

## GOOD QUESTIONS 10

### Given our concern about viruses, what should be done about the absence of immune factors in infant formula?\*

COVID-19, like other viruses, can be related to nutrition in several ways. Anxiety about the epidemic can lead to food hoarding. Food production and delivery systems can be disrupted. People who are poorly nourished are more likely to be infected and less likely to survive if they are infected. Special precautions should be taken during food preparation (Nestle 2020). COVID-19 originated in a live animal food market in Wuhan, China. There are indications that many modern diseases can be attributed to the modern food system (Wallace 2016). The International Food Policy Research Institute has created a Spotlight space on food and COVID-19 at <https://www.ifpri.org/spotlight/ifpri-resources-and-analyses-COVID-19-also-known-coronavirus>

Like many others, Bill Gates has pressed for rapid development of a vaccine for COVID-19. He said, “There is an urgent need to save lives now and also improve the ways we respond to outbreaks in general” (Gates 2020; also see Gates 2018). In taking the long view, we should look backward as well as forward. Why is it that we have had to deal with lethal virus outbreaks every few years? Why are we so vulnerable?

There has been ongoing concern about viruses and other pathogens in infants’ foods, especially breastmilk and infant formula (Gould 2013; IBFAN 2020; WHO and FAO 2017). Along with this concern about intruders into these foods, we should also be alert to what is missing from them. Unlike breastfeeding, feeding with infant formula does not protect and promote the development of infants’ immune systems. There is a lack of what are called *immune factors*. This deserves attention because healthy immune systems protect us from viruses and other threats through infancy and beyond. *Given our concern about viruses, what should be done about the absence of immune factors in infant formula?*

Maureen Minchin points out:

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The milk hypothesis asserts that the artificial feeding of infants is the single greatest avoidable negative input into normal human development and health. As I first said in 1985, it is the largest uncontrolled in vivo experiment in human history, and the scale on which it has occurred has made its effects appear normal – to those blind to history, culture and the broad spectrum of ill health and ‘disease’. (Minchin 2016, 4)

The world has been ignoring the fact that breastfeeding, done well, serves as a vaccine protecting against a broad variety of pathogens in infancy and beyond. There is biological communication between the mother and the infant that adjusts the breastmilk to meet the infant's current needs. As one study put it, “Breastfeeding is a child’s first inoculation against death, disease, and poverty, but also their most enduring investment in physical, cognitive, and social capacity” (Yaya et al. 2020; also see University of California—Riverside. 2016).

The point of this essay is not that breastmilk should be used as a medication of the sort that can be injected into people’s arms to protect against a particular epidemic. Rather, the point is that in the long run, more and better breastfeeding is likely to reduce the need for medicines.

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. (WHO 2017; also see WHO 2018).

Like other viruses, COVID-19 infects some women while they are pregnant, and some become pregnant after infection. The risk levels are not yet clear. As illustrated by the history of HIV/AIDS (ABM 2020; Humphrey 2010; Lever; 2020; Morrison, Ballard, and Greiner 2011; WHO 2020), questions are raised about the risk of transmission of COVID-19 through breastfeeding (Chen et al.; Liu et al. 2020; Qiao 2020; Wang et al. 2020). Questions should also be raised about the potential of breastfeeding to either convey or prevent infection by specific viruses and to mitigate the harm if infection occurs. Following decades-long debates and research on the issue, it has now been recognized that when women are diagnosed as HIV-positive, the benefits of breastfeeding are likely to outweigh the risks of not breastfeeding, especially when the mothers take appropriate antiviral medications (Kuhn and Aldrovandi 2010).

Breastfed infants have immunity to a broad variety of viruses and other health challenges that is not present in infants who are fed with infant formula. This helps to explain the consistent finding that at the population level breastfed infants are healthier than formula-fed infants. We should reflect on this as we prepare for the broad range of viruses and other health threats likely to be encountered in the coming years.

