Generalisability	Y	Y	Y (Chinese)
Applicability	Y	Y	Y

Reference	**Scott JA, Binns CW, Oddy WH, Graham K. Pediatrics 2006;** 117;646-655	**Duong D, Binns CW, Lee AH, Public Health Nutrition 2004** : 7(6), 795–799	**Baghurst P, Pincombe J, Peat B, Henderson A, Reddin E & Antoniou G Midwifery 2007; 23: 382-391.**
Type of study	Prospective cohort study	Prospective cohort study	Prospective cohort
Level of evidence	II(aetiology)	II(aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding at discharge Any breastfeeding duration	Exclusive breastfeeding at discharge from hospital	Fully breastfeeding (breast milk only) Partly breastfeeding (formula and/ or solids and breast milk)
Intervention/ comparator	Maternal grandmother prefers breastfeeding vs prefers bottle or ambivalent (Ref)	Maternal grandmother prefers breastfeeding vs prefers bottle or ambivalent (Ref)	Living situation: On own vs with partner (ref) With parents, other family members or friends vs with partner (ref) Other vs with partner (ref)
N	556 urban, Perth 503 rural, Darling Downs, Queensland	463	317
Population/study information	Mother recruited from maternity wards. Interviewed after birth and Follow-up telephone interviews at 4, 10, 16, 22, 32, 40, and 52 weeks postpartum	A prospective cohort study in a rural population of northern Vietnam	Primiparous mothers South Australia, Australia Recruited from antenatal clinic at large, teaching hospital (sample not necessarily random) First contact prior to baby's birth, follow-up in hospital post delivery, 1 week, 6 weeks, 3 months & 6 months postpartum
Quality	P	P	P
Results	*Duration of Breastfeeding* Adjusted OR of discontinuing any breastfeeding before 12 months 0.71 (0.55,0.9)	*Breastfeeding at discharge* Adj OR. Of exclusive breastfeeding on discharge 3.52 (1.21,10.28)	*On own vs with partner* Adj HR for weaning (95%CI) 0.48 (0.13-1.79) *With parents, other family members or friends vs with partner*

			Adj HR for weaning (95%CI) 1.40 (0.53-3.72) *Other vs with partner* Adj HR for weaning (95%CI) 0.45 (0.12-1.64)
Effect on risk	Where grandmother supported breastfeeding mothers were less likely to discontinue breastfeeding before 12 months	There was an association between exclusive breastfeeding on discharge from hospital and maternal grandmother's preference for breastfeeding	No significant association between weaning from breastfeeding & living situation
Clinical importance	1	1	0
Clinical relevance	1	1	1
Generalisability	Y	Y (Vietnamese)	Y
Applicability	Y	Y	Y

Infant Gender and Breastfeeding

There is insufficient evidence to make a statement of evidence.

There were nine studies included in the evidence table. 8 prospective cohort studies and one cross sectional study with retrospective data.

Only one study found a gender preference in breastfeeding duration.

Studies used to make evidence statement for the association of infant gender and breastfeeding

Reference	**Author Year (Ref no.)** **Leung GM, Lam T & Ho L Obstetrics & Gynecology 2002; 99: 785-794**	**Author Year (Ref no.)** **Qiu L, Binns C, Zhao Y, Lee A & Xie X Asia-Pacific Journal of Public Health 2008; 20: 220-227**	**Scott JA, Binns CW, Aroni RA. J Paediatr Child Health 1997;33:305-307**
Type of study	Prospective cohort study (9 months)	Prospective cohort (6 months)	Prospective cohort
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	No definition	Exclusive BF (WHO) Any breastfeeding	Breastfeeding initiation
Intervention/ comparator	Female vs male (reference)	Infant gender	Female vs male (ref)
N	8327 (final cohort) but 7825 followed up 95% response rate, accounting for 88% of births in the period	1520 of 1551 questionnaires (98% response rate)	556 (77% of women contacted, 58% of eligible women)
Population/study information	Hong Kong All infants brought to health centre for first health check, across 47 centres	City, suburban & rural China Random sample of mothers from hospitals at city, suburban & rural locations. Interview conducted in hospital	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals
Quality	P	P	P
Results	*Adj OR never breast-fed* not sig 0.99 (95%CI 0.90-1.10) *Adj OR breastfed<1 month* not sig 0.87 (95%CI 0.73-1.04) *Adj HR duration* not sig 0.94 (95%CI 0.86-1.02)	No significant effect (results not reported)	Not specified but adjusted for in backwards conditional multivariate logistic regression
Effect on risk	No significant associations between	No significant association between gender	There was no significant independent

	gender of infant and breastfeeding	of infant and initiation of exclusive breastfeeding	association between infant gender and the initiation of breastfeeding
Clinical importance	0	0	1
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Y (Chinese)	Y
Applicability	Y (Chinese)	Y (Chinese)	Y

Reference	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Li L, Scott JA, Binns CW J Hum Lact 2004; 20: 188-195**	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta PAediatr 1999;88: 416-421**
Type of study	Prospective cohort study	Cross-sectional (retrospective recall)	Prospective cohort study
Level of evidence	II (aetiology)	IV (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding at discharge Any breastfeeding duration	Any breastfeeding duration	Any breastfeeding duration
Intervention/ comparator	Males vs Females (ref)	Males vs females	Males vs females (ref)
N	556 urban, Perth 503 rural, Darling Downs, Queensland	506 (95% of 532 women contacted and 17% of 2925 eligible women aged 23-59 estimated from 2001 Census)	556 (77% of women contacted, 58% of eligible women)
Population/study information	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Mandarin speaking Chinese Australia mothers living in Perth 193 gave birth only in home country, 214 only in Australia and 99 gave birth in both countries.	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum
Quality	P	O	P
Results	*Breastfeeding at discharge* Crude OR 0.92 (95% CI 0.67-1.26) *Cessation of breastfeeding* Adj HR 1.28 (95%CI 0.99-1.66)	*Breastfeeding initiation in home country* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant *Breastfeeding initiation in Australia* Adj OR Not specified but controlled for in	Adjusted HR 1.69 (95% CI 1.16-2.50)

		multivariate logistic regression and non-significant *Breastfeeding duration in home country Australia* Not specified but controlled for in multivariate linear regression and non-significant *Breastfeeding duration in Australia* Not specified but controlled for in multivariate linear regression and non-significant	
Effect on risk	There was a non-significant association between infant gender and outcomes with males being less likely to be breastfed at discharge and at greater risk for cessation of breastfeeding	There was no association between infant gender and either breastfeeding initiation or duration among women delivering in their home country and/or Australia	Women who delivered a male infant had a significantly higher risk of stopping breastfeeding at any time to 6 months than women delivered a female infant
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y (Chinese)	Y
Applicability	Y	Y	Y

Reference	**Xu F, Binns C, Zhang H, Yang G & Zhao Y Journal of Human Lactation 2010.**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**	**Clements et al Acta Paediatr, 1997; 86:51-56**
Type of study	Prospective cohort	Prospective cohort study	Prospective cohort study
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding Exclusive breastfeeding (WHO)	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Exclusive BF at discharge Any breastfeeding duration
Intervention/ comparator	Infant's gender (details not provided)	Males vs females (ref)	Male vs female (ref)

N	1256 mothers invited, 1219 agreed (97%) & 1088 fathers agreed (87%) (Analysis undertaken on 1088 couples)	587 (68% of 870 women contacted and 55% of 1068 eligible women)	700
Population/study information	Xinjiang, China Mothers interviewed in hospital & 0.5, 1.5, 2.5, 3.5, 4.5 & 6 months after birth Recruited from 5 hospitals in urban & rural areas Smaller hospitals – all mothers recruited Larger hospitals – mothers recruited every 2nd or 3rd day	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Infants from South West Thames (UK) region were randomly selected from all births, except home births. The subjects were randomly allocated an age at which to be interviewed, in such a way as to ensure that they had a similar age distribution to that previously described for **SIDS** cases. The median age was 90 days (range 30-302 days). The study ran from 14 October 1990 to 13 October 1991.
Quality	P	P	P
Results	Not significant (results not provided)	*Risk of discontinuing any BF* No adjOR reported but non-significant when controlled for in multivariate analysis *Risk of discontinuing full BF* No adjOR reported but non-significant when controlled for in multivariate analysis	*Exclusive BF at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis *Any breastfeeding duration* No adjOR reported but non-significant when controlled for in multivariate analysis
Effect on risk	No effect of infant gender on the risk of discontinuing any or exclusive breastfeeding before 6 months.	There was no association between infant gender and the duration of full and any breastfeeding.	No association with exclusive BF at discharge or duration of any breastfeeding
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Y	Y (English)
Applicability	Y (Chinese)	Y	Y

Infant health status and breastfeeding

Insufficient evidence to make an Evidence Statement.

Nevertheless there is a trend towards showing that infants who are of normal birth weight, but who require admission to NICU do not have as favourable breastfeeding outcomes as other infants.

Studies used to make evidence statement for infant health status

Reference	**Rajan L Midwifery 1994; 10: 87-103.**	**Qiu et al *Asia Pac J Clin Nutr 2007;16 (Suppl 1):458-461***	**Clements et al Acta Paediatr, 1997; 86:51-56**
Type of study	Cross-sectional (6 weeks post delivery)	Prospective cohort study	Prospective cohort study
Level of evidence	IV (aetiology)	II (aetioloigy)	II (aetiology)
Definition of breastfeeding	Not provided	*Any* breastfeeding at discharge	Exclusive BF at discharge Any breastfeeding duration
Intervention/ comparator	Cross-tabulation of problems noted: no problems, one problem, two or more problems	Admitted to NICU vs no admitted to NICUE (ref)	Admitted to neonatal unit yes vs no (ref)
N	1149 (10% of initial survey) via follow-up postal questionnaire	638	700
Population/study information	UK women completing National Birthday Trust Fund Pain Relief in Labour survey	Mothers in Hangzhou, China were recruited and interviewed while in hospital.	Infants from South West Thames (UK) region were randomly selected from all births, except home births. The subjects were randomly allocated an age at which to be interviewed, in such a way as to ensure that they had a similar age distribution to that previously described for **SIDS** cases. The median age was 90 days (range 30-302 days). The study ran from 14 October 1990 to 13 October 1991.
Quality	0	P	P
Results	*Univariate analysis:* Breastfed compared with bottlefed compared with breast and bottle/ other: X^2=9.41, df=4, p=0.05 Trend: a lower percentage of infants with more problems were breastfed	*Any breastfeeding at discharge* Adj Or 0.39 (95% CI0.16-0.92)	*Exclusive BF at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis *Any breastfeeding duration* No adjOR reported but non-significant when controlled for in multivariate analysis
Effect on risk	Significant difference noted between	Negatively associated with admission to	No association with exclusive BF at

	mode of infant feeding and number of infant problems (health status).	NICU	discharge or duration of any breastfeeding
Clinical importance	1	1	1
Clinical relevance	4	1	1
Generalisability	Y (UK)	Y (Chinese)	Y (English)
Applicability	Y (UK)	Y	Y

Location (rural vs urban) and breastfeeding

Sufficient evidence to make a statement if these studies taken in association with breastfeeding statistics. Evidence grade Level C

Australia – no difference or slight increase in rural areas in the smaller cohort studies. Cross sectional studies (eg ABS) show higher ever breastfed rates in rural areas
Eg "Mothers living in capital cities tended to breastfeed for shorter durations than those living in other urban or rural areas". (Jain 1996)

China – a review of 79 reported studies of breastfeeding 1990-2008 found that breastfeeding rates were higher in rural areas. However exclusive breastfeeding rates in the first months were likely to be lower in rural areas, particularly in the ethnic minority areas where complementary feeds (eg tea) are often given in the first weeks after birth (Xu, Qiu et al. 2009).

Studies used to make evidence statement for the association of location (rural vs urban) and breastfeeding

Reference	**Leung GM, Lam T & Ho L Obstetrics & Gynecology 2002; 99: 785-794**	**Qiu L, Binns C, Zhao Y, Lee A & Xie X Asia-Pacific Journal of Public Health 2008; 20: 220-227**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**
Type of study	Prospective cohort study (9 months)	Prospective cohort (6 months)	Prospective cohort study
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	No definition	Exclusive BF (WHO) Any breastfeeding	Any breastfeeding at hospital discharge Any breastfeeding duration (Risk of cessation of breastfeeding)
Intervention/ comparator	Kowloon vs Hong Kong (reference) New Territories vs Hong Kong (reference)	City vs suburb (reference)	Rural (Qld) vs Urban (Perth)
N	8327 (final cohort) but 7825 followed up 95% response rate, accounting for 88% of births in the period	1520 of 1551 questionnaires (98% response rate)	556 urban, Perth 503 rural, Darling Downs, Queensland
Population/study information	Hong Kong All infants brought to health centre for first health check, across 47 centres	City, suburban & rural China Random sample of mothers from hospitals at city, suburban & rural locations. Interview conducted in hospital	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .
Quality	P	P	P
Results	*Adj OR never breast-fed* Kowloon: 1.21 (95%CI 1.05-1.40) New Territories: 1.33 (95%CI 1.16-1.52) *Adj OR breastfed<1 month* Kowloon not sig: 1.02 (95%CI 0.79-1.30) New Territories not sig: 1.14 (95%CI 0.91-1.43) *Adj HR duration* Kowloon not sig: (95%CI 0.96-1.23)	Adj OR exclusive breastfeeding initiation 0.61 (96%CI0.42-0.89)	*Breastfeeding at hospital discharge* Crude OR 0.90 (95%CI 0.65-1.24) *Cessation of breastfeeding* Not specified but adjusted for in multivariate analysis and non-significant

	New Territories not sig: 1.04 (95%CI 0.93-1.17)		
Effect on risk	Women living in Kowloon and the New Territories more likely to have never breastfedthan those living in Hong Kong	Women living in the city less likely to initiate exclusive breastfeeding than those living in the suburbs	There was no difference between rural and urban Australian women with regard to breastfeeding at discharge or overall duration.
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Y (Chinese)	Y
Applicability	Y (Chinese)	Y (Chinese)	Y

Reference	**Qiu L, Binns CW, Zhao Y, Lee AH, Xie X. J Health Popul Nutr (2010) 28(2):189-198**	**Xu F, Binns C, Zhang H, Yang G & Zhao Y Journal of Human Lactation 2010.**	**Binns CW, Gilchrist D, Gracey M et al Public Health Nutr 2004; 7: 857-861**
Type of study	Prospective cohort study	Prospective cohort	Prospective cohort study
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	*Any* breastfeeding at discharge	Any breastfeeding Exclusive breastfeeding (WHO)	Any breastfeeding at discharge from hospital
Intervention/ comparator	Father prefers breastfeeding vs father prefers bottle or ambivalent (ref)	Father suggested breastfeeding (further details not provided)	Rural vs urban (ref)
N	1520	1256 mothers invited, 1219 agreed (97%)	425
Population/study information	Mothers in three locations in Zhejiang, China were recruited and interviewed while in hospital.	Xinjiang, China Mothers interviewed in hospital & 0.5, 1.5, 2.5, 3.5, 4.5 & 6 months after birth Recruited from 5 hospitals in urban & rural areas Smaller hospitals – all mothers recruited Larger hospitals – mothers recruited every 2nd or 3rd day	Self-identified Aboriginal women delivering in the major Perth maternity hospital (n=310) and 5 suburban hospitals (n=115). baseline interviews conducted in prior to discharge.

Quality	P	P	P
Results	Adj OR 0.291 (0.183,0.461) for cessation before 6 months for rural compared to city mothers	Significant longer duration of any breastfeeding in rural areas.	*Breastfeeding at discharge* Crude OR 1.52 (95%CI 0.68-3.39)
Effect on risk	Rural mothers breastfed for longer compared to city mothers	No effect of whether the father suggested breastfeeding on the risk of discontinuing any or exclusive breastfeeding before 6 months.	There was no association between place of residence and breastfeeding (note all mothers in this study delivered in the city)
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Y (Chinese)	Y
Applicability	Y	Y (Chinese)	Y

Socioeconomic status

Sufficient evidence to make a statement if these studies taken in association with breastfeeding statistics. Evidence grade Level C

"The 1995 NHS shows a strong relationship between socioeconomic status and the rate of breastfeeding. Higher socioeconomic status has been associated with higher rates of breastfeeding consistently in Australia and other developed countries" (Donath and Amir 2000).

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Studies used to make evidence statement for socioeconomic status

Reference	**Cooklin AR, Donath SM & Amir LH Acta Paediatrica 2008; 97: pp. 620-623.**	**Britten J, Tappin DM & Elton RA Health Bulletin 2001; 59: 29-36.**	**Scott JA, Shaker, I & Reid M. Birth 2004;31:125-131**	**Wright CM, Parkinson K, Scott J. Public Health Nutr 2006; 9: 686-691**
Type of study	Prospective cohort (Cross-sectional analysis of Longitudinal Study Australian Children –LSAC- data)	Prospective cohort (5 points of data collection from maternity booking to 6 weeks postpartum)	Cross-sectional	Prospective cohort
Level of evidence	II (aetiology)	II (aetiology)	IV(aetiology)	II(aetiology)
Definition of breastfeeding	Any breastfeeding	No definition	Any breastfeeding at discharge	Any breastfeeding Initiation and duration
Intervention/ comparator	Index of Relative Socioeconomic disadvantage (SEIFA), summarized into deciles and treated as a continuous variable	Deprivation category (1=most affluent, 7=most deprived) 3 vs 1+2 (reference) 4 vs 1+2 (reference) 5 vs 1+2 (reference) 6 vs 1+2 (reference) 7 vs 1+2 (reference)	Social deprivation score Highest (levels 6-7) vs lowest (levels 1-2)	Townsend deprivation score Most affluent vs least affluent
N	3697 maternal-infant pairs	1792 recruited at maternity booking (gradual decline in participation rates over time)	108	923 term infants (912 mothers)
Population/study information	Wave 1 data from infant cohort of LSAC aged <12 months in 2003-2004.	Glasgow, Scotland Recruitment from 4 maternity units	Convenience sample of Scottish women recruited from maternity clinic in Glasgow. Breastfeeding at discharge determined from birthing records	All infants term infants (≥37 wk) born between June 1999 and May 2000 in Gateshead UK were eligible. Mothers were recruited from maternity ward or shortly after discharge and baseline data collected. Surveyed at 6 weeks, 4, 8 and 12 months by postal survey.
Quality	P	P	O	P

Results	Adj OR any breastfeeding at 6 months 1.03 (95%CI 1.01-1.06)	Adj OR intention to breastfeed at maternity booking: *3 vs 1+2 (reference)* 0.35 (95%CI 0.20-0.64) *4 vs 1+2 (reference)* 0.59 (95%CI 0.35-0.99) *5 vs 1+2 (reference)* 0.39 (95%CI 0.21-0.70) *6 vs 1+2 (reference)* 0.46 (95%CI 0.29-0.75) *7 vs 1+2 (reference)* 0.30 (95%CI 0.18-0.49)	Crude OR 0.97 (95%CI 0.30-3.23) Not independently significant after adjustment for maternal infant feeding attitudes	*Adjusted OR (95% CI) for initiation of BF* 2.78 (1.6-4.9) *Adjusted OR for ceased BF by 6 weeks* 0.30 (0.13-0.69) *Adjusted OR for still breastfeeding at 4 months* 3.11 (1.3-7.3)
Effect on risk	Mothers from a higher SIEFA category (more socio-economically advantaged) more likely to still be breastfeeding at 6 months	Mothers from deprivation categories 3-7 less likely to intend to breastfeed at maternity booking.	Breastfeeding at discharge was not associated with level of social deprivation	Women in the least deprived quintile were significantly more likely to have initiated breastfeeding and to still be breastfeeding at 4 months, and were less likely to have ceased BF by 6 weeks than women in the most deprived quintile after controlling for other measures of deprivation
Clinical importance	1	1	1	1
Clinical relevance	1	2	1	1
Generalisability	Y	Y (UK)	Y	Y (UK)
Applicability	Y	Y (UK)	Y	Y (UK)

Impact of Maternal Obesity on Breastfeeding Outcomes

Search results
Data were extracted from 1 systematic literature review (utilising data from 22 multinational), and 1 Australian prospective cohort study and 1 Australian cross-sectional study. Sufficient evidence was found to make statements on the relationship between maternal obesity and breastfeeding outcomes. Breastfeeding outcomes investigated included breastfeeding initiation/ at discharge and breastfeeding duration (any or exclusive).

What is the evidence that maternal obesity is negatively associated with breastfeeding outcomes?		
Draft Evidence statement		There is evidence that maternal obesity is negatively associated with the initiation of breastfeeding and probably breastfeeding duration?
Draft Grade		**B**
Component	**Rating**	**Notes**
Evidence Base	Good	1 SLR (22 studies), 1 prospective cohort studies and 1 cross-sectional study
Consistency	Good	The majority of studies (9/10 studies in SLR) reported a negative association between maternal obesity and the initiation of breastfeeding. The evidence was less consistent (7/15 studies in SLR) with regard to breastfeeding duration.
Clinical impact	Good	Majority of studies found a negative association with breastfeeding initiation
Generalisability	Excellent	Most studies in the SLR involved Western populations and other studies were Australian
Applicability	Excellent	Directly applicable

In total 9/10 studies considered in the SLR found that overweight and obese women were less likely to commence breastfeeding. This association was significantly different in all but 3 studies including 2 West Australian studies. 7/15 studies in the SLR reported a shorter duration among obese women than normal weight women after adjusting for confounders. 2 studies in countries with high breastfeeding initiation rates found no association with breastfeeding duration. 1 study from Kuwait found a positive association between higher maternal weight and breastfeeding duration. The recent cohort and the cross-sectional studies reported a negative association with breastfeeding duration.

Whether the mechanism for this association is biological or psychological, behavioural and/or cultural is unclear (Amir & Donath, 2007). Obese women have been reported to experience greater mechanical difficulties of latching on and proper positioning of the infant (Rasmussen and Kjolhede 2004). Despite initial difficulties, with lactation guidance the vast majority of overweight women are able to successfully establish exclusive breastfeeding (Dewey, Nommsen-Rivers et al. 2003).

Studies used to make evidence statement for association of maternal overweight/obesity and breastfeeding

Reference	**Amir and Donath, BMC Pregnancy and Childbirth 2007;7:9**	**Donath and Amir *Maternal and Child Nutrition* (2008), 4, pp. 163–170**	**Forster DA, McLachlan HL & Lumley J International Breastfeeding Journal 2006; 1:18**
Type of study	Systematic review	Cross-sectional analysis of LSAC	Secondary analysis of women enrolled in an RCT. Data treated as a cohort study
Level of evidence	I (aetiology)	IV (aetiology)	II (aetiology)
Definition of breastfeeding	Initiation Intensity (degree of exclusiveness) Total duration of any breastfeeding Delayed onset of lactogenesis	Any breastfeeding at 1 week Any breastfeeding at 6 mo	Any breastfeeding (at 6 months)
Intervention/ comparator	Maternal overweight and/or obese. Most studies used WHO definition Overweight 25-29.99 Obese ≥30	normal-weight body mass index (BMI, kg/m2) 20 to □ 25 to □30, obese BMI _30	Underweight (BMI<20) vs normal weight (BMI 20-25) (ref) Overweight (BMI>25 and <30) vs normal weight (ref) Obese (BMI≥ 30) vs normal weight (ref)
N	27 papers identified, but 5 excluded as they did not define overweight or obesity using BMI or used vague terms. 22 papers considered in the review.	N=3075	981
Population/study information	Medline, CINAHL and the Australian Breastfeeding Association's Lactation Resource Centre up to Jan/Feb 2007. Studies which have examined maternal obesity and infant feeding intention, initiation, duration and delayed onset of lactation were tabulated and summarised.	The sample is children from the infant cohort (about 12 months of age) o fWave 1 (2004) of the Longitudinal Study of Australian Children for whom breastfeeding and maternal information were available (*n* = 3075).	Melbourne, Australia Primiparous women attending a public, tertiary hospital All eligible women approached for participation Data from RCT used investigating effect of 2 pregnancy interventions on breastfeeding initiation & duration Interview in hospital at birth & at 6 months over phone
Quality	P	P	P

Results	*Breastfeeding intention* Obese women less likely to intended to BF and intended to BF for shorter duration *BF initiation* 9/10 studies found that overweight and obese women were less likely to commence breastfeeding. Statistically significant difference in all but 3 studies including 2 WA studies. *Delayed onset of lactation* 3/5 US studies reported an association with delayed onset of breastfeeding. Breastfeeding duration 7/15 studies reported a shorter duration among obese women than normal weight women after adjusting for confounders. 2 studies in countries with high breastfeeding initiation rates found no association. 1 study from Kuwait found a positive association between higher maternal weight and breastfeeding duration.	*Adj OR (95% CI) of stopping breastfeeding by 1 week* Overweight 1.52 (1.02, 2.28) Obese 2.54 (1.70, 3.79) For women who breastfed for at least 1 week, *adj OR (95% CI) of ceasing to breastfeed before 6 months* overweight 1.26 (1.04, 1.53) obese 1.38 (1.10, 1.73)	Adj OR any breastfeeding at 6 months *Underweight (BMI<20) vs normal weight (BMI 20-25)* 1.15 (95%CI 0.70-1.88) *Overweight (BMI>25 and <30) vs normal weight* 0.70 (95%CI 0.43-1.12) *Obese (BMI≥ 30) vs normal weight* 0.49 (95%CI 0.28-0.85)
Effect on risk	Maternal obesity negatively associated with breastfeeding outcomes	Higher rates of cessation in the immediate post-partum period and by 6 mo.	Women with a BMI ≥30 (obese women) less likely to be feeding any breast milk at 6 months.
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Parity and Breastfeeding

Parity has become a difficult variable to study in Australia and China because of the low completed fertility rate (approx 1.8 in both countries).

No evidence statement will be made.

Studies used to make evidence statement for the association of parity and breastfeeding

Reference	**Qiu L, Binns C, Zhao Y, Lee A & Xie X Asia-Pacific Journal of Public Health 2008; 20: 220-227**	**Baxter J, Cooklin AR & Smith J Acta Paediatrica 2009; 98: 1274-1277.**	**Britten J, Tappin DM & Elton RA Health Bulletin 2001; 59: 29-36.**	**Butler S, Williams M, Tukuitonga C & Paterson J The New Zealand Medical Journal 2004; 117.**
Type of study	Prospective cohort (6 months) Cross-sectional analysis of baseline data	Data from Longitudinal Study of Australian Children (LSAC) Retrospective cohort study using infant cohort only	Prospective cohort (5 points of data collection from maternity booking to 6 weeks postpartum)	Prospective cohort
Level of evidence	II (aetiology)	III-2 (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Exclusive BF (WHO) Any breastfeeding	Full breastfeeding Complementary breastfeeding (WHO)	No definition	Exclusive breastfeeding – other (includes water) Not breastfeeding exclusively
Intervention/ comparator	Parity (details not provided)	Firstborn vs ?? (not defined)	1 vs 0 (reference) 2 vs 0 3+ vs 0	2-4 vs 1 (reference) 5+ vs 1 (reference)
N	1520 of 1551 questionnaires (98% response rate)	5090 (54% response rate)	1792 recruited at maternity booking (gradual decline in participation rates over time)	1247
Population/study information	City, suburban & rural China Random sample of mothers from hospitals at city, suburban & rural locations. Interview conducted in hospital	Random sampling through Medicare database Interview with mothers of infants involved in LSAC Study aged 3-19 months Breastfeeding transitions between birth & 1 month and 1 month and 2 months	Glasgow, Scotland Recruitment from 4 maternity units	Auckland, New Zealand 1 or more parent Pacific ethnicity Data part of Pacific Islands Families (PIF) Study through interviews with mothers & hospital records
Quality	P	P	P	P
Results	No significant effect (results not given)	Transitions between birth & 1 month, marginal effects Still full breastfeeding: -5% (95% CI -8, -2) ($p<0.001$)	Adj OR intention to breastfeed at maternity booking: *1 vs 0 (reference)* 0.16 (95%CI 0.12-0.22)	Adj OR not breastfeeding exclusively at 6 weeks post-birth *2-4 vs 1*

		Complementary feeds: 5% (95% CI 3, 7) (p<0.001) Not breastfeeding: 0% (95% CI -2, 2) Transitions between 1 & 2 months, marginal effects Still full breastfeeding: -3% (95% CI -6, -1) (p<0.05) Complementary feeds: 1% (95% CI -1, 3) Not breastfeeding: 2% (95% CI 0, 4) (p<0.05) Still complementary feeds: 1% (95% CI -6, 8)	*2 vs 0* 0.09 (95%CI 0.05-0.15) *3+ vs 0* 0.07 (95%CI 0.04-0.14)	1.06 (95%CI 0.74-1.54) *5+ vs 1* 1.94 (95%CI 1.12-3.35)
Effect on risk	No significant association between parity and initiation of exclusive breastfeeding	For those who were full breastfeeding at birth and at one month, women who had firstborn children less likely to still be full breastfeeding at 1 & 2 months. More likely to be giving complementary feeds at 1 month. For those full breastfeeding at one month, more likely to not be breastfeeding at 2 months.	Multiparous mothers are less likely to intend to breastfeed at time of maternity booking	Women who had 5 or more pregnancies were more likely to be breastfeeding exclusively at 6 weeks post-birth.
Clinical importance	1	1	1	1
Clinical relevance	1	1	2	1
Generalisability	Y (Chinese)	Yes	Y (UK)	Y (Pacific Islanders)
Applicability	Y (Chinese)	Yes	Y (UK)	Y (Pacific Islanders)

Reference	**Scott JA, Binns CW, Aroni RA. J Paediatr Child Health 1997;33:305-307**	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta PAediatr 1999;88: 416-421**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Binns CW, Gilchrist D, Gracey M et al Public Health Nutr 2004; 7: 857-861**
Type of study	Prospective cohort (Cross-sectional analysis of baseline data)	Prospective cohort study	Prospective cohort study	Prospective cohort study (Cross-sectional analysis of baseline data)
Level of evidence	IV(aetiology)	II(aetiology)	II (aetiology)	IV (aetiology)
Definition of breastfeeding	Breastfeeding initiation	Any breastfeeding duration	Any breastfeeding at discharge Any breastfeeding duration	Any breastfeeding at discharge from hospital
Intervention/ comparator	Multiparous vs primiparous	Multiparous vs primiparous	Primparous vs multiparous (ref)	Multiparous vs Primiparous (Ref)
N	556 (77% of women contacted, 58% of eligible women)	556 (77% of women contacted, 58% of eligible women)	556 urban, Perth 503 rural, Darling Downs, Queensland	425
Population/study information	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Self-identified Aboriginal women delivering in the major Perth maternity hospital (n=310) and 5 suburban hospitals (n=115). baseline interviews conducted in prior to discharge.
Quality	P	P	P	P
Results	Not specified but adjusted for in backwards conditional multivariate logistic regression	No specified but adjusted for in backwards conditional Cox regression model	*Breastfeeding at discharge* adjOR 2.08 (95% CI 1.28-3.45) *Risk of cessation of breastfeeding* Not specified but adjusted for in multivariate Cox regression analysis. Not significant	*Breastfeeding at discharge* Adj OR 0.39 (95%CI 0.16-0.94)
Effect on risk	There was no significant	There was no significant	Primiparous women were	Multiparous women were less

	independent association between parity and the initiation of breastfeeding	independent association between risk of cessation of breastfeeding and parity	more likely to be breastfeeding at discharge but there was no association between parity and duration	likely to be breastfeeding at discharge breastfeeding than primiparous
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y	Y
Applicability	Y	Y	Y	Y

Reference	**Scott JA, Shaker, I & Reid M. Birth 2004;31:125-131**	**Scott JA, Binns CW, Graham KI, Oddy WH Borth 2006; 33:37-45**	**Clements et al Acta Paediatr, 1997; 86:51-56**
Type of study	Cross-sectional	Cross-sectional analysis of baseline data of prospective cohort study	Prospective cohort study
Level of evidence	IV (aetiology)	IV (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding at discharge	Any breastfeeding at discharge, Exclusive breastfeeding since birth at discharge (WHO)	Exclusive BF at discharge Any breastfeeding duration
Intervention/ comparator	Multi vs primi (ref)	Multiparous vs primiparous (ref)	Previous pregnancies 0 (ref), 1, 2, 3+
N	108	587 (68% of 870 women contacted and 55% of 1068 eligible women)	700
Population/study information	Convenience sample of Scottish women recruited from maternity clinic in Glasgow. Breastfeeding at discharge determined from birthing records	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Infants from South West Thames (UK) region were randomly selected from all births, except home births. The subjects were randomly allocated an age at which to be interviewed, in such a way as to ensure that they had a similar age distribution to that previously described for **SIDS** cases. The median age was 90 days (range 30-302 days). The study ran from 14 October 1990 to 13 October 1991.

Quality	O	P	P
Results	Crude OR 0.69 (95%CI 0.32-1.47)	*Any breastfeeding at discharge* Adj OR (95% CI) 0.21 (0.0.06-0.71) *Exclusive breastfeeding at discharge* adj OR (95% CI) 1.71 (1.04-2.79)	*Exclusive BF at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis *Any breastfeeding duration* No adjOR reported but non-significant when controlled for in multivariate analysis
Effect on risk	There was not association with parity and breastfeeding at discharge	Multiparous women were less likely to be breastfeeding at discharge but were more likely to be exclusively breastfeeding than primiparous women	No association with exclusive BF at discharge or duration of any breastfeeding
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y (English)
Applicability	Y	Y	Y

Reference	**Xu F, Binns C, Zhang H, Yang G & Zhao Y Journal of Human Lactation 2010.**	**Yeoh BH, Eastwoord J, Phung H & Woolfenden S Journal of Paediatrics & Child Health 2007; 43: 249-255.**	**Kelly YJ & Wyatt RG Public Health Nutrition 2005; 8: 417-421.**
Type of study	Prospective cohort	Cross-sectional	Longitudinal population based survey Prospective cohort
Level of evidence	II (aetiology)	IV (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding Exclusive breastfeeding (WHO)	Any current breastfeeding including token, partial, fully & exclusive (other)	Exclusive breastfeeding - WHO
Intervention/ comparator	Parity (further details not provided)	1-3 vs none (ref) 4-5 vs none (ref) >5 vs none (ref)	Parity (%s only, no comparisons) First child, second or subsequent child
N	1256 mothers invited, 1219 agreed (97%)	9618 babies & mothers	18125

	& 1088 fathers agreed (87%) (Analysis undertaken on 1088 couples)		
Population/study information	Xinjiang, China Mothers interviewed in hospital & 0.5, 1.5, 2.5, 3.5, 4.5 & 6 months after birth Recruited from 5 hospitals in urban & rural areas Smaller hospitals – all mothers recruited Larger hospitals – mothers recruited every 2nd or 3rd day	Sydney, Australia Data from Ingleburn Baby Information Systems Database-IBIS and Obstetrics Package –OBSTET IBIS-data collected at first well-baby clinic after hospital discharge OBSTET-data from hospital birthing units	Four UK countries Data from the Millennium Cohort Study Parental interview at 1, 4 & 6 months after birth Households identified through Dept of Work & Pensions Child Benefit System. Disadvantaged residential areas over-represented
Quality	P	P	P
Results	Not significant (results not provided)	Risk for not breastfeeding: *1-3 vs none* Unadj OR and adj OR not significant (results not provided) *4-5 vs none* Unadj OR (95%%CI) 1.38 (1.12-1.70) Adj OR not significant (results not provided) *>5 vs none* Unadj OR not significant (results not provided) Adj OR (95%CI) 0.43 (0.25-0.75)	<u>No significance testing</u> Initiation (%) First child 75.0 Second or subsequent child 66.7 Exclusive at 1 month (%) First child 32.6 Second or subsequent child 33.9 Exclusive at 4 months (%) First child 2.5 Second or subsequent child 3.7 Exclusive at 6 months (%) First child 0.2 Second or subsequent child 0.4
Effect on risk	No effect of parity on the risk of discontinuing any or exclusive breastfeeding before 6 months.	Women who have had 5 or more pregnancies are at a lower risk for not breastfeeding.	More primiparous mothers initiated breastfeeding. However, more multiparous mothers were exclusively breastfeeding at 1, 4 & 6 months
Clinical	1	1	4

importance			
Clinical relevance	1	1	1
Generalisability	Y (Chinese)	Y	Y (UK)
Applicability	Y (Chinese)	Y	Y (UK)

Maternal age and breastfeeding

There is an association between breastfeeding and maternal age - older mothers are more likely to breastfeed. Mothers under 20 years less likely to breastfeed.

Data were extracted from 16 studies, including 15 prospective cohort studies, 1 retrospective cohort study. Data from 16 publications were used to form the final body of evidence statement, which included 9 studies of Australian women, 4 studies of Chinese women and 3 studies from the UK. One study from New Zealand was not included in the final analysis due to insufficient information. Sufficient evidence was found to make statements on the relationship between maternal age and breastfeeding outcomes for Australia and China.

Breastfeeding outcomes investigated included breastfeeding initiation/ at discharge and breastfeeding duration.

What is the association between maternal age and breastfeeding outcomes?		
Evidence statement		Younger maternal age, particularly less than 20 yrs, may be negatively associated with both the initiation of breastfeeding and breastfeeding duration.
Draft Grade		**B**
Component	**Rating**	**Notes**
Evidence Base	Good	14 cohort studies (13P, 1 N),
Consistency	Good	For Chinese mothers all of the studies found an association with initiation and 3 of 4 with duration. For Australian mothers 5 studies found an association between initiation and age and 6 studies found an association with duration.
Clinical impact	Good	There was a consistent association
Generalisability	Excellent	All studies involved either Australian women or women from relevant population sub-groups
Applicability	Satisfactory	Studies of Chinese women may not be directly relevant to the Australian healthcare context

Studies of women from Australia were considered separate to those of Chinese women. Four cohort studies involving Chinese women reported a negative association between younger maternal age and the initiation of breastfeeding while. Three cohort studies reported that older Chinese women more likely to have a longer breastfeeding duration and one study found no difference.

For Australian mothers 5 studies found an association between initiation and breastfeeding Younger mothers were less likely to breastfeed in hospital. Six cohort studies found an association of duration with older mothers.

In Australia an association between maternal age and breastfeeding outcome is consistently found in earlier studies, but is harder to demonstrate in more recent Australian studies reporting breastfeeding initiation rates of 90% or more.

Studies used to make evidence statement for association of maternal age and breastfeeding outcome

Reference [1]	**Li-Yin Chien LY and Tai CJ BIRTH 2007; 34: 123-130**	**Qiu L, Binns C, Zhao Y, Lee A & Xie X J Health Popul Nutr ((2010) 28(2):189-198**	**Leung GM, Lam T & Ho L Obstetrics & Gynecology 2002; 99: 785-794**
Type of study [2]	Cohort (3 mo)	Prospective cohort (6 months)	Prospective cohort study (9 months)
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding			
Intervention/ comparator [4]	< 20 yrs/ ≥35 yrs	25-29 vs <24 (reference) >34 vs <24 (reference)	25-29 vs ≤24 (reference) 30-34 vs ≤24 ≥35 vs ≤24
N [5]	2079 of 3670 questionnaires returned (56.6% response rate)	1520 of 1551 questionnaires (98% response rate)	8327 (final cohort) but 7825 followed up 95% response rate, accounting for 88% of births in the period
Population/study information [6]	Taiwan Random, proportional sample from birth registry or infants born June-Oct 2003 Postal questionnaires at 1 and 3 months	City, suburban & rural China Random sample of mothers from hospitals at city, suburban & rural locations. Interview conducted in hospital	Hong Kong All infants brought to health centre for first health check, across 47 centres
Quality [7]	P	P	P
Results [8]	Adj OR of initiation during hospital 0.49 (95%CI 0.26-0.90) Adj OR of any BF at 1 mo 0.28 (95% CI 0.10-0.66) Adj OR of any BF at 3 mo 0.28 (95% CI 0.11-0.74)	Adj OR initiation during hospital 25-29: 0.64 (0.44-0.94) >34: 0.63 (95%CI0.40-0.99) Adj OR for cessation before six months ≥30 1 25-29 1.710 (1.085, 2.698) ≤24 1.520 (1.053-2.194)	Adj OR never breastfed 25-29 *not sig*: 0.93 (95%CI 0.78-1.11) 30-34: 0.77 (95%CI 0.64-0.92) ≥35: 0.72 (95%CI 0.58-0.88) Adj OR breastfed<1 month 25-29 not sig: 0.73 (95%CI 0.53-1.01) 30-34: 0.69 (95%CI 0.49-0.95) ≥35: 0.64 (95%CI 0.44-0.93) Adj HR duration 25-29 not sig: 0.96 (95%CI 0.81-1.12)

			30-34: 0.84 (95%CI 0.71-0.99) ≥35 not sig: 0.84 (95%CI 0.70-1.02)
Effect on risk	Younger maternal age (<20 yrs) negatively associated with breastfeeding initiation and prevalence at 1 and 3 mo postpartum	Women aged 25-29 and >34 less likely to initiate exclusive breastfeeding than those aged <24	Women aged over 30 less likely to have never breastfed than those <24 Women aged over 30 less likely to breastfeed for less than one month than those <24 Women aged 30-34 less likely to cease breastfeeding than those aged <24
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y to Chinese sector of population	Y (Chinese)	Y (Chinese)
Applicability	Y (Chinese)	Y (Chinese)	Y (Chinese)

Reference [1]	**Chien L & Tai C Birth 2007; 34: 123-130.**	**Britten J, Tappin DM & Elton RA Health Bulletin 2001; 59: 29-36.**	**Baxter J, Cooklin AR & Smith J Acta Paediatrica 2009; 98: 1274-1277.**
Type of study [2]	Prospective cohort study. Follow-up at 1 & 3 months after delivery	Prospective cohort (5 points of data collection from maternity booking to 6 weeks postpartum)	Data from Longitudinal Study of Australian Children (LSAC) Retrospective cohort study using infant cohort only
Level of evidence	II (aetiology)	II (aetiology)	III-2 (aetiology)
Breastfeeding definition	Exclusive breastfeeding (water not considered) Partial breastfeeding (breast milk & formula) No breastfeeding	No definition	Full breastfeeding Complementary breastfeeding (WHO)
Intervention/ comparator [4]	<20 years vs ≥35 years (reference) 20-24 vs ≥35 years 25-29 vs ≥35 years 30-34 vs ≥35 years	19 vs 30+ years (reference) 20-24 vs 30+ years 25-29 vs 30+ years	25-29 vs under 25 (reference) 30-34 vs under 25 35-35 vs under 25
N [5]	2079 of 3670 questionnaires returned (56.6% response rate) 15 excluded, final n=2064	1792 recruited at maternity booking (gradual decline in participation rates over time)	5090 (54% response rate)
Population/study information [6]	Taiwan Random, national sample from birth registration records	Glasgow, Scotland Recruitment from 4 maternity units	Random sampling through Medicare database Interview with mothers of infants involved in LSAC Study aged 3-19 months Breastfeeding transitions between birth & 1 month and 1 month and 2 months
Quality [7]	P	P	P
Results [8]	Adjusted OR initiation during hospital stay <20 years: 0.49 (95%CI 0.29-0.90) 20-24 years: 0.67 (95%CI 0.48-0.94) 25-29: 0.80 (95%CI 0.59-1.07) 30-34: 0.87 (95%CI 0.64-1.18)	Adj OR intention to breastfeed at maternity booking: *19 vs 30+ years (reference)* 0.22 (95%CI 0.13-0.37) *20-24 vs 30+ years* 0.76 (95%CI 0.51-1.13)	**Age 25-29** Transitions between birth & 1 month, marginal effects, age Still full breastfeeding: 3% (95% CI -1, 8) Complementary feeds: 1% (95% CI -4, 5) Not breastfeeding: -4% (95% CI -7, -2) (p<0.01)

	Adjusted OR breastfeeding 1 month after delivery (type not specified) <20 years: 0.28 (95%CI 0.10-0.66) 20-24 years: 0.73 (95%CI 0.48-1.12) 25-29 years: 1.05 (95%CI0.73-1.50) 30-34 years: 0.98 (95%CI 0.68-1.41) Adjusted OR breastfeeding 3 months after delivery (type not specified) <20 years: 0.28 (95%CI 0.11-0.74) 20-24 years: 0.96 (95%CI 0.63-1.47) 25-29 years: 0.94 (95%CI 0.65-1.35) 30-34 years: 1.31 (95%CI 0.90-1.90)	*25-29 vs 30+ years* 1.19 (95%CI 0.86-1.65)	Transitions between 1 & 2 months, marginal effects Still full breastfeeding: 2% (95% CI -2, 7) Complementary feeds: 1% (95% CI -3, 5) Not breastfeeding: -3% (95% CI -5, -1) (p<0.01) Still complementary feeds: -8 (95% CI -24, 8) **Age 30-34** Transitions between birth & 1 month, marginal effects, age Still full breastfeeding: -7% (95% CI 2, 12) (p<0.01) Complementary feeds: 1% (95% CI -3, 5) Not breastfeeding: -8% (95% CI -11, -4) (p<0.001) Transitions between 1 & 2 months, marginal effects Still full breastfeeding: 3% (95% CI -1, 8) Complementary feeds: 2% (95% CI -1, 6) Not breastfeeding: -6% (95% CI -9, -2) (p<0.01) Still complementary feeds: 6% (95% CI -7, 18) **Age 35-44** Transitions between birth & 1 month, marginal effects, age Still full breastfeeding: 0% (95% CI -7, 7) Complementary feeds: 7% (95% CI 0, 14) (p<0.05) Not breastfeeding: -7% (95% CI -9, -5)

			(p<0.001) Transitions between 1 & 2 months, marginal effects Still full breastfeeding: 3% (95% CI -3, 9) Complementary feeds: 3% (95% CI -3, 9) Not breastfeeding: -6% (95% CI -8, -5) (p<0.001) Still complementary feeds: 3% (95% CI -9, 15)
Effect on risk	Women <20 years less likely to initiate breastfeeding during hospital stay and be breastfeeding at 1 and 3 months after delivery. Women 20-24 years less likely to initiate breastfeeding during hospital stay.	Mothers aged 19 years less likely to intend to breastfeed at maternity booking.	For those who were full breastfeeding at birth, at 1 month, women aged 30-34 more likely to still be breastfeeding. Women aged 35-44 more likely to be giving complementary feeds. For those who were full breastfeeding at birth, at 1 & 2 months, women >25 less likely to not be breastfeeding.
Clinical importance	1	1	1
Clinical relevance	1	2	1
Generalisability	Y (Taiwanese women)	Y (UK)	Yes
Applicability	Y (Taiwanese women)	Y (UK)	Yes

Reference	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Butler S, Williams M, Tukuitonga C & Paterson J The New Zealand Medical Journal 2004; 117.**	**Cooklin AR, Donath SM & Amir LH Acta Paediatrica 2008; 97: pp. 620-623.**
Type of study	Prospective cohort study	Prospective cohort	Prospective cohort (Cross-sectional analysis of Longitudinal Study Australian Children –LSAC- data)
Level of evidence	II(aetiology)	II (aetiology)	II (aetiology)

Definition of breastfeeding	Any breastfeeding at discharge Any breastfeeding duration	Exclusive breastfeeding – other (includes water) Not breastfeeding exclusively	Any breastfeeding
Intervention/ comparator	Age treated as a continuous variable (yrs)	Maternal age – details not provided	15-19 years 20-24 years 30-34 years 35-39 years 40 years & above ALL vs 25-29 years (reference)
N	556 urban, Perth 503 rural, Darling Downs, Queensland	1247	3697 maternal-infant pairs
Population/study information	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Auckland, New Zealand 1 or more parent Pacific ethnicity Data part of Pacific Islands Families (PIF) Study through interviews with mothers & hospital records	Wave 1 data from infant cohort of LSAC aged <12 months in 2003-2004.
Quality	P	0	P
Results	Adj OR for breastfeeding at discharge for a 10 year difference 1.51 (95%CI 1.00-2.90) Adj HR cessation of breastfeeding 0.49 (95%CI 0.38-0.65)	Significance not reached for breastfeeding exclusively at hospital discharge or 6 weeks post birth (results not given) Therefore not included in analysis.	Adj OR any breastfeeding at 6 months *15-19 years* 0.76 (95%CI 0.43-1.33) *20-24 years* 0.94 (95%CI 0.72-1.24) *30-34 years* 1.27 (95%CI 1.06-1.52) *35-39 years* 1.51 (95%CI 1.22-1.84) *40 years & above* 1.52 (95%CI 1.08-2.12)
Effect on risk	There was an inverse gradient in the likelihood of breastfeeding at discharge and	No association between maternal age and exclusive breastfeeding at hospital	Women aged 30 years and above more likely to be breastfeeding at 6 months.

	in the risk of cessation of breastfeeding. That is older women were more likely to be breastfeeding at discharge and to continue breastfeeding for longer compared to younger women.	discharge or at 6 weeks post-birth.	
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y (Pacific Islanders)	Y
Applicability	Y	Y (Pacific Islanders)	Y

Reference	**Binns CW, Gilchrist D, Gracey M et al Public Health Nutr 2004; 7: 857-861**	**Scott JA, Shaker, I & Reid M. Birth 2004;31:125-131**	**Scott JA, Binns CW, Graham KI, Oddy WH Birth 2006; 33:37-45**
Type of study	Prospective cohort study	Cross-sectional	Prospective cohort study
Level of evidence	II(aetiology)	IV(aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding at discharge from hospital	Any breastfeeding at discharge	Any breastfeeding at discharge, Exclusive breastfeeding since birth at discharge (WHO)
Intervention/ comparator	Maternal age in years (continuous variable0	≥ 30 vs < 25 (ref)	< 25 yrs, 25-29, 30-34, ≥35 (ref)
N	425	108	587 (68% of 870 women contacted and 55% of 1068 eligible women)
Population/study information	Self-identified Aboriginal women delivering in the major Perth maternity hospital (n=310) and 5 suburban hospitals (n=115). baseline interviews conducted in prior to discharge.	Convenience sample of Scottish women recruited from maternity clinic in Glasgow. Breastfeeding at discharge determined from birthing records	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.
Quality	P	O	P
Results	*Breastfeeding at discharge* Adj OR 1.12% (95%CI 1.03-1.22)	Crude OR 3.14 (95%CI 1.02-9.65) Not independently significant after adjustment for maternal infant feeding attitudes	*Any breastfeeding at discharge* Crude OR (95% CI) < 25 yrs 1.11 (0.39-3.16) 25-29 0.86 (0.32-2.31) 30-34 2.66 (0.79-8.98) Adj OR Not specified but controlled for in multivariate logistic regression and non-significant *Exclusive breastfeeding at discharge* Adj OR Not specified but controlled for in multivariate logistic regression and non-significant

Effect on risk	Older women were more likely to initiate breastfeeding than younger women	Maternal age was not associated with breastfeeding at discharge after adjustment for maternal infant feeding attitudes	There was no significant independent association between maternal age and any or exclusive breastfeeding at discharge from hospital
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Reference	**Clements et al Acta Paediatr, 1997; 86:51-56**	**Kelly YJ & Wyatt RG Public Health Nutrition 2005; 8: 417-421.**	**Rutishauser IHE & Carlin JB Journal of Epidemiology & Community Health 1992; 46: 559-565.**
Type of study	Prospective cohort study	Prospective cohort	Prospective Cohort
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Exclusive BF at discharge Any breastfeeding duration	Exclusive breastfeeding - WHO	Not defined
Intervention/ comparator	Maternal age at infant's birth < 20 yr, 20-24yrs vs 25+ yrs (ref)	Maternal age (%s only, no comparisons) <20, 20-24, 25-29, 30-24, ≥35	Maternal age: 30 years vs 20 years (ref)
N	700	18125	739 (81%)
Population/study information	Infants from South West Thames (UK) region were randomly selected from all births, except home births. The subjects were randomly allocated an age at which to be interviewed, in such a way as to ensure that they had a similar age distribution to that previously described for **SIDS** cases. The median age was 90 days (range 30-302 days). The study ran from 14 October 1990 to 13 October 1991.	Four UK counties Data from the Millennium Cohort Study Parental interview at 1, 4 & 6 months after birth Households identified through Dept of Work & Pensions Child Benefit System. Disadvantaged residential areas over-represented	Geelong, Australia Primiparous women who chose to breastfeed & attended an infant welfare centre in Barwon region of Victoria, Australia
Quality	P	P	P
Results	*NOT exclusively breastfeeding at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis *Any breastfeeding duration* Adj HR (95% CI) < 20yr 0.97 (0.28-3.35) 20-24 yrs 0.87 (0.49 – 1.54)	<u>No significance testing</u> Initiation (%) <20years 45.7 20-24 years 58.0 25-29 years 69.9 30-24 years 77.0 ≥35 years 80.5 Exclusive at 1 month (%) <20years 12.6	Adj HR cessation of breastfeeding 0.45 (95%CI 0.32-0.65)

		20-24 years 20.8 25-29 years 32.3 30-24 years 39.1 ≥35 years 45.3 Exclusive at 4 months (%) <20years 1.0 20-24 years 1.7 25-29 years 3.0 30-24 years 3.4 ≥35 years 5.7 Exclusive at 6 months (%) <20years 0.2 20-24 years 0.1 25-29 years 0.3 30-24 years 0.3 ≥35 years 0.5	
Effect on risk	No association with exclusive breastfeeding at discharge and with duration of any breastfeeding	The percentage of mothers initiating breastfeeding and breastfeeding exclusuively at 1, 4 & 6 months increased with age. breastfeeding at 1, 4 and 6 months.	Mothers aged 30 years less likely to cease breastfeeding
Clinical importance	1	4	1
Clinical relevance	1	1	1
Generalisability	Y (English)	Y (UK)	Y
Applicability	Y	Y (UK)	Y

Reference	**Yeoh BH, Eastwoord J, Phung H & Woolfenden S Journal of Paediatrics & Child Health 2007; 43: 249-255.**	**Baghurst P, Pincombe J, Peat B, Henderson A, Reddin E & Antoniou G Midwifery 2007; 23: 382-391.**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**
Type of study	Cross-sectional	Prospective cohort	Prospective cohort study
Level of evidence	IV (aetiology)	II (aetiology)	II (aetiology)

Definition of breastfeeding	Any current breastfeeding including token, partial, fully & exclusive (other)	Fully breastfeeding (breast milk only) Partly breastfeeding (formula and/ or solids and breast milk)	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)
Intervention/ comparator	<20 years vs 20-29 years (ref) 30-39 years vs 20-29 years (ref) >40 years vs 20-29 years (ref)	Maternal age	< 20, 20-29 ≥30 (ref)
N	9618 babies & mothers	317	587 (68% of 870 women contacted and 55% of 1068 eligible women)
Population/study information	Sydney, Australia Data from Ingleburn Baby Information Systems Database-IBIS and Obstetrics Package –OBSTET IBIS-data collected at first well-baby clinic after hospital discharge OBSTET-data from hospital birthing units	Primiparous mothers South Australia, Australia Recruited from antenatal clinic at large, teaching hospital (sample not necessarily random) First contact prior to baby's birth, follow-up in hospital post delivery, 1 week, 6 weeks, 3 months & 6 months postpartum	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.
Quality	P	0	P
Results	Adj OR (95%CI) risk for not breastfeeding Results not significant for all ages. Results not provided. Unadj OR (95%CI) for not breastfeeding *<20 years vs 20-29 years* 1.90 (1.59-2.26) *30-39 years vs 20-29 years* 0.86 (0.79-0.94) *>40 years vs 20-29 years* Not significant (results not provided)	Adj HR for weaning (95%CI) 0.991 (0.95-1.03)	*Risk of discontinuing any BF* Adj HR (95%CI) <20 0.57 (0.23-1.41) 20-29 1.55 (1.21 – 1.98) *Risk of discontinuing full BF* Adj HR not specified but controlled for in multivariate logistic regression and non-significant
Effect on risk	Mothers aged <20 years more likely to not breastfeed and mothers aged 30-39 years less likely to not breastfeed (univariate analysis only)	No significant association between weaning from breastfeeding & maternal age	There was no association between maternal age and duration of full breastfeeding but women aged 20-29 were significantly more likely to have discontinued any breastfeeding before 12 months compared with women aged 30 years or older.

Clinical importance	4	0	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Maternal education and breastfeeding outcomes

Search results
Data were extracted from 21 studies, including 16 prospective cohort studies, 1 retrospective cohort study and 4 cross-sectional studies. Data from all studies were used to form the final body of evidence statement, which included 9 studies of Australian women, 8 studies of Chinese women, 3 UK studies and 1 study from New Zealand. Sufficient evidence was found to make statements on the relationship between maternal education and breastfeeding outcomes.

Breastfeeding outcomes investigated included breastfeeding initiation/ at discharge and breastfeeding duration.

What is the association between materal education and breastfeeding outcomes?		
Draft Evidence statement		In Australia, and other Western countries, higher levels of education are associated with better breastfeeding outcomes. In Asian countries, such as China the reverse is the case.
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Good	17 prospective cohort studies (16P, 1 O), 1 retrospective cohort study (P) 3 cross-sectional studies (1P, 2 O)
Consistency	Satisfactory	The direction of effect was different for Western and Asian women
Clinical impact	Good	Substantial
Generalisability	Excellent	All studies involved either Australian women or women from relevant population sub-groups
Applicability	Satisfactory	Studies of Chinese women not directly relevant to the Australian healthcare context

Studies of women from Australia, New Zealand or the UK were considered separate to those of Chinese women. Three prospective cohort studies reported that high level of maternal education was positively associated with the initiation of breastfeeding and 4 prospective cohort studies found no association with initiation. Four prospective cohort studies, 1 retrospective cohort study and 1 cross-sectional study found a positive association between increased maternal education and breastfeeding duration. Three prospective cohort studies reported no association with maternal education.

Amongst Chinese women 3 cohort studies and one cross-sectional study reported a negative association between higher level of education and breastfeeding initiation and 3 cohort studies reported a negative association with duration. One cohort study and one cross-sectional study reported a positive association between high level of maternal education and breastfeeding initiation and duration while one cohort study reported no association with either initiation or duration.

An association between maternal education and breastfeeding outcome was not consistently found across all studies with approximately one third finding no association. However, in those studies reporting an association the majority reported a positive association between higher level of maternal education and breastfeeding initiation and duration amongst Australian and women from other western countries, but a negative association for women in Asian countries such as China.

Studies used to make evidence statement for association of maternal education and breastfeeding outcomes.

Reference [1]	**Cooklin AR, Donath SM & Amir LH Acta Paediatrica 2008; 97: pp. 620-623.**	**Baxter J, Cooklin AR & Smith J Acta Paediatrica 2009; 98: 1274-1277.**	**Forster DA, McLachlan HL & Lumley J International Breastfeeding Journal 2996; 1.**	**Yeoh BH, Eastwood J, Phung H & Woolfenden S Journal of Paediatrics & Child Health 2007; 43: 249-255.**
Type of study [2]	Prospective cohort (Cross-sectional analysis of Longitudinal Study Australian Children –LSAC-data)	Data from Longitudinal Study of Australian Children (LSAC) Retrospective cohort study using infant cohort only	RCT	Cross-sectional
Level of evidence	II (aetiology)	III-2 (aetiology)	II aetiology (intervention study with control and experimental groups analysed as a cohort)	IV (A)
Definition of breastfeeding	Any breastfeeding	Full breastfeeding Complementary breastfeeding (WHO)	Any breastfeeding (at 6 months)	Any current breastfeeding including token, partial, fully & exclusive (other)
Intervention/ comparator [4]	Completed secondary education Certificate Diploma or advanced diploma University degree Other ALL vs incomplete secondary school (reference)	Bachelor degree or higher vs?? (not specified)	Completed secondary (but not tertiary) vs completed tertiary (reference) Did not complete secondary vs completed tertiary (reference)	Other vs TAFE or university (ref) Never attended high school vs TAFE or university (ref) Year 10 vs TAFE or university (ref) Year 12 vs TAFE or university (ref)
N [5]	3697 maternal-infant pairs	5090 (54% response rate)	981	9618 babies & mothers
Population/study information [6]	Wave 1 data from infant cohort of LSAC aged <12 months in 2003-2004.	Random sampling through Medicare database Interview with mothers of infants involved in LSAC Study aged 3-19 months Breastfeeding transitions between birth & 1 month and	Melbourne, Australia Primiparous women attending a public, tertiary hospital All eligible women approached for participation Data from RCT used investigating effect of 2	Sydney, Australia Data from Ingleburn Baby Information Systems Database-IBIS and Obstetrics Package – OBSTET IBIS-data collected at first well-baby clinic after hospital

		1 month and 2 months	pregnancy interventions on breastfeeding initiation & duration Interview in hospital at birth & at 6 months over phone	discharge OBSTET-data from hospital birthing units
Quality [7]	P	P	P	O
Results [8]	Adj OR any breastfeeding at 6 months *Completed secondary education* 1.37 (95%CI 1.06-1.76) *Certificate* 1.33 (95%CI 1.06-1.76) *Diploma or advanced diploma* 1.96 (95%CI1.48-2.61) *University degree* 3.33 (95%CI 2.64-4.21) *Other* 2.21 (95%CI 1.08-4.49)	Transitions between birth & 1 month, marginal effects Still full breastfeeding: 7% (95% CI 4, 10) (p<0.001) Complementary feeds: 2% (95% CI 0, 4) Not breastfeeding: -9% (95% CI -11, -6) (p<0.001) Transitions between 1 & 2 months, marginal effects Still full breastfeeding: 6% (95% CI 4, 9) (p<0.001) Complementary feeds: -1% (95% CI -3, 0) Not breastfeeding: -5% (95% CI -7, -3) (p<0.001) Still complementary feeds: 8% (95% CI 1, 15) (p<0.05)	(Univariate) OR any breastfeeding at 6 months *Completed secondary (but not tertiary) vs completed tertiary* 0.53 (95%CI 0.38-0.75) *Did not complete secondary vs completed tertiary* 0.33 (95%CI 0.22-0.48) Multivariate – not significant (results not provided)	Adj OR (95%CI) risk for not breastfeeding *Other vs TAFE or university* 2.19 (1.70-2.83) *Never attended high school vs TAFE or university* 1.88 (1.38-2.54) *Year 10 vs TAFE or university* 1.86 (1.63-2.11) *Year 12 vs TAFE or university* 1.35 (1.18-1.55)
Effect on risk	Mothers who completed secondary school (and higher) more likely to still be breastfeeding at 6 months. Effect size increases with increasing level of education.	Women with a Bachelor degree or higher more likely to still be full breastfeeding at 1 month and 2 months. Less likely to be not breastfeeding at 1 and 2 months. More likely to still be giving complementary feeds at 2 months.	Women with a lower level of education less likely to be feeding any breast milk at 6 months (univariate analysis) but not significant in multivariate model	Mothers who have not attended TAFE or university are more likely to not be breastfeeding.

Clinical importance	1	1	4	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y	Y
Applicability	Y	Y	Y	Y

Reference [1]	**Butler S, Williams M, Tukuitonga C & Paterson J The New Zealand Medical Journal 2004; 117.**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Baghurst P, Pincombe J, Peat B, Henderson A, Reddin E & Antoniou G Midwifery 2007; 23: 382-391.**	**Scott JA, Binns CW, Graham KI, Oddy WH Borth 2006; 33:37-45**
Type of study [2]	Prospective cohort	Prospective cohort study	Prospective cohort	prospective cohort study
Level of evidence	II (aetiology)	II(aetiology)	II (aetiology)	II (aetiology)
Breastfeeding definition	Exclusive breastfeeding – other (includes water) Not breastfeeding exclusively	Any breastfeeding at discharge Any breastfeeding duration	Fully breastfeeding (breast milk only) Partly breastfeeding (formula and/ or solids and breast milk)	Any breastfeeding at discharge, Exclusive breastfeeding since birth at discharge (WHO)
Intervention/ comparator [4]	Maternal education – details not provided	≥12 yrs vs<12 yrs (ref) for BF at Dx Education treated as a continuous variable (yrs)for risk of cessation of breastfeeding	Some years of high school vs tertiary (ref) Year 12 or equivalent vs tertiary (ref) Technical, trade or TAFE vs tertiary (ref)	≥12 yrs vs < 12 yrs (ref)
N [5]	1247	556 urban, Perth 503 rural, Darling Downs, Queensland	317	587 (68% of 870 women contacted and 55% of 1068 eligible women)
Population/study information [6]	Auckland, New Zealand 1 or more parent Pacific ethnicity Data part of Pacific Islands Families (PIF) Study through interviews with mothers &	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months	Primiparous mothers South Australia, Australia Recruited from antenatal clinic at large, teaching hospital (sample not necessarily random)	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.

	hospital records	.	First contact prior to baby's birth, follow-up in hospital post delivery, 1 week, 6 weeks, 3 months & 6 months postpartum	
Quality [7]	P	P	P	P
Results [8]	Significance not reached for breastfeeding exclusively at hospital discharge or 6 weeks post birth (results not given)	*Breastfeeding at discharge* Crude OR 1.66 (95% CI 1.16-2.38) Adj OR not given but no significant independent association Cessation of breastfeeding Adj HR for a 5 year difference in education 0.49 (95%CI 0.33-0.72)	Adj HR for weaning (95%CI) *Some years of high school vs tertiary* 3.26 (1.70-6.28) *Year 12 or equivalent vs tertiary* 2.80 (1.48-5.27) *Technical, trade or TAFE vs tertiary* 3.79 (1.92-7.48))	*Any breastfeeding at discharge* Crude OR (95% CI) 3.07 (1.46 – 6.40) No adjOR reported but non-significant when controlled for in multivariate analysis *Exclusive breastfeeding at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis
Effect on risk	No association between maternal education and exclusive breastfeeding at hospital discharge or at 6 weeks post-birth.	Maternal education was not significantly associated with breastfeeding at discharge but there was an inverse gradient in the risk of cessation of breastfeeding. That is more educated women were more likely to continue breastfeeding for longer compared to less educated women.	Mothers with lower levels of education are at greater risk of weaning their babies	There was no significant independent association between level of maternal education and any or exclusive breastfeeding at discharge
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y (Pacific Islanders)	Y	Y	Y

Applicability	Y (Pacific Islanders)	Y	Y	Y

III Breastfeeding: early days

The natural patterns of breastfeeding
The sleepy infant
The unsettled infant
Exclusive breastfeeding
Monitoring an infant's progress
Young mothers

Demand feeding, Rooming in and breastfeeding

Feeding on demand and the associated “Rooming Policies” are now standard practice in Australian hospitals and most BFHI accredited institutions in other countries. It is now difficult to conduct studies that demonstrate any effect of demand feeding.

No Evidence Statement has been developed.

Studies used to make evidence statement for the association of infant demand feeding and breastfeeding

Reference	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta Paediatr 1999;88: 416-421**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**	**Guldan et al. J Hum Lact 1995 11: 11-15**
Type of study	Prospective cohort study	Prospective cohort study	Prospective cohort study	Cross-sectional
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	IV (aetiology)
Definition of breastfeeding	Any breastfeeding duration	Any breastfeeding duration (risk of cessation of any breastfeeding)	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Duration of any breastfeeding and exclusive breastfeeding
Intervention/ comparator	Demand feeding prior to hospital discharge vs other	Demand feeding prior to hospital discharge vs other	Demand feeding prior to hospital discharge vs other	Rooming-in in hospital no versus yes
N	556 (77% of women contacted, 58% of eligible women)	556 urban, Perth 503 rural, Darling Downs, Queensland	587 (68% of 870 women contacted and 55% of 1068 eligible women)	363 mother infant pairs
Population/study information	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Infants aged 4-12 months were randomly selected from a randomly selected sub-district of each of Chengdu's 5 districts
Quality	P	P	P	N
Results	No specified but adjusted for in backwards conditional Cox regression model	*Cessation of breastfeeding* No specified but adjusted for in backwards conditional Cox regression model	*Risk of discontinuing any BF* No adjOR reported but non-significant when controlled for in multivariate analysis *Risk of discontinuing full BF* No adjOR reported but non-significant when controlled for in multivariate analysis	Univariate analysis Rooming-in in hospital positively associated with duration of exclusive breastfeeding X^2 $p <$ .0001 and any breastfeeding duration X^2 $p = 0.0002$

Effect on risk	There was no significant independent association between risk of cessation of breastfeeding and whether infant was demand fed prior to hospital discharge	There was no significant independent association between risk of cessation of breastfeeding and whether infant was demand fed prior to hospital discharge	There was no association between whether infant was demand fed prior to hospital discharge and the duration of full and any breastfeeding.	Positive association with breastfeeding duration
Clinical importance	1	1	1	4 (univariate analysis)
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y	Y(Chinese)
Applicability	Y	Y/N	Y	Y

Studies used to make evidence statement for the association of rooming-in and breastfeeding

Reference	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta Paediatr 1999;88: 416-421**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**	**Clements et al Acta Paediatr, 1997; 86:51-56**
Type of study	Prospective cohort study	Prospective cohort study	Prospective cohort study	Prospective cohort study
Level of evidence	II(aetiology)	II(aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding duration (Risk of cessation of breastfeeding)	Any breastfeeding duration (Risk of cessation of breastfeeding)	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Exclusive BF at discharge Any breastfeeding duration
Intervention/ comparator	24 hour hospital rooming-in vs other	24 hr rooming-in vs other (ref)	24 hr rooming-in vs other (ref)	Not bed sharing in 2 weeks prior to interview vs bed hsaring (ref)
N	556 (77% of women contacted, 58% of eligible women)	556 urban, Perth 503 rural, Darling Downs, Queensland	587 (68% of 870 women contacted and 55% of 1068 eligible women)	700
Population/study information	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Infants from South West Thames (UK) region were randomly selected from all births, except home births. The subjects were randomly allocated an age at which to be interviewed, in such a way as to ensure that they had a similar age distribution to that previously described for **SIDS** cases. The median age was 90 days (range 30-302 days). The study ran from 14 October 1990 to 13 October 1991.
Quality	P	P	P	P
Results	No specified but adjusted for in backwards conditional Cox regression model	*Cessation of breastfeeding* Adj HR 0.78 (95%CI 0.59-1.03)	*Risk of discontinuing any BF* No adjOR reported but non-significant when controlled for in multivariate analysis	*NOT exclusively breastfeeding at discharge* Adj OR 2.09 (95% CI 1.25-3.49)

			Risk of discontinuing full BF No adjOR reported but non-significant when controlled for in multivariate analysis	*Duration of any breastfeeding* Adj HR1.93 (95% CI 1.33 - 2.79)
Effect on risk	There was no significant independent association between risk of cessation of breastfeeding and whether infant had roomed-in for 24 hours with mother or not	There was a non-significant independent association between 24 hr rooming-in and breastfeeding duration	There was no association between 24 hour-rooming-in and the duration of full and any breastfeeding.	Bed sharing was positively associated with exclusive breastfeeding at discharge
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	4 (not specifically related to rooming-in in hospital/ measure of bed sharing recorded after Dx from hospital)
Generalisability	Y	Y	Y	Y (English)
Applicability	Y	Y	Y	Y

Exercise and Breastfeeding

Search results

The initial search of the databases included 63 references on exercise and breastfeeding. Data were extracted from 4 references, and these publications were used to form the final body of evidence statement. Sufficient evidence was found to make a statement that breastfeeding is not affected by moderate exercise. No evidence is available to make a statement on exercise at the elite sporting level. The Cochrane review stated that the evidence suggests that both diet and exercise together and diet alone help women to lose weight after childbirth. The sample sizes in the RCTs are generally small and further research is required.

Breastfeeding and Exercise

Does exercise by mothers in the postpartum period affect breastfeeding performance?		
Draft Evidence statement		Exercise by mothers does not affect breastfeeding performance
Draft Grade		B
Component	**Rating**	**Notes**
Evidence Base	Good	1 systematic reviews (1 systematic review, Cochrane, had a primary endpoint of weight loss and effect of exercise on breastfeeding was an incidental finding) 1 narrative review and 2 cohort studies.
Consistency	Satisfactory	The systematic review and one cohort study found no effect. The other cohort study found a positive effect.
Clinical impact	Good	There was no association between exercise and breastfeeding or on infant growth.
Generalisability	Excellent	Australian USA and UK populations
Applicability	Excellent	Directly applicable.

The question of interest is whether exercise by mothers affects breastfeeding performance in any way. Possible mechanisms might include the production of lactic acid during anaerobic exercise that could affect the taste of breast milk. No evidence was found that moderate levels of exercise had any impact on breastfeeding duration or quality. There were no studies found on elite level professional sports and breastfeeding.

Studies used to make evidence statement for Breastfeeding and Exercise

Reference	**Amorim Adegboye 2008 Cochrane review**	**Su 2007Public Health Nutrition**	**McCrory 2001 Nutrition reviews**	**Evenson 2009 J Womens Health**
Type of study	SLR	Cohort	Narrative review	Cohort
Level of evidence	I (aetiology)	II (aetiology)		
Definition of breastfeeding	EBF –defined as a child being fed only on mother's milk	Full Breastfeeding (WHO) Any Breastfeeding	Not stated	Not stated
Intervention Comparator	Exercise	Exercise levels measured as MET-hours per week	Diet and exercise	Survey of barriers to exercise and breastfeeding
N	245	587		N=667
Population/study information	6 trials, RCT and quasi-randomised A series of small RCTs	Population recruited from two hospitals in Perth	Review of studies of overweight women in post partum period	Pregnancy, Infection, and Nutrition (PIN3) Study recruited pregnant women at <20 weeks' gestation seeking prenatal care at clinics associated with the University of North Carolina Hospitals. Singleton pregnancies. Interviewed at 3 and 12 months post partum. 92% initiated breastfeeding
Quality	P	P	N	O
Results	Exercise had no effect on breastfeeding Exercise and diet together assisted in maternal weight loss after birth.	Exercise had no effect on breastfeeding or infant weight gain	Moderate weight loss in overweight lactating women does not impair infant growth	Most women (89%), thought that exercise and physical activity were appropriate at 3 months postpartum, even if they continued to breastfeed.
Effect on risk	None	None	None	None

Clinical importance	1	1	o	0
Clinical relevance	1	1	1	1
Generalisability	N (small sample size)	Y	Y	N
Applicability	Y	Y	Y	N

Cultural differences on Exercise and Breastfeeding

In some Asian cultures it was the historical practice to confine mothers to their home or even to bed for 28 days after birth. Exercise was strictly forbidden. This practice continues in some countries and has even been commercialized. For example, in Korea, in the absence of an extended family (eg grandmother not available to care for the new mother) there are now "nursing homes" available where the new mother can be admitted with her infant for 28 days of total care.

Breastfeeding and Exercise Notes

1. **Evenson (Evenson, Aytur et al. 2009)**

The U.S. Department of Health and Human Services dietary guidelines, which were released toward the end of our data collection period, state that neither acute nor regular exercise adversely affects the mother's ability to successfully breastfeed. Most women agreed that it was acceptable to participate in regular exercise or activity while breastfeeding. The benefits of breastfeeding are widely recognized, and although it is encouraging that such a high percentage of women agreed that is was acceptable to continue exercise, a notable 6% of women with less than a high school education and 5% of non-Hispanic blacks indicated that physical activity and breastfeeding were not compatible.

2. **Physical Activity for Women During Pregnancy and the Postpartum Period (U.S. Department of Health and Human Services 2008)**

Physical activity during pregnancy benefits a woman's overall health. For example, moderate-intensity physical activity by healthy women during pregnancy maintains or increases cardio-respiratory fitness.

Strong scientific evidence shows that the risks of moderate-intensity activity done by healthy women during pregnancy are very low, and do not increase risk of low birth weight, preterm delivery, or early pregnancy loss. Some evidence suggests that physical activity reduces the risk of pregnancy complications, such as preeclampsia and gestational diabetes, and reduces the length of labour, but this evidence is not conclusive.

During a normal postpartum period, regular physical activity continues to benefit a woman's overall health. Studies show that moderate-intensity physical activity during the period following the birth of a child increases a woman's cardiorespiratory fitness and improves her mood. Such activity does not appear to have adverse effects on breast milk volume, breast milk composition, or infant growth. Physical activity also helps women achieve and maintain a healthy weight during the postpartum period, and when combined with caloric restriction, helps promote weight loss.

Key Guidelines for Women During Pregnancy and the Postpartum Period

- Healthy women who are not already highly active or doing vigorous-intensity activity should get at least 150 minutes (2 hours and 30 minutes) of moderate-intensity aerobic activity per week during pregnancy and the postpartum period. Preferably, this activity should be spread throughout the week.
- Pregnant women who habitually engage in vigorous-intensity aerobic activity or are highly active can continue physical activity during pregnancy and the postpartum period, provided that they remain healthy and discuss with their health-care provider how and when activity should be adjusted over time.

Explaining the Guidelines

Women who are pregnant should be under the care of a health-care provider with whom they can discuss how to adjust amounts of physical activity during pregnancy and the postpartum period. Unless a woman has medical reasons to avoid physical activity during pregnancy, she can begin or

continue moderate-intensity aerobic physical activity during her pregnancy and after the baby is born.
When beginning physical activity during pregnancy, women should increase the amount gradually over time. The effects of vigorous-intensity aerobic activity during pregnancy have not been studied carefully, so there is no basis for recommending that women should begin vigorous-intensity activity during pregnancy.
Women who habitually do vigorous-intensity activity or high amounts of activity or strength training should continue to be physically active during pregnancy and after giving birth. They generally do not need to drastically reduce their activity levels, provided that they remain healthy and discuss with their health-care provider how to adjust activity levels during this time.
During pregnancy, women should avoid doing exercises involving lying on their back after the first trimester of pregnancy. They should also avoid doing activities that increase the risk of falling or abdominal trauma, including contact or collision sports, such as horseback riding, downhill skiing, soccer, and basketball.

3. **Levitt**

Levitt wrote an article as a preliminary to a set of SLRs.(Levitt, Shaw et al. 2004) She was able to identify 4 studies of breastfeeding and exercise, but did not list them. As far as can be ascertained these were never published.

4. **Australia National Physical Activity Guidelines** (Department of Health and Ageing 2005)

These guidelines make no mention of lactation.

5. **Amorim Adegboye 2008 Cochrane review (Amorim, Linne et al. 2007)**

Background
Weight retention after pregnancy may contribute to obesity. It is known that diet and exercise are recommended components of any weight loss programme in the general population. However, strategies to achieve healthy body weight among postpartum women have not been adequately evaluated.
Objectives: The objectives of this review were to evaluate the effect of diet, exercise or both for weight reduction in women after childbirth, and to assess the impact of these interventions on maternal body composition, cardiorespiratory fitness, breastfeeding performance and other child and maternal outcomes.
Search strategy: We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (September 2006) and LILACS. We scanned secondary references and contacted experts in the field.
Selection criteria: All published and unpublished randomised controlled trials (RCT) and quasi-randomised trials of diet or exercise or both, among women during the postpartum period.
Data collection and analysis: Three review authors independently assessed trial quality and extracted data. Results are presented using relative risk for categorical data and weighted mean difference (WMD) for continuous data. Data were analysed with a fixed-effect model. A random-effects model was used in the presence of heterogeneity.
Main results: Six trials involving 245 women were included. Women who exercised did not lose significantly more weight than women in the usual care group (one trial; n = 33; WMD 0.00 kg; 95% confidence interval (CI) -8.63 to 8.63). Women who took part in a diet (one trial; n = 45; WMD -1.70 kg; 95% CI -2.08 to -1.32), or diet plus exercise programme (four trials; n = 169; WMD -2.89 kg; 95% CI - 4.83 to -0.95), lost significantly more weight than women in the usual care. There was no difference in the magnitude of weight loss between diet and diet plus exercise group (one trial; n = 43; WMD 0.30 kg; 95% CI -0.60 to 0.66). The interventions seemed not to affect breastfeeding performance adversely.

Authors' conclusions: Preliminary evidence from this review suggests that both diet and exercise together and diet alone help women to lose weight after childbirth. Nevertheless, it may be preferable to lose weight through a combination of diet and exercise as this improves maternal cardiorespiratory fitness and preserves fat-free mass, while diet alone reduces fat-free mass. This needs confirmation in large trials. For women who are breastfeeding, more evidence is required to confirm whether diet or exercise, or both, is not detrimental for either mother or baby.

6. **Su Cohort study in Perth. (Su, Zhao et al. 2007)**

Objectives: To study the relationship between exercise by the mother and breastfeeding initiation and duration, and its effect on infant growth.
Design: A cohort study of mothers and infants, recruited at birth. Infant feeding methods were recorded in detail and breastfeeding was categorised as 'any' or 'full'. Exercise levels were categorised using the metabolic equivalent tasks approach based on details of physical activity recorded in questionnaires.
Setting: Perth, Western Australia.
Subjects: A total of 587 mothers were interviewed on seven occasions over a period of 12 months.
Results: There was no difference in the means of infant weight and length changes, indicating that exercise appeared to have no significant influence on infant growth up to 52 weeks after birth (P=0.236 and 0.974, respectively). The mother's level of exercise was not significantly associated with breastfeeding to 6 or 12 months. This applied to 'full' and 'any' categories of breastfeeding.
Conclusion: Exercise does not affect breastfeeding outcomes at the usual levels of activity undertaken by mothers. Breastfeeding and exercise are important for maintaining and promoting health, and this study provides reassurance to health professionals wishing to encourage mothers to continue both behaviours.

7. **McCory (McCrory 2001)**

For some women, postpartum retention of weight gained during pregnancy may contribute to obesity. A recent 70-week randomized intervention showed that infants of initially overweight, lactating mothers who exercised and dieted to lose an average of 0.5 kg/week grew normally. The findings of this study support the institute of Medicine guidelines for weight loss in overweight women who are exclusively breastfeeding their child.

8. **Evenson (Evenson, Aytur et al. 2009)**

Background and Methods: Physical activity during postpartum is both a recommended and an essential contributor to maternal health. Understanding the beliefs, barriers, and enablers regarding physical activity during the postpartum period can more effectively tailor physical activity interventions. The objective of this study was to document self-reported beliefs, barriers, and enablers to physical activity among a cohort of women queried at 3 and 12 months postpartum. Five questions about beliefs and two open-ended questions about their main barriers and enablers regarding physical activity and exercise were asked of 667 women at 3 months postpartum. Among the sample, 530 women answered the same questions about barriers and enablers to physical activity at 12 months postpartum.
Results: Agreement on all five beliefs statements was high (_89%), indicating that women thought that exercise and physical activity were appropriate at 3 months postpartum, even if they continued to breastfeed. For the cohort, the most common barriers to physical activity at both 3 and 12 months postpartum were lack of time (47% and 51%, respectively) and issues with child care (26% and 22%, respectively). No barrier changed by more than 5% from 3 to 12 months postpartum. For the cohort, the most common enablers at 3 months postpartum were partner support (16%) and desire to feel better (14%). From 3 to 12 months postpartum, only one enabler changed by >5%; women reported baby reasons (e.g., baby older, healthier, not breastfeeding, more active) more often at 12 months

than at 3 months postpartum (32% vs. 10%). Environmental=policy and organizational barriers and enablers were reported less often than intrapersonal or interpersonal barriers at both time points. **Conclusions:** A number of barriers and enablers were identified for physical activity, most of which were consistent at 3 and 12 months postpartum. This study provides information to create more successful interventions to help women be physically active postpartum.

Baby Friendly Hospital Initiative and Breastfeeding Performance

Search results

The initial search of the databases included 110 references on the BFHI and breastfeeding outcomes were identified. Data were extracted from 14 references, and 6 publications were used to form the final body of evidence statements. Sufficient evidence was found to make a statement on the implementation of the BFHI and breastfeeding outcomes. Details of the BFHI program components are found in the WHO/UNICEF documents (Saadeh and Casanovas 2009; WHO/UNICEF 2009)

Is the implementation of the BFHI associated with breastfeeding performance and duration?		
Draft Evidence statement		Implementation of the BFHI improves breastfeeding outcomes
Draft Grade		B
Component	**Rating**	**Notes**
Evidence Base	Good	1 systematic review (of 2 RCT and 4 cohort 1P), 2 invention studies (2P).
Consistency	Good	All studies found a positive effect of the BFHI.
Clinical impact	Good	Direct effect
Generalisability	Excellent	Developed and developing countries
Applicability	Excellent	Directly applicable.

Conclusions

The systematic review included two good quality RCTs, two poor quality experimental studies and four poor quality observational studies. We identified an additional cohort study and two additional observational studies. The BFHI intervention was based on hospital accreditation based on the BFHI principles. The two randomised trials in the table (Kramer and Coutinho) were both included in the SLR by Chung and were both of high quality, one in Belarus and the other in Brazil. All studies were consistent with the implementation of BFHI in a hospital being associated with higher rates of exclusive breastfeeding.

Studies used to make evidence statement for Breastfeeding and the BFHI

Reference	Chung 2008 Ann Int Med	Kramer 2001 JAMA	Coutinho 2005 Lancet
Type of study	SLR	Cluster RCT	RCT
Level of evidence	I (aetiology)	II (intervention)	II (intervention)
Definition of breastfeeding	Exclusive breastfeeding ("no supplement of any kind," "including water while breastfeeding," or "occasional formula is permissible while breastfeeding"); All other breastfeeding regimens (full, partial, mixed, or non-specified) as nonexclusive. breastfeeding initiation as any breastfeeding at discharge or up to 2 weeks after delivery. Breastfeeding durations of <1 month as "no breastfeeding" 1 to 3 months as short-term, 4 to 5 months as intermediate 6 to 8 months as long-term, and 9 or more months as prolonged.	WHO definitions exclusive breastfeeding for 3 or 6 months if they received no solids, non-breast milk, or water or other liquids (other than vitamins or medications) Predominantly breastfed at these ages if they received no solids or non-breast milk; juices, water, teas, and other liquids were permitted	WHO definitions were used:7 Exclusively breastfed if they received only breast milk (no water, other liquids, or solids) and Breastfed if they received breast milk plus other food or liquid (including other milk). Other milk was defined as any non breast milk.
Intervention Comparator	BFHI vs usual practice	BFHI vs usual practice	BFHI vs BFHI plus home visits
N	4 cohort studies 2 RCT studies (Kramer Countinho)	16 hospitals	350
Population/study information		A total of 17046 mother-infant pairs consisting of full-term singleton infants weighing at least 2500 g and their healthy mothers who intended to breastfeed	Two hospitals in an urban area in Brazil and surrounding district Singletons, ≥ 2500g
Quality	P	P	P
Results	BFHI increased the exclusive breastfeeding rates at 3 (43.3% vs. 6.4% (P <0.001) and 6 (7.9% vs. 0.6% (P=0.01)) months.	Infants from the intervention sites were significantly more likely than control infants to be breastfed to any degree at 12 months (19.7% vs 11.4%; adjusted odds ratio [OR], 0.47; 95% confidence interval [CI], 0.32-	BFHI increased the exclusive breastfeeding rates in hospital. BFHI plus home visits increased the exclusive breastfeeding rates to 6 months

		0.69), were more likely to be exclusively breastfed at 3 months (43.3% vs 6.4%; *P*,.001) and at 6 months (7.9% vs 0.6%; *P*=.01),	
Effect on risk	Positive	Positive	Positive
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	N
Applicability	Y	Y	N

Reference	**Abrahams 2009 Int BF J**	**Merten 2005 Pediatrics**	**Bartington 2006 Int J Epid**
Type of study	Observational	Observational	Cohort
Level of evidence	III-2 (intervention)	III-2 (intervention)	II (aetiology)
Definition of breastfeeding	The primary outcome variables were the percent of living children under the age of two months and under the age of six months who were exclusively breastfed at the time of survey. EBF as defined by DHS refers to the practice of giving no food or drink other than human milk, measured by 24-hour recall	Exclusively breastfed infants received nothing except breast milk, predominantly breastfed infants received additional water-based liquids, full breastfeeding included exclusive and predominant breastfeeding, and any breastfeeding was defined as full breastfeeding or the combination of breast milk and any other supplement (liquid or solid).	Any breastfeeding at discharge and one month
Intervention Comparator	Implementation of BFHI	Health facilities BFHI accredited or not accredited	BFHI vs non BFHI accredited maternity units
N	14 countries	3032	17 359 singleton births
Population/study information	Data were taken from the Demographic and Health Surveys (DHS) from 1986-2006. 14 Developing countries	Mothers giving birth in Switzerland from designated baby-friendly hospital (45 hospitals) or in a health facility in the process of being evaluated for BFHI inclusion (31 facilities).	Millennium Cohort
Quality	P	0	

Results	BFHI implementation was associated with average annual increases of 1.54 percentage points in the rate of EBF of infants under two months ($p < 0.001$) and 1.11-percentage points in the rate of EBF of infants under six months ($p < 0.001$); however, these rates were not statistically different from pre-BFHI trends.	The proportion of exclusively breastfed infants 0 to 5 months of age was 42% for infants born in babyfriendly hospitals, compared with 34% for infants born elsewhere. Breastfeeding duration for infants born in baby-friendly hospitals, compared with infants born in other hospitals, was longer if the hospital showed good compliance with the UNICEF guidelines (35 weeks vs 29 weeks for any breastfeeding, 20 weeks vs 17 weeks for full breastfeeding, and 12 weeks vs 6 weeks for exclusive breastfeeding).	Mothers delivering in accredited maternity units were more likely to start breastfeeding than those delivering in units with neither award [adjusted rate ratio: 1.10, 95% confidence interval (CI) 1.05–1.15], but were not more likely to breastfeed at 1 month (0.96, 95% CI 0.84–1.09)
Effect on risk	Positive	Positive	Positive
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

References: (Kramer, Chalmers et al. 2001; Merten, Dratva et al. 2005; Perez-Escamilla 2007; Abrahams and Labbok 2009; Saadeh and Casanovas 2009)

Additional Notes: Baby Friendly Hospitals and Breastfeeding

Many papers assessed were not included because:

1. Little data included – opinion pieces, editorials
2. Applied to neonatal intensive care units and LBW infants.

The Baby-friendly Hospital Initiative (BFHI) was launched by WHO and UNICEF in 1991, following the Innocenti Declaration of 1990. The initiative is a global effort to implement practices that protect, promote and support breastfeeding.

To help in the implementation of the initiative, different tools and materials were developed, field-tested and provided, including a course for maternity staff, a self-appraisal tool and an external assessment tool. Additional tools were developed afterwards, such as monitoring and reassessment tools. Since its launching BFHI has grown, with more than 20,000 designated facilities in 152 countries around the world. The initiative has measurable and proven impact, increasing the likelihood of babies being exclusively breastfed for the first six months.

http://www.who.int/nutrition/topics/bfhi/en/index.html Accessed 8 Oct 2010

BFHI accreditation is based on the 'The Ten Steps to Successful Breastfeeding' a summary of the guidelines for maternity care facilities presented in the Joint WHO/UNICEF Statement Protecting, Promoting and Supporting Breastfeeding: The Special Role of Maternity Services, (WHO, 1989) have been accepted as the minimum global criteria for attaining the status of a Baby-friendly Hospital.

TEN STEPS TO SUCCESSFUL BREASTFEEDING

Every facility providing maternity services and care for newborn infants should:

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within a half-hour of birth.
5. Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breast milk unless *medically* indicated.
7. Practise rooming in - allow mothers and infants to remain together - 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers

National BFHI accreditation authorities are responsible for setting goals based on international standards. In general they include:

- The goal for early initiation should be that newborns are placed skin-to-skin within minutes of birth, remaining for 60 minutes or longer, with all mothers encouraged to support the infant to breastfeed when their babies show signs of readiness.
- The goal for exclusive breastfeeding, as determined at the UN Standing Committee on Nutrition, 2004, should be to increase exclusive breastfeeding to 6 months of age to a minimum of 60% by 2015, with the ultimate goal of approaching 100%.

Note: in countries where women receive voluntary counselling for HIV/AIDS, a proportion of these women will choose replacement feeding.

Even though some of the HIV-positive women will choose exclusive breastfeeding, in such settings, the ultimate goal will remain less than 100%.

- The goal for complementary feeding, as determined at the UN Standing Committee on Nutrition, 2004, from 6 months to 23 months or longer, is that breastfeeding continue to supply 350-500 calories a day, and an additional 3-5 feedings of nutrient rich complementary foods is needed, as described under "optimal feeding".

Since the BFHI began, more than 15,000 facilities in 134 countries have been awarded Baby-Friendly status. In many areas where hospitals have been designated Baby-Friendly, more mothers are breastfeeding their infants, and child health has improved. News of the BFHI accomplishments and articles about effective breastfeeding programmes have been published for ten years in UNICEF's BFHI News.
The country with the most BFHI accredited hospitals is China (>6000), but many of these hospitals may not adhere to the basic principles of the use of infant formula.
In USA only 1.3% of hospitals are BFHI (Saadeh and Casanovas 2009)
In Australia there are currently 73 Baby Friendly accredited health services.
http://www.bfhi.org.au/text/bfhi_hospitals.html Accessed 8 Oct 2010
HANNULA L, A systematic review of professional support interventions for breastfeeding. (Hannula, Kaunonen et al. 2008)
This was a review of variety of interventions and outcomes and so was not included in the BOE table.
Objectives. The objectives of this systematic review were first, to describe how breastfeeding is professionally supported during pregnancy, at maternity hospitals and during the postnatal period. Secondly, to find out how effective interventions are in supporting breastfeeding.
Background. Breastfeeding is an effective way to promote the health of infants. In many countries, the rates for breastfeeding remain lower than recommended. Many studies have examined breastfeeding promotion interventions; some of them are successful and some fail. It is important to find effective combinations of support.
Design. Systematic review.
Methods. Search of CINAHL, Medline and Cochrane Central Register databases were conducted for data collection. The search was limited to articles published in Finnish, Swedish and English between the year 2000 and March 2006, focusing on breastfeeding and breastfeeding support interventions. Two reviewers independently analysed 36 articles in the final analysis.
Results. Interventions expanding from pregnancy to the intrapartum period and throughout the postnatal period were more effective than interventions concentrating on a shorter period. In addition, intervention packages using various methods of education and support from well-trained professionals are more effective than interventions concentrating on a single method.
Conclusions. During pregnancy, the effective interventions were interactive, involving mothers in conversation. The Baby Friendly Hospital Initiative (BFHI) as well as practical hands off -teaching, when combined with support and encouragement, were effective approaches. Postnatally effective were home visits, telephone support and breastfeeding centres combined with peer support.

Breastfeeding and SIDS

BREASTFEEDING AND SUDDEN INFANT DEATH SYNDROME – update of the DAA SLR

What are the benefits of breastfeeding (partial and exclusive) and the risks of not breastfeeding (any and exclusive), to infants and mothers, both in the short term and long term?		
Draft Evidence statement		Not breastfeeding is associated with an increased risk of Sudden Infant Death Syndrome
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	1 Systematic review (23 studies, 18 case-controls, 4 nested case-controls, 1 cohort) of excellent quality with meta-analysis with low risk of bias showing an increased risk of SIDs with "bottle" feeding
Consistency	Good	19 studies had a protective effect for breastfeeding, 1 had no effect and 3 showed a negative effect. Sensitivity analysis conducted in the meta-analysis and similar ORs for bottle feeding shown for studies rated "good" (10 studies, OR range 0.56 to 5.95) or published in last 10 years
Clinical impact	Excellent	Pooled OR for 23 studies was 2.11 (95%CI: 1.66 - 2.68). For higher quality studies only OR = 2.24 ("good" studies) and 2.32 (studies in last 10 years)
Generalisability	Excellent	Generalisable to Australian women and the review includes Australian data
Applicability	Excellent	Directly applicable to Australia

This body of evidence statement had to be stated as “not breastfeeding…” because breastfeeding could not be demonstrated to be protective, possibly due to confounding, whereas *not* breastfeeding could be shown to increase the risk of sudden infant death syndrome.

The studies included in the body of evidence statement are shown in Table 24.4.
The evidence base was updated with two newer reviews. There was no change to the conclusions.

Table 24.4 Studies used to make evidence statements for breastfeeding and sudden infant death syndrome (SIDS)

STUDY DETAILS (Review)	**McVea, K.L.S., P.D. Turner, and D.K. Peppler 2000 [1026]**
Reference	
Affiliation/source of funds	Olson centre for Women's Health, Nebraska
Study design	Meta analysis of 23 studies (18 case-controls, 4 nested case -controls, 1 cohort)
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	1966-1997
Number of studies	23
Total number of participants	>3100 cases 50 000 controls
Population characteristics	Infant populations from UK, Australia, NZ, Canada, USA, ScandInavia.
Range of exposure	Included studies if a minimal definition of SIDs was met and original data were presented to allow calculation of an OR for bottle feeding.
Length of follow-up	Not applicable
Outcome(s) measured	Inclusive definition of SIDS as any sudden, unexplained death of a young child.
INTERNAL VALIDITY	
Databases included in search	MEDLINE and additional hand searches of the references lists and key papers included in the meta-analysis
Statistical analysis methods	ORs and 95% CIs. Random effects model used in the meta-analysis due to heterogeneity of the studies with a pooled OR. Separate "pooled" OR for 2 groups of studies; those with "excellent" or "good" quality ratings published in last 10 years.
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	P
RESULTS	9 studies rated "good", 10 as "fair" and 4 as "poor". Better studies had higher risk for bottle feeding. OR for studies ranged from 0.56 to 5.95. 19 studies had a protective effect for breastfeeding, 1 had no effect and 3 showed a negative effect. Most of the studies were protective. The pooled OR for 23 studies was 2.11 (95% CI: 1.66 - 2.68). For higher quality studies only OR = 2.24 ("good" studies)

	and 2.32 (studies in last 10 years). 9 studies included data on partial breastfeeding and 7 had enough data to estimate SIDs risk; 4 showed a dose response for increasing use of formula feeding but none had sufficient power to demonstrate statistically significant difference for partial versus no breastfeeding.
Outcome	Death from SIDS
EXTERNAL VALIDITY	
Generalisability	Yes
Applicability	Yes
Comments	Data includes Australian studies. The meta-analysis suggested breastfeeding conveys a 50% reduced risk of SIDs
Conclusion	Breastfeeding should be strongly encouraged, independent of SIDs and the evidence for SIDs protection is imperfect due to confounding.

Additional studies used to update evidence statement for Breastfeeding and SIDS

Reference	**Venneman 2009 Pediatrics**	**Ip 2007 Technology Assessment**
Type of study	Case control	SLR
Level of evidence	III	I
Definition of breastfeeding	EBF breast milk only, with no extra bottle of milk formula or solids given at any time of the day. Partial breastfeeding (ABF) was defined as any bottle feeding (milk formula) or solids given in addition to breast milk. Not breastfed was defined as no breast milk.	Ever Breastfeeding (ABF)
Intervention Comparator		Not Breastfed
N	333 infants who died from SIDS and 998 age-matched controls	769 cases of SIDS and 2,681 controls.
Population/study information	German Study of Sudden Infant Death	Seven studies where SIDS was clearly defined with autopsy evidence Developed Countries
Quality	P	P
Results	Breastfeeding reduced risk of SIDS ABF at 2 weeks OR 0.43 (0.27,0.69) EBF at 4 weeks OR 0.48 (0.28,0.82) ABF at 4 weeks OR 0.48 (0.21,1.10)	Breastfeeding reduced risk of SIDS ABF OR 0.64 (0 .51, 0 .81)
Effect on risk	Negative	Negative
Clinical importance	1	1
Clinical relevance	1	1
Generalisability	Y	Y
Applicability	Y	Y

Additional Notes

1. **Clinical Evidence 2009 <u>What are the effects of interventions to reduce the risk of SIDS?</u> (Hauck and Tanabe 2009)**

Reduction in incidence of SIDS

Advice to breastfeed compared with no advice

Advice to breastfeed or breastfeed plus other advice may reduce the incidence of SIDS (very low-quality evidence).

Note:

We found no clinically important results from RCTs comparing advice to breastfeed with no advice. RCTs investigating the effects of advice to breastfeed may be considered unethical.

Benefits: We found no systematic review or RCTs comparing advice to encourage breastfeeding versus no advice (see comment below).

National advice campaigns:

We found one non-systematic review of national campaigns (3 observational studies; 1 of which reported separately) and three additional observational studies conducted after the national advice campaigns. The review and additional observational studies found that the campaigns were all followed by a reduced incidence of SIDS during the data collection periods. However, the campaigns all included additional advice combined with promoting breastfeeding, and in some countries the incidence of SIDS had started to fall before the campaign started.

The second additional observational study found that the incidence of mothers choosing not to breastfeed reduced significantly after the campaign (from 21% before the campaign to 7% after the campaign; $P < 0.001$). The third additional observational study found that rates of children solely being breastfed increased from 53% to 67% after the campaign.

Harms: The studies reported no evidence on harms associated with advice to encourage breastfeeding.

Comment: RCTs investigating the effects of promotion of breastfeeding would be unethical, given the evidence of benefits associated with breastfeeding.

Ip, S., M. Chung, et al. (2007). "Breastfeeding and maternal and infant health outcomes in developed countries."

"Our meta-analysis included only studies that reported clear definitions of exposure, outcomes, and results adjusted for well-known confounders or risk factors for SIDS. The summary estimate found a statistically significant adjusted odds ratio for an association between breastfeeding and a reduced risk of SIDS (adjusted OR 0.64, 95%CI 0.51 - 0.81). We conclude that there is a relationship between breastfeeding and a reduced risk of SIDS."

References used in the evidence statement: (McVea, Turner et al. 2000; Ip, Chung et al. 2007; Vennemann, Bajanowski et al. 2009)

Use of Pacifiers for the Prevention of SIDS

Search results
The initial search of the databases included 68 references on the use of pacifiers and SIDS. Data were extracted from 3 references and these reviews were used to form the final body of evidence statements. Sufficient evidence was found to make a statement on use of a pacifier and the prevention of SIDS.

The systematic review included two systematic reviews and one narrative review. There is a consensus that the use of a pacifier reduces the risk of SIDS. In epidemiological studies the use of a Pacifier is measured in two ways: 'routine use of pacifier' or 'pacifier use last sleep'. There is a remarkably consistent reduction of SIDS with pacifier use. The mechanism by which pacifiers might reduce the risk of SIDS is discussed by Moon in the notes below. The odds ratios use of pacifier in last sleep is lower than for routine use.

Studies used to make evidence statement for Use of Pacifiers and SIDS

Reference	**Moon 2007 Lancet**	**Hauck 2005 Pediatrics**	**Mitchell 2006 Pediatrics**
Type of study	Narrative review for pacifiers	SLR	SLR
Level of evidence	III (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	N/A	N/A	N/A
Intervention Comparator	Pacifier use v's none	Pacifier use at last reference sleep	Pacifier use at last reference sleep
N	4 studies	7 studies	8 studies
Population/study information	6 case control studies 2 Meta - analyses	7 Case control studies 1966-2004 (No RCT's or prospective studies available)	8 case control studies
Quality	P	P	P
Results	Pacifiers reduced risk of SIDS No RR given	Summary OR 0.39(0.31-0.50) 1 SIDS death could be prevented for every 2733 (95% CI: 2416–3334) infants who use a pacifier when placed for sleep (number needed to treat), based on the national SIDS rate and the last-sleep multivariate SOR resulting from this analysis.	There is a remarkably consistent reduction of SIDS with pacifier use. The mechanism by which pacifiers might reduce the risk of SIDS is unknown, Pooled OR for routine use of pacifier 0.83 (0.75,0.93), Pooled OR for pacifier use last sleep 0.48 (0.43, 0.54)
Effect on risk	Negative (reduces risk)	Negative	Negative
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Note: there is overlap of studies between Moon, Mitchell and Hauck

American Academy of Pediatrics Policy Statement
Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children Task Force on Sudden Infant Death Syndrome (American Academy of Pediatrics 2005).

