An Approach to Infant Formula

September 2018
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Disclosures

• We have no relevant financial relationships to disclose
• We do not plan to discuss any Unlabeled/Investigational uses of products
• This is in no way meant to discourage breast feeding
• Acknowledgements
Provider Panel

- Dr. Brian Birch, SLHS
- Dr. Cass Smith, Pediatric Gastroenterology, SLHS
- Dr. Jennifer Merchant, Neonatology, SLHS
- Dr. Scott Snyder, Neonatology, SLHS
- Dr. Tom Patterson, FMRI
- Dr. Angie Beauchaine, PHMG
- Dr. Charles (Chip) Webb, The Allergy Group

Learning Objectives

- Better understand the services and support WIC can provide to patients
- Differentiate between mild feeding problems and symptoms associated with allergy and malabsorption
- Know the indications for the use of extensively hydrolyzed formula (EHF) and amino acid formula (AAF)
Why this project came about

- Numerous patient requests for prescriptions for “Boutique” Infant Formulas

- Treasure Valley data from 2016 indicated that more than $1,000,000 spent by Medicaid on “Boutique” formula annually

Georgia’s Example

- Medicaid, AAP, and WIC worked together to develop Term and Preterm formula algorithms based on the best available data at the time:
  - As a result the use of “Boutique” formulas decreased from 14% to <1%
  - No increase in prescribing of Medically Necessary formulas
An Evidence-Based, Cost-Sensitive Infant Formula Algorithm for the Infant

Government Agencies

• WIC
  • Declining enrollment in Idaho (>50%)
  • Can serve Mothers and children up to 5 years of age
  • All Medicaid and more!!!
  • Federal rules/State processes
  • Block Negotiations on formula

• MEDICAID
  • Rules, regulations, processes
  • Without a medical director during this time
  • DME vs. Formulary
Questions addressed by the panel

- How long is a reasonable formula trial?
- Is a spit up formula medically necessary?
- GER vs. GER(D)
- Probiotics?
- Should Family History of food allergy affect formula choice?
- What are the clinical indications for using EHF and AAF? And for how long?
- Which infants should be fed on the preterm algorithm? And for how long?

What this approach is not:

- It is not a substitute for clinical judgment
- It does not address every possible feeding situation, just the most commonly encountered in general practice
- Reflective of new findings/data/recommendations after August 2018
- A Clinical Practice Guideline
- Part of the Medicaid or WIC process but it has been reviewed by the ICAAP.
WIC Preterm Infant Formula Algorithm

Decision making for formula choice in neonatal period and infancy

Growth goals, feeding intolerance, red flags/warning signs

No feeding intolerance

Feeding Intolerance/GER
Responsive to initial measures

Feeding Intolerance/GER
(Possibly MPA)
Responsive to EH formula

Feeding Intolerance/GER
(Likely MPA)
Responsive to AAF
No feeding intolerance; ideal nutritional plan

Products

- **HMF** - human milk fortifier is a hospital grade medical nutritional added to expressed human milk to provide additional kcals, protein, calcium and phosphorus required for optimal growth in preterm infants before hospital discharge (former severe IUGR or infants with osteopenia may require after discharge). It may be used up to 3-3.5 kg.

- **Preterm formulas** – (Examples are Similac Special Care (SSC), Enfamil Premature Formula (EPF)) is a hospital grade medical nutritional formula with added kcals, protein, calcium and phosphorus required for optimal growth in preterm infants before hospital discharge (former severe IUGR or infants with osteopenia may require after discharge). It may be used up to 3-3.5 kg.

- **Preterm infant discharge formula** (PDF) also known as Post-discharge formula. Examples (Neosure, Enfacare) – is designed for nutritional needs of former preterm infants at the time of hospital discharge. It can be mixed as formula (22 cal/oz can instructions or more per discharge plan) or can be added to mother’s milk to provide additional protein, calories, calcium and phosphorus required for optimal growth in preterm infants after hospital discharge.
Differences from term algorithm

- Most preterm infants require fortified mother’s milk (MM) or Preterm Discharge Formula (PDF) to get nutrients and calories needed for adequate growth and nutrition
- Continue fortified MM or PDF until 6-9 months corrected gestational age (CGA)
- Transition to unfortified MM or term “routine” cow’s milk base formula at 6-9 months CGA assuming catch up growth goals met
- Transition to whole cow’s milk at ~12 months CGA.

