

What are the Risks Associated with Formula Feeding? A Re-Analysis and Review

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ABSTRACT: **Background:** Most infant feeding studies present infant formula use as “standard” practice, supporting perceptions of formula feeding as normative and hindering translation of current research into counseling messages supportive of exclusive breastfeeding. To promote optimal counseling, and to challenge researchers to use exclusive breastfeeding as the standard, we have reviewed the scientific literature on exclusive breastfeeding and converted reported odds ratios to allow discussion of the “risks” of any formula use. **Methods:** Studies indexed in PubMed that investigated the association between exclusive breastfeeding and otitis media, asthma, types 1 and 2 diabetes, atopic dermatitis, and infant hospitalization secondary to lower respiratory tract diseases were reviewed. Findings were reconstructed with exclusive breastfeeding as the standard, and levels of significance calculated. **Results:** When exclusive breastfeeding is set as the normative standard, the re-calculated odds ratios communicate the risks of any formula use. For example, any formula use in the first 6 months is significantly associated with increased incidence of otitis media (OR: 1.78, 95% CI: 1.19, 2.70 and OR: 4.55, 95% CI: 1.64, 12.50 in the available studies; pooled OR for any formula in the first 3 mo: 2.00, 95% CI: 1.40, 2.78). Only shorter durations of exclusive breastfeeding are available to use as standards for calculating the effect of “any formula use” for type 1 diabetes, asthma, atopic dermatitis, and hospitalization secondary to lower respiratory tract infections. **Conclusions:** Exclusive breastfeeding is an optimal practice, compared with which other infant feeding practices carry risks. Further studies on the influence of presenting exclusive breastfeeding as the standard in research studies and counseling messages are recommended. (BIRTH 37:1 March 2010)

Key words: any formula use, breastfeeding, exclusive breastfeeding, formula use, risks of formula use

Exclusive breastfeeding is the recommended source of nutrition for the first 6 months of an infant's life and should be regarded as such in analytical approaches used in the study of infant feeding (1,2). Yet, despite the strength of the data and the recommendations supporting exclusive breastfeeding for infants 0 to 6 months old (1,2), analytical approaches to the study of infant feed-

ing rarely set exclusive breastfeeding as the norm with which any other feeding approach should be compared.

In most studies on infant feeding, findings are presented in a manner that states the *benefits* of breastfeeding, thereby confirming formula use as the standard for comparison. In fact, a recent review determined that the titles of many studies are misleading and imply that

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breastfeeding is associated with increased risk of illness (3). This analytical construction of formula use as the norm and breastfeeding as the deviant, or experimental, behavior is consistent with current social conceptions of infant feeding in developed nations, but inconsistent with the accepted use of the proved optimal treatment approach as the standard, or control, group in research design.

Few women and health care providers in the United States have grown up exposed to the sights and sounds of breastfeeding as “normal” (4–7). Formative research conducted for the U.S. Department of Health and Human Services National Breastfeeding Awareness Campaign confirmed that breastfeeding was seen as the “ideal” and formula use as the “standard,” rather than inferior, behavior among focus group participants (6). In a national survey of infant feeding practices, fewer than 60 percent of respondents believed that “women should have the right to breastfeed in public,” and less than 40 percent agreed that “it is appropriate to show a woman breastfeeding her baby on TV programs” (7). Perceptions of formula feeding as the standard practice have obscured its health risks—fewer than one-half of survey respondents agreed that “feeding a baby formula instead of breast milk increases the chance that the baby will get sick” (7).

Clearly, it is important to explore how prevailing norms can be readjusted to improve suboptimal breastfeeding rates in the developed world. Research on the development of social norms suggests that, “new norms are thought to emerge when costs of compliance with existing norms become too high relative to the rewards” (8). A negative, or disincentive, value from feedback or other sources of information can also influence the construction of behavioral norms by emphasizing the dangers of not practicing a particular behavior (9,10). Studies specific to infant feeding behaviors have shown that breastfeeding intentions and behavior can be predicted and understood through constructs of the Theory of Reasoned Action, the Transtheoretical Model, and the Integrated Change Model. Elements of each of these models emphasize that the likelihood of formula feeding would decrease as its perceived risk-to-benefit ratio increases (11–14). Therefore, to encourage exclusive breastfeeding and its social acceptance, it may be reasonable to underscore the present risks (disincentives) of the alternative, that is, formula feeding, in a manner whereby the health costs of formula use are appropriately perceived as high.

