

# THE JOURNAL OF NUTRITION



journal homepage: https://jn.nutrition.org/

Community and International Nutrition

# Iron-Fortified Foods Are Needed To Meet the Estimated Average Requirement for Iron in Australian Infants Aged 6 to 12 Months



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#### ABSTRACT

**Background:** Meeting iron intake recommendations is challenging for infants 6–12 mo, especially breastfed infants. Three-quarters of Australian infants 6–12 mo have iron intakes below the estimated average requirement (7 mg), placing them at risk of iron deficiency. After 6 mo, breastmilk is no longer sufficient to meet the increased demand for iron, and iron-rich complementary foods are recommended. Iron-fortified foods may be a means of improving iron intake in infants, particularly those that are breastfed.

**Objectives:** The aims of the study were as follows: 1) to examine the effect of milk-type and fortified foods on iron intake and the prevalence of inadequacy in infants 6–12 mo; 2) to model the effect of fixed amounts of iron-fortified infant cereal (IFIC) at 6 levels of iron fortification on total iron intake and the prevalence of inadequacy; and 3) to assess the effect IFIC on the intake of other nutrients in the diet.

**Design:** Secondary analysis of cross-sectional dietary intake data of infants 6-12 mo (n=286) participating in the Australian Feeding Infants and Toddlers Study (OzFITS) 2021.

Results: Median (interquartile range) iron intake was 8.9 (7.5, 10.3); 6.3 (4.5, 8.2); and 2.7 (1.5, 4.4) mg/d in formula-fed, combination-fed, and breastfed infants, respectively. The corresponding prevalence of inadequacy was 19%, 67%, and 96%. Infants who consumed fortified foods had higher median iron intakes than those who did not, 6.2 compared with 1.9 mg/d. Dietary modeling showed that consuming 18 g (300 kJ) of IFIC, fortified at 35 mg/100 g dry weight, reduces the prevalence of inadequacy for iron from 75% to 5% for all infants.

Conclusions: Iron intakes are low in Australian infants, especially for breastfed infants in the second half of infancy. Modeling shows that 300 kJ of IFIC, the current manufacturer-recommended serving, fortified at 35 mg/100 g dry weight, added to infant diets would be an effective means to reduce the prevalence of inadequacy for iron.

Keywords: iron, infant feeding, iron-fortified infant cereal, dietary modeling, Australia

### Introduction

Globally, iron deficiency is the most common nutritional deficiency, with children aged <2 y among the most affected [1]. Iron deficiency leads to anemia, but even in the absence of anemia, iron deficiency in young children has been associated with impaired

behavioral, cognitive, and psychomotor skill development [2]. Term infants are born with sufficient iron stores to last  $\sim$ 6 mo [3]. After that, iron stores become depleted, and breastmilk alone is no longer sufficient to meet the high iron requirements of the older infant. The estimated average requirement (EAR) for iron in Australia, which is based on the US National Academy of Medicine

Abbreviations: AI, Adequate Intake; AUSNUT, Australian Food Supplement and Nutrient Database; EAR, estimated average requirement; FITS, Feeding Infants and Toddler Study; OzFITS, Australian Feeding Infant and Toddler Study; IFIC, Iron Fortified Infant Cereal; IMAPP, Intake Modeling Assessment and Planning Program; NRV, Nutrient Reference Values; UL, Upper Limit.

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EAR [4], is 7 mg/d for infants 6–12 mo; the proportion of the population below this cut-point is at risk of inadequate intake [5].

In 2021, we conducted the Australian Feeding Infants and Toddler Study (OzFITS), a nationwide survey assessing the nutrient intakes of children 6–24 mo [6]. Three-quarters of infants 6-12 mo had iron intakes below the EAR and were at risk of inadequacy [7]. This may be attributable to several factors, particularly high breastfeeding rates and low consumption of iron-rich complementary foods.

The WHO [8] and Australia's National Health and Medical Research Council, and other health authorities recommend breastfeeding for the first year of life and beyond [9,10]. However, breastmilk is a poor source of iron [11], and breastfed infants are at higher risk of inadequate iron intake [12,13]. Thus, infant feeding guidelines in most high-income countries, including Australia, emphasize iron-rich complementary foods, such as iron-fortified cereals, red meat (beef, lamb, or pork), poultry and fish as first foods [10,14,15]. In OzFITS 2021, 223/286 (78%) of infants were breastfed, and the percentage of infants consuming red meat, poultry, and fish was low at 23%, 17%, and 11%, respectively. Among consumers of animal-source foods, red meat, the most bioavailable iron source, supplied only 0.4 mg/d iron [16]. Even if higher amounts of iron-rich animal-source foods were given to infants, it is unlikely they would meet iron requirements, given the small amounts of food infants consume.

