

# 2020 Dietary Guidelines Advisory Committee: Birth to 24 Months Subcommittee

**Chair Kay Dewey**

Lydia Bazzano

Teresa Davis

Sharon Donovan

Elsie Taveras (Presenter)

Chair/Vice Chair Rep Ron Kleinman

**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](https://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](https://www.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](https://www.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



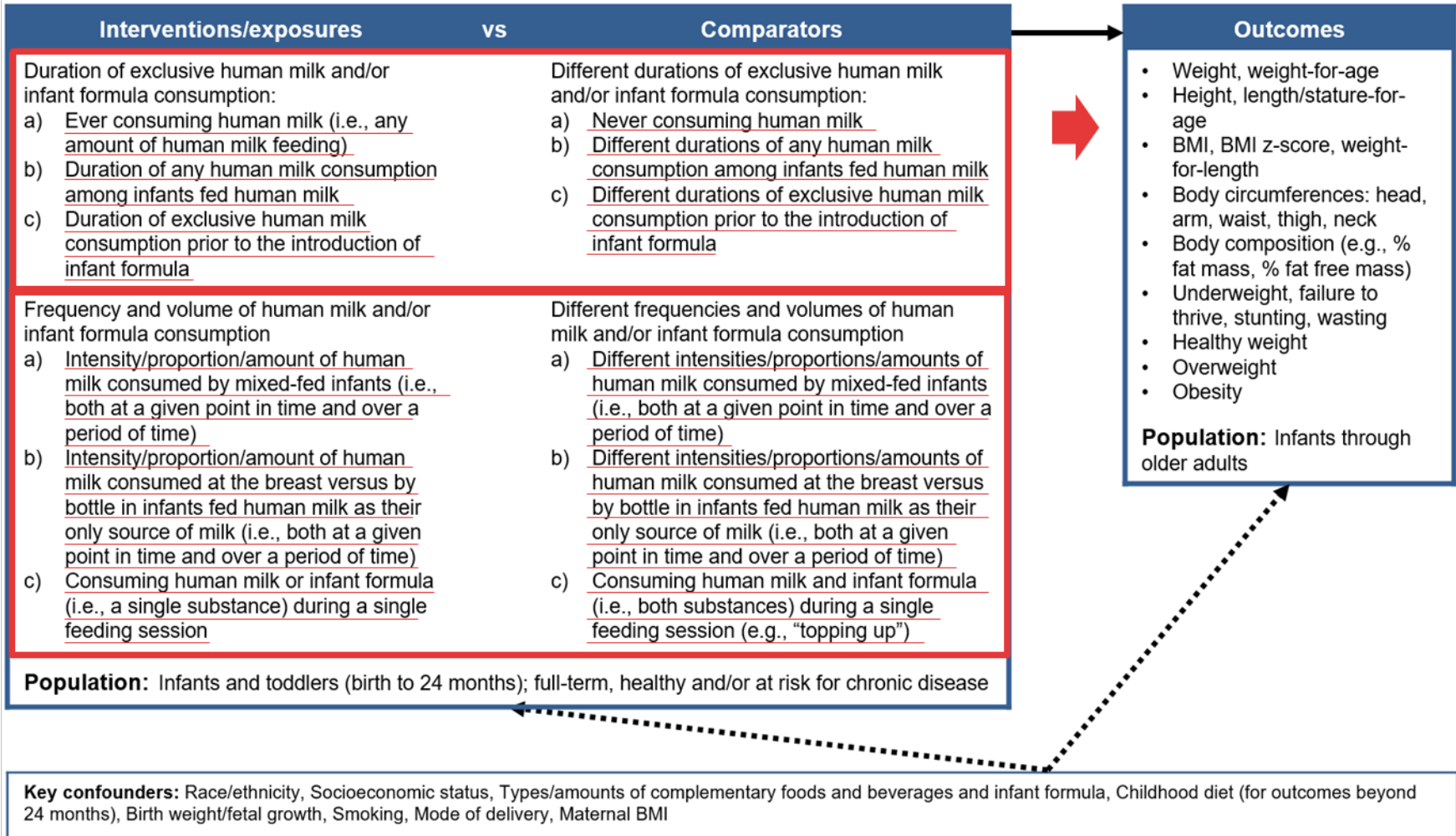
# Key Definitions

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?

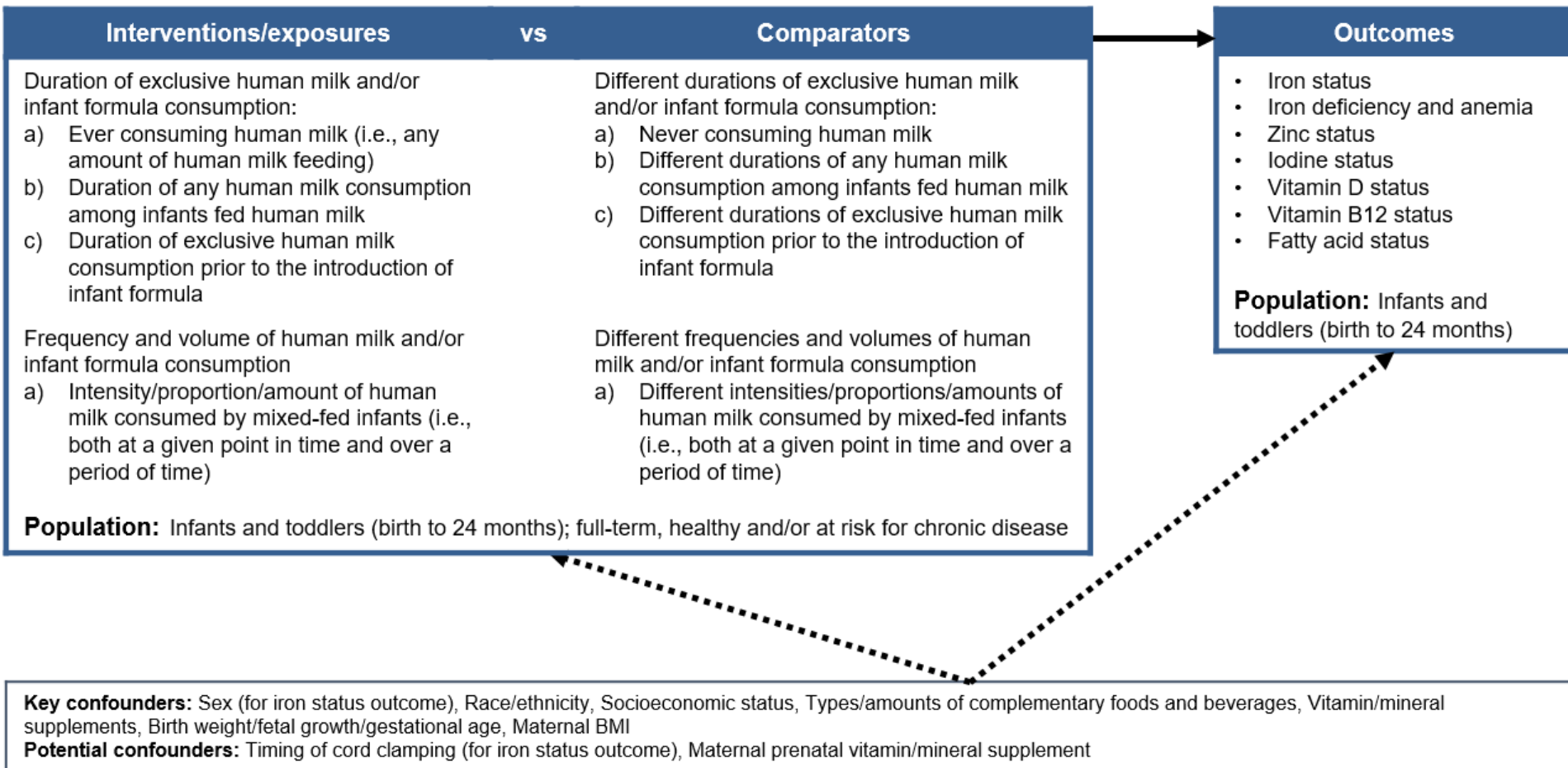


## Legend



- 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?

