



Is the "breast is best" mantra an oversimplification?

Recommendations about breastfeeding—absent critical analysis and removed from context—may overvalue its benefit. Here's a look at the evidence.

PRACTICE RECOMMENDATIONS

- Denourage breastfeeding for its potential to reduce the risk of acute otitis media, upper- and lower-respiratory infections, gastrointestinal infection, and dental malocclusion.
- > Promote breastfeeding for its potential to make a small difference in intelligence quotient and the incidence of overweight and obesity—but not for any other significant impact on long-term health. (B)
- > Consider the needs and preferences of the individual when advocating breastfeeding so as to avoid potentially engendering maternal feelings of guilt and inadequacy.

Strength of recommendation (SOR)

- (A) Good-quality patient-oriented evidence
- B Inconsistent or limited-quality patient-oriented evidence
- C Consensus, usual practice, opinion, disease-oriented evidence, case series

he benefits of breastfeeding for infants have long been touted as numerous and supported by overwhelming evidence. The World Health Organization (WHO), American College of Obstetricians and Gynecologists, American Academy of Pediatrics (AAP), and American Academy of Family Physicians all strongly recommend exclusive breastfeeding for the first 6 months of life, citing numerous health benefits for child and mother. These groups recommend that some breastfeeding be continued through the first 12 months of life, or longer, as desired (the WHO extends the recommendation to 2 years). ¹⁻⁴ In 2000, the Surgeon General of the United States released a strategic plan to increase rates of breastfeeding, ⁵ setting goals (by 2010) of:

- 75% of mothers leaving the hospital breastfeeding
- 50% of babies breastfeeding at 6 months
- 25% of babies breastfeeding at 1 year.

Massive public health campaigns citing data for the many benefits of breastfeeding have been launched with the goal of increasing the breastfeeding rate. In 2014, statistics offered a testament to the success of these campaigns⁶:

- 82.5% of infants had been breastfed "ever"
- 55.3% were breastfed "some"
- 24.9% were breastfed exclusively through 6 months of age
- 33.7% were breastfed "some" at 12 months.

Breastfeeding advocacy has become clouded

In recent years, an increasing number of researchers, physicians, and authors have begun to question whether, in the United States, the benefits of breastfeeding children are exaggerated and the emphasis on breastfeeding might be leading to feelings of inadequacy, guilt, and anxiety among mothers.⁷⁻¹³ In 2016, the US Preventive Services Task Force (USPSTF) amended

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its recommendation to "promote and support breastfeeding" to simply "support breastfeeding"—a change that created substantial debate and prompted the Task Force to clarify its stance in changing the language: In its response to public comment, the USPSTF said that its position regarding promotion had not changed, but the language in the original statement had been revised to "ensure that the autonomy of women is respected." ^{2,14-16}

In contrast, others suggest counseling women on the risks of formula feeding rather than on the benefits of breastfeeding, citing substantial health outcome distinctions. ¹⁷ Indeed, wide-ranging conclusions have been drawn from the same data on the topic, potentially creating uncertainty for physicians on how best to counsel women on their choice of how to feed their infant.

In this article, we address this uncertainty by utilizing the most recent and comprehensive data to examine infant health outcomes. When possible, the number needed to treat (NNT) for a given outcome has been calculated or approximated, allowing the reader to estimate the likelihood of benefit for an individual mother-infant dyad. Exercise caution when interpreting the NNT, however: The numbers suggest causality that cannot be definitively established using the observational data on which those numbers are based.

Infectious disease

Acute otitis media. Exclusive breastfeeding for 6 months is associated with a 43% reduction in the risk of acute otitis media (AOM) by 2 years of age (odds ratio [OR]=0.57; 95% confidence interval [CI], 0.44-0.75). Beyond 2 years of age, or when comparing "ever" and "never" breastfeeding, the effect disappears. All studies in this meta-analysis had serious limitations.¹⁸

Nearly half of children will have at least one case of AOM by one year of age; 80%, by 2 years. ^{19,20} Since the introduction of the heptavalent pneumococcal conjugate vaccine, the rate of AOM at 2 years has fallen by as much as 20%. ²¹ Assuming an incidence of 60% to 80% of AOM by 2 years, only 2 or 3 infants need to be exclusively breastfed for 6 months to prevent

a single case of AOM.¹⁸ Prevention of AOM through breastfeeding may be related to head position during feeding, antibacterial effects of breast milk, protective oral microbiome in the breastfed infant pharynx, and/or prevention of primary viral upper respiratory infection (URI), which nearly always precedes AOM.^{18,19}

