

Navigating Infant Formulas: Considerations When Selecting Formula, Including in Cases of Growth Failure

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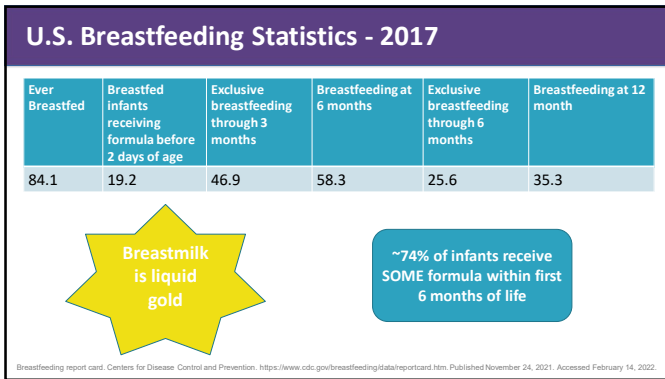


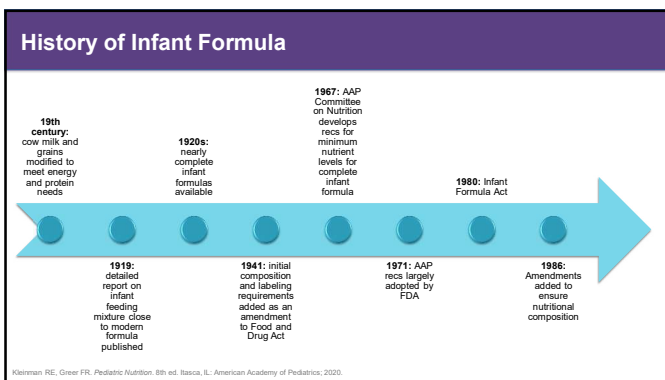
Learning Objectives:

- Identify different categories of infant formula
- Discuss appropriate usage for each type of infant formula
- Define a novel infant formula for term infants with growth failure

Notes:

Nutricia North America supports the use of breast milk wherever possible.





Infant Formula Act of 1980

Amended the Federal Food, Drug & Cosmetic Act
Permits the Secretary of Health and Human Services to revise such requirements, establish quality control procedures, and establish requirements respecting the retention of records of required procedures.

- establishes minimum nutrient requirements
- defines adulteration
- establishes nutrient and quality control procedures
- prescribes recall procedures
- specifies inspection requirements

Newberry RE. The Infant Formula Act of 1980. J Assoc Off Anal Chem. 1982;65(8):1472-1473.

Exempt Infant Formula

What qualifies as an “exempt” infant formula?

- “... an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.”
- U.S. Food and Drug Administration

Center for Food Safety and Applied Nutrition. Exempt infant formulas marketed in the United States. U.S. Food and Drug Administration. <https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category>. Published December 3, 2019. Accessed February 10, 2022.

Medical Foods

What is a ‘Medical Food’?

- “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”
- section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3))

Frequently asked questions about medical foods. May 2016.

Formula Ingredients

- GRAS or FDA-approved safe food additives
- “label claim” of an ingredient is the minimum amount present at the end of shelf life.
- Structure function label claims for infant formula ingredients
 - “truthful and not misleading”
 - “competent and reliable scientific evidence.”

Examples

- Taurine
- DHA/ARA
- Prebiotics/Probiotics
- Lutein/lycopene
- Lactoferrin


GRAS = generally recognized as safe; FDA = Food and Drug Administration; Kleinman RE, Greer FR. Pediatric Nutrition. 8th ed. 2020: 89-90

CASE STUDY: BABY GIRL AVA

CASE STUDY: BABY GIRL AVA

HISTORY

- Born at full term
- Weight 3.48 kg (50%ile); Length 51 cm (>50%ile)
- Exclusively breastfed until 4 months → supplemental formula introduced (200 ml/day)
- 20 weeks: solids introduced; 1 feeding of EBM; remainder formula
- Growing well




CASE STUDY: BABY GIRL AVA

At 7 months of age:

Anthropometric changes:

- Gastroenteritis: 10 days
- Breastmilk & rehydration fluids only
- Parental anxiety
- Feeds provided q 2 hours per grandma's recommendation


- -700 grams (-1 major percentile)
- Length stable (>50%ile)



Types of Infant Formula

Premature	Premature Transitional	Standard Term (Intact Protein)
Partially Hydrolyzed	Extensively Hydrolyzed	Amino Acid Based
Reduced/No Lactose	Soy	Low Mineral


Energy- and nutrient-dense



Types of Formula: Premature

Premature Formula

- Used for preterm infants
- Not recommended post-discharge
- 20-30 kcal/ounce
- Ready to feed; powder advised against in the NICU
- Contains increased protein (3-3.6 grams/100 kcal), iron and micronutrients
- Not appropriate once infant \geq 3600 grams




Malone A, et al. ASPEN Enteral Nutrition Handbook. 2019.

