

2020 Dietary Guidelines Advisory Committee: Pregnancy and Lactation Subcommittee

Subcommittee Chair: Sharon Donovan

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DietaryGuidelines.gov

Status of Questions: Pregnancy and Lactation

Developing the Plan (New protocols to be discussed today)

1. Dietary Patterns:

- Human Milk Composition
- Micronutrient Status
- Infant Developmental Milestones

2. Dietary Supplements and Fortified Foods:

- Vitamin B12
- Omega-3 Fatty
- Vitamin D

3. Maternal Diet:

- Risk of Food Allergies

All protocols discussed in this presentation are available at DietaryGuidelines.gov

Status of Questions: Pregnancy and Lactation

Implementing the Plan (Protocols discussed at last meeting)

1. Dietary Patterns:

- Gestational weight gain
- Postpartum weight loss

2. Dietary Supplements and Fortified Foods:

- Folic acid (5 outcomes)
- Iron (4 outcomes)

All protocols discussed in this presentation are available at DietaryGuidelines.gov

Status of Questions: Pregnancy and Lactation

Still to come (Protocols in development; not presented today)

1. Dietary Patterns:

- Risk of Gestational Diabetes
- Risk of Hypertensive Disorders
- Gestational Age at Birth
- Birth Weight

2. Dietary Supplements and Fortified Foods:

- Iodine

All protocols discussed in this presentation are available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov)

Updates to Protocols Presented in July

Dietary Patterns:

Gestational Weight Gain Postpartum Weight Loss	<p>The inclusion and exclusion criteria for the intervention/exposure were edited to clarify that:</p> <ul style="list-style-type: none">○ specific macronutrient proportion diets will be included when the macronutrient proportions fall outside of the Acceptable Macronutrient Distribution Range (AMDR)○ only studies that describe all macronutrients (i.e., carbohydrates, fat, and protein) in the diet will be included.
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Dietary Supplements and Fortified Foods:

Iron	<ul style="list-style-type: none">• Based on DGAC discussion, protocol updated to include supplements <i>and fortified foods</i>
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Developing the plan: new protocols for dietary patterns

What is the relationship between **dietary patterns** consumed during pregnancy and lactation and:

1. **Human milk composition and quantity?**
2. **Infant developmental milestones, including neurocognitive development?**
3. **Maternal micronutrient status?**

Approach to Answer Questions: NESR Systematic Reviews

Dietary Patterns: Key Definitions

- **Dietary Pattern** – the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed.

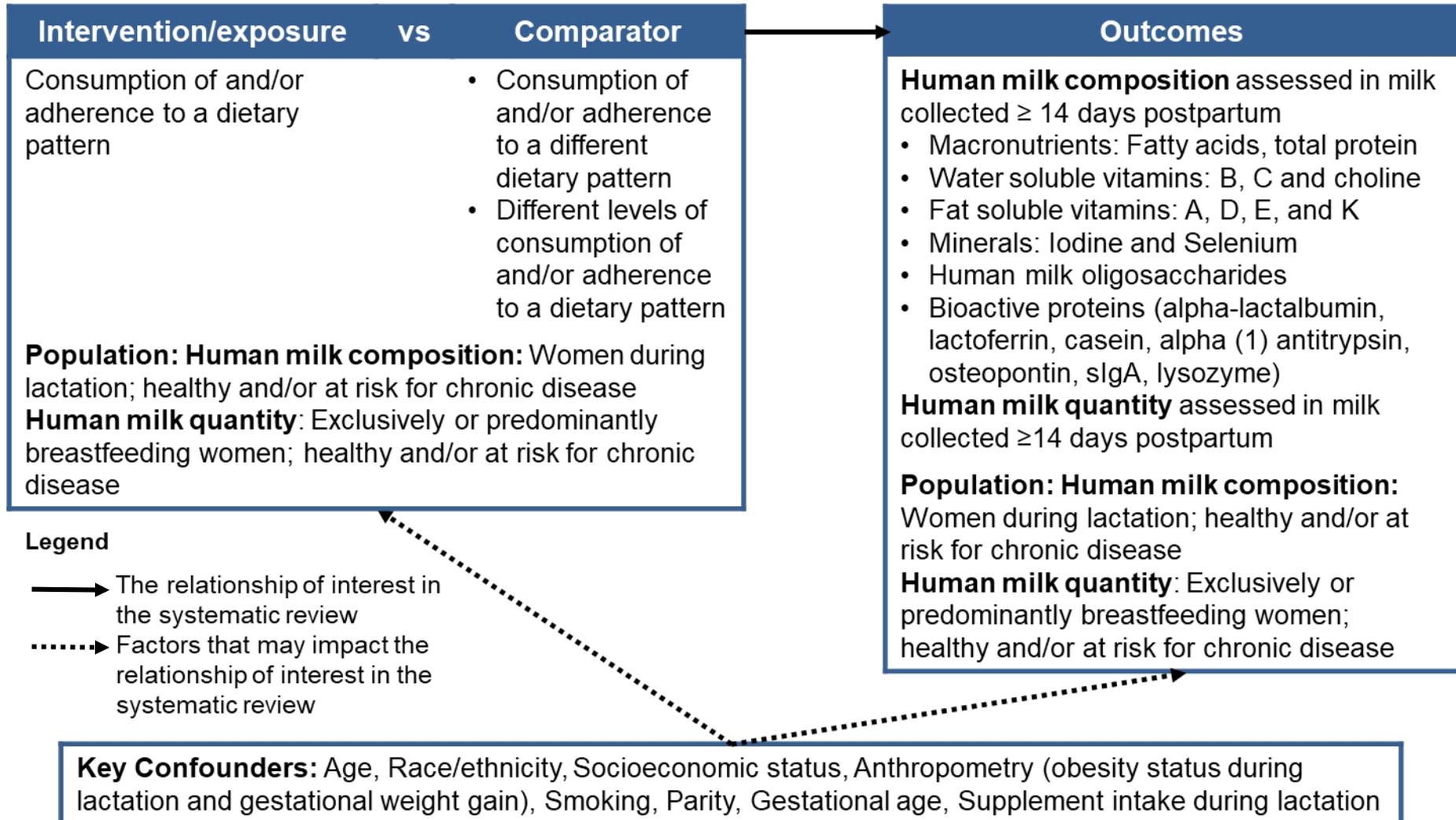
Dietary Patterns: Question

What is the relationship between **dietary patterns** consumed during lactation and **human milk composition and quantity**?

Approach to Answer Question: NESR Systematic Review

What is the relationship between **dietary patterns** consumed during lactation and **human milk composition and quantity**?

Analytic framework



What is the relationship between **dietary patterns** consumed during lactation and **human milk composition and quantity**?

Inclusion/exclusion criteria:

- Standard criteria be used for:
 - Publication Status
 - Language of Publication
 - Country
- Other criteria consistent with Dietary Patterns SC:
 - Intervention/exposure
 - Comparator
 - Date of publication (January 2000-TBD)

What is the relationship between **dietary patterns** consumed during lactation and **human milk composition and quantity**?

Inclusion/exclusion criteria:

Category	Inclusion Criteria	Exclusion Criteria
Study design	<ul style="list-style-type: none">• Randomized controlled trials• Non-randomized controlled trials including quasi-experimental and controlled before-and-after studies• Prospective cohort studies• Retrospective cohort studies• Nested case-control studies• Cross-sectional studies	<ul style="list-style-type: none">• Uncontrolled trials• Case-control studies• Uncontrolled before-and-after studies• Narrative reviews• Systematic reviews• Meta-analyses

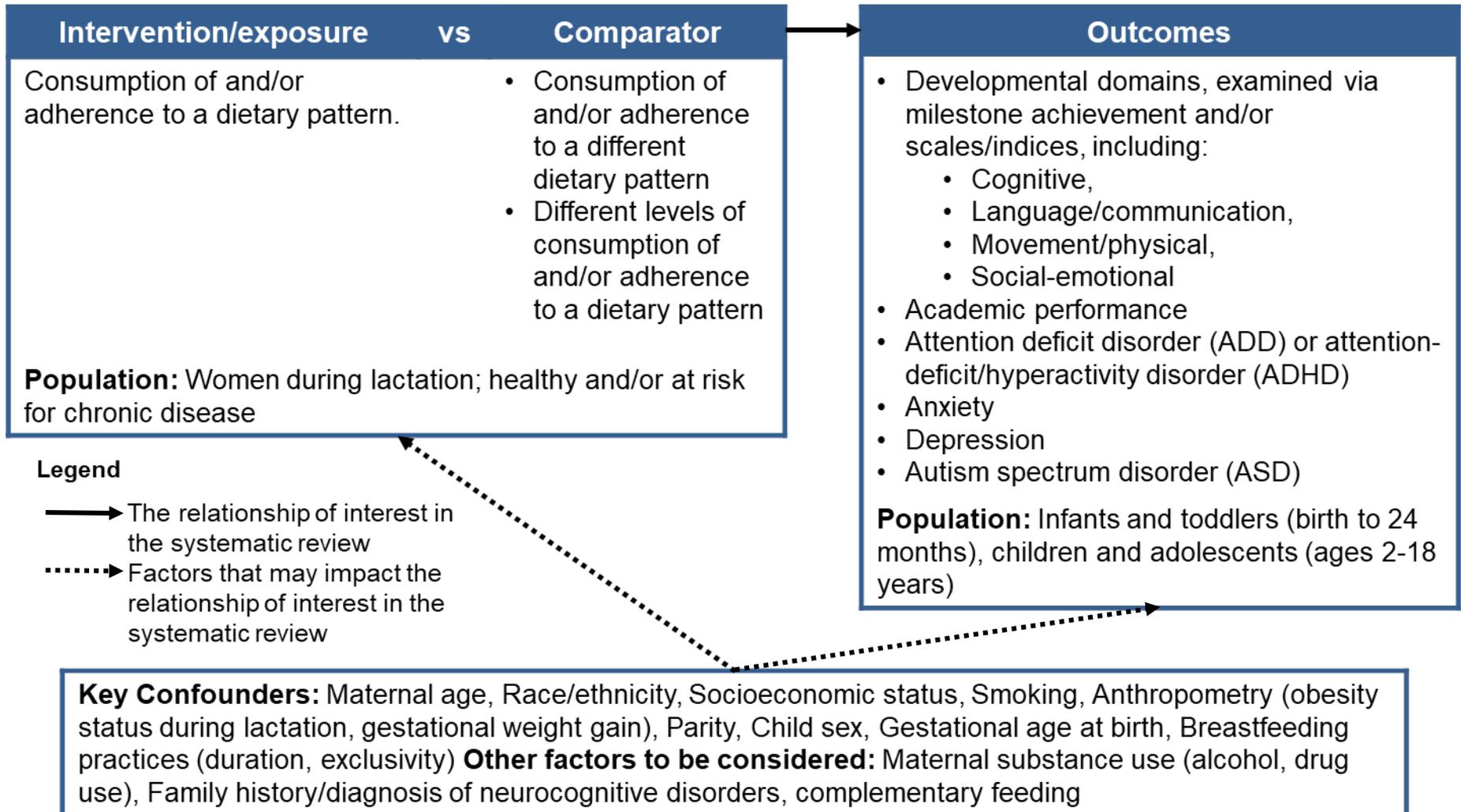
Dietary Patterns: Question

What is the relationship between **dietary patterns** consumed during lactation and **infant developmental milestones, including neurocognitive development?**

Approach to Answer Question: NESR Systematic Review

What is the relationship between dietary patterns consumed during lactation and infant developmental milestones, including neurocognitive development?

Analytic framework:



What is the relationship between **dietary patterns** consumed during lactation and **infant developmental milestones, including neurocognitive development**?

