2020 Dietary Guidelines Advisory Committee: Birth to 24 Months Subcommittee

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DietaryGuidelines.gov

Topic Areas (in order of protocol development)

- Duration, frequency, and volume of human milk/infant formula and growth, size, and body composition*
- Duration, frequency, and volume of human milk/infant formula and micronutrient status*
- Duration of human milk/infant formula and developmental milestones*
- Duration of human milk/infant formula and food allergy/atopic allergic diseases*
- Duration of human milk/infant formula and long-term health outcomes*
- * Protocols to be discussed today; available at DietaryGuidelines.gov

Topic Areas (in order of protocol development)

- Specific nutrients** from supplements and fortified foods and nutrient status*
- Specific nutrients** from supplements and fortified foods and growth, size, and body composition*
- Specific nutrients** from supplements and fortified foods and bone health*

** Includes iron, vitamin D, vitamin B-12, or omega-3 fatty acid

*Protocols to be discussed today; available at DietaryGuidelines.gov

Topic Areas (in order of protocol development)

- Complementary feeding and micronutrient status
- Complementary feeding and growth, size, and body composition
- Complementary feeding and developmental milestones
- Complementary feeding and food allergy/atopic allergic diseases
- Complementary feeding and bone health

Human Milk/Infant Formula

Protocols

All protocols are available to view at:

DietaryGuidelines.gov

Questions

Approach to Answer Questions: New NESR Systematic Reviews

- 1. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and growth, size, and body composition?
- 2. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and micronutrient status?
- 3. What is the relationship between the duration of exclusive human milk and/or infant formula consumption and developmental milestones, including neurocognitive development?

Questions

Approach to Answer Questions: Updates to existing NESR Systematic Reviews

- 4. What is the relationship between the duration of exclusive human milk and/or infant formula consumption and food allergies and atopic allergic diseases?
- 5. What is the relationship between the duration of exclusive human milk and/or infant formula consumption and long-term health outcomes*?

^{*}We chose to update existing NESR systematic reviews on human milk/infant formula and (a) cardiovascular disease and (b) diabetes

Key Definitions

- Human milk mother's own milk provided at the breast (i.e., nursing) or expressed and fed fresh or after refrigeration/ freezing; donor milk will not be examined
- Infant formula commercially prepared infant formula meeting FDA and/or Codex Alimentarius international food standards
- Complementary foods and beverages (CFB) 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

Key Definitions

Feeding methods:

- Human milk feeding feeding human milk alone or in combination with infant formula and/or CFB such as cow's milk
- Exclusive human milk feeding feeding human milk alone and not in combination with infant formula and/or CFB such as cow's milk; inclusive of World Health Organization definitions of exclusive and predominant breastfeeding, which permit limited quantities of drops or syrups containing vitamins, minerals, or medicines; water and water-based drinks such as sweetened water and teas; fruit juice; oral rehydration salts solution; and ritual fluids
- Mixed feeding feeding human milk and infant formula but not CFB such as cow's milk
- Topping up feeding infant formula after human milk during a single feeding session

Birth to 24 Months Subcommittee 2020 Dietary Guidelines Advisory Committee: *Meeting 2*

Analytic Framework: Human milk/infant formula and growth, size, and body composition

Systematic review question: What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and growth, size, and body composition?

Interventions/exposures **Comparators Outcomes** vs Different durations of exclusive human milk Weight, weight-for-age Duration of exclusive human milk and/or infant formula consumption: and/or infant formula consumption: Height, length/stature-for-Ever consuming human milk (i.e., any a) Never consuming human milk age amount of human milk feeding) Different durations of any human milk BMI, BMI z-score, weight-Duration of any human milk consumption consumption among infants fed human milk for-length Body circumferences: head. among infants fed human milk c) Different durations of exclusive human milk Duration of exclusive human milk arm, waist, thigh, neck consumption prior to the introduction of consumption prior to the introduction of Body composition (e.g., % infant formula fat mass. % fat free mass) infant formula · Underweight, failure to Frequency and volume of human milk and/or Different frequencies and volumes of human thrive, stunting, wasting infant formula consumption milk and/or infant formula consumption Healthy weight Intensity/proportion/amount of human Different intensities/proportions/amounts of Overweight milk consumed by mixed-fed infants (i.e., human milk consumed by mixed-fed infants Obesity both at a given point in time and over a (i.e., both at a given point in time and over a period of time) period of time) Population: Infants through Intensity/proportion/amount of human b) Different intensities/proportions/amounts of older adults human milk consumed at the breast versus milk consumed at the breast versus by by bottle in infants fed human milk as their bottle in infants fed human milk as their only source of milk (i.e., both at a given only source of milk (i.e., both at a given point in time and over a period of time) point in time and over a period of time) Consuming human milk or infant formula c) Consuming human milk and infant formula (i.e., a single substance) during a single (i.e., both substances) during a single feeding session feeding session (e.g., "topping up") Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease Key confounders: Race/ethnicity, Socioeconomic status, Types/amounts of complementary foods and beverages and infant formula, Childhood diet (for outcomes beyond