Pacifiers
"Several studies have reported a protective effect of pacifiers on the incidence of SIDS, particularly when used at the time of last sleep. The mechanism for this apparent strong protective effect is still unclear, but several mechanisms such as lowered arousal thresholds have been proposed. Concerns about possible deleterious effects of pacifier use have prevented most SIDS experts and policy makers from making a recommendation for pacifier use as a risk-reducing method. Concerns specifically about breastfeeding have led others to recommend pacifiers only for bottle-fed infants. Although several studies have shown a correlation between pacifiers and reduced breastfeeding duration, the results of well-designed randomized clinical trials indicate that pacifiers do not seem to cause shortened breastfeeding duration for term and preterm infants. One study reported a small deleterious effect of pacifier introduction in the first week of life on breastfeeding at 1 month of age, but this effect did not persist beyond 1 month. Some dental malocclusions have been found more commonly among pacifier users than nonusers, but the differences generally disappeared after cessation. The American Academy of Pediatric Dentistry policy statement on oral habits states that "non-nutritive sucking behaviours (i.e. finger or pacifier) are considered normal in infants and young children … and in general, sucking habits in children to the age of five are unlikely to cause any long-term problems." There is an approximate 1.2- to 2-fold increased risk of otitis media associated with pacifier use, but the incidence of otitis media is generally lower in the first year of life, especially the first 6 months, when the risk of SIDS is the highest. However, pacifier use, once established, may persist beyond 6 months, thus increasing the risk of otitis media. Gastrointestinal infections and oral colonization with *Candida* species were found to be more common among pacifier users."

American Academy of Pediatrics SIDS risk reduction recommendations, (American Academy of Pediatrics 2005)
• Back to Sleep: infants should be placed for sleep in a supine position for every sleep. Side sleeping is not as safe as supine sleeping and is not advised
• Use a firm sleep surface
• Keep soft objects and loose bedding out of the crib
• Do not smoke during pregnancy
• A separate but proximate sleeping environment is recommended: the infant's crib or bassinet should be placed in the parents' bedroom, which, when placed close to their bed, will allow for convenient breastfeeding and contact
• Consider offering a pacifier at nap time and bedtime: the pacifier should be used when placing the infant down for sleep and not be reinserted once the infant falls asleep. If the infant refuses the pacifier, he or she should not be forced to take it. For breastfed infants, delay pacifier introduction until 1 month of age to ensure that breastfeeding is firmly established
• Avoid overheating
• Avoid commercial devices marketed to reduce the risk of SIDS
• Do not use home monitors as a strategy to reduce the risk of SIDS
• Avoid development of positional plagiocephaly: encourage "tummy time" when the infant is awake and observed. This will also enhance motor development. Avoid having the infant

spend excessive time in car-seat carriers and "bouncers," in which pressure is applied to the occiput. Upright "cuddle time" should be encouraged
• Continue the Back to Sleep campaign

Recommendations for sudden infant death syndrome prevention: a discussion document (Mitchell 2007)
Mitchell includes the following comment in his narrative review for the UK Ministry of Health:

Breastfeeding
Advice to breastfeed if possible is included in the SIDS prevention programme in New Zealand, but is not mentioned in the UK Department of Health advice. Almost all studies show that breastfeeding is associated with a reduced risk of SIDS.(McVea, Turner et al. 2000)
However, in countries such as the UK where breastfeeding rates are low and strongly associated with socioeconomic status, adjustment for socioeconomic status decreases the level of protection, leading some authors to conclude that there is no reduced risk. However, the larger studies consistently show a reduced risk of SIDS with breastfeeding even after adjustment for socioeconomic status (Alm, Wennergren et al. 2002). Breastfed infants have more arousals than bottle-fed infants, which may explain a possible protective effect (Horne, Parslow et al. 2004). In addition, breastfeeding reduces infection, which could also be the protective mechanism (Howie 2002).
Even if the recommendation to breastfeed is not included in the specific SIDS prevention advice, it should be included in the general advice, as it reduces morbidity and mortality in infants even in developed countries.

Pacifiers (dummies)
For several years now, The Netherlands has recommended the use of pacifiers in bottle-fed infants. In October 2005, the American Academy of Pediatrics recommended the use of a pacifier throughout the first year of life. Two recent meta-analyses have shown that pacifier use in the last sleep is associated with a reduced risk of SIDS. Hauck and colleagues recommended pacifier use up to 1 year of age (Hauck, Omojokun et al. 2005; Hauck 2006). Concerns about possible adverse effects, especially on breastfeeding, and an increase in otitis media, led the other review69 to recommend that pacifier use should not be discouraged, but not specifically recommended.

Moon. Sudden Infant Death Syndrome (Moon, Horne et al. 2007)
Published case-control studies have shown a significantly reduced risk of SIDS when a pacifier is used at sleep time and two meta-analyses have reported a strong protective effect. Several mechanisms have been postulated to explain this protective effect. Franco and colleagues found a lower arousal threshold in infants who frequently used a pacifier than those who did not during sleep, perhaps allowing increased responsiveness to a life-threatening challenge, such as obstructive apnoea, cardiac arrhythmia, or external conditions leading to hypoxia and asphyxia (Franco, Scaillet et al. 2000). Other theories include an improved ability to breathe through the mouth if the nasal airway becomes obstructed and decreased likelihood of oropharyngeal obstruction by bringing the tongue forward. Use of a pacifier might also reduce SIDS risk by affecting sleep position. Even when pacifiers become dislodged from the mouth after an infant falls asleep, which generally occurs soon after sleep onset the protective effect still persists. Displacement of the pacifier might contribute to increased sleep disruption and greater arousability of the infant.

Use of Pacifiers and Breastfeeding Duration

Search results
The initial search of the databases included 187 references on the use of pacifiers and breastfeeding duration. Data were extracted from 8 references and these publications were used to form the final body of evidence statements. Sufficient evidence was found to make a statement on use of a pacifier before 4 weeks and breastfeeding duration.

Use of Pacifiers and Breastfeeding Duration

Is pacifier use negatively associated with breastfeeding duration?		
Draft Evidence statement		The use of a pacifier before 4 weeks is associated with a reduced duration of breastfeeding (any, full and exclusive).
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Good	1 systematic review 1 meta analysis I RCT 5 cohort studies
Consistency	Satisfactory	The systematic review found an effect for cohort studies, but not for the 4 RCTs. The Meta analysis of 19 cohort study found that the use of pacifiers reduced any and exclusive breastfeeding. The other cohort studies found a negative effect.
Clinical impact	Satisfactory	There was an association between pacifier use and reduced breastfeeding duration
Generalisability	Excellent	US, European, Aust, NZ populations
Applicability	Excellent	Directly applicable.

Studies used to make evidence statement for use of Pacifiers and Breastfeeding Duration

Reference	**Howard 2003**	**Vogel 2001**	**O Connor 2009 Arch Pediatrics**	**Karabulut 2009 Turk J Pediatrics**
Type of study	RCT	Cohort study	SLR	Meta analysis
Level of evidence	II (I)	II (aetiology)	I (aetiology)	II (aetiology)
Definition of breastfeeding	EBF – but Hospital feeds excluded FBF standard ABF	Full breastfeeding was defined as breastfeeding without supplementation with formula, other milk or solids. Water permitted	Definitions not stated	WHO Definitions. EBF received only breast milk with no other liquids or solids. ABF being fully breastfed or receiving both breast milk and a formula, with or without solids
Intervention Comparator	Pacifier before 4 weeks v's none or later	Pacifier use before 4 weeks v's No use or <daily	Pacifier use (Time variable) vs no use	Pacifier use <4 weeks and <6 weeks vs no use
N	700 (3300 initially approached)	350 (79% response) Follow-up to 12 months was 94%		N=13526 for EBF N= 19058 for ABF
Population/study information	Births at Rochester General Hospital Mothers intending to breastfeed for >4 weeks, singleton, wanted to use pacifier or undecided Interviewed approx monthly	Births at North Shore Hospital, Auckland >37 weeks Birth weight > 10th percentile Telephone interviews were conducted at 1, 2, 3, 6, 9 and 12 months postpartum.	4 RCT, 20 Cohort studies, 5 cross sectional studies One study of infants <2500G birth weight. One study of education about pacifier use One study (Howard 2003) showed effect	Cross sectional and cohort studies. 12 studies – cessation of EBF <6 months 19 studies
Quality	P/N/0 P	P	N	P
Results	Pacifiers reduced Any BF HR 1.22 (1.03, 1.44)	Daily pacifier use and duration of full breastfeeding RR 1.35 (1.05, 1.74)	Overall no effect of pacifiers on breastfeeding duration (RCTs had no effect, cohort studies showed some effect) See critique by Kronborg 2009 Birth	Pacifiers reduced duration of EBF and ABF EBF 1.79 (1.45,2.21) ABF 1.95 (1.66-2.29)
Effect on risk	Negative	Negative	None	Negative

Clinical importance	1	1	0	1
Clinical relevance	1	1	1	1
Generalisability	Y to USA ? Aust	Y	N	Y
Applicability	Y	Y	N	Y

Reference	**Kronborg 2009 Birth**	**Butler S, Williams M, Tukuitonga C & Paterson J The New Zealand Medical Journal 2004; 117.**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**	**Clements et al Acta Paediatr, 1997; 86:51-56**
Type of study	Cohort	Prospective cohort	Prospective cohort study	Prospective cohort study
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	EBF –defined as a child being fed only on mother's milk	Exclusive breastfeeding – other (includes water) Not breastfeeding exclusively	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Any breastfeeding duration
Intervention **Comparator**	Pacifier before 2 weeks v's none or later	Dummy used yes vs no (reference)	Pacifier introduced < 4 wk 4-10wk >10 wk Mot using a pacifier at 12 mo (ref)	Pacifier use in last 2 weeks Yes vs no (ref)
N	570	1247	587 (68% of 870 women contacted and 55% of 1068 eligible women)	700
Population/study information	Births in Aarhus, Western Denmark	Auckland, New Zealand 1 or more parent Pacific ethnicity Data part of Pacific Islands Families (PIF) Study through interviews with mothers & hospital records	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Infants from South West Thames (UK) region were randomly selected from all births, except home births. The subjects were randomly allocated an age at which to be interviewed, in such a way as to ensure that they had a

				similar age distribution to that previously described for SIDS cases. The median age was 90 days (range 30-302 days). The study ran from 14 October 1990 to 13 October 1991.
Quality	P	P	P	P
Results	Pacifiers reduced duration of EBF RR adjusted 1.42 (1.18,1.72)	Adj OR not breastfeeding exclusively at 6 weeks post-birth 2.48 (95%CI 1.79-3.44)	*Risk of discontinuing any BF* Adj OR (95% CI) < 4 wk 1.92 (1.40-2.64) 4-10 wk 1.97 (1.13-3.46) > 10 wk 1.61 (0.86-3.00) *Risk of discontinuing full BF* < 4 wk 1.92 (1.39-2.64) 4-10 wk 11.85 (1.06 – 3.22) > 10 wk 1.47 (0.79-2.73)	*Any breastfeeding duration* Adj HR (95% CI) 2.64 (1.81-3.84)
Effect on risk	Negative	Women who gave their babies a pacifier were more likely to not be breastfeeding exclusively at 6 weeks postpartum	Introduction of pacifier before 10 weeks was negatively associated with the duration of full and any breastfeeding.	No association with duration of any breastfeeding
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y (Pacific Islanders)	Y	Y (English)
Applicability	Y	Y (Pacific Islanders)	Y	Y

Both the Baby Friendly Hospital Initiative and the Academy of Breastfeeding Medicine do not permit the use of pacifiers (dummies or soothers) in their protocols (Saadeh and Casanovas 2009; WHO/UNICEF 2009; Philipp 2010)

NOTES

1. There is one Cochrane Protocol, but no review has been completed (Sharifah, Angolkar et al. 2008).
2. Kronborg offers the following critique of the 4 RCTs in the O'Connor SLR (Kronborg and Vaeth 2009)

The four studies presented in the review contribute with valuable information, but each study has limitations, implying that the evidence of no causal effect can be questioned. Briefly, in the study by Schubiger et al the actual use of a pacifier in each group is insufficiently described. In the study by Howard et al early use of a pacifier showed a negative influence on breastfeeding duration. In the study by Kramer et al the primary exposure was educational counselling of the mother and not use of a pacifier, and the study by Collins et al concerned preterm infants (28–<34 wk), for whom pacifier use may have a different role.

References used to form body of evidence statement:

(Clements, Mitchell et al. 1997; Vogel, Hutchison et al. 2001; Howard, Howard et al. 2003; Butler, Williams et al. 2004; Scott, Binns et al. 2006; Kronborg, Vaeth et al. 2007; Karabulut, Yalcin et al. 2009; O'Connor, Tanabe et al. 2009)

IV Breastfeeding: common problems and their management

Hygiene

Nipple Pain and trauma

Search results

The initial search of the databases included 146 references on nipple pain/trauma during breastfeeding. Data were extracted from 25 references, and 2 publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the treatment of nipple pain in lactating women and on the prevention of nipple pain in lactating women. Additional evidence was found on the incidence of nipple pain (2 narrative reviews), but the evidence was not strong enough to develop a body of evidence statement.

TREATMENT FOR NIPPLE PAIN/TRAUMA DURING LACTATION

What are the best forms of treatment for women who experience nipple pain/trauma during lactation?		
Draft Evidence statement		No single intervention offers a significant improvement in the symptoms or duration of nipple pain/trauma
Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	2 Systematic reviews (overlap between studies, 16 RCTs and quasi-experimental studies in total) of high quality.
Consistency	Satisfactory	Both reviews concluded that no single pharmacological or non-pharmacological method offered a significant effect in terms of treating nipple pain/trauma in breastfeeding women.
Clinical impact	Poor	No trial provides sufficient evidence on any intervention to justify widespread uptake of that intervention.
Generalisability	Satisfactory	Majority of studies conducted in developed countries, including Australia
Applicability	Satisfactory	Results are applicable to Australian women

The studies included in the body of evidence statement are shown in the Table below.

The systematic literature review on nipple pain management methods conducted in 2003 included 12 studies comparing education, water compress, breast milk, warm compress, lanolin, aerosol spray, ointment, firm dressing, tea-bag compress, hydrogel dressing, breast shells or oral cloxacillin/erythromycin use in the treatment on nipple pain/trauma. After reviewing the literature the authors summarized the evidence for the treatment of nipple pain/trauma; water compresses reduced nipple pain (one level II study), expressed breast milk reduced duration of cracked nipples (one level II study), hydrogen dressings were associated with a high incidence of infection (one level II study), systemic antibiotics are recommended if a positive culture for Staphylococcus is obtained (one level II study), tea bags may change the smell of the nipple (one level IV study), film dressings reduced eschar and nipple pain and a low level of satisfaction were reported with film dressing (one level IV study). In conclusion there was limited evidence to identify a single intervention that would offer a significant improvement in the treatment of nipple pain/trauma however there is a potential for some intervention to reduce pain and increase comfort and thereby increase breastfeeding duration (Page, Lockwood et al. 2003).

The systematic literature review on prevention and therapies for nipple pain conducted in 2006 included 7 trials comparing water compress, breast milk, lanolin, collagenase, glycerin gel, dexpanthenol, vitamin A, tea-bag compress, glycerin gel therapy and breast shells use in the treatment of nipple pain/trauma. From the findings, the authors deduced that no one topical agent showed superior results in the relief of nipple discomfort. The authors highlight the most important factor in decreasing the incidence of nipple pain is the provision of education for proper breastfeeding technique and latch-on as well as anticipatory guidance with regard to the high incidence of early postpartum nipple pain (Morland-Schultz and Hill 2005).

Neifert's review on the clinical aspects of lactation provides further recommendation for the routine treatment of sore nipples suggesting mothers remove surface moisture after feeding and avoid excessive drying that can crack or damage the skin (Neifert 1999).

PREVENTION OF NIPPLE PAIN/TRAUMA IN LACTATING WOMEN

What interventions are recommended for the prevention of nipple pain/trauma during lactation?		
Draft Evidence statement		No single intervention provides a significant effect in terms of preventing nipple pain/trauma
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	2 Systematic reviews (overlap between studies, 15 RCTs and quasi-experimental studies in total) of high quality.
Consistency	Satisfactory	Both reviews concluded that no single pharmacological or non-pharmacological method offered a significant effect in the prevention of nipple pain/trauma in breastfeeding women.
Clinical impact	Poor	No trial provides sufficient evidence on any intervention to justify widespread uptake of that intervention.
Generalisability	Satisfactory	Majority of studies conducted in developed countries, including Australia
Applicability	Satisfactory	Results are applicable to Australian women

The studies included in the body of evidence statement are shown in the Table below

Page and colleagues reviewed studies that compared education, water compress, breast milk, warm compress, lanolin, aerosol spray, ointment, firm dressing, tea-bag compress, hydrogel dressing, breast shells or oral cloxacillin/erythromycin use in the prevention of nipple pain/trauma. Page and colleagues found warm water compresses prevented nipple pain (one level II study) and keeping nipples clean and dry prevented cracked nipples (one level II study). In conclusion there is potential for some interventions to offer beneficial effects in the prevention of nipple pain/trauma however the evidence for those interventions are limited (Page, Lockwood et al. 2003).

Morland-Schultz and Hill conducted a review on the prevention and treatment of nipple pain included 11 trials compared water compress, breast milk, lanolin, collagenase, glycerin gel, dexpanthenol, vitamin A, tea-bag compress, glycerin gel therapy and breast shells use in the treatment of nipple pain/trauma(Morland-Schultz and Hill 2005). After assessing the evidence the authors found no one method showed superior results in the prevention of nipple pain/trauma and support the finding that proper positioning and correct breastfeeding technique is the best way to prevent nipple/pain trauma.

Incidence of nipple pain/trauma
No evidence base was developed for the incidence of nipple pain/trauma due to the lack of quality studies.

In her review on lactation Neifert states that transient nipple pain attributed to suction injury of the skin usually begins on the second postpartum day, increases between 3 and 5 days, and then markedly improves. No specific treatment is usually required (Neifert 1999).

Neifert articulates that severe nipple pain and trauma that continues after the first few days post partum should not be considered a normal part of breastfeeding. Persistent nipple discomfort is usually linked to incorrect breastfeeding technique or possibly due to infant oral anatomy or feeding habits e.g. abnormal sucking. In line with this view (Tait 2000) reports that poor positioning of the infant and/or poor latch-on is believed to be the most common cause of persistent sore nipples. In addition sore nipples can be aggravated by inappropriate nipple skin care, climate variables, and unique skin sensitivity (Neifert 1999).

Academy of Breastfeeding Medicine Protocols
Nipple pain is a problem of the early period of breastfeeding. ABM Protocols 5 and 7 recognise the importance of nipple pain to the mother and the need to address this issue before discharge from hospital. The most commonly used strategy is to ensure correct attachment and if needed to express breast milk on a temporary basis
"Women need help to ensure that they are able to position and attach their babies at the breast. Those delivered by caesarean section may need additional help from nursing staff to attain comfortable positioning. A trained observer should assess and document the effectiveness of breastfeeding at least once every 8–12 hours after delivery until mother and infant are discharged. Peripartum care of the couplet should address and document infant positioning, latch, milk transfer, baby's daily weight, clinical jaundice, and all problems raised by the mother, such as nipple pain or the perception of an inadequate breast milk supply"(Academy of Breastfeeding Medicine 2008).

"Before leaving the hospital breastfeeding mothers should be able to
a. Position the baby correctly at the breast with no **PAIN** during the feeding
b. Latch the baby to breast properly
c. State when the baby is swallowing milk
d. State that the baby should be nursed a minimum of eight to 12 times a day until satiety, with some infants needing to be fed more frequently
e. State age-appropriate elimination patterns (at least six urinations per day and three to four stools per day by the fourth day of life)
f. List indications for calling a healthcare professional
g. Manually express milk from their breasts" (Philipp 2010)

Studies used to make evidence statement for nipple pain

Reference	**Vogel et al. 1999**	**Centuori et al. 1999 (included in Page et al. & Morland-Schultz & Hill below)**	**Henderson et al. 2001 (included in Page et al. & Morland-Schultz & Hill below)**	**Vogel et al. 1999**
Type of study	Cohort	RCT	RCT	Cohort
Level of evidence	II (aetiology)	II (intervention)	II (intervention)	II (aetiology)
Definition of breastfeeding	Full breastfeeding is defined as infants receiving breast milk with or without supplements of water or juice, but without formula, other milk or solids	WHO definitions for breastfeeding	Not stated	
Intervention/ comparator	reasons mothers stop breastfeeding	Ointment used for nipple pain prevention and treatment (ointment contains albumin, glycerin, paraffin oil, casein, lanolin, petroleum jelly, Zinc oxide, sodium, potassium hydrate and distilled water) vs. no treatment or preventative methods	Postpartum positioning & attachment education	Presence of sore nipples
N	350 mothers. Follow up at 1 yr was 95%	219 mothers (123 intervention group, 96 control group) Follow up at 3 mo was 89%	160 first-time mothers (80 intervention group, 80 control group). Follow up at 6 mo was 94%.	350 mothers. Follow up at 12 months was 94%
Population/study information	Sample consisted of women who delivered a normal term infant at North Shore Hospital, Auckland in 1996. Mothers were interviewed in the immediate postpartum period (usually in the first 48 h) in the maternity ward. Mothers who were discharged	Mothers delivered a healthy infant > 2500g at Istituto per l'Infanzia, a hospital in Italy. Intervention group were instructed to avoid any physical (eg massage), chemical (eg cream), mechanical (eg shield) method of nipple care. Control group used an ointment at	Mothers delivered a healthy infant at a public hospital in Adelaide between June-Sept 1999. Intervention group received structured one-to-one postpartum positioning & attachment education. Control group received usual postpartum care.	Mothers with healthy infants were recruited from an obstetric hospital in Auckland, New Zealand. Face-to-face interview at first days postpartum. Telephone interviews at 1,2,3,6,9 & 12 months postpartum

	home early were interviewed at home. Telephone interviews were conducted when the infants were 1, 2, 3, 6, 9 and 12 mo of age.	onset of nipple pain. Interview at discharge, telephone interview at 2 weeks and 3 mo postpartum	Nipple pain/trauma assessed daily in hospital and telephone interview follow up at 6 weeks, 3 mo, 6 mo postpartum.	
Quality	P	P	P	P
Results	8/242 (2%) women stopped breastfeeding by 12 months due to sore nipples. (more than one reason could have been given)	No difference was found between the intervention and control group in the incidence of sore and cracked nipples. At two weeks postpartum intervention group 73% vs. control group 76% None of the mothers who had stopped breastfeeding by 3 months had done so because of sore nipples. Early infant care practices associated with a higher incidence of nipple soreness (with the control and intervention group analysed together) were the use of a pacifier (79% vs. 65% at 2 weeks) and the use of a feeding bottle (24% vs 12% at 3mo).	Counselling on positioning and attachment and subsequent assessment of breastfeeding decreased the proportion of nipple pain in first-time mothers during the first few days in hospital. Day 2 postpartum: intervention group 39% vs. control group 62% Day 3 postpartum: intervention group 51% vs. control group 68%. No difference between groups at 6 weeks, 3 mo and 6 mo.	Sore nipples in the first month were associated with an increased risk of mastitis Adjusted OR 2.07 (1.17,3.66)
Effect on risk	Sore nipples, although commonly reported by mothers in the sample, was not a major reason for ceasing breastfeeding	None	Postpartum positioning & attachment education reduces the risk of nipple pain only in first few days postpartum.	Sore nipples have an association with the development of mastitis.
Clinical importance	1	4	1	1
Clinical relevance	1	1	1	2

Generalisability	Y	Y-Italy	Y	Y
Applicability	Y	Y-Italy	Y	Y

Reference	**Page et al. 2003**	**Blair et al. 2003**	**Eglash et al. 2006**
Type of study	SLR	Cross-sectional	cross-sectional
Level of evidence	I (aetiology)	IV (aetiology)	IV (aetiology)
Definition of breastfeeding	Varied among studies	Not Stated	Not stated
Intervention/ comparator	Nipple pain management methods (Education, water compress, breast milk, warm compress, lanolin, aerosol spray, ointment, firm dressing, tea-bag compress, hydrogel dressing, breast shells or oral cloxacillin/erythromycin vs. no method and/or another method listed above)	Presence of correct latching & positioning behaviors including: baby's face position, baby's body position, latching process (root, gape, seal, suck) & breastfeeding dynamic (change in nursing pattern and movement of mothers breast)	Treatment with antibiotics for at least 3 weeks to greater than 6 weeks. Average time was 5.7 weeks. (Antibiotics included: cephalexin 500 mg 4x/d , dicloxacillin 500 mg 4x/d, clindamycin 300 mg 4x/d, erythromycin 333 mg 3x/d, and amoxicillin/ clavulanate 875 mg 2x/d)
N		95 healthy breastfeeding mothers	69. Follow up was 93 %
Population/study information	12 out of a potential 38 studies met the inclusion criteria. Studies were categorized according to NHMRC level of evidence.	Participants sequentially reported sore nipples within ten days of giving birth at a hospital in Latvia. Recruited between May – November 2000 All women were exclusively breastfeeding	Participants seen by a physician lactation specialist from 1997-2002, had been diagnosed with sore nipples, mastitis, and/or breast pain lasting for > 1 week and were treated with antibiotics for pain were recruited for the study. Study conducted in Wisconsin
Quality	P	N	0 (No to Q 2.4, 5.3, 7.6)

Results	Warm water compresses prevented nipple pain (one level II study) Keeping nipples clean and dry prevented cracked nipples(one level II study) Water compresses reduced nipple pain (one level II study) Expressed breast milk reduced duration of cracked nipples (one level II study) Hydrogen dressings were associated with a high incidence of infection (one level II study) Systemic antibiotics are recommended if a positive culture for Staphylococcus is obtained. (one level II study) Tea bags may change the smell of the nipple (one level IV study) Film dressings reduced eschar and nipple pain. Low level of satisfaction were reported with film dressing (one level IV study)	57% of infants face at breast was too high 48 % of mother's breast remained stationary during breastfeeding 33% of infant's had head only turned to breast 17% of infant's nose and chin faced away when breastfeeding (17%) 26% of infants breastfed on an angle	The median time that pain of breast/nipples started was at 1 week postpartum. 60% of all patients weaned because of the pain syndrome. 94% of patients studied had pain resolution with the prescribed antibiotics.
Effect on risk	No single intervention offers a significant effect in terms of treating pain/trauma in breastfeeding women.	Indicates pain is related to positioning errors. No one group of attributes was more related to the pain experienced by the mother than another.	Symptoms of deep breast aching, breast tenderness on palpation, and nipple lesions may be suggestive of a bacterial lactiferous duct infection. Treatment with antibiotics for 4 to 6 weeks may be appropriate.
Clinical	1	1	4

importance			
Clinical relevance	1	1	1
Generalisability	Y	Y - Latvia	Y - US
Applicability	Y	Y – Latvia	Y - US

Reference	**Morland-Schultz & Hill 2006**	**Morland-Schultz & Hill 2006**	**McClellan et al. 2008**
Type of study	SLR	SLR	case-control
Level of evidence	I (aetiology)	I (aetiology)	III- 3 (aetiology)
Definition of breastfeeding	Not Stated	Not stated	Not stated. Recruited mothers who 'mainly breastfeeding'. Mainly breastfed defined as >50 % breast milk
Intervention/ comparator	Nipple pain treatment methods (Water compress, breast milk, lanolin, collagenase, glycerin gel, dexpanthenol, vitamin A, tea-bag compress, glycerin gel therapy or breast shells vs. no treatment and/or another treatment listed above)	Nipple pain preventative methods (Education, breast milk, colostrum, warm water compress, clean and dry, lanolin, gentle massage, ointment, chlorhexidine/alcohol spray, tea-bag compress, hydrogel dressing or polyethylene film dressing vs. no method and/or another method listed above)	Mothers with persistent nipple pain from breastfeeding compared to successfully breastfeeding mothers.
N			60 Mothers (30 experiencing persistent pain during breastfeeding, 30 successfully breastfeeding)
Population/study information	7 studies published between 1983-2004 (3 of studies overlap with Page et al. SLR) only 1/7 had sample sizes greater than 100	11 studies published between 1983-2004. only 6/11 had sample sizes greater than 100	Mothers in control group recruited from WA branch of ABA and child health nurses during routine examinations. Mean age 32.3 ± 4.5 years. Infants mean age 55.0 ± 22.7 days. Pain group were recruited via International Board-Certified Lactation Consultants (IBCLC). Mean age 31.8 ± 5.1 years Infants mean age

			49.4 ± 35.5 days
Quality	P	P	0 (7 was a no)
Results	Routine Care Versus Heat Versus Vitamin A Versus Anhydrous Lanolin. Combination of heat, positioning, & anhydrous, lanolin provided greatest relief of nipple pain in shortest time period. (1 Quasi-experimental trial) Water Versus Tea Bags. Were equally effective and more effective compared to no treatment. (1 RCT) USP Lanolin or Lipton Tea Bags Versus Nothing. No significant difference (1 Quasi-experimental trial) Hydrogel Dressing & Mother's Milk Versus Lanolin Cream, Breast Shells, & Mother's Milk. No significant difference between groups. Higher rate of infection in dressing vs control group. (1 RCT) Collagenase Versus Dexpanthenol Versus Warm Water & Soap In first days of trial group using water & soap had significantly more pain. By week 1 of trial, pain had subsided in all groups. (1 RCT)	Expressed Mother's Milk/Colostrum Versus Hydrous Lanolin. No significant difference in nipple pain (1 RCT) Expressed Mother's Milk Versus Warm Wet Compresses Versus Clean & Dry. Pain scores similar over time for 3 groups; wet compresses or EMM less effective in preventing cracked nipples (1 RCT) Ointment Versus Clean & Dry- No significant difference (1 RCT see Centuori et al. 1999 adjacent) Water Versus Tea Bags. No difference in effect. (1 RCT) Hydrogel Dressing Versus Modified Lanolin Ointment. Mean pain scores significantly declined for mothers who used the hydrogel dressing compared to mothers using lanolin ointment. (1 RCT) Modified Lanolin Versus Gentle Massage. Difference not statistically significant (1 experimental trial) Modified Lanolin Versus Mother's Milk	Infants of breastfeeding mothers experiencing persistent nipple pain applied significantly higher vacuum to the breast during breastfeeding despite assistance with positioning and attachment from a lactation consultant. Infants in the pain group mean vacuum: −152.2 ± 43.8 mmHg Infants in the control group mean vacuum: −97.2 ± 37.0 mmHg ($p = 0.001$) Milk intake from one breastfeed for the Pain group was 42% lower than that of the Control group despite similar sucking duration.

	Breast Shells & Lanolin Versus Glycerin Gel Therapy. Greater relief of nipple pain in glycerin gel therapy group (1 RCT) Breast Shells Versus No Treatment. No significant difference in either group. (1 Quasi-experimental trial)	Versus Warm Water Compresses Versus Education. No difference (1RCT) Chlorhexidine/Alcohol Spray Versus Distilled Water. Nipple pain & trauma reduced significantly in intervention group (Chlorhexidine/Alcohol Spray) 1 RCT Postpartum Positioning and Attachment Education Versus Usual Care. See Henderson et al. 2001 Antenatal Teaching Session on Position and Attachment of the Infant to the Breast Versus Standard Antenatal Education. Intervention group had lower pain scores (1 RCT) Polyethylene Film Dressing Versus No Treatment. polyethylene film dressing reduced nipple pain and eschar development compared to no treatment. High attrition rate due to discomfort of removing dressing.	
Effect on risk	No one topical agent showed superior results in the relief of nipple discomfort. The most important factor in decreasing the incidence of nipple pain is the provision of education in relation to proper breastfeeding technique and latch-on as well as anticipatory guidance with regard to the high incidence of early	No one topical agent showed superior results in the relief of nipple discomfort. The most important factor in decreasing the incidence of nipple pain is the provision of education in relation to proper breastfeeding technique	Positive Mothers of infant's with strong intraoral vacuums are at increased risk of nipple pain

	postpartum nipple pain.	and latch-on as well as anticipatory guidance with regard to the high incidence of early postpartum nipple pain.	
Clinical importance	1	1	4
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

References used in the body of evidence table: (Centuori, Burmaz et al. 1999; Vogel, Hutchison et al. 1999; Vogel, Hutchison et al. 1999; Henderson, Stamp et al. 2001; Blair, Cadwell et al. 2003; Page, Lockwood et al. 2003; Morland-Schultz and Hill 2005; Eglash, Plane et al. 2006; McClellan, Geddes et al. 2008)

Nipple Variationns

Search results
The initial search of the databases included 32 references on nipple variations including flat, inverted or non-protractile nipples. Data were extracted from 7 references, and 3 studies were used to form a body of evidence statement about the prevalence of nipple variation in lactating women. The evidence was not strong enough to develop a body of evidence statement for the effect of nipple variation on breastfeeding outcomes.

PREVALENCE OF NIPPLE VARIATIONS

What is the prevalence of nipple variation (at least one flat, inverted or non-protractile nipple) in lactating women?		
Draft Evidence statement		Approximately 8-10% of lactating women have at least one flat, inverted or non-protractile nipple
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Poor	3 studies; 2 cohort, 1 cross-sectional (1P, 20)
Consistency	Satisfactory	The cross-sectional study reported a prevalence 9.8%, both cohorts found the prevalence to be 8%
Clinical impact	Poor	Nipple variation is a common problem experienced by breastfeeding women
Generalisability	Satisfactory	1 study conducted in New Zealand, 1 study conducted in the UK, 1 study conducted in the UK
Applicability	Satisfactory	Results are applicable to Australian women

The studies included in the body of evidence statement are shown in the Table below

The cross-sectional study conducted on 3006 women in the UK found 9.8% (8.8, 10.9) of women were found to have at least one inverted or non-protractile nipple. The study involved trained observers conducting a 'pinch test' on each subject to determine the presence of inverted or non-protractile nipples (Alexander and Campbell 1997).

A cohort study conducted on 350 mothers in New Zealand found 8% of mothers had inverted nipples. The study does not detail how the prevalence of inverted nipples was determined. So it is assumed the researchers used mother's reports (Vogel, Hutchison et al. 1999)

In a cohort of 280 mother-infant pairs in California 8% of mothers were diagnosed as having a flat or inverted nipple. The diagnosis was made by a lactation consultant (Dewey, Nommsen-Rivers et al. 2003).

Effect of Nipple Variation on Breastfeeding Outcomes
No evidence base was developed for the effect of nipple variation on breastfeeding outcomes due to the lack of quality studies.

(Vogel, Hutchison et al. 1999) cohort revealed that inverted nipples were associated with a shorter duration of breastfeeding; multivariate RR 2.02 (1.26, 3.23). The cohort study conducted by (Dewey, Nommsen-Rivers et al. 2003) found a significant association between flat or inverted nipples and suboptimal infant breastfeeding behaviour (according to the IBFAT tool) on day 7 postpartum RR=6.57 (3.16-8.88). Flat or inverted nipples were also associated with delayed onset of lactation on day 0 RR = 2.26 (1.08-3.56).

A cohort study in Iran aimed to determine the association between presence of maternal breast variation (such as flat nipple, inverted nipple, large breast or/and large nipple) and infants weight gain in the first 7 days postpartum. The researchers found that the mean weight of neonates born to mothers without breast variations (53 ± 154.4 g) was significantly larger than the mean difference of neonates' weight in the control group (-162 ± 125.5 g). In response to their finding the authors concluded breast variation in first-time mothers acts as an important barrier to weight gain among breastfed neonates in the early days of life (Vazirinejad, Darakhshan et al. 2009).

Studies used to make evidence statement for nipple variation

Reference	**Alexander et al. 1992**	**Alexander & Campbell 1997**	**Vogel et al. 1999**
Type of study	RCT	Cross-sectional	Cohort
Level of evidence	II (intervention)	IV (aetiology)	II (aetiology)
Definition of breastfeeding	Not stated	Not stated	Full breastfeeding is defined as infants receiving breast milk with or without supplements of water or juice, but without formula, other milk or solids
Intervention/ comparator	Breast shells vs. Hoffman's exercises vs breast shells and Hoffman's exercises vs. no treatment	Prevalence of inverted or non-protractile nipples	Presence of inverted nipples
N	96 women. Follow up at 6 weeks was 100% Randomly allocated to 4 treatment groups Breast shells= 24 Hoffman's exercises= 24 Shells & exercises= 24 Control= 24	3006 women	350 mothers. Follow up at 1 yr was 95%
Population/study information	Women were recruited at 25- 35 weeks in a singleton pregnancy with at least one inverted or non-protractile nipple. Recruitment occurred in Southampton over 23 months in 1987-9. Completed two written questions; first	Sample consisted of women intending to breastfeed who were examined in antenatal clinics in Hants, UK between 1987-9. Trained observers conducted a 'pinch test' on each subject	Sample consisted of women who delivered a normal term infant at North Shore Hospital, Auckland in 1996. Mothers were interviewed in the immediate postpartum period (usually in the first 48 h) in the maternity ward. Mothers who were discharged home early

	after entry to trial, second at 6 weeks		were interviewed at home. Telephone interviews were conducted when the infants were 1, 2, 3, 6, 9 and 12 mo of age.
Quality	0 (No to 3 & 7)	0 (No to 2.3, 5.3)	0
Results	Sustained improvement in nipple anatomy was more common in the untreated groups but the differences were not significant. % difference in sustained improvement in nipple anatomy: shells v no shells -8% (-28, 11) exercises v no exercises -4% (-24, 16) 17/128 women (13%) approached to join the trial decided before delivery that they would bottle feed because they had inverted or non-protractile nipples.	9.8% (8.8, 10.9) of women were found to have at least one inverted or non-protractile nipple. Increasing gestation decreased prevalence of poor nipple anatomy. OR decreases by 3% for each increasing week of gestation. OR 0.969 (0.955-0.983). Increasing parity did not reduce prevalence of poor nipple anatomy. para vs nulliparous women. OR 0.483 (0.366,0.638). Increasing maternal age decreased prevalence of poor nipple anatomy. OR decreases by 6% for each increasing year. OR 0.943 (0.921,0.967)	27 (8%) women had inverted nipples. Inverted nipples were associated with a shorter duration of breastfeeding (study did not clarify length of breastfeeding) Multivariate RR 2.02 (1.26, 3.23)
Effect on risk	Breast shells and Hoffman's exercises do not significantly improve nipple anatomy.	N/A	Inverted nipples were associated with shorter duration of breastfeeding
Clinical importance	4	1	1
Clinical relevance	1	1	1
Generalisability	N sample size small, study groups not comparable	Y	Y
Applicability	Y	Y	Y

Reference	**Dewey et al. 2003**	**Chiummariello et al. 2008**	**Vazirinejad et al. 2009**
Type of study	Prospective cohort	Cross-sectional	Prospective cohort
Level of evidence	II (aetiology)	IV (aetiology)	II (aetiology)
Definition of breastfeeding	Not stated	Not stated	Not stated
Intervention/ comparator	Presence of flat or inverted nipples	Reduction mammoplasty. (superior vs. inferior vs. medial vs. lateral pedicle breast reduction)	Presence of maternal breast variation (such as flat nipple, inverted nipple, large breast or/and large nipple)
N	280 mother-infant pairs. Follow up at day 3 was 96%	105 mothers Group A (superior pedicle breast reduction) = 28 Group B (inferior pedicle breast reduction) = 23 Group C (medial pedicle breast reduction) = 25 Group D (lateral pedicle breast reduction) = 29	100 mother-neonate dyads. Follow up at day 7 was 100%
Population/study information	Sample consisted of mothers who lived in California, and gave birth to a healthy, single, term infant at 1 of 5 area hospitals during the 10-month recruitment period in 1999 and intended to exclusively breastfeed for at least 1 month. Data were collected in the hospital (day 0) and on days 3, 5,	Sample consisted of 368 women who underwent reduction mammoplasty surgery at the department of plastic surgery at the ‘‘La Sapienza’’ University of Rome between 1992-2001. 105 of these women had a child 3 years post surgery and met the inclusion criteria for the study. Women were divided into 4 groups according to the	100 first-time mothers were recruited in the last few days of their pregnancy. They were referred to a Maternity Hospital in Iran, between Feb- June 2006. Group A= 50 mothers with specified breast variations Group B: 50 mothers without such variations

	7, and 14 through home visits % 9 mothers had flat or inverted nipples	surgical technique adopted Data collected from reviewing patient charts and via a telephone interview	 Mothers exclusively breastfed during study period Neonates born full term, > 2500 g Neonates weight was measured after the birth and on day seventh.
Quality	P	0 (no to 2.3, 3.2)	P
Results	Suboptimal infant breastfeeding behaviour (according to the IBFAT tool) on day 7 was significantly associated with flat or inverted nipples. RR=6.57 (3.16-8.88) Delayed onset of lactation on day 0 was associated with flat or inverted nipples. RR = 2.26 (1.08-3.56)	If breastfeeding lasted more than 3 weeks and was not accompanied by any nutritional supplements it was deemed successful Group A = 60.7% successfully breastfed Group B= 43.5% successfully breastfed Group C= 48 % successfully breastfed Group D= 55.1% successfully breastfed	The mean difference in neonates' weight between birth and day seven, among neonates who were born to mothers without breast variations (53 ± 154.4 g) was significantly larger than the mean difference of neonates' weight in the control group (-162 ± 125.5 g)
Effect on risk	Flat or inverted nipples increase the risk of suboptimal infant breastfeeding behaviour	None Reduction mammoplasty techniques supported by medical and paramedical staff permit subsequent breastfeeding	Negative. Breast variation in first-time mothers acts as an important barrier to weight gain among breastfed neonates in the early days of life
Clinical importance	1	4	1
Clinical relevance	1	1	1
Generalisability	Y	Y	N study conducted in Iran
Applicability	Y	Y	Y

References used in the body of evidence table: (Alexander, Grant et al. 1992; Alexander and Campbell 1997; Vogel, Hutchison et al. 1999; Dewey, Nommsen-Rivers et al. 2003; Chiummariello, Cigna et al. 2008; Vazirinejad, Darakhshan et al. 2009)

Nipple Shield Use

Search results
The initial search of the databases included 34 references on nipple shields use during breastfeeding. The detailed search is included in a separate document on searches. Data were extracted from one high quality systematic literature review which was used to form a body of evidence statement on the effects of nipple shield use on breastfeeding outcomes.

EFFECT OF NIPPLE SHIELD USE ON BREASTFEEDING OUTCOMES

What is the physiological response to nipple shield use?		
Draft Evidence statement		Nipple shield use is associated with a decrease in milk transfer however more research investigating this association is required
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Poor	1 SLR (P) on 13 studies (3 studies investigated the physiological response to nipple shield use). All three studies had small sample sizes.
Consistency	Satisfactory	All three studies demonstrated nipple shield use was associated with a decrease in milk transfer
Clinical impact	Poor	Larger studies are required to evaluate the effect of nipple shield use on breastfeeding duration
Generalisability	Satisfactory	SLR conducted in US. Country where each study was conducted is poorly defined.
Applicability	Satisfactory	Results are applicable to Australian women

The systematic literature review conducted in 2010 searched the database for articles published between 1980 and 2009 on the use of nipple shields during breastfeeding (McKechnie and Eglash 2010). The authors investigated 13 articles for detailed review. No high-quality studies have been conducted on nipple shield use since this review.

The review included 3 studies on physiological responses to nipple shield use. All three studies demonstrated nipple shield use was associated with a decrease in milk transfer however the studies had small sample sizes. One well-designed study compared a group of mother's breastfeeding without a nipple shield (n=16) with a group of mothers' breastfeeding with a nipple shield (n=16). The median milk transfer to infants in the group without a nipple shield was 47 g compared to the group with a nipple shield with a transfer of 27 g. Results for another study revealed that the ''Mexican hat'' nipple shield severely impaired milk transfer with a mean volume of 19.5 g compared to a mean volume of 46.4 g in the group without a nipple shield. The thin latex shield also reduced milk transfer to a mean of 29.9 g, but it was not significantly different than milk transfer of 38.4 g in the group not using nipple shield. This nonrandomized study was limited by its small sample size. The third study found subjects expressed significantly more breast milk during pumping sessions with no nipple shield in place compared to pumping with a nipple shield. (McKechnie and Eglash 2010) note that lactating women generally do not use a breast pump with a nipple shield in place therefore findings from this study cannot be generalised to all areas of clinical practice. (McKechnie and Eglash 2010 concluded that larger studies are required to evaluate the effect of nipple shields on maternal hormonal patterns, infant suckling response as well as long-term outcomes such as milk supply, infant weight gain, and duration of lactation.

Eight studies were extracted to assess mother's experiences using a nipple shield. The studies indicated that mothers had positive experiences using a nipple shield, with the majority of mothers maintaining breastfeeding after discontinuing nipple shield use. The authors note that the studies had small sample sizes, limited follow-up time, and poor statistical measures therefore precaution should be taken when interpreting their results.

Nipple shields are commonly used as an intervention for flat/ inverted nipples but the author's did not find a positive association between nipple shield use in this population and breastfeeding duration.

In summary the authors remark that attempts to achieve successful breastfeeding should be made prior to the introduction of a nipple shield. Health professions should follow mothers using a nipple shield to aid them transition away from nipple shield use, monitor breastfeeding outcomes and screen for problems that may occur with their use such as poor milk supply(McKechnie and Eglash 2010).

Other Nipple Problems

Eczema and Dermatitis of the Nipple

Search results

The initial search of the databases included 5 references on eczema or dermatitis of the nipple. The detailed search is included in a separate document on searches. Data were extracted from 3 references. Evidence was found on the management of eczema and dermatitis of the nipple (3 narrative reviews) but the evidence was insufficient to develop a body of evidence statement.

Management of eczema and dermatitis of the nipple

No evidence base was developed for the management of eczema and dermatitis of the nipple due to the lack of experimental studies.
In the narrative review by (Barankin and Gross 2004) it is advised that precipitating allergens and irritants are eliminated and topical corticosteroid preparations are applied appropriately. To prevent infant exposure to topical steroids, the authors stress that topical corticosteroids be applied to the affected areas after the infant has fed and the breast should be thoroughly cleaned before a feed. Ointments are preferable to creams as they are more easily absorbed.(Barankin and Gross 2004) state that moderately potent topical steroids are effective but should be reserved for severe or recalcitrant cases and should be used for no longer than 3–5 days at a time. (Tait 2000) recommends applying a small amount of steroid ointment 4 times a day after feeds to diminish symptoms of eczema/dermatitis of the nipple in within 10–17 days . Similarly (Tait 2000) advises the use of ointments rather than cream to ensure the safety of the infant. In addition (Whitaker-Worth, Carlone et al. 2000) suggest lactating women with nipple eczema air-dry nipples immediately after feeding, and avoid soap and shampoos in the affected area.

Nipple Piercing

Search results

The initial search of the databases included 9 references on nipple piercings and breastfeeding. Data were extracted from 4 references (2 narrative reviews, 1 case-series, 1 commentary) but the evidence was insufficient to develop a body of evidence statement.

Notes on nipple piercings during breastfeeding

Armstrong and colleagues conducted a review on pregnancy, lactation and nipple piercing reported possible complications related to nipple piercings and lactation including; aspiration of jewellery parts by an infant, the jewellery impairing infants suck, metal nipple jewellery causing trauma to the infant's lips, palate, tongue and gums, milk being ejected from the tract created by removing the piercing, scar tissue constricting milk ducts and interfering with milk flow. Armstrong and colleagues cited case-report of poor quality and did not have sufficient evidence to estimate the risk ratio of such adverse events occurring when breastfeeding with a nipple piercing (Armstrong, Caliendo et al. 2006).

Martin's commentary in the Journal of Human Lactation warns of similar potentially hazardous events occurring when breastfeeding with a nipple piercing including; loss of sensation to the nipple, inadequate milk transfer, poor latch, plugged ducts, mastitis, and poor weight gain in the infant (Martin 2004). To overcome this barrier to breastfeeding Martin suggests mothers use a temporary piece of jewellery called a retainer (smooth plastic tube that can be removed and reinserted easily) (Martin 2004). Retainer can be used as a way of facilitating breastfeeding and retaining or preventing the closure of a piercing.

Raynaud's Phenomenon of the Nipple

Search terms

The initial search of the databases included 12 references on Raynaud's phenomenon of the nipple. The detailed search is included in a separate document on searches. Data were extracted from three studies (3 case-series) but the evidence was insuffiecient to develop a body of evidence statement. The information gathered from the three case series have been summarised below.

Notes on Raynaud's phenomenon of the nipple

The case-series by Anderson and colleagues reported 12 cases of Raynaud's phenomenon of the nipple in breastfeeding women (Anderson, Held et al. 2004). Symptoms common to all 12 cases included extreme nipple pain, blanching of the nipple with breastfeeding followed by redness or bluish coloration accompanied by intense throbbing pain, and precipitation of symptoms with environmental cold temperature.

The literature on Raynaud's phenomenon of the nipple indicates that the condition can occur during, following, or in between feedings and the mother does not have to have a history of Raynaud's phenomenon in other parts of the body. The pain caused by Raynaud's phenomenon of the nipple can mimic *Candida albicans* infection therefore it is often misdiagnosed and inappropriately treated (Morino and Winn 2007; Walker 2008). Anderson and colleagues advise health professionals to consider Raynaud's Phenomenon of the nipple as a possibility in breastfeeding women who present with severe breast and nipple pain (Anderson, Held et al. 2004).

The first-line management of Raynaud's phenomenon of the nipples is provision of warmth to the breasts and entire body. Mothers should also avoid vasoconstrictors such as caffeine and nicotine. If symptoms do not improve nifedipine (a calcium channel blocker with vasodilating effects) may be have beneficial effects (Walker 2008).

'Too little milk' Milk Insufficiency

Search results

The initial search of the databases included 202 references on breast milk insufficiency. Data were extracted from 13 references, and 8 publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the prevalence of perceived breast milk insufficiency. Additional evidence was found on the management of breast milk insufficiency (3 narrative reviews) and risk factors for breast milk insufficiency (1 narrative review, 1 cross-sectional), but the evidence was insufficient to develop a body of evidence statement.

Prevalence of perceived breast milk insufficiency in lactating mothers

How does a mother's perceived breast milk insufficiency affect breastfeeding level and duration?

Draft Evidence Statement		Approximately 25-35% of lactating women reduce breastfeeding duration or level due to perceived breast milk insufficiency
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Poor	4 studies [1 SLR, 3 cross-sectional (3P,10)]
Consistency	Satisfactory	Percentage of mothers who reduced breastfeeding duration or level as a result of perceived breast milk insufficiency ranged from 23.4% - 35%. SLR reported a mean of 35%
Clinical impact	Prevalence only	Perceived milk insufficiency is a common concern among breastfeeding women
Generalisability	Satisfactory	Majority of studies conducted in developed countries
Applicability	Satisfactory	Results are applicable to Australian women

(Hill and Aldag 1991; Lee, Lui et al. 2006; Gatti 2008; Hurley, Black et al. 2008).
The studies used to make the body of evidence statement are shown in the Table below

The studies listed come from a variety of cultures and health systems. They show that 'perceived milk insufficiency' is a widespread concern of mothers from all cultures. An alternate explanation is that 'milk insufficiency' is a socially acceptable reason for ceasing breastfeeding. The studies included in the body of evidence statement are shown in the Table.

Management of breast milk insufficiency
A narrative review on the clinical aspects of lactation recommends women with perceived milk insufficiency regularly express any residual milk after a feed to establish and maintain a regular supply (Neifert 1999).
A narrative review on assessing slow growth in breastfed infants suggests 'switch nursing', supplementer tube at the breast and medications to assist lactation as possible methods of managing low milk production (Powers 2001).

Amir's review on managing breastfeeding supply difficulties provides practical suggestions to increase milk supply; improve positioning and attachment, if appropriate increase number and/or duration of feeds, offer both breasts at each feed, express after feed, use a supplemental feeding line instead of a bottle (Amir 2006).

Risk factors for low milk production
Amir's systematic literature review on maternal smoking and breastfeeding examined 16 studies on the effects of smoking on lactation. Amir hypothesized that nicotine in cigarettes may lower prolactin levels which could lead to a decrease in milk supply but did not find sufficient evidence for a physiological mechanism. No studies found maternal smoking was associated with poor infant weight gain. Two studies found that milk volume of smokers was significantly less than non-smokers however studies had a small sample size (n=20, n=41) (Amir 2001).

A cross-sectional study of 384 women comparing mothers who report an inadequate supply of breast milk to mothers who report an adequate supply of breast milk found that perceived insufficient milk supply may reflect a lack of breastfeeding confidence (Hill and Aldag 1991).

Studies used to make evidence statement for milk insufficiency

Reference	**Hill & Aldag 1991**	**Dykes & Williams 1999**	**Amir 2001**
Type of study	cross-sectional	Cohort	SLR
Level of evidence	IV (aetiology)	II (aetiology)	I (aetiology)
Definition of breastfeeding	Poorly defined	Poorly defined	Poorly defined
Intervention/ comparator	Mothers who report an inadequate supply of breast milk vs. mothers who report an adequate supply of breast milk.		Maternal smoking
N	384 mothers	10 women	
Population/study information	A survey was conducted at two private paediatrician offices and 17 WIC agencies. Of sample 190 mothers participated in WIC programs and 194 mothers did not participate in WIC	Women were recruited prior to discharge from a maternity unit, in the north of England, in 1998. Sample comprised of primiparous women who planned to exclusively breastfeed for a minimum of three months. In-depth, interactive telephone interviews were conducted at 6,12 and18 weeks following the birth	Searched all studies on smoking and breastfeeding or infant feeding. Most studies were conducted on small samples of animals or humans; the majority were prior to 1985. Found 16 studies on effects of maternal smoking on lactation
Quality	P	N	P
Results	Of sample 26% (n=100) reported they did not have enough breast milk to satisfy their infant while breastfeeding during first 8 weeks postpartum. Factor analysis suggested that Potential Determinant	Most women expressed their inexperience in the early weeks and a need for more supervision and confidence building from midwives. Infant's behaviour	Several studies report that smokers are more likely to perceive that they have low milk supply however, none of these studies documented poor infant weight gain Two human studies with small sample

	factors (Maternal Confidence, Paternal Support, Maternal Health, Mother-in-Law Disapproval, and Infant Birth weight) accounted for 56.7% of the variance while Potential Indicator factors (Baby Behaviour, Solid Foods, and Formula) accounted for 70.4% of the variance. Maternal Confidence, attitudes and knowledge about breastfeeding was a distinguishing factor between IMS mothers and non-IMS mothers. IMS mothers were less informed about breastfeeding, had more of a problem with privacy while feeding, made their decision to breastfeed later in their pregnancy, intended not to breastfeed as long, believed breastfeeding not to be better than other types of infant feeding, and were less confident during pregnancy about breastfeeding their infant. Overall variance for these factors was 21.4%	caused some mothers to doubt their ability to produce sufficient milk, in particular frequent crying and/or feeding. The unsuccessful breastfeeders (completely stopped breastfeeding before 14 weeks) all carried out at least one practice, during the first six weeks, known to be potentially detrimental to milk production including restricting the duration and/or frequency of breastfeeds, use of nipple shields and introduction of water, formula or dummies.	sizes found that milk volume of smokers was significantly less than non-smokers; Vio et al. 1991 (n=20) Non-smokers 961 g/day, Smokers 693 g/day, ($p < 0.0001$_ Hopkinson et al. 1992 (n=41) Non-smokers expressed 639 ± 344 ml/day, smokers 358 ± 292 ($p = 0.02$)
Effect on risk	Perceived insufficient milk supply may reflect a lack of breastfeeding confidence. Insufficient milk supply syndrome may be characterized by a group of symptoms: decreased infant weight gain, decreased infant	There is a complex and synergistic relationship between socio-cultural influences, feeding management and behaviour, lactation physiology and the woman's psychological state, in relation to perceptions of milk adequacy.	Hypothesized that nicotine in cigarettes lower prolactin levels which may lead to a decrease in milk supply. Evidence for a physiological mechanism is not strong.

	satisfaction, and complementation rather than supplementation with formula.	Difficult to determine whether insufficient breast milk is the result of a mother's lack of confidence to nourish her baby or a physiological milk inadequacy created by incorrect feeding practice Women need to be informed about the supply and demand nature of milk production and how to carry out, with confidence, physiologically-sound feeding practices.	
Clinical importance	1	4	1
Clinical relevance	1	1	1
Generalisability	Y- US	Y – UK	Y
Applicability	Y- US	Y – UK	Y

Reference	**Blyth et al. 2002 (included in Gatti's SLR)**	**Kirkland & Fein 2003 (included in Gatti's SLR)**	**Lee et al 2006**
Type of study	cross-sectional	Cohort	cross-sectional
Level of evidence	IV (aetiology)	II (aetiology)	IV (aetiology)
Definition of breastfeeding	Breastfeeding was defined as receiving any breast milk within the past 24 hours. Breastfeeding was further classified into one of six categories; EBF (breast milk only); almost EBF (breast milk and other fluids but not formula, e.g., vitamins); high breastfeeding (less than 1 bottle of formula per day); partial breastfeeding (at least 1 bottle of formula per day); token breastfeeding (breast given to comfort baby not for nutrition); and bottle-feeding	Poorly defined	Partial breastfeeding defined as less than 70% of nourishment was provided by breast milk.

	(no breast milk at all).		
Intervention/ comparator	perceived breast milk insufficiency	perceived breast milk insufficiency	perceived breast milk insufficiency
N	300 women. 348 were approached, 90.6% participation rate	758 mothers included in study. 2615 women approached (69% response rate). This study used data from 758 of 1803 women who responded.	7,289 healthy infants. 14,366 approached, 50% response rate.
Population/study information	Subjects were recruited from the antenatal clinic of a large metropolitan hospital in Brisbane in their last trimester of pregnancy in 2001. Telephone interviews were conducted at 1week and 4 months postpartum to assess infant feeding methods and breastfeeding confidence using the Breastfeeding Self-Efficacy Scale.	The sample is from the Food and Drug Administration's Infant Feeding Practices Study (IFPS) in 1993. Questionnaires were administered during late gestation and postnatally during months 1 to 7, 9, and 12. This study data from the 8 questionnaires administered beginning at month 2	Subjects were recruited from 46 Maternal and Child Health Clinics in Hong Kong in a 2 week period in 1993. 3161 of sample were < 6 months.
Quality	P	P	0 (No to 2.1, 7.4)
Results	Insufficient milk supply was cited as the reason for change in infant feeding method at 1 Week postpartum (8%) and 4 Months postpartum (24.9%)	Percentage of mother's who thought they were not producing enough milk and gave this as a reason for stopping breastfeeding At 1-2 months 37% At 3-5 months 42% At 6-12 months 20% Percentage of mother's who thought their breast milk did not satisfy the infant and gave this as a reason for stopping breastfeeding At 1-2 months 58% , At 3-5 months 56% At 6-12 months 39%	31.7% of sample cited perceived inadequate milk as a major concern upon breastfeeding. This concern was similar in mothers of 1 month old infants (35.8%) and 4 month old infants (30.8%). Within the breastfed group supplemental infant formula was given to 55% of infants as a meal replacement between 101-130 days post partum.

Effect on risk	Maternal perceptions of insufficient milk supply decreases the duration and level of breastfeeding. Authors conclude further research to determine the extent to which the aetiology is physiological or psychological in nature is required.	When the mother does not have confidence that she is providing an adequate amount of milk for her infant, she is likely to stop breastfeeding, and this concern does not disappear as the infant gets older.	Findings suggest supplemental infant formula feeds increase a mother's perception of insufficient milk supply.
Clinical importance	1	1	4
Clinical relevance	1	1	1
Generalisability	Y	Y- US	Y- Hong Kong
Applicability	Y	Y- US	Y Hong Kong

Reference	**Hurley et al. 2008**	**Gatti 2008**	**Xu et al. 2009**
Type of study	Cross-sectional	SLR	SLR
Level of evidence	IV (aetiology)	I (aetiology)	I (aetiology)
Definition of breastfeeding	EBF= breast milk without additional food or drink, including water.	Poorly defined	EBF: no other food or liquid, with the exception of drops or syrups consisting of vitamins, mineral supplements or medicine FBF: Breastfed and receiving small amounts of culturally valued supplements – water, water-based drinks, fruit juice or ritualistic fluids; Partial BF: mixed feeding with breast milk and other sources of energy and nutrients Any BF: Breast milk with or without other drink, formula or other infant food
Intervention/ comparator	Mother's perceived breast milk insufficiency	Perceived breast milk insufficiency	Chinese mother's perceived breast milk insufficiency

N	767 women completed study. (Approached 1580, recruited 799)	>36, 700	
Population/study information	Conducted telephone surveys in a low-income sample in the USA in 2004. Sample included 365 white, 285 African American and 117 Hispanic mothers who received the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).	20 articles on perceived insufficient milk (PIM) were eligible for the review. Searched articles between 1996-2007 in the English language	Searched studies on breastfeeding in the mainland provinces and autonomous regions of the Peoples Republic of China between 1990 to 2009. Chinese and English language studies were included.
Quality	P	P	P
Results	The most common reason reported for breastfeeding cessation was not having enough milk (23.4%). Median time to breastfeeding cessation was 4 months. Hispanic mothers were more likely than African American and white mothers to cite perceptions of milk insufficiency as there reason for breastfeeding cessation; Hispanic 41.3%, African American 19.5%, White 18.4%.	35% of women who wean early (<4weeks) report PIM as the main reason Women utilize infant satisfaction cues as their main indication of milk supply. Verification of actual milk supply is rarely conducted by clinicians. When added to a regression model sodium levels were no longer significantly predictive of breastfeeding level at 4 weeks. Few studies analyzed the relationship between variables such as age, parity, employment, education, prenatal intentions impact and PIM.	Perceived breast milk insufficiency was the most common reason for discontinuing 'exclusive breastfeeding' or 'any breastfeeding' in China In Xi'an, 'insufficient milk' was the first reason (81%) for terminating breastfeeding. A survey in Hubei province and a study conducted in Kumming showed that in mothers who gave their babies complementary food before four months, 51.7% and 66 % of them respectively, thought their breast milk supply was insufficient.
Effect on risk	Perceived breast milk insufficiency increases the risk of mothers ceasing breastfeeding. Mother's perceptions of milk insufficiency varies be race/ethnicity. Findings also suggest a need for culturally	PIM decreases exclusivity and duration of breastfeeding. More research required to determine who is at risk of PIM.	Perceived breast milk insufficiency increases the risk of mother's ceasing breastfeeding or 'exclusive breastfeeding' before four months.

	appropriate breastfeeding interventions.	Authors recommend practitioners understand the subjective nature and questionable accuracy of PIM and conduct assessments of milk supply (eg by test-weighing)	
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y- US	Y	Y- Chinese mothers only
Applicability	Y –US	Y	Y – China

References used in body of evidence table: (Hill and Aldag 1991; Dykes and Williams 1999; Amir 2001; Blyth, Creedy et al. 2002; Kirkland and Fein 2003; Lee, Lui et al. 2006; Gatti 2008; Hurley, Black et al. 2008; Xu, Qiu et al. 2009)

Notes:
In the 2003 Infant Feeding Guidelines the following table summarised the main factors associated with decreased breastfeeding performance in Australia:

Factors negatively associated with breastfeeding initiation and duration

- maternal smoking
- use of a pacifier
- breast nipple trauma and mastitis
- perceived maternal milk insufficiency
- poor maternal - self esteem / - self confidence/ - coping capacity
- a maternal body mass index > 30.

Summarised from (Baghurst and Binns 2003)

In the Perth Infant Feeding Study II the prevalence of perceived breast milk insufficiency is shown in the following table:

Anxiety over milk supply Perth Infant Feeding Study II 2005

	Hospital	4 months	10 months	16 months	22 months	32 months	40 months	52 months
Insufficient/ inadequate milk supply (%)	12.8	10.1	5.8	4.1	4.1	2.9	1.5	2.3
Baby not gaining enough weight (%)	3.1	2.3	0.6	0.5	0.3	-	-	-
Baby feeding too often/ not satisfied (%)	-	1.6	1.1	0.5	0.3	1.1	-	0.6
Baby refuses to breastfeed/ prefers bottle (%)	-	1.4	1.9	1.1	2.5	3.6	1.0	2.9

Engorgement of the Breast

Search results
The initial search of the databases included 66 references on engorgement and breastfeeding. Data were extracted from 11 references, and 6 publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the treatment of breast engorgement and the prevalence of breast engorgement in lactating women. Additional evidence was found on the prevention of engorgement (one RCT), but the evidence was not strong enough to develop a body of evidence statement.

TREATMENT FOR BREAST ENGORGEMNT DURING LACTATION

What are the best forms of treatment for women who experience breast engorgement during lactation?		
Draft Evidence statement		No pharmacological or non-pharmacological treatments for breast engorgement are associated with significant improvement in symptoms
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Poor	1 Cochrane review (P); no statistically significant evidence that any interventions for the treatment of engorgement were effective, 1 RCT (0); Gua-Sha therapy was associated with reduced risk of symptoms of engorgement.
Consistency	Satisfactory	In Cochrane Review; 1 RCT found acupuncture had greater improvements in symptoms in the days following treatment, 1 RCT found cold pack may be associated with improved symptoms, 1 RCT found protease complex may be associated with improved symptoms, all trials found women tended to have improvements in symptoms over time irrespective of active treatment they received. RCT that was not included in Cochrane review found Gua-Sha therapy was associated with reduced risk of symptoms of engorgement.
Clinical impact	Poor	No trial provides sufficient evidence on any intervention to justify widespread uptake of that intervention.
Generalisability	Good	Cochrane review included RCTs conducted in developing and developed countries, RCT that was not included in Cochrane review conducted in Taiwan
Applicability	Good	Results are applicable to Australian women

The studies included in the body of evidence statement are shown in the Table below

Cochrane review included 8 RCT and quasi RCT with 744 women. The authors concluded "although some interventions may be promising, there is not sufficient evidence from trials on any intervention to justify widespread implementation." There were not sufficient trials on any one intervention to develop a consistent evidence base. Cold packs may offer relief and cause no harm. Acupuncture may reduce symptoms in first few days following treatment. Commonly routine care included expression of breast milk. More research is needed on treatments for this painful and distressing condition (Mangesi and Dowswell 2010).

The RCT comparing Gua-Sha therapy and traditional breast care (hot packs and massage) on breast engorgement found breast pain, breast discomfort and symptoms of engorgement were

statistically significantly better in the intervention group compared to the control group ($p<0.0001$). The trial conducted on 54 postpartum women and a larger study using a more valid method of measurement is required (Chiu, Gau et al. 2010).

ABM Protocol on Breast Engorgement (Berens 2009)

"Engorgement has been defined as "the swelling and distension of the breasts, usually in the early days of initiation of lactation, caused by vascular dilation as well as the arrival of the early milk."

Some degree of breast fullness in the second stage of lactogenesis is considered normal and reassuring to the mother and healthcare provider. Engorgement symptoms occur most commonly between days 3 and 5, with more than two-thirds of women with tenderness on day 5 but some as late as days 9–10. Two-thirds of women experience at least moderate symptoms. More time spent breastfeeding in the first 48 hours is associated with less engorgement.

Manual expression or pumping. If the infant can not successfully nurse, measures should be undertaken to assist the mother with manual expression or pumping, either for a few minutes to allow softening and compressibility of the nipple–areolar complex or for milk extraction. The milk can then be given to the infant by cup, and the mother can be encouraged to nurse more frequently prior to the recurrence of severe breast engorgement. All new mothers should also be instructed in the technique of manual breast expression."

"Anticipatory guidance regarding the occurrence of breast engorgement should be given to all breastfeeding mothers prior to hospital discharge. In many countries where women may have longer hospital stays engorgement may occur in the birth hospital. However, many women are discharged before the expected time of peak symptomatic engorgement. Mothers should be counselled about symptomatic treatment options for pain control. Paracetamol and ibuprofen are both safe options for nursing mothers to take in appropriate doses. Additionally, contact information for breastfeeding supportive advice should be provided. Healthcare personnel seeing either the newborn or mother after discharge should routinely inquire about breast fullness and engorgement."

PREVALENCE OF BREAST ENGORGEMNT DURING LACTATION

What is the prevalence of breast engorgement in lactating women?		
Draft Evidence Statement		Approximately 40% of lactating women experience moderate-severe symptoms of breast engorgement
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Poor	2 studies; 1 cohort, 1 cross-sectional (both 0)
Consistency	Satisfactory	Cross-sectional study found 44.2% of lactating women experienced breast engorgement and leakage between 0 and 5 months postpartum, Cohort study found 46.5% of women reached the very firm- very tender level (highest rating on scale) during the first 14 days post-partum
Clinical impact	Satisfactory	Engorgement is common problem experienced by breastfeeding women
Generalisability	Satisfactory	1 study conducted in Hong Kong, 1 study conducted in US
Applicability	Satisfactory	Results are applicable to Australian women

The cohort study conducted in Iowa assessed engorgement in 114 breastfeeding women. Authors developed a six point engorgement scale to determine level of engorgement, mothers

were asked to report their breast changes twice daily during the first 1-14 days postpartum. Engorgement symptoms occurred most commonly during days 3-5 postpartum. For the majority of women initial engorgement peaked at day 5 however for some women engorgement symptoms did not occur until day 14. Of the women in the study 72% had some form of breast tenderness at day 5 (Hill and Humenick 1994).

The cross-sectional study conducted in Hong Kong assessed 7298 mother's concerns about breastfeeding. Of the mothers whose infants were less than 6 months of age (n=3161), 44.2% of them reported they had breast engorgement and leakage while breastfeeding and considered their engorgement a concern that deterred them from continued breastfeeding. The proportion of mothers reporting engorgement was consistent between infants aged 0-5 months. At 5 months 42.3% of mothers still experienced engorgement (Lee, Lui et al. 2006).

ABM recommendations for engorgement

No evidence base was developed for the prevention of engorgement due to the lack of quality studies.

The ABM clinical guideline states there is no significant difference in the incidence of engorgement when mother received information regarding breastfeeding position and attachment or prenatal nipple conditioning. Certain breastfeeding techniques have been associated with a reduced incidence of engorgement, including emptying one breast at each feeding and varying which breast is offered first. There is insufficient evidence that massaging the breast after feeds in the first 4 days postpartum will lessen the extent of engorgement. Frequent breastfeeding is advocated for the prevention of engorgement, however, the effect of feeding frequency on engorgement has not been thoroughly researched (Berens 2009).

In regards to treatment the ABM's clinical protocol on engorgement basis their recommendations on the 2001 Cochrane review on treatment of engorgement (Snowden, Renfrew et al. 2001). The ABM concludes that there is no benefit for the following treatments as compared with placebo; cabbage leaves, cabbage leaf extract, oxytocin, cold packs, and ultrasound (Berens 2009) .

Studies used to make evidence statement for engorgement (prevalence and treatment)

Reference	**Hill et al. 1994**	**de Oliveira et al. 2006**	**Lee et al 2006**
Type of study	Cohort	RCT	cross-sectional
Level of evidence	II (aetiology)	II (intervention)	IV (aetiology)
Definition of breastfeeding	Poorly defined	Poorly Defined	Partial breastfeeding defined as less than 70% of nourishment was provided by breast milk.
Intervention/ comparator	Prevalence of breast engorgement	30-minute counselling session on breastfeeding technique vs. no 30-minute counselling session on breastfeeding technique	Engorgement prevalence
N	114 women	211 mother-infant pairs. (233 were eligible, 22 refused or were lost to follow up)	7,289 healthy infants. 14,366 approached, 50% response rate.
Population/study information	Breastfeeding women who delivered in two hospitals in Iowa were the sample population. Authors developed a six point engorgement scale to determine level of engorgement, mothers were asked to report their breast changes twice daily during the first 1-14 days postpartum. A researcher visited the mothers in hospital and in the first and second weeks postpartum to ensure that the mother was completing the forms correctly.	Mothers were recruited from the Hospital de Clínicas de Porto Alegre, Brazil in 2003. Intervention group= 74 Control group= 137 Face-to-face interviews and breastfeeding assessments occurred in the maternity ward and at day 7 and 30.	Subjects were recruited from 46 Maternal and Child Health Clinics in Hong Kong in a 2 week period in 1993. 3161 of sample were < 6 months.
Quality	0	P	0 (No to 2.1, 7.4)
Results	Of the women in the study 46.2% reached the very firm-very tender level (rating 6) during the first 1-14 days postpartum.	No difference between groups in the frequency of breast engorgement at 7 and 30 days. At 30 days Engorgement prevalence;	44.2% of mothers reported they had breast engorgement and leakage while breastfeeding and considered their engorgement a concern that deterred them

	Of the women in the study 78% reached the firm-tender level (rating 5) during the first 1-14 days postpartum. Engorgement symptoms occurred most commonly during days 3-5 postpartum. For the majority of women (72%) initial engorgement peaked at day 5 however for some women engorgement symptoms did not occur until day 14.	intervention group = 37.8% control group= 36.5%	from continued breastfeeding. The proportion of mothers reporting engorgement was consistent between infants aged 0-5 months. At 5 months 42.3% of mothers still experienced engorgement. The practice of expressing breast milk into a bottle was not heard of among Hong Kong mothers at the time of the survey.
Effect on risk		A single intervention at maternity is not sufficient to reduce the incidence of breastfeeding problems including engorgement during the first month post partum.	Engorgement is a common concern among mothers living in Hong-Kong
Clinical importance	4	1	4
Clinical relevance	1	1	1
Generalisability	Y- US	Y-South America	Y-Hong Kong
Applicability	Y- US	Y	Y

Reference	**Mangesi & Dowswell 2010**	**Chiu et al. 2010**
Type of study	Cochrane Review	RCT
Level of evidence	I (aetiology)	II (intervention)
Definition of breastfeeding	Poorly Defined	Poorly Defined
Intervention/ comparator	Treatments for breast engorgement; acupuncture versus usual care cabbage leaves (cold versus room temperature leaves) cabbage leaves versus gel packs cold packs versus routine	Scraping (Gua-Sha) vs traditional breast care (hot packs and massage) (Gua-Sha therapy is a Chinese, non-pharmacological therapy which

	care protease complex tablets versus placebo ultrasound versus sham ultrasound subcutaneous oxytocin versus placebo	involves palpation and cutaneous stimulation where the skin is pressured, in strokes, by a round-edged instrument)
N	744	54 postpartum women
Population/study information	8 RCT and quasi-RCTs about treatments for breast engorgement were evaluated. 10 studies were excluded as did not meet inclusion criteria	54 postpartum women with engorgement were selected from a medical center in Taiwan. Intervention group (27); had Gua-Sha therapy, each position was lightly scraped 7 times in two cycles. Control group (27); applied hot packs then massaged for 20 mins Measurements according to a subjective breast engorgement, pain and discomfort scales developed by the authors.
Quality	P	0 (No to 6.3, 7.4)
Results	One RCT found acupuncture vs routine care group had fewer symptoms in the days 3,4 and 5 following treatment RR at day 4; 0.82 (0.69 to 0.96). No difference in symptoms by 6 days. One RCT on protease complex reported findings favouring intervention groups. Women in the active treatment group were less likely to have no improvement in pain RR 0.17 (0.04, 0.74) and swelling RR 0.34 (0.15, 0.79). Study was conducted in 1965. One RCT on cold pack gels found application of cold does not cause harm, and may be associated with improvements in symptoms, although study results are difficult to interpret.	Body temperature, breast temperature, breast engorgement, pain levels, and discomforting levels were statistically different between the two groups at 5 and 30 min after intervention. Control group: After 30 minutes there was an average improvement in breast engorgement, pain and discomfort of 2.67, 2.29 and 2,29, respectively Intervention group: After 30 minutes there was an average improvement in breast engorgement, pain and discomfort of 4.07, 3.97 and 4.2 respectively. Breast pain, breast discomfort and symptoms of engorgement were statistically significantly better in the intervention group compared to the control group ($p<0.0001$)

Effect on risk	No statistically significant evidence that interventions were associated with a more rapid resolution of symptoms; in these studies women tended to have improvements in pain and other symptoms over time whether or not they received active treatment.	Gua-Sha therapy may be used as an effective technique in the management of breast engorgement. Larger study using a more valid method of measurement required.
Clinical importance	1	1
Clinical relevance	1	1
Generalisability	Y	Y
Applicability	Y	Y

References used in body of evidence tables: (Hill and Humenick 1994; de Oliveira, Giugliani et al. 2006; Lee, Lui et al. 2006; Chiu, Gau et al. 2010; Mangesi and Dowswell 2010)

Inflammatory conditions of the breast

Mastitis

Search results
The initial search of the databases included 851 references on mastitis in breastfeeding women. Data were extracted from 35 references, and 12 publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the incidence of mastitis in breastfeeding women and the prevention of mastitis. Additional evidence was found on the treatment of mastitis and the time of presentation of mastitis, but the evidence was not strong enough to develop a body of evidence statement.

THE PREVALENCE OF MASTITIS IN LACTATING WOMEN

What is the prevalence of mastitis in lactating women?		
Draft Evidence statement		Approximately 10-25% of lactating women experience at least one episode of mastitis
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Poor	6 cohort studies (3P, 30)
Consistency	Satisfactory	All 6 studies reported on the percentage of women in their sample that had one or more episodes of mastitis during the study period. On cohort study reported 23.7% in the first year post partum, one cohort study reported 17.3% in first 6 months, one cohort study reported 20% in the first 6 months, one cohort study reported 18% (14%, 21%) in the first 26 weeks, one cohort study reported 9.5 % in the first 12 weeks and one cohort study reported 27.1% in the first 3 months postpartum.
Clinical impact	Prevalence only	Mastitis is a common problem experienced by breastfeeding women
Generalisability	Satisfactory	Populations studied; Australia (4 studies), Scotland (1 study), USA (1 study)
Applicability	Satisfactory	Results are applicable to Australian women

(Fetherston 1997; Vogel, Hutchison et al. 1999; Kinlay, O'Connell et al. 2001; Foxman, D'Arcy et al. 2002; Amir, Forster et al. 2007; Scott, Robertson et al. 2008)

The studies included in the body of evidence statement are shown in the Table below

A literature review conducted by Kvist aimed to clarify the use of the term mastitis in scientific literature. Kvist searched articles on lactation mastitis published in English between 1998- 2008. Clarification of the term mastitis was carried out on each of the 18 articles that met the inclusion criteria. There was inconsistency between the studies on the definition of mastitis. The findings signify the need for an international consensus on the definition of the term and the diagnosis of the condition. The variety of definitions that exist for mastitis could also part explain the contradicting results that are sometimes seen on prevalence rates, risk factors and effectiveness of treatment methods for mastitis (Kvist 2010).

THE PREVENTION OF MASTITIS IN BREASTFEEDING WOMEN

What preventative strategies are effective in reducing the incidence and recurrence of mastitis in

lactating women?		
Evidence statement		No pharmacological or non-pharmacological preventative methods are associated with a reduced occurrence of mastitis in breastfeeding women
Grade		D
Component	**Rating**	**Notes**
Evidence Base	Poor	1 Cochrane review (P); no statistically significant evidence that any preventative interventions is effective in regards to the occurrence of mastitis or breastfeeding exclusivity and duration
Consistency	Satisfactory	All five RCTs included in the Cochrane Review reported the preventative intervention under study had no significant differences in the incidence of mastitis or on breastfeeding outcomes.
Clinical impact	Poor	No trial provides sufficient evidence on any intervention to justify widespread uptake of that intervention.
Generalisability	Satisfactory	Cochrane review included RCTs conducted in developing and developed countries. 1 RCT conducted in Australia
Applicability	Satisfactory	Results are applicable to Australian women

(Crepinsek, Crowe et al. 2010)

The review included in the body of evidence statement is shown in the Table below

Notes on mastitis in lactating women

Three studies reported on the occurrence rate of mastitis during the postpartum period. However due to the lack of high quality studies there was insufficient evidence to form a body of evidence statement. The three studied that were reviewed indicated a high occurrence rate of mastitis early in the postpartum period A cohort study in Australia reported 51% of mastitis cases occurred within the first two weeks postpartum (Fetherston 1997). The cohort study by Scott and colleagues found 53% of initial mastitis episodes and 43% of all episodes occurred during the first four weeks postpartum (Scott, Robertson et al. 2008). Consistent with these rates are the results from a cohort study by Amir and colleagues that found 54% of mastitis episodes occurred in first 4 weeks (Amir, Forster et al. 2007) .

All studies, with the exception of one, did not associate mastitis with poorer breastfeeding outcomes. The majority of studies found no significant difference between incidence of mastitis and breastfeeding duration, and some even found women who had had mastitis were more likely to breastfed for longer than those who did not have mastitis (Vogel, Hutchison et al. 1999; Scott, Robertson et al. 2008). The one study that linked mastitis with poorer breastfeeding outcomes reported 18% of the women who had stopped breastfeeding by three months cited mastitis as the reason for stopping (Fetherston 1997). Alarmingly, the cohort study conducted by Scott and colleagues found a small portion of women (approximately 10%) were inappropriately advised to either stop breastfeeding from the affected breast, or altogether when they had mastitis (Scott, Robertson et al. 2008).

The Cochrane review by Jahanfar and colleagues aimed to examine the effectiveness of antibiotic therapies in the treatment of mastitis. After a thorough research of the literature two RCTs met the inclusion criteria (Jahanfar, Ng et al. 2009). One study compared two different antibiotics (amoxicillin vs. cephradine) and found no differences between the two antibiotics for symptom relief. The second study compared no treatment, breast emptying, and antibiotic therapy, with breast emptying suggesting more rapid symptom relief with antibiotics. Jahanfar & Ng concluded there is very little evidence on the effectiveness of antibiotic

therapy, and more research is needed (Jahanfar, Ng et al. 2009). A narrative review by Abou-Dakn and colleagues investigated 16 studies on the recommendations for the diagnosis and therapy of breast diseases during lactation also concluded that there is insufficient evidence to confirm or refute the effectiveness of the different therapies for the treatment of mastitis (Abou-Dakn, Richardt et al. 2010).
Several studies examined the risk factors for the development of mastitis but the results are inconclusive and further research is required.

Spencer formed the following key recommendations for practice as a result of the evidence on mastitis at the time of publication (Spencer 2008).

KEY RECOMMENDATIONS FOR PRACTICE (used the SORT evidence rating system)	
Clinical recommendation	***Evidence rating***
Optimizing lactation support is essential in women with mastitis.	C (2 publications)
Milk culture is rarely needed in the diagnosis of mastitis, but it should be considered in refractory and hospital-acquired cases.	C (3 publications)
Antibiotics effective against *Staphylococcus aureus* are preferred in the treatment of mastitis.	C (2 publications)
Breastfeeding in the presence of mastitis generally does not pose a risk to the infant and should be continued to maintain milk supply.	C (2 publications)
A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series.	

ABM protocol on mastitis
The ABM has listed predisposing factors in the development of mastitis in breastfeeding women. The ABM note the extent of their association has not been verified. The predisposing factors included traumatised nipples, especially if Staphylococcus aureus colonization is present, infrequent or poor duration of feedings, missing feedings, poor attachment or weak or uncoordinated suckling leading to inefficient removal of milk, illness in mother or baby, oversupply of milk, rapid weaning, pressure on the breast (e.g., tight bra, car seatbelt), blocked nipple pore or duct or Candida infection and maternal stress and fatigue (Academy of Breastfeeding Medicine 2008).
In the management of mastitis, the ABM state that frequent and effective milk removal is the best form of management for mastitis as it reduces milk stasis. Mothers should be advised to breastfeed more frequently, starting on the affected breast. If letdown is too painful feeding may begin on the unaffected breast and then switch to the affected breast once letdown is achieved. Correct positioning of the infant is important in the management of mastitis as is massaging the breast during breastfeeding. Massage should be directed from the blocked area moving toward the nipple. Expressing milk is another method of removing milk from the breast which thereby relieves symptoms of mastitis. The ABM report no evidence of a risk to the healthy, term infant of continuing breastfeeding. Abrupt termination of breastfeeding increases the risk of abscess development, so women who are unable to continue breastfeeding are recommended to express excess milk from breast. Ensuring the mother has adequate rest, fluid, and nutrition are supportive measures the ABM recommend in the

management of mastitis. Applying heat to the breast in the form of a shower or hot pack before feeding may aid milk flow. Some women find application of a cold pack after feeding relieves pain and reduces oedema. In the pharmacologic management of mastitis the ABM have said that women with mastitis should be encouraged to take appropriate medications as indicated. If the symptoms of mastitis fail to resolve within several days of appropriate management, including antibiotics, differential diagnoses should be considered. Methicillin-resistant *S. aureus* [MRSA] has been increasingly isolated in mastitis and breast abscess cases therefore the ABM now recommend clinicians be aware of the likelihood of this occurring in lactating women. If a woman with mastitis is unresponsive to first-line treatment the ABM suggest clinicians order a breast milk culture along with antibiotic sensitivities(Academy of Breastfeeding Medicine 2008).

In preventing mastitis, the ABM state that mothers should be helped to improve infants' attachment to the breast, advised not to restrict feeds and encouraged to express milk if the breasts become too full. Other forms of preventative methods involve; prompt attention to any signs of milk stasis, obtaining adequate rest and good hand and equipment hygiene to prevent a Staphylococcus aureus infection (Academy of Breastfeeding Medicine 2008).

Studies used to make evidence statement for mastitis in breastfeeding women

Reference	**Fetherston 1997**	**Vogel et al. 1999**	**Kinlay et al. 2001**
Type of study	Cohort	Cohort	Cohort
Level of evidence	II (aetiology)	I (i)	II (aetiology)
Definition of breastfeeding	poorly defined	Not stated	poorly defined
Intervention/ comparator	Incidence of mastitis Recurrence rates	Mastitis	Incidence of mastitis in first 6 months Factors statistically related to mastitis
N	306 women	350 mothers. Follow up at 12 months was 94%	1075 1352 approached, 1075 gave consent (80%)
Population/study information	215 breastfeeding mother's from a private maternity hospital and 91 breastfeeding mothers from a public maternity hospital in WA. Included women who were still breastfeeding at 7 days postpartum and intended to continue. Subjects were followed for 3 months Mothers were contacted by phone during the first 3 mon postpartum at 4 weekly intervals Self report questionnaires were administered to mothers	Mothers with healthy infants were recruited from an obstetric hospital in Auckland, New Zealand. Face-to-face interview at first days postpartum. Telephone interviews at 1,2,3,6,9 & 12 months postpartum	Sample included women who delivered at 2 hospitals in NSW in 1994, and who planned to breastfeed. Follow up questionnaires were administered at 3, 8 and 26 weeks
Quality	0	0	P
Results	The cumulative incidence rate for mastitis in the first 3 months postpartum was 27.1% with a	23.7% of sample reported one or more episodes of mastitis symptoms in the first year post partum. Of these 70.5 % received	20% of women had mastitis in first six months Past history of mastitis Adj HR =1.74

	cumulative recurrence rate of 6.5% No significant difference between primiparous women and multiparous women 51% cases of mastitis occurred within the first two weeks postpartum At three months, 71% of cohort women were still breastfeeding, 18% of those who stopped cited mastitis as reason for stopping Mean duration of breast symptoms was 3.9 days (range 24 hours – 12 days).	antibiotics Mothers reporting mastitis in their first year were less likely to wean early than those not experiencing mastitis adj RR 0.67 (0.48,0.94). No association was found with difficulty of infant to latch on. (Univariate RR=1.05 (0.62,1.78))	(1.07,2.81) Blocked ducts Adj HR = 2.43 (1.68,3.49) Cracked nipples Adj HR = 1.44 (CI 1.00-2.07) Use of creams on cracked nipples Adj HR =1.83 (1.22,2.73) ; particularly papaya cream RR = 1.83 (1.36,2.47)
Effect on risk	The high incidence rate of mastitis and its effects on breastfeeding duration demonstrates that mastitis is a significant problem among breastfeeding women	Mastitis is not identified as a major factor in weaning decisions.	In response to the results the author's state that factors such as cracked nipples and blocked ducts should serve as early warning signs and women should be advised to seek early treatment if symptoms of mastitis developed. Authors suggest use of creams may introduce pathogens and should be avoided.
Clinical importance	4	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Reference	**Foxman et al. 2002**	**Amir et al. 2007**	**Scott et al. 2008**
Type of study	Prospective study	Cohort	Cohort

Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	poorly defined	Not stated	Not stated
Intervention/ comparator	Incidence to 12 weeks Describe treatment Identify associations with mastitis	Incidence of mastitis in the first 6 months (retrospective) Factors associated with mastitis	Incidence of mastitis, reoccurrence, timing of episodes. Type of care received from health professionals
N	946 women. Follow up at 12 weeks was 88.8% 1,057 women initially approached	1193 women	420 women. 72% of women invited to take part participated. Follow up at 26 weeks was 95%
Population/study information	Study participants were recruited from women who gave birth at a family birthing center in Michigan and from pregnant women working at a single large company in Nebraska in 1994. The only requirement for enrollment was an intention to breastfeed. Participants were interviewed by telephone at 3, 6, 9, and 12 weeks postpartum or until they ceased breastfeeding.	Combination of data collected during an RCT of breastfeeding education, and a survey of two different birthing venues Women who were planning to give birth or who had delivered at the Royal Women's Hospital and Frances Perry House in Meelbourne between 1999-2001. Inclusion criteria in both studies included primiparity and ability to speak English. Retrospective phone follow up at 6 months; single interview	Study participants were recruited from women who had given birth at the Princess Royal Maternity Hospital in Glasgow between April 2004 and January 2005. Women who were breastfeeding at the time of recruitment were included. Women were followed up at 3,8,18 and 26 weeks and were asked about cases of mastitis they had experienced
Quality	P	0	P
Results	Overall incidence = 9.5 % 8.1% one case, 1.3% two cases, 0.1% three cases	17.3% women in study experienced mastitis in first 6 months.	18% (14%, 21%) had at least one episode of mastitis 68% of those with mastitis reported only

	Highest in first few weeks, then fell. Almost half changed breastfeeding practices 88% received medications (antibiotics, analgesics) Women experiencing mastitis with previous child were more likely to have episode (23.9% incidence) OR = 4.0. (2.64, 6.11) Nipple sores or cracks in the same week as mastitis episode OR = 3.4 (2.04, 5.51) *Decreased* risk if feeding fewer than 10 times a day (in same week) 7-9 times OR = 0.6 (0.41, 1.01); ≤ 6 times OR 0.6 (0.19, 0.82) Duration of breastfeeding was not associated with mastitis.	54% of episodes occurred in first 4 weeks, 71% in first 2 months and 83% in first three months. Nipple damage (pain and cracks) associated with mastitis may predict mastitis OR 1.92 (1.29, 2.86)	one episode, 23 reported two episodes and 9% reported three or more episodes. 53% of initial episodes and 43% of all episodes occurred during the first four weeks postpartum Women who had had mastitis were significantly more likely to be breastfeeding at 26 weeks than those who did not have mastitis (p=0.003) 37% of women managed their first episode of mastitis without consulting a health professional. 78% of women consulting a health professional were prescribed antibiotic.s This was 53% of women with mastitis 6 out of the 57 women with mastitis were inappropriately advised to either stop breastfeeding from the affected breast, or altogether
Effect on risk	Mastitis is a common problem experienced in breastfeeding women. More research is required on the pathogenesis of mastitis and its risk factors.	The prevention and improved management of nipple damage could potentially reduce the risk of lactating women developing mastitis.	Approximately 18% of women are likely to experience one or more episodes of mastitis A small portion of women continue to receive inappropriate advice regarding the management of mastitis from health professionals
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y- USA	Y	Y-Scotland
Applicability	Y-USA	Y	Y- Scotland

Reference	Jahanfar et al. 2009	Crepinsek et al. 2010	Abou-Dakn 2010
Type of study	Cochrane Review	SLR	SLR
Level of evidence	I (a)	I (aetiology)	I (a)
Definition of breastfeeding	Not stated		Not stated
Intervention/ comparator	Antibiotic therapy vs alternative therapies for the treatment of mastitis	preventive interventions for mastitis including breastfeeding education, taking antibiotic medication, topical ointments and anti-secretory factor cereal on the incidence and recurrence of mastitis and breastfeeding outcomes (duration, maternal satisfaction, maternal confidence)	Breast disease
N	125 women	960 women	
Population/study information	Searched for RCTs or quasi-RCTs 11 articles initially found 2 trials met inclusion criteria. One study compared two different antibiotics (amoxicillin vs. cephradine) The second study compared no treatment, breast emptying, and antibiotic therapy	Searched a variety of databases from date they commenced to 2009 on interventions for mastitis. No language restrictions were applied. The search strategy protocol generated 1029 article 'hits'. After screening titles and abstracts, 38 articles remained, 5 of which met the inclusion criteria. The review included RCTs of interventions for preventing mastitis in postpartum breastfeeding women Most of the included studies were of poor study quality and design. Sample size of studies ranged from 10-615	16 studies on recommendations for the diagnosis and therapy of breast diseases during lactation Authors note most studies had rather low evidence levels

Quality	P	P	0 (No to 2, 3, 7)
Results	The study comparing two different antibiotics found there was no differences between the two antibiotics for symptom relief. The study comparing no treatment, breast emptying, and antibiotic therapy, found breast emptying suggested more rapid symptom relief with antibiotics.	In three trials of 471 women, there was no significant differences in the incidence of mastitis between use of antibiotics and no antibiotics RR= 0.43 (0.11,1.61), or in one trial of 99 women comparing two doses RR = 0.38 (0.02, 9.18). No significant differences found for mastitis in three trials of specialist breastfeeding education with usual care (one trial); anti-secretory factor cereal (one trial); and mupirocin, fusidic acid ointment or breastfeeding advice (one trial).	If milk stasis or mastitis is suspected, an ultrasound should be performed to recognize early abscess No indication for weaning in case of milk stasis, puerperal mastitis (except bilateral mastitis). Ineffective milk removal even aggravates symptoms. Initially, conservative therapeutic measures should be tried for at least 24 hrs (antipyretics, physical rest, substitution of liquids, frequent breastfeeding, and emptying of the affected breast) If no improvement in mastitis can be achieved by conservative therapies antibiotics should be given. Antibiotics should be changed if no change in another 24 hrs. Special emphasis on preventative measures
Effect on risk	There is very little evidence on the effectiveness of antibiotic therapy on the treatment of mastitis, and more research is needed.	Insufficient evidence to show effectiveness of any of the interventions, including breastfeeding education, pharmacological treatments and alternative therapies, regarding the occurrence of mastitis or breastfeeding exclusivity and duration. Further adequately powered research is needed	Insufficient evidence to confirm or refute the effectiveness of the different therapies for the treatment of breast diseases during lactation.
Clinical	1	1	1

importance			
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

References used in body of evidence table: (Fetherston 1997; Vogel, Hutchison et al. 1999; Kinlay, O'Connell et al. 2001; Foxman, D'Arcy et al. 2002; Amir, Forster et al. 2007; Scott, Robertson et al. 2008; Jahanfar, Ng et al. 2009; Abou-Dakn, Richardt et al. 2010; Crepinsek, Crowe et al. 2010)

Breast Abscess

Search results

The initial search of the databases included 87 references on breast abscess formation during lactation. Data were extracted from 13 references, and 7 publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the incidence of breast abscesses in lactating women. Additional evidence was found on the prevention and management of breast abscess, but the evidence was not strong enough to develop a body of evidence statement.

PREVALENCE OF BREAST ABSCESS DURING LACTATION

What is the prevalence of breast abscess in lactating women?		
Draft Evidence Statement		Approximately 0.1 – 0.5% of lactating women develop a breast abscess in developed countries, including Australia.
Draft Grade		**D**
Draft Evidence Statement		Approximately 3-10% of lactating women with inflammatory symptoms of the breast later developed a breast abscess
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	6 studies [1 Cochrane review, 1 RCT, 2 cohort, 1 cross-sectional (4P, 1N)]
Consistency	Satisfactory	RCT found 0.1% of the population of women who delivered during the study period developed a breast abscess, cohort study found 0.1% of postpartum mothers required surgery due to a breast abscess, the cohort study found 0.4% of women who commenced breastfeeding developed a breast abscess No cases of abscess were reported in a cohort of 300 mothers. RCT found 3.3% of women with inflammatory symptoms of breast developed a breast abscess, RCT included in Cochrane review found 11% of mastitis cases with no intervention developed an abscess.
Clinical impact	Prevalence only	Breast abscess formation is relatively rare among lactating women
Generalisability	Satisfactory	Most studies conducted in developed countries, including Australia and New Zealand
Applicability	Satisfactory	Results are applicable to Australian women

(Vogel, Hutchison et al. 1999; Amir, Forster et al. 2004; Kvist, Hall-Lord et al. 2007)

The studies included in the body of evidence statement are shown in the Table below

Notes:

Prevention of breast abscess during lactation

The WHO stated that breast abscess is largely preventable through appropriate breastfeeding technique and treating conditions that lead to milk stasis; e.g. engorgement, blocked duct and nipple soreness, promptly (WHO 2000)

No evidence base was developed for the use of antibiotics during inflammatory conditions of the breast to prevent breast abscess due to the lack of quality studies.

The authors of a large cross-sectional study in Sweden stated that low incidence of abscess formation (0.1% in their study of 1,454,068) raised the question as to whether antibiotic therapy is appropriate for all mothers with symptoms of breast inflammation (Kvist and Rydhstroem 2005).

Two trials met the inclusion criteria for the Cochrane review on Antibiotics for mastitis in breastfeeding women. One RCT conduced in 1984 on 213 women comparing no treatment, breast emptying, and antibiotic therapy on mastitis found 11% of mastitis cases with no intervention developed abscess, while none in the group treated with antibiotic therapy suffered from any abscess. Authors of the Cochrane review conclude that more high-quality, recent studies are required to confirm or refute the effectiveness of antibiotic therapy for the treatment of lactational mastitis (Jahanfar, Ng et al. 2009).

Management of Breast Abscess during lactation
No evidence base was developed for the management of breast abscess during lactation due to the lack of quality studies.

In a narrative review of 16 studies on the diagnosis and therapy of breast diseases during lactation the author, Abou-Dakn concludes there is no indication for weaning in case of breast abscess. In the management of breast abscess Abou-Dakn states that needle aspiration should be favored over surgical intervention. Needle aspiration is cheaper, less painful and allows a faster convalescence. Surgical drainage preferred method if abscess is large, or if there are multiple present (Abou-Dakn, Richardt et al. 2010).

The WHO recommend aspirating pus in the breast with a syringe and wide bore needle to confirm the presence of an abscess (WHO 2000).

Studies used to make evidence statement for breast abscess (prevalence, treatment & risk factors)

Reference	**Evan & Heads 1995**	**Vogel et al. 1999**	**Amir et al. 2004**	**Kvist & Rydhstroem 2005**
Type of study	Cohort	Cohort	Cohort	Cross-sectional
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	IV (aetiology)
Definition of breastfeeding	Not stated	Not stated	Not stated	Not stated
Intervention/ comparator	Breast abscess prevalence	breast abscess formation	Breast abscess prevalence	Breast abscess prevalence maternal age vs parity vs gestational age of infant
N	16,351 mothers	350 mothers. Follow up at 12 months was 94%	1311. follow up at 6 months was 91 % (1193)	1,454,068
Population/study information	Women who delivered at the Sothern, Eastern and Central Sydney health service maternity hospitals between 1992-3. Nurses completed a data collection form about incidence of mastitis	Mothers with healthy infants were recruited from an obstetric hospital in Auckland, New Zealand. Face-to-face interview at first days postpartum. Telephone interviews at 1,2,3,6,9 & 12 months postpartum	Women were recruited from two hospitals in Melbourne, the Royal Women's Hospital (public) (1999–2001) and Frances Perry House (private) (2000–2001). Telephone interview at 6 months post partum.	Retrieved data from the Medical Birth Registry and the National Discharge Register in Sweden between 1987-2000.
Quality	N	P	N	P
Results	Of 402 women who had mastitis 10 of these women were hospitalized for drainage of a breast abscess. 4/10 cases received narrow spectrum antibiotics. 7/402 mothers with mastitis were advised to wean by health	No cases of abscess were reported	0.4% (0.14–0.98) of women who commenced breastfeeding developed a breast abscess 2.9% (1.0, 6.7) of women who took antibiotics for mastitis developed abscess.	0.1% women required surgery due to a breast abscess. 65% of breast abscess cases occurred between three and eight weeks postpartum Primiparity OR 3.5 (3.1,3.9)

	professionals.			Maternal age ≥30 y OR 1.6 (1.5,1.8) Post maturity (>41 weeks) OR 1.2 (1.0,1.5)
Effect on risk	Weaning during an episode of mastitis delays resolution and predisposes to breast abscess formation. Health professionals should be educated regarding the necessity of support for the mothers in her efforts to continue breastfeeding during mastitis to prevent breast abscess.		Lower incidence of breast abscess in Australia.	Low incidence ? whether antibiotic treatment is appropriate for all mothers with inflammatory symptoms of breast Primiparous women, mothers over 30 years of age and those giving birth post-maturely may be at increased risk of developing a breast abscess
Clinical importance	4	1	4	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y	Y - Sweden
Applicability	Y	Y	Y	Y - Sweden

Reference	**Kvist et al. 2007**	**Kvist et al. 2008**	**Jahanfar et al. 2009**	**Abou-Dakn 2010**
Type of study	RCT	case-control	Cochrane Review	Narrative review
Level of evidence	II (intervention)	III-3 (aetiology)	I (aetiology)	I (aetiology)

Definition of breastfeeding	Not stated	Not stated	Not stated	Not stated
Intervention/ comparator	acupuncture treatment vs. other care interventions	Bacterial count	Antibiotic therapy vs alternative therapies	Breast disease
N	205 mothers recruited and 210 randomized (5 recruited twice with new symptoms). Follow up at 1-18 days was 99%	658 women 192 cases. Follow up at 6 weeks 84% 466 controls (breast milk donors)	125 women	
Population/study information	Study conducted in a hospital in southern Sweden between 2002 and 2004. 5225 babies were delivered at the unit, 291 had inflammatory symptoms of the breast. 205 agreed to participate. Group 1 (70 women) essential care and the use of oxytocin spray Group 2 (70 women) essential care and treatment by acupuncture needles placed at heart and gallbladder Group 3 (70 women) essential care and treatment by acupuncture needles placed at heart, gallbladder spleen	192 women with mastitis (sample overlaps with Kvist et al. RCT adjacent) 466 breast milk donors living in the same geographical area as the case group. Cases completed a follow up questionnaire at 6 weeks. Midwife carried out the telephone follow-ups in some cases only	Searched for RCTs or quasi-RCTs Two trials met inclusion criteria	16 studies on recommendations for the diagnosis and therapy of breast diseases during lactation Authors note most studies had rather low evidence levels
Quality	P	0 (No to 3 & 7)	P	0 (No to 2, 3, 7)

Results	3.3% of study population (women with inflammatory symptoms of breast) developed a breast abscess. (group 1=5, group 2=1, group 3=1) 0.1% of the population of women who delivered during the study period developed breast abscess women in the acupuncture group were less likely to have abscess compared to women receiving routine care, but the difference between groups did not reach statistical significance RR 0.20 (0.04,1.01)	No significant difference in bacterial counts of women given antibiotics (n =31) vs women not given antibiotics (n = 161) antibiotics No significant difference in bacterial counts between women with (n=7) and without a breast abscess (n-185).	One RCT found 11% of mastitis cases with no intervention developed abscess, while none in the group treated with antibiotic therapy suffered from any abscess. One small trial (n = 25) compared amoxicillin with cephradine for mastitis and found no significant difference in terms of abscess formation	If milk stasis or mastitis is suspected, an ultrasound should be performed to recognize early abscess No indication for weaning in case of breast abscess. In the management of breast abscess needle aspiration should be favored over surgical intervention. Needle aspiration is cheaper, less painful and allows a faster convalescence. Surgical drainage preferred method if abscess is large, or if there are multiple present. No recommendations exist regarding aspiration technique Antibiotics not necessary if abscess cavity is opened and cleared widely.
Effect on risk	Negative (however small sample size) Incidence of breast abscess comparable to Australian study (Amir 2004)	Increasing bacterial counts did not affect the clinical manifestation of mastitis thus bacterial counts in breast milk may be of limited value in the decision to treat with antibiotics.	More research required	
Clinical importance	4	4	1	1
Clinical relevance	1	2	1	1

Generalisability	Y prevalence rates, N efficacy of acupuncture treatment on abscess formation	Y Conducted in Sweden	Y	Y
Applicability	Y prevalence rates, N efficacy of acupuncture treatment on abscess formation	Y	Y	Y

References used for the body of evidence tables: (Evans and Heads 1995; Vogel, Hutchison et al. 1999; Amir, Forster et al. 2004; Kvist and Rydhstroem 2005; Kvist, Hall-Lord et al. 2007; Kvist, Larsson et al. 2008; Jahanfar, Ng et al. 2009; Abou-Dakn, Richardt et al. 2010)

Postnatal Depression and breastfeeding

Sufficient evidence was found to make statements on the prevalence of postnatal depression in women and the relationship between postnatal depression and infant feeding outcomes. Additional evidence was found on the relationship between postnatal depression and infant growth, but since the majority of studies were conducted in developing countries the evidence was insufficient to develop a body of evidence statement.