Iron supplementation is an effective means of meeting iron requirements in infancy [17]. However, adherence is low, partly because of side effects, such as stained teeth, constipation, and nausea [18]. Moreover, an overdose of iron supplements is a cause of accidental poisoning in young children [19]. Iron-fortified infant cereals (IFIC) may be an alternative for infants to meet their iron requirements. In Australia, IFICs are an attractive fortification vehicle as Food Standards Australia New Zealand mandate fortification of these cereals between 20- and 50-mg iron per 100 g dry weight [20].

In this study, we aimed: 1) to examine the effect of milk source (breastmilk only, infant formula only, or a combination) on iron intake and the prevalence of iron inadequacy in Australian infants (6–12 mo); 2) to determine iron intake and the prevalence of iron inadequacy among infants who do and do not consume iron-fortified foods; 3) to model the impact of replacing foods consumed by infants, on an equicaloric basis, with varying amounts of IFIC fortified between 20 and 50 mg/100 g dry weight on iron and key nutrients. The dietary modeling aims to maximize the percentage of infants meeting the EAR for iron while minimizing those exceeding the Australian upper limit (UL) (20 mg/d).

# Methods

# **Participants**

The study design and data collection methods used in OzFITS 2021 have been described elsewhere [6,7]. OzFITS 2021 was a cross-sectional survey designed to assess feeding practices and dietary intakes in children aged 0–2 y. Between April 2020 and April 2021, 1140 caregiver-child dyads across Australia were enrolled through a trial recruitment company [21]. The study was approved by the Women's and Children's Health Network

Human Research Ethics Committee (HREC/19/WCHN/44), and all caregivers gave informed verbal consent.

# **Data collection**

At enrolment, all caregivers completed a telephone-based sociodemographic and child-feeding questionnaire related to feeding practices since birth, including breastfeeding history, formula use, age at which complementary foods were introduced, and dietary supplement use. Questions about breastfeeding were adopted from the 2010 Australian National Infant Feeding Survey [22]. Data were collected and managed using REDCap (Research Electronic Data Capture), a secure web-based platform [23].

Dietary intake was assessed using a 24-h food record [6]. A random subset of caregivers (~30%) was asked to complete a second 24-h food record on a nonconsecutive day to estimate the usual energy and nutrient intake distribution. Caregivers were sent a study package by mail that included a food record booklet and portion size estimation guide [24,25]. Once the study package was delivered, caregivers received a telephone call from staff with instructions on completing the food record. Caregivers were then asked to record everything their child consumed for 24 h starting from midnight, using the food record booklets provided on their assigned record-keeping day. Once completed, caregivers were asked to take photos of the food record(s) and scan or e-mail them to study staff. Interviewers then contacted the caregiver, and techniques described in the 5-pass 24-h recall method were used to review food records with caregivers [26].

Breastmilk intakes were estimated using volume equations based on breastfeeding duration, consistent with previous studies conducted in the UK and Australia [27–29]. Caregivers recorded the number of minutes the child spent actively suckling at the breast to a maximum of 10 min; feeds lasting <2 min were excluded. Expressed breastmilk was recorded as the volume consumed by the infant.

# Handling of food intake data

Dietary data were entered into FoodWorks Professional version 10, which used the 2011/13 Australian Food, Supplement, and Nutrient Database [30]. The nutrient composition for commercial infant and toddler foods was unavailable in FoodWorks, so a study-specific food and Nutrient Database was developed and added. All food items entered into FoodWorks were assigned food group codes based on the AUSNUT classification system [30]. Six caregivers reported giving iron supplements to their infants aged between 6 and 12 mo. Only 2 caregivers reported giving iron supplements to their infants on the day of the 24-h food record. Thus, we did not include the contribution of iron supplements to iron intake.

The first day of each infant's dietary intake was used to classify infants as breastfed, formula-fed, or combination-fed and as consumers or nonconsumers of iron-fortified foods, including formula, IFIC, ready-to-eat breakfast cereals, snack foods, and bread.

# IFIC modeling

Using day 1 and day 2 dietary intake data (original intake data), we modeled the impact of replacing IFICs, infant formula, and breastmilk consumed with a hypothetical cereal (Test IFIC),

matched for energy and nutrients. The nutrient profile of the Test IFIC was similar in nutrient composition to infant cereals on the Australian market (Supplementary Table 1). We examined the theoretical impact of 3 substitution models (consumption scenarios) of Test IFIC (150 kJ, 300 kJ, and 450 kJ) at 6 levels of iron fortification ranging from 20 to 50 mg/100 g dry weight. The amount of iron in the Test IFIC was increased in 5-mg increments in each model to determine the optimal level of fortification.

