## COMPARING BREASTFEEDING AND FEEDING WITH INFANT FORMULA

#### By George Kent

#### ABSTRACT

Global guidelines for infant formula say the ingredients are supposed to be those "which have been proved to be suitable for infant feeding." "Proven" has not been defined, so there has not been any authoritative proof of suitability.

Assessment of infant formula has focused on its ingredients. Globally, the Codex Alimentarius Commission has set out a list of ingredients that should be in all infant formula, while also giving national governments the option to introduce some variations within that framework. As illustrated by the practice in the United States, infant formula that includes the ingredients specified in the global guidelines and in national law is described as *nutritionally adequate*.

This is not good enough. The gold standard against which infant formula should be compared is optimal breastfeeding. The comparison should be based not on examination of formula's ingredients but on examination of its performance. Does infant formula do what it is supposed to do? Does feeding with any particular type of infant formula protect the health of infants and their mothers as well as breastfeeding? If not, it is not *functionally adequate*.

Some might argue that while infant formula is not quite as good as breastfeeding for protecting infants' health, it is not much worse. Families might have their own reasons for feeding their infants with formula. There is a need for serious discussion of the gap between breastfeeding and feeding with formula and about the degree to which considerations other than the infant's health might play a role. New parents should be supported in making wise, well-informed choices about how they will feed their infants.

KEYWORDS: infant formula, breastfeeding, nutritional adequacy, functional adequacy, Codex Alimentarius Commission, Food and Drug Administration.

#### INTRODUCTION

At the global level, the *Codex Alimentarius Commission* develops non-binding guidelines regarding food composition and safety. For infant formula, the guidelines say the ingredients are supposed to be those "which have been proved to be suitable for infant feeding (Codex Alimentarius Commission 2007)." The phrase, "proved to be suitable," has not been defined, so there has not been any authoritative proof of suitability.

Many analysts have made compelling arguments for breastfeeding. Nevertheless, many parents feed their infants with formula. This can be understood when we consider the strong promotion of infant formula by the industry (Changing Markets Foundation 2018; World Health Organization 2016) and also by some governments (Kent 2017), and by the simple fact that people weigh different considerations differently. There is a general consensus that breastfeeding is best for infants' health, but people who support using infant formula are likely to believe there is not a great difference on that dimension, and there are other considerations that should be taken into account as well, such as the lack of support for breastfeeding at the workplace.

The purpose of this essay is to not to compare breastfeeding and feeding with infant formula and report a conclusion, but to prompt constructive discussion of how that comparison should be made, in an analytical framework that accommodates diverse views about what is true and what is important.

#### THE INGREDIENTS APPROACH

The Food and Agriculture Organization of the United Nations and the World Health Organization jointly established the Codex Alimentarius Commission in 1963. Its main purpose is "protecting consumers' health and ensuring fair practices in the food trade (Codex Alimentarius Commission 2019)." In 1976 the Commission adopted a *Codex Standard for Infant Formula*. It includes a list of required ingredients and describes required quality control measures. Many amendments were made in the following years (Codex Alimentarius Commission 2007). The guidelines allow for some variations in the ingredients list, so some national governments set their own standards within the Codex framework.

The Commission's *Statement on Infant Feeding* says, "Numerous formulae have been produced which offer a nutritionally adequate food for infants, and, provided they are prepared under hygienic conditions and given in adequate amounts, there is no contra-indication to the use of such products" (Codex Alimentarius Commission 1976).

What does this language mean? The Commission discussed nutritional adequacy in relation to vegetable protein products:

7.2 The nutritional adequacy of a product can be defined in terms of protein quality and quantity and content of minerals and vitamins.

Such a product should be considered nutritionally equivalent if:

(i) its protein quality is not less than that of the original product or is equivalent to that of casein and

(ii) it contains the equivalent quantity of protein (N = 6.25) and those vitamins and minerals which are present in significant amounts in the original animal products. (Codex Alimentarius Commission 1989, Section 7)

If this understanding of nutritional adequacy is applied to infant formula, presumably equivalence would refer to comparisons with breastmilk, commonly accepted as the gold standard. According to current perspectives, the gold standard would be the result expected when breastfeeding practices are optimum. For optimal breastfeeding, the World Health Organization and the United Nations Children's Fund recommend:

- early initiation of breastfeeding within 1 hour of birth;
- exclusive breastfeeding for the first 6 months of life; and
- introduction of nutritionally-adequate and safe complementary (solid) foods at 6 months together with continued breastfeeding up to 2 years of age or beyond. (World Health Organization 2017)

The basic idea conveyed in the Commission's approach to nutritional adequacy is that if the ingredients in infant formula match the list of required ingredients, then the formula would be described as nutritionally adequate. The law setting out the precise technical meaning of the term "nutritionally adequate" in the U.S. is described below, in the section on the U.S. Food and Drug Administration.