THE PREVALENCE OF POSTANATAL DEPRESSION

What is the prevalence of maternal postnatal depression?		
Draft Evidence statement		Approximately 10-15% of women experience depression (EPDS score ≥ 12) within twelve months of delivery
Draft Grade		**B**
Component	**Rating**	**Notes**
Evidence Base	Good	5 studies; 1 meta- analysis, 3 SLR, 1 cohort study (published 2010) [5P] reported on the prevalence of maternal postnatal depression
Consistency	Poor	1 meta-analysis on 59 studies found the overall prevalence of postpartum depression was 13% (12.3%, 13.4%), 1 SLR on 28 studies reported 19.2% of women had a major or minor depressive episode during the first 3 months postpartum, with 7.2% having major depression, 1 SLR on 143 studies found the prevalence varies among countries from 0%- 60%; the prevalence rates in Australia (from 14 studies) were estimated as 9%, 1 SLR on 64 studies found the prevalence of PPD in Asian countries ranges from 3.5%-63.3%, 1 cohort study in Europe found 11.0% of mothers had a depression episode during the first 6 months after delivery.
Clinical impact	Poor	substantial
Generalisability	Good	The SLR and meta-analysis consist of studies from a variety of developed and developing countries including Australia.
Applicability	Good	Results are applicable to Australian women

The studies included in the body of evidence statement are shown in the Table below

Many epidemiological studies have documented the prevalence of postnatal depression around the world (O'Hara 2009). The prevalence rate is generally estimated to be in the range 10-15% although there is considerable variation reported between countries (Grote, Vik et al. 2010). In developing countries is often reported as higher and the literature contains prevalence of 16% to 35% (Ghubash, AbouSaleh et al. 1997; Cooper, Tomlinson et al. 1999; Patel, Rodrigues et al. 2002). The lowest rates have been reported from Singapore, Malta, Denmark and Malaysia (0.5-9%) with higher rates in Guyana, Costa Rica, Italy, Chile, Taiwan, and Pakistan (34- 63.3%) (Halbreich and Karkun 2006; Klainin and Arthur 2009) However, many of these studies used small and inadequate samples. A review of 59 studies found that the mean prevalence of postpartum cases was 13% with onset mostly within the first three months postpartum (O'Hara and Swain 1996). More recent studies have found that 7% of women experienced a major depressive episode within three months of delivery (Gavin, Gaynes et al. 2005) and when cases of minor depression were included, the 3-month period prevalence rate increased to 19 % (Gavin, Gaynes et al. 2005).

POSTNATAL DEPRESSION AND INFANT FEEDING OUTCOMES

What is the association between postnatal depression and shorter breastfeeding duration?		
Draft Evidence statement		Postnatal depression is associated with a shorter breastfeeding duration
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Good	1 SLR [1P] of 49 studies
Consistency	Good	12 studies in the SLR reported that mothers with depressive symptoms were significantly more likely to discontinue breastfeeding earlier than non-depressed mothers.
Clinical impact	Satisfactory	Moderate
Generalisability	Good	The SLR consist of studies from a variety of developed and developing countries including Australia.
Applicability	Good	Results are applicable to Australian women

The studies included in the body of evidence statement are shown in the Table below

A relationship between postnatal depression and infant feeding outcomes has been found consistently in many studies. A recent systematic literature review on 49 studies by Dennis and McQueen found women with postnatal depression in the early postpartum period may be at heightened risk for negative infant feeding practices. The review categorised the studies into four groups based on the infant-feeding outcome measure they assessed; (1) infant-feeding method, (2) breastfeeding initiation, duration, and exclusivity, (3) breastfeeding difficulties, (4) breastfeeding self-efficacy. Of the studies reviewed, seven found an association between bottle feeding and higher levels of depressive symptoms. Twelve studies, including a cohort study in Australia, suggested that mothers with depressive symptoms were significantly more likely to discontinue breastfeeding earlier than non depressed mothers. A longitudinal cohort study of 1745 women in Australia found that postnatal depression was significantly associated with breastfeeding duration ($p = 0.025$), and that women who experience postnatal depression at any time have a greater risk (RR=1.25) of stopping breastfeeding than women who do not experience postnatal depression (Henderson, Evans et al. 2003).

Despite extensive research, the review by Dennis and McQueen, found only two studies linking depression among postnatal mothers and breastfeeding initiation. While three studies found an association between maternal mood and breastfeeding exclusivity one study that used multivariate analyses did not find this association. Further research is warranted to examine the likelihood of maternal mood negatively impacting breastfeeding initiation and exclusivity. The findings from the review indicate that in addition to offering support to postnatal mothers, health professions should recognise and treat depression in breastfeeding women to prevent the adoption of negative infant-feeding practices.

Additional notes on Postnatal depression

Postnatal depression is a serious health problem for many women in all cultures (Dennis 2005). It is characterized by desolation, sadness, anxiety, fears, irrational thoughts, feelings of inadequacy, loss of libido, tiredness, and dependency (Sichel 2000). Epidemiological studies usually define postnatal depression as occurring within 12 weeks of birth (Wisner, Parry et al. 2002; Hiltunen, Jokelainen et al. 2004). The onset of postnatal depression is within the first 4 weeks after delivery (American Psychiatric Association c2000). In addition, a major depressive episode should be two weeks or longer during which a woman has either depressed mood or feeling of inadequacy or pleasure in activities which are different from normal functioning (Horowitz and Goodman 2005). Moreover, the presence of four or more

of the additional symptoms is required for a diagnosis: significant weight loss when not dieting, weight gain, change in appetite, insomnia, hypersomnia, psychomotor agitation, and retardation almost every day is required for a diagnosis (Horowitz and Goodman 2005).

The Edinburgh Postnatal Depression Scale (EPDS)

In recognition of the importance of diagnosing postnatal depression The Edinburgh Postnatal Depression Scale has been included in previous editions of the Infant Feeding Guidelines for Health Workers. The Edinburgh Postnatal Depression Scale EPDS (Cox, Holden et al. 1987) is a reliable, valid, ten item tool which can be administered easily and is developed to specifically screen for postpartum depression.

Risk factors for postnatal depression

Determining the predisposing factors for postpartum depression is important so women at risk of developing depression can be identified early and the appropriate preventative strategies can be put in place. A meta-analysis of 44 studies found that 'prenatal depression', 'child care stress', 'life stress', 'social support', 'prenatal anxiety', 'maternity blues', 'marital satisfaction', and 'history of previous depression' are predictor variables of postnatal depression (Beck 1996). Several other meta-analyses have found that factors with moderate to strong association with postpartum depression include 'depression and anxiety during pregnancy', 'postpartum blues', 'previous history of depression', 'stressful life events', 'a poor marital relationship', and 'poor social support' (O'Hara and Swain 1996; Beck 2001; Robertson, Grace et al. 2004; Jones, Scott et al. 2010). Other risk factors such as 'low socioeconomic status', 'obstetric factors', and 'difficult infant temperament' were found to be less strongly related to postpartum depression (Beck 2001; Robertson, Grace et al. 2004).

Postnatal depression and growth faltering in infants

Several studies conducted in developing countries have reported an association between post-natal depression and infant growth impairment. A critical review of 11 studies from UK, India, Pakistan, South Africa, Ethiopia, Jamaica, Brazil, Peru, and Vietnam, by Stewart found postnatal depression was associated with growth faltering in developing countries but not in developed countries (Stewart 2007). Stewart provides four possible explanations for the relationship between maternal postnatal depression and infant growth faltering and discusses possible reasons for the discrepancy between countries.

Firstly, confounding factors may not have been adequately accounted for (Stewart 2007). In some studies the association between postnatal depression and under nutrition was not significant after adjusting for confounding factors including poverty, socio-economic status, parental education levels and birth weight. However, the association remained significant after adjustment in the studies in Goa, India, and Rawalpindi, Pakistan (Patel, DeSouza et al. 2003; Rahman, Iqbal et al. 2004). Secondly, the effects of depression such as tiredness, worthlessness and psychomotor slowing can affect the mother's ability to provide proper nutritional care, proper hygiene and appropriate health care seeking behaviours so that the children's growth is affected (Stewart 2007). In addition, symptoms of depression are associated with decreased breastfeeding duration, increased breastfeeding difficulties, and decreased levels of self-efficacy (Dennis and McQueen 2009). Thirdly, the association between stunted growth and postnatal depression may be due to the stress caused by both internal and external factors in bringing up a child who is slow to develop and grow (O'Brien, Heycock et al. 2004; Stewart 2007). Fourthly, the environment in developing countries is more hostile and less favourable for child health so that postnatal depression affects infant nutrition and growth more severely (Patel, DeSouza et al. 2003; Stewart 2007). More

prospective studies, including adjustment for potential confounders are needed to understand the influence of postnatal depression on infant growth in developed countries (Stewart 2007).

Academy of Breastfeeding Medicine Protocol (Academy of Breastfeeding Medicine 2008)

Recommendations for Identifying Women with Postpartum Depression

• The preferred method for identifying women with postpartum depression is the systematic use of a validated screening tool such as the Edinburgh Postnatal Depression Scale or the Postpartum Depression Screening Scale at the obstetrical postpartum visit and at well childcare visits in the postpartum year.
• Ask mothers if they feel down or anxious. Many women with postpartum depression report anxiety as a primary symptom rather than depressed mood. Excessive worrying about the baby's or mother's health should be explored.
• Ask mothers if they are having trouble sleeping even when they are exhausted and their child is sleeping or if they are sleeping all the time and are unable to get out of bed.
• Ask mothers if they are losing or gaining weight. Many women with postpartum depression report a poor appetite, but they eat because they need to keep their strength up or for nursing. Some mothers will gain weight.
• Ask mothers directly but in an open, nonthreatening manner about thoughts or fears of harming their children. For example, "Many new mothers experience anxiety about their new infants. They may have thoughts that are unusual or frighten them such as fears that they may harm their baby. Does this ever happen to you?" Mothers who experience intrusive thoughts do not wish to harm their children and avoid the topics of their fears (i.e., a mother is afraid her baby will drown therefore will not bathe the baby and has her partner bathe the infant). It is important to distinguish the woman with postpartum depression whose intrusive thoughts or fears of harming the infant are incongruent with the mother's wish to keep her infant safe from the woman with postpartum psychosis who is delusional and who may have thoughts of harming her infant to "save the infant from the devil or a life of torment." Delusional mothers are at great risk of harming their infants or themselves and must be immediately evaluated by a psychiatrist.
• Ask mothers if they have concerns or questions about adapting to a new baby.
• Consider the mother's interactions with the infant, including the responsiveness of mom and baby.
• Difficulty in breastfeeding, or not enjoying breastfeeding, may be a warning sign that should be further evaluated.

Despite many publications on antidepressants and breastfeeding, the scientific literature lacks both the breadth and depth for clinicians and mothers to make confident decisions about individual medications. Multiple reviews of the literature broadly suggest TCAs and serotonin reuptake inhibitors are relatively safe, and all recommend individual risk-benefit assessments.

The literature suffers from a lack of any randomized clinical trials in lactating women for any class of antidepressant. The majority of studies are case reports or case series, and most have small samples sizes. Those studies that report larger samples (n _ 25) primarily report a variety of medications. Only six controlled studies (one retrospective five prospective) were found that used a variety of controls—some control for depression, while others do not. None of the studies sufficiently controlled for level of depression. Few studies report infant behavioral outcomes.

Studies used to make evidence statement for the prevalence of postnatal depression

Reference	**Gavin & Gaynes (2005)**	**(Jones, Scott et al. 2010)**	**O'Hara & Swain (1996)**
Type of study	SLR	Cohort study	Meta-analysis
Level of evidence	I (aetiology)	II (aetiology)	I (aetiology)
Definition of breastfeeding	Not defined	Not defined	Not defined
Intervention/ comparator	Prevalence of postnatal depression	Maternal postnatal depression (EPDS score ≥ 13) and later child growth faltering or overweight	Prevalence of postnatal depression
N	Sample sizes of studies ranged from 54 - 4,964	929 children. 1678 were originally recruited. Follow up at 6 months was 95% (n= 879)	12,810 (from 59 studies)
Population/study information	Searched databases for articles published in English between 1980- 2004. Review included cross sectional studies, cohort studies and case-control from developed countries that assessed women for depression during pregnancy or the first year postpartum with a structured clinical interview. 846 articles originally identified. 109 articles were reviewed, 28 met the inclusion criteria 2 of 28 studies were conducted in Australia	Women and their children participating in a European multicenter RCT were included at a median age of 14 days. Participants in the European multicenter RCT were recruited at 11 study sites in five countries (Belgium; Germany; Italy; Poland; Spain). At visits 2, 3 and 6 months after delivery, the mothers were asked to complete the Edinburgh postnatal depression scale (EPDS) EPDS scores of 13 and above at any time were defined as maternal depression. Weight, length, triceps and subscapular skinfold thicknesses were measured, and body mass index (BMI) were calculated	Searched for studies that examined the relationship between postpartum depression and a possible risk factor. Investigations were included if they met the following criteria: (a) reported statistical relationship between variable of interest and postpartum depression (b) variable of interest assessed during either pregnancy or delivery; (c) subjects recruited through random or quasi-random sampling techniques; (d) depression assessed after at least two weeks postpartum (e) postpartum depression assessed using a validated or standardized measure. 59 studies were eligible Women are defined as depressed if they exceed a threshold such as 12/13 on the

		when the children were two years old and converted to standard deviation scores based on the WHO Multicentre Growth Reference Study (MGRS). Six-hundred thirty-two (68%) children were included in the formula-fed intervention arm of the study, and 297 (32%) children were fully breastfed until 4 months of age.	EPDS The mean prevalence of postpartum depression was determined by dividing the number of all postpartum depressed women by the total number of subjects across studies. Confidence intervals for the average prevalence rates were computed using a formula
Quality	P	P	P
Results	The combined point prevalence estimates for meta-analysis ranged from 6.5%- 12.9% at different trimesters of pregnancy and months in the first postpartum year. Prevalence of major and minor depression is highest at the 3rd months at 12.9%. In the forth through to 7 months prevalence is 9.9-10.6%, after which is declines to 6.5%. The combined period prevalence shows that as many as 19.2% of women had a major or minor depressive episode during the first 3 months postpartum, with 7.2% having major depression. All estimates have a wide CI showing significant uncertainty in their true levels	One-hundred two (11.0%) mothers had an EPDS score of 13 or more at any time, indicating maternal depression; at 2 month 6.9% of the mothers, at 3 month 4.3% and at 6 months 4.0% mothers had high EPDS scores.	Overall prevalence of postpartum depression was 0.13 (0.123, 0.134). Self report measures yielded significantly higher estimates of postpartum depression than interview-based methods, Self report (n= 28 studies): 0.14, (0.131, 0.149); Interview (n=31 studies): 0.12 (0.113, 0.127), $p < 0.05$. The type of assessment method employed accounted for an additional nine per cent of the variance. Self-report assessments were associated with higher prevalence estimates than interview-based assessments. In sum, approximately 25% of the variance in prevalence of postpartum depression was accounted for by these

			two variables.
Effect on risk			Approximately 13% of women experience postnatal depression
Clinical importance	4	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y – Europe	Y
Applicability	Y	Y - Europe	Y

Reference	**Halbreich (2006)**	**Klainin & Arthur (2009)**
Type of study	SLR	SLR
Level of evidence	I (aetiology)	I (aetiology)
Definition of breastfeeding	Not defined	Not defined
Intervention/ comparator	prevalence of postpartum depression and depressive symptoms	prevalence of postpartum depression among women in Asian cultures
N		sample sizes ranged from 11 to 2514
Population/study information	Searched databases from 1980 to 2005. Additional articles were identified by being cited in retrieved articles. Studies of women who were already referred to Psychiatric clinics were excluded. All data for the first 12 months postpartum were included For countries with more than a single study, a country weighted mean was calculated by weighing the number of subjects in each report. 143 studies were identified reporting prevalence in 40 countries.	A literature search was undertaken by using various electronic research databases. Studies were eligible for this review if they (a) examined risk factors for PPD, (b) were conducted in Asian countries using quantitative or qualitative methodologies, and (c) were published in English in peer-reviewed journals between 1998 and 2008. Our search strategy resulted in 173 abstracts relating to PPD among Asian women. Subsequently, 109 studies were excluded because they did not fulfil the inclusion criteria.

		A total of 64 studies from 17 Asian countries were reviewed, summarised, and synthesised. The majority of studies collected data cross-sectionally (n = 34; 53.1%) The self-reported EPDS was most frequently used (68.8%; n = 44) followed by the Beck Depression Inventory (BDI) (7.85, n=5) to determine PPD
Quality	P	P
Results	The prevalence of PPD as it is estimated by the EPDS varies among countries from almost 0% to almost 60%. In Singapore, Malta, Denmark and Malaysia there are almost no reports of PPD (0.5–9%), whereas in Guyana, Costa Rica, Italy, Chile, South Africa, Korea and Taiwan PPD is extremely prevalent (34–57.0%). The mean prevalence rate of postnatal depression (EPDS) in Australia estimated from 14 studies is 9%. This variability is despite the fact that in most studies the same instrument—EPDS was used	The prevalence of postpartum depression in Asian countries ranged from 3.5% to 63.3% where Malaysia and Pakistan had the lowest and highest, respectively.
Effect on risk	Authors found a high variability of reported PPD. Authors state that the frequently cited mean prevalence of PPD (10–15%) is not representative of the actual global prevalence and magnitude of the problem.	The wide variation of PPD (3.5–63.3%) may reflect the actual prevalence across countries or perhaps result from methodological limitations across studies. Postpartum depression is prevalent in Asian cultures as in Western cultures
Clinical importance	4	4
Clinical relevance	1	1
Generalisability	Y	Y – Asia
Applicability	Y	Y – Asia

Studies used to make evidence statement for postnatal depression and breastfeeding outcomes

Reference	**Dennis & McQueen (2009)**	**Henderson et al. (2003) (reviewed in Dennis & McQueen adjacent)**
Type of study	SLR	Cohort study
Level of evidence	I (aetiology)	II (aetiology)
Definition of breastfeeding	Varied between studies. Authors stated all but 1 study had an imprecise definition of breastfeeding.	The degree of breastfeeding was defined according to the categories described by Labbok and Krasove.
Intervention/ comparator	Aimed to determine the relationship between postpartum depression and infant feeding outcomes	Postpartum depression (EPDS score> 12 at 8, 24, and 52 wks) Outcome measure: breastfeeding duration
N	Of the 49 eligible studies sample sizes ranged from 22 to 14 609, with a mean of 864 participants.	1745 women (68.5 % of the eligible women approached)

Population/study information	Authors searched various database using specific key words. A hand search of selected specialist journals and reference lists of articles obtained was then conducted. 75 articles were reviewed, of which 49 specifically provided data on postpartum depressive symptom aetiology and infant-feeding outcomes. All studies were published between 1981 and 2007, with samples from 15 countries including Australia, Barbados, Canada, China, Denmark, Finland, France, Hong Kong, Iceland, Ireland, Pakistan, Sweden, United Arab Emirates, US, and the UK. On the basis of these studies, infant-feeding outcomes were subcategorized as (1) infant-feeding method, (2) breastfeeding initiation, duration, and exclusivity, (3) breastfeeding difficulties, and (4) breastfeeding self-efficacy.	Women were part of a larger RCT conducted in 1996-7. Women were recruited on the postnatal wards of two large obstetric hospitals in Perth. Self-report questionnaires were completed at recruitment, and at 2, 6, and 12 months postpartum. Breastfeeding status was determined at each follow-up, and the Edinburgh Postnatal Depression Scale was used to screen for symptoms of depression. Diagnostic psychological interviews were conducted on participants who scored above 12 on the EPDS scale, a stratified sample of women with lower scores, and women being treated for a psychological disorder or who were taking antidepressant medication at each interval.
Quality	P	P
Results	Several studies demonstrated that breastfeeding mothers have lower mean depression scores than bottle-feeding women. In a US study of 802 women they found women who were breastfeeding 3 weeks after delivery were significantly less likely to have depressive symptoms than those who were bottle feeding (OR: 0.60 [95% CI: 0.44–0.81]; *P* =0.008). (Yonkers et al. 2001)	Of the 18% of mothers with depressive symptomatology the onset occurred before 8 weeks in 63% of the cases. Median duration of breastfeeding was 26 weeks for the women with early-onset depression, 28 weeks for the women with late-onset depression, and 39 weeks for the women without depression. After adjustment for confounding factors, early discontinuation of breastfeeding was significantly associated with postpartum depression (adjusted hazard ratio: 1.25 (1.03,1.52). The onset of PPD occurred before

	In a larger UK study of 2375 mothers, bottle feeding at 6 to 8 weeks after delivery was identified through stepwise logistic regression analysis as 1 of 4 variables associated with an EPDS score of > 12 (odds ratio [OR]: 1.52 [95% CI: 1.12–2.06]) (Warner et al. 1996) In a US study of 14 609 mothers women who were bottle feeding (*n* = 9145 [62.6%]) were significantly more likely to report being "very depressed" in the initial months after delivery than those who were breastfeeding (*n* = 5464 [37.4%]) (OR: 1.4 [95% CI: 1.1–1.8]) (Gross et al. 2002) A consistent relationship between postpartum depressive episodes and breastfeeding duration was found among diverse populations. In a study of 159 Australian mothers of whom 91.1% initiated breastfeeding and only 49.6% continued to 24 weeks, increased duration was significantly associated with decreased levels of depressive symptomatology (Papinczak and Turner 2000) In the review 7 studies found an association between bottle feeding and higher levels of depressive symptomatology. 12 studies suggested that mothers with depressive symptomatology were significantly more likely to discontinue breastfeeding earlier than nondepressed mothers. 2 suggest that depressive symptomatology among pregnant women may influence breastfeeding initiation. 3 studies found an association between maternal mood and breastfeeding exclusivity. 1 study that included multivariate analyses did not find that depressive symptomatology significantly predicted exclusivity.	discontinuation of breastfeeding in most cases.
Effect on risk	Women with depressive symptoms in the early postpartum period may be at increased risk for negative infant feeding outcomes including decreased breastfeeding duration, increased	Postnatal depression has a significant negative impact on breastfeeding duration.

	breastfeeding difficulties, and decreased levels of breastfeeding self-efficacy.	
Clinical importance	4	1
Clinical relevance	1	1
Generalisability	Y	Y
Applicability	Y	Y

Studies used to determine the risk factors associated with postnatal depression

Reference	**Beck (2001) (reviewed in Robertson et al. SLR adjacent)**	**O'Hara & Swain (1996) (reviewed in Robertson et al. SLR adjacent)**	**Robertson et al. (2004)**
Type of study	Meta-analysis	Meta-analysis	SLR
Level of evidence	I (aetiology)	I (aetiology)	I (aetiology)
Definition of breastfeeding	Varied between studies in analysis	Varied between studies in analysis	Varied between studies in analysis
Intervention/ comparator	postpartum depression predictors	Relationship between postnatal depression and a variety of non-biological/hormonal risk factors	postpartum depression predictors
N	> 2692	12,810 (from 59 studies)	≈24,000
Population/study information	On-line databases were searched for the 10-year period between 1990-2000 A total of 107 potential studies were located. 84 studies met the sample criteria. 54 (64%) of the studies were journal articles, 28 (34%) were unpublished dissertations, and two studies were unpublished master's theses.	Searched for studies that examined the relationship between postpartum depression and a possible risk factor. Investigations were included if they met the following criteria: (a) reported statistical relationship between variable of interest and postpartum depression (b) variable of interest assessed during	19 databases relating to the medical, psychological, and social science literature were searched using specific inclusion criteria and search terms, in order to identify studies examining antenatal risk factors for postpartum depression.

	44 studies (52%), took place in the United States, 11 (13%) in Canada, 7 (8%) in the United Kingdom, 3 (4%) in New Zealand, two each in Australia, South Africa, Ireland, and France and one each in Japan, Belgium, Portugal, United Arab, Israel, Switzerland, Brazil, China, Nigeria, Netherlands, and Finland. A longitudinal research design was overwhelmingly used in 67 (80%) studies while 17 (20%) studies employed a cross sectional design. The quality of each study included in the meta-analysis was assessed by a modification of the scoring index developed for evaluating research on postpartum depression The authors synthesized the results of studies to determine the magnitude of the relationships between postpartum depression and various risk factors. Using the software system Advanced Basic Meta-Analysis, effect sizes were calculated three ways: unweighted, weighted by sample size, and weighted by quality index score. Homogeneity tests were conducted to identify any outliers in each of the 13 subsets of studies in this meta-analysis. A predictive relationship was considered	either pregnancy or delivery; (c) subjects recruited through random or quasi-random sampling techniques; (d) depression assessed after at least two weeks postpartum (e) postpartum depression assessed using a validated or standardized measure. 59 studies were eligible Women are defined as depressed if they exceed a threshold such as 12/13 on the EPDS	The research studies were of human subjects, empirical, peer-reviewed, and published in English between 1990 and 2002 (excluding seminal studies prior to these dates) 2 major meta-analyses (Ohara & Swain and Beck in columns adjacent) conducted on over 14,000 subjects, as well as newer subsequent large-scale clinical studies were identified. The results of these studies were then summarized in terms of effect sizes as defined by Cohen.

	moderate if *r* = .38		
Quality	P	P	P
Results	13 predictors of postpartum depression were revealed. 10 of the 13 risk factors had moderate effect sizes while 3 predictors had small effect sizes. The mean effect size indicator ranges for each risk factor were as follows: prenatal depression (r = .44 to .46), self esteem (r= .45 to. 47), childcare stress (r= .45 to .46), prenatal anxiety (r= .41 to .45), life stress (r= .38 to .40), social support (r= .36 to .41), marital relationship (r= .38 to .39), history of previous depression (r= .38 to .39), infant temperament (r= .33 to .34), maternity blues (r= .25 to .31), marital status (r= .21 to .35), socioeconomic status (r= .19 to .22), and unplanned/unwanted pregnancy (r= .14 to .17).	Family income and mother's occupation were small, but significant predictors of postpartum depression δ = - 0.141 (-0.21, - 0.08), δ = -0.146 (-0.25, -0.04) respectively. Effect sizes based on the association between family income and postpartum depression were significantly heterogeneous (n = 14; Q(13) = 40.56; p = 0.0001), indicating that the population of effect sizes was not adequately represented by one estimate. Mother's age, marital status, length of relationship with her partner, education, number of children, parity, and pregnancy employment status all failed to significantly predict postpartum depression. Pregnancy and delivery complications delivered a small but significant effect size on postpartum depression δ= 0.26 (0.19, 0.34) r = 0.13. The population of effect sizes was significantly heterogeneous, Q(12) = 1 6 3 . 1 7 ,~< 0.0001, but the variability was adequately explained by the type of postpartum depression assessment used	The following factors were the strongest predictors of postpartum depression: depression during pregnancy (strong/moderate Cohen's effect size= 0.75), anxiety during pregnancy (strong/moderate Cohen's effect size= 0.68), experiencing stressful life events during pregnancy or the early puerperium (strong/moderate Cohen's effect size= 0.61), low levels of social support (strong/moderate Cohen's effect size= 0.64) , and a previous history of depression (strong/moderate Cohen's effect size= 0.58). Neuroticism, marital relationship had a moderate Cohen's effect size. SES and obstetric factors had a smalls Cohen's effect size

		in each study Life events prior to the birth of the child were examined as possible predictors of subsequent postpartum depression. Values from 15 studies were combined and results demonstrated a strong relationship δ = 0.60 (0.54, 0.67) r= 0.29 The effect sizes were significantly heterogeneous, Q(14) = 86.56, p < 0.0001. The nation in which the study was conducted explained significant variance in effect size heterogeneity, Results indicated a small, but significant negative association between marital satisfaction and incidence of postpartum depression δ = - 0.13 (- 0.20, - 0.06) r= - 0.07 The significant heterogeneity in these effect size outcomes, Q(7) = 40.83, p < 0.001, was sufficiently explained by the assessment method The effect size of social support including support from father was of moderate strength (δ= - 0.53 (- 0.67, - 0.39) r= - 0.25 but the population of effect sizes was significantly heterogeneous, Q(4) = 24.05, p< 0.0001.	

Effect on risk	Ten predictors (prenatal depression, self esteem, childcare stress, prenatal anxiety, life stress, social support, marital relationship, history of depression, infant temperament) were considered to have a moderate predictive relationship to postnatal depression.	The strongest predictors of postpartum depression were past history of psychopathology and psychological disturbance during pregnancy, poor marital relationship and low social support, and stressful life events. Indicators of low social status showed a small but significant predictive relation to postpartum depression	The following factors (depression during pregnancy, anxiety during pregnancy, experiencing stressful life events during pregnancy or the early puerperium, low levels of social support, and a previous history of depression) increase the risk of a mother developing postnatal depression
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Reference	**Jones et al. (2010)**	**Klainin & Arthur (2009)**
Type of study	Case-control	SLR
Level of evidence	III – 3 (aetiology)	I (aetiology)
Definition of breastfeeding	poorly defined	Not defined
Intervention/ comparator	Personality and cognitive styles in women	risk factors for postpartum depression among women in Asian cultures
N	274 parous women with major recurrent depression (379 initially included, 105 excluded) 131 controls	sample sizes ranged from 11 to 2514

Population/study information	Parous women with major recurrent depression, who were not in an episode of depression when recruited and assessed were included in the study. The sample was divided into women who had experienced one or more postnatal episodes (postnatal depression (PND) group, n = 143), and women who did not have an episode of depression in relation to childbirth (NPND group, n=131). This sample was compared against healthy female controls (control group, n=173). All patients were part of an ongoing research program on determinants of major effective disorders that initially recruited over 34,000 individuals from GPs across England and Wales. Patients were interviewed face to face by psychiatrists and psychologists. An episode of postnatal depression was defined as an episode of DSM-IV major depression with onset within 6 weeks of delivery Four validated self-rated questionnaires were administered.	A literature search was undertaken by using various electronic research databases. Studies were eligible for this review if they (a) examined risk factors for PPD, (b) were conducted in Asian countries using quantitative or qualitative methodologies, and (c) were published in English in peer-reviewed journals between 1998 and 2008. A total of 64 studies from 17 countries were reviewed, summarised, and synthesised. The majority of studies collected data cross-sectionally (n = 34; 53.1%) The self-reported EPDS was most frequently used (68.8%; n = 44) followed by the Beck Depression Inventory (BDI) (7.85, n=5) to determine PPD Risk factors for postpartum depression were clustered into five major groups: biological/physical (e.g., riboflavin consumption), psychological (e.g., antenatal depression), obstetric/paediatric (e.g., unwanted pregnancy), socio-demographic (e.g., poverty), and cultural factors (e.g., preference of infants' gender).
Quality	0	
Results	The PND group had higher levels of neuroticism compared to the control group (17.04 [16.24, 17.85] vs. 5.14 [4.59, 5.69]) The PND group had higher levels of dysfunctional beliefs, according to the Dysfunctional Attitude Scale total score compared to the control group (98.18 [93.91, 102.45] vs. 71.92 [69.31, 74.53]) The PND group had lower self esteem, according to the Rosenberg Self Esteem Questionnaire, compared to the control group (23.99 [22.96, 25.02] vs. 34.18 [33.63, 34.74])	Twelve studies documented an association between physical/biological factors and PPD The effects of psychological factors on PPD were investigated in 43 studies. Depressive symptoms during pregnancy, antenatal anxiety, past psychiatric history, premenstrual dysphoric disorder, stressful life events, child care stress, negative affect, low self-esteem, poor self image, insecure attachment style, and negative attitude toward employment were strong risk factors. 22 studies examined the role of obstetric/ paediatric factors. Problems during pregnancy, previous

	There was no significant difference between the PND and NPND group	abortion, previous loss of a baby, unplanned pregnancy, unintended pregnancy, negative attitude toward pregnancy, negative attitude toward mother roles, the lack of childcare knowledge, and the absence of breastfeeding were major risk factors 42 studies investigated the links between sociodemographic factors and PPD. Economic difficulties, being hungry in the past month, being a homemaker, being an immigrant, having unemployed or uneducated husband, having a husband with a history of psychiatric disorder, polygamy, domestic violence, dissatisfaction with living conditions, a lack of emotional support, and dissatisfaction with support from husband, parents, and parent-in-law were reported as potential risk factors Traditional postpartum rituals were not found to provide substantial psychological benefits for the new mothers.
Effect on risk	Personality and cognitive vulnerabilities for depression were reported by women with postnatal depression but there was no evidence that they present a specific risk for the onset of depression during the postnatal period.	
Clinical importance	4	4
Clinical relevance	1	1
Generalisability	Y	Y – Asia
Applicability	Y	Y –Asia

Studies used for the association between postnatal depression and infant growth

Reference	**Stewart (2007)**	**Grote et al. (2010)**

Type of study	SLR	Cohort study
Level of evidence	I (aetiology)	II (aetiology)
Definition of breastfeeding	poorly defined	Not defined
Intervention/ comparator	the relationship between postnatal depression and infant growth faltering	Maternal postnatal depression (EPDS score ≥ 13) and later child growth faltering or overweight
N	> 22,000	929 children. 1678 were originally recruited. Follow up at 6 months was 95% (n= 879)
Population/study information	A search was made using Medline for articles published in the last 10 years, that investigated whether there is an association between maternal depression and infant growth impairment Only a small number of articles were found, therefore no articles were excluded on the basis of methodological considerations. 11 studies were included in the review. The studies were either cross-sectional, cohort studies or case control studies. In the cross-sectional studies, underweight and control infants were recruited, and the prevalence of depression in the mothers of the two groups was compared. In the cohort and case control studies, maternal depression was measured antenatally or in the early post-natal period, and the subsequent growth of the infants of depressed and non-depressed mothers was compared. 8 studies from India, Pakistan, South Africa, Ethiopia, Jamaica, Brazil, Peru, and Vietnam and 3 studies from the UK. The results from the studies were assessed for relevance and quality	Women and their children participating in a European multicentre RCT were included at a median age of 14 days. Participants in the European multicentre RCT were recruited at 11 study sites in five countries (Belgium; Germany; Italy; Poland; Spain). At visits 2, 3 and 6 months after delivery, the mothers were asked to complete the Edinburgh postnatal depression scale (EPDS) EPDS scores of 13 and above at any time were defined as maternal depression. Weight, length, triceps and subscapular skinfold thicknesses were measured, and body mass index (BMI) were calculated when the children were two years old and converted to standard deviation scores based on the WHO Multicentre Growth Reference Study (MGRS). Six-hundred thirty-two (68%) children were included in the formula-fed intervention arm of the study, and 297 (32%) children were fully breastfed until 4 months of age.
Quality	P	P

Results	Results expressed as a narrative. The impact of maternal depression upon health-seeking behaviours, breastfeeding and mother–child interaction, and the relationship between antenatal depression and low infant birthweight may explain the effect of infant growth 'failure' upon maternal mood Economic, socio-cultural and confounding factors that may cause the variation between results from different settings	Z-scores for weight-for-length at inclusion of infants of mothers with high EPDS scores (-0.55, SD 0.74) were lower than of those with normal scores (-0.36, SD 0.74; p = 0.013). BMI at age 24 months did not differ in the high (16.3 kg/m2, SD 1.3) and in the normal EPDS groups (16.2 kg/m2, SD 1.3; p = 0.48). All other anthropometric indices also did not differ between groups, with no change by multivariate adjustment.
Effect on risk	.	High maternal postnatal depression score does not have a significant effects on later child growth in developed countries.
Clinical importance	4	1
Clinical relevance	1	1
Generalisability	Y	Y – Europe
Applicability	Y	Y - Europe

References used in body of evidence tables: (O'Hara and Swain 1996; Beck 2001; Henderson, Evans et al. 2003; Robertson, Grace et al. 2004; Gavin, Gaynes et al. 2005; Halbreich and Karkun 2006; Stewart 2007; Dennis and McQueen 2009; Klainin and Arthur 2009; Grote, Vik et al. 2010; Jones, Scott et al. 2010)

Breast Refusal

Search results

The initial search of the databases included 16 references on infant breast refusal. Data were extracted from 2 references (1 narrative review, 1 cross-sectional study) but the evidence was not strong enough to develop a body of evidence statement.

The cross sectional study conducted in the USA on 767 women found 8.9% of the total sample cited that infant rejecting breast was the reasons for not breastfeeding (Hurley, Black et al. 2008). The narrative review warns that the introduction of bottles in infant feeding could lead to breast refusal. The author suggests the use of finger feeding technique (finger feed the baby until the baby starts sucking on the finger with a definite draw) as a method of overcoming breast refusal (Newman 1990).

Breast refusal appears frequently in the literature as a reason for cessation of breastfeeding. However, in the absence of a consistent definition, it is used to describe any occasion when an infant stops breastfeeding for a shorter or longer period. There is a need to diagnose exactly what the problem is with the mother or infant.

The Crying Infant

Search results
The initial search of the databases included 160 references on infant crying. The detailed search is included in a separate document on searches. Evidence was found on the prevalence and management of infant crying (1 narrative review, 1 cohort, 2 cross-sectional) but the evidence was not strong enough to develop a body of evidence statement.

Prevalence of unexplained infant crying
Due to the lack of quality studies no evidence base was developed for the prevalence of infant crying.

Reijnevald and colleagues assessed the impact of varying definitions of excessive crying and infantile colic on prevalence estimates (Reijneveld, Brugman et al. 2001). Parents of 3345 infants aged 1, 3, and 6 months (response: 96.5%) were interviewed on the crying behavior of their infant in a Dutch cross-sectional national population-based study. The authors documented the prevalence of excessive crying according to 10 published definitions relating parent-reported duration of infant crying and the parents' experience.

Prevalence rates of excessive crying varied strongly between definitions, from 1.5% to 11.9%. They were always highest in 1-month-old infants.

Prevalence Rates of Excessive Crying According to 10 Definitions and Mean Number (SEM) of Hours of Crying Per Day During Preceding Week Among the Identified Excessive Criers, by Age Group (1, 3, and 6 Months)

	1 month (n=1128)		3 months (n=1090)		6 months (n=1127)		overall (n=3345)	
Definitions	Rate (%)	Mean (SEM)	Rate (%)	Mean (SEM)	Rate (%)	Mean (SEM)	Rate (%)	Mean (SEM)
A: Crying > 3 h/d on >3 d/wk, >3 wk	2.2	3.78 (0.24)	2.0	4.03 (0.43)	0.3	10.92 (5.58)	1.5	4.33 (0.43)
B: Crying >3 h/d on >3 d/wk, >3 wk	4.0	4.27 (0.27)	2.0	4.03 (0.43)	0.3	10.92 (5.58)	2.1	4.49 (0.34)
C: Crying >3 h/d on >3 d/wk, >2 wk	6.3	4.35 (0.21)	2.4	4.30 (0.40)	0.5	6.83 (3.12)	3.1	4.48 (0.25)
D: Crying >3 h/d on >3 d/wk, 1 wk	9.0	4.40 (0.18)	3.7	3.93 (0.30)	1.3	5.28 (1.31)	4.7	4.36 (0.19)
E: Crying >3 h/d on ≥3 d/wk, 1 wk	12.7	3.81 (0.16)	4.6	3.87 (0.30)	2.0	5.58 (1.30)	6.4	4.01 (0.18)
F: Average crying ≥4 h/d, 1 wk	7.3	5.44 (0.21)	2.8	5.80 (0.46)	1.8	7.50 (1.46)	3.9	5.80 (0.26)
G: Average crying ≥3 h/d, 1 wk	11.2	4.65 (0.17)	4.9	4.62 (0.32)	2.1	6.37 (1.15)	6.2	4.84 (0.19)
H: Inconsolable crying	8.6	3.36 (0.23)	7.3	2.34 (0.24)	3.9	1.96 (0.59)	6.6	2.72 (0.18)
I: Problematic crying	14.3	3.13 (0.16)	6.4	2.88 (0.29)	4.4	2.56 (0.55)	8.4	2.97 (0.15)
J: Cries a lot	17.8	3.00 (0.15)	9.9	2.37 (0.21)	7.7	2.19 (0.41)	11.9	2.66 (0.13)
All infants		1.49 (0.04)		1.01 (0.03)		0.71 (0.04)		1.07 (0.02)

Coinciding with Reijneveld and colleagues findings, the review by Herman and Le on crying in infancy reported the prevalence of excessive crying in infants as between 1.5 % and 40 %. Among those 1 to 6 month so age, 1 month old infants appear to have the highest prevalence (Herman and Le 2007).

Management of excessive, unexplained infant crying

No evidence base was developed for the management of excessive, unexplained crying due to the lack of quality studies.

A cohort of 700 healthy breastfeeding mother–baby dyads in the USA revealed 82 % of women at 16 weeks found breastfeeding was a highly effective calming practice for a crying

infant. The study also found that the use of breastfeeding to comfort infants was a significant predictor of longer partial breastfeeding (but not exclusive or full) duration; HR 0.6 (0.4, 0.9) (Howard, Lanphear et al. 2006).

A cross-sectional study including 5845 Dutch infants compared infant crying in smoking and non-smoking parents. The results showed that infants whose parents were heavy current smokers or whose mothers had been so during pregnancy had a higher prevalence of excessive crying than infants of non-smoking parents; OR 1.80 (1.26, 2.57). In response to their findings the authors indicate parents stopping smoking may reduce excessive infant crying (Reijneveld, Lanting et al. 2005).

Regurgitation, gastroesophageal reflux and feeding related behaviours

Gastroesophageal reflux is the regurgitation of stomach contents to the oesophagus, mouth, or externally, and is recognised by regurgitant vomiting or spilling of feeds. It is common in infancy with more than half of children reported to have GOR at 3-6months of age (Nelson, Chen et al. 1997; Iacono, Merolla et al. 2005; Furuta, Liacouras et al. 2007; Hegar, Dewanti et al. 2009). In the majority of infants GOR spontaneously resolves by 12 months of age. Limited data suggests that breastfeeding is not causative of, nor protective against GOR, although fully breastfed infants regurgitate less frequently than those who are formula or partially breastfed (Heacock, Jeffery et al. 1992; Iacono, Merolla et al. 2005; Hegar, Dewanti et al. 2009).

Assessment of Gastroesophageal reflux

In assessing any infant with GOR it is essential to consider other causes of vomiting including systemic and enteric infections, intestinal obstructions including pyloric stenosis, metabolic disease and neurological disorders. Regurgitant vomiting is the most important symptom of GOR. A range of other symptoms is ascribed to GOR, but it is not always possible to confirm the relationship between GOR and the particular symptoms. For most infants there is no association between GOR and disease (Nelson, Chen et al. 1997; Hegar, Dewanti et al. 2009). A small group of infants will develop complications of GOR growth failure, oesophagitis or respiratory disease. Clinical history of regurgitant vomiting plus poor growth or haematemesis (vomiting blood), apnoea or respiratory symptoms, anaemia, or abnormal posturing warrant a careful medical review and sometimes more detailed investigation (Vandenplas, Rudolph et al. 2009).

More difficult to assess are infants with irritability and feeding refusal. In an Australian study Heine et al investigated a cohort of infants aged 0.5 to 8.2 months who presented with persistent fussiness and found no association between the number of episodes of acid reflux or the total period of acid exposure of the oesophagus and gastroesophageal reflux (Heine, Jordan et al. 2006). They found no association between back-arching and acid reflux. They concluded that in the absence of frequent vomiting GOR is unlikely to account for fussiness in infancy.

Treatment

Although GOR is sometimes distressing for parents, and approximately 20% will seek medical advice, it is important to emphasise the generally benign nature and course of this symptom, with its tendency to spontaneously resolve by twelve months of age. Therapeutic intervention is usually reserved for those infants who have complications of their GOR: poor weight gain and growth, respiratory disease or oesophagitis. Specialised assessment and investigation may be required to clarify the presence and extent of complications.

For complicated GOR, treatment typically employs a series of treatments, ranging from modification of feeding patterns, to surgery (Vandenplas, Rudolph et al. 2009).

Change in feeding pattern

For infants the initial treatments are likely to be modification of volume or duration of feeds, and changes in posture, although there is minimal evidence to support changing feed volume (Ewer, Durbin et al. 1996). There is no evidence to suggest that cessation of breastfeeding is beneficial for gastroesophageal reflux, although feeding more frequently, to ensure smaller volume of milk may be beneficial.

Feed thickening
Thickening of feeds has some benefit in decreasing the amount regurgitated, but has no efficacy in decreasing number of episodes of GOR or acid exposure, and thus has no real place in the management of complicated GOR (Horvath, Dziechciarz et al. 2008). In addition feed thickeners cannot be utilised in breastfeeding. Some have been shown to have adverse side effects, including delaying gastric emptying and increasing GOR.

Posture
GOR is decreased in infants in the flat prone position compared with the supine position, and in the head elevated position in comparison with the flat position (Corvaglia, Rotatori et al. 2007; Martin, Di Fiore et al. 2007; van Wijk, Benninga et al. 2007; Omari 2008; Vandenplas, Rudolph et al. 2009). Recently the supine position at an elevation of 40 degrees was shown in an open trial to be beneficial (Vandenplas, De Schepper et al. 2010). The prone position is however associated with increased risks of SIDS and should not be used for sleeping infants (Dwyer and Ponsonby 2009).

Medication
Prokinetic agents which increase lower oesophageal sphincter pressure or enhance gastric emptying have been utilised in children for gastroesophageal reflux, although there is only limited data supporting efficacy and the recent expert group conclusion that there is no justification for their use in routine use (Hegar, Alatas et al. 2009; Vandenplas, Rudolph et al. 2009; Maclennan 2010).

Proton pump inhibitors are widely prescribed for presumed symptoms of GOR. They effectively decrease acid production, and with this volume of gastric secretions and thus potentially may decrease refluxate volume, but decrease GOR symptoms only as often as placebo (Orenstein, Hassall et al. 2009). Proton pump inhibitors increase the risks of a number of complications, including community acquired pneumonia and enteric infections and should only be used for extended periods where oesophagitis has been confirmed (Orenstein, Hassall et al. 2009; Vandenplas, Rudolph et al. 2009).

Surgery
Infants with persistent GOR with serious complications despite medical therapy should be considered for anti-reflux surgery. It is important to note that anti-reflux surgery can be lifesaving, but carries risks of significant complications (Vandenplas, Rudolph et al. 2009).

Eosinophilic oesophagitis
There are increasingly recognised babies who have some evidence of allergic disease or eosinophilic oesophagitis in association with GOR (Cherian, Smith et al. 2006). These children are often clinically indistinguishable from infants and children with reflux oesophagitis, and will need detailed assessment including endoscopic biopsy for diagnosis (Furuta, Liacouras et al. 2007). These infants if formula fed may benefit from switching from a standard to a hydrolysed formula. Anecdotal evidence suggests that a fully breastfedinfant with GOR and such features may benefit from maternal dietary elimination of suspected protein (Vandenplas, Rudolph et al. 2009).

Studies used to make evidence statements for gastroesophageal reflux (GOR) in infants

Reference	**Ewer et al. (1996)**	**Heacock et al. (1992)**	**Nelson et al (1997)**
Type of study	Case-series	Non-randomized experimental trial with concurrent controls	Cross-sectional study
Level of evidence	IV (aetiology)	III-2 (intervention)	IV (aetiology)
Definition of breastfeeding	Poorly Defined	Poorly defined	Not defined
Intervention/ comparator	Gastric emptying time (range 15-114 minute) Feed volume (range ≈30-60 ml) Number of reflux episodes and number of reflux episodes > 5 minutes during postprandial period	breastfeeding vs. formula feeding	Prevalence of GOR
N	19 preterm infants	74 infants. 104 approached	948 parents
Population/study information	The study was carried out on the Regional Neonatal Intensive Care Unit at Birmingham Maternity Hospital. Gastric emptying was measured in 19 healthy preterm infants that were receiving full enteral feeds via a nasogastric tube. Median gestational age= 32 weeks. No infant had symptomatic reflux before the study. Gastric emptying was measured ultrasonically. Real time ultrasonic images of the gastric antrum were obtained, and measurements of antral cross-sectional area (ACSA) were made	Study comprised of 32 breastfed and 32 formula fed infants delivered at King George V public hospital in NSW between 1989-90. Infants were healthy term newborns aged between 2-8 days. Infants were studied for 4 hours after their milk feed in the morning. GOR was recorded by a pH microelectrode during the third and forth postprandial hours. Sleep state was measured using an electroencephalophogram, electrooculogram, electromyogram, breathing and behavioral observations. Movement was recorded from a piezo-	In 1995 a questionnaire on GOR was distributed to parents of healthy infants 13 months old or younger in 19 practices in the Pediatric Practice Research Group in Chicago. Parents reported frequency of regurgitation in their infants

	immediately before a nasogastric feed and then during subsequent gastric emptying until ACSA returned to its pre-feed value. 24 hour lower oesophageal pH, using an antimony pH electrode, was measured. A reflux episode was defined as a lower oesophageal pH of < 4.0 for 15 seconds or longer. Two feeds were studied in each infant, making a total of 38 recordings.	electric transducer. The range of milk consumed by the infants was 15-115 ml. the difference between formula and breastfed infants was insignificant.	
Quality	P	P	0
Results	There was no correlation between gastric half emptying times and postprandial reflux. Pearson correlation coefficients for half emptying time of the feed and postprandial reflux index, number of reflux episodes, and number of episodes longer than five minutes were 0.15, 0.30, and 0.33, respectively. There was no correlation between gastric emptying rates and any of the indices of gastroesophageal reflux over 24 hours (Pearson correlation coefficient = 0.05), There was no correlation between feed volume and reflux index (Pearson correlation coefficient = 0.05),	In total, the breastfed infants had 83 reflux episodes. Formula fed infants had 144 reflux episodes. There was no significant difference in episodes per hour between breastfed and formula fed infants for any state of sleep or wakefulness. In active sleep, the breastfed infants demonstrated GER episodes of significantly shorter duration than the formula fed neonates. Mean ± SD = 3.0 (1.6,5.2) compared with 8.3 (5.0,13.3) min/h of active sleep respectively. The lower median pH values for GOR in breastfed neonates (2.0) vs formula fed infants (2.5) were significantly different. The volume of milk was unrelated to either the number or duration of reflux episodes.	Regurgitation of at least one episode a day was reported in 50% of 0-3 month olds. At 10-12 months 5% of infants regurgitated at least one episode a day. Peak reported regurgitation was at 4 months (67%)

Effect on risk	Gastric emptying time is not a determinant of asymptomatic gastroesophageal reflux. Gastroesophageal reflux was also unrelated to feed volume and feed type. Authors postulate that inappropriate relaxation of the lower oesophageal sphincter or abnormal oesophageal motility offer more plausible explanations	Authors hypothesis that the lower pH value observed in breastfed infants could reflect more rapid gastric empting. The low pH is more likely to stimulate peristalsis and thus reduce the duration of reflux. Results suggest that feed type is an important variable to consider in evaluating GER.	Regurgitation is common in infancy, and occurs most frequently in infants 3-6 months of age.
Clinical importance	4	4	4
Clinical relevance	1	1	1
Generalisability	Y – UK	Y	Y – US
Applicability	Y – UK	Y	Y- US

Reference	**Heine et al. (2006)**	**Cherian et al. (2006)**	**Iacono et al. (2005)**
Type of study	Prospective cohort	Retrospective audit	Cohort
Level of evidence	II (aetiology)	III-2 (aetiology)	II (aetiology)
Definition of breastfeeding	Poorly defined	Poorly Defined	'breast-fed' was defined as exclusively breastfeduntil the onset of a symptom, 'mixed-fed' was defined as mixed-fed from at least 2 weeks to the onset of a symptom and 'bottle-fed' was defined as being exclusively fed with an adapted milk formula from at least 2 weeks.
Intervention/ comparator	Correlation between persistent infant crying and gastroesophageal reflux	Prevalence of eosinophilic oesophagitis	Frequency of reflux in infants less than 6 months breastfedvs mixed fed vs formula fed on the

			onset of regurgitation in infant from birth to 6 months Other variables evaluated in the study include gestational age, birth weight, mother's age, fathers level of education and gender.
N	151 infants. 208 infants originally enrolled (73%)	278 children	2879 infants. 3000 originally included follow up at 6 month was 96%
Population/study information	Investigated infants aged less than 9 months who were admitted to a hospital in Melbourne for examination into persistent crying/distress. Study took place between 1995 and 1998. Infants included in the study were aged between 0.5 to 8.2 months old. Crying and fussing were charted for 24 h, and parents completed a validated questionnaire on reflux symptoms. All infants underwent oesophageal 24-h pH monitoring. Reflux medications were ceased at least 48 h before the study. A diary was kept on feeding details and posture. Records were computer analysed for the total number of reflux episodes, duration of reflux episodes, and percentage of time with an oesophageal pH< 4.0. A fractional reflux time (FRT) of greater than 10% was considered abnormal.	The study was conducted at the Pediatric Hospital, Princess Margaret Hospital in Perth. Author's carried out a retrospective audit of 328 children who had undergone upper gastrointestinal endoscopy in the years 1995, 1999 and 2004. Of the 328 patients 32 were excluded because of structural abnormalities, inflammatory bowel disease or multiple biopsies. Macroscopic oesophageal findings were obtained from endoscopy notes for 278 of the 296 patients. Macroscopic appearance of the oesophagus at endoscopy, original histological findings and diagnosis were recorded for each child. Biopsy specimens were blindly re-evaluated, with re-coded histological diagnoses compared with original reports.	The study was carried out in 1999 in Italy. 150 paediatricians distributed throughout Italy followed 20 consecutive infants from birth to 6 months. The pediatrician collected data on the infant using a standard clinical chart. The presence of gastrointestinal symptoms relating to GOR were evaluated. Symptoms were recorded whenever the parents requested a clinical check-up or during a set monthly examination. Regurgitation was defined as the loss of a small part of the meal, without retching Type of feeding at entry to the study; 2332 infants (81%) were breastfed, 230 (8%) were mixed-fed and 317 (11%) were bottle-fed

Quality	P	0	0
Results	Twenty-seven (17.9%) of infants with persistent crying had pathological GOR with an FRT >10% Crying and fussing time per 24 h correlated with neither the number of reflux episodes per 24 h (*P* =0.68) nor the FRT (*P* =0.84) There was no significant association between total crying duration per 24 hours and FRT (*P*=0.84) or the number of reflux episodes (*P*=0.68). There was no association between back-arching and acid reflux.	The prevalence of eosinophilic oesophagitis in WA increased over the decade 1995–2004, rising from 0.05 to 0.89 per 10 000 children (18-fold increase). Patients with eosinophilic oesophagitis had a significant increase in the median number of eosinophils by year: 1995, 37; 1999, 41; and 2004, 80	664/2879 (23%) infants suffered from regurgitation during the study period. Infants with regurgitation had a lower birth weight and gestational age than those without this symptom (3213±461 g vs 3279±453 g; *P* < 0.001 for birth weight; 38.98±1.36 weeks vs39.17±1.48 weeks; *P* < 0.005 for gestational age). No difference was observed in regards to type of feeding and regurgitation. Paediatricians suggested a change in feeding method in 414/664 (62.3%) infants with regurgitation
Effect on risk	Authors concluded that in the absence of frequent regurgitation or feeding difficulties a direct causal relationship between persistent infant distress and pathological GOR is unlikely.	There was an increase in the prevalence of eosinophilic oesophagitis between 1995 and 2004. Author's note that although this may be partially accounted for by diagnostic shift and increasing awareness of the significance of mucosal eosinophilia, there was also an increase in severity of inflammation, with increasing eosinophil count and associated features of inflammation in oesophageal biopsy specimens over the study period.	Regurgitation is common in infants during the first 6 months after birth. Results from the study suggest low birth weight and low gestational age is associated with the onset of regurgitation and feeding habits do not influence the onset of regurgitation.
Clinical importance	1	4	4
Clinical relevance	1	1	1

Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Reference	**Martin et al. (2007)**	**Horvath et al. (2008)**	**Orenstein et al. (2009)**
Type of study	Editorial in the Journal of Pediatrics	Meta-analyses	RCT
Level of evidence		I (aetiology)	II (intervention)
Definition of breastfeeding	Not defined	Poorly defined	Not defined
Intervention/ comparator	Optimal positioning for preterm infants to reduce the incidence of GOR	thickened formulas vs standard formula	Lansoprazole vs. placebo for 4 weeks for persisting symptoms attributed to GOR
N		877 participants	216 infants. 162 met the inclusion criteria.
Population/study information		Searched databases in May 2008 for articles relating to the efficacy and safety of thickened feeds for the treatment of gastroesophageal reflux in healthy infants Only RCTs that evaluated thickened feeds used in infants for at least several days for the treatment of gastroesophageal reflux were considered for inclusion. 14 RCTs were included with either a parallel or crossover design The feed thickeners used in the studies were carob-bean gum (7 trials), cornstarch (3 trials), rice starch (2 trials), cereal (1 trial), and soy fiber (1 trial)	Study included infants with symptomatic GOR with crying, fussing or irritability during or within one hour after feeding despite at least one week of non-pharmacological management. Infants were recruited from 16 centres (8 in US and 8 in Poland) I 2007. Study comprised of 3 periods; pretreatment (1-2 weeks before randomization), treatment (maximum 4 weeks of study drug treatment) and post-treatment. Parents were required to institute and record several non-pharmacological methods for 7-14 days including reduction of smoking, one or more feeding strategies and one or more positioning strategies.

			The treatment period included randomization to either lansoprazole or a placebo. After one week of double blind treatment infants discontinuing treatment due to inefficiency were eligible for open label lansoprazole. Symptoms of GOR was collected through daily diaries and weekly visits. A parent completed questionnaire on GOR measured the symptoms the infants had. Post-treatment involved telephone calls and a follow up visit.
Quality	N	P	P
Results		Use of thickened formulas compared with standard formula significantly increased the percentage of infants with no regurgitation RR= 2.91 (1.73,4.91), slightly reduced the number of episodes of regurgitation and vomiting per day RR = -1.37 (-2.53, -0.20], and increased weight gain per day (4 RCTs, Weighted MD: 3.55 g/day [2.6 ,4.5],in fixed-effects model, and 3.7 g/day [1.55, 5.80], in random-effects model) Thickened formula had no effect on the reflux index, number of acid gastroesophageal reflux episodes per hour, or number of reflux episodes lasting >5 minutes but significantly reduced the duration of the longest reflux episode of pH < 4 -8.09 [-11.93 to -4.25] (P < .0001).	Lansoprazole and placebo produced identical responder numbers (54%). The treatment groups did not differ significantly in terms of an secondary efficacy measure. Serious adverse events particularly respiratory tract infections occurred in 10 infants on lansoprazole compared to 2 in the placebo group.

		No definitive data showed that one particular thickening agent is more effective than another. No serious adverse effects were noted. No evidence that the thickened foods differed from the control formulas in terms of safety.	
Effect on risk		Thickening foods are only moderately effective in treating GER in otherwise healthy infants. definitive data to show that a particular thickening agent is more effective than another. Authors suggest physicians that feel treating GOR is important to choose a thickening agent based on patient's preference, cost, product availability.	No difference in effect. There are risks associated with the use of lansoprazole.
Clinical importance	4	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y– US & Poland
Applicability	Y	Y	Y – US & Poland

Reference	**van Wijk et al. (2007)**	**Corvaglia et al. (2007)**	**Furuta et al. (2007)**
Type of study	Non- randomised cross over trial	Non-randomised experimental trial	SLR
Level of evidence	III-2 (intervention)	III-2 (intervention)	I (aetiology)
Definition of breastfeeding	Not defined	Not defined	Not defined
Intervention/ comparator	left lateral position (LLP) vs. right lateral position (RLP)	supine position vs. prone position vs. on the right side vs. on the left side	To develop consensus recommendations on the diagnosis and treatment of eosinophillic esophagitis

		Esophageal exposure to acid and non acid GOR	
N	10 infants	22	754 infants and 323 adults
Population/study information	Infants were healthy preterm infants range premenstrual age (33-38 months) studied at a children's hospital in Adelaide. Each infant was studied twice on 2 consecutive days and were subjected to 2 positioning protocols in an RCT. Infants were positioned in the left lateral position (LLP) or the right lateral position (RLP) and then gavage-fed breast milk or formula. After one hour the position was changed to the other side and recording occurred for another 2 hours. The GE rate was determined using a breath test Impedance tracing was analysed for liquid, gas, and mixed reflux findings using established criteria. Manometry tracings were analysed for transient lower esophageal sphincter relaxation (TLESRs).	Premature infants with frequent regurgitation and postprandial desaturation were included in the study. Reflux indexes were analysed with the infants in 4 different positions; supine, prone, on the right side and on the left side. All infants were analysed for 24 hours. Each infant received 8 meals and underwent continues, simultaneous measurement of intraesophageal pH and multichannel electrical impedance. Each subject measurement of GER was recorded in different postural positions. The infants were randomly assigned a different sequence of possible postural combinations	Reviewed English language medical articles in 2006 relating to eosinophillic esphagitis. Most case reports <3 people, review articles, letters to the editor and abstracts only were excluded A committee of 31 physicians determined the quality of the evidence to support the recommendations. A total of 80 studies met the inclusion criteria
Quality	0	P	P
Results	There was more TLESRs and GER episodes in the RLP (median TLESRs= 9.5, median GER= 11.5 episodes/hour)	The mean esophageal exposure to acid and non-acid GER was lower in the prone position (4.4% and 0.3% respectively) and left side	Recommendations were made on epidemiology, natural history, diagnosis and treatment of eosinophillic esophagitis.

	compared to the LLP (median TLSERs = 5.5, median GER= 7.0 episodes/hour) Gastric half emptying time was significantly faster in the RLP first protocol compared with the LLP first protocol (37.0 ± 21.1 vs 61.2 ± 24.8)	(7.5% and 0.7% respectively) than in positions right side (21.4% and 1.2% respectively) and supine (17.6% and 1.3%)	
Effect on risk	A strategy of RLP for the first postprandial hour with a positional change to the left thereafter may be effective in reducing liquid GER in the late postprandial period	The study indicates placing premature infants in a prone or left lateral position during the postprandial period may limit GOR.	
Clinical importance	4	4	1
Clinical relevance	1	1	1
Generalisability	Y	Y- Italy	Y
Applicability	Y	Y- Italy	Y

Reference	**Hegar, Alatas et al. (2009)**	**Hegar, Dewanti et al. (2009)**	**Dwyer & Ponsonby (2009)**
Type of study	Prospective RCT	Prospective Cohort	Narrative Review
Level of evidence	II (intervention)	II (aetiology)	
Definition of breastfeeding	Poorly defined	Poorly defined	Poorly Defined
Intervention/ comparator	Domperidone vs cisapride Evaluated frequency of regurgitation, acid reflux and cardiac side effects	Prevalence and determinants of infant regurgitation	Association between prone sleep position and sudden infant death
N	20 infants	130 infants. Mothers of 163 (80%) newborns originally approached. Follow up at 1 year was 110 (85%)	

Population/study information	Study conducted in 2007 in Brussels, Belgium Study included infants regurgitating >4 times/day since >2 weeks and with reflux-associated symptoms of discomfort, after conservative treatment failure. Infants were randomly assigned to receive either domperidone (n=10) or cisapride (n=10). Received a dose of both 0.8 mg/kg/day, 3 doses/day. The medication was administered about 15 min before a feeding. The randomization was done via a computer-driven system. At baseline, a pH monitoring and QTc determination were performed in all infants. At baseline the reflux index (RI; duration pH was <4.0 over total duration of the pH monitoring) in the oesophagus, the number of reflux episodes, the number of reflux episodes lasting longer than 5 min and the duration of the longest episode were analysed. The	Infants delivered at the Private Public Hospital at Tangerang, Indonesia, during a 3-month period in 2006 were recruited. Infants were followed up for 1 year Parents recorded prospectively the frequency of regurgitation for 1 week before consultation and every month during the first year of life. Follow-up consultation was every month during the first 6 months, and every 2 months during the next 6 months. Mothers were asked at consultation about feeding method, nutrition related symptoms such as food refusal, irritability of infant etc.	Reviewed epidemiological evidence on prone sleep position and sudden infant death. The review focussed on the results from a large cohort study beginning in 1987 in Tasmania. The study conducted by the same authors of the review sought to obtain prospective evidence on a range of hypotheses relating to SIDS.

	second pH monitoring in treatment conditions was performed after 28 ± 1 days. During each day of the intervention period, all parents had to fill in a symptom diary * Domperidone is an anti-dopaminergic agent that facilitates gastric emptying * Cisapride is a mixed serotonergic agent that facilitates the release of acetylcholine at the synapses of the myenteric plexus		
Quality	P	P	N
Results	Between baseline and week 3, the median daily frequency of regurgitation decreased from 6.22 to 1.45 in the cisapride group, and from 4.80 to 1.35 in the domperidone group. Although there was no difference in the frequency of regurgitation between the groups at baseline, week 2 and week 3, the frequency was lower in the cisapride group on week 1. The median RI decreased in the cisapride group from 3.60% to 1.75%, and in the domperidone group only from 2.70% to 2.45% One child treated with cisapride	Daily spilling was highest during the first month of life (73%) and decreased gradually to 50% during the fifth month of life. During the first 2 months of life, 20% of the infants regurgitated more than four times per day. After the age of 12 months, 4% of the infants had daily regurgitations. Exclusively breastfed infants regurgitated less than partially breastfed infants. The difference is statistically significant at 2, 3 and 6 months. Weight gain between birth and 4 months of age was statistically significantly smaller in infants	Their author's previous prospective study revealed a risk ratio of 4.5 (1.3,15.4). Their case-control study obtained an odds ratio of 3.5 (1.6,7.5) The authors estimated that advice to place infants supine to sleep may have saved in the order of 850 infants annually in Australia and other countries.

	developed a significant QT prolongation.	regurgitating more than four times a day (2903 g) compared with infants who never regurgitate (3015 g)	
Effect on risk	The clinical efficacy of domperidone and cisapride was significant and comparable regarding the frequency of regurgitation. Acid reflux dereased more in the cisapride group but domperidone has a better safety profile Authors point out there was no control group in present study therefore the findings should be regarded with caution.	Regurgitation in infancy is common, decreasing from birth, and tends to disappear by 12 months of age. Results show a transient decrease in weight gain related to the frequency of regurgitation.	The prone sleep position is associated with increased risks of SIDS. Authors advise that sleeping infants not be placed in the prone position.
Clinical importance	4	4	4
Clinical relevance	1	1	1
Generalisability	Y– Belgium	Y – Indonesia	Y
Applicability	Y – Belgium	Y – Indonesia	Y

Reference	**Omari (2008)**	**Vandenplas et al. (2009)**
Type of study	Narrative Review	Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)
Level of evidence		

Definition of breastfeeding	Not defined	
Intervention/ comparator		The purpose of these guidelines is to provide pediatricians and pediatric subspecialists with a common resource for the evaluation and management of patients with gastroesophageal reflux (GER) and gastroesophageal reflux disease (GERD).
N		
Population/study information	Review published in Australia Evaluates the use of left side positioning as a method for the treatment of GOR or related symptoms in infants < 6 months of age	An international panel of pediatric gastroenterologists and epidemiologists developed the guidelines. The guidelines were based on the Delphi principle. Statements were based on SLRs using the best available evidence. More than 600 articles were reviewed for this work.
Quality	N	P
Results	Based on the evidence the authors conclude that there is physiological evidence that left side positioning will reduce the number of reflux events in infants. It is a practical and inexpensive non-pharmacological response to controlling GOR	
Effect on risk		
Clinical importance	4	
Clinical relevance	1	1
Generalisability	Y	Y
Applicability	Y	Y

Reference	**MacLennan et al. (2010)**	**Vandenplas et al. (2010)**
Type of study	Cochrane Review	Open intervention study (Case series; pre test/post test)
Level of evidence	I (aetiology)	IV (intervention)

Definition of breastfeeding	Not defined	Not defined
Intervention/ comparator	cisapride vs placebo vs non-surgical treatments for symptoms of GOR and risk of adverse effects	40° supine body position on infant regurgitation, reflux-associated symptoms and acid reflux.
N	Trials that measured the risk of adverse events with cisapride included 190 participants Trials compared symptoms of GOR after treatment with cisapride or no treatment included including 262 participants	30 infants. 52 originally approached (58%)
Population/study information	Searched databases in 2009 for RCTs comparing oral cisapride therapy with placebo or other non-surgical treatments for children diagnosed with GOR. (excluded trials in which majority of subjects were less than 28 days of age) Ten trials met the inclusion criteria. Eight trials compared symptoms of GOR after treatment with cisapride or no treatment. One study compared cisapride with two dietary interventions, carob bean thickener and corn syrup Adverse events (principally diarrhoea) were reported in four trials	Between 2007 and 2008, the MC-AR Bed was proposed to parents presenting with infants who were referred because of frequent regurgitation (>4 times/day) of at least 2 weeks duration, infant distress time related to feeding Thirty of 52 infants presenting with GOR were evaluated in the Multicare AR-Bed. The Infant- Gastroesophageal Reflux Questionnaire-Revised (I-GERQ-R) and an oesophageal pH monitoring were performed at inclusion and after 1 week.
Quality	P	0
Results	The pooled OR (random-effects model) for cisapride versus placebo for 'same or worse' symptoms versus 'improvement' based on seven trials was 0.34 (0.10, 1.19). There were fewer adverse events in the non-treatment group than in the cisapride group but the difference was not statistically significant (OR for cisapride versus placebo 1.86 [0.88 to 3.93])	8/30 (27%) infants did not tolerate the 40° positioning, and had to be taken out of the study within the first 2 days. In 22/30 (73%) infants the I-GERQ-R and acid reflux decreased significantly with the Multicare AR-Bed. I-GERQ-R showed a clinical meaningful improvement of at least five points in 11/22 (50%) infants tolerating the MC-AR Bed

		The mean duration of use of the Multicare AR-Bed was 3.2 months.
Effect on risk	The authors found no clear evidence that cisapride reduces symptoms of GOR. The midpoint estimate of the summary OR was 0.34 however the authors warn that this result is likely to be an overestimate of the benefits of cisapride due to publication bias. The heterogeneity between studies means results should be interpreted with caution.	A specially made bed that nurses the infant at 40° supine body position will possibly reduced regurgitation, acid reflux and reflux associated symptoms. However as the intervention withdrawal rate was substantial further research is necessary.
Clinical importance	1	4
Clinical relevance	1	1
Generalisability	Y	Y – Belgium
Applicability	Y	Y – Belgium

References used in the body of evidence tables: (Heacock, Jeffery et al. 1992; Ewer, Durbin et al. 1996; Nelson, Chen et al. 1997; Iacono, Merolla et al. 2005; Cherian, Smith et al. 2006; Heine, Jordan et al. 2006; Corvaglia, Rotatori et al. 2007; Furuta, Liacouras et al. 2007; Martin, Di Fiore et al. 2007; van Wijk, Benninga et al. 2007; Horvath, Dziechciarz et al. 2008; Omari 2008; Dwyer and Ponsonby 2009; Hegar, Alatas et al. 2009; Hegar, Dewanti et al. 2009; Orenstein, Hassall et al. 2009; Vandenplas, Rudolph et al. 2009; Maclennan 2010; Vandenplas, De Schepper et al. 2010)

Ankyloglossia

Search results
The initial search of the databases included 185 references on ankyloglossia. Data were extracted from 24 references, 9 of the publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the prevalence of ankyloglossia in infants. The studies on the treatment of ankyloglossia are difficult to interpret as only the most severe cases appear to be included in trials. Further research is needed into the definition of cases that require interventional treatment rather than conservative management (see the ABM protocol below)

PREVALENCE OF ANKYLOGLOSSIA IN INFANTS

What is the prevalence of ankyloglossia in infants?		
Draft Evidence statement		Approximately 3-10% of infants are born with ankyloglossia.
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	2 studies [1 SLR of 24 studies, 1 cross-sectional (1P,10)]
Consistency	Satisfactory	Criteria used for identifying ankyloglossia varied greatly in all studies. 5 studies in SLR (using different diagnostic criteria) found a prevalence of ankyloglossia of between 4% and 10%. Cross sectional study found 3.2% of term infants had ankyloglossia.
Clinical impact	Prevalence only	Ankyloglossia is a relatively common finding in infants
Generalisability	Satisfactory	Most studies conducted in US or UK
Applicability	Satisfactory	Results are applicable to Australian women

The study included in the body of evidence statement is shown in the Table below

EFFECT OF ANKYLOGLOSSIA IN INFANTS

Does ankyloglossia affect breastfeeding outcomes?		
Draft Evidence statement		Ankyloglossia is associated with an increased risk of breastfeeding difficulties
Draft Grade		D
Component	**Rating**	**Notes**
Evidence Base	Poor	3 studies [2 cohort, 1 RCT (20, 1N)]
Consistency	Satisfactory	ALL studies show ankyloglossia is associated with breastfeeding difficulties.
Clinical impact	Satisfactory	Studies suggest breastfeeding difficulties experienced by mother's of infant's with ankyloglossia could reduce duration and level of breastfeeding
Generalisability	Satisfactory	Studies were conducted in the US and UK.
Applicability	Satisfactory	Results are applicable to Australian women

The study included in the body of evidence statement is shown in the Table below

The cohort study conducted by Griffith on 215 infants with ankyloglossia found prior to division, 88% of infants had difficulty latching, 77% of mothers experienced nipple trauma, and 72% had a continuous feeding cycle. Of the sample 104 mothers (48%) were expressing

and cup- or bottle-feeding, as breastfeeding was too painful and inefficient despite expressing their desire to breastfeed (Griffiths 2004).

In the RCT by Hogan and colleagues the researchers reported that 88 out of the 201 infants with tongue tie had problems with feeding (44%) (Hogan, Westcott et al. 2005). A cohort study found that breastfeeding difficulties were experienced by 9 (25%) of the mothers of infants with ankyloglossia compared with 1 (3%) of the control mothers (P<01) (Messner, Lalakea et al. 2000). Of the 36 mothers of affected infants who were followed up and who intended to breastfeed, 30 (83%) successfully breastfed their infants for at least 2 months, compared with 33 (92%) of the 36 mothers of infants in the matched control group (P = .29).

TREATMENT OF ANKYLOGLOSSIA IN INFANTS

How effective is frenotomy in the treatment of ankyloglossia?		
Draft Evidence statement		Frenotomy is an effective treatment for ankyloglossia
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	3 studies [1 SLR, 2 case-series (pre-test, post-test) (1P,20)]
Consistency	Good	ALL studies show a positive benefit of frenotomy with no serious complications
Clinical impact	Satisfactory	Frenotomy improved nipple pain, infant sucking and latch, and increased breastfeeding duration.
Generalisability	Good	Most studies conducted in developed countries, including Australia
Applicability	Good	Results are applicable to Australian women

The study included in the body of evidence statement is shown in the Table below

ABM protocol for ankyloglossia

The ABM report that ankyloglossia occurs in approximately 3.2% to 4.8% of term infants at and in 12.8% of infants with breastfeeding problems. The ABM define partial ankyloglossia as "the presence of a sublingual frenulum which changes the appearance and/or function of the infant's tongue because of its decreased length, lack of elasticity or attachment too distal beneath the tongue or too close to or onto the gingival ridge. Infants with ankyloglossia are at an increased risk of breastfeeding difficulties; 25% in affected versus 3% in unaffected infants. The ABM support the use of the HATLFF tool for the diagnosis and assessment of ankyloglossia. The ABM state that conservative management of tongue-tie may be sufficient, requiring no intervention beyond breastfeeding assistance, parental education, and reassurance (Ballard, Chantry et al.).

In summary the prevalence of ankyloglossia is reported ranging from 3-10%. Diagnosis is hampered by inconsistent definitions, although the use of the Hazelbaker Assessment Tool for Lingual Frenulum Function (HATLFF) provides a tool for objective assessment. There is a large range of severity of ankyloglossia and it appears that only the severe degrees require surgical correction to improve breastfeeding function (Amir, James et al. 2006).

Studies used to make evidence statement for ankyloglossia

Reference	**Messner et al. 2000**	**Ballard et al. 2002 (included in Segal SLR below)**	**Griffiths 2004 (included in Segal SLR below)**	**Hogan et al. 2005 (included in Segal SLR below)**
Type of study	Cohort	case-series	Prospective cohort study	RCT
Level of evidence	II (aetiology)	IV (aetiology)	II (aetiology)	II (intervention)
Definition of breastfeeding	Breastfeeding for a minimum of 2 months postpartum was used as the criterion for determining the percentage of infants who were successfully breastfed. Mothers were considered to be actively breastfeeding for as long as the breastfeeding continued, whether or not the feeding of infants was supplemented with formula; exclusive use of breastfeeding was not required	Not stated	Not stated	Not stated
Intervention/ comparator	Current medical treatment for tongue tie (referral to a lactation consultant) vs. immediate division	frenuloplasty procedure vs solving specific breastfeeding problems	division of tongue tie without an anaesthetic	Current medical treatment for tongue tie (referral to a lactation consultant) vs. immediate division
N	36 mother-infant dyads enrolled in study (50 approached, 9 mothers did not enroll, 5 lost to follow up) 1041 infants initially assessed	3036 infants. Follow up was 99%	215. Follow up at 3 months was 100%	201 infants had tongue tie. 57 infants were part of RCT. Controls= 29 Division= 28

Population/study information	Sample comprised of infants delivered at Lucile Packard Children's Hospital in California, who were admitted to the well-baby nursery "university service" between 1997 and 1998 (n=1041). Newborns underwent oral cavity examination by the attending physician to determine the presence of ankyloglossia as part of the routine newborn evaluation. Of the 1041 newborns examined, 50 were found to have ankyloglossia. Mothers were contacted by telephone each month for 6 months or until they ceased breastfeeding Difficulty with breastfeeding was defined as nipple pain lasting longer than 6 weeks and/or difficulty of the baby latching onto the breast	2763 breastfeeding inpatient infants and 273 outpatient infants with breastfeeding problems in Ohio. Examined all infants for presence of ankyloglossia. Frenoplasty procedure occurred in 123 infants with significant ankyloglossia. Assessed the dyad for infant latch and maternal nipple pain pre and post frenoplasty.	Sample consisted of infants whose tongue ties were divided between December 1999 and December 2001 in the UK. Infants < 3 months. Mothers were contacted at 24 hours and at 3 months after division	1866 babies born in the Princess Anne Hospital and Birth Centres in Southampton in 2002 were actively inspected for a tongue tie. 201 infants had tongue tie. 88/201 had breastfeeding or bottle-feeding problems relating to tongue tie. 57 of these enrolled in RCT (40 breastfed and 17 artificially-fed.) Control group received advice and help about positioning and attachment or different teats and positioning if bottle feeding. If this support and plan of care failed to produce any improvement after 48 h, division was offered to these mothers. Immediate division occurred in division group. Telephone follow-up occurred at 24 h, weekly for 4 weeks and after 4 months post division.
Quality	0	0 (No to 2.3, 7.6)	N	0 (no to 2.3, 5.1)
Results	Fifty newborns were identified with ankyloglossia, for an incidence of 4.8%	Ankyloglossia was diagnosed in 88 (3.2%) of the inpatients and in 35 (12.8%) of the outpatients.	Prior to division, 192 of the 215 infants (88%) had difficulty in latching on to the breast; 167 of their mothers	10.7% of infants out of 1866 sample had tongue tie 88 out of the 201 infants with

	Of the 36 mothers of affected infants who were followed up and who intended to breastfeed, 30 (83%) successfully breastfed their infants for at least 2 months, compared with 33 (92%) of the 36 mothers of infants in the matched control group (P = .29). Breastfeeding difficulties were experienced by 9 (25%) of the mothers of infants with ankyloglossia compared with 1 (3%) of the control mothers (P<01).	Altogether 4.2% of infants had ankylglossia (3.5-5.0) Latch improved in all cases, and maternal pain levels, according to an analog scale of 1 to 10, fell significantly after the procedure: pre frenolplasty :6.9 ±2.31 post -frenoplasty: 1.2 ±1.52	(77%) had painful, sore, or bleeding nipples; and 156 (72%) had a "continuous" feeding cycle (ie, the infant fed inefficiently, became tired and fell asleep, but was still hungry, so slept only for a short time before waking to feed inefficiently again). Overall, 112 mother-infant pairs (52%) experienced all 3 symptoms; 104 mothers (48%) were expressing and cup- or bottlefeeding, as breastfeeding was too painful and inefficient, although they were keen to restart breastfeeding. 124/215 (57%) had improved feeding (according to mothers assessment of efficiency of the latch, nipple pain, infant's feeding and sleeping cycle) immediately 174/215 (80%) had improved feeding at 24 h 139/215 (65%) were still breastfed at 3 mo (any breastfeeding) 204/215 could extend tongue out of mouth at 3 mo	tongue tie had problems with feeding (44%) and of these 75 were breast-fed Control group= 28/ 29 (97%) did not improve after lactation consultant. At 48 h, these 28 were offered division, which all accepted, and 27 improved (96%) and fed normally. Division group= 27/28 infants improved after immediate division and fed normally but one remained on a nipple shield Division of the tongue-tie babies resulted in improved feeding in 54/57 (95%) babies
Effect on risk	Ankyloglossia affects breastfeeding in selected infants.	Ankyloglossia is a relatively common finding in infants and is frequently associated	Division of tongue ties and subsequent support by a qualified lactation consultant,	Tongue-ties can affect feeding. Divisions are safe, successful and improve

		with poor infant latch and maternal nipple pain. Frenuloplasty, in the presence of significant ankyloglossia, seems to be a successful approach to the facilitation of breastfeeding.	might ensure that even more mothers and infants benefit from breastfeeding	feeding for mother and baby significantly better than the intensive skilled support of a lactation consultant.
Clinical importance	4	4	4	4
Clinical relevance	1	1	1	1
Generalisability	Y – US	Y- US	Y- UK	Y – UK
Applicability	Y	Y	Y	Y

Reference	**Dollberg et al. 2006**	**Srinivasan et al. 2006**	**Segal et al. 2007**	**Geddes et al. 2008**
Type of study	case-series (pre-test, post-test)	case-series (pre-test, post-test)	SLR (majority on case-studies)	case-series (pre-test, post-test)
Level of evidence	IV (intervention)	IV (intervention)	I (aetiology)	IV (intervention)
Definition of breastfeeding	Not stated	Not stated	Not stated	Not stated
Intervention/ comparator	Sequence of ankyloglossia management Sequence one; frenotomy, breastfeeding, sham, breastfeeding vs Sequence one; sham, breastfeeding, frenotomy, breastfeeding	Frenotomy procedure		Frenotomy procedure
N	25 mother-infant dyads	27 mother–infant dyads. Follow up at 3 months was 92%	24 studies	24 mother-infant dyads

<table>
<tr><td>Population/study information</td><td>Mothers referred to the lactation clinic at the Lis Maternity Hospital, Israel because of nipple pain. Infants randomized to sequences one= 14 sequences two = 11

After each sham or frenotomy procedure, a latch score and pain score was obtained.</td><td>Infants < 12 weeks were recruited from the Goldfarb Breastfeeding Program between Aug 2004 and Feb 2005. All infants had ankyloglossia and were selected based on the Frenotomy Decision Rule for Breastfeeding Infants (FDRBI) tool.
Frenotomy procedure occurred followed by repeat latch and pain assessments.
A telephone questionnaire was administered 3 months post frenotomy</td><td>Searched studies between 1966 -2006 on ankyloglossia. 183 articles found in initial search.

Case reports, case series, retrospective studies, prospective controlled studies, and randomized controlled trials were included in the analysis.</td><td>Infants experiencing persistent breastfeeding difficulties despite receiving professional advice were referred from King Edward Memorial Hospital or private health centres in Perth.
Mean infant age: 33 ±28 days.

Submental ultrasound scans of the oral cavity were performed before and >7 days after frenulotomy. Milk transfer, pain, and LATCH scores were recorded before and after frenulotomy.
Infant milk intake was measured by using the test-weigh method.</td></tr>
<tr><td>Quality</td><td>N</td><td>0 (No to 7.6)</td><td>P</td><td>0 (No to 2.3, 7.6)</td></tr>
<tr><td>Results</td><td>Significant decrease in pain score after frenotomy than after sham pain score (P=.001).

In the 25 mothers who were treated because of pain or nipple trauma, pain score decreased from 7.1 ± 1.9 to 5.3 ± 2.2 after frenotomy</td><td>Improvement in mean latch score, according to the LATCH tool, between pre-frenotomy and post-frenotomy = 2.5 (2.038, 2.925)

Decrease in mean pain rating, according to pain rating index tool, between pre-frenotomy and post-frenotomy = 11.4 (-15.544, -7.345)</td><td>Criteria used for identifying ankyloglossia varied greatly in all studies.

5 studies (using different diagnostic criteria) found a prevalence of ankyloglossia of between 4% and 10%.

The results of 6 non-randomized studies and 1 randomized study assessing the effectiveness of frenotomy for improving nipple pain, sucking, latch, and continuation of</td><td>Characteristics of the Breastfeed Infants Monitored Before and>7 Days After Frenulotomy

<table>
<tr><td>Variable</td><td>Pre-frenulotomy</td><td>Post-frenulotomy</td></tr>
<tr><td>Milk intake</td><td>50.5±29.1 g</td><td>69.1±31.9 g</td></tr>
<tr><td>Milk transfer (mL/min)</td><td>5.6±3.0 g</td><td>10.5±5.5 g</td></tr>
<tr><td>LATCH score</td><td>7.9±1.4</td><td>9.4±0.8</td></tr>
<tr><td>Pain</td><td>3.6±3.0</td><td>0.5±1.2</td></tr>
</table>
</td></tr>
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			breastfeeding all suggested frenotomy was beneficial. No serious adverse events were reported.	score
Effect on risk	Frenotomy alleviates nipple pain immediately after frenotomy. Frenotomy is an effective therapy for ankyloglossia.	Timely frenotomy and breastfeeding counselling is an effective intervention, improving latch and decreasing nipple pain.	Diagnostic criteria for ankyloglossia are needed Frenotomy is likely an effective treatment	Infants with ankyloglossia showed less compression of the nipple by the tongue post-frenulotomy, which was associated with improved breastfeeding (better attachment, increased milk transfer, and less maternal pain). In the assessment of breastfeeding difficulties, ankyloglossia should be considered as a potential cause.
Clinical importance	4	4	4	4
Clinical relevance	1	1	1	1
Generalisability	Y – Israel	Y	Y	Y
Applicability	Y	Y	Y	Y

References used in body of evidence table: (Messner, Lalakea et al. 2000; Ballard, Auer et al. 2002; Griffiths 2004; Hogan, Westcott et al. 2005; Amir, James et al. 2006; Dollberg, Botzer et al. 2006; Srinivasan, Dobrich et al. 2006; Segal, Stephenson et al. 2007; Geddes, Langton et al. 2008)

Post partum weight loss

Insufficient evidence to make a statement on the effects of breastfeeding alone on post partum weight loss. The Cochrane review suggests a benefit of breastfeeding and exercise by the mother in post partum weight loss, but the sample sizes of 245 suggests the need for further studies.

One further study has been published since the Ip and Cochrane reviews, the study from Hong Kong by To and Wong, which used body composition as the end point. However the sample was small and the method used (bio-electric impedance) is not the most accurate.

Studies used to make the statement on post partum weight loss (breastfeeding and or exercise)

Reference	**Amorim Adegboye Cochrane review 2008**	**IP 2007 Evidence Report/ Technology Assessment**	**IP 2007 Evidence Report/ Technology Assessment**	**To, Wong 2009 ANZ J Obs Gynae**
Type of study	SLR	SLR	SLR	Cohort
Level of evidence	I (aetiology)	I (aetiology)	I (aetiology)	II (aetiology)
Definition of breastfeeding	EBF –defined as a child being fed only on mother's milk	Varying descriptions	Varying descriptions	Any breastfeeding
Intervention Comparator	Exercise /diet/breastfeeding	Intensity of breastfeeding/less intense or none	Intensity of breastfeeding/less intense or none	Any breastfeeding <16 weeks and >16 weeks
N	245 women in six trials	2097	4953	104
Population/study information	6 trials, RCT and quasi-randomised	SLR of breastfeeding and postpartum weight changes. Five prospective cohort studies involving a total of 2097 parous women were identified. Followup durations ranged from 6 months to 15 years. Two studies were conducted in Sweden, two in the United States, and one in Canada. Four studies were of moderate methodological quality (Grade B), and one of poor methodological quality (Grade C).	SLR of Relationship between breastfeeding and return to pre-pregnancy weight A total of three prospective cohort studies were identified, involving 4,318, 540, and 95 women, with follow up durations of 3 years, 1 year and 1.5 years postpartum, respectively. All studies were conducted in the United States.	Hong Kong >36 weeks No complications Body composition measured by bio-electric impedance.
Quality	P	P	P	P
Results	Exercise plus Diet resulted in more weight loss post partum. preferable to lose weight through a combination of dieting and exercise to dieting alone because	The results from the five studies were inconsistent. Among the three studies that examined postpartum weight changes and compared women who exclusively breastfed with women	Overall effect of breastfeeding on return to pre-pregnancy weight or weight retention was negligible. The average weight retention was only within 1 kg range at 1 to 2 years postpartum	The group that was lactating longer had lower residual postnatal weight gain (0.58 kg) as compared to the non-lactating women (2.09 kg; *P* = 0.004). There was no

	exercise is thought to improve circulation and heart fitness, and to preserve lean body mass	who partially breastfed or exclusively bottle-fed, none of them found a significant relationship between weight loss and breastfeeding among the comparison groups		significant difference in the postnatal body fat changes between the lactating and non-lactating group at the postnatal assessment
Effect on risk	Positive (weight loss)	none	none	
Clinical importance	1	1	1	0
Clinical relevance	1	2	1	0
Generalisability	Y	Y	Y	N
Applicability	Y	Y	Y	N

Notes on postpartum weight loss

Ip summarises the issue in the following way (Ip, Chung et al. 2007)

" Despite the fact that the average weight retention associated with child bearing is modest, estimated at approximately 1.51 kg (s.d.=5.95 kg) for some, there is some risk of major weight gain with pregnancy. Ohlin and Rossner 1990 reported changes in body weight that ranged from –12.3 to +26.5 kg from preconception to 1 year postpartum. In various studies, the proportion of women retaining 5 kg or more after 6 months postpartum ranged from 14 to 20%. Studies of the impact of physiological and behavioral influences, such as dietary intake, physical activity, and lactation on postpartum weight change reported mixed results. Studies of postpartum weight changes in lactating and non-lactating women also were equivocal within and across populations, with some showing that the length and intensity of breastfeeding were associated with less weight retention after pregnancy, while other studies reported that women who fed their infants formula lost more weight than women who nursed their infants.

Commonly considered confounders in the relationship between return to pre-pregnancy weight or post-partum weight change and breastfeeding were pre-pregnancy weight or BMI, age, educational level, physical activity, parity, smoking status, dieting practice, and ethnicity."

They then concluded:

"Based on the results from three prospective cohort studies, we concluded that the overall effect of breastfeeding on return-to-pre-pregnancy weight (weight change from prepregnancy or first trimester to 1 to 2 year postpartum) was negligible (less than 1 kg). Results from four prospective cohort studies showed that the effects of breastfeeding on postpartum weight loss were unclear. All seven studies consistently suggested that many other factors have larger effects on weight retention or postpartum weight loss than breastfeeding. Examples of which included annual household income, baseline BMI, ethnicity, gestational weight gain, and energy intake. Undoubtedly, all these factors need to be carefully considered in any future investigation of the relationship between breastfeeding and postpartum weight changes."

V Expressing and storing breast milk

Expression of Breast milk

Summary
The Cochrane review showed that electrical or foot operated pumps are more efficient than hand expression. There have been no further SLRs since the Cochrane review.

Introduction
Expression of breast milk is commonly used in Australia. An online survey of Australian mothers who were members of the ABA found that 98% of respondent s (n= 903) had expressed breast milk but only 30% of the sample responded (Clemons and Amir 2010). A similarly high proportion of US mothers also express. Data from the US National Infant Feeding Practices Study found that 92% of breastfeeding women had expressed breast milk at some time (Labiner-Wolfe, Fein et al. 2008). In the Perth Infant Feeding Study 76% of mothers at one month increasing to 84% at 5 months had expressed their breast milk (Win, Binns et al. 2006).

Cochrane Review Methods of milk expression for lactating women (Becker, McCormick et al. 2008)
"Background: Breastfeeding is important for health. However, not all infants can feed at the breast and effective methods of expressing milk have not been adequately evaluated.
Objectives: To assess acceptability, effectiveness, safety, effect on milk composition, bacterial contamination of milk and cost implications of a range of methods of milk expression, including hand expression and manual, battery and electric pumps.
Search strategy: We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (December 2007), CINAHL (1982 to July 2007), hand searched relevant journals and conference proceedings, scanned secondary references and contacted experts in the field.
Selection criteria: Randomised and quasi-randomised controlled trials that compared one method or technique of milk expression or pumping with other(s), at any time after birth, and cross-over trials that commenced at least 28 days after birth.
Data collection and analysis: Two authors independently assessed trial quality and extracted data. We sought additional information from the trial authors.
Main results: Twelve studies met the inclusion criteria of which six (397 mothers) provided data that could be used in the analyses. Compared with hand expression, one study found a significantly greater total volume of milk expressed over six days both with the electrical pump (373.10 ml, 95% confidence interval (CI) 161.09 to 585.11), and with the foot-operated pump (212.10 ml, 95% CI 9.39 to 414.81); however, the difference found between the foot pump and the electric pump was not significant. Mothers provided with a relaxation tape produced a greater volume of milk at one expression than women not provided with the tape (34.70 ml, 95% CI 9.51 to 59.89). Simultaneous pumping took less time than sequential pumping in one study (3.50 hours/week, 95% CI 1.39 to 5.61). No evidence of difference was found in volume with simultaneous or sequential pumping, or for milk contamination, breastfeeding at discharge, fat content of milk, serum prolactin by method of pumping. Maternal satisfaction, adverse effects on mothers and economic effects of interventions were poorly reported.
Authors' conclusions: Mothers appear to obtain greater total volumes of milk in six days after birth using the electric or foot powered pump tested compared to hand expression, and a

greater volume at one expression during the second week when provided with a relaxation tape. Simultaneous pumping takes less time compared to sequential pumping. Further research with larger numbers and more comprehensive reporting is needed, and mothers' reasons for expressing linked to their evaluation of effectiveness rather than market-led research on equipment performance."

Academy of Breastfeeding Medicine Protocol

The Academy of Breastfeeding Medicine has prepared a protocol for expression and storage of breast milk (Academy of Breastfeeding Medicine 2010). They state: *"Women should wash their hands with soap and water, or a waterless hand cleanser if their hands don't appear dirty, before milk expression. Unclean hands may transmit viruses and bacteria, some of which can cause illness. Studies show that human milk containing fewer bacteria at the time of expression develops less bacterial growth during storage and has higher protein levels compared to milk that has an abundance of bacteria. Milk expression can be achieved by hand or by a pump. There are many factors involved in pump selection, such as cost, availability of pumps, access to electricity, anticipated frequency and ongoing duration of expression, time constraints, comfort, etc. As long as the appropriate steps are taken for hand cleansing and cleaning of pump parts as per the pump manufacturer, there does not seem to be a difference in milk contamination with pumping versus manual expression."*

Indications for mothers to express

No SLR's were identified on this subject.

In the Perth Infant feeding studies there was an increase in the number of mothers expressing breast milk in the decade between the studies. In these studies the most common reasons given by mothers to express breast milk was to manage difficulties in breastfeeding, usually due to distended breasts or mastitis (Binns and Lee 2006; Win, Binns et al. 2006).

In the USA most descriptive papers are in the context of mothers expressing breast milk in the context of returning to paid employment.

There have been clinical reports that expression is being used for assessment of breast milk insufficiency. The volume of expressed breast milk is measured and on the basis of volume a decision is made on breast milk insufficiency. There are no published studies in the English language that have evaluated this procedure. There are a number of theoretical risks associated with this procedure:

- Mothers not familiar with expression may have difficulty with the procedure
- There is no evidence that measurement of 1 or 2 breast milk expressions is an assessment of breast milk adequacy.
- There are better ways of assessing breast milk adequacy
- There are risks to the infant if breastfeeding is discontinued.

Storage of Expressed Breast milk

What is the optimum storage time of expressed breast milk?		
Draft Evidence statement		The optimum storage time of breast milk under clean conditions in a refrigerator 0-4C is around 96 hours
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	poor	1 narrative review, several experimental studies
Consistency	poor	Inconsistent end points, different storage conditions
Clinical impact	Poor	
Generalisability	Poor	Generalisable to Australian women and the review includes Australian data
Applicability	good	Directly applicable to Australia

This body of evidence statement is based on best current practice. The studies published since 2000 do not provide any evidence to change the recommendations of the 2003 NHMRC Guidelines.

Studies Included in the narrative review

1. **Refrigerator Storage of Expressed Human Milk in the Neonatal Intensive Care Unit Slutzah (Slutzah, Codipilly et al. 2010)**

Objective: To provide recommendations for refrigerator storage of human milk, the overall integrity (bacterial growth, cell counts, and component concentrations) of milk was examined during 96 hours of storage at 4_C.
Study design: Fresh milk samples (n = 36) were divided and stored at 4C for 0, 24, 48, 72, and 96 hours. At each time, pH, white cell count, and osmolality were measured and additional samples were stored at -80C until analysed for bacteria and concentrations of lactoferrin, secretory (s)IgA, fat, fatty acids, and protein.
Results: There were no significant changes for osmolality, total and Gram-negative bacterial colony counts or concentrations of IgA, lactoferrin, and fat. Gram-positive colony counts (2.9 to 1.6 X 10^5 colony-forming units per mL), pH (7.21 to 6.68), white blood cell counts (2.31 to 1.85 X 10^6 cells per mL), and total protein (17.5 to 16.7 g/L) declined, and free fatty acid concentrations increased (0.35 to 1.28 g/L) as storage duration increased, $P < .001$.
Conclusions: Changes were minimal and the overall integrity of milk during refrigerator storage was preserved. Fresh mother's milk may be stored at refrigerator temperature for as long as 96 hours.

2. **Davanza. Storage of Human Milk: Accepting Certain Uncertainties (Davanzo, Travan et al. 2010)**

Davanza reviewed the recommended storage periods under refrigeration (0-4C) and found a wide range of recommendations.
2 Days - Hanna 2004, Lawrence 2005, Silvestre D 2006, Martinez 2007
3 days - Jocson 1997, Ogundele 2000, Santiago 2005a
5 days - Sosa 1987, Academy Breastfeeding Medicine 2004, American Academy of Family Physicians 2008, CDC 2009
8 days - Pardou 1994, Biagioli 2003, La Leche League International 2010, UNICEF/WHO 2009
Different factors concur to determine such an uncertainty, among them the shortage of studies and different biochemical and microbiological criteria used to fix a cut off point beyond

which stored human milk is no longer good/safe. Arbitrariness mainly derives from different attitudes of authorities and health workers in defining an expiration date that, at the current state of the art, continues to be the result of a compromise; we do not want babies consume human milk judged as biologically inadequate, while still promoting breastfeeding and therefore mother-infant health.

He then describes the ethical difficulties of further research: we should not have great expectations on future research on this topic. In fact, it would be unethical to perform a controlled study to find out side effects of "expired human milk" on newborns.

3. ABM Clinical Protocol #8: Human Milk Storage Information for Home Use for Full-Term Infants (Academy of Breastfeeding Medicine 2010)

Milk Storage Guidelines (ABM)

Location of storage	Temperature	Maximum recommended storage duration
Room temperature	16–29C (60–85F)	3–4 hours optimal, 6–8 hours acceptable under very clean conditions
Refrigerator	<4C (39F)	72 hours optimal, 5–8 days under very clean conditions
Freezer	<-4C (24F)	6 months optimal, 12 months acceptable

4. Storage of Expressed Breast milk – extract from the 2003 Infant Feeding Guidelines (National Health and Medical Research Council 2003)

The requirements for storing breast milk are more stringent for sick or premature babies in hospital than for healthy babies at home.

Storing breast milk in hospital

Mothers and health workers should wash their hands thoroughly with soap and water before handling breast milk.