This paper seeks to re-position breastfeeding as a natural, normative behavior in the minds of women’s and children’s health care providers by reconfiguring the reported statistics to reflect the risks of formula use rather than the “benefits of breastfeeding.” Specifically, we present odds and risks ratios calculated to reflect the increase in risks of adverse outcomes as a result of formula use. In doing so, we provide health professionals with the quantitative and qualitative information needed

to counsel patients in a manner consistent with United States and international recommendations for exclusive breastfeeding.

Methods

This secondary analysis focused on studies included in the U.S. Agency for Healthcare Research and Quality (AHRQ)-sponsored review of breastfeeding and maternal and infant health outcomes in the developed world (15). The studies addressed eight childhood conditions, including: acute otitis media, atopic dermatitis, lower respiratory tract infections, asthma, type 1 diabetes, and type 2 diabetes. The complete original publications were obtained, and the study design, population size, and definition of breastfeeding were recorded, verified, or both. In addition, a PubMed search was conducted by entering the outcome variables listed before and *exclusive breastfeeding* and *odds ratio*. Other terms used were: *exclusive breastfeeding*, *exclusive breast-feeding*, *exclusive breast feeding*, and *exclusive lactation*.

We evaluated only studies that reported “exclusively breastfed,” “fully breastfed,” or “totally breastfed” as a comparison group. Lack of exclusive breastfeeding in developed countries is an appropriate proxy indicator of formula feeding. Data based on mixed formula and breastfeeding (“partial,” “ever,” “predominately,” or “mixed”) or on an indeterminate minimal duration of exclusive breastfeeding were excluded. Based on the definitions provided, we assumed that “exclusive,” “fully,” and “totally” breastfed infants received no formula within the given time period unless the study mentioned otherwise. Bottle-feeding with expressed human milk was considered the same as breastfeeding for this study. By selecting studies in which the researchers’ definition of “exclusive” or “fully breastfed” excluded any formula use, we ensured that the inverse odds ratios or risk ratios served as true proxies for any formula use during the specified time period.

Odds and risk ratios were taken directly from the original studies or from the AHRQ-sponsored review. Odds and risk ratios, with their corresponding confidence intervals, were calculated by creating the inverse value. *p* values were constructed for the odds and risk ratios listed in the meta-analysis and original studies using Microsoft Excel.

Results

Otitis Media

Otitis media is a common childhood illness that currently affects most children by the time they are 6 years

old (15,16). Table 1 presents the articles reviewed and the association between formula feeding and otitis media. Each of the studies identified achieves statistical significance in the association between formula use and increased occurrence of otitis media. The pooled odds ratio for otitis media if any formula is introduced in the first 3 to 6 months is 2.00 (95% CI: 1.40, 2.78).

Asthma

Asthma (also referred to as recurrent or allergic wheezing) is a highly prevalent chronic disease that affects increasing numbers of children (15,17). One of the greatest risk factors for asthma is family history (15,18). Lack of breastfeeding has been shown to lower the risk of asthma in some studies and increase the risk in others. These contradictory results could be explained by study design differences and variable lengths of breastfeeding in addition to variations in familial history (19). Several studies have focused on maternal diet with the assumption that the composition of the mother's milk differs between asthmatics and nonasthmatics (20). Potential confounders in studies on asthma and breastfeeding include age and socioeconomic status as well as parental smoking and family history (15).

Table 2 presents the articles reviewed and measures of the association between formula feeding and asthma. Six of the eight studies measuring asthma risk with positive family history reported that formula use is associated with increased risk of asthma, but of these six, only one achieved statistical significance: the case-controlled study ($p = 0.030$). Within the group of studies measuring asthma risk with a negative family history, five of the seven studies demonstrated a positive association between formula use and increased asthma, but only two of these are statistically significant, a cohort of 2,187 ($p = 0.027$) and one of 3,384 ($p = 0.011$).

Type 1 Diabetes

Type 1 diabetes mellitus is a disorder in which autoimmune beta-cell destruction leads to decreased levels of insulin. Human milk may provide protection against the onset of type 1 diabetes by conferring passive immunity through secretory immunoglobulin A antibodies and increased β -cell proliferation, and by delaying exposure to possible food antigens (15).

