

# Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis

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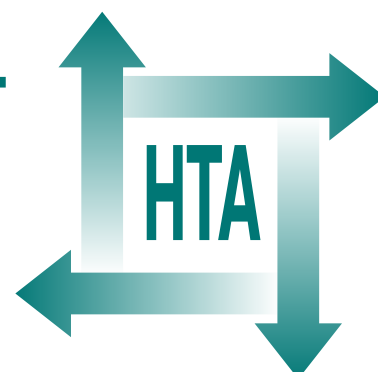


## Executive summary

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## Executive summary

### Background

For preterm, growth-restricted and sick neonates, including those requiring surgery, the use of breastmilk substitutes is associated with increased short- and long-term adverse outcomes. These include mortality and serious morbidity in the infant and adverse health outcomes in the mother. The fragility of such infants, their changing nutritional and health needs, the increased difficulty in producing breastmilk experienced by preterm mothers, the anxiety that is inevitably provoked in mothers and family members, and the fact that health-care staff may not have the skills or the time needed, can make breastfeeding/breastmilk feeding a difficult process. A consequence of the recent improvement in survival rates at all gestations is the increasing numbers of infants in neonatal units with complex needs. Lack of feeding with breastmilk for these infants is an important and costly problem that, if addressed successfully, has the potential to contribute to addressing inequalities in health.

### Objectives

The primary aims of this systematic review and economic analysis were to evaluate the effectiveness and cost-effectiveness of interventions that promote or inhibit breastfeeding or feeding with breastmilk for infants admitted to neonatal units, and to identify an agenda for future research.

### Methods

#### Systematic review of effectiveness and health economics review

Electronic databases (including MEDLINE and MEDLINE In-Process Citations, EMBASE, CINAHL, Maternity and Infant Care, PsycINFO, British Nursing Index and Archive, Health Management Information Consortium, Cochrane Central Register of Controlled Trials, Science Citation Index, Pascal, Latin American and Caribbean Health Sciences, MetaRegister of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness, Health Technology Assessment

Database, National Research Register) were searched using structured searches from inception to February 2008. References of retrieved papers were examined, and experts on the advisory group and clinical advisors were asked to identify further published or unpublished material.

#### Inclusion and exclusion criteria

##### Effectiveness review

Eligible studies had to fulfil all of the following:

- Participants: infants, or mothers of infants, who were admitted to neonatal units; and those linked to such infants and women, including fathers/partners, other family members or health professionals.
- Interventions: any type of intervention that addressed breastfeeding/feeding with breastmilk in neonatal units or following discharge.
- Outcomes: primary outcomes were measures of breastfeeding/breastmilk feeding. Secondary outcomes included clinical/health, process, psychosocial and cost-effectiveness outcomes. Studies that did not report a breastmilk or breastfeeding outcome were excluded.
- Study designs: randomised controlled trials (RCTs), randomised crossover studies, concurrent comparisons and before/after studies. Case studies and studies that did not evaluate an intervention were excluded.

##### Health economics review

Studies were eligible if they were full economic evaluations and were considered to be useful in answering the research question relating to cost-effectiveness.

##### Data extraction and validity assessment

Data were extracted and appraised for quality using structured tables relevant for each study design, based on CRD report 4, NICE guidance methodology and the Cochrane Handbook. Data extraction and quality assessment were independently checked by a second reviewer.

##### Data synthesis

Results from primary studies were assessed and summarised in a qualitative synthesis for each type of intervention and across types of intervention.

Relative risks for outcomes were estimated on an intention-to-treat (ITT) basis where appropriate; the ITT analysis was adjusted where possible for legitimate postrandomisation exclusions. Pooling of relative risks was not considered appropriate due to the heterogeneity of studies.

## Decision analysis

The objective of the model was to estimate the long-term cost utility of enhanced staff contact in promoting breastfeeding to mothers whose infants were admitted to neonatal units. A decision tree was developed to synthesise data on enhanced staff contact, breastmilk effectiveness, incidence of necrotising enterocolitis (NEC) and sepsis, resource use, survival and utilities. The structure of the model was determined by the evidence obtained during early stages of the effectiveness review and by the clinical studies identified in the additional modelling searches. It was finalised by means of a series of meetings with clinical advisors.