• Breast milk is best used when fresh. A mother should try to provide fresh breast milk daily for her baby; if this is not possible, the milk can be stored in a refrigerator or freezer in sterilised plastic containers.
• Breast milk refrigerated at 4°C for 48 hours suffers little loss of nutrients or immunological properties and the bacterial count is actually reduced.
• Freshly expressed milk should be chilled in the refrigerator before being added to zen milk.
• Warmed milk should be given straight away and any amount left over should be discarded.
• Never refreeze or reheat breast milk.
• Label the container with surname, date, and time of expression.
• Do not thaw or warm breast milk in the microwave.
• Thaw breast milk by placing it in either cool or warm water. Shake the milk gently before using it if it has separated.
• Thawed milk should be used within 24 hours.

Mothers should be given advice about cleaning, storing and sterilising equipment

Storing breast milk at home

Very little special handling of a mother's milk is necessary. Since breast milk is already sterile when it comes from the breast, expressed breast milk is safer to use than prepared infant formula. It can be stored in glass or plastic containers, including sealable plastic bags. Freshly expressed milk can be chilled in the refrigerator and added to frozen milk in the freezer.

The following is a simple guide for mothers storing expressed breast milk at home:

• Wash hands thoroughly with soap and water.
• Refrigerate or freeze milk after expressing.
• Use fresh milk whenever possible.
• Freeze milk that will not be used within two days.
• Use the oldest milk first; date the container at the time of collection.

Storing breast milk for home use

Breast milk status	**Room temperature (26°C or lower)**	**Refrigerator (4°C or lower)**	**Freezer (<-4C)**
Freshly expressed into container	6–8 hours If refrigeration is available store milk there	3–5 days Store at back, where it is coldest	2 weeks in freezer compartment inside refrigerator, 3 months in freezer section of refrigerator with separate door, 6–12 months in deep freeze (–18°C or lower)
Previously frozen—thawed in refrigerator but not warmed	4 hours or less—that is, the next feeding	24 hours	Do not refreeze
Thawed outside refrigerator in warm water	For completion of feeding	4 hours or until next feeding	Do not refreeze
Infant has begun feeding	Only for completion	Discard	Discard

Expression and Breastfeeding duration

An insufficient number of studies were available to make a formal evidence statement. All three cohort studies available showed that mothers who expressed breast milk had a longer duration of breastfeeding. In several narrative reviews or uncontrolled studies, expression of breast milk was advocated as an appropriate measure to enable mothers to return to employment and continue breastfeeding.

More research on breast milk expression and breastfeeding outcomes is needed.

Reference	**Win 2006 Int Breastfeeding Journal**	**Hornbeak 2010 Annals Academy of Medicine**	**Fein 2008 Pediatrics**
Type of study	Cohort prospective	Descriptive population study over different time periods	Cohort study
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	breastfeeding is defined as "any breastfeeding" and included infants who were being exclusively, fully or partially breastfed	Expressed Breastfeeding(breast milk only fed via bottle, with no additional food or non-human liquid), Combination (breast milk and non-breast milk, fed via bottle and breast), and Direct (breast milk only fed via breast).	Any breastfeeding
Intervention **Comparator**	Expression of breast milk in first month	Expression of breast milk	Expressed breast milk Not expressed milk
N	587	3009	810
Population/study information	Perth Infant Feeding Study II Prospective cohort study of mothers delivering in two suburban Perth Hospitals.	Singapore Children STARS Study 2000-2008	Cohort of mothers who returned to work in USA. 810 mothers in Infant Feeding Practices Study II
Quality	P	P	P
Results	Association of expression of breast-milk with the risk of discontinuing any breastfeeding *before 6 months* after adjustment for potential confounders RR = 0.71 (0.52, 0.98) *	In a population-based sample of Singaporean Chinese mothers giving birth from 2000 to 2008, breastfeeding initiation and duration increased over time and were independently associated with higher maternal education. This increase was associated with increased milk expression and complementary feeding.	Feeding the infant from the breast during the work day is the most effective strategy for combining breastfeeding and work.
Effect on risk	Positive (expression increases duration)	positive	Positive
Clinical importance	1	1	1

Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

References used in body of evidence table: (Win, Binns et al. 2006; Fein, Mandal et al. 2008; Hornbeak, Dirani et al. 2010)

Notes on Expression

There were several studies on LBW infants and expression which are out of scope for this review. In the literature the term "pumping" is commonly used to reflect the practice in some countries of the use of mechanical milk expression.

Best Practice Guidelines

The Academy of Breastfeeding Medicine advises that all mothers be taught how to express breast milk before discharge from hospital.

"Breastfeeding mothers will be instructed about:

a. Proper positioning and latch-on
b. Nutritive suckling and swallowing
c. Milk production and release
d. Frequency of feeding/feeding cues
e. Hand expression of breast milk and use of a pump if indicated
f. How to assess if infant is adequately nourished and
g. Reasons for contacting the healthcare professional

These skills will be taught to primiparous and multiparous women, provided in written form, and reviewed before the mother goes home devices.

VI Breastfeeding in specific situations

Absolute and relative contra-indications to breastfeeding

There are two recent reviews of reasons for not breastfeeding, one by WHO-UNICEF and the other by the Academy of Breastfeeding Medicine. There are very few contra indications to breastfeeding.

WHO/UNICEF (WHO 2009)
A small number of health conditions of the infant or the mother may justify recommending that she does not breastfeed temporarily or permanently. These conditions, which concern very few mothers and their infants, are listed below with some health conditions of the mother that, although serious, are not medical reasons for using breast milk substitutes. Whenever stopping breastfeeding is considered, the benefits of breastfeeding should be weighed against the risks posed by the presence of the specific conditions listed.

Infants who should not receive breast milk or any other milk except specialized formula
Infants with classic galactosemia: a special galactose-free formula is needed.
Infants with maple syrup urine disease: a special formula free of leucine, isoleucine and valine is needed.
Infants with phenylketonuria: a special phenylalanine-free formula is needed (some breastfeeding is possible, under careful monitoring).

Maternal conditions that may justify permanent avoidance of breastfeeding
HIV infection.

Maternal conditions that may justify temporary avoidance of breastfeeding
Severe illness that prevents a mother from caring for her infant.
Herpes simplex virus type 1 (HSV-1): direct contact between lesions on the mother's breasts and the infant's mouth should be avoided until all active lesions have resolved.
Maternal medication. Specific classes of drugs that require consideration are:
- sedating psychotherapeutic drugs, anti-epileptic drugs and opioids and their combinations may cause side effects such as drowsiness and respiratory depression and are better avoided if a safer alternative is available
- radioactive iodine-131 is better avoided given that safer alternatives are available - a mother can resume breastfeeding about two months after receiving this substance;
- excessive use of topical iodine or iodophors (e.g., povidone-iodine), especially on open wounds or mucous membranes, can result in thyroid suppression or electrolyte abnormalities in the breastfed infant and should be avoided;
- cytotoxic chemotherapy requires that a mother stops breastfeeding during therapy.

Maternal conditions during which breastfeeding can still continue, although health problems may be of concern
Breast abscess: breastfeeding should continue on the unaffected breast; feeding from the affected breast can resume once treatment has started.
Hepatitis B: infants should be given hepatitis B vaccine, within the first 48 hours or as soon as possible thereafter.
Hepatitis C.

Mastitis: if breastfeeding is very painful, milk must be removed by expression to prevent progression of the condition.
Tuberculosis: mother and baby should be managed according to national tuberculosis guidelines.
Substance use:

- maternal use of nicotine, alcohol, ecstasy, amphetamines, cocaine and related stimulants has been demonstrated to have harmful effects on breastfed babies;
- alcohol, opioids, benzodiazepines and cannabis can cause sedation in both the mother and the baby.

Mothers should be encouraged not to use these substances, and given opportunities and support to abstain.

ABM Protocol #23. Breastfeeding Contraindications (Philipp 2010)
Breastfeeding is contraindicated in the following situations:

- Mothers with HIV
- Mothers currently using illicit drugs (e.g., cocaine, heroin) unless specifically approved by the infant's healthcare provider on a case-by-case basis
- Mothers taking certain medications. Most prescribed and over-the-counter drugs are safe for the breastfeeding infant. Some medications may make it necessary to interrupt breastfeeding, such as radioactive isotopes, antimetabolites, cancer chemotherapy, some psychotropic medications, and a small number of other medications.

Alcohol and Breastfeeding

Sources of data

1. Reviews by Giglia. Current review is being updated and will be completed by the end of October
2. AERF Educational guidelines (Giglia Binns)
3. NHMRC Guidelines (based on Giglia and Binns)

Breastfeeding from NHMRC Guidelines (National Health and Medical Research Council 2009)

The rationale for this guideline is based on a review of the evidence

• Internationally and in Australia it is recommended that infants are exclusively breastfed for the first six months of life and that breastfeeding (in addition to complementary foods) is extended into the second year of life.

• Although 75.6 per cent of Australian infants are exclusively breastfed on discharge from hospital following birth, only 12 per cent of infants are exclusively breastfed at 6 months of age and only 19 per cent of infants are receiving any breast milk at 12 months of age (Scott, Binns et al. 2006). It is therefore important to have a policy that will not discourage women from breastfeeding.

• Alcohol enters the breast milk and may persist in the milk for several hours after alcohol consumption (Giglia and Binns 2006). Alcohol adversely affects lactation, infant behaviour (eg feeding, arousal) and psychomotor development of the breastfed baby (Giglia and Binns 2006)• Analysis of the 2001 National Health Survey found that, although most breastfeeding women drink at low levels (up to two standard drinks per week), 17 per cent were drinking more than 7 standard drinks per week. This proportion was significantly higher than in the 1995 survey (13 per cent) (Giglia and Binns 2008)

• Qualitative research has shown that breastfeeding mothers are generally unaware of the effects of alcohol on breastfeeding performance and development of the infant (Giglia and Binns 2007).

• Women who consumed alcohol at levels of more than two standard drinks per day were almost twice as likely to discontinue breastfeeding before the infant was 6 months old than women who drank below this level (Giglia and Binns 2008; Giglia, Binns et al. 2008)

Summary of the evidence

The effect of alcohol consumption by breastfeeding mothers on milk production (lactogenesis), breast milk and infant blood alcohol concentrations, and the breastfeeding infant, have been described in a thorough systematic review of research from 1990–2005 by Giglia and Binns (Giglia and Binns 2006). The reviewers found limited research on the effect of alcohol on lactation and on breastfed infants, most studies having been conducted in animal models. They note that the lack of high quality evidence limits our ability to give women definitive advice. They also comment that an abstinence message may discourage women from breastfeeding and thus provide practical advice to minimise risk to the infant. The reviewers found that consumption of two standard drinks or more a day during lactation was associated with:

• decreased lactational performance (in terms of the milk ejection reflex, milk production by the mother and milk consumption by the baby)

• earlier cessation of breastfeeding

• deficits in infant psychomotor development

• disrupted infant sleep-wake behavioural patterns.

Practical advice

Breastfeeding mothers should be advised that not drinking is the safest option and, specifically, to consider not drinking alcohol during the first month after delivery until breastfeeding is well established. For women who choose to drink after this time, advice should be provided on a recommended maximum level of consumption (eg two standard drinks or less in any one day), the length of time that alcohol is excreted in the breast milk and the optimal timing of breastfeeding in relation to intake. The option of expressing prior to consuming alcohol could also be discussed (Giglia and Binns 2006)

Smoking and breastfeeding

Search Results

Data from 16 studies including 2 SLRs, 12 prospective cohort, 1 retrospective and 1 cross-sectional studies were extracted. Data from these studies were used to form the final body of evidence statement, which included 2 multinational SLRs, 8 studies of Australian women, 2 studies of Chinese women, 1 study from New Zealand and 3 studies from the UK. Sufficient evidence was found to make statements on the relationship between maternal smoking and breastfeeding outcomes.

What is the effect of maternal and paternal smoking on breastfeeding outcomes?		
Draft Evidence Statement		Maternal and paternal smoking is negatively associated with breastfeeding outcomes.
Draft Grade		**A**
Component	**Rating**	**Notes**
Evidence Base	Excellent	2 SLRs, 12 prospective cohort studies, 1 retrospective cohort study and 1 cross-sectional studies
Consistency	Excellent	Majority of studies found a negative association
Clinical impact	Good	There was a consistent association
Generalisability	Excellent	All studies involved either Australian women or women from relevant population sub-groups
Applicability	Good	Studies of Chinese women not directly relevant to the Australian healthcare context

Breastfeeding was independently negatively associated with breastfeeding initiation in larger studies and with breastfeeding duration in almost all studies. Horta et al. reported a pooled odds ratio for 15 studies of 1.93 (95% CI 1.55-2.40) for the likelihood of cessation of breastfeeding before 13 weeks. The findings of the two SLRs were confirmed by the findings of studies published subsequent to these reviews. Most studies investigating a dose response relationship reported a negative association with higher levels of smoking, i.e. more than 10 or 20 cigarettes per day but no association with lower levels of smoking.

Studies of women from Australia, New Zealand or the UK were considered separately to those of Chinese women. Only one cohort study of Australian women failed to find a negative association with 2 cohort studies and a cross-sectional study reporting a negative association with breastfeeding initiation and 7 prospective and 1 retrospective studies showing a negative association with breastfeeding duration.

One cohort study involving Chinese women reported a negative association between smoking and breastfeeding initiation while a second found no association. However, both studies reported a negative association between paternal smoking and breastfeeding outcomes. Whether the mechanism for the association is biological or psychological, behavioral and/or cultural remains unclear.

Studies used to make evidence statement for association of smoking and breastfeeding

Reference	**Amir and Donath Birth; 2002 29: 112-123**	**Horta et al AM J Public Health 2001: 91: 304-307**	**Baghurst P, Pincombe J, Peat B, Henderson A, Reddin E & Antoniou G Midwifery 2007; 23: 382-391.**	**Britten J, Tappin DM & Elton RA Health Bulletin 2001; 59: 29-36.**
Type of study	Systematic review of observational studies	Systematic review	Prospective cohort	Prospective cohort (5 points of data collection from maternity booking to 6 weeks postpartum)
Level of evidence	I (aetiology) Not all studies were prospective cohort studies	I (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Intention to breastfeed Initiation of breastfeeding Any breastfeeding duration	Cessation of BF before 3 months	Fully breastfeeding (breast milk only) Partly breastfeeding (formula and/ or solids and breast milk)	No definition
Intervention/ comparator	Maternal smoking	Smoker vs non-smoker (ref)	Maternal smoking status yes/ yes but quit during this pregnancy vs no (reference)	Yes vs no (reference)
N	6 studies investigated intention to breastfeed 8 studies which used multivariate analysis investigated breastfeeding initiation 11 studies investigated an association between smoking status and breastfeeding duration. 10 studies investigated a dose-response relationship with BF duration	13 studies provided data for a pooled effects analysis	317	1792 recruited at maternity booking (gradual decline in participation rates over time)

Population/study information	Systematic literature search of Cochrane Library (Issue 2, 2001), Medline, CINAHL, Current Contents, PsychInfo, Lactation Resource Centre (grey literature). J Hum Lact and Birth hand searched volumes 1985 to end 2000. Key words were "smoking" AND "breastfeeding"	Systematic literature search of Medline (1966- July 1997) Scientific Citations Index (1985 – July 1997) Pediatrics, J of Pediatrics, NEMJ and Lancet (1966 – July 1997) Key words smoking AND breastfeeding or lactation. Languages included English, French, Spanish and Portuguese	Primiparous mothers South Australia, Australia Recruited from antenatal clinic at large, teaching hospital (sample not necessarily random) First contact prior to baby's birth, follow-up in hospital post delivery, 1 week, 6 weeks, 3 months & 6 months postpartum	Glasgow, Scotland Recruitment from 4 maternity units
Quality	P	P	P	P
Results	*Intention to breastfeed* 5/6 studies reported a significant negative association between maternal smoking and intention to breastfeed. One UK prospective cohort study (ALSPAC) reported a dose-response relationship with # of cigarettes, although no significant difference between light smokers and non-smokers after adjustment for confounders. *Breastfeeding initiation* 5 studies found a significant association after adjustment for confounders whereas 5 reported non-significant association after adjustment for confounders such as social	Pooled OR 1.93 (95% CI 1.55-2.40) For studies with less than 15% loss to follow-up and adequate adjustment for confounders Adjusted OR of 1.50 (95% CI 1.34-1.68)	Adj HR for weaning (95%CI) 1.35 (0.85-2.16) Estimated HR for parsimonious model predicting duration of BF Adj HR (95%CI) 1.49 (0.97-2.28)	Adj OR intention to breastfeed at maternity booking: 0.55 (95%CI 0.41-0.75)

	class. Relationship not significant after adjustment in studies with n <200. *Breastfeeding duration* 10 or 11 studies all reported a univariate association between smoking status and breastfeeding duration. Studies with n < 200 generally reported that association was non-sig after adjustment for confounders. Larger studies generally reported that the association remained after adjustment for confounders. Of the 10 studies which investigated a dose-response relationship, all found a significant negative association between heavy smokers and breastfeeding duration after adjustment for confounders. However 1 found no association among women who smoked < 10 and 2 studies found no association among women who smoked < 20 cigarettes/day			
Effect on risk	Majority of studies reported a negative association between maternal smoking and intention to breastfeed,	Maternal smoking increased the risk of early cessation of breastfeeding	No significant association between weaning from breastfeeding & smoking	Mothers who smoke during pregnancy less likely to intend to breastfeed at time of maternity booking

	initiation of breastfeeding and breastfeeding duration. A dose-response relationship was observed in most studies which stratified for number of cigarettes.			
Clinical importance	1	1	0	1
Clinical relevance	1	1	1	2
Generalisability	Studies from Europe, US, Aust, NZ, Brazil	Y	Y	Y (UK)
Applicability	Y	Y	Y	Y (UK)

Reference	**Cooklin AR, Donath SM & Amir LH Acta Paediatrica 2008; 97: pp. 620-623.**	**Giglia R, Binns CW & Alfonso H Acta Paediatrica 2006.**	**Butler S, Williams M, Tukuitonga C & Paterson J The New Zealand Medical Journal 2004; 117.**	**Donath SM, Amir LH & ALSPAC Study Team Acta Paediatrica 2004; 93: 1514-1518.**
Type of study	Prospective cohort (Cross-sectional analysis of Longitudinal Study Australian Children –LSAC-data)	12 month prospective cohort (follow-up at 4, 10, 16, 22, 32, 40 & 52 weeks postpartum)	Prospective cohort	Prospsective cohort study
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding	Not defined	Exclusive breastfeeding – other (includes water) Not breastfeeding exclusively	Breastfeeding - poorly defined
Intervention/ comparator	Smoked during pregnancy vs did not smoke during pregnancy (reference)	Smoked during pregnancy vs did not smoke during pregnancy (reference)	Smoked during pregnancy vs did not smoke during pregnancy (reference) Smoked yesterday vs did not smoke yesterday (reference)	Any smoking at any time during pregnancy vs no smoking during pregnancy (reference)
N	3697 maternal-infant pairs	587	1247	11 111
Population/study information	Wave 1 data from infant cohort of LSAC aged <12 months in 2003-2004.	Perth, Australia Data part of Perth Infant Feeding Study II (PIFSII) 2 public maternity hospitals, women contacted within 3 days of infant birth Self-administered questionnaire after birth & follow-up telephone interviews	Auckland, New Zealand 1 or more parent Pacific ethnicity Data part of Pacific Islands Families (PIF) Study through interviews with mothers & hospital records	Avon, UK Data from the Avon Longitudinal Study of Parents and Children (ALSPAC) Women living in three districts Questionnaire at 6 & 15 months postpartum Intention to breastfeed collected at 32 wk of pregnancy
Quality	P	P	P	P

Results	Adj OR any breastfeeding at 6 months 0.46 (95%CI 0.38-0.56)	Adj OR breastfeeding at 2 weeks 0.8 (95%CI 0.4-1.6) Adj OR breastfeeding 2wk-6 months 0.2 (95%CI 0.1-0.4) Adi OR breastfeeding> 6 months 0.3 (95%CI 0.2-0.5) Adj HR for breastfeeding duration 1.6 (95%CI 1.2-2.1)	<u>Smoking during pregnancy</u> Adj OR not breastfeeding exclusively at hospital discharge 1.81 (95%CI 1.27-2.58) *Univariate analysis:* OR not breastfeeding exclusively at 6 weeks post-birth 1.84 (95%CI 1.36-2.48) <u>Current smoking</u> Adj OR not breastfeeding exclusively at 6 weeks post-birth 2.26 (95%CI 1.60-3.18)	Adj OR (age & education) not initiating breastfeeding 1.4 (95%CI 1.3-1.6) Adj OR (age, education & intention) not initiating breastfeeding 1.2 (95%CI 1.0-1.4) Adj OR (age & education) not breastfeeding at 3 months 1.6 (95%CI 1.4-1.7) Adj OR (age, education & intention) not breastfeeding at 3 months 1.4 (95%CI 1.3-1.6) Adj OR (age & education) not breastfeeding at 6 months 1.7 (95%CI 1.5-1.9) Adj OR (age, education & intention) not breastfeeding at 6 months 1.5 (95%CI 1.3-1.7) Adj HR (age, education & intention) for breastfeeding duration 1.17 (95%CI 1.10-1.24)
Effect on risk	Mothers who smoked during pregnancy were less likely to still be breastfeeding at 6 months	Mothers who smoked were less likely to be breastfeeding between 2 weeks and 6 months and after 6 months. They were	Women who smoked during pregnancy more likely to not be exclusively breastfeeding at hospital discharge or at 6 weeks	Women who smoked at all any time during pregnancy were more likely to not initiate breastfeeding and not

		also more likely to cease breastfeeding.	post-birth (univariate analysis). Women who smoked yesterday more likely to not be breastfeeding exclusively at 6 weeks post-birth.	be breastfeeding at 3 and 6 months and were more likely to stop breastfeeding at any time.
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y (Pacific Islanders)	Y (UK)
Applicability	Y	Y	Y (Pacific Islanders)	Y (UK)

Reference	**Forster DA, McLachlan HL & Lumley J International Breastfeeding Journal 2996; 1.**	**Gilchrist D, Woods B, Binns CW, Scott JA, Gracey M & Smith H Australian and New Zealand Journal of Public Health 2004; 28:225-228.**	**Giglia RC, Binns CW & Alfonso HS BMC Public Health 2006; 6.**	**Clements et al Acta Paediatr, 1997; 86:51-56**
Type of study	RCT	Prospective cohort (12 months)	Prospective cohort (12 months)	Prospective cohort study
Level of evidence	II (intervention)	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding (at 6 months)	Not provided	Not provided	Exclusive BF at discharge Any breastfeeding duration
Intervention/ comparator	Smoking prior to pregnancy: 1-19 cigarettes/ day vs no (reference) 20 or more cigarettes/.day vs no (reference)	Smoking prior to and during pregnancy vs not smoking. Number of cigarettes smoked/ day also considered.	Stopping smoking during pregnancy vs did not stop smoking (ref)	Number of cigarettes/day Nil (ref), 1-9, 10-19, 20+
N	981	425 completed baseline questionnaire	587 of 870 women contacted completed baseline questionnaires (68%)	700
Population/study information	Melbourne, Australia Primiparous women attending a public, tertiary hospital All eligible women approached for participation Data from RCT used investigating effect of 2 pregnancy interventions on breastfeeding initiation & duration Interview in hospital at birth & at 6 months over phone	Perth, Australia Mothers identifying as Aboriginal in 6 public hospitals Consecutive & unselected sample Interviews in hospital and at 2, 6, 10, 14, 18, 24 & 52 weeks postpartum Data from Perth Aboriginal Mothers Breastfeeding Study (PABS)	Perth, Australia (Perth Infant Feeding Study 2 – PIFSII) Conducted in hospitals, mothers contacted within 3 days of giving birth Self-administered questionnaire completed in hospital. Follow-up interviews at 4, 10, 16, 22, 32, 40 & 52 weeks	Infants from South West Thames (UK) region were randomly selected from all births, except home births. The subjects were randomly allocated an age at which to be interviewed, in such a way as to ensure that they had a similar age distribution to that previously described for **SIDS** cases. The median age was 90 days (range 30-302 days). The study ran from 14 October 1990 to 13 October 1991.
Quality	P	P	P	P

Results	Adj OR any breastfeeding at 6 months *1-19 cigarettes/ day vs no* 1.04 (95%CI 0.70-1.52) *20 or more cigarettes/ day vs no* 0.47 (95%CI 0.26-0.86)	*At discharge:* No significant association between feeding method and smoking. Mothers who smoked (89.6%) just as likely to be breastfeeding as those who did not smoke (89.7%) *At 24 weeks postpartum* Fewer women who smoked were still breastfeeding (58% compared with 64% of non-smokers) however the association was not significant. No significant association between breastfeeding duration & number of cigarettes smoked/ day (X^2=1.15, p=0.283)	Adj OR breastfeeding for longer than 6 months 3.7 (95%CI 1.6-8.8)	*Exclusive BF at discharge* No adjOR reported but non-significant when controlled for in multivariate analysis *Any breastfeeding duration* Adj HR (95% CI) 1-9 1.29 (0.71-2.30) 10-19 1.56 (0.81-2.97) 20+ 2.30 (1.16-4.59)
Effect on risk	Women who smoked 20 or more cigarettes a day were less likely to be feeding with any breast milk at 6 months	Smoking not associated with initiation or duration of breastfeeding in Aboriginal mothers	Women who stopped smoking during pregnancy were more likely to breastfeed for longer than 6 months than those women who did not stop smoking.	No association with exclusive BF at discharge but smoking 20 or more cigarettes/day was negatively associated with duration of any breastfeeding
Clinical importance	1	0	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y (Aboriginal mothers)	Y	Y (English)
Applicability	Y	Y (Aboriginal mothers)	Y	Y

Reference	**Baxter J, Cooklin AR & Smith J Acta Paediatrica 2009; 98: 1274-1277.**	**Kelly YJ & Wyatt RG Public Health Nutrition 2005; 8: 417-421.**	**Leung GM, Ho L & Lam T Paediatric & Perinatal Epidemiology 2002; 16: 236-245.**
Type of study	Data from Longitudinal Study of	Prospective cohort (Longitudinal	Prospective cohort

	Australian Children (LSAC) Retrospective cohort study using infant cohort only	population based survey)	
Level of evidence	III-2 (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Full breastfeeding Complementary breastfeeding (WHO)	Exclusive breastfeeding - WHO	Refers to breastfeeding and exclusive breastfeeding but not defined
Intervention/ comparator	Smoked in pregnancy vs didn't smoke in pregnancy	No of cigarettes smoked/ day postpartum (%s only, no comparisons) Non-smoker, <10/day, 10-19/day, ≥20/day	Maternal smoking yes vs no during pregnancy or baseline visit (ref) Maternal smoking: only during pregnancy, only post-partum, since pregnancy vs non-smoker (ref) No. cigarettes smoked daily by mother at home: none at home, 1-5, ≥6 vs non-smoker (ref) Maternal smoking within 3 metres of infant at home: no, yes vs non-smoker (ref) Paternal smoking at home yes vs no (ref) No. cigarettes smoked daily by father at home: none at home, 1-5, ≥6 vs non-smoker (ref)
N	5090 (54% response rate)	18125	6747 infants recruited & followed-up
Population/study information	Random sampling through Medicare database Interview with mothers of infants involved in LSAC Study aged 3-19 months Breastfeeding transitions between birth & 1 month and 1 month and 2 months	Four UK countries Data from the Millennium Cohort Study Parental interview at 1, 4 & 6 months after birth Households identified through Dept of Work & Pensions Child Benefit System. Disadvantaged residential areas over-represented	Hong Kong Infants brought to health centre for first health check, across 47 centres Self-administered questionnaire at first health check, repet using telephone interview at 3, 9 & 18 months after birth (This analysis based on initial & 3 & 9 month surveys)
Quality	P	P	P

Results	Transitions between birth & 1 month, marginal effects Still full breastfeeding: -5% (95% CI -9, -1) (p<0.01) Complementary feeds: -1% (95% CI -3, 2) Not breastfeeding: 6% (95% CI 3, 9) (p<0.001) Transitions between 1 & 2 months, marginal effects Still full breastfeeding: -3% (95% CI -7, 1) Complementary feeds: 2% (95% CI -1, 5) Not breastfeeding: 1% (95% CI -2, 4) Still complementary feeds: -11 (95% CI -22, 0) (p<0.05)	<u>No significance testing</u> Initiation (%) Non-smoker 76.6 <10/day 63.8 10-19/day 49.8 ≥20/day 42.9 Exclusive at 1 month (%) Non-smoker 38.8 <10/day 26.0 10-19/day 15.9 ≥20/day 13.9 Exclusive at 4 months (%) Non-smoker 3.9 <10/day 1.9 10-19/day 0.9 ≥20/day 1.3 Exclusive at 6 months (%) Non-smoker 0.4 <10/day 0.2 10-19/day 0.0 ≥20/day 0.2	<u>Maternal smoking at home</u> *yes vs no* Adj OR (95%CI) never BF 2.51 (1.63-3.86) Adj OR (95%CI) BF ≤4 mo 1.64 (0.58-4.58) *only during pregnancy vs non-smoker* Adj OR (95%CI) never BF 1.24 (0.84-1.82) Adj OR (95%CI) BF ≤4 mo 3.02 (1.17-7.80) *only smoked post-partum vs non-smoker* Adj OR (95%CI) never BF 5.73 (1.35-24.22) Adj OR (95%CI) BF ≤4 mo Not reported (n<5) *smoked since pregnancy vs non-smoker* Adj OR (95%CI) never BF 3.31 (1.97-5.57) Adj OR (95%CI) BF ≤4 mo 1.41 (0.34-5.92) <u>No. cigarettes smoked-maternal</u> *none at home vs non-smoker* Adj OR (95%CI) never BF 2.04 (0.58-7.13) Adj OR (95%CI) BF ≤4 mo Not reported (n<5) *1-5 vs non-smoker* Adj OR (95%CI) never BF 2.54 (1.36-4.75)

			Adj OR (95%CI) BF ≤4 mo 2.16 (0.38-12.18) *≥6 vs non-smoker* Adj OR (95%CI) never BF 3.72 (1.10-12.60) Adj OR (95%CI) BF ≤4 mo Not reported (n<5) <u>Maternal smoking within 3 metres of infant at home</u> *no vs non-smoker* Adj OR (95%CI) never BF 3.16 (1.86-5.38) Adj OR (95%CI) BF ≤4 mo 1.15 (0.32-4.23) *yes vs non-smoker* Adj OR (95%CI) never BF 3.25 (1.13-9.40) Adj OR (95%CI) BF ≤4 mo Not reported (n<5) <u>Paternal smoking at home</u> *yes vs no* Adj OR (95%CI) never BF 1.22 (1.08-1.39) Adj OR (95%CI) BF ≤4 mo 0.89 (0.69-1.16) <u>No. cigarettes smoked – paternal</u> *none at home vs non-smoker* Adj OR (95%CI) never BF 1.02 (0.83-1.26) Adj OR (95%CI) BF ≤4 mo

			1.25 (0.82-1.90) *1-5 vs non-smoker* Adj OR (95%CI) never BF 1.37 (1.17-1.60) Adj OR (95%CI) BF ≤4 mo 0.84 (0.61-1.16) *≥6 vs non-smoker* Adj OR (95%CI) never BF 1.27 (0.95-1.70) Adj OR (95%CI) BF ≤4 mo 0.59 (0.33-1.05)
Effect on risk	Women who smoked during pregnancy less likely to still be breastfeeding and more likely to not be breastfeeding at one month. At 2 months, less likely to still be giving complementary feeds.	A greater percentage of mothers who were non-smokers initiated breastfeeding and were exclusively breastfeeding at 1, 4 and 6 months. In women who smoked, a greater percent of those who smoked less cigarettes per day initiated breastfeeding and were exclusively breastfeeding at 1, 4 and 6 months.	<u>Maternal smoking</u> --Mothers who smoked more likely to have never BF than those who don't smoke. --Mothers who smoked only post partum or since pregnancy more likely to have never BF and mothers smoking only during pregnancy more likely to BF ≤4 months compared to non-smokers. --Mothers who smoked 1-5 cigarettes/ day more likely to have never BF than non-smokers. --Mothers who are smokers and do or do not smoke within 3 metres of the infant at home more likely to have never breastfed compared to non-smokers. <u>Paternal smoking</u> --Mothers more likely to have never BF if fathers smoke.
Clinical importance	1	4	1

Clinical relevance	1	1	1
Generalisability	Yes	Y (UK)	Y (Chinese)
Applicability	Yes	Y (UK)	Y (Chinese)

Reference	**Rutishauser IHE & Carlin JB Journal of Epidemiology & Community Health 1992; 46: 559-565.**	**Scott JA, Binns CW, Oddy WH & Graham KI Pediatrics 2006; 117: e646-e645.**	**Xu F, Binns C, Zhang H, Yang G & Zhao Y Journal of Human Lactation 2010.**	**Yeoh BH, Eastwoord J, Phung H & Woolfenden S Journal of Paediatrics & Child Health 2007; 43: 249-255.**
Type of study	Prospective Cohort	Prospective cohort study	Prospective cohort	Cross-sectional
Level of evidence	II (A)	II (A)	II (A)	IV (A)
Definition of breastfeeding	Not defined	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Any breastfeeding Exclusive breastfeeding (WHO)	Any current breastfeeding including token, partial, fully & exclusive (other)
Intervention/ comparator	Smoking status postpartum: 10 cigarettes/ day smoked vs non-smoker (ref)	Mother smoked during pregnancy yes vs no (ref)	Paternal smoking (using more than 1 cigarette or equivalent per week) Maternal smoking (details not provided)	Current smoker yes vs no (ref)
N	739 (81%)	587 (68% of 870 women contacted and 55% of 1068 eligible women)	1256 mothers invited, 1219 agreed (97%) & 1088 fathers agreed (87%) (Analysis undertaken on 1088 couples)	9618 babies & mothers
Population/study information	Geelong, Australia Primiparous women who chose to breastfeed & attended an infant welfare centre in Barwon region of Victoria, Australia	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Xinjiang, China Mothers interviewed in hospital & 0.5, 1.5, 2.5, 3.5, 4.5 & 6 months after birth Recruited from 5 hospitals in urban & rural areas Smaller hospitals – all mothers recruited	Sydney, Australia Data from Ingleburn Baby Information Systems Database-IBIS and Obstetrics Package –OBSTET IBIS-data collected at first well-baby clinic after hospital discharge

			Larger hospitals – mothers recruited every 2nd or 3rd day	OBSTET-data from hospital birthing units
Quality	P	P	P	P
Results	Adj HR cessation of breastfeeding 2.48 (95%CI 1.92-3.13)	*Risk of discontinuing any BF to 12 months* 1.35 (1.05-1.73) *Risk of discontinuing full BF to 6 months* Adj HR (95%CI) 1.32 (1.02-1.71)	*Paternal smoking* Adj HR (95%CI) any breastfeeding 1.84 (1.11-3.04) Adj HR (95%CI) exclusive breastfeeding 1.33 (1.09-1.64) *Maternal smoking* Not significant (results not provided)	Adj OR (95%CI) risk for not breastfeeding 1.72 (1.51-1.96)
Effect on risk	Mothers who smoke after the birth of their baby more likely to cease breastfeeding	Mothers who smoked during pregnancy more likely to discontinue full BF to 6 months & any BF to 12 months	When the father smoked, mothers more likely to discontinue any breastfeeding and exclusive breastfeeding before 6 months. No effect of maternal smoking on breastfeeding.	Mothers who smoke are at a higher risk of not breastfeeding.
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y (Chinese)	Y
Applicability	Y	Y	Y (Chinese)	Y

Pharmaceutical and other drugs and breastfeeding

Narrative review

The Therapeutic Goods Administration(TGA) publishes information on the risk of drug use in pregnancy (Australian Drug Evaluation Committee 1999). There have been four updates, available on line.

No similar book is available on pharmaceuticals in lactation in Australia but the TGA website includes the following document:
"Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: From Data To Labelling" a document prepared by the European Medicines Agency (European Medicines Agency 2008)

Given the constantly changing data available, a list of active websites may be more useful than a list of drugs in the guidelines. Many manufacturers simply state that their drugs have not been tested in pregnancy and lactation and are therefore not recommended for use in lactating women. This increases the risk that mothers will stop breastfeeding when it would be safe for them to continue.

Several government institutions are making available information online that can be readily accessed:

Lactmed provided by the US National Library of Medicine is a database of drugs and other chemicals to which breastfeeding mothers may be exposed (http://toxnet.nlm.nih.gov/). It includes information on the levels of such substances in breast milk and infant blood, and the possible adverse effects in the nursing infant. Statements of the American Academy of Pediatrics concerning a drug's compatibility with breastfeeding are provided, as are suggested therapeutic alternatives to those drugs, where appropriate. All data are derived from the scientific literature and fully referenced. Data are organized into substance-specific records, which provide a summary of the pertinent reported information and include links to other NLM databases. Supplemental links to breastfeeding resources from credible organizations are also provided.
The Merck Manual online version also includes a table of drugs contraindicated in breastfeeding. (http://www.merck.com/mmhe/sec22/ch259/ch259a.html)

Postnatal Depression

As discussed in the section on Postnatal Breastfeeding, depression occurs postnatally in approximately 10-15% of mothers. The more severe cases require treatment with anti-depressants (Academy of Breastfeeding Medicine 2008). "Data from a recent meta-analysis indicated that all antidepressants were detected in breast milk but not all were found in infant serum (Weissman, Levy et al. 2004). Infant serum levels of nortriptyline, paroxetine, and sertraline were undetectable in most cases. Infant serum levels of citalopram and fluoxetine exceeded the recommended 10% maternal level in 17% and 22% of cases, respectively. Few adverse outcomes are reported for any of the antidepressants. There were an insufficient number of cases for all other antidepressants to make conclusions."

Drugs of Dependence

The use of drugs of dependency is a difficult problem during lactation (Jansson, Bunik et al. 2009). The WHO Guidelines on Acceptable use of Breast milk substitutes gives the following guidance on Substance use (WHO 2009):

-“ maternal use of nicotine, alcohol, ecstasy, amphetamines, cocaine and related stimulants has been demonstrated to have harmful effects on breastfed babies;
- alcohol, opioids, benzodiazepines and cannabis can cause sedation in both the mother and the baby.
Mothers should be encouraged not to use these substances, and given opportunities and support to abstain.”

Alcohol
Mothers who drink alcohol have a shorter duration of breastfeeding (Giglia and Binns 2006; Giglia, Binns et al. 2008). Advice to mothers who are breastfeeding is available in a pamphlet from the Alcohol Education and Research Foundation (Giglia and Binns 2006)

The Australian categorisation of the risk of drug use in pregnancy is as follows:
• Category A—drugs that have been taken by a large number of pregnant women and women of child-bearing age and for which no proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus has been observed

• Category B1—drugs that have been taken by only a limited number of pregnant women and women of child-bearing age but for which no increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus has been observed. Studies in animals have not shown evidence of an increased occurrence of foetal damage

• Category B2—drugs that have been taken by only a limited number of pregnant women and women of child-bearing age but for which no increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus has been observed. Studies in animals are inadequate or may be lacking, but the available data show no evidence of an increased occurrence of foetal damage

• Category B3—drugs that have been taken by only a limited number of pregnant women and women of child-bearing age but for which no increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus has been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans

• Category C—drugs that, owing to their pharmacological effects, have caused or may be suspected of causing harmful effects on the human foetus or neonate but not malformations. These effects may be reversible. Accompanying texts should be consulted for further details

• Category D—drugs that have caused, are suspected to have caused or may be expected to cause an increased incidence of human foetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects. Accompanying texts should be consulted for further details

• Category X—drugs posing such a high risk of permanent damage to a foetus that they should not be used in pregnancy or when there is a possibility of pregnancy

Return to work and breastfeeding duration

Sufficient evidence was found to make statements on the relationship between maternal and breastfeeding outcomes. Return to work or intention to return to work shortens the duration of breastfeeding.

Search results
Data were extracted from 14 studies, including 10 prospective cohort studies, 2 retrospective cohort study and 2 cross-sectional studies. Data from 11 studies were used to form the final body of evidence statement, which included 8 studies of Australian women, 2 studies of Chinese women and1 study from New Zealand. Data from 3 studies (2 Chinese and 1 UK) were not used as they were related to occupational prestige and not the return to work. Breastfeeding outcomes investigated included breastfeeding initiation/ at discharge and breastfeeding duration.

What is the association between mothers returning to work and breastfeeding outcomes?		
Draft Evidence Statement		Intention to work or return to paid employment is negatively associated with both the initiation of breastfeeding and breastfeeding duration.
Draft Grade		**B**
Component	**Rating**	**Notes**
Evidence Base	Good	9 prospective cohort studies (8P, 1 N), 1 retrospective cohort study (P) 1 cross-sectional study (P)
Consistency	Good	Just over half of the studies found a negative association for one or more breastfeeding outcomes, whilst the remainder found no effect
Clinical impact	Good	Substantial
Generalisability	Excellent	All studies involved either Australian women or women from relevant population sub-groups
Applicability	Satisfactory	Studies of Chinese women not directly relevant to the Australian healthcare context

Studies of women from Australia, New Zealand or the UK were considered separately to those of Chinese women. One prospective cohort study reported that intention to return to work within 6 months was negatively associated with the initiation of breastfeeding and 3 prospective and 1 retrospective cohort study found a negative association between return to employment and breastfeeding duration. Two prospective cohort studies found no association with breastfeeding initiation and 3 found no association with duration.

One cohort study involving Chinese women reported a negative association between maternal employment and the initiation of breastfeeding while another study reported no association. Two cohort studies reported that return to maternal employment was negatively associated with breastfeeding duration.

An association between maternal employment and breastfeeding outcome was not consistently found across all studies with approximately one third finding no association. However, in those studies reporting an association the majority reported a negative association between intention to work or return to paid employment and both breastfeeding initiation and duration.

Paid maternity leave is an important social advance but has not been investigated in this review. Strategies to continue breastfeeding after returning to work are included in the brochure from Dept of Health documents (Breastfeeding Strategy)

Does return to work negatively affect breastfeeding duration

Reference [1]	**Li-Yin Chien LY and Tai CJ Birth 2007; 34: 123-130**	**Leung GM, Lam T & Ho L Obstetrics & Gynecology 2002; 99: 785-794**	**Qiu L, Binns C, Zhao Y, Lee A & Xie X Asia-Pacific Journal of Public Health 2008; 20: 220-227**	**Baxter J, Cooklin AR & Smith J Acta Paediatrica 2009; 98: 1274-1277.**
Type of study [2]	Longitudinal study (3 mo)	Prospective cohort study (9 months)	Prospective cohort (6 months) Cross-sectional analysis of baseline data	Data from Longitudinal Study of Australian Children (LSAC) Retrospective cohort study using infant cohort only
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	III-2 (aetiology)
Definition of breastfeeding		No definition	Exclusive BF (WHO) Any breastfeeding	Full breastfeeding Complementary breastfeeding (WHO)
Intervention/ comparator [4]	Full time work @ 3mo/ Not working @ 3mo	Maternal full time employment Yes vs no (reference)	Mother's job (details not provided)	Returned to work (<3 months full time work) vs not returned to work by 3 months (reference) Returned to work (<3 months part-time or casual work) vs not returned to work by 3 months
N [5]	2079 of 3670 questionnaires returned (56.6% response rate)	8327 (final cohort) but 7825 followed up 95% response rate, accounting for 88% of births in the period	1520 of 1551 questionnaires (98% response rate)	5090 (54% response rate)
Population/study information [6]	Taiwan Random, proportional sample from birth registry or infants born June-Oct 2003 Postal questionnaires at 1 and 3 months	Hong Kong All infants brought to health centre for first health check, across 47 centres	City, suburban & rural China Random sample of mothers from hospitals at city, suburban & rural locations. Interview conducted in hospital	Random sampling through Medicare database Interview with mothers of infants involved in LSAC Study aged 3-19 months Breastfeeding transitions between birth & 1 month and 1 month and 2 months
Quality [7]	P/N/0	P	P	P

Results [8]	No association between maternal employment and BF initiation Adj OR of any BF at 1 mo 0.58 (95% CI 0.46-0.72) Adj OR of any BF at 3 mo 0.38 (95% CI 0.30-0.48) No association with part time employment	*Adj OR never breast-fed* 1.36 (95%CI 1.21-1.53) *Adj OR breastfed<1 month* 2.98 (95%CI 2.43-3.67) *Adj HR breastfeeding duration* 1.86 (95%CI 1.67-2.07)	Adj OR initiation of exclusive breastfeeding Not significant (results not provided)	**Returned to work (<3 months full time work)** Transitions between birth & 1 month, marginal effects Still full breastfeeding: -10% (95% CI -20, -1) (p<0.05) Complementary feeds: 0% (95% CI -6, 6) Not breastfeeding: 10% (95% CI 1, 19) (p<0.05) Transitions between 1 & 2 months, marginal effects Still full breastfeeding: -27% (95% CI -40, -14) (p<0.001) Complementary feeds: 13% (95% CI 2, 23) (p<0.05) Not breastfeeding: 14% (95% CI 4, 25) (p<0.01) Still complementary feeds: -21 (95% CI -52, 10) **Returned to work (<3 months part-time or casual work)** Transitions between birth & 1 month, marginal effects Still full breastfeeding: -1% (95% CI -5, 4) Complementary feeds: 1% (95% CI -3, 4) Not breastfeeding: 0% (95% CI -3, 3) Transitions between 1 & 2

				months, marginal effects Still full breastfeeding: -1% (95% CI -5, 3) Complementary feeds: 2% (95% CI -1, 5) Not breastfeeding: -1% (95% CI -4, 2) Still complementary feeds: -2 (95% CI -13, 9)
Effect on risk	Full time work but not part-time work increased risk of NOT breastfeeding at 1 and 3 mo postpartum	Women who have full time employment more likely to never breastfeed, breastfeed for <1 month and more likely to cease breastfeeding	No significant association between mother's job and initiation of exclusive breastfeeding	For women who were breastfeeding at birth and at one month, women who returned to work full-time were less likely to be still full breastfeeding at 1 and 2 months. Less likely to be giving complementary feeds at 2 months. More likely to be not breastfeeding at 1 and 2 months.
Clinical importance	1	1	0	1
Clinical relevance		1	1	1
Generalisability	Y to Chinese sector of population	Y (Chinese)	Y (Chinese)	Y
Applicability	Y/N	Y (Chinese)	Y (Chinese)	Y

Reference [1]	**Chien L & Tai C Birth 2007; 34: 123-130.**	**Chung W, Kim H & Nam C Public Health Nutrition 2007.**	**Cooklin AR, Donath SM & Amir LH Acta Paediatrica 2008; 97: pp. 620-623.**	**Butler S, Williams M, Tukuitonga C & Paterson J The New Zealand Medical Journal 2004; 117.**
Type of study [2]	Prospective cohort study. Follow-up at 1 & 3 months after delivery	Cross-sectional	Prospective cohort (Cross-sectional analysis of Longitudinal Study Australian	Prospective cohort

			Children –LSAC- data)	
Level of evidence	II (aetiology)	IV (aetiology)	II (aetiology)	II (aetiology)
Breastfeeding definition	Exclusive breastfeeding (water not considered) Partial breastfeeding (breast milk & formula) No breastfeeding	Partial breastfeeding Exclusive breastfeeding – WHO	Any breastfeeding	Exclusive breastfeeding – other (includes water) Not breastfeeding exclusively
Intervention/ comparator [4]	Full time work vs did not work (reference) Part time work vs did not work	Employment status before marriage: No job or white-collar job vs blue-collar job (reference)	0-3 months full-time 0-3 months part-time 0-3 months casual 3-6 months full-time 3-6 months part-time 3-6 months casual ALL compared to reference: women not employed at 6 months	Employed prior to pregnancy no vs yes (reference) Currently employed full or part time – no vs yes (reference)
N [5]	2079 of 3670 questionnaires returned (56.6% response rate) 15 excluded, final n=2064	865	3697 maternal-infant pairs	1247
Population/study information [6]	Taiwan Random, national sample from birth registration records	South Korea Data taken from wider, national survey of 8890 married women aged 15-49	Wave 1 data from infant cohort of LSAC aged <12 months in 2003-2004.	Auckland, New Zealand 1 or more parent Pacific ethnicity Data part of Pacific Islands Families (PIF) Study through interviews with mothers & hospital records
Quality [7]	P	P	P	P
Results [8]	Adjusted OR initiation during hospital stay Full time:1.23 (95%CI 1.03-1.48) Part time: 1.00 (95%CI 0.73-1.37)	Adj OR initiation of partial breastfeeding 0.53 (95%CI 0.36-0.79) Adj OR initiation of exclusive breastfeeding	Adj OR any breastfeeding at 6 months *0-3 months full-time* 0.42 (95%CI 0.27-0.73) *0-3 months part-time*	<u>Employed prior to pregnancy</u> Adj OR not breastfeeding exclusively at hospital discharge 1.41 (95%CI 1.02-1.94)

	Adjusted OR breastfeeding 1 month after delivery (type not specified) Full time: 0.58 (95%CI 0.46-0.72) Part time: 1.12 (95%CI 0.74-1.69) Adjusted OR breastfeeding 3 months after delivery (type not specified) Full time: 0.38 (95%CI 0.30-0.48) Part time: 1.03 (95%CI 0.71-1.50)	0.68 (95%CI 0.49-0.94) Adj OR duration of partial breastfeeding no results given Adj OR duration of exclusive breastfeeding no results given	0.87 (95%CI 0.64-1.21) *0-3 months casual* 0.90 (95%CI 0.62-1.29) *3-6 months full-time* 0.35 (95%CI 0.22-0.55) *3-6 months part-time* 0.49 (95%CI 0.37-0.64) *3-6 months casual* 0.72 (95%CI 0.54-0.97)	Adj OR not breastfeeding exclusively at 6 weeks post-birth 0.72 (95%CI 0.53-0.99) <u>Currently employed</u> Adj OR not breastfeeding exclusively at 6 weeks post-birth 0.30 (95%CI .015-0.60)
Effect on risk	Women working full time more likely to initiate breastfeeding in hospital but less likely to be breastfeeding 1 & 3 months after delivery.	Women with a blue-collar job less likely to initiate partial or exclusive breastfeeding	Mothers working full-time in the first three months after birth were less likely to be breastfeeding at 6 months. Mothers working at all from 3-6 months after birth were less likely to be breastfeeding at 6 months.	At hospital discharge, women who were not employed before pregnancy were more likely to not be breastfeeding. At 6 weeks postpartum they were less likely to not be breastfeeding. Women who were not currently employed were less likely to not be breastfeeding exclusively at 6 weeks post-birth.
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y (Taiwanese women)	Y (Korean women)	Y	Y (Pacific Islanders)
Applicability	Y (Taiwanese women)	Y (Korean women)	Y	Y (Pacific Islanders)

Reference [1]	**Forster DA, McLachlan HL & Lumley J International Breastfeeding Journal 2996; 1.**	**Scott JA, Landers MCG, Hughes RM, Binns CW, P Paediatr Child Health 2001; 37:254-261**	**Kelly YJ & Wyatt RG Public Health Nutrition 2005; 8: 417-421.**	**Rutishauser IHE & Carlin JB Journal of Epidemiology & Community Health 1992; 46: 559-565.**
Type of study [2]	RCT	Prospective cohort study	Longitudinal population based survey Prospective cohort	Prospective Cohort
Level of evidence	II (intervention)	II(aetiology)	II (aetiology)	II (aetiology)
Breastfeeding definition	Any breastfeeding (at 6 months)	Any breastfeeding at discharge Any breastfeeding duration	Exclusive breastfeeding - WHO	Not defined
Intervention/ comparator [4]	Employed at 6 months postpartum – yes vs no (reference)	Intention to return to work within 6 months Yes vs No (ref)	Type of employment Lower managerial & professional vs higher managerial & professional (ref) Intermediate vs higher managerial & professional (ref) Small employers & self-employed vs higher managerial & professional (ref) Lower supervisory & technical vs higher managerial & professional (ref) Semi-routine vs higher managerial & professional (ref) Routine vs higher managerial & professional (ref)	Mother's occupation score (Daniel Occupation Prestige Score) >4 vs <4 (ref)
N [5]	981	556 urban, Perth 503 rural, Darling Downs, Queensland	18125	739 (81%)

Population/study information [6]	Melbourne, Australia Primiparous women attending a public, tertiary hospital All eligible women approached for participation Data from RCT used investigating effect of 2 pregnancy interventions on breastfeeding initiation & duration Interview in hospital at birth & at 6 months over phone	Mother recruited from maternity wards. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum (Perth) and at 2 and6 weeks and 3 and 6 months .	Four UK countries Data from the Millennium Cohort Study Parental interview at 1, 4 & 6 months after birth Households identified through Dept of Work & Pensions Child Benefit System. Disadvantaged residential areas over-represented	Geelong, Australia Primiparous women who chose to breastfeed & attended an infant welfare centre in Barwon region of Victoria, Australia
Quality [7]	P	P	P	P
Results [8]	(Univariate analysis) OR any breastfeeding at 6 months 0.75 (95%CI 0.56-0.99) Mulitvariate analysis – not significant (results not provided)	*Breastfeeding at discharge* adjOR 0.61 (95% CI 0.35-1.06) *Risk of cessation of breastfeeding* Not specified but adjusted for in multivariate Cox regression analysis. Not significant	Adj OR initiation *Lower managerial & professional* 0.56 (95%CI 0.43-0.67) *Intermediate* 0.33 (95%CI 0.2-0.33) *Small employers & self-employed* 0.56 (95%CI0.40-0.71) *Lower supervisory & technical* 0.32 (95%CI 0.25-0.42) *Semi-routine* 0.26 (95%CI 0.21-0.33) *Routine* 0.22 (95%CI 0.18-0.29) Adj OR exclusive breastfeeding at 1 month *Lower managerial & professional* 0.77 (95%CI 0.67-0.91) *Intermediate*	Adj HR cessation of breastfeeding 1.60 (95%CI 1.18-2.18)

			0.56 (95%CI 0.48-0.67) *Small employers & self-employed* 0.71 (95%CI0.59-0.83) *Lower supervisory & technical* 0.63 (95%CI 0.50-0.71) *Semi-routine* 0.43 (95%CI 0.38-0.53) *Routine* 0.42 (95%CI 0.36-0.50) Adj OR exclusive breastfeeding at 4 months *Lower managerial & professional* 0.83 (95%CI 0.63-1.11) *Intermediate* 0.63 (95%CI 0.43-0.83) *Small employers & self-employed* 1.25 (95%CI0.83-2.00) *Lower supervisory & technical* 0.30 (95%CI 0.16-0.59) *Semi-routine* 0.53 (95%CI 0.36-0.77) *Routine* 0.50 (95%CI 0.31-0.77)	
Effect on risk	Women who were working at 6 months were less likely to be feeding any breast milk at 6 months (univariate analysis only)	there was no significant association between breastfeeding at discharge or breastfeeding duration	Compared to women in higher managerial and professional employment, women in other forms of employment less likely to initiate breastfeeding and be exclusively breastfeeding at 1 month. At 4 months, women in	Mothers with an occupation score >4 more likely to cease breastfeeding

			intermediate, lower supervisory & technical, semi-routine & routine employment less likely to be exclusively breastfeeding.	
Clinical importance	4	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y (UK)	Y
Applicability	Y	Y	Y (UK)	Y

Reference	**Scott JA, Aitkin I, Binns CW, Aroni RA Acta Paediatr 1999;88: 416-421**	**Scott JA, Binns CW, Oddy WH, Graham KI, Pediatrics 2006; 117 e643-e655**	**Baghurst P, Pincombe J, Peat B, Henderson A, Reddin E & Antoniou G Midwifery 2007; 23: 382-391.**
Type of study	Prospective cohort study	Prospective cohort study	Prospective cohort
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	Any breastfeeding duration	Discontinuation of *any* before 12 months and *full* breastfeeding before 6 months (WHO)	Fully breastfeeding (breast milk only) Partly breastfeeding (formula and/ or solids and breast milk)
Intervention/ comparator	Future employment intention Mother intended at baseline to be employed part or full time by 6 months post partum vs other	Age of infant when mother returned to work < 6 mo 6-12 mo Not working at 12 mo (ref)	Mother employed: no vs yes (ref) Mother's employment status: full time, part time, missing/ N/A vs maternity leave (ref)
N	556 (77% of women contacted, 58% of eligible women)	587 (68% of 870 women contacted and 55% of 1068 eligible women)	317
Population/study information	Perth, Australia. Mothers recruited within 3 days post-partum from 2 public hospitals and followed to six months. Follow-up telephone interviews at 2,6,10,14,18 & 24 weeks postpartum	Mothers were recruited from maternity wards of two Perth metropolitan hospitals within 72 hrs of birth.	Primiparous mothers South Australia, Australia Recruited from antenatal clinic at large, teaching hospital (sample not necessarily random)

			First contact prior to baby's birth, follow-up in hospital post delivery, 1 week, 6 weeks, 3 months & 6 months postpartum
Quality	P	P	P
Results	No specified but adjusted for in backwards conditional Cox regression model	*Risk of discontinuing any BF* Adj HR (95% CI) < 6 mo 1.69 (1.28-2.34) 6-12 mo 1.50 (1.07-2.09) *Risk of discontinuing full BF* Adj HR (95% CI) < 6 mo 1.42 (10.08-1.88) 6-12 mo 1.63 (1.18-2.25)	<u>Mother employed: yes vs no</u> Adj HR for weaning (95%CI) 1.82 (0.42-7.77) <u>Mother's employment status</u> Adj HR for weaning (95%CI) *Full time vs maternity leave* 0.79 (0.37-1.69) *Part time vs maternity leave* 1.07 (0.54-2.11) *Missing/ NA vs maternity leave* 0.58 (0.13-2.48)
Effect on risk	There was no significant independent association between risk of cessation of breastfeeding and whether a mother intended in the early post partum period to have returned to work (either part or fulltime) by 6 months post partum.	Return to work before 12 months was negatively associated with the duration of full and any breastfeeding.	No significant association between employment/ employment status and weaning from breastfeeding
Clinical importance	1	1	0
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Contraception and Breastfeeding

The Academy of Breastfeeding Medicine has published a detailed protocol on contraception during breastfeeding (Academy of Breastfeeding Medicine 2006).

In a further review of contraception during lactation King concluded:
"The benefits of breastfeeding for both the infant and the mother are undisputed. Longer intervals between births decrease foetal/infant and maternal complications. Lactation is an effective contraceptive for the first 6 months postpartum only if women breastfeed exclusively and at regular intervals, including night time. Because a high percentage of women in the United States supplement breastfeeding, it is important for these women to choose a method of contraception to prevent unintended pregnancies" (King 2007).

Reviews of specific methods include Isley on contraceptive implants (Isley and Edelman 2007), Roy on injectable contraceptives (Roy 2010), and Kapp on oral contraceptives (Kapp, Curtis et al. 2010; Kapp and Curtis 2010).
The main interest in contraception and lactation is in lactational amenorrhoea.

Lactational Amenorrhea

The lactational amenorrhea method (LAM) is described as:
"A postpartum method of family planning. If a woman is amenorrhoeic, fully or nearly fully breastfeeding day and night, and less than six months postpartum, she is 98 percent protected against pregnancy." (WHO 1995)

The Lactational Amenorrhoea Method (ie breastfeeding) provides important benefits for nursing infants. Breastfeeding provides special nutritional benefits to the infant and protects against diarrhoea, coughs and colds, and other common illnesses.

No new studies have been published in Australia on lactational amenorrhea since the last edition of the Infant Feeding Guidelines. We have included summaries of the Cochrane Review (2002) and the most recent study of lactational amenorrhoea in Australia, which was also published in 2002.

1. **Cochrane Review:** Education for contraceptive use by women after childbirth**. (Lopez, Hiller et al. 2002 (reprinted 2010))**

Background: Providing contraceptive education is now considered a standard component of postpartum care. The effectiveness is seldom examined. Questions have been raised about the assumptions on which such programs are based, e.g., that postpartum women are motivated to use contraception and that they will not return to a health centre for family planning advice. Surveys indicate that women may wish to discuss contraception prenatally and after hospital discharge. Nonetheless, two-thirds of postpartum women may have unmet needs for contraception. In particular, many adolescents become pregnant again within a year a giving birth.
Objectives: Assess the effects of educational interventions for postpartum mothers about contraceptive use
Search strategy: We searched the computerized databases of MEDLINE, CENTRAL, EMBASE, CINAHL, PsycINFO, and POPLINE. We also searched for current trials via ClinicalTrials.gov and ICTRP. In addition, we examined reference lists of relevant articles, and contacted subject experts to locate additional reports.

Selection criteria: Randomized controlled trials were considered if they evaluated the effectiveness of postpartum education about contraceptive use. The intervention must have started postpartum and have occurred within one month of delivery.
Data collection and analysis: We assessed for inclusion all titles and abstracts identified during the literature searches with no language limitations. The data were abstracted and entered into RevMan. Studies were examined for methodological quality. For dichotomous outcomes, the Mantel- Haenszel odds ratio (OR) with 95% CI was calculated using a fixed-effect model.
Main results: Eight trials met the inclusion criteria. Of four trials with short-term interventions in the immediate postpartum period, one did not have sufficient data and one was statistically underpowered. The remaining two showed a positive effect on contraceptive use. However, most comparisons did not show an effect in one study and the other had short-term assessments. Of four multifaceted programs with multiple contacts, two showed fewer pregnancies or births among adolescents in the experimental group that had enhanced services, and a structured home-visiting program showed more contraceptive use. The effective interventions were conducted in Australia, Nepal, Pakistan, and the USA.
Authors' conclusions: Postpartum education about contraception led to more contraception use and fewer unplanned pregnancies. Both short-term and multiple- contact interventions had effects. The former were limited by self-reported outcomes or showing no effect for many comparisons. The longer-term interventions were promising and not necessarily more costly than usual care. Health care providers can determine if one of these interventions suits their setting and level of resources.

2. Breastfeeding patterns and return to fertility in Australian women (Gross and Burger 2002)
This cohort study followed six hundred and twenty-four Australian mothers who were interviewed every 2 weeks for 12 months after birth. Mothers completed a daily diary record chart of vaginal bleeding and infant feeding, and completed a detailed diary card of the time and duration of breastfeeds and the frequency and nature of all other feedings once every two weeks.

The median duration of amenorrhoea in the Australian breastfeeding women who participated in the study was over 8.5 months. Breastfeeding was shown to be an effective method of fertility control in the mothers who were sexually active, amenorrhoeic, breastfeeding woman. None of the women in this category became pregnant in the first six months after delivery regardless of whether they were using any other contraceptive.

Specific Conditions

Human Immunodeficiency Virus (HIV) in Breastfeeding Women

Notes on HIV and breastfeeding

Following the first report of transmission of HIV-1 through breastfeeding, the Centers for Disease Control and Prevention (CDC) recommended that HIV-1-infected women in the United States abstain from breastfeeding as replacement feeding is safe, affordable, and culturally acceptable. Avoidance of breastfeeding has continued to be recommended in areas where infant formula is accessible, affordable, safe, and sustainable (Read 2003).

A systematic literature review conducted by (Bulteel and Henderson 2007) involved a detailed search of articles published between 1966-2007 on breastfeeding and HIV. Of the 820 papers that were retrieved 22 papers met the inclusion criteria, 5 of which were meta-analyses. In determining the rate of breastfeeding transmission, the authors reviewed a meta-analysis by Dunn and colleagues that estimated the frequency of breast milk transmission during acute maternal infection to be 29% (95% CI, 16–42) and the additional risk of HIV-1 infection in infants who breastfed for at least 2 years to be 14% (95% CI, 7.0–22.0). The results from this meta-analysis were in line with results from several RCTs and cohort studies that found an increased risk of 15%-18% through breastfeeding when compared to formula feeding. The European Collaborative Study found the odds ratio (OR) of transmission to be 2.25 (95% CI, 0.97– 5.23) in breastfed versus never-breastfed children. All the studies included in the review found breastfeeding posed a substantial risk for additional HIV transmission. It is important to note that the transmission rates observed in these studies were derived from populations that were not receiving the recent advancements in antiretroviral therapy (ARV). The WHO 2010 guidelines now state that previously observed transmission rates of HIV would likely be diminished in the presence of ARV interventions.

A recent Cochrane review aimed to collate and assess the evidence regarding interventions to decrease late postnatal MTCT of HIV. Six randomized clinical trials and one intervention cohort study assessing the efficacy of interventions to prevent MTCT of HIV through breast milk were included in the analysis. The authors concluded that complete avoidance of breastfeeding is efficacious in preventing MTCT of HIV and is recommended in resource rich countries where there it is affordable and there is safe water supply (Horvath, Madi et al. 2009). In situations where breastfeeding does occur the review identified exclusive breastfeeding, and antiretroviral prophylaxis to the breastfeeding infant as preventative measures for the prevention of late postnatal transmission of HIV.

The use of ARV drug prophylaxis in HIV-infected nursing mothers and in HIV-exposed infants may make breastfeeding a safer option in the developing world, where the benefit of breastfeeding infants born to HIV-infected women may exceed the risk of transmission.

The Cochrane reviews summary of evidence on the use of antiretroviral prophylaxis during breastfeeding

Infant nevirapine prophylaxis for six weeks or 14 weeks (among infants of mothers who were counselled to breastfeed exclusively for six months and to consider weaning thereafter) has shown promise with regard to prevention of MTCT of HIV and for improvement in HIV-free survival. Such infant antiretroviral prophylaxis was well-tolerated. However, the implications of the studies to date are that antiretroviral prophylaxis to the breastfeeding infant must continue for the duration of breastfeeding (since the efficacy observed with

administration for six or 14 weeks dissipates after prophylaxis is discontinued). Nevirapine resistance among those infants who fail prophylaxis and become infected while receiving nevirapine warrants further evaluation (Horvath, Madi et al. 2009). In addition to these finding, the Cochrane review that aimed to determine whether, and to what extent, antiretroviral regimens decreased the risk of mother-to-child transmission of HIV also concluded that further research is required. The authors stated that it is unclear to what extent breastfeeding influences the efficacy of antiretroviral treatment as only a few trials in Africa have been conducted and there results were conflicting (Volmink, Siegfried et al. 2007).

In 2010, the World Health Organization (WHO) revised their previous recommendations for HIV-infected mothers. The WHO stated that significant research evidence regarding the use of ARV interventions has accumulated since their last recommendations in 2006. Evidence has been reported that ARVs to either the HIV-infected mother or HIV-exposed infant can significantly reduce the risk of postnatal transmission of HIV through breastfeeding. In the global context the WHO now recommend that where ARVs are available, mothers known to be HIV-infected breastfeed until 12 months of age. The WHO encourage national authorities in each country to decide which infant feeding practice, either breastfeeding with an antiretroviral intervention to reduce transmission or avoidance of all breastfeeding, will be primarily promoted and supported by Maternal and Child Health services. National or sub-national health authorities should decide which strategy that will most likely give infants the greatest chance of HIV-free survival. The decisions should be based on international recommendations and consideration of the:

- socio-economic and cultural contexts of the populations served by maternal, newborn and child health services,
- availability and quality of health services;
- local epidemiology including HIV prevalence among pregnant women;
- main causes of maternal and child undernutrition
- main causes of infant and child mortality.

The revised guidelines state that pregnant women and mothers known to be HIV-infected should be informed of the infant feeding practice recommended by the national or sub-national authority to improve HIV-free survival of HIV-exposed infants and the health of HIV-infected mothers, and informed that there are alternatives that mothers might wish to adopt. If a mother does choose to breastfeed, the WHO advises exclusive breastfeeding and ART interventions.

There is a reduction in HIV transmission with exclusive, compared to mixed, breastfeeding in the first 6 months of life (Stein and Kuhn 2009). Depending on when supplements are introduced and on the components of the infant's diet the odds ratio quantifying the disadvantage of mixed feeding compared to exclusive breastfeeding is estimated to be between 2.5-10 (Stein and Kuhn 2009). Further research is required to determine the physiological mechanism that explains the adverse effects of mixed feeding in young infants of HIV infected mothers. To prevent postnatal MTCT transmission of HIV breastfeeding mothers should receive advice about optimal breastfeeding techniques to avoid cracked nipples, milk stasis and mastitis.

A randomised trial in Zambia aimed to determine whether mixing complementary food and fluid with breast milk at the age of four months would have unfavourable effects. The results demonstrated that abrupt weaning is contraindicated indicating that infants that are breastfed should be weaned gradually (Kuhn, Aldrovandi et al. 2008). In line with these results the

review by (Bulteel and Henderson 2007) concluded that the majority of evidence suggests that mixed feeding is associated with a significantly increased risk of MTCT.
In addition to not breastfeeding, other options besides commercial formulas include heat treatment of expressed breast milk, wet-nursing, or use of human breast milk from donor milk banks. The WHO recent guidelines note that heat treatment of expressed breast milk from HIV-infected mothers, if correctly done, can inactivate HIV. As the methods of heat treatment do not appear to reduce the nutritional or immunological properties of breast milk the practice of heat treatment on expressed breast milk could be considered as a potential approach to safely providing breast milk to their exposed infants (WHO 2010).

In developed countries if a newborn infant whose mother's HIV serostatus is unknown, the health care professional should perform rapid HIV antibody testing on the mother or on the newborn infant, with results reported to the health care professional no later than 12 hours after the infant's birth. If the rapid HIV antibody test result is positive, antiretroviral prophylaxis should be instituted as soon as possible after birth but certainly by 12 hours after delivery, pending completion of confirmatory HIV testing. Assistance with immediate initiation of hand and pump expression to stimulate milk production should be offered to the mother, given the possibility that the confirmatory test result may be negative. If the confirmatory test result is negative, then prophylaxis should be stopped and breastfeeding may be initiated. (Havens, Chakraborty et al. 2008) .

The current guidelines in Australia are for HIV infected women to avoid breastfeeding following the long-held notion that avoidance of breastfeeding by HIV-1-infected women remains the only means by which prevention of breastfeeding transmission of HIV-1 can be absolutely ensured. The WHO state that counselling and support to mothers known to be HIV-infected, and health messaging to the general population, should be carefully delivered so as not to undermine optimal breastfeeding practices among the general population.

Brucellosis in Breastfeeding Mothers

Search results
The initial search of the databases included 5 references on brucellosis in breastfeeding mothers. Data were extracted from three case series but the evidence was insufficient to develop a body of evidence statement. The information gathered from the three reviews have been summarised below.

Notes on brucellosis and breastfeeding
The three case series reviewed reported on a total of five case reports of brucellosis in breastfed infants and each included a brief review of the literature. The three case-series all concluded that breast milk is a probable source of transmission of brucellosis despite two of the case-series not being able to isolate Brucella from the breast milk (Palanduz, Palanduz et al. 2000; Arroyo Carrera, Lopez Rodriguez et al. 2006). The case report conducted by Tikare et al. successfully isolated B. melitensis from the breast milk. Tikare and colleagues attributes the collection of milk prior to the administration of antibiotics as the reason for efficiently identifying Brucella in the milk culture (Tikare, Mantur et al. 2008).

Tikare and colleagues recommends mothers with brucellosis abstain from breastfeeding until the infection has been eliminated. Infants of infected mothers should be closely observed for evidence of brucellosis infection (Tikare, Mantur et al. 2008).

Brucellosis in Australia
There were 31 cases recorded in the Australian National Notifiable Diseases Surveillance System. In the unlikely event that a woman with brucellosis is diagnosed in Australia, breastfeeding should be suspended until treatment is complete.
http://www9.health.gov.au/cda/Source/Rpt_3.cfm (accessed 10 Oct 2010)

Galactosaemia in Infants

Search results

The initial search of the databases included 18 references on galactosaemia in breastfed and formula fed infants. Data were extracted from three narrative reviews but the evidence was not strong enough to develop a body of evidence statement. The information gathered from the three reviews have been summarised below.

Notes on galactosaemia in infants

In infants with galactosaemia, galactose must be excluded from the diet early in life to avoid cirrhosis of the liver, mental retardation, cataracts and hypoglycaemia. Breast milk contains 3.7 g of galactose per 100 ml therefore breastfeeding must be ceased (Thompson, Arrowsmith et al. 2003; Leung and Sauve 2005).

Galactosaemia (galactose-1-phosphate uridyltransferase deficiency) is an indication for the use of lactose free soy formulae. It should be noted that some soy protein formulae contain raffinose and stachyose that are cleaved in the digestive tract under the action of bacterial galactosidases, leading to the liberation of 1,4 galactose that may contribute to elevated galactose-1-P values in erythrocytes of galactosaemic patients (Thompson, Arrowsmith et al. 2003; Agostoni, Axelsson et al. 2006).

The working group of Australasia Society of Inborn Errors of Metabolism (ASIEM) handbook written in 1998 recommends the following foods be avoided when infant commence on solid foods: milk and milk products (except for mature cheese), lactose (used as an ingredient and carrier for flavour in foods e.g. in extruded cheese snacks, take away foods, and some medications), chickpeas, beans, gram flour, fermented soy products. Other foods which may contain some free galactose are recommended in small quantities only (Thompson, Arrowsmith et al. 2003). The ASIEM Galactosaemia handbook is currently being revised and a draft copy is currently available (Thompson and Netting 2010).

Hepatitis B Virus (HBV)

Hepatitis B is one of the most widespread global infections with an estimated 2 billion people showing evidence of past infection and more than 350 million are chronic carriers (WHO 2009). Vaccination has been available since 1982 and over one billion doses of hepatitis B vaccine have been used worldwide since then. In many countries where 8% to 15% of children would have been chronically infected with HBV, vaccination has reduced the rate of chronic infection to less than 1% among immunized children.

By the end of 2006, 164 countries had introduced programs to vaccinate infants against hepatitis B. The WHO has set a goal that by 2010 all countries will have routine immunization coverage at 90% nationally with at least 80% coverage in every district. China has set hepatitis B prevention as a major public health goal (Zhou, Wu et al. 2009). Overall more than 95% of Chinese infants are now vaccinated, although in some rural areas coverage may be a little below this level. The rate in Australia is also approaching 100%.
The management of mothers with hepatitis B aims to reduce the possibility of infants developing hepatitis. The WHO recommends that all infants receive hepatitis B vaccine as part of routine childhood immunization. Where feasible, the first dose should be given within 48 hours of birth or as soon as possible thereafter. This will substantially reduce perinatal transmission, and virtually eliminate any risk of transmission through breastfeeding or breast milk feeding. Immunization of infants will also prevent infection from all other modes of HBV transmission.

Current Australian Recommendations are: (Department of Health and Ageing 2008)
"A birth dose of thiomersal-free monovalent hepatitis B vaccine, followed by doses given in combination vaccines (such as DTPa-hepB, DTPa-hepB-IPV, DTPa-hepB-IPV-Hib or Hib (PRP-OMP)-hepB) at 2, 4 and either 6 or 12 months, is recommended for all children."

The rationale for the universal birth dose is not only to prevent vertical transmission from a carrier mother (recognising that there may be errors or delays in maternal testing, reporting, communication or appropriate response), but also to prevent horizontal transmission in the first months of life from a carrier among household or other close contacts. The birth dose should be given as soon as the baby is physiologically stable, and preferably within 24 hours of birth. Every effort should be made to administer the vaccine before discharge from the obstetric hospital.

Extensive experience indicates that the birth dose of hepatitis B vaccine is very well tolerated by newborn infants. It does not interfere with either the establishment or maintenance of breastfeeding, and it is not associated with an increased risk of either fever or medical investigation for sepsis in the newborn.

The WHO and UNICEF also recommend that all infants be exclusively breastfed for at least 4 and if possible 6 months, and that they continue to breastfeed up to two years of age or beyond. There is no evidence that breastfeeding from an HBV infected mother poses an additional risk of HBV infection to her infant, even without immunization. Thus, even where HBV infection is highly endemic and immunization against HBV is not available, breastfeeding remains the recommended method of infant feeding (WHO 1996).

Before the advent of routine hepatitis B vaccination programs in the USA it was estimated that 30%–40% of chronic infections resulted from perinatal or early childhood transmission

(West and Margolis 1992). In the USA the CDC gives the following counselling message "Hepatitis B virus is not spread by breastfeeding, kissing, hugging, coughing, ingesting food or water, sharing eating utensils or drinking glasses, or casual contact (Centers for Disease Control 2005)." However in the USA in the case of hepatitis B positive mothers routine administration of immune globulin is given with the infant Hepatitis B vaccine.

Hepatis C Virus (HCV)

Search terms
The initial search of the databases included 161 references on hepatitis and breastfeeding. Data were extracted from 14 references, and 8 publications were used to form the final body of evidence statement. Sufficient evidence was found to make statements on mother-to-child-transmission of Hepatitis C through breastfeeding.

MOTHER-TO-CHILD-TRANSMISSION OF HEPATITIS C THROUGH BREASTFEEDING

What is the risk of mother-to-child-transmission of Hepatitis C through breastfeeding?		
Draft Evidence Statement		There is no association between transmission of Hepatitis C and mode of infant feeding
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	6 studies [2 SLR, 2 narrative review, 1 cohort, 1 prospective analysis (1P,50)]
Consistency	Good	All studies document no significant difference in the rate of transmission between infants fed with breast milk and those fed with formula in Hepatitis C mothers that are HIV-negative.
Clinical impact	Satisfactory	HCV infection should not be considered a contraindication to breastfeeding
Generalisability	Satisfactory	The majority of studies were conducted on developed countries in Europe
Applicability	Satisfactory	Results are applicable to Australian women

(European Pediatric Hepatitis C Network 2001; Yeung, King et al. 2001; Mok, Pembrey et al. 2005; Pembrey, Newell et al. 2005; Airoldi and Berghella 2006; Bhola and McGuire 2007)

The studies included in the body of evidence statement are shown in the Table below

What is the risk of mother-to-child-transmission of Hepatitis C through breastfeeding in Hepatitis

C and HIV co-infected mothers?		
Draft Evidence Statement		Hepatitis C mothers co-infected with HIV are at an increased risk of transmitting Hepatitis C through breast milk
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	3 studies [2 narrative review, 1 prospective analysis (30)]
Consistency	Satisfactory	All studies documented that Hepatitis C/HIV co-infected mothers that breastfed were at an increased risk of transmitting Hepatitis C to their infant than those that bottle fed.
Clinical impact	Satisfactory	Odds ratio from European Pediatric Hepatitis C Network study was 6.41 (1.25,32.94) for the risk of transmitting Hepatitis C through breastfeeding vs. formula feeding in Hepatitis C/HIV co-infected mothers
Generalisability	Satisfactory	The majority of studies were conducted on developed countries in Europe
Applicability	Satisfactory	Results are applicable to Australian women

(European Pediatric Hepatitis C Network 2001; Pembrey, Newell et al. 2005; Airoldi and Berghella 2006)

The studies included in the body of evidence statement are shown in the Table below

There is no evidence demonstrating an increased risk of HCV transmission in HIV-negative women who breastfeed. Although HCV has been detected in small amounts in the colostrum and breast milk, the amount of HCV/RNA present is too low to infect the newborn and would be easily inactivated by the infant's gastric juices (Airoldi and Berghella 2006). The majority of studies that have reported no association between type of infant feeding and mother-to-child HCV transmission have had relatively small sample sizes, although an effect of breastfeeding has not been observed in larger studies (Pembrey, Newell et al. 2005). The adjusted odds ratio for breastfeeding was 0.95 (95% CI 0.58–1.40, P= 0.74) in the Italian multi-centre study and 1.52 (95% CI 0.35–5.12, P= 0.5) in the UK/Ireland study. There was no effect of breastfeeding among 916 women with only HCV infection in the European Pediatric Hepatitis C Network (EPHN) retrospective analysis. The recent EPHN prospective study also showed no effect among women with only HCV infection (AOR = 0.92, 95% CI 0.50–1.70, P= 0.80) (Pembrey, Newell et al. 2005).

The safety of breastfeeding in HVV-positive mothers depends on the absence of traumatized, cracked, or bleeding nipples. HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding (Roberts and Yeung 2002; Airoldi and Berghella 2006).

For the HCV/HIV-co-infected mother, the recommendation for breastfeeding should be based on the current HIV care recommendations; breastfeeding is discouraged in women who have consistent access to safe infant formula (Airoldi and Berghella 2006).

Studies used to make evidence statement for Hepatitis C virus (HCV) in breastfeeding mothers

Reference	**Yeung et al. (2001)**	**Mok et al. 2005**	**Bhola & McGuire 2007**	**European Pediatric Hepatitis C Network**
Type of study	SLR	Prospective cohort	SLR	Prospective analysis
Level of evidence	I (aetiology)	II (aetiology)	I (aetiology)	II (aetiology)
Definition of breastfeeding	Poorly defined	Poorly defined	Poorly defined	Poorly defined
Intervention/ comparator	breastfeeding vs. not breastfeeding transmission of HCV to infant	breastfeeding vs. not breastfeeding transmission of HCV to infant	breastfeeding vs. not breastfeeding transmission of HCV to infant	breastfeeding vs. not breastfeeding transmission of HCV to infant in HCV/HIV co-infected women
N	1361 mother-infant pairs (499 breastfed, 862 not breast-fed)	54 infants. (290 in initial cohort)	> 1854 mother–infant pairs	503 women
Population/study information	Studies of mother-to-infant transmission of HCV published between 1990 and 2000 were included in review. There was no language restrictions 10 studies evaluating the role of breastfeeding as a risk factor for HCV transmission were eligible for inclusion. Only one of the studies reported on the extent (duration and exclusivity) of breastfeeding. Almost all studies were prospective cohorts in design. (1 study overlaps with Bhola & McGuire's SLR)	The sample was recruited from the European Paediatric Hepatitis C Network, a prospective study on mother to child transmission of HCV. Infants were followed prospectively from birth, with clinical assessments every three months. 290 infants met the inclusion criteria for HCV infection. Of these, 54 had a PCR (HCV RNA polymerase chain reaction) test performed in the first 3 days of life; 17 were positive, and 37 were negative.	Searched database for studies on MTCT of HCV through breast milk that were published between 1996 and 2006. 44 articles found, 33 of which were deemed irrelevant. 11 studies reviewed in total. All articles were observational studies (cohort studies or case-series). 3 cohort studies had sample sizes greater than 100 (1 study overlaps with Yeung et al's SLR)	Questionnaires were sent to coordinators at 24 centres of the European Paediatric Hepatitis C Virus Network. The 24 centres were in seven countries (Italy, Spain, Germany, Ireland, Scotland, Belgium, Sweden). Coordinators completed one form for each mother-child pair using prospectively collected data recorded in the patient notes or on local databases. Received information of 1,655 mother-child pairs. 181 mother-child pairs. Of the 1,474 hepatitis C virus

			(6 studies were also reviewed in Pembery et al's SLR)	infected women that remained, 503 (35%) were co-infected with HIV
Quality	P	0	0	0
Results	Rates of mother-to-infant transmission between breastfedand non–breastfedinfants were similar. The weighted rate of mother-to-infant transmission was 3.7% and 3.9% for breastfed and non-breastfedinfants, respectively (crude rate 6.0%, SD = 1.1% and 6.3%, SD = 0.8% for breastfedand nonbreast- fed infants, respectively). Although some investigators have detected HCV RNA in breast milk, no definite case of mother-to-infant transmission of HCV via breast milk has been reported.	Breastfedinfants were less likely to be PCR positive in the first 3 days of life than formula fed infants. Authors ? significance of association due to small numbers involved. 38% formula fed infants were PCR positive in the first 3 days postpartum compared to 9% of breastfed infants. Unadjusted OR = 0.16 (0.02, 1.52)	No studies found a difference in the rate of transmission between infants fed with breast milk and those fed with formula.	Among the women with hepatitis C virus infection-only, multivariate analyses did not show a significant effect of breastfeeding; breastfed versus non-breastfed OR = 1.07 (0.57,2.02) (P = 0.83). However, HIV co-infected women who breastfed were about four times more likely to infect their children than those who did not OR = 6.41 (1.25,32.94) (P = 0.03).
Effect on risk	Breastfeeding does not significantly affect HCV transmission.	Although the risk of postpartum transmission of HCV through breastfeeding cannot be excluded the results from this study suggest that it is rare.	Avoidance of breastfeeding is not an effective intervention for preventing mother-to-infant transmission of HCV (grade B).	Breastfeeding increasing the risk of vertical transmission of hepatitis C in infants whose mothers are co infected with HIV Hepatitis C virus/HIV co-infected women should be advised to avoid breastfeeding.

Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y-Europe	Y- Europe	Y-Europe
Applicability	Y	Y-Europe	Y-Europe	Y-Europe

Phenylketonuria (PKU) in Infants

Search Terms

The initial search of the databases included 39 references on PKU and infant feeding. Data were extracted from 9 publications, and have been summarized below. Evidence was insufficient to develop a body of evidence statement.

Notes on infants with PKU

A study by Riva and colleagues demonstrated that the type of feeding of the infant prior to diagnosis plays a key role in outcomes (Riva, Agostoni et al. 1996). The study compared IQ scores of PKU children that were breastfed before diagnosis with children that were bottle fed before diagnosis. Breastfeeding, although practised for only a short period (20–40 days), had a beneficial effect on the behavioural development of the children studied. PKU children who had been breastfed as infants prior to diagnosis scored significantly better (IQ advantage of 14.0 points, $p = 0.01$) than children who had been formula fed. A 12.9-point advantage persisted also after adjusting for social and maternal education status. Components of breast milk have been identified as possible explanations such as its lower content of Phenylalanine (Phe) compared with standard infant formulas, the optimal Phe/Tyr ratio, and its rich source of LC-PUFAs, particularly AA and DHA (Giovannini, Verduci et al. 2007).

Early supplementation with preformed LC-PUFA could be of benefit to infants with PKU that are not being breastfed. An RCT by Agostoni and colleagues evaluated the effects of LC-PUFA supplementation in infants with PKU. The finding showed that a phenylalanine-free formula supplemented with LC-PUFA positively influenced erythrocyte DHA status in PKU infants (Agostoni, Harvie et al. 2006).

Prevalence of PKU in Australia

In Australia there is an incidence of one in every 10,000 to 14,000 births, 1 in 50 people carry the PKU gene, and approximately 2025 babies are diagnosed each year (Purnell 2001).

The management of PKU in Australia

The Australasian Society for Inborn Errors of Metabolism (ASIEM) developed a handbook for families of children with PKU and people with PKU, which provides a practical guide for management

The PKU handbook includes the following information on early infant feeding:
It is possible to breastfeed infants with PKU and keep the plasma Phe at a safe level. Breast milk contains much less Phe than infant formula. However, breast milk alone contains too much Phe for infants with PKU. A Phe-free formula is given by bottle to reduce the infant's appetite before breastfeeding. After diagnosis infants may require a diet of solely Phe-free formula until the high Phe plasma levels drop. Mothers wishing to continue breastfeeding are recommended to express breast milk during this period to ensure their milk supply is maintained. After the first few days, breastfeeds are given after a measured amount of Phe-free formula. Most babies with PKU need about half the usual amount of breast milk, but this varies. If an infant is showing signs of hunger, offer more breastfeeds after their Phe free formula. For the formula fed infant, after the first few days, standard infant formula is usually given before the Phe-free formula. If an infant is showing signs of hunger offer more Phe-free formula. The order in which the Phe-free formula is offered may vary from time to time.

The PKU handbook includes the following information on the introduction of solid foods: Solids are introduced at four to six months and start with very small amounts of low phenylalanine foods such as fruit and vegetables. Phenylalanine levels in rice and wheat are too high. A little milk free margarine can be added to the vegetables for extra energy and to make a smoother puree. Children with PKU also need plenty of essential fats which come from vegetable oils such as olive, canola, soya, sunflower, safflower and peanut oils. From seven to nine months small amounts of food with low phenylalanine content such as stewed apple, low-protein pasta and low-protein custard are introduced. Finger foods and low protein bread with milk-free margarine can be offered to encourage infants to chew. Parents learn to count phenylalanine units in the diet and breastfeeding or infant formula will be decreased from this age.

A cohort study conducted in South Australia aimed to describe the feeding regime of infants diagnosed with PKU and assess the efficacy of this method. Of the 27 infants in the cohort study, 22 of them were receiving breast milk prior to diagnosis and all 22 recommenced breastfeeding once phenylalanine levels were below 600 µmol/L. Upon diagnosis infants were fed phenylalanine-free formula, followed by breastfeeding until satiety. The volume of phenylalanine free formula was altered according to the infant's blood-spot phenylalanine level. Blood-spot phenylalanine level was monitored twice weekly to age 3 months then measured once weekly. The overall median mean duration of breastfeeding supplemented with phenylalanine-free formula was 27.4 weeks. (range 0.7-65.7 weeks). All infants had acceptable metabolic control and growth indicating that breastfeeding plus a phenylalanine-free formula provides safe and acceptable management for infants newly diagnosed with PKU (Sweeney, Netting et al. 2009).

The management of PKU in Europe

In Europe there are no consensus guidelines for the optimal dietary care of PKU infants. The recommendations for breastfeeding PKU infants vary across countries. In Germany a fixed quantity of breast milk, is recommended followed by Phe-free formula until satiety, whereas in Belgium, Norway, Poland, Denmark and the UK recommendations are for a fixed quantity of formula prior to breastfeeding until satiety. The quantity of infant protein substitute is adjusted according to the infant's blood Phe concentrations. The centre in the Netherlands advises an alternating breastfeeding schedule, where the frequency of breastfeeding depends on the infant's blood Phe concentration (van Rijn, Bekhof et al. 2003; Ahring, Belanger-Quintana et al. 2009).

Tuberculosis and Breastfeeding

Search results

The initial search of the databases included 92 references on tuberculosis (TB) and breastfeeding. The detailed search is included in a separate document on searches. Data were extracted from 9 references (8 narrative reviews, 1 case-series-post test) and the information from 8 of those publications has been summarised below.

Notes on tuberculosis and breastfeeding

Breast milk does not contain tubercle bacilli, so women with inactive TB may breastfeed (Pronczuk, Akre et al. 2002; Lawrence and Lawrence 2004; Aquilina and Winkelman 2008; Nhan-Chang and Jones 2010).

Women with untreated, active TB should be separated from the infant to prevent respiratory transmission regardless of mode of infant feeding. A mother may resume breastfeeding once adequate therapy has begun and the mother has a negative sputum culture (Lawrence and Lawrence 2004; Aquilina and Winkelman 2008; Nhan-Chang and Jones 2010).
Once treatment has occurred and the mother has a negative sputum culture expressed breast milk can be given safely to the infant, the only contraindication being when the mothers has an active breast lesion or TB mastitis. In this case, breast milk cannot be fed to the infant until the lesion is healed or the mastitis is eliminated (Lawrence and Lawrence 2004; Aquilina and Winkelman 2008).

The WHO recommend that infants at risk of TB infection receive 6 months of isoniazid preventive therapy (IPT) which includes 5 mg/kg of isoniazid daily, followed by BCG vaccination. Follow-up should be at least every 2 months until treatment is complete. Breastfeeding can be safely continued in children during follow-up. An alternative policy is to give 3 months of IPT, then perform a TST. If the test is negative, daily isoniazid should be stopped and BCG vaccination given. If the test is positive, daily isoniazid should be continued for another 3 months, after which it should be stopped and BCG given (WHO 2007).

First line antituberculin drugs are thought to be compatible with breastfeeding by paediatric groups such as the American Academy of Pediatrics and also by respiratory organisations. Medications listed in the table below have undergone rigorous review. The first line antituberculous drugs cross into breast milk in variable amounts. The mean relative dose of isoniazid transmitted to the infant via breast milk is approximately 1.2% which is considered safe (Singh, Golani et al. 2008). Rifampicin is excreted into breast milk with a milk to plasma ratio of 0.2, an amount that does not cause adverse effects. Pyrazinamide excretion into breast milk is minimal with a maximum of 0.3% of the ingested dose reaching the infant. Streptomycin is excreted into breast milk with a milk to plasma ratio of 0.5 –1.0, no significant absorption by the infant is to be expected from this. Ethambutol is secreted into breast milk with approximate milk to serum ratio of 1 (Ormerod 2001). Hepatotoxicity remains a rare but significant risk to the infant therefore it is essential to observe infant for the presence of symptoms. Other drugs, like streptomycin, need further evaluation because of potential harm to the infant (Frieden, Sterling et al. 2003; Aquilina and Winkelman 2008; Nhan-Chang and Jones 2010).

Syphillis in Breastfeeding Mothers

Search results
The initial search of the databases included 17 references on maternal syphilis during breastfeeding. The detailed search is included in a separate document on searches. Data were extracted from one narrative review but the evidence was insufficient to develop a body of evidence statement.

Notes on maternal syphilis during breastfeeding
A review by Cook reported that treponemes (the causative agents of syphilis) are not present in human milk and breastfeeding is not a mode of transmission of maternal syphilis. Infections of the skin or breast tissue (eg chancres) or cracked, bleeding nipples could be a means of transmission so in these cases breast milk expression is recommended. Cook used case-reports to develop the statements on syphilis in breastfeeding women (Cook 1995).

Notes on the prevalence of ectoparasites, gonorrhoea and epstein barr virus (EBV) in breastfeeding women
The review by Cook also included information on other STDs:
Ectoparasites are spread predominantly by close contact. As breastfeeding is an intimate physical event these potential STDs could be transmitted through its close contact.
Gonorrhoea. Nothing was found in the literature with respect to studies of gonococcal spread via breast milk. However possible risk of drug therapy of this on the breastfed infant
Epstein barr virus (EBV) is a herpes virus. EBV has been demonstrated in breast milk, however the implications of this are unknown. (Cook 1995)

Syphilis in Australia
In Australia there were 2835 cases of syphilis notified in 2009. Recent increases have been in the gay male sector of the population. An effective screening and treatment program for pregnant women for syphilis in Australia means that is unlikely that Syphilis will be an issue for breastfeeding (Australian Institute of Health and Welfare 2010).

VII Safe use of infant formula

Infant Formula

Issues that have changed since the 2003 Guidelines

1.Introduction of solid foods in formula fed infants (Dewey 2005).
There is no evidence in the literature that this should be any different to breastfed infants, that is “introduction of solid foods at around six months of age”.

2. Protein Levels in Infant Formula
Formula fed infants grow at a different rate to breastfed infants and are heavier at 12 months of age and have a slightly increased risk of later obesity (WHO European Region 2007). For this reason, a major trial of lower protein formula was undertaken in Europe (Koletzko, von Kries et al. 2009; Koletzko, von Kries et al. 2009). In this well conducted RCT the authors concluded that a ‘higher protein content of infant formula is associated with higher weight in the first 2 years of life but has no effect on length. Lower protein intake in infancy might

diminish the later risk of overweight and obesity.' Subsequent to this study many brands of infant formula in Europe have improved the quality of the protein they contain and reduced overall protein levels.
Human breast milk contains protein levels of 1-1.1 grams per 100mls compared to cow's milk of 3.3 grams per 100mls (Prentice 1996). The infant formulas on the market in Australia contain amounts of protein that vary from 1.3 to 1.7 grams of protein. Reduction in protein levels is limited by the need to meet minimum amounts of specified amino acids, especially tryptophan.
Under Australian Food regulations (Standard 2.9.1) the protein content of infant formula must be between 0.45 and 0.7 grams per 100KJ, and must also meet specific amino acid requirements.

3. Soy based Infant Formula
A detailed review of the use of soy formula has been published by the Canadian Paediatrics Society (CPS 2009). This statement updates older reviews by the American and Australian paediatricians (Australian College of Paediatrics 1987; American Academy of Pediatrics 1998)
The CPS review concluded:
"Physicians should consider limiting the use of soy-based formulas to those infants with galactosemia or those who cannot consume dairy-based products for cultural or religious reasons."

4. Soy based formulas and Allergy Prevention – Cochrane Review (Osborn and Sinn 2006)
This review was updated to 2009 with no change to conclusions.
Background: Allergies and food reactions in infants and children are common and may be associated with a variety of foods including adapted cow's milk formula. Soy based formulas have been used to treat infants with allergy or food intolerance. However, it is unclear whether they can help prevent allergy and food intolerance in infants without clinical evidence of allergy or food intolerance.
Objectives: To determine the effect of feeding adapted soy formula compared to human milk, cow's milk formula or a hydrolysed protein formula on preventing allergy or food intolerance in infants without clinical evidence of allergy or food intolerance.
Search strategy: The standard search strategy of the Cochrane Neonatal Review Group was used. Updated searches were performed of the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 1, 2006), MEDLINE (1966 -March 2006), EMBASE (1980 - March 2006), CINAHL (1982 - March 2006) and previous reviews including cross references.
Selection criteria: Randomised and quasi-randomised trials that compare the use of an adapted soy formula to human milk, an adapted cow's milk or a hydrolysed protein formula for feeding infants without clinical allergy or food intolerance in the first six months of life. Only trials with > 80% follow up of participants and reported in group of assignment were eligible for inclusion.
Data collection and analysis: Eligibility of studies for inclusion, methodological quality and data extraction were assessed independently by each review author. Primary outcomes included clinical allergy, specific allergies and food intolerance. Where no heterogeneity of treatment effect was found, the fixed effect model was used for meta-analysis. Where significant or apparent heterogeneity was found, results were reported using the random effects model and potential causes of the heterogeneity were sought

Main results: Three eligible studies enrolling high risk infants with a history of allergy in a first degree relative were included. No eligible study enrolled infants fed human milk. No study examined the effect of early, short term soy formula feeding. All compared prolonged soy formula to cow's milk formula feeding. One study was of adequate methodology and without unbalanced allergy preventing co-interventions in treatment groups. One study with unclear allocation concealment and 19.5% losses reported a significant reduction in infant allergy, asthma and allergic rhinitis. However, no other study reported any significant benefits from the use of a soy formula. Meta-analysis found no significant difference in childhood allergy incidence (2 studies; typical RR 0.73, 95%CI 0.37, 1.44). No significant difference was reported in one study in infant asthma (RR 1.10, 95% CI 0.86, 1.40), infant eczema (RR 1.20, 95% CI 0.95, 1.52), childhood eczema prevalence (RR 1.10, 95% CI 0.73, 1.68), infant rhinitis (RR 0.94, 95% CI 0.76, 1.16) or childhood rhinitis prevalence (RR 1.20, 95% CI 0.73, 2.00). Meta-analysis found no significant difference in childhood asthma incidence (3 studies, 728 infants; typical RR 0.71, 95% CI 0.26, 1.92), childhood eczema incidence (2 studies, 283 infants; typical RR 1.57, 95% CI 0.90, 2.75) or childhood rhinitis incidence (2 studies, 283 infants; typical RR 0.69, 95% CI 0.06, 8.00). One study reported no significant difference in infant CMPI (RR 1.09, 95% CI 0.45, 2.62), infant CMA (RR 1.09, 95% CI 0.24, 4.86), childhood soy protein allergy incidence (RR 3.26, 95% CI 0.36, 29.17) and urticaria. No study compared soy formula to hydrolysed protein formula.
Authors' conclusions: Feeding with a soy formula cannot be recommended for prevention of allergy or food intolerance in infants at high risk of allergy or food intolerance. Further research may be warranted to determine the role of soy formulas for prevention of allergy or food intolerance in infants unable to be breastfed with a strong family history of allergy or cow's milk protein intolerance.

5. Prebiotics in Infant Formula - Cochrane Review (Osborn and Sinn 2007)
Background: The composition of the intestinal microflora may be different in individuals with atopic eczema from those without this condition, and such differences may precede the development of eczema. Prebiotics are nondigestible food components that benefit the host by selectively stimulating the growth or activity of non-pathogenic bacteria in the colon. Prebiotics (commonly oligosaccharides) added to infant feeds have the potential to prevent sensitisation of infants to dietary allergens.
Objectives: To determine the effect of prebiotics given to infants for the prevention of allergic disease or food hypersensitivity. SEARCH STRATEGY: This included searches of the Cochrane Central Register of Controlled Trials (Issue 1, 2007), MEDLINE (1966 - February 2007), EMBASE, PREMEDLINE, abstracts of conference proceedings and citations of published articles, and expert informants.
Selection Criteria: Randomised and quasi-randomised controlled trials that compared the use of a prebiotic to no prebiotic; or the use a specific prebiotic compared to a different prebiotic.
Data Collection and Analysis: Assessment of trial quality, data extraction and synthesis of data were performed using standard methods of the Cochrane Neonatal Review Group. MAIN RESULTS: Seven studies were eligible for inclusion. Only two studies reported an allergic disease outcome for 432 infants. Study quality was reasonable, although Moro 2006 reported 20% post-randomisation losses. Moro 2006 enrolled hydrolysed formula fed infants at high risk of allergy and reported a significant reduction in eczema in infants up to six months of age (RR 0.42, 95% CI 0.21, 0.84). Ziegler 2007 enrolled formula fed infants who were not selected on the basis of risk for allergy and reported no significant difference in eczema up to four months of age (RR 1.62, 95% CI 0.62, 4.26). Meta-analysis of the two studies found no significant difference in eczema, but significant heterogeneity was detected.

Differences were potentially attributable to differences in infant risk, prebiotic formulation or measurement of eczema. Analysis of five studies reporting measures of infant growth found no consistent adverse effects.
Authors' Conclusions: There is insufficient evidence to determine the role of prebiotic supplementation of infant formula for prevention of allergies and food hypersensitivity. One small trial of prebiotic oligosaccharides with a high dropout rate reported a reduction in eczema in high risk, formula fed infants. Further trials are needed to determine whether this finding persists over a longer period of time, applies to other manifestations of allergic disease, is associated with reductions in allergen sensitisation, and is reproducible.

6. Probiotics in Infant Formula - Cochrane Review (Osborn and Sinn 2007)
Background: The composition of the intestinal microflora may be different in individuals with atopic eczema from those without this condition, and such differences may precede the development of eczema. Probiotics are live bacteria that colonize the gastrointestinal tract and provide a health benefit to the host. Probiotics added to infant feeds have the potential to prevent sensitisation of infants to dietary allergens.
Objectives: To determine the effect of probiotics given to infants for the prevention of allergic disease or food hypersensitivity. SEARCH STRATEGY: This included searches of the Cochrane Central Register of Controlled Trials (Issue 1, 2007), MEDLINE (1966 - February 2007), EMBASE, PREMEDLINE, abstracts of conference proceedings and citations of published articles, and expert informants. SELECTION CRITERIA: Randomised and quasi-randomised controlled trials that compare the use of a probiotic to no probiotic; or the use a specific probiotic compared to a different probiotic; or a probiotic with added prebiotic to control.
Data Collection and Analysis: Assessment of trial quality, data extraction and synthesis of data were performed using standard methods of the Cochrane Neonatal Review Group.
Main Results: Twelve studies were eligible for inclusion. Allergic disease and / or food hypersensitivity outcomes were assessed in 6 studies enrolling 2080 infants, but outcomes for only 1549 infants were reported. Studies generally had adequate randomisation, allocation concealment and blinding of treatment. However, the findings of this review should be treated with caution due to the high drop out in patient follow-up (17% to 61%). Meta-analysis of five studies reporting the outcomes of 1477 infants found a significant reduction in infant eczema (typical RR 0.82, 95% CI 0.70, 0.95). However, there was significant and substantial heterogeneity between studies. One study reported that the difference in eczema between groups persisted to 4 years age. When the analysis was restricted to studies reporting atopic eczema (confirmed by skin prick test or specific IgE), the findings were no longer significant (typical RR 0.80, 95% CI 0.62, 1.02). All studies reporting significant benefits used probiotic supplements containing L. rhamnosus and enrolled infants at high risk of allergy. No other benefits were reported for any other allergic disease or food hypersensitivity outcome.
Authors' Conclusions: There is insufficient evidence to recommend the addition of probiotics to infant feeds for prevention of allergic disease or food hypersensitivity. Although there was a reduction in clinical eczema in infants, this effect was not consistent between studies and caution is advised in view of methodological concerns regarding included studies. Further studies are required to determine whether the findings are reproducible.