For each model, we replaced foods and drinks consumed by the child starting with IFIC already consumed, then infant formula, and finally, breastmilk. For example, in model 1 (150 kJ, 9 g Test IFIC), if the child consumed 50 kJ of IFIC and 800 kJ of infant formula, all the IFIC and 100 kJ of infant formula was replaced with 150 kJ of Test IFIC and its nutrients. If the child consumed no IFIC or infant formula, 150 kJ of breastmilk was replaced with 150 kJ of Test IFIC and its corresponding nutrients. We then summed each child's total energy and nutrient intake after replacement. Next, we calculated theoretical amounts of iron in 9 g of Test IFIC fortified between 20 and 50 mg/100 g dry weight in 5-mg increments. For example, 9 g of Test IFIC fortified at 20 mg/100 g dry weight contains 1.8-mg iron. After replacement, this amount of iron was added to each child's daily total iron. In total, 6 levels of fortification were evaluated. This process was repeated for models 2 (300 kJ, 18 g Test IFIC) and 3 (450 kJ, 27 g Test IFIC), which replaced energy and nutrients from IFIC, infant formula, and breastmilk consumed by infants in the amounts specified.

The quantity of Test IFIC used in each model was designed to approximate the amount of IFIC consumed by OzFITS 2021 infants (model 1), the manufacturer-recommended serving size (model 2), and to ensure infants remained below the UL for iron (model 3). Because breastfed infants are at a higher risk of inadequate iron intake [31], we ran subgroup analyses that only included breastfed and combination-fed infants.

# Statistical analysis

In the original OzFITS 2021 study, we estimated a minimum sample size of 227 caregiver-child pairs to determine the true prevalence of inadequacy for iron to be within  $\pm 5\%$  and 95% confidence interval. Usual energy and nutrient intake distributions were calculated for the baseline data (original intake data) [7] and each substitution model of Test IFIC at each iron fortification level using Intake Modeling, Assessment, and Planning Program (IMAPP) software [32]. Adjusted energy and nutrient intakes were compared with the nutrient reference values (NRVs) for Australia and New Zealand [5]. EARs are available for only 2 nutrients (iron and zinc) for infants aged <12 mo; therefore, the percentage of infants exceeding the adequate intake (AI) was reported for all other nutrients. Based on original intake data, the percentiles of energy and nutrients were calculated for each milk type and the consumers and nonconsumers of the fortified foods. Percentiles of energy and nutrients were also calculated for the total population (baseline) and each substitution model at each level of iron fortification. The prevalence of inadequate and excessive iron intake was estimated using the EAR and tolerable UL using the cut-point method [33].

#### Results

# Participant characteristics

Of the 976 caregivers of children aged 0–24 mo eligible for a food record, 308 enrolled with an infant between 6 and 12 mo. Of these caregivers, 110 were randomly assigned to record a second days' food record. In total, 286/308 (93%) completed a single day's food record, and 102/286 (36%) completed a second day's food record (Figure 1). The attrition rate for the overall study was ~10%. Approximately 60% of the infants were the only child in the household (Table 1). Caregivers were highly educated, with 80% completing a bachelor's degree or above. More than 50% of participants reported annual household incomes >AUD 100,000. All infants received complementary foods on the day(s) of the food record.

# Effect of milk type and fortified foods

Of infants, 6–12 mo, 183 (64%) received only breastmilk, 63 (22%) received only formula, and 39 (14%) received both formula and breastmilk as their milk source, alongside complementary foods, on the first day of the food record. Median (interquartile range [IQR]) iron intake was highest in infants who received formula only, followed by combination-fed infants, and lowest in breastfed infants: 8.9 (7.5, 10.3); 6.3 (4.5, 8.2); and 2.7 (1.5, 4.4) mg/d, respectively. The corresponding prevalence of inadequacy for iron for each milk feeding type was 19%, 67%, and 96%.

Table 2 highlights the difference in iron intake and prevalence of iron inadequacy between consumers of any fortified foods and nonconsumers of these foods. Infants who received any fortified foods had higher median iron intakes (6.2 compared with 1.9 mg/d) and a lower prevalence of inadequacy (62% compared with 100%) than those who did not. Similarly, infants who received any formula had higher median iron intakes (7.9 mg/d compared with 2.8 mg/d) and a lower prevalence of inadequacy (37% compared with 96%) than infants who did not. Only 25% of infants consumed IFIC with a median (IQR) intake of 8.6 (3.9, 15.0) g/d. Consumers of IFICs had a higher median (IQR) iron intake than nonconsumers, 5.5 (3.9, 8.4) and 3.5 (1.8, 6.7) mg/d, respectively. Consumers of other ironfortified foods (eg, ready-to-eat breakfast cereals, infant snack foods, and bread) also had higher iron intakes, but these foods were consumed by <20% of infants.