Inclusion/exclusion criteria:

- Standard criteria be used for:
 - Study Design
 - Publication Status
 - Language of Publication
 - Country
- Criteria used for all dietary pattern reviews:
 - Intervention/Exposure
 - Comparator
 - Date of publication (January 2000-TBD)
 - Health status of study participants

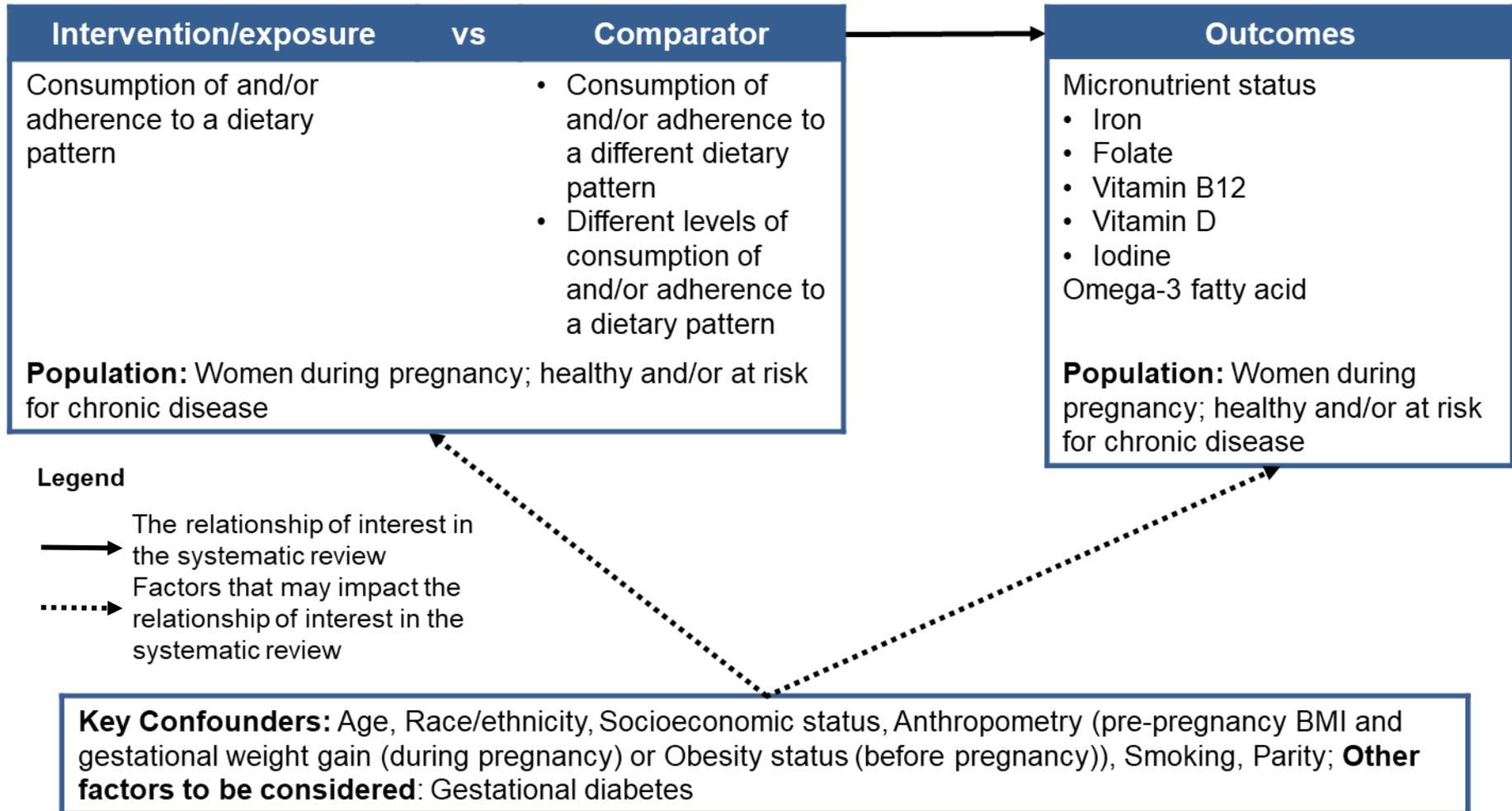
Dietary Patterns: Question

What is the relationship between **dietary patterns** consumed during pregnancy and **(maternal) micronutrient status**?

Approach to Answer Question: NESR Systematic Review

What is the relationship between **dietary patterns** consumed during pregnancy and **micronutrient status**?

Analytic framework:



What is the relationship between **dietary patterns** consumed during pregnancy and **micronutrient status**?

Inclusion/exclusion criteria:

- Standard criteria be used for:
 - Publication Status
 - Language of Publication
 - Country
- Criteria used for all dietary pattern reviews:
 - Intervention/Exposure
 - Comparator
 - Date of publication (January 2000-TBD)
 - Health status of study participants

Developing the plan: new protocols for dietary supplements and fortified foods

What is the relationship between **nutrients* from supplements and/or fortified foods** consumed before and during pregnancy and lactation and:

*** Nutrients:**

- **Vitamin B12**
- **Omega-3 fatty acids**
- **Vitamin D**

- 1. Micronutrient status?**
- 2. Risk of gestational diabetes?**
- 3. Risk of hypertensive disorders during pregnancy?**
- 4. Human milk composition and quantity?**
- 5. Infant developmental milestones, including neurocognitive development?**

Approach to Answer Question: NESR Systematic Review

Supplements & Fortified foods: Key Definitions

- **Dietary Supplement** -- 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** -- the deliberate addition of one or more essential nutrients to a food, whether or not it is normally contained in the food. (FDA)

Supplements & Fortified foods: Key Definitions

- **“Before pregnancy”**-- includes up to 6 months before pregnancy
- **Pre-pregnancy BMI** -- based on health records up to 1 year before and up to and including 1st trimester
- **Gestational weight gain** -- weight a woman gains during pregnancy (CDC)
- **Gestational diabetes** – diabetes occurring during pregnancy in women not previously diagnosed with diabetes (P/B24 Project)

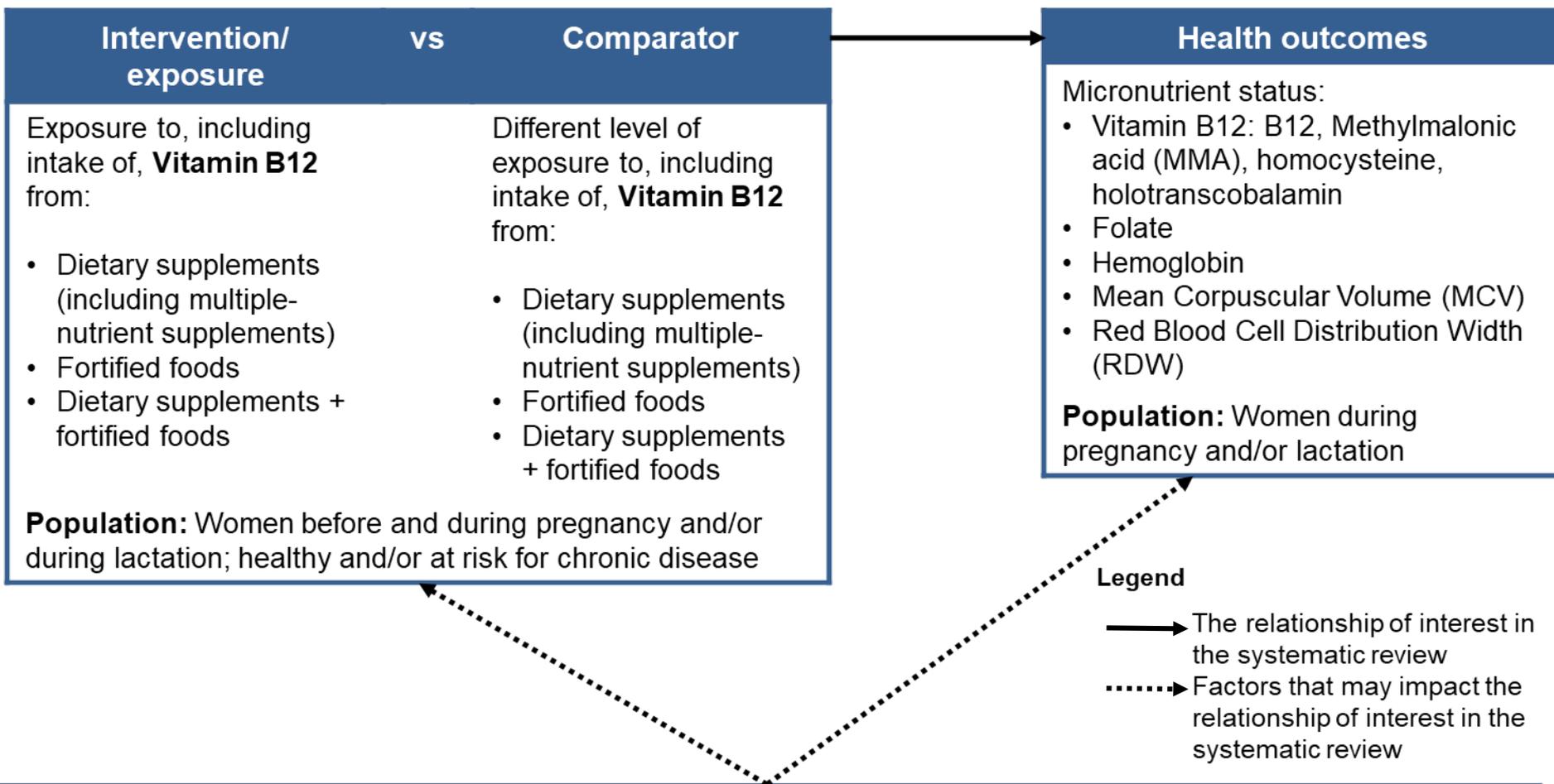
Supplements & Fortified foods: Question

What is the relationship between vitamin B12 from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes (5 outcomes)?

Approach to Answer Question: NESR Systematic Review

What is the relationship between **vitamin B12** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **micronutrient status**?

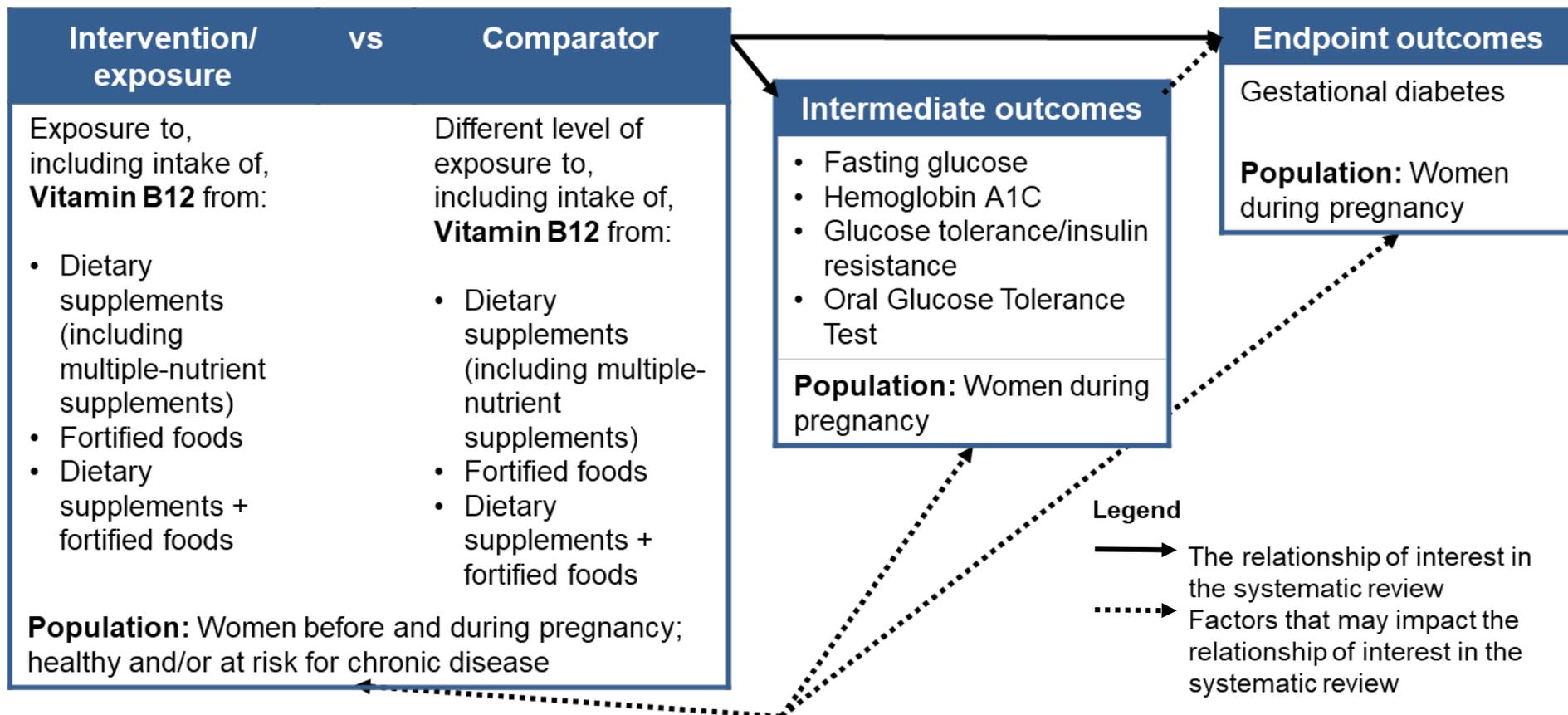
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Vegan/vegetarian diet, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Smoking, Parity; **Other factors to be considered:** Substance use (alcohol, drug use), gestational age

What is the relationship between **vitamin B12** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **risk of gestational diabetes**?

