2020 Dietary Guidelines Advisory Committee:
Pregnancy and Lactation Subcommittee

Subcommittee Chair: Sharon Donovan
  Kathryn Dewey
  Rachel Novotny
  Jamie Stang
  Elsie Taveras

Vice Chair Rep: Ron Kleinman

DietaryGuidelines.gov
3 Topic Areas: (1) Dietary Patterns during pregnancy and lactation

New reviews

• Gestational weight gain*
• Postpartum weight loss*
• Human milk composition and quantity
• Developmental milestones
• Micronutrient status

Reviews from P/B-24

• Gestational diabetes
• Hypertensive disorders during pregnancy
• Gestational age at birth
• Birth weight

*Protocols to be discussed today; available at DietaryGuidelines.gov
### 3 Topic Areas:
1. Dietary Supplements and Fortified Foods
2. Maternal diet and food allergies and atopic allergic diseases

#### Nutrients from Dietary Supplements and Fortified Foods
- **Folic acid (5 outcomes)** *
- **Iron (4 outcomes)** *
- Vitamin B12
- Omega-3 fatty acids
- Vitamin D
- Iodine

#### Health Outcomes
- Micronutrient status
- Risk of gestational diabetes
- Risk of hypertensive disorders during pregnancy
- Human milk composition
- Developmental milestones

*Protocols to be discussed today; available at DietaryGuidelines.gov"
(1) Dietary patterns during pregnancy and lactation

What is the relationship between dietary patterns consumed during...

1. pregnancy and gestational weight gain?
2. lactation and postpartum weight loss?

Approach to Answer Questions: NESR Systematic Review
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.
Analytic Framework: What is the relationship between dietary patterns consumed during pregnancy and gestational weight gain?

<table>
<thead>
<tr>
<th>Intervention/exposure</th>
<th>Comparator</th>
</tr>
</thead>
</table>
| Consumption of and/or adherence to a dietary pattern. | • Consumption of and/or adherence to a different dietary pattern  
• Different levels of consumption of and/or adherence to a dietary pattern |

**Population:** Women during pregnancy; healthy and/or at risk for chronic disease

**Legend**

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

**Outcomes**

- Gestational weight gain: Change in maternal body weight from baseline (before or during pregnancy) to a later time point during pregnancy and/or right before delivery
- Weight gain in relationship to weight gain recommendations, based on pre-pregnancy BMI

**Population:** Women during pregnancy; healthy and/or at risk for chronic disease

**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Physical activity, Smoking, Parity, Anthropometry (Pre-pregnancy BMI), History/diagnosis of gestational diabetes and gestational hypertension
Analytic Framework: What is the relationship between dietary patterns consumed during lactation and postpartum weight loss?

**Intervention/exposure vs Comparator**

- Consumption of and/or adherence to a dietary pattern.
- Consumption of and/or adherence to a different dietary pattern.
- Different levels of adherence to a dietary pattern.

**Population:** Women during lactation; healthy and/or at risk for chronic disease.

**Endpoint outcomes**

- Change in weight from baseline (postpartum) to a later time point during the postpartum period.
- Postpartum weight retention if gestational weight gain is controlled for.

**Population:** Women during lactation; healthy and/or at risk for chronic disease.

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**Legend**

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

**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Physical activity, Parity, Smoking, Anthropometry (Pre-pregnancy BMI and Gestational weight gain), Breastfeeding.
Inclusion and Exclusion Criteria: Dietary patterns during pregnancy and lactation

- Standard NESR criteria:
  - Study Design
  - Publication Status
  - Language of Publication
  - Country