■Upper and lower respiratory tract infections. Infants who are exclusively breastfed for 4 months and partially breastfed after 4 months have a lower risk of URI (OR=0.65; 95% CI, 0.51-0.83) and of lower respiratory tract infection (LRTI; OR=0.50; 95% CI, 0.32-0.72).²²

The effect is stronger for URI among infants exclusively breastfed for at least 6 months (OR=0.37; 95% CI, 0.18-0.74), but is no longer significant by that time for LRTI (OR=0.33; 95% CI, 0.08-1.40). Importantly, AOM was included in the URI group, and, as previously discussed, AOM has independently been shown to have an inverse relationship with breastfeeding duration.

At 7 to 12 months of age, no association was seen between breastfeeding and the incidence of URI. Curiously, an association with LRTI was again detected for infants breastfed exclusively for 4 months and partially thereafter, but was *not* detected with exclusive breastfeeding for at least 6 months (OR=0.46; 95% CI, 0.31-0.69). In this study, in the first 6 months of life, 40% of infants had a URI and 8% had an LRTI. The findings in this cohort suggest an NNT of 6 or 7 for prevention of URI and an NNT of 25 for prevention of LRTI in the first 6 months of life.²²

Children younger than 2 years are estimated to have approximately 6 bouts of the common cold a year, and essentially 100% have at least one bout—perhaps lowering the NNT for URI if applied widely. However, these data are not divided into 6-month intervals, making accurate extrapolation difficult.²³

• Gastrointestinal infection. The rate of diarrheal illness in the first year of life is lower in infants who are exclusively breastfed for at least 4 months and partially breastfed after.

Both the Promotion of Breastfeeding Intervention Trial (PROBIT; a clinical trial in which infants were randomized to a breastfeeding education intervention or standard care) and a 2010 prospective cohort study in the Netherlands of more than 3400 infants

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whether the benefits of breastfeeding are exaggerated. found a reduction in the risk of one or more gastrointestinal (GI) infections at a similar rate.^{22,24}

- In PROBIT, 9.1% of infants in the intervention group, compared to 13.2% in the standard care group (OR=0.60; 95% CI, 0.40-0.91), had one or more GI infections at 12 months of age.²⁴
- In the 2010 Netherlands cohort, 8% of infants had a GI infection by 6 months of age. Infants breastfed exclusively for at least 4 or 6 months had a decreased risk for GI infection (respectively: adjusted OR=0.41; 95% CI, 0.26-0.64 and adjusted OR=0.46; 95% CI, 0.14-1.59). No such association was found for any feeding group 7 to 12 months of age.²²

These studies are notable for the low incidence of GI infection, which is frequently cited as 1.3 to 2.3 episodes per child per year in children younger than 3 years in the United States.²⁵ However, that high incidence has likely declined significantly since the introduction of rotavirus vaccine in 2006. In the years following the introduction of the vaccine, infant visits for gastroenteritis decreased by >90% in all care settings in the South, Northeast, and Midwest regions of the United States and by 53% to 63% in the West region.²⁶ Recent accurate epidemiologic information, in an era of significantly higher vaccination rates, is lacking.

Assuming the low incidence of GI infection reported in PROBIT and the Netherlands trials, about 25 to 30 infants need to be exclusively breastfed for 4 to 6 months to prevent a single GI infection during the first 6 to 12 months of life. ^{22,24} Assuming a 60% incidence by age 12 months *before* introduction of the rotavirus vaccine, the NNT would be approximately 4.²⁴ The true number is likely somewhere between those 2 NNTs.