Feeding Intolerance/GER
Responsive to initial measures

Note Red Flags and Need for immediate evaluation
If symptoms meet severe criteria move to next level and consider specialty consultation
Hydrolyzed formulas are trialed before thickening; Avoid thickening until 42 weeks CGA
Feeding Intolerance/GER (Possibly MPA) Responsive to EH formula

* Move into Term Algorithm if responds to EH formula/dairy free maternal diet

* Note PCP evaluation is required for moving to EH formula

Feeding Intolerance/GER (Likely MPA) Responsive to AAF

*Referral to Peds GI / subspecialist

Note subspecialty referral
Backside of Preterm Algorithm provides nutrition guidance and growth goals.

Discharge Nutrition

What does the preterm baby need after discharge

- Likely less than required in preterm period
- More than a term baby (even if corrected 40+ weeks)
- Estimate >110 kcal/kg, ~2.5-3g/kg protein

Post-discharge Nutrition options are plenty:

- Breastfeed x 4-6 feeds/day + 2-4 fortified (22-24 cal/oz.) feeds
  (or 2-4 full PDF feeds/PT formula)
- Fortify all EBM (22-24)
- All formula: Post discharge formula “PDF” (i.e. Neosure/Enfamil)
  - 22 kcal/oz, higher kcal, protein, calcium/phosphorus & better Ca:Phos ratio (1.7:1) vs term formula, but not as high as preterm formula
  - Allows for catch up growth
  - Continue for 3-12 months CGA*

Vitamins/Iron:

- If all fortified EBM (22-24 kcal/oz) use 1 mL/day PVS w/Fe (400 IU Vit D, 10 mg Fe.)
- If >50-75% as formula, use 0.5 mL/day PVS w/Fe (200 IU Vit D, 5 mg Fe.)
- Note: term, BF babies only need Vit D (D-Vi-Sol: 1 mL/day = 400 IU/day Vit D.)
**Post Discharge Nutrition for the Preterm Infant**

CGA is important for nutritional and developmental assessment of former preterm infants until 2 years of age.

**Calculation for CGA - Adjustment for prematurity**: 40 weeks (term) – gestational age at birth = chronological age – adjustment for prematurity

