From the President

With over 50% of the state’s children receiving assistance during the first year of life, WIC plays an enormous role in the health of Georgia’s children. At an annual food cost in 2012 of $224 million, WIC also represents a significant cost to our state. The Georgia Chapter of the American Academy of Pediatrics has collaborated with the Georgia Department of Public Health to bring you this Special Edition Newsletter providing resources to assist your practice with WIC Infant Formula questions. We are excited to provide “An Evidence Based, Cost-Sensitive Infant Formula Algorithm for the Infant on Georgia’s WIC” by Stanley Cohen, MD (Atlanta). Dr. Cohen, a pediatric gastroenterologist, is known nationally as an expert in the field of infant nutrition and was the founding Chair of the Chapter’s Committee on Nutrition. This algorithm was designed to assist physicians in prescribing appropriate infant formulas free from the marketing influence of formula manufacturers. We believe this algorithm will demonstrate through Georgia’s WIC Program that, when physicians prescribe formulas based on evidence based medicine, the program can save money and children will receive appropriate formulas for their specific medical needs. We hope you find this information helpful to your practice.

Robert Wiskind, MD, FAAP
Chapter President

Nutrition Updates

Upcoming Webinar…
The WIC Food Package & the Evidence-Based, Cost-Sensitive Infant Formula Algorithm for the Healthy Infant on Georgia’s WIC, May 30, 11am - 1pm.

This training will be presented by Stanley Cohen, MD, FAAP, and Kylia Crane, RD, LD, Nutrition Coordinator of the Georgia Chapter AAP. This training was developed in collaboration with the Georgia Dept. of Public Health, Georgia Academy of Family Physicians, and the Georgia OB/GYN Society. This training will be recorded for later viewing and CME will be provided.

Part 1
11:00 am - 11:45 am   The WIC Food Package
11:45 am – 12:00 pm   Question & Answer

Part 2
12:00 pm – 12:45 pm   The Evidence-Based, Cost-Sensitive Infant Formula Algorithm for the Healthy Infant on Georgia’s WIC.
12:45 pm – 1:00 pm    Question & Answer

To register visit: https://www4.gotomeeting.com/register/489726543
If you have any questions, contact Kylia Crane, RD, LD, at 404-881-5093 or kcrane@gaaap.org

EPIC Breastfeeding Program
Did you know there is a free breastfeeding education program in Georgia for health care professionals? The EPIC program (Educating Physicians In their Communities) serves private practices, medical and nursing schools, hospitals, and other groups of health care professionals, both large and small. Attendees earn free CME, GNA, LCERP, and/or CPE continuing education credits. Choose from three programs: Breastfeeding Fundamentals, Supporting Breastfeeding in the Hospital, or the new Advanced Breastfeeding Support program. To schedule an EPIC program, contact Arlene Toole, Program Director, at (404) 881-5095 or Andrea Perry, Program Coordinator at (404) 881-5068. Visit the EPIC website at www.GaEpic.org.

Georgia Breastfeeding Coalition
Are you a breastfeeding advocate? Would you like to stay abreast of current breastfeeding information and news? Then you should participate in the Georgia Breastfeeding Coalition! For information on the coalition please contact Claire Eden, Coordinator of the Georgia Breastfeeding Coalition at ceden@gaaap.org or (404) 881-5089.

Inside this issue...

- Prescribing Special Formulas & Medical Foods on Georgia WIC , pg. 2
- “An Evidence Based, Cost-Sensitive Infant Formula Algorithm for the Infant on Georgia’s WIC,”  pg. 3
Prescribing of Special Formulas & Medical Foods on Georgia WIC

Food Package Change

In 2009, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) significantly changed the food packages that participants receive to improve the nutrition and health of pregnant women, breastfeeding and non-breastfeeding postpartum women, infants and children up to age five. The food packages were designed to promote and support the establishment of successful, long-term breastfeeding, provide WIC participants with a wide variety of foods including fruits, vegetables, and whole grains, and provide greater flexibility in tailoring food packages to accommodate medical needs and cultural food preferences of WIC participants.

Impact to your practice

These changes not only affected the choices of foods that your patients can receive but it also required you to individualize the package based off your patient’s unique medical needs. Significant changes were made to the process of authorizing and prescribing special formulas & medical foods. Medical Documentation forms were created by Georgia’s WIC Program to make it easier to document the specific information required by the United States Department of Agriculture regulations.

