



Addressing the Infant Formula Shortage

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Outline

- Review FDA regulations of infant formulas
- Infant formula types and purposes
- “Do” and “Don’t” during shortage
- What about cow milk?
- What about breast-feeding/chest-feeding and breastmilk
- Harm Reduction approaches



Regulation of Infant Formula

- Infant Formula Act of 1980 authorized Food and Drug Administration (FDA) to assure quality control of infant formulas
 - Prior to this, variation in formulas associated with high rates of iron deficiency anemia and other nutrient deficiencies
- Current FDA regulations require specific minimum amounts for 29 nutrients and maximum amounts for 9 of those nutrients
 - <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-107/subpart-D/section-107.100>
- “Exempt formulas” used for infant who has inborn error of metabolism, low birth weight, or unusual medical or dietary need

<https://www.fda.gov/food/people-risk-foodborne-illness/questions-answers-consumers-concerning-infant-formula#1>



FDA Required Components of Infant Formulas

- Carbohydrate (sugars like lactose, sucrose, corn syrup)
- Protein (such as casein, whey, soy, etc...)
- Fat and linoleic acid (essential fatty acid the body does not make)
- Vitamins
 - A, C, D, E, K, B1, B2, B6, B12; niacin; folic acid; pantothenic acid, biotin, (choline, inositol – in non-cow milk formulas)
- Minerals
 - Calcium, phosphorous, magnesium, iron, zinc, manganese, copper, iodine, selenium, sodium, potassium, chloride



Selecting formula during shortage

- Most importantly - ALL FDA approved formula have basic components to keep babies healthy
- Some babies tolerate one formula better than others
- Some babies need special formulas, but not most
- Using formulas in same class during shortage may reduce normal transition baby experiences with formula changes
- Limited data to support impact of additions (see next slides)
- Formulas may be on more than one list because modifications made may address more than one concern
 - Example – reduce lactose, reduce size of protein (partially hydrolyze)



FORMULA TYPES		GOAL of MODIFICATION
Cow-milk-based	Standard	
	Low-lactose (sugar)	Reduce gassiness
	Prebiotics	Reduce GI upset by promoting healthy gut microbiome
	Added rice or thickener	Reduce reflux symptoms
	Protein partially broken (hydrolyzed/hydrolysate)	Reduce milk protein allergy and GI upset
Soy-milk-based		Some babies tolerate soy protein better than cow-milk protein
Elemental amino acid-based (<i>by prescription only</i>)	Made from amino acids (what proteins made of) – no long protein chains	For infants with severe milk protein allergy, eosinic esophagitis or gastritis
Preterm formula	Higher calorie, iron and other micronutrients	Extra calories and nutrients for babies born early
Special formula	e.g. for kidney disease	



Additions to infant formulas

- **Prebiotics:** compounds in food that induce growth or activity of beneficial micro-organisms such as bacteria
 - Purpose - increase healthy organisms in gut to reduce GI upset
- **Lactoferrin:** protein found naturally in human milk that impacts iron regulation
- **Milk Fat Globule Membrane (MFGM):** complex structure present in human milk, made up of lipids and proteins that surround milk fat globules
 - Purpose - support infant brain development
- **DHA & ARA (Docosahexaenoic acid & arachidonic acid):** long-chain polyunsaturated fatty acids naturally present in human milk and other foods
 - Purpose - help brain and eye development
- **Rice or thickening agents**
 - Purpose - reduce spitting up (reflux)



Standard Cow Milk Based Formulas

- Similac Advance
- Similac Pro Advance
- Similac 360 Total Care
- Similac Organic
- Pure Bliss by Similac
- Enfamil Infant
- Enfamil NeuroPro Infant
- Enfamil Enspire
- Enfamil Simply Organic
- Enfamil A2
- Parent's Choice Advantage (Walmart)
- Parent's Choice Infant (Walmart)
- Parent's Choice Organic (Walmart)
- Parent's Choice Supplementation (Walmart)
- Up & Up Advantage (Target)
- Up & Up Infant (Target)
- Mama Bear Infant (Amazon)
- Mama Bear Advantage (Amazon)
- Mama Bear Organic (Amazon)
- Earth's Best Organic Dairy
- Happy Baby Organic
- Burt's Bees Organic Infant Milk
- Little Journey's Advantage (Aldi)
- Little Journey's Infant (Aldi)
- Plum Organics Grow Well Organic
- Plum Organics Premium
- Kirkland Signature ProCare (COSTCO)
- Kirkland Signature Infant (COSTCO)
- Comforts Advantage (Kroger)
- Comforts Infant (Kroger)
- Member's Mark Advantage (Sam's Club)
- Member's Mark Infant (Sam's Club)
- HEB Baby Advantage (HEB)
- HEB Baby Infant (HEB)
- CVS Health Advantage (CVS)
- CVS Health Infant (CVS)
- Always My Baby Advantage (Giant)
- Always My Baby Infant (Giant)
- Tippy Toes Advantage (Weis Markets)
- Tippy Toes Infant (Weis Markets)



