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Strategies for the Prevention of Iron Deficiency: Iron in Infant Formulas and Baby Foods

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Iron deficiency is the most prevalent nutrition deficiency among infants and young children in industrialized as well as developing countries. It is a condition that is preventable through appropriate dietary measures. The infant born at term is endowed with a sizable amount of iron, which allows the infant to be fed a nearly iron-free diet (e.g., breast milk) for 4–6 months without becoming overtly iron deficient. This has led some to conclude that depletion of iron stores in healthy infants is a normal and, hence, innocuous process that usually gives way to gradual repletion of iron stores as dietary diversification leads to greater iron intakes.

Preservation of maternal iron stores at the expense of infant iron stores may have offered survival advantages to the human species during evolution. But there is no evidence that depletion of iron stores can offer advantages to infants in industrialized or developing countries. On the contrary, there is ample documentation of short-term as well as long-term adverse effects from iron deficiency. Prudence therefore dictates that a high priority be assigned to the prevention of iron depletion and deficiency among infants and young children worldwide.

Iron Nutriture in the United States—Recent Trends

The intake of iron by infants and children in the United States has been increasing over the past three or four decades. In the early 1960s, the median intake of iron by a 6-month-old infant was 9.1 mg/day.[1]

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Iron Intake by Infants in the United States

The intake of iron by infants and children in the United States has increased over the past three or four decades. In the early 1960s the mean intake of iron by 6-month-old infants was 9.1 mg/day (Filer and Martinez, 1964). As may be seen from Table 1, in the 1970s and 1980s mean iron intakes by infants in the United States ranged from 12.84 to 15.50 mg/day. The intake reported for 1994 (16.0 mg/day) suggests an upward trend in recent years. A more pronounced upward trend is noticeable for iron intakes by 1–2-year olds (Table 1). Iron intakes during the second year of life are consistently lower than intakes during the first year of life. Increased iron intake by infants in recent years is probably attributable to increased feeding of formula rather than fluid cow milk during the latter part of the first year of life and to increased usage of iron-fortified formula.[2]

Not only has the quantity of iron in the infant's diet increased during the past three or four decades, but the bioavailability of the iron consumed is now greater than in the past. In the 1960s infant cereals, which provided a high percentage of the iron in the infant's diet, were fortified with insoluble iron salts of poor bioavailability, and, although most infant cereals were subsequently fortified with electrolytic iron, this iron is also believed to be of poor bioavailability.[3–5] At present, a much greater percentage of iron in the infant's diet is obtained from infant formulas, and the form of iron is ferrous sulfate, a readily absorbed iron salt.

Iron Nutrition Status of Infants in the United States

Concurrent with an increase in iron intake in the United States since 1970, there has been a decrease in the prevalence of anemia and of iron deficiency

Table 1. Intake of iron (mg/day) by infants and toddlers in the United States*

Survey#	Year	Age: <1 year		Age: 1–2 years	
		Mean	SEM	Mean	SEM
NHANES I	1971–74	—	—	7.35	0.16
NFCS	1977–78	14.0	0.59	7.4	0.13
NHANES II	1976–80	12.84	0.93	8.57	0.13
NHANES III	1988–91	15.50	0.50	9.53	0.24
CSFII	1988–91	14.2	1.13	9.1	0.36
CSFII	1994	16.0	—	10.9	—

* Slightly modified from Third Report on Nutrition Monitoring in the United States (Interagency Board for Nutrition Monitoring and Related Research, 1995), except for CSFII 1994, which is from Cleveland et al.[32]

NHANES, National Health and Nutrition Examination Survey; NFCS, Nationwide Food Consumption Survey; CSFII, Continuing Survey of Food Intakes by Individuals.