"No contra-indication" must mean that feeding with nutritionally adequate infant formula is as good as breastfeeding in terms of its performance. If formula had no deficiencies, there would be no difference in expected health outcomes between the two methods of feeding. In the 1970s the Commission might have believed there would be no difference. However, feeding with formula regularly leads to worse health outcomes than breastfeeding for both mother and child. Many studies have demonstrated this (Bartick and Reinhold 2010; Bartick et al. 2016; Caron 2018; Chen and Rogan 2004; Grayson 2016; Gupta et al. 2018; Ip et al. 2007; Jung 2015; Kent 2017; Payne and Quigley 2016; Piwoz and Huffman 2015; Rollins et al. 2016; Save the Children 2018; Stevens, Patrick, and Pickler 2009; Thurow 2016; World Health Organization 2013a, 2013b; Zimmerman 2016).

Some manufacturers try to address deficiencies of infant formula by adding ingredients that supposedly bring it closer to breastmilk. Adding an ingredient to the mix in formula is not likely to have an impact comparable to the role of that component in breastmilk. The suggestion that an additive can bring infant formula close to breastmilk in terms of its functions makes little sense, especially where there is no consensus on how the distance between them should to be measured.

Often the claims about the benefits of additives and other modifications of infant formulas are not confirmed through high quality independent research (Belamarich, Bochner, and Racine 2016; Hughes et al. 2017). I have reviewed the literature on the supposed benefits from adding certain manufactured fatty acids to formula and found the arguments unconvincing (Kent 2014a). A Cochrane Systematic Review of the available evidence showed the claims were not supported (Jasani et al. 2017). Referring to this review, a recent study agreed, explaining, "simply adding nutrients present in breast milk to formula does not necessarily mimic the biological effects of such nutrients in breast milk because the benefits of the latter depend on a complex balance between its various components" (Hartwig et al. 2019, 55).

It is not only additives to formula but also additives to breastmilk that should be challenged for evidence of their efficacy in improving health outcomes. I have raised that question about a product called Evivo designed to be added to breastmilk to help develop infants' immune systems (Kent 2018). [Editor: See letters to the editor in this issue of World Nutrition.]

Manufacturers sometimes add a new ingredient to an infant formula product and then say the new version is *closer* to breastmilk. One critical study charged, "Nestlé also continues to sell several products (in the US, Switzerland, Spain and Hong Kong) that claim to be the 'closest to breastmilk,' but with very different ingredients from each other (Changing Markets Foundation 2018)." How can products with differing ingredients all be closest?

Saying an infant formula product is *closer* is not the same as saying it is *close* to breastmilk. New York is closer than New Jersey to Paris, but that does not mean New York is close to Paris. The deficiencies of formula cannot be resolved simply by adding new ingredients into the mix.

## FUNCTIONALITY

It is becoming clear that comparisons should be made not on the basis of matching up ingredients lists but on comparing the results obtained--the "functions" of the food in producing desirable outcomes. As the Institute of Medicine put it, "The alternative to matching human-milk composition is to match breastfeeding performance (Institute of Medicine 2004)."

Where good data can be obtained, it might be possible to compare the relative risks of death and various forms of illness and other outcomes occurring with different feeding methods. To illustrate, it might be discovered or estimated that infants who use one feeding method have a relative risk of 1.3, that is, they have a 30% higher risk of experiencing ear infections during their first year when compared with those who use another feeding method. This is the approach used in a report from the World Alliance for Breastfeeding Action (WABA 2012) and also in a study by Stanley Ip and colleagues (Ip et al. 2007).