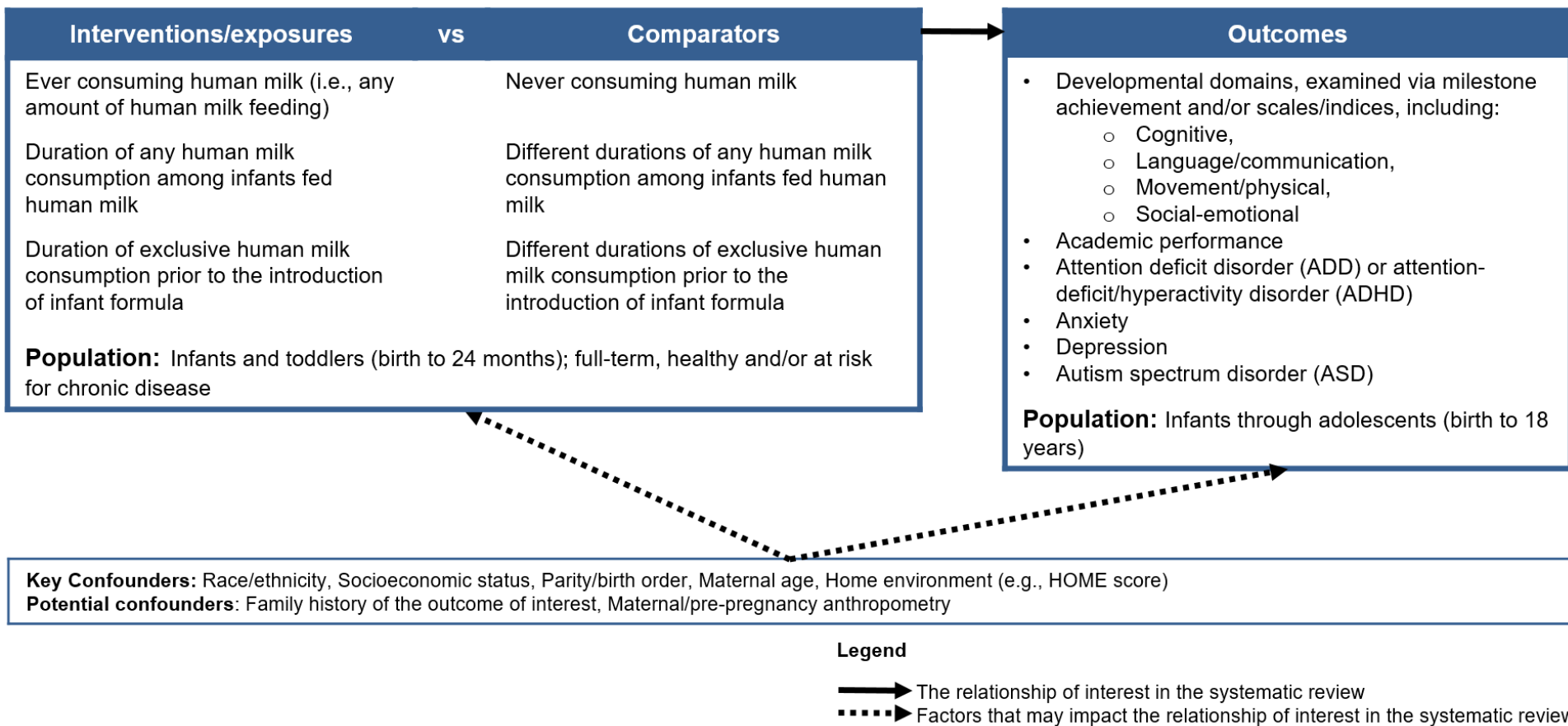


## Legend

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

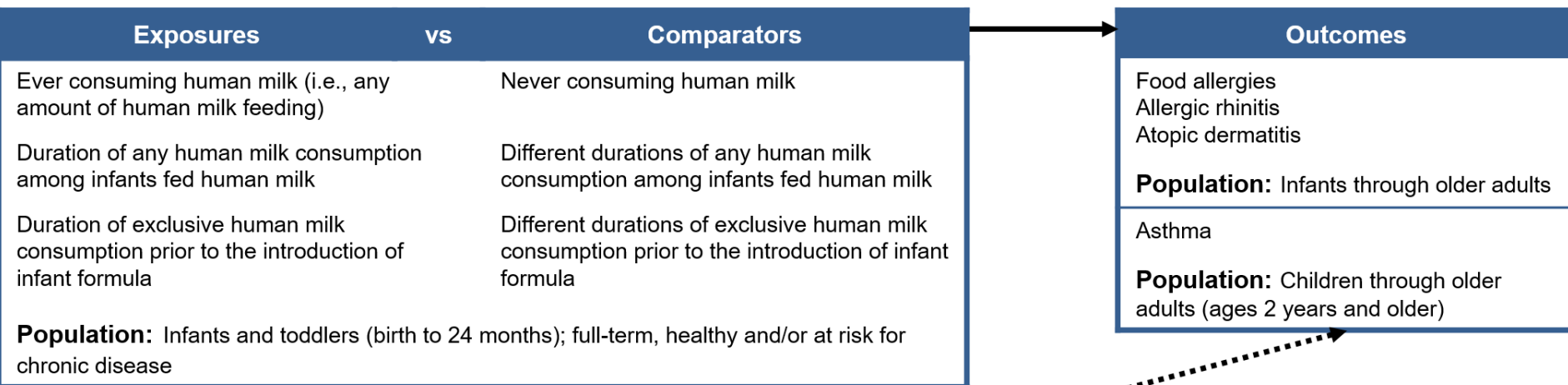
# Analytic Framework: Human milk/infant formula and developmental milestones