7. Probiotics in Infant Formula - Cochrane Review (Osborn and Sinn 2009)
Background: Allergies and food reactions are common and may be associated with foods including cow's milk formula. Formulas containing hydrolysed proteins have been used to treat infants with allergy or food intolerance. However, it is unclear whether hydrolysed

formula can be advocated for prevention of allergy and food intolerance in infants without evidence of allergy or food intolerance.

Objectives: To determine the effect of feeding hydrolysed formulas compared with cow's milk formula or breast milk on allergy and food intolerance in infants and children. If hydrolysed formulas are effective, to determine whether extensively or partially hydrolysed formulas are most effective and to determine which infants benefit, including those at low or high risk of allergy and receiving early, short-term or prolonged formula feeding.

Search Strategy: The standard search strategy of the Cochrane Neonatal Review Group was used. The review was updated with searches of the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 1, 2006), MEDLINE (1966-March 2006), EMBASE (1980-March 2006) and CINAHL (1982-March 2006) and previous reviews including cross references.

Selection Criteria: Randomised and quasi-randomised trials that compare the use of a hydrolysed infant formula to human milk or cow's milk formula. Trials with >80% follow up of participants were eligible for inclusion.

Data Collection and Analysis: Eligibility of studies for inclusion, methodological quality and data extraction were assessed independently by each review author. Primary outcomes included clinical allergy, specific allergies and food intolerance. Meta-analysis was conducted using a fixed effects model

Main results: Two trials compared early, short termhydrolysed formula to humanmilk feeding. No significant difference in infant allergy or childhood cow's milk allergy (CMA) were reported. No eligible trial compared prolonged hydrolysed formula to human milk feeding. Two trials compared early, short term hydrolysed formula to cow's milk formula feeding, but reported no significant benefits. One large quasirandom study reported a reduction in infant CMA of borderline significance in low risk infants (RR 0.62, 95% CI 0.38, 1.00). Ten eligible studies compared prolonged feeding with hydrolysed formula versus cow's milk formula in high risk infants. Meta-analysis found a significant reduction in infant allergy (seven studies, 2514 infants; typical RR 0.79, 95% CI 0.66, 0.94), but not in the incidence of childhood allergy (two studies, 950 infants; typical RR 0.85, 95% CI 0.69, 1.05). There was no significant difference in infant eczema (eight studies, 2558 infants, typical RR 0.84, 95% CI 0.68, 1.04), childhood eczema incidence (two studies, 950 infants, typical RR 0.83, 95% CI 0.63, 1.10), childhood eczema prevalence (one study, 872 infants; RR 0.66, 95% CI 0.43, 1.02), or infant or childhood asthma, rhinitis and food allergy. One study reported a significant reduction in infants with CMA with confirmed atopy (RR 0.36, 95% CI 0.15, 0.89). Subgroup analysis of trials blinded to formula found no significant difference in infant allergy (four studies, 2156 infants; typical RR 0.87, 95% CI 0.69, 1.08) or childhood allergy incidence (one study, 872 infants; RR 0.91, 95% CI 0.73, 1.14). No eligible trial examined the effect of prolonged hydrolysed formula feeding on allergy beyond early childhood. There is evidence that preterm or low birthweight infants fed a hydrolysed preterm formula have significantly reduced weight gain, but not in other growth parameters (head circumference or length). Studies in term infants report no adverse effects on growth. Subgroup analysis of trials of partially hydrolysed versus cow's milk formula found a significant reduction in infant allergy (six studies, 1391 infants; typical RR 0.79, 95% CI 0.65, 0.97) but not childhood allergy, or infant or childhood asthma, eczema or rhinitis. Methodological concerns were the same as for the overall analysis. Analysis of trials of extensively hydrolysed formula versus cow's milk formula found no significant differences in allergy or food intolerance. Infants fed extensively hydrolysed formula compared with partially hydrolysed formula had a significant reduction in food allergy (two studies, 341 infants; typical RR 0.43, 95% CI 0.19, 0.99), but there was no significant difference in all allergy or any other specific allergy incidence. Comparing extensively hydrolysed casein

containing formula with cow's milk formula, one study (431 infants) reported a significant reduction in childhood allergy incidence (RR 0.72, 95% CI 0.53, 0.97). Meta-analysis found a significant reduction in infant eczema (three studies, 1237 infants; typical RR 0.71, 95% CI 0.51, 0.97). One study reported a significant reduction in childhood eczema incidence (RR 0.66, 95% CI 0.44, 0.98) and prevalence (RR 0.50, 95% CI 0.27, 0.92).
Authors' conclusions: There is no evidence to support using a hydrolysed formula for the prevention of allergy compared to exclusive breastfeeding. In high risk infants who are unable to be completely breastfed, there is limited evidence that prolonged feeding with a hydrolysed formula compared to a cow's milk formula reduces infant and childhood allergy and infant CMA. In view of methodological concerns and inconsistency of findings, further large, well designed trials comparing formulas containing partially hydrolysed whey, or extensively hydrolysed casein to cow's milk formulas are needed.

8. Thickened formula for gastro-oesophageal reflux.
There is one Cochrane Review available Feed thickener for newborn infants with gastro-oesophageal reflux (Huang, Forbes et al. 2002 2009 reprint).
Background: Gastro-oesophageal reflux (GOR) is common in newborn infants. A common first line management is the use of feed thickeners.
Objectives: In newborn infants with GOR, to evaluate the use of feed thickeners in reducing signs and symptoms of GOR, acid episodes on pH monitoring and histological evidence of oesophagitis.
Search strategy: We searched MEDLINE from 1966 to March 2004, the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 2, 2004). CINAHL from 1982 to December 2001, and conference and symposia proceedings published in Pediatric Research 1990 to 1994.We also searched conference proceedings for the European Society for Paediatric Gastroenterology and Nutrition (ESPGAN) and the North American Society for Pediatric Gastroenterology and Nutrition (NASPGAN) from1994 to December 2001. We did not restrict the searches to the English language.
Selection criteria: All randomised controlled trials that examine the effects of thickening formulas on treating gastro-oesophageal reflux in neonates. The eligible studies were to compare thickened feeds to no intervention (unthickened feeds).
Data collection and analysis: Two independent reviewers identified potential studies from the literature search. Quality was independently assessed by two independent reviewers.
Main results: No studies fulfilled the requirements for inclusion in the systematic review
Authors' conclusions: There is no evidence from randomised controlled trials to support or refute the efficacy of feed thickeners in newborn infants with GOR. Given the absence of evidence, we cannot recommend using thickening agents for management of GOR in newborn infants.

9. Infant Formulae for other specific conditions.
Some infant formulas on the market in Australia are advertised for the treatment of various conditions such as diarrhoea, hungry infant. No randomised controlled trials could be found to recommend the use of any of these formulas.

10. Notes on Preparation of Infant Formula
There were insufficient studies on the same topic to develop a formal evidence base

Washing bottles in less developed countries (Ma, Zhang et al. 2009)
Although breastfeeding is the best choice for most infants, infant formula is used widely, commonly introduced during the neonatal period, and usually given to infants in bottles that

can be difficult to clean. Infant feeding bottles were artificially contaminated with low and high inocula of bacterial enteric pathogens and the efficacy of several cleaning and chlorine disinfection protocols were evaluated. Rinsing with soapy water followed by tap water was the most effective cleaning method and reduced pathogen load in the low and high inoculum groups.

Submersion in 50 ppm hypochlorite solution for 30 minutes resulted in no identifiable pathogens among the bottles. This result was comparable to boiling. When combined with hand-washing, use of safe water, and appropriate storage of prepared infant formula, these simple, inexpensive practices could improve the microbiological safety of infant formula feeding in less developed settings.

USA Preparation of formula Labiner-Wolfe (Labiner-Wolfe, Fein et al. 2008)
Results from the Infant Feeding Practices Study II
The majority of formula-feeding mothers did not receive instruction on formula preparation (77%) or storage (73%) from a health professional. Thirty percent did not read some of the safe-use directions on the formula package label; an approximately equal percentage (38%) thought that both powdered (which is not sterile) and ready-to-feed (which is sterile) formula were unlikely to contain germs; and 85% believed that following safe-storage directions was very important. Among the mothers of the youngest infants analysed, 55% did not always wash their hands with soap before preparing infant formula, 32% did not adequately wash bottle nipples between uses, 35% heated formula bottles in a microwave oven, and 6% did not always discard formula left standing for more than 2 hours. The prevalence of these unsafe practices was similar among mothers of older infants. No consistent pattern of maternal characteristics was associated with unsafe practices.
Conclusions: Many mothers do not follow safe practices when preparing infant formula. Additional research is needed to understand why more mothers do not follow safe formula-handling recommendations.

SLR on Infant Formula Errors (Lakshman, Ogilvie et al. 2009)
Results: Six qualitative studies and 17 quantitative studies (involving 13 263 participants) were included.
Despite wide differences in study design, context, focus and quality, several consistent themes emerged. Mothers who bottle-fed their babies experienced negative emotions such as guilt, anger, worry, uncertainty and a sense of failure. Mothers reported receiving little information on bottle-feeding and did not feel empowered to make decisions. Mistakes in preparation of bottle-feeds were common.

Lakshman and colleagues were unable to find any studies that examined how mothers made decisions about the frequency or quantity of bottle feeds. This is obviously a serious deficiency in the knowledge base.

11. Bottled Water
Bottled Water has not previously been recommended in Australia, mainly because it has not been fluoridated. However in the UK it is regarded as safe (Osborn and Lyons 2010). There are environmental issues with recommending the use of bottled water.

12. Formula Preparation
There have been revised recommendations on temperatures and preparation from WHO (WHO 2007)

Infant Formula Manufacturers of Australia (now the Infant Nutrition Council)
Food Standards Authority (UK)
European Food Standards Authority (safety of powdered formula)
CDC

13. Storage of Infant Formula

The current recommendation of the manufacturers of infant formula is that and feed left in a bottle be discarded and not stored.

VIII Complementary foods

The appropriate age to introduce solids from all food groups

In addition to the evidence outlined in the subsequent sections, further information can be found in the Evidence Report underpinning the *2013 Australian Dietary Guidelines*; http://www.eatforhealth.gov.au/guidelines/guideline-development.

IX Foods not suitable for infants or that should be used with care

Nuts

UK Food Standards Recommendations: Nuts in infancy are okay but not whole nuts until > 3 years due to the risk of choking

Cow's Milk

Search results

The initial search of the databases included 370 references on unmodified cow and/or goat milk and infant feeding. Data were extracted from 26 references, and 17 publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the proportion of infants fed unmodified cow's milk before 12 months of age, the potential determinants of the early introduction of unmodified cow's milk and the effects of feeding cow's milk to infants less than 12 months of age. Additional evidence was found on the association between cow's milk intake and occult gastrointestinal blood loss (1 controlled trial, 1 cross sectional study, 1 case-control study) but the evidence was not strong enough to develop a body of evidence statement.

THE PROPORTION OF INFANTS FED UNMODIFIED COW'S MILK BEFORE 12 MONTHS OF AGE

How many infants are fed unmodified cow's milk before 12 months of age?		
Draft Evidence Statement		The majority of infants are given cow's milk before the recommended age of 12 months
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	6 studies [3 cohort study, 3 cross sectional study (4P, 20)]
Consistency	Satisfactory	All studies observed infant's being fed cow's milk before 12 months of age; a cohort study in NZ reported 69% of infants were being given cow's milk as a beverage before the age of 12 months, in a Perth cohort study 81.8% of infants had consumed cow's milk as a drink at least once before 12 months and 39.1% of the infants were having cow's milk daily, a cohort study in Europe found by 12 months 50.7% of infants had received cow's milk A proportion of infants less than 12 months of age are consuming a significantly high amount of cow's milk; a Sydney cross sectional study reported 5% of 6-9 month and 13% of 9-12 month-old infants consumed over a litre of cow's milk a day, another cross-sectional study in Australia found at 9 months cow's milk was the main drink for 5% of infants, a Perth cohort study found at 40 weeks 6.2% of infants had cow's milk daily, a cross-sectional study in USA 22% of infants aged 9-11 months consumed cow's milk on a daily basis. The average age of introduction of cow's milk was found to be between 40 and 51 weeks; a mean age of 40 weeks, a median age of 41.5 weeks and a mean age of 11.8 months was reported in three separate studies.
Clinical impact	Poor	Slight
Generalisability	Satisfactory	Populations studied were Australia (3 studies), New Zealand (1 study), US (1 study), Europe (1 study)
Applicability	Satisfactory	Results are applicable to Australian women

(Oti-Boateng, Seshadri et al. 1998; Heath, Tuttle et al. 2002; Briefel, Reidy et al. 2004; Binns, Graham et al. 2007; Fussman, Todem et al. 2007; Conn, Davies et al. 2009)

The studies included in the body of evidence statement are shown in the Table below

THE POTENTIAL DETERMINANTS OF THE EARLY INTRODUCTION OF UNMODIFIED COW'S MILK TO INFANTS

What factors are predictive of the introduction of cow's milk before 12 months of age		
Draft Evidence Statement		Low maternal educational and low socioeconomic status are associated with the introduction of unmodified cow's milk to infants less than 12 months of age
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Good	1 SLR (P) of 21 studies. Strong evidence was found for two demographic determinants; low maternal education and low socioeconomic status. (Strong evidence denoted that the determinant was examined in three or more high-quality studies and ≥75% of results was consistent).
Consistency	Satisfactory	In studies that measured low maternal education and low socioeconomic status on the introduction of cow's milk ≥75% of results were consistent
Clinical impact	Satisfactory	Moderate
Generalisability	Good	Populations studied in SLR were from developed countries, including Australia.
Applicability	Good	Results are applicable to Australian women

(Wijndaele, Lakshman et al. 2009)

The SLR by Wijndaele and colleagues aimed to identify the potential determinants of the early introduction of unmodified cow's milk and early weaning. Seven electronic literature databases (Medline, Psycinfo, CINAHL, BNI, Embase, ASSIA, and Web of Knowledge) were searched for documents in any language from the year of database inception until April 24, 2008. A total of 12,230 documents were retrieved from the electronic database search, of which 78 studies in developed countries, published between 1976 and 2008 met the inclusion criteria. Twenty-four studies were carried out in the United States, eight in Canada, 37 in Europe (of which 23 were in the United Kingdom), eight in Australia, and one in New Zealand. Study quality was systematically assessed in terms of representativeness, sample size, method of determining outcome, and approach to statistical analysis. The distribution of evidence for each determinant was visualized in a harvest plot showing the strength and direction of associations found and the quality of relevant studies. The strength of evidence for each determinant was summarized as strong, moderate, limited, or inconclusive, using an algorithm based on the consistency of the results of studies of the highest available quality. Strong evidence denoted that the determinant was examined in three or more high-quality studies and ≥75% of results were consistent (Wijndaele, Lakshman et al. 2009).

Of the 78 articles investigated, 21 reported on the potential determinants of early introduction of cow's milk. In total, 24 potential determinants were identified (11 demographical, three biological, three behavioural, three psychosocial, and four health and social care). Only three had been uniquely studied as potential determinants of cow's milk (introduction of complementary foods before the recommended age, number of women in the household, and

maternal attitude to infant feeding).Strong evidence was found for two demographic determinants (low maternal education and low socioeconomic status). One demographic determinant (young maternal age) and two behavioural determinants (absence or short duration of breastfeeding and introduction of complementary foods before the recommended age) were supported by a moderate level of evidence. Four potential demographic determinants (maternal employment, family type, infant sex, and parity) were found to have no association with the age of introduction of cow's milk.

The authors conclude that mothers of lower educational attainment or socioeconomic status are more likely to introduce unmodified cow's milk early into their babies' diet. The early introduction of cow's milk was not associated with maternal employment, single parenthood, parity, or infant sex.

EFFECTS OF FEEDING UNMODIFIED COW'S MILK TO INFANTS LESS THAN 12 MONTHS

What are the risks associated with feeding unmodified cow's milk to infants less than 12 months of age?		
Draft Evidence Statement		Feeding infants with whole cow's milk before 12 months of age is associated with an increased incidence of iron deficiency
Draft Grade		**D**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	7 studies [4 cohort study, 3 cross sectional study (2 P, 5 O)]
Consistency	Satisfactory	6 studies reported a negative association between cow's milk intake between 6-12 months of age and iron status
Clinical impact	Poor	Slight
Generalisability	Satisfactory	Populations studied were UK, Denmark, Canada, NZ, Iceland, Brazil and Australia
Applicability	Satisfactory	Results are applicable to Australian women

(Lehmann, Gray-Donald et al. 1992; Michaelsen, Milman et al. 1995; Wharf, Fox et al. 1997; Oti-Boateng, Seshadri et al. 1998; Heath, Tuttle et al. 2002; Thorsdottir and Gunnarsson 2006; Fernandes, de Morais et al. 2008)

The studies included in the body of evidence statement are shown in the Table below

Notes on the introduction of unmodified cow's milk in infancy
Cow's milk feeding is the most consistent risk factor negatively influencing iron status in the first year of life (Faldella, Corvaglia et al. 2003). Cow's milk is a poor source of iron owing to a low iron content and a low iron bioavailability. Consumption of cow's milk also reduces the bioavailability of non-haem iron provided by other foods and may be associated with occult loss of blood from the gastrointestinal tract. A controlled trial by Ziegler and colleagues suggested that cow's milk can provoke microscopic intestinal bleeding if consumed early in infancy, but this effect does not continue beyond 12 months of age. Ziegler and colleagues compared the effects of cow's milk feeding on stool Hb concentration in 7.5 month old infants and 12 month old infants (Ziegler, Jiang et al. 1999). In the trial all infants were fed formula for 1 month and then pasteurized cow's milk for 2 months. Infants 7.5 months of age showed a significant increase in stool Hb concentration after cow's milk feeding where-as 12 month old infants had no significant increase in the proportion of guaiac-positive stools with cow's milk. The results indicate that cow's milk before the age of 12

months is associated with intestinal blood loss. As the response to cow's milk had disappeared in infants older than 12 months of age, Ziegler and colleagues concluded that the gastrointestinal tract of healthy infants gradually loses its responsiveness to cow's milk (Ziegler, Jiang et al. 1999).

A cross sectional study conducted in Brazil on 98 infants did not find a statistically significant difference in the presence of occult intestinal blood in breastfed infants compared to infants who were fed with cow's milk (p= 0.449). However serum ferritin was significantly lower (p=0.004) in infants who received cow's milk and they were positive for occult faecal blood, implying that occult faecal blood loss is an aggravating factor of iron deficiency in infants fed whole cow's milk (Fernandes, de Morais et al. 2008). A case-control study in Turkey assessed the cow's milk intake of infants (4 months to 3 years old) who experienced chronic constipation and anal fissure against the cow's milk intake of infants with no signs of these problems. In this study 25/30 cases were consuming more than 200 mL cow's milk compared to 11/30 controls OR 8.6 (0.23, 0.74). In summarizing their results the author's wrote that the delayed introduction of cow's milk and a consequent increase in breastfeeding duration may reduce chronic constipation and anal fissure in early childhood.

It has been suggested that cow's milk intake can affect linear growth and later blood pressure and risk of obesity, but the evidence is not convincing. A randomised trial carried out by Larnkjaer and colleagues investigated the effects of high protein intake in the form of whole milk (WM) on growth and insulin-like growth factor I (IGF-I) from 9 to 12 months of age. Intake of WM significantly increased the protein energy percentage (PE%) of the infants. When comparing WM to IF as the primary milk source for 3 months, the results did not show WM had an effect on growth. However, the authors observed that positive effect of WM on IGF-I in boys and the positive association between protein energy percentage intake and IGF-I at 9 and 12 months is consistent with the hypothesis that a high milk intake stimulates growth (Larnkjaer, Hoppe et al. 2009).

A cohort study conducted by Fussman and colleagues compared cow's milk consumption between 6 and 12 months of age with no cow's milk consumption between 6 and 12 months on the development of asthma in a cohort study of 696 infants from Germany, Austria, and England (Fussman, Todem et al. 2007). They found no association between cow's milk consumption between 6 and 12 months and childhood asthma [OR = 0.81; (0.55, 1.20)] and concluded that cow's milk consumption does not protect against childhood asthma.

Most European countries recommend delaying the introduction of cow's milk until 12 months, but some countries (eg, Canada, Sweden, Denmark) recommend that cow's milk can be introduced from 9 or 10 months (Agostoni, Decsi et al. 2008). The ESPGHAN committee on nutrition suggests that recommendations on the age for introduction of cow's milk should take into consideration traditions and feeding patterns in the population, especially the intake of complementary foods rich in iron and the volume of milk consumed. Similar to the current Australian recommendations, the ESPGHAN committee on nutrition states that it is acceptable to add small volumes of cow's milk to complementary foods, but it should not be used as the main drink before 12 months (Agostoni, Decsi et al. 2008). An excessive intake of cow's milk before one year of age, or thereafter, can limit the intake and diversification of complementary foods in the diet, which is important in exposing the infant to new tastes and textures that promote the development of eating skills (Cattaneo 2006).

Studies used to make evidence statement for introduction of unmodified cow's milk before 12 months

Reference	**Andiran et al. 2003**	**Binns et al. 2007 (included in Wijandaele SLR below)**	**Briefel et al. 2004**	**Coleman 2006 (included in Wijandaele SLR below)**
Type of study	Case-control	Cohort	Cross-sectional	Cross-sectional
Level of evidence	IV (aetiology)	II (aetiology)	IV (aetiology)	IV (aetiology)
Definition of breastfeeding	Poorly defined	Poorly defined	EBF = consuming only breast milk and no other food or fluid with the exception of water	Poorly defined
Intervention/ comparator	consuming > 200 mL of cow's milk/day vs < 200 mL of cow's milk/day breastfed for > 4 months vs. breastfed for < 4 months	Introduction of whole cow's milk to infants	Introduction of cow's milk before 12 months.	Maternal age, Maternal education (completion of high school vs. college/trade vs. university) Household income (<20,000, 20,000-59,999. >60,000) Parity Smoking vs not smoking, Prenatal plans (breastfeed vs. formula vs. combo) Information received (attended prenatal class, pregnancy info, start of solid food info, formula feeding info)
N	60 children	587 mothers	3,022 infants	1,781 mothers 2,797 approached. 2,058 (73.6%) at 3 months 1781 (63.7%) mothers at 9 months

Population/study information	Two groups of 30 consecutive children aged between 4 months and 3 years that attended the departments of Pediatric Surgery and Pediatrics at Fatih University, Ankara, Turkey. Cases: experienced chronic constipation and anal fissure in whom surgical causes were excluded Controls: no signs of chronic constipation and anal fissure The daily consumption of cow's milk either as unadulterated cow's milk or cow's milk formula, and the duration of breastfeeding from the birth to weaning were recorded. Clinical and dietetic parameters were recorded from birth to three year (unclear of frequency of recordings). Milk consumption was recorded in multiplies of 50 mL in dietetic records.	Mothers part of the Perth Infant Feeding Study (PIFS II) conducted in 2002-2004. Study was undertaken at two public urban hospitals in Perth. Participants completed an initial questionnaire while in hospital relating to infant feeding practices and preferences and were then followed up at regular intervals (seven telephone interviews) for 12 months.	Infants aged 4-24 months (2,024 aged 4-11 months, 998 aged 12-24 months) Infants selected for participation in the FITS (Feeding Infants and Toddlers Study) conducted in 2002. Data were collected via telephone interviews and 24-hour recalls collected for research of university of Minnesota.	Mothers of health term infants who gave birth in 2002-3 in South Ontario were invited to take part in the Infant feeding survey. Telephone interviews conducted at 3 and 9 months postpartum
Quality	0 (No to 6.2 and 7.4	P	P	0
Results	Mean daily consumption of cow's milk: 756 mL(range 200–1500 mL) cases v 253 mL (range 0–1000 mL) controls. ($P < 0.001$) Number of children consuming	At 40 weeks 6.2% of infants had cow's milk daily. At 52 weeks 39.1% of infants had cow's milk daily and 81.8% of infants had consumed cow's milk as a drink at least once. The median age	22% of infants aged 9-11 months consumed cow's milk on a daily basis. 5% of infants aged 9-11 months were fed reduced fat	12.7% of mothers fed their infant non-formula cow's milk as the primary source of milk at 9 months. Mean age of mothers

	more than 200 mL cow's milk daily: 25/30 cases vs. 11/30 control. OR 8.6 (0.23,0.74) Breastfeeding duration: 5.8 month (range 0–18 months) cases v 10.1 months (range 2–24 months) controls. ($P < 0.006$). Number of children were breastfed for less than 4 months: 16/30 cases v 5/30 control. OR 5.7 (0.13,0.66) Atopical cutaneous and respiratory symptoms were also found to be higher in cases v controls. ($P < 0.05$).	for the introduction of cow's milk was 41.5 weeks. Infants who were given solids earlier than four months were more likely to be introduced to cow's milk before 12 months OR 2.06 (1.4,3.1). Mothers who had a lower score on the IOWA Infant Feeding Attitudes Scale, indicating a favourable attitude towards formula feeding, were more likely to give cow's milk earlier OR 1.83(1.21,1.77). Fathers not supportive of breastfeeding or were ambivalent infants were more likely to be given cow's milk. OR 1.70 (1.23, 2.58)	or low fat milks. Mean age that cow's milk was introduced was 11.8 months	introducing cow's milk; before 9 months= 27.1, after 9 months= 28.9 Maternal age Adj OR = 0.96 Percentage of mothers whose household income is < $60, 000 and introduced cow's milk before 9 months= 60.2, after 9 months= 48.6 Percentage of mothers whose household income is > $60, 000 and introduced cow's milk before 9 months= 21.7, after 9 months= 35.2 Household income Adj OR = 0.92 Percentage of mothers who attended prenatal classes and introduced cow's milk before 9 months= 64.1, after 9 months= 77.1 Attended prenatal class Adj OR = 0.81
Effect on risk	Delayed introduction of cow's milk and a consequent increase in breastfeeding duration may reduce chronic constipation and anal fissure in early childhood.	The majority of infants in this study were given cow's milk before the recommended age of 12 months. Results suggest the need for further education programs.	A portion of parents and caregivers require guidance about delaying the introduction of cow's milk until one year of age.	Younger maternal age, lower household income and non-attendance at prenatal class is predictive of the introduction of cow's milk before 9 months.
Clinical	1	1	4	1

importance				
Clinical relevance	1	1	1	1
Generalisability	Y- Turkey	Y	Y -USA	Y- Canada
Applicability	Y	Y	Y	Y

Reference	**Conn et al. 2009**	**Couper et al. 1999**	**Esfarjani et al. 2001**	**Fernandes et al. 2008**
Type of study	Cross-sectional	Cohort	case-control	cross-sectional
Level of evidence	IV (aetiology)	II (aetiology)	III-3 (aetiology)	IV (aetiology)
Definition of breastfeeding	poorly defined	poorly defined		
Intervention/ comparator	Food and nutrient intakes of 9-month-old infants	Introduction of cow's milk and the development of early islet antibodies in early life	Never fresh cow's milk in first 2 years of life vs. fed cow's milk at 1-3 months vs. fed cow's milk > 3 months. Development of IDDM	breastfed (plus complementary food, with the exception of cow's milk) vs. fed whole cow's milk (plus complementary food) on occult fecal blood loss
N	341 parent-infant dyads. (557 parents approached, 507 completed survey 166 were excluded due to over/under reporting)	317 children	104 children	98 infants

Population/study information	Parents were part of a longitudinal study of child growth and development. Parents of infants were randomly recruited from an antenatal clinic at a public hospital and three privately practising obstetricians in Adelaide in 1998–2000. Telephone or face-to-face interviews on consumption size and proportion of food (compared with a 4 d diary had adequate relative validity) occurred at 9 months of age. Researchers used published Estimated Average Requirements to determine adequacy of dietary intake.	317 newborns with a family relative with type one diabetes from 268 families were recruited during pregnancy and followed prospectively from birth for a median of 29 months (4-73) in Victoria and South Australia. Parents kept a home diary to record infant feeding, illnesses, medications which was reviewed at each 6-month visit. A questionnaire was administered at each 6 month visit to assess infant feeding. Venous blood samples were taken at birth, 6 months, 12 months, 18 months, 24 months and at continuing 6 month intervals. Insulin antibodies and antibodies to tyrosine phosphatase, IA2, and GAD65 were measured on serum samples. HLA typing was performed on umbilical venous blood.	Sample comprised of 52 IDDM patients and 52 matched controls. subjects were selected from different hospitals in Tehran, Iran aged between 1.5-14 years. Mothers completed a questionnaire about their child's pattern of feeding designed to gather information of duration and level of breastfeeding and introduction of cow's milk.	Infants in sample were recruited from a Pediatric Public Health Primary Care Unit in Brazil. Infants were 9-12 months of age. Gathered diet history from parents. Infants were categorized into two groups; breastfed (plus complementary food, with the exception of cow's milk) n= 23 vs. fed whole cow's milk (plus complementary food) n=64 Collected blood samples to measure serum iron, Hb concentration , total iron binding capacity, serum ferritin, transferrin concentration . Weighed infants Used the Hexagon OBTI kit to determine occult fecal blood loss and the Kato-Katz technique to examine the parasites in the stool.
Quality	P	P	0	P
Results	At 9 months cow's milk was the main drink for 5% of infants.	Analysis showed no relationship between introduction of cow's milk and the development of	55.8% of IDDM children and 36.5% of the control group had never fed by fresh cow's	There was no statistically significant difference in the presence of occult intestinal

	Zn intake was inadequate for 1% of 9 month old infants not breastfed Fe intake was inadequate for 9% of 9 month old infants not breastfed	islet autoimmunity. Children with one antibody positive; introduction of cow's milk (months) = mean 10.9±0.04, median 12 Children with two or more antibody positive; introduction of cow's milk (months) = mean 10.0±0.09, median 10.5 Children antibody negative; introduction of cow's milk (months) = mean 10.5±0.03, median 11	milk in the first two years of life.	blood in breastfed infants (8/23 34.8%) compared to infants who were fed with cow's milk (30/64 46.9%). p= 0.449. The comparison of body iron indicators in accordance to positive or negative occult fecal blood, did not show any significant difference in the breastfed group. Serum ferritin was significantly lower (p=0.004) in infants who received cow's milk and were positive for occult fecal blood.
Effect on risk	A portion of Australian infants had a weaning diet low in Fe indicating the need to further emphasis delaying cow's milk until 12 months of age.	Results showed no prospective association between introduction of cow's milk and the development of islet autoimmunity in high risk children.	The data does not indicate an association between early exposure to cow's milk and later development of IDDM.	In infants fed whole cow's milk occult fecal blood loss in an aggravating factor of iron deficiency.
Clinical importance	4	1	4	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y-Iran	Y- Brazil
Applicability	Y	Y	Y-Iran	Y- Brazil

Reference	Fussman et al. 2007	Haisma et al. 2005	Heath et al. 2002	Thorsdottir & Gunnarsson 2006
Type of study	Cohort	Cohort	Cohort	Review of two cohorts
Level of evidence	II (aetiology)	II (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding		Study defined EBF as 'receiving nothing but breast milk, not even water'.		
Intervention/ comparator	Cow's milk consumption between 6 and 12 months vs. No cow's milk consumption between 6 and 12 months Development of asthma	Infants receiving only breast milk vs. infants receiving cow's milk in addition to breast milk on minimal observable energy expenditure (MOEE)	Iron intake and prevalence of iron deficiency anemia in children aged 9 months-2 years.	<500 ml cow's milk daily vs. >500 ml cow's milk daily at 12 months on iron status
N	696	62	83. At follow up was 73 (89%)	210 eligible children. >70% were involved in the Fe-status surveys at age 1, 2 and 6 years. 114 children had blood samples taken at 12 months
Population/study information	This cohort was assembled in 1997 and 1998 for the "Study on the Prevention of Allergy in Children in Europe" (SPACE). This cohort focused on the newborn cohort, from Germany, Austria, and England. After the birth, a short questionnaire was completed by the parents to ascertain information regarding their	The study was part of a larger study on the influence of SES on energy requirements conducted in Brazil. From the database of the larger study, infants which met the inclusion criteria were selected. Mother's on infants were visited at home when infant was 7 months old. Infants were categorised into BM or BCM on day 0 of the study according to	Sample consisted of healthy term Caucasian infants resident in Dunedin, New Zealand born between 1995-6. Infants were followed from age 9 months to 2 years. Dietary intake was determined using estimated diet records at 9, 12, 18 and	Collected and analysed data from two cohorts: a longitudinal study on infant nutrition, cohort 1 (n= 180); a cross-sectional study of 2-year-olds, cohort 2 (n=130). In both cohorts; growth data were collected at healthcare centres. Dietary consumption was recorded throughout the first year (once monthly).

	newborn. At each of the 6-, 12-, 18-, 24-, and 36-month follow-up contacts the parents of each offspring were instructed to complete a more in-depth questionnaire about the child's living environment and feeding habits. Information on asthma and wheezing was provided by parents at four follow-ups (12, 18, 24, and 36 months).	mothers recall. Of 62 infants, 35 were categorised into the BM group (receiving only breast milk with or without solids) an 27 were categorised into the BCM group (receiving cow's milk in addition to breast milk with solids) Breast-milk intake was measured using deuterium oxide, complementary food intake by 1-d food weighing, total energy expenditure and total body water using doubly labeled water; anthropometric indices were also calculated	24 months of age	Weighed-food records for 2 days at 2, 4, 6, 9 and 12 months of age and for 3 days at 2 and 6 years of age were used in the analysis of food and nutrient intake. Blood samples were taken at 1, 2 and 6 years of age for analyses of Hb, serum ferritin (SF), serum transferrin receptors, mean corpuscular volume (MCV) and erythrocyte distribution width Icelandic Developmental Inventory (evaluates the motor and verbal development of children aged 3–6 years) was completed by the mothers of seventy-seven participants from cohort 1, but as there were only thirty-six participants from cohort 2 no results are presented.
Quality	P	P	0	P
Results	An infant was exposed to cow's milk in 9.9% (69/696) of the study population by the 6-month follow-up, by 12 months 50.7% (338/696) had ever received cow's milk.	In examining food and nutrient intake by feeding group, breast-milk intake was higher in the BM than in the BCM group (761 ±231 vs. 464 ±352 mL/d, respectively, $P = 0.001$).	Their median iron intakes ranged from 4.3 mg (at 12 months) to 7.0 mg (at 9 months) per day and were below estimated requirements at all ages. At 9, 12 and 18 months of age,	At 12 months of age 41% of infants were iron depleted, 20% were iron deficient, and 2.7 % had IDA. It was demonstrated by regression analysis that Fe

	No association between cow's milk consumption (between 6 and 12 months) and childhood asthma was found for the concurrent effects model OR = 0.81 (0.55, 1.20).	Cow's milk volume, was higher in the BCM than in BM group (232 ± 227 *mL/d* 25 ± 60 p= 0.001). The infants classified as BM consumed 25 ± 60 mL/d of cow's milk on the day of food weighing. In the BCM group, 5 infants had an intake of cow's milk of 0 mL/d on the day that food weighing took place. MOEE was 1672 ± 175 kJ/d in BM compared with 1858 ± 210 kJ/d in BCM infants ($P <$ 0.001) If infants were classified on the basis of their actual intake of cow's milk on the day of food weighing (BM: n =21; BCM: n = 34) the difference remained significant ($P < 0.01$) for MOEE.	7% (n = 4) of the infants had iron deficiency anaemia. More than two-thirds (69%) were being given cow's milk as a beverage before the age of 12 months. The mean age of introduction of cow's milk as a beverage was 40 weeks for those who introduced cow's milk before 12 months.	status was negatively associated with cow's milk consumption at 9–12 months (significant at >460 g/d) All Fe status indices, except Hb, differed significantly between the children receiving <500 ml cow's milk daily (mean SF= 20.1 µg/L, mean MCV=77.3 fl) and those receiving >500 ml cow's milk daily (mean SF= 9.7 µg/L, mean MCV=73.1 fl). Fe-deficient 1-year-olds (n=10) had lower fine motor scores (46.7) when they were 6 years old than those who were not Fe-deficient (49.3; n=53; p= 0.011)
Effect on risk	Results indicate cow's milk consumption does not protect against childhood asthma. The apparent protection of cow's milk against asthma may result from parents of asthmatic children avoiding cow's milk, rather than actual prophylaxis.	Finding suggest complementary feeding with cow's milk alters the sleeping metabolic rate in breastfed infants. The author's hypothesise that the effect occurs in part through a higher protein intake in BCM infants, but even after adjusting for protein intake, the effect of feeding group remained	The iron intakes of this group of Caucasian infants and young children appeared inadequate.	The results suggest that Fe deficiency at 12 months of age affects development at 6 years of age. Cow's milk consumption was the dietary factor most strongly associated (negatively) with Fe status indices in both the infant

		significant therefore either a bioactive factor in cow's milk is responsible for the higher SMR in BCM infants, or alternatively, some factor associated with breast milk or breastfeeding keeps SMR low in BM infants. Author's comment that these findings deserve attention in regards "metabolic programming" and the development of obesity later in life.		study and the study of 2-year-olds.
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y- Europe	Y-Brazil	Y- NZ	Y- Iceland
Applicability	Y-Europe	Y-Brazil	Y-NZ	Y- Iceland

Reference	**Zielger et al. 1999**	**Larnkjaer et al. 2009**	**Lehmann et al. 1992**	**Oti-Boateng et al. 1998**
Type of study	Non-randomized controlled trial	RCT	Cohort	Cross-sectional
Level of evidence	III-2 (intervention)	II (intervention)	II (aetiology)	IV (aetiology)
Definition of breastfeeding	Poorly defined			
Intervention/ comparator	Cow's milk feeding on stool Hb concentration	Whole cow's milk (WM) vs. infant formula as the primary milk source for 3 months on	risk factors for prevalence of iron deficiency anaemia (IDA)	Cow's milk intake during 6-12 months of age on iron status.

		growth and insulin-like growth factor I (IGF-I) from 9 to 12 months of age.		
N	62 infants completed the study. 68 initially enrolled (92%)	94 infants initially included. Follow up at 3 months was 83 infants (88%)	218 mother-infant pairs. (299 mother-infant pairs eligible)	234 children. (325 approached)
Population/study information	Sample included 34 7.5 months old infants, 17 which were formerly breastfed (1B) and 17 that were formerly formula-fed (1F) and 28 12 month old infants, 18 which were formerly breastfed (2B) and 10 that were formerly formula-fed (2F). At enrolment mothers were interviewed about type of feeding infants had received since birth All infant's were fed formula for 1 month and then pasteurized cow's milk for 2 months. Stools were collected for quantitative determination of haemoglobin. Stools were collected during the baseline period (1,14 and 28 days before the start of cow's milk feeding) and 3,7,10,14,28,42 and 56 days after the start of cow's milk feeding. Blood samples were collected to assess iron status just before the change from formula to cow's milk and 7,28 and 56 days	9 month old infants were recruited from the Danish CPR registry Infants were randomized to receive either whole cow's milk (n=38) or infant formula (n=45) and fish oil or no fish oil. Parents recorded the diet of the children at 9 and 12 months over 7 consecutive days by use of a precoded dietary record developed for children Anthropometric variables, IGF-I concentrations, serum urea nitrogen (SUN) were recorded before and after the intervention.	Infants 10 to 14 months of age were identified from registration lists of births from May 1988 to August 1989 in five of the poorest health districts in Montreal. During a home visit capillary blood samples were obtained from the child, and the mother answered a questionnaire about infant-feeding practices. Infants with a serum ferritin level of 10 ug/L or less and either a haemoglobin level of 1 15 g/L or less or a mean corpuscular volume of 72 fL or less were considered as having IDA.	Sample included 6-24 month old children living in Adelaide recruited from Flinders Medical Centres and from immunization clinics and Child and Adolescent Family Health Service Centres (CAFHS) 82% Caucasian and 18% Asian. Dietary intake was estimated from a retrospective 24 hour semiquantitative diet recall questionnaire administered to their parents.

	after the start of cow's milk feeding.			
Quality	0	P	0	0
Results	Infants fed cow's milk from 7.5 months of age showed a significant increase in guaiac-positive stools and in stool Hb concentration. The proportion of groups 1-B and 1-F together was significantly greater during cow's milk feeding than during baseline ($p<0.05$) Effects were largely limited to infants who had been breastfed early in life. In group 1-B 22.4% of infant stools 1-B were guaiac-positive; the increase over baseline was statistically significant ($P< 0.05$). In group 1-F, 14.4% of stools were positive, a proportion not significantly higher than during baseline. Contrary to 7.5 month old infants, 12 month old infants had no significant increase in the proportion of guaiac-positive stools upon cow milk feeding. Iron nutritional status was the same in both groups.	WM significantly increased the protein energy percentage (PE%; $P\leq0.001$) The WM intervention increased IGF-I in boys ($P= 0.034$) but not in girls Including all infants in the analysis there was a significant correlation between weight and IGF-I at 12 months ($r=0.316$, $P=0.017$), and PE% was positively associated with IGF-I after adjusting for sex and breastfeeding at both 9 ($r=0.329$, $P=0.015$) and 12 months ($r=0.272$, $P=0.044$).	IDA was found in 25% of the infants (19%, 31%). whole cow's milk before 6 months of age was a risk factor for IDA [OR= 3.56 (1.07 , 11.26)]	5% of 6-9 month and 13% of 9-12 month-old infants consumed over a litre of cow's milk a day. 69% of Caucasian children were classified iron sufficient, 25% as non-anaemic iron deficiency (NAID) and 6% were IDA. 72% of Caucasian children were classified iron sufficient, 14% as non-anaemic iron deficiency (NAID) and 14% were IDA Multivariate analysis showed that cow's milk intake was associated with serum ferritin < 15µg/L ($r^2= 0.10$, $p<0.001$)

Effect on risk	Cow's milk feeding before the age of 12 months is associated with intestinal blood loss. The results indicated that by 12 months the observed response to cow's milk has disappeared. The authors conclude that the GIT of healthy infants gradually loses its responsiveness to cow's milk.	Randomization to WM had no overall effect on growth. However, the positive effect of WM on IGF-I in boys and the positive association between PE% intake and IGF-I at 9 and 12 months is consistent with the hypothesis that a high milk intake stimulates growth	The consumption of whole cow's milk before 6 months of age was a significant independent predictor of IDA.	Iron nutrition in Australia remains a concern. Iron depletion is associated with early consumption of cow's milk.
Clinical importance	4	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y- US	Y- Denmark	Y- Canada	Y
Applicability	Y- US	Y- Denmark	Y- Canada	Y

Reference	Michaelsen et al. 1995	Nguyen et al. 2004	Wharf et al. 1997	Wijndaele et al. 2009
Type of study	Cohort	Cohort	Cross-sectional	SLR
Level of evidence	II (aetiology)	II (aetiology)	IV (aetiology)	I (aetiology)
Definition of breastfeeding	Poorly defined	Poorly defined	Poorly defined	
Intervention/ comparator	cow's milk intake at 6-9 months of age on iron status	Cow's milk intake at 12, 15 and 18 months on Iron deficiency	Cow's milk intake at 8 months on plasma ferritin levels	Potential determinants of early introduction of cow's milk
N	91 infants. (251 approached, 65% participation rate). Follow up at 12 months was 84 infants.	210. Follow up at 18 months was 174 (83%)	181	
Population/study information	Infants were part of a larger Danish study. In this present study infants were followed from birth to 12 months. Iron intake was examined by 24 hour food records that occurred monthly from birth to 12 months. Iron status was determined by venous blood samples that were taken at 2, 6 and 9 months of age.	This present study was part of a larger cohort study investigating growth and feeding practices of Vietnamese infants living in Sydney. Vietnamese women were recruited from antenatal clinics from three main public hospitals in South-western Sydney. In this cohort healthy term Vietnamese infants were followed from birth to 18 months. Anthropometry, dietary intake and feeding practices measured at seven time points. Dietary intake was assessed using 24 hour recalls. Socio-demographic data were collected from the parents at the first home visit. At 18 months iron status was examined by full blood count	Healthy full-term infants aged 4, 8, 12 and 18 months, living in or near to the city of Norwich were selected for recruitment to the study. The daily iron intake of the infants was measured from a previously validate diet history obtained by interview using a standardised question sheet Capillary blood samples were analysed for haemoglobin, mean cell volume, haematocrit, zinc protoporphyrin and plasma ferritin concentration.	Seven electronic literature databases were searched for documents in any language from the year of database inception until 2008. 12,230 documents were retrieved from the electronic database search, of which 78 met the inclusion criteria. 78 studies in developed countries, published between 1976 and 2008 were found (8 of which were conducted in Australia) Study quality was systematically assessed distribution of evidence for each determinant was visualized in a harvest plot showing the strength and direction of associations found

		and plasma ferritin concentration in 129/152 (85%) of the eligible children. Iron depletion was defined as a plasma ferritin level <10 µ g/L. Iron deficiency without anaemia was defined as iron depletion plus MCV < 70fl and IDA was defined that plus Hb < 110 g/L.		and the quality of relevant studies. The strength of evidence for each determinant was summarized as strong, moderate, limited, or inconclusive, using an algorithm based on the consistency of the results of studies of the highest available quality. Strong evidence denoted that the determinant was examined in three or more high-quality studies and ≥75% of results were consistent.
Quality	0	0	0	P
Results	At 9 months of age, 5% had anaemia (Hb < 105 g/L) but none had IDA (serum ferritin < 13 µg/L and transferring saturation < 10%) During the 6-9 month period, intake of cow's milk was negatively associated with changes in serum ferritin (p = 0.07) in the multivariate analysis model	Multivariate regression analysis showed cow's milk intake at 15 and 18 months was negatively associated with iron deficiency (p<0.001) but not cow's milk intake at 12 months (p=0.092). The mean intake of cow's milk at 12 months was < 40 mL/day	In the 8 month old infants (n=54) intake of cow's milk was negatively associated with plasma ferritin concentrations (Coefficient b= -0.678, P<0.05)	Strong evidence was found for two demographic determinants (low maternal education and low socioeconomic status). One demographic determinant (young maternal age) and two behavioural determinants (absence or short duration of breastfeeding and introduction of complementary foods before the recommended age) were supported by a moderate level of evidence. Four potential demographic determinants (maternal employment, family type, infant sex, and parity) were found to have no association on with the age of introduction

				of cow's milk.
Effect on risk	Consuming cow's milk between 6-9 months of age increases an infant's risk of depleting their iron stores.	No association was found between cow's milk intake at 12 months of age on iron deficiency however this was likely because the intake of cow's milk at this point was too small to cause an effect. Cow's milk intake at 15 and 18 months increased the risk of iron deficiency.	The amount of cow's milk ingested at 8 months plays a role in determining body iron stores.	Mothers of lower educational attainment or socioeconomic status are more likely to introduce unmodified cow's milk early into their babies' diet. The early introduction of cow's milk was not associated with maternal employment, single parenthood, parity, or infant sex.
Clinical importance	1	1	1	1
Clinical relevance	1	4	1	1
Generalisability	Y- Denmark	Y- Vietnamese population in Australia	Y- UK	Y
Applicability	Y- Denmark	Y - Vietnamese population in Australia	Y- UK	Y

References used in body of evidence tables: (Lehmann, Gray-Donald et al. 1992; Michaelsen, Milman et al. 1995; Wharf, Fox et al. 1997; Oti-Boateng, Seshadri et al. 1998; Couper, Steele et al. 1999; Ziegler, Jiang et al. 1999; Esfarjani, Azar et al. 2001; Heath, Tuttle et al. 2002; Andiran, Dayi et al. 2003; Briefel, Reidy et al. 2004; Nguyen, Allen et al. 2004; Haisma, Wells et al. 2005; Coleman 2006; Thorsdottir and Gunnarsson 2006; Binns, Graham et al. 2007; Fussman, Todem et al. 2007; Fernandes, de Morais et al. 2008; Conn, Davies et al. 2009; Larnkjaer, Hoppe et al. 2009; Wijndaele, Lakshman et al. 2009)

Goat's milk

Search terms
The initial search of the databases included 370 references on unmodified cows' and/or goat's milk and infant feeding. Data were extracted from 5 references but the evidence was not strong enough to develop a body of evidence statement. No high-quality observational studies or experimental trials were found regarding the introduction of goat's milk to infants before 12 months of age. The articles retrieved for review were predominantly case reports that included a brief review of the literature.

Notes on Goat's milk
An exclusive, whole goat's milk diet can cause severe morbidity and potentially mortality in infants, including electrolyte imbalances, metabolic acidosis, megaloblastic anaemia, and antigenicity. Despite the recommendations to delay the introduction of unmodified goat's milk until 12 months of age, infants may be consuming high amounts of goat's milk due to their parent's beliefs. Information promoting this practice abounds on the internet with claims that goat's milk is less allergenic than cows' milk and is a suitable substitute for infants with cow's milk allergy. In vitro studies have revealed an extensive cross-reactivity between cow's milk and goat's milk protein (Basnet, Schneider et al. 2010).

Goat's milk has high electrolyte and protein concentrations giving it a high renal solute load. Goat's milk contains 50 mg of sodium and 3.56 g of protein per 100 mL, approximately 3 times the respective values in breast milk, 17 mg and 1.03 g per 100 mL. The recommended adequate intake for sodium and protein for infants below 6 months of age are 120 mg/day and 10 g/day, respectively. Newborn infants have immature kidneys putting them at substantive risk for hypernatremia and azotemia especially if they are dehydrated. Metabolic acidosis has been described in infants fed whole goat's milk (Hendriksz and Walter 2004), which is likely the result of its high protein content.

Folate deficiency with anaemia is another risk in infants fed goat's milk. Goat's milk is low in vitamin B12 and significantly low in folate. Goat's milk has 6 µg/L of folate per litre compared with breast milk's 50 µg per litre. Infants younger than 6 months of age need 65 µg/day of folate. Due to its very low levels of folate and vitamin B12, consumption of goat's milk during infancy can result in severe megaloblastic anaemia (Ziegler, Russell et al. 2005). Infantile vitamin B12 deficiency is a medical emergency due to the potential for severe, irreversible neurological damage. Unpasteurized goat milk has additional infectious risks and has been associated with the development of infections such as Q fever, toxoplasmosis, brucellosis and Escherichia coli O157:H7–associated haemolytic uremic syndrome (Basnet, Schneider et al. 2010).

Systematic evaluation of feeding unmodified goat's milk to infants less than one year of age is lacking, but the current literature is consistent in advocating against this practice. Health professionals need to be aware of the prevalence of unhealthy alternative diets that promote feeding goat's milk to infants and inform parents of the potential dangers associated with this practice.

Reduced-fat milks - existing section
Fruit juices - existing section
Honey – existing section
Tea - existing section

X Infant feeding and later Outcomes

Asthma and Atopy

Note additional evidence has been added to the original review.

What are the benefits of breastfeeding (partial and exclusive) and the risks of not breastfeeding (any and exclusive), to infants and mothers, both in the short term and long term?		
Draft Evidence Statement		Breastfeeding is associated with a reduced risk of asthma and atopic disease.
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	1 Systematic review of cohort studies (Negative quality) and unclear the number of studies included but had 83 references cited. 1 meta analysis of 9 prospective studies
Consistency	Good	ALL studies show increased risk of asthma and atopic disease when NOT breastfed.
Clinical impact	Satisfactory	Odds ratios in the range of 0.8 for decreased risk of asthma and atopic disease.
Generalisability	Good	Can be applied to lactating Australian women and their infants.
Applicability	Good	Applicable to Australia.

The studies included in the body of evidence statement are shown below.

Table 1 Summary used to make evidence statements for breastfeeding and asthma and atopic disease

STUDY DETAILS (Review)	**Oddy 2009 (Oddy 2009)**
Affiliation/source of funds	
Study design	Systematic Review of Cohort studies
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	Not reported but most papers in the publication range of 1981 to 2002
Number of studies	Not reported specifically, about 4 cohort studies, but 83 references cited. A table is given that specifies the inclusion criteria for assessing quality of the studies. Children had to be followed for at least 5 years.
Total number of participants	>4300
Population characteristics	Infants cohorts, both random population samples and cohorts of infants with a family history of asthma or atopy
Range of exposure	Exposure criteria given: 1. Non-reliance on late maternal recall of breastfeeding; 2. Blind ascertainment of infant feeding history; 3. Sufficient duration of breastfeeding; 4. Sufficient exclusivity of breastfeeding
Length of follow-up	5-17 yrs
Outcome(s) measured	Outcome criteria: 1. Strict diagnostic criteria; 2. Blind ascertainment of outcomes; 3. Consideration of severity of outcome; 4. Consideration of age of onset of outcome
INTERNAL VALIDITY	
Databases included in search	not reported
Statistical analysis methods	Statistics: 1. Control for confounding factors; 2. Assessment of dose-response effects; 3. Assessment of effects in children at high risk of outcome; 4. Adequate statistical power
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	Negative but summarising previously published systematic review and giving a guide to interpretation of the studies

RESULTS	
Outcome	Odds ratios in the range of 1.2 to 1.5 for increased risk of asthma and atopic disease all show increased risk when not breastfed. Authors quote a previously published meta-analysis of 9 studies showing that children breastfed for at least 3 months were significantly protected against development of asthma, OR= 0.80 and other meta analyses with a similar protective effect (26%-30%) for exclusive breastfeeding during the first 3 months from developing asthma, allergic rhinitis and atopic eczema.
EXTERNAL VALIDITY	
Generalisability	y
Applicability	y
Comments	
Conclusion	All studies that met the strict criteria for breastfeeding and atopic disease demonstrated a protective effect of breast-milk or, conversely, a risk with formula feeding. However, the continuing protective effect of breastfeeding on asthma and atopy later in adolescence and adulthood has yet to be confirmed in larger longitudinal studies. Given the many benefits conferred by breast-milk, breastfeeding should continue to be promoted as the preferred infant feeding method for the first 6 months and up to two years, as recommended by WHO.

Studies used to make evidence statement for Breastfeeding and Asthma/Atopy – update 2008-2009 of DAA review

Reference	**Tanaka 2008 Int J Tuberc Lung Dis**	**Chuang 2010 Pediatr Allergy Immunol**	**Scholtens 2009 Thorax**	**Ip 2007 Tech Assess Report**
Type of study	Cross sectional	Cohort	Cohort	SLR Meta analysis
Level of evidence	III (aetiology)	II (aetiology)	II (aetiology)	I (aetiology)
Definition of breastfeeding	EBF –infant given only breast milk and no formula since birth Any breastfeeding	The initiation and duration of (any) breastfeeding were measured. Solids feeding was defined as the infant receiving any solid food (e.g. fruit mash, porridge, or dairy products), and data on the start and kinds of feeding were collected.	Breastfeeding was defined as any breastfeeding, including partial breastfeeding. It was measured at 3 and 12 months	2 studies stated exclusive breastfeeding, others undefined
Intervention Comparator	EBF >=4 months compared to EBF<4 months	Exercise levels measured as MET-hours per week	Diet and exercise	Breastfeeding ,3/12 compared to breastfeeding >3 months
N	1957	587	3115	9 studies Studies ranged from 1,037 to 4,964 N=9386 follow-up
Population/study information	Fukuoka Child Health Study A subset of data from a larger study Data obtained at 3 year health examinations. Response 23.7%	Birth Cohort Taipei 20,172 pairs (83.4%) were reviewed completely. To avoid reverse causality, 2399 children with AD in the first 6 months of life were excluded and 18,733 were finally recruited. Outcome measure was a physician's diagnosis of atopic eczema within 6 and 18 months	Dutch children born in 1996/1997 who participated in the PIAMA (Prevention and Incidence of Asthma and Mite Allergy) birth cohort study. Questionnaires at 3months and yearly Blood samples at 8 years and specific IgE components measured.	Pregnancy, Infection, and Nutrition (PIN3) Study recruited pregnant women at <20 weeks' gestation seeking prenatal care at clinics associated with the University of North Carolina Hospitals. Singleton pregnancies. Interviewed at 3 and 12 months post partum. 92% initiated breastfeeding
Quality	P/N/0 N	P	P	P

Results	EBF for >4 months associated with lower rates of asthma at three years Adjusted OR 0.69(0.6-0.96)	Adjusted odds ratios < 4 months (n=847)1.00 (Reference) 4–6 months (n=16,045) 1.11 (0.80, 1.53) p=0.539 >6 months (n=1881)1.08 (0.74, 1.57) p=0.698	Breastfeeding is associated with a lower asthma risk in children until 8 years of age without evidence of attenuation and regardless of the family history of allergy Adj OR by length of ABF Asthma 1-16 weeks 0.82 (0.61, 1.09) >16weeks 0.57 (0.41, 0.80) Chronic Asthma 1-16 weeks 0.87 (0.62, 1.24) >16weeks 0.57 (0.41, 0.80)	Meta-Analysis of prospective cohort studies of the association between asthma risk and breastfeeding ≥ 3 months for children with positive family history of asthma or atopy (excluding Wright 2001) OR 0.60 (0.43, 0.82) Meta-Analysis of prospective cohort studies of the association between asthma risk and breastfeeding ≥ 3 months for children with positive family history of asthma or atopy (including Wright 2001) OR 0.81 (0.41, 1.60) NOTE: The heterogeneity can be explained by a single study. Compared with the other studies in the analyses, the age of follow-up was 13 years in Wright 2001, while it ranged from 2 to 9 years in the other studies Meta-Analysis of prospective cohort studies of the association between

				asthma risk and breastfeeding ≥ 3 months for children without family history of asthma or atopy OR = 0.74 (0.60, 0.92)
Effect on risk	Decrease	None	Decrease	Decrease
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	N (Japan)	Y	Y	Y
Applicability	Y	Y	Y	Y

Reference	**Ip 2007 Gdalevich 2001**	**Miyake 2008 Pediatr Allergy Immunol:**	**Kusunoki 2010 Pediatr Allergy Immunol:**
Type of study	Meta analysis	Cohort study	large-scale cross-sectional study
Level of evidence	I (aetiology)	II (aetiology)	III (aetiology)
Definition of breastfeeding		Exclusive breastfeeding duration was defined as the period when the infants were given only breast milk, (no formula or solids) Water was not stated Partial breastfeeding duration was the period when the infants had received breast milk, regardless of exclusivity.	Complete breastfeeding. Mixed feeding. Complete artificial feeding. Asthma was categorised using a questionnaire comparable with the one used by the International Study of Asthma and Allergies in Childhood (ISAAC) and was prepared and validated by the Study Group of Epidemiology of Allergic Diseases founded by the Japanese Ministry of Health and Welfare. Asthma, atopic eczema, allergic rhinitis, food allergy
Intervention Comparator	≥ 3 mo of exclusive breastfeeding vs. without ≥ 3 mo of exclusive breastfeeding	Exclusive vs. Partial breastfeeding	Any Breastfeeding Vs Complete artificial feeding.
N	Ip found no studies to update Gdalevich. N= 4,158	N=763 infants	13,215 parents responded (response rate, 90.1%).

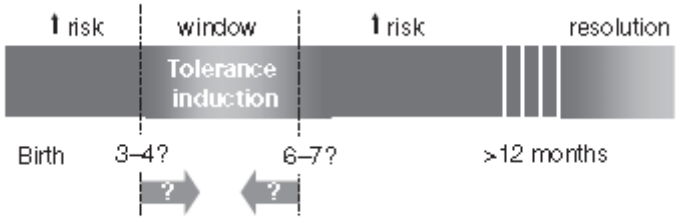
<table>
<tr>
<td>Population/study information</td>
<td>18 prospective cohort studies in developed countries
Term infants</td>
<td>A birth cohort of 763 infants from the Osaka Maternal and Child Health Study.
One survey in hospital and 2 more before 3 years of age. Times of surveys varied.
The definition of asthma used in this study was determined by a positive response to the written question “Has your child been diagnosed by a physician as having asthma?” Wheeze was defined as present if the mother answered “yes” to the written question “Has your child had wheezing or whistling in the chest in the last 12 months?”</td>
<td>Allergic Schoolchildren in Kyoto study
Schoolchildren aged 7–15 yrs.</td>
</tr>
<tr>
<td>Quality</td>
<td>P</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Overall OR 0.68 (95% CI 0.52 - 0.88, fixed effect model);
When restricted to those with positive family history, OR 0.58 (95%CI 0.41 - 0.92)
When restricted to those without family history, OR 0.84 (95%CI 0.59 - 1.19)
Authors’ conclusion: “There is a substantial protective effect of breastfeeding against atopic dermatitis in children with a family history of atopy.”</td>
<td>
<table>
<tr><td>Wheeze</td><td></td><td></td></tr>
<tr><td>Exclusive breastfeeding</td><td>Negative parental allergic history</td><td>positive parental allergic history</td></tr>
<tr><td><4 months</td><td>1.00</td><td>1.00</td></tr>
<tr><td>>4 months</td><td>0.79 (0.43,1.44)</td><td>1.03 (0.65,1.63)</td></tr>
<tr><td>Partial breastfeeding</td><td></td><td></td></tr>
<tr><td><6 months</td><td>1.00</td><td>1.00</td></tr>
<tr><td>>6 months</td><td>0.91 (0.45,1.91)</td><td>1.20 (0.71,2.08)</td></tr>
<tr><td>Asthma</td><td></td><td></td></tr>
<tr><td>Exclusive breastfeeding</td><td></td><td></td></tr>
<tr><td><4 months</td><td>1.00</td><td>1.00</td></tr>
<tr><td>>4 months</td><td>0.62 (0.17,2.05)</td><td>1.34 (0.52,3.54)</td></tr>
</table>
</td>
<td>To examine whether the reverse-causation-associated
factors affected the higher prevalence of AD and FA in those with complete breastfeeding, multivariate analysis with and without
those factors as confounders was performed.
There was a significantly higher proportion of complete breastfeeding among those with greater risk of allergic diseases (presence of family history, either eczema or wheeze within 6 months after birth, or FA in infancy).
Therefore, our multivariate analysis included these risks as confounding factors, and we found that the promoting effects of breastfeeding on AD and FA disappeared.
In conclusion, our data clearly showed the inhibitory effect of breastfeeding on the prevalence of BA at school age.</td>
</tr>
</table>

		Partial breastfeeding			The apparent promoting effect of breastfeeding on the prevalence of AD and FA is most likely because of reverse causation.
		<6 months	1.00	1.00	
		>6 months	0.38 (0.11,1.37)	0.80 (0.30,2.39)	
		*Adjustment for maternal age, indoor domestic pets, family income, maternal and paternal education, maternal smoking during pregnancy, baby's sex, baby's older siblings, household smoking in same room as infant, and time of delivery before third survey..			
Effect on risk	Decrease where family history of atopy	Breastfeeding not related to asthma or wheezing			Breastfeeding not related to asthma or wheezing
Clinical importance	1	1			1
Clinical relevance	1	0			0
Generalisability	Y	N			Y
Applicability	Y	N			Y

1

Notes on Infant Feeding and Allergy

1. **Introduction of solid foods and allergy. From Prescott (Prescott, Smith et al. 2008)**



Factors that influence the capacity for tolerance:

- optimal colonisation
- genetic pre-disposition
- allergen properties (dose, interval, timing, preparation)
- gut permeability/maturity/pH
- continued breast feeding?
- other immunomodulatory factors (fatty acids? stress? antioxidants?)

Fig. 1. Possible 'window of tolerance' for introduction of complementary foods.

Note: If there is a window for tolerance between 4-7 months, then introducing solids "around six months" will meet the allergy concerns and address concerns about early introduction of complementary foods.

2. **The current recommendations of the Australasian Society of Clinical Immunology and Allergy (Jennings and Prescott 2010)**

Box 1 Key points underlying changes in complementary feeding practices

- There is little evidence that delaying the introduction of complementary solid foods beyond 6 months reduces the risk of allergy, and there have been some suggestions that delaying introduction of foods may actually increase (rather than decrease) allergy.
- There is insufficient evidence to support previous advice to specifically delay or avoid potentially allergenic foods (such as egg, peanuts, nuts, wheat, cow's milk and fish) for the prevention of food allergy or eczema. This also applies to infants with siblings who already have allergies to these foods.
- More research is needed to determine the optimal time to start complementary solid foods. On the basis of currently available evidence, many experts across Europe, Australia and North America recommend introducing complementary solid foods from around 4—6 months.
- Based on Infant Feeding Advice of the Australasian Society of Clinical Immunology and Allergy (http://www.allergy.org.au/images/stories/pospapers/ascia_infantfeedingadvice_oct08.pdf).

Feeding advice based on current evidence (as at September 2008)
Current advice from the Australasian Society of Clinical Immunology and Allergy

Target population
All children, including those with siblings who already have allergies or children affected by eczema (even though these children are at higher risk of allergies).

Breastfeeding
Breastfeeding is recommended for at least 6 months and is encouraged for as long as the mother and infant wish to continue, without any maternal dietary restrictions. This is for the many nutritional and non-nutritional benefits of breastfeeding for both the mother and infant. It is thought that continuation of breastfeeding at the time foods are first introduced may help prevent the development of allergy to those foods.

Infant formulas before 4 months
If complementary formula is required before solid foods are started, recommendations vary. Where there is no family history of allergic disease in the infant's parents or siblings, a standard cow's milk formula may be used. Infants with a family history of allergy (parents or siblings) should be started on a partially hydrolysed cow's milk formula (usually labelled "HA" or hypo-allergenic). For known cow's milk allergy, these formulas are not suitable; elemental formulas are used instead. Soy milk and other mammalian milks (eg, goat's milk) are not recommended for allergy prevention or for infants with known cow's milk allergy.

Starting complementary foods
From 4-6 months onwards. When a child is ready, parents should consider introducing a new food every 2-3 days, according to what the family usually eats (regardless of whether the food is thought to be highly allergenic). In this way, reactions can be more clearly identified and the food excluded (or continued) as a part of a varied diet. Infants are unlikely to develop a new allergy to any food that is already tolerated, if it is given regularly. Breast milk or an appropriate infant formula should remain the main source of milk until 12 months of age, although cow's milk can be used in cooking or with other foods.

Allergenic foods
There are no particular allergenic foods that need to be avoided. Some children will develop allergies, but there is no way of accurately predicting who. If there is any reaction to a food, parents should exclude that food until the child is reviewed by a medical practitioner with experience in food allergy.
Based on Infant Feeding Advice of the Australasian Society of Clinical Immunology and Allergy (http://www.allergy.org.au/images/stories/pospapers/ ascia_infantfeedingadvice_oct08.pdf).

3. **British Nutrition Foundation systematic Literature Review for the UKFSA (Thompson, Miles et al. 2008)**

Systematic review of literature on early life patterns of exposure to, and avoidance of, food allergens and later development of sensitisation and clinical food allergy, with particular reference to peanut allergy.

Conclusions

The systematic review has not provided sufficient evidence to make firm conclusions particularly in the area of non-dietary exposure to peanuts and timing of introduction of solids. None of the studies we found met the SIGN criteria for a good quality study. The few studies that were identified assessed a wide range of exposures/interventions and methods of diagnosis of sensitisation and allergy differed between studies, with few using double blind placebo controlled trials. The heterogeneous nature of the evidence makes it difficult to synthesise the evidence in order to develop firm, clear conclusions:
The available evidence from human studies does not suggest that maternal exposure to or avoidance of food allergens during pregnancy or lactation leads to the subsequent development of food sensitisation or food allergy in the child. On the contrary, information from studies in lactating rats

suggests that exposure to ovalbumin via maternal oral intake, particularly at high doses, may protect the offspring from the development of sensitisation to ovalbumin. Studies of cord blood mononuclear cell responses and allergens published since 1998 suggest that the cord blood mononuclear cell responses observed after *in vitro* stimulation with food allergens are not necessarily the consequence of foetal exposure to, or sensitisation by maternally consumed food allergens.

Evidence from human studies does not suggest that dietary exposure to or avoidance/delaying introduction of allergenic foods in childhood provides protection from subsequent development of sensitisation or allergy to foods. There are few studies that have investigated the timing of introduction of allergenic foods and more research is required in this area. Evidence from animal studies suggests that oral exposure to low doses of food protein may induce sensitisation; whereas high doses may result in tolerance. This would argue that attempts at avoidance of exposure to food allergens could potentially be harmful, rather than protective, if it proves impossible to avoid the relevant food allergens altogether. The results of investigations in animals need to be confirmed and their relevance to humans explored, in particular the concept of "small" and "larger" amounts in human terms.

There is little information in humans available on the effects of non-dietary exposure to peanuts on the development of sensitisation and allergy. However, one study did show an increased risk of peanut allergy in children who were exposed to skin creams containing peanut oil. There is some supportive evidence from experimental animal studies examining responses to peanut or ovalbumin. Further studies in humans are required in this area.

There appears to be confusion among the general public about the 1998 COT advice and it has not been interpreted as intended. More than 60% of women report having reduced (few totally avoided) consumption of peanuts during pregnancy and lactation, including those not targeted by the COT advice. There appears to have been a rise in the prevalence of peanut sensitisation and allergy between 1989 and 1996 but there is no evidence of any significant changes in the prevalence of peanut allergy in the UK since that time.

Introduction (or avoidance) of Peanuts (Committee on Toxicology 2008)

Conclusions and recommendations (December 2008)
"68. From the evidence that was reviewed, the Committee has drawn the following conclusions:
i. It is unclear whether prevalence rates of peanut sensitisation and allergy in the UK have changed since the previous COT recommendations were issued in 1998.
ii. The new evidence that has become available since 1998 reduces the suspicion that maternal consumption of peanut or peanut products during pregnancy might predispose infants to the development of peanut sensitisation and allergy. In particular, it now appears that *in vitro* responses to allergens by umbilical cord blood mononuclear cells do not necessarily reflect maternal exposure to the allergens concerned. In addition, there is now limited human evidence, consistent with a larger body of animal data, suggesting that non-oral routes of exposure to peanut, such as via the skin, may be relevant to the development of peanut sensitisation and allergy during early childhood. This casts doubt on the previous assertion that reactions to peanut on first known dietary exposure are necessarily indicative of sensitisation *in utero* or and/or during lactation. Data from animal studies indicate that exposure of damaged skin to egg (ovalbumin) or peanut allergens can result in the induction of IgE-mediated systemic allergic responses.

iii. Animal studies that have been reported since 1998 suggest that maternal oral exposure to the hens' egg allergen, ovalbumin, during gestation and/or lactation, particularly at high doses, may

protect offspring from developing allergic responses to this allergen. There are no comparable data for peanut proteins in animals, or for humans, but the finding raises the possibility that maternal dietary consumption of peanut might in some circumstances reduce the risk of peanut allergy in offspring.

iv. Overall, the evidence now available does not indicate whether maternal dietary consumption of peanut during pregnancy or lactation is more likely to increase or decrease the risk of sensitisation and allergy to peanut in the child. An effect in either direction is possible, and it is possible that the direction of effect could differ according to the level of intake. Alternatively, there could be no effect at all.

v. Human data relating dietary consumption or avoidance of peanut or other allergenic foods in childhood to the development of sensitisation or allergy or tolerance to peanust, are limited and inconsistent. Data from animal studies suggest that, for peanut proteins and ovalbumin, the nature of the immune response may depend on dose, with high exposures tending to induce tolerance and low exposures sensitisation. However, there are no comparable published data for humans at this time.

69. The shift in the balance of evidence since 1998 is such that the Committee believes that the previous precautionary advice to avoid peanut consumption during pregnancy, breastfeeding and infancy, where there is atopy or atopic disease in family members, is no longer appropriate.

70. However, the Committee considers that the basis of the more general recommendations made in 1998 is still justified and, therefore, recommends that:
(i) In common with the advice given for all children, infants with a parent or sibling with an atopic disease should be breastfed exclusively for around 6 months;
and,
(ii) Infants and children who are allergic to peanuts or peanut products, should not consume them or foods that contain them; and also recommends that:
(iii) those who are allergic to peanut should seek advice from medical professionals about avoidance strategies.

71. However, it should be recognised that there remains scientific uncertainty about the determinants of peanut sensitisation and allergy. Thus, further changes to this advice may be warranted in the future, as and when new data become available. In particular, studies are currently underway to investigate the impact on allergic outcomes of early dietary introduction of peanut and/or other allergenic foods into the infant diet, and these studies have the potential to provide more definitive data in the next 5 to 7 years.

72. In addition, the Committee recommends that further studies are needed in humans:
a. to determine whether and to what extent the skin and respiratory tract are important routes of sensitisation to peanut and other food allergens, and if they are, to determine the importance of timing and dose, and the underlying mechanisms; and
b. to investigate whether and how oral dose levels influence the development of sensitisation, allergy or tolerance to peanut and other allergenic foods.
73. The Committee also noted the need for clearer information on temporal trends in peanut consumption and the prevalence of peanut allergy in UK infants and children, as well as on infant weaning practices in the UK."

Final Comments - Allergy, Asthma and Breastfeeding

The issue of breastfeeding and allergy is an interesting one. At present the WHO and most major professional and national bodies, including the NHMRC recommend exclusive breastfeeding until "around 6 months of age". This policy is associated with the lowest levels of morbidity and mortality. The recent policy statement from the American Academy of Pediatrics states (Greer, Sicherer et al. 2008) "There is evidence that breastfeeding for at least 4 months, compared with feeding formula made with intact cow milk protein, prevents or delays the occurrence of atopic dermatitis, cow milk allergy, and wheezing in early childhood." There is nothing in the statement recommending the introduction of solids before 6 months.

A recent review in the NEJM (Lack 2008) states the following "Recent studies suggest that infants who are exposed to food allergens early through the oral route are less likely to have food allergies than infants without such exposure,(Kull, Bergstrom et al. 2006; Poole, Barriga et al. 2006) but such observational cohort studies are subject to confounding and the possibility of reverse causality. An ongoing randomized trial (www.leapstudy.co.uk) involving infants at high risk for food allergy is comparing early exposure to high doses of food allergens with complete avoidance of these allergens during infancy. Results will be available in 2013. However the applicability of trials on at risk populations will need to be assessed.

Reverse causality is a real issue as national bodies have been recommending exclusive breastfeeding for infants with a family history of allergy for 2 or 3 decades (NHMRC since 1979). Mothers of infants who are at risk of asthma or atopy were more likely to continue breastfeeding. Hence breastfeeding could be associated with asthma/atopy in case control or cohort studies (Tanaka, Miyake et al. 2010).

After the onset of symptoms of eczema or a wheeze, mothers would tend to prolong the duration of exclusive breastfeeding because of the general belief in its protective effect.(Laubereau, Brockow et al. 2004) This is not the duration of breastfeeding leading to eczema or wheezy disorder, but in fact, the onset of symptoms has lead to longer duration of breastfeeding. Only long-term observations, of the start and end of exposure and disease, or randomized controlled trials (that would probably be unethical) could be used to reduce this source of bias.(Giwercman, Halkjaer et al. 2010) (Bisgaard and Bonnelykke 2010)

The UK Food Standards Authority Committee on Toxicology summarized the current evidence:
"In common with the advice given for all children, infants with a parent or sibling with an atopic disease should be breastfed exclusively for around 6 months;"

There would appear to be no reasons to restrict the introduction of any particular foods or groups of foods to infants in an effort to prevent allergy or promote tolerance.

Obesity and infant feeding

The duration of Exclusive/Any Breastfeeding, the age of Introduction of Complementary Foods and the development of overweight/ obesity

Summary

There is evidence that breastfeeding protects against later obesity

The strength of evident that breastfeeding duration protects against later obesity is not strong. But there are many other good reasons to promote breastfeeding (exclusive and any breastfeeding). Increasing breastfeeding intensity and duration may decrease population rates of obesity and overweight in children and adults.

The issues to be considered include:

1. Minimisation of morbidity and mortality. The relationship between breastfeeding and infant morbidity and mortality, including hospitalisation rates is well established in developed and developing countries.
2. Appropriate growth
    a. Minimise undernutrition, stunting and organ development at one end of the spectrum
    b. Minimise obesity – short and long term risks (the U-shaped risk curve)
    c. If complementary foods are introduced too late nutritional deficiencies will result
3. Suppression of breast milk production
    Loss of readily absorbed and biologically optimised mix of nutrients
4. Introduction of GIT Infection
5. Changes in the human microbiome introduced by changes in diet
6. Prevention (reduction) of allergy by introducing solid foods at the most appropriate time.

Specific questions to consider that have become topical since the 2003 NHMRC Guidelines

1. Obesity has emerged as a major (perhaps the major) public health nutrition issue
2. Rates of allergic disorders have increased in Western countries. Various versions of the "hygiene" hypothesis have suggested the earlier introduction of solids as a way of reducing food allergies". To date the trials conducted have been on populations at increased risk of allergic disease.
3. How do parents and health professionals interpret the present recommendation of around 6 months? It is evident in Australia that almost all mothers introduce solids before the currently recommended time.
    a. Perth Infant Study. By 16 weeks 57% of infants had consumed solids increasing to 89% at 26 weeks
    b. In the 2001 National Health Survey 90% of infants were having solids at 6 months (Donath and Amir 2005)

Definitions

The definitions used for complementary foods vary. The WHO include infant formula. The term 'solid foods' is not really appropriate as most of the first foods given to infants are semi-liquid. The term "spoon foods" is commonly used in Europe. In this document the term solid foods will be used as it is in most common use in Australia.

There are similar difficulties with "weaning". This is used variously as "cessation of breastfeeding" and "the introduction of solid foods". It will not be used in these guidelines.

**The 2003 Guidelines **
The NHMRC Dietary Guidelines for Children (2003) included the following questions related to the introduction of solids:
"Introduction of solid foods
The expression introduction of solids describes the process whereby an infant, having previously been fed solely milk, gradually becomes accustomed to a variety of other foods until he or she can deal with the general family diet. The expression is preferable to weaning because it more accurately conveys the idea that the process does not involve cessation of breastfeeding.
Four main questions arise in connection with the introduction of solid foods:
• *At what age should solid foods be introduced?*
• *What foods should be introduced?*
• *How should foods be introduced?*
• *How can the risk of infection be reduced?*

What does time mean?
The timing of introduction of solids is described in different ways. Here are some examples:

a) At six months
b) Around six months
c) Around six months and never before 4 months (the current Australian position)
d) Not before six months
e) Around six months - not before 17 weeks but should not be delayed beyond 26 weeks
f) Introduction of complementary solids from around 4-6 months

Previously in Australia the recommendation was 4-6 months. This was interpreted by many mothers as at the beginning of the 4th month (ie 12-13 weeks). There are similar difficulties with the existing recommendation of 'around six months'. Does this mean from 20 or 21 weeks? In fact the 'around six months' was deliberately chosen following focus group testing to reflect individual variation in infant requirements.
The most difficult to interpret is "around 4-6 months" which is being communicated to mothers as "from 12 weeks".

International Recommendations
Most government agencies and professional organisations have recommended exclusive breastfeeding until 6 months or around 6 months. (see below for some examples).
However in the past five years several professional organisations with an interest in allergy have suggested that solids should be introduced during a "window of tolerance" (Prescott, Smith et al. 2008)

Statements on Breastfeeding Exclusive to Six months
Exclusive breastfeeding is defined as feeding the infant only breast milk, with no supplemental liquids or solids except for liquid medicine and vitamin/mineral supplements

The US government agencies and national professional associations in the United States generally recommend infants be exclusively breastfed for the first 6 months of life, and continue to breastfeed at least through the first year of life. Examples include:

1 *Healthy People 2010* Washington, DC: US Department of Health and Human Services; 2000. Target16-19. Increase the proportion of mothers who breastfeed their babies. "Approximately the first six months of life" (U.S. Department of Health and Human Services 2000)

2. Centre for Disease Control (has two recommendations in different documents- endorses Healthy People 2010 and see below)
3. American Academy of Pediatrics. Breastfeeding and the use of human milk. "gradually beginning around 6 months" (Gartner, Morton et al. 2005)
4. American Dietetics Association (James and Lessen 2009) "exclusive breastfeeding provides optimal nutrition and health protection for the first 6 months of life and breastfeeding with complementary foods from 6 months until at least 12 months of age is the ideal feeding pattern for infants"
5. American Public Health Association A call to action on breastfeeding: A fundamental public health issue. **Policy Number:** 200714 **Policy Date:** 11/6/2007
Web site. http://www.apha.org/advocacy/policy/policysearch/default.htm?id_1360. Accessed Oct 7, 2010.

International organisations
World Health Organization (WHO) and United Nations Children's Fund (UNICEF)
"Over the past decades, evidence for the health advantages of breastfeeding and recommendations for practice have continued to increase. WHO can now say with full confidence that breastfeeding reduces child mortality and has health benefits that extend into adulthood. On a population basis, exclusive breastfeeding for the first six months of life is the recommended way of feeding infants, followed by continued breastfeeding with appropriate *complementary foods* for up to two years or beyond."
http://www.who.int/child_adolescent_health/topics/prevention_care/child/nutrition/breastfeeding/en/index.html Accessed 7 Oct 2010
The Bellagio Child Survival Study Group identified breastfeeding during the first year as one of the most important strategies for improving child survival (Claeson, Gillespie et al. 2003; Jones, Steketee et al. 2003; Bryce, Black et al. 2005)

Australia.
NHMRC, Infant Feeding Guidelines 2003; Exclusive breastfeeding for around six months.
RACGP; Encourage, support and promote exclusive breastfeeding for the first 6 months of life (Royal Australian College of General Practitioners 2009)
Australian Breastfeeding Association; Breast milk contains all the nutrients your baby needs for at least the first six months of his life and continues to be the most important part of his diet throughout the first year, supplying half or more of his nutrients till his first birthday and up to one third to his second birthday. http://www.breastfeeding.asn.au/bfinfo/general.html

The Paediatrics & Child Health Division of The Royal Australasian College of Physicians in its revised 2007 statement on breastfeeding:
"Healthy breastfed babies do not need other fluids. The NHMRC recommends exclusive breastfeeding to 6 months based upon WHO and Cochrane reviews that demonstrated no disadvantage to growth associated with exclusive breastfeeding and evidence demonstrating some protection from gastrointestinal infection in exclusively breastfed infants. However the introduction of complementary foods between 4 and 6 months, for healthy infants who are developmentally ready has not proven deleterious."
http://www.racp.edu.au/page/policy-and-advocacy/paediatrics-and-child-health

Canada
Health Canada; Encourage exclusive breastfeeding for the first 6 months of life, as breast milk is the best food for optimal growth. Breastfeeding may continue for up to 2 years and beyond.

http://www.hc-sc.gc.ca/fn-an/pubs/infant-nourrisson/nut_infant_nourrisson_term_3-eng.php Accessed 8 Oct 2010
The Canadian Paediatric Society recommends exclusive breastfeeding for the first six months of life for healthy, term infants. Breast milk is the optimal food for infants, and breastfeeding may continue for up to two years and beyond. Sept 2009
http://www.cps.ca/english/statements/n/breastfeedingmar05.htm Accessed 7 Oct 2010
China
The Ministry of Health recommends exclusive breastfeeding until 6 months of age (Wang, Binns et al. 2009)

India
Exclusive breastfeeding to six months (Gupta, Dadhich et al. 2010)

New Zealand
Infants are exclusively breastfed for the first six months of life, and thereafter receive safe and adequate complementary foods while breastfeeding continues for up to two years of age or beyond. (National Breastfeeding Advisory Committee of New Zealand 2009)

United Kingdom
Breastfeeding is natural and normal and gives your baby the best start. The Department of Health recommends exclusive breastfeeding for the first 6 months of life and can continue to benefit your baby along with solid foods for many months after. Every day you breastfeed makes a difference to your baby's health now and in the future. http://www.breastfeeding.nhs.uk/ Accessed 9 October 2010

After reviewing the introduction of solids, including allergenic foods such as peanuts, the UK Food Standards Authority reached the following conclusion (Thompson, Miles et al. 2008);
"In common with the advice given for all children, infants with a parent or sibling with an atopic disease should be breastfed exclusively for around 6 months;"

Statements on exclusive Breastfeeding 4-6 months

USA - Centers for Disease Control
"Exclusive breastfeeding is recommended for the first 4–6 months of life, and breastfeeding together with the age-appropriate introduction of complementary foods is encouraged for the first year of life." (Centers for Disease Control and Prevention 2009)

ESPGHAN (European Society for Pediatric Gastroenterology, Hepatology, and Nutrition
On the basis of available data, the Committee considers that exclusive or full breastfeeding for around 6 months is a desirable goal (ESPGHAN Committee on Nutrition, in preparation). In all infants, in consideration of their nutritional needs, developmental abilities, and reported associations between the timing of introduction of complementary feeding and later health, which are discussed later, the introduction of complementary foods should not be before 17 weeks but should not be delayed beyond 26 weeks (Agostoni, Decsi et al. 2008).

History of the changes in breastfeeding duration recommendations (Agostoni, Decsi et al. 2008)
"In early 2000 a WHO-commissioned systematic review of the optimal duration of exclusive breastfeeding (Kramer and Kakuma 2002; Kramer and Kakuma 2002; Kramer, Guo et al. 2003; Kramer and Kakuma 2004) compared mother and infant outcomes with exclusive breastfeeding for 6 months versus 3 to 4 months. Of 20 eligible studies identified, only 2 were randomized intervention trials of different exclusive breastfeeding recommendations, both conducted in a developing world

setting (Honduras). All of the studies from the developed world were observational. The review concluded that there were no differences in growth between infants exclusively breastfed for 3 to 4 months versus 6 months. An analysis of observational data from a trial of breastfeeding promotion in Belarus found that during the period from 3 to 6 months, infants who were exclusively breastfed for 6 months experienced less morbidity from gastrointestinal infection than did those exclusively breastfed for 3 months followed by partial breastfeeding, even though no significant differences in risk of respiratory infectious outcomes or atopic eczema were apparent (Kramer, Guo et al. 2003) However, the extent to which conditions and practices in Belarus resemble those in other European countries may be questioned.

A second systematic review, commissioned in the late 1990s and published in 2001 (Lanigan, Bishop et al. 2001) specifically addressed the optimal age for introducing solid foods and included studies in both breastfed and formula-fed infants. The authors concluded that there was no compelling evidence to support a change in the 1994 UK Department of Health recommendation or the (then current) WHO recommendation (both 4–6 months).

Following the WHO systematic review and expert consultation, in 2001 the World Health Assembly revised its recommendation to exclusive breastfeeding for 6 months and partial breastfeeding thereafter. In the recommendations from the expert consultation, it was stated that the recommendation applies to populations, and it was recognized that some mothers would be unable to, or would choose not to, follow this recommendation and that these mothers should also be supported to optimise their infant's nutrition (WHO 2001). Many countries have since adopted this recommendation for the duration of exclusive breastfeeding, sometimes with qualifications, whereas other countries continue to recommend the introduction of complementary feeding between 4 and 6 months. However, there has been disagreement between advisory bodies even within the same country, reflecting the limited scientific evidence from industrialised countries upon which the WHO recommendation was based, and the fact that the recommendation is far removed from current feeding practices in many countries. Given that the WHO recommendation is not directly applicable to formula-fed infants, some countries have adopted different recommendations regarding the introduction of complementary foods in these infants."

American Public Health Association Recommendations

As the nation's oldest and largest public health organization, the APHA calls on health professionals, researchers, and political decision makers in the United States and globally to take the following steps:

1. Affirm that exclusive breastfeeding for 6 months with continued breastfeeding for at least the first 1 to 2 years of life, is the biologic norm and that all alternative feeding methods carry health risks in comparison, with rare exceptions.
2. Recognize that breastfeeding is appropriately viewed as a public health issue and insist that maternal/child and comprehensive public health policies include attention to breastfeeding protection, education, promotion, and support, with particular attention to exclusive breastfeeding, early breastfeeding initiation, and disparities in breastfeeding rates.
3. Identify the exclusive breastfeeding rate as a leading health indicator in the goals for the nation and ensure the national collection of comprehensive, unbiased, accurate, consistent breastfeeding data, including data on breastfeeding initiation, duration, and exclusivity. (Leading health indicators in Healthy People 2010 reflect the major health concerns of our nation, have the ability to motivate action, have available data to track progress, and have relevance to broad public health issues.)
4. Insist on consistent, recognized, or both explicit definitions for patterns of breastfeeding within scientific publications and reports, including definitions of exclusive breastfeeding, full breastfeeding, mixed feeding, and complementary feeding.

5. Require that any medical recommendation or intervention that may disrupt initiation of breastfeeding or interrupt breastfeeding be based on reliable evidence that also takes into consideration the risks of alternative feeding, including both short-term and long-term sequelae to mother and child.
6. Denounce aggressive marketing of human milk substitutes, particularly marketing in health care settings, and insist on compliance with the International Code of Marketing of Breast-milk Substitutes.
7. Provide adequate funding for breastfeeding in both domestic and foreign aid programs, as well as adequate funding for basic and program research. Increased dedicated funding for breastfeeding support is needed by the National Institutes of Health, CDC, and The US Department of Agriculture, as well as for US Agency for International Development and in the United States support to United Nations agencies, especially UNICEF, WHO, and the United Nations High Commissioner for Refugees.
8. Implement activities outlined in Innocenti Declaration 2005 to operationalize the 9 target areas of the WHO Global Strategy on Infant and Young Child feeding, as affirmed by all nations at the World Health Assembly, 2003 and 2005.
9. Incorporate all components of the Baby-friendly Hospital Initiative into the requirements of accreditation of all maternity services and include its community-based components in disaster planning, community programming, and outpatient clinical practices.

The American Academy of Pediatrics statement on Breastfeeding and Complementary Foods (Gartner, Morton et al. 2005)
Complementary foods rich in iron should be introduced gradually beginning around 6 months of age. Preterm and low birth weight infants and infants with hematologic disorders or infants who had inadequate iron stores at birth generally require iron supplementation before 6 months of age. Iron may be administered while continuing exclusive breastfeeding.
• Unique needs or feeding behaviours of individual infants may indicate a need for introduction of complementary foods as early as 4 months of age, whereas other infants may not be ready to accept other foods until approximately 8 months of age.
• Introduction of complementary feedings before 6 months of age generally does not increase total caloric intake or rate of growth and only substitutes foods that lack the protective components of human milk.
• During the first 6 months of age, even in hot climates, water and juice are unnecessary for breastfed infants and may introduce contaminants or allergens.
• Increased duration of breastfeeding confers significant health and developmental benefits for the child and the mother, especially in delaying return of fertility (thereby promoting optimal intervals between births).
• There is no upper limit to the duration of breastfeeding and no evidence of psychologic or developmental harm from breastfeeding into the third year of life or longer.
• Infants weaned before 12 months of age should not receive cow's milk but should receive iron-fortified infant formula.

AGE OF INTRODUCTION OF SOLID FOODS and OVERWEIGHT

S1.5 SOLID FOODS from NHMRC Dietary Guidelines literature review

Search results
The initial search of the databases included 862 references on the age of introduction of solid foods. Data were extracted from 11 references, and 10 publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the relationships between age of introduction of solid foods and development of overweight and development of allergic symptoms. Additional evidence was found on the relationship between introduction of solid foods and diarrheal disease (one cohort study), but the evidence was not sufficient to develop a body of evidence statement.

Is the age of solid food introduction in children associated with the development of overweight later in life?		
Draft Evidence statement		Age of introduction of solid foods is not associated with risk of overweight in children younger than the age of 7 years.
Grade		Grade removed – see below.
Component	**Rating**	**Notes**
Evidence Base	Good	1 systematic review (of 1 systematic review and 3 cohort studies - 1N), 2 cohort studies (2P).
Consistency	Satisfactory	The systematic review and one cohort study found no effect. The other cohort study found a positive effect.
Clinical impact	Poor	There was no association.
Generalisability	Excellent	USA and UK populations
Applicability	Excellent	Directly applicable.

Original Conclusions S1.5
The systematic review included one systematic review and three cohort studies in its analysis, all finding no relationship between the age of weaning and development of infant or child overweight. However, the review was of poor quality and did not critically analyse the included studies. Weaning was defined as the introduction of solid foods in this publication, but in the individual studies this may have been different than defining 'weaning' to the introduction of solid foods. The two cohort studies contributing to the body of evidence statement were both of high quality and were both conducted in the UK. One reported that age of introduction of complementary feeding was not associated with obesity at seven years, while the other reported that introduction of solid foods before age 4 months was associated with increased risk of overweight at three years.

Complementary feeding was not defined in the publication, but it is commonly known as the transition from infant formula or breast milk to solid foods. Overall, the current evidence appears to suggest that age of introduction of solid foods has no effect on the risk of overweight in children, but due to the inconsistencies care must be taken when using this statement to guide practice. References (Reilly, Armstrong et al. 2005; Hawkins and Law 2006; Hawkins, Cole et al. 2009)

Update on Complementary Foods and Obesity
When additional reviews are included and the question is widened to include childhood and adulthood (instead of specifically stating 7 years) there is evidence (low quality) that later introduction of solid foods was associated with lower levels of obesity. The evidence is well reviewed in Ip (Ip, Chung et al. 2007) and Monasta (Monasta, Batty et al. 2010)

Is the age of solid food introduction in children associated with the development of overweight later in life?		
Draft Evidence Statement		Age of introduction of solid foods is associated with increasing risk of overweight in children
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Good	
Consistency	Satisfactory	The systematic review and one cohort study found no effect. The other cohort study found a positive effect.
Clinical impact	Poor	There was no association.
Generalisability	Excellent	USA and UK populations
Applicability	Excellent	Directly applicable.

S1.5 Studies used to make evidence statement for age of introduction of solid foods and overweight. (seven years)

Reference	**Reilly 2005 British J of Nutr 94: 869-872**	**Hawkins 2009 J Epidemiol Community Health 63(2): 147-155.**	**Hawkins 2006 Int J Pediatr Obes 1(4): 195-209.**
Type of study	Cohort	Cohort	Systematic review of 4 studies (1 systematic review, 3 cohort studies)
Level of evidence	II (aetiology)	II (aetology)	I (aetiology)
Intervention/ comparator	Early life risk factors for development childhood obesity at age 7 yrs, including age at which complementary feeding is begun (<1, 1-2, 2-3, 3-4, or 4-6 mo). Complementary feeding was not defined in the publication.	Risk factors at various levels (individual, family, community and area) for development of childhood overweight. Included introduction of solid foods at < 4 mo compared to ≥ 4 mo .	Relationship between breastfeeding and weaning on development of overweight in preschool children. Weaning is defined as the introduction of solid foods in this publication.
N	13 971 at baseline 8234 at follow-up 5493 for analysis	18 296 at baseline 14 630 at follow-up 13 188 for analysis	Number of subjects not provided. Breastfeeding: 15 studies; Weaning: 4 studies.
Population/study information	Children born in 1991-92, from the Avon longitudinal study of parents and children (ALSPAC), followed from birth till age 7 yrs. Mothers lived in 3 health districts centred in Bristol, UK. Mainly white and singleton.	Children born 2000-02, from the Millennium Cohort Study. Followed from birth until age 3 yrs. Parents were residents in England, Wales, Scotland, and Northern Ireland. The study over-represented children living in disadvantaged areas and from ethnic minority groups.	Preschool children in US and UK
Quality	P	P	N
Results	Following adjustment for confounding factors, breastfeeding (p=0.464) and timing of introduction of complementary feeding (p=0.296) were not significantly related to the risk of obesity at age 7 yrs.	In the fully adjusted model, introduction to solid foods < 4 mo adj OR 1.12 (95% CI: 1.02-1.23) was associated with a increased risk of early childhood overweight; while breastfeeding > 4 months (0.86, 0.76 to 0.97) (compared with none) was associated with a decreased risk of early childhood overweight.	There may be an inverse relationship between breastfeeding (unclear if duration or ever) and later overweight (no difference between preschool children, older children, or adults). There is no relationship between time of weaning and overweight during infancy or in children younger than age 7 yrs. However, there was no quantitative data reported.

Effect on risk (Increase/None/Protect)	None	Increase for solid introduction at < 4 months	None
Clinical importance	3	1	N/A
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Additional studies used to make evidence statement for age of introduction of solid foods and overweight. (any age) Studies used to make evidence statement for Introduction of Complementary Foods and Weight gain

Reference	**Baker Michaelsen 2004 AJCN**	**Burdette 2006 AJCN**	**Griffiths 2008 Arch Dis Child**	**Monasta Cattaneo 2010 Obesity Reviews**
Type of study	Cohort	Cohort –retrospective	Cohort	SLR
Level of evidence	II (aetiology)	III-2 (aetiology)	II (aetiology)	II (aetiology)
Definition of breastfeeding	"any breastfeeding" was used in these analyses (total duration of breastfeeding) The duration of any breastfeeding was categorized into quartiles (<20, 20–31.9, 32–40, and >40 wk). Complementary foods were defined as mush or porridge in the questionnaire; infant formula was not classified as a complementary food.	Data on breastfeeding, formula feeding, and the timing of the introduction of complementary foods were obtained from the mothers when the children were 3 y old.	Any breastfeeding	Any breastfeeding Exclusive breastfeeding
Intervention Comparator	Introduction of comp foods <16 weeks compared to >16 weeks	Introduction of Comp foods before 4 months compared to >4 months	(3) Age at introduction of solid foods: in which the mother introduced solids before four calendar months (17.4 weeks), ie, introduced solid foods early.	Breastfeeding duration
N	5330	313		

Population/study information	Danish National Birth Cohort (DNBC), a national cohort study	313 preschool-aged children who were participating in a prospective cohort study (exposure data obtained retrospectively. Body composition measured using DEXA	10 533 3-year-old children from the UK Millennium Cohort Study.	Included 22 SLR's Quality 11 moderate and 11 low.
Quality	P	N	P	P
Results	After adjustment the early introduction of comp foods resulted in 0.7kg heavier infant at 12 months	Children did not differ significantly in fat mass if they were introduced to complementary foods before or after 4 mo of age (x ± SE 4.49 ± 0.12 and 4.63 ± 0.12 kg, respectively; *P* ± 0.42). Neither breastfeeding nor the timing of the introduction of complementary foods was associated with adiposity at age 5 y.	Early introduction of solids was not associated with faster weight gain after adjustment for height z-score at 3 years (20.01, 95% CI 20.04 to 0.03).	Factors associated with later overweight and obesity: maternal diabetes, maternal smoking, rapid infant growth, no or short breastfeeding, obesity in infancy, short sleep duration, <30 min of daily physical activity, consumption of sugar-sweetened beverages
Effect on risk	Positive	Positive	Neutral	Positive
Clinical importance	1	1	1	
Clinical relevance	1	1	1	
Generalisability	Y	N	Y	Y
Applicability	Y	N	Y	Y

References used in body of evidence tables: (Baker, Michaelsen et al. 2004; Reilly, Armstrong et al. 2005; Burdette, Whitaker et al. 2006; Hawkins and Law 2006; Griffiths, Smeeth et al. 2009; Hawkins, Cole et al. 2009; Monasta, Batty et al. 2010)

Studies used to make evidence statement for breastfeeding and obesity later in life

Reference	**Arenz et al. 2004**	**Horta et al. 2007**	**Harder et al. 2005**	**Ip et al. 2007**
Type of study	Meta- analysis	Meta-analysis (included	Meta-analysis	SLR

		studies in earlier meta-analyses and additional newer studies)		
Level of evidence	I (aetiology)	I (aetiology)	I (aetiology)	I (aetiology)
Definition of breastfeeding	Definitions varied among studies included in analysis	Definitions varied among studies included in analysis	Definitions varied among studies included in analysis	Definitions varied among studies included in analysis. Authors state the exclusivity of breastfeeding was not described in the majority of the studies
Intervention/ comparator	Breastfeeding (time variable) v shorter duration of breastfeeding and/or formula feeding Never BF or partly BF < 3 months vs. BF ≥ 3 month; mostly or only BF vs. mostly or only formula feeding in the first 6 months; BF never vs. ever; BF never vs. > 6 months, BF groups: <1 week, 1 week-1 months, 2-3 months, 4-6 months, 7-9 month, > 9 months (exclusivity of BF not reported).	Breastfed vs. non-breastfed infants	Median duration of breastfeeding (exclusive or partial) categories: < 1 month, 1-3 month, 4-6 months, 7-9 months, > 9month.	Breastfeeding (time variable) vs. shorter duration of breastfeeding and/or formula feeding
N	> 69 000 children included in the final analysis. Children were at least one year of age from developed countries.	Studies with > 1500 participants	120,831 subjects from developed countries.	

Population/study information	9 studies were used for the meta analyses (2 cohort, 7 cross-sectional). 19 studies were not eligible. Studies were published between1996 – 2003.	33 out of a potential 38 studies (25 cohort, 3 case-control, 10 cross-sectional) were included in the meta-analyses	17 studies (16 cohort, 1 case-control) were used. 32 were not eligible. Studies were published between 1996 – 2003.	3 meta-analyses (Arenz, Owen & Harder)
Quality	P	P	P	P
Results	Any breastfeeding reduced the risk of obesity in childhood. Adjusted OR 0.78 (0.71,0.85)	Breastfeeding vs. not breastfeeding reduced the risk of obesity in later life. Pooled OR 0.78 (0.72,0.84)	Breastfeeding duration was inversely and linearly associated with the risk of being overweight. Regression coefficient 0.94 (0.89, 0.98) Each month of breastfeeding up until 9 months was found to be associated with a 4 percent decrease in risk up. OR 0.96/month of breastfeeding, (0.94, 0.98).	Emphasized how sensitivity analyses carried out by Arenz and Owen showed a continuous reduction of the effect of breastfeeding on overweight and obesity when more factors were accounted for in the analysis.
Effect on risk	Negative	Negative	Negative	Negative
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y	Y
Applicability	Y	Y	Y	Y

Reference	**Owen et al. 2005 (Ped)**	**Owen et al. 2005 (Am J Clin Nutr)**	**Monasta et al. 2010**	**Kramer et al. 2007**
Type of study	SLR & meta-analysis	SLR & meta-analysis	SLR	Randomized trial
Level of evidence	I (aetiology)	I (aetiology)	I (aetiology)	II (intervention)

Definition of breastfeeding	Few studies stated their definition of exclusive breastfeeding therefore the exclusiveness of infant feeding was based on the classification given in each article.	Few studies stated their definition of exclusive breastfeeding therefore the exclusiveness of infant feeding was based on the classification given in each article.	Definitions of breastfeeding differed across reviews	Followed WHO definitions
Intervention/ comparator	Breastfeeding v formula feeding	Any breastfeeding v formula feeding	Breastfeeding (time variable) v shorter duration of breastfeeding and/or formula feeding	Completely weaned within the first month v breastfed exclusively for ≥6 mo with continued breastfeeding to any degree until 12 mo of age
N	289 900 subjects (infants, children, adults) included for meta-analysis	355 301 subjects (large proportion of subjects overlap with Owen et al. 2005 Ped meta-analyses)		17 046 subjects. Follow up to 6.5 y was 81.5 % (13 889) Completely weaned within the first month n = 1136 Breastfed exclusively for ≥6 mo with continued breastfeeding to any degree until ≥ 12 mo of age n = 215
Population/study information	61 observational studies from 1966 to 2003. 28 of these studies were included for meta-analysis	36 observational studies (31 published, 5 unpublished) out of a potential 70 studies.	Review of 7 SLRs	The mother-infant pairs were enrolled from 31 Belarussian maternity hospitals and their affiliated clinics all infants were born at term, weighed ≥ 2500 g. Mother-infant pairs participated in a breastfeeding promotion intervention as part of the BFHI.