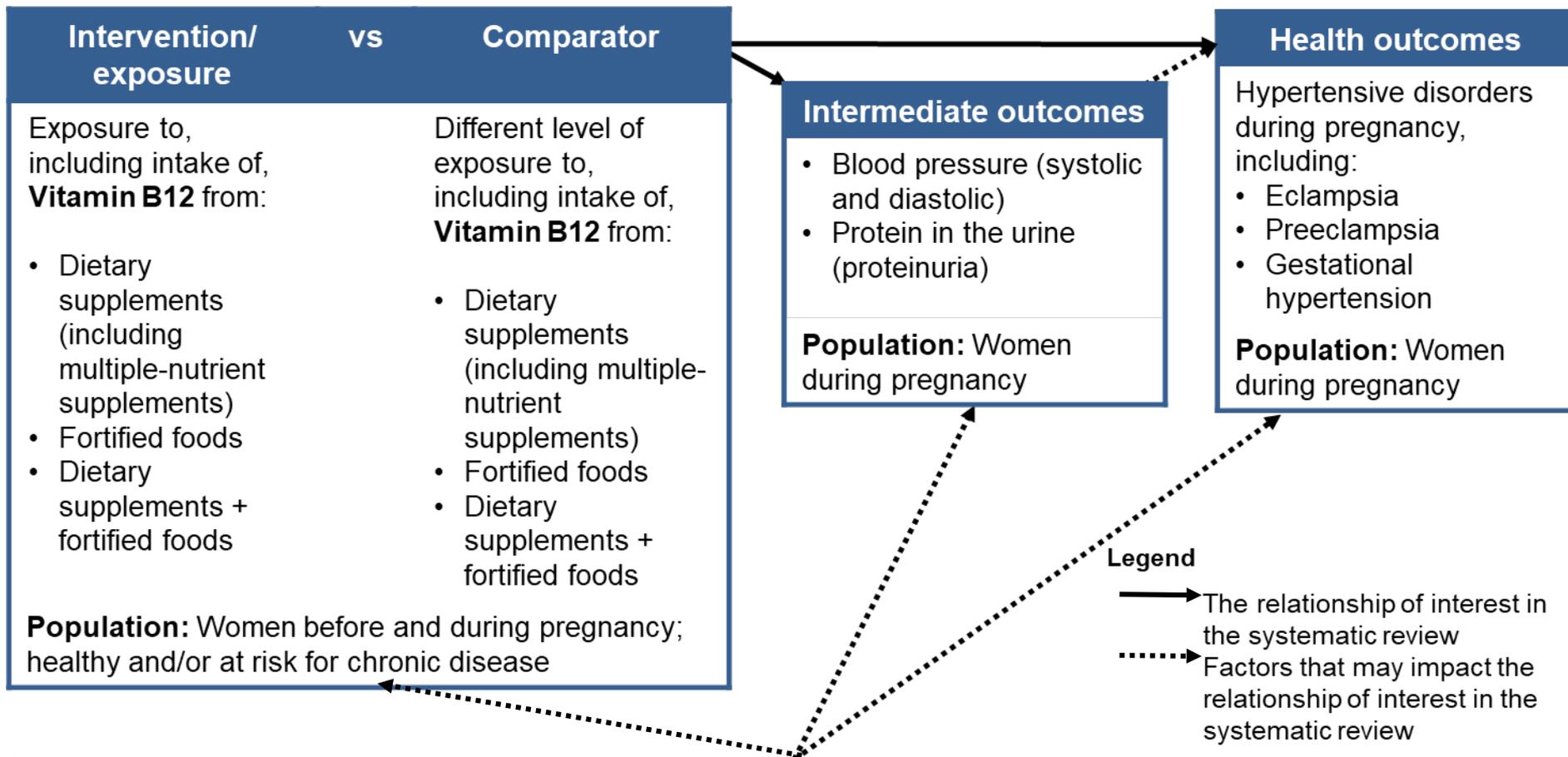
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Vegan/vegetarian diet, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy)), Smoking, Family history of diabetes or pre-diabetes, Parity; **Other factors to be considered:** Physical activity, substance use (alcohol, drug use), large infant prior (Large for Gestational Age), enrolled in intervention/prevention trial, gestational age

What is the relationship between **vitamin B12** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **risk of hypertensive disorders during pregnancy**?

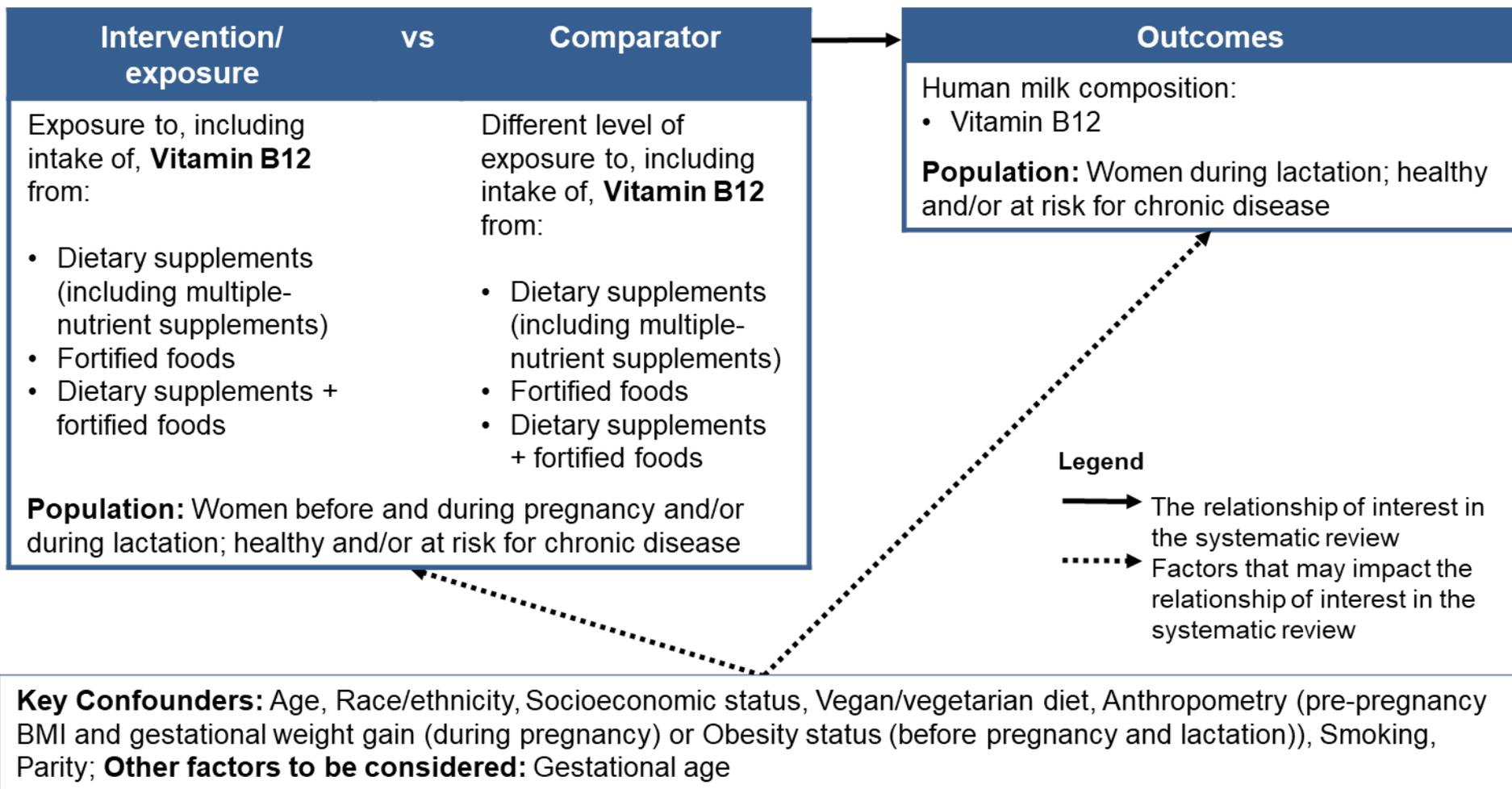
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Vegan/vegetarian diet, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy)), Diagnosis of gestational diabetes, Smoking, History/diagnosis of hypertension or CVD, Parity; **Other factors to be considered:** Physical activity, substance use (alcohol, drug use), gestational age

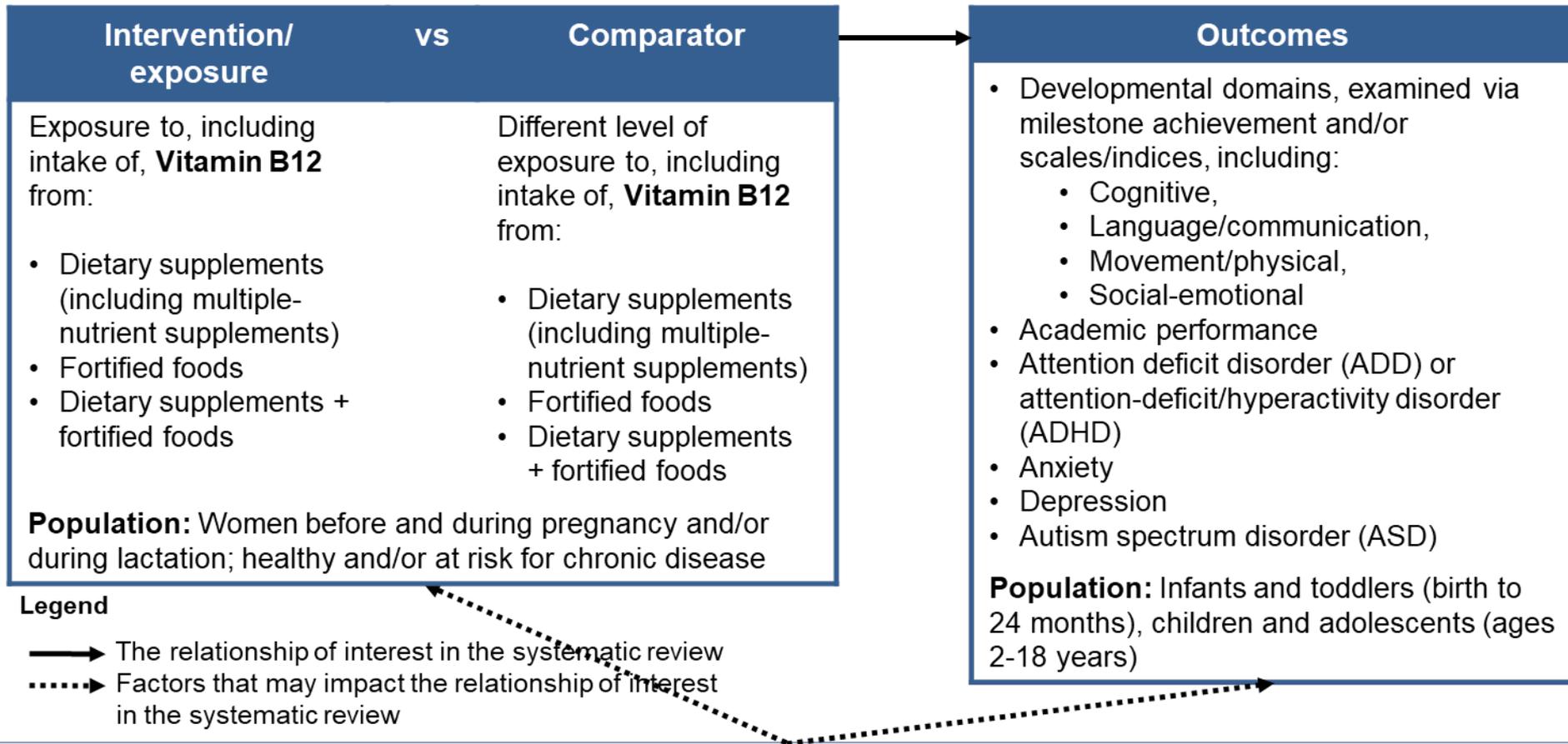
What is the relationship between **vitamin B12** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **human milk composition**?

Analytic framework:



What is the relationship between **vitamin B12** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **infant developmental milestones, including neurocognitive development**?

Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Vegan/vegetarian diet, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Smoking, Parity, Child sex, Gestational age, Breastfeeding practices (intensity, duration); **Other factors to be considered:** Maternal substance use (alcohol, drug use), Family history/diagnosis of neurocognitive disorders, complementary feeding

What is the relationship between **vitamin B12** from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes (5 outcomes)?

Inclusion/exclusion criteria:

- Standard criteria be used for:
 - Publication Status
 - Language of Publication
 - Country
- Criteria used for the supplements and fortified foods reviews:
 - Study design
 - Date of publication (January 1980-TBD)
 - Study participants
 - Health status of study participants

What is the relationship between **vitamin B12** from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes (5 outcomes)?