A statement from the American Academy of Pediatrics, last updated in 2012, refers to the 2007 study by Ip's team as, "To date, the most comprehensive publication that reviews and analyzes the published scientific literature that compares breastfeeding and commercial infant formula feeding as to health outcomes" (American Academy of Pediatrics. 2012). That study focused on high-income countries. The lack of attention by global agencies to low-income countries is a problem, especially in the face of the rapid changes in feeding practices in many low-income countries. Clearly, more research should be done on comparisons of the impacts of different methods of feeding infants.

An approach developed in the U.S. with the support of the Kellogg Foundation can be used to compare different methods of feeding. The system uses results from a simulation model to estimate the lifetime impact on health care outcomes and costs. It is based on data for each of the 50 states in the U.S. (Stuebe et al. 2017) The tool can be accessed at

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<u>http://www.usbreastfeeding.org/p/cm/ld/fid=438</u>. In principle, this approach could be applied in any place where there is good data or there are good estimates of the information it requires. Even without good data based on local circumstances, the approach could be simplified and used to open discussion of many concerns about choosing feeding methods.

The relative risk approach to the comparison of feeding alternatives is rarely utilized in antenatal education. The data required for it have not been collected in a widespread and systematic way. One reason is that there are serious ethical concerns about doing randomized controlled trials in the feeding of infants. Even so, more research could be done on an observational basis. The intensive promotion of infant formula throughout the world provides opportunities for comparative studies of disease patterns before and after the introduction of infant formula on a large scale (Kent 2015). Ideally, there would be constant monitoring of infant feeding, providing a flow of data that makes it possible for researchers to constantly estimate the associations between feeding methods and outcomes.

Just as with pharmaceuticals, infant formula should be not only safe but also effective in doing what it is supposed to do. Children should be fed in ways that result in good physical growth, strong immune systems, good visual acuity, good intellectual development, and so on. The method of feeding should minimize the likelihood of a broad range of health problems not only in the infant but in the mother as well.

The term "nutritional inadequacy" suggests some ingredients are missing. It would be helpful to adopt a distinct term such as "functional inadequacy" to refer to the performance of infant formula. Does it do what it is supposed to do? Does feeding with any particular type of infant formula protect the health of infants and their mothers as well as breastfeeding? If not, it is functionally inadequate.

#### U.S. FOOD AND DRUG ADMINISTRATION

In the United States, the Food and Drug Administration is the primary agency responsible for ensuring the quality of infant formula. Remarkably, beyond the ingredients list, the only quality factors that concern the FDA are normal physical growth and the biological quality of the formula's protein component. In 2014, as they were preparing revisions of the rules, I commented on this approach to the FDA:

This means that of the many different functional requirements, the only one to be assessed for infant formula is its efficacy in leading to adequate physical growth in the short term. The language of the rules implies that if an infant formula leads to adequate physical growth over a period as short as fifteen weeks, it is of good quality.

It should not be suggested that quality on a single dimension is sufficient when infant formula must perform well on many different dimensions. There are many studies that demonstrate this. To illustrate, in *21 Dangers of Infant Formula*, the World Alliance for Breastfeeding Action shows 21 different ways in which feeding with infant formula appears to function less effectively than breastfeeding

(see <u>http://www.waba.org.my/whatwedo/advocacy/pdf/21dangers.pdf</u>). Each of them represents a concern about the quality of infant formula.

It is misleading to suggest that a short-term measure of infants' physical growth can reasonably be viewed as a measure of the overall quality of infant formula (Kent 2014a).

The FDA did not respond to my comments.

The ingredients that must be included in infant formula in order to be described as nutritionally adequate under U.S. law are listed in Section i, Nutrient Requirements, at 21 U.S. Code, Section 350a – Infant Formulas, available at <u>https://www.law.cornell.edu/uscode/text/21/350a</u> Under U.S. law, any infant formula that complies with the list of required nutrients is regarded as nutritionally adequate.

The ingredients in breastmilk and in infant formula might match at some level of abstraction, in terms of broad categories such as protein, fats, and vitamins, but they would match only partly and only in a narrow sense (Heslett, Hedberg, and Rumble 2007). Many of the ingredients in breastmilk are absent from formula or are very different from those in formula.

Even if two foods included the same types of ingredients in the same proportions, that would not guarantee they matched in their structure, the organization through which the components work together. No one thinks mixing bits of metal and rubber together in a sack is likely to produce a bicycle. No one thinks a collection of the ingredients of a cell phone in a bag would perform like a cell phone (Greenspan 2019).