Quality	P	P	P	P
Results	Breastfed subjects were less likely to be defined as obese than were formula-fed subjects. OR 0.87 (0.85,0.89).	Breastfeeding was associated with a slightly lower mean BMI than was formula feeding. Mean difference in BMI= -0.04 (-0.05, -0.02). Mean difference in BMI for the age of outcome measurement infants and children aged < 5 y = -0.01 (-0.03, 0.01) children aged 5–9 y = -0.05 (-0.08, -0.02) older children & adolescents = -0.19 (-0.25, -0.13) Adults = -0.11 (-0.17,-0.04)	Authors conclude breastfeeding has a possible protective factor for later overweight and obesity however more research is required.	None of the observed differences suggested lower adiposity in the group with prolonged and exclusive breastfeeding than in the group with less breastfeeding. Infants breastfed exclusively for 6 mo with continued breastfeeding to any degree until ≥ 12 mo of age had higher mean BMIs [cluster-adjusted difference: 0.3 (0.4, 0.5)] and triceps skinfold thicknesses [1.3 (0.7, 1.9)mm] than infants weaned within the first month.
Effect on risk	Negative	Negative (however difference only small)	Negative	None
Clinical importance	1	1	1	1
Clinical relevance	1	1	1	1
Generalisability	Y	Y	Y	Y - Belarus. Conditions may differ from Australia
Applicability	Y	Y	Y	Y

Reference	**Oddy et al. 2006**	**Singhal & Lanigan 2007**	**Smith 2007**
Type of study	SLR	SLR	SLR
Level of evidence	I (aetiology)	I (aetiology)	I (aetiology)

Definition of breastfeeding	Definitions varied among studies	Definitions varied among studies	FBF= excludes BMS, includes solids & drinks
Intervention/ comparator	Breastfeeding duration	Breastfeeding v formula feeding	Print media advertising of commercial BMS
N			
Population/study information	Review of studies on infant feeding & overweight/obesity risk in childhood, adolescence & adulthood	Reviews of studies on infant feeding, growth acceleration and overweight/obesity risk	Reviews of studies on infant feeding and obesity risk in later life. Epidemiological data on full breastfeeding feeding trends in Australia 1927- 2007. Data on advertising of commercial BMS from 1950-1985.
Quality	0 (2,3,4,7 were No)	0 (2,3,4,7 were No)	0 (3,4,5,7 were No)
Results	Exclusive or predominant breastfeeding to 6 months of age is protective against the development of obesity later in life.	Breastfeeding reduces long-term obesity risk. Authors ? effect related to the slower growth and relative undernutrition associated with breastfeeding compared with formula feeding.	Artificial infant feeding is a risk factor for pediatric obesity. Authors ? association between increase in advertising of BMS and increase in obesity prevalence in middle-age adults.
Effect on risk	Negative	Negative	Negative
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	Y	Y
Applicability	Y	Y	Y

Reference	**Metzger & McDade 2010**	**Plagemann & Harder 2007**	**Stettler 2007**
Type of study	Retrospective cohort	Meta-analyses	SLR
Level of evidence	III-2 (aetiology)	I (aetiology)	I (aetiology)

Definition of breastfeeding	None stated	Definitions varied among studies	Definitions varied among studies
Intervention/ comparator	Any breastfeeding	Breastfeeding v formula feeding	Breastfeeding (time variable) v shorter duration breastfeeding or formula feeding
N	118 participants (59 sibling pairs)		
Population/study information	Participants were part of the 2002 Child Development Supplement of the Panel Study of Income Dynamics, a survey of families in the US. Participants were between 9-19 yrs old at outcome measurement.	23 studies (19 cohort, 4 case-control) (2/23 studies used exclusive breastfeeding as their intervention, remaining studies used non exclusive breastfeeding as their intervention) (2/23 studies were from Australia/New Zealand)	Review of observational and experimental studies on breastfeeding, infancy weight gain and childhood or adulthood obesity
Quality	P	P	P
Results	Breastfed siblings were less likely to have a BMI > 85th percentile in childhood or adolescence compared to their non-breastfed infant AOR = 0.42 The breastfed sibling had an adolescent BMI that was 0.39 std dev lower than his or her siblin	Breastfeeding is associated with a decreased risk of overweight/obesity in children later life, compared to formula-feeding. OR = 0.75 (0.71,0.79) The pooled odds ratio shifted towards no effect in Australia/New Zealand studies OR =1.06 (0.88,1.29)	Observational studies show a negative association between any breastfeeding and obesity in childhood or adulthood. Observational studies show a positive association between rapid infancy weight gain and obesity in childhood or adulthood. Limited experimental evidence of causal relationship between any breastfeeding and obesity risk.
Effect on risk	Negative	Negative	Negative
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	? Y as meta-analyses showed no effect in Aus studies	Y

Applicability	Y	? Y as meta-analyses showed no effect in Aus studies	Y

References used in body of evidence tables: (Arenz, Ruckerl et al. 2004; Harder, Bergmann et al. 2005; Owen, Martin et al. 2005; Owen, Martin et al. 2005; Plagemann and Harder 2005; Oddy 2006; Horta, Bahl et al. 2007; Ip, Chung et al. 2007; Kramer, Matush et al. 2007; Singhal and Lanigan 2007; Smith 2007; Stettler 2007; Metzger and McDade 2010; Monasta, Batty et al. 2010)

Studies used to make evidence statement for duration of breastfeeding and weight gain

Reference	**Baker Michaelsen 2004 AJCN**	**Burdette 2006 AJCN**	**Griffiths 2008 Arch Dis Child**
Type of study	Cohort	Cohort –retrospective	Cohort
Level of evidence	II (aetiology)	III-2 (aetiology)	II (aetiology)
Definition of breastfeeding	"any breastfeeding" was used in these analyses (total duration of breastfeeding) The duration of any breastfeeding was categorized into quartiles (<20, 20–31.9, 32–40, and >40 wk). Complementary foods were defined as mush or porridge in the questionnaire; infant formula was not classified as a complementary food.	Data on breastfeeding, formula feeding, and the timing of the introduction of complementary foods were obtained from the mothers when the children were 3 y old.	Three infant feeding practices (exposure variables) were examined: (1) Breastfeeding initiation: in which the mother put her baby to the breast at least once;23 (2) Duration of breastfeeding: in which the mother, having started breastfeeding, stopped before four calendar months (17.4 weeks), ie,stopped early;
Intervention Comparator	Breastfeeding duration <20 weeks compared to >40 weeks	Any Breastfeeding None, <3 months, 3-5, 6-12, >12 months	
N	N=5330	N=313	N = 10533
Population/study information	Danish National Birth Cohort (DNBC), a national cohort study	313 preschool-aged children who were participating in a prospective cohort study (exposure data obtained retrospectively. Body composition measured using DEXA	10533 3-year-old children from the UK Millennium Cohort Study. Singleton births
Quality	P	N	P

Results	Compared with those who were breastfed for the longest duration (>40 wk), those who were breastfed for the shortest duration (<20 wk) gained 317.4 g more from birth to 1 year	There was no significant difference in adjusted fat mass between those ever breastfed and those never breastfed (x ±SE: 4.48 ± 0.09 and 4.76 ± 0.17 kg, respectively; P = 0.17). Children who were breastfed for a longer duration and those who were breastfed without concurrent formula feeding did not have significantly lower fat mass than did those children who were never breastfed. .	After adjustment for confounding factors, conditional weight gain was significantly associated with breastfeeding initiation; infants given no breast milk gained weight more quickly than those receiving any breast milk. Conditional weight gain was also significantly associated with breastfeeding duration infants breastfed for less than 4 months gained weight more quickly than those breastfed for longer, and this association remained after adjustment for age at introduction of solid foods. Both of these associations remained even after adjustment for the child's height z-score at 3 years. (adjusted regression coefficient (difference in z-scores) 0.06, 95% CI 0.02 to 0.09), as did those breastfed for less than 4 months (0.05, 95% CI 0.01 to 0.09) versus those breastfed 4 months or longer.
Effect on risk	Positive	Positive	Positive
Clinical importance	1	1	1
Clinical relevance	1	1	1
Generalisability	Y	N	N
Applicability	Y	N	N

References used in body of evidence table: (Baker, Michaelsen et al. 2004; Burdette, Whitaker et al. 2006; Griffiths, Smeeth et al. 2009)

Additional Notes

Horta: Meta-analysis of breastfeeding and obesity (Horta, Bahl et al. 2007).

Summary tables and graph of meta-analysis

Figure 3.3. Odds ratio and its 95% confidence interval of being considered as overweight/obese, comparing breastfed vs. non-breastfed subjects in different studies. Whether the estimate was for males (M), females (F) and all (A) is indicated in parenthesis

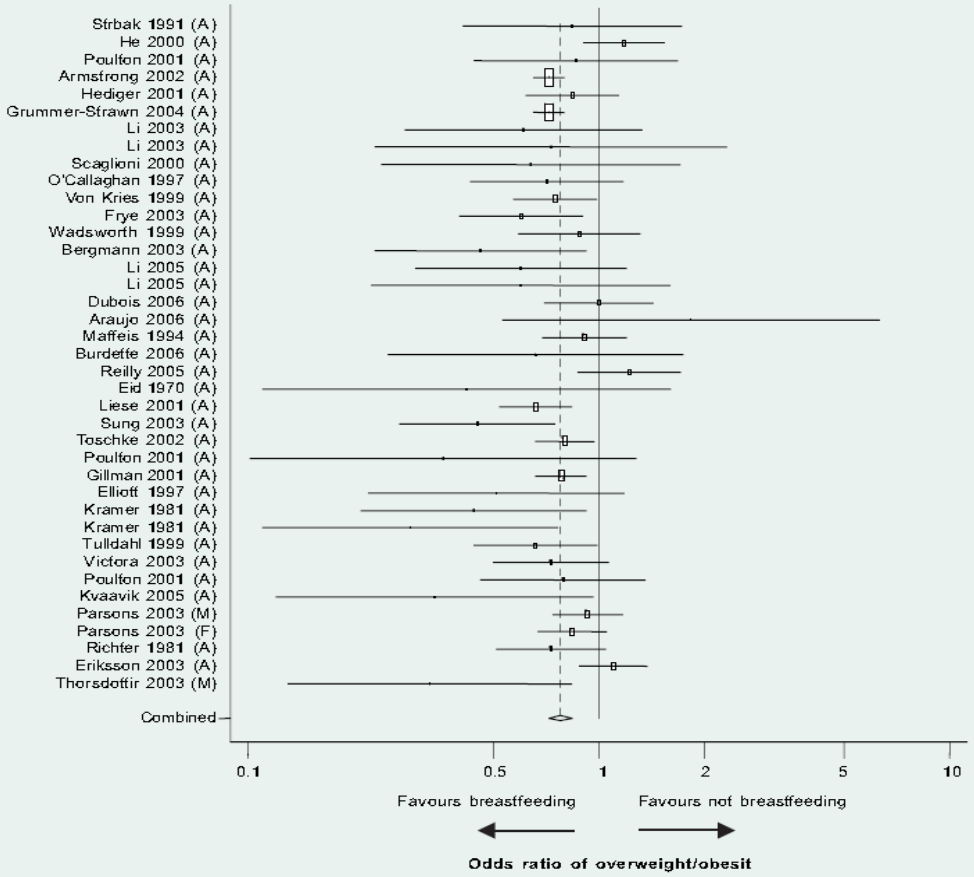


Table 3.2. Breastfeeding and the risk of overweight and obesity in later life: Random-effects meta-analyses of risk of overweight/obesity by subgroup

Subgroup analysis	Number of estimates	Pooled odds ratio and 95% confidence interval	P value
By age group			
1 to 9 years	22	0.79 (0.71 to 0.87)	0.001
9 to 19 years	11	0.69 (0.60 to 0.80)	0.001
>19 years	6	0.88 (0.74 to 1.04)	0.13
By study size			
<500 participants	11	0.51 (0.35 to 0.75)	0.001
500–1499 participants	11	0.79 (0.66 to 0.93)	0.006
≥1500 participants	17	0.80 (0.74 to 0.87)	0.001
By year at birth			
Before 1980	13	0.83 (0.73 to 0.95)	0.008
After 1980	22	0.78 (0.72 to 0.85)	0.001
By study design			
Cross-sectional	26	0.79 (0.72 to 0.87)	0.001
Case-control	3	0.58 (0.23 to 1.45)	0.24
Cohort	10	0.75 (0.69 to 0.83)	0.001
By length of recall of breastfeeding			
<3 years	24	0.79 (0.71 to 0.87)	0.001
≥3 years	15	0.76 (0.67 to 0.86)	0.001
By categorization of breastfeeding			
Ever breastfed	12	0.75 (0.67 to 0.83)	0.001
Breastfed for a given number of months	23	0.78 (0.71 to 0.86)	0.001
By control for confounding			
None	16	0.76 (0.64 to 0.91)	0.004
Adjusted for socioeconomic status	3	0.72 (0.66 to 0.79)	0.001
Adjusted for socioeconomic status and parental anthropometry	20	0.77 (0.71 to 0.84)	0.001
By study setting			
High-income country	33	0.77 (0.71 to 0.83)	0.001
Middle/Low-income country	6	0.82 (0.62 to 1.09)	0.18
Total	39	0.78 (0.72 to 0.84)	

The WHO Euro Division reached the following conclusions on Overweight and Infant Feeding (WHO European Region 2007)

Substantial evidence indicates that breastfeeding offers a small but significant protective effect against later childhood and adolescent overweight. Large-scale studies have shown elevated levels of overweight among children at school entry age (5 or 6 years old) who had been formula-fed as infants compared with the breastfed *(von Kries, Koletzko et al. 1999))*, with a dose-dependent effect according to the duration of breastfeeding. A sample of 32 000 preschool children showed lower prevalence of obesity among those who had been breastfed after adjusting for socioeconomic status, birth weight and gender *(Armstrong and Reilly 2002)* A longitudinal study found an elevated likelihood of obesity among children aged 2–6 years who had been bottle-fed; although mothers' smoking behaviour, BMI and socioeconomic status strongly influenced the risk of their children's being overweight, the difference between bottle and breastfed babies remained after controlling for these factors *(Bergmann, Bergmann et al. 2003)* There are several possible reasons for the link between feeding method and later adiposity: bottle-feeding may discourage appetite self-regulation, especially if the mother expects the standard bottle portion to be fully consumed at a feeding session. In addition, weaning practices from milk onto solid food may differ between mothers

who breastfeed and those who bottle-feed, with earlier weaning and more energy-dense weaning food being introduced for the bottle-fed infant. Further, the nature of the weaning food may differ: there is some evidence that infants given formula may be less likely to consume vegetables and fruit and more likely to consume commercial infant drinks compared with infants who were breastfed *(Noble and Emmett 2006)*

Monasta (2010) Infant Feeding and overweight and obesity

Seven systematic reviews, six of which were classified as of moderate quality using the AMSTAR score, examined the association between infant feeding and obesity later in life. Arenz and colleagues reviewed nine studies meeting their inclusion criteria, with over 69 000 participants (Arenz, Ruckerl et al. 2004). They found that breastfeeding had an inverse association with childhood obesity (pooled adjusted OR 0.78; 95%CI 0.71– 0.85). Four studies in the review reported an inverse dose– response effect of breastfeeding duration on the risk of obesity. Similar results have been found in studies conducted subsequent to this review (Li, Goran et al. 2007; Moschonis, Grammatikaki et al. 2008; Woo, Dolan et al. 2008; Hawkins, Cole et al. 2009), while other studies found no association between breastfeeding and obesity later in life until adulthood ((Davis, Weigensberg et al. 2007; Michels, Willett et al. 2007; Ochoa, Moreno-Aliaga et al. 2007; Scholtens, Gehring et al. 2007). Owen and collaborators examined the association between breastfeeding and BMI throughout life (Owen, Martin et al. 2005). Despite a significant difference in the mean BMI for breastfed compared with formula-fed infants (lower BMI for breastfed infants: -0.04; 95%CI -0.05, -0.02), the adjustment for possible confounders (socioeconomic status, maternal smoking during pregnancy, maternal BMI) in 11 studies removed the effect. A similar reduction of the association between breastfeeding and obesity after controlling for confounders was reported also by other researchers ((Toschke, Martin et al. 2007; Procter and Holcomb 2008). In a subsequent review, Owen and collaborators compiled 28 studies providing OR estimates on a total of almost 299 000 subjects (Owen, Martin et al. 2005). Breastfeeding appeared to be associated with reduced risk of obesity if compared with formula feeding (pooled OR 0.87; 95%CI 0.85–0.89). Adjustment for three major potential confounders (parental obesity, maternal smoking and social class) was reported in six studies and the OR, even if closer to one, remained statistically significant (pooled adjusted OR 0.93; 95%CI 0.88–0.99). Harder and colleagues reviewed the literature using exclusively formula-fed subjects as the referent (Harder, Bergmann et al. 2005). The duration of breastfeeding was inversely associated with the risk of overweight (regression coefficient 0.94, 95%CI 0.89–0.98) and the results were confirmed using categorical analysis (<1 month of breastfeeding: OR 1.00; 95%CI 0.65–1.55; 1–3 months: OR 0.81; 95%CI 0.74–0.88; 4–6 months: OR 0.76; 95%CI 0.67–0.86; 7–9 months: OR 0.67; 95%CI 0.55–0.82; >9 months: OR 0.68; 95%CI 0.50–0.91). In their systematic review on maternal and infant health outcomes of breastfeeding (Ip, Chung et al. 2007) Ip and colleagues analysed three already cited reviews (Arenz, Ruckerl et al. 2004; Harder, Bergmann et al. 2005; Owen, Martin et al. 2005), emphasizing how sensitivity analyses carried out by Arenz and Owen showed a continuous reduction of the effect of breastfeeding on overweight and obesity when more factors were accounted for in the analysis. They also underlined how exclusive breastfeeding was not considered in most of the included studies. Horta and collaborators, in a systematic review published by the WHO (Horta, Bahl et al. 2007), obtained 39 estimates of the effect of breastfeeding on the prevalence of overweight and obesity. In a random-effect model, breastfed individuals were less likely to be overweight and/or obese, with a pooled OR of 0.78 (95%CI 0.72–0.84). Control for confounding, age at assessment, year of birth and study design did not modify the effect of breastfeeding.

Finally, in their systematic review, Plagemann and Harder found that breastfeeding is associated with decreased risk of overweight, decreased blood cholesterol and blood pressure and a reduced risk of developing type 2 diabetes later in a child's life (Plagemann and Harder 2005). All the studies included in these systematic reviews on the association between breastfeeding and obesity, however, were observational. The only randomized trial that looked at the effect of an intervention on breastfeeding rates and duration, and subsequently at the effects of breastfeeding on obesity, did not report a lower prevalence of adiposity (measured as BMI and waist or hip circumference) among children in the intervention group compared with the control group (Kramer, Matush et al. 2007; Kramer, Matush et al. 2009). Randomization, however, was applied to clusters, as opposed to individuals, and looking at the effect of breastfeeding on obesity was not among the primary objectives of the study.

Breastfeeding and Obesity Notes

Whitehouse conference on obesity (White House Task Force on Childhood Obesity 2010)

Children who are breastfed are at reduced risk of obesity.(Owen, Martin et al. 2005) Studies have found that the likelihood of obesity is 22% lower among children who were breastfed.(Arenz, Ruckerl et al. 2004) The strongest effects were observed among adolescents, meaning that the obesity-reducing benefits of breastfeeding extend many years into a child's life. Another study determined that the risk of becoming overweight was reduced by 4% for each month of breastfeeding. This effect plateaued after nine months of breastfeeding (Harder, Bergmann et al. 2005).

Despite these health benefits, although most (74%) babies start out breastfeeding, within three months, two-thirds (67%) have already received formula or other supplements. By six months of age, only 43% are still breastfeeding at all, and less than one quarter (23%) are breastfed at least 12 months.(Centers for Disease Control and Prevention 2009) In addition, there is a disparity between the prevalence of breastfeeding among non-Hispanic black infants and those in other racial or ethnic groups. For instance, a recent CDC study showed a difference of greater than 20 percentage points in 13 states.(Grummer-Strawn, Scanlon et al. 2008)

The protective effect of breastfeeding likely results from a combination of factors. First, infant formula contains nearly twice as much protein per serving as breast milk. This excess protein may stimulate insulin secretion in an unhealthy way.(Dewey, Heinig et al. 1993; Heinig, Nommsen et al. 1993) Second, the biological response to breast milk differs from that of formula. When feeding a baby, the mother's milk prompts the baby's liver to release a protein that helps regulate metabolism.(Hondares, Rosell et al. 2010) Feeding formula instead of breast milk increases the baby's concentrations of insulin in his or her blood, prolongs insulin response,84 and, even into childhood, is associated with unfavorable concentrations of leptin, a hormone that inhibits appetite and controls body fatness.(Singhal, Farooqi et al. 2002) Despite the well-known health benefits of breastfeeding and the preference of most pregnant women to breastfeed,(Shealy, Scanlon et al. 2008) numerous barriers make breastfeeding difficult. For first-time mothers, breastfeeding can be challenging, even for those who intend to breastfeed. For those who have less clear intent to breastfeed, cultural, social, or structural challenges can prevent breastfeeding initiation or continuation. For example, immediately after birth, many babies are unnecessarily given formula and separated from their mothers, making it harder to start and practice breastfeeding. Also, hospital staff are often insufficiently trained in breastfeeding support.

The Joint Commission on the Accreditation of Hospitals, the body that accredits hospitals and health care organizations for most State Medicaid and Medicare reimbursement, now expects hospitals to track and improve their rates of exclusive breastfeeding. Hospitals that meet specific criteria for optimal breastfeeding-related maternity care are designated as “Baby Friendly” by Baby-Friendly U.S.A. This non-governmental organization has been named by the U.S. Committee for UNICEF as the designating authority for UNICEF/WHO standards in the United States. Currently only 3% of births in America occur in Baby-Friendly facilities (Centers for Disease Control and Prevention 2009).

While breastfeeding could be far more widespread than it is today, it is not a viable alternative for all mothers and babies. Specific guidance and support options should also be made available for those who cannot breastfeed. Parents and caregivers of babies also may benefit from guidance about when to start feeding them solid foods, since early introduction of solids (prior to six months) increases the risk for childhood obesity (Kramer 1981; Wilson, Forsyth et al. 1998; Taveras, Gillman et al. 2010).

Breastfeeding and Bowel Disease: Coeliac Disease and Inflammatory Bowel Disease

Search results

The initial search of the databases included 34 references on the development of celiac disease and inflammatory bowel disease (Crohn's disease and ulcerative colitis) and breastfeeding. Data were extracted from 2 systematic literature reviews to form the final body of evidence statements.

BREASTFEEDING AND THE DEVELOPMENT OF INFLAMMATORY BOWEL DISEASE

Is the duration of breastfeeding associated with lower rates of development of Inflammatory Bowel Disease and Coeliac Disease?		
Draft Evidence Statement		Breastfeeding is associated with lower rates of coeliac disease and inflammatory bowel disease (Crohn's disease and ulcerative colitis)
Draft Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Poor	2 systematic review
Consistency	Satisfactory	One systematic review coeliac disease One systematic review coeliac disease and inflammatory bowel disease.
Clinical impact		There was a weak association.
Generalisability	Excellent	USA and UK populations
Applicability	Excellent	Directly applicable.

Conclusions

The systematic reviews included only case-control studies in their analyses, which is to be expected from the population prevalence of these conditions. The description of breastfeeding was inadequate and the meta-analyses were conducted on the basis of any breastfeeding vs not breastfed. There is weak evidence that breastfeeding is protective against the development of coeliac disease.

Reference	Akobeng 2006 Arch Dis Child	Barclay 2009 J Pediatrics
Type of study	SLR Meta analysis Coeliac Disease	SLR Meta analysis Crohn's Disease and Ulcerative colitis
Level of evidence	II (aetiology)	II (aetiology)
Definition of breastfeeding	Ever breastfed, Never Breastfed, Duration of Ever Breastfed	Breastfeeding was only defined in 3 of the 8 studies
Intervention Comparator	Ever breastfed Vs never breastfed	
N	1131 cases 3493 controls	1542 cases 2620 controls
Population/study information	Six Case control studies	Eight Case control studies
Quality	P All the six included studies were graded ''B''	P All the eight included studies were graded ''B''
Results	Effect of breastfeeding at the time of gluten introduction on development of CD. OR= 0.48 (0.40, 0.59) Increasing duration of breastfeeding is associated with a reduced risk of coeliac disease	Breast milk exposure had a significant protective effect (OR, 0.69; 95% CI, 0.51-0.94; P = .02) in developing early-onset IBD. A non-significant difference was demonstrated for ulcerative colitis and Crohn's disease individually (OR, 0.72; 95% CI, 0.51-1.02; P = .06; OR, 0.64; 95% CI, 0.38-1.07; P = .09, respectively)
Effect on risk	Reduced risk	Reduced risk in breastfed infants
Clinical importance	1	1
Clinical relevance	1	1
Generalisability	Y	Y
Applicability	Y	Y

References used in body of evidence table: (Akobeng, Ramanan et al. 2006; Barclay, Russell et al. 2009)

One additional study has been published since this review (Gearry, Richardson et al. 2010). This is an additional case-control study from NZ with 638 prevalent Crohn's disease and 653 prevalent ulcerative colitis cases. A protective effect for breastfeeding was found in this study. The authors recommend further research on a duration-response protective association.

Notes on Coeliac Disease and IBD – abstracts of relevant articles

Akobeng (Akobeng, Ramanan et al. 2006).

Background: Coeliac disease (CD) is a disorder that may depend on genetic, immunological, and environmental factors. Recent observational studies suggest that breastfeeding may prevent the development of CD.

Aim: To evaluate articles that compared effects of breastfeeding on risk of CD.

Methods: Systematic review and meta-analysis of observational studies published between 1966 and June 2004 that examined the association between breastfeeding and the development of CD.

Results: Six case-control studies met the inclusion criteria. With the exception of one small study, all the included studies found an association between increasing duration of breastfeeding and decreased risk of developing CD. Meta-analysis showed that the risk of CD was significantly reduced in infants who were breastfeeding at the time of gluten introduction (pooled odds ratio 0.48, 95% CI 0.40 to 0.59) compared with infants who were not breastfeeding during this period.

Conclusions: Breastfeeding may offer protection against the development of CD. Breastfeeding during the introduction of dietary gluten, and increasing duration of breastfeeding were associated with reduced risk of developing CD. It is, however, not clear from the primary studies whether breastfeeding delays the onset of symptoms or provides a permanent protection against the disease. Long term prospective cohort studies are required to investigate further the

Barclay (Barclay, Russell et al. 2009)

Objectives: To assess the current evidence for the role of breastfeeding in the development of early onset inflammatory bowel disease (IBD) with a systematic review.

Study Design: An electronic database search was performed (January 1966-January 2008) with keywords related to IBD and breastfeeding, looking specifically for studies that reported outcome in early-onset disease (<16 years of age) and "any exposure" to breast milk as the variables. Meta-analysis of studies included for review was then performed by using a random effects model, and results were expressed as odds ratios (OR) with 95% CIs.

Results: A total of 79 articles were identified, 20 of which were found describing breastfeeding in relation to the development of IBD; 8 of these articles included separate early-onset groups. One study did not describe "any exposure" to breast milk for the early onset group, so 7 studies were included in the meta-analysis. Breast milk exposure had a significant protective effect (OR, 0.69; 95% CI, 0.51-0.94; P = .02) in developing early-onset IBD. A non-significant difference was demonstrated for ulcerative colitis and Crohn's disease individually (OR, 0.72; 95% CI, 0.51-1.02; P = .06; OR, 0.64; 95% CI, 0.38-1.07; P = .09, respectively). CONCLUSIONS: The current evidence demonstrates a possible protective effect for breast milk in the development of early onset IBD. However, the quality of existing data is generally poor. These findings need to be investigated in well-designed prospective studies of the relation between breastfeeding and CD.

Schack-Nielsen (Schack-Nielsen and Michaelsen 2006) Narrative review

Coeliac disease is considered to be an autoimmune disease, and breastfeeding has been shown in a meta analysis of six case–control studies to have a protective effect that, with the exception of one small study, was dose-dependent. The meta-analysis further showed that breastfeeding at the time of introduction of gluten was protective against coeliac disease (odds ratio 0.48) compared with infants who were not breastfed during this period. As the authors state, however, it is not clear from the included studies whether breastfeeding delays the onset of symptoms or provides a permanent protection against the disease.

The immuno-modulatory properties of breast milk have also been suggested to have a protective effect against inflammatory bowel disease. In a meta-analysis from 2004 [37] including 17 studies, exclusive breastfeeding of any duration was associated with a reduced risk of Crohn's disease (odds ratio 0.67) and ulcerative colitis (odds ratio 0.56). It was, however, not clearly described in all the studies whether exclusive breastfeeding was compared with non-exclusive breastfeeding or exclusive bottle feeding. The significant protective effects of breastfeeding persisted when only the four studies judged to be of high quality were included in the meta-analysis. The results from a population-based case–control study [38] that was judged using the criteria of Klement and colleagues [37] to be of high quality did, however, show that breastfeeding was associated with an increased risk of Crohn's disease odds ratio 2.1). On the other hand, breastfeeding was not related to ulcerative colitis.

Moffat 2009 A population-based study of breastfeeding in inflammatory bowel disease: initiation, duration, and effect on disease in the postpartum period. (Moffatt, Ilnyckyj et al. 2009)
This paper is not directly related to the question of aetiology, but is useful in the management of mothers with IBD. . Breastfeeding is not associated with an increased risk of disease flare and may even provide a protective effect against disease flare in the postpartum year

Objectives: We aimed to assess breastfeeding practices and the impact of breastfeeding on disease flare during the postpartum year in inflammatory bowel disease (IBD).
Methods: Women of childbearing age from 1985 to 2005 were identified from the University of Manitoba IBD Research Registry. Questionnaires were completed regarding pregnancy and the postpartum period. Data for initiation and duration of breastfeeding were compared with population-based regional data.
Results: Of 204 eligible women, 132 (64.7%) responded to the survey, yielding information on 156 births. Breastfeeding was initiated in 83.3% of women with IBD (n=132), 81.9% of Crohn's disease patients (CD, n=90), and 84.2% of ulcerative colitis patients (UC, n=39) vs. 77.1 % in the general population (P>0.05 for all). Of women with IBD, 56.1% breastfed for >24 weeks vs. 44.4% of controls (P=0.02). The rate of disease flare in the postpartum year was 26% for those who breastfed vs. 29.4% in those who did not (P=0.76) in CD and 29.2% vs. 44.4% (P=0.44) in UC. The odds ratio of disease flare postpartum for those who breastfed vs. those who did not was 0.58 (95% CI: 0.24-1.43), 0.84 (0.19-9.87), and 0.51 (0.12-2.2) for IBD total, CD, and UC, respectively. Risk of disease flare was not related to age at pregnancy, duration of disease, or socioeconomic status.
Conclusions: Women with IBD are as likely as the general population to breastfeed their infants. Breastfeeding is not associated with an increased risk of disease flare and may even provide a protective effect against disease flare in the postpartum year.

The foetal origins of adult disease hypothesis

The idea that nutrition and other factors early in life can influence growth and health in later life is not new, but the hypothesis has become widely accepted only in the past few decades. The term 'programming' originated 30 years ago in Germany (Koletzko, von Kries et al. 2009), and the concept was subsequently developed by Barker. In a paper published 25 years ago, Barker noted a correlation between high neonatal mortality and deaths from coronary heart disease 40 to 50 years later (Barker and Osmond 1986) and he hypothesised that neonatal mortality could be a surrogate indicator for the effects of early nutrition. Since that time, Barker's group has published more than 100 papers on the subject and other researches have published thousands of papers.

Originally, the hypothesis related early life nutrition (prenatal) as reflected in weight at birth to subsequent disease patterns. In the last decade, however, the hypothesis has been further developed and refined to include not only birthweight but also body leanness at birth and growth during childhood (Godfrey and Barker 2001). Understanding of early influences on later diseases has expanded to encompass the concepts of metabolic programming, developmental plasticity and the new science of epigenetics (Solomons 2009).

The original studies on which Barker based his hypothesis involved a cohort of men and women born in Hertfordshire between 1911 and 1920. The maternal and child health nurses in the county had kept excellent records, which had been preserved and were available for research. Follow-up of the cohort about 50 years later showed that those who had a low birthweight were more likely to die of coronary heart disease (see Table 1) or to develop metabolic syndrome (Barker 1998).

Table 1 Death rates from coronary artery disease among 16 000 men and women born in Hertfordshire between 1911 and 1920, by birthweight

Birthweight (pounds)	Standardised mortality ratio	Deaths (number)
<5.5	100	57
5.6–6.5	81	137
6.6–7.5	80	298
7.6–8.5	74	289
8.6–9.5	55	103
>9.5	65	57
All	74	941

A more recent systematic review of similar studies has found a 25% decrease in diabetes risk for every one kg increase in weight at birthweight (Whincup, Kaye et al. 2008). However, this relationship only holds for what is regarded as the normal range of birthweights (2500- 4000 or 4500grams) with the association between birthweight and diabetes becoming positive at high birthweights (Yajnik 2010). The risk of macrosomia and metabolic syndrome has been well recognised.

Barker's original studies were criticized on the basis of confounding by social class or biased results from the relatively low follow-up rate may have resulted in biased results. Since that time, however, the results of other published studies have overcome these objections, with a large number of studies across

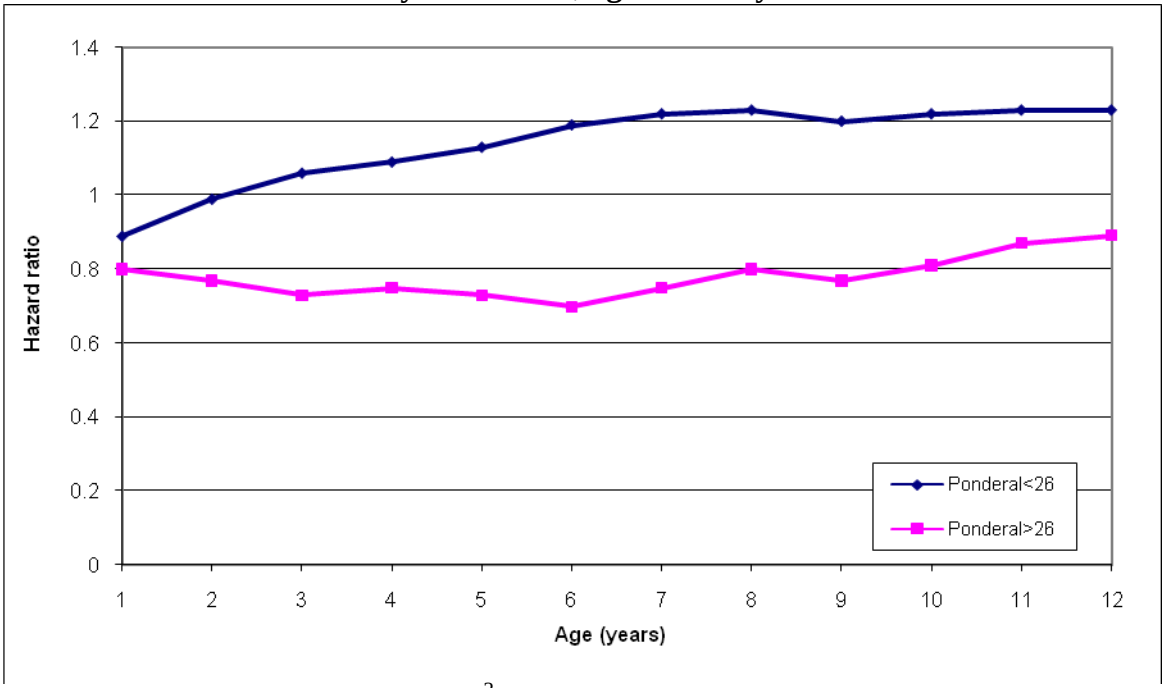
different cultures with different endpoints strengthening the hypothesis. Most notable are the studies from Scandinavia, particularly Helsinki, where a comprehensive database and excellent follow-up have allowed for more detailed work (Forsén, Eriksson et al. 1999; Forsen, Eriksson et al. 2000; Barker, Osmond et al. 2009). The Finnish studies added to knowledge of how growth during infancy and childhood modifies health outcomes. The path of growth during childhood modifies the risk of disease associated with small body size at birth. The highest death rates from coronary heart disease were found in men who were thin at birth but who had accelerated growth rates during the first year of life, resulting in above average body mass at one year. Other confirmatory studies for the hypothesis have come from continuing analysis of the results of the famine in Holland during World War II (Roseboom, Van der Meulen et al. 2000). Epidemiological studies supporting the hypothesis are now being published from non-European countries (Fan, Zhang et al. 2010).

The hypothesis has become more complex because it is apparent that, in addition to birthweight, other dimensions of body shape at birth and subsequent growth from childhood into adulthood must be considered (Barker 2001). More recently, the status of the placenta at birth has been used as a proxy for assessment of overall prenatal nutritional status. There is also evidence of a ‘‘U’’ shaped relationship between placental-to-foetal weight ratio and heart disease (Thornburg, O'Tierney et al. 2010).
The current version of the developmental origins hypothesis describes a relationship between those who had low birthweight or were thin or short at birth or failed to grow in infancy and later disease. As adults, children in these categories develop increased rates of coronary heart disease, stroke, type 2 diabetes and hypertension. But as noted the relationship is U-shaped.

Death rates from coronary heart disease increase in those with poor prenatal or infant nutrition followed by improved postnatal nutrition and a trend towards obesity. The patterns differ for those who later develop stroke, type 2 diabetes or hypertension (Eriksson, Forsen et al. 2000) and there are slightly different patterns for each gender. Common to all, however, is a period of reduced early growth during the period of developmental plasticity followed by a period of accelerated growth (Bruce and Hanson 2010). People who were small at birth are more prone to developing type II diabetes or coronary heart disease if they become overweight as adults.

Detailed analysis of the Finnish cohort has shown two pathways whereby growth may lead to subsequent coronary heart disease. In one, thinness at birth is followed by rapid weight gain in childhood. In the other, failure of infant growth is followed by persisting thinness during childhood. Both are associated with short stature in childhood (Eriksson, Forsen et al. 2001). Figure 1 illustrates the combined influences of thinness at birth—a ponderal index of less than 26 (ponderal index = weight/height^3)—and subsequent growth rates. For example, a male who is thin at birth but who gains one standard deviation of body mass index by the age of 6 years has a hazard ratio of 1.2. This compares with a male born with a normal body shape and who also gains weight but whose subsequent risk of coronary heart disease remains below average.

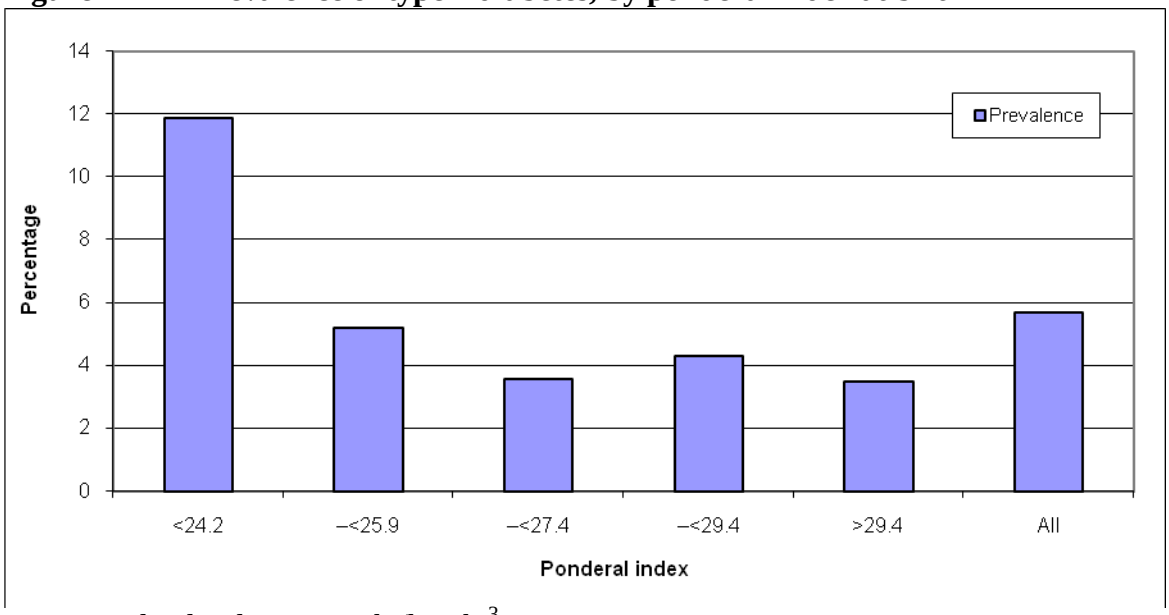
Figure 1 Hazard ratios for coronary heart disease associated with a standard deviation increase in body mass index, ages 1 to 12 years



Note: Ponderal index = weight/height^3.

An Australian contribution to the hypothesis has been documentation of the influence of low birthweight on the subsequent development of chronic renal disease through studies of Aboriginal Australians in the Northern Territory. The association might be mediated through impaired nephrogenesis caused by intra-uterine malnutrition. The current epidemic of renal disease in Aboriginal Australians may be, at least partly a result of the higher incidence of low-birthweight babies and the improvements in life expectancy in this population (Hoy, Rees et al. 1999; Spencer, Wang et al. 2001; Singh and Hoy 2004). Type 2 diabetes in adulthood is also related to body size in early life. Barker's original studies in Hertfordshire showed that diabetes was related to low birthweight (Barker and Osmond 1986). However, in studies in Swedish males by Lithell, thinness at birth (see Figure 2) was found to be a stronger predictor (Lithell, McKeigue et al. 1996), and the importance of macrosomia is also recognised.

Figure 2 Prevalence of type 2 diabetes, by ponderal index at birth



Note: Ponderal index is weight/height^3.

Several systematic literature reviews have linked hypertension with birthweight and early development (Barker 2004; Bruce and Hanson 2010). The relationship between low birthweight and hypertension holds in developed and developing countries. The foetal origins hypothesis proposes that these chronic diseases develop as a result of adaptations the foetus makes when it is undernourished (Barker, Gelow et al. 2010). These adaptations can be cardiovascular, metabolic or endocrine, and they appear to permanently change the structure and function of the body. A specific adaptation proposed is diversion of oxygenated blood away from the trunk to the brain. There may also be alterations to the hormonal systems that regulate growth and maturation and alterations to body composition.

One mechanism for the association may be the way in which the hypothalamo–pituitary–adrenal axis is programmed (Clark 1998). Programming of this axis is one hypothesis that can explain the link between the foetal environment and development and later disease. An excess of glucocorticoids may be associated with hypertension and glucose intolerance. Some animal data are available to support this hypothesis, and human studies have found that reduced size at birth was associated with higher fasting 9am plasma cortisol concentrations in adults. Raised plasma cortisol concentrations were, in turn, associated with higher blood pressure and inversely related to measures of glucose tolerance. The resultant long-term alterations in the set-point of several major hormonal axes would explain the increased prevalence of type 2 diabetes in low-birthweight infants (Phillips 1998).

These adaptations permanently ‘re-program’ the physiology of the body. Influences on foetal programming include the mother’s body composition before, during and after pregnancy; diet during pregnancy; and postnatal nutrition and growth. The documentation of epigenetic mechanisms and their testing on animal models has increased understanding of these aetiological factors (Weaver, 2009)(Bruce and Hanson 2010; Groom, Elliott et al. 2010). These studies demonstrate that an epigenetic state of a gene can be established through early in life experience, and is potentially reversible in adult life. The epigenetic modifications in response to environmental influences may ensure

stable yet dynamic regulation that mediates persistent changes in phenotype over the lifespan. (Weaver 2009)

The gradual understanding of epigenetic, biochemical and endocrine mechanisms has added to the body of evidence. The challenge is to discover more about the cellular and molecular mechanisms giving rise to these associations. But, while the mechanisms are not yet fully understood, it is not too early to begin to apply the findings to public health interventions. Evaluation of appropriate interventions could expand our knowledge of the mechanisms involved.

One interesting aspect of the foetal origins hypothesis is its ability to explain differences in the prevalence and timing of chronic disease epidemics in different countries. For some time epidemiologists have been puzzled by the 'French paradox', whereby mortality from ischaemic heart disease in France is about a quarter of that in Britain but the major risk factors are similar. It is thought that under-certification of ischaemic heart disease in France could account for about 20 per cent of the difference and that the high consumption of alcohol in France—and of red wine in particular—could explain a small amount of the difference. However, Barker has reviewed the development of maternal nutrition programs in the two countries and suggests that the earlier concern of the French with improving nutrition has protected them from this chronic disease epidemic.[1]

Optimising the trajectory of growth for long term outcomes

There have now been a number of direct studies of breastfeeding and health outcomes and long term health (Horta, Bahl et al. 2007; Ip, Chung et al. 2007). On this basis it appears that breastfeeding moderates the influence of prenatal effects that might program less health beneficial outcomes. After birth, breastfeeding and the appropriate introduction of complementary foods (around six months) results in a growth trajectory that is within the lower risk part of the U-shaped growth curve.

Later introduction of complementary foods was associated with lower adult adiposity. In an analysis of pooled data, 10912 subjects aged, 15-41 years, from five prospective birth-cohort studies in low-/middle-income countries (Brazil, Guatemala, India, Philippines and South Africa) found a relationship between later introduction of complementary foods and adult adiposity. Body mass index changed by 0.19 kg/m^2 (0.1, 0.37) and waist circumference by 0.45 cm (0.02,0.88) per 3-month increase in age (Fall, Borja et al. 2010).

The Copenhagen Perinatal Cohort was established in 1959–1961 (n = 5068) with regular follow-up. With the group now in their early 40s, this study suggests that introduction of complementary foods at a later age (within the range of 2 to 6 mo) is protective against overweight in adulthood. The study did not support a protective effect of a longer duration of BF against obesity. The risk of overweight at age 42 years decreased or tended to decrease, with increasing age (in mo) at introduction of spoon-feeding [odds ratio (OR): 0.94; 95% CI: 0.86, 1.02], vegetables (OR: 0.90; 95% CI: 0.81, 0.98), meat (OR: 0.93; 95% CI: 0.87, 1.00), and firm food (OR: 0.92; 95% CI: 0.86, 0.98) but not egg (OR: 0.98; 95% CI: 0.91, 1.05) (Schack-Nielsen, Sorensen et al. 2010).

Implications for public health

In the past decade the concepts of developmental origins adult disease, early life programming and epigenetics have become better established (Waterland and Michels 2007; Waterland 2008). They provide a theoretical basis for understanding for patterns of chronic disease. For example in Australia the differential in morbidity and mortality between Aboriginal Australians and other Australians is a good public health example. The theory provides a theoretical basis for several public health nutrition interventions including:

- Prevention programs that aim to divert foetal programming must involve nutrition and health throughout the life cycle, beginning with the nutrition of young girls (Yajnik 2010)
- prenatal care—nutrition and health care programs to minimise the number of low-birthweight babies and thin babies (ponderal index <26). Many factors contribute to low birth, including appropriate maternal nutrition and weight gain.
- postnatal growth—programs to avoid under-nutrition or the development of overweight or obesity during childhood, including increasing the proportion of mothers exclusively breastfeeding to around six months. This would be an extension of present growth monitoring at child health clinics to ensure universal care.

In Australia, low birthweight is observed more often in the babies of younger or older mothers, first-time mothers, single mothers and indigenous mothers. Cigarette smoking, alcohol consumption and the nutritional status of pregnant women are also factors.

The overall proportion of low-birthweight infants in Australia is relatively low by international standards at 6.2% in 2007, but in Aboriginal Australians it was significantly higher at 13.7% (Australian Institute of Health and Welfare 2010). It is interesting to note that in the United States the prevalence of low birthweight in black Americans is about the same as that for Australian Aboriginal people.[i] Programs to reduce the prevalence of low birthweight should be a high priority. Maternal nutrition is particularly important, not just during pregnancy but also prior to conception. The nutrition of girls is obviously very important, so that they enter adulthood in a state of nutrition that prepares them for pregnancy.

Conclusion

The Developmental Origins of Adult Disease hypothesis explains many facets of the current epidemic of chronic disease occurring around the world, but many aspects of the hypothesis and the developing science of epigenetics need further research. These developments suggest that further programs for maternal, prenatal and child nutrition should be implemented. Programs designed to achieve the goals of improved maternal and child nutrition can be justified on many grounds, have no downside, and should therefore be promoted without waiting for further evidence.

XI Interpretation of the WHO Code for health workers in Australia

Definition of a health worker

What is a Health Worker?

It is important to define the meaning of health worker. The International Code of Marketing of Breast-Milk Substitutes (the WHO Code), the WHO Code FAQ and the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (The MAIF Agreement) define 'health worker'. The relevant sections of these documents are printed below.

All documents refer to the extensive responsibilities of health workers under the Code and Agreement. The WHO Code defines health worker broadly, full-time and part-time, paid and unpaid. A reasonable interpretation of the Code's definition would be "any person associated in any way with the health system, private of public, who gives, or is in a position to give, advice on infant feeding to another person". The WHO Code specifically excludes "pharmacies or other established sales outlets."

In 2010 the World Health Assembly adopted the WHO Global Code of Practice on the International Recruitment of Health Personnel which included the flowing definition:
(WHO 2010)

"Health workers are people engaged in actions whose primary intent is to enhance health. These include people who provide health services – such as doctors, nurses, midwives, pharmacists, laboratory technicians – as well as management and support workers – such as hospital managers, financial officers, cooks, drivers and cleaners."

Health Workforce Australia (http://www.hwa.gov.au/) accessed 10 Oct 2010) does not appear to have its own definition of health worker, although they refer to the WHO definition above. The Commonwealth Code of Practice for the International Recruitment of Health Workers (www.the**commonwealth**.org/) does not include a definition, but refers to the WHO document and to "registration".

While the MAIF agreement excludes pharmacies and retail outfits it includes the following definition:

"Health care professional' *- a professional or other appropriately trained person working in a component of the health care system, including pharmacists and voluntary workers."*

Taking the Code and the Agreement together it would seem the intended definition of health worker in the Australian context is:

"any person associated in any way with the health system, private of public, who gives, or is in a position to give, advice on infant feeding to another person, including pharmacists"

This would fit with the perceptions of many pharmacies who advertise themselves as a source of primary health care and health information.
The WHO Code and the MAIF agreement contain clauses on education for the general population and heath workers.

When Australia became a signatory to the WHO Code its response included the following:

a) The development of the MAIF agreement
b) The National Breastfeeding Strategy
c) The Development of the Infant Feeding Guidelines for Health Workers to provide guidance on appropriate infant feeding strategies.

Extracts from the WHO Code (WHO 1981)

Pre-amble

“Affirming that health care systems, and the health professionals and other health workers serving in them, have an essential role to play in guiding infant feeding practices, encouraging and facilitating breastfeeding, and providing objective and consistent advice to mothers and families about the superior value of breastfeeding, or, where needed, on the proper use of infant formula, whether manufactured industrially or home-prepared;

"Health care system" means governmental, nongovernmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this Code, the health care system does not include pharmacies or other established sales outlets.

"Health worker" means a person working in a component of such a health care system, whether professional or non-professional, including voluntary unpaid workers.

Article 6. Health care systems

6.1 The health authorities in Member States should take appropriate measures to encourage and protect breastfeeding and promote the principles of this Code, and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Article 4.2

6.5 Feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.

Article 7. Health workers

7.1 Health workers should encourage and protect breastfeeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.

7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottlefeeding is equivalent or superior to breastfeeding. It should also include the information specified in Article 4.2.

7.3. No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.

7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.

7.5 Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points:
(a) the words "Important Notice" or their equivalent;
(b) a statement of the superiority of breastfeeding;
(c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;
(d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation. Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breast milk substitute and for illustrating methods of preparation. The terms "humanized", "materialized" or similar terms should not be used. Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. When labels give instructions for modifying a product into infant formula, the above should apply.

WHO CODE Frequently Asked Questions 2008 edition (WHO 2008)
Q. What aspects does the code cover?
The Code sets out detailed provisions with regard to, *inter alia*:
1. Information and education on infant feeding.
2. Promotion of breast-milk substitutes and related products to the general public and mothers.
3. Promotion of breast-milk substitutes and related products to health workers and in health care settings.
4. Labelling and quality of breast-milk substitutes and related products.
5. Implementation and monitoring of the Code.

Q. Does the code restrict promotional activities to health workers and in health care settings?
The Code and subsequent relevant WHA resolutions call for a total prohibition of any type of promotion of products that fall within their scope in the health services. Furthermore, donations of free or subsidized supplies of breast-milk substitutes or other products, as well as gifts or personal samples to health workers, are not allowed in any part of the health care system. Also, information provided by

manufacturers and distributors to health professionals regarding products should be restricted to scientific and factual matters.

The MAIF agreement (Department of Health and Ageing 2003)
The MAIF agreement includes the following definitions:

'Health care system' - governmental, non-governmental or private institutions engaged, directly or indirectly, in health care for mothers, infants and pregnant women and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this document, the health care system does not include pharmacies or other retail outlets.

'Health care professional' - a professional or other appropriately trained person working in a component of the health care system, including pharmacists and voluntary workers.

Appendix

NHMRC literature review for the revision of the Australian Dietary Guidelines

Sections of the literature review that relate to infant feeding

5 DAIRY (S1.1 & Cat 2 S2.6)

Dairy consumption in infants
Evidence was found on dairy consumption and lipid profile in infants (three randomised controlled trials) but was not strong enough to develop a body of evidence statement.

Dairy and Lipid Profile in Infants
One randomised controlled trial of healthy infants in Belgium (n=189, positive quality) reported that ad libitum consumption of infant milk formula with 0.6 g/100 mL of GOS/lcFOS (9:1) did not affect serum cholesterol levels compared to control formula. Total cholesterol and LDL cholesterol in breast-fed infants were higher compared to formula-fed infants ($p<0.016$) (Alliet 2007).

Two randomised controlled trials of healthy infants in the USA compared the effect of consumption of regular infant formula versus infant formula supplemented with 40-100 mg/L cholesterol versus breast milk. Demmers 2005 (neutral quality) reported that plasma cholesterol concentrations were higher and cholesterol synthesis was lower at 4 months in the groups with a higher intake of dietary cholesterol (n=47). At 12 months, Bayley 2002 (neutral quality) did not see a change in cholesterol synthesis, plasma total cholesterol, or plasma LDL cholesterol levels in the groups with a higher intake of dietary cholesterol (n=49), and Demmers did not see the differences maintained at 18 months. This suggests there is "no imprinting of cholesterol biosynthesis," and that differences in plasma lipid profiles before the introduction of solid foods do not last (Demmers 2005).

Dairy and Child Growth
One large cohort study (neutral quality) of 16,491 healthy infants reported that compared to breast milk, formula and other milks increased weight and length growth during infancy from three months to 12 months. There was no difference in growth among infants receiving whole cow's milk compared to formula (Kramer 2004).

9 FISH (S1.1)

Data was extracted from papers for the following outcomes but there was inadequate evidence base to create body of evidence statements.

Fish and Allergic Disease
A cohort study was conducted on Swedish infants (Alm et al. 2009).
The Swedish study used self reported eczema and found Odds ratio (95% CI) of eczema for age at introduction of fish
Gp 1: 1.1 (0.4-2.9); Gp 2: 0.7 (0.6-0.9); Gp 3: 0.6 (0.5-0.7); Gp 4: 1 (Ref)
Odds ratio (95% CI) eczema for frequency of fish consumption
Gp 1: 1 (Ref); Gp 2: 0.88 (0.64-1.20); Gp 3: 0.86 (0.62-1.20); Gp 4: 1.32 (0.86-2.02); Gp 5: 2.73 (1.80-4.13)
Odds ratio (95% CI) eczema for usually eats lean fish, 0.81 (0.68-0.97).

Fish and Infant Cognition

There were three cohort studies examining fish consumption and infant cognitive outcomes. The VIVA cohort of 135 mother-infant pairs found that Each extra fish serve/wk was associated with higher visual recognition memory (VRM) score 2.9 (95%CI 0.2 to 5.4). When mercury was added to the model as a potential confounder, this VRM score increased to 4.0 (95%CI 1.3 to 6.7) points higher (Oken et al. 2005).

Two studies reported outcomes from the AVON cohort. The first in 7421 mother-infant pairs examined the relationship between fish consumption and validated developmental questionnaires at 15 and 18 months. The found an OR of 0.7 for low test score and 1.4 for language for high scores, with some items significant, and with a significant P for increasing consumption of fish. The second in 8764 at the 6mth follow-up and 5000 at the 8 year old follow-examined fish consumption against validated scale domains for gross motor, fine motor, communication, and social skills, completed by parents when their child was 6, 18, 30 & 42 mths at follow-up. Significant OR were found for full IQ and verbal ability with a significant P for increasing consumption of fish.

11 EGGS (S1.1)

EGGS and CORONARY HEART DISEASE

Does a particular intake of eggs affect the risk of coronary heart disease in adults?		
Evidence statement		Consumption of eggs daily is not associated with increased risk of coronary heart disease
Grade		B
Component	**Rating**	**Notes**
Evience Base	Excellent	13 level II trials (RCTs – mostly positive studies, only 3 neutral studies), 1 level III-1 study (positive) and 5 level III-2 studies (1 neutral, remainder positive). 2 cross-sectional and 1 pre-test post test study not extracted.
Consistency	Good	Fairly consistent that there is no effect of egg consumption on risk of CVD (15 No Effect (11 RCT studies, 1 III-1 study, 3 cohort studies); 4 showed increased risk (2 cohort studies and 2 RCT showed slight increases in one measure of blood lipids).
Clinical impact	Poor	Majority of ORs cross 1 or p value not significant for differences between groups for RCTs.
Generalisability	Good	Populations in body of evidence relevant to adults of most ages and genders and also include Australian Aborigines, infants and older people.
Applicability	Excellent	Directly applicable to Australian healthcare context

One of the thirteen trials used to develop the body of evidence statement for eggs and coronary heart disease was conducted on infants.

Study used to make evidence statement for eggs (in infancy) and coronary heart disease

Makrides 2002
Block RCT

II
7 mth intervention and either: 1) Four n-3 egg yolks per wk; 2) Four regular egg yolks per wk; 3) no dietary intervention/ blood lipids
44-47
6 mth old Australian infants born at term with birth wts >2.5 kg and no known protein intolerances or allergies. Assigned to n-3 egg, no diet intervention or regular egg for 7 mths. TC changes examined. No follow up.
Neutral
No differences in TC levels between interventions.
None
3
2
y
y

12 FATS AND OILS (S1.1)

FATS AND OILS and CARDIOVASCULAR DISEASE

Two cohort studies (both O) of infant diet and cardiovascular disease. One, (Ohlund et al., 2008) looked at infant diet and then serum cholesterol over a six month period and found that PUFA is protective of lipid profile, and quality of the fat is important in an infant diet. The second cohort (Ness et al. 2005) measured childhood diet and followed up after 30 and 50 years with mortality data in adults. SFA and total fat in childhood diet found to be protective of all cause mortality and deaths attributable to cardiovascular disease. The second of these studies findings are not consistent with adult disease findings. These studies were not included in the body of evidence statement.

13 SODIUM AND SALT (S1.1)

SODIUM AND BLOOD PRESSURE - Children and adolescents

Does a particular intake of salt or sodium affect blood pressure in children and adolescents?		
Evidence Statement		Consumption of a diet high in sodium increases blood pressure in children aged <18 y.
Grade		A
Component	**Rating**	**Notes**
Evidence Base	Excellent	1 level I meta-analysis with low risk of bias, and 1 level II study (review), 2 level IV studies (non-systematic reviews) with high risk of bias (negative quality rating)
Consistency	Excellent	BP reduction with Na reduction demonstrated in a Cochrane review.
Clinical impact	Good	Reductions of BP of the magnitude: systolic: -1.17 mm Hg; diastolic: - 1.29 mm Hg in children and adolescents. Insufficient evidence for infants.
Generalisability	Good	Population studies in body of evidence similar to the target population for the guideline
Applicability	Excellent	Directly applicable to Australian healthcare context.

A level I meta-analysis of 10 trials in children and adolescents (N = 966) found that Na restriction over a median intervention of 4 weeks resulted in significant reductions in blood pressure (systolic: -1.17 mm Hg; diastolic: - 1.29 mm Hg). In the same meta-analysis, three trials of infants (N = 551) with a median duration of 20 weeks found a significant reduction in systolic blood pressure of -2.47 mm Hg. Further long-term studies are needed to assess whether Na restriction in early childhood result in beneficial BP reductions later in life but at the present time there is enough evidence to warrant a body of evidence statement in this age group.

Table 13.1 Studies used to make evidence statement for sodium and blood pressure

Reference [1]	**He 2006**	**Robertson 2003**	**Geleijnse, 2002**
Type of study [2]	Meta-analysis (13 RCTs; 10 in children/adolescents; 3 in infants)	Non-systematic review (2 non-systematic reviews; 1 cohort, 2 RCTs; 5 cross section;)	Non-systematic review [6 RCTs, 1 cohort, 1 cross section]
Level of evidence [3]	I	IV	IV
Intervention/ comparator [4]	Low Na diet vs. high/normal Na diet / Blood Pressure	Na reduction / Blood Pressure	Reduced Na in infancy and childhood / Blood Pressure
N [5]	Children/adolescents: N = 966. Infants: N = 551	Not stated; 5 meta analyses cited	Not stated
Population/study information [6]	Children ≤18y incl newborn and infants. Follow-up: Children/adolescents: 2wks to 3 years (median = 4 weeks). Infants: 8 weeks to 6 months (median = 20 wks)	neonates, children, adults, elderly; NT and HTs	Infants and children < 18yrs
Quality [7]	P	N	N
Results [8]	Children: For sodium intake reductions of 42% (IQR = 7 to 58%), BP reductions of systolic: 1.17 mm Hg (95% CI 1.78 - 0.56 mm Hg, p 0.001); diastolic: 1.29 mm Hg (95% CI 1.94 - 0.65 mm Hg, p 0.0001). Infants: reduction in systolic BP = 2.47 mm Hg (95% CI 4.00 - 0.94 mm Hg, p 0.01).	Na reduction lowers BP, more so in hypertensives than normotensives (no numerical values given)	Inconclusive
Clinical importance [9]	1. A clinically important benefit for the full range of plausible estimates	1. A clinically important benefit for the full range of plausible estimates	No measure of effect provided.
Clinical relevance [10]	1. Evidence of an effect on patient-relevant outcomes, including benefits	Evidence of an effect on patient-relevant outcomes, including benefits	3. No clinically important effects.
Generalisability	y	y	y
Applicability	y	y	y

Comments	First meta-analysis of RCTs in children and infants. Relatively small BP reductions, but clinically significant if preventive of BP increases with age into adulthood.	Non-systematic review. Na reduction lowers BP (No estimate of effect given). No trials cited showed increases in BP with a restriction.	Not systematic review, but due to limited studies in infants and children was included. Further studies needed to assess whether Na restriction in early childhood result in beneficial BP reductions later in life.

14 SUGARS (S1.1)

SUGARS and DENTAL DISEASE

Does a particular intake of sugars effect the risk of dental disease?		
Evidence Statement		Frequent consumption of added sugars is associated with increased risk of dental caries.
Grade		**C**
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	1 level 1V systematic review (low risk bias) and 4 level 111-2 prospective cohort studies (low to medium risk bias)
Consistency	Good	The systematic review (25 of 31 studies found no association) and 1 of the cohort studies determined that the amount of sugars consumed is not associated with dental caries. 1 of the cohort studies report increased risk of dental caries with increased amount of sugars consumed. However, the systematic review (19 of 31 studies found an association) and 3 of the 4 cohort study found an association with the frequency of sugars consumed and dental caries.
Clinical impact	Good	A summary statistic is not reported in the systematic review. For the cohort studies, the majority of 95% CIs for RRs exclude 1 (OR range from 2.0 (1.2 to 3.4)) - 3.04 (1.07 to 8.64)).
Generalisablty	Good	Males and females less than 35 years of age in North America and Europe.
Applicability	Good	Applicable to Australian healthcare context with few caveats

The systematic review (Anderson et al. 2009) is of people living in Asia, Europe and North America, who are aged 1 – 35 years. The cohort studies (Levy et al. 2003, Ruottinen et al. 2004, Marshall et al. 2007 and Warren et al. 2009) were of North American and European children (infants to 11 years of age), and were relatively small for this type of study. While the evidence suggests that a frequent intake of foods and beverages high in added sugars increases the risk of dental caries there is insufficient evidence provided in the searched published literature between 2002 and 2009 to determine a dose-response.

Table 14.4 Studies used to make evidence statements for sugars and dental disease

Reference [1]	**Levy et al. 2003**	**Marshall et al. 2003**	**Ruottinen et al. 2004**	**Warren et al. 2009**
Type of study [2]	Cohort	Cohort	Cohort	Cohort
Level of evidence [3]	III-2	III-2	III-2	III-2
Intervention/ comparator [4]	Dietary intake was partitioned into eleven broad categories: water, formula, breast milk, cow's milk, juices and juice drinks, non-juice beverages as purchased, beverages made from frozen concentrates, beverages made from powdered concentrates, ready-to-feed baby food, infant cereal made from powder, and other foods made with water (Jell-O®, soup, etc.).	Dietary intake was partitioned into eleven broad categories: water, formula, breast milk, cow's milk, juices and juice drinks, non-juice beverages as purchased, beverages made from frozen concentrates, beverages made from powdered concentrates, ready-to-feed baby food, infant cereal made from powder, and other foods made with water (Jell-O®, soup, etc.).	Mean±SD in high sucrose group 52.6± 13.1 g/d range 25.7-82.8 g/d; Low sucrose group 32.5± 18.5 g/d range 5.3-81.6 g/d	Dietary intake was partitioned into eleven broad categories: water, formula, breast milk, cow's milk, juices and juice drinks, non-juice beverages as purchased, beverages made from frozen concentrates, beverages made from powdered concentrates, ready-to-feed baby food, infant cereal made from powder, and other foods made with water (Jell-O®, soup, etc.).
N [5]	291 children	396 children	66 children	128 infants
Population/ study information [6]	US Children 6 weeks - 4 years old, mean age 5.17 years at dental exam; 53.3% female; 99% white	US Children 6 weeks - 7 years old, mean age 3.2 years at dental exam; 51.3% female; 97.2% white	Finnish children mean age 10 years (range 8-11)	Us infants age range 6-24 months; mean age 12.6 months; 58% male; 75% Caucasian
Quality [7]	O	P	O	O
Results [8]	Frequency of sugar sweetened beverage consumption and dental caries OR = 1.26, P=0.21; Frequency of milk consumption and dental caries OR = 0.69, P=0.05; Frequency of milk + sugar sweetened beverage consumption and dental caries OR = 1.70, P=0.005	Frequency of soda pop consumption and dental caries OR 2.2 (95% CI 1.4-3.6, P=0.05) Frequency of powdered beverage consumption and dental caries OR 2.0 (1.2- 3.4, P=0.05)	Decayed, missing and filled teeth in high vs. low sucrose intake group - mean±SD 3.9±3.9 in high sucrose and 1.9±2.5 in low sucrose, P=0.032; Frequency of sucrose intake and caries risk - in high sucrose consumers r=0.376; p =0.031; in low r =0.033, p =0.854	Sugar sweetened beverage consumption and caries OR 3.04 (95% CI 1.07–8.64, P= 0.04)

Effect on risk (Increase/None /Protect)	None	Increase	Increase	Increase
Clinical importance[9]	1	1	1	1
Clinical relevance [10]	1	1	1	1
Generalisability	Yes	Yes	Yes	Yes
Applicability	Yes	Yes	Yes	Yes

18 LIFE COURSE (S1.3)

LIFE COURSE FOOD CONSUMPTION and BIRTH WEIGHT

Is birth weight associated with children adopting appropriate life course consumption and dietary patterns?

Evidence statement	Increased birth weight, especially above 4000g, is associated with increased risk of overweight or obesity in childhood, adolescence, and later in life.
Grade	A

Component	**Rating**	**Notes**
Evidence Base	Excellent	13 cohort studies (11 P, 2 0).
Consistency	Good	10 of the 13 cohort studies found a significant association between birth weight and increased incidence of overweight or obesity later in life.
Clinical impact	Good	Odds ratios for increased overweight/obesity associated with increased birth weight ranged from 1.0 to 2.3.
Generalisability	Excellent	Western populations, such as Australia, Germany, USA, and UK.
Applicability	Excellent	Directly applicable.

As shown in the Process Manual, cohort studies are level II evidence, making this an excellent evidence base. Ten of the 13 cohort studies found a significant association between high birth weight and increased BMI, waist circumference, skinfold thicknesses, or incidence of overweight or obesity either in childhood, adolescence, or later in life. Two additional cohorts reported an inverse association only in males, not females. However, the evidence is consistent and strong enough to guide practice.

Table 18.1 Studies used to make evidence statement for life course food consumption and birth weight

Reference [1]	**Sturm 2008**	**Yang 2008**	**Goldani 2007**
Type of study [2]	Cohort	Cohort	Cohort
Level of evidence	II	II	II
Intervention/ comparator [4]	Effect of birth weight (regressor variable) on change in BMI in children	Association between birth weight (per 100 g) and prevalence of overweight and obesity in early adulthood (ages 18-26 yrs)	Association of birth weight (<2500 g, 2500-2999 g, 3000-3499 g, 3500-3999 g, >4000 g) on mean BMI at age 17yrs.
N [5]	6918 at 3yrs, 4557 at 5yrs	20 745 at baseline 9542 at follow-up.	3468 at baseline 1189 at follow-up
Population/study information [6]	Children starting kindergarten in 1998-9 school year in over 1000 US schools (Early Childhood Longitudinal Study - Kindergarten Class). 5 year follow up.	Adolescents 12-18yrs followed from 1995 till 2001-2002 (18-26 yrs old), from the National Longitudinal Study of Adolescent Health, United States.	Males born in Ribeirao Preto, Brazil (most developed economic area of Brazil) in 1978-79, and who enlisted in army in 1997-98; data taken at birth and at age 17yrs.
Quality [7]	P	P	0
Results [8]	Using data adjusted for confounders, birth weight was not associated with a significant change in BMI from either kindergarten to third grade (-0.039 kg/m^2, SE 0.021m, P=0.-63) or kindergarten to fifth grade (-0.041 kg/m^2, SE 0.030, P=0.177).	For males, birth weight (each 100 g increase) is associated with an increased prevalence of overweight adj OR 1.03, (95% CI 1.00-1.07) in early adulthood. There was no association in females.	BMI at age 17yrs was higher with birth weight >4000 g 1.37 kg/m^2 (95% CI 0.22-2.53) P<0.05 compared to birth weight of <2500g. Not adjusted for many confounding variables.
Effect on risk	None	Increase for males, none for females	Increase
Clinical importance	1	1	1
Clinical relevance	2	2	2
Generalisability	y	y	y
Applicability	y	y	y

Table 18.1 Studies used to make evidence statement for life course food consumption and birth weight (cont.)

Reference [1]	Mamun 2005	Salsberry 2007	Dubois 2006
Type of study [2]	Cohort	Cohort	Cohort
Level of evidence [3]	II	II	II
Intervention/ comparator [4]	Association between birth weight (continuous variable) and development of overweight at ages of 5-14yrs.	Effect of birth weight on development of early adolescent overweight (age 12yrs).	Relationship between birth weight (<2500 g, 2500-4000 g, >4000 g) and development of overweight in pre-school children.
N [5]	7223 at baseline 2934 for analysis	7207 at baseline, 3368 for analysis	1514
Population/study information [6]	Children born 1981-1984 at one of two major obstetric hospitals in Brisbane. (Mater-University of Queensland Study of Pregnancy - MUSP). Followed for 14yrs.	Children born between 1980-1990 in USA of mother's in the National Longitudinal Study of Youth. 46% white, 32% black, 22% Hispanic. Mean age 13.0yrs. 12yrs follow-up.	Children born in Quebec, Canada in 1998 (Longitudinal Study of Child Development in Quebec). 4-5 yr follow-up.
Quality [7]	P	P	P
Results [8]	Increased birth weight adj RR 2.10 (95% CI 1.50-2.94) had an increased risk of a child being overweight/obese at age 5 and 14 yrs.	Higher birth weight (birth weight categories not defined) was associated with greater risk of adolescent overweight (adj OR 1.01 (95% CI 1.00-1.01).	Children with a birth weight <2500 g were at increased risk of obesity using Cole criteria adj OR 3.14 (95% CI 1.16-8.53) but were not at increased risk of being overweight (BMI >95th percentile). Children with a birth weight >4000 g were at increased risk of overweight adj OR 2.30 (95% CI 1.41-3.74) but were not at increased risk of obesity.
Effect on risk	Increase	Increase	Increase for both high and low birth weight
Clinical importance	1	1	1
Clinical relevance [10]	2	2	2
Generalisability	y	y	y
Applicability	y	y	y

Reference [1]	Dubois 2006	Classen 2005	Reilly 2005
Type of study [2]	Cohort	Cohort	Cohort

Level of evidence [3]	II	II	II
Intervention/ comparator [4]	Effect of birth weight (<2500 g, 2500-2999 g, 3000-4000 g, >4000 g) on weight for stature >95th percentile at age 5 mo and BMI >95th percentile at age 4.5 yrs.	Relationship between birth weight (75 ounces or less vs. 150 ounces or more) on development of overweight or obesity in children over the age of 8 yrs.	Relationship between birth weight (continuous: 100 g units) and development of obesity at age 7 yrs.
N [5]	2103 at baseline 1944 at year 5	4980	13 971 at baseline 5493 at age 7 yrs
Population/study information [6]	Random sample of children born in Quebec, Canada in 1998. 48.9% female. 5yr follow-up.	Children aged 2-18yrs in US (NLSY79), 50% male, 30% black, 20% Hispanic. 18yr follow-up.	Children in the UK followed from birth (Avon longitudinal study of parents and children - ALSPAC) at age 7y.
Quality [7]	P	P	P
Results [8]	Birth weight of >4000 g was associated with an increased risk of having a weight-for-stature >95th percentile at age 5 mo unadj OR 1.6 (95% CI 1.0-2.5) and BMI >95th percentile at age 4.5 yrs unadj OR 2.3 (95% CI 1.4-3.7). Adjusted OR was not reported.	Birth weight >95th percentile is related to a 5% increase in overweight or obese youth (adj marginal effect probit estimate = 0.057 (SE 0.025), P<0.05).	100 g increase in birth weight was independently associated with the risk of obesity adj OR 1.05 (95% CI 1.03-1.07) at age 7 yrs.
Effect on risk	Increase	Increase	Increase
Clinical importance	1	1	1
Clinical relevance [10]	2	2	2
Generalisability	y	y	y
Applicability	y	y	y

Table 18.1 Studies used to make evidence statement for life course food consumption and birth weight (cont.)

Reference [1]	**Burke 2005**	**Kuh 2002**	**Hawkins 2009**	**Araujo 2009**
Type of study [2]	Cohort	Cohort	Cohort	Cohort
Level of evidence	II	II	II	II

Intervention/ comparator [4]	Effect of birth weight (continuous variable) with change in BMI to age 8yrs.	Relationship of birth weight (continuous variable) to waist:hip ratio and waist circumference in adults.	Relationship between birth weight z-score and development of childhood overweight at age 3yrs.	Effect of birth weight (<2.850, 2.850-3.180, 3.180-3.500, >3.500g) and ponderal index at birth (<2.53, 2.53-2.70, 2.71-2.89, >2.89g/cm^3) on prevalence of obesity, mean triceps measure (mm), mean subscapular measure (mm), and BMI at age 11 yrs.
N [5]	1430	5362 at baseline 3266 at follow-up, 3174 for analysis.	18 296 at baseline 14 630 at follow-up 13 188 for analysis.	5249
Population/study information [6]	Children in Australia aged 16 wks of gestation to age 8 yrs (Western Australia Pregnancy Cohort Study). Surveyed at age 1, 3, 6, and 8yrs.	Children born in England, Scotland and Wales, from the Medical Research Council's National Survey of Health and Development, followed from birth until age 43 yrs.	Children born between 2000 and 2002, from the Millennium Cohort Study. Followed from birth till age 3 yrs. Parents were residents in England, Wales, Scotland, and Northern Ireland. The study over-represented children living in disadvantaged areas and from ethnic minority groups.	Infants born at a hospital in Pelotas, Brazil in 1993. Mean birth weight 3156 g. 11 yr follow-up.
Quality [7]	P	0	P	P
Results [8]	Change in BMI at the age of 8 yrs was positively associated with birth weight 0.573 kg/m^2 (95% CI 0.259-0.886) P=0.001, adjusted.	In men, birth weight (adj) was significantly and positively associated with waist circumference 1.00cm (95% CI 0.48-1.52), P<0.001. There was no association in women.	In the fully adjusted model, birth weight z-score was associated with early childhood overweight adjusted OR 1.36 (95% CI 1.30-1.42).	Birth weight and ponderal index were all positively related to BMI, incidence of obesity, and skin fold measurements at age 11 yrs. Birth weight was the strongest predictor, with a BMI increase (adj) at age 11 yrs of 0.46 kg/m^2 for each z-score increase in birth weight. Prevalence of obesity trended upwards with each increase in quartile of birth weight (P trend

				< 0.001).
Effect on risk	Increase	Increase in men, none in women	Increase	Increase
Clinical importance	1	1	1	1
Clinical relevance	2	2	2	2
Generalisability	y	y	y	n
Applicability	y	y	y	y

LIFE COURSE FOOD CONSUMPTION and BREASTFEEDING

Is breastfeeding associated with children adopting appropriate life course consumption and dietary patterns?

Evidence statement	Compared to infants who are formula fed, being breastfed is associated with reduced risk of becoming obese in childhood, adolescence, and early adulthood.
Grade	A

Component	**Rating**	**Notes**
Evidence Base	Excellent	1 meta-analysis (neutral quality) of 4 historical cohort, 13 prospective cohort, 2 case-control, and 10 cross-sectional studies, involving over 600,000 subjects
Consistency	Excellent	All 29 individual studies reported some protective effect, but not all were significant.
Clinical impact	Excellent	Odds ratio for developing obesity was 0.87 (95% CI 0.85-0.89) in breast-fed subjects compared to formula-fed subjects.
Generalisability	Excellent	Includes both western and developing countries.
Applicability	Excellent	Directly applicable.

All 29 individual studies in the meta analysis found some protective effect, although not all were significant. Most of the studies were in children and adolescents, and only two extended into early adulthood. The pooled meta analysis statistic showed a significant association between being breastfed and the development of obesity later in life in both the crude analysis and with adjustment for paternal BMI, maternal SES, and maternal smoking. However, with the adjusted analysis, only six individual studies could be included. One additional meta analysis examining body mass index was not included in the body of evidence statement; this second meta analysis included 16 of the same studies as included in the first meta-analysis, and only examined mean BMI without distinguishing between those who were overweight compared to obese.

Table 18.2 Studies used to make evidence statement for life course food consumption and breastfeeding.

Reference [1]	**Owen 2005**	**Owen 2005**
Type of study [2]	Meta analysis of 4 historical cohort, 13 prospective cohort, 2 case-control, 10 cross-sectional studies	Meta-analysis of 17 prospective cohort, 2 historical cohort, 13 cross-sectional studies)
Level of evidence [3]	I	I
Intervention/ comparator [4]	Association between infant feeding and development of obesity later in life	Association between infant feeding and mean BMI (absolute) later in life
N [5]	672 161	Not provided
Population/study information [6]	Children born 1946-1996, most followed through childhood or adolescence, with 2 studies following through early adulthood (age 33 yrs maximum); Canada, UK, Germany, Sweden, Czech Republic, China, Turkey, Australia, New Zealand, Italy, Slovak Republic, USA.	6-week-old infants followed minimum of 1 yr, maximum of 70yrs; USA, The Netherlands, Italy, UK, Germany, Denmark, Australia, New Zealand, China, Czech Republic, Brazil.
Quality [7]	0	0
Results [8]	Breastfed subjects were less likely to be defined as obese than were formula-fed infants OR 0.87 (95% CI 0.85-0.89). All individual studies reported some protective effect of breastfeeding, but not all were significant. Definition of obesity varied among studies.	This study found lower mean BMIs in subjects who had been breastfed in infancy than in those who had been formula-fed in the crude analysis (difference in BMI -0.04 (95% CI -0.05 to -0.02). This small effect was halved by adjustment for maternal BMI in early life and became non-significant with meta-analysis of 11 studies that simultaneously adjusted for maternal BMI, maternal SES, and maternal smoking.
Effect on risk (Increase/None/Protect)	Protect	None
Clinical importance [9]	1	2
Clinical relevance [10]	2	2
Generalisability	y	y
Applicability	y	*y*

LIFE COURSE FOOD CONSUMPTION and EXCESS WEIGHT GAIN DURING CHILDHOOD

Is excess weight gain relative to height associated with children adopting appropriate life course consumption and dietary patterns?		
Evidence statement		Excessive weight gain relative to height during childhood is associated with an increased risk of overweight later in life.
Grade		A
Component	**Rating**	**Notes**
Evidence Base	Excellent	1 systematic review (of 14 cohort studies and 1 cross-sectional study) (1 P), 3 cohort studies (3 P).
Consistency	Good	16/18 cohort studies were consistent.
Clinical impact	Excellent	Relative risks ranged from 1-4.
Generalisability	Excellent	Western populations, including Australia, and USA.
Applicability	Excellent	Directly applicable.

The systematic review included 15 cohort studies and one cross-sectional study, involving over 325 000 participants. The cross-sectional data was not included in developing the body of evidence statement due to the low level of evidence. All but two of the 15 cohort studies included in the review reported a positive association between rapid growth and development of overweight, obesity, or other anthropometric measures, regardless of their definitions. The three additional cohort studies retrieved, one conducted in Australia, support this conclusion. These additional cohort studies were considered level II evidence as randomised controlled trials are not feasible due to the life course nature of the question. Although the effect of catch up growth is rarely differentiated in the studies and needs to be studied further, the evidence base is strong and consistent, and this statement can be used to guide practice.

Table 18.4 Studies used to make evidence statement for life course food consumption and rapid growth during childhood

Reference [1]	**Monteiro 2005**	**Mamun 2005**	**Dubois 2006**
Type of study [2]	Systematic review of 14 cohort studies and 1 cross-sectional study	Cohort	Cohort
Level of evidence	I	II	II
Intervention/ comparator [4]	Effect of rapid weight gain in infancy and childhood on obesity later in life. Measurements of growth included: weight gain from birth to age 4 mo-1 yr, variations in BMI z-score from birth to age 12-15 yrs, variations or increase in >0.67 standard deviation in weight-for-age z-score from birth to age 4 mo-15 yrs, variations or increase in >0.67 standard deviation in height-for-age z-score from age 20 mo to age 15 yrs, increase in >0.67 standard deviation in weight-for-height z-scores from age 20 mo to age 43 mo, change in length-for-age z-score from age 15 d to age 3 yrs, weight gain greater than 90^{th} or 97^{th} percentile of standard population from birth to age 6 mo-1 yr, percent of final adult height acquired by age 7 yrs, and being small for gestational age and being above 2 standard deviations in height at age 18-25 yrs.	Relationship between rate of weight gain (nearest gram per day) during the first 6 mo of life and overweight and obese status at ages 5 yrs and 14 yrs (overweight = BMI >17.42 for a boy and 17.15 for a girl at age 5 yrs, >22.62 for a boy and >23.34 for a girl at age 14 yrs; obese = BMI >19.30 for a boy and >19.17 for a girl at age 5 yrs, >27.63 for a boy and >28.57 for a girl at age 14 yrs).	Relationship between monthly weight gain from 0-5 mo (in quintiles) on development of child's overweight (BMI >95th percentile) by age 4.5yrs.
N [5]	325,412	7223 at baseline 2934 for analysis	2103 at baseline 1944 at year 5
Population/study information [6]	Infants and children	Children born 1981-1984 at one of two major obstetric hospitals in Brisbane. (Mater-University of Queensland Study of Pregnancy). Followed for 14 yrs.	Random sample of children born in Quebec, Canada in 1998. 48.9% female. 5 yr follow-up.
Quality [7]	P	P	P

Results [8]	All but 2 studies reported a positive association between rapid growth – regardless of definition – and occurrence of overweight, obesity, or greater adiposity measures, regardless of age at which measured. No summary statistic is reported. Examples of individual data: for every 100 g of monthly weight gain in first 4 mo of life, there was a 38% increase (P<0.001) in risk of overweight at age 7 yrs; subjects with ≥ 1 increase in standard deviation in weight-for-age z-score between birth to 4 mo had a 5.2-fold risk of developing obesity (P=0.008) and 6.2-fold risk of developing overweight (P=0.003); growth rates of height, weight, and BMI above mean values at age 7 yrs (+0.3 to 0.4 z-scores) were associated with obesity at age 64-75 yrs.	Rate of weight gain was positively associated with the transition from overweight or obese to normal as well as to the continuity of overweight or obesity. 1 g per day of weight gain in first 6 mo of life was associated with an increased risk of a child moving from normal weight status to overweight or obese adj RR 1.02 (95% CI 1.00-1.05), moving from overweight or obese to normal weight status adj RR 1.07 (95% CI 1.04-1.09), and being overweight/ obese at both age 5 and 14 yrs adj RR 1.06 (95% CI 1.04-1.08).	Weight gain in the 4th and 5th quintiles during the first 5mo of life was associated with increased risk of childhood overweight (BMI >95th percentile) at age 4.5 yrs: 4th quintile adj OR 1.8 (95% CI 1.0-3.5), 5th quintile adj OR 3.9 (95% IC 1.9-7.9).
Effect on risk	Increase	Mixed	Increase
Clinical importance	1	1	1
Clinical relevance	2	2	2
Generalisability	y	y	y
Applicability	y	y	y

20 AGE OF INTRODUCTION OF SOLID FOODS (S1.5)

S1.5 SOLID FOODS

Search results

The initial search of the databases included 862 references on the age of introduction of solid foods. The detailed search is included in a separate document on searches. Data was extracted from 11 references, and 10 publications were used to form the final body of evidence statements. Sufficient evidence was found to make statements on the relationships between age of introduction of solid foods and development of overweight and development of allergic symptoms. Additional evidence was found on the relationship between introduction of solid foods and diarrheal disease (one cohort study), but the evidence was not strong enough to develop a body of evidence statement.

AGE OF INTRODUCTION OF SOLID FOODS and OVERWEIGHT

Is the age of solid food introduction in children associated with the development of overweight later in life?		
Evidence statement		Age of introduction of solid foods is not associated with risk of overweight in children younger than the age of 7 years.
Grade		C
Component	**Rating**	**Notes**
Evidence Base	Good	1 systematic review (of 1 systematic review and 3 cohort studies - 1N), 2 cohort studies (2P).
Consistency	Satisfactory	The systematic review and one cohort study found no effect. The other cohort study found a positive effect.
Clinical impact	Poor	There was no association.
Generalisability	Excellent	USA and UK populations
Applicability	Excellent	Directly applicable.

The systematic review included one systematic review and three cohort studies in its analysis, all finding no relationship between the age of weaning and development of infant or child overweight. However, the review was of poor quality and did not critically analyse the included studies. Weaning was defined as the introduction of solid foods in this publication, but in the individual studies this may have been slightly different than our objective to examine the introduction of solid foods. The two cohort studies contributing to the body of evidence statement were both of high quality and were both conducted in the UK. One reported that age of introduction of complementary feeding was not associated with obesity at seven years, while the other reported that introduction of solid foods before age 4 months was associated with increased risk of overweight at three years. Complementary feeding was not defined in the publication, but it is commonly known as the transition from infant formula or breast milk to solid foods. Overall, it appears that age of introduction of solid foods has no effect on the risk of overweight in children, but due to the inconsistencies care must be taken when using this statement to guide practice.

Table 20.1 Studies used to make evidence statement for age of introduction of solid foods and overweight.

Reference [1]	**Reilly 2005**	**Hawkins 2009**	**Hawkins 2006**
Type of study [2]	Cohort	Cohort	Systematic review of 4 studies (1 systematic review, 3 cohort studies)
Level of evidence [3]	II	II	I
Intervention/ comparator [4]	Early life risk factors for development childhood obesity at age 7 yrs, including age at which complementary feeding is begun (<1, 1-2, 2-3, 3-4, or 4-6 mo). Complementary feeding was not defined in the publication.	Risk factors at various levels (individual, family, community and area) for development of childhood overweight. Included introduction of solid foods at < 4 mo compared to ≥ 4 mo .	Relationship between breastfeeding and weaning on development of overweight in preschool children. Weaning is defined as the introduction of solid foods in this publication.
N [5]	13 971 at baseline 8234 at follow-up 5493 for analysis	18 296 at baseline 14 630 at follow-up 13 188 for analysis	Number of subjects not provided. Breastfeeding: 15 studies; Weaning: 4 studies.
Population/study information [6]	Children born in 1991-92, from the Avon longitudinal study of parents and children (ALSPAC), followed from birth till age 7 yrs. Mothers lived in 3 health districts centred in Bristol, UK. Mainly white and singleton.	Children born 2000-02, from the Millennium Cohort Study. Followed from birth until age 3 yrs. Parents were residents in England, Wales, Scotland, and Northern Ireland. The study over-represented children living in disadvantaged areas and from ethnic minority groups.	Preschool children in US and UK
Quality [7]	P	P	N
Results [8]	Following adjustment for confounding factors, breastfeeding (p=0.464) and timing of introduction of complementary feeding (p=0.296) were not significantly related to the risk of obesity at age 7 yrs.	In the fully adjusted model, introduction to solid foods < 4 mo adj OR 1.12 (95% CI: 1.02-1.23) was associated with a increased risk of early childhood overweight; while breastfeeding > 4 months (0.86, 0.76 to 0.97) (compared with none) was associated with a decreased risk of early childhood overweight.	There may be an inverse relationship between breastfeeding (unclear if duration or ever) and later overweight (no difference between preschool children, older children, or adults). There is no relationship between time of weaning and overweight during infancy or in children younger than age 7 yrs. However, there was no quantitative data reported.
Effect on risk (Increase/None/Protect)	None	Increase for solid introduction at < 4 months	None

Clinical importance [9]	3	1	N/A
Clinical relevance [10]	1	1	1
Generalisability	y	y	y
Applicability	y	y	y

AGE OF INTRODUCTION OF SOLID FOODS and ALLERGIC SYNDROMES

Is the age of solid food introduction in children associated with the development of allergic syndromes?		
Evidence statement		Delay in the introduction of solid foods until after the age of 6 months is associated with increased risk of developing allergic syndromes.
Grade		D
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	1 poor quality systematic review of 11 prospective studies (1N), 2 randomised controlled trials (2P), 4 cohort studies (4P).
Consistency	Poor	Studies examined different foods and different allergies. Overall, 3 cohort studies and 1 RCT reported an increase in any allergy with the introduction of solids after age 4-7 months. 1 cohort study reported a reduction in food allergy with the introduction of solids before age 4 months. These associations become inconsistent when dividing into food allergy and other allergies. 2 cohort studies reported an increase in food allergy with the introduction of solids after age 4-6 months, 1 cohort found no association between food allergy and introduction of solids after age 7 months, and 1 cohort reported a reduction in food allergy with the introduction of solids before age 4 months. 1 cohort study reported an increase in other allergies with the introduction of solids after age 7 months, 1 RCT reported an increase in other allergies only with introduction of meat after age 6 months and only in high risk subjects, 1 cohort reported no association between development of other allergies and introduction of solid foods after age 4-6 months, and 1 cohort reported no association between development of other allergies and introduction of solids before age 4 months. The final cohort study reported a reduction in development of both food and other allergies with the introduction of fish at age 3-8 months compared to 9 months or older.
Clinical impact	Poor	Introduction of solids after age 4-6 months: Food allergy OR range from 1.85 to 7.85; Other allergy OR range from 0.44 to 20.86. Introduction of solids before age 4 months: Food allergy OR range from 0.39 to 0.49 with CI not crossing 1; Other allergy OR range 0.32 to 1.45.
Generalisability	Excellent	USA and UK populations
Applicability	Excellent	Directly applicable.

The systematic review was of very poor quality. The review authors used a systematic method to retrieve studies, but the included studies were not listed, quality was not assessed, eligibility criteria were not identified, and data abstraction was not discussed. The authors of the review concluded that the evidence relating the age of introduction of solid foods to the development of atopy is lacking, inconclusive, and inconsistent, but also recommended the exclusion of supplemental foods during the first 6 months of life due to the risk of the development of allergic symptoms. The systematic review did not contribute to the body of evidence statement. One of the randomised controlled trials measured age of introduction of solid foods, but did not report any results on this. This study also did not contribute to the body of evidence statement. Therefore, only one randomised controlled trial and four cohort studies were used to develop the statement. The other randomised controlled trial reported no association between either age at introduction of solid foods in general, specific type of solid food introduced, or diversity of foods and the development of eczema. However, increased risk was reported with delay of the introduction of meat until after 6 months, but only in subjects with a

family history of allergy. Two cohort studies examined the late introduction of solids in general, and reported conflicting results. One cohort study (Snijders 2008) reported no association with food allergies but an increased risk of other allergies with the introduction of solids after age 7 months, while the other cohort study (Zutavern 2008) reported an increased risk of food allergies, but no association with other allergies with the introductions of solids at 4-6 months or after 6 months. The latter cohort study also reported a reduced risk of food allergy with early diversity of foods (both one to two, and three to eight, food groups before age 4 months), but reported no association between age at introduction of solids and allergic sensitisation to cow's milk, peanut, or hen's egg. A third cohort study (Poole 2006) reported that delaying the initial exposure to cereal grains until after age 6 months significantly increased the risk of developing wheat allergy during childhood, suggesting that early introduction of cereal grains is protective. Age of introduction of rice cereal had no association. The final cohort study (Kull 2006) reported that children who were introduced to fish between age 3-8 months had fewer allergies (asthma, eczema, and allergic rhinitis) compared to children introduced to fish at age 9 months or older, suggesting that early introduction of fish is protective. Therefore, although the data appear to suggest that delaying the introduction of solid foods until after age 6 months may increase the risk of certain allergies, the data are somewhat conflicting and may only occur in subjects with a family history of allergy, and there are not enough studies on either solid foods in general or specific types of solid foods to use this to guide practice. As three of the five studies reported introduction of solids after six months, the timeframe of six months rather than four months is used in the body of evidence statement.

Table 20.2 Studies used to make evidence statement for age of introduction of solid foods and allergic syndromes

Reference [1]	**Snijders 2008**	**Zutavern 2008**	**Filipiak 2007**
Type of study [2]	Cohort	Cohort	RCT
Level of evidence	II	II	II
Intervention/ comparator [4]	Effect of duration of breast feeding, age at introduction of cow's milk and age at introduction of solids on development of eczema, atopic dermatitis, recurrent wheeze and sensitisation at age 2 yrs.	Effect of delayed introduction of solids until after 4 mo or introduction of a diversity of foods at 4 mo on development of allergy	Effect of delayed introduction of solids on development of eczema in a high risk group
N [5]	2558 infants	2073 children	Intervention group 2,252 Control group 3739
Population/study information [6]	KOALA birth cohort Study, The Netherlands. Healthy infants.	from L I S A birth cohort study, Germany. Examined both total cohort, and subset of cohort with no skin or allergic symptoms.	birth cohort Germany. Examined both entire cohort and subset of cohort with a family history of allergy.
Quality [7]	P	P	P
Results [8]	Introduction of solids after 7 mo increases the risk of eczema at age 2 yrs OR 2.10 (1.17-3.76), recurrent wheeze OR 3.52 (1.42-8.73), atopic dermatitis OR 9.46 (2.05-43.61), any sensitisation OR 4.31 (1.14-16.22), and the risk of sensitisation to one or more inhaled allergens OR 20.86 (2.17- 200.75). Introduction of solids after 7 mo was not associated with sensitisation to cow's milk OR 1.85 (0.35-9.37), peanut OR 7.85 (0.58-106.55), or hen's egg OR 5.88 (0.45-76.85).	1. Delay in introducing solid foods until 4-6 mo (OR range from 0.60-1.35) or > 6 mo (OR range from 0.44-1.45) has no effect on the diagnosis or symptoms of eczema, asthma, or allergic rhinitis. 2. Delay in introducing solid foods until 4-6 mo or > 6 mo appears to increase the odds of sensitisation to food allergens: Introduced 4-6 mo, OR 2.15 (1.28-3.62); Introduced > 6mo, OR 1.88 (0.98-3.58). 3. Relative to infants not introduced to solids in the first 4 mo, introduction of a diversity of food groups by 4 mo has no effect on diagnosis or symptoms of eczema, asthma, or allergic rhinitis or on the development of sensitisation to inhaled allergens (OR range from 0.32-1.45). 4. Relative to infants not introduced to solids in the first four mo, the introduction of a diversity of foods protects against sensitisation to foods: Introduced 1-2 food groups, OR 0.38 (0.19-0.73); Introduced 3-8 food groups, OR 0.49 (0.24-0.98).	1. No association between the time of introduction of solids and the development of doctor diagnosed or symptomatic eczema 2. No association between diversity of solid foods at 4 months and the development of doctor diagnosed or symptomatic eczema 3. With family history of allergy, delaying the introduction of solids until after 6 mo had no effect on development of doctor diagnosed or symptomatic eczema 4. With family history of allergy the introduction of meat and meat products after the age of 6 mo increased the risk of doctor-diagnosed eczema OR 1.42 (1.11-1.81) 5. With family history of allergy the

			introduction of dairy products, vegetables, fruit, cereal or egg after the age of 6 mo had no effect on the risk of doctor-diagnosed or symptomatic eczema
Effect on risk	Late solids: increase for eczema, atopic dermatitis, recurrent wheeze, inhaled allergens; None for food sensitisations.	Late solids: None for eczema, asthma, or rhinitis. Increase for food allergen sensitisation. Early solids: None for eczema, asthma, or rhinitis. Protect for food allergen sensitisation for early food diversity.	Increase for late meat in high risk subjects. None for other foods in high risk subjects. None for regular subjects.
Clinical importance	1	1	3
Clinical relevance	1	1	1
Generalisability	y	y	y
Applicability	y	y	y

Table 20.2 Studies used to make evidence statement for age of introduction of solid foods and allergic syndromes (cont.)

Reference [1]	**Kull 2006**	**Poole 2006**	**Becker 2004**	**Fiocchi 2006**
Type of study [2]	Cohort	Cohort	RCT	Systematic review of 11 prospective studies
Level of evidence	II	II	II	I
Intervention/ comparator [4]	Association between fish consumption during the first year of life and development of allergic diseases by age 4yrs.	Association between cereal-grain exposures (wheat, barley, rye, oats) in the infant diet and development of wheat allergy.	Avoidance of house dust mite, pet al.lergen and tobacco smoke plus breastfeeding, and delayed introduction of solid foods with control (nothing). Dependent variable is development of asthma or atopy.	Relationship between introduction of solids and development of allergy
N [5]	4089 at baseline 3670 at follow-up 2614 for analysis	1819 at baseline 1612 at follow-up and for analysis.	Intervention= 278 but data only obtained for 246. Control=267 but data only obtained for 230.	Number of subjects not provided; 11 studies examining allergic risk with timing of intro of solid foods.
Population/study information [6]	Children born in 1994-96 in Stockholm, Sweden, from the Children, Allergy, Milieu, Stockholm, Epidemiological survey [BAMSE], followed from birth until age 4 yrs. Healthy infants only - those with eczema or recurrent wheeze during the first year of life were excluded.	US Children born in 1993–2004, from the Diabetes Autoimmunity Study in the Young [DAISY]. Identified by either newborn screening for HLA genotype at St Joseph's Hospital in Denver, Colorado, US (n = 1111), or first-degree relatives of individuals with type 1 diabetes mellitus from the Denver metropolitan area (n = 501). 70% non-Hispanic white, 23% Hispanic. Followed from birth till mean age of 4.7 yrs.	Children born with high risk of developing asthma based on immediate family history. Canada.	Not provided, but assume it includes western populations. Healthy vs high risk population not reported in study.
Quality [7]	P	P	P	N
Results [8]	An inverse association was observed in analyses based on age at introduction of fish.	Delaying initial exposure to cereal grains until after 6 mo significantly increase the risk	No specific data was reported on association with delayed introduction of solids and risk of	Evidence of a link between the early introduction o solid foods in general and the onset of

	Children introduced to fish between 3-8 mo of age had a reduced risk for asthma OR 0.73 (95% CI 0.55–0.97), eczema (OR 0.77, 0.64–0.92), allergic rhinitis (OR 0.77, 0.60–0.97), and sensitization to food and airborne allergens (OR 0.78, 0.64–0.95) at age 4 yrs compared with children introduced to fish at 9 mo or older. Fish consumption of 2-3 times per month at age 12 mo is associated with reduced risk of allergy at age 4 yrs: Asthma OR 0.82 (0.54-1.29), eczema OR 0.71 (0.53-0.95), allergic rhinitis OR 0.51 (0.35-0.73), at least one allergic disease OR 0.58 (0.45-0.76).	of developing wheat allergy at mean age of 4.7yrs (OR: 3.8, 95% CI (1.18-12.28)), after adjusting for breastfeeding duration, introduction of rice cereal, family history of allergy, and history of food allergy before 6 mo of age. The timing of rice-cereal introduction was not significantly associated with wheat allergy after adjustment for cereal-grain exposure, breastfeeding duration, and family history of allergy.	asthma or atopy.	atopy is conflicting and inconsistent. Evidence as to an optimal time for the introduction of any individual solid food in the infant's diet is lacking. The introduction of solid foods is not an ideal research end point because its full benefit depends on the duration of breastfeeding. But, authors recommend: (1) Exclusion of supplemental foods is indicated during the first 6 months of life because if has a preventative effect against the onset of allergic symptoms. (2) The introduction of supplemental foods during the first 4 months of life has been associated with a higher risk of allergic disease up to the age of 10 yrs. Data was not quantified.
Effect on risk	Protect for fish	Increase: late grains; none: late rice	N/A	Increase for early intro
Clinical importance	1	1	N/A	N/A
Clinical relevance	1	1	1	1
Generalisability	y	y	y	y
Applicability	y	y	y	y

21 DIETARY PATTERNS (U1.1)

What dietary patterns, food groups (not nutrients) are associated with health and disease outcomes in the general population and vulnerable groups including low socio economic status, Aboriginal and Torres Strait Islanders and culturally and linguistically diverse groups, and those living in rural and remote areas, without serious disease?