## Framing recommendations

To inform implications for policy and practice and recommendations for research, two additional approaches were used:

- Seven expert clinical informants from neonatal units in the UK and internationally identified key factors in introducing successful breastfeeding/breastmilk feeding-related change.
- Based on the findings of the study, the research team and advisory group members agreed implications for policy, practice and education and prioritised suggestions for future research studies.

## Results

### Health economics review

No studies met the selection criteria.

### Effectiveness review

A total of 48 studies met the selection criteria, of which 65% (31/48) were RCTs, and 17% (8/48) were conducted in the UK. Topics and numbers of studies identified were:

- increased mother and baby contact (12)
- interim feeding methods and related interventions (6)

- methods of expressing breastmilk (6)
- enhancing breastmilk production (7)
- supporting optimal nutritional intake from breastmilk (3)
- breastfeeding education and support (6)
- staff training (2)
- early hospital discharge with home support (2)
- organisation of care (4).

Studies were heterogeneous in terms of design, intervention, participants and outcomes measured. Seven were rated as good quality and 28 as moderate quality. Although the results should be viewed with some caution as a result, a useful evidence base has been identified.

*Increased mother and baby contact (nine RCTs, two before/after and one crossover study)* There is strong evidence that short periods of kangaroo skin-to-skin contact, of up to one hour at all visits, increased the duration of any breastfeeding up to 1 month after hospital discharge [risk ratio (RR) 4.76, 95% confidence interval (CI) 1.19 to 19.10] and for more than 6 weeks (RR 1.95, 95% CI 1.03 to 3.70) among clinically stable infants in industrialised settings, and daily contact improved health outcomes at 2 and 6 months in all settings.

*Interim feeding methods and related interventions (five RCTs, one crossover study)* The evidence for the use of cup feeding versus bottle feeding is limited, but it may increase breastfeeding at discharge and reduce the frequency of oxygen desaturation. Lack of staff training is an important confounder. There is no evidence to support the use of gavage feeding versus bottle feeding or the use of caregivers' fingers in place of pacifiers.

*Methods of expressing breastmilk (five RCTs, one crossover study)* Simultaneous pumping with an electric pump has advantages in the first two weeks. Once discharged home, the mother may also benefit from a hand-operated pump or hand expression, potentially increasing scope for more widespread provision by neonatal units within limited budgets.

*Enhancing breastmilk production (five RCTs, two crossover studies)* Pharmaceutical galactagogues seem to have little role to play among mothers who have recently given birth; there may be a role for these in later lactation for mothers whose milk production is not meeting their infant's needs if used with supportive care. There is some evidence to support the use of relaxation-related interventions for mothers.

*Supporting optimal nutritional intake from breastmilk (two RCTs, one concurrent comparison)* Enhancing the composition of mother's own milk offers an apparently simple method for optimising protein and lipid intake. Good quality evidence of effectiveness is lacking.

*Breastfeeding education and support (three RCTs, three before/after studies)* There is strong evidence for the effectiveness of peer support at home (in Manila) for mothers of term, low birthweight infants on any breastfeeding up to 24 weeks (RR 2.18, 95% CI 1.45 to 3.29) and exclusive breastfeeding from birth to 6 months (RR 65.94, 95% CI 4.12 to 1055.70), and for the effectiveness of peer support in hospital and at home for mothers of infants in Special Care Baby Units on providing any breastmilk at 12 weeks [odds ratio (OR) 2.81, 95% CI 1.11 to 7.14;  $p = 0.01$ ]. There is more limited evidence for the effectiveness of skilled professional support in a US Neonatal Intensive Care Unit on infants receiving any breastmilk at discharge (OR 2.0, 95% CI 1.2 to 3.2,  $p = 0.004$ ).

*Staff training (two before/after studies)* Limited evidence suggests that educational interventions delivered to a multidisciplinary staff group may increase health-care professionals' knowledge and can increase initiation rates and duration of breastfeeding. Lack of staff training is an important barrier to implementation of effective interventions.