Medical Documentation & Qualifying Medical Diagnoses

Medical documentation is required to prescribe special formulas & medical foods for a specific medical diagnosis, not based on preference or tolerance. These qualifying medical conditions include life-threatening disorders, diseases, or medical conditions that impair the digestion, absorption or utilization of nutrients that could adversely affect the patient’s nutritional status. These conditions include, but are not limited to premature birth, low birth weight, failure to thrive, inborn errors of metabolism & metabolic disorders, specific gastrointestinal disorders, malabsorption syndromes, immune system disorders, or severe food allergies requiring an elemental formula.

Non qualifying medical conditions that will not be accepted include non-specific formula/food intolerance, patient or parent/caregiver preference, or prescribing solely for the purpose of enhancing nutrient intake or managing body weight without the presence of an underlying medical condition.

Formula Request for Undiagnosed Conditions

There may be instances when the parents/caregivers of your patients request specific formulas. This could be for various reasons, however if this routinely happens for specific high-risk diagnosis/conditions that don’t match that patient’s medical needs, we encourage you to contact the State WIC Compliance Office. There have been reported incidents, which are currently under investigation. Collaboration with physicians and WIC is vital to educating families about appropriate nutrition and reducing fraudulent activities.

To access the GA WIC Medical Documentation Forms please visit: http://wic.ga.gov/hcprovider.asp
• Use Form #1 to prescribe special formulas and/or medical foods and to approve the WIC foods allowed based on a patient’s medical condition(s). Instructions and resources for form completion are included.
• Use Form #2 to provide referral data and to authorize special food substitutions for children.

These fillable forms can be saved, printed, signed and then faxed to the local WIC clinic or provided to the WIC participant. If you have any questions please contact the GA WIC Program at 1-800-228-9173.
The intent of infant nutrition is to provide an optimal feeding that meets the growing infant’s needs. That implies that for each infant there is indeed an optimal or “best” food. Breastmilk is considered the gold standard, delivering the infant’s necessary nutrients including factors that enhance brain development and immune regulation. Infant formula and their additives try to achieve similar outcomes for those who are not solely breast fed.

Breastfeeding infants should be given 400 i.u. of Vitamin D daily, and an iron supplement of 1 mg/kg/day may be needed from 4 to approximately 6 months of age, when iron fortified foods are usually introduced. If issues with nursing arise (such as failure to latch or poor suckling), or if the infant is having symptoms that may be related to the feeding, help is available so that breastfeeding usually can continue. In those rare instances when breastfeeding is contraindicated [1], when it is not desired, or unable to be accomplished despite help from experienced lactation experts, infant formulas can be used safely.

The choice of formula should be based on the infant’s health, associated conditions and cost (in terms of formula expense and decreased utilization of medical resources including office visits or hospitalizations). Because cost is a relevant factor, breastmilk with supplemental vitamins is far less expensive than underwriting formula throughout infancy (See the table below). Even among the different formulas, the cost difference between “routine” cow’s milk based formula and specialized formulas can be substantial. For WIC approved formulas, this translates into approximately $150 versus $510 or more per month for a single infant consuming 32 ounces of formula per day (See table).

Therefore, this cost-sensitive, annotated algorithm (Algorithm A) has been developed for primary care physicians to address appropriate infant formula utilization for the generally healthy infant* and appropriate reasons/methods to change formulas should they encounter common conditions such as gastroesophageal reflux [2], infantile colic or irritability [3], allergies [4], rectal bleeding/ colitis [5], malabsorption [6], or common but nonspecific signs and symptoms including constipation [7] and decreased weight gain [8]. The formula must be continued for a sufficient time to assure an adequate trial [9] provides the intended benefit of reducing the measurable costs for families and those organizations/programs underwriting the feedings. However, many causes of perceived feeding intolerance will not resolve by changing formulas. If a change does not result in symptom relief, return to the previous, often less costly, formula is appropriate.

Premature infants (<37 weeks) have unique feeding needs and a separate algorithm has been developed to assist with the requirements of this population (Algorithm B). The appropriate formula for the premature infant is determined by the infant’s gestational age, post-term age, any additional diagnosis and whether the infant is inpatient or has been discharged. Premature infants should do well on breastmilk with human milk fortifier added until the infant has achieved all oral feedings or a body weight of 1800g or nears the time of discharge from the hospital. Fortification of breastmilk is indicated for the preterm to meet protein and mineral needs for optimal growth, and Vitamin D supplementation is required as well. If the mother makes the decision to supplement with formula or not breastfeed, a premature formula should usually be prescribed. Additionally, soy infant formulas should not be used in the preterm infant weighing less than 1800g (4 pounds) due to increased risk of osteopenia and nutrient deficiencies. Preterm and immunocompromised infants are at risk for developing infection and should not receive powdered infant formula because it is not considered sterile. Only commercially sterile liquid formula is recommended prior to hospital discharge.

