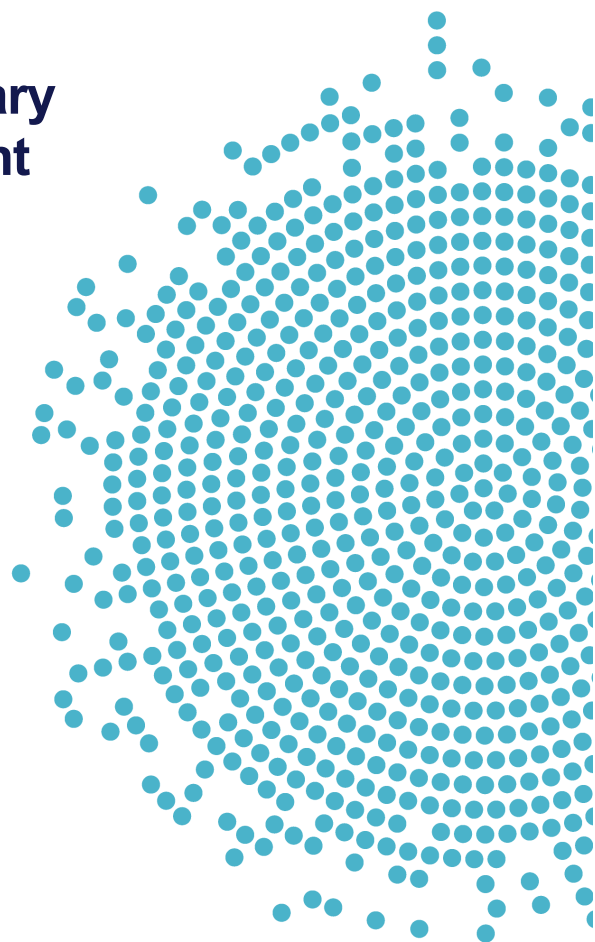


Timing of Introduction of Complementary Foods and Beverages and Micronutrient Status: A Systematic Review

Julie E. Obbagy, PhD, RD,^a Laural K. English, PhD,^b Tricia L. Psota, PhD, RD,^a Perrine Nadaud, MS,^b Kirsten Johns, MS,^b Yat Ping Wong, MLS, MPH,^c Nancy Terry, MLS,^d Nancy F. Butte, PhD, RD,^e Kathryn G. Dewey, PhD,^f David M. Fleischer, MD,^g Mary Kay Fox, MEd,^h Frank R. Greer, MD,ⁱ Nancy F. Krebs, MD, MS,^j Kelley S. Scanlon, PhD, RD,^k Kellie O. Casavale, PhD, RD,^l Joanne M. Spahn, MS, RDN,^m Eve Stoodly, PhD^m



^a Systematic review analyst, Nutrition Evidence Systematic Review (NESR) team; Office of Nutrition Guidance and Analysis (ONGA), Center for Nutrition Policy and Promotion (CNPP), Food and Nutrition Service (FNS), U.S. Department of Agriculture (USDA)

^b Systematic review analyst, NESR team; Panum Group under contract with FNS, USDA

^c Systematic review librarian, NESR team; ONGA, CNPP, FNS, USDA

^d Biomedical librarian, NESR team; National Institutes of Health Library, U.S. Department of Health and Human Services (HHS)

^e Member, Complementary Feeding Technical Expert Collaborative, Pregnancy and Birth to 24 Months Project; Baylor College of Medicine, Emeritus

^f Member, Complementary Feeding Technical Expert Collaborative, Pregnancy and Birth to 24 Months Project; University of California, Davis

^g Member, Complementary Feeding Technical Expert Collaborative, Pregnancy and Birth to 24 Months Project; University of Colorado Denver School of Medicine, Children's Hospital Colorado

^h Member, Complementary Feeding Technical Expert Collaborative, Pregnancy and Birth to 24 Months Project; Mathematica Policy Research

ⁱ Member, Complementary Feeding Technical Expert Collaborative, Pregnancy and Birth to 24 Months Project; University of Wisconsin, Madison, Emeritus

^j Member, Complementary Feeding Technical Expert Collaborative, Pregnancy and Birth to 24 Months Project; University of Colorado School of Medicine, Department of Pediatrics

^k Member and Federal Expert Group Liaison, Complementary Feeding Technical Expert Collaborative, Pregnancy and Birth to 24 Months Project; Office of Policy Support, FNS, USDA

^l Project Lead, Pregnancy and Birth to 24 Months Project; Office of Disease Prevention and Health Promotion, HHS

^m Project Lead, Pregnancy and Birth to 24 Months Project; NESR team, ONGA, CNPP, FNS, USDA

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Complementary Feeding Technical Expert Collaborative (TEC):

- Nancy F. Butte, PhD, RD, United States Department of Agriculture /Agricultural Research Service, Children's Nutrition Research Center, Baylor College of Medicine, Department of Pediatrics, Emeritus
- Kathryn G. Dewey, PhD, University of California, Davis, Department of Nutrition
- David M. Fleischer, MD, Children's Hospital Colorado, University of Colorado School of Medicine, Department of Pediatrics, Section of Allergy and Immunology
- Mary Kay Fox, Med, Mathematica Policy Research
- Frank R. Greer, MD, University of Wisconsin School of Medicine and Public Health, Department of Pediatrics, Emeritus
- Nancy F. Krebs, MD, MS, University of Colorado School of Medicine, Department of Pediatrics
- Kelley S. Scanlon, PhD, RD, United States Department of Agriculture, Food and Nutrition Service (formerly of the Centers for Disease Control and Prevention, Division of Nutrition, Physical Activity, and Obesity)

Nutrition Evidence Systematic Review (NESR) team:

- Julie E. Obbagy, PhD, RD USDA, Lead Analyst (05/2016-project completion)
- Laural K. Englishⁱ, PhD, Panum Group, Analyst (11/2016-project completion)
- Tricia L. Psota, USDA, Lead Analyst (07/2015-06/2016)
- Perrine Nadaudⁱ, MS, Panum Group, Analyst (07/2015-05/2016)
- Kirsten Johnsⁱ, MS, USDA, Panum Group, Analyst (07/2015-05/2016)
- Yat Ping Wong, MLS, MPH, USDA, Librarian
- Nancy Terry, MLS, NIH, Librarian

Project Leads:

- Eve Essery Stoody, PhD, USDA
- Joanne M Spahn, MS, RD, FADA, USDA
- Kellie O Casavale, PhD, RD, HHS

Federal Expert Group (FEG)-Technical Expert Collaborative (TEC) Liaisons:

- Kelley S. Scanlon, PhD, RD, United States Department of Agriculture, Food and Nutrition Service (formerly of the Centers for Disease Control and Prevention, Division of Nutrition, Physical Activity, and Obesity)

All TEC and NESR team members, Project leads, and FEG-TEC liaisons participated in establishing the research questions, analytic framework, and study inclusion and exclusion criteria. JEO, LKE, TLP, PN, KJ, YWP, and NT developed and conducted the literature search, screened search results, and identified studies for inclusion. JEO and LKE extracted data and assessed risk of bias for included studies. NFC, KGD, MKF, FRG, NFK, DF and KSS reviewed and provided substantive feedback on all systematic review materials, including the synthesis of the body of evidence, conclusion statement,

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and grade of the strength of the evidence. JEO prepared this report and EES provided oversight. All authors critically reviewed and approved the final report. The authors declare no conflicts of interest.

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INTRODUCTION

This document describes a systematic review conducted to answer the following question: What is the relationship between timing of introduction of complementary foods and beverages and micronutrient status? This systematic review was conducted as part of the Pregnancy and Birth to 24 Months (P/B-24) Project by USDA's Nutrition Evidence Systematic Review (NESR).

