Feeding preterm babies after they are discharged: Current practices and use of novel infant formulas

Steven A. Abrams, MD

Professor, Department of Pediatrics
Dell Medical School
at the University of Texas at Austin
sabrams@austin.utexas.edu

Objectives

- Identify strategies for management of preterm and other high-risk infants after hospital discharge
- Recognize novel products for infant feeding entering the market including new infant formulas from Europe and Australia/New Zealand
- Identify pathways forward for the introduction of novel formulas in the US market for full-term infants

Planning for Discharge

Transition to home feeding plan <u>at least 3 days before discharge</u>

- Weight gain should be demonstrated over 3 days, not "can go home if gains weight overnight"

Training for family in special feeds/techniques

- Especially mixing powder formula
- Written instructions in a language of the parent's fluency
- Consider 24-hour pre-discharge care by parents

Purchase nutritional products as needed

- Infant formulas: Identify stores with formula or on-line options including formula company's direct shipment
- Multivitamins and iron
- Other equipment such as feeding tubes

Oral feeding before Discharge

- Breastfeeding (if planned) as much as possible
  - Arrange lactation support as needed for post-discharge
- Use *ad lib* feeds when possible
  - If not, be very clear about ranges of feedings and timing range for feeds
  - Transition, if possible, to more physiological feeding schedule. Does the baby need to eat every 3 hours? Why? Give family a plan for spacing feeds during night.

Transitional Formulas

- Two products in current use in US. Nutrient contents are mostly mid-range between term and preterm formulas. Protein approx. 2.8 g/100 kcal compared to approx. 2.0 g/100 kcal for routine cow milk formulas.
- Liquid RTF is 22 kcal/fl oz. Also sold as powder which can be prepared to higher nutrient and energy concentrations which is often useful for fluid restriction such as babies with bronchopulmonary dysplasia
  - Relative risk:benefit needs to be considered in using powder before 44-46 weeks PMA

Use of Transitional Formulas Post-discharge

- About 20 studies in infants < 1800 g BW
  - Most show growth benefits in at least a subgroup
  - Large safety margin in use of these formulas
- Evidence strongest for:
  - Males < 1250g BW
- Other findings
  - Increased bone mineral content – variable, not always seen
  - No effect on neuro-development (small studies?)
  - Only 1 very long-term study with mixed findings at 8 years of age hard to interpret (Ruys et al, AJCN, 2017;vol 106;pp 549-558.)

Cochrane Review: Young et al, 2016

We included 16 eligible trials with a total of 1251 infant participants. Trials (N = 11) that compared feeding infants with 'postdischarge formula' (energy density about 74 kcal/100 mL) versus standard term formula (about 67 kcal/100 mL) did not find consistent evidence of effects on growth parameters up to 12 to 18 months post term.

Trials (N = 5) that compared feeding with 'preterm formula' (about 80 kcal/100 mL) versus term formula found evidence of higher rates of growth throughout infancy (weighted mean differences at 12 to 18 months post term: about 500 g in weight, 5 to 10 mm in length, 5 mm in head circumference).

Recommendations to prescribe 'postdischarge formula' for preterm infants after hospital discharge are not supported by available evidence. Limited evidence suggests that feeding ‘preterm formula’ (which is generally available only for in-hospital use) to preterm infants after hospital discharge may increase growth rates up to 18 months post term.

Cochrane Database of Systematic Reviews 2016, Issue 12. Art. No.: CD004696.

Transitional Formulas: Options for Use

- Cochrane review may not have adequately represented very small infants and missed key benefits in highest risk infants
- For infants < 1800 g birth weight, consider transition to these formulas from 24 kcal/oz preterm formula at about 2.0 kg
    - May delay to about 3 kg if serum alkaline phosphatase activity > 600 IU/dL or BPD with fluid restriction
    - Often transition to these formulas when ready to be fed “ad lib” but at least 3 days before discharge
    - Recognize limits of data related to this practice
- Consider using some mixture of preterm and transitional formula in face of significant NICU growth failure

Preterm Infants over 1800 g at Birth?