<table>
<thead>
<tr>
<th>NUTRITIONAL INFORMATION</th>
<th>VITAMIN AND IRON INFORMATION</th>
</tr>
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<tbody>
<tr>
<td>• Optimal nutrition can prevent long-term problems with poor head/brain growth, slow weight gain, rickets, anemia, ultimate short stature and poor neurodevelopmental outcomes.</td>
<td>• After discharge, preemies can grow quickly, outstripping their mineral and Vit D stores and developing rickets. Adequate Ca, Phos, Vit D can prevent metabolic bone disease.</td>
</tr>
<tr>
<td>• Premature infants and those with risk factors for poor growth such as chronic lung disease, congenital heart disease and neonatal abstinence can better achieve optimal nutrition with use of Post-discharge formula (PDF), or fortified breast milk.</td>
<td></td>
</tr>
<tr>
<td>• PDF (Neosure or EnfamilCare) 2.3 cal/oz contains extra calories, protein, vitamins and minerals compared to standard formula.</td>
<td>• Iron is needed to replenish stores and prevent Fe deficiency.</td>
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<tr>
<td></td>
<td>• Low iron stores have been associated with neurodevelopmental impairments.</td>
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<tr>
<td></td>
<td>• Infant mult-vit + FE has (per ml) 10 mg FE, 400 IU Vit D.</td>
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<td></td>
<td>• Breast milk has (per liter) 0.1 mg FE, 20 IU Vit D.</td>
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<tr>
<td></td>
<td>• PDF has (per liter) 13.4 mg FE, 521 IU Vit D.</td>
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<tr>
<td></td>
<td>• Premature infants need 2.4 mg/kg/day of total FE (from foods or combo feeds &amp; supplement).</td>
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<td></td>
<td>• Term BFs infants need 1 mg/kg FE at 4 mo. of age.</td>
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<thead>
<tr>
<th>RECIPES</th>
<th>GROWTH GOALS</th>
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<tbody>
<tr>
<td>• To make PDF 24 cal/oz: Mix .9 oz of water and 5 unpacked level scoops of formula.</td>
<td></td>
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<tr>
<td>• Ready to feed liquid is recommended until 44 wks CGA to decrease risk of infection from bacterial contamination of powdered formula.</td>
<td></td>
</tr>
<tr>
<td>• Promote proper clean handling/mixing of powder especially for former premature infants.</td>
<td></td>
</tr>
<tr>
<td>• Use scoop provided in can for recipe.</td>
<td>We recommend use of:</td>
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<tr>
<td></td>
<td>• Fenton growth chart up to 50 weeks CGA.</td>
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<td></td>
<td>• Begin using the WHO growth chart from 44-46 weeks CGA to 2 years CGA. Fenton &amp; WHO overlap from 40-50 weeks and may be compared.</td>
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<tr>
<td></td>
<td>• Infant should have weekly weight checks at least until 1 month after discharge or 44 weeks CGA.</td>
</tr>
</tbody>
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1) Ideally catch up growth should occur by one year CGA for best neurodevelopmental outcome. The growth goals in above table account for catch up growth goals if you use CGA.

2) Change to term formula from post discharge formula at 6-9 months CGA if catch up growth goals achieved. If catch up growth is sub-optimal continue post discharge formula until 12 months CGA. Transition to whole milk is indicated at 12 months CGA if catchup growth goals achieved and for optimal neuro development continue whole milk until 2 years of age. If catch up growth suboptimal consider pediatric formula supplement (examples Pediasure, Boost Kids essentials). **At any point, if suboptimal catch up growth, consider individualizing growth goals using Peditools and consultingEditions with RD.**

3) HMF – Human Milk Fortifier is a hospital grade medical nutritional added to expressed breast milk to provide additional kcal, protein, Calcium and Phosphorous. It may be used up to 3-3.5 kg post NICU discharge or consult with Peds RD for former IUGR infants or those with osteopenia.

4) Preterm formula (examples SSC – Similac Special Care, Enfamil Premature) is a hospital grade medical nutritional formula with added kcal, protein, Calcium and Phosphorous. It may be used up to 3-3.5 kg post-discharge for former IUGR infants or those with osteopenia.

5) Alimentum may provide better Ca/Phos absorption than Nutramigen which is more important in this high risk population.

6) Consider

   • Peds RD consult.
   • Concentrated feedings may be required for growth.
   • Use of thickeners (infant cereal) before 42 weeks is not recommended.
   • Soy formulas are not recommended.

Please note products may change or new products may become available. If you have questions please contact peds RD.

References:


Catch up growth goals

- Catch up growth ideally occurs within 1 year
- Use CGA for growth goals

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Term – 4mo CGA</th>
<th>4-8 mo CGA</th>
<th>8-12 mo CGA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight gain</td>
<td>~6-8 oz/wk</td>
<td>~3-4 oz/wk</td>
<td>~1.5-2.5 oz/wk</td>
</tr>
<tr>
<td>Weight gain</td>
<td>~.18-.24 kg/wk</td>
<td>~.07-.12 kg/wk</td>
<td>~.04-.08 kg/wk</td>
</tr>
<tr>
<td>Length gain</td>
<td>~1 cm/wk</td>
<td>~0.5 cm/wk</td>
<td>~.4 cm/wk</td>
</tr>
<tr>
<td>HC gain</td>
<td>~0.5 cm/wk</td>
<td>~0.2 cm/wk</td>
<td>~.1 cm/wk</td>
</tr>
</tbody>
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Fenton chart