The purpose of the P/B-24 Project was to conduct a series of systematic reviews on diet and health for women who are pregnant and for infants and toddlers from birth to 24 months of age. This project was a joint initiative led by USDA and HHS, and USDA's NESR carried out all of the systematic reviews. A Federal Expert Group (FEG), a broadly representative group of Federal researchers and program leaders, also provided input throughout the P/B-24 Project. More information about the P/B-24 Project has been publishedⁱⁱ and is available on the NESR website: <https://nesr.usda.gov/project-specific-overview-pb-24-0>.

NESR, formerly known as the Nutrition Evidence Library (NEL), specializes in conducting food- and nutrition-related systematic reviews using a rigorous, protocol-driven methodology. To conduct each P/B-24 systematic review, NESR's staff worked with a Technical Expert Collaborative (TEC), which is a group of 7–8 leading subject matter experts.

NESR's systematic review methodology involves developing and prioritizing systematic review questions, searching for and selecting studies, extracting and assessing the risk of bias of data from each included study, synthesizing the evidence, developing a conclusion statement, grading the evidence underlying the conclusion statement, and recommending future research. A detailed description of the methodology used in conducting systematic reviews for the P/B-24 Project has been publishedⁱⁱⁱ and is available on the NESR website: <https://nesr.usda.gov/pb-24-project-methodology-0>. In addition, starting on page 21, this document includes details about the methodology as it was applied to the systematic review described herein. An [analytic framework](#) that illustrates the overall scope of the question, including the population, the interventions and/or exposures, comparators, and outcomes of interest, is found on page 21. In addition, the [literature search plan](#) that was used to identify studies included in this systematic review is found on page 21.

ⁱⁱ Stoody EE, Spahn JM, Casavale KO. The Pregnancy and Birth to 24 Months Project: a series of systematic reviews on diet and health. *Am J Clin Nutr*. 2019;109(7):685S–97S. doi: [10.1093/ajcn/nqy372](https://doi.org/10.1093/ajcn/nqy372).

ⁱⁱⁱ Obbagy JE, Spahn JM, Wong YP, Psota TL, Spill MK, Dreibelbis C, et al. Systematic review methodology used in the Pregnancy and Birth to 24 Months Project. *Am J Clin Nutr*. 2019;109(7):698S–704S. doi: [10.1093/ajcn/nqy226](https://doi.org/10.1093/ajcn/nqy226).

List of abbreviations

| Abbreviation | Full name |
|---------------------|--|
| BF | Breastfed or breastfeeding |
| CFB | Complementary foods and beverages |
| FEP | Free erythrocyte protoporphyrin |
| FEG | Federal Expert Group |
| FF | Formula fed or formula feeding |
| Hb | Hemoglobin |
| Hct | Hematocrit |
| HHS | Department of Health and Human Services |
| ID | Iron deficiency |
| IDA | Iron deficiency anemia |
| MCV | Iron deficiency |
| NEL | Nutrition Evidence Library |
| NESR | Nutrition Evidence Systematic Review |
| NIH | National Institutes of Health |
| P/B-24 | Pregnancy and Birth to 24 Months Project |
| RCT | Randomized controlled trial |
| RDW | Red cell distribution width |
| SF | Serum ferritin |
| TEC | Technical Expert Collaborative |
| Tf | Transferrin |
| TfR | Transferrin receptor |
| TIBC | Total iron binding capacity |
| UK | United Kingdom |
| US | United States |
| USDA | United States Department of Agriculture |

| Abbreviation | Full name |
|--------------|---------------------|
| ZPP | Zinc-protoporphyrin |

WHAT IS THE RELATIONSHIP BETWEEN TIMING OF INTRODUCTION OF COMPLEMENTARY FOODS/BEVERAGES AND MICRONUTRIENT STATUS?

PLAIN LANGUAGE SUMMARY

What is the question?

- The question is: What is the relationship between timing of introduction of complementary foods and beverages and micronutrient status?

What is the answer to the question?

- Moderate evidence suggests that introducing complementary foods and beverages at 4 months of age compared to 6 months of age offers no long term advantages or disadvantages in terms of iron status among healthy, full-term infants who are breastfed, fed iron fortified formula, or both.
- There is not enough evidence to determine the relationship between timing of introduction of complementary foods and beverages and zinc, vitamin D, vitamin B12, folate, or fatty acid status.

Why was this question asked?

- This important public health question was identified and prioritized as part of the U.S. Department of Agriculture and Department of Health and Human Services Pregnancy and Birth to 24 Months Project.

How was this question answered?

- A team of Nutrition Evidence Systematic Review staff conducted a systematic review in collaboration with a group of experts called a Technical Expert Collaborative

What is the population of interest?

- Generally healthy infants and toddlers who were fed complementary foods and beverages from ages 0-24 months and had micronutrient status examined through 24 months of age

What evidence was found?

- This review includes 9 studies.
- These studies compared the age when complementary foods and beverages were first introduced and micronutrient status.
- Complementary foods and beverages are foods and beverages other than human milk or infant formula provided to an infant or young child.
- Most studies found no relationship the age when complementary feeding started and micronutrient status.
- Studies need to consider other factors that could impact this relationship.

How up-to-date is this review?

- This review includes literature from 1/1980 to 3/2016.

Technical abstract

Background

- Complementary feeding is the process that starts when human milk or infant formula is complemented by other foods and beverages, beginning during infancy and typically continuing to 24 months of age.
- This systematic review was conducted by the Nutrition Evidence Systematic Review team as part of the U.S. Department of Agriculture and Department of Health and Human Services Pregnancy and Birth to 24 Months Project.
- The goal of this systematic review was to answer the following research question: What is the relationship between timing of introduction of complementary foods and beverages and micronutrient status?

Conclusion Statement and Grades

- Moderate evidence suggests that introducing complementary foods and beverages at 4 months of age compared to 6 months of age offers no long term advantages or disadvantages in terms of iron status among healthy, full-term infants who are breastfed, fed iron fortified formula, or both. (Grade: Moderate – Iron Status)
- There is not enough evidence to determine the relationship between timing of introduction of complementary foods and beverages and zinc, vitamin D, vitamin B12, folate, or fatty acid status. (Grade: Grade Not Assignable - Zinc, Vitamin D, Vitamin B12, Folate, and Fatty Acid Status)

Methods

- The systematic review was conducted by a team of staff from the Nutrition Evidence Systematic Review in collaboration with a Technical Expert Collaborative.
- A literature search was conducted using 4 databases (CINAHL, Cochrane, Embase, and PubMed) to identify articles published from January 1980 to March 2016 that examined the age when complementary foods and beverages (CFB) were first introduced and micronutrient status. CFB were defined as foods and beverages other than human milk or infant formula provided to an infant or young child. Micronutrient status outcomes included iron, zinc, vitamin B12, folate, vitamin D, and/or folate status. A manual search was done to identify articles that may not have been included in the electronic databases searched. Articles were screened in a dual manner, independently by 2 NESR analysts, to determine which articles met predetermined criteria for inclusion.
- Data from each included article were extracted, risks of bias were assessed, and both were checked for accuracy. The body of evidence was qualitatively synthesized, a conclusion statement was developed, and the strength of the evidence (grade) was assessed using pre-established criteria including evaluation of the internal validity/risk of bias, adequacy, consistency, impact, and generalizability of available evidence.

Summary of Evidence

- Nine studies published from 1/1980 to 3/2016 met the inclusion criteria for this systematic review, with most studies examining the relationship between timing

of introduction of CFB and iron status. Few studies examined zinc, vitamin D, vitamin B12, folate, and/or fatty acid status.

- The majority of studies reported no significant associations between timing of CFB introduction and micronutrient status.
- Additional factors that need to be considered in examining the relationship between the age at which CFB are introduced and micronutrient status include: birth weight, post-natal growth, type of feeding (breast, formula, or mixed feedings), iron stores at birth, and intake and absorption of iron from sources other than human milk, including types and amounts of CFB being consumed.

FULL REVIEW

Systematic review question

What is the relationship between timing of introduction of complementary foods and beverages and micronutrient status?

