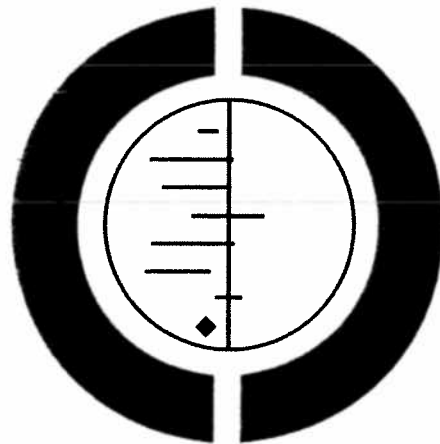


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# Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding (Review)

Jaafar SH, Jahanfar S, Angolkar M, Ho JJ



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[Intervention Review]

## Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

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### ABSTRACT

#### Background

To successfully initiate and maintain breastfeeding for a longer duration, the World Health Organization's Ten Steps to Successful Breastfeeding recommends total avoidance of artificial teats or pacifiers for breastfeeding infants. Offering the pacifier instead of the breast to calm the infant may lead to less frequent episodes of breastfeeding and as a consequence may reduce breast milk production and shorten duration of breastfeeding; however, this remains unclear.

#### Objectives

To assess the effect of unrestricted versus restricted pacifier use in healthy full-term newborns whose mothers have initiated breastfeeding and intend to exclusively breastfeed, on the duration of breastfeeding, other breastfeeding outcomes and infant health.

#### Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (14 March 2012).

#### Selection criteria

Randomised and quasi-randomised controlled trials comparing unrestricted versus restricted pacifier use in healthy full-term newborns who have initiated breastfeeding regardless of whether they were born at home or in the hospital.

#### Data collection and analysis

Two authors independently assessed the studies for inclusion, assessed risk of bias and carried out data extraction. Data were checked for accuracy.

#### Main results

We found three trials (involving 1915 babies) for inclusion in the review but have included only two trials (involving 1302 healthy full-term breastfeeding infants) in the analysis. Meta-analysis of the two combined studies showed that pacifier use in healthy breastfeeding infants had no significant effect on the proportion of infants exclusively breastfed at three months (risk ratio (RR) 0.99; 95% confidence interval (CI) 0.93 to 1.05), and at four months of age (RR 0.99; 95% CI 0.92 to 1.06) and also had no effect on the proportion of infants partially breastfed at three months (RR 1.00; 95% CI 0.98 to 1.13), and at 4 months of age (RR 1.01; 95% CI 0.98 to 1.03).

## Authors' conclusions

Pacifier use in healthy term breastfeeding infants, started from birth or after lactation is established, did not significantly affect the prevalence or duration of exclusive and partial breastfeeding up to four months of age. However, evidence to assess the short-term breastfeeding difficulties faced by mothers and long-term effect of pacifiers on infants' health is lacking.

## PLAIN LANGUAGE SUMMARY

### Effect of pacifier use on duration of breastfeeding in full-term infants

Breast milk is superior to other baby foods in providing balanced nutrition and protection against allergy and infection to newborns. Breastfeeding is recommended by the World Health Organization, exclusively in the first six months and then as a dietary supplement. Breastmilk production and supply are maintained by frequent suckling of the breast and nipple stimulation. A pacifier is a non-nutritive sucking device used to calm an infant that has become a cultural norm in many parts of the world. However there is a widespread belief that pacifiers may interfere with breast milk production and lead to discontinuation of breastfeeding.

Our review concluded that for mothers who are motivated to breastfeed their infants, pacifier use before or after breastfeeding was established did not significantly affect the prevalence or duration of exclusive and partial breastfeeding up to four months of age. The review provided moderate evidence from three randomised controlled trials (involving 1915 babies) comparing unrestricted with restricted pacifier use by healthy, full-term breastfeeding infants; two of the trials (1302 babies) were included in the analysis. However, there is a widespread belief that pacifiers may interfere with breast milk production and lead to discontinuation of breastfeeding.

## BACKGROUND

The superiority of breast milk in providing balanced nutrition, protection against allergy and infection in newborns is well documented (Chandra 1979; Oddy 2001). Thus, the World Health Organization (WHO) Expert Consultation recommends that infants be exclusively breastfed (infant receives only breast milk with no other liquids including water or solids) up to the first six months of life and as a dietary supplement thereafter. In order to successfully initiate and maintain breastfeeding for longer duration, and avoid supplementary feeding, the WHO's Ten Steps to Successful Breastfeeding recommends artificial teats or pacifiers should not be given for breastfeeding infants. The use of a pacifier, a non-nutritive sucking device to calm an infant, is relatively widespread and has become a cultural norm in many parts of the world (Barros 1995). Pacifiers are often believed to be harmless or even necessary and beneficial for infants' development (Victora 1997). However, the use of pacifiers for breastfeeding infants remain controversial.

Breastmilk production and supply are maintained by frequent suckling of the breast and nipple stimulation (Aarts 1999; Neville 1988). In order to breastfeed successfully, infants must learn to attach and suckle properly at the breast during the first few days of life. Effective breast sucking technique requires the infant to have a wide open mouth, with the tongue under the areola. Expression of milk from the breast is by slow and deep sucks, while sucking on a pacifier is basically superficial sucking (Righard 1992) where the

infant is sucking on a teat with short and fast sucks using minimal effort. The mechanical differences between sucking at the breast and sucking on a pacifier may result in 'nipple confusion' (Gomes 2006; Neifert 1995), incorrect latching onto the breasts and superficial sucking on the mother's nipples (Righard 1998). Improper technique of sucking on the breasts may lead to cracked nipples and mastitis, which may further impede breastfeeding. Evidence from a cohort study reported that breastfeeding difficulties during the first week of postpartum were significantly associated with termination of breastfeeding by week 10 of life (Scott 2005). There are beliefs, based on observational evidence, that early exposure of infants to the pacifier is associated with cessation of exclusive breastfeeding by three to six months (Mascarenhas 2006; Scott 2005), and overall breastfeeding by 12 months (Scott 2005). Offering the pacifier instead of the breast to calm the infant may lead to less frequent episodes of breastfeeding. This in turn may reduce breast milk production and shorten duration of breastfeeding in the long term (Howard 1999). Furthermore, infants may get used to the pacifier, and develop a preference for an artificial teat instead of the mother's nipple.

On the other hand, it remains unclear whether breastfeeding cessation and a maternal intention to wean the infant from exclusive breastfeeding precedes the use of a pacifier or vice versa. It is possi-

ble that a mother may have experienced breastfeeding difficulties early and intended to stop breastfeeding, by introducing the pacifier to the infant in preparation to take on bottle feeding. Interestingly, evidence also shows that pacifiers can have a positive effect on breastfeeding, as they may help to take the infant off the breast and thereby increase the interval between feedings and possibly breast milk intake by the infant (Victoria 1997). Observational evidence also indicates that occasional use of the pacifier has no effect on breastfeeding duration compared to daily pacifier use (Ullah 2003; Vogel 2001) and thus it remains unclear whether pacifiers are an independent causal factor for reducing breastfeeding duration. In addition, the use of pacifiers might be protective against sudden infant death syndrome (Mitchell 2006; Saririan 2006), although its mechanism is unknown. However, prolonged non-nutritive sucking on the pacifier is associated with an increased risk of recurrent acute otitis media (Jackson 1999), oral candidiasis (Darwazeh 1995) and dental malocclusion (Caglar 2005).

Pacifier use is a life style choice so it is not possible to assign mothers randomly to pacifier versus no pacifier use. Therefore, to answer this question, studies could assign mother-infant pairs to unrestricted compared with restricted pacifier use.

Therefore, the aim of this review is to study the effect of restricted pacifier exposure in healthy infants whose mothers have initiated breastfeeding and intend to exclusively breastfeed, on the duration of breastfeeding and infant health.

## OBJECTIVES

To assess the effect of unrestricted versus restricted pacifier use in healthy full-term newborns whose mothers have initiated breastfeeding and intend to exclusively breastfeed, on the duration of breastfeeding, other breastfeeding outcomes and infant health.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

All randomised controlled trials including quasi-randomised trials.

#### Types of participants

Healthy full-term newborns whose mothers have initiated breastfeeding and intend to exclusively breastfeed regardless of whether they were born at home or in hospital. We will exclude studies including newborns exposed to bottle feeding prior to enrolment.

### Types of interventions

Unrestricted or actively encouraged use of a pacifier compared with advice against pacifier use. We excluded studies evaluating occasional pacifier use to provide procedural pain relief.

### Types of outcome measures

#### Definition of breastfeeding and partial breastfeeding

Full or exclusive breastfeeding is defined as no food (solid or liquid including water) other than breast milk. Almost exclusive breastfeeding allows infrequent supplemental liquids, other than milk formula, and in partial breastfeeding other milk supplements are regularly given along with breastfeeding (Labbok 1990).

#### Primary outcomes

Duration of breastfeeding as measured by one of the following:

1. mean duration of full breastfeeding (months) as defined by Labbok 1990;
2. mean duration of any or partial breastfeeding (months);
3. prevalence or proportion of infants being fully or partially breastfed at three, four and six months of age.

#### Secondary outcomes

1. Rate of breastfeeding difficulties (cracked nipples, breast engorgement, mastitis).
2. Maternal satisfaction and level of confidence in parenting.
3. Mean episode/frequency of infant crying and fussing per day.
4. Infants' health: incidence of sudden infant death syndrome, oral candidiasis, otitis media and dental malocclusion.

### Search methods for identification of studies

#### Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (14 March 2012).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;

4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts. Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group. Trials identified through the searching activities described above were each assigned to a review topic (or topics). The Trials Search Co-ordinator searched the register for each review using the topic list rather than keywords. We did not apply any language restrictions.

### Data collection and analysis

Three review authors independently assessed for inclusion all the potential studies identified as a result of the search strategy. We resolved any disagreement through discussion.

### Selection of studies

Three review authors independently assessed for inclusion all the potential studies identified as a result of the search strategy. We resolved any disagreement through discussion.

### Data extraction and management

We designed a form to extract data. For eligible studies, at least two review authors extracted the data using the agreed form. We resolved discrepancies through discussion. We entered data into Review Manager software (Higgins 2009) and checked it for accuracy.

When information regarding any of the above was unclear, we contacted authors of the original reports to provide further details.

### Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2009). We resolved any disagreement by discussion.

#### (1) Sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it produced comparable groups.

We assessed the methods as:

- adequate (any truly random process, e.g. random number table; computer random number generator);

- inadequate (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
- unclear.

#### (2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal the allocation sequence and determined whether intervention allocation was foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- adequate (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- inadequate (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear.

#### (3) Blinding (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding could have affected the results. We assessed blinding separately for different outcomes or classes of outcomes. We assessed the methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel;
- adequate, inadequate or unclear for outcome assessors.

#### (4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or was supplied by the trial authors, we re-included missing data. We assessed methods as:

- adequate;
- inadequate;
- unclear.

We would not include studies for analysis if:

- (A) more than 20% of participants excluded;
- (B) more than 20% of analysis not in randomisation groups and not possible to restore participants to correct group.

### (5) Selective reporting bias

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- adequate (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review had been reported);
- inadequate (where not all the study's pre-specified outcomes had been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that was expected to have been reported);
- unclear.

### (6) Other sources of bias

We described for each included study any important concerns we had about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- yes;
- no;
- unclear.

### (7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2009). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - see Sensitivity analysis.

## Measures of treatment effect

### Dichotomous data

For dichotomous data, we presented results as summary relative risk with 95% confidence intervals.

### Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. If we had found trials that measured the same outcome but used different methods we planned to use the standardised mean difference to combine trials. If there was evidence of skewness, this was reported.

## Unit of analysis issues

### Cluster-randomised trials

We did not identify any cluster-randomised trials for inclusion. In future updates of this review, if we identify cluster-randomised trials for inclusion they will be included in the analyses along with individually randomised trials. We will adjust their sample sizes or standard errors using the methods described in the *Handbook* (Higgins 2009) using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We planned to acknowledge heterogeneity in the randomisation unit and perform a sensitivity or subgroup analysis to investigate the effects of the randomisation unit.

### Dealing with missing data

For included studies, we noted levels of attrition. We did not include studies for analysis if more than 20% of participants were excluded, or if more than 20% of participants analysed were not in their original randomisation group and it was not possible to restore participants to the correct group.

For all outcomes, we carried out analyses on an intention-to-treat basis, i.e. we included all participants randomised to each group in the analyses, and all participants analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

### Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the  $T^2$ ,  $I^2$  and  $\text{Chi}^2$  statistics. We regarded heterogeneity as substantial if  $I^2$  is greater than 30% and either  $T^2$  is greater than zero, or there is a low P-value ( $< 0.10$ ) in the  $\text{Chi}^2$  test for heterogeneity.

### Assessment of reporting biases

In future updates of this review, if there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry.



For continuous outcomes we will use the test proposed by Egger 1997, and for dichotomous outcomes we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

### Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2008). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. In future updates of this review, if there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. We will treat the random-effects summary as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

If we use random-effects analyses, we will present the results as the average treatment effect with its 95% confidence interval, and the estimates of  $T^2$  and  $I^2$ .

### Subgroup analysis and investigation of heterogeneity

In future updates of this review, if we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it. If there were sufficient studies, we intended to carry out the following subgroup analyses: by the infant age at introduction of the pacifier (0 to eight weeks, eight to 16 weeks, after 16 weeks), and by the duration of breastfeeding measured by the following:

1. mean duration of exclusive breastfeeding (months);
2. mean duration of any breastfeeding (months);
3. proportion of infants exclusively or partially breastfed at four and six months of age.

### Sensitivity analysis

In future updates of this review, as more data become available, we will carry out sensitivity analysis to explore the effect of trial quality. This will involve analysis based on our rating of selection bias and attrition bias. We will exclude studies of poor quality (those rated as 'unclear' or 'no') from the analysis in order to assess for any substantive difference to the overall result.

## RESULTS

### Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

### Results of the search

The search identified nine reports of five randomised controlled trials (RCTs). We have included three studies and excluded two.

### Included studies

*See* Characteristics of included studies. We included three studies involving 1915 babies (Jenik 2009; Kramer 2001; Schubiger 1997). However, only two of these studies (involving 1302 babies: Jenik 2009; Kramer 2001) contribute data to the analyses.

*Jenik 2009*: a multicentre-trial evaluated pacifier use in breastfeeding infants once lactation was well established for whether it reduced the prevalence or duration of breastfeeding. A total of 1021 mothers highly motivated to breastfeed were recruited and randomly assigned to whether pacifier was offered ( $n = 528$ ) or not offered ( $n = 493$ ). The study was designed as a non-inferiority trial and only mothers who were already successfully breastfeeding at two weeks and who indicated their intention to continue to do so for at least three months were enrolled. Mothers with breast problems that could interfere with breastfeeding (sore nipples, mastitis, inverted nipples, breast surgery) were not included. Participating mothers were interviewed at one, two, three, four, five, six, eight, 10 and 12 months after births or until breastfeeding ended. Interviews were conducted by a research assistant using a structured questionnaire designed to assess exclusive or any breastfeeding prevalence, duration of breastfeeding and whether the baby had used a pacifier. The primary outcome was prevalence of exclusive breastfeeding at three months. The main secondary outcomes were the prevalence of exclusive and any breastfeeding and duration of any breastfeeding. Primary analysis was by intention to treat. Comparison between the two groups in the study did not show any difference in the baseline characteristics namely the infant birthweight, mode of delivery, maternal age and education, and onset of breastfeeding.

*Kramer 2001*: a double-blind RCT, examined whether or not regular pacifier use is related to weaning by three months of age. A total of 281 healthy breastfeeding women who intended to breastfeed their infant longer and their healthy term singleton infants were randomised to one of two counselling interventions provided by a trained research nurse. In the experimental group ( $n = 140$ ) the mother was asked to avoid pacifier use when the infant cried or fussed and to first offer the breast and, failing that, to try carrying or rocking the infant. In the control group ( $n = 141$ ) all options were discussed for calming the infant, including breastfeed-

ing, carrying, rocking and pacifier use. To ascertain the outcome mothers were asked to complete a validated behaviour diary on three consecutive days, when their infants were four, six and nine weeks of age. Study mothers were interviewed at three months by a research assistant who was blinded to the intervention status of the mother. A total of 258 (91.8%) mother-infant pairs completed three months follow-up.

Schubiger 1997: a multicentre prospective randomised trial evaluated whether avoidance of bottles and pacifiers in the first five days of life affected long-term breastfeeding performance. However, as a result of high attrition bias (more than 20% loss of participants), we have not included data from this study in the analysis. This is in accordance with our prespecified inclusion criteria for analysis.

### Excluded studies

We have excluded two studies from the review (Collins 2004; Howard 2003). One study (Collins 2004) compared use of bottles and pacifiers versus cup feeding in preterm breastfeeding infants who wanted to breastfeed their infant. The other excluded study (Howard 2003) compared the effect of early versus late pacifier use in term infants on duration of breastfeeding. For further information, see Characteristics of excluded studies.

### Risk of bias in included studies

All three included studies employed computerised central randomisation. The method of allocation concealment was 'adequate' in two studies (Jenik 2009; Kramer 2001). These two studies used consecutively numbered, opaque sealed envelopes but in one of the trials (Schubiger 1997) the method of concealment was 'unclear', as it reported use of sealed envelopes but did not state whether these were sequentially numbered. Two studies reported blinding of research nurse and outcome assessors (Jenik 2009; Kramer 2001). In both studies blinding of the care-giver was not mentioned. It would not be feasible to blind participants to the intervention. One study did not mention whether there was any blinding. Overall, the dropout rate was less than 10% from both arms, i.e. 4.9% versus 4.5% in Jenik 2009, 9.3% versus 7.1% in Kramer 2001 respectively. However, in Schubiger 1997, the total dropout rate was 45% versus 10.5% which did not satisfy our prespecified inclusion criteria for analysis. We detected no selective reporting or other potential source of bias in any of the included studies.