Hospitalization

Risk of infection is decreased. A large cohort study in Scotland, involving more than 500,000 children, found an association between exclusive breastfeeding for 6 to 8 weeks and decreased risk of hospitalization within the first

6 months of life. Formula-fed and mixed-fed infants had an increased hazard ratio (HR) for hospitalization for common childhood illness (HR=1.40; 95% CI, 1.35-1.45 for formula-fed infants and HR=1.18; 95% CI, 1.11-1.25 for mixed-fed infants).²⁷ The study also found increased rates of hospitalization for conditions for which other meta-analyses have failed to show a protective effect from breastfeeding—leading to suspicion of residual confounding in the study. Another United Kingdom cohort demonstrated lower rates of hospitalization for GI infection (NNT=171) and LRTI (NNT=115) among exclusively breastfed infants by 8 months of age.²⁸

Risk of neonatal readmission is increased. Late preterm infants who are exclusively breastfed are nearly twice as likely to be hospitalized as breastfed term or non-breastfed preterm infants, primarily due to dehydration, failure to thrive, weight loss, and hyperbilirubinemia. In fact, exclusive breastfeeding at discharge from the hospital is likely the single greatest risk factor for hospital readmission in newborns.29,30 Term infants who are exclusively breastfed are more likely to be hospitalized compared to formula-fed or mixed-fed infants, due to hyperbilirubinemia, dehydration, hypernatremia, and weight loss (number needed to harm (NNH)=71).30-32 For weight loss >10% of birth weight with or without hospitalization, the NNH for breastfed infants is 13.32

Many of these hospitalizations and events could be avoided with appropriate monitoring and medically indicated supplementation; the likelihood of long-term harm is low. Formula supplementation is often avoided if possible in hospitals to promote exclusive breastfeeding; however, several small randomized clinical trials have demonstrated that limited formula supplementation in breastfed infants does not affect the breastfeeding continuation rate at 3 and 6 months, and, therefore, might be a way to decrease infant rehospitalization.^{33,34}

Necrotizing enterocolitis

In preterm infants, breastfeeding has been associated with a lower rate of necrotizing enterocolitis. In the 2007 Agency for Healthcare Research and Quality report, the association

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was found to be only marginally statistically significant, and the authors warned that, first, evidence is old and heterogeneous and, second, present preterm formula is much different than the formula used in earlier studies of preterm infant nutrition and necrotizing enterocolitis.³⁵ A 2012 Cochrane review included newer studies in its analysis but reached the same conclusion on the quality and heterogeneity of available evidence, with a NNT of 25.³⁶

Sudden infant death syndrome

There is a statistically significant association between sudden infant death syndrome (SIDS) and feeding method. Infants whose cause of death is SIDS are approximately one half as likely to have been breastfed as matched controls.^{35,37}

In 2005, AAP did not recommend breast-feeding as a means to reduce the risk of SIDS because available evidence was mixed, and studies at the time were poorly controlled. Since that time, case-control meta-analyses have shed additional light on the association between SIDS and feeding method. 35,37

The protective effect exists for any amount of breastfeeding and is stronger for exclusive breastfeeding, suggesting a protective role—not simply an association. Caution should be employed with this conclusion, however, because the studies included in the meta-analysis used univariate analysis primarily and did not control sufficiently for known confounders. In addition, the authors warn that publication bias might overestimate the association.³⁸

Potential mechanisms of a protective role include decreased risk of infection and greater arousability from sleep in breastfed infants. Assuming a protective role, available data suggest that more than 3500 infants need to be breastfed to prevent one case of SIDS.³⁹

Allergic disease

Asthma. There is evidence of a small protective effect of breastfeeding "ever" on asthma at 5 to 18 years of age in high-income countries (OR=0.90; 95% CI, 0.83-0.97). A family history of asthma or atopy did not affect this finding. The authors note there is some evidence of

publication bias in this review, which is the largest and most comprehensive on the topic.⁴⁰

With a lifetime prevalence of asthma in the United States of approximately 13.2%, this association would confer an NNT of roughly 76.⁴¹ Earlier, the literature demonstrated mixed and conflicting evidence, and some experts suggested an effect only when there is a family history of asthma or atopy.³⁶

Eczema. For children younger than 2 years, there is low-grade- and very-low-grade-quality evidence that exclusive breastfeeding longer than 3 to 4 months is associated with a reduced risk of eczema (OR=0.74; 95% CI, 0.57-0.97).⁴⁰

Previously, data suggested that this association existed only in children who had a family history of atopy.³⁵ The protective association, however, exists regardless of family history and does not persist beyond 2 years of age. The authors noted evidence of publication bias, reverse causation, and misdiagnosis of early childhood rashes as eczema as limitations of their findings.⁴⁰