Conclusion statement

Moderate evidence suggests that introducing complementary foods and beverages at 4 months of age compared to 6 months of age offers no long term advantages or disadvantages in terms of iron status among healthy, full-term infants who are breastfed, fed iron fortified formula, or both.

There is not enough evidence to determine the relationship between timing of introduction of complementary foods and beverages and zinc, vitamin D, vitamin B12, folate, or fatty acid status.

Grade

Moderate: Iron Status; **Grade Not Assignable:** Zinc, Vitamin D, Vitamin B12, Folate, and Fatty Acid Status

Summary

- Complementary foods and beverages (CFB) were defined as foods and/or beverages other than human milk or infant formula (liquids, semisolids, and solids) provided to an infant or young child to provide nutrients and energy. This systematic review includes studies that compared different ages at which complementary foods were introduced.
- Micronutrient status outcomes included iron, zinc, vitamin D, vitamin B12, folate, and/or fatty acid status from birth to 24 months of age.
- Nine studies published from 1/1980 to 3/2016 met the inclusion criteria for this systematic review, with most studies examining the relationship between timing of introduction of CFB and iron status. Few studies examined zinc, vitamin D, vitamin B12, folate, and/or fatty acid status.
- The majority of studies reported no significant associations between timing of CFB introduction and micronutrient status.
- Additional factors that need to be considered in examining the relationship between the age at which CFB are introduced and micronutrient status include: birth weight, post-natal growth, type of feeding (breast, formula, or mixed feedings), iron stores at birth, and intake and absorption of iron from sources other than human milk, including types and amounts of CFB being consumed.

Description of the evidence

Nine articles were included in the systematic review that examined the relationship between the timing of first introduction of CFB and micronutrient status from birth to 24mo of age. Most of the studies examined the relationship between timing of introduction of CFB and iron status [1-7], with 2 studies assessing the relationship with zinc [3, 4], and 1 study each examining folate [8], vitamin B12 [8], and vitamin D status [9]. There were no studies identified that assessed fatty acid status in relation to the timing of CFB introduction (**Table 1**).

The studies included subjects who were healthy, with many excluding subjects with illnesses or conditions that could impact complementary feeding or nutritional status. In addition, the studies included subjects who had a normal birthweight (≥ 2500 g) and/or were born at full term (>37 weeks (wk)), though a few did not describe the birth weight or gestational age of subjects [1, 4, 6]. Per the inclusion criteria, the studies were conducted in countries that were ranked as very high or high on the Human Development Index [10]. Two studies specified that the sample was majority white [3, 9], and 1 included a population that consisted of 50% white and 50% Asian children [5]. The other studies did not specify the racial/ethnic background of subjects; but they were conducted in representative populations from the countries in which they were conducted (i.e., China, Greece, Iceland, Iran, the UK, and Norway).

Timing of CFB Introduction and Iron Status

Seven studies examined the relationship between timing of introduction of CFB and iron status, including 3 RCTs [2-4], 1 prospective cohort study [7], 1 nested case-control study [5], and 2 case-control studies [1, 6] (Table 1).

All 3 RCTs examined the effects of introducing CFB at different ages on iron status. Jonsdottir et al. [2] randomized exclusively BF infants to start receiving CFB at either 4mo or 6mo of age. Kattelman et al. [3] randomized FF infants to receive CFB beginning at either 3-4mo or 6mo of age. Details regarding the infant formula consumed, and whether it was fortified with iron or zinc, were not provided, as subjects consumed commercial infant formulas of the parents' choice. However, based on the time during which the study was conducted in the US, it can be assumed that those formulas were supplemented with iron (~ 10 - 12 mg/L, though "low iron" formulas (1.1 - 1.5 mg/L) [11] were also available). Lonnerdal et al. [4] randomized FF infants to receive CFB at 4mo, or to continue exclusive FF until 7mo. The formula consumed by infants contained 7mg/L iron and 7mg/L zinc; the micronutrient content of the cereal provided to infants at 4mo was not described. Jonsdottir et al. [2] and Kattelman et al. [3] did not provide CFB to subjects, nor were subjects provided with specific instructions as to the types of CFB to introduce; so CFB were either commercial or home-prepared foods selected by the parents. Jonsdottir et al. [2] reported that among infants who received CFB, mean daily intake of iron was only 0.6 mg, with the main dietary sources of iron being infant cereals (67%), infant formula (17%), and fruit purées (8%). In addition, they reported that iron intake did not correlate with any iron status indices at 6mo, nor did total food or formula intake. Kattelman et al. [3] reported that while the infants who received CFB earlier had significantly greater iron intake at 4, 5, and 6mo, mean iron intakes in both groups were reportedly adequate, and there were no differences in mean iron intake between groups after 6mo of age. Further, Kattelman et al. [3] also reported that there were no differences between the groups in meat intake (red meat, poultry, or seafood) at 12mo or 24mo of age.

The observational studies defined the timing of introduction of CFB in different ways, and included subjects with varied infant milk feeding practices (i.e., whether they were primary fed breast milk, infant formula, and/or cow's milk at the time when complementary feeding began). Ghorashi et al. [1] and Morton et al. [5] both analyzed age of introduction to CFB as a continuous variable, which represented the mean, in months, when solid food was first introduced. Subjects in Ghorashi et al. [1] were majority BF (65%), though 11% were FF, and 25% received a mixture of breast milk, infant formula, and cow's milk, and there were no differences in milk feeding practices

between cases of iron deficiency and controls. Approximately 25% of subjects in Morton et al. [5] were BF, and a significantly greater percentage of iron deficient compared to iron sufficient infants were fed full cow's milk before 6mo of age (44% vs. 7%). Thorsdottir et al. [7] examined the duration of exclusive breastfeeding as a continuous variable, which was based on monthly assessments of whether infants were exclusively BF or had been introduced to other types of liquids or solids besides breast milk. While this definition could include infant formula, the authors noted that in Iceland, where the study was conducted, it is commonly recommended that infants weaned from breast milk should receive cow's milk after the age of 6mo. Tympa-Psirropoulou et al. [6] looked at age of introduction to CFB and age of introduction to meat. While age of CFB introduction was not defined, age of meat introduction was examined categorically, comparing introduction at 5, 6, and 7mo of age. Iron deficient cases in this study had shorter duration of breastfeeding, and were more likely to be fed fresh cow's milk vs. fortified cow's milk, after BF or infant formula were discontinued, compared to iron sufficient control subjects.

Several different markers of iron status were assessed at a variety of ages from 4mo through 24mo in the studies included in this systematic review, including hemoglobin (Hb), serum ferritin (SF), mean corpuscular volume (MCV), hematocrit (Hct), red cell distribution width (RDW), total iron binding capacity (TIBC), transferrin receptor (TfR), and zinc-protoporphyrin (ZPP). Reference values for markers of iron status in infants and toddlers up to 24mo of age are not well developed, and suggestions have been made to reevaluate the criteria for evaluating iron status in young children [12]. A discussion of results for each marker reported in the studies in this systematic review is found below.

Results for Hemoglobin (Hb), Iron Deficiency (ID), Iron Deficiency Anemia (IDA), and Anemia

All 7 studies that examined iron status assessed Hb as a marker of ID in relation to the timing of CFB introduction, though few significant findings were reported. The studies varied in terms of the age at which Hb was measured and how ID, IDA, and anemia were defined, as well as in regards to the populations examined.

None of the RCTs including BF and FF infants in this systematic review reported any significant differences in mean Hb between infants introduced to CFB at 4mo vs. 6 or 7mo [2-4]. In addition, Kattelman et al. [3] found no significant differences in the proportion with low Hb (<100g/L), and Jonsdottir et al. [2] found no significant differences in the proportion of infants with IDA (defined as Hb<105g/L, MCV<74fl, and SF<12ug/L) or ID (defined as MCV<74fl and SF<12ug/L).