## BIODYNAMICS OF IMMUNE FACTORS

The International Lactation Consultant Association (ILCA) explains how breastfeeding strengthens infants' immune systems:

The milk ejection reflex is a muscular contraction that pushes milk out to the baby. But did you know that once the milk ejection reflex slows, muscles relax and pull baby's saliva back in? Lactocytes respond to saliva exposure by producing particular macrophages. If the baby has been exposed to an infection, at the next feeding, he will get leukocytes and antibodies to fight that specific infection (Lactationmatters 2020, Item 2; also see Sweeney et al. 2018).

Thus, the breastmilk adapts to address the infant's current needs through a form of biological communication. These breastmilk leukocytes are living things, unlike the ingredients in infant formula.

ILCA also explained the importance of colostrum, the first milk, in developing the infant's immune system:

Babies get very few calories at the breast during the first 48 hours, because the calories in colostrum are not intended for digestion. They come from immune cells, designed to populate the immune system. Rather than thinking of colostrum as calories, think of it as an immune system transfer (Lactationmatters 2020, Item 3).

ILCA also points out that the introduction of foods other than breastmilk during the first few months can disturb the development of the infant's immune system:

At birth, babies have very different proportions of specific bacteria in their gut microbiome compared to their birthing parent's. Over the first 12 months of life, the baby's microbiome shifts to strongly resemble the birthing parent's. However, this shift is accelerated by the introduction of formula or the feeding of solid foods. As soon as the baby ingests anything other than human milk, the gut microbiome changes rapidly, and it does not go back. This may explain why formula fed infants experience more auto-immune and infectious illness (Lactationmatters 2020, Item 7).

The differences in health impacts resulting from formula feeding and breastfeeding have been documented in many ways (American Academy of Pediatrics 2012; Ip et al. 2007; WABA 2012). There are good studies and reviews specifically on the role of breastfeeding in strengthening immunity (e.g., Cacho and Lawrence 2017; Field 2005; Ghosh et al. 2016; Goldman 2007; Goldman 2019; Hanson 2004; Jackson and Nazar 2006; Lönnerdal 2000;

Minchin 2015; Minchin 2016; also see Kent 2005). The basic biodynamics of the immune factors have been understood for many years (Packard 1982, 68-107).

Some formula manufacturers say they are narrowing the degree of difference between breastfeeding and formula feeding. Similac claims that its infant formula with 2'FL HMO (human milk oligosaccharide) provides “support for baby’s developing immune system (Similac 2020).” They say, “The addition of 2’-FL HMO that is structurally identical to that found in breast milk is another groundbreaking step toward narrowing the gap between breast milk and formula.” However, breastmilk contains hundreds of different HMOs in combinations that are different from mother to mother. Similac does not present any evidence that their additive brings infants’ immune systems anywhere close to what is obtained with breastfeeding.

The natural version of that HMO and its context has a different structure. Simply mixing an engineered ingredient into formula and expecting it to perform in the same way as it might during the breastfeeding process is a bit like assuming you can put a container of high-octane gasoline into the back seat of an electric car and expect that to improve the car’s performance. There is a long history of efforts to add immune factors to infant formula (Packard 1982, 100-107), but with little success.

## THE INGREDIENTS APPROACH

The design of infant formula is based on the idea of matching the ingredients in formula with those in breastmilk. They can be made to match only to a small extent and in a narrow sense. Breastmilk, particularly when provided during direct breastfeeding, has many live, active components beyond nutrients, including hormones, bioactive molecules, microorganisms of various kinds, oligosaccharides, and other complex factors still unknown. Even if they both 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. Why would anyone think that feeding with a mixed collection of ingredients would have the same biodynamic effects as breastfeeding? The ingredients of a car include metal, rubber, glass and other things, but that is different from listing the various dynamics sub-systems that are central to the actual operation of the car. A car is much more than a box of parts. To make the point more simply, no one thinks mixing bits of metal and rubber together in a sack is likely to produce a bicycle.

Manufactured ingredients in formula are not likely to have a beneficial impact comparable to similar ingredients in breastmilk. Manufacturers’ claims about the benefits of additives to infants are rarely confirmed through independent research. The benefits they provide might be every small. Each additive that comes along implicitly acknowledges a deficiency in the formula. The idea that some mixture of ingredients or some new additive could make feeding with infant formula as healthful for infants as breastfeeding does not make sense.