*Early hospital discharge with home support (two RCTs)* Very limited evidence suggests that this intervention is unlikely to improve and may adversely affect the duration of breastfeeding, although some benefits for infection rates and readmission rates to hospital may occur.

*Organisation of care (four before/after studies)* Baby Friendly accreditation of the associated maternity hospital resulted in improvements in several breastfeeding-related outcomes for infants in neonatal units.

## Economic analysis

Enhanced staff contact, which provided additional skilled professional support in hospital, was found to be more effective and less costly (due to reduced neonatal illness) than normal staff contact in both the base case and the majority of sensitivity analysis scenarios. Additional support ranged from 0.009 quality-adjusted life-years (QALYs) to 0.251 QALYs more beneficial per infant and ranged from £66 to £586 cheaper per infant across the birthweight

subpopulations. Donor milk would become cost-effective if the mechanisms by which it is provided were improved.

## Conclusions

New evidence has been identified to inform care and future research, and the economic analysis is the first in this complex and important field and offers a model for future decision analysis.

Consistent national data are currently lacking on disease and length of stay, individual infant treatment pathways, health and development post discharge and resource use for infants starting life in neonatal units in the UK.

The evidence base mainly relates to infants who are clinically stable. Despite the limitations of the evidence base, kangaroo skin-to-skin contact, peer support, simultaneous breast milk pumping, multidisciplinary staff training and the Baby Friendly accreditation of the associated maternity hospital have been shown to be effective, and skilled support from trained staff in hospital has been shown to be potentially cost-effective. Many of these interventions inter-relate: it is unlikely that specific clinical interventions will be effective if used alone, and particularly in the absence of staff training or of an environment in which mothers are encouraged and supported in having close and ongoing contact with their infants, and to breastfeed/express breastmilk. Several interventions including kangaroo skin-to-skin contact have been shown to be more effective among women who intend to breastfeed.

## Implications for policy and practice

This group of infants should be included in national public health policy developments. National surveillance of feeding, health and cost outcomes for infants and mothers in neonatal units is needed, and consideration should be given to linking this information with Public Service Agreement targets on breastfeeding and infant mortality. There is a need to develop consensus definitions of the initiation and duration of breastfeeding/breastmilk feeding with specific reference to infants admitted to neonatal units and their mothers; definitions are proposed here. Mothers need to have ongoing encouragement and consistent support for breastfeeding/breastmilk feeding, daily kangaroo skin-to-skin contact with

their infants, and facilities to express and store breastmilk. This will require multidisciplinary staff training, continuing support for the Baby Friendly Initiative (BFI) accreditation of maternity units, and improvement of facilities for parents on neonatal units.

## Implications for research

There is a need for high-quality studies that examine feeding and health outcomes of infants and their mothers, developmental outcomes, costs, and the views of staff and parents. Studies should include women from low-income families and from diverse ethnic groups. Preliminary and pilot evaluation work on staff training, 'best practice' kangaroo skin-to-skin contact and peer support is recommended, to be followed by intervention studies as follows:

Level 1 priorities are:

- a study of kangaroo skin-to-skin contact for clinically less stable, possibly very preterm infants and their mothers

- a multifaceted intervention study of a supportive environment and staff training
- a study of peer support in hospital and at home.

Level 2 priorities are:

- studies of single or combined interventions including initiating and sustaining milk production; interim feeding methods; enhancing nutritional composition of breastmilk; and the impact of BFI accreditation of the associated maternity hospital on neonatal care
- a study of staff education, training and behaviour change.

## Publication

Renfrew MJ, Craig D, Dyson L, McCormick F, Rice S, King SE, *et al.* Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis. *Health Technol Assess* 2009;**13**(40).

# NIHR Health Technology Assessment programme

The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

The HTA programme is needs led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, from the public and consumer groups and from professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA programme then commissions the research by competitive tender.

Second, the HTA programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Third, through its Technology Assessment Report (TAR) call-off contract, the HTA programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

The final reports from HTA projects are peer reviewed by a number of independent expert referees before publication in the widely read journal series *Health Technology Assessment*.

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Reports are published in the HTA journal series if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA programme as project number 06/34/02. The contractual start date was in May 2007. The draft report began editorial review in June 2008 and was accepted for publication in January 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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