Type of Formula: Premature Transitional

Premature Transitional

- Used post-discharge
- Energy dense (22 kcal/ounce)
- Available in powder and RTF
- Higher in protein and some minerals
- May be used up to 1 year of age




RTF = ready to feed. Teller IC, et al. Clin Nutr. 2016. Malone A, et al. ASPEN Enteral Nutrition Handbook. 2019.

**Type of Formula: Standard Cow Milk-Based Formula
Term Infants**

Standard term formula

- 20 kcal/ounce
- Powder or RTF
- Most commonly used
- Intact or partially hydrolyzed milk protein
- Many contain added prebiotics




- Galactosemia
- Cow milk allergy
- Certain Inborn Errors of Metabolism

CMA = cow milk allergy; Malone A, et al. ASPEN Enteral Nutrition Handbook, 2019.

Type of Formula: Soy

Soy formula

- Contains soy protein
- Non-lactose carbohydrate source
- Free of cow milk protein and lactose
- 20 kcal/ounce
- Available as powder
- Often initiated because of perceived formula intolerance



Shaha J, Greer F. American Academy of Pediatrics, Committee on Nutrition. Pediatrics. 2009;123(5):1062-1069

Type of Formula: Soy

Indications	Contra-indications
Galactosemia	Preterm infants with birthweight <1800 grams
Congenital lactase deficiency	Reduction of colic
Transient lactase deficiency	Cow milk protein-induced enterocolitis or enteropathy
Documented immunoglobulin E-associated allergy to cow milk who are not also allergic to soy protein	
Parents seeking a vegetarian diet	

Shaha J, Greer F. Pediatrics. 2009;123(5):1062-1069

Type of Formula: Reduced Lactose

Reduced Lactose

- Reduced Lactose
- Contains milk protein
- Considered for infants with lactose intolerance
- Can be useful post-illness when lactose absorption is decreased

Secondary Lactase Deficiency

- Can occur initially in premature infants
- May occur after diarrheal illness

55% of term infant formula consumed contains reduced lactose

7.5% of infants estimated to require reduced lactose formula

CMA = cow milk allergy; Stzalkowski A, Young B. Curr Dev Nutrition. 2021; Heyman, et al. Pediatrics. 2006.

Type of Formula: Lactose-Free

Lactose-Free

- Lactose completely removed
- Corn-based carbohydrate source
- Contains milk protein
- Indicated for congenital lactase deficiency and galactosemia
- NOT appropriate for CMA

Congenital Lactase Deficiency:


- Infants born without lactase enzyme
- Extremely RARE
- Low survival prior to 20th century

CMA = cow milk allergy; Heyman, et al. Pediatrics. 2006.

Type of Formula: Low Mineral

Low Mineral

- Used for infants with impaired renal function
- Calcium:phosphorus ratio designed to manage serum calcium disorders
- Powdered formula
- 20 kcal/ounce
- Exempt infant formula



Nelms CL. Front Pediatr. 2018.

Type of Formula: Metabolic

Metabolic Formula

- Used for infants with inborn errors of metabolism
- Exempt infant formula
- Used under guidance of a healthcare professional

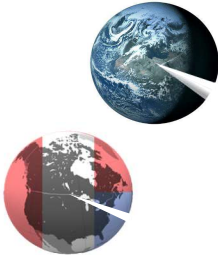
Inborn Errors of Metabolism

A group of rare disorders resulting in the excessive accumulation of an amino acid or other product along the metabolic pathway for lack of a natural enzyme required to digest certain foods.

Kisudzka et al. Am Fam Physician. 2019.