**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?



# 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?



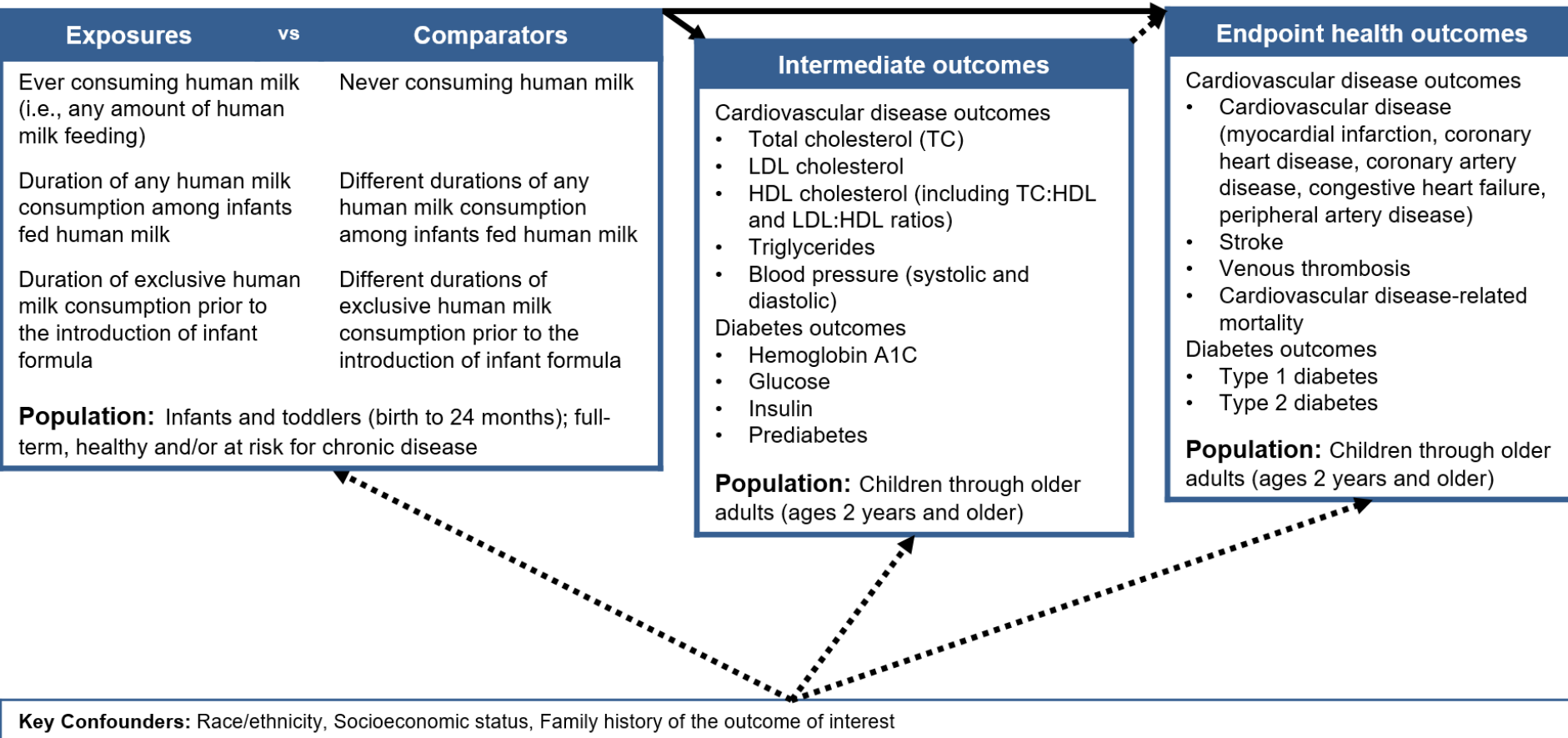
**Key confounders:** Race/ethnicity, Socioeconomic status, Type of infant formula, Timing/type of CFB, Smoking, Family history of atopic allergic diseases, Mode of delivery, Childcare arrangement, Number of siblings/family design, Urban/rural environment, Animals/pets/farming exposure

## 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?



## 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
<b>Date of publication</b>	January 1980 – July 2019*  <i>*For updates to existing systematic reviews, this includes an original search and an update search:</i> <ul style="list-style-type: none"> <li>• Original January 1980-March 2016</li> <li>• Update March 2016-July 2019</li> </ul>	Articles published prior to or after January 1980 – July 2019
<b>Size of study groups</b>	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  
 2020 Dietary Guidelines Advisory Committee: *Meeting 2*



# Inclusion and Exclusion Criteria

Category	Inclusion Criteria	Exclusion Criteria
Age of study participants	<u>Growth, size, and body composition:</u> <ul style="list-style-type: none"> <li>• Infants through older adults</li> </ul>	
	<u>Food allergies and atopic allergic diseases:</u> <ul style="list-style-type: none"> <li>• Infants through older adults (food allergies, allergic rhinitis, atopic dermatitis)</li> <li>• Children through older adults (asthma)</li> </ul>	<u>Food allergies and atopic allergic diseases:</u> <ul style="list-style-type: none"> <li>• Infants and toddlers (asthma)</li> </ul>
	<u>Long-term health outcomes (CVD, diabetes):</u> <ul style="list-style-type: none"> <li>• Children through older adults</li> </ul>	<u>Long-term health outcomes (CVD, diabetes):</u> <ul style="list-style-type: none"> <li>• Infants and toddlers</li> </ul>
	<u>Developmental milestones, including neurocognitive development:</u> <ul style="list-style-type: none"> <li>• Infants through adolescents</li> </ul>	<u>Developmental milestones, including neurocognitive development:</u> <ul style="list-style-type: none"> <li>• Adults and older adults</li> </ul>
	<u>Micronutrient status:</u> <ul style="list-style-type: none"> <li>• Infants and toddlers</li> </ul>	<u>Micronutrient status:</u> <ul style="list-style-type: none"> <li>• Children through older adults</li> </ul>

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
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**

**2020 Dietary Guidelines Advisory Committee: *Meeting 2***

# Specific Nutrients from Supplements and/or Fortified Foods Protocols

**All protocols are available to view at:**

**[DietaryGuidelines.gov](https://www.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?

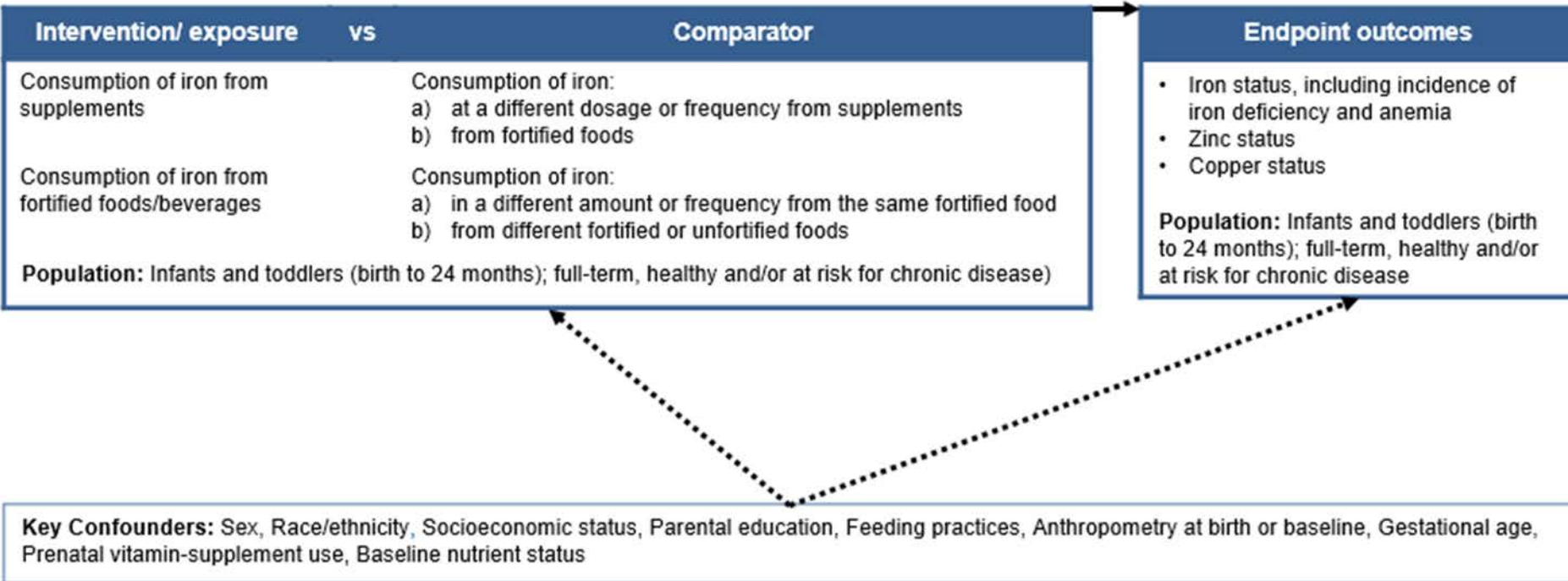
\*\* Includes iron, vitamin D, vitamin B-12, and omega-3 fatty acids