Gilchrist et al. (2004) reported smoking and infant feeding practices in a cohort of Indigenous mother who delivered infants (n=425) at Perth hospital from 2000-2001. While they found high rates of maternal smoking they did not find any relationship with lower rates of breastfeeding initiation or duration at 24 weeks post-partum. They note the relationship between maternal smoking and low infant birth weight.
Mackerras (2006) This editorial discussed the implications of a study by Binns et al. in 2006 in the same journal issue and whether the higher rates of breastfeeding in the Indigenous population described are confounded or not by virtue of using a sample of indigenous women delivering in a publica hospital in Perth.
Binns (2006) The study documented the breastfeeding initiation and duration rates of Aboriginal mothers (n=425) delivering in six public hospitals and followed them up for six months. At discharge 89.4% (CI 86.6-92.1) of mothers were breastfeeding, declining to 58.8% (CI 53.5-64.1) at six months. These rates were higher when compared with non-Aboriginal mothers, but lower than the highest socioeconomic group. The authors reported that less than one-third of Aboriginal mothers achieved the World Health Organization recommendation exclusive breastfeeding until the infant is six months.

24 BREASTFEEDING (U1.5)

Search results
The initial search of the databases included 985 references for *U1.5 What are the benefits of breastfeeding (partial and exclusive) and the risks of not breastfeeding (any and exclusive), to infants and mothers, both in the short term and long term?* 292 reviews were retrieved and 101were included but only eight higher quality reviews were used to form the body of evidence statements and some additional papers from the 1.7 Endnote were used.

Sufficient evidence was found to make body of evidence statements for breastfeeding benefits and risks for mothers and infants, as detailed below. There were no recent good quality reviews of supplements. The majority of studies were excluded because they were not reviews.

A summary of non-systematic reviews that were recent have been included as an appendix. There was some overlap between this question and the searches for question *U1.7 What nutritional factors are important in optimising breastfeeding outcoumes?* and consequently some reviews from U1.7 have been used to inform the body of evidence statements in this review.

BREASTFEEDING AND ADULT DISEASE OUTCOMES

What are the benefits of breastfeeding (partial and exclusive) and the risks of not breastfeeding (any and exclusive), to infants and mothers, both in the short term and long term?	
Evidence statement	Being breastfed initially, particularly exclusively breastfed is associated with lower blood cholesterol concentrations in adult life.
Grade	C

Evidence statement		Being breastfed in infancy is associated with lower systolic and diastolic blood pressure up to adolescence.
Grade		B
Component	**Rating**	**Notes**
Evidence Base	Good	2 Systematic reviews (2P) comparing adult chronic disease outcomes for infants who were breastfed versus formula fed, with both showing protecting. The review on adult cholesterol levels included 13 cohort and 4 cross-sectional studies. The review on blood pressure included 2 RCTs, 9 cohorts and 4 cross-sectional studies.
Consistency	Good	Majority of studies consistent for both outcomes. In some studies the infant feeding group definitions of breastfeeding versus formula feedings were not completely exclusive.
Clinical impact	Good	Important at the population level. Meaningful reduction in plasma cholesterol level in adults after 17 to >50 years follow-up, of approx. 0.4mmol/L reduction for those breastfed, up to 0.15mmol/L reduction for those exclusively breastfed compared to those formula fed in infancy. From the meta-analysis, mean reduction was found in systolic (1.4 mmHg) and diastolic blood pressure (0.5 mmHg reduction) in breastfed versus bottle fed infants at up to 17 years.
Generalisability	Excellent	Breastfeeding definitions and rates are applicable to Australian women
Applicability	Excellent	Studies conducted in Northern & Southern Europe, Eastern Europe, USA, South America, New Zealand, UK, South Africa and Australia and majority are directly applicable to Australia.

The studies included in the body of evidence statement are shown in Table 24.1.

Table 24.1 Summary used to make evidence statements for breastfeeding and adult disease onset.

STUDY DETAILS (Review)	**Owen et al. 2008**
Reference	
Affiliation/source of funds	University of London, University of Bristol, Umea University, Royal Free and University College Medical School, University of Southhampton, Southhampton General Hospital, State University of new York, The George Institute Sydney, Children's Hospital Zagreb, John Radcliffe Hospital Oxford, Turku University Central Hospital, University of Amsterdam, University of Otago; Supported by the British Heart Foundation Project
Study design	Meta Analysis (4 cross sectional, 2 historical cohort, 10 prospective cohort, 1 retrospective cohort)
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	1950 to 2007
Number of studies	17
Total number of participants	17 498 (12 890 breastfed, 4608 formula fed)
Population characteristics	Formula and breast fed infants followed up until 17 - 71 yrs; in 7 studies it was possible to compare groups of subjects who were exclusive breastfeeders and bottle feeders, in the remaining 10 studies the infant feeding groups were not completely exclusive Northern Europe, Eastern Europe, USA, South America, New Zealand
Range of exposure	Initital infant feeding practices
Length of follow-up	16 to 71 years
Outcome(s) measured	PRIMARY: 1. Concentrations of total blood cholesterol in adult life
INTERNAL VALIDITY	
Databases included in search	Medline, Embase, Web of Science
Statistical analysis methods	Fixed effect models, mean difference, SE, chi-squared tests, meta-regression and sensitivity analysis
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	P
RESULTS	
Outcome	10/17 studies related breastfeeding to a lower mean concentration of total cholesterol in later life than was associated with formula

	feeding. There was evidence of marked heterogeneity between studies (X^2=30, P=0.02). In a fixed effects model the breastfed subjects had marginally lower total cholesterol then did formula fed subjects mean diff: -0.04 mmol/L (95% CI 0.08-0.00 mmol/L). The pooled estimate from a random effects model was similar -0.05 mmol/L (95% CI -0.12-0.02 mmol/L). The mean difference was unaffected by exclusion of one study with nearly half of the statistical weight or after adjustment for age, current SEP, BMI, smoking status or all. The overall mean difference in total cholesterol from the 7 studies reporting data for exclusive breast and bottle feeding was stronger mean difference -0.15 mmol/L (95% CI: 0.23- -0.06 mmol/L) than that in the remaining 10 studies that did not report exclusive feeding. The mean differnce was little affected by adjustment on a within-study basis for age, current SEP, BMI, and smoking status.
EXTERNAL VALIDITY	
Generalisability	y
Applicability	y
Comments	
Conclusion	Initial breastfeeding (particularly when exclusive) may be associated with lower blood cholesterol concentrations in later life. Moves to reduce the cholesterol content of formula feeds below those of breast milk should be treated with caution

BREASTFEEDING AND MATERNAL AND INFANT OUTCOMES

What are the benefits of breastfeeding (partial and exclusive) and the risks of not breastfeeding (any and exclusive), to infants and mothers, both in the short term and long term?		
Evidence statement		Infants who are exclusively breastfed for six months experience less morbidity from gastrointestinal infection than those who are mixed breastfed as of three or four months.
Grade		B
Evidence statement		Infants, from either developing or developed countries, who are exclusively breastfed for six months or longer do not have deficits in growth compared to those who are not exclusively breastfed.
Grade		B
Evidence statement		There are no apparent risks in a general recommendation for exclusive breastfeeding for the first six months of life, in both developing and developed-countries. However, infants should still be managed individually in order to achieve sufficient growth and minimise adverse outcomes.
Grade		B
Evidence statement		Mothers of infants exclusively breastfed for 6 months or more have more prolonged lactational amenorrhea.
Grade		B
Component	**Rating**	**Notes**
Evidence Base	Excellent	8 Systematic reviews [3 are Cochrane; 3 with meta-analysis (5P, 1O, 2N)]; 5 protective effect on breastfeeding success, 1 had no results and 1 found maternal perceived insufficient milk supply increased risk of lactation failure.
Consistency	Good	Definitions of breastfeeding (exclusive, partial, any) vary across studies. Consistent for support prolonging breastfeeding. Some of the same studies covered by the reviews
Clinical impact	Good	For provision of support, the RR for ceasing breastfeeding was approx.0.65 to 0.9. When expressed as odds ratios for continued breastfeeding the ORs for support ranged from 1.9 to 5.2.
Generalisability	Excellent	Breastfeeding definitions and rates are applicable to Australian women
Applicability	Good	While some reviews include studies conducted in developing countries, only those applicable to developed countries have been applied in developing the BOEs

The studies included in the body of evidence statement are shown in Table 24.2.

Table 24.2 Summary used to make evidence statement for breastfeeding and maternal and infant outcome

STUDY DETAILS (Review)	Szajewska et al. 2006	Kramer et al. 2002	Bhutta et al. 2008
Affiliation/source of funds	Medical University of Warsaw, Dr. von Hauner Children's Hospital, Ludwig-Maximilians-University of Munich	McGill University, WHO Expert Committee on the optimal duration of exclusive breastfeeding	Aga Khan University Bangladesh, Centre for Health and Population Research, Johns Hopkins Bloomberg School of Public Health USA, London School of Hygiene and Tropical Medicine, University of California, Federal University of Rio Grande de Sul Brazil, Sitaram Bhartia Institute of Science and Research India, World Bank Washington, Save the Children UK, Emergency Nutrition Network, International Food Policy Research Institute, Food for Education Programmes, Global Alliance against malnutrition, Bill and Melinda Gates Foundation, UNICEF Innocenti Research Centre
Study design	Systematic Review	Meta-Analysis	Systematic Review
Level of evidence	III-1 Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method).	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	1966-2004	Prior to 1966 - 2000	NS
Number of studies	1	22 (11 from developing and 11 from developed countries)	34
Total number of participants	170 infants (experimental group = 83; control group = 87)	9998	NS
Population characteristics	OI	Lactating mothers and their healthy, term, singleton infants from developed and developing countries	Breastfed and non breastfed infants from developing countries
Range of exposure	Experimental group received 5% glucose water from bottle, after breastfeeds,	To assess the effects of exclusive breastfeeding for 6 or more vs 3-4 mo with	Effect of promotion strategies on exclusive breastfeeding rates for infants younger then

	during the first 3 days of life	continued mixed breastfeeding until at least 6 mo	6 mo and on continued breastfeeding up to 12 mo
Length of follow-up	4 mo	NS	0-6 mo
Outcome(s) measured	Proportion of exclusively breastfed infants between birth and 6 mo, the proportion of infants receiving any breast milk at fixed time points between birth and 6 mo, the proportion of infants still being breastfed at the end of their first year of life, breastfeeding duration, proportion of infants receiving infant formula between birth and 6 mo	All infant and maternal health outcomes; infant outcomes especially growth (weight, length, head circumference, z scores, weight-for-age, length-for-age, weight for age, infections, morbidity, mortality, micronutrient status, neuromotor and cognitive development, asthma, atopic eczema, other allergic diseases, type 1 DM, blood pressure, adult chronic diseases. Maternal outcomes especially postpartum weight loss, duration of lactational amennorrhea, chronic diseases (osteoporosis, breast and ovarian cancer)	Mortality, breastfeeding duration, breastfeeding pattern (exclusive, partial, predominant)
INTERNAL VALIDITY			
Databases included in search	Medline, Embase, Cinahl, Cochrane	Medline, Oldmedline, Cinahl, EBM Reviews -Best Evidence, Sociofile, Cochrane, CAB Abstracts, EMBASE Psychology, EconLit, IMEMR, AIM, LILACS, Healthstar	Cochrane Library, ExtraMed, WHO Reproductive Health Library
Statistical analysis methods	Intention to treat analysis, p value	Controlled clinical trials: Adequacy of randomization and concealment, losses to follow up analysis, measurement of outcome, 5 point Jadad scale Observational studies were assessed for control for confounding, losses to follow up, and assessment of outcomes as follows: for growth and morbidity outcomes, losses to follow up, assessment of outcome. All studies were stratified according to study design (controlled trials vs observational),	Multiplicative model, mortality RR, stunting OR

		provenance (developed vs developing), timing of feeding comparison (3 to 7 months vs prolonged (> 6 months)).	
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	P	P	O
RESULTS			
Outcome		Indicators of child health (GIT infection, development of asthma, allergies, iron status), growth and development, and on maternal health (resumption of menses, postpartum weight loss). Comparison one: controlled trials of exclusive versus mixed breastfeeding for 4 - 6 mo, developing countries and Comparison two: observational studies of exclusive versus mixed breastfeeding for 3 -7 months, developing countries and Comparison three: observational studies of prolonged (more than 6 mo) exclusive versus mixed breastfeeding, developing countries are not relevant to Australia. Comparison 4 is relevant to the Australian population: Observational studies of exclusive versus mixed breastfeeding for 3-7mo in developed countries. Studies were heterogeneous with a WMD of -12.45 (95% CI -23.46 to -1.44) g/mo & should be interpreted with caution, although even the lower 95% confidence limit is compatible with a lower weight gain in the EBF group. Given the large weight gains in both groups in the Belarussian study, the higher gain in	Beginning breastfeeding within the first days after birth lowers mortality even in exclusively breastfed infants. One review showed that all forms of extra support increased the duration of 'any breastfeeding' with the RR for stopping any breastfeeding before 6 mo being 0.91 (95% CI 0.86-0.96). All forms of support affected the duration of exclusive breastfeeding more strongly than the likelihood of any breastfeeding RR 0.81 (0.74-0.89). Lay and professional support extended breastfeeding duration (RR before 4-6 wks 0.65 (0.51-0.82); RR before 2 months 0.74 (0.66-0.83).Further reviews reported that with individual counselling the OR of exclusive breastfeeding were increased in the neonatal period (15 studies; OR 3.45 (95% CI 2.2-5.42) p<0.0001; random effects) and at 6 mo (9 studies; OR 1.93 (95% CI 1.18-3.15) p<0.0001. Group counselling increased odds of exclusive breastfeeding in the neonatal period (6 studies; OR 3.88 (95% CI2.09-7.22) p<0.0001; random effects) and at 6 mo (5 studies; OR 5.19 (95% CI 1.9-14.15) p<0.00001; random

		the MBF group is not necessarily a beneficial outcome. Heinig 1993 and Kramer 2000a also reported on weight gain between 6 -9 mo (outcome two) (significant heterogeneity), (P = .04) and dominated by the larger size of the Belarussian study. The pooled WMD was -2.26 (95% CI -16.94 to +12.42) g/mo. Akeson 1996a, Heinig 1993, and Kramer 2000a reported on weight gain from 8 - 12 months (outcome three); the WMD was -1.82 (95% CI -16.72 to +13.08) g/mo, which excludes a reduced length gain in the EBF group of 5% of the mean and 10% of the SD for the Belarussian study. For length gain at 3 - 8 months (outcome four), the studies again show significant (P < .01) heterogeneity. Kramer 2000a found a slightly but significantly lower length gain in the EBF group at 4 - 8 months (difference -1.1 (95% CI -1.7 to - 0.5) mm/mo), whereas the pooled analysis yielded a WMD of - 0.4 (95% CI -0.7 to 0.0) mm/mo; the lower confidence limit is statistically compatible with a reduced length gain of less than 4% of the mean and 10% of the SD for the Belarussian study. Heinig 1993 and Kramer 2000a also reported on length gain at 6 - 9 months (WMD -0.4 (95% CI -1.0 to +0.1) mm/mo) (outcome five). For the 8 -12 moh period, the results show a slightly but significantly higher length gain in the EBF group (WMD+0.9 (95% CI +0.3 to +1.4)) mm/mo (outcome six). Observational analyses from	effects). A study on a national mass media campaign in Honduras reported that it increased exclusive breastfeeding from 48-70% at 1 mo, from 24-31% at 4 mo, from 7-12% at 6 mo. The WHO growth reference study showed that infants exclusively breastfed were on average 360 g and 100 g heavier at 4 and 6 mo then predominantly non breastfed children on whom the US NCHS growth curves were based. Exclusive breastfeeding reduced HIV transmission compared with partial was reported in 1 study and a further study showed that HIV-free survival did not differ in infants who were HIV-negative at 4 mo and were abruptly weaned or continued to be breastfed. Authors created a cohort model of child mortality and stunting by modelling the survival and linear growth status of the annual birth cohort of children from birth until 3 yrs in 36 countries with 90% of the global burden of stunted children. In children aged 6-23 mo the baseline breastfeeding category is breastfed (RR 1.0) vs non breastfed (RR 2.3). using this model, authors reported that mortality risk ratio for exclusive breastfeeding (age <1 mo) was 1.0 and 1.48 for predominant breastfeeding, 2.85 for partial breastfeeding and 14.4 for no breastfeeding. In the same model for ages 6-35.9 mo, the mortality risk ratio for predominant breastfeeding was 1.0 and 2.3 for no breastfeeding. Authors also reported on the effect of nutrition-related

		the Belarussian study (Kramer 2000a) also include data on weight-for-age, length-for-age, and weight for length z-scores at six, nine, and 12 mo. Means in both the EBF and MBF groups were well above (+0.5 to +0.6) the reference values at all three ages. Nonetheless, the weight-for-age z-score was slightly but significantly lower in the EBF group at all three ages: WMD -0.09 (95% CI -0.16 to -0.02) at 6 mo, -0.10 (95%CI -0.18 - -0.02) at 9 months, and -0.09 (95% CI -0.17 - -0.01) at 12 mo (outcomes seven to nine). Length-for-age z scores were very close to the reference (0) at 6 and 9 mo and slightly above the reference (0.15) at 12 mo. Again, the EBF group had slightly but significantly (except at 12 mo) lower values: WMD -0.12 (95% CI -0.20- -0.04) at 6 mo,-0.14 (95%CI -0.22 - -0.06) at 9 mo, and -0.02 (95%CI-0.10 - +0.06) at 12 mo (outcomes 10 to 12). Mean weight for-length z-scores were high and rose (from about 0.65 to 0.80) from 6 -12 mo, with no significant differences between the EBF and MBF groups at any age: WMD +0.02 (95% CI -0.07- +0.11) at 6 mo, +0.03 (95% CI -0.06 - +0.12) at 9 mo, and -0.08 (95% CI -0.17 - +0.01) at 12 mo (outcomes 13 to 15). The prevalence of low (less than -2) z-scores did not differ significantly in the two Belarussian feeding groups for any of the three z-scores at any of the three ages, although the small number of infants with low z-scores provided low statistical power to detects	interventions on mortality and stunting in 36 countries. A 99% coverage with breastfeeding promotion and support resulted in 11.6, 9.9 & 9.1% in proportional reduction in deaths before 12, 24 and 36 mo respectively. The % of DALYs averted at 36 mo was 21.9 million for 99% coverage with breastfeeding promotion and support.

		such differences. RRs (and 95% CIs) for low weight-for-age were 0.92 (0.04 -19.04) at 6 mo, 1.52 (0.16-14.62) at 9 mo and 1.15 (0.13- 10.31) at 12 mo (outcomes 16 to18). For length-for-age, the corresponding figures were 1.53 (0.84 -.78) at 6 mo, 1.46 (0.80-2.64) at 9 mo, and 0.66 (0.23 -1.87) at 12 mo (outcomes 19 to 21). For weight - for-length, the figures were 0.31 (0.02- 5.34) at 6 mo, 1.14 (0.24- 5.37) at 9 mo, and 1.15 (0.13-10.31) at 12 mo (outcomes 22 to 24). The Belarussian study also provided data on head circumference. No significant differences were observed at 6 mo (difference -1.0 (95% CI -2.3 - +0.3) mm) (outcome 25) or 9 mo (+0.7 (95% CI -0.6 - +2.0) mm) (outcome 26), but the EBF group had a slightly but significantly larger circumference at 12 mo (outcome 27): difference = +1.9 (95% CI +0.6 - +3.2) mm. Heinig 1993 reported nearly identical sleeping time (729 versus 728 minutes/day) in the two groups (outcome 28). Akeson 1996a reported similar total amino acid and essential amino acid concentrations at 6 mo of age in the two feeding groups (outcomes 29 and 30). Both Kramer 2000a and a cohort study from Finland (Kajosaari 1983) reported an atopic eczema at one yr (outcome 31). The two studies showed statistically significant (P= .03) heterogeneity, with Kajosaari 1983 reporting a significantly reduced risk RR 0.40 (95% CI 0.21 to 0.78), but the larger Belarussian study finding a much lower	

		absolute risk in both feeding groups and no risk reduction with EBF RR 1.00 (95% CI 0.60 to 1.69). Although Kajosaari 1983 also reported a reduced risk of a history of food allergy (outcome 32), double food challenges showed no significant risk reduction RR 0.77 (95% CI 0.25 -2.41) (outcome 33). Neither Oddy 1999 nor Kramer 2000a found a significant reduction in risk of recurrent (2 or more episodes) wheezing in the EBF group pooled RR 0.79 (95% CI 0.49 -1.28) (outcome 34). In the Kajosaari 1983 study, the reduction in risk of any atopy at five years (outcome 35) in the EBF group was nonsignificant RR 0.68 (95% CI 0.40 -.17), and no reduction in risk was observed for atopic eczema RR 0.97 (95% CI 0.50 - 1.89) (outcome 36). A reduction in risk of borderline significance was observed for pollen allergy at five years RR 0.53 (95% CI 0.28-1.01) (outcome 37). Both Kajosaari 1983 and Oddy 1999 reported on risk of asthma at 5 - 6 yrs (outcome 38); the pooled RR was 0.91 (95% CI 0.61-1.36). Reduced risks of history of food allergy RR 0.61 (95% CI 0.12 - 3.19) (outcome 39) and allergy to animal dander RR 0.81 (95% CI 0.24 - 2.72) at five years (outcome 40) were far from achieving statistical significance. Oddy 1999 found no reduction in risk of a positive skin prick test at 6 yrs in the EBF group RR 0.99 (95% CI 0.73-1.35) (outcome 41). A small Italian study of hematologic outcomes at 12 mo by	

		Pisacane in 1995 reported a statistically significantly higher hemoglobin concentration (117 versus 109 g/L (95% CI for the difference = +4.03 to +11.97 g/L)) (outcome 42), a nonsignificant reduction in anemia (hemoglobin less than 110 g/L) RR 0.12 (95% CI 0.01- 1.80) (outcome 43), a nonsignificantly higher ferritin concentration WMD+4.7 (95% CI -6.3 - +15.7mcg/L)(outcome 44), and a nonsignificant reduction in the risk of low (less than 10 mcg/L) ferritin concentration RR 0.42 (95% CI 0.12 - 1.54) (outcome 45) among infants in the EBF group. Of note in this study is that the exclusive and mixed breastfeeding continued in both groups until at least 12 mo (a criterion for selection into the Pisacane 1995 study).Kramer 2000a recorded only one and two deaths (outcome 46) among the 621 and 2862 Belarussian infants in the EBF and MBF groups, respectively (RR 2.30 (95% CI 0.21-25.37). The EBF had a significantly reduced risk of one or more episodes of gastrointestinal infection in the first 12 mo of life RR 0.67 (95% CI 0.46 - 0.97) (outcome 47), which was maintained in a multivariate mixed model controlling for geographic origin, urban vs rural location, maternal education, and number of siblings in the household adjusted OR 0.61 (95% CI 0.41- 0.93).No significant reduction in risk was observed for hospitalization for gastrointestinal infection, however RR 0.79 (95% CI 0.42-.49) (outcome 48). In the	

		above-mentioned Australian cohort study, Oddy 1999 found no significant reduction of risk for one or more episodes of upper respiratory tract infection (outcome49) in the EBF group RR 1.07 (95% CI 0.96-1.20). Neither Oddy 1999 nor Kramer 2000a found a significantly reduced risk of two or more such episodes pooled RR 0.91 (95% CI 0.82 -1.02) (outcome 50). Nor did Oddy 1999 find a significant reduction in risk of 4 or more episodes of upper respiratory infectionRR 0.82 (95% CI 0.52 -1.29) (outcome 51) or of one or more episodes of lower respiratory tract infection (RR 1.07 (95%CI 0.86-1.33) (outcome 52). Kramer 2000a found a small and nonsignificant reduction in risk of 2 or more respiratory tract infections (upper and lower combined) RR 0.90 (95% CI 0.79 - 1.03) (outcome 53). The combined crude results of Oddy 1999and Kramer 2000a show a substantial and statistically significant reduction in risk for hospitalization for respiratory tract infection pooled RR 0.75 (95% CI 0.60 - 0.94), but the crude risk reduction in Kramer 2000a was nearly abolished and became statistically nonsignificant in a multivariate mixed model controlling for geographic region, urban vs rural location, maternal education and cigarette smoking, and number of siblings in the household adjusted OR 0.96 (95% CI 0.71- 1.30) (outcome 54).In a study from Tucson, Arizona, (Duncan 1993) reported no	

		difference in the average number of episodes of acute otitis media in the first 12 mo of life (outcome 55) in the exclusive vs MBF groups (1.48 vs. 1.52 episodes, respectively) (95% CI for the difference -0.49 to +0.41 episodes).Duncan 1993 and Kramer2000a both found a slightly elevated risk for one or more episodes of otitis media pooled RR 1.28 (95% CI 1.04 -1.57) (outcome56), but Duncan 1993 found a nonsignificant reduction in risk for frequent otitis media RR 0.81 (95% CI 0.43-1.52) (outcome57).	
EXTERNAL VALIDITY			
Generalisability	y	y - for the results of the studies conducted in developed countries	n
Applicability	y	y	y
Comments	The unclear randomization and allocation concealment processes in the study suggest selection bias was possible. Furthermore the use of a telephone interview further suggests recall/reporting bias	Definitions of exclusive breastfeeding varied across studies	In the cohort model of child mortality and stunting, the protective effect of breastfeeding is assumed to cease when the child reaches 2. Although authors have considered a number of breastfeeding interventions and reviews, details of these interventions and reviews are not provided.
Conclusion	There remains considerable uncertainty about the effect of brief exposure to water, breast-milk substitutes, or other liquids on the success and duration of breastfeeding	Infants who are exclusively breastfed for 6 mo experience less morbidity from gastrointestinal infection than those who are mixed breastfed as of 3 or 4 mo, and no deficits have been demonstrated in growth among infants from either developing or developed countries who are exclusively breastfed for 6 mo or longer. Moreover, the mothers of such infants have more prolonged lactational amenorrhea.	Proven nutrition-related interventions offer many possibilities for the reduction of the related burden of disease in both the short and the long term. The evidence for benefit from nutrition interventions is convincing.

		Although infants should still be managed individually so that insufficient growth or other adverse outcomes are not ignored and appropriate interventions are provided, the available evidence demonstrates no apparent risks in recommending, as a general policy, exclusive breastfeeding for the first 6 mo of life in both developing and developed-country settings. Large randomized trials are recommended in both types of setting to rule out small effect son growth and to confirm the reported health benefits of exclusive breastfeeding for 6 mo or beyond.	

Table 24.2 Summary used to make evidence statement for breastfeeding and maternal and infant outcome (cont.)

STUDY DETAILS (Review)	Britton et l. 2007	Abdulwadud et al. 2007	Baird et al. 2009
Affiliation/source of funds	University of York, UK	ASEBE TEFERI, Ethiopia; IMPART; BC Centre of Excellence for Women's Health, Canada	University of Southhampton, South Hampton General Hospital UK, Medical Research Council
Study design	Meta Analysis	Meta Analysis	Systematic Review of (3 systematic reviews)
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.	111-211	III-1 Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method).
Date of search	1966-2005	1951 - 2006	1966-2008
Number of studies	34	0 trials have evaluated this	3
Total number of participants	29 385 mother - infant pairs	N/A	NS
Population characteristics	Pregnant women intending to breastfeed, postpartum women intending to breastfed and women breastfeeding their babies; Canada, USA, UK, Brazil, Bangladesh, Australia, India, Nigeria, Italy, Iran, Netherlands, Belarus, Mexico, Sweden	NA	Breastfeeding mothers or pregnant women intending to breastfeed from disadvantaged backgrounds (in developed countries),
Range of exposure	Intervention: Pregnant or lactating women intending to breastfed receiving contact with an individual or individuals (professional or volunteer) offering support which is supplementary to standard care with the purpose of facilitating continued breastfeeding Comparator: Mothers receiving usual postnatal care which varies between and	Intervention: Any type of workplace strategy to encourage, assist and support breastfeeding for women returning to work after birth Comparator: Women receiving usual care	Intervention: Reviews on interventions promoting and prolonging breastfeeding and providing support for mother who are breastfeeding. Interventions include breastfeeding literature, lay support, professional support, peer support and 1 on 1 counselling

	within countries		
Length of follow-up	Up to 9 mo post partum	NA	NS
Outcome(s) measured	PRIMARY: 1. Effect of the interventions on duration of any breastfeeding to specified points in time; 2. Stopping feeding before 4 to 6 wks and 2, 3, 4, 6, 9 and 12 mo SECONDARY: 1. Exclusive breastfeeding; 2. Measures of neonatal and infant morbidity; 3. Measures of maternal satisfaction with care or feeding method	Primary: 1. Rate, duration and prevalence of exclusive breastfeeding. Secondary: 1. Employer-related; 2. Mother-related; 3. Infant-level outcomes	Breastfeeding initiation, breastfeeding duration
INTERNAL VALIDITY			
Databases included in search	Cochrane Pregnancy and Childbirth Group's Trials Register, medline, Embase, MIDIRS	Cochrane Pregnancy and Childbirth Group's Trials Register, Central, Medline, Cinahl, Lilacs, C2-Spectr	Cochrane, Database of Abstracts of Reviews of Effectiveness, Health Technology Database, Medline
Statistical analysis methods	RevMan 2003; Relative risks; random effects model; subgroup analyses	Intended to use RevMan 2003, fixed effect meta analysis, random effects model	RR
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)			
RESULTS			
Outcome	There is a beneficial effect on the duration of any breastfeeding up to 6 mo with the implementation of any form of extra support RR 0.91 (95% CI 0.86-0.96). Authors divided trials into 3 categories - high (> 80%), intermediate (60-80%) or low (<40%) initiation rates in the local area. Analysis of the trials conducted in settings with immediate initiation demonstrated all forms of support had a significant benefit	No randomised controlled trials or quasi-randomised controlled trials were identified	Interventions that use education and 1 on 1 support are effective in increasing breastfeeding initiation rates. Any form of additional support for mothers who are breastfeeding increases the duration of breastfeeding. Many of the studies reviewed were targeted at low income groups

	on breastfeeding RR 0.92 (95% CI 0.85-0.98), whereas there was no significant effect where there were high or low breastfeeding initiation rates RR 0.91 (95% CI 0.81- 1.01) and RR 0.88 (95% CI 0.69-1.12). The effect of any support on mothers exclusively breastfeeding is greater than on women continuing any form of breastfeeding RR 0.81 (95% CI 0.74- 0.89). Professional support vs usual care showed professional support to be effective at 4 mo only RR in 5 trials 0.78 (95% CI 0.67-0.91). The overall effect of extra support on stopping any breastfeeding did not reach statistical significance. Professional support resulted in a beneficial effect on exclusive breastfeeding RR in 16 trials 0.94 (95% CI 0.87 -1.01). Professional support showed to be beneficial on exclusive breastfeeding rates RR 0.91 (95% CI 0.84-0.98). Trials using lay people to conduct breastfeeding interventions demonstrated a significant decrease in breastfeeding cessation RR 0.86 (95% CI 0.76- 0.98). Combined lay and professional support vs usual care showed a significant reduction in cessation of any breastfeeding RR 0.84 (95% CI 0.77- 0.92) especially in the first 2 mo RR before 4 to 6 wks 0.65 f(95% CI 0.51- 0.82); RR before 2 mo 0.74 (95% CI 0.66-0.83). 2 studies showed a significant reduction in cessation of exclusive breastfeeding RR 0.62 (95% CI 0.50- 0.77). Studies using face to face support showed a statistically significant benefit RR for giving up any breastfeeding		

	0.85 (95% CI 0.79 to 0.92). No significant effect was demonstrated when phone and face to face support were provided on breastfeeding continuation RR 1.00 (95% CI 0.91 -1.09). One study demonstrated a significant reduction in risk of 1 or more GI infections and atopic eczema in those receiving support from health professional trained in WHO/UNICEF Baby Friendly Initiative. A further study found no significant difference between peer peer and control group mean score on the Maternal Breastfeeding Evaluation Scale (mean scores 52.81 (SD 5.69) vs 52.98 (SD 5.94) p=0.26).		
EXTERNAL VALIDITY			
Generalisability	y - although some studies were conducted in developing countries	n/a	y
Applicability	y	N/A	y - note that the review focused on women from disadvantaged backgrounds but included studies on women generally.
Comments		The lack of evidence resulting from this review emphasises the need for further research into breastfeeding education and support in the workplace post delivery	The objectives of this review were focused on all interventions directed at changing health behaviours of young women from disadvantaged backgrounds and included smoking, physical activity and diet.

Conclusion	Additional professional support was effective in prolonging any breastfeeding, but its effects on exclusive breastfeeding were less clear. WHO/UNICEF training courses appeared to be effective for professional training. Additional lay support was effective in prolonging exclusive breastfeeding, while its effects on duration of any breastfeeding were uncertain. Effective support offered by professionals and lay people together was specific to breastfeeding and was offered to women who had decided to breastfeed. Further trials are required to assess the effectiveness (including cost-effectiveness) of both lay and professional support in different settings, particularly those with low rates of breastfeeding initiation, and for women who wish to breastfeed for longer than three months. Trials should consider timing and delivery of support interventions and relative effectiveness of intervention components, and should report women's views. Research into appropriate training for supporters (whether lay or professional) of breastfeeding mothers is also needed.	No trials have evaluated the effectiveness of workplace interventions in promoting breastfeeding among women returning to paid work after the birth of their child. The impact of such intervention on process outcomes is also unknown. Randomised controlled trials are required to establish the benefits of various types of workplace interventions to support, encourage and promote breastfeeding among working mothers.	Consistent evidence was found of intervention features associated with effective changes in a number of health behaviours. Interventions to change health behaviours of women of child-bearing age from disadvantaged backgrounds require: an educational approach delivered in person by professionals or peers; provide continued support after the initial intervention; some evidence to t that social support from peers and family involvement in the intervention maybe important. These findings are of relevance to the design of an intervention to improve diet in this group of women.

Table 24.2 Summary used to make evidence statement for breastfeeding and maternal and infant outcome (cont.)

STUDY DETAILS (Review)	**Gatti. 2008 [491]**	**Ines Couto de Oliveira et al. 2001 [483]**
Affiliation/source of funds	Centre for Health Disparities Research, University of Pennsylvania, National Institute of Health Institutional Training Grant	Brazilian Government Agency CAPES.

Study design	Systematic review (15 prospective, longitudinal; 3 cross sectional, 3 secondary analysis of datasets)	Systematic review (33 experimental & 31 quasi-experimental studies)
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.	I
Date of search	1996-2007	1980-1999
Number of studies	20	64
Total number of participants	36 700	>3700
Population characteristics	Healthy, full term breastfeeding dyads during the first 6 mo of life	Pre-natal, and post-natal women
Range of exposure	Examine reasons why women had low rates of duration and exclusivity of breastfeeding &/or associations between perceived milk supply and other maternal perceptions. 4 of the studies examined tools to predict insufficient milk supply. This was done through validated questionnaires, tools, Theory of planned behaviour, standard definitions, non validated tools, open ended questions, H & H Lactation Scale, The Perceived Insufficient Milk Tool	Primary care interventions designed to extend breastfeeding duration (exclusive, full, or any kind of breastfeeding) during the prenatal and/or postnatal period. Interventions that took place during the delivery period only were excluded.
Length of follow-up	1 month to 24 months	Range from 2 to 12 mobut most to 6 mo
Outcome(s) measured	Breastfeeding levels, reasons for ceasing breastfeeding, supplementation and breastfeeding level, breastfeeding difficulties, breastfeeding self efficacy, breastfeeding satisfaction, prediction of breastfeeding at 12 wks, breastfeeding support, perceptions of milk supply, coping strategies of PIM, risk factors for early cessation.	Extension of breastfeeding (Full, partial or any kind of breastfeeding) at points in time varying from 4 wks to 6 mo. Main outcome measure was the proportion of mothers breastfeeding at or until a specified time point. Some studies reported median or mean breastfeeding duration.
INTERNAL VALIDITY		
Databases included in search	Cinahl, Medline, Pubmed	Literature search used an earlier systematic infant-feeding review that focused on the developed world as the starting point. Additional databases searched (Medline, Popline, Health- Star, CAB-Health, Cochrane Library, CINAHL, and Lilacs) using the key words promotion, intervention, assessment, programme, community,

		education, effect, impact, and evaluation (linked to breastfeeding).
Statistical analysis methods	Factor analysis, regression, survival analysis	Present the interventions' maximum duration of effect that proved was statistically significant at a 90% level. The effects presented are the percentage of exclusive breast-feeding among intervention and control groups, and corresponding P value. The attributable fraction and 95% confidence intervals were constructed when data presented by the authors were conclusive or suggestive of effect. The attributable fraction (AF) was defined as the proportion of the outcome rate achieved in the intervention group that is due to the intervention, and is a measure of effectiveness. It is the difference between breastfeeding rates in the intervention (I) and control groups, expressed as a proportion of the rate in the intervention group: AF=(I - C)/I. or from the relative risk (RR). ; AF = (RR – 1)/RR.
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)		P
RESULTS		
Outcome	Many women were found to discontinue breastfeeding during the 1st few weeks post partum as a result of Perceived Insufficient Milk (PIM) supply. Many women used infant satisfaction cues (e.g. crying, unsettled) as their primary indicators of milk supply. The H & H Lactation Scale and the Perceived Insufficient Milk Tool have been found useful to identify women at risk during early post-partum. Furthermore, PIM was associated with early weaning and / or decreased exclusivity in 10 studies. PIM was also associated with lower self efficacy or maternal confidence scores. Use of formula in hospital was associated with PIM in 3 studies and ceasing breastfeeding before leaving the hospital was related to PIM in 1 study.	Effect on duration with Prenatal Interventions: 6 of 8 studies effective (4 of 6 RCTs) with AF ranging from 19-78% for full BF at 6 mo to any BF at 4 wk.Effect on duration with Postnatal Interventions:3 of 9 studies effective (2 of 8 RCTs) with AF ranging from 15-53% for any BF at 2 mo to full BF at 6 mo. Effect on duration with BOTH Pre- and Postnatal Interventions: 7 of 9 studies effective (3 of 4RCTs) with AF ranging from 20-92% for full BF at 4 mo in 2 studies; One study had an AF of 91% for full BF at 5 mo. Effect on duration with both Hospital and Postnatal Interventions: 4of 7 studies effective (3 of 6RCTs) with AF ranging from 24-88% for any BF at 4 mo to exclusive BF at 4 mo. Effect on duration with both Hospital and Pre- and Postnatal Interventions: All 4 studies effective (3 RCTs) with AF ranging from 20- 100% for any BF at 1month to full BF at 6 mo.
EXTERNAL VALIDITY		
Generalisability	y	1

Applicability	y	1
Comments	The majority of the studies reviewed identified IM as PIM. Both of the terms have different definitions.	
Conclusion	PIM is one of the most common and influential reasons for low rates of breastfeeding duration and exclusivity. Future research should be conducted to determine who is at high risk and to further validate screening tools; and whether PIM is a physiological or psychological issue. Perceived milk supply is considered modifiable and well-informed interventions to reduce the incidence of PIM might be a key element for improving rates of successful breastfeeding.	The primary health care units should inform, encourage, and support pregnant women in breastfeeding; the maternity hospitals should allow women to bond with their babies and help them to establish breastfeeding; and the primary health care units should be able to guide, reinforce, and support this practice continuously, completing the cycle. Although there is evidence supporting the effectiveness of primary care strategies in extending breastfeeding duration, there is a need for broad-based, well-designed studies testing the effect of the combination of the procedures referred above, preferably spanning the prenatal and postnatal periods, to encourage the development of evidence-based protocols concerning the promotion, protection, and support of breastfeeding in primary care.

BREASTFEEDING AND ASTHMA AND ATOPY

What are the benefits of breastfeeding (partial and exclusive) and the risks of not breastfeeding (any and exclusive), to infants and mothers, both in the short term and long term?		
Evidence statement		Breastfeeding is associated with a reduced risk of asthma and atopic disease.
Grade		C
Component	**Rating**	**Notes**
Evidence Base	Poor	1 Systematic review of cohort studies (Negative quality) and unclear the number of studies included but had 83 references cited.
Consistency	Good	ALL studies show increased risk of asthma and atopic disease when NOT breastfed.
Clinical impact	Satisfactory	Odds ratios in the range of 1.2 to 1.5 for increased risk of asthma and atopic disease.
Generalisability	Good	Can be contextualised to lactating Australian women and their infants.
Applicability	Good	Applicable to Australia.

The studies included in the body of evidence statement are shown in Table 24.3.

Table 24.3 Summary used to make evidence statements for breastfeeding and asthma and atopic disease

STUDY DETAILS (Review)	**Oddy 2009**
Affiliation/source of funds	
Study design	Systematic Review of Cohort studies
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	Not reported but most paper in the publication range of 1981 to 2002
Number of studies	Not reported specifically, about 4 cohort studies, but 83 references cited. A table is given that specifies the inclusion criteria for assessing quality of the studies. Children had to be followed for at least 5 years.
Total number of participants	>4300
Population characteristics	Infants cohorts, both random population samples and cohorts of infants with a family history of asthma or atopy
Range of exposure	Exposure criteria given: 1. Non-reliance on late maternal recall of breastfeeding; 2. Blind ascertainment of infant feeding history; 3. Sufficient duration of breastfeeding; 4. Sufficient exclusivity of breastfeeding
Length of follow-up	5-17 yrs
Outcome(s) measured	Outcome criteria: 1. Strict diagnostic criteria; 2. Blind ascertainment of outcomes; 3. Consideration of severity of outcome; 4. Consideration of age of onset of outcome
INTERNAL VALIDITY	
Databases included in search	not reported
Statistical analysis methods	Statistics: 1. Control for confounding factors; 2. Assessment of dose-response effects; 3. Assessment of effects in children at high risk of outcome; 4. Adequate statistical power
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	Negative but summarising previously published systematic review and giving a guide to interpretation of the studies
RESULTS	

Outcome	Odds ratios in the range of 1.2 to 1.5 for increased risk of asthma and atopic disease all show increased risk when not breastfed. Authors quote a previously published meta-analysis of 9 studies that showed that children breastfed for at least 3 months were significantly protected against development of asthma, OR= 0.80 and other meta analyses with a similar protective effect (26%-30%) for exclusive breastfeeding during the first 3 months from developing asthma, allergic rhinitis and atopic eczema.
EXTERNAL VALIDITY	
Generalisability	y
Applicability	y
Comments	
Conclusion	From the studies that met the strict criteria for breastfeeding and atopic disease, all demonstrated a protective effect of breast-milk feeding or conversely, a risk of formula feeding. However, the continuing protective effect of breastfeeding on asthma and atopy later in adolescence and adulthood has yet to be confirmed in larger longitudinal studies. Given the many benefits conferred by breast-milk, breastfeeding should continue to be promoted as the preferred infant feeding method for the first 6 months and up to two years, as recommended by WHO.

BREASTFEEDING AND SUDDEN INFANT DEATH SYNDROME

What are the benefits of breastfeeding (partial and exclusive) and the risks of not breastfeeding (any and exclusive), to infants and mothers, both in the short term and long term?		
Evidence statement		Not breastfeeding is associated with an increased risk of Sudden Infant Death Syndrome
Grade		C
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	1 Systematic review (23 studies, 18 case-controls, 4 nested case-controls, 1 cohort) of excellent quality with meta-analysis with low risk of bias showing an increased risk of SIDs with "bottle" feeding
Consistency	Good	19 studies had a protective effect for breastfeeding, 1 had no effect and 3 showed a negative effect. Sensitivity analysis conducted in the meta-analysis and similar ORs for bottle feeding shown for studies rated "good" (10 studies, OR range 0.56 to 5.95) or published in last 10 years
Clinical impact	Excellent	Pooled OR for 23 studies was 2.11 (95%CI: 1.66 - 2.68). For higher quality studies only OR = 2.24 ("good" studies) and 2.32 (studies in last 10 years)
Generalisability	Excellent	Generalisable to Australian women and the review includes Australian data
Applicability	Excellent	Directly applicable to Australia

This body of evidence statement had to be stated as “not breastfeeding…” because breastfeeding could not be demonstrated to be protective, possibly due to confounding, whereas *not* breastfeeding could be shown to increase the risk of sudden infant death syndrome.

The studies included in the body of evidence statement are shown in Table 24.4.

Table 24.4 Studies used to make evidence statements for breastfeeding and sudden infant death syndrome (SIDS)

STUDY DETAILS (Review)	**McVea, K.L.S., P.D. Turner, and D.K. Peppler 2000**
Reference	
Affiliation/source of funds	Olson centre for Women's Health, Nebraska
Study design	Meta analysis of 23 studies (18 case-controls, 4 nested case -controls, 1 cohort)
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	1966-1997
Number of studies	23
Total number of participants	>3100 cases 50 000 controls
Population characteristics	Infant populations from UK, Australia, NZ, Canada, USA, ScandInavia.
Range of exposure	Included studies if a minimal definition of SIDs was met and original data was presented to allow calculation of an OR for bottle feeding.
Length of follow-up	Not applicable
Outcome(s) measured	Inclusive definition of SIDS as any sudden, unexplained death of a young child.
INTERNAL VALIDITY	
Databases included in search	MEDLINE and additional hand searches of the references lists and key papers included in the meta-analysis
Statistical analysis methods	ORs and 95% CIs. Random effects model used in the meta-analysis due to heterogeneity of the studies with a pooled OR. Separate "pooled" OR for 2 groups of studies; those with "excellent" or "good" quality ratings published in last 10 years.
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	P
RESULTS	9 studies rated "good", 10 as "fair" and 4 as "poor". Better studies had higher risk for bottle feeding. OR for studies ranged from 0.56 to 5.95. 19 studies had a protective effect for breastfeeding, 1 had no effect and 3 showed a negative effect. Most of the studies were protective. The pooled OR for 23 studies was 2.11 (95% CI: 1.66 - 2.68). For higher quality studies only OR = 2.24 ("good" studies) and 2.32 (studies in last 10 years). 9 studies included data on partial breastfeeding and 7 had enough data to estimate SIDs risk; 4

	showed a dose response for increasing use of formula feeding but none had sufficient power to demonstrate statistically significant difference for partial versus no breastfeeding.
Outcome	Death from SIDS
EXTERNAL VALIDITY	
Generalisability	Yes
Applicability	Yes
Comments	Data includes Australian studies. The meta-analysis suggested breastfeeding conveys a 50% reduced risk of SIDs
Conclusion	Breastfeeding should be strongly encouraged, independent of SIDs and the evidence for SIDs protection is imperfect due to confounding.

26 OPTIMISING BREASTFEEDING OUTCOMES (U1.7)

What nutritional factors are important in optimizing breastfeeding outcomes?

Search results

The initial search of the data bases included 555 references for *U1.7 What nutritional factors are important in optimizing breastfeeding outcomes?* and the specified disease outcomes with 40 duplicates. The detailed search is included in a separate document on searches. In all 87 references concerning nutritional factors and breastfeeding outcomes were retrieved, 18 had data extracted and 12 systematic reviews were used to form the body of evidence statements. Sufficient evidence was found to make Body of Evidence statements for nutritional factors relating to alcohol, selenium, support for breastfeeding and maternal perceived milk supply in relation to breastfeeding outcomes for mothers and infants, as detailed below. There were no recent good quality reviews of nutrients and breastfeeding, except for alcohol and selenium.

There were two systematic reviews on n-3 long chain polyunsaturated fatty acid (LCPUFA) supplementation and infant outcomes, but they reviewed those same RCTs [103] and [189]. Therefore no body of evidence statement was made. Collectively, these reviews suggest that there is no evidence supporting a beneficial effect in term infants on visual development as measured by electrophysiological tests, with supplementation of LCPUFAs. There is also suggestive, but inconclusive, evidence for a beneficial effect of maternal and supplementation during pregnancy and lactation on infant mental development and longer term cognition, but the evidence is inconclusive beyond age two years.

The majority of studies were excluded because they were not reviews. The abstract of non-systematic reviews that were recent have been included at the end of this section.

ALCOHOL, CAFFEINE AND BREASTFEEDING OUTCOMES

What nutritional factors are important in optimizing breastfeeding outcomes?		
Evidence statement		Consumption of alcohol by lactating women in the range of 0.3-0.8g/ kg body weight is associated with increased risk of adverse infant outcomes.
Grade		B
Component	**Rating**	**Notes**
Evidence Base	Good	2 Systematic reviews; 1 (P) had 24 studies, with 14 in humans (6 level III-1, 2 level III-2, 2 level II, 4 level IV, 10 level V (all animal) and 1 (N)) the number was not reported but had 33 references cited.
Consistency	Excellent	Decreased lactational performance with increasing alcohol consumption.
Clinical impact	Good	Maternal alcohol doses associated with adverse infant outcomes (development, feeding, sleeping) varied from 0.3g/kg to 0.8g/kg. Lactational performance reduced from maternal intakes of 0.5-1g/kg body weight.
Generalisability	Good	Human studies can be contextualised to lactating Australian women and their infants.
Applicability	Satisfactory	Only human data has been considered, but there is limited data in humans compared to the studies done in animal, mostly rats.

The studies included in the body of evidence statement are shown in Table 26.1.

There were two systematic reviews that examined alcohol and breastfeeding outcomes. The positive quality review by Giglia & Binns 2006 is a comprehensive review of both human and animal studies and covers the literature on the effect of alcohol on breastfeeding physiology, lactogenesis and milk "let down", in detail. It addresses three questions in particular; the effect of alcohol on lactogenesis; the effect of maternal blood alcohol on breast milk and infant blood alcohol and the effect of breast milk alcohol on the infant. Evidence tables are provided to summarise studies for; 1) The effect of alcohol on the mother (1 review, 2 level II, 4 level III-1, 1 level III-2, 2 level IV studies); 2) The effect of alcohol on the infant (5 level III-1, 1 level III-2, 1 level IV). The authors also synthesise advice for lactating women based on their evidence synthesis. This was that breastfeeding women should:-

1. Not consume alcohol in the first month of the infant life
2. After that, limit alcohol to 1-2 standard drink per day, consumed after breastfeeding
3. For occasions where more will be consumed then consider the option of expressing milk in advance and skipping one feed.

The second review by Haber & Allnutt. 2005 was of negative quality and covered both alcohol and caffeine. This paper draws on similar literature but also encompasses studies on caffeine intake. There were only limited human studies on caffeine and not enough data to make a Body of Evidence Statement. Data was not extracted into summary tables within this review and it was only provided in a narrative style. While the authors' state their intention to provide guidance to lactating women on appropriate consumption of alcohol and caffeine, their statement are not explicit and there is not a clear link to their evidence synthesis.

Table 26.1 Summary of studies to make evidence statements for alcohol, caffeine and breastfeeding outcomes

STUDY DETAILS (Review)	Giglia & Binns 2006	Haber et al. 2005
Affiliation/source of funds	Curtin University of Technology Australia, National Health and Medical Research Council	Royal Hospital for Women, Australian Catholic University Sydney
Study design	Systematic Review	Systematic Review
Level of evidence	III-1 Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method).	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	1990-2005	1966-2004
Number of studies	24 (14 human & 10 rat studies)	Not reported but 33 references cited
Total number of participants	NS	NS
Population characteristics	Lactating human and rat mothers, age not reported	Lactating mothers; no other details provided
Range of exposure	Maternal alcohol intake of <0.5 - >2 g / kg body weight (human studies only)	Not always reported but ranges from 1-3 standard drinks of wine (120 mL = I standard) to as much alcohol as the mothers could manage; whereas for caffeine ranges are from 36 to 750 mg
Length of follow-up	NS	NS
Outcome(s) measured	Time taken for alcohol to reach human milk, effect of alcohol intake on milk ejection reflex, infant milk and alcohol consumption, oxytocin and prolactin levels, milk yield, breastfeeding initiation and duration, infant motor development	Alcohol Studies: 1. Alcohol content of breast milk; 2. Transfer of alcohol in breast milk; 3. Alcohol infrared absorption and electrochemical reaction; 4. Oxytocin response; 5. Breast milk production and consumption; 6. Infant feeding pattern; 7. Infant motor development; 8. Infants sleep-wake patterns; 9. Breast milk flavour Caffeine Studies: 1. Excretion of caffeine in breast milk; 2. Iron concentrations in milk and infant iron status at 1 month of age; 3. Breast milk composition
INTERNAL VALIDITY		
Databases included in search	PubMed, Cinahl, Proquest, Science Direct, Web of Knowledge	Cinahl, Medline, Cochrane, Psychinfo, ProQuest, University of Technology Health Source database
Statistical analysis methods	Varies by study; not indicated for majority of studies	NS

Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	P	N
RESULTS		
Outcome		No tables provided
EXTERNAL VALIDITY		
Generalisability	y	y
Applicability	n	n
Comments		The authors did not state any quantitative results for all studies including p value or confidence intervals
Conclusion	Alcohol intake by lactating mothers in amounts recommended as 'safe' for nonlactating women may have a negative effect on infant development and behaviour. Clear guidelines for alcohol consumption are required for lactating women and health professionals to guide breastfeeding mothers to make educated choices regarding alcohol intake during this critical period of infant development.	The research reviewed in this paper suggests that maternal consumption of alcohol and caffeine prior to breastfeeding can have a detrimental effect on breastfed infants. The degree of risk seems to vary according to the drug in question. The negative effects of caffeine and alcohol for example when taken in moderation do not necessarily outweigh the benefits of breastfeeding to the infants. A cup of coffee or a glass of wine should cause no problem, especially if taken according to recommendations.

SELENIUM AND BREASTFEEDING OUTCOMES

What nutritional factors are important in optimizing breastfeeding outcomes?		
Evidence statement		Breast-feeding is associated with higher infant selenium status compared to formula-feeding.
Grade		C
Component	**Rating**	**Notes**
Evidence Base	Satisfactory	1 Systematic review (O) with >190 references covering all aspects of selenium (Se) nutrition in relation to breast milk and maternal factors impacting on this.
Consistency	Good	Internationally, there is a wide range of breast-milk Se concentrations, dependent on Se consumed in natural foods which is impacted by the Se content of the soils where foods are grown. Despite wide variation in median Se breast milk concentration worldwide and that infants commonly do not achieve recommendations, Se status is greater in breast-fed than in formula-fed infants.
Clinical impact	Satisfactory	The Australian studies (1983-1997) reporting breast milk Se concentrations, indicate they are comparable to the median concentrations reported internationally. Maternal Se status and most dietary intakes appear not sufficient to optimise breastfed infant's Se status, but are still associated with higher Se status compared to formula-fed infants.
Generalisability	Excellent	Breast milk Se concentrations are generalisable to Australian women and the review includes Australian data.
Applicability	Excellent	Directly applicable to Australia. Australian soil Se concentrations will vary by region and therefore Se intake and breast milk concentration.

The study included in the body of evidence statement is shown in Table 26.2.

This is a major review that discusses selenium (Se) nutrition during breast-feeding, including environmental and maternal constitutional factors that affect breast-milk-Se metabolism and secretion. Papers in this review were located via a literature search of Medline and Web of Science on Se and breast milk. The following headings are covered; Selenium species in breast milk; Maternal constitutional factors; Environmental factors; Selenium prophylaxis and breast-feeding; Selenium interactions and breast-feeding; Excess selenium in breast milk; Breast-feeding and the infant's selenium status.

The median Se concentration from studies worldwide are 26, 18, 15 and 17 ug/L in colostrum (0-5 days), transitional milk (6-21 days), mature milk (1-3 months) and late lactation (>5 months) respectively. Se recommendations are not achieved by approx. 30% of the reported breast milk Se Concentrations but Se status in breast-fed infants is greater than formula-fed infants. For reported Se breast milk concentrations in Australia the Se concentrations for fore and hind milk (10.8-13.9 ug/L) were comparable to mature milk (15ug/L).

Table 26.2 Summary of studies used to make evidence statements for selenium and breastfeeding outcomes

STUDY DETAILS (Review)	**Dorea 2002**
Affiliation/source of funds	University of Brazil
Study design	Systematic review
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	NS
Number of studies	not reported but > 190 references
Total number of participants	NS
Population characteristics	NS; Lactating women from > 10 countries (developed and developing)
Range of exposure	Not relevant but a Table of Se concentrations in breast milk given from 16 studies by stage of lactation. Table also given for Se concentration for fore- and hind-milk.
Length of follow-up	
Outcome(s) measured	Selenium concentration in breast milk including fore and hind milk
INTERNAL VALIDITY	
Databases included in search	Medline and Web of Science
Statistical analysis methods	
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	O
RESULTS	
Outcome	Tables given for: Se concentration in breast milk and maternal plasma or serum concentrations (Table 26.3); Summary of studies comparing mean selenium concentrations in breast milk of term and preterm mothers (Table 26.4); Summary of mean breast-milk selenium concentrations in studies comparing countries or regions in the same country (Table 26.5); Summary of studies comparing breast-milk selenium concentrations in relation to natural-food selenium intake and dietary habits (Table 26.6); Summary of studies

	comparing breast-milk selenium concentrations and maternal dietary intake of selenium in natural foods (Table 26.7); Summary of breast-milk selenium concentrations compared with selenium prophylaxis studies (Table 26.8). Summary of studies that measured breast-milk selenium concentrations in breast milk from different parts of the world (Table 26.9). Australian data is reported in Tables 26.2, 26.3, 26.4 and 26.5. The median Se concentration from studies worldwide are 26, 18, 15 and 17 ug/L in colostrum (0-5d), transitional milk (6-21d), mature milk (1-3months) and late lactation (>5 months) respectively. Se recommendations are not achieved by approx. 30% of the reported breast milk Se Concentrations but Se status in breast-fed infants is greater than formula-fed infants. For reported Se breast milk concentrations in Australia the Se concentrations for fore and hind milk (10.8-13.9) were comparable to mature milk (15ug/L).
EXTERNAL VALIDITY	
Generalisability	y
Applicability	y
Comments	
Conclusion	Maternal Se status reflects Se intake and modulates Se concentrations in human milk. Se bioavailability in natural foods (organic) or maternal supplements (organic and inorganic) has an important impact on breast-milk Se compounds. As a consequence, total Se in breast milk shows a wide variation, reflecting the content of natural foods grown in different soils. Se prophylaxis is effective in raising maternal Se status and increasing both breast-milk Se and milk GPX activity. The mammary gland secretes Se quite effectively as Se-containing amino acids in milk proteins and this chemical form protects the infant from excessive maternal Se. Current estimates of Se intakes of adults place most diets as sub-optimal in meeting daily Se requirements. Although maternal Se status under most diets may not be sufficient to provide optimal serum Se concentrations and full expression of GPX activity, breast-fed infants consistently show higher Se status than formula-fed infants.

FACTORS ASSOCIATED WITH ENHANCED BREASTFEEDING SUCCESS AND DURATION

What factors are important in optimizing breastfeeding outcomes?		
Evidence statement		Pre-natal and Perinatal support for breastfeeding can increase the proportion of women breastfeeding (both exclusive and non-exclusive) up to age 6 months.
Grade		A
Evidence statement		Breastfeeding support (any type) increases duration of both exclusive and non-exclusive breastfeeding both in the immediate post-natal period and at 6 months of age.
Grade		B
Evidence statement		Maternal perceived insufficient milk (PIM) supply is associated with increased risk of early cessation of lactation.
Grade		C
Component	**Rating**	**Notes**
Evidence Base	Excellent	8 Systematic reviews [3 are Cochrane; 3 with meta analysis (5P, 1O, 2N)]; 5 protective effect on breastfeeding success, 1 had no results and 1 found maternal perceived insufficient milk supply increased risk of lactation failure.
Consistency	Good	Definitions of breastfeeding (exclusive, partial, any) vary across studies. Consistent for support prolonging breastfeeding. Some of the same studies covered by the reviews
Clinical impact	Good	For provision of support, the RR for ceasing breastfeeding was approx.0.65 to 0.9. When expressed as odds ratios for continued breastfeeding the ORs for support ranged from 1.9 to 5.2.
Generalisability	Excellent	Breastfeeding definitions and rates are applicable to Australian women
Applicability	Good	While some reviews include studies conducted in developing countries, only those applicable to developed countries have been applied in developing the BOEs

The studies included in the body of evidence statement are shown in Table 26.3.

Table 26.3 Summary used to make evidence statement for breastfeeding and maternal and infant outcome

STUDY DETAILS (Review)	Szajewska et al. 2006	Kramer et al. 2002	Bhutta et al. 2008
Affiliation/source of funds	Medical University of Warsaw, Dr. von Hauner Children's Hospital, Ludwig-Maximilians-University of Munich	McGill University, WHO Expert Committee on the optimal duration of exclusive breastfeeding	Aga Khan University Bangladesh, Centre for Health and Population Research, Johns Hopkins Bloomberg School of Public Health USA, London School of Hygiene and Tropical Medicine, University of California, Federal University of Rio Grande de Sur Brazil, Sitaram Bhartia Institute of Science and Research India, World Bank Washington, Save the Children UK, Emergency Nutrition Network, International Food Policy Research Institute, Food for Education Programmes, Global Alliance against malnutrition, Bill and Melinda Gates Foundation, UNICEF Innocenti Research Centre
Study design	Systematic Review	Meta Analysis	Systematic Review
Level of evidence	III-1 Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method).	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Date of search	1966-2004	Prior to 1966 - 2000	NS
Number of studies	1	22 (11 from developing and 11 from developed countries)	34
Total number of participants	170 infants (experimental group = 83; control group = 87)	9998	NS
Population characteristics	OI	Lactating mothers and their healthy, term, singleton infants from developed and developing countries	Breastfed and non breastfed infants from developing countries
Range of exposure	Experimental group received 5%	To assess the effects of exclusive	Effect of promotion strategies on exclusive

	glucose water from bottle, after breastfeeds, during the first 3 days of life	breastfeeding (EBF) for 6 or more vs. 3-4 months with continued mixed breastfeeding (MBF) until at least 6 months	breastfeeding rates for infants younger than 6 months and on continued breastfeeding up to 12 months
Length of follow-up	4 months	NS	0-6 months
Outcome(s) measured	Proportion of exclusively breastfed infants between birth and 6 months, the proportion of infants receiving any breast milk at fixed time points between birth and 6 months, the proportion of infants still being breastfed at the end of their first yr of life, breastfeeding duration, proportion of infants receiving infant formula between birth and 6 months	All infant and maternal health outcomes; infant outcomes especially growth (weight, length, head circumference, z scores, weight-for-age, length-for-age, weight for age, infections, morbidity, mortality, micronutrient status, neuromotor and cognitive development, asthma, atopic eczema, other allergic diseases, type 1 diabetes, blood pressure, adult chronic diseases. Maternal outcomes especially postpartum weight loss, duration of lactational amennorrhea, chronic diseases (osteoporosis, breast and ovarian cancer)	Mortality, breastfeeding duration, breastfeeding pattern (exclusive, partial, predominant)
INTERNAL VALIDITY			
Databases included in search	Medline, Embase, Cinahl, Cochrane	Medline, Oldmedline, Cinahl, EBM Reviews -Best Evidence, Sociofile, Cochrane, CAB Abstracts, EMBASE Psychology, EconLit, IMEMR, AIM, LILACS, Healthstar	Cochrane Library, ExtraMed, WHO Reproductive Health Library
Statistical analysis methods	Intention to treat analysis, p value	Controlled clinical trials: Adequacy of randomization and concealment, losses to follow up analysis, measurement of outcome, 5 point Jadad scale Observational studies were assessed for control for confounding, losses to follow up, and assessment of outcomes as follows: for growth and morbidity outcomes, losses to follow up,	Multiplicative model, mortality RR, stunting OR

		assessment of outcome. All studies were stratified according to study design (controlled trials vs. observational), provenance (developed vs. developing), timing of feeding comparison (3 to 7 months vs. prolonged (> 6 months)).	
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)	P	P	O
RESULTS			
Outcome		Indicators of child health (GIT infection, development of asthma, allergies, iron status), growth and development, and on maternal health (resumption of menses, postpartum weight loss).Comparison one: controlled trials of exclusive vs. mixed breastfeeding for 4-6 months, developing countries and Comparison two: observational studies of exclusive versus mixed breastfeeding for 3-7 months, developing countries and Comparison three: observational studies of prolonged (more than 6 months) exclusive versus mixed breastfeeding, developing countries are not relevant to Australia. Comparison 4 is relevant to the Australian population: Observational studies of exclusive versus mixed breastfeeding for 3-7 months in developed countries. Studies were heterogeneous with a WMD of -12.45 (95% CI -23.46 - -1.44) g per month & should be interpreted with caution,	Beginning breastfeeding within the first days after birth lowers mortality even in exclusively breastfed infants. One review showed that all forms of extra support increased the duration of 'any breastfeeding' with the RR for stopping any breastfeeding before 6 months being 0.91 (95% CI 0.86-0.96). All forms of support affected the duration of exclusive breastfeeding more strongly than the likelihood of any breastfeeding RR 0.81 (CI 0.74-0.89). Lay and professional support extended breastfeeding duration RR before 4-6 weeks 0.65 (CI 0.51-0.82); RR before 2 months 0.74 (CI 0.66-0.83). Further reviews reported that with individual counselling the OR of exclusive breastfeeding were increased in the neonatal period (15 studies; OR 3.45 (95% CI 2.2-5.42) p<0.0001; random effects) and at 6 months of age (9 studies; OR 1.93 (95% CI 1.18-3.15), p<0.0001). Group counselling increased odds of exclusive breastfeeding in the neonatal period (6 studies; OR 3.88 (95%

		although even the lower 95% confidence limit is compatible with a lower weight gain in the EBF group. Given the large weight gains in both groups in the Belarussian study, the higher gain in the MBF group is not necessarily a beneficial outcome. Heinig 1993 and Kramer 2000a also reported on weight gain between six and nine months (outcome two) (significant heterogeneity), (P = .04) and dominated by the larger size of the Belarussian study. The pooled WMD was -2.26 (95% CI -16.94- 12.42) g per month. Akeson 1996a, Heinig 1993, and Kramer 2000a reported on weight gain from 8-12 months (outcome three); the WMD was -1.82 (95% CI -16.72-13.08) g per month, which excludes a reduced length gain in the EBF group of 5% of the mean and 10% of the SD for the Belarussian study. For length gain at three to eight months (outcome four), the studies again show significant (P < .01) heterogeneity. Kramer 2000a found a slightly but significantly lower length gain in the EBF group at four to eight months (difference -1.1 (95% CI -1.7- - 0.5) mm per month), whereas the pooled analysis yielded a WMD of - 0.4 (95% CI -0.7 - 0.0) mm per month; the lower confidence limit is statistically compatible with a reduced length gain of less than 4% of the mean	CI2.09-7.22) p<0.0001; random effects) and at 6 months (5 studies; OR 5.19 (95% CI 1.9-14.15) p<0.00001; random effects). A study on a national mass media campaign in Honduras reported that it increased exclusive breastfeeding from 48-70% at 1 month, from 24-31% at 4 months, from 7-12% at 6 months. The WHO growth reference study showed that infants exclusively breastfed were on average 360 g and 100g heavier at 4 and 6 months then predominantly non breastfed children on whom the US NCHS growth curves were based. Exclusive breastfeeding reduced HIV transmission compared with partial was reported in 1 study and a further study showed that HIV-free survival did not differ in infants who were HIV-negative at 4 months and were abruptly weaned or continued to be breastfed. Authors created a cohort model of child mortality and stunting by modelling the survival and linear growth status of the annual birth cohort of children from birth until 3 years in 36 countries with 90% of the global burden of stunted children. In children aged 6-23 months the baseline breastfeeding category is breastfed (RR 1.0) vs. non breastfed (RR 2.3). Using this model, authors reported that mortality risk ratio for exclusive breastfeeding (age <1 month) was 1.0 and 1.48 for predominant breastfeeding, 2.85 for partial breastfeeding and 14.4 for no breastfeeding. In the same model for ages 6-35.9 months, the mortality risk ratio for predominant breastfeeding was 1.0 and 2.3

		and 10% of the SD for the Belarussian study. Heinig 1993 and Kramer 2000a also reported on length gain at 6-9 months (WMD -0.4 (95% CI -1.0 - 0.1) mm per month) (outcome five). For the 8-12 month period, the results show a slightly but significantly higher length gain in the EBF group (WMD 0.9 (95% CI 0.3-1.4)) mm per month (outcome six). Observational analyses from the Belarussian study (Kramer 2000a) also include data on weight-for-age, length-for-age, and weight for-length z-scores at 6, 9, and 12 months. Means in both the EBF and MBF groups were well above (+0.5 to +0.6) the reference values at all three ages. Nonetheless, the weight-for-age z-score was slightly but significantly lower in the EBF group at all three ages: WMD -0.09 (95% CI -0.16 - -0.02) at six months, -0.10 (95% CI -0.18 - -0.02) at 9 months, and -0.09 (95% CI -0.17 to-0.01) at 12 months (outcomes seven to nine). Length-for-age z scores were very close to the reference (0) at 6 and 9 months and slightly above the reference (0.15) at 12 months. Again, the EBF group had slightly but significantly (except at 12 months) lower values: WMD -0.12 (95% CI -0.20 - -0.04) at 6 months,-0.14 (95% CI -0.22 to -0.06) at 9 months, and -0.02 (95% CI-0.10 - 0.06) at 12 months (outcomes 10 to 12). Mean weight for-length z-scores were high and rose (from	for no breastfeeding. Authors also reported on the effect of nutrition-related interventions on mortality and stunting in 36 countries. 99% coverage with breastfeeding promotion and support resulted in 11.6, 9.9 & 9.1% in proportional reduction in deaths before 12, 24 and 36 months respectively. The % of DALYs averted at 36 months was 21.9 million for 99% coverage with breastfeeding promotion and support.

		about 0.65 to 0.80) from 6 to 12 months, with no significant differences between the EBF and MBF groups at any age: WMD 0.02 (95% CI -0.07- 0.11) at six months, 0.03 (95% CI -0.06 - 0.12) at 9 months, and -0.08 (95% CI -0.17- 0.01) at 12 months (outcomes 13 to 15). The prevalence of low (less than -2) z-scores did not differ significantly in the two Belarussian feeding groups for any of the three z scores at any of the three ages, although the small number of infants with low z-scores provided low statistical power to detect such differences. RRs (and 95% CIs) for low weight-for-age were 0.92 (0.04 -19.04) at 6 months, 1.52 (0.16-14.62) at 9 months and 1.15 (0.13-10.31) at 12 months (outcomes 16 to18). For length-for-age, the corresponding figures were 1.53 (0.84-2.78) at six months, 1.46 (0.80-2.64) at 9 months, and 0.66 (0.23-1.87) at 12months (outcomes 19 to 21). For weight for- length, the figures were 0.31 (0.02- 5.34) at 6 months, 1.14 (0.24- 5.37) at 9 months, and 1.15 (0.13-10.31) at 12 months (outcomes 22 to 24). The Belarussian study also provided data on head circumference. No significant differences were observed at six months (difference -1.0 (95% CI -2.3 - 0.3) mm) (outcome 25) or 9 months (+0.7 (95% CI -0.6 to +2.0) mm) (outcome 26), but the EBF group had a slightly but significantly larger	

		circumference at 12 months (outcome 27): difference = +1.9 (95% CI 0.6 - 3.2) mm. Heinig 1993 reported nearly identical sleeping time (729 versus 728 minutes per day) in the two groups (outcome 28). Akeson 1996a reported similar total amino acid and essential amino acid concentrations at 6 months of age in the two feeding groups (outcomes 29 and 30). Both Kramer 2000a and a cohort study from Finland (Kajosaari 1983) reported an atopic eczema at one year (outcome 31). The two studies showed statistically significant (P= .03) heterogeneity, with Kajosaari 1983 reporting a significantly reduced risk (RR 0.40; 95% CI 0.21-0.78), but the larger Belarussian study finding a much lower absolute risk in both feeding groups and no risk reduction with EBF RR 1.00 (95% CI 0.60-1.69). Although Kajosaari 1983 also reported a reduced risk of a history of food allergy (outcome 32), double food challenges showed no significant risk reduction RR 0.77 (95% CI 0.25-.41) (outcome 33).Neither Oddy 1999 nor Kramer 2000a found a significant reduction in risk of recurrent (two or more episodes) wheezing in the EBF group pooled RR 0.79 (95% CI 0.49 -1.28) (outcome 34). In the Kajosaari 1983 study, the reduction in risk of any atopy at five years (outcome 35) in the EBF group	

		was nonsignificant RR 0.68 (95% CI 0.40 -1.17), and no reduction in risk was observed for atopic eczema RR 0.97 (95% CI 0.50 -1.89) (outcome 36). A reduction in risk of borderline significance was observed for pollen allergy at five years RR 0.53 (95% CI 0.28- 1.01) (outcome 37). Both Kajosaari 1983 and Oddy 1999 reported on risk of asthma at 5-6 years (outcome 38); the pooled RR was 0.91 (95% CI 0.61-1.36). Reduced risks of history of food allergy RR 0.61 (95% CI 0.12-3.19) (outcome 39) and allergy to animal dander RR 0.81 (95% CI 0.24 - 2.72) at five years (outcome 40) were far from achieving statistical significance. Oddy 1999 found no reduction in risk of a positive skin prick test at 6 years in the EBF group RR 0.99 (95% CI 0.73- 1.35) (outcome 41). A small Italian study of hematologic outcomes at 12 months by Pisacane in 1995 reported a statistically significantly higher hemoglobin concentration (117 versus 109 g/L (95% CI for the difference = 4.03- 11.97 g/L)) (outcome 42), a nonsignificant reduction in anemia (hemoglobin < 110 g/L) RR 0.12 (95% CI 0.01-1.80) (outcome 43), a nonsignificant higher ferritin concentration WMD+4.7 (95% CI -6.3 - 15.7mcg/L) (outcome 44), and a nonsignificant reduction in the risk of low (less than 10 mcg/L) ferritin concentration RR 0.42 (95% CI 0.12 -	

		1.54) (outcome 45) among infants in the EBF group. Of note in this study is that the exclusive and mixed breastfeeding continued in both groups until at least 12 months (a criterion for selection into the Pisacane 1995 study).Kramer 2000a recorded only one and two deaths (outcome 46) among the 621 and 2862 Belarussian infants in the EBF and MBF groups, respectively RR 2.30 (95% CI 0.21-25.37). The EBF had a significantly reduced risk of one or more episodes of gastrointestinal infection in the first 12 months of life (RR 0.67 (95% CI 0.46- 0.97) (outcome 47), which was maintained in a multivariate mixed model controlling for geographic origin, urban versus rural location, maternal education, and number of siblings in the household (adjusted OR 0.61 (95% CI 0.41 - 0.93).No significant reduction in risk was observed for hospitalization for gastrointestinal infection, however RR 0.79 (95% CI 0.42-1.49) (outcome 48). In the above-mentioned Australian cohort study, Oddy 1999 found no significant reduction of risk for one or more episodes of upper respiratory tract infection (outcome49) in the EBF group RR 1.07 (95% CI 0.96-1.20). Neither Oddy 1999 nor Kramer 2000a found a significantly reduced risk of two or more such episodes pooled RR 0.91 (95% CI 0.82 -1.02) (outcome 50). Nor did Oddy	

		1999 find a significant reduction in risk of 4 or more episodes of upper respiratory infection RR 0.82 (95% CI 0.52 - 1.29) (outcome 51) or of one or more episodes of lower respiratory tract infection RR 1.07 (95%CI 0.86-1.33) (outcome 52). Kramer 2000a found a small and nonsignificant reduction in risk of two or more respiratory tract infections (upper and lower combined) RR 0.90 (95%CI 0.79 -1.03) (outcome 53). The combined crude results of Oddy 1999and Kramer 2000a show a substantial and statistically significant reduction in risk for hospitalization for respiratory tract infection pooled RR 0.75 (95% CI 0.60-0.94), but the crude risk reduction in Kramer 2000a was nearly abolished and became statistically nonsignificant in a multivariate mixed model controlling for geographic region, urban versus rural location, maternal education and cigarette smoking, and number of siblings in the household adjusted OR 0.96 (95% CI 0.71- 1.30) (outcome 54).In a study from Tucson, Arizona, (Duncan 1993) reported no difference in the average number of episodes of acute otitis median the first 12 months of life (outcome 55) in the exclusive versus MBF groups (1.48 vs. 1.52 episodes, respectively) (95%CI for the difference -0.49 -0.41 episodes). Duncan 1993 and Kramer2000a both found a slightly elevated risk for one or	

		more episodes of otitis media pooled RR 1.28 (95% CI 1.04 -1.57) (outcome56), but Duncan 1993 found a nonsignificant reduction in risk for frequent titis media RR 0.81 (95% CI 0.43-1.52) (outcome57).	
EXTERNAL VALIDITY			
Generalisability	Y	Y - for the results of the studies conducted in developed countries	N
Applicability	Y	Y	Y
Comments	The unclear randomization and allocation concealment processes in the study suggest selection bias was possible. Furthermore the use of a telephone interview further suggests recall/reporting bias	Definitions of exclusive breastfeeding varied across studies	In the cohort model of child mortality and stunting, the protective effect of breastfeeding is assumed to cease when the child reaches 2. Although authors have considered a number of breastfeeding interventions and reviews, details of these interventions and reviews are not provided.

Table 26.3 Summary used to make evidence statement for breastfeeding and maternal and infant outcome (cont.)

STUDY DETAILS (Review)	**Britton et al. 2007**	**Abdulwadud et al. 2007**	**Baird et al. 2009**	**Gatti. 2008**	**Ines Couto de Oliveira et al. 2001**
Affiliation/source of funds	University of York, UK	ASEBE TEFERI, Ethiopia; IMPART; BC Centre of Excellence for Women's Health, Canada	University of Southampton, South Hampton General Hospital UK, Medical Research Council	Centre for Health Disparities Research, University of Pennsylvania, National Institute of Health Institutional Training Grant	Brazilian Government Agency CAPES.

Study design	Meta Analysis	Meta Analysis	Systematic Review of (3 systematic reviews)	Systematic review (15 prospective, longitudinal; 3 cross sectional, 3 secondary analysis of datasets)	Systematic review (33 experimental & 31 quasi-experimental studies)
Level of evidence	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.	111-211	III-1 Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method).	III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.	I
Date of search	1966-2005	1951 - 2006	1966-2008	1996-2007	1980-1999
Number of studies	34	0 trials have evaluated this	3	20	64
Total number of participants	29385 mother - infant pairs	N/A	NS	36700	>3700
Population characteristics	Pregnant women intending to breastfeed, postpartum women intending to breastfed and women breastfeeding their babies; Canada, USA, UK, Brazil, Bangladesh, Australia, India, Nigeria, Italy, Iran, Netherlands, Belarus, Mexico, Sweden	NA	Breastfeeding mothers or pregnant women intending to breastfeed from disadvantaged backgrounds (in developed countries),	Healthy, full term breastfeeding dyads during the first 6 months of life	Pre-natal, and post-natal women

Range of exposure	Intervention: Pregnant or lactating women intending to breastfeed receiving contact with an individual or individuals (professional or volunteer) offering support which is supplementary to standard care with the purpose of facilitating continued breastfeeding Comparator: Mothers receiving usual postnatal care which varies between and within countries	Intervention: Any type of workplace strategy to encourage, assist and support breastfeeding for women returning to work after birth Comparator: Women receiving usual care	Intervention: Reviews on interventions promoting and prolonging breastfeeding and providing support for mother who are breastfeeding. Interventions include breastfeeding literature, lay support, professional support, peer support and 1 on 1 counselling	Examine reasons why women had low rates of duration and exclusivity of breastfeeding &/or associations between perceived milk supply and other maternal perceptions. 4 of the studies examined tools to predict insufficient milk supply. This was done through validated questionnaires, tools, Theory of planned behaviour, standard definitions, non validated tools, open ended questions, H & H Lactation Scale, The Perceived Insufficient Milk (PIM) Tool	Primary care interventions designed to extend breastfeeding duration (exclusive, full, or any kind of breastfeeding) during the prenatal and/or postnatal period interventions that took place during the delivery period only were excluded.
Length of follow-up	Up to 9 months post partum	NA	NS	1 month to 24 months	Range from 2 to 12 months but most to 6 months.
Outcome(s) measured	Primary: 1. Effect of the interventions on duration of any breastfeeding to specified points in time; 2. Stopping feeding before 4 to 6 weeks and 2, 3, 4, 6, 9 and 12 months. Secondary: 1. Exclusive breastfeeding; 2. Measures of neonatal and infant morbidity; 3. Measures of maternal	Primary: 1. Rate, duration and prevalence of exclusive breastfeeding. Secondary: 1. Employer-related; 2. Mother-related; 3. Infant-level outcomes	Breastfeeding initiation, breastfeeding duration	Breastfeeding levels, reasons for ceasing breastfeeding, supplementation and breastfeeding level, breastfeeding difficulties, breastfeeding self efficacy, breastfeeding satisfaction, prediction of breastfeeding at 12 weeks, breastfeeding support, perceptions of	Extension of breastfeeding (full, partial or any kind of breastfeeding) at points in time varying from 4 weeks to 6 months. Main outcome measure was the proportion of mothers breastfeeding at, or until, a specified time point. Some studies reported median or mean breastfeeding duration.

	satisfaction with care or feeding method			milk supply, coping strategies of PIM, risk factors for early cessation.	
INTERNAL VALIDITY					
Databases included in search	Cochrane Pregnancy and Childbirth Group's Trials Register, Medline, Embase, MIDIRS	Cochrane Pregnancy and Childbirth Group's Trials Register, Central, Medline, Cinahl, Lilacs, C2-Spectr	Cochrane, Database of Abstracts of Reviews of Effectiveness, Health Technology Database, Medline	Cinahl, Medline, Pubmed	Literature search used an earlier systematic infant-feeding review that focused on the developed world as the starting point. Additional databases searched (Medline, Popline, Health- Star, CAB-Health, Cochrane Library, CINAHL, and Lilacs) using the key words promotion, intervention, assessment, programme, community, education, effect, impact, and evaluation (linked to breastfeeding).
Statistical analysis methods	RevMan 2003; Relative risks; random effects model; subgroup analyses	Intended to use RevMan 2003, fixed effect meta analysis, random effects model	RR	Factor analysis, regression, survival analysis	Present the interventions' maximum duration of effect that proved was statistically significant at a 90% level. The effects presented are the percentage of exclusive breast-feeding among intervention and control groups, and corresponding P value. The attributable

					fraction and 95% confidence intervals were constructed when data presented by the authors were conclusive or suggestive of effect. The attributable fraction (AF) was defined as the proportion of the outcome rate achieved in the intervention group that is due to the intervention, and is a measure of effectiveness. It is the difference between breastfeeding rates in the intervention (I) and control groups, expressed as a proportion of the rate in the intervention group: AF = (I - C)/I. or from the relative risk (RR). ; AF = (RR – 1)/RR.
Overall quality assessment (Positive/Negative or Neutral) plus descriptive)					P
RESULTS					
Outcome	There is a beneficial effect on the duration of any breastfeeding up to 6 months with the	No randomised controlled trials or quasi-randomised controlled trials were	Interventions that use education and 1 on 1 support are effective in increasing	Many women were found to discontinue breastfeeding during the first few weeks post	Effect on duration with Prenatal Interventions: 6 of 8 studies effective (4 / 6 RCTs) with AF ranging

	implementation of any form of extra support RR 0.91 (95% CI 0.86- 0.96). Authors divided trials into 3 categories - high (> 80%), intermediate (60-80%) or low (<40%) initiation rates in the local area. Analysis of the trials conducted in settings with immediate initiation demonstrated all forms of support had a significant benefit on breastfeeding RR 0.92 (95% CI 0.85- 0.98), whereas there was no significant effect where there were high or low breastfeeding initiation rates RR 0.91 (95% CI 0.81 -1.01) and RR 0.88 (95% CI 0.69- 1.12). The effect of any support on mothers exclusively breastfeeding is greater than on women continuing any form of breastfeeding RR 0.81 (95% CI 0.74-0.89). Professional support vs. usual care showed professional support to be effective at 4 months only RR in 5 trials 0.78	identified	breastfeeding initiation rates. Any form of additional support for mothers who are breastfeeding increases the duration of breastfeeding. Many of the studies reviewed were targeted at low income groups	partum as a result of Perceived Insufficient Milk (PIM) supply. Many women used infant satisfaction cues (e.g. crying, unsettled) as their primary indicators of milk supply. The H & H Lactation Scale and the Perceived Insufficient Milk Tool have been found useful to identify women at risk during early post-partum. Furthermore, PIM was associated with early weaning and / or decreased exclusivity in 10 studies. PIM was also associated with lower self efficacy or maternal confidence scores. Use of formula in hospital was associated with PIM in 3 studies and ceasing breastfeeding before leaving the hospital was related to PIM in 1 study.	from 19-78% for full BF at 6mo to any BF at 4 weeks. Effect on duration with Postnatal Interventions: 3 / 9 studies effective (2 / 8 RCTs) with AF ranging from 15-53% for any BF at 2 months to full BF at 6 months. Effect on duration with BOTH Pre- and Postnatal Interventions: 7 / 9 studies effective (3 / 4 RCTs) with AF ranging from 20-92% for full BF at 4 months in 2 studies; One study had an AF of 91% for full BF at 5 months. Effect on duration with BOTH Hospital and Postnatal Interventions: 4 / 7 studies effective (3 / 6RCTs) with AF ranging from 24-88% for any BF at 4 months to exclusive BF at 4 months. Effect on duration with both Hospital and Pre- and Postnatal Interventions: All 4 studies effective (3 RCTs) with AF ranging from 20- 100% for any BF at 1 month to full BF at 6 months.

	(95% CI 0.67- 0.91). The overall effect of extra support on stopping any breastfeeding did not reach statistical significance. Professional support resulted in a beneficial effect on exclusive breastfeeding RR in 16 trials 0.94 (95% CI 0.87 - 1.01). Professional support showed to be beneficial on exclusive breastfeeding rates RR 0.91 (95% CI 0.84 -0.98). Trials using lay people to conduct breastfeeding interventions demonstrated a significant decrease in breastfeeding cessation RR 0.86 (95% CI 0.76 - 0.98). Combined lay and professional support vs. usual care showed a significant reduction in cessation of any breastfeeding RR 0.84 (95% CI 0.77- 0.92) especially in the first 2 months RR before 4 to 6 weeks 0.65 (95% CI 0.51- 0.82); RR before 2 months 0.74 (95% CI				

	0.66- 0.83). 2 studies showed a significant reduction in cessation of exclusive breastfeeding RR 0.62 (95% CI 0.50- 0.77). Studies using face to face support showed a statistically significant benefit RR for giving up any breastfeeding 0.85 (95% CI 0.79- 0.92). No significant effect was demonstrated when phone and face to face support were provided on breastfeeding continuation RR 1.00 (95% CI 0.91- 1.09). One study demonstrated a significant reduction in risk of 1 or more GI infections and atopic eczema in those receiving support from health professional trained in WHO/UNICEF Baby Friendly Initiative. A further study found no significant difference between peer peer and control group mean score on the Maternal Breastfeeding Evaluation Scale (mean scores 52.81 (SD 5.69) vs. 52.98 (SD				

	5.94) p=0.26).				
EXTERNAL VALIDITY					
Generalisability	y - although some studies were conducted in developing countries	n/a	y	y	1
Applicability	y	n/a	y - Note that the review focused on women from disadvantaged backgrounds but included studies on women generally.	y	1
Comments		The lack of evidence resulting from this review emphasises the need for further research into breastfeeding education and support in the workplace post delivery	The objective's of this review were focused on all interventions directed at changing health behaviours of young women from disadvantaged backgrounds and included smoking, physical activity and diet.	The majority of the studies reviewed identified IM as PIM. Both of the terms have different definitions.	
Conclusion	Additional professional support was effective in prolonging any breastfeeding, but its effects on exclusive breastfeeding were less clear. WHO/UNICEF training courses appeared to be effective for professional training. Additional lay support	No trials have evaluated the effectiveness of workplace interventions in promoting breastfeeding among women returning to paid work after the birth of their child. The impact of such intervention on process outcomes is also unknown. Randomised	Consistent evidence was found of intervention features associated with effective changes in a number of health behaviours. Interventions to change health behaviours of women of child-bearing age from	PIM is one of the most common and influential reasons for low rates of breastfeeding duration and exclusivity. Future research should be conducted to determine who is at high risk and to further validate screening tools; and whether PIM is a physiological or	The primary health care units should inform, encourage, and support pregnant women in breastfeeding; the maternity hospitals should allow women to bond with their babies and help them to establish breastfeeding; and the primary health care units should be able to

	was effective in prolonging exclusive breastfeeding, while its effects on duration of any breastfeeding were uncertain. Effective support offered by professionals and lay people together was specific to breastfeeding and was offered to women who had decided to breastfeed. Further trials are required to assess the effectiveness (including cost-effectiveness) of both lay and professional support in different settings, particularly those with low rates of breastfeeding initiation, and for women who wish to breastfeed for longer than three months. Trials should consider timing and delivery of support interventions and relative effectiveness of intervention components, and should report women's views. Research into appropriate training for supporters (whether lay or professional) of	controlled trials are required to establish the benefits of various types of workplace interventions to support, encourage and promote breastfeeding among working mothers.	disadvantaged backgrounds require: an educational approach delivered in person by professionals or peers; provide continued support after the initial intervention; some evidence to t that social support from peers and family involvement in the intervention maybe important. These findings are of relevance to the design of an intervention to improve diet in this group of women.	psychological issue. Perceived milk supply is considered modifiable and well-informed interventions to reduce the incidence of PIM might be a key element for improving rates of successful breastfeeding.	guide, reinforce, and support this practice continuously, completing the cycle. Although there is evidence supporting the effectiveness of primary care strategies in extending breastfeeding duration, there is a need for broad-based, well-designed studies testing the effect of the combination of the procedures referred above, preferably spanning the prenatal and postnatal periods, to encourage the development of evidence-based protocols concerning the promotion, protection, and support of breastfeeding in primary care.

	breastfeeding mothers is also needed.				

30 FOOD SAFETY (N1.5)

Recommendations for safe preparation and storage of infant formula and breast milk
Table 30.4 summarises recommendations about the preparation of powdered infant formula (PIF) and storage of breast milk. *Enterobacter sakazakii* is recognised as an emerging opportunistic pathogen and the etiological agent of life-threatening bacterial infections in infants. PIF is not a sterile product and PIF has been shown to contain *E. sakazakii*. To reduce the risk of infection, reconstitution of formula should be undertaken by caregivers using good hygienic practice and in accordance with the product manufacturer's food safety guidelines (Drudy, Mullane et al. 2006; Redmond and Griffith 2009).

Many of the same recommendations apply to the storage of expressed breast milk. However breast milk may be stored frozen for longer term storage, or kept up to 5 days refrigerated up to 4°C, although caution is needed when dealing with preterm infants (Dalidowitz 2005; Eglash 2005).

Table 30.4 Recommendations for safe preparation and storing of infant formula and breast milk

Recommendations	Organisations
Wash hands with soap and water and use a clean space to work before preparing any formula	WHO DOHA
Boil fresh water and allow to cool before making up formula	WHO DOHA
Prepare formula just before a baby's feed. Extra formula can be stored in the refrigerator at ≤5°C for no more than 24 hours.	WHO DOHA
Always warm bottles in a water bath and not the microwave	WHO DOHA
Discard any food than has not been consumed within 2 hours	WHO
All bottles and teats should be rinsed in cold water, washed in hot soapy water, rinsed and sterilized before being used again	WHO DOHA
Store expressed breast milk in date labelled sterilized containers for up to 2 weeks frozen, or up to 5 days refrigerated at ≤4°C	ABM

Sources: (Eglash 2005; World Health Organization 2007; Department of Health and Ageing 2009)

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Monitoring Breastfeeding in Australia

To date all monitoring of breastfeeding in Australia has been done by cross sectional, retrospective or small regional cohort studies. While much useful data are available (see Appendix Breastfeeding Rates in Australia below), many studies use different definitions and sampling methods that make comparisons difficult (Binns, Fraser et al. 2009). An adequate National Breastfeeding Strategy will require detailed data that is representative, accurate and reproducible for program development and monitoring. The standard definitions of categories of breastfeeding should be used. This implies the use of a cohort methodology to accurately record the dynamic nature of infant feeding. The best model for Australia is the US program.

Infant Feeding Practices Study II (Centers for Disease Control 2010)
"In response to the nation's continued need to understand and improve the health status of mothers and children, the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention, in collaboration with other federal agencies, conducted a longitudinal consumer-based research study. This study collected information from mothers using a series of questionnaires administered from the woman's seventh month of pregnancy through the infant's first year of life. The study provides detailed information about

- Foods fed to infants, including breast milk and infant formula
- Factors that may contribute to infant feeding practices and to breastfeeding success
- Mothers' intrapartum hospital experiences, sources of support, and postpartum depression
- Mothers' employment status and child care arrangements
- Infant sleeping arrangements
- Other issues such as food allergies, experiences with breast pumps, and WIC participation
- Diets of pregnant and postpartum women

The study also served as a vital component to an evaluation of the Department of Health and Human Services' (DHHS) National Breastfeeding Awareness Campaign."
The justification of the study proposal is available (Division of Market Studies Office of Scientific Analysis and Support Food and Drug Administration 2004).
The questionnaires are available (http://www.cdc.gov/ifps/data/index.htm) and the raw data will be made available on request.
The following papers have been published from the study:
Fein, Sara B., Laurence M. Grummer-Strawn, Tonse N. K. Raju. 2008. Editors' Preface. *Pediatrics*: 122(suppl 2): S25-S27.
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Issues in selecting a growth reference for Australia

Introduction

The early nutrition and growth of infants has an important effect on early morbidity and mortality and there is increasing evidence of the medium and long term effects on health. Infant growth is now recognised as one of the influences on health and longevity later in life and breastfeeding is the backbone of early nutrition. There have been many reviews of the benefits of breastfeeding or the consequences of not breastfeeding, and the main benefits have been summarised in the NHMRC Infant Feeding Guidelines (Baghurst and Binns 2003). Evidence continues to accumulate about the role of early growth and breastfeeding in the development of adult disease (Smith and Harvey 2010). Of particular topical evidence is the high rate of obesity in modern western societies in all age groups. When reviewing the early origins of obesity Monasta and colleagues summarised current understanding and concluded that "breastfeeding may be a protective factor for later overweight and obesity" (Monasta, Batty et al. 2010). The White House report on childhood obesity included the estimate of Harder that breastfeeding offered 22% protection against childhood obesity and that this protection increased with duration until it plateaued at 9 months (Harder, Bergmann et al. 2005; White House Task Force on Childhood Obesity 2010).

When discussing animal models of early dietary influences Patel notes that "dietary practices for infants have undergone vast changes in the past 50 years. Extrapolation of the results from the rat model to the human scenario suggests that feeding practices currently implemented for infants could be one of the contributing factors to the obesity epidemic. A decline in breastfeeding rates has been recorded and concomitantly, there has been an increase in formula feeding coupled with early introduction of supplemental foods (carbohydrate-enriched) for babies (Patel and Srinivasan 2010). Patel postulates that the early introduction of carbohydrate-rich supplemental foods exposes the infant to increased carbohydrate during the critical period of organ development. Such a situation could have deleterious long-term consequences for these infants with eventual development of obesity and metabolic syndrome, as observed in the rat model (Patel and Srinivasan 2010).
The protein content of infant formula also has an effect on the rate of growth. It has been proposed that a higher protein intake stimulates secretion of insulin-like growth factor I (IGF-I) and consecutively cell proliferation. This results in accelerated growth and an increase in the amount and cellularity of adipose tissue (Koletzko, von Kries et al. 2009). The increased rate of growth and propensity towards obesity in formula fed infants has been the subject of a major European trial (Koletzko, von Kries et al. 2009). An infant formula with a lower level of protein resulted in a lower rate of growth that was closer to the growth pattern of breastfed infants.

Growth rates in infancy are related to disease later in life according to, the Developmental Origins of Adult Disease Hypothesis (DOAD or DOHAD), which has been the subject of extensive reviews (Barker 2007; Barker, Gelow et al. 2010; Groom, Elliott et al. 2010). The rate of growth in early infancy is related to health as an adult, including the incidence of hypertension, obesity, metabolic syndrome and hypertension (Singhal, Cole et al. 2007; Tzoulaki, Sovio et al. 2010)

On the other hand slow growth (undernutrition) results in increased rates of infectious disease. An extensive literature on undernutrition in developing countries going back to the pioneering work of Schrimshaw and Jelliffe has recently been re-confirmed in an economically-advanced society (Hui, Schooling et al. 2010)

Appropriate growth is essential for health and optimal development, both short term and throughout the lifespan. As with many other nutritional parameters the risk appears to be U-shaped.

- In the infant, growth that is too slow confers high risk for morbidity and mortality in the short term and developmental problems in the longer term
- Growth that is too rapid predisposes to later adult disease.

There is also risk attached to antenatal development as reflected in infant birthweight

- Birthweights <2500 grams are at increased risk – short term and longer term adult disease
- Birthweights >4500 grams (macrosomia) are also at increased risk

Again this appears to be a U-shaped distribution of risk.

Numerous studies affirm that growth of breastfed infants differs in trajectory from growth of formula fed infants (Dewey, Peerson et al. 1992; Dewey 1998). Evidence is accumulating that breastfeeding, with exclusive breastfeeding to around 6 months, will produce growth rates that are most compatible with short and long term health (at the minima point of inflection of the "U")

For all these reasons the promotion of breastfeeding is of paramount importance to the health of the individual and to the overall burden of public health. Exclusive breastfeeding to around 6 months and then for a longer period accompanied by appropriate complementary foods is the best way to feed all infants (Baghurst and Binns 2003).

The growth of infants is determined by the type and quantity of food received -ideally breast milk. But the relationship can also work in reverse, with the growth of the infant influencing the type and amount of foods given. During the first few months of life infants are weighed frequently and growth rates influence decisions on the method of feeding made by the parents, community nurses and family practitioners. Growth patterns frequently determine the discontinuation of breastfeeding and the introduction of complementary foods (de Onis, Garza et al. 1997). If an infant is determined to be growing too slowly, a decision may be made to supplement breastfeeding with other foods (eg infant formula) or even to stop breastfeeding altogether. Breastfeeding (preferably exclusive breastfeeding) for six months generally results in a rate of growth compatible with the best life course outcomes. Early introduction of infant formula or complementary foods may increase the proportion of adipose tissue in the infant.

The new WHO Growth Reference (WHO Coordinating Group 2006)

The study of growth has fascinated scientists for many years and the history of its study has been documented by Garn (Garn 1980). The growth reference most widely used around the world is the NCHS 2000 reference, which was previously endorsed by the World Health Organisation (Centers for Disease Control and Prevention 2000). Growth charts based on this reference, or on the earlier version of this reference, have been included in personal health records in many countries, including Australia (WHO 1978; Binns 1985). In 2000, the US charts were revised to eliminate some minor anomalies around two years of age, the data used for infants was updated and the calculation of some percentiles was revised (Centers for Disease Control and Prevention 2000)..

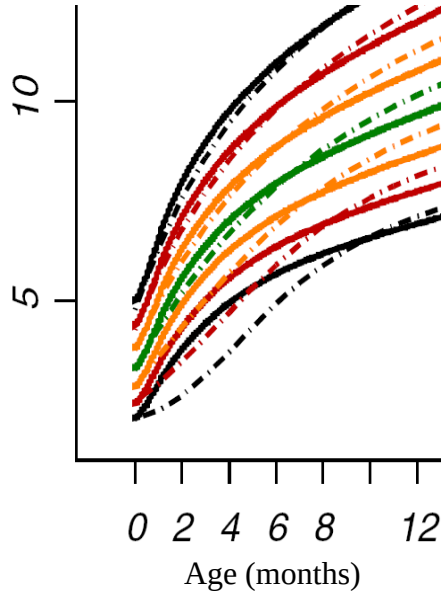
It was recognised that the old WHO (NCHS) reference includes a high proportion of formula fed infants and may not accurately reflect the growth of breastfed infants. Exclusively breastfed babies grow at a slightly lower rate than the NCHS reference and concern was expressed that the existing growth reference was too high and might lead mothers to introduce complementary foods unnecessarily (de Onis, Garza et al. 1997). However it was thought that if the charts were used as a reference (and not as a standard) the difference was not all that important (Dewey 1998). De Onis expressed concerns about the existing growth reference: *"the NCHS curves are inappropriate for healthy, breastfed infants. Recent research shows that infants fed according to recommendations by the WHO and who live under conditions that favour the achievement of genetic growth potentials grow less rapidly than, and deviate significantly from, the NCHS reference. The negative deviations are large enough to lead health workers to make faulty decisions regarding the adequate growth of breastfed infants, and thus to mistakenly advise mothers to supplement unnecessarily or to stop breastfeeding altogether. Given the health and nutritional benefits of breastfeeding, this potential misinterpretation of the growth pattern of healthy breastfed infants has great public health significance. The premature introduction of complementary foods can have life-threatening consequences for young infants in many settings, especially where breastfeeding's role in preventing severe infectious morbidity is crucial to child survival"*. (de Onis, Garza et al. 1997).

The concerns expressed by the WHO and others led to the development of a new growth reference by WHO (WHO 2006). The development process has been described in great detail (de Onis, Garza et al. 2004; de Onis, Onyango et al. 2006; WHO 2006). After a decade of work the WHO published their results, with the following description: The new standards adopt a fundamentally prescriptive approach designed to describe how all children should grow rather than the more limited goal of describing how children grew at a specified time and place (de Onis, Garza et al. 2007). Previously WHO had used the term reference, but now felt confident enough about the new growth study to refer to it as a standard for breastfed infants.

However the new WHO growth reference is actually heavier for the first six months of life than the previously used reference. Ziegler has summarized the ways that the new WHO growth reference differs from the NCHS reference (Ziegler and Nelson 2007). In particular they noted that "during the first 6 months of life, WHO weight and length at all percentiles are larger than weight and length by any other chart." When compared to the NCHS and CDC 2000 references, the new WHO reference is heavier for the first six months of life as can be seen in the weight-for-age comparisons in Figure 1 (WHO 2006; de Onis, Garza et al. 2007) (Binns and Lee 2006). The reasons for this are not know, but probably relate to the highly selected sample, with less than 4% of the infants screened being included in the final sample.