Cow Milk Allergy (CMA) is not uncommon

- Global prevalence:
 - 1.9 - 4.9% of infants¹
- North American prevalence:
 - ~2% of US infants^{2,3}
 - Most common food allergen in infancy and early childhood²



1. Soosy et al. Pediatr Allergy Immunol. 2015;21(1):125. 2. Gbure et al. Pediatrics. 2011;128(5):e117. 3. Wessner et al. Annals of Allergy, Asthma & Immunology. 2013;111:515.

Poll Question

Respond in the right-hand panel in the live event – Click 'SUBMIT' when done

When should an infant with **POOR GROWTH** get a hypoallergenic formula (an eHF or an AAF)? *Choose all that apply*


- A. Cow milk allergy diagnosis
- B. Allergic to multiple foods, including cow milk
- C. Cow milk allergy + GI tract and/or skin symptoms
- D. Chronic lung disease

eHF = extensively hydrolyzed formula; AAF = amino acid-based formula

Type of Formula: Partially Hydrolyzed

Partially Hydrolyzed

- Protein source: cow milk
- Molecular weight less than 3000 Da
- NOT hypoallergenic
- Not appropriate for infants with CMA, EoE, FPIES




Low, et al. 2013. CMA = cow milk allergy; EoE = eosinophilic esophagitis; FPIES = food protein-induced enterocolitis syndrome/

Type of Formula: Extensively Hydrolyzed (eHF)

Extensively Hydrolyzed

- Protein source: cow milk
- Molecular weight less than 3000 Da
- Hypoallergenic
- May be appropriate for infants with CMA, FPIES




American Academy of Pediatrics Committee on Nutrition. Pediatrics. 2000. CMA = cow milk allergy; EoE = eosinophilic esophagitis; FPIES = food protein-induced enterocolitis syndrome.

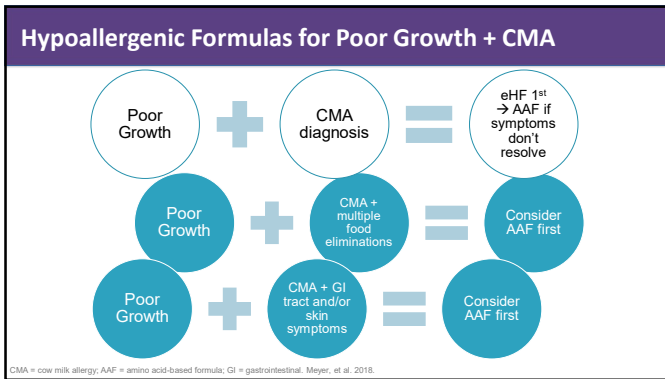
Type of Formula: Amino Acid-Based

Amino Acid-Based

- Milk protein free
- Comprised of 100% free amino acids
- Hypoallergenic
- CMA, EoE, FPIES, Multiple food allergies
- Malabsorption disorders



CMA = cow milk allergy; EoE = eosinophilic esophagitis; FPIES = food protein-induced enterocolitis syndrome.



Only 2 formula types are Hypoallergenic

Formula type: (protein source)	Amino acid-based (AAF)	Extensively hydrolyzed (eHF)	Partially hydrolyzed (pHF)	Regular (Intact protein)
Protein source	100% free amino acids	Cow milk	Cow milk	Cow milk
Peptide size, kilodaltons	N/A (free AAs ~0.12 ¹)	Most <1.5 ² Up to 5% >3.5 ³	Dairy: Most <5 ³ and up to 18% >6 ³	Dairy: 14-67 ³ Sov: 20-225 ⁴
Allergenicity	Least	←————→ Most		
Hypoallergenic?	☑ YES	☑ YES	☒ NOT HYPOALLERGENIC	☒ NOT HYPOALLERGENIC

1. <https://www.seas.upenn.edu/~cis535/Fall2004/HW/GC835HW6b.pdf>, July 3, 2018. 2. American Academy of Pediatrics Committee on Nutrition. 2000. 3. Lowe, et al. 2013:9-31-41. 4. Hongprabhus et al. 2014.

Only 2 formula types are Hypoallergenic

Formula type: (protein source)	Amino acid-based (AAF)	Extensively hydrolyzed (eHF)	Partially hydrolyzed (pHF)	Regular (Intact protein)
Protein source	100% free amino acids	Cow milk	Cow milk	Cow milk
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Allergenicity	Least	←————→ Most		
Hypoallergenic?	☑ YES	☑ YES	☒ NOT HYPOALLERGENIC	☒ NOT HYPOALLERGENIC

Hypoallergenic:
95% chance of being tolerated by 90% of children with CMA AND contain extensively hydrolyzed milk protein or amino-acids as it's protein source.