# 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?



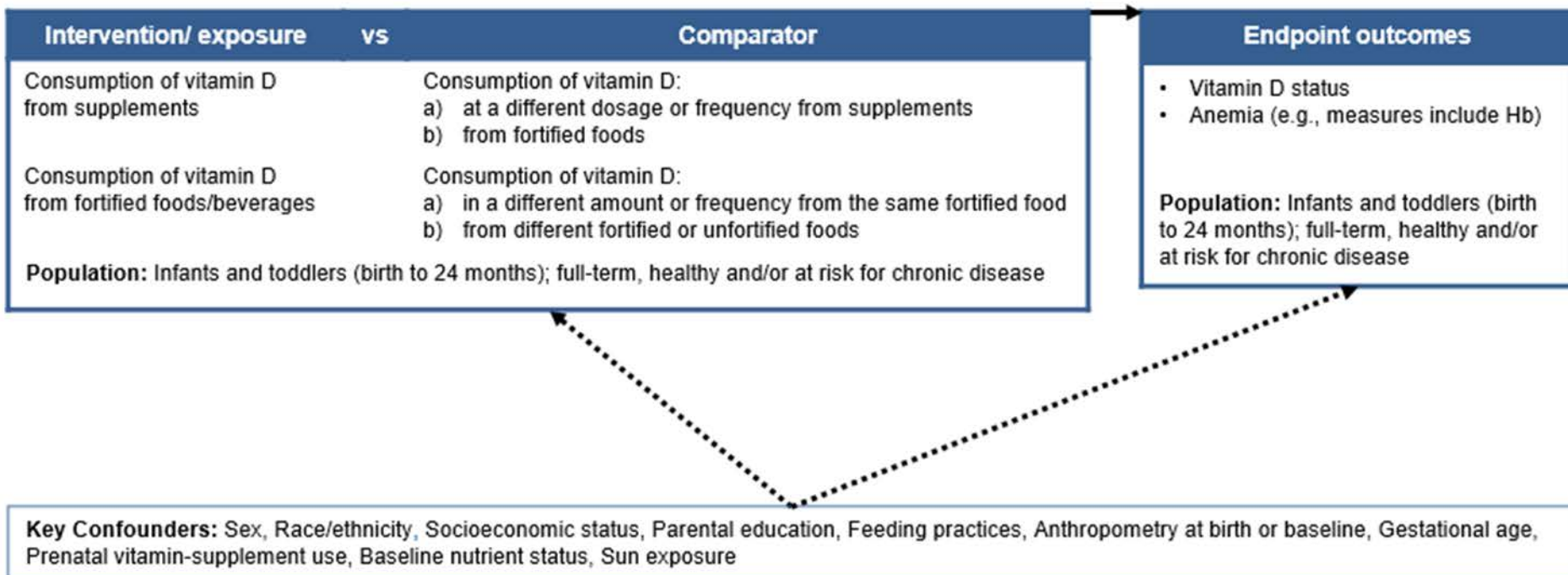
## Legend

- > 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?



## Legend

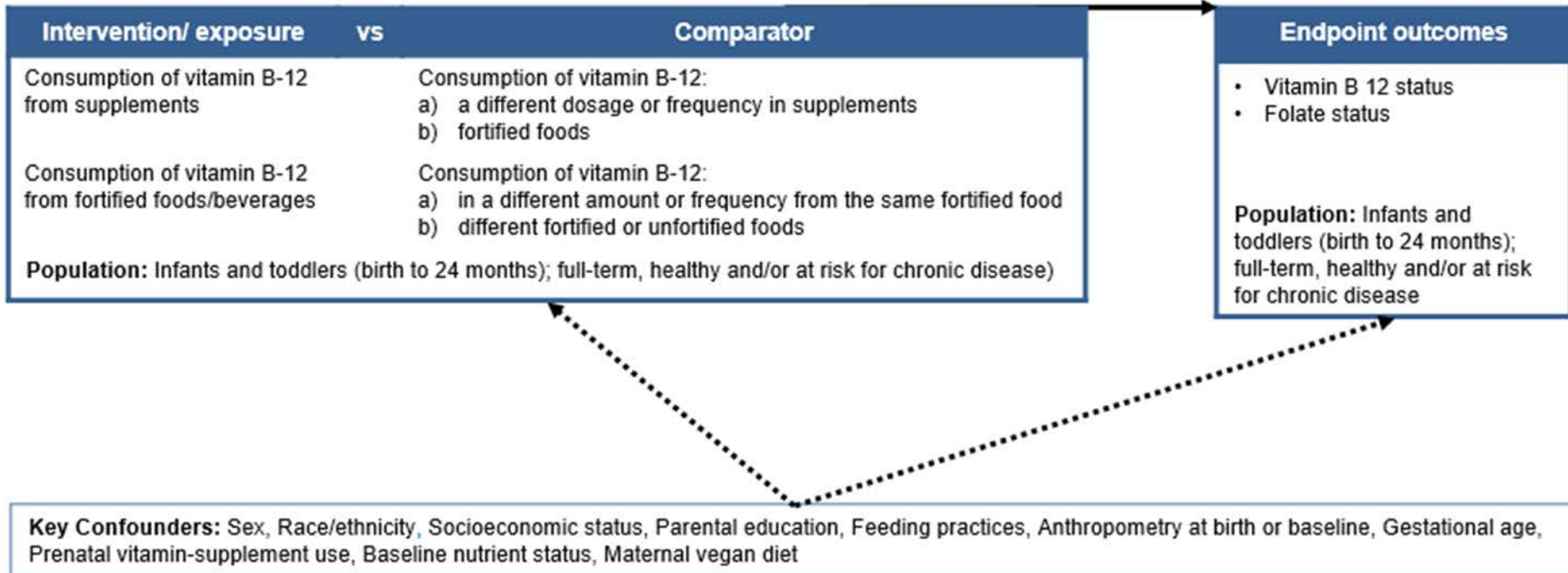
- > The relationship of interest in the systematic review
- .....> Factors that may impact the relationship of interest in the systematic review