Table 3 reports iron intakes in the original (OzFITS 2021) study and the 3 substitution models using the Test IFIC at 6 levels of iron fortification. In OzFITS 2021, the median iron intake was 4.3 mg/d, and the prevalence of inadequate iron intake was 75%. At the 25-mg/100-g fortification level, 62% and 36% of infants would still be at risk of inadequate iron in model 1 (150 kJ Test IFIC) or model 2 (300 kJ Test IFIC), respectively. Fortification above 35-mg/100-g iron was unacceptable as 5%–20% of infants would exceed the UL under model 3 (450 kJ Test IFIC). The optimal fortification level was 35 mg/100 g; only 5% of infants under model 2 (300 kJ Test IFIC) had iron intakes below the EAR, and only 2% under model 3 (450 kJ Test IFIC) exceeded the UL. However, half of the infants under model 1 (150 kJ Test IFIC) would have iron intakes below the EAR. Nevertheless, this

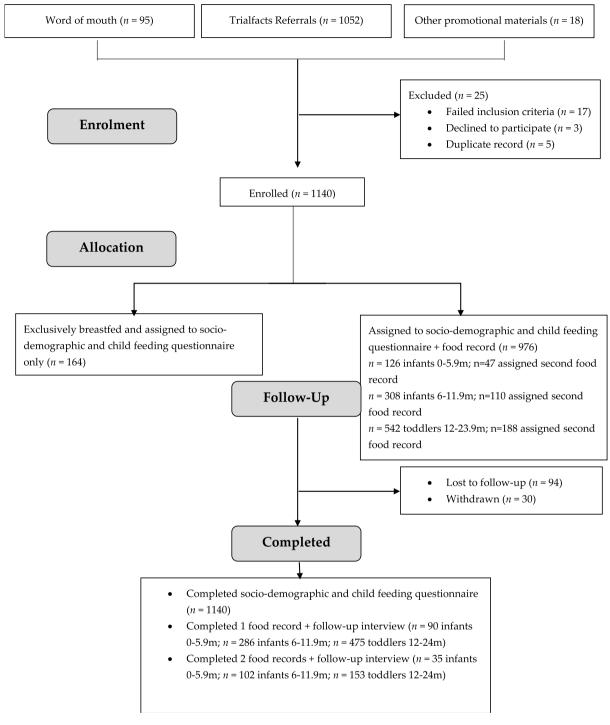


FIGURE 1. Participant Flow Diagram OzFITS 2021.

fortification level would still increase their iron intake by  $\sim$ 2.4 mg/d at the 50th percentile.

Supplementary Tables 2–5 show the effect of replacing IFIC already consumed, infant formula, and breastmilk, matched for energy and nutrients, with Test IFIC at 150, 300, and 450 kJ/d on the distribution of energy and nutrients and NRV compliance. Protein intake remained constant with a median of 20 g/d in all substitution models, but fat intake decreased by 5 g/d, and carbohydrate intake increased by 17 g/d under model 3 (450 kJ Test IFIC). The percentage of infants above the AI for fat (30 g/d) fell

from 64% at baseline to 40% under model 3 (450 kJ Test IFIC). In this model, the percentage of infants above the AI for carbohydrates (95g/d) increased from 23% to 44%. For zinc, 17% of infants were <EAR at baseline; this remained similar under all 3 substitution models ranging from 17% to 25%. The percentage who exceeded the UL for zinc (5 mg/d) remained constant between 22% and 27%. For other micronutrients, the percentage of the population above the AI in each model was within 10% of the baseline.

Table 4 reports iron intakes in the original (OzFITS 2021) study and the 3 substitution models using the Test IFIC at 6 levels

**TABLE 1** Characteristics of caregivers and infants (n = 308)

Characteristic	Mean $\pm$ SD or $n$ (%)
Caregiver	
Age, y	$34\pm4$
Educational attainment	
Year 10 or 11	1 (3)
Secondary school	8 (3)
Certificate or diploma	47 (16)
Bachelor's degree or above	230 (80)
Born in Australia	212 (74)
Family income (AUD) <sup>2</sup>	
<40,000	5 (2)
40,001–70,000	29 (10)
70,001–105,000	54 (19)
105,001–205,000	151 (53)
>205,000	43 (15)
Not disclosed	4 (1)
Number of children in the household	
1 Child	175 (61)
2 Children	90 (32)
> 2 Children	21 (7)
Child	
Age (mo)	$8.6\pm1.7$
Sex (female)	140 (49)
Milk feeding type <sup>1</sup>	
Breastmilk only	184 (64)
Formula only	63 (22)
Combination	39 (14)

 $<sup>^{1}</sup>$  Milk infant received on day 1 of food record. Combination, the infant received both breastmilk and formula. N=286.

of iron fortification for breastfed and combination-fed infants. OzFITS 2021 median iron intake was lower (2.9 mg/d), and the prevalence of inadequacy for iron was higher (92%) in this subgroup compared with the main analysis with all infants. Under model 1 (150 kJ Test IFIC), fortification at 25 mg/100 g minimally reduced the prevalence of inadequacy to 83%. Under model 2 (300 kJ Test IFIC), the reduction in the prevalence of inadequacy was greater, falling to 51%.