1. <https://www.seas.upenn.edu/~cis535/Fall2004/HW/GC835HW6b.pdf>, July 3, 2018. 2. American Academy of Pediatrics Committee on Nutrition. 2000. 3. Lowe, et al. 2013:9-31-41. 4. Hongprabhus et al. 2014.

U.S. Formula Consumption

Formula purchased from major retailers 2017-2019:

Protein Type	% of Formula Purchased
Intact	74.1
Soy	5
Partially Hydrolyzed	11.1
Extensively Hydrolyzed	7.1
Amino Acid-Based	0.3

Matches liberal estimates of CMA

CMA = cow milk allergy; Strzalkowski A., Young B. 2021.

What are risks associated with the use of infant formula powder?

Formula Risks: Mixing Errors

Always a risk of mixing errors with powdered formula

Concentrating and fortifying with formula increases risk

Low literacy and numeracy increase risk

In a study conducted by Altazan et al.:

19% of prepared bottles contained proper amount of formula



78% over-dispensed
11% additional powder



3% under-dispensed

Altazan AD, et al. 2019.

Formula Risks: Infection

Common Culprits

- **Cronobacter Sakazakii**
 - Naturally occurring germ
 - Grows in dry foods (powdered formula)
 - Can cause sepsis, meningitis, NEC and death in infants
- **Salmonella**
 - Occurs most often in infants
 - Can be found in powdered infant formula or in contaminated water when preparing concentrated liquid formula







CDC Prevention Guidelines


1. Breastfeed
2. Clean, Sanitize, Store Feeding Items
3. Use liquid formula when possible
4. Store powdered formula safely
5. Wash hands

FDA: powdered infant formula should not be used in the NICU unless there is no alternative

Cronobacter infection and infants. 2022. NEC = necrotizing enterocolitis; RTF = ready to feed

LIMITATIONS OF CURRENT PRACTICE OF FORMULA FORTIFICATION

-  Tolerability and Hydration
-  Unbalanced Nutrient Ratio
-  Mixing Errors
-  Delays in Advancing
-  Parental Stress
-  Breastfeeding



Poll Question

Respond in the right-hand panel in the live event – Click 'SUBMIT' when done


Which limitation with powdered formula most concerns you?

- A. Mixing errors (i.e. concentration errors)
- B. Infection from improper handling or contaminated water
- C. Caregiver stress
- D. Not available for all needs (e.g. 30 kcal/fl oz for increased energy)

Types of Infant Formula

Premature	Premature Transitional	Standard Term (Intact Protein)
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Energy- and nutrient-dense




CASE STUDY: BABY GIRL AVA

At 9 months of age:

- Sufficient energy and protein intake
- Vitamins and minerals for growth
- Improved feeding routine

Regimen change:

- Formula maintained at 500 mL/day (1 BF at night)
- Switch to energy-dense infant formula
 - +23 kcal/kg and +0.6 grams protein/kg/day



Formula Regimen Change

Volume maintained at 500 mL/day

ENDF replaced standard term formula

↑ 26 kcal/kg/day ↑ 0.6 g pro/kg/day

ENDF = energy and nutrient-dense formula; fl = fluid; oz = ounce; mL = milliliter; kcal = kilocalorie; kg = kilogram

Poll Question

Respond in the right-hand panel in the live event – Click 'SUBMIT' when done

How familiar are you with ready-to-feed energy- and nutrient-dense infant formula (RTF ENDF; 30 kcal/fl oz)?

- A. This event is my first time hearing about this formula type
- B. I've heard of this formula type but have not seen its use in practice
- C. I've cared for infants on an RTF ENDF initiated by another provider
- D. I've recommended an RTF ENDF in my clinical practice

Type of Formula: Energy- and nutrient-dense

- 30 kcal/oz term infant formula
- High protein/nutrient content
- Less than 400 mOsm/kg
- Ready to feed/sterile
- Nutritionally complete
- Supported by clinical evidence



ENDF = energy- and nutrient-dense formula; ASPEN 2022 Fact Sheet.