Table 3 presents the association between formula feeding and type 1 diabetes. In two studies on type 1 diabetes, McKinney et al found a significant association between early formula use and increased type 1 diabetes ($p = 0.01$). In Tenconi's study, one of the few studies that was constructed to assess the risk of formula use (as opposed to the benefits of breastfeeding), the association did not achieve significance.

Type 2 Diabetes

Type 2 diabetes mellitus is an increasingly prevalent disorder in which the body has developed a resistance to insulin and insulin receptors, resulting in high blood sugar levels. It has been proposed that the polyunsaturated fatty acids contained in breastmilk maintain adequate numbers of insulin receptors in the brain and thereby regulate long-term glucose and insulin metabolism (21). Table 4 presents the association between formula feeding and type 2 diabetes.

Atopic Dermatitis

Atopic dermatitis is an increasingly prevalent chronic inflammatory skin disease that is considered to be a result of both genetic and environmental factors. Studies on the association of breastfeeding with atopic dermatitis have yielded mixed results, some suggesting a protective effect, others showing no significant relationship,

Table 1. Odds Ratios for Risk of Otitis Media Associated with Any Formula Use

<i>Study</i>	<i>Study Design</i>	<i>Number of Participants</i>	<i>Health Issue</i>	<i>Duration of Exclusive Breastfeeding</i>	<i>Odds Ratio for Risk of Otitis Media with Any Formula Use</i>	<i>p</i>
Duffy et al (26)	Prospective cohort	238	Otitis media	≥ 3 mo	In the first 3 mo 2.70 (1.10, 6.67)	0.030
Scariati et al (27)	Prospective cohort	1,410	Otitis media/ear infection	≥ 6 mo	In the first 6 mo 1.78 (1.19, 2.70)	0.005
Duncan et al (16)	Prospective cohort	1,013	Otitis media	≥ 4 mo	In the first 4 mo 1.64 (1.08, 2.50)	0.020
Duffy et al (26)	Prospective cohort	238	Otitis media	≥ 6 mo	In the first 6 mo 4.55 (1.64, 12.50)	0.004

Table 2. Odds Ratios for Risk of Asthma with Any Formula Use

Study	Study Design	Number of Participants	Health Issue	Duration of Exclusive Breastfeeding	Odds Ratio for Risk of Asthma with Any Formula Use	p
Buscino et al (28)	Prospective observational	101	Asthma risk with positive family history of asthma or atopy	≥6 mo	In the first 6 mo 3.85 (0.78, 33.33)	NS
Marini et al (18)	Case-control	279 patients and 80 controls	Asthma risk with positive family history of asthma or atopy	≥5 mo (glucose water allowed)	In the first 5 mo 2.00 (1.10, 3.85)	0.02
Kull et al (19)	Prospective longitudinal cohort	3,384	Asthma risk with positive family history of asthma or atopy	≥4 mo	In the first 4 mo 1.37 (0.83, 2.33)	NS
Fergusson et al (29)	Prospective birth cohort	1,110	Asthma risk with positive family history of asthma or atopy	≥4 mo	In the first 4 mo 0.84 (0.22, 4.76)	NS
Hide and Guyer (30)	Prospective birth cohort	843	Asthma risk with positive family history of asthma or atopy/asthma or bronchitis	≥3 mo	In the first 3 mo 1.37 (0.35, 7.69)	NS
McConnochie and Roghmann (31)	Prospective cohort	223	Asthma risk with positive family history of asthma or atopy/wheezing	≥6 mo	In the first 6 mo 2.08 (0.63, 7.69)	NS
Wright et al (20)	Prospective longitudinal newborn cohort	1,043	Asthma risk with positive family history of asthma or atopy	≥4 mo	In the first 4 mo 0.11 (0.05, 0.29)	0.00
Hide and Guyer (32)	Prospective birth cohort	843	Asthma risk with negative family history of asthma or atopy/asthma or bronchitis	≥3 mo	In the first 3 mo 0.79 (0.25, 2.94)	NS
Gordon et al (33)	Prospective cohort	239	Asthma risk with negative family history of asthma or atopy/eczema-asthma syndrome	≥3 mo	In the first 3 mo 2.56 (0.73, 11.11)	NS
Fergusson et al (29)	Prospective birth cohort	1,110	Asthma risk with negative family history of asthma or atopy	≥4 mo	In the first 4 mo 0.98 (0.40, 2.86)	NS
Wright et al (20)	Prospective longitudinal newborn cohort	1,043	Asthma risk with negative family history of asthma or atopy	≥4 mo	In the first 4 mo 1.49 (0.80, 2.78)	NS
Wilson et al (34)	Prospective cohort	545	Asthma risk with negative family history of asthma or atopy	≥15 wk	In the first 15 wk 2.13 (0.93, 5.56)	NS
Oddy et al (35)	Prospective birth cohort	2,187	Asthma risk with negative family history of asthma or atopy	≥4 mo	In the first 4 mo 1.25 (1.52, 1.02)	0.03
Kull et al (19)	Prospective longitudinal cohort	3,384	Asthma risk with negative family history of asthma or atopy	≥4 mo	In the first 4 mo 1.72 (1.14, 2.63)	0.01