### Effects of interventions

#### Primary outcomes

We included two out of three RCTs enrolling 1302 healthy full-term breastfeeding infants for analysis (Jenik 2009; Kramer 2001).

Both of the trials contributed to at least one of the primary outcomes, i.e. proportion of infants partially or exclusively breastfed at three and four months of age. Comparison between pacifier use (intervention) and restricted pacifier use (control) revealed that there was no significant difference in the proportion of infants exclusively breastfed at three months (risk ratio (RR) 0.99; 95% confidence interval (CI) 0.93 to 1.05, two studies, 1228 babies (Analysis 1.1)) and at four months of age (RR 0.99; 95% CI 0.92 to 1.06, one study, 970 babies (Analysis 1.2)). There was also no significant difference in the proportion of infants partially breastfed at three months (RR 1.00; 95% CI 0.98 to 1.13, two studies, 1228 babies (Analysis 1.3)), or at four months (RR 1.01; 95% CI 0.98 to 1.03, one study, 970 babies (Analysis 1.4)). Thus, pacifier use in full-term breastfeeding infants after birth or after the establishment of lactation did not significantly affect the prevalence or duration of exclusive or partial breastfeeding up to the age of four months.

None of the included studies reported data on the other primary outcomes, i.e. mean duration of partial or exclusive breastfeeding.

#### Secondary outcomes

None of the included studies reported data on any of our prespecified secondary outcomes: rate of breastfeeding difficulties (mastitis, cracked nipples, breast engorgement); infant's health (dental malocclusion, otitis media, oral candidiasis; sudden infant death syndrome); maternal satisfaction and level of confidence in parenting; or mean episode/frequency of infant crying and fussing per day.

## DISCUSSION

Our review suggests that, in highly motivated mothers, pacifier use was not associated with a reduction in the rate or duration of exclusive or partial breastfeeding, regardless of whether the pacifier was introduced before or after lactation has established.

The WHO 'Ten Steps To Successful Breastfeeding' are valuable guidelines for hospitals. Some recommendations however, are based on observational studies. The use of pacifier is a common practice in many populations and thus, without having a solid scientific evidence of its impact on breastfeeding duration, this recommendation should be reviewed. The proposed mechanism for the relationship between reduced breastfeeding and pacifier use is that when infants use pacifiers they tend to suck on the breast less, and as a result the milk supply is reduced, and subsequently fails. Our review contradicts the finding of a meta-analysis of 31 cross-sectional and cohort studies (Karabulut 2009) enrolling several thousand infants that reported the use of pacifiers was associated with shortened duration of exclusive and of any breastfeeding before six months of age (RR 2.02; 95% CI 1.62 to 2.51 and RR 2.76; 95% CI 2.08 to 3.7 respectively).

Our review consists of two multicentre RCTs involving six tertiary hospitals from two different countries, enrolling 1302 participants in total. The risk of bias of the included studies were generally low. Nevertheless, there was no significant heterogeneity found among the studies. Both trials showed consistently that pacifier use did not significantly affect duration of breastfeeding. The summary effects obtained in our results were all consistently between 0.99 and 1.01 and 95% CIs were narrow. The rate of pacifier use in the restricted pacifier use was about 40% in both studies hence this could have a diluting effect the summary estimate. However, in view of the consistent proximity to 1.0 with extremely tight 95% CIs, if there is any effect it must be extremely small.

Several factors might affect breastfeeding duration such as maternal age, education, social status, and unrestricted mother-infant contact, as well as psychosocial factors like maternal intention to breastfeed, self-efficacy, breastfeeding confidence and earlier experience of breastfeeding (Kronborg 2004; Righard 1998). Comparison of baseline characteristics of the participants in both included trials showed no significant difference in the maternal age, education, and social and parity status. Mothers enrolled into these trials were highly motivated to continue breastfeeding. Jenik 2009 included only mothers who had successfully established breastfeeding after two weeks, while Kramer 2001 enrolled mothers after childbirth before lactation was established. In spite of the high motivation level of women in both of the included trials the breastfeeding rates at three months was very different, 34% in Kramer compared with more than 85% in Jenik, suggesting that the effect of the intervention would be similar across a range of breastfeeding rates. Thus, our review concludes that pacifier use before or after breastfeeding is established does not affect duration of breastfeeding when mothers are motivated to breastfeed their infants. The finding of this review, however, may not apply to mothers who are less motivated or who have no desire to breastfeed their infants longer.

Both studies in the review also reported that a proportion of mother-infant pairs in the trial did not comply with the recommendation to which they were randomised. This rate of non-compliance is not surprising in a population of diverse cultural background. Real-life situations such as intense infant crying, and infant preferences, may have influenced the use of pacifiers. This result is consistent with the intention-to-treat analysis, suggesting that recommending the use of a pacifier in a similar population does not influence breastfeeding success or duration. Kramer 2001 reported no significant difference in the mean frequency of cry and

fuss behaviour per day between the pacifier users and non-users at six weeks and nine weeks of age. However, the study did not contribute sufficient data to allow this outcome to be analysed.

This review was unable to evaluate any of the secondary outcomes (the effect of pacifier use on breastfeeding difficulties faced by the mothers, and the effect of pacifier on long-term infant health, e.g. dental malocclusion, otitis media, dental caries and sudden infant death syndrome). Thus, to answer these questions, we recommend a RCT to evaluate these effects.

## AUTHORS' CONCLUSIONS

### Implications for practice

In motivated mothers, there is moderate evidence that pacifier use in healthy term breastfeeding infants before and after lactation is established does not reduce the duration of breastfeeding up to four months of age. However, there is insufficient information on the potential harms of pacifiers on infants and mothers. In the light of the current review we recommend that until further information becomes available on the effects of pacifiers on the infant, mothers who are well motivated to breastfeed be enabled to make a decision on the use of a pacifier based on personal preference.

### Implications for research

Further research is recommended to address the effect of pacifier use on duration of breastfeeding that include less motivated women. We also recommend well-designed RCTs to assess the rate breastfeeding difficulties faced by mothers associated with pacifier use and the long-term effect of pacifier use on mother and infant health.

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As part of the pre-publication editorial process, this review has been commented on by two peers (an editor and referee who is external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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\* Indicates the major publication for the study

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## **SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment**

Task Force on Sudden Infant Death Syndrome

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## POLICY STATEMENT

# SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment

## abstract



Despite a major decrease in the incidence of sudden infant death syndrome (SIDS) since the American Academy of Pediatrics (AAP) released its recommendation in 1992 that infants be placed for sleep in a non-prone position, this decline has plateaued in recent years. Concurrently, other causes of sudden unexpected infant death that occur during sleep (sleep-related deaths), including suffocation, asphyxia, and entrapment, and ill-defined or unspecified causes of death have increased in incidence, particularly since the AAP published its last statement on SIDS in 2005. It has become increasingly important to address these other causes of sleep-related infant death. Many of the modifiable and nonmodifiable risk factors for SIDS and suffocation are strikingly similar. The AAP, therefore, is expanding its recommendations from focusing only on SIDS to focusing on a safe sleep environment that can reduce the risk of all sleep-related infant deaths, including SIDS. The recommendations described in this policy statement include supine positioning, use of a firm sleep surface, breastfeeding, room-sharing without bed-sharing, routine immunizations, consideration of using a pacifier, and avoidance of soft bedding, overheating, and exposure to tobacco smoke, alcohol, and illicit drugs. The rationale for these recommendations is discussed in detail in the accompanying "Technical Report—SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment," which is included in this issue of *Pediatrics* ([www.pediatrics.org/cgi/content/full/128/5/e1341](http://www.pediatrics.org/cgi/content/full/128/5/e1341)). *Pediatrics* 2011;128:1030–1039

## INTRODUCTION

Sudden infant death syndrome (SIDS) is a cause assigned to infant deaths that cannot be explained after a thorough case investigation, including a scene investigation, autopsy, and review of the clinical history.<sup>1</sup> Sudden unexpected infant death (SUID), also known as sudden unexpected death in infancy, is a term used to describe any sudden and unexpected death, whether explained or unexplained (including SIDS), that occurs during infancy. After case investigation, SUIDs can be attributed to suffocation, asphyxia, entrapment, infection, ingestions, metabolic diseases, arrhythmia-associated cardiac channelopathies, and trauma (accidental or nonaccidental). The distinction between SIDS and other SUIDs, particularly those that occur during an observed or unobserved sleep period (sleep-related infant deaths), such as ac-

## TASK FORCE ON SUDDEN INFANT DEATH SYNDROME

### KEY WORDS

SIDS, sudden infant death, infant mortality, sleep position, bed-sharing, tobacco, pacifier, immunization, bedding, sleep surface

### ABBREVIATIONS

SIDS—sudden infant death syndrome  
SUID—sudden unexpected infant death  
AAP—American Academy of Pediatrics

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**TABLE 1** Summary and Strength of Recommendations

## Level A recommendations

- Back to sleep for every sleep
- Use a firm sleep surface
- Room-sharing without bed-sharing is recommended
- Keep soft objects and loose bedding out of the crib
- Pregnant women should receive regular prenatal care
- Avoid smoke exposure during pregnancy and after birth
- Avoid alcohol and illicit drug use during pregnancy and after birth
- Breastfeeding is recommended
- Consider offering a pacifier at nap time and bedtime
- Avoid overheating
- Do not use home cardiorespiratory monitors as a strategy for reducing the risk of SIDS
- Expand the national campaign to reduce the risks of SIDS to include a major focus on the safe sleep environment and ways to reduce the risks of all sleep-related infant deaths, including SIDS, suffocation, and other accidental deaths; pediatricians, family physicians, and other primary care providers should actively participate in this campaign

## Level B recommendations

- Infants should be immunized in accordance with recommendations of the AAP and Centers for Disease Control and Prevention
- Avoid commercial devices marketed to reduce the risk of SIDS
- Supervised, awake tummy time is recommended to facilitate development and to minimize development of positional plagiocephaly

## Level C recommendations

- Health care professionals, staff in newborn nurseries and NICUs, and child care providers should endorse the SIDS risk-reduction recommendations from birth
- Media and manufacturers should follow safe-sleep guidelines in their messaging and advertising
- Continue research and surveillance on the risk factors, causes, and pathophysiological mechanisms of SIDS and other sleep-related infant deaths, with the ultimate goal of eliminating these deaths entirely

These recommendations are based on the US Preventive Services Task Force levels of recommendation ([www.uspreventiveservicestaskforce.org/uspstf/grades.htm](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm))

Level A: Recommendations are based on good and consistent scientific evidence (ie, there are consistent findings from at least 2 well-designed, well-conducted case-control studies, a systematic review, or a meta-analysis). There is high certainty that the net benefit is substantial, and the conclusion is unlikely to be strongly affected by the results of future studies

Level B: Recommendations are based on limited or inconsistent scientific evidence. The available evidence is sufficient to determine the effects of the recommendations on health outcomes, but confidence in the estimate is constrained by such factors as the number, size, or quality of individual studies or inconsistent findings across individual studies. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.

Level C: Recommendations are based primarily on consensus and expert opinion.

cidental suffocation, is challenging and cannot be determined by autopsy alone. Scene investigation and review of the clinical history are also required. Many of the modifiable and nonmodifiable risk factors for SIDS and suffocation are strikingly similar. This document focuses on the subset of SUIDs that occurs during sleep.

The recommendations outlined herein were developed to reduce the risk of SIDS and sleep-related suffocation, asphyxia, and entrapment among infants in the general population. As defined by epidemiologists, risk refers to the probability that an outcome will occur given the presence of a particular factor or set of factors. Although all of the 18 recommendations cited below are intended for parents, health care providers, and others who care for infants, the last 4 recommendations are also directed toward health policy

makers, researchers, and professionals who care for or work on behalf of infants. In addition, because certain behaviors, such as smoking, can increase risk for the infant, some recommendations are directed toward women who are pregnant or may become pregnant in the near future.

Table 1 summarizes the major recommendations, along with the strength of each recommendation. It should be noted that there have been no randomized controlled trials with regards to SIDS and other sleep-related deaths; instead, case-control studies are the standard.

Because most of the epidemiologic studies that established the risk factors and on which these recommendations are based include infants up to 1 year of age, these recommendations for sleep position and the sleep envi-

ronment should be used consistently for infants up to 1 year of age. Individual medical conditions might warrant that a physician recommend otherwise after weighing the relative risks and benefits.

For the background literature review and data analyses on which this policy statement and recommendations are based, please refer to the accompanying "Technical Report—SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment," available in the online version of this issue of *Pediatrics*.<sup>2</sup>

## RECOMMENDATIONS

1. Back to sleep for every sleep—To reduce the risk of SIDS, infants should be placed for sleep in a supine position (wholly on the back) for every



sleep by every caregiver until 1 year of life.<sup>5-7</sup> Side sleeping is not safe and is not advised.<sup>4,6</sup>

- a. The supine sleep position does not increase the risk of choking and aspiration in infants, even those with gastroesophageal reflux, because they have protective airway mechanisms.<sup>3,9</sup> Infants with gastroesophageal reflux should be placed for sleep in the supine position for every sleep, with the rare exception of infants for whom the risk of death from complications of gastroesophageal reflux is greater than the risk of SIDS (ie, those with upper airway disorders, for whom airway protective mechanisms are impaired),<sup>10</sup> including infants with anatomic abnormalities such as type 3 or 4 laryngeal clefts who have not undergone antireflux surgery. Elevating the head of the infant's crib while the infant is supine is not recommended.<sup>11</sup> It is ineffective in reducing gastroesophageal reflux; in addition, it might result in the infant sliding to the foot of the crib into a position that might compromise respiration.
- b. Preterm infants are at increased risk of SIDS,<sup>12,15</sup> and the association between prone sleep position and SIDS among low birth weight infants is equal to, or perhaps even stronger than, the association among those born at term.<sup>14</sup> Preterm infants and other infants in the NICU should be placed in the supine position for sleep as soon as the infant is medically stable and significantly before the infant's antici-

pated discharge, by 32 weeks' postmenstrual age.<sup>15</sup> NICU personnel should endorse safe-sleeping guidelines with parents of infants from the time of admission to the NICU.

- c. There is no evidence that placing infants on the side during the first few hours of life promotes clearance of amniotic fluid and decreases the risk of aspiration. Infants in the newborn nursery and infants who are rooming in with their parents should be placed in the supine position as soon as they are ready to be placed in the bassinet.
  - d. Although data to make specific recommendations as to when it is safe for infants to sleep in the prone or side position are lacking, studies that have established prone and side sleeping as risk factors for SIDS include infants up to 1 year of age. Therefore, infants should continue to be placed supine until 1 year of age. Once an infant can roll from supine to prone and from prone to supine, the infant can be allowed to remain in the sleep position that he or she assumes.
2. Use a firm sleep surface—A firm crib mattress, covered by a fitted sheet, is the recommended sleeping surface to reduce the risk of SIDS and suffocation.
    - a. A crib, bassinet, or portable crib/play yard that conforms to the safety standards of the Consumer Product Safety Commission and ASTM International (formerly the American Society for Testing and Materials) is recommended.<sup>16</sup> In addition, parents and providers should

check to make sure that the product has not been recalled. Cribs with missing hardware should not be used, and the parent or provider should not attempt to fix broken components of a crib, because many deaths are associated with cribs that are broken or have missing parts (including those that have presumably been fixed). Local organizations throughout the United States can help to provide low-cost or free cribs or play yards for families with financial constraints.

- b. Only mattresses designed for the specific product should be used. Mattresses should be firm and maintain their shape even when the fitted sheet designated for that model is used, such that there are no gaps between the mattress and the side of the crib, bassinet, portable crib, or play yard. Pillows or cushions should not be used as substitutes for mattresses or in addition to a mattress. Soft materials or objects such as pillows, quilts, comforters, or sheepskins, even if covered by a sheet, should not be placed under a sleeping infant. If a mattress cover to protect against wetness is used, it should be tightly fitting and thin.
- c. Infants should not be placed for sleep on beds because of the risk of entrapment and suffocation.<sup>17,18</sup> In addition, portable bed rails should not be used with infants because of the risk of entrapment and strangulation.
- d. The infant should sleep in an area free of hazards, such

as dangling cords, electric wires, and window-covering cords, because they might present a strangulation risk.

- e. Sitting devices, such as car safety seats, strollers, swings, infant carriers, and infant slings, are not recommended for routine sleep in the hospital or at home.<sup>19–23</sup> Infants who are younger than 4 months are particularly at risk, because they might assume positions that can create risk of suffocation or airway obstruction. When infant slings and cloth carriers are used for carrying, it is important to ensure that the infant's head is up and above the fabric, the face is visible, and that the nose and mouth are clear of obstructions.<sup>24</sup> After nursing, the infant should be repositioned in the sling so that the head is up, is clear of fabric, and is not against the adult's body or the sling. If an infant falls asleep in a sitting device, he or she should be removed from the product and moved to a crib or other appropriate flat surface as soon as is practical. Car safety seats and similar products are not stable on a crib mattress or other elevated surfaces.<sup>25–29</sup>
3. Room-sharing without bed-sharing is recommended—There is evidence that this arrangement decreases the risk of SIDS by as much as 50%.<sup>5,7,30,31</sup> In addition, this arrangement is most likely to prevent suffocation, strangulation, and entrapment that might occur when the infant is sleeping in an adult bed.
    - a. The infant's crib, portable crib, play yard, or bassinet

should be placed in the parents' bedroom close to the parents' bed. This arrangement reduces SIDS risk and removes the possibility of suffocation, strangulation, and entrapment that might occur when the infant is sleeping in the adults' bed. It also allows close parental proximity to the infant and facilitates feeding, comforting, and monitoring of the infant.