Reliable epidemiologic evidence on the incidence of eczema in infants in the United States is limited, but the prevalence in the United States in children younger than 17 years is approximately 10.7% (with wide regional variation). Extrapolating these data generously, the NNT to prevent eczema in the first 2 years of life could be estimated at approximately 36.42

and very-low-grade-quality evidence that more breastfeeding, compared to less breastfeeding, is associated with a lower risk of allergic rhinitis in children younger than 5 years (OR=0.79; 95% CI, 0.63-0.98). The association exists regardless of family history and disappears after 5 years of age. The differentiation of allergic rhinitis from rhinovirus infection (for which there is higher-quality evidence of a protective effect with breastfeeding) must be considered when interpreting these data.⁴⁰

Reliable epidemiologic evidence on allergic rhinitis in children younger than 5 years is lacking, and incidence varies by region. A rough estimate, using data from 6- and 7-year-olds, indicates an NNT of 54 to 70.43

• Food allergy. There is no evidence to suggest an association between breastfeed-

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ing and food allergy, either as protective or as a risk factor, and studies are limited.⁴⁰ Interestingly, as data accumulate associating early exposure to foods with protection, some authors have proposed reexamining the recommendation from WHO and US health organizations for exclusive breastfeeding for the first 6 months of life.^{7,44}

Dental health

Dental caries. There is consistent evidence that breastfeeding beyond 12 months of age is associated with the development of dental caries of deciduous teeth to 6 years of age (OR=2.90; 95% CI, 2.33-3.60). Many of the studies that showed this association did not control for the introduction of sugary foods and drinks, and there was a trend toward publication bias showing the association.⁴⁵

■ Dental malocclusion. There is consistent evidence for approximately a two-thirds reduction in malocclusions in deciduous teeth in breastfed infants (OR=0.32; 95% CI, 0.25-0.40). Although the large majority of these data come from low-income and middle-income countries, the incidence of malocclusion is not thought to be associated with socioeconomic status, as so many other breastfeeding outcomes are.⁴⁶

Childhood leukemia

In the largest meta-analysis available, a statistically significant inverse relationship between any breastfeeding for >6 months and childhood leukemia is evident in developed countries (OR=0.84; 95% CI, 0.78-0.91), although significant heterogeneity among studies and lack of control for confounding variables are significant limitations. In particular, an association has been demonstrated with acute lymphoblastic leukemia (ALL) but not with acute myelogenous leukemia.⁴⁷ Given the rarity of childhood ALL, approximately 12,500 infants would need to be breastfed to prevent one case.⁴⁸

Long-term outcomes

Cognitive development. Several studies conducted in developed countries have linked breastfeeding to positive cognitive

outcomes in children, including higher intelligence quotient (IQ). 35,49-52

These effects are conflicting, however, in studies that include sibling analysis and ones that control for maternal IQ.^{8,35,43,52-54} In the 2013 WHO meta-analysis, breastfeeding was associated with an increase of 2.2 points on normalized testing when only high-quality studies were included.⁵¹ A 2015 meta-analysis identified 4 high-quality studies with a large sample size and recall time <3 years, which demonstrated a mean difference of 1.76 points in IQ (95% CI, 0.25-3.26) in childhood and adolescence.⁵² Although statistically significant, this modest increase is of questionable clinical benefit and of unknown duration.

breastfeeding and obesity later in life is debatable. A large, systematic 2014 review of 15 cohort and 10 cross-sectional studies found a significantly reduced risk of childhood obesity among children who were breastfed (adjusted OR=0.78; 95% CI, 0.74-0.81). However, the review included studies that controlled for different confounders, and smaller effects were found in studies in which more confounders were taken into account.

The 2013 WHO meta-analysis found a small (approximately 10%) reduction in the prevalence of overweight or obese children, but cautioned that residual confounding and publication bias were likely.⁵¹ At 6.5 and 11.5 years of follow-up, PROBIT failed to demonstrate a protective effect for exclusively or "ever" breastfed infants.⁵⁶ Sibling analysis similarly fails to demonstrate a statistically significant relationship.⁸

A 2015 meta-analysis of 23 high-quality studies with a sample size >1500 children and controlled for important confounders showed a pooled reduction in the prevalence of overweight or obesity of 13% (95% CI, 6-19).⁵⁷ The protection in this meta-analysis showed a dilution of the effect as the participants aged and an inverse relationship of the effect with sample size.