- Minimal research and outcome data
  - Transitional formulas are often more expensive for government payment sources (WIC) and are slightly more expensive for families
  - Some anecdotal evidence that long-term use or use in late preterm infants can lead to excessive weight gain
  - Some use for infants > 1800 g BW. Use of routine formulas may also lead to desirable outcomes
    - My practice is not to encourage routine use in infants > 2.2 kg or 34 0/7 weeks at birth
      - Consider use in these infants with conditions limiting growth, nutrient intake or significant mineral deficiencies

Supporting Human Milk Feeding After Discharge

- Several studies have shown human milk-fed infants grow more slowly than formula-fed preterm infants after d/c
- Few interventions have been studied in breastfed infants
- An evolving area
  - Former preterm infants who are breastfed drop %iles on growth curve. May lead to stopping breast feeding.
  - Slow(er) growth may or may not be harmful

Fortification of Breast Milk at Home?

- Significant disruption of breast-feeding dyad
- Accurate measurement of milk volume and fortificant?
- Bacterial contamination potential for powders
- Effect of fortificant on absorption and other nutritional factors from HM

Complementary Formula Feeds

- Relatively less interruption of breastfeeding
- No concerns about sterility if use liquid formulas
- Current approach I recommend
    - 5-6 feedings/day of expressed breast milk or breastfeeding
    - 2-3 feedings/day of transitional formula or 1-2 feedings/day of 30 kcal/oz formula (currently more feasible than in the past)
    - This may not meet entirety of needs but maximizes breast milk use
    - Some may use up to ½ feeds as transitional formula to fully meet protein needs < 39 weeks PMA
    - Re-evaluate need for formula at 48-52 weeks PMA
- If mother does not wish to use any formula, can follow baby closely for growth, serum total alkaline phosphatase activity post-discharge
- Individualize for infants needing fluid restriction or with poor growth history

Intakes of key nutrients from typical enriched post-discharge feedings for preterm infants, assuming milk intake of 160 mL/kg per day

Feeding strategy	Breast milk plus formula supplements (give BOTH of the below daily)			Formula
Breast milk	**6 feeds**	**5 feeds**	**6 feeds**	
Premature discharge formula	**2 feeds at 22 kcal/oz (75 kcal/100 mL)[1,2]**	**3 feeds at 22 kcal/oz (75 kcal/100 mL)[1,2]**	**2 feeds at 30 kcal/oz (100 kcal/100 mL)[3]**	**8 feeds at 22 kcal/oz (75 kcal/100 mL)[1,2]**
Energy (kcal/kg/day)	112	113	120	117
Protein (g/kg/day)	1.9	2.2	2.3	3.4
Calcium (mg/kg/day)	59 to 64	70 to 76	94 to 100	125 to 144
Phosphorus (mg/kg/day)	34 to 35	41 to 42	49 to 56	74 to 80

This table uses the following assumptions:

- Feeding intake is 160 mL/kg/day
- Breast milk provides 20 kcal/oz with 0.9 g/dL of protein[4]

For infants who are less than 44 weeks gestational age, a liquid formulation of premature discharge formula[1,2] or premature formula[3] should be used rather than a powdered formulation. Nutrient compositions of these formulas are based on commonly used commercial brands, as cited.

References:

