MeritCare Medical Center **12/2009**

Aunt Cathy's Guide to:

Choosing Appropriate Infant Milks and Formulas

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Part 1: Nutrition issues in breastfeeding.

The ideal food for most babies is **human milk.** Even for this nearly Universal Truth however, there are exceptions (e.g. infants with the rare inborn metabolic error "galactosemia" may not have human milk.) Formulas are attempts to provide similar nutrition for healthy babies who are not breast-fed, or to meet the nutritional requirements of infants with special health problems. The American Academy of Pediatrics recommends human milk for at least the first year of life.

Although it is less common in America than in other nations, nursing through the second year (or even longer) is also beneficial and the practice is increasing. [However, it is important to note that, for reasons described later, it is not recommended to breastfeed the baby exclusively without the addition of selected other foods after six months, and without vitamin D supplementation throughout breastfeeding.]

This part of the paper will focus primarily on some evolving issues regarding the assurance of macronutrient and micronutrient adequacy in human milk. Commercial formulas and cow's/goat's milk ssues in infant feeding will follow.

[For a more complete discussion of the many benefits of human milk and a review of the data now available that demonstrates its clear superiority to any formula for most babies, please see my separate paper entitled "Some Issues in Breastfeeding."]

Macronutrients: Carbohydrate, Protein and Lipids

The best infant diets are those which provide adequate but not excessive amounts of calories, protein, vitamins, minerals and fluid, with a distribution of calories from carbohydrate, protein and fat in the "desirable range". This is the range within which babies have been seen to grow well without excessive metabolic stress. (Fomon) It appears that most babies are fairly flexible little people and tend to do well within a fairly broad range of feeding practices.

Percent of calories from:	**CHO**	**PRO**	**FAT**

Desirable range:	35 - 65	7 - 16	30 - 55
Human milk:	38	7	55

Why is human milk at the lower end of the range in protein?

Human milk has a protein content on the lower end of the range and a fat content on the upper end. This is acceptable because the forms of protein and fat are so perfectly suited to baby's immature digestive and metabolic systems that absorption and utilization of these nutrients is optimal. The protein content will continue to stay in the appropriate range even when mothers are protein deficient. This is because protein goes into the milk at mother's expense if there is an inadequacy. No other food has protein that is so well absorbed or well utilized, so it is best to avoid the extremes of the "desirable range" if something other than human milk is fed.

Neither the protein nor calcium content of the milk is greatly affected by current maternal diet, but that does mean that maternal dietary inadequacies will be compensated for by a loss from the mother's stores or tissues. For that reason, a poor intake is certainly not optimal for mother's health. **Mother and baby should not be in competition for nutrients**. There are also specific examples of the many benefits associated with assuring the adequacy and absorbability of maternal calcium intake during both pregnancy and breastfeeding.

For example, the adequacy of current calcium intake and absorption has been shown to decrease the developing baby's exposure to harmful substances that may be stored in the mother's bones. This includes heavy metals like lead. If the mother has to mobilize her bone calcium to replace blood calcium lost to the fetus or the milk, any lead present in her bones would be freed and enter the bloodstream along with the calcium.

Do breast-fed babies need anything else?

Unlike the protein content, maternal diet/stores CAN be a factor in the amount of several vitamins and minerals in mother's milk. These include iodine, zinc, B-vitamins and vitamin C, so attention must be paid to the adequacy of her intake. The fat soluble vitamins (A, D, E and K) are now being re-evaluated in this regard as well. **There are also important substances like DHA (Docosahexaenoic Acid) being studied. DHA is an omega-3 fat critical to brain and retinal development.** DHA levels can be quite variable depending on the mother's current intake and stores, and worldwide the DHA content of human milk has been found to be decreasing. This is now seen to be a serious issue during pregnancy as well. Some individuals have now been found to have more difficulty than other people in making DHA and the related omega-3 fat EPA. Usually these fats are made from the omega-3 "essential fatty acid" precursor linolenic acid found in plants and plant oils. Clearly, we need to look closer at the adequacy of the mother's diet and nutritional status in general.

Many health professionals erroneously assume that mother's milk will have all the nutrients needed by the baby regardless of mother's nutrient intake. It is the same concept

as the old "perfect parasite" theory of a generation or two ago that presumed that babies simply took whatever they needed from the mother's body during pregnancy. That view has been disproved and discarded long ago, but for some reason the same old idea continues to be erroneously applied to the concept of nutritional adequacy in lactation. The following sections describe some of these issues in the current research.

Micronutrient Issues: Vitamins

Vitamin D

An epidemic of vitamin D inadequacy in people of all ages has been the focus of literally hundreds of recent reports in the scientific literature. For years, vitamin D inadequacy has been assumed to be a non-issue because most of the time, deficiency lacks the only symptom that has traditionally led physicians to even look for it: that is, overt bone deformity in children. It has long been (erroneously) assumed that everybody easily produces generous amounts of vitamin D from the action of sunlight on skin. Additionally, as vitamin D is found naturally in very few foods, it has been added to milk and a few other foods more recently in the US. However, the **amount** currently added is insufficient to maintain appropriate blood vitamin D levels in most cases. **Vitamin D deficiency is now recognized as very common, very dangerous, very often unevaluated and rarely corrected. The health consequences are very serious, but the entire situation is very easy to fix once the issue is recognized.**

Maternal/child vitamin D deficiency issues deserve a close look here.

[The following is an excerpt on specific vitamin D deficiency issues in lactation from my paper "Aunt Cathy's Guide: My Current Top Five Ways to Improve Your Family's Nutrition."

There is <u>much</u> more on multiple vitamin D issues in that publication, including recommendations for action. A version is also available with many references from reports in the scientific literature.]

Vitamin D Inadequacy in Breastfeeding Alert

Interestingly, mother's milk is an amazingly nutritious food and breastfeeding is certainly encouraged. However, the milk does not contain vitamin D. This is probably because when people were invented nobody lived in Fargo. As an adaptation to live well up here, we need to have a furnace, a coat, really good mittens and vitamin D. It is that simple.

Because of the finding of serious vitamin D deficiency in many breast-fed babies, in 2003 the American Academy of Pediatrics recommended that breastfed babies be given "at least 200 iu of vitamin D by two months of age." **In 2008 that recommendation was changed to**

400 iu/day for ALL infants and they recommended starting it right away because many babies were actually born with inadequate stores of vitamin D because their mothers were deficient during pregnancy (in spite of taking prenatal vitamins.)

This change brings US recommendations in line with those of their Canadian colleagues who have recommended 400 iu for babies, and at least 800 iu for everyone else up there for several years now. Here are some details of the kind of research that led to this change in recommendation:

A recent study in Boston of 380 healthy infants and toddlers who were seen for a routine health visit found that the prevalence of vitamin D deficiency (defined as ≤20 ng/mL) was 12% (44 of 365 children), and 146 children (40%) had levels below an accepted optimal threshold (≤30 ng/mL.*)

[Prevalence of Vitamin D Deficiency Among Healthy Infants and Toddlers. ***Arch Pediatr Adolesc Med.*** 2008;162(6):505-512. Neonatal vitamin D status at birth at latitude 32 degrees 72': evidence of deficiency. J Perinatol. 2007 Sep;27(9):568-71.]

The same Boston authors studied the therapeutic amounts of vitamin D supplementation needed to correct the low vitamin D status of the children. They concluded that these two approaches were effective for bringing low vitamin D levels into the range of ≥30 ng/mL* within a 6 week treatment period: Daily 2000 IU vitamin D2 or D3, **or** Weekly 50,000 IU vitamin D2 .

[Treatment of Hypovitaminosis D in Infants and Toddlers. J Clin Endocrinol Metab. 2008 Apr 15.]

*However, note that a report described earlier suggested that the healthiest ranges of serum vitamin D may in fact be above this "optimal threshold" of ≥30 ng/mL, and that it might be in the range of 36-48 ng/mL.

[Optimal serum 25- hydroxyvitamin D levels for multiple health outcomes. Adv Exp Med Biol. 2008;624:55-71.]

There are concerns about inadequacy of vitamin D in breastmilk (or in any infant feeding regimen) in MANY areas beyond its relationship to the pattern of bone deformity we call rickets. Most are not visible.

Inadequacy of vitamin D is now known to be an independent risk factor for an ever-widening range of negative health conditions:

Diabetes (both **Type 1** and **Type 2)** **Osteoarthritis** and **Osteoporosis**

Multiple Sclerosis	**End-Stage Renal Disease**
Lupus, Fibromyalgia and **Scleroderma**	**Depression**
Cardiovascular Disease (both heart attack and especially congestive heart failure)	**Cancer of the Breast, Colon, Prostate, Pancreas** and other types
Sarcopenia (muscle weakness) and **Falls**	**Developmental Problems**
Rheumatoid Arthritis	**Immune System Compromise**
Pre-eclampsia in Pregnancy	**All-Cause Mortality**

Clearly, assuring the mother's vitamin D adequacy is very important to her health as well as the health of her infant, but this is a topic outside the scope of the present article.

"The recommended adequate intakes for vitamin D are inadequate, and, in the absence of exposure to sunlight, a *minimum* of 1000 IU vitamin D is required to maintain a healthy concentration of 25(OH)D in the blood."

Optimal serum 25- hydroxyvitamin D levels for multiple health outcomes. Adv Exp Med Biol. 2008;624:55-71.

Prevalence of Vitamin D Deficiency Among Healthy Infants and Toddlers *Arch Pediatr Adolesc Med.* 2008;162(6):505-512. Treatment of Hypovitaminosis D in Infants and Toddlers. J Clin Endocrinol Metab. 2008 Apr 15.] Prevalence of Vitamin D Deficiency Among Healthy Infants and Toddlers *Arch Pediatr Adolesc Med.* 2008;162(6):505-512. Vitamin D Status: Measurement, Interpretation, and Clinical Application. Ann Epidemiol. 2008 Mar 8. Sunlight, UV-radiation, vitamin D and skin cancer: how much sunlight do we need? Adv Exp Med Biol. 2008;624:1-15. Vitamin D deficiency: a worldwide problem with health consequences. Am J Clin Nutr. 2008 Apr;87(4):1080S-6S. Neonatal vitamin D status at birth at latitude 32 degrees 72': evidence of deficiency. J Perinatol. 2007 Sep;27(9):568-71.Am J Clin Nutr. 2004 Mar;79(3):362-71)] [See my "Top Five" handout for much more on vitamin D.]

Vitamins B12 and B6

The B vitamins play many critical roles in metabolism and inadequacy can compromise the growth and development of the baby. An America, serious deficiency of B vitamins is presumed to be extremely rare, but it is now recognized that some of them need a much closer look. Most health professionals are aware that alcohol abuse frequently results in dangerous deficiency of thiamin and folic acid, and of course, perinatal alcohol abuse is even more problematic. But there are other specific concerns about vitamins B12 and B6 that deserve some special attention during both pregnancy and breastfeeding.

As described earlier, for some nutrients (e.g. calcium and protein,) a relatively deficient mother will still provide a good amount to the fetus/baby even at her own body's expense.

However, **all of the water soluble vitamins (B vitamins and vitamin C) will fail to be provided optimally to the baby if mother is deficient … maternal needs for these nutrients must be met before she "shares."**

Vitamin B12

Recently, for example, it was found that **babies of mothers who had an inadequate intake of vitamin B12 have deficiency levels even if the mother's labs show her own vitamin B12 level to still be in the normal range.** Deficiency is extremely injurious to the nervous system of both mother and baby. The following are three circumstances that put people at special risk.

1. Because vitamin B12 is found naturally only in animal products, **vegans are well known to be at great risk** unless they take a vitamin supplement containing vitamin B12. There are MANY reports in the scientific literature about this problem and the damage to the infants when it occurs during pregnancy or lactation. <u>But simply assuring that the vegan mother has been taking a supplement regularly for quite some time is all one needs to do</u>.

   But if she has <u>not</u> been taking one, or has only begun to take vitamin B12 during pregnancy, for example, her vitamin B12 status could easily still be too low for the fetus/baby to receive the needed amount for optimal development. As vitamin B12 is extremely non-toxic, ideally in this situation a physician or other provider should consider giving her a therapeutic level to correct a suspected deficiency right away.