Lower Lactose Cow Milk-Based Formulas

(purpose reduce gassiness)

- Similac Sensitive
- Similac Pro Sensitive
- Similac 360 Total Care Sensitive
- Enfamil NeuroPro Sensitive
- Parent's Choice Sensitivity (Walmart)
- Up & Up Sensitivity (Target)
- Mama Bear Sensitivity (Amazon)
- Earth's Best Organic Sensitivity
- Happy Baby Organic Sensitive Formula
- Burt's Bees Organic Sensitive
- Little Journey's Sensitivity (Aldi)
- Comforts Sensitivity (Kroger)
- Member's Mark Sensitivity (Sam's Club)
- HEB Baby Sensitivity (HEB)
- CVS Health Sensitivity (CVS)
- Always My Baby Sensitivity (Giant)
- Tippy Toes Sensitivity (Weis Markets)



Reduce GI Upset - Cow Milk-Based Formulas

(added prebiotics, reduce protein size, other modifications)

- Similac Total Comfort
- Similac Pro Total Comfort
- Enfamil NeuroPro Gentlease
- Enfamil Gentlease
- Enfamil Enspire Gentlease
- Enfamil Reguline
- Gerber Good Start Gentle
- Gerber Good Start Gentle Pro
- Gerber Good Start Gentle Supreme
- Gerber Good Start Soothe Pro
- Parent's Choice Gentle (Walmart)
- Parent's Choice Tender (Walmart)
- Up & Up Gentle (Target)
- Up & Up Complete Comfort (Target)
- Mama Bear Gentle (Amazon)
- Earth's Best Organic Gentle
- Burt's Bees Organic Ultra Gentle
- Little Journey's Gentle (Aldi)
- Plum Organics Gentle
- Comforts Gentle (Kroger)
- Comforts Tender (Kroger)
- Member's Mark Gentle (Sam's Club)
- CVS Health Complete Comfort (CVS)
- HEB Baby Complete Comfort (HEB)
- Always My Baby Gentle (Giant)
- Tippy Toes Gentle (Weis Markets)



Added Rice Cow-Milk-Based Formulas

(Purpose: added rice to thicken to reduce reflux)

- Similac For Spit Up
- Enfamil AR
- Parent's Choice Added Rice (Walmart)
- Up & Up Added Rice Starch (Target)
- Comforts Added Rice Starch (Kroger)
- CVS Health Added Rice Starch (CVS)
- HEB Baby Added Rice Starch (HEB)
- Tippy Toes Added Rice Starch (Weis Markets)



Soy-Milk Based Formulas

- Similac Isomil
- Enfamil Prosobee
- Gerber Good Start Gentle Soy
- Parent's Choice Soy (Walmart)
- Up & Up Soy (Target)
- Mama Bear Soy (Amazon)
- Earth's Best Non-GMO Plant Based Soy
- Little Journey's Soy (Aldi)
- Comforts Soy (Kroger)
- CVS Health Soy (CVS)
- HEB Baby Soy (HEB)
- Tippy Toes Soy (Weis Markets)

Smaller Protein Size Formulas (For milk protein allergy, consult doctor for use)

- Similac Alimentum
- Mead Johnson Nutramigen
- Mead Johnson Pregestimil
- Gerber Extensive HA
- Parent's Choice Hypoallergenic (Walmart)
- Up & Up Hypoallergenic (Target)
- Comforts Hypoallergenic (Kroger)
- CVS Health Hypoallergenic (CVS)
- Well Beginnings Hypoallergenic (Walgreens)
- Tippy Toes Hypoallergenic (Weis Markets)
- HEB Baby Hypoallergenic (HEB)



Specialty Formulas

(consult pediatric professional)

Preterm Formulas

higher calorie and higher amount
micronutrients for babies born early
- usually <36 weeks

- Similac Neosure
- Enfamil NeuroPro Enfacare

Elemental Amino Acid Based Formulas (usually prescription needed)

- Neocate Infant
- Neocate Syneo
- Mead Johnson Puramino DHA/ARA (infant)
- Nestle Alfamino infant
- Elecare Infant (product part of recall)



Why the formula shortage?