among infants and preschool children. Based on transferrin saturation data reported in the first and second National Health and Nutrition Examination Surveys (NHANES I and II), the percentage of iron-deficiency in children less than 3 years of age was 11% in 1970–1975 and 5% in 1976–1980.[6] Because iron deficiency is the predominant cause of anemia in infants and young children, a decline in prevalence of anemia is also presumptive evidence of improvement in iron nutritional status. From 1976 through 1985, the prevalence of anemia decreased from 6.8% to 3.1% in low-income children in 6 states[7] (Yip et al., 1987a). The prevalence of anemia was also shown to decline among children aged 9–23 months from middle-income families in Minneapolis, Minnesota, from 6.2% in 1969–73 to 2.7% in 1982–86.[8] This favorable trend observed both in low-income and middle-income families can be attributed in part to increased intake of iron, and probably also in part to the greater bioavailability of iron in the current diet.

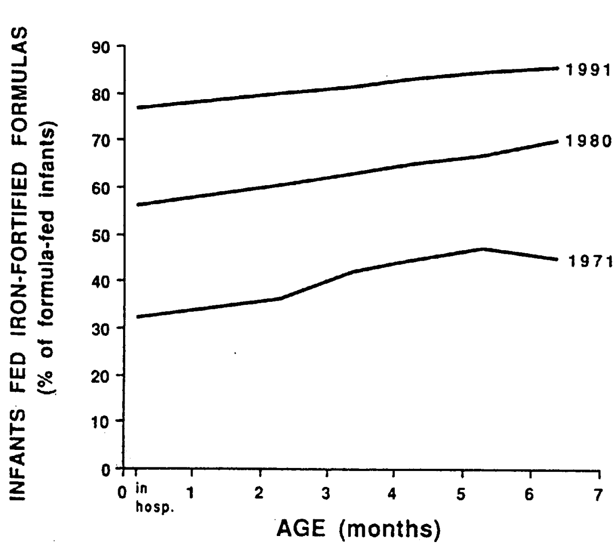

Figure 1. Percentage of formula-fed infants in the United States fed iron-fortified formulas in 1971, 1980, and 1991. From Fomon.[3]

Iron-Fortified Infant Formulas

Infant formula is an excellent vehicle for iron fortification because it is consumed by the infant in bulk quantity. In addition, it can be fortified with a highly available form of iron, ferrous sulfate, without causing discoloration or rancidity. Formulas usually contain ascorbic acid at levels of 50 mg/L or more. Stekel et al.[9] showed that erythrocyte incorporation of ^{59}Fe (a reflection of iron absorption) was significantly greater when ascorbic acid concentration of formula was 100 mg/L or more than when it was 50 mg/L or less. However, cow milk protein and calcium are potent inhibitors of iron absorption[2] and the concentration of these inhibitors in formulas studied by Stekel et al.[9] was approximately twice that of milk-based formulas currently marketed in the United States. In formulas marketed in the United States, with their much lower concentrations of protein and calcium than those studied by Stekel et al.,[9] concentrations of ascorbic acid of 50 mg/L in infant formulas are probably sufficient to result in major enhancement of iron absorption.

In the United States, formulas are fortified with iron in the form of ferrous sulfate to meet a label claim of 12 mg/L, whereas in Europe the label claim for iron is typically 6–8 mg/L. In the United States even "unfortified" or low-iron infant formulas contain small amounts of added iron, providing 1.5–4.0 mg/L.

Iron-fortified formulas were introduced in the United States in the late 1960s. As Figure 1 shows, acceptance of iron-fortified formulas has greatly increased over the years. In 1971, 32% of infants were fed iron-fortified formula during the first month of life. That percentage rose to 77% by 1991. From 1971 to 1991 two important changes in infant feeding explain, in part, the increase in use of iron-fortified formulas. The more important was the introduction and subsequent growth of the Special Supplemental Food Program for Women, Infants and Children (WIC), a federally funded assistance pro-