2. One of the less well recognized **emerging risk factors for vitamin B12 deficiency is among people who have GERD (gastro-esophageal reflux disease) and use PPI (proton pump inhibitor) medications that prevent gastric acid production.** Natural sources of vitamin B12 require the presence of gastric acid before it can be absorbed. [This is different from the role of Intrinsic Factor in vitamin B12 absorption.] **People who use these medications cannot absorb vitamin B12 from natural sources, but they can easily get around this problem by taking a supplement that contains vitamin B12 …** just like vegans but for a different reason. In this case it is because the crystalline B12 in supplements does not require the presence of acid in order to become absorbable. But also just like vegans, if she has been taking the medication for a long time and only recently begun to take supplemental vitamin B12, there may be a degree of deficiency sufficient to warrant giving a therapeutic amount.

3. It is becoming increasingly common for women of childbearing age to have undergone **bariatric surgery (gastric bypass for weight loss)** prior to becoming pregnant. Long-term vitamin and mineral status in the women is rarely evaluated, but when it IS, there are several nutrients commonly found to be seriously inadequate even with the use of prescribed supplements. Additionally, months/years after the actual surgery many woman stop taking their prescribed supplements. This is even more common among people with less ability to afford them.

   Deficiency of vitamin B12 is just one of several problems that are of great concern in the special pregnancy/lactation context. This mother may have <u>several</u> severe

nutritional problems that are very likely to have gone unrecognized. Unfortunately, the simple multivitamin that solved vitamin B12 problems for vegans and PPI users is unlikely to be an adequate intervention here. What should be done about it is outside the scope of this paper, but vitamin B12 shots would likely be a necessary. Heightening the awareness of healthcare professionals about the existence of the problem is a good place to start.

[Please see my "Vitamin B12" handout for more information about problem issues with this nutrient.]

Vitamin B6

Adequacy of **vitamin B6** in exclusively breast-fed infants has been found to rely often on gestationally accumulated stores. **For some infants, human milk alone without supplemental foods may be insufficient to meet vitamin B6 needs after 6 months of age** (*Pediatr Gastroenterol Nutr* 1996 23(1):38-44.) Earlier introduction of meats or the use of a multivitamin drop will correct this situation. Most infant vitamin drops contain vitamin B6 and they often contain iron, but they do not contain zinc. Meats are the richest sources of vitamin B6 and well-absorbed iron and zinc … the three nutrients that have been observed to "drop out" of breastmilk after 6 months. This argues for reversing our most recent traditional pattern of introduction of solids by introducing meats by about age 6 months instead of introducing it after 10 months or later. This problem can also be addressed by using a crushable-type multivitamin with minerals instead of an infant vitamin drop; it contains all three of the micronutrients (zinc, iron and vitamin B6) that decrease so precipitously in mother's milk after 6 months. It can be crushed and added to baby food.

Micronutrient Issues: Minerals

Iron

The **iron** inhuman milk is very well absorbed – the vest of them all, with estimates between 25% and 50% absorption. Compare this with the next best source of iron (meats, at about 20%) and with the much less absorbable form in plants and pills (which are 0.25-2% absorbed.) But although it is well absorbed, but there is not a great deal of it. Most term babies are presumed to have enough iron stored up so they do not "run out" until about 4 months of age. Since this is the age at which many babies begin to have the developmental skills to eat from a spoon, providing foods that are good iron sources plus the iron in mother's milk may be adequate.

On the other hand, one might argue for providing an additional source of iron (e.g. an iron drop) to avoid emptying baby's iron reserves before he/she actually "runs out." Premature babies often have poorer iron stores because the iron (like zinc, calcium and other minerals) is stored in the baby's body primarily in the third trimester of pregnancy. The iron "cost" of growth is high, and inadequacy of iron stores can have serious consequences. Anemia is associated with decreased ability to learn and to pay attention that can remain a problem for months after the anemia itself is corrected by treatment. Additionally, the "presumed iron stores" of the average

term baby are just that … "presumed," not "assessed." Historically this approach has not always served us well.

Iron-deficiency anemia has also been found to be associated with increased likelihood of being identified as mildly or moderately mentally retarded in school. This is likely because iron has many important rolls in all of the cells of the body, including such tasks as oxygen transport, energy production, protection against environmental toxins, and brain neurotransmitter function. As was the case with calcium, good iron status also decreases the absorption of lead, a known agent of severe injury to brain, bone and kidneys. Iron deficiency increases absorption of iron from the environment, and the process accidentally increases the absorption of lead as well.

Reliance on hemoglobin as a marker for iron status is risky without also having information about the adequacy of the person's iron intake. This is because hemoglobin levels often remain normal until iron stores are depleted. A low hemoglobin is a sign of trouble, but a normal one tells very little about the status of iron stores. Measures of iron stores (like ferritin) are rarely used at present in evaluating babies who appewar to be healthy. But asking specific questions about regular iron supplement use and/or meat consumption tells us a lot about the likelihood of their being an unrecognized iron deficiency in a particular woman or infant.

Providing additional iron may decrease the effectiveness of one of the substances in human milk that helps to control bacterial growth: lactoferrin binds iron that E. coli bacteria in the gastro-intestinal tract need in order to reproduce. Giving additional iron will make more iron available to the bacteria, too. It is not clear that this is a big problem, however, since there are many other bacteria-fighting substances in human milk that are not affected by the presence of iron. The fact that most formula-fed infants thrive while regularly receiving generous dietary iron that is not bound to lactoferrin suggests that is not a major problem. After all, these babies receive none of the many other protective substances in breast milk either.

Complicating the picture is the finding that the iron in infant cereal that has traditionally been used to provide iron in baby's diet may not be as well absorbed as had been believed. Its ability to provide useable iron to the infant has been questioned, but so far no one has questioned whether iron provided in the form of fortified cereal increases the risk of E coli infection in breast-fed (or any) infants. Two practices can sometimes have an effect on the absorption of iron in infants:

1) Iron supplements given with a milk or formula feeding are likely to be less well absorbed compared with supplements fed with an acidic food or meat. Additionally, there is some ability to up-regulate iron absorption if stores are low.

2) Although in some cultures it is common to feed tea to infants, the tannins in it greatly reduce inorganic iron absorption in both infants and adults. This does not appear to be a problem for organic iron forms such as are found in breastmilk and meats, so feeding tea to breastfed infants does not induce iron deficiency anemia the way it can in those not breastfed.

   Interestingly, in some world situations the traditional feeding of tea to infants has actually been of great benefit in terms of child survival for the simple reason that the water fed to baby has been boiled and germs have been destroyed. Together, protective

mother's milk and boiling any water fed to baby are a terrific combination where bacteria and parasites make the water unsafe.

For more on iron ins-and-outs, please see my handouts
"Nutrition Support of Iron Deficiency" and "Nutrition Support of Hemochromatosis Therapy."

Zinc

Zinc has been found to need some attention in breast-fed infants. The same mineral storage patterns are seen for both iron and zinc, with the third trimester being the major period of mineral accretion in the fetus. For this reason, preterm infants are especially likely to have poor zinc stores.

For term infants, the combination of a well-nourished mother who provided normal fetal zinc stores and then provides human milk meets growth needs until about age six months. After that time, zinc may be inadequate as described earlier. Of course, a history of poor zinc nutrition of the mother complicates the picture further. Some studies have found that zinc supplementation of exclusively breastfed infants in these circumstances improves growth or other parameters of zinc adequacy [e.g. *Lancet* 2000 Jun 10;355(9220.)]

Supplementing a mother who has adequate zinc status does not correct this problem because the zinc content of the milk begins to drop regardless of her zinc status. As described earlier, a change in recommended "starter food" patterns has been suggested that includes an earlier introduction of meats (the most abundant source of bioavailable forms of both iron and zinc, and also a generous source of vitamin B6) in breast-fed infants [*Acta Paediatr* 1998;87(6); *J Mammary Gland Biol Neoplasia* 1999;4(3)].

Again, note that infant vitamin drops do <u>not</u> provide zinc (or any minerals except iron and sometimes fluoride) and they contain no folic acid. So if earlier introduction of meats is undesirable, the best way to assure adequacy of zinc, iron and vitamin B6 would be to give a crushed chewable children's multivitamin with minerals. Nutrient levels will not exceed safe ranges with this dosage, and this approach also provides baby with the 400 iu of vitamin D recommended for all infants by the American Academy of Pediatrics and the Canadian health groups as well. If texture is an issue, the pill can be crushed to a fine powder using a small mortar and pestle. These are sold in kitchen stores and discount stores (often for $10 or less) because they are used to crush fresh spices. The powder can be mixed into any baby food.

More information about the zinc content and foods, zinc absorption
and some special zinc-related issues in fetal alcohol syndrome, are included in my handouts:
"Nutrition Support of Iron Deficiency" and "Thinking about Prenatal Nutrition and Fetal Alcohol Syndrome (FAS.)"

Iodine

Another nutrient problem that has recently been found to need more attention is IODINE DEFICIENCY. In many parts of the world including the US iodine deficiency is common, and the traditional international approach to solving it has been to add iodine to salt. However, it appears that the amount obtained from iodized salt is actually not sufficient during pregnancy, and that even in areas that have been thought to have corrected iodine deficiency many women obtain too little.

Iodine deficiency is the number one cause of preventable mental retardation in the world. The resurgence of the problem of iodine deficiency in the US has great importance in pregnancy and lactation in particular because of the devastating effects on the intellectual development of the child. Iodine deficiency can also result in a serious lack of energy in anyone affected because it impairs the function of the thyroid gland. **The World Health Organization is now increasing the recommendation for iodine intake, especially in pregnancy.**

Here is an excerpt from a presentation by UNICEF Deputy Executive Director Kul Gautam:

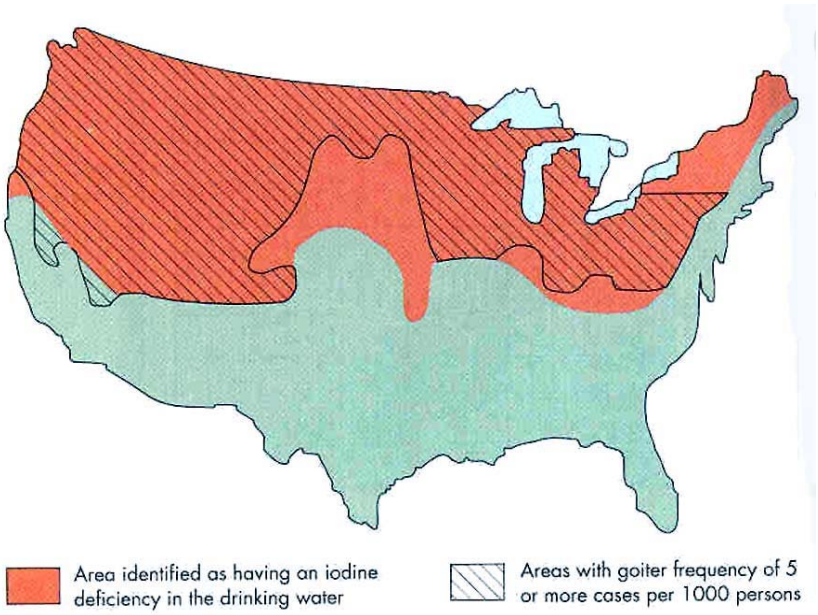
"… IDD is the single greatest cause of preventable mental retardation. Severe deficiencies cause cretinism, stillbirth and miscarriage. But even mild deficiency can significantly affect the learning ability of populations. Scientific evidence shows alarming effects of IDD. Even a moderate deficiency, especially in pregnant women and infants, lowers their intelligence by 10 to 15 IQ points, with incalculable damage to social and economic development of nations and communities. Today over 1 billion people in the world suffer from iodine deficiency, and 38 million babies born every year are not protected from brain damage due to IDD…"

UNICEF Deputy Executive Director Kul Gautam
This quotation comes from the website http://www.saltinstitute.org/Issues-in-focus/Food-salt-health/Iodized-salt-other-additives. It has much more information about the problems of (and solutions for) IDD.