- Other criteria consistent with Dietary Patterns SC:
  - Date of publication (January 2000)
  - Intervention/exposure
  - Comparator
### Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Category</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
</table>
| **Study participants** | • Women during pregnancy  
                        | • Women during lactation (postpartum weight loss only)                              | • Animal and *in vitro* models  
                        |                                                                                      | • Pregnancies conceived ONLY using Assisted Reproductive Technologies  
                        |                                                                                      | • Studies that exclusively enroll multiple gestation pregnancies  
                        |                                                                                      | • Studies that ONLY report combined data for singleton and multiple gestation pregnancies  
                        |                                                                                      | • Studies that enroll lactating and non-lactating mothers and ONLY present combined data for lactating and non-lactating mothers (only for postpartum weight loss) |
| **Temporality**   | • Studies that assess exposure prior to outcome                                     | • Studies that assess outcome prior to exposure                                      |
## Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Category</th>
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</thead>
<tbody>
<tr>
<td>Health status of study participants</td>
<td>• Studies that enroll mothers who are healthy and/or at risk for chronic disease</td>
<td>• Studies that exclusively enroll mothers who gave birth to preterm (&lt;37 weeks)</td>
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<td>• Studies that enroll some mothers diagnosed with a disease</td>
<td>• Studies that exclusively enroll mothers diagnosed with a disease, including severe undernutrition or hospitalized with an illness or injury</td>
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<td>• <strong>Studies that enroll some or all mothers classified as underweight or obese prior to pregnancy</strong></td>
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<td></td>
<td>• Studies that enroll <strong>some</strong> mothers who were severely undernourished prior to pregnancy</td>
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</table>
Questions

What is the relationship between nutrients from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes?

Approach to Answer Question: NESR Systematic Review
• **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)
Key Definitions

- **Fortification**: As defined by the 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.
What is the relationship between folic acid 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
Analytic Framework: What is the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and lactation and micronutrient status?

<table>
<thead>
<tr>
<th>Intervention/exposure</th>
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<th>Comparator</th>
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<tbody>
<tr>
<td>Exposure to, including intake of, <strong>Folic acid</strong> from:</td>
<td></td>
<td></td>
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<tr>
<td>• Dietary supplements (including multiple-nutrient supplements)</td>
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<tr>
<td>• Fortified foods</td>
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<tr>
<td>• Dietary supplements + fortified foods</td>
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</tbody>
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<table>
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<tr>
<th>Health outcomes</th>
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<tbody>
<tr>
<td>Micronutrient status:</td>
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<tr>
<td>• Folate</td>
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<tr>
<td>• Vitamin B12</td>
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<tr>
<td>• Hemoglobin</td>
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<tr>
<td>• Mean Corpuscular Volume (MCV)</td>
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<tr>
<td>• Red Blood Cell Distribution Width (RDW)</td>
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</tbody>
</table>

**Population:** Women during pregnancy and/or lactation

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

**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation))
Analytic Framework: What is the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and gestational diabetes?

<table>
<thead>
<tr>
<th>Intervention/exposure</th>
<th>Comparator</th>
<th>Intermediate outcomes</th>
<th>Endpoint outcomes</th>
</tr>
</thead>
</table>
| Exposure to, including intake of, Folic acid from: | Different level of exposure to, including intake of, Folic acid from: | • Fasting glucose  
• Hemoglobin A1C  
• Glucose tolerance/insulin resistance  
• Oral Glucose Tolerance Test | Gestational diabetes  
**Population:** Women during pregnancy |
| • Dietary supplements (including multiple-nutrient supplements)  
• Fortified foods  
• Dietary supplements + fortified foods | • Dietary supplements (including multiple-nutrient supplements)  
• Fortified foods  
• Dietary supplements + fortified foods |  
**Population:** Women before and during pregnancy; healthy and/or at risk for chronic disease |

**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain during pregnancy) or Obesity status (before pregnancy)), Family history of diabetes or pre-diabetes

Pregnancy and Lactation Subcommittee  
2020 Dietary Guidelines Advisory Committee: Meeting 2
Analytic Framework: What is the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and hypertensive disorders during pregnancy?

