2020 Dietary Guidelines Advisory Committee: Birth to 24 Months Subcommittee

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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

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	vs	Comparators
Duration of exclusive human milk and/or infant formula consumption: a) Ever consuming human milk (i.e., any amount of human milk feeding) b) Duration of any human milk consumption among infants fed human milk c) Duration of exclusive human milk consumption prior to the introduction of infant formula		Different durations of exclusive human milk and/or infant formula consumption: a) Never consuming human milk b) Different durations of any human milk consumption among infants fed human milk c) Different durations of exclusive human milk consumption prior to the introduction of infant formula
Frequency and volume of human milk and/or infant formula consumption a) Intensity/proportion/amount of human milk consumed by mixed-fed infants (i.e., both at a given point in time and over a period of time) b) Intensity/proportion/amount of human milk consumed at the breast versus by bottle in infants fed human milk as their only source of milk (i.e., both at a given point in time and over a period of time) c) Consuming human milk or infant formula (i.e., a single substance) during a single feeding session		Different frequencies and volumes of human milk and/or infant formula consumption a) Different intensities/proportions/amounts of human milk consumed by mixed-fed infants (i.e., both at a given point in time and over a period of time) b) Different intensities/proportions/amounts of human milk consumed at the breast versus by bottle in infants fed human milk as their only source of milk (i.e., both at a given point in time and over a period of time) c) Consuming human milk and infant formula (i.e., both substances) during a single feeding session (e.g., "topping up")

Outcomes

- Weight, weight-for-age
- Height, length/stature-for-age
- BMI, BMI z-score, weight-for-length
- Body circumferences: head, arm, waist, thigh, neck
- Body composition (e.g., % fat mass, % fat free mass)
- Underweight, failure to thrive, stunting, wasting
- Healthy weight
- Overweight
- Obesity

Population: Infants through older adults

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

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 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?

Interventions/exposures	vs	Comparators
Duration of exclusive human milk and/or infant formula consumption: a) Ever consuming human milk (i.e., any amount of human milk feeding) b) Duration of any human milk consumption among infants fed human milk c) Duration of exclusive human milk consumption prior to the introduction of infant formula		Different durations of exclusive human milk and/or infant formula consumption: a) Never consuming human milk b) Different durations of any human milk consumption among infants fed human milk c) Different durations of exclusive human milk consumption prior to the introduction of infant formula
Frequency and volume of human milk and/or infant formula consumption a) Intensity/proportion/amount of human milk consumed by mixed-fed infants (i.e., both at a given point in time and over a period of time)		Different frequencies and volumes of human milk and/or infant formula consumption a) Different intensities/proportions/amounts of human milk consumed by mixed-fed infants (i.e., both at a given point in time and over a period of time)
Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease		

Outcomes

- Iron status
- Iron deficiency and anemia
- Zinc status
- Iodine status
- Vitamin D status
- Vitamin B12 status
- Fatty acid status

Population: Infants and toddlers (birth to 24 months)

Key confounders: Sex (for iron status outcome), Race/ethnicity, Socioeconomic status, Types/amounts of complementary foods and beverages, Vitamin/mineral supplements, Birth weight/fetal growth/gestational age, Maternal BMI
Potential confounders: Timing of cord clamping (for iron status outcome), Maternal prenatal vitamin/mineral supplement

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 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
Ever consuming human milk (i.e., any amount of human milk feeding)		Never consuming human milk
Duration of any human milk consumption among infants fed human milk		Different durations of any human milk consumption among infants fed human milk
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

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease

Outcomes

- Developmental domains, examined via milestone achievement and/or scales/indices, including:
  - Cognitive,
  - Language/communication,
  - Movement/physical,
  - Social-emotional
- Academic performance
- Attention deficit disorder (ADD) or attention-deficit/hyperactivity disorder (ADHD)
- Anxiety
- Depression
- Autism spectrum disorder (ASD)

Population: Infants through adolescents (birth to 18 years)

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?

Exposures	vs	Comparators
Ever consuming human milk (i.e., any amount of human milk feeding)		Never consuming human milk
Duration of any human milk consumption among infants fed human milk		Different durations of any human milk consumption among infants fed human milk
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

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease

Outcomes

Food allergies
Allergic rhinitis
Atopic dermatitis

Population: Infants through older adults

Asthma

Population: Children through older adults (ages 2 years and older)

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?