[For more detail on the most recent research on this topic in the scientific literature, please see my handout "New Attention to an Old Problem: Iodine Deficiency in Pregnancy and Lactation"

The area of the United States that used to be designated the "goiter belt" because of low iodine in the soil is shown on the map on the next page. The actual iodine content of foods depends on where they were grown, and some protection has likely been provided to the low-iodine regions by the fact that at least some produce may have been grown in an iodine-sufficient region. This is a new issue to keep in mind as we promote growing one's own food and buying from local producers instead of transporting produce from far away. Local food production is terrific for many reasons, but if one lives in n iodine-poor region, it is important to assure iodine sufficiency via a demonstrably adequate intake from some form of iodine supplement.

Map showing spatial correlation between the former "Goiter Belt*" in the northern U.S. and areas where the iodine content of drinking water is naturally low. **www.uwsp.edu/gEo/faculty/ozsvath/images/goiter_belt.htm**
[*Goiter is an abnormal enlargement of the thyroid gland, often due to iodine deficiency.]



Back home in America, many people under age 50 who live in iodine-poor regions of the country are quite unaware that they should select "iodized salt." The public health hoopla that accompanied the iodizing of salt in the mid 1950s somehow faded away and the issue went off the radar. Many people of child-bearing age today have no knowledge that this was once a widespread deficiency disease in the US of critical importance to everyone's health, and especially the development of infants and children … and they don't know it has come back.

Even when one intends to buy the iodized salt, the packaging is often very similar and they are side-by-side on the shelf at the store.

Most specialty salts that are popular now, like sea salt or exotic salts, are also not iodized. Additionally, we frequently are advised to cut back on salt for other health reasons, which can further limit iodine intake. The choice of salt as the way to supplement iodine was made well before ideas of sodium restriction were common for health reasons. Other factors have made an inadequate intake much more likely today, as described in the excerpt below from a website on this topic:

"…In the United States, from the outset, salt producers cooperated with public health authorities and made both iodized and plain salt available to consumers at the same price. **Even so, the Salt Institute estimates that only about 70% of the table salt sold in the United States is iodized.**

Salt used in processed foods is not iodized. Given that people are cooking less at home and buying either restaurant or processed foods, **iodine intakes in the U.S. have declined from about 250 µg/day to 157 micrograms/day. Public health authorities recommend 150 µg or more** and the need is

particularly acute for expectant mothers. Daily Iodine intakes of 1,000 - 1,100 µg are safe for adults and children over 4 years of age…"

http://www.saltinstitute.org/Uses-benefits/Salt-in-Food/Essential-nutrient/Iodized-salt

Also, because it has long been assumed that the iodine deficiency problem was "solved" **in the US, at present many vitamin pills contain no iodine at all, including many prenatal vitamins.** So, this is one more nutrient that a person should check for when they select a multivitamin. Choose iodized salt if you do use salt, and people who use little salt should be sure to find an iodine supplement, especially if they live in the northern half of the country.
The problem of iodine deficiency needs to be put back on our radar; this is a very newly recognized and extremely important health problem that needs attention.

[**Some newer references:** Iodine Content of prenatal multivitamins in the United States. NEJM. **2009**;360:939-940. Iodine deficiency in pregnancy and the effects of maternal iodine supplementation on the offspring: a review. Am J Clin Nutr. **2009** Feb;89(2):668S-72S. Iodine status of the U.S. population, National Health and Nutrition Examination Survey 2003-2004. Thyroid. **2008** Nov;18(11):1207-14.]

Fluoride

Fluoride is low in human milk and whether the mother's fluoride intake affects the amount in milk is still subject to some debate. The recommendations for using fluoridated water, fluoride drops, fluoride toothpaste and topical fluoride treatments have changed many, many times over the years that I have been involved in pediatric nutrition.

The American Dental Association has a current list of very specific recommendations on all aspects of the topic of fluoride as it relates to dental issues. It is available at this website:

http://www.ada.org/public/topics/fluoride/infantsformula.asp

Miscellaneous: Omega 3 Fats in Mother's Milk:

Fetal and Infant Development Issues:

The discussion of omega-3 fats in particular is included here because it is unrelated to the macronutrient function of fat discussed later… that is, as a sources of calories. Oils rich in omega-3 fatty acids perform many specific important metabolic functions. They have important implications in pregnancy and infant nutrition in particular. DHA (a long-chain omega-3 fatty acid) is a major fat of the brain, and research is growing that providing some pre-formed DHA is advantageous. Other health benefits continue to be identified, including the (so far) a possibility of decreased risk of preterm delivery and decreased risk of allergies.

[There are many additional health benefits identified for other age groups as well, as described in some detail in my paper "All Those Lipids: Recommendations for Using Different Types of Fats and Oils (Omega-3, Omega-6 and Monounsaturated Oils)"]

The particular concern for the breastfed baby is the finding that the amount of DHA in pregnant women and breastfeeding women around the world has been decreasing with changing diets. Fish and fish oil provide ready-made DHA. Taken during pregnancy it improves the DHA content of the fetal brain, and during lactation it increases the amount of pre-formed DHA provided to the infant.

The "pre-formed" part is important: it is now recognized that there is considerable variation in the ability of different individuals to efficiently operate the pathways that make alpha-linolenic acid into EPA and then into DHA. Alpha-linolenic acid is the form of omega-3 fat found in plants. Flax, canola and walnut oil are the most generous sources. Many --- perhaps even most ---people can use it to make the DHA as needed. But for many people there is a clear benefit from getting at least some EPA and DHA "ready-made" in fish and fish oil supplements. This appears to be particularly true during pregnancy and lactation.

DHA made from an algae source is also available as a supplement, and it is the kind used in some supplements designed for pregnant women and in some children's gummi supplements. This is the same form used to provide pre-formed DHA in infant formulas. It can be a reasonable source of DHA depending on the dosage or amount-per-gummi. However, it does NOT contain any EPA … the omega-3 fat between linolenic acid and DHA.

EPA has many metabolic roles in the body involving inflammation, blood clotting, the immune system and other functions, and a person with an inability to produce DHA will likely have a difficulty to make EPA as well. For that reason, fish oil as a supplement for pregnant and nursing women has advantages over the products that only provide DHA. Fish oil supplements are easily available now that are free of mercury and other substances that would be of concern when eating fish to get these special oils.

Part 2: Cow's/goat' s milk as the primary feeding for infants.

In addition to the possible concerns mentioned above about the use of milks from cows and goats as supplemental foods, they are inappropriate for use as the primary feeding product in place of human milk or commercial formula because they fall outside of the "desirable range" of carbohydrate, protein and fat, and can present problems for some infants.

This is especially true for very young babies or for those who have special health problems. In addition, 2% (low fat) and skim milk provide inadequate calories (about 15 and 11 calories per ounce, respectively), so babies tend to drink even more of these products than they would whole milk, formula or human milk, which all provide about 20 calories per ounce.

Percent of calories from:	**CHO**	**PRO**	**FAT**

Desirable range:		35 - 65	7 - 16	30 - 55
Cow's milk:	**Whole:**	30	20	50
	2% :	38	26	36
	Skim :	57	40	3
	Goat's milk:	27	19	54

Are there any other problems?

At a time when many American infants were being fed skim milk, Fomon et al, (1974) showed that young infants fed skim milk as their major food drank about 1.5 times the amount normally taken, in an effort to get adequate calories. As you can see on the chart above, the amount of protein would be very high, and since so much of the baby's energy would be derived from protein, there would be a large amount of nitrogenous waste produced that must be excreted via the kidney (i.e., a high "Renal Solute Load.")

This has the potential to result in dehydration because of the obligatory loss of water to excrete the waste products; sometimes the loss of fluid can be more than the baby can afford. In very young infants or in those with special health problems, including those with growth failure, diarrhea, or fluid limits, a high "Renal Solute Load" can be dangerous.

These milks are also less than ideal because they contain up to 8 times as much sodium as is in human milk and formula. If skim milk is used as described above, that can mean a sodium intake of 12 times the amount in human milk, since the baby will drink so much more of it.

In addition, these milks do not provide complete nutrition, because they are poor sources or iron, vitamins C and B-6, copper, zinc and essential fatty acids. Vitamins A and D are also low unless they are added in processing.

Most commercial milk has vitamin D added, but milk obtained directly from a dairy farm or the family barnyard often has none. As a result, severe vitamin D deficiency is not uncommon among many “farm” children, especially in the north *[Rickets in the Dairy State*. Wisconsin Medical Journal. 2004;103:84-87. 7.]

In addition to these problems, goat's milk is also naturally low in folic acid (a B-vitamin especially important during periods of rapid growth because of its role in DNA production), and offers no special advantage over cow's milk. Many commercial canned goat's milks do have folic acid added.

I was involved in the care of an infant whose exclusive (“natural”) diet of raw goat’s milk landed him in the hospital at age 4 months, very near death, with overt scurvy, anemia and neurologic problems from deficiency of folic acid, vitamins C, B6, D and several other nutrients. Fortunately, emergency treatment saved this baby’s life, but there is no way to determine if there will be any long-term consequences of such severe malnutrition of multiple nutrients during infancy. These are serious issues.

Babies who are allergic to cow's milk protein are often allergic to goat's milk, too. Unpasteurized milks are not recommended due to the risk of bacterial contamination. Heat treatment also improves the digestibility of the milk, but the milk fat remains much harder for

babies to digest than the fat in human milk or commercial formulas, and it is a poor source of linoleic and alpha-linolenic acid, the essential fatty acids.

Some babies appear to have a sensitivity to cow's milk (but usually not to formula) that causes bleeding from the intestine. The amount of blood loss is often so small as to be unnoticeable in the stool, but it can result in a serious loss of iron. This blood loss, along with the poor iron content of cow's milk, can contribute to the development of anemia.

I have seen young children with this kind of "cow's milk anemia" related to these factors plus a diet pattern that provided too much of the child's calories in the form of milk/yogurt/cheese, etc., and very little other foods. Interestingly, several children had been identified as anemic, but the solution recommended was just to give a supplement of inorganic iron (e.g. ferrous sulfate.) This is particularly unlikely to be very helpful because:

1) milk impairs absorption of inorganic iron and

2) the basic problem of dietary imbalance is not addressed so multiple other critical (but less likely to be tested for) nutritional inadequacies remain uncorrected.

Essential Fatty Acids

Of the linoleic acid found in butterfat (the fat in cow's milk,) it appears that only 50-80% of the total amount is in the form of linoleic acid that is biologically active (Fomon 93), so the values shown on the chart on the next page overestimate the actual amount of linoleic acid available for metabolic uses. This is another clear indication why cow's milk or goat's milk should only be used as a part of a child's diet and certainly not as the main source of calories.

Other forms of fat need to be included in an infant's diet, as cow's milk fat alone can actually result in essential fatty acid deficiency. I once observed this situation in a child admitted to the intensive care unit in our hospital with a variety of unusual symptoms. A careful diet assessment revealed that nearly all of his fat intake was in the form of dairy fat. A laboratory measurement of the triene:tetraene ratio then confirmed the suspected EFA deficiency.

Note that the table below is addressing the relative inadequacy of linoleic acid (the omega-6 essential fatty acid.) It does not address the additional inadequacy of linolenic acid (the omega-3 essential fatty acid) discussed earlier as being so important for making subsances such as EPA and DHA. Further, most vegetable oils are not well-balanced in the ratio of omega-6 to omega-3 fatty acids. The essential fatty acids in corn oil, for example, are almost all omega-6.

[For additional information on this issue please see
"All Those Lipids: Recommendations for Using Different Types of Vegetable Oils
(Omega-3, Omega-6 and Monounsaturated Oils.)"]

Essential Fatty Acids

Suggested Intake: (FAO/WHO) and regulation level for formulas is 1.2 % of energy as Linoleic Acid. Goal is to provide 500 mg/day (Foman 93)

Linoleic Acid per 100 kcals & intake per 18 or 24 oz milk/day (Fomon 93)	Linoleic Acid as a Percent of Total Fat (Worthington Roberts 96)	Total PUFAs mg/oz	Total PUFAs as a Percent of Total Fat (Pennington: Bowes & Church 94)
Cow's milk:			
Whole: 1.12 mg/100 kcals 18 oz = 4.1 mg 24 oz = 5.4 mg	1%	37	4
2% : 0.92 mg/100 kcals 18 oz = 2.5 mg 24 oz =3.3 mg	1%	25	4
Skim : 0.02mg/100 kcals 18 oz = 0.04 mg 24 oz =0.05 mg	1%		
Human milk:	5%	200	14.3

So why do people want to use cow's milk for infants?