Table 2. Iron Absorption from Milk-Based Formula

Reference	Number of infants	Age (months)	Iron in formula (mg/L)	Test meal (mL)	Erythrocyte Incorporation % of dose	Erythrocyte Incorporation mg/d	Method
Rios et al.[12]	14	4–7	11.7	120	3.9	0.365*	^{59}Fe erythrocyte incorporation
	15		21.7	120	3.6	0.625*	
Saarinen and Siimes[13]†	10	11–13	0.8	50	12.0	0.080*	^{59}Fe whole body counting
	10		6.8	50	9.0	0.512*	
	10		12.8	50	7.0	0.688*	
Stekel et al.[9]	22	5–18‡	12.0	100–250	10.3	0.989*	^{59}Fe erythrocyte incorporation
Fomon et al. unpublished data	26	5	8.0	3 × 240	3.5	0.269	^{58}Fe erythrocyte incorporation
	20	5	12.0	3 × 240	2.5	0.291	
Davidsson et al. (unpublished data)	10	5	1.4	3 × 333	10.6	0.148	^{58}Fe erythrocyte incorporation

* For assumed formula intake of 0.8 L/d.
† Absorption rather than erythrocyte incorporation.
‡ Some subjects Fe-deficient.

gram for low-income families. Formula-fed infants enrolled in this program received iron-fortified formulas, and by 1991 approximately 40% of infants in the United States were enrolled in this program. The other change was the increasing use of isolated soy protein-based formulas, which had increased by 1991 to the point where about 20% of formula-fed infants received isolated soy protein based formulas. Such formulas are iron-fortified.

Figure 1 also indicates that older infants are more likely than younger infants to be fed iron-fortified formulas. There seems to be more reluctance to feed iron-fortified formulas to younger infants. The belief seems to exist that iron-fortified formulas cause disturbances of gastrointestinal function that manifest themselves in fussiness, colic, excessive gas, regurgitation, constipation, and loose stools. However, little objective documentation of these purported adverse effects has been produced. On the contrary, Oski[10] was able to show that in infants observed from 3 to 42 days of age, no difference existed in feeding intolerance, abdominal cramps, and stool characteristics between infants fed iron-fortified and noniron-fortified formula. Similarly, Nelson et al.[11] reported results of three studies—two of which were conducted in double-blind fashion, where infants were alternately fed iron-fortified and noniron-fortified formulas. Greenish and dark-colored stools were significantly more common when infants were fed iron-fortified formulas than when they were fed noniron-fortified formulas. However, there was no difference in fussiness, cramping, colic, flatus, regurgitation, or stool consistency. Thus, while it cannot be ruled out that an occasional infant may be "intolerant" of fortification iron, it appears that if adverse effects occur, they must be rare.

Availability of Iron from Fortified Infant Formulas

A number of studies have addressed the question of how available fortification iron is to infants. Comparisons between studies are hampered by the diversity of study methods used, including differences in the size of test meals and by differences in the age of infants and in their iron nutriture. Table 2 presents a summary of the salient features of published (and two unpublished) studies. Rios et al.[12] studied two groups of normal infants aged 4–7 months using erythrocyte incorporation of ^{59}Fe given with 120 mL of iron-fortified formula. None of the infants was anemic, but iron status was otherwise undefined. Geometric mean incorporation of ^{59}Fe was 3.9% and 3.6%, respectively. For an infant consuming 0.8 L of formula per day, this would represent 0.365 mg and 0.625 mg of iron incorporated into erythrocytes each day.

Saarinen and Siimes[13] used whole-body counting 2 weeks after ingestion of ^{59}Fe in a small amount (50 mL) of formula. Three groups of 10 infants aged 11–13 months were studied, using each of three formulas containing 0.8 mg/L, 6.8 mg/L, and 12.8 mg/L of iron, respectively, in the form of ferrous sulfate. Geometric mean retention of ^{59}Fe was 12%, 9%, and 7% of intake, respectively (equivalent [assuming formula intake of 0.8 L/day] to retention of 0.080 mg/day, 0.512 mg/day, and 0.688 mg/day). The high rates of absorption are probably explained, at least in part, by the small size of the test feedings.