- Supply issues for ingredients, packaging, labor as well as shipping
- Recall earlier this year contributed as well
- Duration unknown, but urgent need is recognized with efforts underway to reverse situation as quickly as possible



DO: If Can't Find Formula

- Contact your pediatrician for samples (if available), WIC office, 2-1-1 (United Way), food pantries
- Check smaller stores/pharmacies
- Shop online from well-recognized sites rather than individually sold or auctions which may sell expired or lower quality products
- Do not purchase formula from overseas; not FDA-reviewed or approved and may not meet nutritional and safety standards
- For most babies, OK to switch to any available formula, including store brands, unless baby on extensively hydrolyzed or amino acid-based formula (hypoallergenic) such as Alimentum/Nutramigen/ Elecare
- With brand changes, babies may get an upset stomach, be little fussy or have change in stooling (bowel movements) as they adjust to change



DO NOT: If Can't Find Formula

- Do NOT make your own formula - not safe; do not meet baby's nutritional needs; infant deaths reported from use of some homemade formulas
- Do NOT add extra water to “stretch” supply -- can cause nutritional imbalances and lead to serious health problems. Always mix formula as directed by manufacturer
- Do NOT switch to cow's milk* - difficult to digest under 1* year, not correct nutrient balance, can lead to health problems (**See AAP statement during*)
- Do NOT use milk alternatives - not recommended under 1 year, especially plant-based milks which are low in protein and minerals
- Do NOT use recalled or expired formula
- Do NOT use toddler formulas - not recommended under 1 year, not FDA regulated. May be OK for a few days if no other choice and close to first birthday



Important to Prepare Formula Properly

Infant formula available in 3 forms

1. Ready to Feed formula

- *Preparation:* none - no mixing or adding (currently hard to find)

2. Concentrated liquid formula

- Usually in 13 oz cans
- *Preparation:* mix equal volume formula concentrate with equal volume of water

3. Powdered formula

- *Preparation:* for every scoop of formula powder – add 2 ounces water
 - ratio 2 oz water per level, unpacked scoop of powder
- Detailed formula preparation instructions from CDC:
<https://www.cdc.gov/nutrition/infantandtoddlernutrition/formula-feeding/infant-formula-preparation-and-storage.html>



Cow's Milk during shortage?

- Ideally, cow milk not started before 12 months
- Ideally, transition from formula or breastmilk to cow's milk gradually
 - Rapid transition babies can have constipation or diarrhea
 - Before 12 months, increases risk of low iron and anemia (early age low iron associated with lower IQ)
- Harm reduction approach during shortage
 - AAP statement* – **if baby older than 6 months** and usually on cow milk-based formula (not formula for allergies or other special health needs), in a pinch can feed whole [cow's milk](#) for a brief time until shortage better
 - **This is not ideal and should not become routine**
 - **Maybe** use whole cow milk to stretch formula rather than replace (e.g. 6 oz bottle – mix 2 oz whole milk and 4 oz prepared formula)
 - Do NOT use low fat, 2%, or skim milk

<https://www.healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/Are-there-shortages-of-infant-formula-due-to-COVID-19.aspx>



Iron Rich Foods

- Babies should start baby foods around 6 months, should be rich in iron
- CDC:
<https://www.cdc.gov/nutrition/infantandtoddlernutrition/vitamins-minerals/iron.html>
- Heme iron found in animal products easily absorbed by body
 - Red meat (beef, pork, lamb, goat, venison), Poultry (chicken, turkey), eggs, seafood
- Non-Heme iron found in plants less easily absorbed by body - eating along with sources high in Vitamin C increases absorption
 - Iron-fortified infant cereals, tofu, beans and lentils, dark green leafy vegetables
 - Vit C sources: citrus fruit, berries, papaya, tomato, sweet potato, broccoli, cabbage



Supplemental Nutrition Program for Women Infants and Children (WIC)