Some people have the mistaken notion that unpasteurized cow's milk or goat's milk is somehow more nutritious or "natural" . . . which it is for baby cows and goats. For human infants it is significantly less appropriate than human milk or formula, and as already described, it is potentially dangerous. The major reasons for switching from commercial formula to cow's milk (pasteurized or not) during the first year are cost and convenience factors.

For young infants or those with health problems, this practice should not be encouraged. However, if the infant is at least six months old, is a healthy baby, and is eating the equivalent volume of 2-1/2 to 3 jars of baby food daily, some of the problems with whole cow's milk can be tempered.

For example, by adding three 4-oz servings of cereal, fruit, or vegetables daily, the carbohydrate portion of the diet moves into the acceptable range, and the protein percentage decreases down to the acceptable range. By filling up on other foods, the baby will probably also drink less milk, which will also decrease the protein and sodium intake. If one selects the other foods carefully (including meats and a wide variety of other nutrient-dense foods), some of the other nutritional shortcomings can be remedied as well, such as decreasing the high sodium content and improving the vitamin /mineral content of the diet.

Because of the observations about inadequacy noted above, a few years back when I was first working for the (brand new) WIC Program, the American Academy of Pediatrics decided that switching from human milk or formula to whole milk would be acceptable after age six months "for babies who were eating a variety of foods." However, studies were done that showed that although it is possible to achieve a balanced diet this way, most babies who had been put onto

whole milk, in fact did **not** receive a balanced and appropriate diet.

So the recommendation of human milk or formula for the first year of life was re-instituted. The more recent questions about the safety of pasteurized cow's milk products during infancy (e.g. yogurt, cottage cheese and ice cream) as adjunct foods do not represent a major policy change. [Interestingly, during the AAofP's "6-months-is-ok" period, WIC held its ground and continued to provide only iron-fortified formula to non-breastfeeding infants for the entire first year of life. Way to go, WIC!]

One further caution before switching to cow's milk or goat's milk is to be sure that the baby regularly eats table foods that contain some (especially omega-3 rich) vegetable oils in order to obtain appropriate levels of essential fatty acids. Most baby foods are extremely low in fat, as are many of the "starter" table foods like fruit, crackers and cereals. Other dairy foods like cheese, butter or yogurt provide only the same limited amount as milk does, even when the total fat content is high.

So, especially when the baby is eating commercial baby foods as a major part of the diet and has switched to milk, extra care must be taken to provide sufficient essential fatty acids. Fortunately, this can be done quite easily when one is aware that it is an issue. **Hydrogenated oils like margarine and shortening should not be considered as sources of essential fatty acids because the hydrogenation process significantly decreases the essential fatty acid content of the product.** This is in addition to the well-known concerns about partially hydrogenated oils forming trans fat.

What about evaporated milk formula?

Many people have been raised on home-made evaporated milk formula, although it is rarely used today. Its major advantage is its lower cost than commercially made formulas, while being better suited to infants than regular cow's milk. Because it is canned, it has been sterilized and the heat treatment makes the protein more digestible. Corn syrup or sugar has traditionally been added to adjust the proportion of carbohydrate, protein and fat, as shown below. Water is added to adjust the calories to 20 calories per oz, (the same calories as in human milk, formulas and whole milk). (See the chart on the next page)

Percent of calories from:	**CHO**	**PRO**	**FAT**
Desirable range:	35 - 65	7 - 16	30 - 5
Evaporated Milk Formula made with Corn Syrup:	45	15	40

Digestion and absorption are still not as good as is seen with human milk and formula, because the form of fat is more difficult for babies to digest in addition to being a poor source of essential fatty acids. Milk fat can be quite constipating for some children, but the corn syrup usually has an osmotic laxative effect to counter it.

In the 1980s a concern was raised about the safety of corn syrup for small infants (*J. Food Protect*. 1989:45,1028); some samples were found to contain heat-resistant spores of Clostridia botulinum, a type of bacteria that has been associated with a form of SIDS (Sudden Infant Death Syndrome). It was estimated that about 5% of SIDS cases at that time may have been due to "infant botulism" linked to the use of corn syrup or honey in young infants.

For this reason it was suggested that if this type of formula is used, that sugar replace corn syrup or honey in the formula. Since then, manufacturing techniques improved and corn syrup no longer is regarded as a risk factor for developing infant botulism (*J Food Protect.* 1991), although honey should continue to be avoided in the first year of life. [Note: Honey baked into foods like graham crackers is safe because the high temperature of preparation kills the spores. This question comes up often.]

Human milk or commercial infant formulas are still preferred over evaporated milk formula because of their more complete nutrition and better digestibility. As with any cow's milk product, evaporated milk formula is naturally low in iron, copper, selenium, zinc, essential fatty acids, and vitamins C and B-6. Vitamins A and D are usually added. Therefore, a registered dietitian or physician who is knowledgeable about these issues should look carefully at a baby's whole feeding plan to assess its adequacy. A supplement may be recommended if other foods are not providing these missing nutrients. However, my experience has been that nobody looks at this issue at all, so careful nutrient supplementation in this situation is theoretically possible but practically non-existent. And, as the babies do not “look funny” their deficiency state usually remains unrecognized.

Part 3: Which commercial formulas are used most often for healthy babies?

Most babies are fed **"standard" formulas that use cow's milk as a base**, but which have been adjusted to be as much as possible like human milk, although it is clear that not all the qualities of human milk can ever be duplicated. For example, many of the immunologic properties of human milk are "live cells," and even if they were present in cow's milk they would be destroyed by commercial processing. **Most babies will do well on any of the commercial standard formulas**. There are few major differences among the brands because the Infant Formula Act makes it necessary for all products to conform to specific standards. However, there are some minor differences among them (within the overall guidelines) and occasionally a baby may do better on one product over another.

Protein:

One difference among milk-based formulas is in the **proportion of casein milk protein to whey milk protein**. Cow's milk protein is 82% casein to 18% whey. Human milk has been reported to be about 40% casein to 60% whey (although estimations vary). In the belief that altering this ratio may improve digestibility, Enfamil [Mead Johnson] and Similac [Abbott, formerly Ross Labs] have been adjusted to have a casein:whey ratio near 40:60, although the protein in Enfamil LactoFree [Mead Johnson] and “Similac Lactose Free*” [Abbott,] is all casein. In 2007 the name of Similac Lactose Free was changed to “Similac Sensitive”

In 2005 Mead Johnson introduced "Enfamil® Gentlease™ LIPIL®" which has a 40:60 casein: whey ratio, but then hydrolyzes the protein (partially breaks the protein into very small bits.) As is the case with Nestle Good Start Supreme, the hydrolyzed protein is intended to be easy to digest, but they do not claim that the particle size is small enough for it to be used for milk-allergic babies. See more in the discussion of allergy later.

Some "store brands" are now available that are essentially like "SMA", a product formerly made Nestle Good Start **Supreme** is a product in which all of the protein is whey, and the whey has been broken down to smaller length peptides (hydrolyzed.) **In the fairly recent past there was a change in the protein form in products marked as Nestle Good Start – the products named "Nestle Good Start" will no longer be a protein hydrolysate unless it says "Good Start Supreme."** This new distinction will be importance to people who are particularly interested in using a hydrolysate.

In any case, the whey in all of these products is still cow's milk whey (primarily lactoglobulin,) and different in amino acid content from human milk whey, (primarily lactalbumin,) so a clear advantage/disadvantage of a particular casein:whey ratio has not been established for healthy, term infants. For example, the intact (unhydrolyzed) whey fraction may be the more allergenic of the two major types of cow's milk protein in some circumstances, so it is unclear that increasing its proportion in formula is automatically beneficial. Some research suggests that the amino acid pattern in the whey fraction may actually be of higher biological value for humans, although this is an issue only in certain clinical applications and among athletes consuming (usually unnecessarily) expensive sports protein powders. This is not of importance in the feeding of healthy babies who are receiving standard amounts of calories and protein.

There does appear to be an advantage to using whey-adjusted products for **premature** infants, whose immature systems are less able to cope with large amounts of casein. In the past, for some of these babies, a high casein content (e.g. 82%) which in the (now pretty distant) past was associated with an increased risk of problems with acidosis and with the formation of lactobezoars. For this reason, all formulas developed for use with premature babies are whey adjusted products. However, many other formulation changes have occurred since then as well, and it does not appear that an all-casein product is still an important concern.

For "normal infants," in actual practice, it may be that an individual baby will do better with one form or the other, so it might be worth a try to switch formulas if there appear to be digestive problems. For example, the hydrolyzed whey product Nestle Good Start Supreme and the newest formulation of Similac Advance have been shown to be helpful for many **constipated** babies.

Compared with the too-common approaches of inappropriately removing an essential nutrient (iron), adding a lot of simple sugars (e.g. corn syrup,) or giving medications that impair absorption of nutrients (e.g. mineral oil,) a trial on one of these products is clearly a nutritionally superior method of managing constipation. WIC Programs may have policies limiting the ability to try non-contract formulas in this way, but the nutritionists will still want to know about these issues for problem solving.

Of course, one should first help the caretaker differentiate true constipation from simple failure to have a daily bowel movement. Anything up to "every three days" can be a normal

pattern as long as stools are soft. The misunderstanding about what is in fact true constipation accounts for quite a lot of waste of time and resources for WIC offices, physicians, and other health professionals.

Carbohydrate

Other standard formulas that may be helpful in specific problem situations are Enfamil Lactofree Lipil, Enfamil Gentlease Lipil [Mead Johnson] and Similac Lactose- Free* Advance [Abbott, formerly Ross.] * [as of 4/07 called "Similac Sensitive"]

The Enfamil Lactofree Lipil and Similac Sensitive Advance feature a cow's milk base (100% casein) with the **milk sugar (lactose)** removed and replaced by glucose polymers. The Enfamil Gentlease Lipil product has a 40% casein:60%whey ratio with the protein hydrolyzed. It is not completely lactose free but it is described as having only a fourth as much lactose as regular Enfamil Lipil. They promote it for babies who "show transient intolerance to lactose but who are not lactose intolerant." These formulas may be useful for lactose intolerant infants for whom soy formula had been almost the only option in the past, especially when there are concerns about soy, or the higher quality protein source or slightly better calcium absorption seen with cow's milk formulas is an issue for a particular baby.

True lactose intolerance of more than a transient nature is quite uncommon in healthy infants, however. Consider that even among ethnic groups with a high incidence of lactose intolerance among adults, the primary carbohydrate in mother's milk around the world is lactose. It is likely that much of the "improvement" sometimes described when the formula is changed to one of these products is less due to the lactose in the name and more to the removal of the whey. There is no evidence that babies who are fed a lactose-free formula later "have trouble" making lactose. This is an often-voiced theoretical concern of some health professionals. Consider the many babies who "graduate" from an entire first year of lactose-free formula (including soy formulas) and then easily make the switch to regular milk.

[See "Aunt Cathy's PMS System of Baby Formula Decision-Making" for an example of formula choice problem-solving that uses the lactose issue as an example.]

Non-protein Nitrogen (Nucleotides) and "Probiotics"

Human milk contains a significant amount of "non-protein nitrogen", much of it in the form of **nucleotides and/or nucleosides**. . . the material used to make DNA and RNA. There is evidence and speculation that nucleotides in human milk especially promote the development of the intestinal tract and the immune system. These are tissues with the fastest "turn-over" time, and the need for nucleic acids for replacing these tissues may be greater than what can be easily provided by endogenous production by an immature liver.

For this reason, and because of the teleologic evidence of the presence of nucleotides in human milk, many commercial formulas have added them. Large studies are in progress to determine if this addition brings about a measurable change in susceptibility to infection, etc.