The optimal level of iron fortification of the Test IFIC in this subgroup was 35 mg/100 g. At 35 mg/100 g, only 6% of infants under model 2 (300 kJ Test IFIC) had inadequate iron intakes; no

infants exceeded the UL under model 3 (450 kJ Test IFIC). Under model 1 (150 kJ Test IFIC), 72% still had inadequate iron intakes at this fortification level; but the median iron intake doubled from 2.9 to 5.8 mg/d. At 40 mg/100 g, the prevalence of inadequacy was 0% for infants under model 2 (300 kJ Test IFIC). Under model 1 (150 kJ Test IFIC), the prevalence of inadequacy decreased from 92% to 62%. Only 1% of infants exceeded the UL at this fortification level under model 3 (450 kJ Test IFIC).

Supplementary Tables 6–9 show the effect of replacing IFIC already consumed, infant formula, and breastmilk, matched for energy and nutrients, with Test IFIC at 150, 300, and 450 kJ/d on the distribution of energy and nutrients and NRV compliance for breastfed only and combination-fed infants. The change in macronutrient intakes from baseline in the 3 models was not markedly different from that observed in the main analysis. For zinc, the prevalence of inadequacy ranged from 22% to 26% for all models tested, similar to the main analysis. The percentage of infants who exceeded the UL for zinc (5 mg/d) in the models was lower in this subgroup analysis than in the main analysis, never exceeding 10%. The percentage of infants exceeding the AI for all micronutrients also did not differ from the baseline by >10% in all the models tested.

# Discussion

To our knowledge, this is the first study to model the impact of infant cereals fortified with iron at a range of fortification levels on iron intakes and the prevalence of inadequacy according to milk feeding type. OzFITS 2021 data showed breastfed and combination-fed infants to have a lower median intake and a higher prevalence of inadequacy for iron compared with formula-fed infants. Using OzFITS 2021 intake data as the base case, dietary modeling with IFIC increased median iron intakes from 4.3 to 9.8 mg/d and reduced the prevalence of inadequacy from 75% to 5% for all infants. The effect was even more pronounced in breastfed and combination-fed infants, with median iron intakes increasing from 2.9 to 8.8 mg/d and the prevalence of inadequacy falling from 92% to 6%.

Meeting iron requirements is challenging in late infancy, especially for breastfed infants (10). Iron in breast milk is

**TABLE 2**Percentiles of iron intake and prevalence of inadequate iron intakes (% <EAR) in infants 6–12 m consuming or not consuming iron-fortified foods<sup>1</sup>.

	Consumers			Nonconsum	Nonconsumers			
	n (%)	Iron (mg/d) 50 <sup>th</sup> (25 <sup>th</sup> , 75 <sup>th</sup> )	% <ear<sup>2</ear<sup>	n (%)	Iron (mg/d) 50 <sup>th</sup> (25 <sup>th</sup> , 75 <sup>th</sup> )	% <ear< th=""></ear<>		
All infants $(n = 286)$								
Any fortified food <sup>3</sup>	185 (65)	6.2 (3.9, 8.4)	62	101 (35)	1.9 (1.1, 3.0)	100		
Formula	102 (36)	7.9 (6.6, 9.7)	37	184 (64)	2.8 (1.5, 4.4)	96		
Iron-fortified infant cereals	74 (26)	5.5 (3.9, 8.9)	64	212 (74)	3.5 (1.8, 6.7)	79		
Breakfast cereal <sup>4</sup>	55 (19)	5.9 (2.7, 8.3)	62	231 (81)	4.0 (1.9, 6.7)	78		
Infant Snack foods <sup>5</sup>	35 (12)	6.2 (4.4, 9.3)	60	251 (88)	4.0 (1.9, 6.9)	77		
Iron-fortified bread <sup>6</sup>	11 (4)	4.1 (2.1, 7.0)	55	275 (96)	4.1 (2.1, 7.0)	76		

Abbreviations: EAR, estimated average requirement.

 $<sup>^{2}</sup>$  1 AUD = 0.69 USD on 13th February 2023.

<sup>&</sup>lt;sup>1</sup> Based on adjusted iron intakes derived from IMAPP.

<sup>&</sup>lt;sup>2</sup> Iron EAR is 7 mg/d (5).

<sup>&</sup>lt;sup>3</sup> Infant consumed one or more iron-fortified food on day 1 of the food record.

<sup>&</sup>lt;sup>4</sup> Any ready-to-eat iron-fortified breakfast cereal (i.e., Corn Flakes and Weet-Bix).