ENDF Patient Population



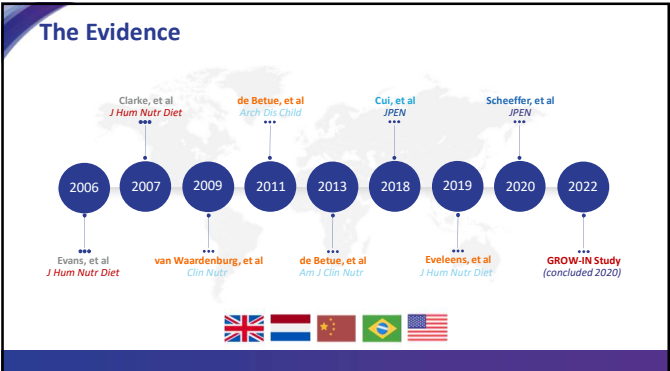
RELATED DIAGNOSES & CONDITIONS

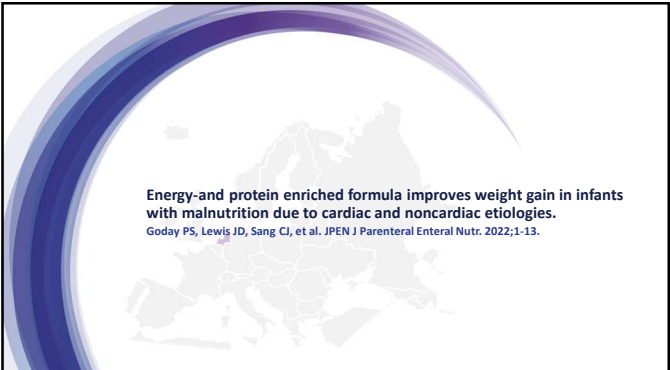
Congenital Heart Disease	Chronic Lung Disease
Cystic Fibrosis	Neurological Syndromes
Respiratory Syncytial Virus	Non-Disease-Related Failure to Thrive

Research Review

Evidence-based energy- and nutrient-dense infant formula for the management of growth failure







Goday, et al. 2022.
UNIVERSITY OF WISCONSIN | WAKE FOREST UNIVERSITY | GI CARE FOR KIDS | EAST CAROLINA UNIVERSITY |
NEMOURS CHILDREN'S HOSPITAL | TEXAS CHILDREN'S HOSPITAL

Study design: Prospective, open-label

Energy and Nutrient Dense Formula
(Targets set by site investigator)

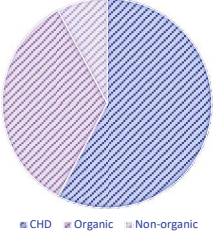
✓ 16-weeks ✓ Early Success

Goday, et al. JPEN J Parenter Enteral Nutr. 2022;1-13

Goday, et al. 2022.
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NEMOURS CHILDREN'S HOSPITAL | TEXAS CHILDREN'S HOSPITAL

Study Population: n=26

- Route of nutrition: PO or enteral
- Diagnosis: malnutrition
- Age: 1-8 months
- Expected Intake: $\geq 80\%$ from ENDF for 16 weeks



■ CHD ■ Organic ■ Non-organic

Goday, et al. JPEN J Parenter Enteral Nutr. 2022;1-13
PO = per os, ENDF = energy and nutrient dense formula, CHD = congenital heart defects

Goday, et al. 2022.
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Week 4 3 4 Week 8

Week 2 2 5 Week 12

Baseline 1 6 Week 16

Growth Tolerance Safety

Goday, et al. JPEN J Parenter Enteral Nutr. 2022;1-13

Goday, et al. 2022.
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Outcomes: Nutrient Intake

	kcal/kg/d
Total energy intake	123±32
ENDF intake	116±32

94%

Goday, et al. JPN J Parenter Enteral Nutr. 2022;1-13

Goday, et al. 2022.
UNIVERSITY OF WISCONSIN | WAKE FOREST UNIVERSITY | GI CARE FOR KIDS | EAST CAROLINA UNIVERSITY | NEMOURS CHILDREN'S HOSPITAL | TEXAS CHILDREN'S HOSPITAL

Outcomes: Growth

Weight-for-Age	Length-for-Age	Weight-for-Length	Head Circumference
+0.86 ± 0.74 mean WAZ from baseline (p=0.0001)	+0.25 ± 0.61 mean LAZ from baseline (p=0.003)	+0.77 ± 0.81 mean WLZ from baseline (p=0.0001)	+0.54 ± 0.68 mean HCZ from baseline (p=0.001)

