What Connects Us

Allegheny County Department of Human Services



5/26/2022 **Provider Briefing**



Agenda

4:30 – 4:40: Welcome and agenda

4:40 – 5:10: The Formula Shortage: Presentation by the Allegheny County Health Department, followed by Q&A

5:10 – 5:30: Policy & Legislative Updates/Election Update/ Solicitations/Announcements

Next Meeting: Thursday, June 23, 2022

Presentation



Addressing the Formula Shortage

Allegheny County Health Department UPMC Children's Hospital of Pittsburgh

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-l/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-foodborneillness/questions-answers-consumers-concerning- infantformula#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 –<u>ALL</u> 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)

FORMULATYPES		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 (by prescription only)	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 (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)



- 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)



- 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







- Contact your pediatrician for samples (if available), WIC office, 2-I-I (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 <u>FDA</u>-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 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 I* year, not correct nutrient balance, can lead to health problems (*See AAP statement during)
- Do NOT use milk alternatives not recommended under I year, especially plantbased 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** <u>older than 6 months</u> and usually on cow milk-based formula (not formula for allergies or other special health needs), in a pinch can feed whole <u>cow's milk</u> 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





- 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)



- PAWIC 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





- 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

<u>La Leche League: https://www.llli.org/breastfeeding-info/relactation/#:~:text=Hand%20express%20or%20pump%20at,before%20and%20after%20each%20feeding</u>

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

- I. 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 milkbased 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

USDAWIC Flexibilities

USDA Infant Formula Safety

Shortage and Recall Information



Family Center website: https://familycenters.alleghenycounty.us/

DHS website: https://www.alleghenycounty.us/human-services/index.aspx

Hello Baby website: https://www.hellobabypgh.org/infant-formula-shortage/



Policy and Legislative Update

Medicaid & CHIP Coverage



- During the COVID-19 Public Health Emergency (PHE), certain Medicaid and CHIP requirements were waived, preventing people from losing coverage during the pandemic. The PHE is set to expire on July 15th, unless extended again by the Biden administration.
- Because the Biden administration has not formally indicated when the "unwinding" will begin, and due to advocacy by hospitals around increasing COVID cases, it seems very likely the PHE will be renewed for another 90 days in July.
- Once the PHE ends, this will trigger an "unwinding" that will require states to resume conducting MA and CHIP coverage renewals.
- We'll need everyone's partnership to help participants complete their renewals!
- Key messages for participants:
 - I) Update contact information Make sure COMPASS/CAO has current mailing address, phone number, email or other contact information.
 - 2) Check your mail PA DHS will mail letters about Medicaid or CHIP coverage. This letter will let people know if they need to complete a renewal form to see if they still qualify.
 - 3) Complete your renewal form (if you get one) Fill out the form and return it right away to help avoid a gap in Medicaid or CHIP coverage.





- White House Conference on Hunger, Nutrition, and Health Update
 - The White House is announcing virtual, regional listening sessions to share ideas and experiences with hunger and diet-related diseases in our communities in the lead up to the White House Conference on Hunger, Nutrition, and Health which will be hosted in September.
 - These listening sessions are open to the public. Please register using the links below, and we encourage you to register for the region you live in.
 - Northeast, MidAtlantic, Puerto Rico, & U.S. Virgin Islands: June 7, 2022, 10am-12pm EDT. Register here.*

House Committee Votes in Favor of Amendments to Major Mental Health Bill

- On May 18, the House Committee on Energy and Commerce held a hearing to discuss the <u>Restoring Hope for Mental Health and Well-Being Act</u>, a legislative package aimed at addressing substance use treatment, prevention, recovery, workforce, and more.
- The Committee voted in favor of adding amendments that would remove the X-Waiver requirement, greatly increase access to buprenorphine, and require health care providers to complete a one-time training on best practices in caring for patients with a substance use disorder as a condition of receiving or renewing a registration to prescribe controlled substances for treatment,.
- The legislative package is expected to be voted on in the House sometime in June. It is unclear how this package will fair in the Senate.