- PA WIC has 5-year contract with Abbott Nutrition for infants not fully fed breastmilk
 - Typical WIC formula provided: Similac Advance
 - Work with infant's pediatric provider if different formula needed
 - Do NOT need a prescription from doctor for: Soy Isomil, Similac Sensitive, Similac Total Comfort, and Similac for Spit-up
 - All other formulas require prescription
 - Can prescribe **non**-Abbott Nutrition products for specialty formulas



WIC Modifications During Formula Shortage

- During formula shortage, PA State WIC working closely with USDA and Abbott Nutrition to offer formula substitutions
 - List of available substitutions: <https://www.pawic.com>
 - Specific substitutions for each type of formula
 - Substitutions also found on WIC Shopper App
 - Call local WIC office with questions about formulas available
 - During formula shortage, prescriptions can include more than one formula in case preferred formula not available
 - Decreases need to go back and forth between WIC clinic and pediatric provider
 - Many specialty formulas on back order



Breastfeeding

- Ideally get breastfeeding off to a good start from beginning
- Assist birthing families in accessing education/support resources
 - Prenatal breastfeeding reading, classes, videos, or consultation
- Start at delivery with skin-to-skin and latch in first hour, when possible
- Get assistance while in hospital
- Know who to call for support after you go home
- If nursing is painful - get help/support asap
- Remember - any breastmilk is better than none
- PA Breastfeeding Resource Guide by County:
<https://www.health.pa.gov/topics/Documents/Programs/Infant%20and%20Children%20Health/Breastfeeding%20Referral%20Guide.pdf>



Restarting Breastfeeding (Re-lactation)

- Can birthing people restart their milk supply?
- Some can, but it will require **Determination and Time**
 - Good idea to follow shortage strategies in tandem with re-lactation
 - Easier if recently stopped breastfeeding
- One approach
 - Start by offering breast before any formula at all feedings
 - Let baby stay on each side for a few minutes, longer if you hear swallowing
 - Then offer formula
 - If baby wants more 10-15 min after feeding, reoffer breast before more formula
 - This approach will slowly (over a couple of weeks) increase supply
 - Can use pumps too



Re-lactation Resources

- CDC: <https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/supporting-families-with-relactation.html>
- La Leche League: <https://www.llli.org/breastfeeding-info/relactation/#:~:text=Hand%20express%20or%20pump%20at,before%20and%20after%20each%20feeding>
- Kelly Mom: <https://kellymom.com/ages/adopt-relactate/relactation-resources/>



What about Donor Human Milk?

Academy of Breastfeeding Medicine 2017 Position Statement

Informal Breast Milk Sharing for Healthy Term Infant:

<https://www.liebertpub.com/doi/10.1089/bfm.2017.29064.nks>

1. Donors should not have medical illness (e.g. HIV) or take medication not recommended during breastfeeding, or using legal or illegal drugs (cannabis, nicotine, smokes, etc)
2. Donors should be screened (blood tested)
3. Local community-based sharing preferred
4. Not purchased or shared on internet

Human Milk Banking Association of North America (HMBANA):

<https://www.hmbana.org>

- Local - Mid-Atlantic Mothers' Milk Bank (<https://midatlanticmilkbank.org/>)
- Mission - improve the health and survival of medically vulnerable infants and young children through the safe collection, pasteurization, and provision of donor human milk.
- During national formula shortage, milk bank continues to focus on these populations
- Lactating people with extra milk can donate for hospitals and outpatient babies in need



Take Home Messages

- Formula shortage scary for parents with infants
- Important to provide real-world harm reduction approach because sometimes families can't find any formula
- Best to choose formulas in same family to minimize impact
 - If baby tolerates cow milk formula – use any available in this category
 - Baby may be bit fussier or have change in stool appearance or frequency for few days to couple of weeks
 - Call if baby has blood in stool, excessive vomiting, fussy and not able to calm
 - If baby has cow milk protein allergy diagnosed by doctor – do not use any cow milk-based formulas - use formula from Smaller Protein Size Formulas
 - If baby requires prescription formula and none available – donor human milk may be option
 - If need medical advice, call baby's health care provider



Resources

- [AAP HealthyChildren.Org Information](#)
- [FDA Infant Safety Do's & Don't's](#)
- [USDA WIC Flexibilities](#)
- [USDA Infant Formula Safety](#)