None of the observational studies of BF, FF and mixed-fed infants reported significant associations between age of CFB introduction and Hb. Ghorashi et al. [1] found no significant differences in age of CFB introduction between cases with IDA (Hb<10.5g/dl) and controls, nor did Morton et al. [5] between IDA cases (Hb<11g/dl and SF<10ug/L) and iron sufficient controls, or Tympa-Psirropoulou et al. [6] between IDA cases (Hb<11g/dl, SF<10ug/l, and other low red-cell indices) and controls. Thorsdottir et al. [7] found no significant associations between duration of exclusive BF and Hb at 12mo or prevalence of IDA (defined as Hb<105g/l, SF<12ug/l, and MCV<74fl). However, Tympa-Psirropoulou et al. [6] did find that a significantly higher percentage of controls were introduced to meat earlier (at 5mo and 6mo), and a significantly higher percentage of IDA cases were introduced to meat later (at 7mo).

Results for Serum Ferritin (SF)

Three studies examined SF in relation to the timing of CFB introduction, including 2 of the RCTs and 1 prospective cohort study. Jonsdottir et al. [2] reported that exclusively breastfed infants introduced to CFB at 4mo had significantly higher median serum ferritin at 6mo compared to those who were still exclusively BF at 6 mo. There were no significant differences between groups in the proportion of infants with SF<12ug/L. Kattelman et al. [3] found no significant differences in mean SF at 12 or 24mo of age between FF infants introduced to CFB at 4mo vs. 6mo, or in the proportion with low SF (<12ug/L). Thorsdottir et al. [7] found that longer duration of exclusive BF (i.e., later introduction of CFB) was associated with significantly higher SF at 12mo.

Results for Other Measures of Iron Status

A number of other measures or indicators of iron status were also examined. Three studies, including 2 RCTs and 1 cohort study, assessed MCV in relation to the timing of CFB introduction, all reporting no significant associations. Jonsdottir et al. [2] found no significant differences in MCV at 6mo, and Kattelman et al. [3] found no significant differences in MCV at 12 or 24mo of age between infants introduced to CFB at 4mo vs. 6mo. In addition, Thorsdottir et al. [7] found that longer duration of exclusive BF was not significantly associated with MCV at 12mo. At 6 mo Jonsdottir et al. [2] found no significant differences in RDW or TIBC between infants introduced to CFB at 4mo compared to those who were exclusively BF until 6 mo. Finally, Thorsdottir et al. [7] found no significant associations between duration of exclusive BF and TfR at 12mo of age.

Timing of CFB Introduction and Zinc Status

Two RCTs examined the relationship between timing of CFB introduction and zinc status (**Table 2**). Kattelman et al. [3], as described above, randomized FF infants to receive CFB (commercial or home-prepared foods selected by the parents) beginning at 3-4mo or 6mo of age. Details regarding the infant formula (selected by parents) consumed were not provided however, based on the time during which the study was conducted, it can be assumed that those formulas were fortified with zinc. Lonnerdal et al. [4] randomized FF infants to receive CFB (cereal) at 4mo, or to continue exclusive FF until 7mo. The nutritional content of the cereal was not described but the formula consumed by all infants contained 7mg/L iron and 7mg/L zinc.

Results from Kattelman et al. [3] showed no differences in serum zinc levels at 12 or 24mo of age between study groups. Lonnerdal et al. [4] reported that earlier introduction of CFB at 4mo vs. 7mo resulted in significantly higher levels of plasma zinc at 6mo and 7mo of age.

Timing of CFB Introduction and Folate and Vitamin B12 Status

One prospective cohort study was identified that examined the relationship between timing of CFB introduction and folate and vitamin B12 status in BF infants (Table 2). In this study, Hay et al. [8] defined CFB as foods and beverages other than breast milk or breast milk substitutes, and analyzed timing continuously as the time (in days) since the introduction of CFB. Results showed that in BF infants, timing of CFB introduction was not significantly associated with serum cobalamin at 6 or 12mo of age. However, earlier introduction of CFB was associated with decreased serum folate at 6mo, but not 12mo.

Timing of CFB Introduction and Vitamin D Status

One RCT was identified that examined the relationship between timing of CFB introduction and vitamin D status (Table 2). In this study, Bainbridge et al. [9] randomly assigned FF infants to receive rice cereal, in addition to formula, from 16 to 26wk, or to continue exclusive FF through 26wk. All infants consumed the same amount of vitamin D- and iron-fortified formula. Use of supplemental vitamin D among infants or their mothers was not described. Results showed no significant differences between groups in serum 25 hydroxyvitamin D at 26wk, or change between 16 and 26wk.

Evidence synthesis

Moderate evidence suggests that introducing CFB at 4mo compared to 6mo of age offers no long term advantages or disadvantages in terms of iron status among healthy, full-term infants who are BF, fed iron fortified formula, or both. There is not enough evidence to determine the relationship between timing of introduction of CFB and zinc, vitamin D, vitamin B12, folate, or fatty acid status.

The RCTs included in this systematic review were designed to directly examine the effects of the specific timing of introduction of CFB for the first time on micronutrient status, while the observational studies examined the direction and strength of the association between timing of introduction and micronutrient status. The definitions and analytic techniques used in the observational studies were inconsistent, making it difficult to determine the specific ages at which CFB were introduced, particularly when duration of exclusive BF was analyzed as a continuous variable. Therefore, the data from these studies were not relied upon as heavily in drawing conclusions about timing of CFB introduction and its impact on micronutrient status.

The reported effects from the RCTs, which had fewer concerns related to internal validity, were also more likely to be the true effects of the timing of introduction of CFB and micronutrient status compared to the results from the prospective cohort studies. In particular, the major methodological limitation of concern from the latter studies relates to confounding bias from factors such as education, socioeconomic status, sex, maternal age, race/ethnicity, feeding practices aside from CFB (breast milk vs. infant formula), birth size, and gestational age. Few of the cohort studies described baseline characteristics of subjects, making it impossible to determine whether the comparison groups differed on any of these potential confounders at baseline. In addition, the observational studies adjusted for few of the key confounders listed above in outcome analyses. Finally, it is likely that several studies were not powered or did not include sufficient sample size to adequately analyze results from certain sub-sets of study subjects.

Most of the studies included subject populations that were generalizable to the US population, though there is a lack of data that applies to lower-income or racial/ethnic minority populations. While the interventions/exposures and nutritional status biomarkers considered in the studies are applicable to the US population, most of the studies examined subjects who were not at risk for insufficient iron stores, and therefore, the clinical or practical significance of the findings for deficient subjects is difficult to determine. Furthermore, because few of the studies reported the types and amounts of CFB consumed by infants, it is also difficult to determine whether the types of CFB introduced to infants were similar to those commonly fed to US infants.

Research recommendations

In order to better assess the relationship between the timing of introduction of CFB and micronutrient status, additional research is needed:

- Additional studies, including both randomized controlled trials and prospective cohort studies with sufficient sample sizes, that examine the specific age at which CFB are introduced and nutritional status outcomes of public health concern, primarily iron status, but also zinc, vitamin D, vitamin B12, folate, and/or fatty acid status.
- Research that adjusts for key confounding factors, such as education, socioeconomic status, sex, maternal age, race/ethnicity, feeding practices aside from CFB (breast milk vs. infant formula), birth size, and gestational age.
- Research in more diverse populations with varying racial/ethnic and socioeconomic backgrounds, and with increased risk of poor nutritional status (including ID, and IDA).
- Research regarding the timing of introduction to CFB in relation to micronutrient status should eventually incorporate cut-points of biomarkers that are based on reference data in infants ages 0-12mo, for which development is in progress.