<sup>&</sup>lt;sup>5</sup> Snacks designed for infants which are fortified with iron (i.e., rusks and biscuits).

<sup>&</sup>lt;sup>6</sup> Commercially manufactured bread that is fortified with iron.

**TABLE 3** Percentiles of iron intake and the prevalence of inadequate and excessive intakes in infants aged 6–12 mo (n = 286) modeled using 3 quantities of iron-fortified infant cereal (9, 18, and 27 g) fortified at 6 levels of iron fortification 20–50 mg iron/100 g dry weight<sup>1</sup>

	Dry cereal weight (g)	Distributi	on of iron inta	ke			NRV compliance (%	<b>%</b> )
		10th	25th	50th	75th	90th	<ear<sup>2 (7 mg)</ear<sup>	>UL (20 mg)
OzFITS 2021	0	1.1	2.1	4.3	7.0	9.5	75	0
9g IFIC (150 KJ)								
20 mg/100 g	9	2.6	3.4	5.3	8.4	11.5	65	0
25 mg/100 g	9	3.0	3.9	5.8	8.8	11.9	62	0
30 mg/100 g	9	3.4	4.3	6.3	9.3	12.3	57	0
35 mg/100 g	9	3.9	4.8	6.7	9.7	12.7	53	0
40 mg/100 g	9	4.3	5.2	7.2	10.1	13.1	48	0
45 mg/100 g	9	4.8	5.7	7.6	10.6	13.6	43	1
50 mg/100 g	9	5.2	6.1	8.1	11.0	14.0	37	1
18g IFIC (300 KJ)								
20 mg/100 g	18	4.6	5.4	7.1	9.4	11.8	49	0
25 mg/100 g	18	5.5	6.3	8.0	10.4	12.6	36	0
30 mg/100 g	18	6.4	7.2	8.9	11.3	13.5	22	0
35 mg/100 g	18	7.3	8.1	9.8	12.2	14.4	5	0
40 mg/100 g	18	8.2	9.0	10.7	13.1	15.3	0	1
45 mg/100 g	18	9.1	9.9	11.6	14.0	16.2	0	2
50 mg/100 g	18	10.0	10.8	12.5	14.9	17.1	0	2
27g IFIC (450 KJ)								
20 mg/100 g	27	6.5	7.5	9.2	11.3	13.5	18	0
25 mg/100 g	27	7.9	8.8	10.5	12.7	14.8	0	0
30 mg/100 g	27	9.2	10.2	11.9	14.0	16.1	0	1
35 mg/100 g	27	10.6	11.5	13.2	15.4	17.5	0	2
40 mg/100 g	27	11.9	12.9	14.6	16.7	18.8	0	5
45 mg/100 g	27	13.3	14.3	15.9	18.1	20.2	0	10
50 mg/100 g	27	14.6	15.6	17.3	19.4	21.5	0	20

Abbreviations: NRV, nutrient reference value; EAR, estimated average requirement; UL, tolerable upper intake level.

more bioavailable than other sources of iron; however, it contains  $\sim 0.5$  mg/L compared with the 10--12 mg/L in formula [34]. In our study, the median iron intake for breastfed infants was 2.7 mg/d, compared with 8.9 mg/d in formula-fed infants and 6.3 mg/d in combination-fed infants. Similar patterns were observed in the 2016 US FITS; breastfed, formula-fed, and mixed-fed infants had median iron intakes of 3.3, 16.8, and 9.6 mg/d, respectively [12]. Only one other Australian study has compared iron intakes in breast and formula-fed infants from 6 to 12 mo. In this Melbourne-based study, Atkins et al. [27] (n = 457) found breastfed infants had a lower mean iron intake (6.3 mg/d) than formula-fed infants (11.4 mg/d) [27].

Infant feeding recommendations emphasize the inclusion of iron-rich complementary foods such as meat, fish, and poultry. However, a 100 g serving of ground beef would only provide 2.6-mg iron, making up one-third of an infant's estimated energy requirements  $\sim \! 1000 \text{kJ}$  [30]. Moreover, these foods are not commonly consumed in this age group and contributed < 0.5-mg total iron in Australian studies [27,35] and < 0.04 mg in the 2016 US FITS [12], similar to our study. Thus, alternative strategies to increase iron intake, such as iron-fortified foods, may be needed to increase iron intake.

At present, a large proportion of Australian infants do not consume iron-fortified foods. Ready-to-eat iron-fortified breakfast cereals and bread are consumed by <20% of infants, are not designed for infants, and have low levels of iron fortification. Some infant snacks are fortified with iron but are not widely consumed. IFICs were consumed by one-quarter of infants in our study; however, iron intakes among consumers were only

1.5 mg higher than in nonconsumers due to the small quantities consumed.