**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?



## Legend

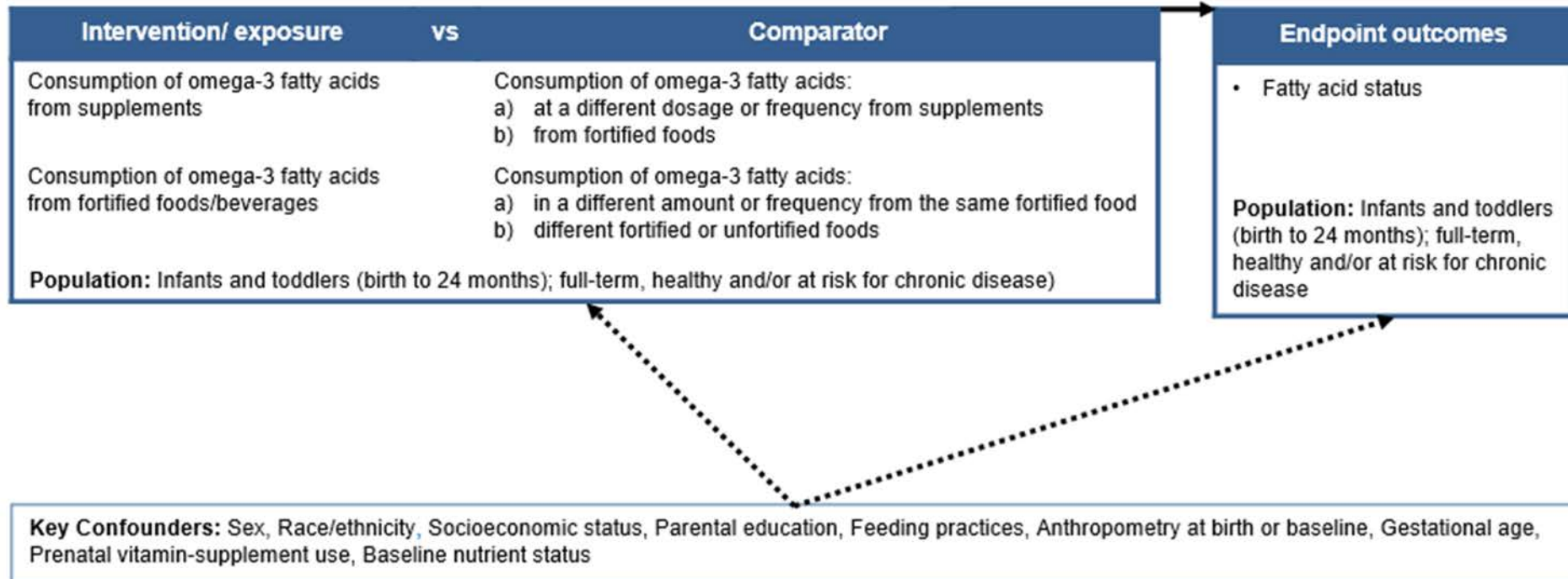
- The relationship of interest in the systematic review
- Factors that may impact the relationship of interest in the systematic review

**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?



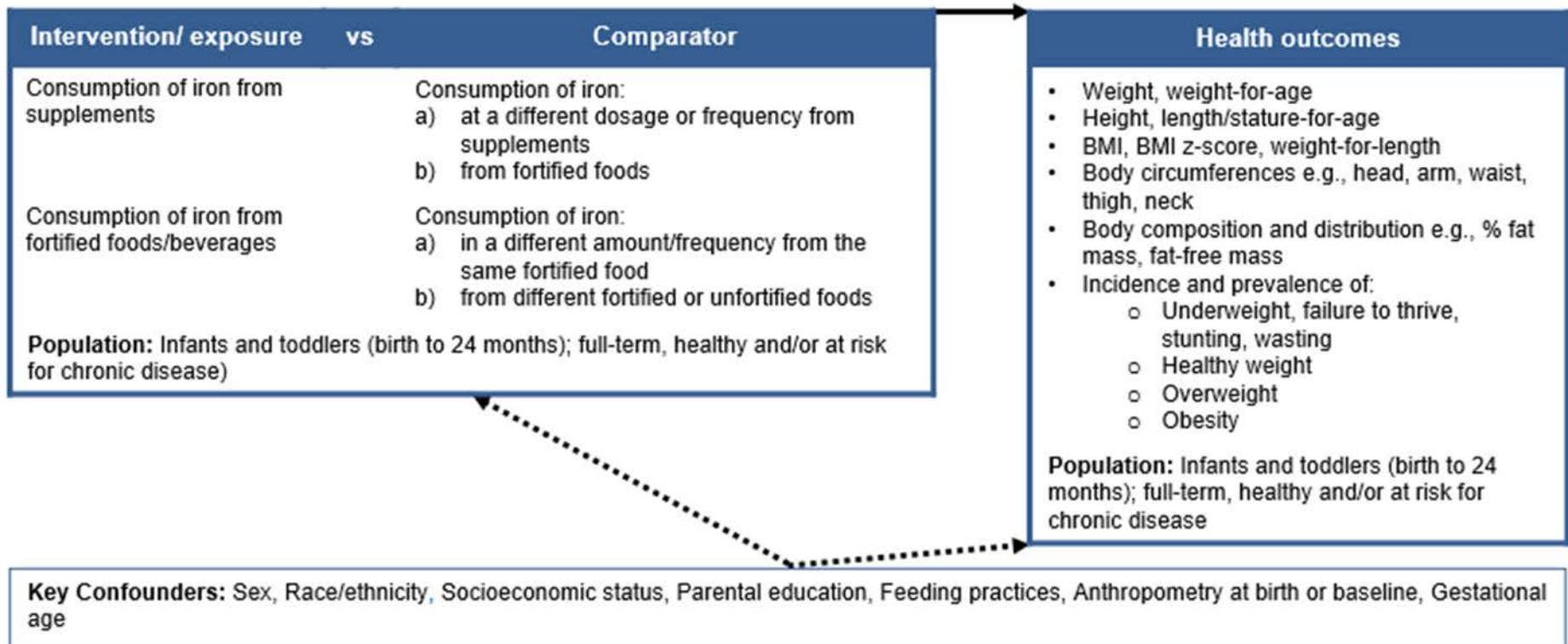
## Legend

- 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?