Table 1. Description of studies examining the relationship between timing of first introduction of any complementary foods and beverages (CFB) and iron status.

| Reference; study design; n; country | Intervention or exposure | Results for hemoglobin (Hb) | Results for serum ferritin (SF) | Results for other iron status measures |
|--|---|--|---|---|
| Randomized Controlled Trials | | | | |
| Jonsdottir, 2012 (2); 100; Iceland | Exclusively BF infants randomized to receive CFB: 4mo vs. 6mo | Hb, IDA, ID at 6mo: No significant group differences | SF at 6mo: 70.0 ug/L (IQR=73.3) vs. 44.0 ug/L (IQR=53.8); P=0.02 SF<12ug/L at 6mo: v | RDW, TIBC at 6mo: No significant group differences |
| Kattelman, 2001 (3); 133; US | FF infants randomized to receive CFB: 3-4mo vs. 6mo of age | Hb, Hb>100g/L at 12 or 24mo: No significant group differences | SF, SF<12ug/L at 12 or 24mo: No significant group differences | MCV, MCV<70um at 12 or 24mo: No significant group differences |
| Lonnerdal, 1990 (4); NR; China | FF infants randomized to receive CFB: 4mo vs. 7mo of age | Hb at 5, 6, or 7mo: No significant group differences | | |
| Observational Studies | | | | |
| Ghorashi, 2008 (1); Case-Control Study; 60 IDA Cases, 60 Controls; Iran | Age of CFB introduction: Mean, mo | IDA cases (Hb<10.5g/dl) vs. controls: No significant group differences | | |
| Morton, 1988 (5); Nested Case-Control Study; 55; UK | Age of CFB introduction: Mean, mo | IDA cases (Hb<11g/dL, SF<10ug/L) vs. controls at 6mo: No significant group differences | | |
| Thorsdottir, 2003 (7); Prospective Cohort Study; 114; Iceland | Age of CFB introduction: Duration of exclusive BF; continuous | Hb or IDA at 12mo: No significant associations | SF at 12mo: r ² =0.05; P=0.011 | MCV, TfR at 12mo: : No significant associations |

| Reference; study design; n; country | Intervention or exposure | Results for hemoglobin (Hb) | Results for serum ferritin (SF) | Results for other iron status measures |
|--|--|---|--|---|
| Tympa- Psirropoulou, 2005 (6) ; Case- Control Study; 75 IDA Cases, 75 Controls; Greece | Age of CFB introduction: Not defined | IDA cases (Hb<11g/dl) vs. controls: No significant group differences | | |
| | Age of meat introduction: Percentage introduced at 5mo, 6mo, 7mo | IDA cases vs. controls: 5.3% vs.10.7%, 45.3% vs. 81.3%, 8% vs. 49.3%; P<0.001 | | |

Table 2. Description of studies examined the relationship between timing of introduction of complementary foods and beverages (CFB) and zinc, vitamin B12, folate, and vitamin D status.

| Reference; study design; n; country | Intervention or exposure | Results |
|--|---|--|
| Zinc status | | |
| Kattelman, 2001 (3) ; RCT; 133; US | FF infants randomized to receive CFB: 3-4mo vs. 6mo of age | Serum zinc at 12 and 24mo: No significant group differences |
| Lonnerdal, 1990 (4) ; NR; China | FF infants randomized to receive CFB: 4mo vs. 7mo of age | Plasma zinc at 6mo: 0.85±0.13 vs. 0.78±0.15, P<0.05 Plasma zinc at 7mo: 0.87±0.18 vs. 0.75±0.15, P<0.05 |
| Folate and vitamin B12 status | | |
| Hay, 2008 (8) ; Prospective Cohort Study; 241; Norway | Age of CFB introduction: Time in d since CFB introduction (end of exclusive BF) | Serum folate at 6mo: -0.26; P<0.001 Serum folate at 12 mo: No significant associations Serum cobalamin at 6 or 12mo: No significant associations |
| Vitamin D status | | |
| Bainbridge, 1996 (9) ; RCT; 41; US | FF infants randomized to receive CFB: 16wk vs. 26wk of age | 25-hydroxyvitamin D or 1, 25-dihydroxyvitamin D at 26wk, or change from 16 to 26wk: No significant group differences |

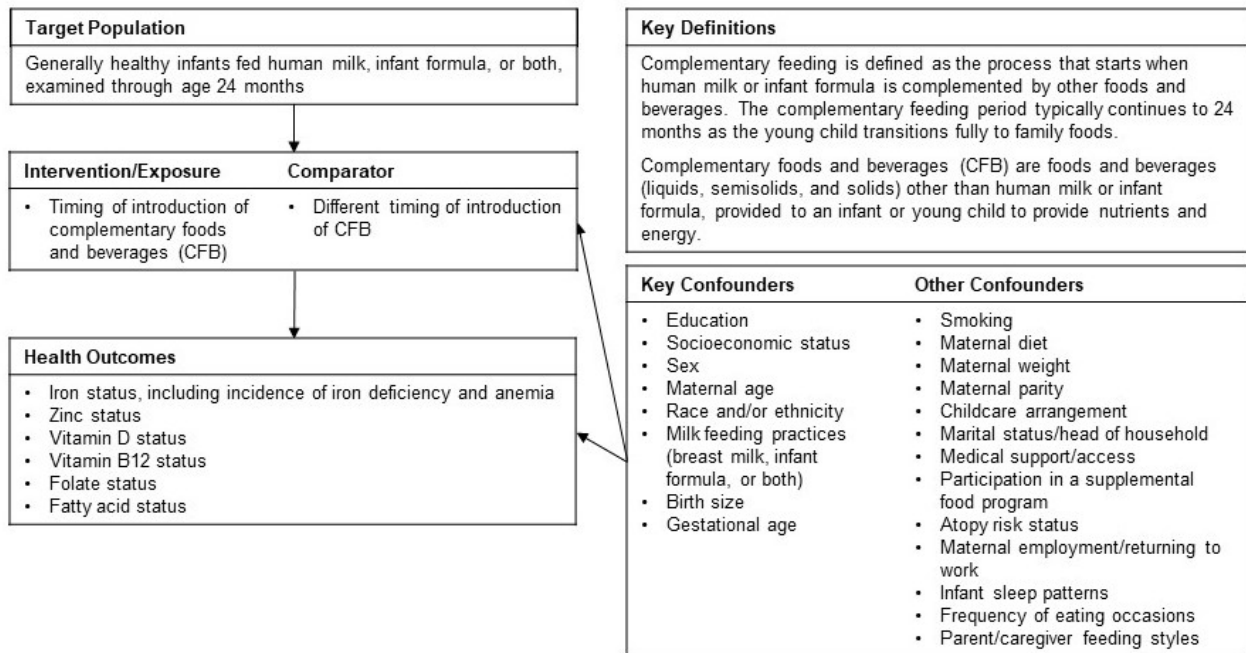
Included articles

1. Ghorashi, et al., Supplemental food may not prevent iron-deficiency anemia in infants. *Indian J Pediatr*, 2008. 75(11): p. 1121-4.
2. Jonsdottir, et al., Timing of the introduction of complementary foods in infancy: a randomized controlled trial. *Pediatrics*, 2012. 130(6): p. 1038-45.
3. Kattelman, et al., Effect of timing of introduction of complementary foods on iron and zinc status of formula fed infants at 12, 24, and 36 months of age. *J Am Diet Assoc*, 2001. 101(4): p. 443-7.
4. Lonnerdal, et al., Effects of formula protein level and ratio on infant growth, plasma amino acids and serum trace elements. II. Follow-up formula. *Acta Paediatr Scand*, 1990. 79(3): p. 266-73.
5. Morton, et al., Iron status in the first year of life. *J Pediatr Gastroenterol Nutr*, 1988. 7(5): p. 707-12.
6. Tympa, P., et al., Nutritional risk factors for iron-deficiency anaemia in children 12-24 months old in the area of Thessalia in Greece. *Int J Food Sci Nutr*, 2005. 56(1): p. 1-12.
7. Thorsdottir, I., et al., Iron status at 12 months of age -- effects of body size, growth and diet in a population with high birth weight. *Eur J Clin Nutr*, 2003. 57(4): p. 505-13.
8. Hay, et al., Folate and cobalamin status in relation to breastfeeding and weaning in healthy infants. *Am J Clin Nutr*, 2008. 88(1): p. 105-14.
9. Bainbridge, R.R., et al., Effect of rice cereal feedings on bone mineralization and calcium homeostasis in cow milk formula fed infants. *J Am Coll Nutr*, 1996. 15: p. 383-8.