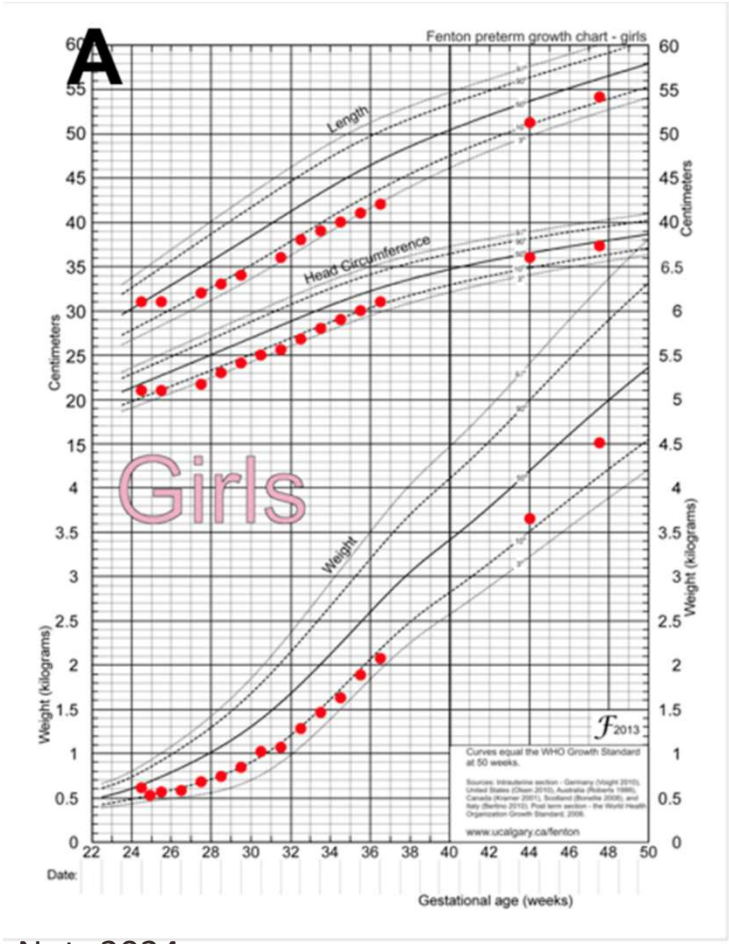
1. *Similac Neosure (premature discharge formula). Nutrition information available at: https://abbottnutrition.com/similac-neosure (Accessed on January 6, 2025).*
2. *Enfamil Enfacare (premature discharge formula). Nutrition information available at: https://www.meadjohnson.com/pediatrics/us-en/product-information/products/premature/enfamil-enfacare (Accessed on January 6, 2025).*
3. *Similac Special Care 30. Nutrition information available at: https://abbottnutrition.com/similac-special-care-30 (Accessed on January 6, 2025).*
4. *Pediatric Nutrition Handbook, 7th ed, Kleinman RE, Greer FR (Eds), American Academy of Pediatrics, Elk Grove Village, Illinois 2014.*

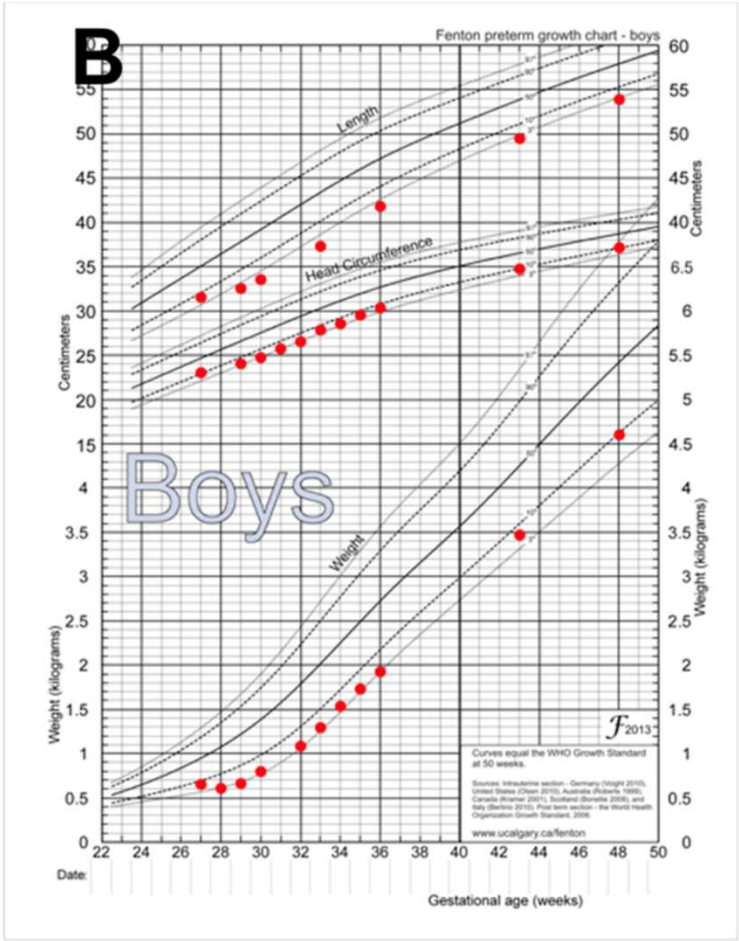
Graphic 118736 Version 3.0

Post-discharge: How long to continue transitional formula or complementary feeds?

- One guidance is to stop at 4-6 mo corrected age if all growth parameters are > 25%ile (Bhatia, J Perinatol 2005)
  - If not gaining excessive weight, then continuing until 9 mo CGA is reasonable
  - Emphasis should be on monitoring length, FOC
  - However, key is to follow growth curves. If maintains proportional growth > 3-5%ile this may be appropriate for that infant and can move to all breastfeeding or routine formula (see: Fenton et al, Adv Nutr 2024)
- Rarely wish to stop at less than 48 weeks PMA as 40-48 weeks are critical catch-up time period (Adamkin, J Perinatol 2006). Most currently continue until 48-52 weeks if growth maintained

“Finding your percentile and sticking to it!”