Goday, et al. JPN J Parenter Enteral Nutr. 2022;1-13
WAZ = weight-for-age z-score; LAZ = length-for-age z-score; WLZ = weight-for-length z-score; HCZ = head circumference z-score

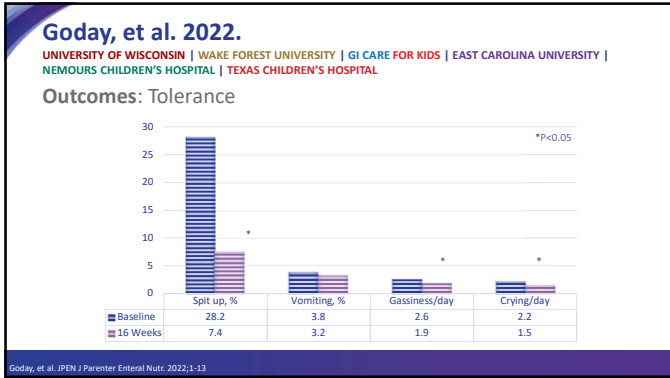
Goday, et al. 2022.
UNIVERSITY OF WISCONSIN | WAKE FOREST UNIVERSITY | GI CARE FOR KIDS | EAST CAROLINA UNIVERSITY | NEMOURS CHILDREN'S HOSPITAL | TEXAS CHILDREN'S HOSPITAL

Outcomes: Growth

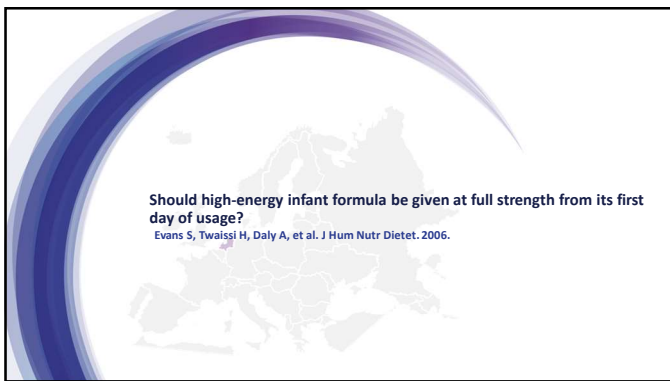
Percentage of infants who achieved weight gain velocity > WHO median:

87% → ≥1 time point
63% → Overall study period
13% → "Early Success"

Goday, et al. JPN J Parenter Enteral Nutr. 2022;1-13
WHO = World Health Organization







Some infants may benefit from transitioning onto ENDF

Design

- Randomized, controlled trial (non-blinded)
- 2-week intervention with ENDF
- Birmingham Children's Hospital

Study Population

- Infants with diagnosis of failure to thrive
- 73% (n=22) of the infants had CHD
- 93% (n=28) standard formula (20 kcal/fl oz) previously

Full Strength (FS) Start (n = 18)	Graded Start (n = 12)
Full strength at day 1	ENDF diluted with water
	Day 1: 80% (24 kcal/ fl. oz)
	Day 2: 90% (27 kcal/ fl. oz)
	Day 3: 100% (30 kcal/ fl. oz)

Outcomes & Results

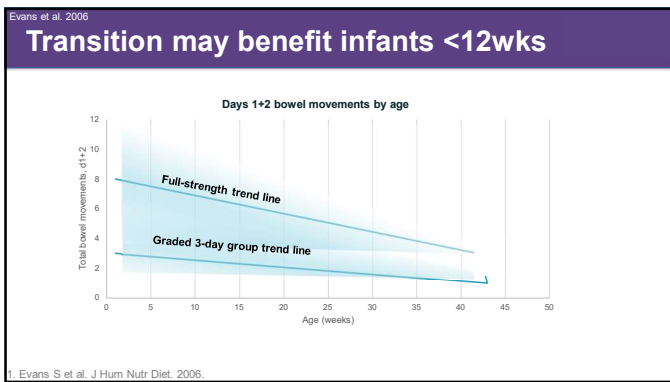
1 - Tolerance: Emesis & Stool Frequency

- ↑ stool frequency in first 2 days for FS group (p=0.02), inversely correlated with age
- No differences in emesis

2 - Anthropometry: Weight, Length, HC, MUAC

- Non-significant trend to higher weight for FS group

ENDF = energy- and nutrient-dense formula; CHD = congenital heart defect; FS = full strength. 1. Evans S et al. J Hum Nutr Diet. 2006.