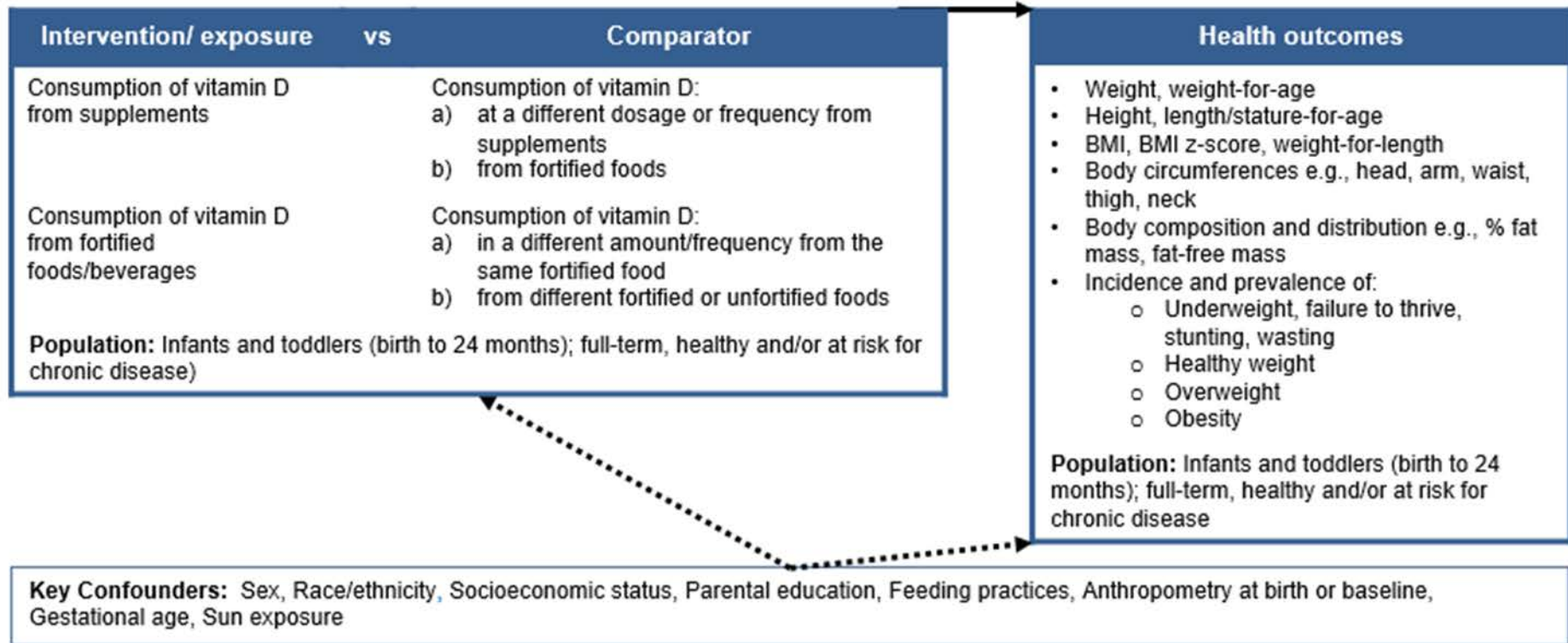
## Legend

- 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?



## Legend

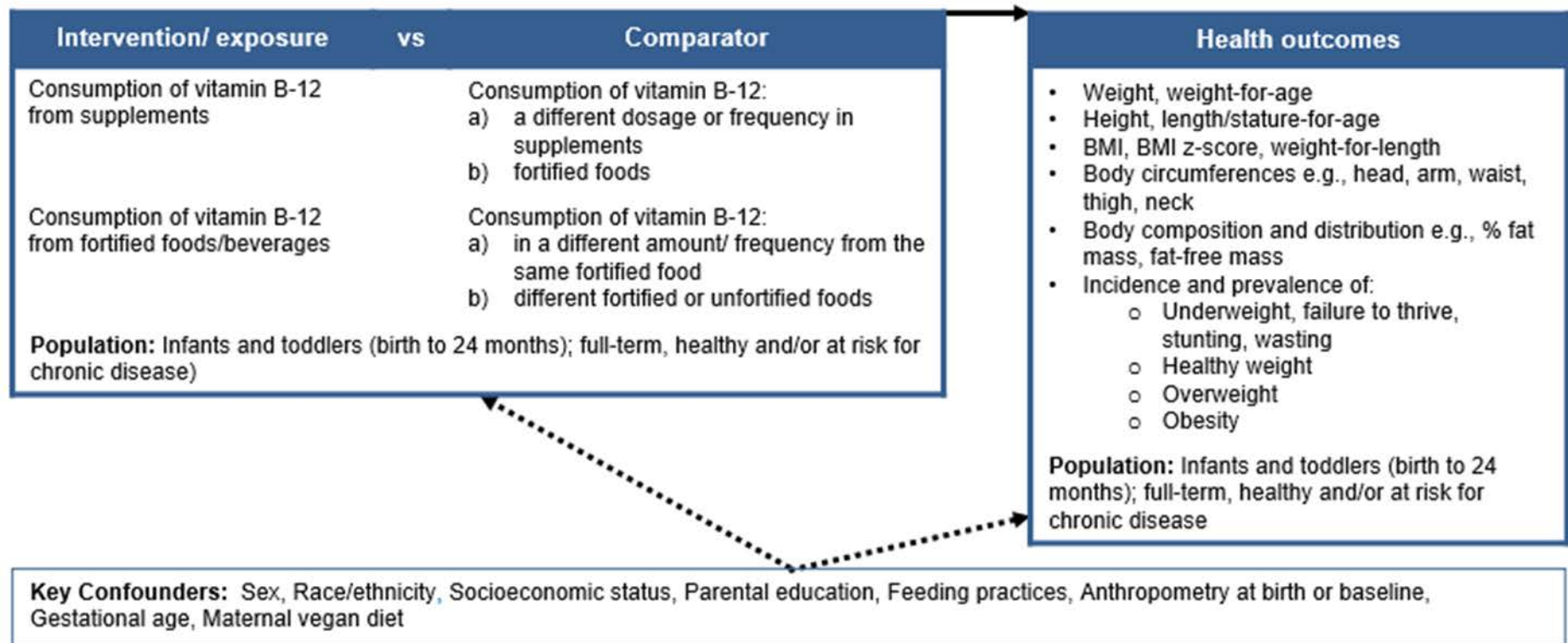
- The relationship of interest in the systematic review  
 Factors that may impact the relationship of interest in the systematic review

**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?



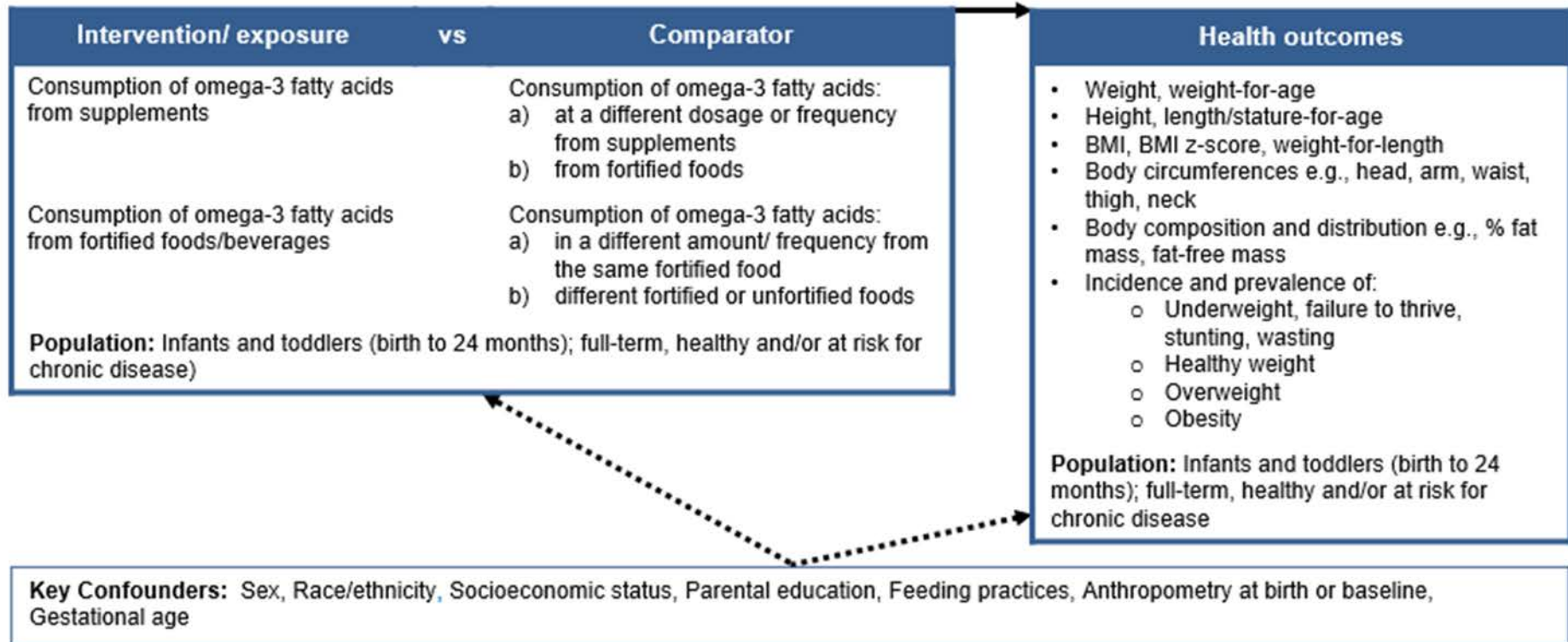
## Legend

- 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?