This ingredients focus has dominated worldwide, not the functional health outcomes focus. The design of infant formula or entire diets has been based on the idea of getting the intake of

ingredients right. This reductionist approach is troublesome in dealing with food and nutrition generally, not just infant formula. As nutritionist Carlos Monteiro explains:

Nutrition science is taught and practiced as a biochemical discipline. Practically all nutritionists now categorise food in terms of its chemical composition, as do most lay writers. This almost universal perception of nutrition is evident in textbooks and scientific journals, and on food labels, journalism, and 'diet books'. The identification of food with its chemistry is a defining characteristic of modern nutrition science, as invented in the early 19th century. Seeing food in terms of its chemistry has enabled the industrialisation of food systems. In particular, it has made possible the formulation of ultra-processed products from 'refined' or 'purified' chemical constituents of foods – oils, proteins, carbohydrates, and their fractions – together with 'micronutrients' – vitamins and minerals.... Identification of food mainly with its chemical constituents at best has limited value, and in general has proved to be unhelpful, misleading, and harmful to public health (Monteiro 2011).

The ingredients approach serves the interests of food manufacturers, not consumers. For many people, the entryway to a lifetime of ultra-processed foods is infant formula (Kent 2012). To a person used to eating home-made soup, soup made from a powder tastes insipid. To ensure that babies and young children retain and expand their taste for artificial, manufactured food, formula companies also produce a wide range of toddler formula and other ultra-processed baby foods.

Infant formula should not be evaluated based on its ingredients alone. The question is, does the mix *function* in the same way as the product it is supposed to emulate. Does it do what it is supposed to do? It is supposed to protect and promote infants' health. Breastfeeding is the gold standard against which performance should be measured.

The basic ingredients list required for a product to be labeled infant formula are set out in global recommendations from the Codex Alimentarius Commission, the primary global agency providing recommendations relating to food quality. In 1976 the Commission issued a *Statement on Infant Formula* that said, "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).

"No contra-indication" suggests that, in relation to infants' health, feeding with nutritionally adequate infant formula is as good as breastfeeding. It might be *assumed* that if formula had the right list of ingredients there would be no difference in expected health outcomes between the two methods of feeding. This assumption is incorrect.

In the basic global standards for infant formula, the ingredients are those that have been "proved to be suitable for infant feeding" (Codex Alimentarius Commission 2007, Section 3.1.1). How the individual ingredients or the collection of them in a feeding bottle could be proved to be suitable is not explained. Proof of suitability should be based on the functional characteristics of the product. The simple undeniable reality is that feeding with infant formula does not lead to

health outcomes as good as those expected from the gold standard, breastfeeding (Kent 2014; Kent 2017, 127-128).

United States law relating to nutrition requirements for infant formula is presented in the Code of Federal Regulations at 25 CFR 107.100. It can be accessed at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=107.100> It is a list of required ingredients. The Food and Drug Administration (FDA) is responsible for regulating infant formula. The many documents describing its regulations show no significant interest in immunity (FDA 2020).

To the FDA, “nutrition requirements” mean that formula must be made with a list of required ingredients. Beyond the ingredients list, the only quality factors that concern the FDA are normal physical growth (height, weight), the biological quality of the formula’s protein component, and its renal solute load. It is misleading to suggest that a short-term measure of infants’ physical growth can serve as an adequate measure of the functional adequacy of infant formula.

The United States Supplemental Nutrition Program for Women, Infants, and Children, commonly known as WIC, has an *Infant Feeding Guide* for staff members who provide nutrition counseling and education to WIC’s participants (USDA 2019). Its 276 pages speak about nutrients and their importance for growth and development. The implicit assumption is that if you get the list of ingredients right and deliver them in the right proportions, you are providing a good diet. This approach is commonly used in assessing the diets of adults as well (NASEM 2020).

In the FDA approach, complying with the required ingredients list and fulfilling some short-term benchmarks of infants’ physical growth are enough to indicate the overall quality of infant formula (Kent 2014; Kent 2015; Kent 2017, 129-130). This is disappointing, and maybe illegal, given that the FDA is the primary government agency in the U.S. responsible for ensuring the quality of infant formula. This impacts the health of infants in the United States and also in the other countries whose government agencies follow FDA’s policies.