Good catch up growth
Neurodevelopment trumps all other goals – why we fortify

**NICHD Growth Observational Study**

![Graph showing growth data](image)

**Slower vs faster growth**

Follow-up at 7.5-8 years of age

*Neurocognitive* development

<table>
<thead>
<tr>
<th>Feeding</th>
<th>Faster growth</th>
<th>Slower growth</th>
<th>p</th>
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<tbody>
<tr>
<td>Average IQ</td>
<td>99.4</td>
<td>94.8</td>
<td>0.05</td>
</tr>
<tr>
<td>% with IQ &lt;85</td>
<td>14</td>
<td>31</td>
<td>0.02</td>
</tr>
<tr>
<td>% with CP</td>
<td>1.5</td>
<td>12</td>
<td>0.03</td>
</tr>
<tr>
<td>% with IQ &lt;85 and/or CP</td>
<td>15</td>
<td>38</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Extrauterine growth failure
B. Latal-Hajnal et al., J Pediat 2003;143:163-70

MDI at age 2 yr
AGA, no growth failure 101.7
SGA, catch-up 98.2

AGA, growth failure 94.9
SGA, no catch-up 94.7

Does slow growth have positive effects?
Slow growth may lead to more favorable cardiovascular health outcomes
It definitely leads to bad neurocognitive outcomes
Therefore, slow growth is unequivocally worse than faster growth
Disadvantages clearly outweigh advantages
The z score is the standard deviation (SD) above or below the mean. A z score of 0 is the same as a 50th percentile, ± 1.0 plots at the 15th or 85th percentiles, respectively, ± 2 at roughly the 3rd or 97th percentiles.

Children who are very large or very small can't be accurately tracked on the standard growth charts. To understand and assess their growth, their weight needs to be converted to z scores. Plotting their z scores against their age gives an accurate picture of their weight patterns.

I need Help – contact information

- Pediatric RD
- NICU RD
NICU Follow UP Clinic Growth Assessments

Suboptimal catch up growth example

- Scenario:
  - Decel in growth of former 25 4/7 week infant at ~4 months CGA.
  - Infant started solids before 4 months CGA.
  - Infant switched from Neosure to term infant formula 1 week after NICU d/c.
  - Infant is partially breast fed and supplemented with bottle feeds of term infant formula

- Recommendations:
  - RD recommended to resume Neosure or Enfacare for formula part of feeds.
  - Continue breast feeding.
  - Continue solids but do not let solids replace breast feeding or bottles.
  - Continue to provide breast milk or infant formula until at least 12 months CGA.
Suboptimal catch up growth example

- Wt/age %ile/z-score using WHO 0-2 growth charts
- Age of infant: 7 months
- Using CGA: 3 months 3 weeks  
  Z-score: -0.81
- Z-score: 0.41 when d/c'ed from NICU.
- Z-score: -0.81 when seen in follow up clinic.

Suboptimal catch up growth example

- Length
- OFC
Suboptimal catch up growth example

- Wt/Lt

![Graph showing growth trajectory]

Optimal catch up growth example

- Scenario:
  - Former 26 0/7 weeker
  - Infant discharged on breast milk fortified with Neosure 24kcal/oz then transitioned to exclusive breast feeding within a couple months after NICU d/c.

- Recommendations:
  - Continue breast feeding
  - Continue introducing solids/offering table foods
  - Provide breast milk (or term infant formula) until 1 year CGA
Optimal catch up growth example

- Wt/age %ile/z-score using WHO 0-2 growth charts.
- Infant age: 10 months 3 weeks
- CGA: 7 months 2 weeks
- Not using CGA for growth charts since catch up growth achieved

Z-score: -0.44

Optimal catch up growth example

- Lt
- OFC
Optimal catch up growth example

- Wt/Lt

Preterm algorithm page 1
Questions?

THANK YOU