# IMMUNIZATION, COGNITIVE DEVELOPMENT, AND COMMUNICATIONS

The Institute of Medicine said:

Initially the goal of infant formulas was to match the growth rate of the breastfed infant. However over time it was recognized that breastfeeding may confer several other potential advantages to the infant . . . including:

- prevention of infectious diseases . . .,
- neurodevelopment, and
- protection from chronic diseases in childhood

These perceived and potential advantages of breastfeeding are the impetus behind many of the proposed additions of ingredients to infant formulas. Not all of these advantages are necessarily attributable to the nutritional content of human milk. Advantages resulting from a fundamentally different interaction between the nursing mother and her infant or to a selection bias of mothers who choose to breastfeed cannot be matched by simply adding nutrients to cow milk. (Institute of Medicine 2004, 7)

They were aware that it is not possible to match the functional qualities of breastfeeding simply by adding new ingredients, saying:

Historically one approach to match human-milk composition is to add new ingredients . . . for the composition of formulas and human milk). This turns out to be a quixotic quest since human milk is a complex body fluid that is variable not only among individuals, but within an individual over time. In addition, it contains components, such as live cells and bioactive compounds, that either cannot be added to formulas or cannot survive a shelf life. (Institute of Medicine 2004)

Their statement recognizes that breastfeeding is beneficial (functional) not only for ensuring good physical growth of the infant but also for protection against diseases (immune system development) and to ensure good development of the intellect and vision (cognitive development). This is well known to pediatricians and others who study infant feeding, but not fully appreciated in the general population.

The immune function of breastfeeding has been studied, sometimes with alarming implications for formula feeding (Goldman 2007; Minchin 2015; 2016; Newmark 2019). Among those references, Maureen Minchin argues that formula has been responsible for cumulative intergenerational damage across whole populations. She sees formula as the single most important postnatal factor in modern epidemics of inflammatory disease and offers substantial evidence to support that view. The role of breastfeeding in cognitive development has also been recognized, especially in relation to intelligence and visual acuity (Girard, Doyle, and Tremblay 2017; Horta, de Mola, and Victora 2015; Horta, Hartwig, and Victora 2018; Victora 2015).

Another function of breastfeeding, rarely discussed in the literature on infant feeding, is its support for the exchange of information between the mother and infant during the feeding process. The Institute of Medicine's comment about "interaction between the nursing mother and her infant" refers to the active communication that goes on between them during breastfeeding, a process that is far more limited during feeding with formula.

During breastfeeding, some of the communication is biological. There are important bioactive factors in breastmilk, absent in infant formula, that change systematically from month to month (Kakulas 2019; Vass et al. 2019). Their roles are modulated through steady communication. With direct breastfeeding, signals come from the infant to the mother about the infant's needs, and the mother can respond with suitably modified breastmilk. She might not be aware of that process, but her biology responds appropriately.

Here is a description, written decades ago, about how "breastmilk is custom-made to suit each baby":

It varies nutritionally from country to country. A thirsty baby in hot weather will find more thirst-quenching feed at his mother's breast, if his mother drinks more liquid, than a baby in a wintry climate. It varies with the time of day and even during the course of the feed: a baby's equivalent of soup to a rich dessert is available at one breast, while a drink to wash it down is waiting at the other. If the baby is extra hungry, and sucks more vigorously, the breast will obligingly produce larger helpings. A dainty eater's delicate sucking will inform the breast to dish up less. (Vittachi 1982)

A group of scientists offered this broad account of the multi-dimensional exchanges during breastfeeding:

Mammals owe part of their evolutionary success to the harmonious exchanges of information, energy and immunity between females and their offspring. This functional reciprocity is vital for the survival and normal development of infants, and for the inclusive fitness of parents. It is best seen in the intense exchanges taking place around the mother's offering of, and the infant's quest for, milk. All mammalian females have evolved behavioural and sensory methods of stimulating and guiding their inexperienced newborns to their mammae, whereas newborns have coevolved means to respond to them efficiently. Among these cues, maternal odours have repeatedly been shown to be involved-but the chemical identity and pheromonal nature of these cues have not been definitively characterized until now. (Schaal et al. 2003; also see Blass 2003; Doucet et al. 2009)