INTRODUCING ENERGY- and NUTRIENT-DENSE FORMULAS (ENDF)

GUIDELINES TO SUCCESSFULLY INTRODUCE ENERGY NUTRIENT DENSE FORMULAS (ENDF)

Infants <12 weeks of age:

Administer full strength formula and alternate with current feed or dilute to 24 kcal/oz and grade to full strength over 3 days to avoid frequent stools

Infants >12 weeks to 18 months:

Full strength and full transition from day 1

Alternate breast milk/breast feeding and ENDF feeding

1. Evans S et al. J Hum Nutr Diet. 2006.

Consider as supplement to breast milk

Ready-to-feed 24
24 kcal/fl oz
1000 kcal = ~42 fl oz

20% less formula volume

ENDF
30 kcal/fl oz
1000 kcal = ~33 fl oz

ENDF = energy and nutrient-dense formula; fl = fluid; oz = ounce

Increase caloric density of EBM

Ratio of Feed (EBM: ENDF)	Caloric Density (kcal/ounce)
4:1	22
3:2	24
2:3	26
1:2	27
1:4	28

EBM = expressed breast milk; ENDF = energy- and nutrient-dense formula

When to transition off ENDF?

- Catch-up growth achieved (weight + length)
- Grow-In study criteria:
 - Weight/length z-score ≥ 0
 - Weight velocity increase +2 z-scores over 4-8 weeks
- Switch or transition to lower caloric density formula

ENDF = energy- and nutrient-dense formula; Goday, et al. J Pediatr Enterol Nutr.

Poll Question
Respond in the right-hand panel in the live event – Click 'SUBMIT' when done

Which patient scenarios are appropriate for an ENDF?
(energy- and nutrient-dense formula) *Choose all that apply*

- A. Malnutrition / Poor growth
- B. CHD + fluid restriction
- C. RSV + increased energy needs
- D. Additional calories/protein to supplement human milk

CHD = congenital heart disease; RSV = respiratory syncytial virus


CASE STUDY: BABY GIRL AVA

Once feeds increased:

- Refusal of feeds
- Extended feeding time (45-60 min.)
- Food intake low
- Taking 500 ml formula

Anthropometric changes:

- Weight/age ↓ 2 major percentiles within 8 weeks
- Length/age ↓ 1 major percentile



CASE STUDY: BABY GIRL AVA

4 weeks after regimen change:

- Weight/age increase from 9th to 25th %ile
- Amenable to solid foods
- Self-feeding
- Reduced parental anxiety



CASE STUDY: BABY GIRL AVA


FIGURE 1: CYCLE OF BIOLOGICAL, SOCIAL AND BEHAVIORAL EVENTS THAT HAVE LED TO FEEDING DIFFICULTIES AND FALTERING GROWTH*

1. Biological gastroenteritis

2. Biological diarrhea and vomiting leads to weight loss


3. Social anxiety about weight loss leads to compensatory techniques to increase weight gain

4. Behavioral & Biological altered feeding practice leads to feeding difficulties as natural hunger and satiety is ignored



ENDF for the management of growth failure


- ENDF provide optimal energy, protein, and micronutrients to support lean tissue gain for catch-up growth and support increased protein needs during critical illness
- ENDF is well tolerated
- Clinical evidence has shown ENDF promote catch-up growth in disease and non-disease related growth failure



ENDF = energy and nutrient-dense formula; Nutrition Management of Term Infants with Growth Failure
http://www.nutricia.com/UploadedFiles/Documents/Guidelines_and_Clinical_Resources/ENDF_Resources/Infant_Growth_Failure_Factheet.pdf Accessed February 10, 2022

Summary:

- Choosing appropriate formula is important for the pediatric patient when breastmilk is not available
- Complete assessment needs to be obtained by the HCP, including any medical conditions that may affect energy/nutrient needs
- Energy- and nutrient-dense infant formula is new to the U.S. and may be beneficial for infants with growth failure or increased energy requirements.
- Numerous formulas for dietitians to navigate; it's our responsibility to make sure we're appropriately providing formula to our patients



References

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