- b. Devices promoted to make bed-sharing "safe" (eg, in-bed co-sleepers) are not recommended.
- c. Infants may be brought into the bed for feeding or comforting but should be returned to their own crib or bassinet when the parent is ready to return to sleep.<sup>6,32</sup> Because of the extremely high risk of SIDS and suffocation on couches and armchairs,<sup>5,5,6,51,52</sup> infants should not be fed on a couch or armchair when there is a high risk that the parent might fall asleep.
- d. Epidemiologic studies have not demonstrated any bed-sharing situations that are protective against SIDS or suffocation. Furthermore, not all risks associated with bed-sharing, such as parental fatigue, can be controlled. Therefore, the American Academy of Pediatrics (AAP) does not recommend any specific bed-sharing situations as safe. Moreover, there are specific circumstances that, in epidemiologic studies, substantially increase the risk of SIDS or suffocation while bed-sharing. In particular, it should be stressed to

parents that they avoid the following situations at all times:

- i. Bed-sharing when the infant is younger than 3 months, regardless of whether the parents are smokers or not.<sup>5,7,31–34</sup>
  - ii. Bed-sharing with a current smoker (even if he or she does not smoke in bed) or if the mother smoked during pregnancy.<sup>5,5,54–56</sup>
  - iii. Bed-sharing with someone who is excessively tired.
  - iv. Bed-sharing with someone who has or is using medications (eg, certain antidepressants, pain medications) or substances (eg, alcohol, illicit drugs) that could impair his or her alertness or ability to arouse.<sup>7,37</sup>
  - v. Bed-sharing with anyone who is not a parent, including other children.<sup>3</sup>
  - vi. Bed-sharing with multiple persons.<sup>3</sup>
  - vii. Bed-sharing on a soft surface such as a waterbed, old mattress, sofa, couch, or armchair.<sup>3,5,6,31,32</sup>
  - viii. Bed-sharing on a surface with soft bedding, including pillows, heavy blankets, quilts, and comforters.<sup>5,58</sup>
- e. It is prudent to provide separate sleep areas and avoid co-bedding for twins and higher-order multiples in the hospital and at home.<sup>59</sup>
4. Keep soft objects and loose bedding out of the crib to reduce the risk of SIDS, suffocation, entrapment, and strangulation.
    - a. Soft objects, such as pillows and pillow-like toys, quilts, comfort-

- ers, and sheepskins, should be kept out of an infant's sleeping environment.<sup>40-45</sup>
- b. Loose bedding, such as blankets and sheets, might be hazardous and should not be used in the infant's sleeping environment.<sup>3,6,46-51</sup>
  - c. Because there is no evidence that bumper pads or similar products that attach to crib slats or sides prevent injury in young infants and because there is the potential for suffocation, entrapment, and strangulation, these products are not recommended.<sup>52,53</sup>
  - d. Infant sleep clothing that is designed to keep the infant warm without the possible hazard of head covering or entrapment can be used.
5. Pregnant women should receive regular prenatal care—There is substantial epidemiologic evidence linking a lower risk of SIDS for infants whose mothers obtain regular prenatal care.<sup>54-57</sup>
  6. Avoid smoke exposure during pregnancy and after birth—Both maternal smoking during pregnancy and smoke in the infant's environment after birth are major risk factors for SIDS.
    - a. Mothers should not smoke during pregnancy or after the infant's birth.<sup>1,58-61</sup>
    - b. There should be no smoking near pregnant women or infants. Encourage families to set strict rules for smoke-free homes and cars and to eliminate secondhand tobacco smoke from all places in which children and other nonsmokers spend time.<sup>62,63</sup>
    - c. The risk of SIDS is particularly high when the infant bed-
      - shares with an adult smoker.<sup>5,6,34-36</sup>
  7. Avoid alcohol and illicit drug use during pregnancy and after birth—There is an increased risk of SIDS with prenatal and postnatal exposure to alcohol or illicit drug use.
    - a. Mothers should avoid alcohol and illicit drugs periconceptionally and during pregnancy.<sup>64-70</sup>
    - b. Parental alcohol and/or illicit drug use in combination with bed-sharing places the infant at particularly high risk of SIDS.<sup>7,37</sup>
  8. Breastfeeding is recommended.
    - a. Breastfeeding is associated with a reduced risk of SIDS.<sup>71-73</sup> If possible, mothers should exclusively breastfeed or feed with expressed human milk (ie, not offer any formula or other non-human milk-based supplements) for 6 months, in alignment with recommendations of the AAP.<sup>74</sup>
    - b. The protective effect of breastfeeding increases with exclusivity.<sup>73</sup> However, any breastfeeding has been shown to be more protective against SIDS than no breastfeeding.<sup>73</sup>
  9. Consider offering a pacifier at nap time and bedtime—Although the mechanism is yet unclear, studies have reported a protective effect of pacifiers on the incidence of SIDS.<sup>3,7,32</sup> The protective effect persists throughout the sleep period, even if the pacifier falls out of the infant's mouth.
    - a. The pacifier should be used when placing the infant for sleep. It does not need to be reinserted once the infant falls asleep. If the infant refuses the pacifier, he or she should not be forced to take it. In those cases, parents can try to offer the pacifier again when the infant is a little older.
  - b. Because of the risk of strangulation, pacifiers should not be hung around the infant's neck. Pacifiers that attach to infant clothing should not be used with sleeping infants.
  - c. Objects such as stuffed toys, which might present a suffocation or choking risk, should not be attached to pacifiers.
  - d. For breastfed infants, delay pacifier introduction until breastfeeding has been firmly established,<sup>74</sup> usually by 3 to 4 weeks of age.
  - e. There is insufficient evidence that finger-sucking is protective against SIDS.
10. Avoid overheating—Although studies have revealed an increased risk of SIDS with overheating,<sup>75-78</sup> the definition of overheating in these studies varied. Therefore, it is difficult to provide specific room-temperature guidelines for avoiding overheating.
    - a. In general, infants should be dressed appropriately for the environment, with no more than 1 layer more than an adult would wear to be comfortable in that environment.
    - b. Parents and caregivers should evaluate the infant for signs of overheating, such as sweating or the infant's chest feeling hot to the touch.
    - c. Overbundling and covering of the face and head should be avoided.<sup>79</sup>

- d. There is currently insufficient evidence to recommend the use of a fan as a SIDS risk-reduction strategy.
11. Infants should be immunized in accordance with recommendations of the AAP and the Centers for Disease Control and Prevention—There is no evidence that there is a causal relationship between immunizations and SIDS.<sup>90</sup> Indeed, recent evidence suggests that immunization might have a protective effect against SIDS.<sup>91–93</sup> Infants should also be seen for regular well-child checks in accordance with AAP recommendations.
  12. Avoid commercial devices marketed to reduce the risk of SIDS—These devices include wedges, positioners, special mattresses, and special sleep surfaces. There is no evidence that these devices reduce the risk of SIDS or suffocation or that they are safe.
    - a. The AAP concurs with the US Food and Drug Administration and Consumer Product Safety Commission that manufacturers should not claim that a product or device protects against SIDS unless there is scientific evidence to that effect.
  13. Do not use home cardiorespiratory monitors as a strategy to reduce the risk of SIDS—Although cardiorespiratory monitors can be used at home to detect apnea, bradycardia, and, when pulse oximetry is used, decreases in oxyhemoglobin saturation, there is no evidence that use of such devices decreases the incidence of SIDS.<sup>94–97</sup> They might be of value for selected infants but should not be used routinely.
 

There is also no evidence that routine in-hospital cardiorespiratory monitoring before discharge from the hospital can identify newborn infants at risk of SIDS.

    14. Supervised, awake tummy time is recommended to facilitate development and to minimize development of positional plagiocephaly.
      - a. Although there are no data to make specific recommendations as to how often and how long it should be undertaken, supervised, awake tummy time is recommended on a daily basis, beginning as early as possible, to promote motor development, facilitate development of the upper body muscles, and minimize the risk of positional plagiocephaly.<sup>98</sup>
      - b. Diagnosis, management, and other prevention strategies for positional plagiocephaly, such as avoidance of excessive time in car safety seats and changing the infant's orientation in the crib, are discussed in detail in the recent AAP clinical report on positional skull deformities.<sup>98</sup>
    15. Health care professionals, staff in newborn nurseries and neonatal intensive care nurseries, and child care providers should endorse the SIDS risk-reduction recommendations from birth.<sup>98–91</sup>
      - a. Staff in NICUs should model and implement all SIDS risk-reduction recommendations as soon as the infant is clinically stable and significantly before anticipated discharge.
      - b. Staff in newborn nurseries should model and implement these recommendations beginning at birth and well before anticipated discharge.
    - c. All physicians, nurses, and other health care professionals should receive education on safe infant sleep.
    - d. All child care providers should receive education on safe infant sleep and implement safe sleep practices. It is preferable that they have written policies.
  16. Media and manufacturers should follow safe-sleep guidelines in their messaging and advertising.
 

Media exposures (including movie, television, magazines, newspapers, and Web sites), manufacturer advertisements, and store displays affect individual behavior by influencing beliefs and attitudes.<sup>99,91</sup> Media and advertising messages contrary to safe-sleep recommendations might create misinformation about safe sleep practices.<sup>92</sup>

    17. Expand the national campaign to reduce the risks of SIDS to include a major focus on the safe sleep environment and ways to reduce the risks of all sleep-related infant deaths, including SIDS, suffocation, and other accidental deaths. Pediatricians, family physicians, and other primary care providers should actively participate in this campaign.
      - a. Public education should continue for all who care for infants, including parents, child care providers, grandparents, foster parents, and babysitters, and should include strategies for overcoming barriers to behavior change.
      - b. The campaign should continue to have a special focus

on the black and American Indian/Alaskan Native populations because of the higher incidence of SIDS and other sleep-related infant deaths in these groups.

- c. The campaign should specifically include strategies for increasing breastfeeding while decreasing bed-sharing and eliminating tobacco smoke exposure.
- d. These recommendations should be introduced before pregnancy and ideally in secondary school curricula for both boys and girls. The importance of maternal preconceptional health and avoidance of substance use (including alcohol and smoking) should be included in this training.
- e. Safe-sleep messages should be reviewed, revised, and reissued at least every 5 years to address the next generation of new parents and products on the market.

18. Continue research and surveillance on the risk factors, causes, and pathophysiological mechanisms of SIDS and other sleep-related infant deaths, with the ul-

timiate goal of eliminating these deaths entirely.

- a. Education campaigns need to be evaluated, and innovative intervention methods need to be encouraged and funded.
- b. Continued research and improved surveillance on the etiology and pathophysiological basis of SIDS should be funded.
- c. Standardized protocols for death-scene investigations should continue to be implemented. Comprehensive autopsies that include full external and internal examination of all major organs and tissues (including the brain), complete radiographs, metabolic testing, and toxicology screening should be performed. Training about how to conduct comprehensive death-scene investigation offered to medical examiners, coroners, death-scene investigators, first responders, and law enforcement should continue, and resources for maintaining training and conduct of these investigations need to be allocated. In addition, child death reviews, with involvement of pediatricians

and other primary care providers, should be supported and funded.

- d. Improved and widespread surveillance of SIDS and SUID cases should be implemented and funded.
- e. Federal and private funding agencies should remain committed to all aspects of the aforementioned research.

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**SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations  
for a Safe Infant Sleeping Environment**

Task Force on Sudden Infant Death Syndrome

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## **AAP SIDS Policy Statement Summary Sheet in regards to Breastfeeding**

1. Breastfeeding is recommended
  - a) Breastfeeding is associated with a reduced risk of SIDS. If possible, mothers should exclusively breastfeed or feed with expressed human milk (i.e., not offer any formula or other non-human milk-based supplements for 6 months.
  - b) The protective effect of breastfeeding increases with exclusivity. However, any breastfeeding has been shown to be more protective against SIDS than no breastfeeding.
2. For breastfed infants, delay pacifier introduction until breastfeeding has been firmly established, usually by 3 to 4 weeks of age.
3. The campaign should specifically include strategies for increasing breastfeeding while decreasing bed-sharing and eliminating tobacco smoke exposure.
4. Infants may be brought into the bed for feeding or comforting but should be returned to their own crib or bassinet when the parent is ready to return to sleep.

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PRESS  
RELEASE

# Randomised trial comparing hand expression with breast pumping for mothers of term newborns feeding poorly

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## ABSTRACT

**Objective** Breast pumping or hand expression may be recommended when newborns latch or suck poorly. A recent trial found worse outcomes among mothers who used a breast pump in the early postpartum period. The objective of this study was to compare bilateral electric breast pumping to hand expression among mothers of healthy term infants feeding poorly at 12–36 h after birth.

**Design** Randomised controlled trial.

**Setting** Well-baby nursery and postpartum unit.

**Patients** 68 mothers of newborns 12–36 h old who were latching or sucking poorly were randomly assigned to either 15 min of bilateral electric pumping or 15 min of hand expression.

**Main outcome measures** Milk transfer, maternal pain, breastfeeding confidence and breast milk expression experience (BMEE) immediately after the intervention, and breastfeeding rates at 2 months after birth.

**Results** The median volume of expressed milk (range) was 0.5 (0–5) ml for hand expressing mothers and 1 (0–40) ml for pumping mothers ( $p=0.07$ ). Maternal pain, breastfeeding confidence and BMEE did not differ by intervention. At 2 months, mothers assigned to hand expression were more likely to be breastfeeding (96.1%) than mothers assigned to breast pumping (72.7%) ( $p=0.02$ ).

**Conclusions** Hand expression in the early postpartum period appears to improve eventual breastfeeding rates at 2 months after birth compared with breast pumping, but further research is needed to confirm this. However, in circumstances where either pumping or hand expression would be appropriate for healthy term infants 12–36 h old feeding poorly, providers should consider recommending hand expression.

## INTRODUCTION

The many benefits of breastfeeding<sup>1–8</sup> have encouraged the establishment of Healthy People breastfeeding goals.<sup>9–10</sup> Although rates of initiation have risen and are now close to target, rates of breastfeeding at time points after initiation are still well below target.<sup>3–9</sup> Paediatricians, obstetricians, lactation consultants, nurses and peer counsellors have all been shown to promote breastfeeding.<sup>11–19</sup> However, few specific provider recommendations have been examined in clinical trials for their effect on eventual breastfeeding duration.

One common provider recommendation is early milk expression, either using a breast pump or using hand expression.<sup>20–21</sup> Chapman *et al*<sup>22</sup> conducted a randomised trial comparing breast pumping to no

## What is already known on this topic

- ▶ Poor infant suck and latch are common in the newborn period.
- ▶ Breast milk expression using either hand expression or a pump is often recommended for mothers of newborns latching or sucking poorly.
- ▶ No previous studies have reported the effect of type of milk expression on breastfeeding outcomes.

## What this study adds

- ▶ Expressed milk volume at 12–36 h did not differ by method of expression.
- ▶ Mothers randomly assigned to hand expression at 12–36 h were more comfortable being seen expressing than mothers randomly assigned to pumping.
- ▶ Mothers randomly assigned to hand expression were more likely to be breastfeeding at 2 months than mothers randomly assigned to pumping.

intervention for mothers after Caesarean delivery and found a trend toward decreased breastfeeding duration in the pumping group. Other investigators, including Schwartz *et al*,<sup>23</sup> Morton *et al*<sup>24</sup> and Win *et al*,<sup>25</sup> have conducted observational studies on the association between breast pumping and/or hand expression and eventual breastfeeding duration. The results of these studies have been mixed, and due to their observational design, they may have some confounding by varying reasons for early expression practices. Milk expression may provide additional breast stimulation to increase milk production, but the hormonal response to expression is not identical to infant sucking,<sup>26</sup> and expression may have other important differences from sucking as well. Nevertheless, because the degree to which an infant empties a breast influences the future rate of milk synthesis (at least during mature milk production),<sup>27</sup> experts often recommend milk expression for mothers with breastfeeding challenges.<sup>21–28</sup> Because some studies have shown that breast pumping removes more

milk than hand expression,<sup>26 29 30</sup> breast pumping may be seen as superior to hand expression. However, some experts have observed that hand expression may result in larger milk volumes immediately after birth.<sup>24 31</sup> The difference between the effect of early breast pumping and the effect of early hand expression on eventual breastfeeding prevalence is unknown.

Infants who are not latching well or not sucking well when latched are at increased risk of early breastfeeding discontinuation.<sup>32</sup> Excessive newborn weight loss, initiation of formula, maternal pain, maternal frustration and lower milk production due to inadequate breast stimulation may all contribute to breastfeeding discontinuation in this group, and milk expression is often recommended to improve breast stimulation and milk production. However, no studies have examined the effect of the method of early milk expression on breastfeeding outcomes for such newborns. We conducted a randomised controlled trial comparing the effect of breast pumping to that of hand expression for mothers of healthy term infants 12–36 h old who were not latching well or not sucking well when latched.