The study by Saarinen and Siimes[13] is the only study using whole body counts to estimate iron retention. In the study by Stekel et al.,[9] a large number of infants ranging in age from 5 months to 18 months were studied. In one group of 22 infants fed a formula similar in composition to U.S. formulas, geometric mean incorporation of ^{59}Fe was 10.3% of the dose, equivalent to 0.989 mg/day for an infant ingesting 0.8 L of formula. The relatively high percentage of the iron isotope incorporated into erythrocytes is probably explained by the high values contributed by iron-deficient infants.

We have recently completed two studies, the results of which are included in Table 2.[14, unpublished] Both of these studies used erythrocyte incorporation of the stable isotope ^{58}Fe as label, and in both studies the label was administered in a sizable quantity of formula (720 mL and 1 L, respectively) consumed over a period of 3 days. In both studies the amount of total dietary iron actually consumed was determined, thus permitting calculation of the amount of dietary iron actually incorporated per day into erythrocytes. The study of Fomon et al.[14] was designed to determine erythrocyte incorporation of iron in infants fed formula with iron concentration of 8 mg/L and in infants fed formula with iron concentration of 12 mg/L. As Table 2 indicates, 2 weeks after administration of formula labeled with ^{58}Fe, geometric mean erythrocyte incorporation of ^{58}Fe adjusted for plasma ferritin concentration was 3.49% with formula containing 8 mg/L, and 2.57% with formula containing 12 mg/L. These percentages translated to 0.269 mg/day and 0.291 mg/day, respectively, of iron incorporated into erythrocytes. The difference in erythrocyte incorporation of iron (0.022 mg/d) is nutritionally trivial in view of the estimated requirement for absorbed iron of 0.55 to 0.75 mg/d. Thus, it may be concluded that infants incorporate nearly identical amounts of iron when fed formulas providing 8 or 12 mg/L of iron. Iron concentration of 8 mg/L may be preferable because there is less likelihood of adverse effects of iron on absorption of copper and zinc.[15–17] It is also of interest to note that the amounts of iron incorporated from either formula (8 mg/L or 12 mg/L) are only about one-half the estimated amount by which total hemoglobin iron increased each day, i.e., 0.59 mg.[14] This suggests that infants utilize storage iron for growth even when offered abundant amounts of dietary iron. Most likely, infants with poor iron nutriture derive a greater proportion of iron needed for hemoglobin synthesis from the diet than the infants studied by Fomon et al.[14] who had a good iron status.

In a study by Davidsson et al.,[unpublished] 10 infants were given a dose of ^{58}Fe together with one L of formula with iron concentration of 1.4 mg/L over 3 days. Geometric mean erythrocyte incorporation of ^{58}Fe was 10.6% of the dose, substantially higher than the percentages observed by Fomon et al.[14] in infants of similar age studied with the same technique. However, the amount of iron incorporated into erythrocytes averaged only 0.148 mg/day, about one-half the amount incorporated by infants fed formulas with iron concentration of 8 or 12 mg/L. It is therefore evident that infants fed formula with iron content of 1.4 mg/L have to draw more heavily on iron stores to meet ongoing iron needs for hemoglobin synthesis.

The studies summarized in Table 2 concern availability of iron from milk-based formulas. Limited information is available concerning iron availability from soy formulas in infants. In the study by Rios et al.,[12] erythrocyte incorporation of ^{59}Fe from a soy-based formula was determined in 13 infants between 4 and 7 months of age. Geometric mean incorporation was 5.4% of the dose, which was somewhat greater (not statistically significant) than incorporation from milk-based formulas. In adult subjects, Gillooly et al.[18] found iron availability to be markedly less from a soy-based formula than from a milk-based formula. Similarly, in the adult subjects studied by Hertrampf et al.,[19] availability of iron from a soy formula was only 1.7%. Davidsson et al.[20] determined erythrocyte incorporation of ^{58}Fe or ^{57}Fe in infants aged 13 to 30 weeks. Isotopes were administered in 217 g of soy-based formula with iron concentration ranging from 15.7 to 16.8 mg/L. In three groups of 10 infants each, geometric mean incorporation was 5.5%, 3.9% and 5.7%, respectively.