According to another researcher:

Close body contact of the infant with his/her mother helps regulate the newborn's temperature, energy conservation, acid–base balance, adjustment of respiration, crying, and nursing behaviors. Similarly, the baby may regulate—i.e., increase—the mother's attention to his/her needs, the initiation and maintenance of breastfeeding, and the efficiency of her energy economy through vagus activation and a surge of gastrointestinal tract hormone release resulting in better exploitation of ingested calories. The effects of some of these changes can be detected months later. (Winberg 2005)

Direct breastfeeding is not a passive one-way process like filling a car's gas tank, where the only feedback is that loud click when the nozzle says the gas tank is full. There is a vast difference between infant formula and breastmilk, and another vast difference between delivering breastmilk through a bottle or tube and breastfeeding with direct warm contact between mother and child, each actively communicating with the other throughout the entire process. This dynamism is often missing from descriptions of the infant feeding process.

We tend to think of eyes, ears, and skin as sensory organs. Breasts usually are not categorized that way, except in relation to sexuality. In the context of infant feeding, usually breasts are seen simply as passive fuel pumps, not as active instruments of communication.

Information about the way breastfeeding modifies breastmilk to meet infants' current needs is available to experts in academic journals, but it is rarely translated into non-scientific language and made readily available. One example of such a translation is that done by Hassiotou and her colleagues of their highly technical paper into a more reader-friendly one (Hassiotou et al. 2013; Kakulas 2013; also see Bode et al. 2014; Newmark 2013).

Nutrition should be understood as a process, not the contents of a package. To think of infant feeding as nothing more than a fuel transfer of a mix of unconnected ingredients trivializes everything and everyone involved.

### ASSESSING THE GAP

In its Statement on Infant Feeding in1976, the Codex Alimentarius Commission recognized that there are conditions under which the use of infant formula could make good sense:

However, poor health of the mother and certain social conditions can reduce lactation, separate the infant from the mother or otherwise make breast-feeding impossible. In these circumstances it is necessary to use alternative foods such as infant formula to overcome the lack of breast- milk. (Codex Alimentarius Commission)

However, the Commission apparently did not anticipate the extent to which the manufacture of infant formula would become a huge global industry (Baker et al. 2016). They did not consider the potentials for remedying the conditions that impede breastfeeding such as lack of family leave for working women and scarcity of well-trained lactation counselors. They did not consider the possibilities of breastfeeding by a wet nurse or obtaining breastmilk from a human milk bank.

The Commission did not make a clear distinction between what might be best for most infants in a population and what might be best in special circumstances. Infant formula could be viewed as a type of medication, called for to address specific needs, with its limited use guided by good evidence and agreed principles.

There is widespread agreement that at the population level, feeding with infant formula is generally worse for infants' health than breastfeeding. A key question that remains is whether feeding with infant formula is *extremely* worse for infants, with a wide gap between them, and thus generally unacceptable, or only *moderately* worse, with only a small gap between them, and therefore acceptable. There is little consensus on the answer, and no clear consensus on how the question should be addressed.

Seeking a single global answer to the question of whether the difference is minor or alarming might not be wise. Instead, the question could be addressed in relation particular localities and particular family situations, based on recognition that the answers might depend on local circumstances. To illustrate, it is clear that the health risks are far higher in places where there is a high likelihood that powdered infant formula will be mixed with unclean water. In those circumstances, governments could strictly limit the availability of infant formula. Areas with high-quality water could have less strict limitations. Some limitations might be applicable

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everywhere. Doing this well would require increasing and improving the research on these issues, and getting parents, health care providers, and policymakers to seek a stronger basis in evidence for their work.

The key point here is that when comparing alternative methods of feeding infants it is important to go beyond placing them into rank order regarding the likely impacts for the infant's health (best, second best, third best, etc.). It is important to also estimate the *degree* of difference. This is important because where there is little difference, other considerations can be taken into account when assessing the feeding options. The option that is second best on the health scale could become the first choice because of considerations other than health.

The WABA study mentioned earlier discussed 21 ways in which the feeding method can affect the health of infants and their mothers (WABA 2012). There are many other qualities that might be of interest to parents and policy makers. To some people it is important to know whether the product is kosher or halal, or made with genetically modified organisms (GMOs), or one for which the manufacturing process was somehow exploitative or harmed the environment. Economic costs can be important. Adults consider many different qualities when choosing their foods, so it is not surprising that they might consider many qualities beyond health when choosing their infant's food.