Upon discharge, most infants will be placed on a transitional formula of 22 cal/oz until 6-9 months adjusted in order to continue to meet the infant’s increased nutrient needs. Once the infant has reached 6-9 months post-term (adjusted age), the infant should be place on a “routine” cow’s milk based protein formula unless they have one of the underlying conditions illustrated in Algorithm A. Of note, issues of weight gain and reflux may be more frequent and significant in the pre-term infant and may require earlier evaluation. Infants with special needs or metabolic conditions, enteral infections, and toddlers are not included here since their needs are different.

Stanley A. Cohen, MD, FAAP
Kylia Crane, RD, LD

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Acknowledgement: We appreciate the thoughtful review and input from the numerous dietitians, pediatricians and pediatric gastroenterologists who have helped in improving every aspect of this project.

Pediatrics by the Sea
June 12-15, 2013
The Ritz-Carlton Amelia Island, Fla.

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# Average Monthly Cost of Georgia's WIC-Approved Infant Formulas*

*Average retail grocery price as of Nov 2010 – Jan 2011.

Amount of formula is based on an infant consuming 32 ounces (1 qt) a day for a month (30 days).

<table>
<thead>
<tr>
<th>Breastmilk with Vitamin D 400 l.u. daily supplement</th>
<th>Tier 1 Formula</th>
<th>Tier 2 Formulas</th>
<th>Tier 3 Formulas</th>
<th>Tier 4 Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Powdered (12 oz)</td>
<td>Powdered (12.3-12.9 oz.)</td>
<td>Powdered (16 oz.)</td>
<td>Powdered (14.1 oz.)</td>
</tr>
<tr>
<td></td>
<td>RTF (1 qt)</td>
<td>RTF (1 qt)</td>
<td>RTF (1 qt)</td>
<td>RTF (1 qt)</td>
</tr>
</tbody>
</table>
| “Routine” Cow’s Milk Based (Partially Hydrolyzed 100% Whey) | Yield 85 oz/32 oz=2.65  
30 days/2.65=11.32 cans a mo  
12 cans x price $12.49=$149.88 | Price $6.38 x 30 days=$191.40  
$149.88 | Soy Protein | Yield 90 oz/32 oz=2.81  
30 days/2.81=10.67 cans a mo  
11 cans x price $13.96=$153.56 | Price $6.55 x 30 days=$196.50  
$153.56 | Extensively Hydrolyzed Casein (100% casein) | Avg. yield 114 oz/32 oz=3.56  
30 days/3.56=8.42 cans a mo  
9 cans x price $24.84=$223.56 | Price $9.17 x 30 days=$275.10  
$223.56 | Amino Acid Elemental | Avg. yield 90 oz/32 oz=2.81  
30 days/2.81=10.67 cans a mo  
11 cans x price $46.53=$511.83 | -  
$511.83 | Cow’s Milk Based with Rice Starch | Avg. yield 91.5 oz/32 oz=2.85  
30 days/2.85=10.52 cans a mo  
11 cans x price $14.49=$159.39 | Price $6.16 x 30 days=$184.80  
$159.39 | Extensively Hydrolyzed Casein containing MCT oil (100% casein) | Avg. yield 112 oz/32 oz=3.50  
30 days/3.50=8.57 cans a mo  
9 cans x price $28.71=$258.39 | -  
$258.39 | Partially Hydrolyzed Casein & Whey (60% whey: 40% casein) | Avg. yield 87 oz/32 oz=2.71  
30 days/2.71=11.07 cans a mo  
12 cans x price $14.99=$179.88 | Price $6.99 x 30 days=$209.70  
$179.88 | Extensively Hydrolyzed Casein containing MCT oil (100% casein) | Avg. yield 112 oz/32 oz=3.50  
30 days/3.50=8.57 cans a mo  
9 cans x price $28.71=$258.39 | -  
$258.39 | Tier 4 Formula | Avg. yield 90 oz/32 oz=2.81  
30 days/2.81=10.67 cans a mo  
11 cans x price $46.53=$511.83 | -  
$511.83 | 

### Increasing caloric density of standard powdered infant formula*

<table>
<thead>
<tr>
<th>4 oz container</th>
<th>8 oz container</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 Kcal/oz</td>
<td>4 ½ scoops</td>
</tr>
<tr>
<td>24 Kcal/oz</td>
<td>5 scoops</td>
</tr>
</tbody>
</table>

* This does not apply to Cow’s Milk Based with Rice Starch and Neocate infant formulas.
Breastmilk or Tier 1 “Routine” Cow’s Milk Based Infant Formula

This algorithm begins with breastmilk as the optimal starting point for feeding infants. If the decision to not breastfeed or to supplement with infant formula is made, the infant should be started on Tier 1 “routine” cow’s milk based protein infant formula. The exception to this is an infant who has GI bleeding or strong family history of severe allergy. An evaluation is recommended to determine whether the mother’s diet can be modified or whether soy or an extensively hydrolyzed casein formula would be indicated.