Inclusion/exclusion criteria:

Category	Inclusion Criteria	Exclusion Criteria
Study Design	<ul style="list-style-type: none"> • Randomized controlled trials • Non-randomized controlled trials including quasi-experimental and controlled before-and-after studies • Prospective cohort studies • Retrospective cohort studies • Nested case-control studies • Cross-sectional studies (for human milk composition only) 	<ul style="list-style-type: none"> • Uncontrolled trials • Case-control studies • Cross-sectional studies (for outcomes: micronutrient status, gestational diabetes, hypertensive disorders, developmental milestones, including neurocognitive health) • Narrative reviews • Systematic reviews • Meta-analyses • Uncontrolled before-and-after studies
Date of publication	<ul style="list-style-type: none"> • January 1980 – TBD 	<ul style="list-style-type: none"> • Articles published prior to January 1980

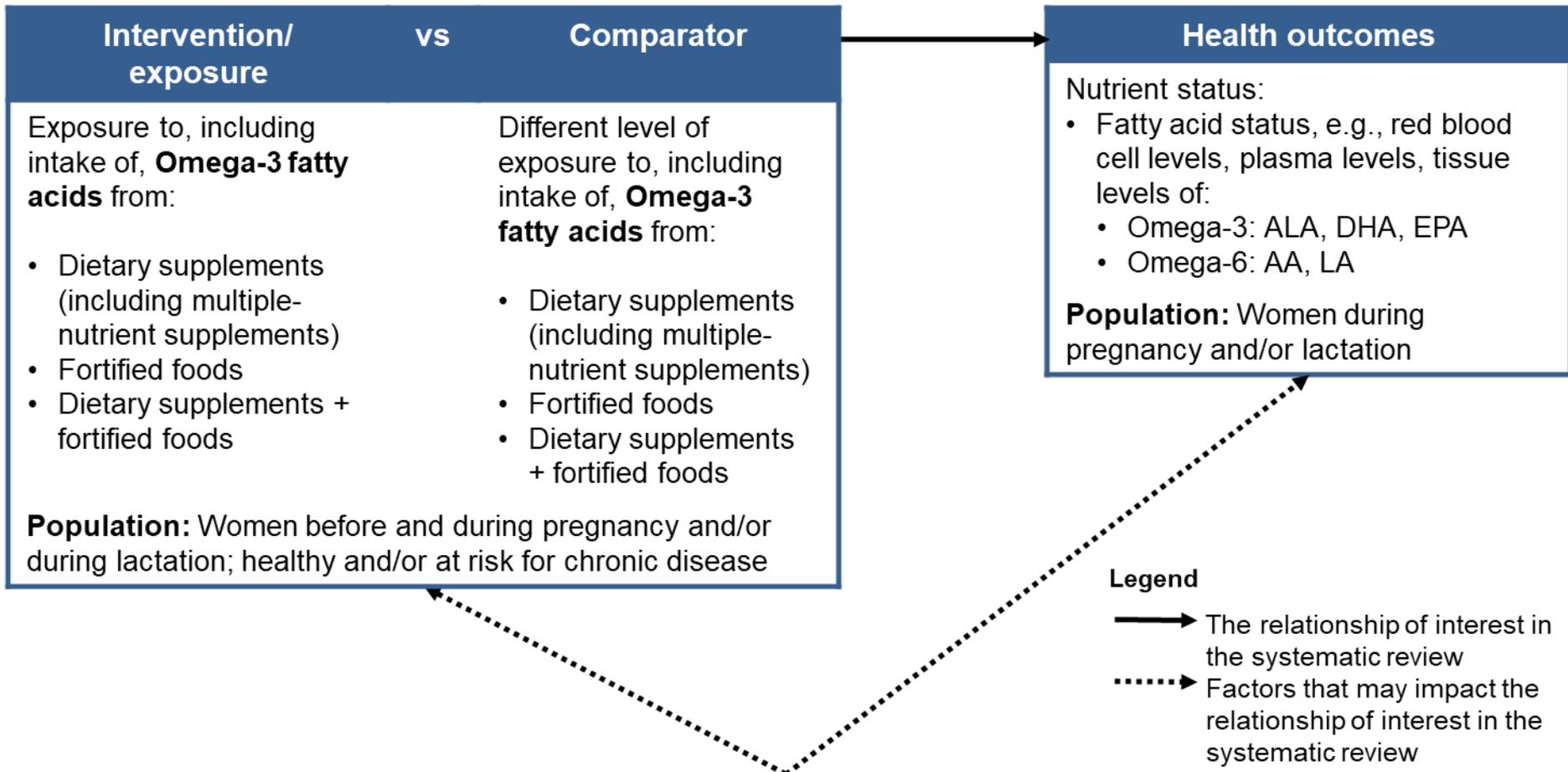
Supplements & Fortified foods: Question

What is the relationship between omega-3 fatty acids from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes (5 outcomes)?

Approach to Answer Question: NESR Systematic Review

What is the relationship between **omega-3 fatty acids** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **micronutrient status**?

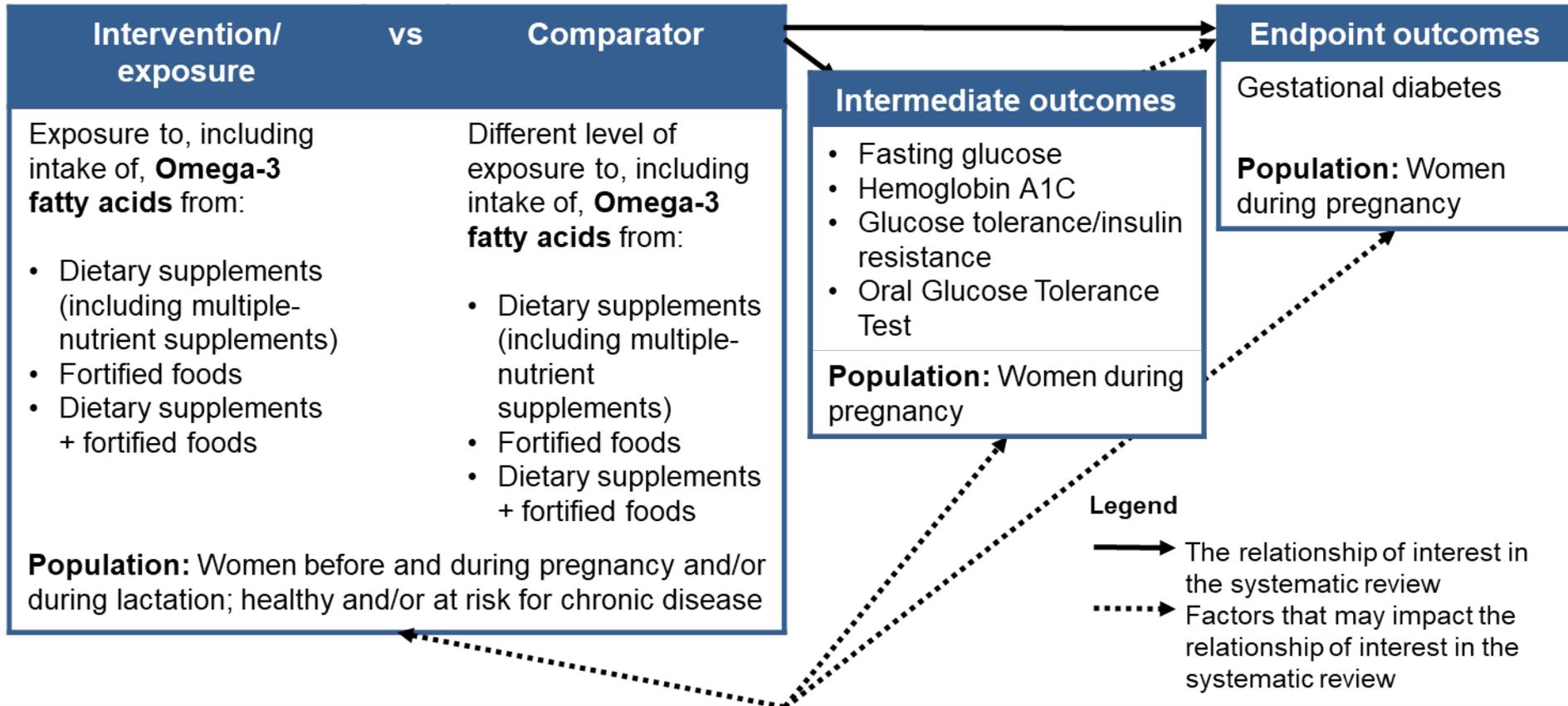
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Fish and other seafood consumption, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Smoking, Parity; **Other factors to be considered:** Substance use (alcohol, drug use), gestational age

What is the relationship between **omega-3 fatty acids** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **risk of gestational diabetes**?

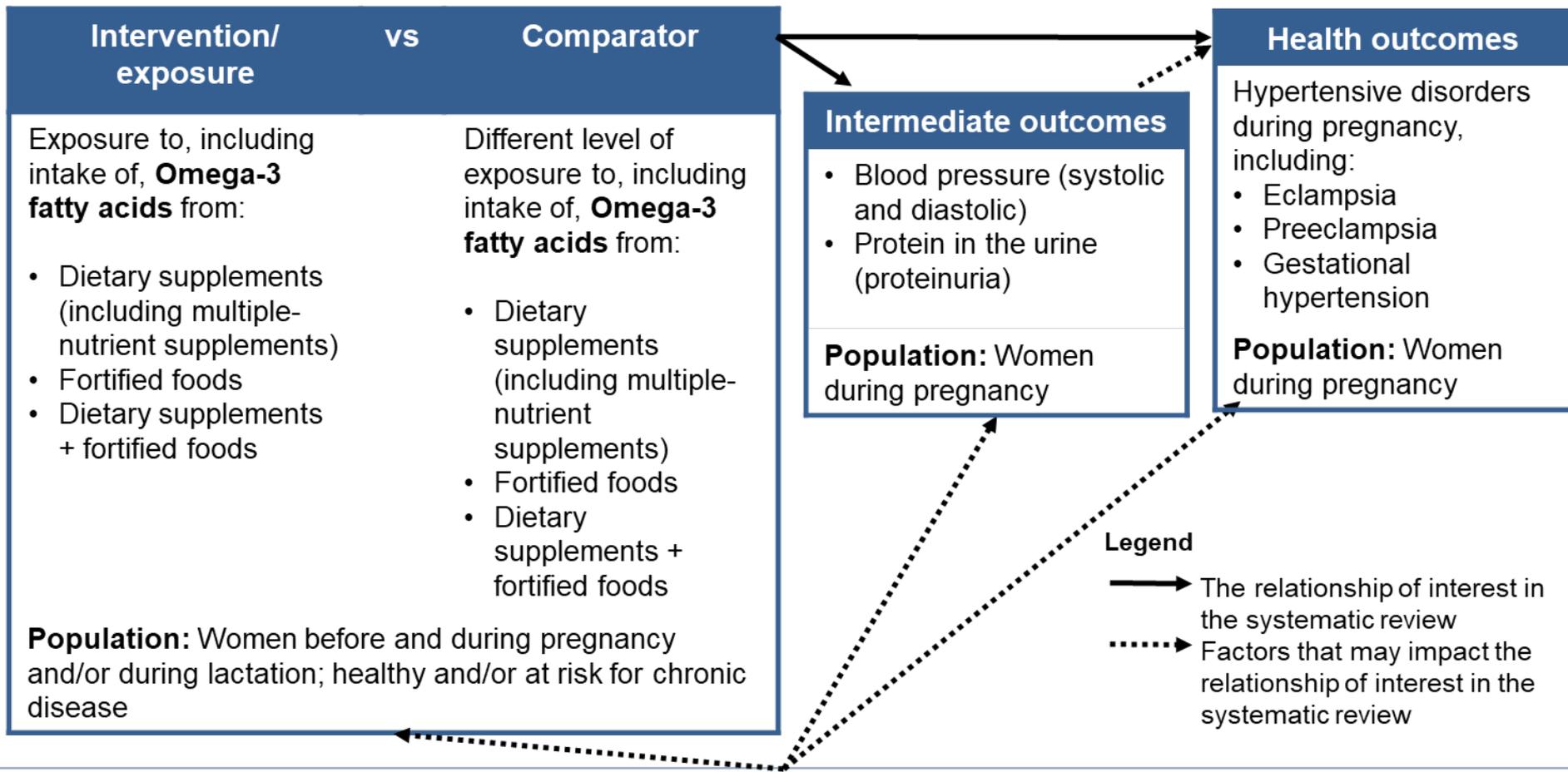
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Fish and other seafood consumption, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy)), Smoking, Family history of diabetes or pre-diabetes, Parity; **Other factors to be considered:** Physical activity, substance use (alcohol, drug use), large infant prior (Large for Gestational Age), enrolled in intervention/prevention trial, gestational age

What is the relationship between **omega-3 fatty acids** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **risk of hypertensive disorders during pregnancy**?