## PATIENTS AND METHODS

We enrolled mother–infant pairs 12–36 h after birth where the infants were not latching well or not sucking well when latched. Pairs were excluded if mothers were <18 years old, did not speak English or had a history of low milk supply or breast surgery other than cyst removal, or if infants were <37 weeks gestation, <2000 g birth weight or received level II or III care. Poor latch and/or poor suck was determined by a study doctor or nurse by maternal interview and review of any lactation consultation at the time of recruitment. The study sample was drawn in 2007–2009 from the population of the well-baby nurseries and postpartum units at the University of California San Francisco (UCSF) Medical Center, Kaiser Permanente South Sacramento Medical Center and Stanford University Medical Center. Informed consent was obtained from all subjects by the study doctor or nurse. This study was approved by the UCSF Committee on Human Research, the Kaiser Permanente Institutional Review Board and the Stanford University Administrative Panel on Human Subjects in Medical Research.

We randomly assigned 68 mother–infant pairs to either breast pumping or hand expression using blocked randomisation, stratified by site and delivery method. Sample size was determined to allow 80% power to detect a 5 ml difference in expressed milk volume between the two study groups with an  $\alpha$  of 0.05. The allocation sequence for randomisation was generated by an independent biostatistician; assignments were placed into sealed opaque envelopes by an independent administrative assistant. Immediately following enrolment, the study investigator opened sequential envelopes in the presence of a second clinician and revealed the randomisation arm. Thus we had complete allocation concealment, although no blinding was possible. Infants were then weighed on a Babyweigh scale (Medela, McHenry, Illinois, USA) using the test weighing technique, in which the infant is weighed prior to feeding on a scale with an accuracy of 2 g and then reweighed after feeding on the same scale. After initial weighing, mothers attempted to breastfeed their infants with advice and support from a study doctor or nurse. Following the breastfeeding attempt, mothers randomly assigned to breast pumping were taught breast pumping by the study doctor or nurse and then used a bilateral electric breast pump (Ameda Elite Hospital

Grade Breast Pump; Ameda, Lincolnshire, Illinois, USA) for 15 min in a single session under supervision of the study doctor or nurse. The breast pump vacuum setting was initially begun at the lowest level (30 mm Hg) and then gradually increased as tolerated by the mother. Mothers assigned to hand expression were taught hand expression by a study doctor or nurse and then performed hand expression for 15 min in a single session under supervision of the study doctor or nurse. After milk expression, the entire expressed milk volume was measured by syringe and mothers in both groups fed their babies any expressed milk using a syringe, cup or spoon. Infants were subsequently reweighed on the same scale.

Immediately following these procedures, the study investigator verbally administered three questionnaires. First, in order to measure breastfeeding confidence, mothers were asked questions from a slightly modified version of the Breastfeeding Self-Efficacy Scale–Short Form (BSES-SF),<sup>33</sup> rating each item on a scale from 1 ('strongly disagree') to 5 ('strongly agree'). Second, mothers were asked questions from a modified Holdcroft scale<sup>34</sup> of breastfeeding-related pain, which assessed pain in the breast, lower abdomen, back and perineum on a scale of 0–10. Third, mothers were asked questions from a newly developed breast milk expression experience (BMEE) measure, which included questions about social support for milk expression and personal and learning experience of milk expression. Mothers were then reminded that they could continue to use their method of milk expression if desired but were not under an obligation to do so. Phone follow-up by various investigators at 1 week, 1 month and 2 months assessed breastfeeding, milk expression and formula use. See box 1 for survey questions used to assess breastfeeding, milk expression and formula use. After 3 months of enrolment, due to low follow-up rates, study procedures were revised to include the collection of at least two phone numbers for follow-up, and were further revised after 9 months to include the collection of at least three phone numbers for follow-up. Completion rate rose from 30% to 81.6% following these changes.

We compared the effect of method of expression on the dichotomous outcomes of breastfeeding and breast pumping using  $\chi^2$  tests. We compared the effect of method of expression on our primary outcome of expressed milk volume and maternal pain using the Mann–Whitney test. We compared the effect of method of expression on continuous outcomes of BSES-SF scores and BMEE scores using the Student *t* test.

### Box 1 Survey questions on breastfeeding, milk expression and formula use at 1 week, 1 month and 2 months

1. Within the past 24 h, since yesterday at this time, has the infant received any breast milk?
2. Within the past 24 h, has the infant received any breast milk directly from nursing?
3. Within the past 24 h, has the infant received any expressed breast milk?
4. Within the past 24 h, has the infant received any formula?
5. In the past 24 h, has the infant received any water, juice or tea?
6. Are you expressing breast milk?

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All analyses were conducted using Stata 9.2 (Stata, College Station, Texas, USA).

## RESULTS

Overall, 35 (51.5%) mothers were assigned to the hand expression group and 33 (48.5%) to the pumping group. The two study groups were similar at baseline (table 1).

The median volume of expressed milk (25th–75th percentile) was 0.5 ml (0–1) for hand expressing mothers (range 0–5 ml), and 1 ml (0–3) for pumping mothers (range 0–40 ml) ( $p=0.07$ ). The median change in weight of infants before and after all feeding (including breastfeeding and feeding of expressed milk) was 0 g (–3 to 5) for the pumping group (range –8 to 98 g), and 0 g (–1 to 2) for the hand expression group (range –4 to 14 g) ( $p=0.72$ ).

There were no significant differences between the groups for any of the individual items in the BSES-SF or for the full scale (table 2). The BMEE differed for two questions whose

wordings necessarily varied with treatment group. Mothers assigned to pumping had more agreement with the statement 'I don't want anyone to see me pumping' ( $3.0\pm 1.2$ ) than mothers who hand expressed did with the statement 'I don't want anyone to see me hand expressing' ( $2.3\pm 1.1$ ) ( $p<0.05$ ). Mothers who were assigned to pumping had lower agreement with the statement 'The instructions for using the pump are clear' ( $4.1\pm 0.9$ ) than mothers who hand expressed did with the statement 'The instructions for hand expressing are clear' ( $4.5\pm 0.5$ ) ( $p<0.05$ ). In our cohort, 33 (48.5%) mothers reported a pain score of 5 (of 10) or greater in one or more areas (either breast, lower abdomen, back or perineum). Pain scores during and after the milk expression intervention differed little by study group. However, breast pain scores measured during the feeding before the intervention were significantly higher in the hand expression group than in the breast pump group (22.9% vs 6.1% with breast pain scores  $\geq 5$ ), so it is possible that this pre-existing difference between the groups masked an effect of the intervention. For additional results on pain, see table 3.

At 1 week, 35 (57.4%) babies had received formula, including 17 (58.6%) in the pump group and 18 (56.3%) in the hand expression group. The 37 (62.7%) mothers expressing milk at 1 week included 18 (66.7%) from the group originally assigned to pumping and 19 (59.4%) from the group originally assigned to hand expression; one mother from each group reported using hand expression at 1 week. The 40 (78.4%) mothers expressing milk at 1 month included 16 (72.7%) from the group originally assigned to pumping and 24 (82.3%) from the group originally assigned to hand expression; two mothers from each group reported using hand expression at 1 month.

Final outcome assessment at 2 months was obtained for 48 mothers (70.6%). Absence of outcome ascertainment at

**Table 1** Cohort characteristics

Characteristic	Breast pump group (N=33)	Hand expression group (N=35)	p Value
Infant age (h), mean $\pm$ SD	20.8 $\pm$ 7.8	20.9 $\pm$ 6.7	0.95
Male gender	23 (69.7%)	17 (48.6%)	0.08
Birth weight (kg), mean $\pm$ SD	3.31 $\pm$ 0.5	3.50 $\pm$ 0.5	0.23
Gestational age (weeks)	39.1 $\pm$ 1.3	39.4 $\pm$ 1.1	0.27
Vaginal delivery	27 (77%)	24 (72.7%)	0.67
Maternal age (years)	30.2 $\pm$ 6.6	30.2 $\pm$ 6.3	0.98

**Table 2** Outcomes immediately following intervention: item scores\* for items differing by group

	Randomised comparison		
	Breast pump group	Hand expression group	p Value
<b>BSES items and scale</b>			
I can always comfortably breastfeed with my family members present	3.2 $\pm$ 1.3	3.8 $\pm$ 1.2	0.058
I can always know when to switch from one breast to the other	3.2 $\pm$ 1.2	2.6 $\pm$ 1.3	0.080
Total BSES	3.4 $\pm$ 0.8	3.4 $\pm$ 0.7	0.994
<b>BMEE items and scale</b>			
I don't want anyone to see me (pumping/hand expressing)	3.0 $\pm$ 1.2	2.3 $\pm$ 1.1	0.021
The instructions for (using the pump/hand expressing) are clear	4.1 $\pm$ 0.9	4.5 $\pm$ 0.5	0.036
Total score, 11-item BMEE	3.4 $\pm$ 0.4	3.4 $\pm$ 0.6	0.901
Expressed milk volume (ml)	2.9 $\pm$ 7.7	0.8 $\pm$ 1.4	0.136
Weight change before feed to after feed (g)	0.8 $\pm$ 3.5	4.2 $\pm$ 19.1	0.334

\*Items scored on a 1–5 scale, from 1, strongly disagree to 5, strongly agree. p Values are for randomised assignment to breast pump compared to hand expression.

BMEE, breast milk expression experience; BSES, Breastfeeding Self-Efficacy Scale.

**Table 3** Number of subjects with a pain score  $\geq 5$  (out of 10) in the hand expression (n=35) and pumping (n=33) groups

	During feeding, prior to the expression intervention		During the expression intervention		After expression intervention	
	Hand	Pump	Hand	Pump	Hand	Pump
Breast	8 (22.9)**	2 (6.1)**	2 (5.7)	2 (6.1)	1 (2.9)	2 (6.1)
Abdomen	10 (34.5)*	4 (15.4)*	4 (11.4)	2 (6.1)	8 (22.9)	3 (9.1)
Back	3 (8.6)	3 (9.1)	2 (5.7)	3 (9.1)	6 (17.1)	3 (9.1)
Perineum	5 (14.3)	5 (15.2)	5 (14.3)	5 (15.2)	12 (34.3)	13 (39.4)
Any location	18 (51.4)	13 (39.4)	11 (31.4)	11 (33.3)	17 (48.6)	17 (51.5)

Values are N (%).

\* $p<0.10$ , \*\* $p<0.05$ .

**Table 4** Outcomes immediately following intervention: item scores\* for items differing by study group

	Breastfeeding at 2 months	No breastfeeding at 2 months	p Value
<b>BSES items and scale</b>			
I can always comfortably breastfeed with my family members present	3.7±1.2	2.7±1.4	0.055
I can always know when to switch from one breast to the other	3.0±1.3	2.9±0.9	0.859
Total BSES	3.5±0.7	2.7±0.7	0.019
<b>BMEE items and scale</b>			
I don't want anyone to see me (pumping/hand expressing)	2.5±1.1	3.4±1.1	0.062
I had no problems figuring out how to (use the pump/hand express colostrum/milk)	3.8±1.0	3.0±0.6	0.048
The instructions for (using the pump/hand expressing) are clear	4.3±0.6	3.4±1.0	0.002
Total score, 11-item BMEE	3.5±0.5	3.2±0.3	0.134

\*Items scored on a 1–5 scale, from 1, strongly disagree to 5, strongly agree.

p Values are for eventual outcome of breastfeeding at 2 months compared to no breastfeeding at 2 months.

BMEE, breast milk expression experience; BSES, Breastfeeding Self-Efficacy Scale.

2 months did not differ by study group, with nine mothers in the hand expression group and 11 mothers in the pump group lost to follow-up for 2-month outcomes ( $p=0.49$ ). Mothers assigned to the hand expression group were more likely to be breastfeeding at 2 months (97.1%) than mothers assigned to the breast pump group (72.7%) ( $p=0.02$ ). The relative risk for breastfeeding at 2 months was 1.32 (1.01–1.73) for the hand expression group compared to the breast pump group.

At 2 months, 41 (85.4%) mothers were still breastfeeding and seven had stopped breastfeeding. Mothers who stopped breastfeeding by 2 months had lower scores in the immediate postpartum period for the modified BSES-SF, with a mean score of  $2.7\pm 0.74$  compared with mothers who continued breastfeeding at 2 months, with a mean BSES-SF score of  $3.5\pm 0.66$  immediately after birth ( $p=0.02$ ). See table 4 for additional differences between mothers who eventually breastfed through 2 months and mothers who did not. At 2 months, 36 (75%) mothers were expressing milk, including 15 (68.2%) from the group originally assigned to breast pumping and 21 (80.8%) from the group originally assigned to hand expression ( $p=0.31$ ). All study mothers who were expressing breast milk at 2 months were using a pump and none was using hand expression. The majority of mothers who were expressing milk at 2 months (53.1%) stated that they did so to store milk for times of maternal–infant separation. Few (15.6%) of the mothers at 2 months stated that they expressed milk in order to improve their milk supply, and the proportion of mothers expressing milk at 2 months in order to improve their milk supply did not differ by randomisation arm.

## DISCUSSION

Our randomised study found that mothers of healthy, term, poorly feeding infants randomly assigned to hand expression at 12–36 h were more likely to be breastfeeding at 2 months than mothers randomly assigned to breast pumping. Our results could not be explained by milk volume, breastfeeding self-efficacy, pain or BMEE, which all differed little between the groups. However, the hand expression group reported increased comfort expressing milk with others present compared to the breast pump group, and the hand expression group also showed a trend towards increased comfort breastfeeding with others present. It is possible that hand expressing made mothers feel more comfortable breastfeeding and/or expressing with others present, or that pumping made mothers feel less comfortable breastfeeding and/or expressing with others present. This trend may have contributed to the success of the intervention, since we also found a trend towards

increased rates of breastfeeding at 2 months among mothers who reported increased comfort breastfeeding with others present during the birth hospitalisation.

Since few mothers in our study used hand expression after the first week, we believe our results may be potentially attributable to two important differences between pumping and hand expression that are specific to the immediate postpartum period. First, mothers in the hand expression group reported greater comfort expressing milk with others present than mothers in the breast pump group. Feeling awkward or embarrassed in the presence of others might be an important barrier to continued successful breastfeeding in the immediate postpartum period. Second, milk volumes in this study cohort were very small, with median volumes of 1 ml in both groups. It is possible that the small volume of colostrum expressed by both groups appeared 'normal' in the hand expression group but appeared 'insufficient' for the mothers in the pump group, who used the large collecting system of the pump.

Potential additional causes for our results include bias or chance. A potential source of bias for this study could be that follow-up at 2 months was completed for 70.6% of subjects. If mothers in the hand expression group had lower rates of follow-up than those in the pump group, and if mothers who were not breastfeeding at 2 months were more likely to be lost to follow-up than mothers who were breastfeeding at 2 months, this might introduce bias to account for our results. However, there was no difference between the study arms in loss to follow-up. Furthermore, most loss to follow-up occurred in the early study participants, prior to establishment of improved follow-up procedures. Since our randomisation occurred in randomly permuted blocks of two and four, we had an even distribution to both randomisation arms throughout the time period of our study, and therefore loss to follow-up from early subjects due to suboptimal follow-up procedures is unlikely to account for any difference found between study groups.

Our study has several important limitations. First, we included only mothers of healthy term infants 12–36 h old who were not latching well or not sucking well when latched. While this is a large and important group, our findings may not apply to mothers of younger or older infants, or to mothers expressing milk for other reasons, such as engorgement or maternal–infant separation. Second, our study did not include a group randomised to receive no intervention. Therefore, we cannot report how either hand expression or breast pumping would compare to no intervention for our study population. Third, our study attempted to identify potential reasons for

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an effect of method of expression on eventual breastfeeding prevalence, including breastfeeding confidence as measured by breastfeeding self-efficacy, expression experience and pain. However, few differences in these measures reached statistical significance when we compared the two groups. It is possible that a larger sample size would have provided the statistical power to better identify the factors contributing to the effect of method of milk expression, but it is also possible that other, unmeasured factors were significant contributors to or mediators of the effect. The indication of no significant difference between the two groups on enrolment (table 1), however, suggests that the randomisation procedure was effective in controlling for confounders. Fourth, we do not have data on LATCH score, incidence of ankyloglossia, maternal body mass index or other predictors of breastfeeding rates. However, we would expect these factors to have been approximately evenly distributed by the randomisation, so bias from this source appears to be unlikely.

Our results need to be confirmed by other studies. If confirmed, further research is needed to determine how method of expression affects eventual breastfeeding rates, for example, by impacting maternal embarrassment, by impacting maternal perception of milk supply, or by some other mechanism. A recent systematic review found that the literature on maternal experience associated with milk expression is limited.<sup>50</sup> Our study revealed overall low volumes of expressed milk, high background levels of postpartum pain, and high overall concern about expressing and/or breastfeeding in front of others. The impact of these factors on maternal experience requires further study.

Although breast pumping is a fast and efficient method of milk expression once mature milk supply is established, there has been little previous study of breast pumping in the immediate postpartum period. One previous trial suggested that breast pumping in the immediate postpartum period may have a negative effect on breastfeeding duration, and no previous research has demonstrated either that pumping is beneficial for mothers at 12–36 h or that hand expression is harmful. Therefore, based on the previous literature and our results, we believe that in circumstances where either pumping or hand expression would be appropriate for healthy term infants 12–36 h old feeding poorly, teaching hand expression rather than breast pumping might improve breastfeeding rates at 2 months.

## CONCLUSION

Mothers who were randomly assigned to hand expression shortly after birth were more likely to be breastfeeding at 2 months than those assigned to breast pumping shortly after birth. The mechanism for the association between early method of expression and later breastfeeding prevalence is unknown, and further research is needed to confirm our results and explore the reasons for an association between early expression practice and later breastfeeding outcomes. However, given the lack of previous evidence to support breast pumping in this population and the results of our study, providers should consider teaching hand expression instead of pumping to mothers of healthy term newborns feeding poorly after birth in cases where either method of expression might be appropriate.

