Infant and Pediatric Formulas: What Hot?

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Objectives

• Familiarize audience with types of formulas (infant and pediatric)

• Indications for use

• Discuss new products/trends in oral formulations and enteral feeds
BREASTMILK

• Ideal nutrition source for newborns and infants
• Optimal for growth and development
• Over 200 non-nutritional and bioactive components
  • Modulate GI tract and immune function
  • Enhances brain development
• Plays a role in development of chronic disease later in life
• Convenient, inexpensive
• Bonding
Breastmilk has MORE of the Good Things Babies Need
See for Yourself!

Breastmilk

Antibodies
Anti-Cancer (HAMLET)
Growth Factors
Enzymes
Disease Fighting Stem Cells
Hormones
Anti-Viruses
Anti-Allergies
Anti-Parasites
Probiotics
Prebiotics
Minerals
Vitamins
Fat
DHA/ARA
Carbohydrates
Protein
Water

*Not all formulas have prebiotics and probiotics.
Breastmilk Composition

• Dynamic and variable in its nutritional and non-nutritional qualities and composition:
  • throughout the stages of lactation
  • between mothers
  • throughout the day
  • throughout a breastfeeding or pumping session

• Carbohydrate
  • 10-12g/100 kcal for lactose
  • Primary CHO Lactose
  • Prebiotic oligosaccharides (HMO)
Breastmilk Composition

- **Protein**
  - Approximately 1.3 - 1.7g/100 kcal
  - Source: Casein and whey
  - Most abundant proteins are casein, α-lactalbumin, lactoferrin, secretory immunoglobulin IgA, lysozyme, and serum albumin
    - Lactoferrin can help prevent spread of pathogenic bacteria
    - IgA destroys bacteria, protects mucosal barrier
  - Protein levels decrease in human milk over the first 4 to 6 weeks or more of life regardless of timing of delivery
Breastmilk Composition

• Fat
  • 4.8 to 5.4 g/100 kcal
  • 50% of total calories come from fat
  • Predominantly saturated fat
  • Essential polyunsaturated fats, linoleic acid and alpha-linolenic acid → convert to arachidonic acid (ARA), docosahexanoic acid (DHA), eicosapentaenoic acid (EPA)
    • Breastmilk DHA, EPA and AA are linked to maternal diet
    • May regulate growth, inflammatory responses, immune function, vision, neurodevelopmental outcomes and brain development
Infant Formulas

Infant Formula Act of 1980

• Due to diagnosis of Chloride deficiency after one of the major manufacturer reformulated some of its formula products and omitted salt. The act required formula makers to use specific nutrients.

• 1986 amendment defined minimum concentrations of 29 nutrients and established quality control standards for commercial production of infant formulas (includes organic formulas)

• 2014 amendments:
  • To ensure formula manufacturers test their products for salmonella and other pathogens before distribution.
  • Require formula companies to prove to the FDA that they are including specific nutrients
  • Rules also are aimed at new companies that come into the market.
  • Reasoning: growing number of unregulated infant formula and emphasis on ‘natural’ or ‘organic’

https://www.govinfo.gov/content/pkg/STATUTE-94/pdf/STATUTE-94-Pg1190.pdf
Human Milk Fortifier

- Enfamil Human Milk Fortifier Acidified Liquid
- Similac Human Milk Fortifier Extensively Hydrolyzed Protein Concentrated liquid
- Prolacta Human Milk Fortifier (human milk based)
  - Designed to improve nutritional quality of BM for premature infants only - only available in hospital NICUs
  - Provides increased protein
  - Provides 2 ½ times more Ca and P for bone mineralization
  - Provides increased micronutrients - Vit A, Vit D, iron (not Prolacta)
Preterm Formulas

• Similac Special Care Advance (20, 24, 30, HP)

• Premature Enfamil Lipil (20, 24, 30, HP).