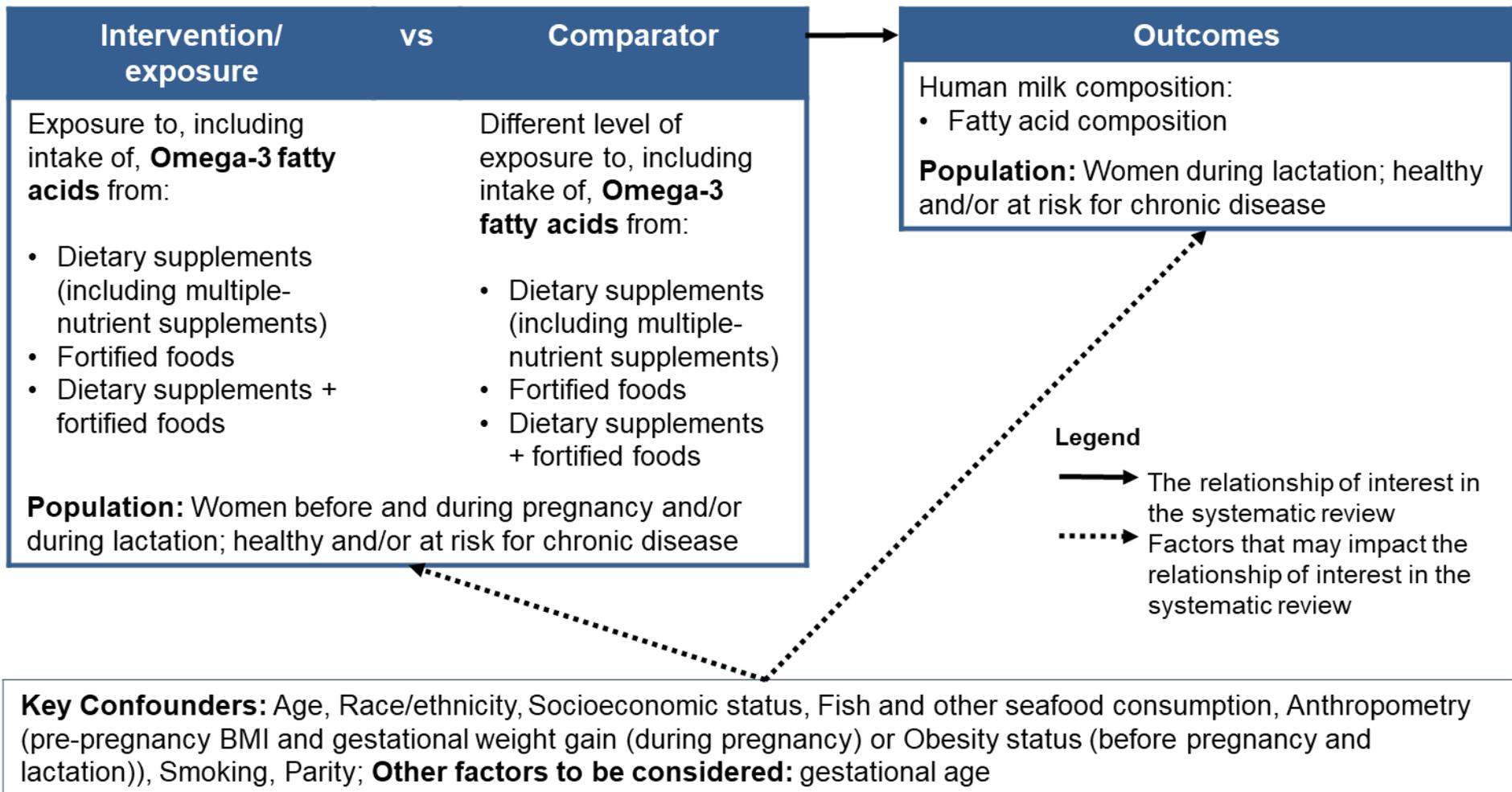
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Fish and other seafood consumption, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy)), Smoking, Diagnosis of gestational diabetes, Parity; **Other factors to be considered:** Physical activity, substance use (alcohol, drug use), gestational age

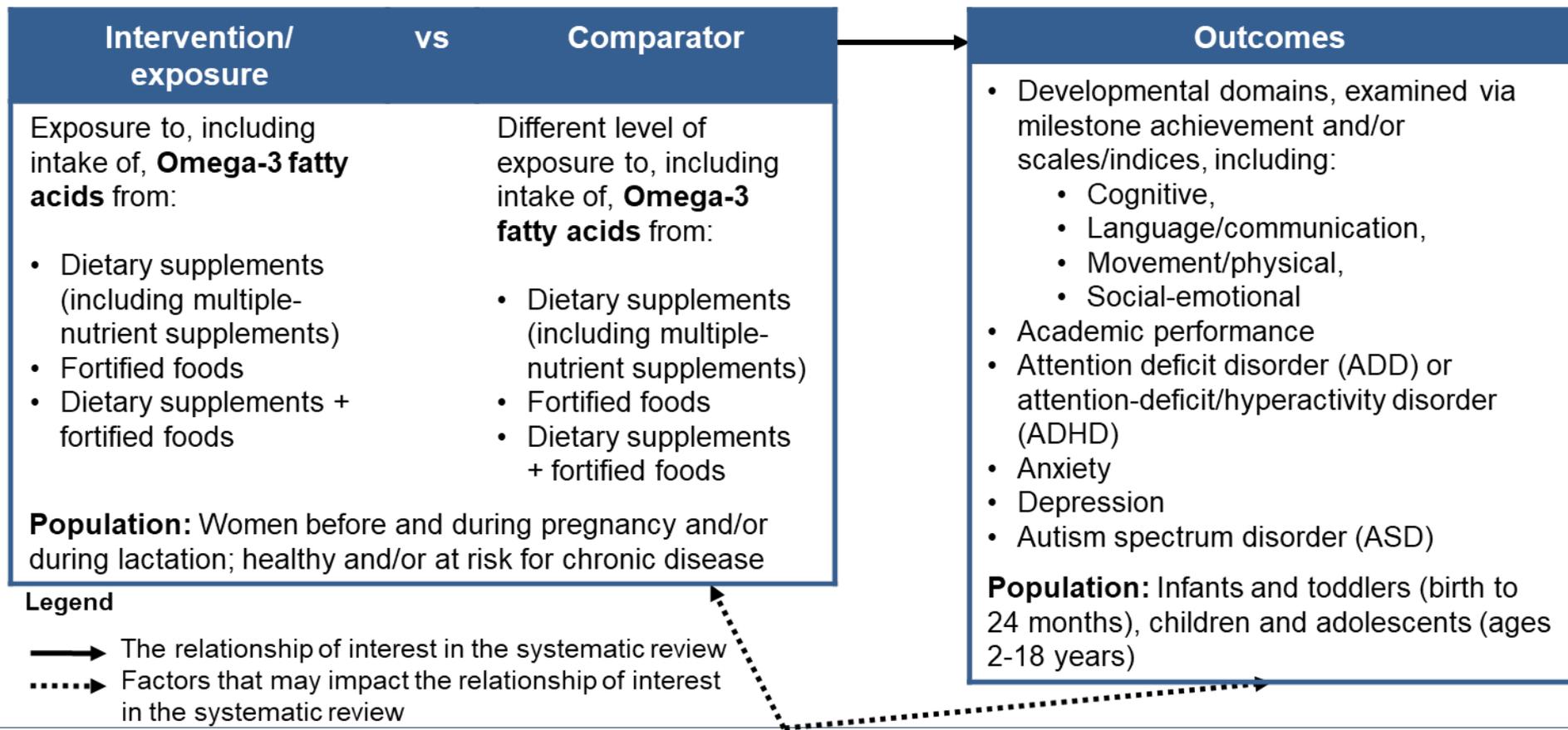
What is the relationship between **omega-3 fatty acids** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **human milk composition**?

Analytic framework:



What is the relationship between **omega-3 fatty acids** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **infant developmental milestones, including neurocognitive development**?

Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Fish and other seafood consumption, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Smoking, Parity, Child sex, Gestational age, Breastfeeding practices (intensity, duration); **Other factors to be considered:** Maternal substance use (alcohol, drug use), Family history/diagnosis of neurocognitive disorders, complementary feeding

What is the relationship between **omega-3 fatty acids** from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes (5 outcomes)?

Inclusion/exclusion criteria:

- Standard criteria used for:
 - Publication Status
 - Language of Publication
 - Country
- Criteria used for the supplements and fortified foods reviews:
 - Study design
 - Date of publication (January 1980-TBD)
 - Study participants
 - Health status of study participants

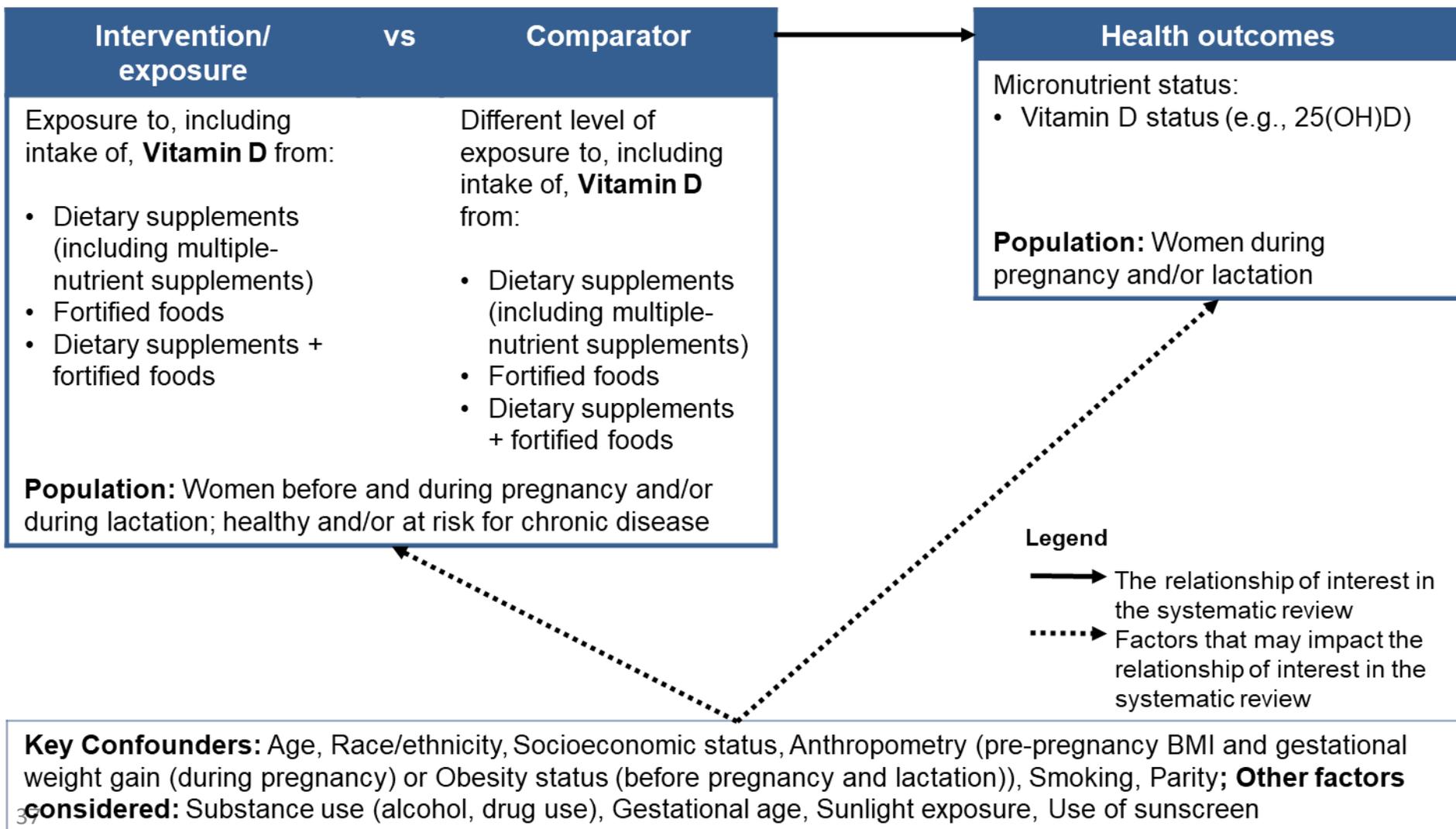
Supplements & Fortified foods: Question

What is the relationship between vitamin D from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes (5 outcomes)?