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**Competing interests** None.

**Ethics approval** This study was conducted with the approval of the UCSF Committee on Human Research, the Kaiser Permanente Institutional Review Board and the Stanford University Administrative Panel on Human Subjects in Medical Research.

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# Breast Pumps: Don't Be Misled - Get the Facts

These days, many new mothers return to the workplace with a briefcase in one hand—and a breast pump kit in the other.

For those moms working outside the home who are breastfeeding their babies (and those who travel or for other reasons can't be with their child throughout the day), using a breast pump to "express" (extract) their milk is a must.

The Food and Drug Administration (FDA) oversees the safety and effectiveness of these medical devices.

New mothers may have a host of questions about choosing a breast pump. What type of breast pump should they get? How do they decide ahead of time which pump will fit in best with their daily routines? Are pumps sold "used" safe?

## Choosing the Right Pump for You

Kathryn S. Daws-Kopp, an electrical engineer at FDA, explains that all breast pumps consist of a few basic parts: a breast shield that fits over the nipple, a pump that creates a vacuum to express the milk, and a detachable container for collecting the milk.

There are three basic kinds of pump: manual, battery-powered and electric. Mothers can opt for double pumps, which extract milk from both breasts at the same time, or single, which extract milk from one breast at a time.

Daws-Kopp, who reviews breast pumps and other devices for quality and safety, suggests that mothers talk to a lactation consultant, whose



### Breast Pump Basics

- a. **Breast shield:** Cone-shaped cup that fits over the nipple and surrounding area.
- b. **Pump:** Creates the gentle vacuum that expresses milk. The pump may be attached to the breast-shield or have plastic tubing to connect the pump to the breast shield.
- c. **Milk container:** Detachable container that fits below the breast shield and collects milk as it is pumped.

*“For many mothers, using a breast pump to extract milk for their nursing baby is a must.”*

expertise is in breastfeeding, or other health care professional about the type of breast pump that will best fit their needs. Questions for new moms to keep in mind include:

- How do I plan to use the pump? Will I pump in addition to breastfeeding? Or will I just pump and store the milk?
- Where will I use the pump? At work? When I’m traveling?
- Do I need a pump that’s easy to transport? If it’s electric, will I have access to an outlet?
- Does the breast shield fit me? If not, will the manufacturer let me exchange it?

**Should You Buy or Rent?**

There’s also the decision of whether to buy or rent a breast pump. Many hospitals, lactation consultants and specialty medical supply stores rent breast pumps for use by multiple users, Daws-Kopp notes.

These pumps are designed to decrease the risk of spreading contamination from one user to the next, she says, and each renter needs to buy a new accessories kit that includes breast-shields and tubing.

“Sometimes these pumps are labeled “hospital grade,” says Daws-Kopp. “But that term is not one FDA recognizes, and there is no consistent definition. Consumers need to know it doesn’t mean the pump is safe or hygienic.”

Daws-Kopp adds that different companies may mean different things when they label a pump with this term, and that FDA encourages manufacturers to instead use the terms “multiple user” and “single user” in their labeling. “If you don’t know for sure whether a pump is meant for a single user or multiple users, it’s safer to just not get it,” she says.

The same precaution should be taken for “used” or second-hand pumps.

Even if a used pump looks really clean, says Michael Cummings, M.D., an obstetrician-gynecologist at FDA, potentially infectious particles may survive in the breast pump and/or its accessories for a surprisingly long time and cause disease in the next baby.

**Keeping It Clean**

According to FDA’s recently released website ([www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BreastPumps/default.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BreastPumps/default.htm)) on breast pumps, the first place to look for information on keeping the pump clean is in the instructions for use. In general, though, the steps for cleaning include:

- Rinse each piece that comes into contact with breast milk in cool water as soon as possible after pumping.
- Wash each piece separately using liquid dishwashing soap and plenty of warm water.
- Rinse each piece thoroughly with hot water for 10-15 seconds.
- Place the pieces on a clean paper towel or in a clean drying rack and allow them to air dry.

If you are renting a multiple user device, ask the person providing the pump to make sure that all components, such as internal tubing, have been cleaned, disinfected, and sterilized according to the manufacturer’s specifications.

Cummings notes that there are many benefits to both child and mother from breastfeeding. “Human milk is recommended as the best and exclusive nutrient source for feeding infants for the first six months, and should be continued with the addi-

tion of solid foods after six months, ideally until the child is a year of age,” he says.

The benefits are both short- and long-term. In the short-term, babies can benefit from improved gastrointestinal function and development, and fewer respiratory and urinary tract infections. In the long-term, children who have been breast fed may be less obese and, as adults, have less cardiovascular disease, diabetes, inflammatory bowel disease, allergies, and even some cancers.

Cummings adds that moms and their families benefit by the bonding experience and economically as well, since a reduction in acute and chronic diseases in the baby saves money.

For women considering this option, FDA’s website offers resources and information on breast pumps and breastfeeding. These include information on the selection and care of the pumps, in addition to describing signs of an infection or injury related to their use.

Find this and other Consumer Updates at [www.fda.gov/ForConsumers/ConsumerUpdates](http://www.fda.gov/ForConsumers/ConsumerUpdates)

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# Effect of Progestin Compared With Combined Oral Contraceptive Pills on Lactation

## A Randomized Controlled Trial

Eve Espey, MD, MPH, Tony Ogburn, MD, Lawrence Leeman, MD, MPH, Rameet Singh, MD, MPH, Katie Ostrom, MD, and Ronald Schrader, PhD

**OBJECTIVE:** To estimate the effect of progestin-only compared with combined hormonal contraceptive pills on rates of breastfeeding continuation in postpartum women. Secondary outcomes include infant growth parameters, contraceptive method continuation, and patient satisfaction with breastfeeding and contraceptive method.

**METHODS:** Postpartum breastfeeding women who desired oral contraceptives were randomly assigned to progestin-only and combined hormonal contraceptive pills. At 2 and 8 weeks postpartum, participants completed in-person questionnaires that assessed breastfeeding continuation and contraceptive use. Infant growth parameters including weight, length, and head circumference were assessed at 8 weeks postpartum. Telephone questionnaires assessing breastfeeding, contraceptive continuation, and satisfaction were completed at 3–7 weeks and 4 and 6 months. Breastfeeding continuation was compared between groups using Cox proportional hazards regression. Differences in baseline demographic characteristics and in variables between the two intervention groups were compared using  $\chi^2$  tests, Fisher exact test, or two-sample *t* tests as appropriate.

**RESULTS:** Breastfeeding continuation rates at 8 weeks (progestin-only 63.5%; combined hormonal 64.1%), contraceptive continuation, and infant growth parameters did not differ between users of progestin-only and combined hormonal contraceptive pills. Infant formula supplementation and maternal perception of inadequate milk supply were associated with decreased rates of breastfeeding in both groups.

**CONCLUSION:** Choice of combined hormonal or progestin-only contraceptive pills administered 2 weeks postpartum did not adversely affect breastfeeding continuation.

**CLINICAL TRIAL REGISTRATION:** ClinicalTrials.gov, www.clinicaltrials.gov, NCT01465022.

(*Obstet Gynecol* 2012;119:5–13)

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**LEVEL OF EVIDENCE: I**

Contraception for breastfeeding women should be highly effective and not impair lactation. Prompt initiation of contraception after delivery reduces the likelihood of unintended pregnancy and, in low-resource settings, reduces maternal and infant morbidity and mortality.<sup>1,2</sup> Progestin-only pills are traditionally the oral contraceptive of choice because of concerns that combined pills may reduce breast milk production and, in turn, result in early discontinuation of breastfeeding or poor infant growth.<sup>3–7</sup> In nonbreastfeeding women, combined pills are known to have several advantages over progestin-only pills, such as fewer side effects, better efficacy, and higher continuation rates.<sup>8,9</sup> Nonetheless, if combined pills diminish the quality or quantity of breast milk in a clinically meaningful way, then progestin-only pills will be preferable for most breastfeeding women desiring oral contraception. If combined pills have a negligible clinical effect on breastfeeding outcomes, then combined pills are a better contraceptive choice for most breastfeeding women.

See related editorial on page 1.

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Our aim was to estimate the effect of postpartum use of progestin-only pills compared with combined pills on breastfeeding continuation at 8 weeks postpartum. Secondary outcomes included infant growth, contraceptive method continuation, and patient satisfaction with both breastfeeding and the assigned oral contraceptive.

## MATERIALS AND METHODS

This double-blind randomized trial was conducted at the University of New Mexico between January 2005 and June 2008. The University of New Mexico Human Research Review Committee approved the study and all women gave written informed consent. We enrolled postpartum women aged 15–45 years who delivered at the University of New Mexico Hospital who intended to breastfeed, planned to use oral contraceptives as their family planning method, and were willing to be randomized to either progestin-only pills or combined pills. Women were excluded if they had: 1) medical contraindications to combined pills, including a history of venous thromboembolism, uncontrolled hypertension, or complex migraine headaches; 2) preterm birth (less than 37 weeks); 3) a small-for-gestational-age (less than 2,500 g) or large-for-gestational-age (more than 4,500 g) newborn; or 4) a newborn with a major congenital anomaly.

Study information was distributed using a flyer at the 35-week visit to women receiving prenatal care at University of New Mexico Health Sciences-affiliated clinics and who planned to deliver at University of New Mexico Hospital. Research nurses approached eligible participants after delivery and provided details about the study. Monetary compensation of \$20 was provided at enrollment, 2 weeks and 2 months postpartum, for a total of \$60 for women who completed the entire study.

Consented participants completed a questionnaire that included patient characteristics including insurance type, smoking history, breastfeeding history, and history of contraceptive use. Infant length, weight, and head circumference (occipitofrontal) measurements were obtained using a study-dedicated scale throughout the patient's participation to avoid measurement inconsistencies. At enrollment, to ensure that all women had access to contraception whether or not they continued in the study, women were given an envelope containing a written prescription for the oral contraceptive of their provider's choice to be filled in case they decided against study participation.

One week postpartum, participants were contacted by telephone. Those who discontinued breast-

feeding or who no longer wished to participate were encouraged to start contraception and follow-up with a routine postpartum visit. Those who continued breastfeeding and reaffirmed their interest in participation were scheduled for a 2-week study visit during which they were randomized to the study medications. The randomization sequence was generated in blocks of six by a general clinical research center biostatistician. The randomization consisted of forcing each consecutive block of six participant identifications to have precisely three treatment assignments from each of the two groups, but randomly permuting the order of those assignments using standard statistical software (SAS).

The randomization list was e-mailed to the research pharmacist, who alone had access to randomization information for the duration of the study. The research nurse notified the research pharmacist when randomizations were needed and the research pharmacist dispensed the initial supply of blinded medication that was indicated on the randomization list, assigning participants to the next available treatment.

At the 2-week study visit, participants completed a questionnaire, growth assessments of their infants were performed, and participants received study medication. The progestin-only pills group used 0.35 mg of norethindrone once per day orally and the combined pills group took 1 mg of norethindrone and 0.035 mg of ethinyl estradiol (E2) once per day orally for 21 days, followed by 7 days of placebo pills. We chose norethindrone-containing combined oral contraceptives and progestin-only pills to eliminate the potential effect of the type of progestin on oral contraceptive continuation.<sup>10</sup> The norethindrone dose in the combined oral contraceptives was higher than that in the progestin-only pills, reflecting conventional use. The research pharmacist prepared pill packs by removing assigned pills from their blister packs and placing them in red plastic capsules. All pills were placed in identical monthly pill dispensers to disguise their appearance. Because there were 7 days of placebo in the combined pills but not in the progestin-only pills arm, the pharmacist ensured that cells were filled in the proper order, numbered from 1 through 28. Once filled by the research pharmacist, the cells were taped shut until the participant needed the product for that block of days.

At 2 weeks postpartum, participants returned to the University of New Mexico Hospital and met with the research nurse. At this visit, women completed a questionnaire regarding breastfeeding progress, in-



cluding continuation, supplementation with formula, the perception of adequate milk supply, and satisfaction with breastfeeding. Infant growth parameters (weight, height, and head circumference) were obtained and plotted on a growth curve. Women received 8 weeks of the previously blinded oral contraceptives at this visit and the research nurse observed the woman taking her first pill. The research nurse instructed the participants about the importance of using the pills in order.

Participants were telephoned weekly by the research nurse between 3 and 7 weeks postpartum and completed a verbal questionnaire that addressed continuation of and satisfaction with breastfeeding, the use of supplemental formula, and satisfaction with the oral contraceptive. At 2 months postpartum, participants returned to the hospital for a follow-up visit and completed a research nurse-administered questionnaire identical to the telephone follow-up questionnaires. The infant's length, weight, and head circumference were obtained and plotted on the growth curve. Participants received an additional 4 months of oral contraceptives prepared by the research pharmacist in the same manner as the initial supply. Participants were contacted by telephone at 4 and 6 months and completed the same questionnaire.

All study personnel and participants were blinded to treatment assignment for the duration of the study. The randomization code was unlocked and revealed to the researchers only after participant recruitment and data collection were complete.

Our primary outcome measure was the continuation of breastfeeding in women using progestin-only pills compared with women using combined pills at 8 weeks postpartum. Secondary end points included breastfeeding rates at 4 and 6 months postpartum. We chose 8 weeks as the time point for our primary breastfeeding continuation end point with the expectation that any negative effect of combined oral contraceptives on breastfeeding would be evident by then. Secondary outcome measures were infant weight and length, and continuation and satisfaction with the contraceptive method. Additional analyses examined reasons for discontinuing breastfeeding, discontinuing oral contraceptives, and for supplementing infant feeding with formula.

Sample size calculation, based on the primary study aim, indicated that 120 participants divided equally between the two groups would provide a power of 80% at a two-sided significance level of 5% to detect a difference in continuation of breastfeeding of 35% in the combined pills group compared with 60% in the progestin-only pills group at 8 weeks

postpartum. The calculation was based on the assumption that 50% of women would still be breastfeeding at 8 weeks postpartum and that the study was powered for a hazard ratio of 2. Anticipating a 20% loss to follow-up, this number was increased to 150 study participants. Recruitment was expanded to 200 women because of a higher than expected loss of participants between enrollment and randomization.

Statistical analyses were conducted using SAS 9.2. Differences in baseline demographic characteristics and in variables between the two intervention groups were compared using  $\chi^2$  tests, Fisher exact test, or two-sample *t* tests as appropriate. Significance for all analyses was set at  $P < .05$ .

A survival model was used for analysis of the primary outcome of breastfeeding duration. Continuation of breastfeeding was compared between the two groups using Cox proportional hazards regression adjusting for time-varying covariates of formula supplementation (supplemented with formula in the time period preceding each contact) and adequate milk production (the woman's perception that milk production was adequate in the time period preceding each contact). Breastfeeding duration data were censored from two sources: women still breastfeeding at the end of the study and women in the study for some number of weeks but with whom contact was lost before 6 months (loss to follow-up). Although the main study end point was 8 weeks, the survival analysis used the full 6-month follow-up period. Treatment group was fit as a factor in the model; the variables oral contraceptive history and breastfeeding history (for which there was some imbalance of groups at baseline) were entered as covariates. The time-varying covariates ("currently supplementing" and "have concerns about milk supply") were entered as well (for the previous time period). For the time-varying covariates, when there was a missing value for a time period, the last available value was carried forward. No similar data imputation was needed for the primary outcome of breastfeeding duration.

Although contact times were discrete (weeks 2–8 and months 4 and 6), an exact date for breastfeeding discontinuation was determined by the interviewer, allowing times until stopping breastfeeding to be treated as a continuous variable. Participants who discontinued breastfeeding before 8 weeks were discontinued from the study and infant growth parameters were not obtained at 8 weeks.

Two-sample *t* tests were used to analyze the two groups for measures of infant length and weight. Measures of oral contraceptive continuation and sat-



isfaction were assessed by logistic regression after adjusting for previous use of oral contraceptives.