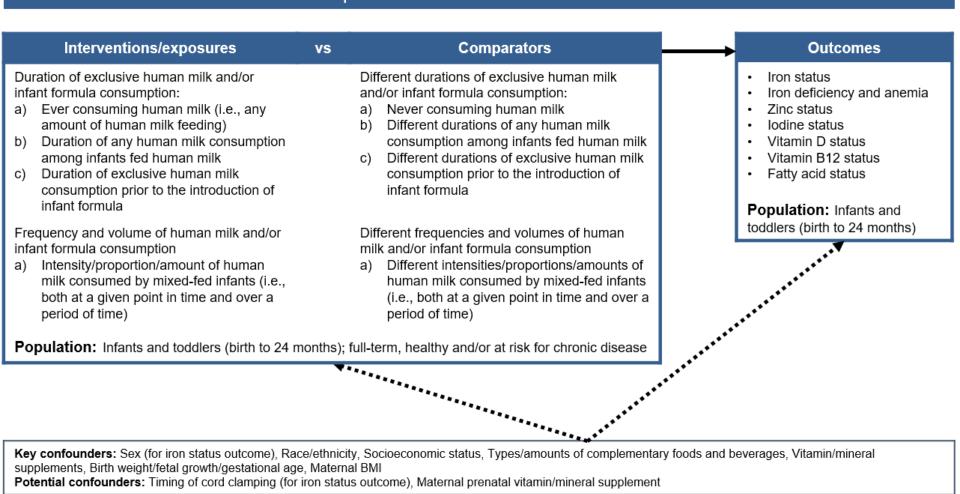
The relationship of interest in the systematic review

Factors that may impact the relationship of interest in the systematic review

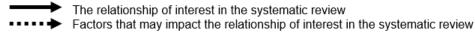
24 months), Birth weight/fetal growth, Smoking, Mode of delivery, Maternal BMI

Analytic Framework: Human milk/infant formula and micronutrient status

Systematic review question: What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and micronutrient status?



Legend



Analytic Framework: Human milk/infant formula and developmental milestones

Systematic review questions: What is the relationship between the duration of exclusive human milk and/or infant formula consumption and developmental milestones, including neurocognitive development?

Interventions/exposures	vs	Comparators	Outcomes
Ever consuming human milk (i.e., any amount of human milk feeding)		Never consuming human milk	 Developmental domains, examined via milestone achievement and/or scales/indices, including:
Duration of any human milk consumption among infants fed human milk		Different durations of any human milk consumption among infants fed human milk	 Cognitive, Language/communication, Movement/physical, Social-emotional
Duration of exclusive human milk consumption prior to the introduction of infant formula		Different durations of exclusive human milk consumption prior to the introduction of infant formula	 Academic performance Attention deficit disorder (ADD) or attention- deficit/hyperactivity disorder (ADHD) Anxiety
Population: Infants and toddlers (bir for chronic disease	th to 24 n	nonths); full-term, healthy and/or at risk	DepressionAutism spectrum disorder (ASD)
	٧.	*****	Population: Infants through adolescents (birth to 18 years)
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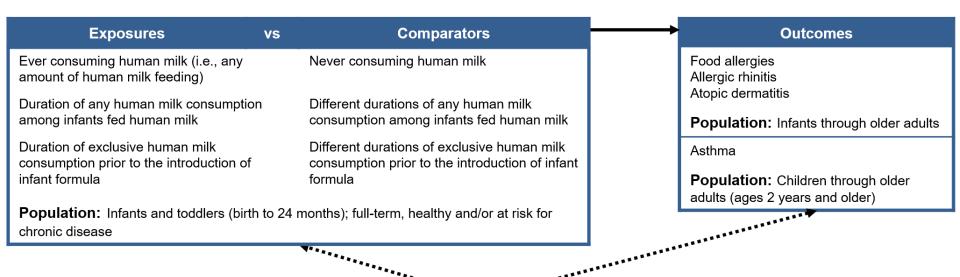
Key Confounders: Race/ethnicity, Socioeconomic status, Parity/birth order, Maternal age, Home environment (e.g., HOME score) **Potential confounders:** Family history of the outcome of interest, Maternal/pre-pregnancy anthropometry