Fenton et al. Adv Nutr 2024.

Growth monitoring

- Should monitor weight, length (use length board) and FOC. Use gender-specific WHO curves when possible. Use corrected age to 2 years
- Recognition that some drop-off, especially in weight %iles will occur in breast-fed preterms
- Drop in length %iles is not desirable
- Monitor for excessive weight gain or weight/length
- Bone catch-up is usual in first 2-3 months after d/c
    - Do not routinely check alk phos unless < 1500 g birthweight AND not receiving any supplement to HM
- Smallest infants have poorer catch-up

Iron

- Iron status should be monitored: Prefer both serum ferritin and CBC
- Preterm infants and those < 2500 g birth weight should be supplemented with iron at time of hospital discharge
- Iron intake should be at least 2 mg/kg/day. May adjust based on iron status. Would not usually exceed 3-4 mg/kg/d
- For formula-fed infants, may need small supplement to achieve 3 mg/kg/day, can be combined with vitamin D
  - Recommend using ferrous sulfate unless clearly not tolerated. Some babies will tolerate alternate forms better.

Not Generally Recommended for Most Former Preterms

- Soy formulas – little need in any infant population
- Lactose-free formulas – not harmful but no specific benefits
- Hydrolyzed casein protein formulas without clear evidence of protein intolerance
- Amino acid-based formula except intestinal failure patients or protein intolerance not responsive to hydrolyzed casein formulas
- Reflux/spitting thickened formulas – may have very limited role
- Non-pasteurized donor milk
- Any thickening agents
- Goat milk (not the formula, that's okay), almond milk, etc
- Early introduction of solid foods. Allergy related early introduction may be considered as with full-term infants. Most authors recommend adjusting for gestational age

Lab Testing Post-Discharge

- There is no need for routine lab testing in most preterm infants after discharge except iron status
- Consider checking total alk phos activity at 40-48 weeks PMA if last alk phos was > 600 IU/L OR history of rickets OR < 1250 g BW and exclusive HM feeding
- No need for routine vitamin D (serum 25-OHD) testing if receiving appropriate dietary intake of at least 400 IU/day
- If discharged with conjugated bilirubin > 0.3 mg/dL, this should be followed. It is not uncommon for TPN cholestasis to persist for several months

How are new formulas evaluated by the FDA?

- Growth monitoring studies
  - Generally monitoring is short term (e.g. 4-6 months)
  - Standards exclude including late preterms who are often fed standard formulas
  - Comparison is with current formulas, not human milk
  - Include some evaluation of adverse effects
  - Focus is on safety, not necessarily benefits to the new formula
- Animal protein study (PER)
  - Historical test used to evaluate growth based on protein source in laboratory rats
  - Inaccurate approach. Rats are not people. Alternatives used in other countries
  - Broad based safety evaluation comparison with current formula/product

Growth standard

Observations of 720 infants fed milk-based or isolated soy protein-based formulas and of 419 breast-fed infants indicated that the sex-related difference in rate of gain in weight from 8 to 112 days of age was 4.7 g/day for formula-fed infants and 3.6 g/day for breast-fed infants.[11] The difference in rate of gain between formula-fed and breast-fed infants during this age interval was 2.4 g/day for males and 1.3 g/day for females. On this basis, the Task Force recommends that a feeding-related difference in weight gain of more than 3 g/day over a 3 to 4 month period (although it is less than the sex-related difference) should be considered nutritionally significant.