Exposures	vs	Comparators
Ever consuming human milk (i.e., any amount of human milk feeding)		Never consuming human milk
Duration of any human milk consumption among infants fed human milk		Different durations of any human milk consumption among infants fed human milk
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

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease

Intermediate outcomes

Cardiovascular disease outcomes
- Total cholesterol (TC)
- LDL cholesterol
- HDL cholesterol (including TC:HDL and LDL:HDL ratios)
- Triglycerides
- Blood pressure (systolic and diastolic)

Diabetes outcomes
- Hemoglobin A1C
- Glucose
- Insulin
- Prediabetes

Population: Children through older adults (ages 2 years and older)

Endpoint health outcomes

Cardiovascular disease outcomes
- Cardiovascular disease (myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease)
- Stroke
- Venous thrombosis
- Cardiovascular disease-related mortality

Diabetes outcomes
- Type 1 diabetes
- Type 2 diabetes

Population: Children through older adults (ages 2 years and older)

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

Inclusion and Exclusion Criteria

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

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
2020 Dietary Guidelines Advisory Committee: *Meeting 2*

Inclusion and Exclusion Criteria

Category	Inclusion Criteria	Exclusion Criteria
Date of 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*	Articles published prior to or after January 1980 – July 2019
Size of study groups	Studies with ≥30 participants per study group or a power analysis indicating that the study is appropriately powered for the outcome(s) of interest	Studies with <30 participants per study group with no power analysis indicating that the study is appropriately powered for the outcome(s) of interest

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

Inclusion and Exclusion Criteria

Category	Inclusion Criteria	Exclusion Criteria
Age of study participants	Growth, size, and body composition: • Infants through older adults	
	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
	Developmental milestones, including neurocognitive development: • Infants through adolescents	Developmental milestones, including neurocognitive development: • Adults and older adults
	Micronutrient status: • Infants and toddlers	Micronutrient status: • Children through older adults

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

Inclusion and Exclusion Criteria

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

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/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

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?

Intervention/ exposure	vs	Comparator
Consumption of iron from supplements		Consumption of iron: a) at a different dosage or frequency from supplements b) from fortified foods
Consumption of iron from fortified foods/beverages		Consumption of iron: a) in a different amount or frequency from the same fortified food b) from different fortified or unfortified foods
Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)		

Endpoint outcomes

- Iron status, including incidence of iron deficiency and anemia
- Zinc status
- Copper status

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, Prenatal vitamin-supplement use, Baseline nutrient status

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 nutrient status

2020 Dietary Guidelines Advisory Committee: *Meeting 2*

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?

Intervention/ exposure	vs	Comparator
Consumption of vitamin D from supplements		Consumption of vitamin D: a) at a different dosage or frequency from supplements b) from fortified foods
Consumption of vitamin D from fortified foods/beverages		Consumption of vitamin D: a) in a different amount or frequency from the same fortified food b) from different fortified or unfortified foods
Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease		

Endpoint outcomes

- Vitamin D status
- Anemia (e.g., measures include Hb)

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, Prenatal vitamin-supplement use, Baseline nutrient status, 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 nutrient status

2020 Dietary Guidelines Advisory Committee: *Meeting 2*

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?

Intervention/ exposure	vs	Comparator
Consumption of vitamin B-12 from supplements		Consumption of vitamin B-12: a) a different dosage or frequency in supplements b) fortified foods
Consumption of vitamin B-12 from fortified foods/beverages		Consumption of vitamin B-12: a) in a different amount or frequency from the same fortified food b) different fortified or unfortified foods
Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)		

Endpoint outcomes

- Vitamin B 12 status
- Folate status

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, Prenatal vitamin-supplement use, Baseline nutrient status, 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 nutrient status

2020 Dietary Guidelines Advisory Committee: *Meeting 2*

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?

Intervention/ exposure	vs	Comparator
Consumption of omega-3 fatty acids from supplements		Consumption of omega-3 fatty acids: a) at a different dosage or frequency from supplements b) from fortified foods
Consumption of omega-3 fatty acids from fortified foods/beverages		Consumption of omega-3 fatty acids: a) in a different amount or frequency from the same fortified food b) different fortified or unfortified foods
Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)		

Endpoint outcomes

- Fatty acid status

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, Prenatal vitamin-supplement use, Baseline nutrient status

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 nutrient status

2020 Dietary Guidelines Advisory Committee: *Meeting 2*

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?

Intervention/ exposure	vs	Comparator
Consumption of iron from supplements		Consumption of iron: a) at a different dosage or frequency from supplements b) from fortified foods
Consumption of iron from fortified foods/beverages		Consumption of iron: a) in a different amount/frequency from the same fortified food b) from different fortified or unfortified foods

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)

Health outcomes

- Weight, weight-for-age
- Height, length/stature-for-age
- BMI, BMI z-score, weight-for-length
- Body circumferences e.g., head, arm, waist, thigh, neck
- Body composition and distribution e.g., % fat mass, fat-free mass
- Incidence and prevalence of:
  - Underweight, failure to thrive, stunting, wasting
  - Healthy weight
  - 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

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
Consumption of vitamin D from supplements		Consumption of vitamin D: a) at a different dosage or frequency from supplements b) from fortified foods
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

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)

Health outcomes

- Weight, weight-for-age
- Height, length/stature-for-age
- BMI, BMI z-score, weight-for-length
- Body circumferences e.g., head, arm, waist, thigh, neck
- Body composition and distribution e.g., % fat mass, fat-free mass
- Incidence and prevalence of:
  - Underweight, failure to thrive, stunting, wasting
  - Healthy weight
  - 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

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?