**Intervention/exposure** vs **Comparator**

- Exposure to, including intake of, **Folic acid** from:
  - Dietary supplements (including multiple-nutrient supplements)
  - Fortified foods
  - Dietary supplements + fortified foods

- Different level of exposure to, including intake of, **Folic acid** from:
  - Dietary supplements (including multiple-nutrient supplements)
  - Fortified foods
  - Dietary supplements + fortified foods

**Population**: Women before and during pregnancy; healthy and/or at risk for chronic disease

**Intermediate outcomes**

- Blood pressure (systolic and diastolic)
- Protein in the urine (proteinuria)

**Population**: Women during pregnancy

**Health outcomes**

Hypertensive disorders during pregnancy, including:
- Eclampsia
- Preeclampsia
- Gestational hypertension

**Legend**

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

**Key Confounders**: Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy)), Diagnosis of gestational diabetes

Pregnancy and Lactation Subcommittee
2020 Dietary Guidelines Advisory Committee: Meeting 2
Analytic Framework: What is the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and lactation and human milk composition?

<table>
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<td>• Dietary supplements + fortified foods</td>
<td>• Dietary supplements + fortified foods</td>
<td></td>
</tr>
</tbody>
</table>

**Population:** Women before and during pregnancy and/or during lactation; healthy and/or at risk for chronic disease

**Outcomes:**
- Human milk composition:
  - Folate

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

**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation))

Pregnancy and Lactation Subcommittee
2020 Dietary Guidelines Advisory Committee: Meeting 2
Analytic Framework: What is the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and lactation and developmental milestones, including neurocognitive development?

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</table>

**Population:** Women before and during pregnancy and/or during lactation; healthy and/or at risk for chronic disease

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

**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 and toddlers (birth to 24 months), children and adolescents (ages 2-18 years)

**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Child sex, Gestational age, Breastfeeding
Inclusion and Exclusion Criteria: **Folic acid** from Dietary supplements and Fortified food

- Standard criteria used for:
  - Publication Status
  - Language of Publication
  - Country
# Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Category</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Design</strong></td>
<td>• Randomized controlled trials</td>
<td>• Uncontrolled trials</td>
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<tr>
<td></td>
<td>• Non-randomized controlled trials including quasi-experimental and controlled before-and-after studies</td>
<td>• Case-control studies</td>
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<tr>
<td></td>
<td>• Prospective cohort studies</td>
<td>• Cross-sectional studies (for outcomes: micronutrient status, gestational diabetes, hypertensive disorders, developmental milestones, including neurocognitive health)</td>
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<td></td>
<td>• Retrospective cohort studies</td>
<td>• Narrative reviews</td>
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<td></td>
<td>• Nested case-control studies</td>
<td>• Systematic reviews</td>
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<tr>
<td></td>
<td>• <strong>Uncontrolled before-and-after studies</strong></td>
<td>• Meta-analyses</td>
</tr>
<tr>
<td></td>
<td>• <strong>Cross-sectional studies (for human milk composition only)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Date of publication</strong></td>
<td>• January 1980 – June 2019</td>
<td>• Articles published prior to January 1980</td>
</tr>
</tbody>
</table>
# Inclusion and Exclusion Criteria

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</tr>
</thead>
<tbody>
<tr>
<td>Study participants</td>
<td>• Human participants</td>
<td>• Non-human participants (e.g., animal or in-vitro models)</td>
</tr>
<tr>
<td></td>
<td>• Studies that exclusively enroll women who became pregnant using Assisted Reproductive Technologies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Studies that exclusively enroll women with multiple gestation pregnancies</td>
<td>• Studies that exclusively enroll women who became pregnant using Assisted Reproductive Technologies</td>
</tr>
</tbody>
</table>
| Health status of study participants | • Studies that enroll participants who are healthy and/or at risk for chronic disease, **including those with obesity**  
• Studies that enroll **some** participants diagnosed with a disease or with the health outcome of interest: Gestational diabetes; Hypertensive disorders of pregnancy; Neurocognitive disorders; Studies that enroll some participants who are deficient in folate  
• Studies that enroll **some** mothers with infants who are born preterm  
• Studies that enroll mothers diagnosed with the outcome of interest that is to be examined in the infant/child | • Studies that exclusively enroll participants diagnosed with a disease, or hospitalized with an illness or injury.  
• Studies that exclusively enroll participants with the outcome of interest  
• Studies that exclusively enroll infants born preterm, infants with low birth weight, and/or infants born small for gestational age |
Question

What is the relationship between iron from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes (4 outcomes)?