Most IFICs in Australia are fortified at 20–25 mg/100 g dry weight. Among consumers in OzFITS 2021, the median amount of IFIC consumed was 9 g/d dry weight. Based on our modeling, this would supply an additional 1–1.5-mg iron daily. If the amount of iron in IFICs was increased to 35 mg/100 g, these infants would receive an additional 2.4-mg iron, and the prevalence of inadequacy would drop from 75% to 53%. Whereas 53% appears to be a high prevalence of inadequacy, the EAR is not a threshold above or below which a child's adequacy for iron is assured, but a continuum of risk, and any increase in iron intake would be beneficial.

Fortifying IFICs with 35 mg/100 g iron and encouraging caregivers to provide 100-g prepared IFIC (300 kJ) would be a practical approach for most infants to achieve the EAR for iron. It is also encouraging that in a high consumption scenario (450 kJ), only 2% of infants would be exposed to iron intakes above the UL. The UL in the Australian NRVs is 20 mg compared with the 40 mg UL set for this age group in the US and Canadian Dietary Reference Intakes [33] and may not present significant risk. Infants would unlikely consume 450 kJ of IFIC (~150 g prepared cereal), and even then, it would not be daily: the UL is based on long-term exposure [33].

In our dietary modeling, we substituted infant formula and breastmilk with IFIC; therefore, it was necessary to assess the effect of the substitution on the intake of other nutrients. Apart from iron and zinc, all other nutrients in this age group lack an EAR and only have AIs. Thus, it is difficult to assess the effect of

<sup>&</sup>lt;sup>1</sup> The usual intake distributions were determined by running original intake data (OzFITS 2021) and each model through IMAPP.

<sup>&</sup>lt;sup>2</sup> Iron EAR is 7 mg/d and UL is 20 mg/d (5).

**TABLE 4** Percentiles of iron intake and the prevalence of inadequate and excessive intakes in breastfed or combination-fed infants aged 6–12 mo (n = 223) modeled using 3 quantities of iron-fortified infant cereal (9, 18, and 27 g) fortified at 6 levels of iron fortification 20–50 mg iron/100 g dry weight<sup>1</sup>

	Dry cereal weight (g)	Distributi	on of iron inta	ke			NRV compliance (%	%)
		10th	25th	50th	75th	90th	<ear<sup>2 (7 mg)</ear<sup>	>UL (20 mg)
OzFITS 2021	0	1.0	1.8	2.9	5.0	6.7	92	0
9g IFIC (150 KJ)								
20 mg/100 g	9	2.6	3.3	4.4	6.0	7.5	85	0
25 mg/100 g	9	3.0	3.8	4.9	6.4	7.9	83	0
30 mg/100 g	9	3.5	4.2	5.3	6.9	8.4	76	0
35 mg/100 g	9	3.9	4.7	5.8	7.3	8.9	72	0
40 mg/100 g	9	4.4	5.1	6.2	7.8	9.3	62	0
45 mg/100 g	9	4.8	5.6	6.7	8.2	9.8	57	1
50 mg/100 g	9	5.3	6.0	7.1	8.7	10.2	47	1
18g IFIC (300 KJ)								
20 mg/100 g	18	4.5	5.1	6.1	7.4	8.8	69	0
25 mg/100 g	18	5.4	6.0	7.0	8.3	9.7	51	0
30 mg/100 g	18	6.3	6.9	7.9	9.2	10.6	27	0
35 mg/100 g	18	7.2	7.8	8.8	10.1	11.5	6	0
40 mg/100 g	18	8.1	8.7	9.7	11.0	12.4	0	0
45 mg/100 g	18	9.0	9.6	10.6	11.9	13.3	0	0
50 mg/100 g	18	9.9	10.5	11.5	12.8	14.2	0	0
27g IFIC (450 KJ)								
20 mg/100 g	27	6.5	7.1	8.2	9.6	10.8	20	0
25 mg/100 g	27	7.8	8.5	9.6	10.9	12.2	0	0
30 mg/100 g	27	9.2	9.8	10.9	12.3	13.5	0	0
35 mg/100 g	27	10.5	11.2	12.3	13.6	14.9	0	0
40 mg/100 g	27	11.9	12.5	13.6	15.0	16.2	0	1
45 mg/100 g	27	13.2	13.9	15.0	16.3	17.6	0	1
50 mg/100 g	27	14.6	15.2	16.3	17.7	18.9	0	4

Abbreviations: NRV, nutrient reference value; EAR, estimated average requirement; UL, tolerable upper intake level.

adding IFIC on the nutritional adequacy of diets; however, intakes above the AI can be assumed to be adequate. IFIC is a cereal, so it was not unexpected that carbohydrate intake would increase and fat would decrease with increasing amounts of IFIC. The micronutrient AIs remained within 10% for all nutrients suggesting that even in the highest consumption scenario (450 kJ Test IFIC), intakes would not be significantly altered. On average, infants aged 6–12 mo received 1800 kJ from breastmilk or infant formula, so replacing 300 kJ of breastmilk or formula with IFICs would not markedly affect nutrient intake. Thus, Australian health authorities may need to advise parents, particularly those who choose to breastfeed, to increase the amount of IFIC they offer their children. Further, Food Standards Australia and New Zealand may need to consider increasing the minimum level of iron fortification in IFICs.