Another area of research into formula manipulations that may provide immune benefits to formula-fed babies is the addition of **"friendly" micro-organisms** (now commonly referred

to as "**Probiotics**") to a formula. For example, supplementing infant formula with Bifidobacterium bifidum and Streptococcus thermophilus was found to reduce the incidence of acute diarrhea and rotavirus shedding. Rotavirus is a common plague of day care facilities, and many health-care dollars are spent in treating it. The "decreased shedding" aspect has the potential to significantly curtail the spread of diarrheal disease to others. [*Am J Gastroenterol* 2000;95(1 Suppl)]

Research has continued, and more recently, Nestle introduced a trademark fiber they call "Probio." It is intended to promote the growth of "friendly" intestinal flora. Both products are designed for children after age one. In the spring of 2007 Nestle introduced a new infant formula with live/active cultures of the non-pathogenic "probiotic" organism "Bifidobacteria lactis" – often abbreviated as "B. lactis." The can has the words "Natural Cultures to Support a Healthy Immune System" and a trademark circle featuring the capital letter B with a small L inside a smaller circle. The word "bifidus" is printed along the upper arc of the larger circle. The name of this new product is: Nestle Good Start® Supreme Natural Cultures.™ It is regarded as a standard or routine infant formula. It is made with 100% whey, partially hydrolyzed, and with DHA & ARA, two polyunsaturated fats that are discussed below.

Pre-biotic refers to substances in the formula that promote the growth of friendly micro-organisms **Pro-biotics)** Abbot's new Similac Advance EarlyShield™ is an example of a product that features both pre- and pro- biotics, DHA and ARA, antioxidants and nucleotides. Mead Johnson's new Enfamil® PREMIUM™ with Triple Health Guard™ has these things but it has pre-biotics but no pro-biotics. There are now many store-brands featuring one or more of these components as well.

These changes in product design and the formula names the manufacturers assign to each version continue at a rapid pace. Papers like this one become outdated virtually overnight because of name changes alone. So instead of comparing the fine points of these, it will have to suffice to describe what the nucleotides, DHA/ARA, Pre- and Pro-biotics are generally about. A simple chart can sort out the specifics.

Fat Content

The standard formulas also adjust the **fats** by controlling the **types and proportions of saturated, monounsaturated, and polyunsaturated lipids, and the families of polyunsaturated fatty acids (omega-3 vs omega-6)**. There has been a trend toward trying to produce a lipid profile in infants closer to that seen with the consumption of human milk, recognizing that the fatty acid pattern of mother's milk itself will vary with her intake and with her ability to produce certain 20 and 22 carbon fatty acids from the essential fatty acid substrates.

New insights about the role of various forms of fat in the production of prostaglandins, in immune function, in brain development, in micronutrient absorption, in constipation problems, and in long-term cardiovascular health have prompted several companies to focus on this aspect of the formula. Enfamil, Similac, Nestle and some store brands all have adjusted lipid profiles of one or more of their products in the recent past, and they have changed their formula names to reflect this. As yet, not all the formulas in a company's product line have been altered in this way, although all are working in that direction. These changes are welcome. However, there are still areas in which the lipid pattern of formulas differs significantly from human milk, and from each other.

For example, human milk has significant amounts of **cholesterol** and varying amounts and ratios of **long chain omega-3 fatty acids (eicosapentaenoic acid -- EPA, and docosahexaenoic acid -- DHA) and long chain omega-6 fatty acid (arachidonic acid—ARA.)** These fats appear to have many important roles in infant development, especially of the brain and retina.

What is unclear at present is whether all or even most infants (especially sick or premature infants) are able to produce appropriate amounts of these substances from the precursors traditionally provided in formula (linoleic and alpha-linolenic acid.) The enzyme systems that accomplish these transformations in more mature people may not be adequately developed in infants. The ability of adults to do this is also known to be sometimes marginal, and may be especially so during pregnancy.

Providing the **preformed EPA and DHA** in particular may also be very important in pregnancy; for example, low consumption of fish (the primary dietary source) is associated with increased risk of preterm birth, and as mentioned earlier, providing fish oil in pregnancy may decrease allergy problems in infants. ARA is less likely to be similarly low in the maternal diet as it is provided in meats. This may become a research question in regard to vegetarian mothers, however.

Until 2001, none of the formulas in the U.S. had altered their composition to provide preformed ARA, EPA and DHA comparable to human milk. In part this was because it takes a long time to establish the safety and appropriateness of any changes in infant formulas, and such changes would involve government approval. In Europe and Asia, ARA and DHA have been added for years to at least some formulas, and now they are also being added in America.

The manufacturers of Enfamil (Mead Johnson) have added the word **"Lipil"** to the names of products that contain ARA and DHA, and recently they have discontinued production of the older product without these beneficial fats. The manufacturers of Similac (Abbott Nutrition; formerly Ross Labs) have added the word **"Advance "** in the names of their formulas with the addition of ARA and DHA. Three Nestle formulas have these fats added at this time: their products called "**Nestle Good Start Supreme DHA & ARA**," "**Nestle Good Start II Supreme DHA & ARA,**" and **Nestle Good Start Supreme Soy DHA and ARA."** At least some store brands have begun to add them as well. ARA is arachidonic acid, the 20-carbon omega-6 fatty acid) and DHA is the 22-carbon omega 3 fatty acid. At this time, EPA is <u>not</u> added (eicosapentaenoic acid is the 20-carbon omega-3 fatty acid.)

The ARA and DHA are not derived from fish or animal fat but from microorganisms. This source is FDA approved. The products for premature infants now have these fatty acids added as well, as have their respective soy and lactose-free milk-based formulas. There are some differences in the relative amounts of DHA that are currently added to the formulas (see chart next page.) As of 2007, the addition of DHA and ARA is gradually being added to other infant formulas in each company's product line because the research has continued to see positive outcomes in terms of some measures of infant development.

Percent of Fat Provided as DHA and ARA*

(*True at one time and likely to change one way or another at any given moment.)

	Nestle Good Start with DHA and ARA	Enfamil Lipil	Similac Advance
DHA 22 carbon omega-3	0.29	0.32	0.15
ARA 20 carbon omega-6	0.59	0.64	0.40

Another lipid-related difference between formula and human milk is that none of the formulas contain any cholesterol. This is reportedly because of difficulties with it not staying well blended in the product. As cholesterol has many critical roles in infant development (such as myelin production, cell membrane stability, and production of vitamin D, steroid hormones and bile acids) its absence in commercial infant formulas is not necessarily ideal. Since human milk is high in cholesterol and it is a precursor to so many important substances, there is some concern about the ability of all babies (especially sick or premature infants) to manufacture sufficient quantities to meet their needs optimally.

Similac no longer contains a form of fat used in some other formulas called palm olein, and studies by Ziegler *et al.* suggested that this change improved absorption of the fat and of minerals such as calcium which can be lost when fat is poorly absorbed. Along with the casein:whey ratio change, this fat blend change may also account for the reported decreased problem with constipation compared with their older formulation.

Iron

For years. most standard formulas came in two types: with and without **iron fortification** at the currently recommended level. Iron fortification is recommended by the American Academy of Pediatrics (AAP), so babies given low-iron formula usually also receive supplemental iron, at least by about 2 months of age. Those not given iron are at greater risk of using up iron stores, especially if iron-rich foods are not used. These products had a warning label that they are "deficient in iron" and should be used only with a close look at baby's total nutrition plan. Unfortunately, many health professionals mistakenly believed that "low iron" simply means that it provides "adequate-but-not-excessive" iron. Non-iron versions are on the way out.

Most "with iron" products contain 10-12 mg of iron per liter; some "low iron" products contained only 1-1.5 mg/L; others up to 4.7. Because of this confusion about iron labeling, there was a resurgence in the incidence of anemia in infants, which prompted the AAP to issue a statement that there is no place in normal infant feeding for low-iron formula.

In 2007, in order to prevent this kind of confusion and the possibility of babies receiving inadequate iron, Mead Johnson (maker of Enfamil Lipil) discontinued production of a low-iron formula altogether. **It has been shown in many studies that iron fortification of formula does not cause constipation.** It is interesting to note that one of the formulas that works so well in resolving constipation problems (Nestle Good Start Supreme) only comes "with iron." However, the belief that iron causes constipation is deeply ingrained in the public. **It is somewhat disconcerting**

to realize that some people apparently would choose to remove an essential nutrient from their child's diet in order to form "the perfect stool"!

Because of the anemia problem, the amount of iron in some "low iron" products has been increased somewhat, and others may be changed in the future. In 2007 production of the "Low Iron" version of Similac (Abbott Nutrition; formerly Ross Labs) was discontinued. If a "low iron" product appears to be better tolerated than the "with iron" form by a particular infant, they often do well with providing the needed iron as a drop instead. This is not an option if the baby is receiving formula from the WIC program (the Special Supplemental Food Program for Women, Infants and Children), which is mandated to provide only iron fortified formula in most states.

Again, it is useful to note that meats -- especially red meats -- provide generous amounts of organic iron. This form is much better absorbed (in some studies more than 10 times more) than the inorganic iron in formula or supplements. It is also common for people to stop giving the iron drops to the baby because "she doesn't like it" or because "it stains his clothes," so there is concern about the baby actually getting the prescribed iron when administered this way.

What about Soy Formulas?

If a baby does not do well on the standard formulas, perhaps because of difficulty digesting milk sugar (**lactose intolerance**) or because of **allergy to cow's milk proteins**, the next choice has traditionally been a soy-based product. The use of soy formula for allergic babies is discussed in the "Allergy" section below. For lactose intolerance, either soy or the cow's milk based formulas "Enfamil LactoFree Lipil" or "Similac Lactose Free Advance" [as of 4/07 called "Similac Sensitive"] can be used.

As noted, true lactose intolerance is rare in infants, even among ethnic groups with a high incidence of lactose intolerance in adulthood. All human milk is naturally high in lactose, and nearly all babies have the digestive enzymes necessary to digest it and absorb it. Sometimes a baby may be temporarily lactose intolerant due to gastroenteritis or other bowel conditions. Serious malnutrition can also cause temporary lactose intolerance. Although babies are often switched to a lactose-free product when they have gastroenteritis or diarrhea of any etiology, it is not at all clear that this is necessary. Consider that we advise breastfeeding mothers to continue nursing if the baby is sick, and this product only comes with lactose.

Except in extreme cases of bowel damage or "starvation stools" (often caused by malnutrition resulting from inappropriate withholding of adequate nutrition in an attempt to treat diarrhea,) studies indicate that <u>most infants recover well from occasional diarrhea when one simply continues to feed them their regular breastmilk or formula in the normal way</u>. Although not a harmful practice, many health professionals switch these infants to a soy product simply because of pressure from the parents to "do something" to treat the diarrhea, rather than because of clear benefit.

One comparison of an experimental soy-based formula with the carbohydrate as lactose Vs sucrose did support the idea of a small benefit of providing a non-lactose carbohydrate formula during diarrheal illness (*Arch Pediatr Adolesc Med*. 1999.) Whether the magnitude of

benefit is worth the effort of switching formulas is unclear. And, although breast milk is high in lactose, continued nursing is clearly recommended for many reasons instead of switching to a lactose-free or any other formula.

One modified soy product is promoted primarily as a treatment for diarrhea: "Isomil DF" (DF= "Diarrhea Formula") is lactose free and in addition contains dietary soy fiber. This product appears to reduce the duration of watery stools somewhat, but not the total volume of diarrheal stools (*Pediatrics* 92,'93). As it is often considerably more expensive than standard or regular soy formulas, the overall benefit in diarrhea management is not that clear, and since the place of fiber per se in infant diets is also unclear, it remains to be seen if this product will fill a crucial niche. The cost may be prohibitive as well.

On the other hand, use of this product is far superior to feeding only electrolyte replacement solutions for more than 24 hours. Enfamil's Enfalyte and Abbott's Pedialyte are examples of this kind if product. They are intended for short-term use only, and they are not complete nutrition products. They have no protein or fat, only a few calories as carbohydrate, and some electrolytes to replace those lost with diarrhea. However, there have been cases of babies fed only these solutions far too long … "until they can form the perfect stool." And of course, they never do. The intestinal tract has nothing to work with to recover normal function. This is one cause of "starvation stools" in the developed world. In parts of the world it is usually due to combinations of malnutrition and dysentery.