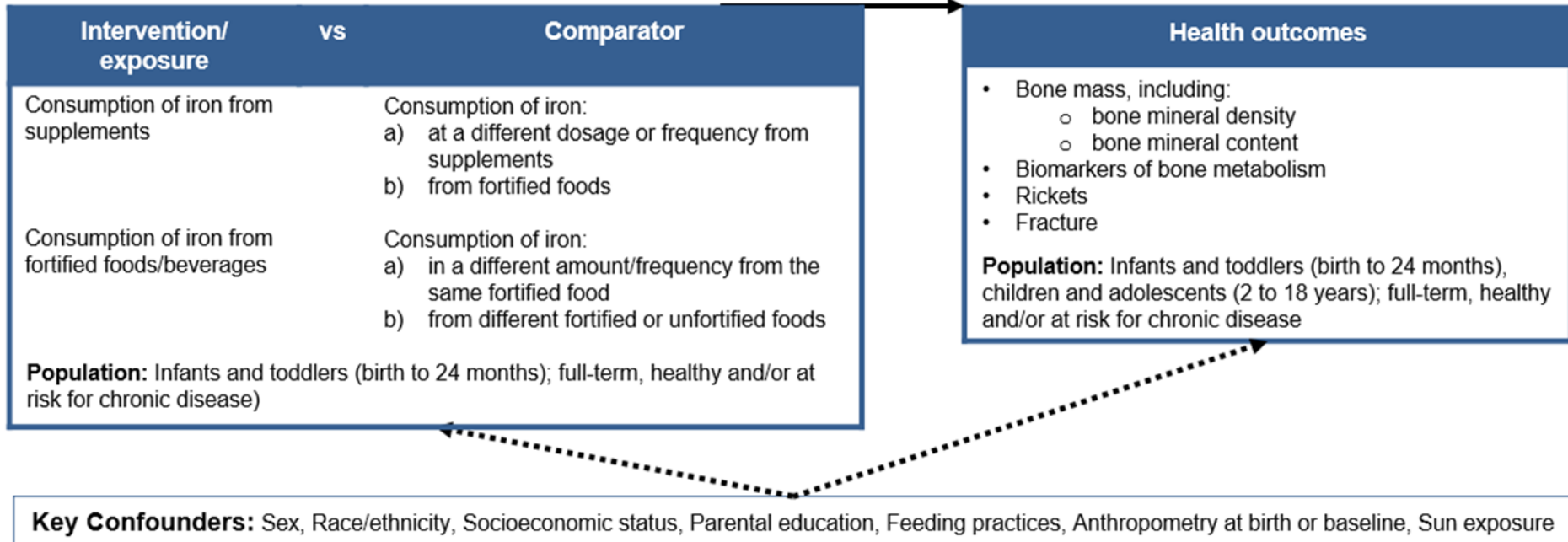
## Legend

- 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?



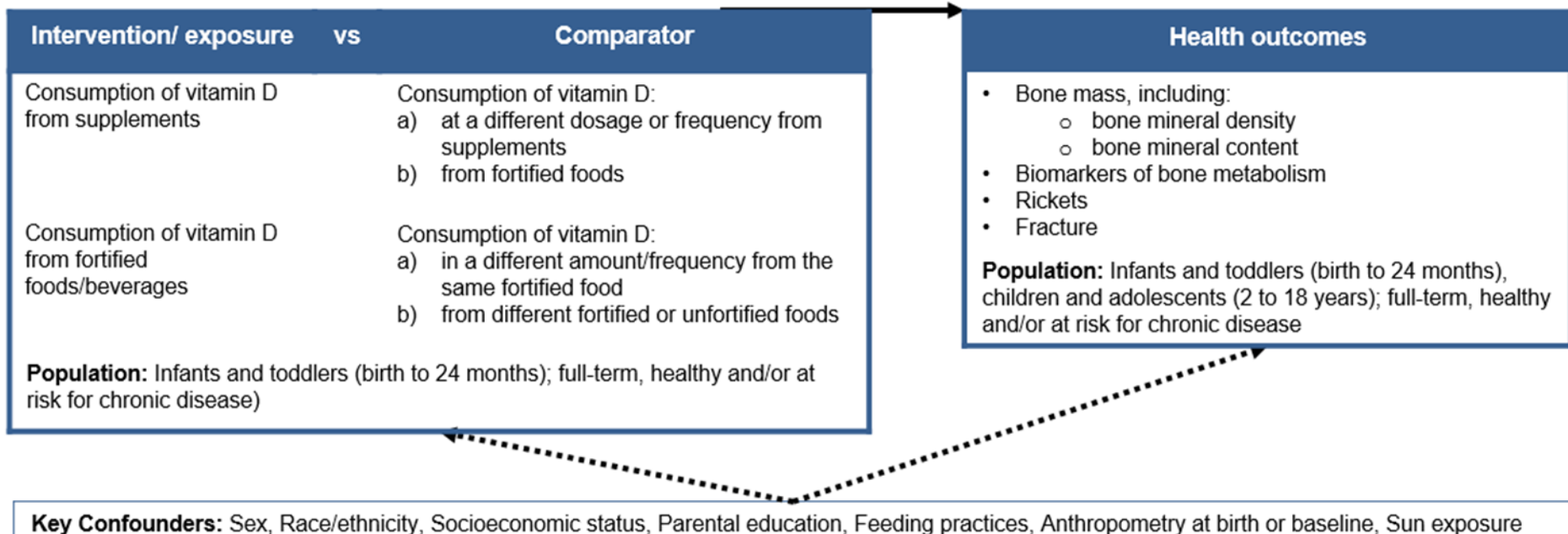
## Legend

- ▶ 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?