Legend

The relationship of interest in the systematic review
■■■■ Factors that may impact the relationship of interest in the systematic review

Analytic Framework: Human milk/infant formula and food allergies and atopic allergic diseases

Systematic review question: What is the relationship between the duration of exclusive human milk and/or infant formula consumption and food allergies and atopic allergic diseases?



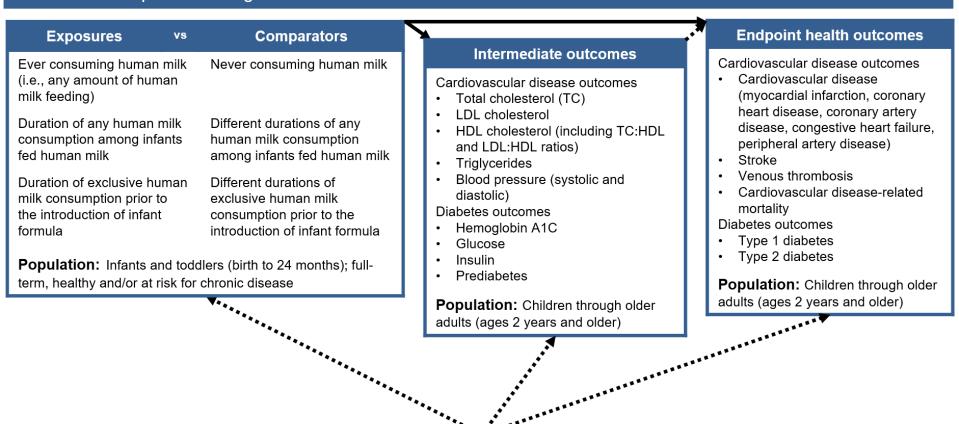
Key confounders: Race/ethnicity, Socioeconomic status, Type of infant formula, Timing/type of CFB, Smoking, Family history of atopic allergic diseases, Mode of delivery, Childcare arrangement, Number of siblings/family design, Urban/rural environment, Animals/pets/farming exposure

Legend

The relationship of interest in the systematic review
 ► Factors that may impact the relationship of interest in the systematic review

Analytic Framework: Human milk/infant formula and long-term health outcomes

Systematic review question: What is the relationship between the duration of exclusive human milk and/or infant formula consumption and long-term health outcomes?



Key Confounders: Race/ethnicity, Socioeconomic status, Family history of the outcome of interest

Legend

The relationship of interest in the systematic review

Factors that may impact the relationship of interest in the systematic review

- Propose standard criteria be used for:
 - Publication Status
 - Language of Publication
 - Study Participants
 - Health Status of Participants

Category	Inclusion Criteria	Exclusion Criteria
Date of	January 1980 – July 2019*	Articles published prior to or after
publication		January 1980 – July 2019
	 *For updates to existing systematic reviews, this includes an original search and an update search: Original January 1980-March 2016 Update March 2016-July 2019 	
Size of study	Studies with ≥30 participants per	Studies with <30 participants per
groups	study group or a power analysis	study group with no power analysis
	indicating that the study is	indicating that the study is
	appropriately powered for the	appropriately powered for the
	outcome(s) of interest	outcome(s) of interest

Category	Inclusion Criteria	Exclusion Criteria
Age of	Growth, size, and body composition:	
study	 Infants through older adults 	
participants	 Food allergies and atopic allergic diseases: Infants through older adults (food allergies, allergic rhinitis, atopic dermatitis) Children through older adults (asthma) 	 Food allergies and atopic allergic diseases: Infants and toddlers (asthma)
	Long-term health outcomes (CVD, diabetes):Children through older adults	Long-term health outcomes (CVD, diabetes):Infants and toddlers
	<u>Developmental milestones, including</u><u>neurocognitive development</u>:Infants through adolescents	Developmental milestones, including neurocognitive development:Adults and older adults
	Micronutrient status: Infants and toddlers	Micronutrient status:Children through older adults

Category	Inclusion Criteria	Exclusion Criteria
Country	Studies conducted in countries	Studies conducted in countries
	ranked as high or very high	ranked as medium or lower
	human development*	human development*