A new soy hydrolysate product was recently developed and marketed as "Nestle Good Start II Supreme Soy DHA & ARA." It is designed for babies and children from 9-24 months. It is both lactose free and milk protein free, so for those who would benefit from a hydrolysate formula (for whatever reason), the option of a completely dairy free product may be useful.

Since soybeans provide incomplete protein, (they are especially low in the essential amino acid methionine,) methionine is added to improve the **quality of the protein**. In addition, soy formulas have an **increased quantity of protein**, to make up for the somewhat decreased digestibility and absorption. Soy formula is often used by vegan families who prefer to provide no animal-based foods, or those with other strict dietary practices that makes using a milk-based formula more problematic (e.g. Jewish dietary laws prohibiting milk and meat at the same meal.)

It is common to try soy formulas if a baby does not do well on standard formula, but it has traditionally been assumed to be best not to keep the baby on the soy product if the switch did not lead to improvement. While a baby can certainly grow well on soy formulas, there is somewhat better absorption of calcium and certain other nutrients with cow's milk based standard formulas, so for now the standard cow's milk-based formulas are the formula choice of most physicians. However, with the interesting recent discoveries of potential benefits of soybean consumption for the general public (such as possible decreased risk of heart disease, cancer, osteoporosis and menopause discomfort,) this general preference may change. The jury is still out on whether soy is everything it is being promoted for.

Soy infant formulas are made from "soy protein isolate," not from the whole soybean, so there is much work to be done to determine if the products as currently made provide any special benefits. Sometimes switching to a soy formula helps with constipation (and other times it seems to contribute to it.) However, since **all recognized soy infant formulas are fortified with iron**, a trial on soy is reasonable and does not jeopardize the child's nutrition, as some interventions can

(see above.) If it does help a constipated baby, it is due to some other (non iron-related) aspect of the formula change (i.e. the form of protein, fat or carbohydrate.) In spite of the possible benefits of soy consumption observed in adults, avoid home-made soy formulas, or so-called "soy milks" for infants, since there may be serious problems in nutritional adequacy with any do-it-yourself formula, especially if protein is incomplete. Unfortunately, I have seen a baby with permanent neurologic injury from having been fed an exclusive diet of this kind of home-made "formula."

Because of the higher protein content but lower overall protein quality, it may be wise to think of the average .56 g protein/oz of soy formula as equivalent to the average .45 g protein/oz in cow's milk-based formula when intake levels provide protein at the lower end of the desirable range. Otherwise, there is the potential for the protein intake to appear to be marginally adequate, when its actual bioavailability may be less. When there is concern about a baby's ability to handle protein waste products (such as in renal or hepatic disease,) remember that there is more urea to excrete with soy products than with human milk or milk-based formulas because of the lower biological value of vegetable protein. Soy formulas are not designed for use by premature infants; short term use may not be detrimental and soy formulas may be used in the usual way once the child has achieved "term baby" size and nutritional status. However, as will be discussed later, the special needs of preterm infants will not be met by these products designed for term babies.

Research into the properties of **soy phytoestrogens** on conditions such as menopause and osteoporosis has raised the issue of the effect (if any) of providing phytoestrogen-rich soybeans as the central component of an infant's diet. There are concerns that the observed high serum levels of phytoestrogens may have an untoward effect on hormonal development or other metabolic derangement. At present, the experts disagree on whether soy formulas are quite safe or whether they should be avoided.

As with earlier concerns raised about exposure to cow's milk protein formulas and a possible link to diabetes, it leaves health care professionals in a tough place: For bottle-fed babies, should we recommend milk-based or soy based formula as the first choice? Are they both equally safe? Is either or both unsafe? How large is the relative risk? Should we recommend a hypo-allergenic hydrolysate like Ross' Alimentum or Mead Johnson's Nutramigen (at much greater expense and less acceptance due to flavor and olfactory aspects)? How about a hydrolyzed-but-not-quite-hypoallergenic product like Nestle Good Start Supreme? The best answer, of course, is to encourage breast-feeding, but when that is not an option what should be done? Stay tuned . . .there is simply not enough research and consensus of expert opinion yet to make a recommendation. Allergy-related issues will be addressed in the next few pages.

Because soy formulas are lactose free they are also used by infants and children with the inborn metabolic error called "**galactosemia**". Although some galactose may be present in the product as a component of some small (3-5 unit) oligosaccharides (not as lactose or free galactose,) at present it appears that the carbohydrate in this form is not digested and therefore there is no free galactose absorbed. **It is critical that infants with this condition not be confused with those who are "lactose intolerant."** Lactose intolerance causes gas and diarrhea when lactose is consumed, but lactose consumption by the child with galactosemia causes mental retardation and other serious damage.

Using fermented dairy products (e.g. yogurt) or enzyme additives such as "Lact-Aid" or "Dairy Ease" to break down lactose in foods/beverages may help intestinal discomfort of lactose intolerance, but they **cannot make lactose safe for the child with galactosemia**. Because of trace amounts of lactose in the "LactoFree" and "Similac Lactose Sensitive"milk-based formula described above, these products are not recommended by their manufacturers as the best choice for infants or children with galactosemia. The new "reduced lactose" Enfamil Gentlease Lipil has much more than trace amounts of lactose (one fourth the amount in regular Enfamil Lipil,) so it is clearly not to be used for babies with galactosemia.

Are there any differences among the soy products?

The type of vegetable fats used vary somewhat, from a single-source fat to combinations of coconut, soy, and/or safflower oils. The fat blends are an area of considerable interest, and as with the standard formulas there has been recent reformulation of some soy formula products to achieve lipid profiles closer to that of human milk. However, as with cow's milk based standard formulas discussed earlier, there has been a recent change in some products by Mead Johnson, Nestle and Abbott Nutrition to include some of the very long chain fatty acids (DHA and ARA) as has been discussed earlier. So far, as with standard formulas, none of the soy products have been adjusted to provide cholesterol or EPA at levels comparable to those in human milk.

Standard and soy infant formulas provide 20 calories per oz.

Percent of calories from:	CHO	PRO	FAT
Desirable range (Fomon):	35 - 65	7 - 16	30 - 55
Standard formula (cow's milk based): (Enfamil Lipil, Enfamil Gentlease Lipil, Enfamil LactoFree Lipil, Nestle Good Start, Nestle Good Start Supreme with DHA & ARA, Parent's Choice, Similac Advance, Similac Sensitive Advance, etc.)	41 - 43	9 - 11	48 - 50
Soy formulas: (Enfamil Prosobee. Nestle Good Start Soy, Parent's Choice Soy, Similac Isomil Advance, Enfamil Prosobee Lipil)	39 - 45	11 - 13	45 - 49

Soy products also vary in the type of carbohydrate used. Isomil uses corn syrup and sucrose, but there is also a product called Isomil SF, which is sucrose-free and contains only the corn syrup. Enfamil Prosobee uses corn syrup alone. There are certain rare conditions in which there would be an important reason for choosing one carbohydrate source over another (e.g. hereditary sucrase-isomaltase deficiency,) or other special needs.

However, the most common reasons for using soy formula (milk protein sensitivity or lactose intolerance) do not require any particular carbohydrate or combination to be used. Some babies may prefer the flavor of one product over another. In addition, some physicians or dietitians may prefer, and so recommend, one product over another, usually as a result of familiarity with a particular product. And, of course, WIC health professionals will have one product as their "contract formula."

Formula Choices for Babies with Allergies

True allergy is much less common than commonly believed; to be an allergy IgE must be involved. Most formula intolerances are not due to allergy, although people commonly describe almost any formula intolerance as an allergic reaction. Some infants are genetically at greater risk of allergy than average. For most babies at risk of allergy, human milk is best because of factors in it which decrease risk of allergy development at the level of the infant's intestine; there may also be less exposure to antigens than would occur with any intact cow's milk or soy protein.

It is true, however, that intact proteins (including cow's milk proteins) have been found to be present in some women's milk. In such cases, it may be helpful to have the nursing mother refrain from eating the protein(s) to which the child reacts (with guidance from the dietitian to assure that her diet continues to be complete in spite of any limitations imposed.) There is evidence that even the mother's diet during pregnancy may be a factor in allergy development of certain infants, contributing to allergy risk, and as described earlier, possibly helpful in decreasing risk of allergy development. It is also unclear whether breastfeeding or using special hypo-allergenic formulas prevents or merely delays the development of allergies in children with a strong genetic propensity to develop allergies.

For some allergic infants a hypoallergenic "protein hydrolysate" product may be necessary. The protein is snipped into such small pieces that the body's immune system does not recognize them as any particular protein. Therefore, products with "hydrolyzed protein" ("Similac Alimentum Advance", "Enfamil Nutramigen Lipil" and "Enfamil Pregestimil Lipil") should not cause an allergic response (although there have been isolated cases even with these. Nutramigen and Pregestimil are both made by the same company (Mead Johnson). The difference between them is in the fat blend. Both have the same hydrolyzed protein, but Pregestimil also has about half the fat provided as MCT oil. This has applications for babies with certain types of digestion and absorption problems.

Pregestimil is also somewhat more costly and harder to find, so if the baby's problem is related to allergy and not gastrointestinal issues, Nutramigen would be the first choice of the two if using Mead Johnson products. Abbott makes Alimentum, a single product designed for use with both allergy and gastrointestinal problems and it only comes with the MCT adjustment. There is no problem in providing MCT in the formula even if the problem being addressed is allergy only, however, so it is useful in both situations.

In rare cases a true elemental product made with synthetic amino acids (such as "EleCare," "Neocate," "Neocate One +" or "Vivonex Pediatric") or peptides ("Peptamen Jr.) may have to be used. See the formula list at the end of this paper for information about these products). Interestingly, the "Nestle FAS Free Amino Acid" product is marked "Not hypoallergenic" on the label. "Nestle Good Start Supreme" is only partially hydrolyzed and should not be regarded as truly hypoallergenic. This is also true for the new Enfamil Gentlease Lipil.

There may be a role for this type of product as a feeding for potentially allergic infants before cow's milk allergy has developed, however, since it was seen to result in fewer infants developing an allergic response than when fed formulas with intact protein. As Nestle "Good Start Supreme" and Enfamil Gentlease Lipil are less expensive (plus better tasting and more readily available) than the more hydrolyzed products, they may be a good choice to use preventively**.** However, there is a fairly recent change in the Nestle product: if the word "Supreme" is not on the label, the product is not hydrolyzed. For the Enfamil product, the word "Gentlease" is the indicator that the product is hydrolyzed. As noted earlier, there is now a soy hydrolysate available for babies and children from 9-24 months called "Nestle Good Start II Supreme Soy DHA ARA." Nestle's recent (2007) addition of Bifidobacteria lactis to Good Start Supreme is also being described as contributing to decreased allergy risk or severity because of improved intestinal health.

Whether or not soy formula is the formula of choice for a child genetically at risk of serious allergy problems has been the focus of discussion in the medical literature. Although it has been thought that soy protein is probably as allergenic as cow's milk (and therefore a poor first choice), it now appears that its use in children who develop a cow's milk allergy is usually safe, and that earlier estimates of the prevalence of soy allergy may not have been accurate. As soy formulas are also less expensive and more widely available than hypoallergenic products, they are also a reasonable choice.

Formula Choices for Premature Babies:

Premature babies have very special nutritional needs because of 1) immature organ

systems, which decrease tolerance of nutritional excesses and deficiencies, and 2) special growth needs related to the rate of growth and tissue development (e.g. bone mineralization) that occur during what is normally the third trimester of pregnancy. For this reason, formulas for prematures typically **have higher nutrient levels per fluid volume** (e.g., 24 kcal/oz instead of the standard 20; and higher levels of protein and minerals such as calcium, sodium, and phosphorus.)

Lower calorie level products are also available, primarily as introductory products that are comparable to dilute-strength feedings. The protein is cow's milk based, and all have a 60%:40% whey-to-casein ratio. All have modifications of carbohydrate (variable proportions of lactose and glucose polymers) and fat (all contain some MCT, but proportions vary by product, and all except the modular component products are now fortified with ARA and DHA.) The exact needs of prematures are quite variable, depending on such factors as size for gestational age and the presence of serious medical complications. Even without these complications, there is much that is not known about what is optimal nutrition for the "premie."