NS = nonsignificant.

and two showing a positive association between breastfeeding and atopic disorders (22,23). Table 5 presents the association between formula feeding and atopic dermatitis. Eight of the 13 studies of atopic dermatitis with a positive family history reported a positive association between formula use and increased dermatitis, but only two achieved significance. Four of the six studies of atopic dermatitis with a negative family history found an association between formula use and increased dermatitis but none achieved statistical significance.

Hospitalization Secondary to Lower Respiratory Tract Infections

Respiratory infection is reported to be the most common medical problem and leading cause of hospitalization among infants and children (15,24). Immunoglobulins found in human milk are believed to bolster infantile immune systems and protect against infections such as those affecting the lower respiratory tract (25). Table 6 presents the association between formula feeding and hospitalization secondary to lower respiratory tract infections. All studies found a positive association between formula use and increased hospitalization owing to lower respiratory tract infections, with two achieving statistical significance.

Overall, the results revealed that “any formula use” is associated with increased incidence of otitis media, asthma, type 1 diabetes, type 2 diabetes, atopic dermatitis, and hospitalization secondary to lower respiratory tract infections in infants in multiple studies. In many of these studies, this positive association does not achieve

statistical significance; however, it is important to note that no study found a protective effect of formula use.

Discussion

These secondary analyses were undertaken to allow support for healthy infant feeding behaviors by taking the available evidence and re-expressing it as risks, or health costs, of formula use. Expressed in this manner, behavioral theory would argue that the risk of formula use becomes too high relative to the “rewards,” and families would be increasingly likely to choose exclusive breastfeeding. This construct supports the feasibility of the creation of a social norm based on the perceived costs of compliance with existing formula-use norms. In this manner, the data provided should aid in clinical counseling and in health social marketing, and encourage researchers to reconsider the selection of standard and experimental groups in the study of infant feeding. In summary, expression of the “risks of formula use” rather than only the “benefits of breastfeeding” could modify general perception, inform and reform clinical counseling, and lead to normalization of optimal infant feeding, that is, exclusive breastfeeding.

One of the strengths of this analysis is that it is based on studies with exclusive breastfeeding as the reference rather than “any breastfeeding” or a continuum of breastfeeding definitions. This reconstruction allowed us both to create a more clearly defined standard for the definition of “any formula use” versus exclusive breastfeeding and to address the recommendation of optimal feeding. In addition, because the durations of exclusive

Table 3. Odds Ratios for Risk of Type 1 Diabetes with Any Formula Use

<i>Study</i>	<i>Study Design</i>	<i>Number of Participants</i>	<i>Health Issue</i>	<i>Duration of Exclusive Breastfeeding</i>	<i>Odds Ratio for Risk of Type 1 Diabetes with Any Formula Use</i>	<i>p</i>
McKinney et al (36)	Case-control	196 patients and 325 controls	Type 1 diabetes	Initial	In the initial feedings 1.67 (1.12–2.44)	0.01
Tenconi et al (37)	Case-control	159 patients and 318 controls	Type 1 diabetes	3 mo	In the first 3 mo 1.30 (0.81–2.09)	NS

NS = nonsignificant.