From: Clinical testing of infant formulas with respect to nutritional suitability for term infants. AAP, CON, June 1988 and Nelson et al, 1989: https://www.sciencedirect.com/science/article/pii/0378378289900571

Limitations in current approaches to evaluation of new formulas

- Virtually no data assessing cost/benefit
- Virtually no data related to interaction of bioactives, especially those in “different formulas”
- Information and data are not presented in a fashion useful to consumer or pediatricians
- Few data on meaningful clinical outcomes related to infection or allergy prevention/management
- Hard to connect common infant symptoms (e.g. colic) to specific components of human milk or formula

NASEM report: May 5, 2025

NASEM report: Clinical studies

Recommendation 4: The Food and Drug Administration (FDA) should publish a single guidance document that describes: (1) the preferred design features of a growth monitoring protocol and explains how FDA uses required information in its evaluation that a formula supports normal physical growth, and the conditions under which alternative designs may be acceptable to FDA; and (2) guidance that outlines the conditions under which a growth monitoring study is needed. That guidance should take into account (1) whether the change in infant formula could reasonably affect growth, (2) if a new ingredient is normally found in human milk, (3) the extent to which prior studies have examined the effect of a new ingredient on growth, and (4) information about the effects of addition of the ingredient on the level of or bioavailability of a nutrient, whose deficiency over the course of the study would be manifested in reduced growth.

NASEM report: Clinical studies

Conclusion 7: Conducting a research study in which a new formula is compared to an existing approved one, referred to by the term "concurrent control" as used in 21 CFR § 106.96(b)(5), is conventionally interpreted by investigators and FDA to mean the need for a randomized controlled trial (RCT). An RCT may be needed to demonstrate the absence of a negative effect on growth of infant formula–fed infants because of a change in formulation or processing of an infant formula. However, an RCT may not be needed under certain conditions, and suitable data could be generated in a single-arm study in which the growth of infants receiving the test formula is compared to the WHO/CDC growth standard.

DHA

- DHA is not a required ingredient in US formulas but is found in ALMOST all currently marketed ones. “The average DHA content of all formula purchased in US was: 12.6 mg/100 kcal. This DHA concentration is far below the minimum required DHA concentrations of infant formula (Stage 1) set by the European Commission of 20 mg/100 kcal” (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10143847/)
  - I tend to support the European view, but this is not settled science
  - DHA should always be given in appropriate ratio with ARA to ensure growth
  - More common for European formulas to use fish oil as a source, in US mostly use algal source. Not clear which is better/safer but probably doesn’t matter as mercury contamination of fish oil used in formulas is likely very minimal

Some specific issues: CHO effects on metabolism?

- Families (and internet commentators) often confuse CSS (glucose polymers) with high fructose corn syrup
- In Europe, CSS may be used only in non-organic formulas, nearly all formulas use lactose
- Clinical significance of current research not definitive but provide evidence for concern about use of lactose-reduced formula
- Of note, is that there are virtually no known or likely benefits of not using lactose as CHO source in infant formulas for term infants
- Even protein hydrolysates may consider using lactose except for infants with severe diarrhea

CHO source in formula

- One small study suggested possible issues with food enjoyment, fussiness at 2 years of age in infants who receive corn syrup solids (CSS) in formula
  - Groups also differed in protein source and the CSS group included soy and partial hydrolysates likely chosen due to fussiness
  - Note that “food enjoyment” was identical in all groups at 2 yrs
- Differences in microbiome also found based on CHO source
- Another study showed faster weight gain with non-lactose CHO in infants
- One study demonstrated lower glucose, higher insulin in babies after single feeding of CSS containing compared to lactose-based formula

Hampson, Hailey E et al.” *Nutrients* vol. 14,5 1115. 7 Mar. 2022, Jones RB, et al.. *Gut Microbes*. 2020;12(1):1813534, Kong et al J Nutr 2021;151:1572-80. Slupsky CM, et al. Sci Rep. 2017;7(1):3640

Minerals

TABLE F-3 Infant Formula Minerals and Trace Elements Content Standards

		CODEX		US		AU/NZ		Canada		EU	
Minerals and Trace Elements	**Unit of Measurement**	**Minimum Level**	**Maximum Level**	**Minimum Level**	**Maximum Level**	**Minimum Level**	**Maximum Level**	**Minimum Level**	**Maximum Level**	**Minimum Level**	**Maximum Level**
Calcium	mg/100 kcal	50	N/A	60	N/A	N/A	N/A	50	N/A	50	140
	mg/100 kJ	12	N/A	N/A	N/A	12	N/A	N/A	N/A	12	33.5
Phosphorus	mg/100 kcal	25	N/A	30	N/A	N/A	N/A	25	N/A	25	90
	mg/100 kJ	6	N/A	N/A	N/A	6	25	N/A	N/A	6	21.5
Calcium/ Phosphorus Ratio	N/A	1:1	2:1	1.1:1	2:1	1.2:1	2:1	1.2:1	2:1	1:1	2:1
Magnesium	mg/100 kcal	5	N/A	6	N/A	N/A	N/A	6	N/A	5	15
	mg/100 kJ	1.2	N/A	N/A	N/A	1.2	4	N/A	N/A	1.2	3.6
Iron	mg/100 kcal	0.45	N/A	0.15	3	N/A	N/A	0.15	N/A	0.3	1.3
	mg/100 kJ	0.1	N/A	N/A	N/A	0.2	0.5	N/A	N/A	0.07	0.31

Closer look at iron

Table 1

International regulatory bodies requirements for iron and DHA in infant formula.