1. Although breastfeeding is optimal for infants, there are a few conditions under which breastfeeding may not be in the best interest of the infant. Breastfeeding is contraindicated in infants with classic galactosemia (galactose 1-phosphate uridyltransferase deficiency); mothers in Georgia who are infected with human immunodeficiency virus (HIV); those with human T-cell lymphotropic virus infection; those with herpetic lesions when localized on the breast; those with miliary tuberculosis while contagious; those who are receiving antimetabolites, chemotherapy agents or a small number of other medications until they clear the milk; or those ingesting drugs of abuse.

Tier 2: Indications for use of Soy Protein, Cow’s Milk Based with Rice Starch, and Partially Hydrolyzed Casein & Whey Infant Formulas

2. Gastroesophageal reflux (ICD-9 530.81) is common in the infant. Concern arises when the reflux causes weight loss, failure to thrive, feeding difficulties, or it is associated with intermittent torticollis, respiratory illnesses/symptoms. A rice starch formula can be used though the effectiveness is limited if a gastric acid blocker is being used. Alternatively, infant cereal can be added to the current formula (adding 5 calories per teaspoon of infant cereal). Intestinal obstruction, pyloric stenosis, metabolic conditions, allergies, urinary tract and other infections, neurological problems and cancers can also present with vomiting and must be differentiated from gastroesophageal reflux.

3. Infantile colic is distinguished by inconsolable irritability for a period of approximately 2-4 hours per day between 3 weeks and 4 months of age. When irritability is more prolonged or occurs outside those time parameters, other conditions including allergies, Gastroesophageal reflux, or infection should be considered. Irritability is so nonspecific, it can represent reflux, allergy, intestinal “spasm” or a non GI cause. Evaluation is the key and any formula change should consist of a minimum trial of 3 – 7 days unless severe vomiting intervenes, requiring reevaluation. Again, if formula change does not resolve the problem, revaluation and return to the previous formula may be appropriate.

Lactose free formulas have only been helpful in exceedingly rare situations, since lactose intolerance is either genetic (usually starting in children after five years of age and rarely in infancy) or secondary and transient beginning as a result of damage to the intestinal villi (in which case the cause should be identified). It often is useful to consider a trial of soy formula for possible milk protein allergy (also alleviating lactose intolerance). Should that trial fail, reevaluation and progression along the algorithm are warranted.

4. Formula-induced allergies may present with rash (atopic dermatitis/eczema), vomiting, wheezing, and/or cough. They should be diagnosed carefully so that infants are not excluded from some formulas unnecessarily. Cow’s milk allergy (ICD-9 558.3) is the predominant cause. Studies demonstrate that 10-14% of infants with cow’s milk allergy also have reactions to soy. Those who have non-IgE reactions to milk may have a 40% cross reactivity to soy. Thus, the majority of infants are likely to tolerate soy and this allows most infants to use soy formulas safely and with less expense than immediately employing an extensively hydrolyzed casein formula ($14 vs 25 per can, a difference of over $70/month). This differs from other recommendations for an extensively hydrolyzed casein formula that may be more focused on efficacy and/or phytoestrogens contained in soy formulas, although the adverse effects and potential benefits of the phytoestrogens are yet to be clearly established. Because a single study evaluating partially hydrolyzed casein formula shows it may be equivalent to soy formula in lessening infant fussiness, it is only recommended for physicians and families who do not wish to use soy products. Since the current contract’s milk based formula contains partially hydrolyzed whey protein, further discussion of that Tier 1 formula is not needed here.

When a strong family history of allergy exists (evidence of atopy marked by asthma, eczema, allergic rhinitis or food allergy in a first degree relative), elimination of cow’s milk and soy products with the use of an extensively hydrolyzed formula may lessen the development of atopic dermatitis and childhood food allergies. As a result, the physician has the option of using a soy formula. Alternatively, an extensively hydrolyzed casein formula can be employed initially or after a soy trial. This remains an area of controversy as noted above—and as a result either option is warranted. Other studies advocate the introduction of infant foods (before 6 months of age) since that too may help prevent later allergy.