The strengths and limitations of OzFITS 2021 have been described previously [6,7]. As with all dietary assessment methods, there are limitations that are well described. We acknowledge that our sample is not representative of the Australian population. Our population is more educated and economically advantaged. However, our breastfeeding rates and duration and infant formula use are consistent with the 2010 Australian National Infant Feeding Survey [22]. In Australia, as in the United States, breastfeeding rates are lower, and formula feeding rates are higher in the less educated and economically advantaged [36,37]. Paradoxically, infants from socially advantaged families might be at greater risk of inadequate iron intake. Given government recommendations to breastfeed for one year and beyond, we owe it to mothers who follow this

advice to ensure their child receives sufficient iron [9,10]. Our modeling replaced IFIC already consumed by infants, formula, and breastmilk with Test IFIC on an equicaloric basis; however, infant feeding behavior may not reflect this replacement in practice. Further research is needed to confirm if this substitution strategy aligns with infant energy regulation.

A key strength of the study was the direct data capture afforded by the food record, which led to robust measures of dietary intake. Unique household recipes, including those from ethnically diverse groups, were captured along with seasonal variation in intake as data collection was completed over one full year. We only used day 1 of the food record to classify infants as consumers or nonconsumers of iron-fortified foods, which may have under or overestimated the number of consumers of fortified foods. However, for infants, we had 2 days of recalls for 36%; >90% of those that consumed iron-fortified cereals on day 1 also consumed them on day 2. A challenge inherent in assessing dietary intake in this age group is obtaining accurate estimates of breastmilk intake. Like other studies, we relied on volume equations based on breastfeeding duration [38]. Moreover, the nutrient composition of breastmilk was obtained from the 2011/13 AUSNUT database [30], the values for which are based on US data collected >30 y ago [39]. Finally, there is uncertainty around the EARs, especially for young children. Further research is needed to evaluate the iron status of older infants using biomarkers to corroborate the high prevalence of inadequate intakes in this group.

In conclusion, Australian infants are not meeting the EAR for iron, especially breastfed infants. Our dietary modeling suggests

<sup>&</sup>lt;sup>1</sup> The usual intake distributions were determined by running original intake data (OzFITS 2021) and each model through IMAPP.

<sup>&</sup>lt;sup>2</sup> Iron EAR is 7 mg/d and UL is 20 mg/d [5].

that one serving of IFIC (300 kJ, 18g) fortified at 35 mg/100 g per day would be an effective means to increase iron intake and reduce the prevalence of inadequacy in this age group, particularly for breastfed and combination-fed infants who are at greater risk for inadequate intakes. Our dietary modeling used current intakes of infants aged 6–12 mo to replace IFIC already consumed, formula, and breastmilk with Test IFIC on an equicaloric basis. However, it is unknown if infants replace energy from formula or breastmilk in this manner. Further research is needed to test the feasibility of this replacement strategy in infants.

# **Author contributions**

For the original OzFITS 2021 study, the roles and contributions were as follows:

The authors' responsibilities were as follows – TJG, MM: conceived of the study and obtained funding; NAM, TJG, MJN, MM: developed the research protocol and methodology; NAM: oversaw the collection of the original data; NAM, TJG: completed formal analysis; NAM, TJG, MJN, MM: drafted and approved the original manuscripts.

For the current study, the authors' responsibilities were as follows – NAM, TJG: conceived the study; NAM, TJG: developed the research protocol; NAM, TJG, JAG: carried out the formal analysis; NAM, TJG, JAG: wrote the first draft of the paper; all authors: provided critical input and read and approved the final manuscript.

# Conflict of interest

NAM was supported by an Adelaide Scholarship International from the University of Adelaide. MM was supported by an Australian National Health and Medical Research Council (NHMRC) Investigator Grant (APP2016756); MJN was supported by an NHMRC fellowship (Early Career Fellow APP1156518). The other authors report no conflicts of interest.

# **Funding**

This work was supported by a grant in aid (to MM and TJG) from the Nestlé Nutrition Institute (Australia). The Nestlé Nutrition Institute had no role in the design of this study either in its execution, analyses, interpretation, or decision to submit results.

# Data availability

Data described in the article, code book, and analytic code may be available upon request pending application and author approval.

# Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tjnut.2023.08.018.

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