Regulatory Body	Age (Months)	Formula Type	Minimum	Maximum
Iron (mg/100 kcal)				
Food and Drug Administration	0–12	All	0.15 [1]	3.0
European Commission	0–6	Non-Soy-Based	0.3	1.3
	6–12	Non-Soy-Based	0.6	2.0
	0–6	Soy-Based	0.45	2.0
	6–12	Soy-Based	0.9	2.5

Iron comparison

- Iron: EU allows 0.3 to 1.3 mg/100 kcal (2 to 8 mg/liter) for 0-6 mo
  - US allows 0.15 to 3 mg/100 kcal (1 to 20 mg/liter). Must have a label statement that additional iron may be required if < 1 mg/100 kcal (6.5 mg/L)
  - WIC rules mandate a minimum of 6 mg/L (slightly adjusted during formula shortages of 2022)
  - Must US formulas are 12 mg/L for over 50 years, a few at 8 mg/L. Most European formulas are 5-7 mg/L
  - Therefore, most US formulas exceed maximum European guidance. Most European formulas fall at the edge of low iron designation/WIC limits

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/able-groupe-recalling-products-labeled-infant-formula-formulas-have-insufficient-iron-levels

Who is right about iron??

Evidence supports European, not US approach

Adolescents who received iron-fortified formula as infants from 6 to 12 months of age at levels recommended in the US had poorer cognitive outcomes compared with those who received a low-iron formula. (Gahagan et al)

S. Gahagan, E. Delker, E. Blanco, R. Burrows, B. Lozoff, Randomized controlled trial of Iron-Fortified versus Low-Iron Infant Formula: developmental Outcomes at 16 years, J Pediatr 212 (2019) 124–130, e1.
And M. Domellof, C. Braegger, C. Campoy, V. Colomb, T. Decsi, M. Fewtrell, et al., Iron requirements of infants and toddlers. J Pediatr Gastroenterol Nutr, 2014 58 (1) (2014) 119–129.
[19] E.F.S.A. NDA Panel, (EFSA Panel on Dietetic Products Nutrition and Allergies). Scientific opinion on the essential composition of infant and follow-on formulae, EFSA J 12 (7) (2017) 3760.

Seed oils!!!

- They are in EVERY infant formula in order to provide EFA in proper ratios. Some TODDLER formulas don’t have them, but they are used as part of a mixed diet, not sole food source
- Small variations and decreases in amount based on use of whole milk fat, but not a large decrease
- This is a deflection and confusion, nothing to do with country of origin or quality and safety of an infant formula (babies are not little adults!)

Other issues related to new formulas

- Equity issues
  - If novel products including bioactives lead to improved clinical outcomes, should they always be included in WIC versions?
  - Do we need to reassess the Infant Formula Act/FDA guidance list and levels of nutrients regulated?
  - Most of the recently imported formulas have bioactives, will they continue to be available to WIC recipients?
- Concerns re: sourcing and contamination including environmental issues
- Effects on shelf life, transport, mixing characteristics
- Specific risks associated with preterm or immunocompromised infants

Goat milk-based formula?

- Allowed in Europe based on EFSA review of literature. Also allowed in antipodean countries (Aus/NZ)
  - Several recently imported infant formula in US use goat-milk protein
  - One study in 2014 found similar growth, biochem outcomes, no allergy or other noted benefits of goat's milk-based formula
- Additional study in 2015 found similar results, no benefit in crying, stool patterns
- No safety concerns. All are fully folate-fortified
- Currently have 3 infant formulas in use in the US that are goat milk-protein based and registered with FDA (one permanent, two pending permanent registration)

Zhou et al British Journal of Nutrition 2014, 111, 1641–165 ,
Xu M, Wang Y, Dai Z, Zhang Y, Li Y, Wang J. Food Nutr Res. 2015 Dec 10;59:28613.