Approach to Answer Question: NESR Systematic Review

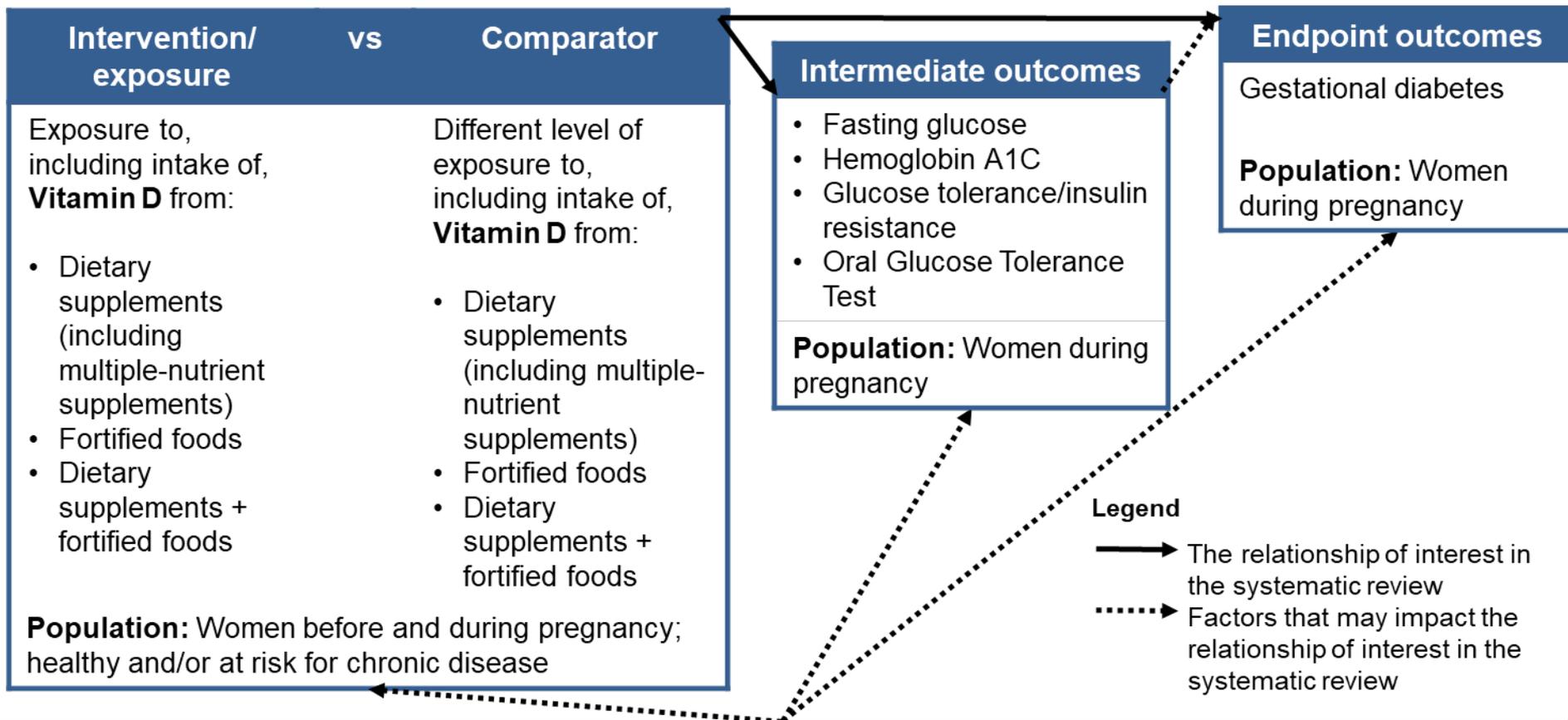
What is the relationship between **vitamin D** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **micronutrient status**?

Analytic framework:



What is the relationship between **vitamin D** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **risk of gestational diabetes**?

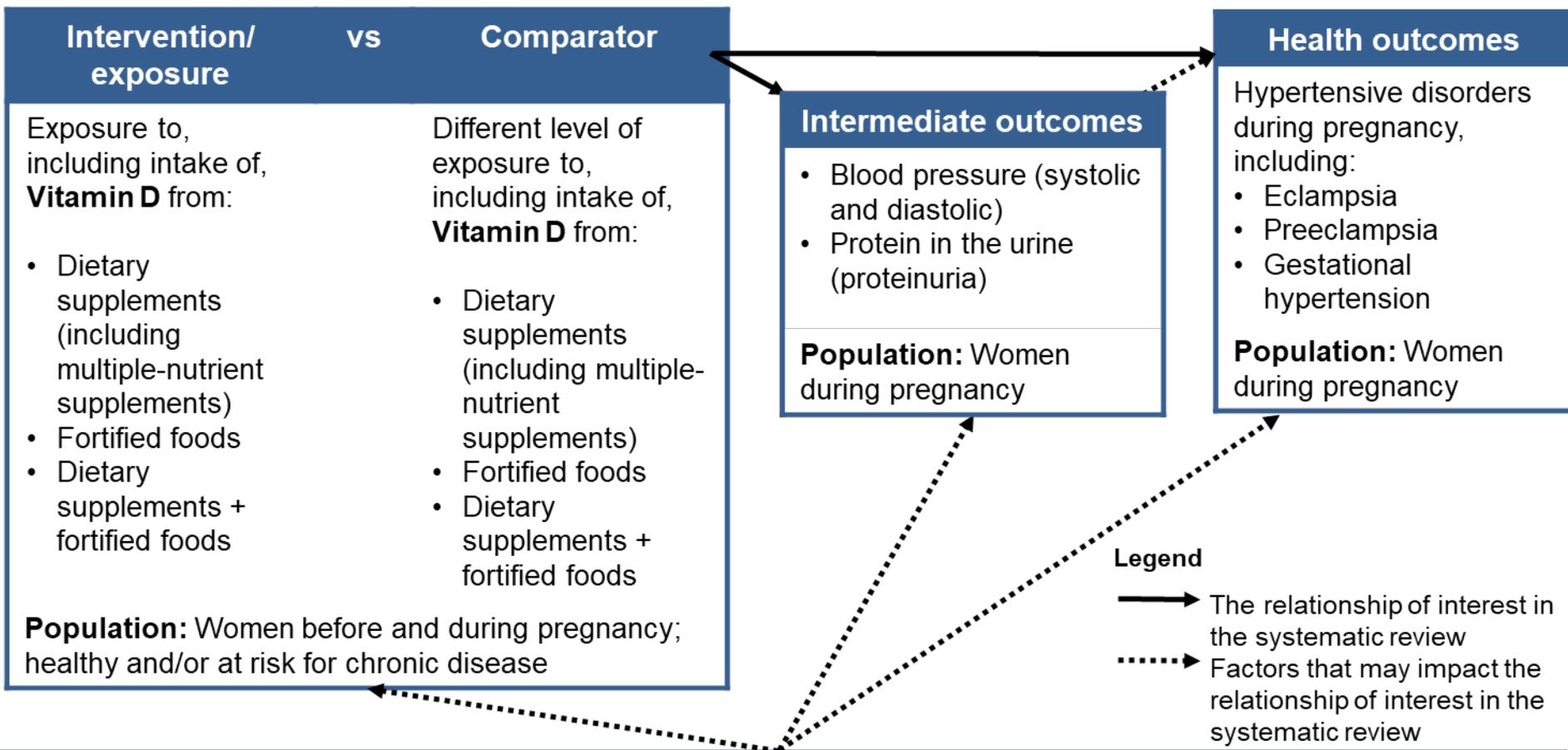
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy)), Smoking, Family history of diabetes or pre-diabetes, Parity; **Other factors considered:** Physical activity, Substance use (alcohol, drug use), Large infant prior (Large for Gestational Age), Enrolled in intervention/prevention trial, gestational age, Sunlight exposure, Use of sunscreen

What is the relationship between **vitamin D** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **risk of hypertensive disorders**?

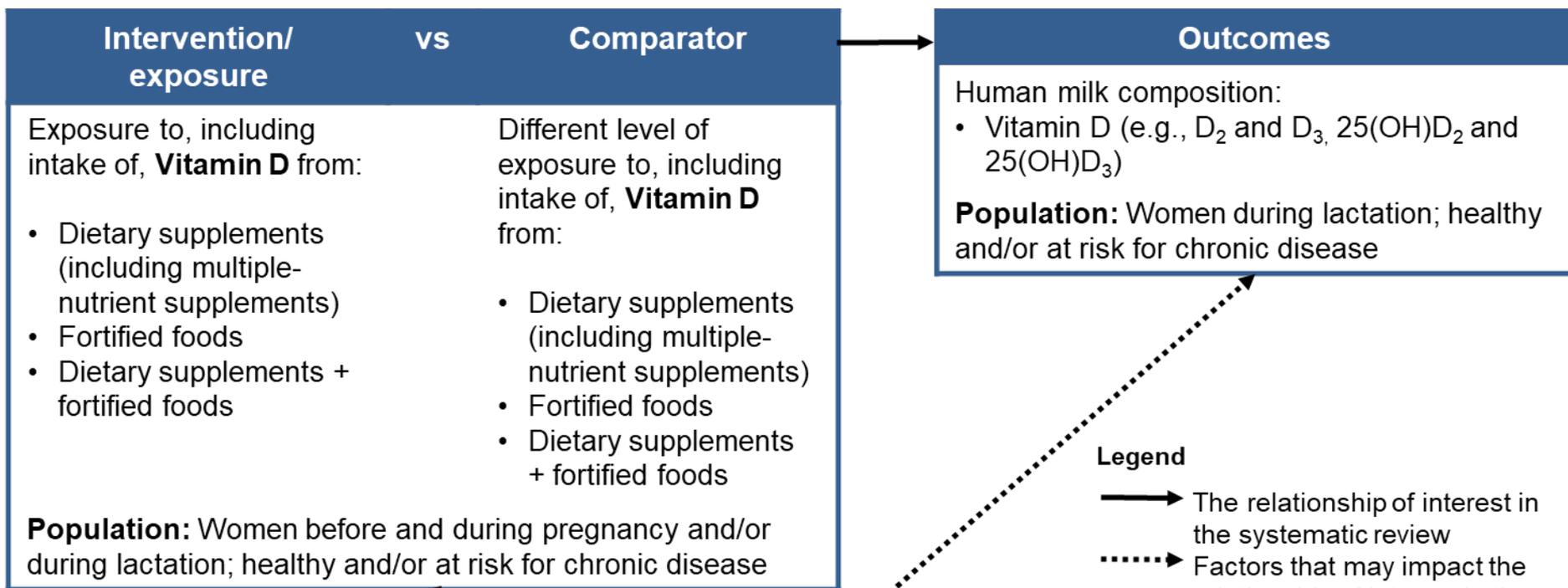
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy)), Diagnosis of gestational diabetes, Smoking, History/diagnosis of hypertension or CVD (for all nutrients), Parity; **Other factors considered:** Physical activity, Substance use (alcohol, drug use), Gestational age, Sunlight exposure, Use of sunscreen

What is the relationship between **vitamin D** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **human milk composition**?

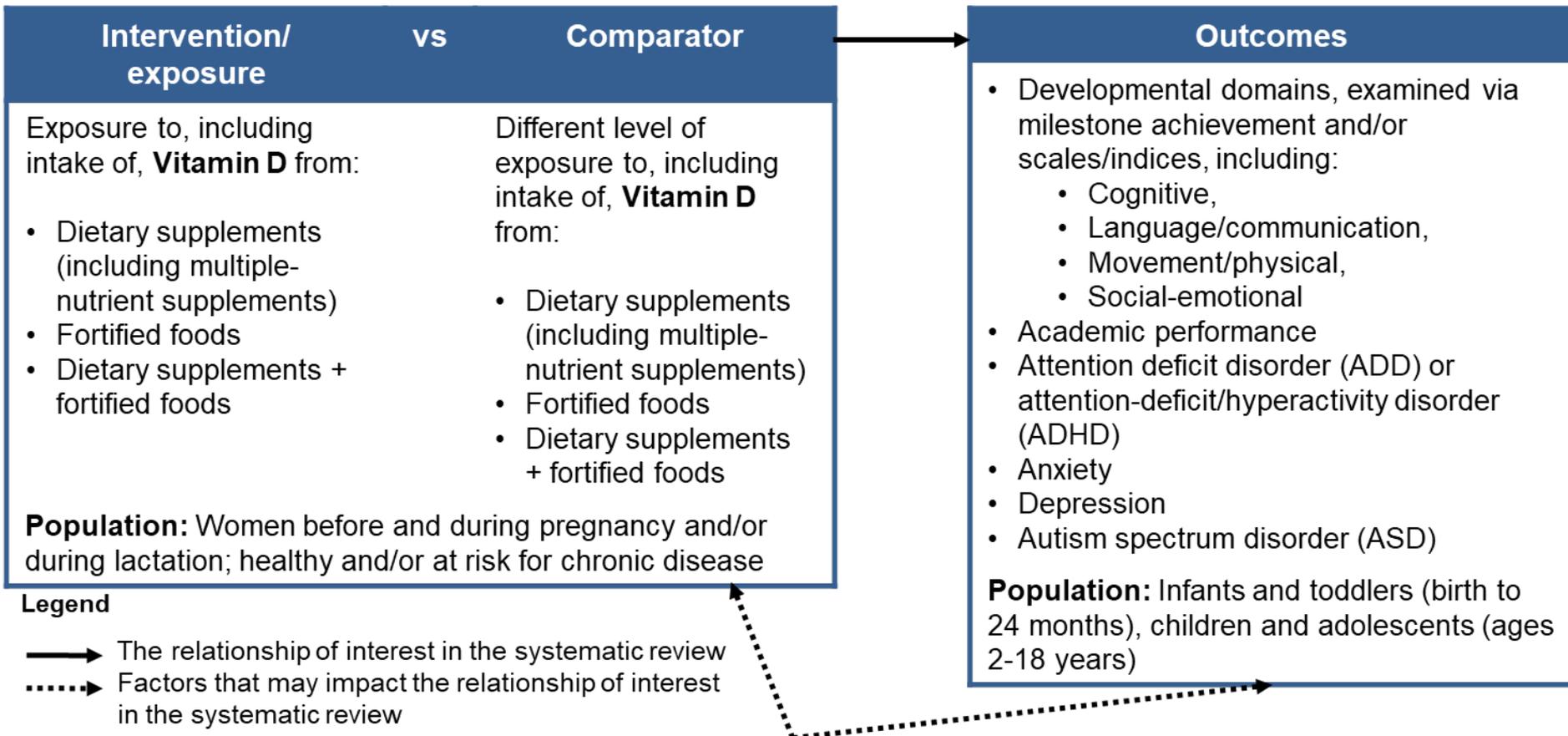
Analytic framework:



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Smoking, Parity; **Other factors to be considered:** Gestational age, Sunlight exposure, Use of sunscreen

What is the relationship between **vitamin D** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **infant developmental milestones, including neurocognitive development**?

