Evidence-based Infant Feeding: What the Research Says

Minnesota Perinatal Hospital Leadership Summit
May 19, 2016

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Objectives

- Explain evidence-based infant feeding including the science behind why artificial milk has risks.
- Discuss implementation and updates to the Joint Commission Perinatal Core Measure on Exclusive Breastmilk feeding (PC-05)
- Describe ways to increase exclusive breastmilk feeding rates in hospitals

"A survey of available data shows that the reaction of infants to human and cow’s milk differs... The lowered incidence of respiratory infections and severe eczema in the breast-fed infant is a very real, practical consideration... It would appear that breast feeding is superior to artificial feeding from the physiologic viewpoint.

The physician who is impressed by the remarkable adaptability of the human organism will, whether giving advice in the care of a well child or in ministering to the sick, interfere minimally with natural processes. We have erred too often in the past... Artificial feeding should be reserved for the instances where an honest attempt at breast feeding has failed."

Use of Artificial Baby Milk in breastfeeding infants may cause diabetes, gastroenteritis, otitis media, upper and lower respiratory tract infections, asthma, allergic disease, necrotizing enterocolitis, inflammatory bowel disease, celiac disease, leukemia and lymphoma.
History of Artificial Baby Milk

- Pre-1800s: Wet nursing is the primary substitute for breastfeeding, animal milks are used but contamination and feeding method are severe limiting factors.
- “Pap” - bread soaked in water or milk; “Panada” - cereals cooked in broth (Stevens, 2009).
- 1800s: Development of rubber nipple, glass bottle

History of Artificial Baby Milk

- 1860s - Commercial formula is invented - Leibig’s formula. Nestlé begins commercial production
- Condensed or evaporated milk + additives (usually corn syrup) remains more popular than commercial formula - up until 1960
- Yet, infant formula was profitable enough to lead Nestlé to become the largest food company in the world

History of Artificial Baby Milk

- 1929 - The American Medical Association creates an approval process for commercial infant formula; this requires manufacturers to exclusively market to physicians and hospitals (Greer, 1991)
- Micronutrients are being added to infant formulas, but scurvy and Vitamin B6 deficiency continue to be issues

History of Artificial Baby Milk

- 1960s Use of commercial formula surpasses home made recipes of artificial baby milk
- The FDA begins regulating infant formula content and requires minimum levels of micronutrients; iron is added to formula
- In the US breastfeeding reaches historic low in 1971, with < 30% initiating
History of Artificial Baby Milk

- 1970s: Formula companies begin directing attention to developing countries
- 1974 WIC program begins including providing infant formula to low-income families

- 1980-1986 The Infant Formula Act strengthens FDA regulation of commercial formula after major brand recall for Chloride deficiency

- 1988- Nestlé obtains Carnation and begins direct to consumer advertising of infant formula in the United States. Other brands follow suit

- 1997 - Wyeth "Store-brand" infant formula manufacturing begins in the US. The next two decades see multiple new brands and manufacturers of formula
- 2014 - FDA passes rule requiring formula companies test for pathogens and nutrient content, but "FDA does not approve infant formulas before they can be marketed."
**Composition of Human Milk**

**Macronutrients**
- Protein: casein, whey proteins (α-lactalbumin, lactoferrin, secretory immunoglobulin IgA, lysozyme, and serum albumin)
- Fat: (the most variable component) Palmitic, Oleic acids, LCPUFA, DHA
- Carbohydrate: Lactose, Oligosaccharides

**Micronutrients**
- Vitamins A, B1, B2, B6, B12, D, and iodine
- (vitamin K very low)

**Bioactive Factors**
- “affect biological processes or substrates and hence have an impact on body function or condition and ultimately health”
- Produced and secreted by the mammary epithelium, or produced by cells carried within the milk
Bioactive Factors

- Cells – WBC, macrophages, stem cells
- Immunoglobulins – IgA, IgG, IgM
- Cytokines
- Chemokines – G-CSF, MIF
- Cytokine inhibitors
- Growth Factors
- Hormones
- Oligosaccharides

Bioactive Factors: Function

- “Human milk contains a variety of factors with medicinal qualities that have a profound role in infant survival and health.” (Ballard 2013)
  - A few examples:
    - Cytokines communicate with cells to influence immune activity - Either to enhance inflammation and defend against infection, or to reduce inflammation.
    - Growth factors aid in intestinal maturation and repair, and in growth and development of the enteral nervous system.