Tier 3 & Tier 4: Indications for use of Extensively Hydrolyzed Casein & Extensively Hydrolyzed Casein containing Medium Chain Triglycerides (MCT), and Amino Acid Elemental Infant Formulas

5. Rectal bleeding (ICD-9 578.9) in an infant, when infection is not the cause, can be the result of infant formula/food or a food in the mother’s diet (usually milk or dairy products). If mom is supplementing, consider eliminating intact milk based proteins from mom’s diet. Prompt evaluation, possibly including endoscopy, is usually needed to differentiate the cause, since the benign condition of lymphoid hyperplasia needs to be distin-
guished from Food Protein-Induced Enterocolitis (FPIES), which can result in severe vomiting, diarrhea, dehydration and potentially in life-threatening shock. Fortunately, these conditions can be resolved with elimination of the offending food. In this rare situation, milk is often the offending agent. The greater cross-reactivity to soy (30-64%) necessitates prompt transition to an extensively hydrolyzed casein formula.

6. Malabsorption (ICD-9 579) results in partially digested fat in the stool and often in distention, weight loss, a lack of weight gain and/or failure to thrive. The underlying cause should be identified so it can be treated effectively and resolved when possible. Changing the formula is often only a temporary measure, but until evaluation can occur, an extensively hydrolyzed casein formula with medium chain triglycerides (MCT) would be indicated. The presence of failure to thrive may implicate other factors or conditions to consider—these children should be promptly referred for evaluation if they do not respond to a formula change within days, at which point, an amino acid formula may be indicated.

7. While infant formulas are designed to produce stools close to the residue from human milk after digestion, the range of normal bowel movements vary between infants and even in the same infant. It is usually not necessary to change formulas because of less frequent or difficult bowel movements. Soy typically is the most constipating. The addition of rice cereal to any of the formulas often thickens stools as well. Hydrolysates often change the color of the stool, loosening them to some degree and provoking mucus that may accompany the bowel movements. Formulas with prebiotics often produce looser, more frequent stools as well. High sugar syrup, and prune juice can loosen stools but in doing so, they often cause considerable gas and discomfort. Extra water during the day, glycerin suppositories and/or a small amount of a laxative, such as dioctyl sodium succinate, may be useful as the first option for constipated infants.

8. Decreased weight gain may result from numerous causes, and is often associated with inadequate caloric intake or loss (vomiting or diarrhea). Diarrhea, malabsorption or vomiting require thoughtful evaluation and may require a temporary or enduring formula change. When these symptoms are not present and inadequate intake is the predominant symptom, formula change is generally not effective. Carefully guided concentration of the formula (1 additional scoop of “routine” formula powder in 8 ounces raises the caloric density to approximately 24-25 kcal/oz) or the addition of rice cereal to the formula in small quantities (1 tsp yields 5 calories given through Y or cross cut nipples) can assist weight gain in some instances. Careful, ongoing monitoring is necessary to monitor weight gain and the baby’s general condition, remembering that renal solute load is increased along with the increase in protein and nutrients. When actual weight loss or persistent lack of adequate weight gain is present, expeditious evaluation is important.

9. The adequacy of a formula trial depends on the underlying symptoms or supposition as to their cause. For vomiting or diarrhea, this may take 1-3 days to see symptoms improve; for reflux, 1-7 days; irritability 1-7 days; constipation 3-14 days; allergy 1-30 days.

Introduction of “routine” cow’s milk based formula after an infant has been on an extensively hydrolyzed casein formula or an amino acid elemental formula should proceed slowly and in small increments. Symptoms that prompted the use of these formulas will dictate when a “routine” cow’s milk based protein formula will be introduced. Symptoms such as GI bleeding or soy intolerance would allow a trial of a “routine” cow’s milk based formula for introduction at 6-9 months, however more severe symptoms such as malabsorption or severe allergies would necessitate delaying any introduction of “routine” cow’s milk based formula before 12 months old.

New Book By Stanley Cohen, MD

Book Signing at Pediatrics by the Sea
The Ritz-Carlton
Amelia Island, Fla
Saturday, June 15, 2013

Also available through Amazon.com


Visit the Chapter website for more information regarding these events...www.GAaap.org

CALENDAR

Upcoming Webinar:
The WIC Food Package & the Evidence-Based, Cost-Sensitive Infant Formula Algorithm for the Healthy Infant on Georgia’s WIC
May 30, 2013
11am - 1pm
Call for registration information.
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