• Gerber Good Start Premature (24, 24 High Protein)
  • Meets specific micronutrient needs of preemies: higher in protein, vitamins, minerals
  • Protein and fat easier to digest; higher MCT content
  • Available in the hospital
  • Generally used until the infant is 2500-3000g
Transitional Formulas

- Enfamil Enfacare
- Similac Expert Care Neosure

- Comes standard at 22cal/oz
- Meets specific nutrient needs higher in protein, calcium, phosphorus and other nutrients compared to term formula
- For use in premature infants until 12 months
Term Infant Formulas
Term Infant Formulas

- Differing nutritional requirements
  - Premature vs term infants

- Allergies or intolerances to bovine or soy protein

- Medical issues
  - Liver disease or malabsorption
  - Chylothorax
  - Renal dysfunction
  - Inborn errors of metabolism
  - Seizure disorders

- Marketing in response to parental request/preference and consumer trends
Standard Formulas

• Non fat milk; whey
• 20 kcals/oz
• 2g protein/100 kcals
• 5.1-5.6 g fat/100 kcals
Term Infant Formulas

Sensitive Formulas

• Lactose Free
• Partial Hydrolysates (colic)
• Added rice starch (reflux)
Term Infant Formula

Soy Formula

• Enfamil Prosobee

• Similac Soy Isomil

• Gerber Good Start Soy

• Vegetarian diet preferred (not lacto-vegetarian)

• AAP discourages the use of soy formulas for infants born <1850g
• Contains phytates which can bind with Ca and Zn >> decreasing their bioavailability
• Lower protein quality
• No benefit in preventing atopic disease in healthy or high-risk infants
• No benefit in preventing or managing infantile colic or fussiness

Term Infant Formulas

Extensively Hydrolyzed Formulas

• Lactose free
• Hydrolyzed proteins (Casein or whey)
• May have altered fat profiles (33 -55% MCT oil)
• Higher protein content (~3g/100 kcal)
• Hypoallergenic
• GI disorders
Term Infant Formulas

Elemental

• Amino acid based; contain MCT oil (33-43%)
• Higher protein content (~3g/100 kcal)
• Used for severe formula intolerance/allergies
• Eosinophilic Esophagitis (EoE)
• Malabsorption/GI disorders
Fat modified formulas

- Very high MCT (>80%)
- Chylothorax
- Liver failure
- Metabolic Disorders involving long chain fats

Low electrolyte formula

- Renal disorders/Endocrine disorders
- Low in Calcium, Phosphorus, Potassium and Iron
What’s Hot?

Organic formulas
What’s Hot?

- Not made in the USA
- Higher standards for sustainable, organic farming (Detemer)
  - Not registered with the FDA
    - Recalls; adverse effects
  - European labelling standards not equivalent
    - Not always in English
  - Nutrition of formulas not equivalent
- Pure Bliss - Abbott
  - Made in Ireland - grass fed cows

What’s Hot?

• Neuocognitive support
  • 2002 - DHA added to infant formula in US
    • Improved neurocognitive outcomes with DHA/ARA
  
• MFGM - Milk fat globule membrane (Enfamil Neoropro)
  • Sphingomyelin (supports neuronal growth)
  • Gangliosides (supports myelination; synaptic transmission)
  • Shown to improve cognitive outcomes

What’s Hot?

Prebiotics

• Added to support growth of Bifido and Lactobacillus species in the gut.

• GOS - galactooligosaccharides
  • Enfamil, Similac lines

• HMO - 2’FL human milk oligosaccharides
  • Similac Proadvance
  • Gerber Gentle/Soothe
What’s Hot?

Infant Formulas with Probiotics

• Gerber Gentle/Extensive HA
  • B. lactis

• Gerber Soothe
  • L. reuteri

• Nutramigen
  • L. rhamnosus GG

• Neocate Syneo
  • B. breve
What’s Hot?

Infant Probiotic Drops

• Gerber Gentle
  • B. lactis
  • 1 billion CFU/5 drops

• Gerber Soothe
  • L. reuteri Protectis
  • 100 million CFU/5 drops

• Culturelle for Babies
  • L. rhamnosus GG and B. lactis
  • 3.5 billion CFU/5 drops
What’s Hot?