ANALYTIC FRAMEWORK

The analytic framework (Figure 1) illustrates the overall scope of the systematic review, including the population, the interventions and/or exposures, comparators, and outcomes of interest. It also includes definitions of key terms and identifies key confounders considered in the systematic review. This is the analytic framework for the systematic review conducted to examine the relationship between timing of introduction of complementary foods and beverages and micronutrient status.

Figure 1: Analytic framework



SEARCH PLAN AND RESULTS

Inclusion and exclusion criteria

The inclusion and exclusion criteria are a set of characteristics to determine which studies will be included or excluded in the systematic review. This table provides the inclusion and exclusion criteria for the systematic review question: What is the relationship between timing of introduction of complementary foods and beverages and micronutrient status?

Table 3. Inclusion and exclusion criteria

| Category | Inclusion Criteria | Exclusion Criteria |
|--------------|----------------------------------|------------------------------------|
| Study design | Randomized controlled trials | Cross-sectional studies |
| | Non-randomized controlled trials | Uncontrolled studies |
| | Prospective cohort studies | Pre/post studies without a control |

| | | |
|--|--|--|
| | Retrospective cohort studies | Narrative reviews |
| | Case-control studies | Systematic reviews |
| | Pre/post studies with a control | Meta-analyses |
| Independent variable (intervention or exposure) | Timing of introduction to complementary foods and beverages (i.e., foods and beverages other than human milk or infant formula (liquids, semisolids, and solids) provided to an infant or young child to provide nutrients and energy) | Consumption of fluid cow's milk before 12 months of age |
| Comparator | Different timing of introduction of CFB | N/A |
| Dependent variables (outcomes) | Iron status, including incidence of iron deficiency and anemia | N/A |
| | Zinc status | |
| | Vitamin D status | |
| | Vitamin B12 status | |
| | Folate status | |
| | Fatty acid status | |
| Date range | January 1980 - March 2016 | |
| Language | Studies published in English | Studies published in languages other than English |
| Publication status | Studies published in peer-reviewed journals | Grey literature, including unpublished data, manuscripts, reports, abstracts, conference proceedings |
| Country^{1, 2, 3} | Studies conducted in Very High or High Human Development Countries | Studies conducted in Medium or Low Human Development Countries |
| Study participants | Human subjects | Hospitalized patients, not including birth and immediate post-partum hospitalization of healthy babies |
| | Males | |
| | Females | |
| Age of study participants | Age at intervention or exposure: Infants (0-12mo); Toddlers (12-24mo) | Age at intervention or exposure: Child (2-5 years (y)); Child (6-12y); Adolescents (13-18y); Adults (19y and older); Older adults (65 to 79y); Older adults (80+y) |
| | Age at outcome: Infants (0-12mo); Toddlers (12-24mo) | Age at outcome: Child (2-5y); Child (6-12y); Adolescents (13-18y); Adults (19y and older); Older adults (65 to 79y); Older adults (80+y) |
| Health status of study participants | Studies done in generally healthy populations | Studies that exclusively enroll subjects with a disease or with the health outcome of interest |
| | Studies done in populations where infants were full term (≥ 37 wk gestational age) | Studies done in hospitalized or malnourished subjects |

Studies done in populations with elevated chronic disease risk, or that enroll some participants with a disease or with the health outcome of interest

Studies of exclusively pre-term babies (gestational age <37wk) or babies that are small for gestational age (<2500g)

Studies of subjects with infectious diseases (e.g. HIV/AIDS) (or with mothers diagnosed with an infectious disease)

¹ United Nations Development Programme. Human Development Report 2014: Reducing Vulnerabilities and Building Resilience. Available from: [\(http://hdr.undp.org/en/content/human-development-report-2014\)](http://hdr.undp.org/en/content/human-development-report-2014).(19)

² Medium Development countries were originally included, but due to concerns about generalizability to the U.S. of study participants (i.e., baseline health status) and complementary foods and beverages typically consumed, a decision was made to exclude "Medium" countries in October 2017.

³ When a country was not included in the HDI ranking, country classification from the World Bank was used instead (51)

Search terms and electronic databases used

[PubMed, US National Library of Medicine](#) (1966 to 9 March 2016):

Date(s) Searched 12/9/2015; 3/9/2016

Search Terms:

((Complementary OR supplementary OR wean* OR transition* OR introduc* OR "Infant Nutritional Physiological Phenomena"[Mesh:noexp] OR weaning[mesh])

AND (feeding* OR food* OR beverage*[tiab] OR beverages[mh] OR eating OR diet[tiab] OR diet[mh] OR meal*[tiab] OR meals[mh] OR "Food and Beverages"[Mesh] OR diets[tiab] OR cereal*[tiab] OR "Edible Grain"[Mesh] OR bread*[tiab] OR whole grain* OR juice*[tiab] OR milk[tiab] OR "Milk"[Mesh] OR dairy[tiab] OR "Dairy Products"[Mesh] OR meat[tiab] OR cheese[tiab] OR yogurt[tiab] OR yoghurt*[tiab] OR fruit*[tiab] OR "Fruit"[Mesh] OR vegetable*[tiab] OR "Vegetables"[Mesh] OR egg*[tiab] OR "Eggs"[Mesh] OR nut[tiab] OR nuts[tiab] OR peas[tiab] OR beans[tiab] OR legume*[tiab] OR snack*[tiab])) OR "infant food"[mesh]

AND

nutritional status[mh] OR nutritional status*[tiab] OR Nutrition Status*[tiab] OR "Nutritional Requirements"[Mesh] OR Iron[mh] OR iron[tiab] OR "Anemia"[Mesh] OR "Anemia"[tiab] OR iron deficien*[tiab] OR ferritin*[tiab] OR ferrous[tiab] OR "Transferrin"[Mesh] OR "Transferrin"[tiab] OR zinc OR "Vitamin D"[Mesh] OR "Vitamin D"[tiab] OR "Vitamin D Deficiency"[Mesh] OR "Vitamin B 12"[Mesh] OR "Vitamin B 12"[tiab] OR "Vitamin B12"[tiab] OR "Vitamin B 12 Deficiency"[Mesh] OR Cobamide*[tiab] OR Cobalamin*[tiab] OR Cyanocobalamin[tiab] OR Folate[tiab] OR "Folic Acid"[Mesh] OR folacin[tiab] OR vitamin b9*[tiab] OR Fatty acid*[tiab] OR "Fatty Acids"[Mesh:noexp] OR fatty acid*[tiab] OR "Fatty Acids, Unsaturated"[Mesh:noexp] OR Arachidonic acid*[tiab] OR linolenic acid*[tiab] OR linoleic acid*[tiab] OR Docosahexaenoic Acid*[tiab] OR Eicosapentaenoic Acid*[tiab] OR gamma-Linolenic

Acid*[tiab] OR "Arachidonic Acids"[Mesh] OR "Fatty Acids, Essential"[Mesh] OR "Fatty Acids, Omega-3"[Mesh] OR "Fatty Acids, Omega-6"[Mesh] OR alpha-Linolenic Acid*[tiab] OR "Fatty Acids, Essential"[Mesh] OR "Linolenic Acids"[Mesh] OR "Trans Fatty Acids"[Mesh] OR "Fatty Acids, Monounsaturated"[Mesh] 905815

NOT (editorial[ptyp] OR comment[ptyp] OR news[ptyp] OR letter[ptyp] OR review[ptyp] OR systematic[sb])

OR ((Solid food*) OR solids)); AND

OR

Nutrition*[ti] OR nutritional status[mh] OR nutritional status*[tiab] OR Nutrition Status*[tiab] OR "Child Nutrition Sciences"[majr] OR nutrient*[ti] OR "Nutritional Requirements"[Mesh]