*Standard criterion

Classify human development using Human Development Index (HDI) the year the study was conducted

Tailored criterion

Classify human development using 2014 HDI Report to achieve consistency across the new and existing systematic reviews & ensure that follow-up data from studies included in the existing reviews are included in the update

Specific Nutrients from Supplements and/or Fortified Foods

Protocols

All protocols are available to view at:

DietaryGuidelines.gov

Questions

Approach to Answer Questions: New NESR Systematic Reviews

- 1. What is the relationship between specific nutrients ** from supplements and/or fortified foods consumed during infancy and toddlerhood and nutrient status?
- 2. What is the relationship between specific nutrients ** from supplements and/or fortified foods consumed during infancy and toddlerhood and growth, size, and body composition?
- 3. What is the relationship between specific nutrients ** from supplements and/or fortified foods consumed during infancy and toddlerhood and bone health?

^{**} Includes iron, vitamin D, vitamin B-12, and omega-3 fatty acids

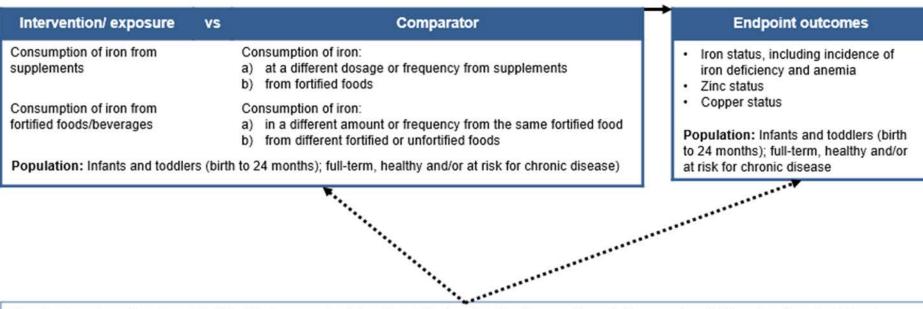
Key Definitions

- **Dietary supplements** a product (other than tobacco) that: is intended to supplement the diet; contains one or more dietary ingredients (including vitamins; minerals; herbs or other botanicals; amino acids; and other substances) or their constituents; is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and is labeled on the front panel as being a dietary supplement. (ODS, Dietary Supplement Health and Education Act, 1994)
- Fortification— as defined by the U.S. Food and Drug Administration (FDA), the deliberate addition of one or more essential nutrients to a food, whether or not it is normally contained in the food. Fortification may be used to prevent or correct a demonstrated deficiency in the population or specific population groups; restore naturally occurring nutrients lost during processing, storage, or handling; or to add a nutrient to a food at the level found in a comparable traditional food. When cereal grains are labeled as enriched, it is mandatory that they be fortified with folic acid

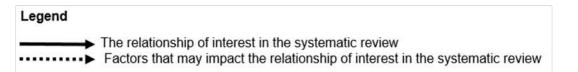
Birth to 24 Months Subcommittee 2020 Dietary Guidelines Advisory Committee: *Meeting 2*

Analytic Framework: Iron and Nutrient status

Systematic review question: What is the relationship between iron from supplements and/or fortified foods consumed during infancy and toddlerhood and nutrient status?

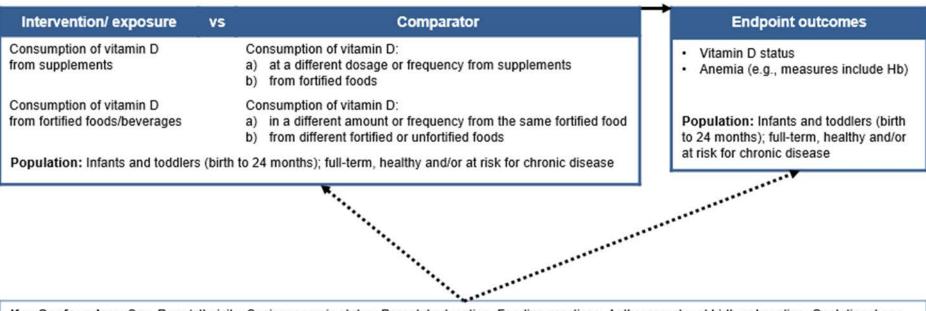


Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Gestational age, Prenatal vitamin-supplement use, Baseline nutrient status

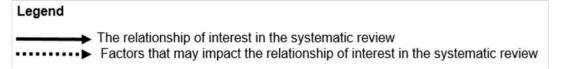


Analytic Framework: Vitamin D and Nutrient status

Systematic review question: What is the relationship between vitamin D from supplements and/or fortified foods consumed during infancy and toddlerhood and nutrient status?