Effect of Iron Fortification of Formula on Iron Nutriture

Table 3 presents a summary of the published studies assessing the effect of iron fortification of formula on iron nutrition status of term infants. In the studies listed in Table 3, commercially prepared milk-based formulas were used, with the exception of the milk-based product reported by Hertrampf et al.[19] and the studies reported by Stekel et al.[20] The latter two reports concern formulas that were prepared in the home from full-fat cow's milk powder fortified with vitamins A and D, ascorbic acid (100 mg per 100 g of powder), and ferrous sulfate. Studies were included in Table 3 if infants were followed at least to age 9 months.

The outcome uniformly shows that iron fortification led to substantial improvement in iron nutriture and prevention of iron deficiency. In several studies the true extent of the difference in iron nu-

Table 3. Iron Nutritional Status of Term Infants Fed Iron-Fortified Formula

Reference	Number of infants	Study period (months)	Formula iron (mg/L)	Comment on iron nutritional status
Marsh et al.[28]	30	0–9	12	Higher hemoglobin, SI; less Iron-deficient anemia
	44	0–9	0	
Andelman and Sered[29]	603	0–18	12	9% anemia vs.
	445	0–18	0	76% anemia
Kattamis et al.[30]	15	0–9	12	Higher hemoglobin, SI
	15	0–9	0	
	16	0–9	0	
Saarinen[31]	47	0–12	11	Less iron deficiency
	29	0–12	0	
Hertrampf et al.[19]	45	3–9	15	Satisfactory
	47*	3–9	15	Satisfactory
Haschke et al.[27]	43	4–12	11	Higher ferritin at 12 months
	45	4–12	0	
Stekel et al.[20]	276	3–15	15	Less iron deficiency at 9 and 15 months
	278	3–15	0	

* ISP-based.

tritional status between infants fed high iron and low iron formulas was underestimated because subjects that became iron deficient were removed from the study and treated with iron.

The effect of iron fortification of a soy-based formula was studied by Hertrampf et al.[19] In spite of the generally low availability of iron from soy formulas in adult subjects,[18,19] at 9 months of age the incidence of anemia among 47 infants fed soy formula was nearly as low (4.3%) as among infants fed iron-fortified milk formula (2.2%) and much lower than among breast-fed infants not receiving supplemental iron.[18]

Iron in Beikost

With the exception of meat, which provides substantial amounts of highly available heme iron, beikost (foods other than milk or formula) tends to be low in intrinsic iron. Therefore, beikost is not a useful source of iron unless fortified with iron.

Cereals

In the United States, cereals are the first beikost items introduced into the infant's diet. Infant cereals are fortified with iron at a level of 45 mg/100 g dry cereal. Fortification of cereals with iron poses considerable problems because those iron sources that are relatively soluble and bioavailable cause fat oxidation and are responsible for discoloration upon reconstitution of cereals with milk or water. For this reason, cereals are usually fortified with electrolytic iron powder, a form of elemental iron. To be sufficiently nonreactive, electrolytic iron of relatively large particle size is used. Based on the few available data from studies in humans, Fomon[3] and Hurrell et al.[4] have suggested that availability of iron from non-iron fortified sources is probably low.