Table 4. Odds Ratios for Risk of Type 2 Diabetes with Any Formula Use

<i>Study</i>	<i>Study Design</i>	<i>Number of Participants</i>	<i>Health Issue</i>	<i>Duration of Exclusive Breastfeeding</i>	<i>Odds Ratio for Risk of Type 2 Diabetes with Any Formula Use</i>	<i>p</i>
Pettitt et al (38)	Retrospective cohort	720	Type 2 diabetes	≥2 mo	In the first 2 mo 2.44 (1.08, 5.56)	0.03

Table 5. Odds Ratios for the Risk of Atopic Dermatitis with Any Formula Use

Study	Study Design	Number of Participants	Health Issue	Duration of Exclusive Breastfeeding	Odds Ratio for Risk of Atopic Dermatitis with Any Formula Use	p
Laubereau et al (22)	Prospective randomized double-blind trial	3,903	Atopic dermatitis with positive family history	≥4 mo	In the first 4 mo 1.09 (0.80–1.49)	NS
Gordon et al (33)	Prospective cohort	239	Atopic dermatitis with positive family history/eczema and/or asthma	≥3 mo	In the first 3 mo 0.76 (0.36–1.61)	NS
Businco et al (28,39)	Prospective study	101	Atopic dermatitis with positive family history/asthma/eczema	≥6 mo	In the first 6 mo 0.83(0.15–5.56)	NS
Cogswell et al (40–42)	Prospective study	73	Atopic dermatitis with positive family history	>1 mo	In the first month 0.74 (0.25–2.22)	NS
Herrmann et al (43)	Prospective study	138	Atopic dermatitis with positive family history	≥3 mo	In the first 3 mo 2.33 (0.78–6.67)	NS
Hide and Guyer (30,32,44)	Prospective study	486	Atopic dermatitis with positive family history/eczema	≥3 mo	In the first 3 mo 0.86 (0.30–2.86)	NS
Marini et al (18)	Case-control study	279 patients and 80 controls	Atopic dermatitis with positive family history	≥5 mo	In the first 5 mo 1.69 (0.86–3.85)	NS
Matthew et al (45)	Case-control study	23 patients and 19 controls	Atopic dermatitis with positive family history/Eczema	≥3 mo	In the first 3 mo 5.88 (1.11–33.33)	0.04
Poysa et al (46)	Case-control study	91 patients and 72 controls	Atopic dermatitis with positive family history/eczema	≥3 mo	In the first 3 mo 1.23(0.41–3.70)	NS
Pratt (23)	Prospective cohort	198	Atopic dermatitis with positive family history/eczema	≥3 mo	In the first 3 mo 2.50 (0.65–14.29)	NS
Van Asperen et al (47)	Prospective birth cohort	79	Atopic dermatitis with positive family history	≥2 mo	In the first 2 mo 0.60 (0.18–1.89)	NS
Berth-Jones et al (48)	Prospective birth cohort	413	Atopic dermatitis with negative family history	≥4 mo	In the first 4 mo 2.27 (1.10–5.00)	0.03
Fergusson et al (49,50)	Birth cohort study	1,143	Atopic dermatitis with negative family history/eczema	≥4 mo	In the first 4 mo 1.54 (0.90–2.78)	NS
Hide and Guyer (30,32,44)	Prospective cohort	486	Atopic dermatitis with negative family history/eczema	≥3 mo	In the first 3 mo 0.63 (0.29–1.41)	NS
Pratt (23)	Prospective cohort	198	Atopic dermatitis with negative family history/Eczema	≥3 mo	In the first 3 mo 0.56 (0.11–3.70)	NS
Tariq et al (51)*	Prospective cohort	1,174	Atopic dermatitis with negative family history/eczema	≥3 mo	In the first 3 mo 1.27 (0.85–1.89)	NS
Laubereau et al (22)	Prospective randomized double-blind trial	3,903	Atopic dermatitis with negative family history	≥4 mo	In the first 4 mo 1.03 (0.83–1.30)	NS

*Most recent data used.
NS = nonsignificant.