Microbial interaction

- Prebiotics: substrates for beneficial bacteria - Provides them with a growth advantage over potential pathogens
- HMOs are probably specifically evolved to benefit bacteria- that are specifically evolved to benefit humans
- Antiadhesive antimicrobials that serve as soluble glycan receptor decoys and prevent pathogen attachment.

HMOs affect development and maturation

- Intestinal epithelial development: HMOs modulate gene expression, which leads to changes in cell surface glycans (important for protection of the gut)
- HMOs provide Sialic acid, a nutrient for brain development
**Immune system effects**

- HMOs modulate lymphocyte cytokine production, potentially leading to a more balanced Th1/Th2 response.
- HMOs reduce selectin-mediated cell–cell interactions in the immune system and decrease leukocyte rolling on activated endothelial cells, potentially leading to reduced mucosal leukocyte infiltration and activation.

**Pasteurized Human Milk**

- Heat treatment reduces amount and decreases activity of certain proteins.
- Yet, clearly superior to artificial formulas in preterm infants (NEC).
- Little research on term infant outcomes but presumed superior.

**What is the harm in a little formula?**

- Immediate change in stool
- Alters intestinal biome, contributing to susceptibility to disease
- Leads to early weaning and decreased production of breastmilk
- Threat on the immature intestine
  - Cow milk protein (allergic)?
  - Feeding without bioactive factors?
  - Or simply less human milk, and less bioactive factors

**What about Hydrolyzed Formula?**
Leonardi-Bee\textsuperscript{5} hydrolysed whey based formula. There was no evidence to support the health claim approved by the US Food and Drug Administration that a partially hydrolysed formula could reduce the risk of eczema nor the conclusion of the Cochrane review that hydrolysed formula could prevent allergy to cows' milk.

CONCLUSION

These findings do not support current guidelines that recommend the use of hydrolysed formula to prevent allergic disease in high-risk infants.

REVIEW REGISTRATION

PROSPERO CRD42013004252.

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**The Joint Commission**

Perinatal Core Measure #5
Exclusive Breastmilk Feeding

- Joint Commission began requiring reporting of PCM#5 for hospitals with over 2000 deliveries per year in 2014.
- Initially two components of the measure, Exclusive breastmilk feeding rate of all term infants, with some exceptions (ie mother with HIV), and 5A exclusive breastmilk feeding of mothers who expressed a preference to breastfeed on admission.
October 2015:
- 5A measure has been dropped, and there are no more exceptions to measure 5
- Now includes all hospitals with over 300 deliveries per year
- (Hospitals were focusing on correctly capturing mother’s preference in order to drive the numerator down and get a better rate – this distracted from the overall goal)

Only PCM 5?
- Difficult to compare between hospitals but the JC says they are tracking to make sure hospitals are making improvements

However, because some women do not want to exclusively breastfeed despite recommendations, and since The Joint Commission is not accounting for these preferences, The Joint Commission expects that performance on PC-05 will remain well below 100 percent. Therefore, PC-05 will not be included in the Top Performer on Key Quality Measures® recognition program (as reported in the March 18, 2015 issue of Joint Commission Online), nor will it be included in the composite rate for the performance improvement accreditation standard, PI.02.01.03, element of performance.
Available evidence suggests that a performance rate of 70 percent on PC-05 is an achievable target for hospitals to strive to achieve.

Results from 2014 are available on The Joint Commission Quality Check website

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How can hospitals improve?
- Banked human donor milk
- The 10 Steps - Baby Friendly Hospital initiative
- Staff education
- Prenatal breastfeeding education
- Eliminating free formula samples (in hospital and given at discharge)
- System wide clinical protocols and order sets with embedded breastfeeding best practice protocols
Allina Health Experience

Exclusive Breastfeeding Rate, Allina Overall

1. Staff education
2. Patient information/handouts
3. Data tracking and monthly reporting to hospital managers

* Lines represent statistical process control limits (J.J. Wheeler)

How else can hospitals improve?

- Partner with WIC
- Address disparities

Figure 1. Breastfeeding Initiation Among Minnesota WIC Participants

Healthy People 2020

Allina Health Hospitals

Exclusive breastfeeding of all term singleton infants
Summary

- 150 year history of Artificial baby milk, motivation for advancements are commercial- remains very different than human milk.
- Human milk is complex and has factors such as HMOs that have essential functions that we are only beginning to understand.
- The absence of biofactors may explain why infants fed formula have worse outcomes than those fed human milk.

Selected References


Bode L. Human Milk Oligosaccharides: Every baby needs a sugar mama. Glycobiology. 2012 Sep; 22(9): 1347-1358


Physicians, formula companies, and advertising: A historical perspective.