Breastfeeding is, therefore, unlikely to play a significant, if any, role in combatting the obesity epidemic.

■ Hypertension. A meta-analysis of high-quality trials demonstrates a <1 mm Hg

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reduction in systolic blood pressure and no significant difference in diastolic pressure in breastfed infants.⁵⁷ Similarly, no significant effect of breastfeeding on blood pressure has been demonstrated in trials of preterm infants.⁵¹

- Type 2 diabetes. Available data are limited and heterogeneous for the association between breastfeeding and later development of type 2 diabetes. Only 2 high-quality trials were identified in the 2013 WHO metanalysis, and their results conflict.⁵¹ A 2015 meta-analysis identified only 3 high-quality studies, without a statistically significant relationship.⁵⁷
- Dyslipidemia. Although earlier data suggested an association between breast-feeding and reduced cholesterol levels later in life, the 2013 WHO meta-analysis and a 2015 meta-analysis concluded that no association exists. The limited data available for preterm infants conflict. 51,57
- **Growth.** There is no evidence that feeding method has a short- or long-term effect on weight gain or length gain in preterm or term infants. ^{35,36,58}
- Death. No clear association has been found between mortality and breastfeeding status in developed countries, except for the association with SIDS.³⁵

What issues frame and guide counseling on breastfeeding?

There is that "problem" with the evidence. The evidence for infant breastfeeding status and its association with health outcomes faces significant limitations; the great majority of those limitations tend to overestimate the benefits of breastfeeding. Nearly all evidence is based on observational studies, in which causality cannot be determined and self-selection bias, recall bias, and residual confounding limit the value or strength of the findings.

Breastfeeding rates are strongly socially patterned alongside socioeconomic status, race, and education level, all of which are simultaneously strongly tied to short- and long-term health outcomes. Other factors limiting the strength of the data set include varying definitions of infant feeding practices in dif-

ferent studies, varying definitions of outcomes and diseases, reverse causation, and evidence of publication bias in many meta-analyses. Given these shortcomings, the NNTs in this article probably represent a best-case scenario for breastfeeding outcomes for infants in the United States (TABLE 118,22-24,28,36,39-43,47,48).

■ Data need to be put into context. The NNTs for many breastfeeding outcomes (TABLE) compare favorably with other recommended interventions, particularly for other preventive care measures. Two examples: 81 mg/d aspirin for a 50-year-old man has an NNT of 35 to 45 for preventing nonfatal myocardial infarction, and the number needed to invite to screen with mammography to prevent one breast cancer death for a 50-year-old woman is 1339.^{59,60}

In both of these examples, >95% of patients will not benefit from the intervention, yet these preventive measures are routinely recommended and have a significant impact at the public health level. Notably, these outcomes are more serious than most breastfeeding outcomes; have a longer-lasting effect, better-quality data, and better data for potential harms; are causally linked to the intervention; and require much less effort and commitment of time than breastfeeding.

The question must be reckoned with: Can advocacy be harmful?

In recent years, a growing number of concerns have been raised about:

- the potential harms of breastfeeding advocacy
- exaggeration of the benefits of breastfeeding
- promotion of breastfeeding at the expense of evidence-based medicine.

The "Ten Steps to Successful Breastfeeding" program of the Baby-friendly Hospital Initiative (BFHI; launched by UNICEF and WHO) has come under scrutiny because of an increasing number of reports of sudden unexpected postnatal collapse; fall injuries; modeling and encouragement of unsafe sleep practices; an overly rigid resistance to the use of formula supplementation; and the ban on pacifier use. 61,62 The BFHI, promoted by the Centers for Disease Control and Preven-

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The use of pacifiers before last sleep is more protective against SIDS than breastfeeding.