**Evivo** – Evolve Biosystems

- **B. Infantis EVC001**
  - 8 billion CFU/packet given once daily
  - Ability to consume HMOs
  - Increases short chain fatty acids
  - Lower intestinal pH, improve gut barrier function
  - Recent study showed persistent colonization of gut for 30 days beyond the trial period.

Frese, SA et al. Persistence of Supplemented Bifidobacterim longum subsp. Infantis EVC001 in Breastfed infants. mSphere 2:e00501-17 (2017)
Pediatric Formulas

Similar categories as infant formulas

- Milk (Casein/whey) based
- Soy
- Semi-elemental
- Disease specific
Pediatric Formulas

Standard Formulas

• Milk protein based
• 1-1.5 kcal/ml
• Protein ~30-45 g/L
• Used as supplements or tube feedings
• Ages 1-13 years
Pediatric Formulas

Soy Formulas

• Bright beginnings
  • Perrigo Nutritionals
  • Prebiotics (scFOS, inulin)
  • DHA

• Pediasmart
  • Nature’s One
  • No DHA/Prebiotics
Pediatric Formulas

Semi-elemental

- Feeding intolerance
- Malabsorption
- 1, 1.2, 1.5 kcal/ml
- 30-48g pro/L (whey)
- Prebiotic fiber (FOS)
- High MCT content (60/40)
Elemental

- Impaired GI function
- Allergy
- EOE

Pediatric Formulas
Renal Formula

- Renastart
- Indicated for use in children 1 year +
- 1 - 2 kcal/ml; 15g - 30g/L
- Very low in potassium and phosphorus
- Used for supplementation
Pediatric Formulas

Modular Formulas

- Used for increasing macronutrient content of formulas in calories, carbohydrate, fat and protein
What’s Hot?

FOOD!
What’s Hot?

Home Blenderized Tube Feeding

• Customize diet to avoid allergens/additives
  • Corn, dairy, soy, added sugars

• Improved GI symptoms
  • GERD, constipation, diarrhea

• Lower cost compared to commercial formula
  • Insurance coverage of enteral feeds varies between plans

Food based Formulations

• Nestle
  • Compleat pediatric
    • 1 kcal/ml or 0.6 kcal/ml
    • Food powders; purees; pea protein
    • Fortified
  • Compleat organic blends
    • 1.27 kcal/ml
    • Chicken or plant based
    • Whole foods
    • Fortified

• Abbott
  • Pediasure Harvest
    • 1 kcal/ml
    • Whole foods
    • Fortified

• Functional Formularies
  • Nourish
    • 1.2 kcals/g
    • Whole food; vegan
    • Fortified

• Real Food Blends
  • 6 varieties
    • 1.27 kcal/g
    • Whole foods
    • Not fortified

• Kate Farms
  • 1.2 kcal/ml, 1.5 kcal/ml
    • Hydrolyzed pea protein
    • Proprietary superfood blend
    • Fortified
Strained Green Beans

- **Management of diarrhea in SBS**
  - Drenckpohl et al. added dietary green beans as a source of fiber to infant formula (elemental) improved the stool patterns in neonates who became feeding intolerant as a result of complications associated with a bowel resection.

- CHLA patients on continuous enteral feeds, use 2:1 ratio of formula to stage 2 strained green beans run over 4 hours (eg. 6oz formula:3 oz green beans)

Coverage for Formulas

• State programs
  • WIC - Women, Infant and Children
    • Cover standard formula (limited to state contract)
    • Can assist with specialty formulas as last resort

• State insurance programs
  • Medi-Cal - infant/pediatric specialty formula
    • oral/tube feeding
  • CCS - California Children’s Services (condition specific)
    • Not all formulas covered
  • EPSDT - Early Periodic Screening, diagnosis, treatment
    • May cover formulas not on Medi-cal formulary

• Private insurance programs
  • Typically don’t pay for oral supplements
  • Usually cover tube feedings
• For Infants, Breastmilk is goal standard
• Infant formulas are tightly regulated and monitored in the US.
• Many formulas exist to meet multiple medical needs
• Formula companies continue to develop new products based on emerging science and consumer demand.