Analytic framework:



What is the relationship between **vitamin D** from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes (5 outcomes)?

Inclusion/exclusion criteria:

- Standard criteria used for:
 - Publication Status
 - Language of Publication
 - Country
- Criteria used for other Supplements and Fortified Foods reviews:
 - Study design
 - Date of publication (January 1980-TBD)
 - Study participants
 - Health status of study participants

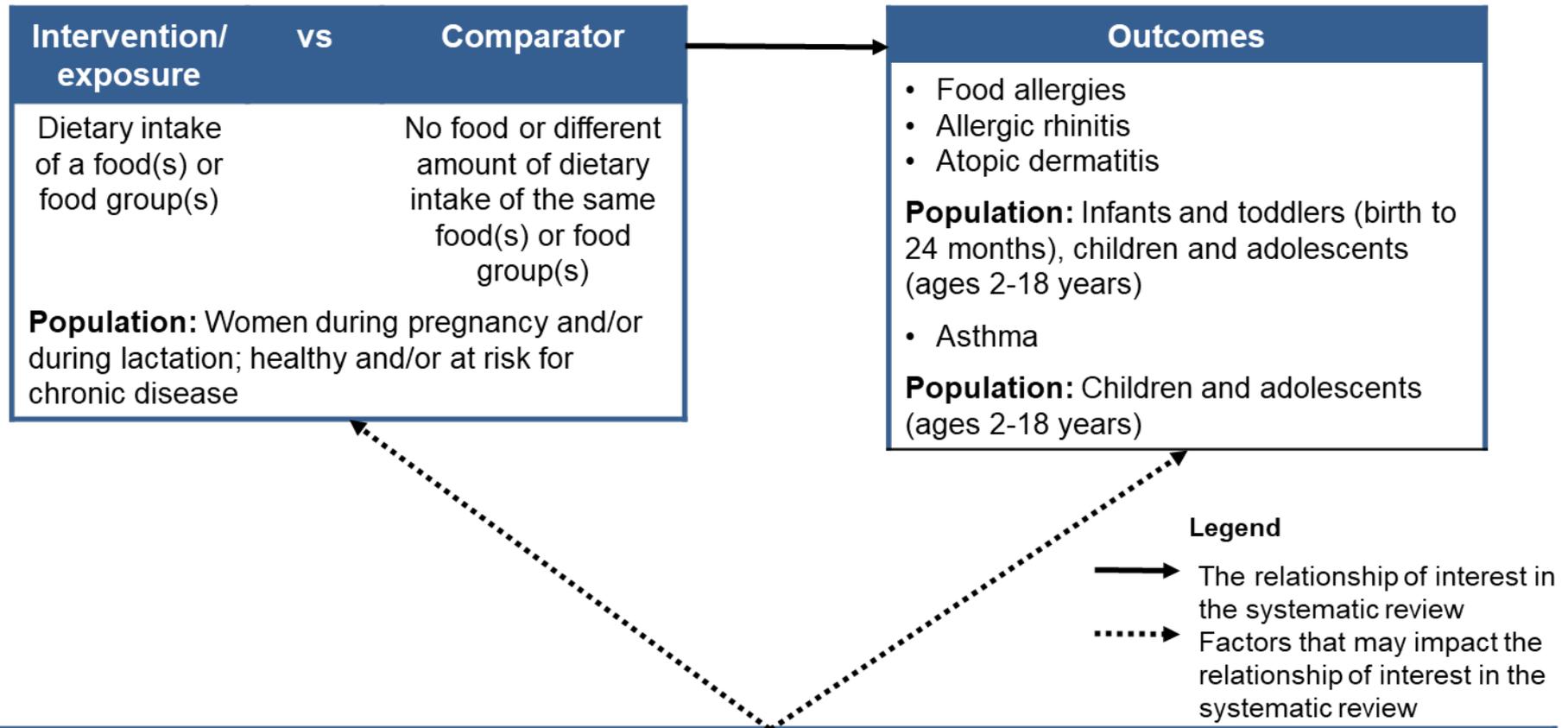
Developing the plan: new protocols for maternal diet question

What is the relationship between **maternal diet** during pregnancy and lactation and **risk of infant and child food allergies and atopic allergic diseases?** (1 outcome)

Approach to Answer Question: NESR Systematic Review

What is the relationship between **maternal diet** consumed during pregnancy and lactation and **risk of infant and child food allergies** and **atopic allergic diseases**?

Analytic framework:



Key Confounders: Maternal age, Race/ethnicity, Socioeconomic status, Smoking, Family history of atopic allergic diseases, Gestational age at birth, Birth weight, Mode of delivery, Breastfeeding practices (intensity, duration), Timing of introduction of complementary foods and beverages (CFB), Types of CFB, Urban/rural environment, Animals/pets/farming exposure; **Other factors to be considered:** Sex, Maternal substance use (alcohol, drug use), Indoor and outdoor environment

What is the relationship between **maternal diet** consumed during pregnancy and lactation and **risk of infant and child food allergies** and **atopic allergic diseases**?

Inclusion/exclusion criteria:

- Standard criteria used for:
 - Publication Status
 - Language of Publication
 - Country
- Criteria used for review:
 - Study Design
 - Date of publication (January 1980-TBD)

Implementing the plan: 2 Questions

What is the relationship between **folic acid** from supplements and/or fortified foods consumed before and during pregnancy and lactation and:

- **human milk composition?**
- **risk of gestational diabetes?**

Approach to Answer Question: NESR Systematic Review

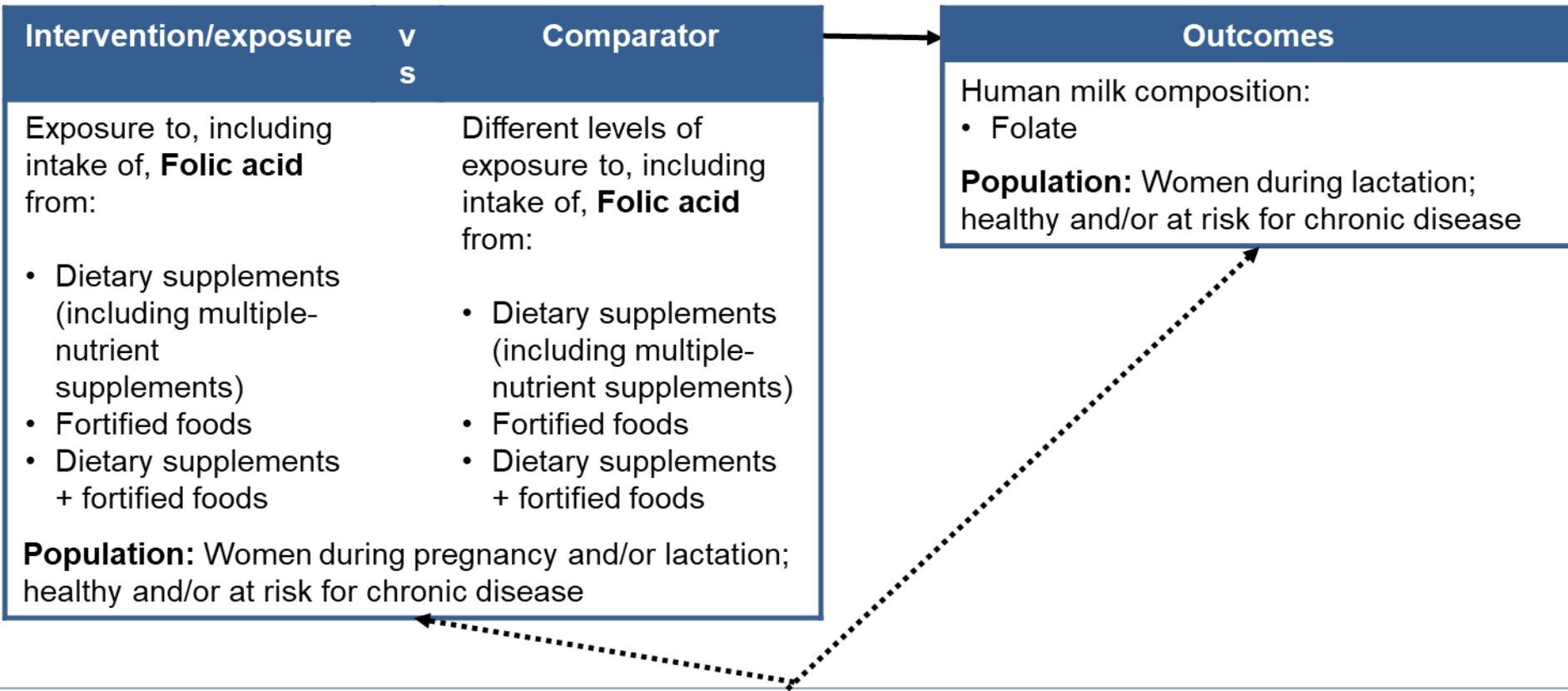
Implementing the plan: Question

What is the relationship between **folic acid** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **human milk composition**?

Approach to Answer Question: NESR Systematic Review

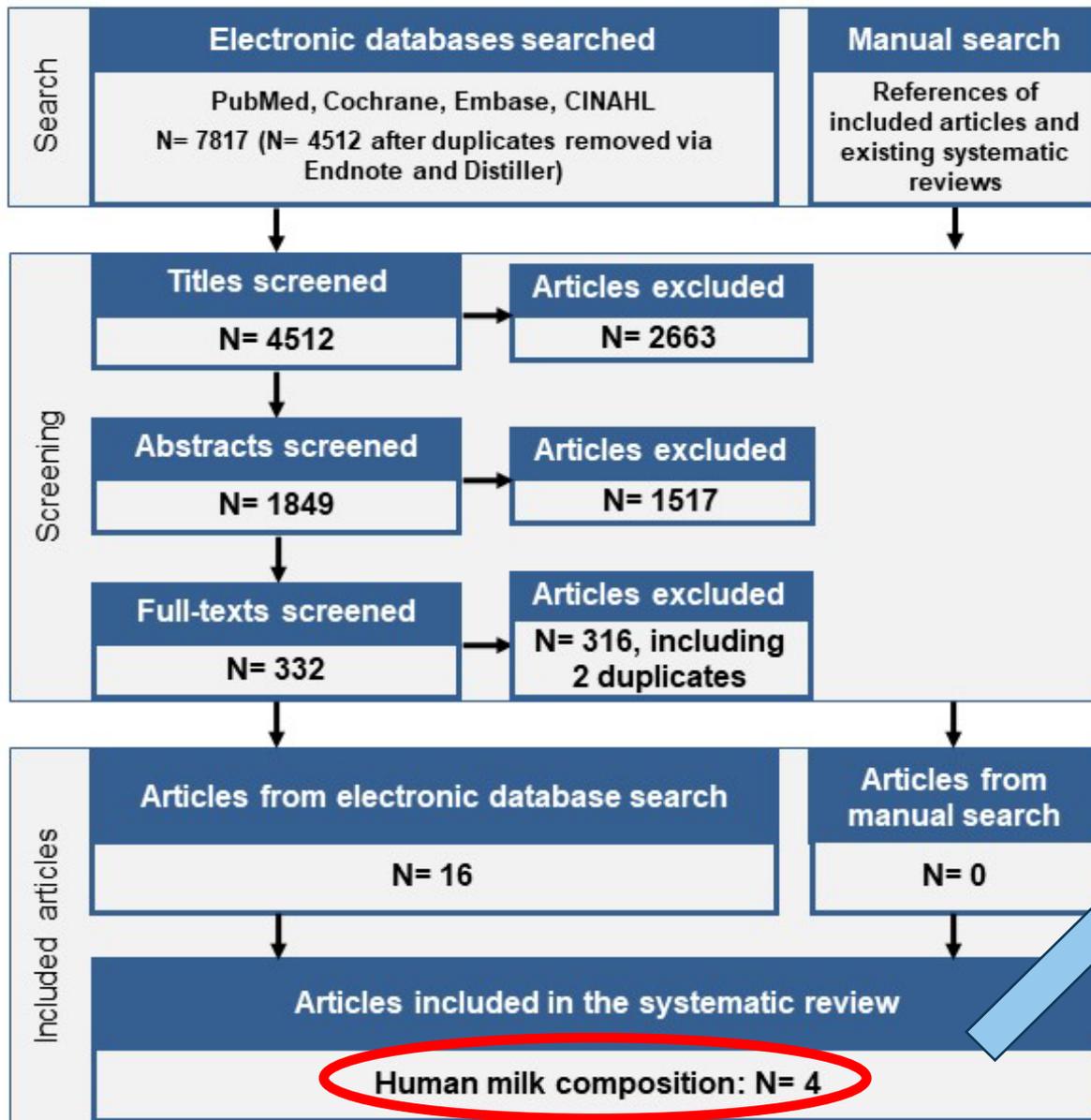
Analytic Framework

Systematic review question: What is the relationship between **folic acid** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **human milk composition**?