TABLE
Breastfeeding NNT to achieve short-term infant health varies widely

Outcome prevented	Type of feeding	Duration of feeding	NNT	Age of benefit
Acute lymphoblastic leukemia ^{47,48}	Any breastfeeding	>6 mo	12,500	<18 y
Acute otitis media ¹⁸	Exclusively breastfed	6 mo	2 or 3	<2 y
Allergic rhinitis ^{40,43} *	Any breastfeeding	Longer confers greater benefit	54-70	<5 y
Asthma ^{40,41}	Any breastfeeding	Not reported	76	5-18 y
Eczema ^{40,42} *	Exclusively breastfed	>3-4 mo	36	<2 y
Gastrointestinal infection ^{22,24}	Exclusively breastfed	4 mo	4-30	<12 mo
Gastrointestinal infection hospitalization ²⁸	Exclusively breastfed	4-6 mo	171	<8 mo
Lower respiratory-tract infection ²²	Exclusively breastfed	4 mo	25	<6 mo
Lower respiratory-tract infection hospitalization ²²	Exclusively breastfed	4-6 mo	115	<8 mo
Necrotizing enterocolitis ^{36†}	Exclusively breastfed	Throughout the preterm period [‡]	25	<1 y
Sudden infant death syndrome ³⁹	Any breastfeeding	Longer duration confers greater benefit	>3500	<1 y
Upper respiratory-tract infection ^{22,23}	Exclusively breastfed	6 mo	6 or 7	<6 mo

NNT, number needed to treat.

tion, is increasingly being adopted by hospitals with the expressed goal of increasing the breastfeeding rate from birth to discharge.

Some of the "Ten Steps," such as the call for skin-to-skin care and 24-hour rooming-in, have well-established benefit yet, when performed without supervision, can have the rare but serious unintended consequences of sudden unexpected postnatal collapse (the incidence of which may be higher than that of SIDS) and unsafe sleeping practices. 62,63

Furthermore, despite evidence that early formula supplementation, when medically necessary, does not adversely impact the breastfeeding rate, the "Ten Steps" program advises that giving formula before breast milk comes in might "lead to failure to breastfeed." ^{33,34,61,63}

Similarly, the ban on pacifiers is contrary to available evidence. The use of pacifiers before last sleep is more protective against SIDS than breastfeeding (NNT=2733), and there is

evidence at one hospital that BFHI-inspired pacifier restriction is associated with a decrease in the rate of breastfeeding. 64,65

Other harms of advocacy are even more poorly studied. Most of the evidence for harm comes from the psychology and social science literature—not the medical literature, perhaps because the prevailing opinion in the medical community is that breastfeeding has overwhelming evidence for benefit. In fact, in the USPSTF's 2008 recommendation, the evidence review of breastfeeding promotion practices in primary care did not identify a single study that measured harm; in the 2016 update of that recommendation, only 2 such studies were identified. 15,66

The literature that does investigate harm consistently finds that women who have difficulty breastfeeding or choose formula feeding report feelings of inadequacy, guilt, loss of agency, anxiety, and physical pain during breastfeeding that interferes with

^{*}Poor epidemiologic information available for calculation of applicable duration of feeding, with regional variation.

[†]Preterm only

[‡]In studies in which this information is provided; not all studies in the meta-analysis provided this information.



1) their ability to bond or otherwise care for their infant and 2) competing work obligations. ^{11-13,67-69} Given the lack of attention paid to these variables in the medical literature, it is the individual mother who is best positioned to weigh these factors against the benefits of breastfeeding.

Shared decision-making is best—for mother and baby

Breastfeeding might prevent certain infections in as many as 50% of infants, but a mother unable to breastfeed can take solace in the fact that >95% of breastfed infants will not realize any benefit from the preventive potential of breastfeeding in regard to hospitalization or allergic disease, and >99% will not realize benefit from either the prevention of SIDS or ALL, or from improvement in longterm health measures (except for, perhaps, a slightly higher IQ). The "breast is best" mantra is likely true at a public-health level; for the individual mother-infant dyad, however, where there is a need to balance personal, social, family, and financial factors, that mantra is an oversimplification.

Regrettably, there is a paucity of data on the risks of breastfeeding promotion—an area that deserves more study. Balancing the abundant, but often limited-quality, data on the benefits of breastfeeding and the sheer lack of data regarding the risks of advocacy represents a clinical and an ethical challenge for physicians. It is a challenge that can only be resolved through individualization of care and shared decision-making, in which the physician is expert on the benefits of breastfeeding, and the mother is expert on the personal circumstances to be weighed against those benefits.

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