Three formula companies make formulas for prematures: "Enfamil Premature Formula / EPF Lipil" (Mead Johnson) “Good Start Premature” (Nestle) and "Similac Special Care Advance" (Abbott). Mead Johnson and Abbott also make a **powdered** and liquid **products to add to human milk** ("Human Milk Fortifier") and Abbott also makes a liquid product to mix with human milk ("Similac Natural Care Advance"). These fortifiers are designed to allow babies to receive the many benefits of human milk (digestibility, immune factors, etc.) while meeting the increased protein, vitamin, mineral and caloric density needs of premature infants.

The powder has the advantage of allowing more of the mother's milk to be utilized, which increases intake of the important immune and digestive benefits of human milk while providing the extra calories, protein and nutrients needed by premature infants. The liquid is easy to mix well, and may be most helpful when only a small amount of mother's milk is available for use. New issues about the safety of powdered fortifiers are discussed later.

Initially, none of these products was designed for use outside of hospitals, but now that discharge from the hospital is occurring earlier and at lower body weights because of insurance company reimbursement policies, iron-fortified formulas for premature babies are now produced for home use. In the past, once an infant had reached about 2 kg weight, or was otherwise considered to be ready for discharge, all of the formula companies recommended switching to a product designed for term babies. By this size, they were assumed to have accomplished their third trimester bone mineralization, so there was no longer thought to be a need for the increased calcium, sodium and phosphorus found in formulas for prematures.

However, research measuring bone density has shown that for many of these babies bone mineralization has not been completed by hospital discharge, even among some who had achieved weights above 2 kg. For a month or more post discharge from the hospital, there may be a continued need for the special "premie" formula especially for babies who were very premature, or who were very sick. As follow-up bone density measures are rarely available, monitoring alkaline phosphatase levels may help determine when the special product is no longer needed.

Not all babies will require the continued use of the specialized products for premature infants. If higher calorie needs continue because of fluid restrictions or hypermetabolic conditions (e.g. bronchopulmonary dysplasia), modifications of standard formulas for term infants are often much more appropriate than the products described above. They are also more readily available, since these premature products are very expensive and not always easy to obtain in rural areas. For example, a **24 Kcal/oz (non-premature) infant formula can be made by using less water in diluting liquid formula concentrate (9 oz water to 13 oz can) or powdered formula (3 scoops powder to make 5 oz formula).**

The premature products above come only in a ready-to-feed form. "Similac NeoSure Advance" [Ross] and "Enfamil EnfaCare Lipil" [Mead Johnson] have been designed for **home use** for those prematures who have a continued need for extra nutrients. In general, they provide 22 kcal/oz mixed according to their "standard" recipe, but they can be prepared at whatever caloric density is appropriate by adjusting the proportions of water and formula powder. Prepared to 22 calories/oz, they are about halfway between a premature product and regular formula for most nutrients. Protein is at levels closer to the premature products described above.

They may be cheaper than other premature products, however, and (depending on stores) comparable in price to regular formula. They are being promoted as suitable for the entire first year of a premature infant's life (not just a few months post discharge), and the nutrient levels do fall within the guidelines of the Infant Formula Act for standard formulas, so continued use should do no harm. They come in a ready-to-feed 3 oz (EnfaCare Lipil) or 4 oz (NeoSure Advance) bottle and in powder form. **For babies described as "osteopenic", or those who were very small or very sick premature infants, these products may not be adequate**, and the true hospital-type premature products may be needed for at least a month or so after discharge to optimize growth.

As with the standard formulas, the very long-chain fatty acids (ARA and DHA) were added to formulas for premature infants in the US. Most experts agree that if there were a group most likely to be unable to accomplish the production of very long chain fats from the linoleic and linolenic acid precursors, it would be premature infants. For this reason, Enfamil Premature Formula (EPF), Good Start Premature and Similac Special Care have added ARA and DHA to their products for preterm babies, adding the Lipil (Enfamil) and Advance (Similac) designations. They have also been added to Enfamil EnfaCare and Similac NeoSure. None of these formulas has pre-formed EPA at this time.

Another new issue in the care of premature or immune-compromised infants in hospitals is a concern about possible risk of ***Enterobacter sakazakii*** infection when powdered formulas are prepared. This includes the powdered human milk fortifier products. The FDA has recommended that powdered infant formulas not be used in neonatal intensive care settings unless there is no alternative available. The problem is that the powder itself is not sterile. For this reason, even careful handling of the formula during preparation does not result in a sterile product. If powdered pproducts must be used, special aseptic preparation techniques have been recommended. [This web-site has details and specific recommendations: www.cfsan.fda.gov/~dms/inf-ltr3.html] This development occurred in 2002 and it (continues to) result in changes in infant formula packaging and in their preparation in hospital settings.

Although this issue is directed at hospital care, it is a good reminder of the importance of addressing appropriate formula preparation techniques with caretakers of all infants. In response to the concerns about powders in the NICU, Abbott (formerly Ross Labs) has formulated a new **30 kcal/oz Special Care liquid**, which can be diluted with sterile water when there is a need for the caloric density of a premie formula that provides more than the 24 kcal/oz provided by the regular Special Care.

What are all those other formula products that are sometimes used?

A large number of products have been specially formulated to meet the unusual nutritional needs of children with inborn errors of metabolism, with digestive diseases, or with severe limits on the amount of sodium or minerals that they can tolerate. Because these products are made to very careful specifications and require complicated production techniques, they are often quite expensive and may not be easy to obtain on short notice. Because the market is so small, the companies that manufacture them often do so at a financial loss as a public service. These products are discussed in a separate section of this paper.

What about all those formula products changes?

Luckily for us all, it is now easy to access plenty of detail about specific products on line. As they change every five minutes, this is going to be a much more up-to-date resource than this paper. I just google them whenever a question comes up about the latest name-change, etc.

For example, here are some websites that have all the information:

Abbott

http://abbottnutrition.com/Products/Nutritional-Products.aspx

Mead Johnson

http://www.mjn.com/app/iwp/HCP/Content2.do?dm=mj&id=HCP_Home/Product_Information/Product_Descriptions&iwpst=B2C&ls=0&csred=1&r=3437784865)

Nestle

*www.**nestlegoodstart**.com/*

Part 4. Thinking about When to Recommend Using Whole Milk, Low Fat (2%) Milk or Skim Milk

A. What percent of calories is provided by fat in each type of milk?

At a time when many American infants were often being fed skim milk, Fomon et al, (1974) showed that young infants fed skim milk as their major food drank about 1.5 times the amount normally taken, in an effort to get adequate calories. This was a concern for several reasons:

1. The amount of protein would be very high because skim milk provides 40% of calories as protein. This is much more than in whole milk (20%) or human milk (7%.) Because so much of the baby's energy would be derived from protein, there would be a large amount of nitrogenous waste produced that must be excreted via the kidney (i.e., it would contribute to a high "Renal Solute Load"). In the first months of life, this can result in dehydration because of the obligatory loss of water to excrete the waste products; sometimes the loss of fluid can be more than the baby can afford. In very young infants or in those with special health problems, including those with growth failure, diarrhea, or fluid limits, a high "Renal Solute Load" can be dangerous. It becomes much less of an issue in an older baby or child who is growing normally.

2. The **volume of milk** required to achieve a particular caloric intake is about twice as much for skim milk compared with whole milk or human milk. Some children, as noted above, simply could not take in enough volume to maintain appropriate fat stores and to grow. I call that problem "Tiny Tummy Syndrome." However, they will try hard to take in the calories they need and so they do increase the volume of milk, resulting in an even higher net protein intake provided in inadequate calories.

3. The essential fatty acid content of cow's milk was discussed earlier in the infany feeding section and there is a chart there of EFA levels indifferent types of cow's milk. The same applies here. **The major point is that NONE of these milks (skim, 2% or whole) have much in the way of essential fatty acids, so it is not a reason to insist on whole milk for a child.**

What About after One Year? Whole? 2%? Skim?

After one year, whole cow's milk has been recommended for most children until age two. This recommendation is being seriously reconsidered at this time. **Lower fat milks can also be appropriate** based on a particular child's caloric requirements and the presence of other sources of fat in the diet. A complete review of this topic is beyond the scope of this paper, but it is useful to note that the global "whole-milk-to-age-two" concept is a public health guideline, and it is not intended to tie the hands of qualified health care professionals who determine that an individual child would be better served by using 2% or even skim milk. As shown later**, there are no magic qualities of cow's milk fat that make it an essential component of a child's diet.**

Consider that the breast-fed baby receives no cow's milk fat at all, nor does the formula-fed baby because the fat is replaced by vegetable oils. So why, at age one, would a child suddenly "need" milk fat? And unlike human milk, infant formulas provide no cholesterol (the precursor to myelin) at all. Interestingly, the milk fat is not the baby's primary source of cholesterol, so skim milk is not very different in regard to pre-formed cholesterol content than whole milk. (See chart on the next page.)

As noted earlier, cow's milk fat is a poor source of essential fatty acids, including those leading to production of DHA, a major fat involved in brain development. It is no more beneficial to the myelinization of a child's brain than any other source of acetate (the 2-carbon unit that is the substance from which cholesterol and then myelin are produced.) Acetate can be made from any calorie source … carbohydrate, protein or fat. **Interestingly, the reason I am given most often by health professionals for insisting on whole milk for a toddler is because "he needs it for brain development." Unfortunately, all that milk fat only provides a lot of calories and not the truly and directly brain-building components DHA or cholesterol.**

It is useful to consider that children have a growth schedule to keep, and if for some reason calories are inadequate, the child will burn fat stores to continue to grow in length and continue brain-building operations. If calories remain inadequate, linear growth will next be compromised and available energy will be preferentially used for brain-building. What this means is a child with inadequate calories will not have to make a judgment like "Gosh! I just can't decide! Should I make a brain or a fat bottom?" Anyway, it means that one could conclude that a child of appropriate/normal weight and apparent fat stores would have adequate calories for brain-building. When I see a little "Three-Roller" toddler (related to the number of rolls of fat on thighs) in my office, I do not worry that he would be at risk of getting inadequate calories "for his brain" if I switch him to skim milk from whole.

Consideration of these issues can allow for safe and intelligent departures from the "whole milk until two" recommendations, even as we wait for official changes to come from professional associations. This is especially true when insisting on feeding a high fat milk is contrary to the child's best interests, as is often the case with children with handicaps that decrease mobility, or overweight children whose caloric intake is clearly already generous.

The negative effect of whole milk on the overall nutritional quality of the diet

Many American toddlers are already consuming a generous amount of calories as fat from other food sources. **The use of whole milk also actually decreases the amount of other foods that a child with a normal appetite would consume.** If our model is that healthy infants will control their intake of calories to match their caloric requirements (and it is,) then feeding a diet that is higher in calorie-to-nutrient ratio would certainly decrease the over-all nutrient content.

Here is a simple example:

The calories in 4 oz whole milk is equal to the calories in
4 oz skim milk + 4 oz strained carrots.

They provide the same calories. Which provides more nutrients?

Insisting on using a high fat milk with a chubby toddler is generally not in his/her best interest. One consideration might be whether this would encourage excessive caloric intake, but the more likely response of an otherwise healthy child is that he/she will simply eat less food in general to obtain the appropriate (lower) number of calories, so **the nutrient:calorie ratio of the diet will decline.** This is especially non-helpful if the parent tells you that the child's usual diet features foods already high in fat like macaroni and cheese, french fries, potato chips, butter, gravy, peanut butter and hot dogs [I know … there is a choking issue with these last two especially that is very real. But the fact is, in real life many babies and toddlers are commonly fed these foods: "I give it to him because he really likes it."]

If the rest of the child's diet is described as above, it is already a very generous source of fat. It would be hard to come up with a logical reason why one would want to increase it further by insisting that the baby use whole milk simply because he/she is "not yet two."

Is there a risk of essential fatty acid deficiency if we give skim milk before age two instead of whole milk? No, for these reasons:

1. **There is the same risk of EFA deficiency** whether one uses whole, 2% or skim milk because, as shown earlier, none of these milks is a good source of essential fatty acids.