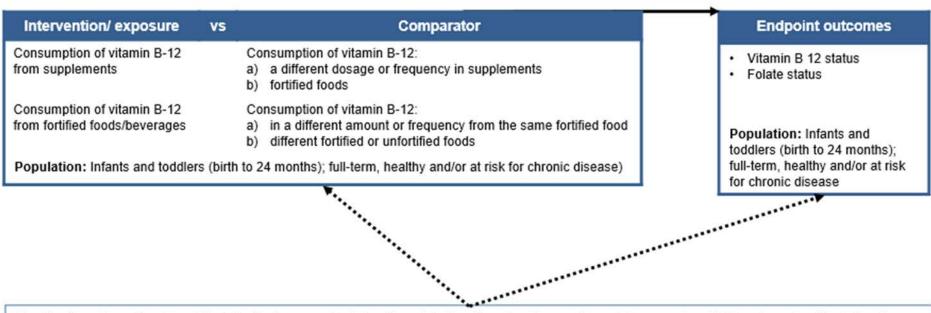


Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Gestational age, Prenatal vitamin-supplement use, Baseline nutrient status, Sun exposure

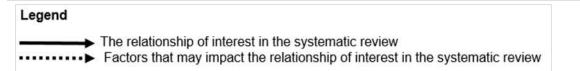


Analytic Framework: Vitamin B-12 and Nutrient status

Systematic review question: What is the relationship between vitamin B-12 from supplements and/or fortified foods consumed during infancy and toddlerhood and nutrient status?



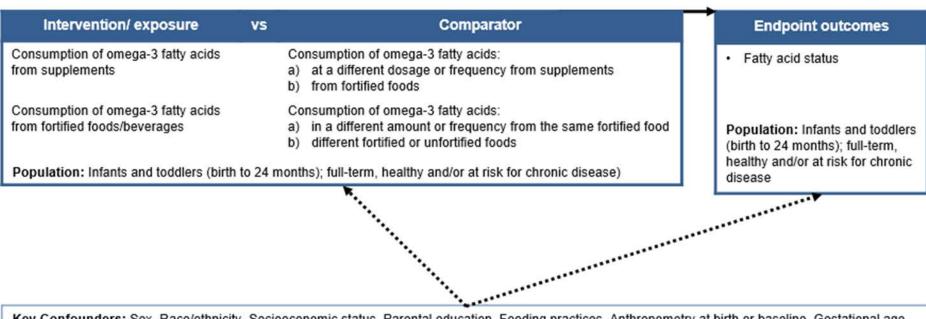
Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Gestational age, Prenatal vitamin-supplement use, Baseline nutrient status, Maternal vegan diet



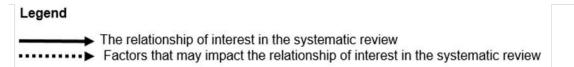
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Analytic Framework: Omega-3 fatty acids and Nutrient status

Systematic review question: What is the relationship between omega-3 fatty acids from supplements and/or fortified foods consumed during infancy and toddlerhood and nutrient status?

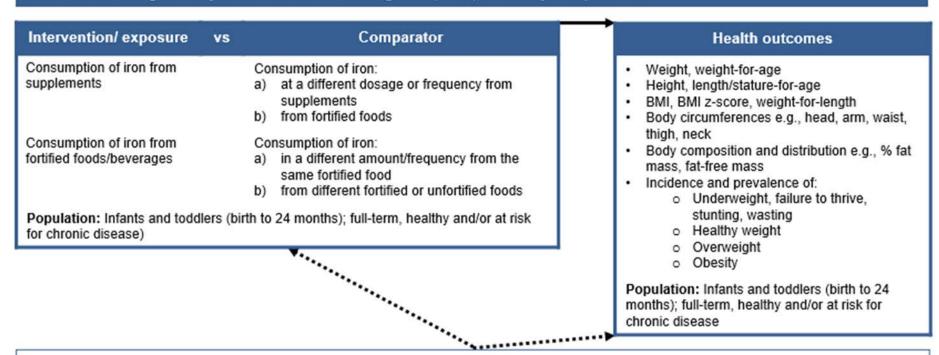


Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Gestational age, Prenatal vitamin-supplement use, Baseline nutrient status



Analytic Framework: Iron and Growth, size, body composition

Systematic review question: What is the relationship between iron from supplements and/or fortified foods consumed during infancy and toddlerhood and growth, size, and body composition?



Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Gestational age

Legend

The relationship of interest in the systematic review
Factors that may impact the relationship of interest in the systematic review

Specific nutrients from supplements and/or fortified foods and growth, size, and body composition

Analytic Framework: Vitamin D and Growth, size, body composition

Systematic review question: What is the relationship between vitamin D from supplements and/or fortified foods consumed during infancy and toddlerhood and growth, size, and body composition?

Intervention/ exposure	vs Comparator	Health outcomes
Consumption of vitamin D from supplements	Consumption of vitamin D: a) at a different dosage or frequency from supplements b) from fortified foods	Weight, weight-for-age Height, length/stature-for-age BMI, BMI z-score, weight-for-length Body circumferences e.g., head, arm, waist,
Consumption of vitamin D from fortified foods/beverages	Consumption of vitamin D: a) in a different amount/frequency from the same fortified food b) from different fortified or unfortified foods	thigh, neck Body composition and distribution e.g., % fat mass, fat-free mass Incidence and prevalence of: Underweight, failure to thrive,
Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)		stunting, wasting O Healthy weight O Overweight
	***************************************	Obesity Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease

Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Gestational age, Sun exposure

Legend

The relationship of interest in the systematic review

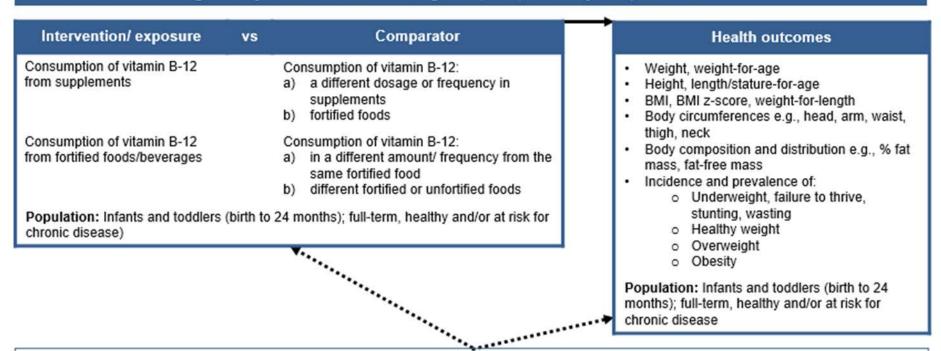
Factors that may impact the relationship of interest in the systematic review

Specific nutrients from supplements and/or fortified foods and growth, size, and body composition

2020 Dietary Guidelines Advisory Committee: *Meeting 2*

Analytic Framework: Vitamin B-12 and Growth, size, body composition

Systematic review question: What is the relationship between vitamin B-12 from supplements and/or fortified foods consumed during infancy and toddlerhood and growth, size, and body composition?



Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Gestational age, Maternal vegan diet

Legend

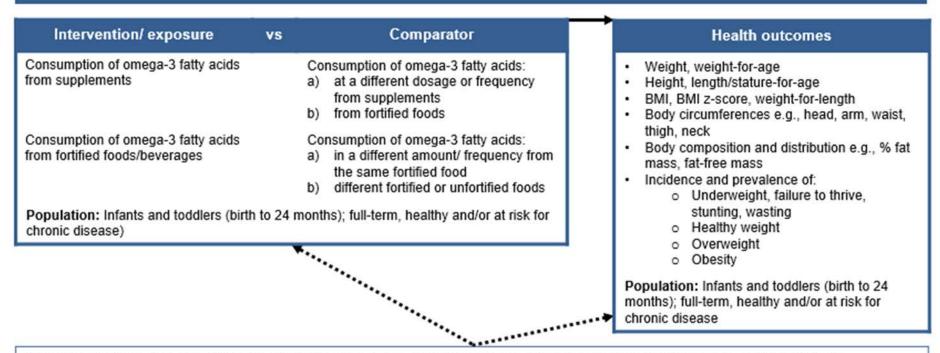
The relationship of interest in the systematic review

Factors that may impact the relationship of interest in the systematic review

Specific nutrients from supplements and/or fortified foods and growth, size, and body composition

Analytic Framework: Omega-3 fatty acids and Growth, size, body composition

Systematic review question: What is the relationship between omega-3 fatty acids from supplements and/or fortified foods consumed during infancy and toddlerhood and growth, size, and body composition?



Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Gestational age

The relationship of interest in the systematic review
Factors that may impact the relationship of interest in the systematic review

Specific nutrients from supplements and/or fortified foods and growth, size, and body composition

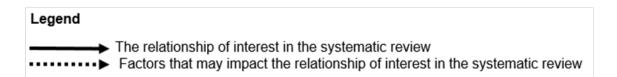
2020 Dietary Guidelines Advisory Committee: Meeting 2

Analytic Framework: Iron and Bone health

Systematic review question: What is the relationship between iron from supplements and/or fortified foods consumed during infancy and toddlerhood and bone health?

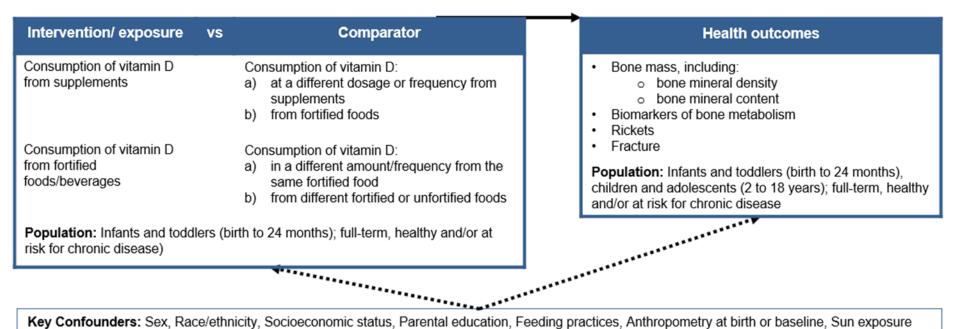
Intervention/ exposure	Vs	Comparator	Health outcomes	
Consumption of iron from supplements	a)	nsumption of iron: at a different dosage or frequency from supplements from fortified foods	 Bone mass, including: bone mineral density bone mineral content Biomarkers of bone metabolism Rickets 	
Consumption of iron from fortified foods/beverages	a)	nsumption of iron: in a different amount/frequency from the same fortified food from different fortified or unfortified foods	Fracture Population: Infants and toddlers (birth to 24 months), children and adolescents (2 to 18 years); full-term, health and/or at risk for chronic disease	
Population: Infants and to risk for chronic disease)	oddlers (birth to	o 24 months); full-term, healthy and/or at	*****	

Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Sun exposure

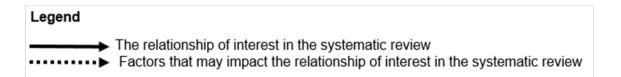


Analytic Framework: Vitamin D and Bone health

Systematic review question: What is the relationship between vitamin D from supplements and/or fortified foods consumed during infancy and toddlerhood and bone health?

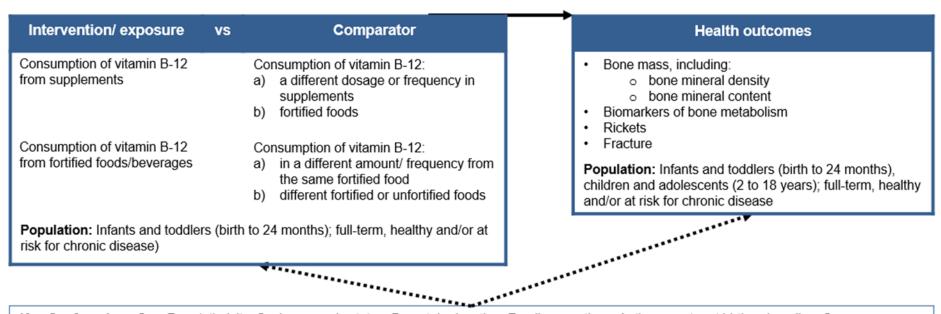


Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Sun exposure

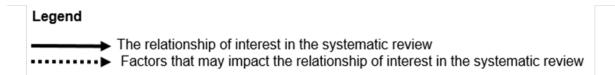


Analytic Framework: B-12 and Bone health

Systematic review question: What is the relationship between vitamin B-12 from supplements and/or fortified foods consumed during infancy and toddlerhood and bone health?