- With the Primaries settled, State lawmakers returned to Harrisburg this week and will begin budget negotiations in earnest over the course of June.
- The Independent Fiscal Office (IFO) released its **Revised Revenue Estimate and Projections for FY 2022-2023** earlier this week.
 - Based on very strong personal and corporate income tax collections through April 2022 and projections for the remainder of the fiscal year, the revised estimate for FY 2021-22 is \$47.73 billion, \$5.82 billion above the IFO's official estimate of \$41.9b in June of last year, giving the state a small but unexpected surplus.
 - Federal funds related to a temporary increase in the Federal Medical Assistance Percentage (FMAP) used to calculate federal reimbursements for Medicaid programs have offset State DHS program costs over the last two fiscal years. The enhanced FMAP remains in effect until the termination of the national public health emergency declaration and is currently expected through September 2022. Enhanced FMAP funds offset \$1.7 billion in DHS Medical Assistance program costs in FY 2020-21 and \$2.5 billion in FY 2021-22. The extension of the enhanced FMAP into the first quarter of FY 2022-23 is expected to provide an additional \$0.9 billion in federal COVID relief for the coming fiscal year.





- The Gainey Administration recently released the long-awaited <u>Transition Team Report</u>, which is filled with recommendations for improving City government and policies.
- The report includes recommendations in many areas, including Rebuilding Trust Between Community and Public Safety" and "Coordination with Existing Human Service and Public Health Ecosystem."
- From Recommendation 17: "To improve resident outcomes, the City of Pittsburgh needs to better coordinate with the existing human services and public health ecosystem"
- Recent legislation passed by Pittsburgh City Council to expand inclusionary zoning to Bloomfield and Polish Hill has been challenged in court by local real estate interests
 - The bill, which passed earlier this month, mandates low-income housing requirements with any new large-scale development.

Election Update - Statewide



Governor – Josh Shapiro won an unopposed race for the D gubernatorial nomination, and will face Trump-endorsed State Sen. Doug Mastriano in the General. A last ditch effort by state Rs to coalesce behind former R Congressman Lou Barletta failed, and Mastriano absolutely crushed the crowded field, winning every county in PA.

Lt. Governor – McKeesport State Rep. Austin Davis handily won the D nomination after campaigning with Shapiro, and will face current Oakmont State Rep Carrie Del Rosso (R) in the General in a surprise win for her in a crowded Republican field. Both LG candidates are from Allegheny County.

US Senate – Too close to call and headed for a recount on the Republican side: Trumpendorsed Dr. Mehmet Oz (R) now leads by less than 1000 votes statewide in a squeaker over Pittsburgh area hedge fund manager David McCormick (R). McCormick has filed a lawsuit seeking to count undated mail-in ballots, as he has trended to do better with mail-in votes, but the advantage does seem to be with Oz as the recount begins.

The winner will face John Fetterman (D) in the General, who unsurprisingly easily defeated US Rep Conor Lamb in the D Primary. Fetterman's victory was resounding: he won all 67 counties, including Philly, where it was thought Lamb could best him.

Election Update - Congress



Congressional – Allegheny County

12th **District** – State Rep. Summer Lee edged out lawyer Steve Irwin with a few thousand votes to become the first black woman elected to Congress from Western PA. She will face Plum businessman Mike Doyle (R), who is not the longtime former 12th District Dem Congressman who just retired, but rather someone with the exact same name.

17th District – Attorney, veteran and Pitt professor Chris Deluzio beat Sean Meloy handily for the D nomination, and will face former Ross Township Commissioner Jeremy Schaffer (R) in the general, who trumped two other challengers for the seat Conor Lamb vacated to run for Senate.