"Vitamin B Deficiency"[Mesh] OR "Vitamins"[Mesh] OR Iron[mh] OR iron[tiab] OR "Anemia"[Mesh] OR "Anemia"[tiab] OR iron deficien*[tiab] OR ferritin*[tiab] OR ferrous[tiab] OR "Transferrin"[Mesh] OR "Transferrin"[tiab] OR zinc OR "Vitamin D"[Mesh] OR "Vitamin D"[tiab] OR "Vitamin D Deficiency"[Mesh] OR "Vitamin B 12"[Mesh] OR "Vitamin B 12"[tiab] OR "Vitamin B12"[tiab] OR "Vitamin B 12 Deficiency"[Mesh] OR Cobamide*[tiab] OR Cobalamin*[tiab] OR Cyanocobalamin[tiab] OR Folate[tiab] OR "Folic Acid"[Mesh] OR folacin[tiab] OR vitamin b9*[tiab] OR Fatty acid*[tiab] OR "Fatty Acids"[Mesh:noexp] OR fatty acid*[tiab] OR "Fatty Acids, Unsaturated"[Mesh:noexp] OR Arachidonic acid*[tiab] OR linolenic acid*[tiab] OR linoleic acid*[tiab] OR Docosahexaenoic Acid*[tiab] OR Eicosapentaenoic Acid*[tiab] OR gamma-Linolenic Acid*[tiab] OR "Arachidonic Acids"[Mesh] OR "Fatty Acids, Essential"[Mesh] OR "Fatty Acids, Omega-3"[Mesh] OR "Fatty Acids, Omega-6"[Mesh] OR alpha-Linolenic Acid*[tiab] OR "Fatty Acids, Essential"[Mesh] OR "Linolenic Acids"[Mesh] OR "Trans Fatty Acids"[Mesh] OR "Fatty Acids, Monounsaturated"[Mesh]

AND

infant* OR baby OR babies OR toddler* OR newborn*[tiab] OR "Child, Preschool"[Mesh] OR preschool*[tiab] OR pre-school*[tiab] OR "early childhood"[tiab] OR "early years"[tiab] OR pre-k[tiab] OR pre-primary[tiab] OR under five*[ti] OR young child*[ti] OR "head start"[tiab] OR prekindergarten[tiab] OR pre-kindergarten[tiab] OR weaning*

OR limit to child, preschool in PubMed?

NOT (editorial[ptyp] OR comment[ptyp] OR news[ptyp] OR letter[ptyp] OR review[ptyp] OR systematic[sb])

Embase, Elsevier (1947 to 9 December 2015):

Date(s) Searched: 12/9/2015

Search Terms:

(Complementary OR supplementa* OR wean* OR transition* OR introduc* OR family)
NEAR/3 (feed* OR food* OR beverage* OR eating OR diet)

OR

(Complementary OR transition* OR introduct* OR wean*) AND (food/exp OR 'baby
food'/exp OR 'cereal'/exp OR 'dairy product'/exp OR 'egg'/exp OR 'fruit'/exp OR
'meat'/exp OR 'sea food'/exp OR 'milk'/exp OR fish/exp OR 'poultry'/exp OR
'beverage'/exp OR 'vegetable'/exp OR nut/exp OR pea/exp OR meal/exp)

OR

(Complementary OR supplementa* OR wean* OR transition* OR introduc*) NEAR/5
(‘whole grain’ OR ‘whole grains’ OR dairy OR egg OR eggs OR meat OR poultry OR
seafood OR fruit* OR milk OR fish* OR poultry OR beverage* OR vegetables* OR pea
OR peas OR nut OR nuts OR cereal OR bread* OR yog*urt* OR cheese* OR juice*
OR rice OR soup OR legume* OR snack* OR meal*) (for Embase)

AND

(infant*:ti,ab OR infant/exp) OR (baby OR babies OR toddler* OR newborn* OR
nursery*):ti,ab OR 'newborn'/exp OR 'newborn care'/exp OR preschool*:ti,ab OR pre-
school:ti,ab OR 'preschool child'/exp OR 'infancy'/exp OR “early childhood”:ti,ab OR
“early years” OR pre-k:ti,ab OR 'nursery'/exp OR 'nursery school'/exp OR
prekindergarten:ti,ab OR pre-kindergarten:ti,ab OR weanling*

AND ([in process]/lim OR [article]/lim OR [article in press]/lim) AND ([embase]/lim NOT
[medline]/lim)

AND

Limit to humans

OR

'nutritional status'/exp OR ((nutrition* OR diet) NEAR/3 (status OR requirement* OR
state)):ti,ab OR 'nutritional requirement'/exp

OR

'ferrous ion'/exp OR ferrous:ti,ab OR 'iron absorption'/exp OR 'iron deficiency
anemia'/exp OR anemia:ti,ab OR 'iron blood level'/exp OR 'iron'/exp OR 'ferritin'/exp
OR ferritin:ti,ab OR transferrin:ti,ab OR 'transferrin'/exp OR 'vitamin D'/exp OR 'vitamin
D deficiency'/exp OR 'zinc'/exp OR zinc:ti,ab OR 'cyanocobalamin'/exp OR “vitamin
d”:ti,ab OR “vitamin b12”:ti,ab OR “vitamin b 12”:ti,ab OR cyanocobalamin:ti,ab OR
'folic acid'/exp OR 'folic acid':ti,ab OR folate:ti,ab OR folacin:ti,ab OR 'cobalamin'/exp
OR cobalamin*:ti,ab OR 'cobamamide'/exp OR 'cobamamide':ti,ab OR
cyanocobalamin*:ti,ab OR 'fatty acid'/exp OR (fatty NEXT/1 acid*):ti,ab OR
(Arachidonic acid*):ti,ab OR (linolenic NEXT/1 acid*):ti,ab OR (linoleic NEXT/1
acid*):ti,ab OR (Docosahexaenoic NEXT/1 Acid*):ti,ab OR (Eicosapentaenoic NEXT/1
Acid*):ti,ab OR (gamma-Linolenic NEXT/1 Acid*):ti,ab OR (alpha-Linolenic NEXT/1

Acid*):ti,ab

**Cochrane Central Register of Controlled Trials, John Wiley & Sons in the
Cochrane Library (searched August 2015):**

Date(s) Searched: 12/2015

Search Terms:

(feed* OR food* OR beverage* OR diet* OR 'whole grain' OR 'whole grains' OR dairy
OR egg OR meat OR poultry OR seafood OR fruit* OR milk OR fish* OR poultry OR
vegetables* OR pea OR nut OR cereal OR beverage* OR bread* OR seafood OR
yog*urt* OR cheese OR juice) NEAR/3 (Complementary OR supplementa* OR wean*
OR transition* OR introduct* OR family)

OR

((nutrition* OR diet) NEAR/3 (status OR requirement* OR state))

AND

ferrous OR iron OR anemia OR ferritin OR zinc OR "vitamin d" OR "vitamin b12" OR
"vitamin b 12" OR cyanocobalamin OR 'folic acid' OR folate OR folacin OR cobalamin*
OR 'cobamamide' OR cyanocobalamin* OR (fatty NEXT/1 acid*) OR (Arachidonic
acid*) OR (linolenic NEXT/1 acid*) OR (linoleic NEXT/1 acid*) OR (Docosahexaenoic
NEXT/1 Acid*) OR (Eicosapentaenoic NEXT/1 Acid*) OR (gamma-Linolenic NEXT/1
Acid*) OR (alpha-Linolenic NEXT/1 Acid*)

NOT (supplement*ti,ab OR pubmed OR embase)

AND (infant* OR baby OR babies OR toddler* OR newborn* OR nurser* OR
preschool* OR pre-school OR "early childhood" OR pre-k OR prekindergarten OR
pre-kindergarten OR "early years")

NOT (pubmed OR embase OR supplement*:ti OR preterm:ti)

**CINAHL Plus with Full Text, EBSCO (Cumulative Index to Nursing and Allied
Health Literature; 1937 to 14 December 2015):**

Date(s) Searched: 12/14/2015

Search Terms:

(MH "Food and Beverages+") OR (MH "Food") OR (MH "Diet") OR (MH "Eating") OR
(MH "Eating Behavior") OR (MH "Taste") OR (MH "Taste Buds") OR (MH "Cereals")
OR (MH "Dairy Products") OR (MH "Yogurt") OR (MH "Cheese") OR (MH "Milk") OR
(MH "Eggs") OR (MH "Fruit") OR (MH "Fruit Juices") OR (MH "Meat") OR (MH
"Seafood") OR (MH "Fish") OR (MH "Poultry") OR (MH "Vegetables") OR (MH "Nuts")
OR (MH "Legumes") OR (MH "Bread") AND (Complementary OR supplementa* OR
wean* OR transition* OR introduc*)

OR

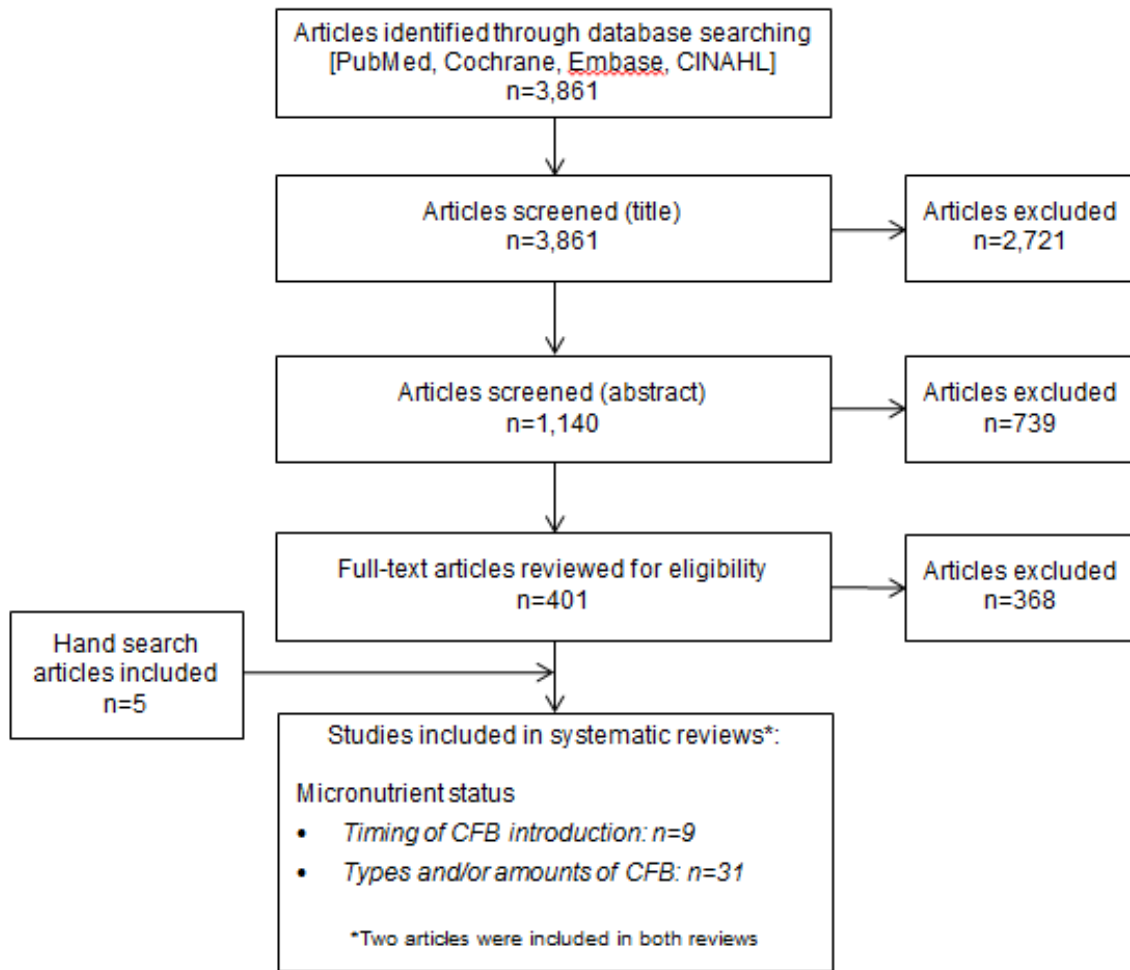
('whole grain' OR 'whole grains' OR dairy OR egg OR eggs OR meat OR poultry OR seafood OR fruit* OR milk OR fish* OR poultry OR vegetables* OR pea OR peas OR nut OR nuts OR cereal OR beverage* OR bread* OR seafood OR yog*urt* OR cheese* OR juice*) N5 (Complementary OR supplementa* OR wean* OR transition* OR introduc* OR family)

AND

(MH "Nutritional Status") OR "nutritional status" OR (MH "Nutritional Requirements") OR (MH "Vitamin D") OR (MH "Vitamin D Deficiency") OR (MH "Vitamin B12 Deficiency") OR (MH "Anemia") OR "anemia" OR (MH "Anemia, Iron Deficiency") OR (MH "Iron") OR (MH "Zinc") OR (MH "Vitamin B12") OR (MH "Vitamin B12 Deficiency") OR (MH "Folic Acid") OR (MH "Niacin") OR (MH "Folic Acid Deficiency") OR "folate" OR "folacin" OR cyanocobalamin* OR cobalamin* OR cobamamide* OR (MH "Fatty Acids") OR "fatty acids" OR (MH "Fatty Acids, Omega-6") OR (MH "Fatty Acids, Omega-3") OR (MH "Fatty Acids, Unsaturated") OR (MH "Trans Fatty Acids") OR (MH "Fatty Acids, Monounsaturated") OR (MH "Fatty Acids, Saturated") OR (MH "Fatty Acids, Essential") OR (MH "Arachidonic Acids") OR (MH "Docosahexaenoic Acids") OR (MH "Linolenic Acids") OR (MH "Linoleic Acids")

Limit to "all infant" OR (MH "Infant") OR (MH "Infant, Newborn") OR (MH "Infant Behavior") OR (MH "Infant Feeding") OR (MH "Infant Feeding Schedules") OR (MH "Child, Preschool")

Figure 2: Flow chart of literature search and screening results



Flow chart of literature search and screening results for articles examining the relationship between complementary feeding and micronutrient status. The results of an electronic database search were screened in a dual, step-wise manner by reviewing titles, abstracts, and full text articles to determine which articles met the criteria for inclusion. A manual search was done to ascertain articles not identified through the electronic database search. The systematic review on timing of introduction of CFB included nine articles, and the systematic review on types and amounts of CFB consumed included 33 articles.

Excluded articles

The table below lists the excluded articles with at least one reason for exclusion, and may not reflect all possible reasons.

Table 4. Excluded articles

| | Citation | Rationale |
|---|--|--|
| 1 | Bioavailability of milk zinc in infants. <i>Nutr Rev.</i> 1984;42:220-2. | Study design, Dependent variable |
| 2 | Nutritional findings in the U.S. preschool and young school-age population. <i>J Bergen Cty Dent Soc.</i> 1984;50:14-6. | Age |
| 3 | Aboud,F. E.,Moore,A. C.,Akhter,S.. Effectiveness of a community-based responsive feeding programme in rural Bangladesh: a cluster randomized field trial. <i>Matern Child Nutr.</i> 2008;4:275-86. | Independent variable, Dependent variable |
| 4 | Abrams,S. A.,O'Brien,K. O.,Wen,J.,Liang,L. K.,Stuff,J. E.. Absorption by 1-year-old children of an iron supplement given with cow's milk or juice. <i>Pediatr Res.</i> 1996;39:171-5. | Independent variable, Dependent variable |
| 5 | Abrams,S. A.,Wen,J.,Stuff,J. E.. Absorption of calcium, zinc, and iron from breast milk by five- to seven-month-old infants. <i>Pediatr Res.</i> 1997;41:384-90. | Study design, Independent variable |
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