2. **For "normal, healthy children" who were either breastfed or fed commercial formulas for the first year, both feeding products provided generous EFAs and the child's fat stores would therefore contain generous amounts.** This assumes that the child has reasonably appropriate "normal healthy" fat stores upon visual inspection; an emaciated child would of course be at greater risk of EFA deficiency … but that child is not a member of the "normal, health children" group and a lot of rules will be different.

3. **Ironically, an example of the primary exception to the assumption of good EFA stores in a child with reasonable fat stores would be one who was switched to milk (whole, 2% or skim) at age 6 months or so of age**. That child will have had 6 months of EFA-free milk, so his/her fat stores are less trustworthy in this regard. In terms of stored EFA fat at least, we ARE what we eat!

There is also an historical perspective to consider:

When the "whole milk until age two" recommendation was established, there was no WIC Program, and many poor children actually got too few calories to grow and develop well.

Skim milk costs a few cents less per gallon, so the poorest families chose it. The AAP "whole milk" recommendation was an attempt at that time to remedy that situation to at least improve the adequacy of calories during this important period of brain development. That is ALL it addressed.

The WIC Program was established in the late 1970s to encourage breast-feeding by giving food to low-income nursing mothers, and by funding replacement of cow's milk (of any kind) for non-nursing infants with far more nutritious commercial formula. This particular poverty-related health problem has long ago disappeared … no poor babies in America have to be fed skim milk because of financial need. But the whole milk recommendation remains with us in spite of considerable evidence that it is really not ideal, and sometimes frankly suboptimal. It takes a long time for official positions to be changed.

The protein and micronutrient content of skim, 2% and whole milk is quite comparable. Vitamins A and D are equally fortified in all three. The only real difference is the calorie content:

Per 8 fluid oz	Protein (g)	Calories (Kcals)	Cholesterol (mg)	Calcium (mg)	Phosphorus (mg)	Vit. D (iu)	Vit. A (iu)	Vit. B2 (mg)	Potassium (mg)
Skim milk	8.4	86	4	300	300	100	500	0.3	406
2% Low Fat milk	8.1	121	18	297	232	100	500	0.2	399
Whole milk	8.2	159	33	291	228	100	500	0.4	370

(data from Pennington, J. Bowes & Church's Food Values of Portions Commonly Used 16th Ed.)

Interpretation of the chart above:

The difference in the cholesterol content is not a very significant, especially as we know that infants fed formula instead of mother's milk receive no pre-formed cholesterol at all for the first year. This means that infants apparently can make their own cholesterol to myelinate their brains and for normal formation of cell membranes. The exceptions are those with a rare metabolic defect called Smith-Lemli-Opitz Syndrome which interferes with the ability to make cholesterol.

The protein and micronutrient differences are also not significant.

The difference in calories <u>is</u> significant:

A teaspoon pat of butter has about 36 kcals.
The difference between skim and 2% milk is 35 kcals.
The difference between 2% and whole milk is 38 kcals.

So, one could picture their relative caloric and fat value as follows:
Skim milk = 8 oz Skim Milk
2% milk = 8 oz skim milk with a pat of butter floating in it.
Whole milk = 8 oz skim milk with 2 pats of butter floating in it.

Comparison of Skim Milk, 2% Low Fat Milk and Whole Milk

Today in the USA, the situation is quite different from the situation in the early 1970s described above. Because of programs like WIC, more babies are being breastfed, and no non-breastfed baby has to use skim milk instead of formula to save a few pennies and in the process receive only half the calories per oz.

It is also interesting to note that there is **a priority system among the body's tissues**, and a child's calories will be preferentially used for brain development at the potential cost to other tissues. Therefore, if a child has normal-to-generous fat stores on board one can assume that calories, at least, are sufficient for brain development. [Think of it this way: A toddler who takes in too few calories to meet all of his/her needs will NOT choose to have "thunder thighs"(also called "two-rollers") instead of a well-made brain.] The misunderstanding of this situation often leads to inappropriate use of high fat milk out of concern "for his brain."

See **"Aunt Cathy's PMS System of Baby Formula Decision-Making"** on the next page for a quick example of problem solving that uses the "Whole-2%-or-Skim" issue as an example.

Aunt Cathy's "PMS" System for Decision-Making:

Aunt Cathy
Cathy Breedon PhD, RD, CSP, FADA
Prenatal/Pediatric Nutrition Specialist

Whole, 2% or Skim Milk for Ages 1-2.

Sorting out the formulas or questions about when to use whole milk or skim milk can be complicated by issues unrelated to the science of nutrition. For example, a formula may not be usable in a situation for which it might be helpful because of costs, contracts with other formula companies, or confusion because of the way a product is promoted.

Health professionals serving large infant-feeding programs like WIC ("Special Supplemental Food Program for Women, Infants and Children" of the Dept. of Agriculture) often find this sort of confusion to be very costly in terms of time, money and frustration. In response to hearing these concerns raised by many state WIC programs, I devised a way of thinking about a formula and milk choice issue that attempts to sort out the important aspects from those that are irrelevant or changeable. The following example examines the question of the need to use whole milk after the first birthday until a child is two (which remains the current AAP recommendation):

The "Whole Milk Dilemma"

Many health professionals expressed concern that insisting on the use of whole milk for all of this age group of children may be inappropriate for those with lower than average ability to expend calories (e.g. children with spina bifida) and those who are already in the overweight / obese categories. However, they felt obligated to follow the official AAP recommendation.

In some states WIC programs did not allow clients to use whole milk without getting a physician's prescription. Much time and money was invested in obtaining documentation that the child needed a lower-calorie product. Policies and flow-charts had to be established to assure that these issues were handled correctly. Here's a great example:

"Proposed Policy Regarding the Use of 2% or Skim Milk by Children under Age Two Participating in the _____ State WIC Program.

1. For children observed to have three rolls of fat on the thigh, the Nutritionist may call the child's physician to request a prescription for skim or 2% milk to be used in place of whole milk.

2. Children under age two who have two or fewer rolls of fat on the thigh are to receive whole milk. Their fat stores will be monitored at clinic visits. Should they develop a third roll of fat, a prescription will be requested as described above."

It sounds pretty silly and unhelpful, but it was real.

This is especially irritating to the client and the MD when have both agreed that the child is doing very well on 2% or skim milk. So, lets look at the **"PMS"** of this issue:

P = Policy	M = Marketing	S = Science

Policy: "Only whole milk will only be allowed from the end of the first year of life until age two."

Marketing is not really an issue/problem with this issue (but it sometimes certainly IS.)

Science**:**

1. The only difference between whole, 2% and skim milk is in the **amount of fat and calories** per ounce. **Other nutrients are provided in the same amounts**.

2. The **form of fat** in the milk is a **very poor source of essential fatty acids**, it can be somewhat **constipating**, and **there is no special property of cow's milk fat (or goat's milk fat) that promotes brain development** … babies just need calories for that. None of the formulas contain milk fat so a formula-fed infant got none in the important first year. Neither did the breastfed baby because Mother's milk does not contain cow's milk fat either. So why would it be so important that children between ages 1 and 2 be fed a large percentage of their calories in the form of cow's milk fat, and why would we insist on it? Answer: I can't think of one.

3. Babies need adequate calories to grow and to myelinate their brains. Before the WIC Program was established many poor babies did not get enough calories because skim milk was a few cents cheaper than whole milk. **The reason for the AAofP recommending whole milk was to try to at least provide enough calories for the baby's growth and development, and whole milk has twice the calories of skim.** Once the WIC Program was established, no infant should be at risk of obtaining inadequate calories for growth and development because of poverty. The original reason for the recommendation is gone.

4. Insisting on using high fat milk in this situation may result in excess caloric intake, and if so it could contribute to obesity, the more common problem these days. However, usually it does NOT result in over consumption of calories, because the baby self –regulates caloric intake. But in that case it would certainly decrease the content of vitamins, minerals and protein in the children's diets because satiety induced by all those fat calories would cause them to eat less of other foods.

5. However, in the extreme, such as when a child has very low caloric requirements because of being able to move very little, this can cause lots of trouble. Similarly, it can cause real problems if (for example) the child is tube-fed and therefore unable to regulate his/her caloric intake. Additionally, policies that require waiting until a child is demonstrably overweight or obese before allowing a lower fat milk to be used are clearly not in children's best interests. (See my handout on nutrition for children with special needs for more information.)

Conclusions: In this scenario, it appears that the **Science** evaluation did not argue against using skim or 2% milk in children ages 1-2. What remains then is to determine if there is a good reason for continuing a **Policy** of requiring WIC nutritionists to provide only whole milk for children of this age group. If so, this also totally undermines the idea that professional WIC nutritionists are able to evaluate the appropriateness of a child's nutrition and to act on it. **If no good reasons can be proposed for requiring whole milk at this age, then CHANGE THE POLICY to use the form of milk or milk substitute judged to be best by the WIC health care professional who is considering the needs of the individual child in his/her care.**

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Regarding "A Trial Back on . . ."
A WIC Nutritionist Question

I received this <u>excellent question</u> in the mail, and I think it's a discussion worth sharing:

"At our WIC program, we are able to provide several different formulas if an infant does not tolerate our contract formulas. Typically, at the age of 5-6 months we will ask parents to reintroduce a contract product. We do this on the basis that as an infant gets older, he or she may tolerate the formula better than before (mainly due to the fact that the infant is tolerating solid foods at this point). This has been in practice long before my time here and I'm now looking for evidence/research to back this up."

Reply: The practice of re-trying a baby who did not tolerate a formula back on the original product was originally based on three things:

1) For many years, doctors and nutrition people perceived that soy-based products were inherently significantly lower quality than milk-based products. My formula handout discusses where we are with that. Basically, unlike some years ago, there is no big nutritional advantage to switching back to milk-based formulas for non-premature babies or those who are otherwise healthy.

If the baby's initial intolerance problem was in fact <u>allergy</u>-related (i.e. involving immunoglobulin E and not just a lactose intolerance type of issue,) such a trial would not be a great idea because allergy to cow's milk CAN "go away" but not usually in the first year. If it <u>were</u> a true allergy I would be very hesitant to just switch them back at 6 months (or whenever) without specific orders for safety reasons. If the baby were to have a severe anaphylactic reaction, for example, there could be very serious consequences.

An additional feature to consider here is the issue of trust between the nutritionist and the client. Many parents perceive the insistence on a re-trial of the formerly-problematic formula as being dangerous and foolhardy. We say, "well, if he still has the problem we can always switch back." However, the "if he still has the problem" part suggests that we pretty casually put their baby in what may be jeopardy.

Now, if it were very important to switch back, that is one thing. But if not? Why would we put them through this kind of anxiety-inducing experience? This is especially a problem when the parents feel very strongly about staying on the present product. We have the power to make them switch ("take it or leave it,") but to do it when there is no pressing reason (like a relative non-issue such as the perceived nutritional value of milk-based vs soy-based) it does have the potential to harm to our relationships with them.

2. A lot of the "switch back to the old formula" has roots in the use of more pricey hypoallergenic formulas in place of standard or soy products. In this situation, if the problem is not of a true allergy nature (rendering the hydrolyzation of the protein unnecessary) then the family or the WIC program can save some money by moving toward an intact-protein formula. However, if it is a true allergy, the same caveats apply as above. Example: hypoallergenic formula might be used for a colicky baby for whom it seemed to be helpful in the first months of life; however, most babies are not colicky after 6 months and they would likely do fine on standard or soy formula, saving big bucks. But colic is not an "allergy" and a recurrence is not potentially life-threatening the way an allergic response can be.

3. WIC costs have also been players in this drama, as the more costly hypoallergenic formulas have sometimes not been on a state's rebate formula list. In that case, the WIC people may be very eager to get back onto any of the "contract" formulas for budgetary reasons. However, again, in that case the primary urge is financial and not baby health, so we really have to be cautious about the circumstances in which we "make" the baby switch back.

So, the bottom line is that it is sort of a relic of the past to insist on switching back from soy-based back to milk-based. In regard to trials of intact protein in place of a hypoallergenic formula, it would depend on whether or not the reason for the switch initially was because of a true allergy. If it is an allergy I wouldn't see any big (non-financial) reason to switch back. Risks to baby health trump thriftiness every time in this situation.

Hope this helps! Cathy B.