## IGNORING THE NEED FOR IMMUNE FACTORS

Like Codex, the FDA systematically ignores infants’ need for immune factors. There are no national or global regulations that require systematic comparisons of the effectiveness of infant formula with the effectiveness of breastfeeding in maintaining infants’ health.

The Institute of Medicine tried to bring the issues to the government’s attention:

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)

The bullet points highlight the need for immune factors. Unfortunately, there has been no substantial response to this insight.

The manufacturers and marketers of infant formula have had many critics, but little has been said about the immunity issue. This is unfair to children. If they are fed with formula, they are not likely to resist viruses and other threats to their health as well as they could if they had been breastfed. The evidence for this is strong. Formula manufacturers agree, but don't say much about it.

To interpret WIC's silence about immune factors, it helps to know that the WIC program provides about half the infant formula used in the U.S. at no cost to the parents. Through WIC, working together with formula manufacturers, the U.S. government is a large-scale promoter of infant formula (Kent 2017). Like WIC, the U.S. Food and Drug Administration does not discuss the absence of immune factors in infant formula.

## POLICY REMEDIES

The United Nations Children's Fund and other agencies have been clear about the importance of breastfeeding in protecting infants' health (UNICEF 2020), but they should do more to facilitate and coordinate work on immunity issues.

The Academy of Breastfeeding Medicine, a staunch advocate of breastfeeding, has provided good advice on how to minimize the risk of transmission of the COVID-19 virus from mother to infant during breastfeeding (Academy of Breastfeeding Medicine 2020; also see Anderson 2020). Curiously, it did not mention the point that breastfeeding might help to prevent infection and reduce the harm to infants who are infected. At this stage we don't know whether it actually can do those things for COVID-19, but experience with various pathogens certainly suggests the possibility.

Viruses and other pathogens in breastmilk are likely to be less harmful than pathogens in infant formula because of the medicinal value of breastmilk—or more precisely—breastfeeding (Verhasselt 2020). The immune factors deployed through the breastfeeding process can play a significant role in limiting the harm.

Maureen Minchin said artificial feeding “is the largest uncontrolled in vivo experiment in human history” but in a genuine experiment, researchers collect and analyze data so they can understand what is going on. There has been little effort to collect and analyze data on the health impacts of

different methods of infant feeding on a large scale. It would not be difficult to have health records show whether the individual was predominantly breastfed or predominantly formula-fed during the first six months of life. That would open the potential for deep analysis of the short- and long-term impacts of children's first medicine. There is no good reason to avoid doing that.

Breastfeeding has the potential to provide protection, but the extent to which it actually does that in specific circumstances is an empirical question. Many small studies have been done, but there is a need for more large studies to consolidate knowledge about how and when breastfeeding functions like a vaccine or in other ways is beneficial to maternal and child health. There is a need for deeper research comparing breastfeeding and feeding with infant formula in modern epidemics.

It is difficult to find funding for that sort of research, but there are settings in which it could be done at little cost. WIC already does detailed studies on infant feeding practices and health outcomes among the program's participants (USDA 2020). However, it seems to avoid making systematic comparisons of the health outcomes of breastfed infants and formula-fed infants in their program. It would not be difficult to survey the incidence of infectious diseases and other health indicators and compare the rates of those who are breastfed with the rates of those who are formula-fed. Similar studies could be done by governmental or nongovernmental agencies everywhere. Family-oriented hospitals and clinics could explore associations between how infants are fed and their subsequent health conditions. Of course, statistical manipulation would be needed to reduce the impact of the sizeable selection bias that would be present in most cultures. Such research would be particularly valuable when conducted in social groups where breastfeeding is practiced mainly by the poor.

Studies on how the infectivity of viruses is affected by infant feeding practices can be done in many different ways. One is suggested by a study of the risks of COVID-19 transmission from China to various countries (Haider et al. 2020). Along with data on other variables, data on the prevalence of formula feeding in those countries could be used to estimate its association with the level of risk. The hypothesis would be that populations with more widespread use of infant formula are likely to face higher risks of contracting the virus.