Vegan protein formula

- Formula approved in Australia (also sold in other Asian countries) using pea and rice protein source
  - Approval in UK/Europe appears pending
  - Not clear if seeking registration in US (the FDA does not publish pending requests)
- A rice base formula is also marketed in EU countries
  - Regulatory status a bit unclear, but appears to be approved as a special nutritional product (hydrolyzed rice protein) https://www.sciencedirect.com/science/article/pii/S0929693X19300570
  - An important distinction is that specialized formulas in the EU are categorized as: "Foods for special medical purposes (FSMPs)" not as infant formulas and require an indication for their use, although it does not appear that this has any strict enforcement in many EU countries

Organic/GMO free

- European and some US formulas often contain organic designation which may have different meanings
- Organic label dictates non-GMO; however non-GMO label does not dictate organic ingredients
- Toxic exposures can occur from a variety of aspects of any type of formula production
- No strong evidence of risk to limited GMO exposure that may occur in some (esp soy) non-GMO-free formulas
- Substantial added costs to some of these designations, but families often choose them
- FDA needs to continuously work to establish standards for all infant nutrition products for potentially toxic exposures

de Mendonça Pereira BF, et al. Compr Rev Food Sci Food Saf. 2020 Jul;19(4):1378-1396

A2 milk

- A2 milk refers to milk from cows who naturally genetically make A2 casein protein. Single amino acid difference from A2 beta-casein. Claimed to be more similar to human milk casein, less “toxic” metabolites. Data are not compelling in adults
- Limited studies NOT in infants suggest better tolerance to A2 protein
- Unaware of ANY studies in neonates/infant formula fed infants comparing A2 vs others
- US produced and international formulas have included A2-only milk
- Controlled trials would be valuable to assess A2 milk, however, it is not a substantial cost issue and not harmful

Sheng X, Li Z, Ni J, Yelland G.. J Pediatr Gastroenterol Nutr. 2019 Sep;69(3):375-382.

A few other variations of note

- Postbiotics after bacterial fermentation producing bioactives
- Clean label designation
- Whole cow milk fat instead of vegetable fat is common, BUT some vegetable fat is generally included to achieve needed essential fatty acid levels
- Sourcing of DHA/ARA using non-hexane purified algal source
  - Some European formulas use fish oil, but generally most formulas use algal sourced DHA
- Absence of emulsifier – no carrageenan in European formulas per EFSA regulations
- Note that many of these are found in recently imported formulas

Operation Stork Speed

The FDA uses its authorities, both longstanding and newly granted, to uphold the safety, nutritional adequacy and resilience of infant formula and the infant formula supply. The FDA is:

- Starting the nutrient review required by law by issuing a Request for Information in the coming months to start the first comprehensive update and review of infant formula nutrients by the FDA since 1998
- Increasing testing for heavy metals and other contaminants in infant formula and other foods children consume
- Extending the personal importation policy
- Encouraging companies to work with the FDA on any questions regarding increased transparency and clearer labeling
- Communicating regularly with consumers and industry stakeholders as significant developments occur to ensure transparency, including information regarding nutrients and health outcomes
- Collaborating with the National Institutes of Health and other scientific bodies to address priority scientific research gaps regarding short- and long-term health outcomes associated with formula feeding in infancy and childhood across the lifespan

The FDA remains committed to infant formula safety and nutritional quality and is taking all actions to ensure the U.S. infant formula supply ranks best in the world.

https://www.hhs.gov/press-room/operation-stork-speed.html

Are European formulas “better” than American ones? Parents ask!

- Confused question: All formulas are “global” with raw materials sourced globally (e.g. vitamin premixes)
- US currently imports many formulas registered by FDA produced in Europe as well as Australia/NZ with FDA registration and supervision
- Standards can be different, but characteristics (e.g. whole milk fat inclusion) sought be some families are found in these formulas more often than in US based formulas. There isn’t anything special that you can’t obtain via FDA registered formulas from both US and other countries
- Use of non-FDA registered formulas violates US regulations, may not be safe and should be discouraged

Summary and conclusions

- Unique needs of preterm infants continue post-discharge
- Non-US produced formulas may have some small, but meaningful differences than many US ones (iron level, fat sources)
- Specialized formulas should only be used as truly needed. Some types have substantial costs without clear benefit
- Revision of FDA approach to formula evaluation is needed
- My grandchildren are extremely cute