Figure 1. Comparison of weight-for-age Z scores for boys (new WHO reference (solid lines); old WHO-NCHS reference (dashed lines).

Z-Scores -3 to +3 shown ((WHO 2006), Page 105)



Breastfeeding patterns are usually established while the mother is in hospital or soon after. Weight monitoring by the mother and community health services is commenced after the infant is discharged from hospital. At this point there are no further opportunities to begin breastfeeding. If growth patterns are to influence breastfeeding in the first six months of life, it may be to reduce breastfeeding rates, 'exclusive' or 'any' breastfeeding. It is important to determine if the new WHO growth reference could influence breastfeeding rates, particularly for the first six months infants.

By using the new, heavier WHO reference under the age of six months, more infants will fall below the percentile lines usually used to assess adequacy of growth and be diagnosed as underweight, a point acknowledged by WHO and the Royal College of Physicians (de Onis, Garza et al. 2007; SACN/RCPCH Expert Group on Growth Standard 2007). The exact proportion of infants falling below the 5th percentile (or --2Z scores or whatever cutoff point is used) will depend on the infant's age and the overall nutritional status of the population being studied. Since growth faltering is the most common reason for advising the cessation of exclusive breastfeeding, this is a real risk and one acknowledged by Cattaneo, in spite of his support of the new growth standard (Cattaneo and Guoth-Gumberger 2008). The risk of lower rates of exclusive breastfeeding and increased exposure to unnecessary complementary or supplementary feeds is a risk of using the new WHO growth reference instead of the CDC2000 reference. The introduction of complementary foods unnecessarily before six months of age may reduce the mother's breast milk supply and could lead to the cessation of any breastfeeding, an unfortunate outcome for the future health of the infant.
Before the WHO Growth reference is introduced in Australia, it is important to ask if the introduction of the new WHO growth reference will reduce breastfeeding (exclusive and any) rates.

If it is possible that the introduction of a new growth reference will reduce breastfeeding, can education for health professionals and mothers eliminate or mitigate the damage?
Given the almost universal use of growth charts, it is surprising that such a major change to the most common method of infant monitoring would be introduced without first conducting a randomised controlled trial. No trials have been reported in the literature , but a small pilot

study, a randomised controlled trial (n=537) in Hangzhou PR China comparing the effects of two growth charts on breastfeeding rates has indicated that the risk may be real. In this study, the full breastfeeding rates at three months were 26% in the heavier (WHO) chart group and 30% in the lighter (CDC) group (Zhu, Shao et al. 2009). This suggests a full scale randomised controlled trial is needed.

An increasing number of countries are expressing concerns about the new WHO reference and are recommending that it not be used (Júlíusson, Roelants et al. 2010). In the UK, a decision has been made to use the new reference, but the first 2 weeks have been removed from the chart, the 50th percentile (median) has been de-emphasised and the chart includes lower percentiles (0.4 and 2 percentiles) that have not previously been included in growth charts prepared for general use. Including these lower percentiles gives the UK the opportunity to educate health workers to use a lower percentile to assess the adequacy of the growth of infants. Providing that growth is proceeding above the 2nd percentile and velocity is satisfactory this is the equivalent of the 5th percentile on the previous growth charts.

Issues in the debate

There is need to confirm the following

- The optimal growth trajectory for infants to maximise short and long term health gains.
- Which growth reference will promote the healthiest growth trajectory?
- Which growth reference will promote breastfeeding to meet the NHMRC goals?

These issues are all important public health issues for Australia and need to be addressed as part of a child health policy.

Conclusion

Growth is a most important determinant of health. The choice of a growth reference should be based on promoting optimal health and breastfeeding rates. Using the new WHO reference in the first six months of life could impact on breastfeeding rates. A basic question remains to be answered. If there is a risk to one of the most important components of public health nutrition, how could a change to the growth reference be contemplated without first conducting a randomised controlled trial? Such a move would not be accepted for any other paediatric intervention, such as vaccination. Why take the risk with a nutrition factor as important as breastfeeding?

National and International Statements on Infant Feeding

The joint WHO/UNICEF recommendations for breastfeeding
Breastfeeding is the normal way of providing young infants with the nutrients they need for healthy growth and development. Virtually all mothers can breastfeed, provided they have accurate information, and the support of their family, the health care system and society at large. Colostrum is recommended by WHO as the perfect food for the newborn, and feeding should be initiated within the first hour after birth. Exclusive breastfeeding is recommended up to 6 months of age, with continued breastfeeding along with appropriate complementary foods up to two years of age or beyond. WHO and CDC now define breastfeeding to include feeding expressed milk. When the mother or her own expressed breast milk is not available, the WHO recommends the feeding of another mother's milk or banked human milk in preference to the use of artificial baby milks.

Academy of Breastfeeding Medicine (ABM) Position of Breastfeeding (2008)
In accordance with the WHO the ABM define optimal infant and young child feeding as exclusive breastfeeding for 6 months, and continued breastfeeding for at least 1 and up to 2 years or longer, with age-appropriate complementary feeding. Feeding other than direct breastfeeding should be supported only for valid medical reasons or absence of the mother. Breastfeeding should be continued for up to 2 years and beyond for as long as the mother and child desire. Medical professionals have a responsibility to promote, protect, and support breastfeeding.

The International Baby Food Action Network (IBFAN)
Breastfeeding for six months, followed by appropriate complementary feeding practices, with continued breastfeeding for up to two years or beyond, provides the key building block for child survival, growth and healthy development. It is also the most cost- effective health strategy with respect to infant survival and health. Besides having a major positive influence on the short- and long-term health of each human being, breastfeeding affords important health benefits to mothers who practise it.

Australia and New Zealand:
Australian Breastfeeding Association (ABA). Position Statement
Breastfeeding is an integral part of the reproductive process, the natural and ideal way of feeding the infant and a unique biological and emotional basis for child development. Breast milk contains all the nutritional requirements for a baby's growth for the first 6 months and remains the most important part of the infant's diet, with the addition of family foods, until around 12 months. Breast milk continues to be a valuable source of nutrition for as long as mother and baby breastfeed. Mother and baby should be encouraged and supported to breastfeed after birth as soon as the baby indicates readiness. Colostrum is all that is needed for baby's nutrition until lactation is fully established unless medical advice indicates otherwise. To develop and maintain a good milk supply, babies should breastfeed frequently. If a mother's milk is not available the ABA supports the practise of feeding of another mother's milk.

The Dietitians Association of Australia (DAA) (2010)
The DAA support the recommendation listed in the AGHE. The DAA recommend infants receive only breast milk until the age of six months and that breastfeeding be continued until at least the age of 12 months. The DAA do not have a recommendation for when to stop

breastfeeding. For infants who are not breastfed, a commercial infant formula is a satisfactory feed, and should be continued until 12 months of age. Around the age of six months, solid foods should be added to the infant's diet in addition to the nutrition of the breast milk. To maintain the mother's breast milk supply it is important to offer solid foods after breastfeeding when starting solid food with the infant. Start with a single grain cereal such as a commercial baby rice cereal. Gradually increase the texture, amounts, variety and frequency of foods offered according to the infant's progress with the changed diet. By the age of 12 months children will be able to share family meals and eat a wide variety of foods.

Australasian Society of Clinical Immunology and Allergy (ASCIA) (2010)
Summary of their practical advice for parents and families:
Breastfeeding is recommended for at least 6 months.
Breastfeeding can continue beyond 12 months, or for as long as mother and infant wish to continue.
From 4-6 months commence on solids when your child is ready.
Consider introducing a new food every 2-3 days.
Give one new food at a time so that reactions can be more clearly identified.

The Australian College of Midwives (ACM) and the Baby Friendly Health Initiative (BFHI) Position Statement
The ACM/BFHI protect, promote and support breastfeeding as unequalled in providing optimal food and nurturing to ensure the healthy physiological and psychological growth and development of infants. The ACM/BFHI recommend infants receive breast milk for the first 6 months of life which requires no supplementation. Thereafter the ACM/BFHI recommend infants receive appropriate complementary foods with continued breastfeeding for up to two years and beyond. The ACM / BFHI fully support the importance of informed decision making. ACM / BFHI support the World Health Organisation (WHO) & United Nations International Children's Fund (UNICEF) belief that donor mothers milk is the first alternative where the baby's' own mother's milk is not available.

The Public Health Association of Australia
The association notes that breastfeeding is a normal process that requires social and structural support for mothers to ensure supportive environments for optimal breastfeeding benefit. In accordance with the WHO recommends that all babies are exclusively breastfed for at least the first six months of life and together with complementary food, breastfeed ideally for up to two years. While exclusive breastfeeding for 6 months is optimal, breastfeeding for even a few weeks, or partially, is beneficial and has definite advantages over not breastfeeding at all. The risks of not breastfeeding may be long term

The Pharmaceutical Society of Australia (PSA). Position statement (2004)
The Pharmaceutical Society of Australia (PSA) supports the WHO Code. Pharmacists should not promote breast milk substitute products to the general public in such a manner that would discourage breastfeeding. The PSA supports the Dietary Guidelines for Children and Adolescents in Australia incorporating the Infant Feeding Guidelines for Health Workers. The PSA recognises that a proportion of women are unable to breastfeed for various reasons. These women should also be given support and advice. Pharmacists must respect the right of parents to make informed choices on the method of infant feeding.

Royal Australian College of General Practitioners (RACGP) (2007)
The RACGP supports the NHMRC Dietary guidelines for children and adolescents in

Australia incorporating the Infant feeding guidelines for health workers. The RACGP supports the WHO International code of marketing of breast milk substitutes' and will not accept practices that undermine the code. The RACGP states that breastfeeding should be promoted as the most appropriate method for feeding infants and one that offers protection against infection and some chronic diseases. General practitioners should encourage and support exclusive breastfeeding in the first 6 months, then the introduction of complementary foods and continued breastfeeding thereafter. It is recommended that breastfeeding continue until 12 months of age and thereafter as long as mutually desired. General practitioners should acknowledge that mothers have the right to breastfeed wherever and whenever their baby requires, support breastfeeding mothers in the paid work force to continue breastfeeding, prescribe medication that is compatible with breastfeeding, acknowledge that even partial breastfeeding is of great value and maintain skills in the diagnosis and management of common breastfeeding problems.

Royal Australasian College of Physicians (RACP) (2007)
The RACP affirms that breast milk is superior to formula. The Division supports the NHMRC Infant Feeding Guidelines for Health Workers. The Division supports the International Code of Marketing of Breast milk Substitutes (1981) and the Voluntary Agreement of the Marketing in Australia of Infant Formulae (1992).

In terms of breastfeeding management, the RACP states that breastfeeding is almost universally successful when there is good management and no medical intervention or exposure to alternative feeding methods. There is evidence that offering a breastfeed within the first few hours of birth is good for mothers, infants and for ongoing breastfeeding. "Rooming-in", or keeping the infant with the mother for 24 hours a day, has been shown to facilitate breastfeeding and promote bonding. Infants should be fed on demand in recognition that mothers have varying breast capacities and milk production rates. Offering complementary feeds, whether water, glucose or formula, when there is no medical reason, has been shown to adversely affect the establishment and maintenance of successful breastfeeding. There is also a need to recognise the possible dangers associated with artificial feeding such as possible contamination of feeds, infection and incorrect reconstitution. The early use of bottles and dummies/pacifiers can interfere with the establishment of breastfeeding, altering the infant's sucking capacity and reducing stimulation of the breasts, with the likely result of poor establishment or maintenance of lactation. Paediatricians should consult their local drug information centre before suggesting that breastfeeding be interrupted or ceased because of maternal medications.

The National Breastfeeding Advisory Committee to the Director-General of Health in New Zealand
The Committee fully and unequivocally supports the recommendation of the WHO Global Strategy for Infant and Young Child Feeding as a goal for New Zealand: Infants are exclusively breastfed for the first six months of life, and thereafter receive safe and adequate complementary foods while breastfeeding continues for up to two years of age or beyond.

America:
American Academy of Pediatrics (AAP). Policy Statement on Breastfeeding and the use of human milk (2005)
The AAP supports the WHO recommendations for exclusive breastfeeding up to 6 months of age, with continued breastfeeding along with appropriate complementary foods up to two years of age or beyond. The AAP states that breastfeeding is sufficient to support optimal

growth and development for approximately the first 6 months of life and provides continuing protection against diarrhoea and respiratory tract infection. Complementary foods rich in iron should be introduced gradually beginning around 6 months of age. Unique needs or feeding behaviours of individual infants may indicate a need for introduction of complementary foods as early as 4 months of age, whereas other infants may not be ready to accept other foods until approximately 8 months of age. Increased duration of breastfeeding confers significant health and developmental benefits for the child and the mother, especially in delaying return of fertility. There is no upper limit to the duration of breastfeeding and no evidence of psychologic or developmental harm from breastfeeding into the third year of life or longer. Infants weaned before 12 months of age should not receive cow's milk but should receive iron-fortified infant formula

Although economic, cultural, and political pressures often confound decisions about infant feeding, the AAP firmly adheres to the position that breastfeeding ensures the best possible health as well as the best developmental and psychosocial outcomes for the infant.

American Dietetic Association (ADA). Position statement on breastfeeding (2009)
It is the position of the American Dietetic Association that exclusive breastfeeding provides optimal nutrition and health protection for the first 6 months of life and breastfeeding with complementary foods from 6 months until at least 12 months of age is the ideal feeding pattern for infants. Breastfeeding is an important public health strategy for improving infant and child morbidity and mortality, and improving maternal morbidity, and helping to control health care costs.

United States Breastfeeding Committee (2010)
The United States Breastfeeding Committee recommends that healthy full-term infants be exclusively breastfed for about six months. Optimal breastfeeding contributes to normal growth and improved child and adult health outcomes. Months four through six are defined as a critical period in the continuation of exclusive breastfeeding because a significant proportion of women prematurely wean their babies during this time. Two of the most important factors for the premature discontinuation of exclusive breastfeeding are the return to work and misperceptions regarding infants' nutritional needs.

The only acceptable maternal reasons for which "breast milk feeding should be avoided" as HIV infection, human t-lymphotrophic virus type I or II, substance abuse and/or alcohol abuse, active, untreated tuberculosis, taking certain medications, undergoing radiation therapy, active, untreated varicella, active herpes simplex virus with breast lesions
In some of these cases, the infant can and should be exclusively fed breast milk or donor human milk

National Network for Child Care (NNCC), USA (accessed Oct 2010)
The NNCC states that breastfeeding is the preferred method of infant feeding. However, if breastfeeding is not adopted or is discontinued before 12 months of age, iron-fortified infant formula is the best alternative. Breast milk and infant formula are the only foods recommended for the first 4 to 6 months of life. Vitamin and mineral supplements usually are not necessary and should be given only when recommended by a physician. Solid foods may be introduced at about 4 to 6 months.

American Academy of Family Physicians (AAFP). Policy Statement on Breastfeeding (accessed Oct 2010)

Breastfeeding is the physiological norm for both mothers and their children. Breast milk offers medical and psychological benefits not available from human milk substitutes. The AAFP recommends that all babies, with rare exceptions, be breastfed and/or receive expressed human milk exclusively for the first six months of life. Breastfeeding should continue with the addition of complementary foods throughout the second half of the first year. Breastfeeding beyond the first year offers considerable benefits to both mother and child, and should continue as long as mutually desired. Family physicians should have the knowledge to promote, protect, and support breastfeeding.

Canadian Paediatric Society (accessed Oct 2010)

The Canadian Paediatric Society recommends exclusive breastfeeding for the first six months of life for healthy, term infants. Breast milk is the optimal food for infants, and breastfeeding may continue for up to two years and beyond. (The Canadian Paediatric Society previously recommended exclusive breastfeeding for four to six months).

The Canadian Paediatric Society state:

Breastfeeding is rarely contraindicated. Neither smoking nor environmental contaminants are necessarily contraindications to breastfeeding. Moderate, infrequent alcohol ingestion, the use of most prescription and over-the-counter drugs and many maternal infections do not preclude breastfeeding.

Vitamin D deficiency is a health concern in Canada. Infant formulas and milks are fortified with vitamin D. Breastfed infants should also receive extra vitamin D in the form of a supplement.

Foods provided to infants must be free of pathogens, appropriate in size and texture, nutritionally sound and fed safely.

If an infant is not breastfed, or is partially breastfed, commercial formulas are the most acceptable alternative to breast milk until 9 to 12 months of age. The use of nutritionally incomplete alternate milks as the sole source of nutrition for infants is inappropriate. Pasteurized whole cow's milk, however, is an important component of a mixed infant diet after 9 months of age. For infants unable to take cow's milk products, continue commercial soy formula until 2 years of age.

Six month old infants are physiologically and developmentally ready for new foods, textures and modes of feeding. By 1 year of age, the ingestion of a variety of foods from the different food groups is desirable.

Europe:

The European Society for Paediatric Gastroenterology, Hepatology and Nutrition and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (2008)

ESPGHAN states exclusive breastfeeding for around 6 months is a desirable goal. Weaning onto solid foods should begin by 6 months but not before 4 months. Breastfeeding should continue throughout weaning particularly the early stages. Introducing gluten between 4 and 7 months while breastfeeding may reduce the risk of coeliac disease, type 1 diabetes and wheat allergy. High allergen foods such as egg and fish do not need to be delayed until after 6 months as there is no evidence that this will reduce the likelihood of allergies

European Society for Social Pediatrics and Child Health (ESSOP) Position Statement (2009)

ESSOP supports the WHO established recommendations for infant feeding advocating exclusive breastfeeding for 6 months followed by complementary feeding and continued breastfeeding 2 years longer or more.

The Department of Health in England (2003)
Issued a statement in 2003; Breastfeeding is the best form of nutrition for infants. Exclusive breastfeeding is recommended for the first six months (26 weeks) of an infant's life as it provides all the nutrients a baby needs. Breastfeeding should be continued beyond six months alongside appropriate solid foods.'
The Department of Health in England previously stated additional foods should be introduced at 4 to 6 months.

Paediatric Group of the British Dietetic Association. Position Statement
Exclusive breastfeeding from birth until weaning is the optimal way to feed young infants. Continuing breastfeeding throughout weaning may reduce the risk of coeliac disease, type 1 diabetes and wheat allergy

Asia:
Indian National Guidelines on Infant and Young Child Feeding
Current recommendation:
Initiation of breastfeeding immediately after birth, preferably within one hour.
Exclusive breastfeeding for the first six months
Appropriate and adequate complementary feeding from six months of age while continuing breastfeeding.
Continued breastfeeding up to the age of two years or beyond.

Despite India's support for optimal infant feeding, a report by Gupta stated in India there is a lack of policy status for 'National guidelines on infant and young child feeding', no sustained action to revive baby friendly hospital initiative's', no policy framework for protecting and supporting breastfeeding in private sector and informal sector for working women, lack of stated strategy on communication for infant and young child feeding and there is no policy on infant and young child feeding in action plans for disasters. (Gupta, Dadhich et al. 2010)

Chinese Ministry of Health (2009) (Wang, Binns et al. 2009)
The Chinese Ministry of Health has emphasized breastfeeding in public-health programmes. China aims for exclusive breastfeeding until six months of age.

Interventions to Promote Breastfeeding

Community Support of Breastfeeding: Approaches to communicating the benefits of breastfeeding.
The benefits of breastfeeding can be presented to the community as 'benefits' or as the 'risk of formula feeding'. It has been the position of breastfeeding organisations for some years that the correct way to present information to the community is the increased risks of formula feeding compared to breastfeeding. However the message 'breastfeed your infant or it might die or will be less intelligent', while true, is a politically hard message to sell.

In the USA a national survey showed the following apparently contradictory trends. While 74% disagreed with the statement 'infant formula is as good as breast milk' at the same time only 24% agreed that 'feeding a baby formula instead of breast milk increases the chances the baby will get sick' (Li, Rock et al. 2007). This is despite the fact that in developing and developing countries formula fed infants have greater morbidity and mortality. In 2002

Smith calculated that not breastfeeding led to extra costs to the ACT health system of $1-2 million per year from just five diseases (Smith, Thompson et al. 2002).
Stuebe gives the following account of a series of advertisements which were developed in the USA to promote breastfeeding, but did not make it to air (Stuebe and Schwarz 2010). The Advertising Council found that mothers who were advised about the 'benefits of breastfeeding' viewed lactation as an option, while mothers who were told of the risks of not breastfeeding were far more likely to say that they would breastfeed their infants (Stuebe and Schwarz 2010). There are no similar studies reported from Australia.
Another divergence of public attitudes is shown by the attitude to breastfeeding in public places in the US in 2003 (Li, Rock et al. 2007).
Mothers who breastfeed should do so in private places; 37%
I am comfortable when mothers breastfeed their babies near me in a public place, such as a shopping center, bus station, etc.; 48%

Legislation
It is important that mothers breastfeed where and whenever their baby needs it. In WA, for instance, legislation has now been passed to rule out discrimination on the basis of breastfeeding. The legislation needs to apply nationally. From the WA Act:
10A. (1) Discrimination on the ground of breastfeeding
For the purposes of this Act a person (in this subsection referred to as the discriminator) discriminates against another person (in this subsection referred to as the aggrieved person) on the ground of breastfeeding if on the ground of —
(a) aggrieved person breastfeeding or bottle feeding an infant or proposing to do so;
(b) a characteristic that appertains generally to persons who are breastfeeding or bottle feeding; or
(c) a characteristic that is generally imputed to persons who are breastfeeding or bottle feeding, the discriminator treats the aggrieved person less favourably than, in circumstances that are the same or not materially different, the discriminator treats or would treat a person who was not breastfeeding or bottle feeding; and
(2) For the purposes of this Act, a person (in this subsection referred to as the discriminator) discriminates against another person (in this subsection referred to as the aggrieved person) on the ground of breastfeeding or bottle feeding if the discriminator requires the aggrieved person to comply with a requirement or condition –
(a) with which a substantially higher proportion of persons who are not breastfeeding or bottle feeding comply or are able to comply;
(b) which is not reasonable having regard to the circumstances of the case; and
(c) with which the aggrieved person does not or is not able to comply.

Education
Education for Parenthood
To improve the health and wellbeing of infants, UNICEF recommends improving the health and wellbeing of future mothers and their education. This includes care of the infant and infant feeding. There is, of course, equal justification to extend the education to future fathers.

Antenatal Education, including Fathers
The decision to breastfeed and to continue to breastfeed are influenced by numerous factors including maternal age, ethnicity, social class, marital status, education, family and partner support, alcohol consumption, early return to work, smoking and deciding to breastfeed prior to pregnancy. (Giglia, Binns et al. 2006; Scott, Binns et al. 2006; Giglia, Binns et al. 2008).

Some of these can be potentially influenced by education programs, while others such as ethnicity or maternal age cannot be changed. But even with these variables the identification of 'at risk' groups can assist in the targeting of support programs.

There is strong evidence that fathers can influence the initiation of breastfeeding, (Scott, Binns et al. 1997; Scott, Binns et al. 1997; Wolfberg, Michels et al. 2004) contribute to maternal breastfeeding confidence (Ekstrom, Widstrom et al. 2003), and impact decisions regarding duration and weaning (Hauck and Irurita 2003; Hauck 2004; Swanson and Power 2005). Without fathers' support mothers are more likely to breastfeed for a shorter duration (Scott, Aitkin et al. 1999). Focus group, cohort and longitudinal studies have shown that the support of fathers is critical for initiation and continuance of breastfeeding (Scott, Binns et al. 1997; Sharma and Petosa 1997; Scott, Landers et al. 2001).

Sharma and Petosa (Sharma and Petosa 1997) identified fathers' support as one of the strongest and most consistent variables associated with women's willingness to breastfeed and yet there are few programs that have sought to enhance this support. There has been little research in this area, with little known about the nature of a father's support required by the mother and there have been few programs that have specifically targeted fathers. While some programs targeting the father's role in promoting breastfeeding have been effective in increasing initiation rates (Stremler and Lovera 2004; Wolfberg, Michels et al. 2004), less success has been achieved regarding impact on duration.

An Italian randomised control trial that provided a breastfeeding training session for fathers resulted in a 10% increase (25% versus 15%) in breastfeeding prevalence rates six months after birth. The intervention aimed to provide support and education about management of the most common lactation difficulties (Pisacane, Continisio et al. 2005). In contrast, an American randomised controlled trial of a paternal education intervention did not have a significant impact upon breastfeeding prevalence rates at eight weeks post-birth. However, this intervention class on breastfeeding promotion did influence initiation rates (74% versus 41%) as more women whose partners attended classes chose to commence breastfeeding compared to a control group who were only offered a baby care class.(Wolfberg, Michels et al. 2004) Evidence regarding effective strategies to assist fathers in their supportive role with their breastfeeding partner has been piloted in the Perth Infant Feeding III project from herein called FIFI and the results will soon be available.

In a systematic review of factors that positively influence breastfeeding duration to 6 months Meedya identified three groups of modifiable factors that influence women's breastfeeding decisions (Meedya, Fahy et al. 2010). These were breastfeeding intention, breastfeeding self-efficacy and social support. Fathers were a component of the social support. Socio-demographic factors that affect prolonged breastfeeding behaviours were also identified as age, marital status, education and income level. There is strong evidence that older age, being married, being well educated and having a higher income are each associated with longer breastfeeding duration. However these cannot be modified after the pregnancy has commenced.

Meedya concluded "What is known is that women have positive and prolonged breastfeeding experiences when they have a strong desire to breastfeed for longer periods of time, when they are confident in their ability to breastfeed and are well supported by their family. There have been no interventional studies that have simultaneously aimed to address these three issues simultaneously i.e. to enhance the women's breastfeeding intention, to enhance her

sense of self-efficacy and to strengthen her supports. It is reasonable to assume that research aimed at modifying these three factors together is likely to be more successful than trying to modify each one individually."

The National Institute of Clinical Studies identified the best available evidence on Breastfeeding Promotion (National Institute of Clinical Studies 2005)
"Evidence suggests that long-term intensive promotion of breastfeeding is most successful, spanning the pre and postnatal period, and involving multiple contacts with a professional breastfeeding promoter or peer counsellor. Well-conducted educational and support interventions for mothers prior to, and immediately after, childbirth are effective in improving rates of initiation as well as duration of breastfeeding (up to three months). Interventions that target hospital practices are particularly effective, such as rooming-in, early skin-to-skin contact and non-use of commercial hospital discharge packs. Factors such as the support of the baby's father and the time at which the decision to breastfeed is made (preferably before or early in the pregnancy) are also important. Professional and peer support have had a significant impact on short-term duration and exclusivity of breastfeeding. Peer support is particularly effective for low income, ethnic minority or disadvantaged groups. Postnatal home visits may enhance effectiveness. One-to-one education is best for persuading those women planning to use infant formula to change to breastfeeding. Beyond three months, interventions involving parenting groups, face-to-face contacts and home visiting by professional or trained peer counsellors may be effective, particularly in maintaining exclusive breastfeeding. Cultural and language-specific interventions, in conjunction with clinic visits, are associated with some increases in breastfeeding duration."

In Hospital
There is good evidence that applying the Baby Friendly Hospital Initiative principles – including those relating to prelacteal feeds, is effective in promoting breastfeeding (See evidence in BFHI section)

Cochrane Reviews
Support for breastfeeding mothers (Britton, McCormick et al. 2009)
Background: There is extensive evidence of the benefits of breastfeeding for infants and mothers. In 2003, the World Health Organization (WHO) recommended infants be fed exclusively on breast milk until six months of age. However, breastfeeding rates in many developed countries continue to be resistant to change. OBJECTIVES: To assess the effectiveness of support for breastfeeding mothers. SEARCH **Strategy**: We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (January 2006), MEDLINE (1966 to November 2005), EMBASE (1974 to November 2005) and MIDIRS (1991 to September 2005).
Selection Criteria: Randomised or quasi-randomised controlled trials comparing extra support for breastfeeding mothers with usual maternity care.
Data Collection and Analysis: Two authors independently assessed trial quality and extracted data.
Main Results: We have included 34 trials (29,385 mother-infant pairs) from 14 countries. All forms of extra support analysed together showed an increase in duration of 'any breastfeeding' (includes partial and exclusive breastfeeding) (relative risk (RR) for stopping any breastfeeding before six months 0.91, 95% confidence interval (CI) 0.86 to 0.96). All forms of extra support together had a larger effect on duration of exclusive breastfeeding than on any breastfeeding (RR 0.81, 95% CI 0.74 to 0.89). Lay and professional support together extended duration of any breastfeeding significantly (RR before 4-6 weeks 0.65, 95% 0.51 to

0.82; RR before 2 months 0.74, 95% CI 0.66 to 0.83). Exclusive breastfeeding was significantly prolonged with use of WHO/UNICEF training (RR 0.69, 95% CI 0.52 to 0.91). Maternal satisfaction was poorly reported.
Authors' Conclusions: Additional professional support was effective in prolonging any breastfeeding, but its effects on exclusive breastfeeding were less clear. WHO/UNICEF training courses appeared to be effective for professional training. Additional lay support was effective in prolonging exclusive breastfeeding, while its effects on duration of any breastfeeding were uncertain. Effective support offered by professionals and lay people together was specific to breastfeeding and was offered to women who had decided to breastfeed. Further trials are required to assess the effectiveness (including cost-effectiveness) of both lay and professional support in different settings, particularly those with low rates of breastfeeding initiation, and for women who wish to breastfeed for longer than three months. Trials should consider timing and delivery of support interventions and relative effectiveness of intervention components, and should report women's views. Research into appropriate training for supporters (whether lay or professional) of breastfeeding mothers is also needed.

Alternative versus conventional institutional settings for birth (Hodnett, Downe et al. 2010)
Background: Alternative institutional settings have been established for the care of pregnant women who prefer and require little or no medical intervention. The settings may offer care throughout pregnancy and birth, or only during labour; they may be part of hospitals or freestanding entities. Specially designed labour rooms include bedroom-like rooms, ambient rooms, and Snoezelen rooms.
Objectives: Primary: to assess the effects of care in an alternative institutional birth environment compared to care in a conventional institutional setting. Secondary: to determine if the effects of birth settings are influenced by staffing, architectural features, organizational models or geographical location.
Search Strategy: We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 May 2010).
Selection Criteria: All randomized or quasi-randomized controlled trials which compared the effects of an alternative institutional maternity care setting to conventional hospital care.
Data Collection and Analysis: We used standard methods of the Cochrane Collaboration Pregnancy and Childbirth Group. Two review authors evaluated methodological quality. We performed double data entry and have presented results using risk ratios (RR) and 95% confidence intervals (CI).
Main Results: Nine trials involving 10684 women met the inclusion criteria. We found no trials of freestanding birth centres or Snoezelen rooms. Allocation to an alternative setting increased the likelihood of: no intrapartum analgesia/anaesthesia (five trials, n = 7842; RR 1.17, 95% CI 1.01 to 1.35); spontaneous vaginal birth (eight trials; n = 10,218; RR 1.04, 95% CI 1.02 to 1.06); breastfeeding at six to eight weeks (one trial, n = 1147; RR 1.04, 95% CI 1.02 to 1.06); and very positive views of care (two trials, n = 1207; RR 1.96, 95% CI 1.78 to 2.15). Allocation to an alternative setting decreased the likelihood of epidural analgesia (seven trials, n = 9820; RR 0.82, 95% CI 0.75 to 0.89); oxytocin augmentation of labour (seven trials, n = 10,020; RR 0.78, 95% CI 0.66 to 0.91); and episiotomy (seven trials, n = 9944; RR 0.83, 95% CI 0.77 to 0.90). There was no apparent effect on serious perinatal or maternal morbidity/mortality, other adverse neonatal outcomes, or postpartum hemorrhage. No firm conclusions could be drawn regarding the effects of variations in staffing, organizational models, or architectural characteristics of the alternative settings.

Authors' Conclusions: When compared to conventional settings, hospital-based alternative birth settings are associated with increased likelihood of spontaneous vaginal birth, reduced medical interventions and increased maternal satisfaction.

Individual or group antenatal education for childbirth or parenthood, or both (Gagnon and Sandall 2007)

Background: Structured antenatal education programs for childbirth or parenthood, or both, are commonly recommended for pregnant women and their partners by healthcare professionals in many parts of the world. Such programs are usually offered to groups but may be offered to individuals.

Objectives: To assess the effects of this education on knowledge acquisition, anxiety, sense of control, pain, labour and birth support, breastfeeding, infant-care abilities, and psychological and social adjustment.

Search Strategy: We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (April 2006), CINAHL (1982 to April 2006), ERIC (1984 to April 2006), EMBASE (1980 to April 2006) and PsycINFO (1988 to April 2006). We hand searched the Journal of Psychosomatic Research from 1956 to April 2006 and reviewed the reference lists of retrieved studies.

Selection Criteria: Randomized controlled trials of any structured educational program provided during pregnancy by an educator to either parent that included information related to pregnancy, birth or parenthood. The educational interventions could have been provided on an individual or group basis. Educational interventions directed exclusively to either increasing breastfeeding success, knowledge of and coping skills concerning postpartum depression, improving maternal psycho-social health including anxiety, depression and self-esteem or reducing smoking were excluded.

Data Collection and Analysis: Both authors assessed trial quality and extracted data from published reports.

Main Results: Nine trials, involving 2284 women, were included. Thirty-seven studies were excluded. Educational interventions were the focus of eight of the studies (combined n = 1009). Details of the randomization procedure, allocation concealment, and/or participant accrual or loss for these trials were not reported. No consistent results were found. Sample sizes were very small to moderate, ranging from 10 to 318. No data were reported concerning anxiety, breastfeeding success, or general social support. Knowledge acquisition, sense of control, factors related to infant-care competencies, and some labour and birth outcomes were measured. The largest of the included studies (n = 1275) examined an educational and social support intervention to increase vaginal birth after caesarean section. This high-quality study showed similar rates of vaginal birth after caesarean section in 'verbal' and 'document' groups (relative risk 1.08, 95% confidence interval 0.97 to 1.21).

Authors' Conclusions: The effects of general antenatal education for childbirth or parenthood, or both, remain largely unknown. Individualized prenatal education directed toward avoidance of a repeat caesarean birth does not increase the rate of vaginal birth after caesarean section.

Major Reviews of Infant Feeding 2000-10

A list of major reviews followed by selected extracts

Reviews

Ip Breastfeeding and Maternal and Infant Health outcomes in developed countries (Ip, Chung et al. 2007; Ip, Chung et al. 2009)

Chung Ip Interventions in primary care to promote breastfeeding: an evidence review for the U.S. Preventive Services Task Force (Chung, Raman et al. 2008)

Kramer Cochrane Review Duration of Exclusive Breastfeeding (Kramer and Kakuma 2002)

Renfrew Breastfeeding promotion for Infants in Neonatal Units (Renfrew, Craig et al. 2009)

Horta (WHO) Evidence on the long term effects of breastfeeding (Horta, Bahl et al. 2007)

CDC. The CDC Guide to Breastfeeding Interventions (Shealy, Li et al. 2005)

CDC. Recommended Community Strategies and Measurements to Prevent Obesity in the United States (Centers for Disease Control and Prevention 2009)

Monasta Early-life determinants of overweight and obesity: a review of systematic reviews (Monasta, Batty et al. 2010)

Cattaneo Protection, promotion and support of breastfeeding in Europe: progress from 2002 to 2007 (Cattaneo, Burmaz et al. 2010)

WHO Documents:

Global Strategy for Infant Feeding (WHO-UNICEF) (WHO 2003)

WHO Systematic Review of Duration of Exclusive Breastfeeding (WHO 2001)

WHO Evidence for Ten Steps to Promote Breastfeeding (WHO/CHD 1998)

Infant and young Child Feeding – Model chapter (WHO 2009)

Acceptable medical reasons for the use of breast milk substitutes (WHO-UNICEF) (WHO 2009)

BFHI Principles revised 2009 (WHO/UNICEF 2009)

Global Health Risks (WHO) (WHO 2009)

Michaelson: Feeding and Nutrition of Infants and Young Children (WHO Euro Division) (Michaelsen, Weaver et al. 2000)

Guiding Principles for the complementary feeding of the breastfed child (PAHO) (Dewey 2000; WHO 2002)

Australian Documents:

Australia: The Healthiest Country by 2020 – National Preventative Health Strategy – the roadmap for action

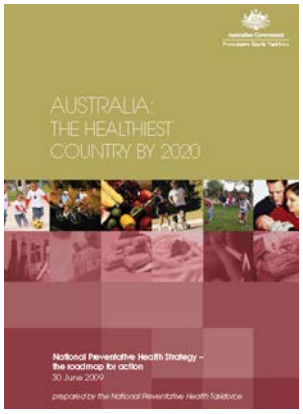
Australian Centre for Asthma Monitoring 2009. Asthma in Australian children: findings from *Growing Up in Australia*, the Longitudinal Study of Australian Children.

Australian Institute of Health and Welfare 2008. Making progress: the health, development and wellbeing of Australia's children and young people.

Australian Institute of Health and Welfare. A picture of Australia's children 2009.

Abstracts and summaries of reviews

Australia: The Healthiest Country by 2020 – National Preventative Health Strategy – the roadmap for action ISBN: 1-74186-919-6 Online ISBN: 1-74186-920-X Publications Number: P3 -5444 (c) Commonwealth of Australia 2009



Sections related to breastfeeding.

Pg. 38 Performance Indicators for Obesity, Tobacco and Alcohol Prevention

Health outcome measures (all to be reported by Indigenous status)

Deaths attributable to tobacco, alcohol, overweight and obesity

Hospital separations for tobacco, alcohol, overweight and obesity

Determinants of health measures (all to be reported by Indigenous status and by index of relative social disadvantage of place of residence)

Proportion of adults who are daily smokers

Proportion of adult smokers who have attempted to quit in last year or who intend to quit in next three months

Proportion of children who smoke at least weekly or monthly and proportion who have smoked at least 100 cigarettes

Proportion of adults and children who live in a home where anyone smokes indoors

Proportion of adults and children at risk of long-term harm from alcohol

Proportion of adults and children at risk of short-term harm from alcohol at least once a month

Proportion of adults and children overweight or obese

Proportion of adults and children eating sufficient daily serves of fruit and vegetables

Proportion of adults insufficiently physically active to obtain a health benefit

Proportion of people walking, cycling or using public transport to travel to work or school

Proportion of babies breastfed for six months or more

Pg. 44-46 Act early and throughout life

'A life-course perspective is essential for the prevention and control of noncommunicable diseases. This approach starts with maternal health and prenatal nutrition, pregnancy outcomes, exclusive breastfeeding for six months, and child and adolescent health; reaches children at schools, adults at worksites and other settings, and the elderly; and encourages a healthy diet and regular physical activity from youth into old age.'

The life course of individuals is shaped by their experiences in the earliest years of their life. The early childhood period has a profound impact on all aspects of development, and establishes the foundations of an individual's future development. Early childhood experiences may place children on health and developmental pathways that are costly and difficult to change. Therefore, children necessarily form the cornerstone of any prevention agenda. Research indicates that: *'virtually every aspect of early human development, from the brain's evolving circuitry to the child's capacity for empathy, is affected by the environments and experiences that are encountered, in a cumulative fashion, beginning in the prenatal period and extending throughout the early childhood years'.* In short, what happens to children at the earliest age has direct, identifiable outcomes in areas such as their health, life expectancy, the extent to which they rely on the economic and social support of

the community and their capacity to contribute productively to their society. Children with poorer health do significantly less well in school, complete fewer years of education, and have significantly poorer health as well as lower earnings as adults. Investments in children's health make significant differences not only to their health outcomes but also to a broad range of social, demographic and economic factors. There is strong evidence to show that investments that improve children's health lead to higher cognitive development and school attainment, increased propensity for parents to invest in children, reduced cost of medical care and increased participation of parents in the labour market; all of which are associated with improved economic performance and stronger economic growth as well as reduced inequality in societies studied. *'…from conception, the early years of a child's life influence health outcomes and life opportunities; an equitable start for all Australian children offers the best life chances for health and wellbeing in later years' (Quote from submission)*

The literature shows that 'making greater investment in children's health results in better educated and more productive adults, sets in motion favourable demographic changes, and shows that safeguarding health during childhood is more important than at any other age because poor health during children's early years is likely to permanently impaired them over the course of their life'. The significance of these findings is reinforced by epidemiological evidence that adult disease can be linked to factors as early in the life course as foetal nutrition. Babies born with low birth weight, especially small for gestation age, are at increased risk of hypertension, dyslipidaemia, insulin resistance, type 2 diabetes, ischemic heart disease and breast or prostate cancer in adult life. The impact of poor nutrition during pregnancy (as indicated by low birth weight) can be compounded by ongoing poor nutrition and poor early childhood circumstances. Studies have found that poor early childhood circumstances, including low income and family discord, interfere with healthy development and lead to increased risks of onset of asthma, hypertension, diabetes, coronary heart disease and stroke or heart attack in adults, as well as significantly increased risk of poor mental health. This same combination of conditions interferes with cognitive development and health capital in childhood, reduces educational attainment, and leads to worse labour market and health outcomes in adulthood. While it is true that Australia, like the United Kingdom and the United States, is a wealthy country with generally good social services, recent UNICEF figures indicate that we have little reason for complacency and much yet to do. UNICEF recently established benchmarks for OECD countries in infant mortality, birth weight and immunisation. Australia was below the benchmark in each of these three areas (see Figure 1.7 below).

Figure 1.8:

Australia's Performance Against UNICEF Benchmarks For Early Childhood Health

	Benchmark	Australia	Number of OECD countries which exceed / below benchmark
Infant mortality	< 4per 1000 live births	5 per 1000 live births	10/15
Low birthweight	< 6% below 2500 g	6.4% below 2500 g	8/17
Immunisation 12-23 months	Average rate 95%	Average rate 92.7%	10/15

Source: Adapted from UNICEF, (2008) 'The child care transition, *Innocenti Report Card 8*'. UNICEF Innocenti Centre, Florence.

While research has demonstrated that children's life courses can be significantly disrupted by poor early childhood experiences, it is also demonstrated that high-quality preventative programs can substantially change this life course. Although no single program has been identified as a 'magic bullet', there is substantial evidence that by acting early governments are in a position to ameliorate the effects of poor quality environments and intervene in the intergenerational transmission of disadvantage. In summarising this research, the National Scientific Council on the Developing Child has identified a number of core principles, which they have labelled 'effectiveness factors'. The first of these identifies that access to basic medical care for pregnant women and children can help prevent threats to healthy development as well as provide early diagnosis and appropriate management as problems emerge. Evidence supporting this factor includes the positive effects of adequate prenatal and early childhood nutrition on healthy brain development, and the developmental benefits for very young children when parental problems such as maternal depression are identified and treated effectively. Similarly, there is extensive research to indicate that children's participation in quality early childhood programs can make a substantial difference to cognitive and social outcomes. Longitudinal studies in the United States, following significantly disadvantaged families, have demonstrated substantial differences in wellbeing, income, social participation and adjustment between adults who experienced high-quality early childhood programs compared to those who did not. Taken as a whole, the extensive research on early childhood gives Australia an excellent platform from which to reform and further develop its service systems for children and their families. P128-9
Breastfeeding and early growth patterns provide the only period in which there is clear evidence to support the concept of a critical period of development associated with long-term consequences. Other stages of childhood, however, may offer good opportunities to *modify* behaviour. For example, there is limited evidence that behaviours such as liking fruit and vegetables can be established in early childhood. Breastfed babies show slower growth rates than formula-fed babies, and this may contribute to the reduced risk of obesity later in life shown by breastfed babies. Observational studies suggest a longer duration of breastfeeding to be associated with a decrease in the risk of overweight in later life. As a result, in Europe and the United States high priority has been placed on research strategies investigating the effects of breastfeeding to prevent the development of obesity.
In addition to the protective role breastfeeding may have in several chronic diseases, breastfeeding (including delaying the introduction of solids until babies are six months old) plays an important role in helping to prevent obesity in children. This has been attributed to physiological factors in human milk as well as feeding and parenting patterns associated with breastfeeding. Weaning practices are also thought to be important, given the association between the characteristic weight gain seen in early childhood at approximately five years of age (early adiposity rebound) and later obesity.
The proportion of children receiving breast milk declines steadily with age. While the proportion of Australian infants ever breastfed was around 86–88% between 1995 and 2005, in 2001 less than half (48%) of all infants were receiving any breast milk at the age of six months, and none were being exclusively breastfed. In 2001, the proportion of Australian children receiving breast milk was higher among more highly educated and older mothers (aged over 30 years). Indigenous mothers in non-remote areas appear to be less likely to initiate and continue breastfeeding than other Australian mothers. There is a need to ensure the development of targeted interventions to improve maternal and child health among low SES and Indigenous women, as well as for younger and less educated mothers, particularly in regard to increasing levels and duration of breastfeeding.
The national toll-free breastfeeding helpline was recently upgraded (March 2009) to provide 24-hour support and breastfeeding information through Australian Government funding.

Funding has also been allocated to providing training for health professionals and research to support breastfeeding, including barriers and enablers to breastfeeding, indicators of breastfeeding rates and the development of dietary guidelines for pregnant and breastfeeding women. It is recognised that the Taskforce should work with other relevant groups to ensure the implementation of programs in maternal and child health that are likely to deliver benefits in relation to obesity prevention.

Action 7.1 ***Establish and implement a national program to alert and support pregnant women and those planning pregnancy to the 'lifestyle' risks of excessive weight, insufficient physical activity, poor nutrition, smoking and excessive alcohol consumption.***
Action 7.2 ***Support the development and implementation of a National Breastfeeding Strategy in collaboration with the state and territory governments.***

Pg. 133 Antenatal, maternal and child health Services
Poor nutrition in the first years of life and low birth weight are associated with lifetime higher rates of overweight and obesity, and increased risk of chronic disease later in life. Well-resourced and best-practice antenatal, maternal and child health services are a core component of comprehensive primary healthcare, and should include antenatal care, encouragement and support of breastfeeding, programs to monitor infant growth and development, support and advice to parents about child nutrition, and child growth monitoring and action. All primary healthcare services serving Indigenous communities should be resourced to deliver such services as a critical investment in future health. There are numerous examples of health services that have acted on maternal and child health effectively, including Central Australian Aboriginal Congress, the Townsville Aboriginal and Islander Health Service, Nganampa Health Council, Maari Ma Health Aboriginal Corporation and the Northern Territory Government's *Strong Women, Strong Babies, Strong Culture*.
Pg. 248 Guideline 4: Pregnancy and breastfeeding: A.
For women who are pregnant or planning pregnancy, not drinking is the safest option. B. For women who are breastfeeding, not drinking is the safest option.

Australian Centre for Asthma Monitoring 2009. Asthma in Australian children: findings from *Growing Up in Australia*, the Longitudinal Study of Australian Children. Cat. no. ACM 17. Canberra: AIHW. ISBN 978 1 74024 960 7

Asthma in Australian children

Findings from *Growing Up in Australia*, the Longitudinal Study of Australian Children

October 2009

This report presents results from ACAM's analysis of data from Growing Up in Australia: the Longitudinal Study of Australian Children. There are two cohorts, anInfant cohort n=5,107 and a kindergarten cohort of n=4,983. Follow-up rates approximated 90%

P17 Exclusive breastfeeding of infants from birth to six months is recommended for short- and long-term health benefits, including a reduction in respiratory infections (Kramer & Kakuma 2004; NHMRC 2003). To date, findings on the effect of breastfeeding on the development of asthma are inconsistent. Some studies have associated breastfeeding with a reduction in the incidence of childhood asthma (Chandra 1997; McVeagh 2002; Oddy 2000; Oddy et al. 1999; Saarinen & Kajosaari 1995), while a number suggest breastfeeding is ineffective in reducing asthma (Mihrshahi et al. 2007; Wright & Holberg 2000) and others have even indicated that breastfeeding could potentially be a risk factor (Duncan & Sears 2008; Sears et al. 2002). Some of the observed differences are explained by different ages at which wheeze or asthma outcomes were assessed. Those studies assessing wheeze before age five years have tended to demonstrate a protective effect, whereas those examining the impact of breastfeeding on asthma in school-age children or later have not shown this beneficial effect. Data from the LSAC suggests a strong protective effect of breastfeeding on wheezing in infancy, which increases with increasing breastfeeding duration. In fact, our results indicate that any duration of breastfeeding can protect infants from developing wheeze or asthma. We found that after adjusting for all other factors, the dose-response effect remained statistically significant ($p = 0.0008$). These results reflect those of the Canadian National Longitudinal Survey of Children and Youth which illustrated that the protective effect of breastfeeding was higher as duration of breastfeeding increased (Dell & To 2001).

Table A.2: Independent baseline risk factors for wheeze or asthma by 2 year follow-up in the infant cohort (multivariable analysis, n=3,913)

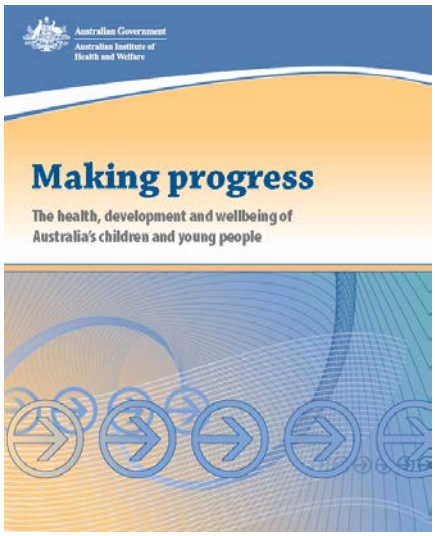
Any breastfeeding			<0.0001
Not breastfed	1.00		
Less than 2 months	0.90	0.64–1.23	
2 to 4 months	0.73	0.53–1.00	
5 to 6 months	0.67	0.47–0.96	
7 to 12 months	0.59	0.43–0.80	
More than 12 months	0.56	0.41–0.78	

Summary of findings

• The development of wheeze or asthma in early life is associated with factors that have been linked, directly or indirectly, to reduced airway function. These include exposure to tobacco smoke, being male, child care attendance, presence of older siblings, maternal age, gestational age and admission to NICU.

• Longer duration of breastfeeding within the first 12 months of life is associated with a reduced risk of wheeze or asthma during infancy.

Australian Institute of Health and Welfare 2008. Making progress: the health, development and wellbeing of Australia's children and young people. Cat. no. PHE 104. Canberra: AIHW. ISBN 978 1 74024 835 8



Note: Caution needs to be exercised in interpreting the information given in this document as the definitions of breastfeeding used may not be standard ones. For example sometimes exclusive breastfeeding may be determined on the basis of the infant's feeds in the past 24 hours instead of since birth. Retrospective data may also give different results to longitudinal cohort studies.

Breastfeeding

Measure: Percentage of infants fully or exclusively breastfed at 4 and 6 months of age

Breastfeeding is extremely important in promoting healthy development in children. Breast milk provides the best nutritional start for infants and helps to protect against infectious disease.[47] Breastfeeding is also associated with long-term benefits, including improved cognitive development and protection against immune-related diseases such as Type 1 diabetes, celiac disease, inflammatory bowel disease and possibly some forms of cancer.[48] Breastfeeding has many positive health effects for mothers, as well as encouraging bonding between mother and child.[49]

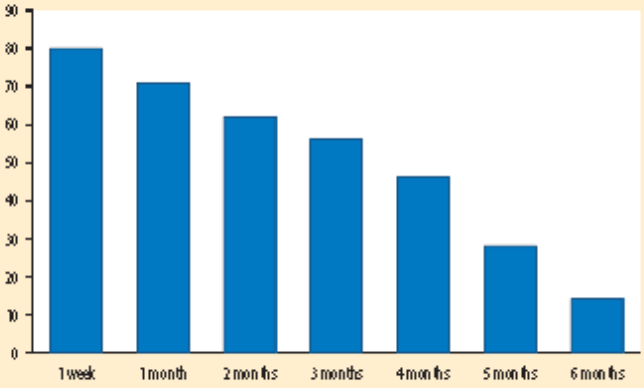
'Exclusive' breastfeeding is defined as the infant receiving only breast milk and no other food or drink, including water, while 'fully' breastfeeding infants can receive other fluids such as juice or water. The Australian dietary guidelines for children and adolescents recommend exclusive breastfeeding of infants until around 6 months of age to achieve optimal growth, development and health.[49]

Currently, Australia has no reliable national data collection to effectively monitor infant feeding practices, and the inconsistent use of definitions and terms makes it difficult to compare studies of the rates of breastfeeding.

The proportion of infants exclusively breastfed at 4 months of age has been endorsed by Health, Community and Disability Services Ministers as a Headline Indicator of children's health, development and wellbeing.[3]

- 46% of infants were fully breastfed at 4 months of age, falling to 14% at 6 months, according to a longitudinal study of infants in 2004.

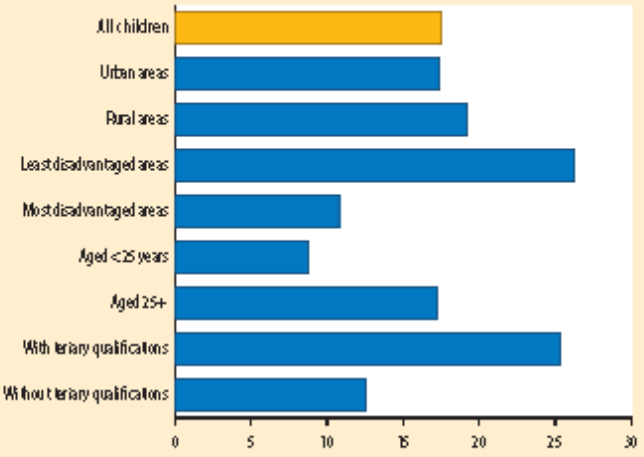
Percentage of 0–1 year olds fully breastfed, by age, 2004



Source: Growing up in Australia: The Longitudinal Study of Australian Children, AIFS 2008.[47]

- According to state surveys, 18% of children in NSW[51] (2005–06) and 15% in Victoria[50] (2006) had been exclusively breastfed up to 6 months of age.
- Exclusive breastfeeding rates in NSW were substantially lower for infants with mothers younger than 25, mothers without tertiary qualifications and those living in areas of the greatest socioeconomic disadvantage.

Percentage of 0–4 year olds who were exclusively breastfed at 6 months, NSW, 2005–06



Source: NSW Child Health Survey, Centre for Epidemiology and Research 2008.[51]

Key messages

- Rates of breastfeeding decline substantially within the first 6 months after birth.
- One in seven infants were fully breastfed at 6 months of age, and there is currently no national data available on exclusive breastfeeding.
- Rates of exclusive breastfeeding in NSW were half as high among younger and less educated women, and women living in the most disadvantaged areas.

Australian Institute of Health and Welfare 2009.
A picture of Australia's children 2009. Cat. no. PHE 112. Canberra: AIHW. ISBN 978 1 74024 929 4

Globally, deaths of children under 5 years have reached a record low, falling below 10 million per year in 2006 from almost 13 million in 1990. Much of the progress is a result of the widespread adoption of basic health interventions, such as early and exclusive breastfeeding, immunisation against once-common and deadly childhood infectious diseases, and improved nutrition (UNICEF 2007a). Australia has also shown significant progress in reducing infant and child deaths, particularly as a result of the work of neonatal intensive care units, increased community awareness of the risk factors for sudden infant death syndrome (SIDS), and reductions in vaccine-preventable diseases through national childhood immunisation programs.

Breastfeeding

Breastfeeding promotes the healthy growth and development of infants and young children and is also associated with economic benefits. No national data are currently available on 'exclusive' breastfeeding of infants up to 4 or 6 months of age.

Breastfeeding is the normal way to feed infants and is important in promoting the healthy growth and development of infants and young children. Infants are born with an immune system that is not fully developed and breast milk (containing mothers' antibodies) provides the best nutritional start for infants, reducing the risk of morbidity and mortality from infectious diseases. There is a large volume of research on the health benefits of breastfeeding in infancy and childhood, but it has been difficult to establish a causal relationship. There is convincing evidence that breastfeeding protects infants against infectious diseases, including gastrointestinal illness, respiratory tract infections and middle ear infections. Other possible benefits include a reduced risk of SIDS, Type 1 diabetes and some childhood cancers; however, further research is required.

There is conflicting evidence as to whether breastfeeding has a protective effect against asthma and other allergies in childhood (Kramer et al. 2007). There is some evidence that

having been breastfed may reduce the incidence of high cholesterol, high blood pressure, obesity and diabetes later in life, and improve cognitive development (Horta et al. 2007). More exclusive and longer periods of breastfeeding show the strongest associations between breastfeeding, lower rates of infant illnesses and better cognitive development. The benefits of breastfeeding also extend to the mother. These include quicker recovery after childbirth, reduced risk of ovarian cancer and possible reduced risk of breast cancer, post-menopausal hip fractures, osteoporosis and maternal depression, although further research is required (Ip, Chung et al. 2007); Productivity Commission 2008).

Evidence is also accumulating to show that breastfeeding improves mother–infant bonding and secure attachment between mother and child (Allen & Hector 2005). Economically, the benefits of breastfeeding relate to health-care costs, productivity and household expenses. Where an infant is not breastfed or is weaned prematurely, a number of studies have found an increase in health-care costs for associated infant illnesses (for example, gastrointestinal illness) (Productivity Commission 2008). Productivity may be reduced as a result of parental absences from work due to infant illness (León-Cava et al. 2002). Breastfeeding has been endorsed by the AHMC, CDSMC and the AESOC as a Children's Headline Indicator priority area (see *Part X* for further information).

Recommendations for breastfeeding

The WHO recommends that all infants should be exclusively breastfed up to 6 months of age to achieve optimal growth, development and health (WHO 2002) (see Box 9.1 for breastfeeding definitions used in this chapter). Infants who are exclusively breastfed up to 6 months do not show any deficits in weight or length gain and thus there are no apparent risks associated with recommending exclusive breastfeeding for the first 6 months of life as a public health policy. The Australian Dietary Guidelines for Children and Adolescents (NHMRC 2003a) also recommend exclusive breastfeeding until around 6 months of age, and note that breastfeeding to 12 months and beyond has continuing value to both infant and mother. These recommendations are based on the nutritional, health, social and economic benefits of breastfeeding

How many Australian babies are breastfed?

Difficulties in measurement arise in relation to the recommendation of exclusive breastfeeding to around 6 months of age, as solids are often introduced to the infant around this time. As such, issues around the age of infants in any sample need to be considered carefully in order to collect robust and policy relevant information on exclusive breastfeeding. For this reason, the age of 4 months has been specified for the Children's Headline Indicator until such a time as reliable national data can be collected on exclusive breastfeeding 'up to' 6 months of age (Vic DHS 2008). A further difficulty relates to maternal long-term recall of feeding practices. Currently, Australia has no reliable national data collection system to effectively monitor infant feeding practices, and the inconsistent use of definitions and terms makes it difficult to compare studies of breastfeeding rates (House of Representatives Standing Committee on Health and Ageing 2007; Webb et al. 2001).

Information on breastfeeding is therefore patchy in Australia: Data on exclusive breastfeeding are currently available for New South Wales, Victoria, Queensland and Western Australia, but not at 4 months of age. National data are available at 4 months of age from the Growing up in Australia: the Longitudinal Study of Australian Children (LSAC). However, this is for predominantly (fully) breastfed infants, rather than exclusively breastfed. National data are available from the ABS 2004–05 National Health Survey, but this is for a

combined measure of exclusive or complementary breastfeeding. Information from these data sources are presented here, although none is currently suitable for reporting on the Children's Headline Indicator at the national level. The Australian Government is planning to conduct an Australian National Infant Feeding Survey in 2009.

Exclusively breastfed Four Australian states have collected information on exclusive breastfeeding; however, none collected this information at 4 months of age. Due to different survey methods, the results between these states should not be directly compared.

In Queensland, according to the 2006–2007 Infant Nutrition Project, 38% of infants were exclusively breastfed at 2 months of age, declining to 10% at 5 months of age. This was based on mothers' 24-hour recall of infant-feeding practices (Queensland Health: Paul et al. 2007).

Among Victorian children under 2 years in 2006, 48% were exclusively breastfed at 3 months of age, declining to 15% at 6 months of age (Vic DHS 2006).
In New South Wales, 18% of children aged 0–4 years were exclusively breastfed at 6 months of age in 2005–06 (NSW Department of Health 2008).
In Western Australia in 2006–07, 12% of children aged 0–4 years were exclusively breastfed for 6 months or more (Wood & Daly 2007).

Predominantly breastfed
The LSAC provides information on predominant breastfeeding for a cohort of 5,000 infants aged 0–1 year in 2004 (AIFS 2008). For this cohort, the proportion of infants predominantly breastfed decreased from 91% at birth to 46% at 4 months and 14% at 6 months of age (Figure 9.1). Notably, the proportion of predominantly breastfed infants dropped by 11 percentage points between birth and 1 week of age. As the proportion of infants predominantly breastfed declined with age, the proportion of infants receiving complementary breast milk increased. At 6 months of age, 40% of infants were complementary breastfed, compared with 11% at 1 month.

Exclusive or complementary breastfeeding
Nationally in 2004–05, an estimated 88% of children aged 0–3 years had been breastfed at some point. However, the proportion that are breastfed (either exclusive or complementary) decreases as the age of the infant increases. Of children aged 1 year in 2004–05, 86% were reported to have been breastfed at less than 1 month of age, but only 57% were still being breastfed at 4 months and only half (51%) at 6 months of age (AIHW analysis of ABS 2004–05 National Health Survey confidentialised unit record file).

Do rates of breastfeeding vary across population groups?
Currently, there are no national data available on exclusive breastfeeding for Indigenous infants or infants in remote or low socioeconomic status areas. National data on exclusive or complementary breastfeeding and state-based data for exclusive breastfeeding are presented here.

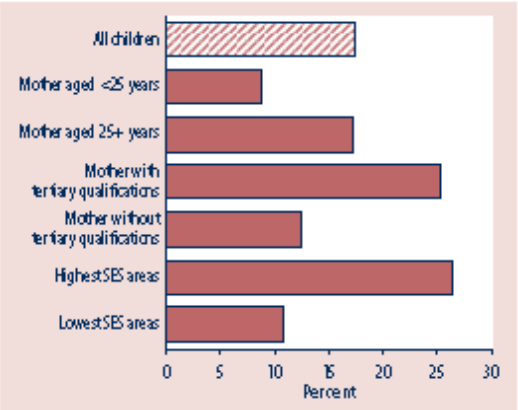
Nationally, of Indigenous children aged 1 year in 2004–05 in non-remote areas, an estimated 80% were breastfed (either exclusive or complementary) at less than 1 month of age, dropping to 62% and 48% at 4 and 6 months of age, respectively. The corresponding proportions for non-Indigenous infants were 88%, 58% and 52% (AIHW analysis of ABS 2004–05 National Aboriginal and Torres Strait Islander Health Survey).

With regard to exclusive breastfeeding, according to the 2000–2002 Western Australian Aboriginal Child Health Survey, over half (53%) of Indigenous infants aged less than 6 months were reported as being exclusively breastfed, dropping to 7% at age 6–11 months (Zubrick et al. 2004).

According to the 2005–06 New South Wales Population Health Survey, exclusive breastfeeding of children at 6 months of age was statistically significantly lower for infants with mothers – without tertiary qualifications (13% compared with 25% for those with tertiary qualifications) – living in the lowest socioeconomic status (SES) areas (11% compared with 26% for those in the highest SES areas) – aged younger than 25 years (9% compared with 17% for mothers aged 25 years and over) (Figure 9.2) (NSW Department of Health 2008).

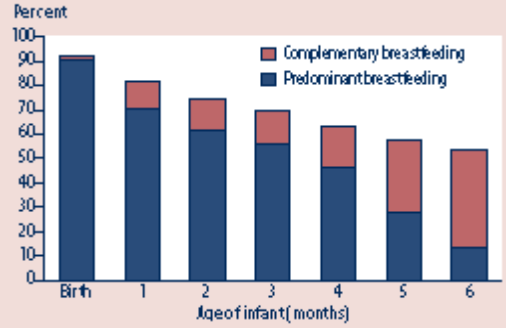
Employment and breastfeeding

There is some evidence that a mother's employment status and number of hours worked influences the initiation and duration of breastfeeding. Studies from the United Kingdom and the United States have found that mothers who plan on returning to work while their infant is relatively young are less likely to start breastfeeding than mothers who either do not return to work, or who plan on returning to work when the infant is older (Chatterji & Frick 2005; Hawkins et al. 2007; Noble & The ALSPAC Study Team 2001). It has also been found that mothers who initiate breastfeeding and return to work while the infant is young have a reduced duration of breastfeeding (Chatterji & Frick 2005). Australian research, based on the LSAC, found that women not in paid employment were more likely to breastfeed their infant at 6 months of age than employed women (56% compared with 39% and 44% of mothers working full and part time, respectively). The lowest rates of breastfeeding at 6 months were among those where the mother resumed full-time employment before 3 months (42%) or between 3 and 6 months (39%) (Cooklin et al. 2008). Data from the LSAC also show that the type of employment may influence breastfeeding. Infants were more likely to be breastfed at 6 months of age if their mother was self-employed (58%), compared with permanent or casual employment (45% and 49%, respectively) (AIFS 2008).



Note: See Appendix 7 Method for explanation of SES.
Source: NSW Department of Health 2008.

Figure 9.2: Proportion of 0–4 year olds exclusively breastfed at 6 months, New South Wales, 2005–06



Source: Growing up in Australia: the Longitudinal Study of Australian Children, Waves 1 and 2 (birth cohort) (AIFS 2008).

Figure 9.1: Breastfeeding practices for children aged 0–1 years, by month of age, 2004

Box 9.1: Definitions of breastfeeding

'Exclusive breastfeeding' requires that the infant receive only breastmilk (including milk expressed or from a wet nurse), with the exception of oral rehydration solutions, drops or syrup (consisting of vitamins, minerals and medicines). This excludes non-human milk or formula.

'Predominant breastfeeding' requires that the infant receive breastmilk (including milk expressed or from a wet nurse) as the predominant source of nourishment. The infant may also receive water or water-based drinks, fruit juice, oral rehydration solutions, drops or syrup (consisting of vitamins, minerals and medicines), but not non-human milk or formula. Predominantly breastfed may also be referred to as 'fully breastfed' in some sources.

'Complementary breastfeeding' requires that the infant receive breastmilk (including milk expressed or from a wet nurse) and solid or semi-solid food. This means that the infant may receive any food or liquid, including non-human milk and formula, in addition to breastmilk. Complementary breastfeeding may also be referred to as 'partial breastfeeding' in some sources.

Source: WHO 2008a.

Note: These definitions are applied in different ways to different studies in Australia.

WHO Acceptable reasons for the use of breast milk substitutes (WHO-UNICEF)
WHO/NMH/NHD/09.01, 2009 Web: *www.who.int/child_adolescent_health/*
World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland

Infants who should not receive breast milk or any other milk except specialized formula

- Infants with classic galactosemia: a special galactose-free formula is needed.
- Infants with maple syrup urine disease: a special formula free of leucine, isoleucine and valine is needed.
- Infants with phenylketonuria: a special phenylalanine-free formula is needed (some breastfeeding is possible, under careful monitoring).

Infants for whom breast milk remains the best feeding option but who may need other food in addition to breast milk for a limited period

- Infants born weighing less than 1500 g (very low birth weight).
- Infants born at less than 32 weeks of gestational age (very pre-term).
- Newborn infants who are at risk of hypoglycaemia by virtue of impaired metabolic adaptation or increased glucose demand (such as those who are preterm, small for gestational age or who have experienced significant intrapartum hypoxic/ischaemic stress, those who are ill and those whose mothers are diabetic) if their blood sugar fails to respond to optimal breastfeeding or breast-milk feeding.

Maternal conditions that may justify permanent avoidance of breastfeeding

- HIV infection: if replacement feeding is acceptable, feasible, affordable, sustainable and safe.

Maternal conditions that may justify temporary avoidance of breastfeeding

- Severe illness that prevents a mother from caring for her infant, for example sepsis.
- Herpes simplex virus type 1 (HSV-1): direct contact between lesions on the mother's breasts and the infant's mouth should be avoided until all active lesions have resolved.
- Maternal medication: see information for specific drugs. *(For most drugs the risk is less than not breastfeeding)*

Maternal conditions during which breastfeeding can still continue, although health problems may be of concern

- Breast abscess: breastfeeding should continue on the unaffected breast; feeding from the affected breast can resume once treatment has started.
- Hepatitis B: infants should be given hepatitis B vaccine, within the first 48 hours or as soon as possible thereafter.
- Hepatitis C.
- Mastitis: if breastfeeding is very painful, milk must be removed by expression to prevent progression of the condition.
- Tuberculosis: mother and baby should be managed according to national tuberculosis guidelines.
- Substance use: Specific information is needed for each substance. Mothers should be encouraged not to use these substances, and given opportunities and support to abstain.

BFHI Principles revised 2009 (WHO-UNICEF)

The Baby-friendly Hospital Initiative was conceived in the early 1990s in response to the 1990 Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding call for action. Since the Baby-Friendly Hospital Initiative (BFHI) was launched by UNICEF and WHO in 1991-1992, the Initiative has grown, with more than 20,000 hospitals having been designated in 156 countries around the world over the last 15 years. The BFHI has measurable and proven impact, however, it is clear that only a comprehensive, multi-sector, multi-level effort to protect, promote and support optimal infant and young child feeding, including legislative protection, social promotion and health worker and health system support via BFHI and additional approaches, can hope to achieve and sustain the behaviours and practices necessary to enable every mother and family to give every child the best start in life.

The 2002 WHO/UNICEF *Global Strategy for Infant and Young Child Feeding* (GSIYCF) calls for renewed support - with urgency - for exclusive breastfeeding from birth for 6 months, and continued breastfeeding with timely and appropriate complementary feeding for two years or longer.
The nine operational areas of the Global Strategy are:
1. Appoint a national breastfeeding co-ordinator, and establish a breastfeeding committee.
2. Ensure that every maternity facility practices the *Ten Steps to Successful Breastfeeding.*
3. Take action to give effect to the International Code of Marketing of Breast-milk Substitutes and subsequent relevant resolutions of the World Health Assembly.
4. Enact imaginative legislation protecting the breastfeeding rights of working women.
5. Develop, implement, monitor and evaluate a comprehensive policy covering all aspects of infant and young child feeding.
6. Ensure that the health care system and other relevant sectors protect, promote and support exclusive breastfeeding for six months and continued breastfeeding for up to two years of age or beyond, while providing women with the support that they require to achieve this goal, in the family, community and workplace.
7. Promote timely, adequate, safe and appropriate complementary feeding with continued breastfeeding.
8. Provide guidance on feeding of infants and young children in exceptionally difficult circumstances, which include emergencies and parental HIV infection.
9. Consider what new legislation or other suitable measures may be required to give effect to the principles and aim of the International Code of Marketing of Breast milk Substitutes and to subsequent relevant World Health Assembly resolutions.

Ten Steps to Successful Breastfeeding
Every facility providing maternity services and care for newborn infants should:
1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within a half-hour of birth.
5. Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breast milk unless *medically* indicated.
7. Practise rooming in - allow mothers and infants to remain together - 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

In 2005, the fifteenth anniversary of the Innocenti Declaration, an assessment of progress and challenges was carried out, culminating in a second Innocenti Declaration 2005 on Infant and Young Child Feeding, highlighting the importance of early initiation of breastfeeding, suggesting ways to strengthen action on breastfeeding and outlining urgent activities for the nine operational areas of the Global Strategy.

There is an extensive set of BFHI documents available detailing the steps to be taken for national plans as well as specific training modules for health staff.

WHO Global health risks: mortality and burden of disease attributable to selected major risks. WHO Geneva 2009 ISBN 978 92 4 156387 1

This document is an update of previous WHO analysis of the global burden of disease and risks. The data base is updated to include 2004 data.

Pg. v (summary)

"A total of 10.4 million children died in 2004, mostly in low- and middle-income countries. An estimated 39% of these deaths (4.1 million) were caused by micronutrient deficiencies, underweight, suboptimal breastfeeding and preventable environmental risks. Most of these preventable deaths occurred in the WHO African Region (39%) and the South-East Asia Region (43%)".

The main changes in the 2004 estimates are as follows:

Risk factor exposure estimates were revised if new estimates were available. For some risk factors (see Annex A) previously estimated population exposures were used.

Where a recent peer-reviewed meta-analysis was available, relative risks from the 2000 CRA analysis were updated. Likewise, some minor revisions to methods based on peer-reviewed publications from WHO programmes or collaborating academic groups were incorporated and are explained in Annex A.

Two additional risk factors have been included: suboptimal breastfeeding and high blood glucose, based on published peer-reviewed work.

Pg. 9

In low-income countries, relatively few risks are responsible for a large percentage of the high number of deaths and loss of healthy years. These risks generally act by increasing the incidence or severity of infectious diseases. The leading risk factor for low-income countries is underweight, which represents about 10% of the total disease burden. In combination, childhood underweight, micronutrient deficiencies (iron, vitamin A and zinc) and suboptimal breastfeeding cause 7% of deaths and 10% of total disease burden. The combined burden from these nutritional risks is almost equivalent to the entire disease and injury burden of high-income countries.

Figure 6: Deaths attributed to 19 leading risk factors, by country income level, 2004.

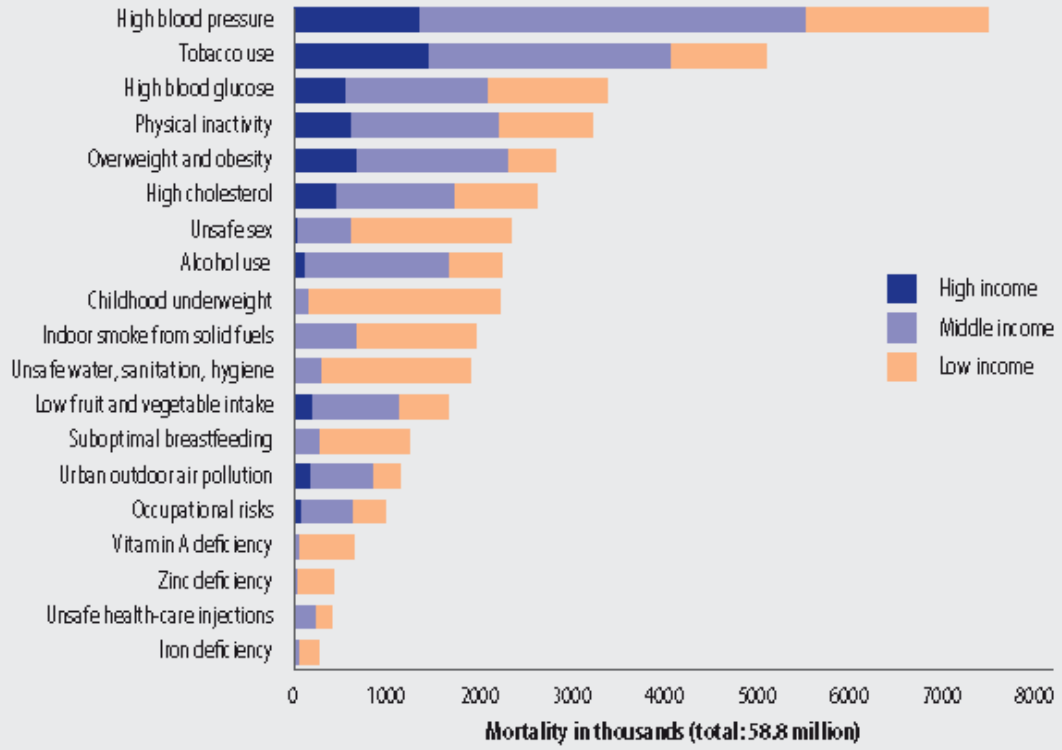


Figure 7: Percentage of disability-adjusted life years (DALYs) attributed to 19 leading risk factors, by country income level, 2004.

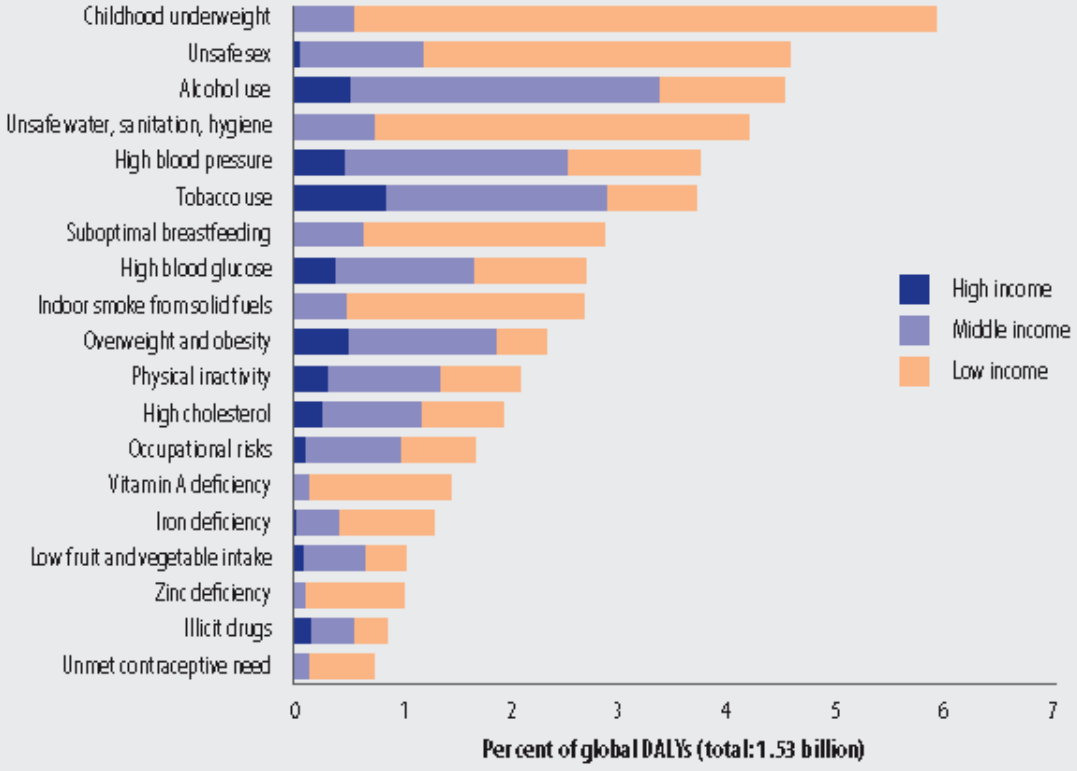


Table 1: Ranking of selected risk factors: 10 leading risk factor causes of death by income group, 2004

	Risk factor	Deaths (millions)	Percentage of total		Risk factor	Deaths (millions)	Percentage of total
	World				*Low-income countries*[a]		
1	High blood pressure	7.5	12.8	1	Childhood underweight	2.0	7.8
2	Tobacco use	5.1	8.7	2	High blood pressure	2.0	7.5
3	High blood glucose	3.4	5.8	3	Unsafe sex	1.7	6.6
4	Physical inactivity	3.2	5.5	4	Unsafe water, sanitation, hygiene	1.6	6.1
5	Overweight and obesity	2.8	4.8	5	High blood glucose	1.3	4.9
6	High cholesterol	2.6	4.5	6	Indoor smoke from solid fuels	1.3	4.8
7	Unsafe sex	2.4	4.0	7	Tobacco use	1.0	3.9
8	Alcohol use	2.3	3.8	8	Physical inactivity	1.0	3.8
9	Childhood underweight	2.2	3.8	9	Suboptimal breastfeeding	1.0	3.7
10	Indoor smoke from solid fuels	2.0	3.3	10	High cholesterol	0.9	3.4
	Middle-income countries[a]				*High-income countries*[a]		
1	High blood pressure	4.2	17.2	1	Tobacco use	1.5	17.9
2	Tobacco use	2.6	10.8	2	High blood pressure	1.4	16.8
3	Overweight and obesity	1.6	6.7	3	Overweight and obesity	0.7	8.4
4	Physical inactivity	1.6	6.6	4	Physical inactivity	0.6	7.7
5	Alcohol use	1.6	6.4	5	High blood glucose	0.6	7.0
6	High blood glucose	1.5	6.3	6	High cholesterol	0.5	5.8
7	High cholesterol	1.3	5.2	7	Low fruit and vegetable intake	0.2	2.5
8	Low fruit and vegetable intake	0.9	3.9	8	Urban outdoor air pollution	0.2	2.5
9	Indoor smoke from solid fuels	0.7	2.8	9	Alcohol use	0.1	1.6
10	Urban outdoor air pollution	0.7	2.8	10	Occupational risks	0.1	1.1

[a] Countries grouped by gross national income per capita – low income (US$ 825 or less), high income (US$ 10066 or more).

Table 2: Ranking of selected risk factors: 10 leading risk factor causes of DALYs by income group, 2004

	Risk factor	DALYs (millions)	Percentage of total		Risk factor	DALYs (millions)	Percentage of total
	World				*Low-income countries*[a]		
1	Childhood underweight	91	5.9	1	Childhood underweight	82	9.9
2	Unsafe sex	70	4.6	2	Unsafe water, sanitation, hygiene	53	6.3
3	Alcohol use	69	4.5	3	Unsafe sex	52	6.2
4	Unsafe water, sanitation, hygiene	64	4.2	4	Suboptimal breastfeeding	34	4.1
5	High blood pressure	57	3.7	5	Indoor smoke from solid fuels	33	4.0
6	Tobacco use	57	3.7	6	Vitamin A deficiency	20	2.4
7	Suboptimal breastfeeding	44	2.9	7	High blood pressure	18	2.2
8	High blood glucose	41	2.7	8	Alcohol use	18	2.1
9	Indoor smoke from solid fuels	41	2.7	9	High blood glucose	16	1.9
10	Overweight and obesity	36	2.3	10	Zinc deficiency	14	1.7
	Middle-income countries[a]				*High-income countries*[a]		
1	Alcohol use	44	7.6	1	Tobacco use	13	10.7
2	High blood pressure	31	5.4	2	Alcohol use	8	6.7
3	Tobacco use	31	5.4	3	Overweight and obesity	8	6.5
4	Overweight and obesity	21	3.6	4	High blood pressure	7	6.1
5	High blood glucose	20	3.4	5	High blood glucose	6	4.9
6	Unsafe sex	17	3.0	6	Physical inactivity	5	4.1
7	Physical inactivity	16	2.7	7	High cholesterol	4	3.4
8	High cholesterol	14	2.5	8	Illicit drugs	3	2.1
9	Occupational risks	14	2.3	9	Occupational risks	2	1.5
10	Unsafe water, sanitation, hygiene	11	2.0	10	Low fruit and vegetable intake	2	1.3

[a] Countries grouped by 2004 gross national income per capita – low income (US$ 825 or less), high income (US$ 10 066 or more).

Table 3: Deaths and DALYs attributable to six risk factors for child and maternal undernutrition, and to six risks combined; countries grouped by income, 2004

Risk	World	Low income	Middle income
Percentage of deaths			
Childhood underweight	3.8	7.8	0.7
Suboptimal breastfeeding	2.1	3.7	1.1
Vitamin A deficiency	1.1	2.2	0.3
Zinc deficiency	0.7	1.5	0.2
Iron deficiency	0.5	0.8	0.2
Iodine deficiency	0.0	0.0	0.0
All six risks	6.6	12.7	2.1
Percentage of DALYs			
Childhood underweight	6.0	9.9	1.5
Suboptimal breastfeeding	2.9	4.1	1.7
Vitamin A deficiency	1.5	2.4	0.4
Zinc deficiency	1.0	1.7	0.3
Iron deficiency	1.3	1.6	1.0
Iodine deficiency	0.2	0.2	0.3
All six risks	10.4	15.9	4.4

Suboptimal breastfeeding

Breast milk is the healthiest source of nutrition for infants. WHO recommends that infants should be exclusively breastfed during their first 6 months, and continue to receive breast milk through their first 2 years. In developing countries, only 24–32% of infants are exclusively breastfed at 6 months on average, and these percentages are much lower in developed countries. Rates of any breastfeeding are much higher, particularly in Africa and South-East Asia, with over 90% of infants aged 6–11 months breastfed.

Breastfeeding reduces the risk of many perinatal infections, acute lower respiratory infections and diarrhoea in infants below 23 months. Despite the higher prevalence of breastfeeding found in the developing world, developing countries bear more than 99% of the burden of suboptimal breastfeeding. Suboptimal breastfeeding is responsible for 45% of neonatal infectious deaths, 30% of diarrhoeal deaths and 18% of acute respiratory deaths in children under 5 years.

Iodine deficiency

Iodine is essential for thyroid function. Iodine deficiency is one of the most easily preventable causes of mental retardation and developmental disability. Maternal iodine deficiency has also been associated with lower mean birth weight, increased infant mortality, impaired hearing and motor skills.

Although salt iodization and iodine supplementation programmes have reduced the number of countries where iodine deficiency remains a problem, about 1.9 billion people – 31% of the world population – do not consume enough iodine. The most affected WHO regions are South-East Asia and Europe *(13)*. The direct sequelae of iodine deficiency, such as goitre, cretinism and developmental disability, resulted in 3.5 million DALYs (0.2% of the total) in 2004.

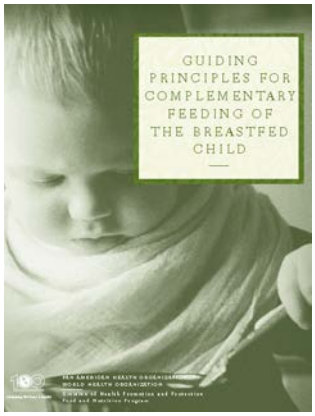
Risks for child health

In 2004, 10.4 million children under 5 years of age died: 45% in the WHO African Region and 30% in the South-East Asia Region. The leading causes of death among children under 5 years of age are acute respiratory infections and diarrhoeal diseases, which are also the leading overall causes of loss of healthy life years. Child underweight is the leading individual risk for child deaths and loss of healthy life years, causing 21% of deaths and DALYs. Child underweight, together with micronutrient deficiencies and suboptimal breastfeeding, accounted for 35% of child deaths and 32% of loss of healthy life years worldwide. Unsafe water, sanitation and hygiene, together with indoor smoke from solid fuels, cause 23% of child deaths. These environmental risks, together with the nutritional risks and suboptimal breastfeeding, cause 39% of child deaths worldwide.

Suboptimal breastfeeding

We based our analysis on the methods of Black et al., who recently published an analysis of the global burden of suboptimal breastfeeding *(9)*. Black et al. provide data for breastfeeding levels for 30 developing countries and 12 regions, mainly covering the developing world. Data were limited for developed countries; therefore, prevalence estimates from the United States of America (USA) and Australia were used *(43, 44)*. The breastfeeding prevalence for the USA was applied to all high-income countries that were not covered by Black and colleagues and were not located in the WHO Western Pacific Region. Breastfeeding prevalence from Australia was applied to all Western Pacific countries not covered by Black and colleagues In this analysis, relative risks for diarrhoeal diseases, lower respiratory tract infections and infectious perinatal conditions were calculated for children aged under 24 months. Relative risks were calculated for these conditions across four exposure categories (exclusive, predominant, partial and non-breastfeeding) in the 0–5 months age group and two (any and non-breastfeeding) in the 6–23 month age group. Relative risks and prevalence data for perinatal infections were estimated only for the 0–1 month age group for all countries. Optimal breastfeeding is defined as exclusive breastfeeding for the first 6 months of life and continued breastfeeding through the second year of life *(9)*.

Black RE, Allen LH, Bhutta ZA, Caulfield LE, de Onis M, Ezzati M et al. Maternal and child undernutrition 1 — maternal and child undernutrition: global and regional exposures and health consequences. *Lancet*, 2008, 371:243–260.



PAHO Guiding Principles for Complementary Feeding of the Breastfed Child
Originally written by Kathryn Dewey for the WHO Global Consultation on Complementary Feeding, December 10-13, 2001.

Complementary feeding is defined as the process starting when breast milk alone is no longer sufficient to meet the nutritional requirements of infants, and therefore other foods and liquids are needed, along with breast milk. The target age range for complementary feeding is generally taken to be 6 to 24 months of age, even though breastfeeding may continue beyond two years.

The Expert Consultation observed that, on a population basis, there is no adverse effect of exclusive breastfeeding for six months on infant growth. The nutrient needs of full-term, normal birth weight infants typically can be met by human milk alone for the first 6 months if the mother is well nourished (WHO/UNICEF, 1998). However, in certain circumstances, some of the micronutrients may become limiting before 6 months. In the case of iron, the infant's reserves at birth play a major role in determining the risk for anemia during infancy because the iron concentration of human milk is low. Normal birth weight infants whose mothers had good prenatal iron status usually have adequate liver iron reserves, and thus the risk of iron deficiency before six months is low.

Low birth weight infants and infants of mothers with prenatal iron deficiency may be at risk of iron deficiency. For prevention of iron deficiency among infants at risk prior to six months, complementary foods are not likely to be as effective as medicinal iron drops (Dewey et al., 1998; Domellof et al., 2001).)

Other nutrients that may become limiting before 6 months include zinc and certain vitamins. The zinc concentration of human milk is relatively low, although its bioavailability is high. Low liver reserves of zinc at birth may predispose some infants to zinc deficiency (Zlotkin et al., 1988), similar to the situation for iron. To date there is little evidence that zinc deficiency limits growth of exclusively breastfed infants prior to 6 months of age (though it may do so after 6 months; Brown et al 2002). As mentioned above for iron, however, medicinal zinc supplements may be more effective than complementary foods at preventing zinc deficiency in young infants.

Vitamin deficiencies are generally rare in exclusively breastfed infants, but when the mothers' diets are deficient, their infants may have low intakes of certain vitamins (such as vitamin A, riboflavin, vitamin B6, and vitamin B12). In these situations, improving the mother's diet or giving her supplements is the recommended treatment, rather than providing

complementary foods to the infant. Vitamin D deficiency may occur among infants who do not receive much exposure to sunlight, but giving vitamin D drops directly to the infant generally prevents this.

Given that growth is generally not improved by complementary feeding before six months even under optimal conditions (i.e., nutritious, microbiologically safe foods) and that complementary foods introduced before six months tend to displace breast milk (Cohen et al., 1994; Dewey et al., 1999), the Expert Consultation concluded that the potential health benefits of waiting until six months to introduce other foods outweigh any potential risks. After six months of age, however, it becomes increasingly difficult for breastfed infants to meet their nutrient needs from human milk alone (WHO/UNICEF, 1998). Furthermore, most infants are developmentally ready for other foods at about six months (Naylor and Morrow).

Breastfeeding Rates in Australia

A number of studies that give breastfeeding rates in Australia are listed here. None of the available studies give reliable national results. The following difficulties are noted:

1. Most studies are cross sectional in nature. Since infant feeding is a dynamic process, a cohort study with regular data collection is required to gain accurate information.
2. Sometimes definitions that are used are not standard. Exclusive breastfeeding is defined as "an infant has received only breast milk from his/her mother or a wet nurse or expressed breast milk and no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines since birth". In other cases the classification of exclusive breastfeeding is made on the basis of the past 24 hours
3. In many cases the samples are not nationally representative.

However after taking these caveats into account the breastfeeding rates in Australia are:
Any breastfeeding 90-92% initiation and approximately 50% are breastfeeding at six months.
Exclusive breastfeeding. Very few infants are exclusively breastfed until 6 months

Studies reporting on breastfeeding rates in Australia

	2007 Australian National Children's Nutrition and Physical Activity Survey	**2007-2008 Report on Child Health from the New South Wales Population Health Survey**	**2004–05 National Aboriginal and Torres Strait Islander Health Survey (NATSIHS)**
Type of study	Cross-sectional	Cross-sectional	Cross-sectional
Breastfeeding definitions	Measured proportion of children that were 'ever breastfed' Definition poorly defined	Ever breastfed: An infant has been put to the breast, even if only once, and/or an infant has received expressed breast milk Exclusively breastfed: An infant has received only breast milk from his/her mother or a wet nurse or expressed breast milk and no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines (in last 24 hours). Predominantly breastfed predominant source of nourishment has been breast milk but the infant has also received water and water-based drinks. All other food-based fluids are excluded, in particular non-human milk (in last 24 hours). Fully breastfed: An infant was fully breastfed if he/she receives breast milk as the main source of nourishment, includes exclusively breastfed and predominantly breastfed infants (in last 24 hours).	Ever breastfed: An infant has been put to the breast, even if only once, and/or an infant has received expressed breast milk Exclusively breastfed: An infant has received only breast milk from his/her mother or a wet nurse or expressed breast milk and no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines. Predominantly breastfed predominant source of nourishment has been breast milk but the infant has also received water and water-based drinks. All other food-based fluids are excluded, in particular non-human milk. Fully breastfed: An infant is fully breastfed if he/she receives breast milk as the main source of nourishment (includes exclusively breastfed and predominantly breastfed infants)
Population/ study information	A total of 4,487 children took part, divided into the following age groups: 2–3 years, 4–8 years, 9–13 years and 14–16 years. Households with children aged 2-16	In total, 5,171 interviews were conducted with parents or carers of children aged 0-15 year. The overall participation rate was 63.5 %. Questions on breastfeeding were only asked of parents of children aged 0-23 months	10,439 Indigenous Australians of all ages Parent or caregiver responded for children. Information is 'as reported' by respondents In 27% of children aged 0–3 years an adult

	years were randomly selected using Random Digit Dialling. Caregiver or parent recalled/reported if infant had “ever breastfeeding”		other than the child’s mother responded for the child
Results	The majority (90%) of children were breastfed for a period during their infancy. Boys ever been breastfed(%); 93 (2-3 yrs), 90 (4-8 yrs), 92 (9-13 yrs), 91 (14-16 yrs) Girls ever been breastfed(%); 93 (2-3 yrs), 89 (4-8 yrs), 88 (9-13 yrs), 93 (14-16 yrs) All children ever been breastfed(%); 93 (2-3 yrs), 89 (4-8 yrs), 90 (9-13 yrs) 92 (14-16 yrs)	The proportion of children aged 0-23 months who were breastfed at each month of age declined from 91.1 per cent at birth to 80.5 per cent at 1 month, 69.0 per cent at 3 months, 54.8 per cent at 6 months, and 28.3 per cent at 12 months. The proportion of children aged 0-23 months who were fully breastfed at each month of age declined from 91.1 % at birth to 74.4 % at 1 month, 58.8 % at 3 months, 26.3 % at 6 months, and 1.1 % at 12 months. The proportion of children aged 0-23 months who were exclusively breastfed at each month of age declined from 91.1 % at birth to 67.0 % at 1 month, 49.9 % at 3 months, 16.7 % at 6 months, and 0.2 % at 12 months. In 2007-2008, 89.8 % of children aged 0-23 months had ever been breastfed. In 2007-2008, 28.3 % of children aged 0-23 months were breastfed at 12 months. In 2007-2008, 16.7 % of children aged 0-23 months were exclusively breastfed at 6	In 2004-5 approximately 42% of Indigenous children aged 0–3 years in remote areas were currently being breastfed, 43% had previously been breastfed and14% had never been breastfed. This compared to 13%, 65% and 21% of Indigenous infants in non-remote areas respectively. A higher proportion of non-Indigenous children (aged 0–3 years) than Indigenous children had been breastfed for 12 months or more, 14% compared with 11%.

		months. In 2007-2008, 48.3 % of children aged 0-23 months were introduced solids before 6 months (decreased from 69.4% in 2001)	

	Growing Up in Australia longitudinal study of Australian children. Commenced 2004	**2001 Australian National Health Survey (NHS)**	**2004–05 Australian National Health Surveys (NHS)**
Type of study	Cohort	Cross-sectional	Cross-sectional
Breastfeeding definitions	Fully breastfeeding: receiving breast milk as the main source of nutrition; under this definition the infant may also receive water or water-based drinks but no other food or milk	Fully breastfeeding infant was 'fully' breastfeeding only until time of introduction of first substitute (breast milk substitutes or solid food). Therefore consuming juice, water etc. may be classified as 'fully' breastfeeding	
Population/ study information	The study commenced in 2004 with two cohorts - families with 4-5 year old children (cohort K) and families with 0-1 year old infants (cohort B) In 2004 (wave 1) the total infant cohort available for analysis comprised 5,045 infants aged 3 to 14 months In wave 2 there were 4,606 families in the B cohort children(response rate 91%). The mother/ caregiver was interviewed, face-to-face. Breastfeeding status was derived from mothers' reports	There were 1,883 children under three years of age in the sample. 640 children were under one year old, 630 were under two years and 613 were under three years old. The age of the child was recorded in months. The questions were answered on behalf of the child by a parent, 83% of the time by the mother. Infant feeding questions were asked by personal inter view in respect to all 1,883 children aged under three years of age.	Sample sizes were 1508 for initiation of breastfeeding in the and 1299 for breastfeeding at 12 months.

	In wave 3 in 2008-9 parents were asked to report on their infant's time use by completing a diary for one weekday and one weekend day, on pre-specified dates. In the diary, each day is divided into 15 minute intervals. Diaries were excluded if they had too much missing data The number of children who met these criteria was 2,878		
Results	For wave 2 of the B cohort; 92 % of children were breastfed at birth. When children were one week old, 88 % were still being breastfed By the time the children were aged one month, only 71 %were fully breastfed, with another 11 per cent receiving complementary breast milk. Rate of full breastfeeding fell to 62 % at age 2 months, 56 % at age 3 months and 46 % at age 4 months. At 12 months, 28 % of children were still breastfed; at 18 months, 9 % of children; and at 24 months, 5 % were still being breastfed. At 3 months old, 11 % were fed solids. The percentage of infants on solids rose to 38 % at 4 months and 62 % at 5 months. At 6 months, 91 % of infants had started solids.	At 25 weeks 65.1 % (62.2-68.0) of infants were regularly receiving solid food At 51 weeks 95.7% (94.3-97.1) of infants were regularly receiving solid food	Weighted estimates of proportions of infants breastfeeding in 2004–05; 87.8% (86.0–89.7) initiated breastfeeding, 64.4 % (61.3–67.5) breastfeeding at 3 months, 50.4 % (47.1–53.8) breastfeeding at 6 months, 23.3 (20.0–26.7) breastfeeding at 12 months

Table 1: Percentage of children breastfed, Australia, 1998-2001 and 1992-1995.

	Australia 1998-2001 % (95% CI)	Australia 1992-95 % (95% CI)
At discharge from hospital	83.3	81.8
	(81.5-85.1)	(80.3-83.3)
Fully breastfed at 13 weeks	57.3	57.1
	(54.0-60.6)	(55.4-58.9)
Fully and partially breastfed	64.3	62.6
at 13 weeks	(61.3-67.3)	(60.8-64.4)
Fully breastfed at 25 weeks	18.4	18.6
	(16.1-20.7)	(17.1-20.1)
Fully and partially breastfed	49.0	46.2
at 25 weeks	(46.3-51.6)	(44.4-47.9)
Fully breastfed at 52 weeks	1.2	2.5a
	(0.6-1.9)	(1.7-3.2)
Fully and partially	24.9	21.1a

	In wave 3; 43 % of infants reported to be breastfeeding at the time that children's activities were recorded in time use diaries		

	1995 National Health Survey	**Perth Infant Feeding Study Mark 2 (PIFS II) 2002-3**
Type of study	Cross-sectional	Cohort
Breastfeeding definitions	Breastfeeding was classified as 'exclusive' if the child did not consume infant formula, cow's milk, other milk substitutes or solid food on a regular basis. A child who was regularly consuming large amounts of fruit juice, and also receiving other foods on an irregular basis, would therefore have been classified as being exclusively breastfed.	Fully breastfed: receives breast milk as the main source of nourishment, that is, with or without water, water-based drinks, fruit juice, or oral rehydration solution, but does not receive any other liquids (including breast milk substitutes) or solids. Exclusively breastfed infants are those who have had breast milk alone, with the exception of vitamins, mineral supplements or medicines. Partially breastfed infants who have received breast milk as well as other fluids including breast milk substitutes.
Population/ study information	The 1995 NHS was conducted on a multistage area sample of private dwellings and a list sample of non-private dwellings in all States and Territories of Australia. The final sample size was 21 787 households. For each child under the age of 4 years, a number of questions relating to breastfeeding was asked to the parent. There were 3252 children under 4 years of age in the sample. Of these, 782 were under 1 year old, 818 were 1 year old, 856 were 2 year old and 796 were 3 year old. Parents of children under 4 yrs were asked about that child's feeding habits in the first year of life.	Sample included 587 eligible mothers of healthy newborn infants (68% response rate). Mothers delivered between mid-September 2002 and mid-July 2003 at two public hospitals in Perth. mothers completed a questionnaire in hospital about how they were feeding their newborn. All participants were then followed up by telephone to ascertain how they were feeding their infants at home at 4,

		10, 16, 22, 32, 40 and 52 wk postpartum.
Results	**Table 2** Percentage of children breastfed, Australia and by State, 1992–95	At hospital discharge, 93.8% of mothers in 2002/3 were breastfeeding At 16 weeks (n=486) 63% were classified as any breastfeeding and 11.4% were fully breastfeeding At 22 weeks (n=483) 51.3% were classified as any breastfeeding and 4.3% were fully breastfeeding At 52 weeks (n=455) 22.1 % were classified as any breastfeeding

	At discharge from hospital % (95% CI)	Exclusively breastfed at 13 weeks % (95% CI)	Exclusively and partially breastfed at 13 weeks % (95% CI)	Exclusively breastfed at 25 weeks % (95% CI)	Exclusively and partially breastfed at 25 weeks % (95% CI)
Australia	81.8 (80.3, 83.3)	57.1 (55.4, 58.9)	62.6 (60.8, 64.4)	18.6 (17.1, 20.1)	46.2 (44.4, 47.9)
NSW	78.4 (72.5, 84.3)	56.6 (52.9, 60.4)	60.0 (56.4, 63.5)	17.2 (14.1, 20.4)	44.2 (40.1, 48.4)
VIC	82.2 (80.3, 84.1)	56.0 (53.1, 58.9)	61.7 (58.9, 64.6)	18.3 (15.9, 20.7)	45.0 (42.2, 47.7)
QLD	84.1 (80.9, 87.3)	56.3 (52.5, 60.1)	63.8 (60.0, 67.6)	19.2 (15.7, 22.6)	47.7 (43.3, 52.0)
SA	82.2 (79.6, 84.9)	53.3 (49.9, 56.8)	62.2 (59.0, 65.5)	18.4 (15.0, 21.8)	46.1 (42.3. 49.9)
WA	87.0 (83.7, 90.3)	62.8 (58.3, 67.3)	69.0 (64.5, 73.5)	21.9 (17.8, 25.9)	50.6 (46.1, 55.1)
Tasmania	78.1 (73.2, 83.1)	60.2 (52.9, 67.4)	63.0 (55.9, 70.1)	22.3 (16.4, 28.2)	43.9 (36.9, 50.8)
NT	88.5 (84.8, 92.1)	70.9 (64.9, 77.0)	76.3 (70.6, 81.9)	24.6 (20.1, 29.0)	64.7 (57.6, 71.8)
ACT	90.1 (86.9, 93.3)	63.8 (59.3, 68.3)	68.7 (64.2, 73.2)	17.0 (14.1, 20.0)	53.8 (48.3, 59.4)

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