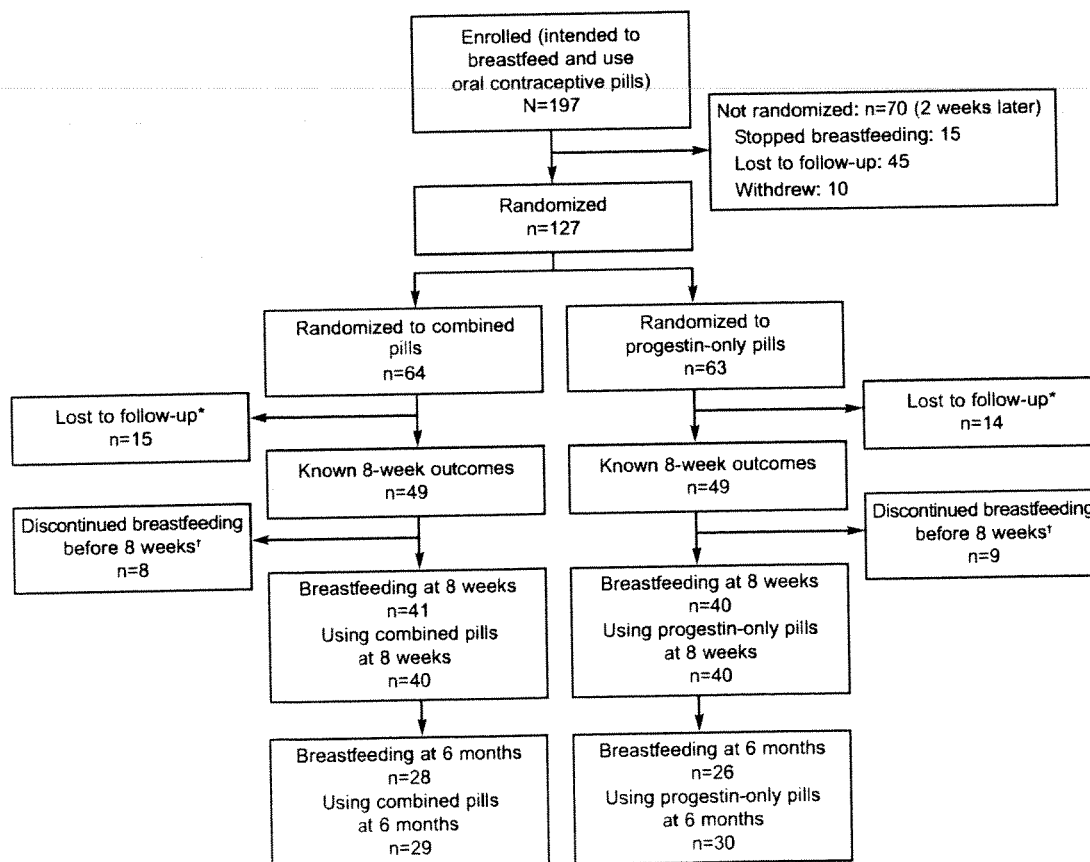
## RESULTS

A total of 197 postpartum women who met inclusion criteria were enrolled before discharge from the hospital. At the 1-week phone call, 127 (63%) remained eligible and were randomized; 64 received combined pills and 63 received progestin-only pills. Outcomes of study participants are summarized in a flow diagram (Fig. 1). Seventy enrolled patients were not randomized, most commonly because they did not keep their follow-up appointment. Women who were not randomized were less likely to be high school graduates and less likely to be employed than those who were randomized (Table 1).

Patient characteristics were similar between the two groups, except that combined pill users were more likely to have used oral contraceptives previ-

ously, whereas progestin-only pills users were more likely to have breastfed previously (Table 1). At 2 weeks postpartum, before initiation of pills, the number of women exclusively breastfeeding and the number of women who perceived inadequate milk supply did not differ between groups (Table 1); 63.8% of all study participants were exclusively breastfeeding and 22% perceived inadequate milk supply. No protocol deviations occurred.

Survival analysis demonstrated no difference in the primary outcome of breastfeeding continuation between the two oral contraceptive groups over the full 6 months of follow-up (Fig. 2). Maternal breastfeeding supplementation with formula ("supplementing") or maternal concern for inadequate milk supply ("milk concerns") was predictive of breastfeeding discontinuation (Table 2). At the primary end point of 8 weeks, the number of women continuing to breastfeed between the two groups was not different: 64.1%



**Fig. 1.** Study flow. \*These participants were unable to be contacted at some weekly time point between 2 and 8 weeks but contributed observations to the survival analysis until they were lost to follow-up. †These participants were known to have discontinued breastfeeding before 8 weeks and contributed observations to the survival analysis until they discontinued breastfeeding.

*Espy. Effect of Oral Contraceptives on Lactation. Obstet Gynecol 2012.*



**Table 1. Baseline Characteristics of Combined Oral Contraceptive and Progestin-Only Oral Contraceptive Groups**

Characteristic	Combined Oral Contraceptive (n=64)	Progestin-Only Pill (n=63)	P (Combined Oral Contraceptive Compared With Progestin-Only Pill)*	Not Randomized (n=70)	P (Not Randomized Compared With Randomized)*
At enrollment					
Age	23.8±4.4	25.0±5.4	.10	23.4±5.0	.84
High school graduate	38 (59.4)	29 (46.8)	.21	24 (34.3)	.01
Multiparous	37 (57.8)	38 (61.3)	.72	39 (55.7)	.65
Married or living as married	50 (78.1)	43 (69.4)	.31	47 (67.1)	.33
Race			>.99		.12
Hispanic	54 (84.4)	55 (87.3)		67 (95.7)	
Non-Hispanic	6 (9.4)	5 (7.9)		2 (2.9)	
White					
Other	4 (6.3)	3 (4.8)		1 (1.4)	
Medicaid	21 (32.8)	18 (29.5)	.70	27 (38.6)	.34
Private insurance	10 (15.6)	5 (8.1)	.27	3 (4.3)	.12
Employed	18 (28.1)	16 (25.8)	.84	7 (10.0)	.01
Smoker	2 (3.1)	3 (4.8)	.68	3 (4.3)	>.99
Breastfed with a previous pregnancy	27 (42.2)	37 (59.7)	.05	31 (44.3)	.46
Used oral contraceptives in the past	45 (70.3)	29 (46.8)	.01	43 (61.4)	.76
At 2 wk postpartum					
Exclusively breast feeding	45 (70.3)	36 (57.1)	.14	Not breastfeeding or unknown	Not applicable
Perception of inadequate milk supply	10 (15.6)	18 (28.6)	.09	Not breastfeeding or unknown	Not applicable

Data are mean±standard deviation or n (%) unless otherwise specified.  
\* P based on *t* test for age and Fisher exact for all other variables.

of women in the combined pills group and 63.5% in the progestin-only pills group were still breastfeeding (Fig. 3).

Over the 8-week study period, growth parameters between infants did not differ between groups, either in percent change in weight ( $P=.56$ ), length ( $P=.41$ ), or head circumference ( $P=.79$ ) (Fig. 4). The box plots in Figure 4 demonstrate considerable overlap for the distributions of these variables between the two groups. At weekly time points between 2-week and 8-week visits, breastfeeding women did not differ in the percentage who continued to use pills. Of those continuing to breastfeed at 8 weeks, 98% of participants assigned to combined pills and 100% assigned to progestin-only pills continued their pills (Fig. 3). Additionally, the number of women lost to follow-up was similar between the two groups at 8 weeks ( $P>.99$ ).

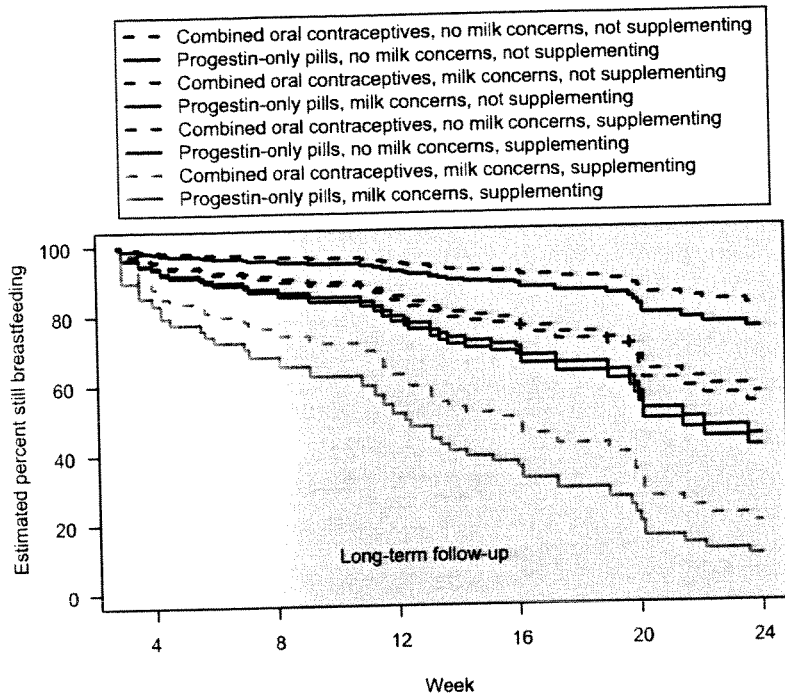
Groups did not differ in reasons cited for discontinuing breastfeeding or contraceptive pills during the

6 months of the study (Table 3). Of women who discontinued breastfeeding, 44% of the progestin-only pills group and 55% of the combined pills group reported stopping because of a perceived lack of milk supply ( $P=.80$ ). Of those who discontinued their oral contraceptive, 23% of progestin-only pills users and 21% of combined pill users reported stopping because of a perceived negative effect of the assigned oral contraceptive on milk supply. Other reasons women gave for discontinuation of breastfeeding or oral contraceptives are shown in Table 3.

Groups at 2 and 8 weeks did not differ in satisfaction with breastfeeding, oral contraceptive use, perception of adequate milk supply, or supplementation with formula ( $P>.05$ ). At 8 weeks, all women who continued to breastfeed were somewhat or very satisfied with their oral contraceptive and 93% of combined pills users and 95% of progestin-only pills users were somewhat or very satisfied with breastfeeding. There were no pregnancies reported in the first 8







**Fig. 2.** Cox proportional hazards regression for breastfeeding continuation fit with time-varying covariates of milk concerns and supplementing.  $n=64$  for combined oral contraceptives and  $n=63$  for progestin-only pills.

Espey. *Effect of Oral Contraceptives on Lactation. Obstet Gynecol* 2012.

weeks in those continuing in the study and no adverse events reported during the 6 months of the full follow-up period.

## DISCUSSION

We found that breastfeeding duration and infant growth did not differ between women who initiated progestin-only pills compared with combined pills at 2 weeks postpartum. Reasons cited for discontinuing breastfeeding did not differ between groups; maternal perception of inadequate milk supply was the most common reason cited. We found that introduction of supplementation with formula or a perceived lack of

milk supply correlated with breastfeeding discontinuation, whereas type of OCP used had no effect. Even at 2 weeks postpartum, approximately one third of women were already supplementing with formula and one fifth perceived inadequate milk supply.

Breastfeeding rates at 8 weeks in our study were similar to rates found in the New Mexico Pregnancy Risk Assessment Monitoring System data. Overall, 84% of women in New Mexico initiate breastfeeding; however, only 60% are breastfeeding through 2 months postpartum.<sup>11</sup> Although 64% of our randomized study participants were breastfeeding at 8 weeks, only 28.3% were exclusively breastfeeding, agreeing with findings of generally low exclusive breastfeeding rates in U.S. women between 6 and 12 weeks postpartum.<sup>12,13</sup>

Other studies examining the effect of hormonal contraceptives on lactation and growth have demonstrated mixed results.<sup>3-7,14-16</sup> The most robust was a 1988 quasi-randomized trial of progestin-only pills compared with combined pills that found a lower volume of milk expressed in the combined pill group but no differences between groups in infant growth, breastfeeding continuation, and reasons for breastfeeding discontinuation.<sup>14</sup> Earlier trials, limited by methodologic flaws, demonstrate some differences in rates of breastfeeding and few differences in infant and child outcomes.<sup>4-5,15</sup> Additionally, some trials suggest lower pregnancy rates in women using progestin-only pills.<sup>4,5</sup>

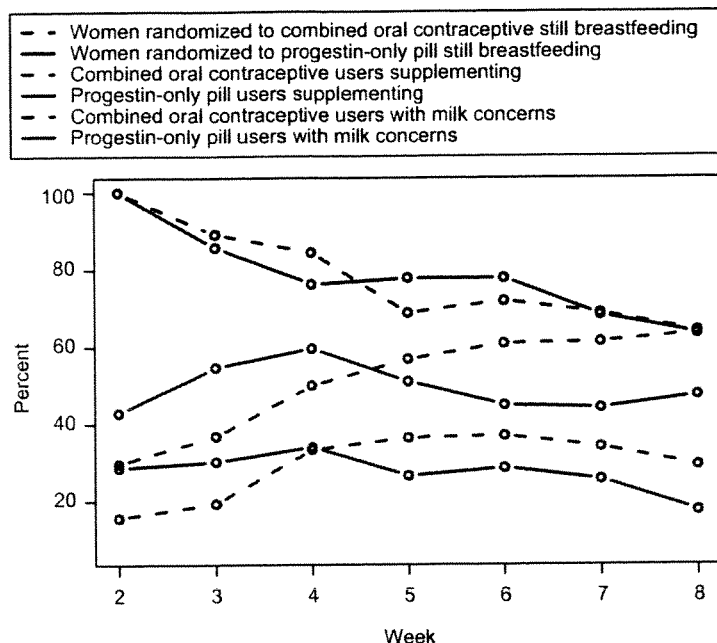
**Table 2.** Summary of Cox Proportional Hazards Analysis for Breastfeeding Continuation Analysis With Time-Varying Covariates of Milk Concerns and Supplementing

Effect	Hazard Ratio for Stopping Breastfeeding (CI)	P
Oral contraceptive: progestin-only pill compared with combined oral contraceptive	1.42 (0.76-2.65)	.270
Supplementing: Yes compared with no	2.81 (1.09-7.23)	.033
Milk concerns: Yes compared with no	2.07 (1.37-5.91)	.005

CI, confidence interval.





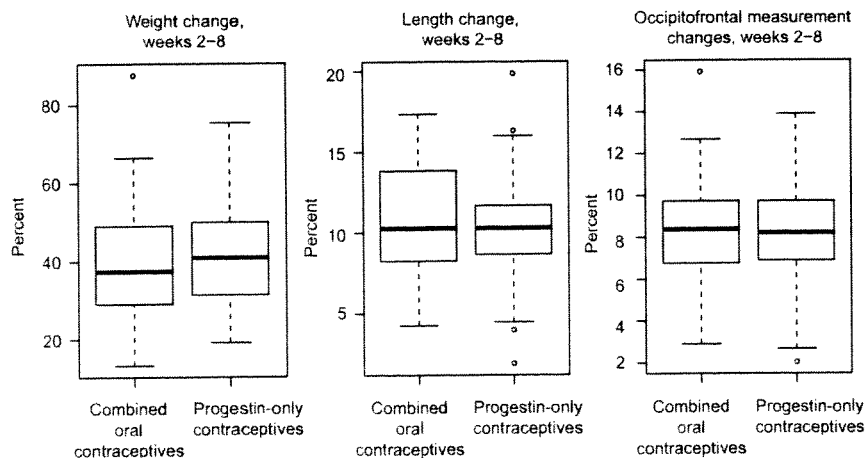


**Fig. 3.** Breastfeeding outcomes at 8 weeks. Continued breastfeeding in combined pills (n=64) compared with progestin-only pill (n=63) groups. Percentage still breastfeeding for a group is the percentage still breastfeeding of the number originally randomized to the group. Percentage supplementing or with milk concerns for a group is the percentage supplementing or with milk concerns of those who still are breastfeeding within the group.

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Our study has limitations. The sample size was calculated to identify a 25% difference in continuation of breastfeeding at 2 months between the two study groups. Our findings highlight the need for a large randomized controlled trial with the aim of demonstrating equivalency between progestin-only pills and combined pills; our results support the feasibility of such a study. The high loss to follow-up rate in our study is explained partly by the recruitment of many participants from clinics that serve a population of women who are undocumented and mobile. Additionally, the results may not be applicable beyond the patient population studied, who were generally Hispanic and without an identified payment source for

health care. Given the extent of early supplementation of breastfeeding with formula in our population, our results apply only to women with ready access to formula. Although women randomized to progestin-only pills were more likely to have breastfed in the past, they would have skewed the results to show more, not less, of an effect on reducing breastfeeding duration; it is unlikely that this difference had an effect on the results of the study. The combined oral contraceptive used in this study contains 35 micrograms of ethinyl E2, the highest dose in current common use. The lack of an effect on breastfeeding is reassuring with regard to formulations containing lower amounts of ethinyl E2.



**Fig. 4.** Infant growth. Changes in weight, length, and occipitofrontal measurements in infants of women using combined oral contraceptive compared with those using progestin-only pills between weeks 2 and 8. n was 41 and 40, respectively, for infants in the combined oral contraceptive and progestin-only pills with weight and length. For occipitofrontal measurement, the respective n was 40 and 38.

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**Table 3. Primary Reasons for Discontinuing Breastfeeding and Oral Contraceptives Between the Combined Oral Contraceptive and Progestin-Only Contraceptive Groups**

Reasons for Discontinuation (Through the 6 mo of the Study)	Combined Oral Contraceptive	Progestin-Only Pill	P*
Discontinued breastfeeding			
Milk supply	11 (55)	12 (44)	.80
Return to school or work	3 (15)	3 (11)	>.99
Uncomfortable or difficult	1 (5)	2 (7)	>.99
Baby: latch or infection	3 (15)	7 (26)	.72
Mother: infection, pregnant, or changed mind	2 (10)	3 (11)	>.99
Discontinued oral contraceptives			
Milk supply	4 (21)	3 (23)	>.99
Side effects	6 (32)	5 (38)	.82
Not sexually active	0	1 (8)	>.99
Use problem: using another method, could not remember, or ran out	7 (37)	3 (23)	.71
Pregnant	2 (11)	1 (8)	.63

Data are n (%) unless otherwise specified.

\* Fisher exact test.