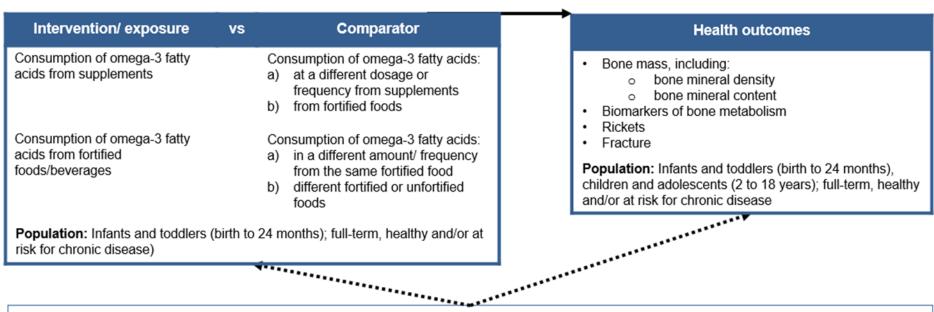


Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Sun exposure Maternal vegan diet

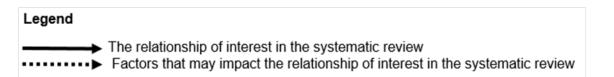


Analytic Framework: Omega-3 fatty acids and Bone health

Systematic review question: What is the relationship between omega-3 fatty acids from supplements and/or fortified foods consumed during infancy and toddlerhood and bone health?



Key Confounders: Sex, Race/ethnicity, Socioeconomic status, Parental education, Feeding practices, Anthropometry at birth or baseline, Sun exposure



- Propose standard criteria be used for:
 - Study Design
 - Publication Status
 - Country
 - Language of Publication
 - Study Participants
 - Health Status of Participants

Category	Inclusion Criteria	Exclusion Criteria
Interventions/ exposures	 Studies that examine consumption of iron, vitamin D, vitamin B-12, or omega-3 fatty acids from: supplements fortified foods/beverages Studies that specify the 	 Studies that do not specify the dosage /amount/fortification level received of the specific nutrient
	 dosage/amount/fortification level received of the specific nutrient Studies that examine animal products that contain added nutrients as a result of feeding the animal a specialized diet 	 Studies that vary nutrients other than the nutrient of interest without controlling for that variation

Specific nutrients from supplements and/or fortified foods and: nutrient status; growth, size, and body composition; bone health 2020 Dietary Guidelines Advisory Committee: *Meeting 2*

Category	Inclusion Criteria	Exclusion Criteria
Age of study participants	 Age at intervention or exposure: Infants and toddlers (birth to 24 mo) Age at outcome: Infants and toddlers (birth to 24 mo) For Bone Health outcomes only: Children and adolescents (2 to 18 yrs) 	Age at intervention or exposure or outcome: • Children and adolescents (2-18 yrs) • Adults (19 -64 yrs) • Older adults (65 yrs and older)
Source of foods, beverages, or nutrients	 Vitamin and mineral supplements (e.g., iron drops) Fortified foods/beverages Commercially prepared infant formula meeting FDA and/or Codex Alimentarius international food standards (e.g., milk-based, soy, partially-hydrolyzed, extensive-hydrolyzed, amino acid-based) 	 Donor or banked milk Unfortified or fortified human milk

Specific nutrients from supplements and/or fortified foods and: nutrient status; growth, size, and body composition; bone health 2020 Dietary Guidelines Advisory Committee: *Meeting 2*

Next Steps

• Implement the protocols for the questions:

- Duration, frequency, and volume of human milk/infant formula and growth, size, and body composition
- Duration, frequency, and volume of human milk/infant formula and micronutrient status
- Duration of human milk/infant formula and developmental milestones
- Duration of human milk/infant formula and food allergy/atopic allergic diseases
- Duration of human milk/infant formula and long-term health outcomes
- Specific nutrients from supplements and fortified foods and nutrient status
- Specific nutrients from supplements and fortified foods and growth, size, and body composition
- Specific nutrients from supplements and fortified foods and bone health

Next Steps

- Develop the remaining protocols:
 - Complementary feeding and micronutrient status
 - Complementary feeding and growth, size, and body composition
 - Complementary feeding and developmental milestones
 - Complementary feeding and food allergy/atopic allergic diseases
 - Complementary feeding and bone health
- Plan meeting with Data Analysis and Food Pattern Modeling cross-cutting working group to discuss assessing food group and nutrient intakes among children birth to 24 mo

2020 Dietary Guidelines Advisory Committee: Birth to 24 Months Subcommittee



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