It is possible to do observational studies such as comparing patterns of illness in young children after large-scale introduction of infant formula into areas where it is not yet commonly used (Baker et al. 2016; Kent 2015). Individuals can be tracked over their life spans to find out whether infants who are breastfed tend to be more resistant to infectious diseases than those who are fed with infant formula (Horta, de Mola, and Victora 2015; Victora et al. 2016).

In any sort of study, there can be confounding elements that muddle the findings, but they can be discussed. If the differences in health impacts are strong, those differences will shine through. It appears that there is little funding for studies to compare the health impacts of feeding with formula and breastfeeding. Perhaps some corporations and government agencies do not want the differences to be known.

Many studies on immunity focus on the biodynamics of immunity. We need to do more to appreciate their importance in maintaining health during infancy and beyond at the individual

level and at the population level. Many immunity studies are highly technical. It is difficult to find articles or teaching materials designed to help parents, health care workers, and government regulatory agencies understand the importance of breastfeeding for development of immune systems.

There is a need for more studies and also better use of the studies that are already available. They consistently demonstrate the importance of breastfeeding in developing immune systems, but those findings have been ignored by government agencies that should be giving more attention to them.

We need better evidence-based comparisons of the health impacts of different methods of feeding, and we also need ways of presenting that evidence that would be meaningful to new parents, health care workers, and regulators. There are far too many questionable claims about the safety and the benefits of foods for infants and young children, especially those related to immunity.

There are no global recommendations and no national-level requirements that infant formula must strengthen infants' immune systems to any extent, let alone a degree comparable to that achieved with breastfeeding. The inattention to immune systems during the early stages of establishing regulations for infant formula might be forgivable because immune systems were not well understood. However, it has now been half a century since the discovery of leukocytes, and there have been many opportunities to update the regulations. There is a real need for regulators to acknowledge this deficiency of infant formula. In terms of human well-being, the costs of ignoring it are far too high.

Action can be taken to support parents in making well-informed decisions about how they will feed their infants. With better teaching materials, health care workers can provide parents with better information about the differences in likely health impacts with different methods of feeding.

Obviously, advertisements for infant formula do not draw attention to the absence of immune factors in it. Formula is categorized as a food, not a medicine, so the regulatory agencies do not require manufacturers and sellers to acknowledge its deficiencies. For adults, many deficiencies of specific foods are unimportant because their consumers have diverse diets. However, when the food product constitutes the entire diet and the consumers are the most vulnerable segment of the population, the risks are huge and ignored far too often. National governments could insist that infant formula should be categorized as a medicine, not just another food. Then the distributors would be required to provide information about the risks linked to feeding with formula and acknowledge the absence of immune factors.

Regulatory agencies should not focus their attention on the list of ingredients in infant formula. Instead, they should be required to assess the quality of any infant formula product by comparing its performance with that expected with optimal breastfeeding practices. When the performance of infant formula is lower, there should be open discussion about the degree to which it is lower, with distinctions made between deficiencies that are small and thus acceptable, or substantially

lower, meaning the product should not be fed to infants or at least not constitute their entire diet (Kent 2020).

Feeding infants with infant formula and breastfeeding have different impacts on both the infant's and the mother's health. The central concern here is that, in contrast with breastfeeding, feeding with infant formula does not strengthen infants' immune systems. This has important impacts on health during and beyond infancy. Most parents, health workers, researchers, and government regulators give little attention to these impacts. There is a need for widespread recognition of this major deficiency in infant formula.

A recent report acknowledged, "Federal Vaccine Development Sites Ill-Suited to Counter COVID-19 Epidemic (Willman 2020). Currently, COVID-19 is drawing a great deal of attention, but it is not going to be the last dangerous virus. More will emerge, perhaps including some strange ones (Zhong et al. 2019). While public media focus our attention on the current threat, for the long run we should make better use of a well-understood, proven, and readily available broad-spectrum remedy for infants and young children.

The scientific knowledge presently available suggests that if more people were optimally breastfed as infants, the risk of infection from any future virus would be lower than it is now and the harm resulting from infection also would be lower. It is likely to "flatten the curve" of many different types of epidemics, especially those that have a major impact on infants. If the objective is to achieve better public health, better support for optimum breastfeeding would be a good long-term investment.

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