Recommendations for using or avoiding combined pills in postpartum breastfeeding women vary. The Centers for Disease Control and Prevention United States medical eligibility criteria for contraceptive use recently updated its guidance on initiation of combined pills for postpartum women based on evidence that the increased risk of thromboembolism persists through 21 days postpartum. In postpartum breastfeeding women, initiation before 21 days is ranked as category 4 (unacceptable health risks); initiation at 21–29 days for women at low risk for thromboembolism is rated category 3 (theoretical or proven risks generally outweigh advantages) because of concerns about a negative effect on breastfeeding, and initiation at more than 42 days is rated category 2 (advantages generally outweigh theoretical or proven risks).<sup>17</sup> The American College of Obstetricians and Gynecologists endorses this recommendation.<sup>18</sup> The World Health Organization assigns a category 4 (unacceptable health risk) for initiation of combined pills within 6 weeks of delivery and a category 3 (theoretical or proven risks usually outweigh the advantages) for initiation of combined pills from 6 weeks to 6 months in primarily breastfeeding women.<sup>19</sup> The recommendations of the International Planned Parenthood Federation are similar to those of the World Health Organization.<sup>20</sup> In 2010, a Cochrane review concluded that current data were insufficient to make recommendations on the effect of hormonal contraception on milk quality and quantity because of a lack of methodologically sound trials.<sup>21</sup>

The lack of recent literature on the effect of combined hormonal contraception on breastfeeding is surprising given the worldwide popularity of combined

oral contraceptives and the importance and prevalence of breastfeeding. If, as our study suggests, there is no difference in effect of progestin-only pills compared with combined pills on breastfeeding continuation or infant outcomes, then women who desire an oral contraceptive should be encouraged to use combined pills, initiated no earlier than 21 days postpartum because of their greater effectiveness and the negative consequences of unintended pregnancy.<sup>22</sup> This study demonstrates the feasibility of a larger equivalency study to clarify the clinical effect of combined oral contraceptive use on lactation. Our data are reassuring that combined pills do not have a major effect on breastfeeding continuation or infant growth.

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# Choosing a Method of Birth Control if Breastfeeding

If you are breastfeeding, there are some things you need to know before you choose a birth control method. There are many types of birth control available today. This information will help you pick the method that is right for you.

## Information for Breastfeeding Women



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### HOW DO I CHOOSE WHICH METHOD OF BIRTH CONTROL IS BEST FOR ME?

Your choice depends on a number of things such as age of your baby, need for temporary or permanent protection against pregnancy, feelings about having another baby, and you and your partner's comfort levels with a method of birth control.

### HOW SOON AFTER MY BABY IS BORN CAN I START USING BIRTH CONTROL?

Some methods of birth control can be used right after your baby is born. Others should be used only after your baby is older. The chart below lists when each birth control method can be used. **Talk with your doctor for more information.**

### WHEN METHODS OF BIRTH CONTROL CAN BE USED

BIRTH CONTROL METHOD	USE SIX WEEKS AFTER BIRTH	USE SIX WEEKS-TO-SIX MONTHS AFTER BIRTH	USE MORE THAN SIX MONTHS AFTER BIRTH
Emergency contraceptive pill	Yes	Yes	Yes
Combined birth control pill	No	No	Yes
Progesterone-only birth control pill	No	Yes	Yes
Progesterone shot	No	Yes	Yes
Diaphragm/cervical cap	No	Yes	Yes
Spermicide	Yes	Yes	Yes
Condom	Yes	Yes	Yes
Copper (plain) IUD	Yes	Yes	Yes
IUD with hormones	No	Yes	Yes
Female sterilization	Yes	Yes	Yes
Natural family planning	No	Yes	Yes
Lactational amenorrhea method	Yes	Yes	No

Source: World Health Organization: *Improving access to quality care in family planning – medical eligibility criteria for initiating and continuing use of contraceptive methods*. 2<sup>nd</sup> edition. Geneva: World Health Organization, Family and Reproductive Health Division, 2000. WHO/RHR/00.02.

## WILL BREASTFEEDING KEEP ME FROM GETTING PREGNANT?

Using breastfeeding for birth control is called the "lactational amenorrhea method" (LAM). It can be very effective, but only if:

- Your baby is less than six months old **and**
- Your baby gets all of his or her food from breastfeeding (no formula or cereal) **and**
- You have not had a period since your baby was born.

If **all three** of the above are true for you, your risk of getting pregnant is about 2%. This is because you are very unlikely to ovulate (release an egg from the ovary) under these conditions.

If any of these things are not true for you, you must use another method of birth control if you do not want to get pregnant.

## WHAT ABOUT OTHER NATURAL FAMILY PLANNING METHODS?

Natural family planning methods are also called "fertility awareness-based" family planning. To use these methods you have to be able to tell when you are ovulating. When you are breastfeeding this can be very difficult to do, especially when your baby is very young. As your baby gets older it gets easier to tell when you are ovulating.

If you want to use a natural family planning method of birth control, it is very important that you understand how to use it properly. **Talk with your doctor** about where to learn about natural family planning methods.

## CAN I USE A DIAPHRAGM WHEN I AM BREASTFEEDING?

A diaphragm is a barrier method of birth control. Other barrier methods include cervical caps, spermicides and condoms. Breastfeeding women can safely use all of these.

Condoms and spermicides can be used at any time after your baby's birth.

A diaphragm or cervical cap should be used only after your uterus shrinks back to its normal size. This is usually six weeks after your baby's birth.

If you were using a diaphragm or cervical cap before your baby was born, you may need a different size after you have your baby.

If you use your old one you may get pregnant if it does not fit properly. Your doctor will check the size you need. It is important to have this done before the first time you have intercourse after your baby's birth.

## IS IT SAFE TO USE AN IUD WHEN I AM BREASTFEEDING?

There are two types of IUDs. Some have hormones in them and others don't.

Breastfeeding women can safely use IUDs without hormones in them. Some types of IUDs can be put in the uterus immediately after delivery, but it is best to wait four-to-six weeks after delivery for other types.

If the IUD is put in too soon it may fall out or tear the uterus. **Talk with your doctor** about which kind of IUD is best for you and when it should be put in.

IUDs with hormones in them should only be used after your baby is six weeks old. This is because it is not known if the hormone is safe for a baby less than six weeks old.

## CAN I GET MY TUBES TIED IF I AM PLANNING TO BREASTFEED?

Getting your tubes tied is also called "female tubal sterilization." This surgery should not affect your milk supply or your ability to breastfeed.

If you would like to get your tubes tied, **talk with your doctor** before you have your baby. For best results, this is usually done in the week after your baby is born or after your baby is six weeks old.

You and your partner may want to consider male sterilization. This is called a vasectomy.

**Ask your doctor** for more information as both these methods are permanent.

### CAN I TAKE THE BIRTH CONTROL PILL WHEN I AM BREASTFEEDING?

There are several kinds of birth control pills. Some can be used soon after your baby is born and others should only be used once the baby is older.

Birth control pills that contain only progesterone are sometimes called the "mini-pill." These are usually started at six weeks. Most physicians agree that this pill will not decrease your milk supply.

"Combined" birth control pills contain estrogen and progesterone. This kind of birth control pill should only be used after your baby is six months old because it may decrease your milk supply.

Breastfeeding mothers can safely use the emergency contraceptive pill ("morning after pill") no matter the ages of their babies.

### WHAT ABOUT THE BIRTH CONTROL SHOT?

The progesterone shot can be used after your baby is six weeks old.

### HOW WILL I KNOW IF MY BIRTH CONTROL PILL OR SHOT IS DECREASING MY MILK SUPPLY?

The following changes may mean that you do not have enough milk for your baby:

- Your baby is not as happy as usual
- Your baby does not gain weight as well as he or she should
- Your breasts feel less full than they used to feel

If these changes happen right after starting the birth control pill or getting the birth control shot, the pill or shot is probably reducing your milk supply. **See your doctor** to discuss if this is the case.

### WHAT ARE MY CHANCES OF GETTING PREGNANT?

For most methods of birth control your chances of getting pregnant depend on how carefully you use them. That is why in the "real world" most methods of birth control are not as effective as they would be with perfect use.

The "perfect use" and "real world" chances of getting pregnant when using the different methods of birth control are illustrated in the chart below.

NUMBER OF PREGNANCIES PER 100 WOMEN DURING FIRST YEAR OF USE		
BIRTH CONTROL METHOD	'PERFECT USE'	'REAL WORLD USE'
Combined birth control pill	0.1	5.0
Progesterone-only birth control pill	0.5	5.0
Progesterone shot	0.1	N/A
Diaphragm/cervical cap	6.0	20.0
Spermicide	6.0	26.0
Condom	3.0	14.0
Copper (plain) IUD	0.6	0.8
IUD with hormones	1.5	2.0
Female tubal sterilization	0.5	0.5
Natural family planning	1.0 - 9.0	20.0
Lactational amenorrhea method	0.5	2.0

Source: Planned Parenthood Federation of America Inc. Birth Control: Facts About Birth Control. PPFA [www.plannedparenthood.org/bc/bcacts/htm](http://www.plannedparenthood.org/bc/bcacts/htm). 1998-2002.



## WHAT IF I GET PREGNANT WHEN I AM STILL BREASTFEEDING?

You can continue to breastfeed while you are pregnant as long as you have not had a premature labour, there is no risk of a premature birth with this pregnancy, you have no bleeding and you are gaining a proper amount of weight. For more information about breastfeeding during pregnancy, **see your doctor.**

## IS THERE ANYTHING ELSE I NEED TO KNOW BEFORE I CHOOSE A BIRTH CONTROL METHOD?

If you have trouble making enough milk for your baby, you need to be especially careful which method of birth control you choose. It is important that you **not** use one of the methods that might decrease your milk supply, such as birth control pills and shots.

You might have a higher chance of having trouble making enough milk for your baby if you have or have had:

- breast reduction surgery
- twins or triplets
- a premature baby
- not enough milk for a previous baby
- one breast much smaller than the other
- thyroid problems that are not being treated
- some kinds of infertility
- a problem making enough of the milk hormone prolactin

If you have or have previously had any of these things, be sure to **tell your doctor** before you choose a birth control method.



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March 2004

# U.S. Obstetrician–Gynecologists’ Estimates of Their Patients’ Breastfeeding Rates

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**OBJECTIVES:** To estimate obstetrician–gynecologists’ promotion and support of breastfeeding and their perception of patient breastfeeding practices to examine whether variation in physician practice contributes to low breastfeeding rates.

**METHODS:** We conducted a survey study of 290 members of the Collaborative Ambulatory Research Network, a sample of college fellows (response rate 48.3%). We compared the results with the Centers for Disease Control and Prevention state-by-state Breastfeeding Report Card data: 75% or more initiating breastfeeding termed high, 65–74% termed medium, and 64% or lower termed low. The survey consisted of questions regarding physician and patient demographics, physician satisfaction regarding breastfeeding practices, opinions and knowledge of breastfeeding, opinions of breastfeeding duration, and physicians’ effort toward encouraging breastfeeding. An “effort” score was created from these questions.

**RESULTS:** Physicians’ perceptions of breastfeeding initiation rates were consistent with Centers for Disease Control and Prevention data for high (77.3%±1.5%), medium (70.9%±2.7%), and low states (59.4%±3.4%).

Physicians with a high proportion of African American or Medicaid-eligible patients reported lower rates of initiating breastfeeding; a high proportion of Medicaid-eligible patients was associated with lower breastfeeding at 3, 6, and 12 months. More physicians were satisfied in high breastfeeding states (72.7%) than in medium (60%) or low states (34.3%). We found no association between the effort score and physician age or patient demographics; however, women (10.2±0.2) scored higher than men (8.6±0.3,  $P=.001$ ). Effort score did not differ among high, medium, or low breastfeeding states.

**CONCLUSION:** Physician satisfaction reflected perceived patient behavior. Physician effort scores were similar across patient breastfeeding behavior. Patient demographics rather than physician practice predicted low breastfeeding rates.

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Breastfeeding provides a public health benefit at little or no cost. The advantages of breastfeeding over formula feeding have been demonstrated in multiple studies.<sup>1</sup> The benefits from breast milk to the infant include immunologic, developmental, and nutritional, among others, and are so compelling that the American Academy of Pediatrics recommends exclusive breastfeeding for the first 6 months and that breastfeeding continue for at least 12 months and thereafter as long as it is mutually desired.<sup>1</sup> The American College of Obstetricians and Gynecologists (the College) recommends that exclusive breastfeeding be continued until the infant is approximately 6 months old. A longer breastfeeding experience is beneficial.<sup>2</sup>

Recognizing the importance of breastfeeding as a public health measure, the U.S. Public Health Service set forth breastfeeding goals in Healthy People 2010<sup>3</sup>; these goals have been updated in Healthy People 2020<sup>4</sup> (Table 1). This public health campaign has improved breastfeeding rates in the United States;





**Table 1. Breastfeeding Goals From Healthy People 2010 and Healthy People 2020**

	Healthy People 2010 Goals <sup>3</sup>	Healthy People 2020 Goals <sup>4</sup>
Mothers initiating breastfeeding	75	81.9
Breastfeeding at 6 mo	50	60.6
Breastfeeding at 12 mo	25	34.1
Exclusively breastfeeding at 3 mo	40	46.2
Exclusively breastfeeding at 6 mo	17	25.5

Data are %.

however, the only goal that was achieved by 2010 was that 50% of mothers were breastfeeding at 6 months.<sup>5</sup> There is a need to study why progress is so slow. To that end, we present results of a survey study regarding practice patterns and attitudes of obstetrician-gynecologists (ob-gyns) toward promoting breastfeeding in their patients. We compare the rates of breastfeeding among their patients as estimated by the physicians to the Centers for Disease Control and Prevention (CDC) state-by-state Breastfeeding Report Card<sup>6</sup> data to assess how realistic the perceptions of ob-gyns are regarding their patients' breastfeeding behavior and to assess whether there are geographic patterns of physician attitude or practice that might affect breastfeeding rates.

## MATERIALS AND METHODS

Surveys were mailed in July 2010 to 600 members of the College. The survey consisted of 58 questions covering a range of topics: physician and patient population demographics, satisfaction regarding the breastfeeding practices of their patients, opinions and knowledge of breastfeeding, opinions regarding breastfeeding education and practice responsibilities, opinions regarding discussion of breastfeeding practices, recommendations regarding the duration of breastfeeding, and ratings regarding their opportunity to provide breastfeeding education.

Participants were all members of the College's Collaborative Ambulatory Research Network, a group of college fellows who agree to participate in four to six surveys every 12 months. Collaborative Ambulatory Research Network members are a representative sample (by age, sex, and geographic location) of the College's membership, which includes more than 90% of ob-gyns in the United States. During the more than 20-year history of the Collaborative Ambulatory Research Network, comparisons of their responses on surveys with those of randomly selected fellows have

rarely indicated any significant differences. Approximately half of Collaborative Ambulatory Research Network members were randomly selected for this survey. Second and third mailings were sent 3 and 7 weeks after the initial mailing to encourage nonresponders.

Responses were entered into a computer-based software package data file for analysis. The study identification number, sex, birth date, and geographic location for all physicians were entered into the database to allow comparison of basic demographic categories of responders and nonresponders. The institutional review board of Georgetown University School of Medicine approved the research.

Summary values are given as mean  $\pm$  standard error of the mean or  $\pm$ 95% confidence interval (CI) for proportion estimates. Analyses were conducted with an  $\alpha$  set at 0.05. We tested differences in proportions between subgroups using  $\chi^2$  tests and differences in means using analysis of variance *F* tests. Nonparametric tests were used for scale response items. Correlations were calculated using the Pearson correlation coefficient between continuous parameters and the Spearman correlation coefficient when one or more of the parameters were ordinal.

The CDC published data on the average percentage of women initiating breastfeeding by state.<sup>4</sup> To estimate the extent to which the physician responses correspond to CDC data, each physician was assigned a value based on the state in which they practice: 1=CDC data show 75% or more of women initiating breastfeeding (high); 2=65–74% of women initiating breastfeeding (medium); and 3=64% or fewer of women initiating breastfeeding (low).

## RESULTS

A total of 290 ob-gyns returned the survey, a response rate of 48.3%. Of the 290 who returned the questionnaire, 230 reported seeing pregnant patients. Only these responses were used in the analysis. A comparison of responders and nonresponders indicated no significant difference in age. Female ob-gyns aged 50 years or younger responded at a greater rate (51.1%) than men of the same age group (40.0%). There was no significant difference in response between male and female physicians aged 51 years or older.

Of the respondents, 55.8% were women. The average age of the sample was  $50.6 \pm 0.6$  years; men were significantly older than women ( $55.1 \pm 0.9$  compared with  $47.0 \pm 0.7$ ,  $P < .001$ ). Mean years in practice was  $17.7 \pm 0.6$  (range 2–40 years). There was a roughly even split between physicians who reported being breastfed (47.6%) as children and those who did



not (43.7%). However, 87.5% of ob-gyns with children (n=216) report that they or their spouse breastfed an infant.

Physician estimates of percentage of patients on Medicaid correlated significantly to the race and ethnicity of patients with lower estimates of Medicaid eligibility associated with higher percentages of white ( $r=-0.31$ ,  $P<.001$ ) and Asian Pacific Islander ( $r=-0.23$ ,  $P=.001$ ), and higher estimates of Medicaid eligibility associated with higher percentages of African American ( $r=0.18$ ,  $P=.01$ ), Hispanic ( $r=0.30$ ,  $P<.001$ ), and Native American ( $r=0.20$ ,  $P=.003$ ) patients. The greatest average percentage of patients eligible for Medicaid was reported among physicians who practice in rural areas and towns of 5,000–50,000 ( $51.5\% \pm 3.2\%$ ) and urban inner cities ( $46.3\% \pm 5.5\%$ ). Physicians reported the lowest breastfeeding rates in these areas (Table 2).

The responding physicians overwhelmingly agreed with the statements that breastfeeding conveys nutritional ( $97.4\% \pm 2.1\%$ ) and immunologic ( $98.7\% \pm 1.5\%$ ) benefits to the infant. Most agreed that exclusive breastfeeding is the best option ( $87.4\% \pm 4.3\%$ ); however, most also agreed that breastfeeding is a personal choice ( $77.7\% \pm 5.4\%$ ), and  $55.0\% \pm 6.4\%$  agreed that formula is an acceptable option that will not harm the infant. Female physicians were more likely to respond that they strongly agree that exclusive breastfeeding is the best option ( $68.5\% \pm 6.0\%$  compared with  $44.4\% \pm 6.4\%$ ,  $P=.005$ ).