There is a general consensus that in choosing how to feed an infant the highest priority should be the infant's health, but other considerations can also affect the choice. The idea of considering qualities other than health impacts is not troubling if there is little difference in the likely health impacts of the alternatives. A choice that makes little difference for an individual might make a large difference cumulatively, for the population as a whole. Researchers should give more attention to that distinction.

There is not enough knowledge and discussion about the degree of difference between breastfeeding and feeding with infant formula. One group believes:

The health benefits of breastfeeding tend to be presented as overwhelming, and imply that formula feeding will cause health problems. But the evidence shows a far less drastic difference between breastfed and formula-fed babies. (BPAS 2017)

Others disagree. Some strong advocates of breastfeeding feel the differences are very serious, and therefore women should be required to breastfeed. One legislator has proposed that companies that market infant formula should be fined and the use of feeding bottles should be banned (Shoichet 2013). Some people propose that infant formula should be available only with prescriptions from doctors. The position taken here, however, is that, with some exceptions, parents should make their own well-informed decisions about how to feed their infants. This means they should be well informed about the likely impacts of alternative approaches to feeding their infants.

It is not just mothers who should be well informed. In some cultures, fathers or mothers-in-law have the major role in deciding how the infant is to be fed. Relatives, health care workers, and

government agencies might have roles as well, providing information, advice, and recommendations. All of them should have good information available to them, in appropriate forms.

In some cases, the mother may not to be able to process the information well, even if it is provided in an appropriate format. She might not want to deal with it. She could defer to well-informed advisers and agree to accept their recommendations. Nevertheless, parents should be encouraged to make their own well-informed decisions.

If there is little difference in the health impacts of different methods of feeding there is little reason for intervention by health workers or government policymakers. However, if one feeding option is viewed as extremely dangerous, strong pressure or even coercive legal measures might be taken to prevent its use. This has been a major concern in discussions of breastfeeding in the context of HIV/AIDS (Kent 2005). It also comes up when parents make extremely bad choices about how to feed their infants, as in the case of a vegan couple that fed their infant with some sort of potato mash (Postmedia News 2019).

What level of difference should be considered important enough to require government intervention to ensure that the better option is followed? Experts in infant feeding have not found good ways to measure and discuss the degree of difference. People can agree that a particular scientific finding is accurate but disagree on whether it should be quietly accepted or viewed as a cause for alarm. Those disagreements need to be addressed in order to design sensible risk management policies relating to infant feeding.

## CONCLUSIONS

The Codex Alimentarius Commission said infant formula should be "proved to be suitable for infant feeding." This challenge should not be ignored any longer.

There is potential for building consensus on the issues by funding more independent research centered on direct comparison of the performance of breastfeeding with the performance of infant formula in various contexts. Indeed, all feeding alternatives should be compared in terms of their performance.

There is room for improvement in the ways in which research findings are communicated to new parents. Rather than simply delivering the views of experts, emphasis should be placed on empowering parents to make their own well-informed decisions about how to feed their infants. More should be done to explain breastfeeding's distinctive role in relation to cognitive development, immune system development, and the adaptation of breastmilk to meet infants' needs through steady communications between mother and infant.

Government agencies should take the lead in helping everyone, especially parents, health care workers, and policymakers, understand and compare the expected performance of different methods of feeding infants in their settings. The broad social environment and particularly the antenatal education experienced by new parents should be shifted toward empowering them to make wise well-informed decisions. Government agencies, the food industry, and the health care system should support that effort.

In 1976 the Codex Alimentarius Commission issued a *Statement on Infant Feeding* which said, "it is necessary to encourage breastfeeding by all possible means in order to prevent that the decline in breastfeeding, which seems to be actually occurring, does not lead to artificial methods of infant feeding which could be inadequate or could have an adverse effect on the health of the infant" (Codex Alimentarius Commission 1976)." Back then they thought artificial methods of infant feeding *could* have an adverse effect on the health of infants. Now we know that it does, with certainty. There is a clear need for better research, better antenatal education of new parents, and constructive discussion of policies to deal with what has become a very serious issue.

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