## Legend

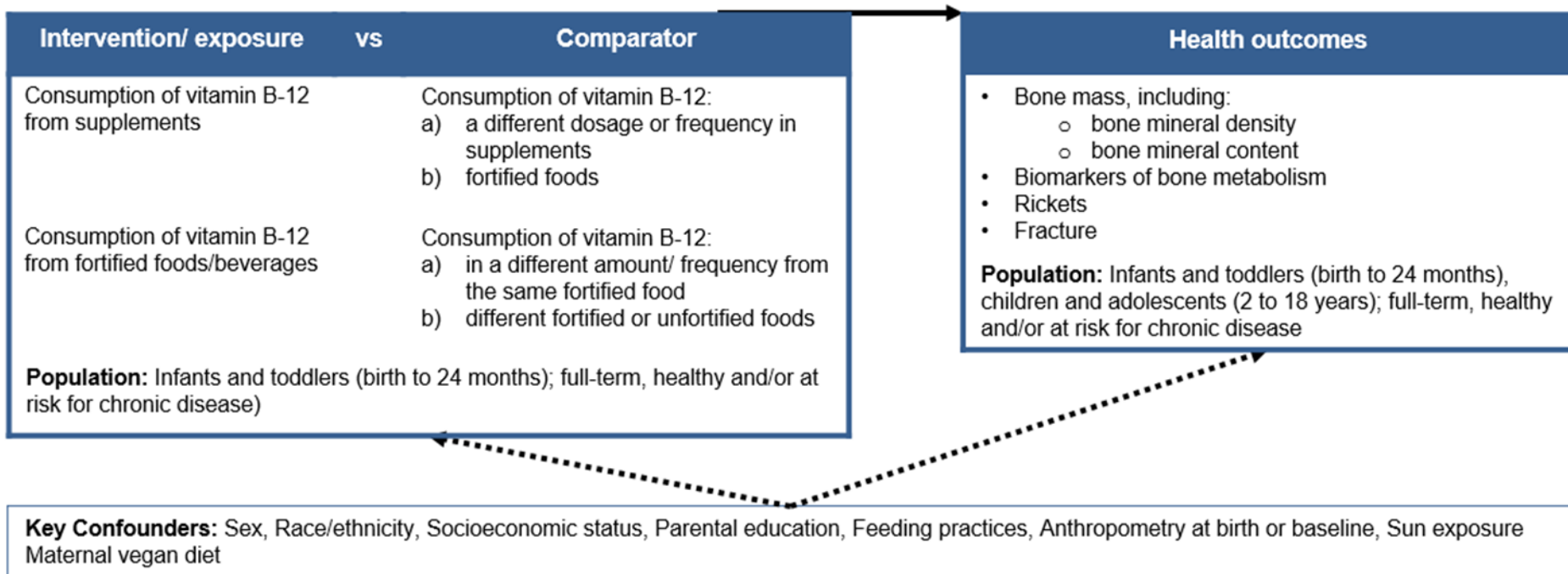
- ▶ The relationship of interest in the systematic review
- .....▶ Factors that may impact the relationship of interest in the systematic review

**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?



## Legend

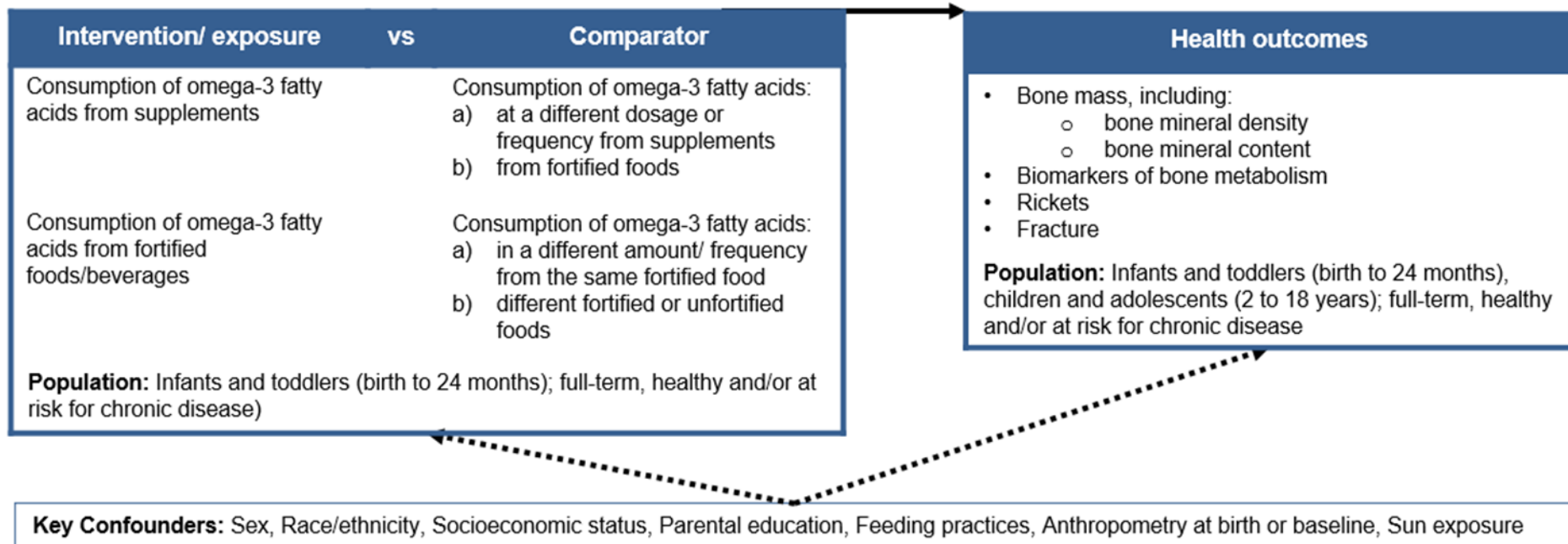
- ▶ The relationship of interest in the systematic review
- .....▶ Factors that may impact the relationship of interest in the systematic review

**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?



## 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  
2020 Dietary Guidelines Advisory Committee: *Meeting 2***

# Inclusion and Exclusion Criteria

Category	Inclusion Criteria	Exclusion Criteria
<b>Interventions/ exposures</b>	<ul style="list-style-type: none"><li>• Studies that examine consumption of iron, vitamin D, vitamin B-12, or omega-3 fatty acids from:<ul style="list-style-type: none"><li>• supplements</li><li>• fortified foods/beverages</li></ul></li><li>• Studies that specify the dosage/amount/fortification level received of the specific nutrient</li><li>• Studies that examine animal products that contain added nutrients as a result of feeding the animal a specialized diet</li></ul>	<ul style="list-style-type: none"><li>• Studies that do not specify the dosage /amount/fortification level received of the specific nutrient</li><li>• Studies that vary nutrients other than the nutrient of interest without controlling for that variation</li></ul>

**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***

# Inclusion and Exclusion Criteria

Category	Inclusion Criteria	Exclusion Criteria
<b>Age of study participants</b>	<p>Age at intervention or exposure:</p> <ul style="list-style-type: none"> <li>• Infants and toddlers (birth to 24 mo)</li> </ul> <p>Age at outcome:</p> <ul style="list-style-type: none"> <li>• Infants and toddlers (birth to 24 mo)</li> <li>• <i>For Bone Health outcomes only:</i> Children and adolescents (2 to 18 yrs)</li> </ul>	<p>Age at intervention or exposure or outcome:</p> <ul style="list-style-type: none"> <li>• Children and adolescents (2-18 yrs)</li> <li>• Adults (19 -64 yrs)</li> <li>• Older adults (65 yrs and older)</li> </ul>
<b>Source of foods, beverages, or nutrients</b>	<ul style="list-style-type: none"> <li>• Vitamin and mineral supplements (e.g., iron drops)</li> <li>• Fortified foods/beverages</li> <li>• 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)</li> </ul>	<ul style="list-style-type: none"> <li>• Donor or banked milk</li> <li>• Unfortified or fortified human milk</li> </ul>

**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

**Members:**

Kay Dewey  
Lydia Bazzano

Teresa Davis

Sharon Donovan

Ron Kleinman

**Support Staff:**

Cria Perrine

Jen Lerman

Kelley Scanlon

Eve Stooddy (DFO rep)

Laural English

Darcy Güngör

Emily Madan

Julie Obbagy

Sudha Venkatramanan

Nancy Terry

[DietaryGuidelines.gov](https://DietaryGuidelines.gov)