The responding physicians reported that, on average,  $27.4\% \pm 1.3\%$  of their patients choose to formula-feed rather than breastfeed. Thus, on average,  $72.6\% \pm 1.3\%$  of their patients initiate breastfeeding. The estimated proportion of patients that choose to exclusively breastfeed was  $50.5\% \pm 1.6\%$ . The responding physicians estimated that  $47.9\% \pm 1.5\%$  of their patients are breastfeeding at 3 months,  $26.8\% \pm 1.2\%$  at 6 months, and only  $10.6\% \pm 0.7\%$  at 12 months. Female physicians on average estimated a higher proportion of their patients choose to initiate breastfeeding ( $75.1\% \pm 1.7\%$  compared with  $69.6\% \pm 2.0\%$ ,  $P=.038$ ) and a higher

proportion of their patients continue to breastfeed at 12 months ( $12.1\%$  compared with  $8.5\%$ ,  $P=.012$ ).

Physicians caring for a higher proportion of African American patients report more patients who choose not to breastfeed ( $r=-0.261$ ,  $P<.001$ ) and fewer that exclusively breastfeed ( $r=-0.331$ ,  $P<.001$ ). The reverse relationship was found for Asian Americans: physicians caring for more Asian American and Pacific Islander patients report more patients choose to breastfeed ( $r=0.233$ ,  $P=.001$ ) and exclusively breastfeed ( $r=0.153$ ,  $P=.023$ ). This pattern was the same for breastfeeding at 3, 6, and 12 months with high Asian and Pacific Islander patient populations associated with high breastfeeding rates and high African American patient populations associated with low breastfeeding rates, although at 12 months, the result was only a trend for the proportion of African American patients ( $r=-0.129$ ,  $P=.058$ ). No significant relationships were found between choosing to breastfeed and the percentages of white, Hispanic, Native American, or multiracial patients; however, the proportion of white patients was associated with exclusive breastfeeding ( $r=0.262$ ,  $P<.001$ ).

Eligibility for Medicaid also was related to patient breastfeeding behavior. Physicians with a higher proportion of patients eligible for Medicaid were more likely to report a lower proportion choosing to initiate breastfeeding ( $r=-0.465$ ,  $P<.001$ ), exclusively breastfeed ( $r=-0.416$ ,  $P<.001$ ) as well as lower rates of breastfeeding at 3 ( $r=-0.455$ ,  $P<.001$ ), 6 ( $r=-0.352$ ,  $P<.001$ ), and 12 months ( $r=-0.295$ ,  $P<.001$ ). Because the estimated proportion of African American and Asian Pacific Islander patients correlates to the proportion of Medicaid-eligible patients (positively and negatively, respectively), we calculated the partial correlations of these ethnicity variables with initiating breastfeeding and breastfeeding at 3, 6, and 12 months controlling for the proportion of Medicaid-eligible patients and vice versa. The negative correlation between choosing to initiate breastfeeding and the proportion of African American patients remained significant ( $r=-0.207$ ,  $P=.003$ ). However,

**Table 2. Practice Location and Breastfeeding**

	Initiate Breastfeeding	Breastfeeding at 3 mo	Breastfeeding at 6 mo	Breastfeeding at 1 y
Suburban	74.7±2.0	48.9±2.4	29.6±2.0	12.0±1.3
Urban, non-inner city	76.5±2.2	54.1±2.5	28.6±2.0	11.7±1.2
Urban, inner city	67.6±4.5	35.5±4.8	19.7±3.3	8.2±1.9
Small town or rural	66.0±2.8	42.7±3.3	24.0±2.9	8.1±1.5
P	.011	.001	.048	.116

Data are mean percent±standard error of the mean unless otherwise specified.



there were no longer any significant correlations between the proportion of African American patients and the estimated proportion of patients breastfeeding at 3, 6, or 12 months. The results for Asian Pacific Islanders remained significant in all cases. The proportion of Medicaid-eligible patients remained significantly negatively associated with choosing to breastfeed and to the proportion of patients breastfeeding at 3, 6, and 12 months after controlling for the proportion of African American and Asian Pacific Islander patients.

### Geographic Location

Physicians practicing in states with high breastfeeding initiation rates (per CDC Breastfeeding Report Card data) report on average higher proportions of their patients choose to initiate breastfeeding than do physicians who practice in medium states; physicians who practice in low states report the lowest rates of breastfeeding initiation ( $P < .001$ ). These results match well with the CDC data on geographic variation in breastfeeding initiation rates (Table 3). The physicians appear to be pessimistic about their patients' breastfeeding behavior at 6 and 12 months, because they estimate lower proportions of their patients to be breastfeeding at these times than the CDC data indicate. However, the patterns were consistent with the CDC data: physicians practicing in states where CDC data shows high rates of breastfeeding at 6 and 12 months reported on average significantly higher rates (Table 3;  $P = .005$ ).

Physician sex and practice location did not vary significantly with the CDC geographic breastfeeding rate. Similarly, there was no significant difference in

the percentage of Medicaid-eligible patients based on the CDC geographic groupings, presumably because low income is spread throughout all geographic regions rather than clustered in specific states. However, physicians from the high breastfeeding states reported the lowest estimated proportion of African American patients (10.7%) and the highest estimated proportions of Hispanic (19.9%) and Asian American patients (5.5%). In the medium and low breastfeeding states, the values were 22.5%, 10.2%, and 2.6% for African American, Hispanic, and Asian American Pacific Islander patients, respectively ( $P < .001$ ).

### Physician Satisfaction

More physicians report being satisfied with their patients' breastfeeding behavior than unsatisfied (56.8% satisfied, 33.6% not satisfied, and 9.6% neutral). Ob-gyns who report being satisfied with the proportion of their patients who breastfeed have a significantly higher average mean percentage ( $62.0\% \pm 1.9\%$ ) of patients who choose to exclusively breastfeed compared with physicians who are unsatisfied ( $33.91\% \pm 2.3\%$ ;  $P < .001$ ). Physicians who are unsatisfied with the proportion of their patients breastfeeding have a significantly lower average mean percentage ( $58.0\% \pm 2.2\%$ ) of patients who choose to initiate breastfeeding compared with those who are satisfied ( $82.7\% \pm 1.1\%$ ;  $P < .001$ ). Physicians who are satisfied with their patients' breastfeeding behavior estimate a significantly higher average mean percentage of their patients to be breastfeeding at 3 months ( $58.4\% \pm 1.6\%$  compared with  $33.3\% \pm 2.2\%$ ;  $P < .001$ ), 6 months ( $34.8\% \pm 1.6\%$  compared with  $16.6\% \pm 1.3\%$ ;  $P < .001$ ), and 12 months ( $13.0\% \pm 1.1\%$  compared with  $7.9\% \pm 1.0\%$ ;  $P = .002$ ).

**Table 3. Physician Estimates of Patient Breastfeeding Behavior by Centers for Disease Control and Prevention Report Card 2010 Geographic Breastfeeding Rates**

	75 % or more women initiate breastfeeding	65–74 % of women initiate breastfeeding	64 % or fewer women initiate breastfeeding
CDC data, states grouped by percentage of patients initiating breastfeeding			
College survey, same group of states—physician report of percentage of patients initiating breastfeeding	77.3 % $\pm$ 1.5 %	70.9 % $\pm$ 2.7 %	59.4 % $\pm$ 3.4 %
CDC data, states grouped by percentage of patients breastfeeding at 6 mo			
College survey, same group of states—physician report of percentage of patients breastfeeding at 6 mo	50 % or more breastfeeding at 6 mo 33.3 % $\pm$ 2.5 %	40–49 % breastfeeding at 6 mo 26.0 % $\pm$ 2.0 %	39 % or fewer breastfeeding at 6 mo 23.5 % $\pm$ 1.7 %
CDC data, states grouped by percentage of patients breastfeeding at 1 y			
College survey, same group of states—physician report of percentage of patients breastfeeding at 1 y	25 % or more breastfeeding at 1 y 13.2 % $\pm$ 1.6 %	20–24 % breastfeeding at 1 y 10.5 % $\pm$ 1.2 %	19 % or fewer breastfeeding at 1 y 8.8 % $\pm$ 0.9 %

CDC, Centers for Disease Control and Prevention; College, American College of Obstetricians and Gynecologists. Data are mean percent  $\pm$  standard error of the mean.



Physicians with greater percentages of African American patients are more likely to report being unsatisfied with the proportion of their patients breastfeeding ( $P=.02$ ). No differences were found with any other racial or ethnic group. Additionally, physicians who report being unsatisfied with the proportion of their patients who breastfeed estimate they have a significantly higher average mean percentage of patients who are Medicaid-eligible ( $51.1\% \pm 3.0\%$  compared with  $26.3\% \pm 2.2\%$ ,  $P<.001$ ).

Significant differences were found in physician satisfaction levels by CDC geographic region with 72.7% of physicians practicing in high breastfeeding rate states reporting satisfaction with the proportion of their patients breastfeeding compared with 60% reporting satisfaction in medium states and only 34.3% reporting satisfaction in low states ( $P<.001$ ). Even within geographic regions, physician satisfaction reflected estimated patient breastfeeding behavior. For example, physician satisfaction was associated with the estimated proportion of patients breastfeeding at 6 months in all three regions ( $r>0.48$ ,  $P<.001$  in all cases; Fig. 1).

Physician satisfaction with breastfeeding rates was also influenced by the physicians' opinions about breastfeeding and formula. Significant differences were found in satisfaction based on the responses to the following question: "Feeding an infant formula is an acceptable option that will not negatively affect the child." Of those who disagree that formula is an acceptable option, only 35.9% are satisfied with the proportion of their patients that breastfeed their babies compared with 59.7% for those who agree with the statement and 64.5% for those who were neutral regarding formula ( $P=.003$ ).

### Physician Practice and Effort

Thirteen questions on the survey were considered to reflect physicians' effort toward encouraging breastfeeding by their patients. An "effort" score was created from these questions with a possible range of 0–14 (Table 4). Three of 10 responding physicians scored 12 points or higher. There was no association between physician age and effort score; however, women ( $10.2 \pm 0.2$ ) scored higher than men ( $8.6 \pm 0.3$ ,  $P=.001$ ). Effort score was not associated with any patient demographic parameters. There was no difference in effort score between physicians from the different CDC geographic breastfeeding rate categories. Effort score was not associated with the estimated proportion of patients that initiate breastfeeding or who are breastfeeding at 3, 6, or 12 months. Effort score was associated with the physicians' opinions of

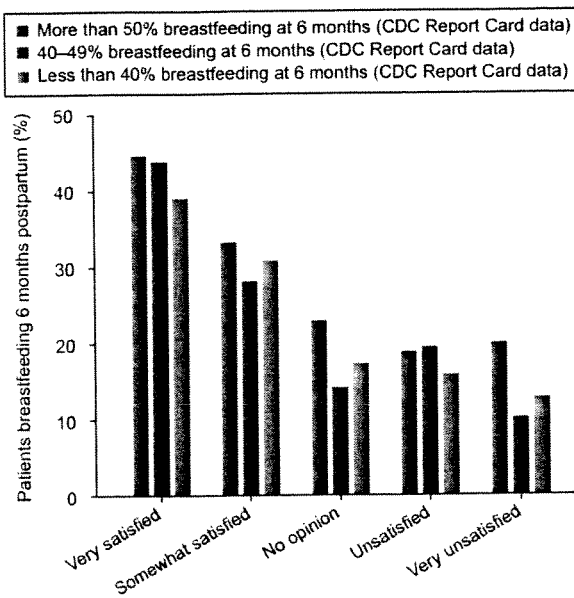


Fig. 1. The estimated proportion of patients breastfeeding at 6 months by reported physician satisfaction and Centers for Disease Control and Prevention (CDC) Breastfeeding Report Card state designation.

Queenan. Breastfeeding Rates of Ob-Gyn Patients. *Obstet Gynecol* 2012.

breastfeeding and formula feeding. Both physicians that agreed that exclusive breastfeeding was the best option if possible and physicians that disagreed with the statement that formula feeding is an acceptable option had higher Effort scores (Table 5).

### DISCUSSION

Breastfeeding is a valuable asset to an infant's health. Expert opinion concludes that increasing breastfeeding rates in the United States would have a significant public health benefit, especially among poor and African American populations in which rates are low. To devise evidence-based interventions to increase breastfeeding, it is important to study what factors influence the decision to choose breastfeeding or formula feeding. Because the mother's choice to breastfeed and its initiation generally occur during the period of obstetric care, ob-gyns' attitudes and performance might influence the rate of breastfeeding within their practice.

Physician reports of breastfeeding rates were consistent with the geographical data collected by the CDC. Physicians in states with higher breastfeeding rates reported higher on-average estimated breastfeeding rates and vice versa. However, the surveyed physicians appeared to be pessimistic about their patients' breastfeeding behavior, estimating significantly lower rates at 6



**Table 4. Questions That Make Up the Physician Effort Score**

Question	Percentage of Respondents Obtaining Points for Each Question
"In your practice environment, does most responsibility to do the following lie with you and your staff or with the pediatrician/family physician and that staff?" (Responsibility lies with other physician, score=0; responsibility lies with me or is shared with other physician, score=1.)	80.0
Provide breastfeeding information in discharge planning	77.4
Observe or assess breastfeeding in the postpartum ward	96.1
Educate and encourage pregnant women regarding breastfeeding	89.6
Change delivery room or nursery practices to increase breastfeeding	
"In your opinion, how important is it that you—the physician—personally do the following even if other staff are also involved?" (Not important or somewhat important, score=0; very important, score=1.)	76.1
Ask pregnant patients about their feeding plans	57.0
Find out why a woman does not plan to breastfeed	60.4
Try to help a woman reduce obstacles to breastfeeding	20.0
Discuss breastfeeding when appropriate as part of breast examinations for women from puberty through childbearing years	58.7
Serve as a resource on breastfeeding issues after delivery and discharge	71.3
Ask about breastfeeding intrapartum and at postpartum visits	63.9
Collaborate with other professional and community resources to promote breastfeeding	38.3
Help a woman work with her employer so she can continue to breastfeed after returning to work	81.7
Physician report of use of lactation consultants as a way of providing breastfeeding information to patients in their practices (no, score=0; yes, score=2)*	

\* This question was weighted heavier than other questions (as indicated by a score of 2 points for a positive response) in determining physician effort because it requires the physician to commit additional office resources and the extra responsibility to oversee the consultant.

and 12 months than the CDC data indicate (Table 3). This may reflect their lower rate of contact with their patients postpartum, resulting in an underestimation of breastfeeding in their patients.

There were no differences in physicians' opinions regarding breastfeeding across the CDC geographic categories. However, in states with low breastfeeding rates, the physicians report greater dissatisfaction with their patients' breastfeeding behavior. This pattern held true even within CDC categories with physician satisfaction strongly associated with patients' breastfeeding behavior (Fig. 1). Physicians

in the lower breastfeeding states did not appear to have lowered expectations for appropriate levels of breastfeeding.

Areas that are indicative of the physicians' approach to encouraging breastfeeding in their patients include responsibility, importance, and use of lactation consultants (Table 4). Our data indicate that physicians in low breastfeeding states provide just as much effort to educate and encourage breastfeeding as physicians in states with high breastfeeding rates. It appears that the physicians in the states with low breastfeeding rates show dedication and efforts to

**Table 5. Physician Effort Score by Physician Opinion Regarding Breastfeeding and Formula Feeding**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	P
Exclusive breastfeeding, when possible, is the best option	10.5±0.2 (132)	9.2±0.3 (67)	6.3±0.6 (26)	4.5±1.5 (2)	13 (1)	<.001
Feeding an infant formula is an acceptable option that will not negatively affect the child	9.0±0.5 (24)	9.2±0.3 (100)	9.6±0.4 (63)	10.7±0.4 (35)	11.6±1.1 (5)	.036

Data are mean±standard error of the mean (n) unless otherwise specified.



promote breastfeeding but have appropriate dissatisfaction over the low rates. Considering the role of these physicians, there is no apparent evidence that they contribute to their patients' low breastfeeding rates. These data support the hypothesis that socio-cultural factors within patient populations are more important determinants of breastfeeding than are physician attitudes and practices.

One strength of this study is the ability to compare our survey results with established and reliable CDC breastfeeding data. Because there was agreement with many of the surveys' assessments of breastfeeding practices, it lends credibility to the softer data of trying to assess physician dedication. The availability of Collaborative Ambulatory Research Network, the College collaborative group for surveying, is a second strength. They are a valuable time-tested and validated resource. A weakness of this study is the reliance on physician self-report and the inherent subjective quality of asking physicians to rate their satisfaction with patient behavior. The survey hopefully provides accurate information, but the actual practice performances and opinions reported are not certifiable. The sample size was sufficient for statistically significant comparisons; however, the 95% CI for proportional results could be as high as 6.5%. There also is a potential for nonresponse bias.

The results of this study indicate that further research to understand why African American mothers are less likely to breastfeed is needed. Re-evaluation of the Medicaid program also is indicated to assure all practical support is offered to mothers to encourage breastfeeding. The education and promotion of breastfeeding and the use of lactation consultants by ob-gyns is to be applauded. Ob-gyns appear to be making good faith efforts to encourage breastfeeding, but their endeavors do not appear to be able to overcome other factors (eg, economic, educational, cultural, and so forth) that may be limiting the rates of breastfeeding in some populations.

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