Election Update – General Assembly



- All but two incumbents won their primaries in Allegheny County, but there were two upsets:
 - Longtime advocate LaTasha Mayes beat sitting State Rep Martell Covington for Mayor Ed Gainey's vacated State Rep seat. Covington had just won the special election to replace Gainey for the remainder of this year and was a technical incumbent, but lost by just over a 1,000 votes in a three-way race. Mayes had chosen not to run for the special, and focused her efforts on the Primary.
 - South Hills incumbent Mike Puskaric (R) lost handily to attorney Andrew Kuzma (R) in a rematch from 2020.
- Statewide, nine incumbents in the State House and Senate trail to challengers, and three more lost in member-vs-member primaries.
- Two of these incumbents who appear to have lost their primaries include both House and Senate Appropriations (R)chairs, Stan Saylor and Pat Browne



Announcements





DHS Solicitations Webpage

RFP for Equity Training

Due Date: Wednesday, June 8, 2022

RFI for a Racial Equity Training and Support Directory

• Due Date: Wednesday, June 15, 2022

RFP for Community-Led and Community-Operated Informal Mental Health Supports

Due Date: Wednesday, June 22, 2022

- HHS Announces Its First-Ever <u>Behavioral Health Recovery Innovation Challenge</u>
 - The goal of this challenge is to identify innovations developed by peer-run or community-based organizations, and entities that may partner with them—such as local or state governments, health systems, hospitals, or health plans—that advance recovery.
 - The deadline for submission is July 15, 2022. The purse prize is up to \$400,000. The competition will offer up to 10 awards.



Consolidated Public Benefits Webpage



- Consolidates all public benefits information on one page on the Allegheny County website (https://www.alleghenycounty.us/human-services/public-benefits-overview.aspx)
- Provides brief descriptions and links to applications for each benefit.
- Mirrors the layout at Allegheny Connect (due for launch this summer)
- Will eventually house additional resources:
 - Income eligibility matrix
 - Benefit/provider matrix
 - Training materials, including recorded trainings







Join the DHS Team!

https://alleghenycounty.bamboohr.com/jobs/



Next Meeting

6/23/22 4:30 – 5:30 p.m.

Meeting notices and reminders will come from the staff of the Office of Equity and Engagement.

Monthly meetings can be accessed at https://us06web.zoom.us/j/81751270241.

Here is the link to sign up to receive those notices:

https://lp.constantcontactpages.com/su/Uvw6IMX/ProviderBriefings

Or email us at DHS-OEE@AlleghenyCounty.us

Key Contacts



Questions for the Allegheny County Health Department

https://www.alleghenycounty.us/healthdepartment/index.aspx

Questions for DHS about Covid-19 or to Request a Lock Box for a Client

- DHS-COVID19Planning@alleghenycounty.us
- Use the subject field to indicate the category of your question (e.g., child welfare vaccine requirements, behavioral health masking policy, lock box request).

Key DHS staff

- Payment inquiries: Dan Evancho <u>Dan.Evancho@alleghenycounty.us</u>
- Contract inquiries: <u>Jennifer.Wernert@alleghenycounty.us</u> or <u>Laura.Brigido@alleghenycounty.us</u>
- Provider Briefing Questions: <u>DHS-OEE@alleghenycounty.us</u>

United Way 2-1-1

• For basic needs assistance or general COVID-19 inquiries call the 24/7 COVID19 Hotline at 1-888-856-2774. Language services available.



Addressing the Infant Formula Shortage

Allegheny County Health Department UPMC Children's Hospital of Pittsburgh





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



Allegheny County



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 <u>ALL</u> 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)



Allegheny County



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 (by prescription only)	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

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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) Plum Organics Grow Well Organic
- Parent's Choice Infant (Walmart)
- Parent's Choice Organic (Walmart)
- Parent's Choice Supplementation (Walmart)

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- 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 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)

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- 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)

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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

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- 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 <u>FDA</u>-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 plantbased milks which are low in protein and minerals
- Do NOT use recalled or expired formula

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 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

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- 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** <u>older than 6 months</u> and usually on cow milk-based formula (not formula for allergies or other special health needs), in a pinch can feed whole <u>cow's milk</u> 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

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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

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- 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

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- 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%20
 Children%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

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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,befo
 re%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

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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



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Resources

- AAP HealthyChildren.Org Information
- FDA Infant Safety Do's & Don't's
- USDA WIC Flexibilities
- USDA Infant Formula Safety