Table 6. Odds Ratios for the Risk of Hospitalization Secondary to Lower Respiratory Tract Diseases (LRTI) Associated with Any Formula Use

<i>Study</i>	<i>Study Design</i>	<i>Number of Participants</i>	<i>Health Issue</i>	<i>Duration of Exclusive Breastfeeding</i>	<i>Odds Ratio (95% CI) for Risk of LRTI Hospitalization with Any Formula Use</i>	<i>p</i>
Bachrach et al (24)	Meta-analysis of seven observational studies	Breastfed, 3,201; not breastfed, 1,324	Hospitalization for LRTIs	≥2 mo (includes some who were breastfed for >9 mo, not EBF)	In the first 2 mo 3.57 (1.85, 7.14)	0.00
Ball and Wright (52)	Prospective cohort from two different data sets	944 674/644	Hospitalization for LRTIs	≥3 mo	In the first 3 mo 3.13 (0.53–20.00)	NS
Beaudry et al (25)	Retrospective cohort	776	Hospitalization for LRTIs	≥26 wk	In the first 6 mo 7.69 (0.48–100.00)	NS
Howie et al (53)	Prospective cohort	618	Hospitalization for LRTIs	≥13 wk	In the first 3 mo 6.67 (0.89–50.00)	NS
Oddy et al (35)	Prospective cohort	2,187	Hospitalization for LRTIs/ respiratory symptoms	≥4 mo	In the first 4 mo 1.61 (0.81–3.23)	NS
Quigley et al (54)	Longitudinal cohort	15,890	Hospitalization for LRTIs	≥4 mo	In the first 4 mo 1.52 (1.09–2.13)	0.01

EBF = exclusive breastfeeding; NS = nonsignificant.

breastfeeding in the studies vary from only 0 to 6 months, any formula use is then compared with a variety of durations of optimal feeding. The fact that the odds and risk ratios remain significant even with shorter durations of exclusive breastfeeding would indicate that this analysis represents a conservative picture of the potential risks of any formula use. If more studies included 6 months of exclusive breastfeeding, we would expect more findings to achieve significance. Finally, by including expressed milk in our definition of “exclusively breastfed,” we allowed for another possible underestimation of potential risks of nonoptimal feeding.

This analysis is limited primarily by the fact that very few studies have used exclusive breastfeeding for 6 months, the inverse of which is our proxy for any formula use within the first 6 months, as a comparison group. When more studies are available, it will be easier to provide this information. Another major limitation is that the definition of exclusive breastfeeding also varied across the studies in other ways. For example, some studies defined the exclusive breastfeeding groups as “not receiving any formula.” Although this definition was acceptable for our data calculations on risks of formula use, these groups might have been introducing nonformula supplements such as water to their infants, and the effect of completely exclusive breastfeeding

would be further underestimated. The studies reviewed also included a wide range of study designs with varying durations of exclusive breastfeeding. Therefore these analyses are limited in that we cannot quantify the formula use but, rather, can only state the calculated risks related to “any formula use.” Furthermore, no validation method was performed on the mothers’ reporting in these studies. As with most literature reviews, our results may have been affected by publication bias and, even though much research has been conducted on breastfeeding and associated health outcomes, it is limited by the impossibility of blinded case-control design. As a result, we conclude that increased attention should be paid in future studies to definitions of breastfeeding, full description of feeding patterns, durations of exclusive breastfeeding, and use of exclusive as the standard.

The odds/risk ratio construct using exclusive breastfeeding as the norm is most appropriate given the global acceptance that exclusive breastfeeding is optimal for health, survival, and development of the young infant, and therefore should be treated as the best available standard for feeding in this age group. Now that these figures are available, we hope that future research will be conducted on how mothers and their health care providers and others respond to the new risk language and if rates of exclusive breastfeeding are influenced as a result.

Conclusions

The contribution of these analyses is that the presentation of the results in this manner provides the reader with data to view exclusive breastfeeding as normal and formula use as the health-risk behavior. This language should be useful for educating health care workers, patients, and the general public as to what is optimal, normal infant feeding behavior and what is, by definition, deviant or experimental. By providing the results in this manner we are emphasizing the disincentives of the risk behavior, in this case any formula use, and avoiding language that prevents exclusive breastfeeding from being perceived as the social norm. Furthermore, standards for research design demand that alternative interventions be compared with what is considered to be the current “best” approach. Therefore, it follows that breastfeeding research should construct a study design in this manner, with 6 months of exclusive breastfeeding as the standard against which any other form of feeding should be compared. We assume that when more studies portray their results in this format, we will begin to see a widespread adjustment in the language and hence the attitudes and practices related to infant feeding, favoring the healthful normative practice of exclusive breastfeeding.

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