Intervention/ exposure	vs	Comparator
Consumption of vitamin B-12 from supplements		Consumption of vitamin B-12: a) a different dosage or frequency in supplements b) fortified foods
Consumption of vitamin B-12 from fortified foods/beverages		Consumption of vitamin B-12: a) in a different amount/ frequency from the same fortified food b) different fortified or unfortified foods

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)

Health outcomes

- Weight, weight-for-age
- Height, length/stature-for-age
- BMI, BMI z-score, weight-for-length
- Body circumferences e.g., head, arm, waist, thigh, neck
- Body composition and distribution e.g., % fat mass, fat-free mass
- Incidence and prevalence of:
  - Underweight, failure to thrive, stunting, wasting
  - Healthy weight
  - 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, 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?

Intervention/ exposure	vs	Comparator
Consumption of omega-3 fatty acids from supplements		Consumption of omega-3 fatty acids: a) at a different dosage or frequency from supplements b) from fortified foods
Consumption of omega-3 fatty acids from fortified foods/beverages		Consumption of omega-3 fatty acids: a) in a different amount/ frequency from the same fortified food b) different fortified or unfortified foods

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)

Health outcomes

- Weight, weight-for-age
- Height, length/stature-for-age
- BMI, BMI z-score, weight-for-length
- Body circumferences e.g., head, arm, waist, thigh, neck
- Body composition and distribution e.g., % fat mass, fat-free mass
- Incidence and prevalence of:
  - Underweight, failure to thrive, stunting, wasting
  - Healthy weight
  - 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

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: 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
Consumption of iron from supplements		Consumption of iron: a) at a different dosage or frequency from supplements b) from fortified foods
Consumption of iron from fortified foods/beverages		Consumption of iron: a) in a different amount/frequency from the same fortified food b) from different fortified or unfortified foods
Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)		

Health outcomes

- Bone mass, including:
  - bone mineral density
  - bone mineral content
- Biomarkers of bone metabolism
- Rickets
- Fracture

Population: Infants and toddlers (birth to 24 months), children and adolescents (2 to 18 years); 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, 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 bone health
2020 Dietary Guidelines Advisory Committee: *Meeting 2*

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?

Intervention/ exposure	vs	Comparator
Consumption of vitamin D from supplements		Consumption of vitamin D: a) at a different dosage or frequency from supplements b) from fortified foods
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

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)

Health outcomes

- Bone mass, including:
  - bone mineral density
  - bone mineral content
- Biomarkers of bone metabolism
- Rickets
- Fracture

Population: Infants and toddlers (birth to 24 months), children and adolescents (2 to 18 years); 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, 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 bone health

2020 Dietary Guidelines Advisory Committee: *Meeting 2*

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?

Intervention/ exposure	vs	Comparator
Consumption of vitamin B-12 from supplements		Consumption of vitamin B-12: a) a different dosage or frequency in supplements b) fortified foods
Consumption of vitamin B-12 from fortified foods/beverages		Consumption of vitamin B-12: a) in a different amount/ frequency from the same fortified food b) different fortified or unfortified foods
Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)		

Health outcomes

- Bone mass, including:
  - bone mineral density
  - bone mineral content
- Biomarkers of bone metabolism
- Rickets
- Fracture

Population: Infants and toddlers (birth to 24 months), children and adolescents (2 to 18 years); 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, Sun exposure 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 bone health
2020 Dietary Guidelines Advisory Committee: *Meeting 2*

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?

Intervention/ exposure	vs	Comparator
Consumption of omega-3 fatty acids from supplements		Consumption of omega-3 fatty acids: a) at a different dosage or frequency from supplements b) from fortified foods
Consumption of omega-3 fatty acids from fortified foods/beverages		Consumption of omega-3 fatty acids: a) in a different amount/ frequency from the same fortified food b) different fortified or unfortified foods

Population: Infants and toddlers (birth to 24 months); full-term, healthy and/or at risk for chronic disease)

Health outcomes

- Bone mass, including:
  - bone mineral density
  - bone mineral content
- Biomarkers of bone metabolism
- Rickets
- Fracture

Population: Infants and toddlers (birth to 24 months), children and adolescents (2 to 18 years); 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, 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 bone health
2020 Dietary Guidelines Advisory Committee: *Meeting 2*

Inclusion and Exclusion Criteria

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

Specific nutrients from supplements and/or fortified foods and: nutrient status; growth, size, and body composition; bone health

Inclusion and Exclusion Criteria

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 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 do not specify the dosage /amount/fortification level received of the specific nutrient
		• 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

Inclusion and Exclusion Criteria

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

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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