Walter et al.[22] conducted a large clinical trial designed to assess the effectiveness of infant cereal as a source of iron. The double-blind trial involved 515 infants who were randomly assigned to iron-fortified or non-iron-fortified rice cereal at 4 months of age and were studied to 15 months of age. Infants were otherwise either breast-fed or fed iron-fortified or low-iron formula. Breast-fed infants consumed about 26 g of cereal per day, and formula-fed infants about 30 g/day. Among breast-fed infants, 27% developed iron-deficiency anemia by 15 months if fed the nonfortified cereal, compared to 13% among those fed the iron-fortified cereal. Among infants fed noniron-fortified formula, the corresponding percentages were 24% and 8%. These results clearly show that feeding of iron-fortified cereal can improve iron nutriture in infants receiving little iron from other sources. However, even when cereal was consumed in quantities that exceeded those consumed by most infants in the United States, infant cereal did not reliably prevent iron deficiency.

In the study by Fuchs et al.,[23] one group of infants was fed liquid, pasteurized cow milk and was provided iron-fortified cereal, with the instruction to feed 43 g of cereal per day, i.e., more than twice the average amount consumed by infants in this age group. At 12 months of age, infants had a significantly poorer iron nutrition status, as indicated by serum ferritin concentration, than infants fed iron-fortified formulas. The results suggest that, at least in infants consuming cow milk as the major beverage, feeding of iron-fortified cereal is not a reliable means of preventing iron deficiency.

Forms of iron with higher bioavailability than electrolytic iron that are suitable for fortification of cereals are clearly desirable. Hurrell et al.[24] determined in adult subjects the availability of iron from infant cereals fortified with, among other sources, ferrous fumarate and ferrous succinate. Iron from ferrous fumarate was as available as iron from ferrous sulfate, and iron from succinate was nearly as available. In infants, Fomon et al.[24] confirmed that iron from ferrous fumarate ingested with cereal is of similar availability as iron from ferrous sulfate ingested with cereal. These results indicate that there are alternate sources of iron for cereal fortification that warrant further exploration. A promising source, NaFe EDTA[25] deserves special attention and should be studied in infants.

Beikost Containing Meat

From an iron perspective, meat is an attractive food choice. Meat not only provides heme iron that is well absorbed, it also enhances the absorption of dietary nonheme iron.[26] Because of the latter property, meat-containing foods would seem to be particularly suitable vehicles for fortification iron. Haschke et al.[27] provided evidence that regular consumption of iron-fortified beikost containing meat is effective in preventing iron deficiency in infants fed low-iron formula. Fomon et al.[24] determined the availability of iron from an iron-fortified vegetable-beef preparation and found it to be somewhat less than that from a wet-packed cereal-fruit preparation similarly fortified with ferrous sulfate. In subsequent (unpublished) studies, the authors similarly failed to demonstrate increased availability of fortification iron from beikost items with higher meat content than the vegetable-beef preparation. The exception was strained beef, which was associated with a threefold increase in availability of fortification iron.

Summary and Conclusions

1. The need for absorbed iron during the first year of life is so great that satisfactory iron nutritional status can be assured only with the aid of iron-fortified foods or use of a medicinal iron supplement.
2. Iron-fortification of infant formula offers a highly effective means of providing adequate amounts of available iron. Iron added to formula usually reaches a large proportion of infants, it is safe, free of known hazards, and well accepted.
3. The optimal level of iron fortification of infant formulas has yet to be established. It appears that 12 mg/L, the level used in the United States, is unnecessarily high. The optimal iron level depends somewhat on the intended use of formula, e.g., when used as the primary feeding mode or as a follow-up or supplementary feeding in breast-fed infants.
4. Iron fortification of infant cereals is feasible, but its effectiveness is hampered by the poor availability of iron sources currently used. Because of the modest effectiveness of fortification iron provided with cereals, it appears imprudent to rely on cereals as the sole source of dietary iron for infants and young children.
5. Other foods commonly consumed by infants can be fortified with iron. If they are dry-packed, the same restrictions apply as for infant cereals. If wet-packed, ferrous sulfate can be used. The inclusion of meat in such foods is desirable, although an enhancing effect of meat on the availability of fortification iron has not been demonstrated for levels of meat commonly used in such foods.

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