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Smoking, Parity; **Other factors to be considered:** Gestational age

Literature Search and Screening Results



4 Included articles:

- 3 RCTs
- 1 Uncontrolled before-and-after study

All 4 studies addressed the question - what is the relationship between **follic acid** from supplements consumed during lactation and **human milk folate**?

Description of the Evidence: 3 RCTs

- **Sample characteristics**

- n=14-23/group (n= 29-66/study)
- US, Canada
- ~33y, mostly white, high SES (2 studies)
- Adolescents (~17y), mostly white, low SES (1 study)

- **Interventions varied by**

- Dose: 300 µg/d, 400 µg/d, 1.0 mg/d FA; 400 µg/d 5-MTHF
- Initiation: within 1 wk postpartum or 3 mo postpartum
- Duration: 12 wk or 16 wk

- **Outcomes: all reported human milk folate**

- Other outcomes: unmetabolized milk folic acid, soluble milk folate binding protein (1 study)

Folic acid and human milk

2020 Dietary Guidelines Advisory Committee: Meeting 3

Description of the Evidence: 1 uncontrolled before-and-after study

- **Sample characteristics**

- n=16 (1 group)
- Japan
- Only participant characteristic reported: women in study from “same SES group”

- **Intervention**

- Dose: 1.0 mg/d FA
- Initiation: 3 to 25 weeks postpartum
- Duration: 4 weeks

- **Outcome: Human milk folate**

Summary of the Evidence Synthesis

- Despite some methodological variation, none of the studies found an association between folic acid supplementation in lactating women and human milk folate levels
- **Assessment of the evidence:**
 - Studies were direct and precise
 - Results were consistent
 - There were some concerns regarding risk of bias and generalization

DRAFT Conclusion Statement and Grade

- **Moderate** evidence suggests that consumption of folic acid supplements during lactation, among women in high or very high HDI countries, does not influence folate levels in human milk.
- No evidence is available to draw a conclusion about the relationship between folic acid from supplements consumed before and/or during pregnancy and human milk folate. (**Grade not assignable**)
- No evidence is available to draw a conclusion about the relationship between folic acid from fortified foods consumed before and/or during pregnancy and lactation and human milk folate. (**Grade not assignable**)

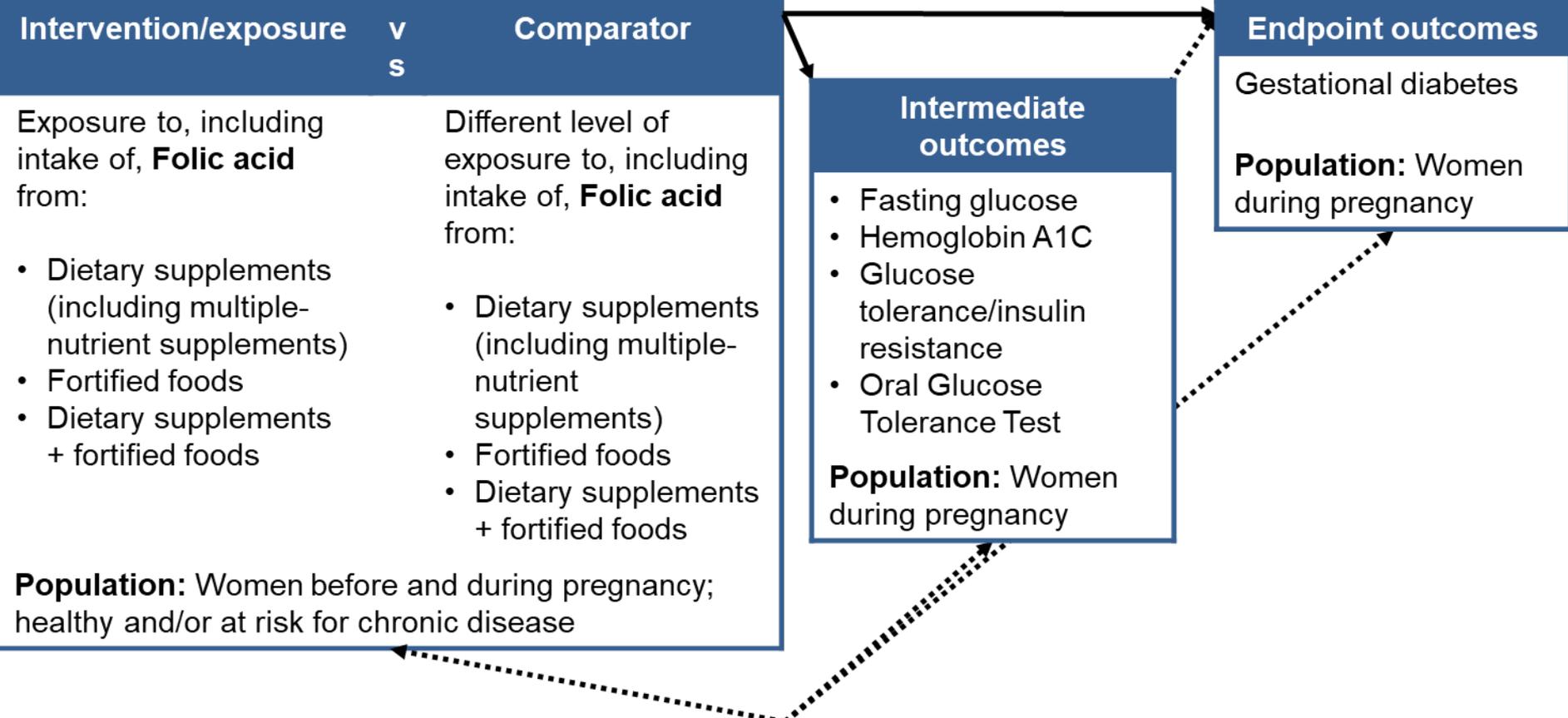
Implementing the plan: Question

What is the relationship between **folic acid** from supplements and/or fortified foods consumed before and during pregnancy and lactation and **gestational diabetes**?

Approach to Answer Question: NESR Systematic Review

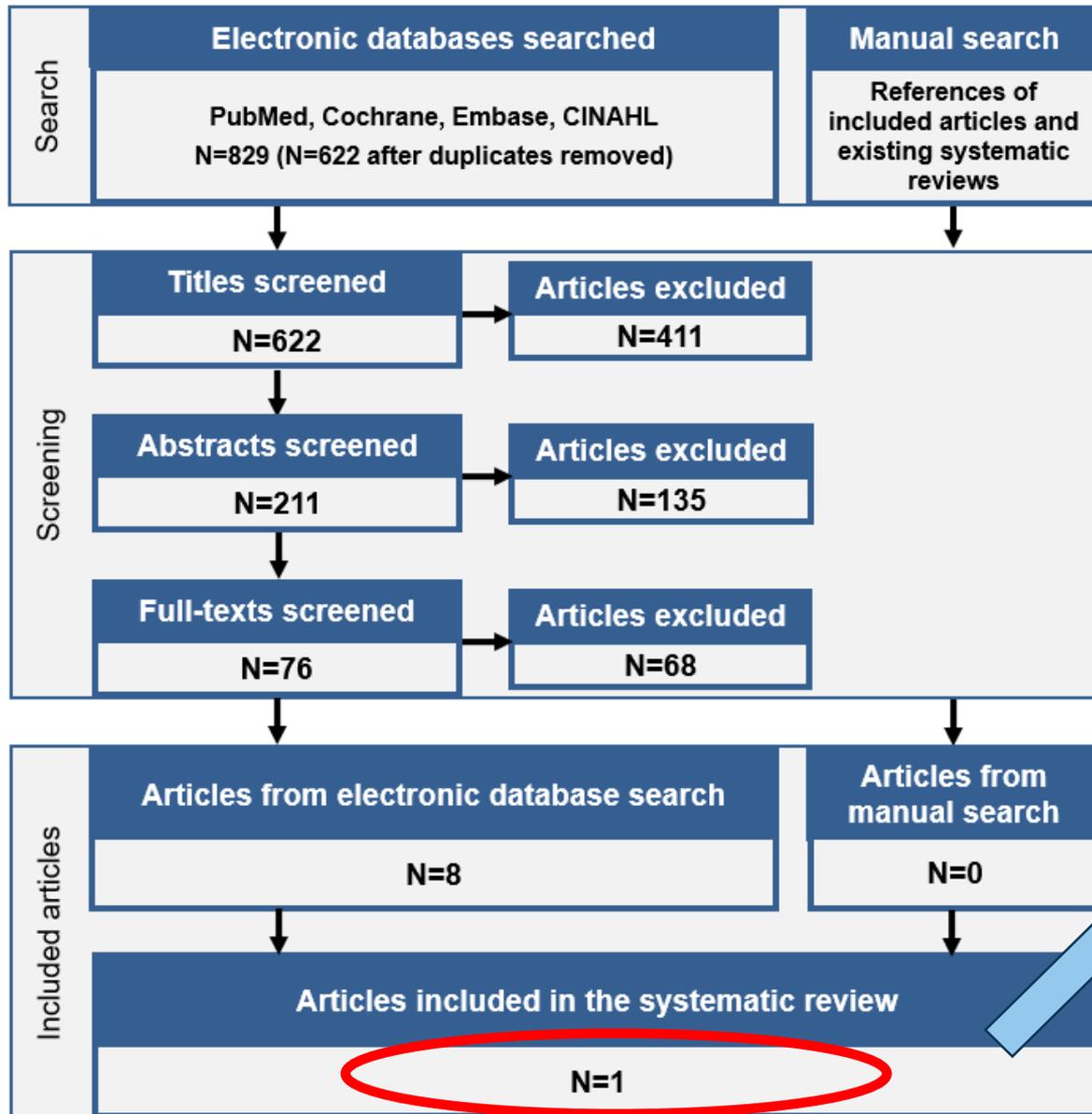
Analytic Framework

Systematic review question: What is the relationship between **folic acid** from supplements and/or fortified foods consumed before and during pregnancy and **risk of gestational diabetes**?



Key Confounders: Age, Race/ethnicity, Socioeconomic status, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy)), Smoking, Family history of diabetes or pre-diabetes, Parity; **Other factors to be considered:** Physical activity, substance use (alcohol, drug use), large infant prior (Large for Gestational Age), enrolled in intervention/prevention trial, gestational age

Literature Search and Screening Results



1 Included article:

- 1 Non-randomized controlled trial

This study addressed the question - what is the relationship between **folic acid** from supplements consumed during pregnancy and risk of gestational diabetes?

Description of the Evidence:

1 Non-randomized controlled trial

- **Sample characteristics**

- n=7,812
- China
- ~20-40y, non-smokers, non-drinkers

- **Intervention**

- Dose: 0, 400, or 800 $\mu\text{g}/\text{d}$ FA suggested based on
 - MTHFR & MTRR polymorphisms
 - Stage of pregnancy
- Initiation: not clear
- Duration: through delivery

- **Outcome: Gestational diabetes**

Folic acid and gestational diabetes

2020 Dietary Guidelines Advisory Committee: *Meeting 3*

Summary of the Evidence Synthesis

- Among women who consumed folic acid supplementation based on genotype and stage of pregnancy, there was a **significantly lower incidence of gestational diabetes** compared to women who did not consume folic acid supplements before or during pregnancy
 - Control vs Intervention: 3.24% vs 0.27%, $P < 0.05$
- **Assessment of the evidence:**
 - There were concerns regarding risk of bias
 - There was insufficient evidence to evaluate directness, precision, consistency, and generalizability of results

DRAFT Conclusion Statement and Grade

- Insufficient evidence is available to draw a conclusion about the relationship between folic acid from supplements and/or fortified foods consumed before and/or during pregnancy and the risk of gestational diabetes. (Grade not assignable)

Cross-cutting discussions with other SCs

PL SC has interactions with other SCs to discuss areas of overlap.

- **Dietary Patterns**

- Joint meetings to discuss dietary pattern definition

- **Fats and Seafoods**

- Joint meetings to discuss “the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant?”

- **Food Pattern Modeling & Data Analysis**

- Joint meeting with B24 and PL to discuss data sources

- **Beverages and Added Sugars**

- Provided input on Analytical Frameworks pertinent to PL

2020 Dietary Guidelines Advisory Committee: Pregnancy and Lactation Subcommittee

Subcommittee members:

Sharon Donovan (SC chair)

Kathryn Dewey

Rachel Novotny

Jamie Stang

Elsie Taveras

Ron Kleinman (Chair rep)

Support staff:

Jean Altman

Janet de Jesus (DFO Rep)

Jenna Fahle (Detail)

Julia Kim

Julie Nevins

Julie Obbagy

Kripa Raghavan

Sara Scinto-Madonich

Maureen Spill

Nancy Terry



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