Approach to Answer Question: NESR Systematic Review
Analytic Framework: What is the relationship between **iron** from supplements consumed before and during pregnancy and lactation and **micronutrient status**?

<table>
<thead>
<tr>
<th>Intervention/exposure</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Exposure to, including intake of, <strong>Iron</strong> from:</td>
<td>Different levels of exposure to, including intake of, <strong>Iron</strong> from:</td>
</tr>
<tr>
<td>• Dietary supplements (including multiple-nutrient supplements)</td>
<td>• Dietary supplements (including multiple-nutrient supplements)</td>
</tr>
</tbody>
</table>

**Population:** Women before and during pregnancy and/or during lactation; healthy and/or at risk for chronic disease

**Health outcomes**
- Iron status
- Iron deficiency, iron deficiency anemia, and anemia

**Population:** Women during pregnancy and/or lactation

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

**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Baseline hemoglobin
Analytic Framework: What is the relationship between iron from supplements consumed before and during pregnancy and gestational diabetes?

<table>
<thead>
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<tr>
<td>Exposure to, including intake of, Iron from:</td>
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<td>- Dietary supplements (including multiple-nutrient supplements)</td>
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</table>

Population: Women before and during pregnancy; healthy and/or at risk for chronic disease

Intermediate outcomes:
- Fasting glucose
- Hemoglobin A1C
- Glucose tolerance/insulin resistance
- Oral Glucose Tolerance Test

Population: Women during pregnancy

Key Confounders: Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Baseline hemoglobin, Family history of diabetes or pre-diabetes

Legend:
- The relationship of interest in the systematic review
- Factors that may impact the relationship of interest in the systematic review
Analytic Framework: What is the relationship between iron from supplements consumed before and during pregnancy and hypertensive disorders during pregnancy?

**Intervention/exposure vs Comparator**

- Exposure to, including intake of, **Iron** from:
  - Dietary supplements (including multiple-nutrient supplements)
- Different level of exposure to, including intake of, **Iron** from:
  - Dietary supplements (including multiple-nutrient supplements)

**Population:** Women before and during pregnancy; healthy and/or at risk for chronic disease

**Intermediate outcomes**

- Blood pressure (systolic and diastolic)
- Protein in the urine (proteinuria)

**Population:** Women during pregnancy

**Health outcomes**

Hypertensive disorders during pregnancy, including:
- Eclampsia
- Preeclampsia
- Gestational hypertension

**Population:** Women during pregnancy

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**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Baseline hemoglobin, Diagnosis of gestational diabetes

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Pregnancy and Lactation Subcommittee
2020 Dietary Guidelines Advisory Committee: Meeting 2
Analytic Framework: What is the relationship between iron from supplements consumed before and during pregnancy and lactation and developmental milestones, including neurocognitive development?

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**Population:** Women before and during pregnancy and/or during lactation; healthy and/or at risk for chronic disease

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

**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 and toddlers (birth to 24 months), children and adolescents (ages 2-18 years)

**Key Confounders:** Age, Race/ethnicity, Socioeconomic status, Smoking, Parity, Anthropometry (pre-pregnancy BMI and gestational weight gain (during pregnancy) or Obesity status (before pregnancy and lactation)), Baseline hemoglobin, Child sex, Gestational age, Breastfeeding
Inclusion and Exclusion Criteria: Iron from Dietary Supplements

• Standard criteria used for:
  • Study design
  • Publication Status
  • Language of Publication
  • Country

• Criteria identical to folic acid and health outcomes questions used for:
  • Date of publication (January 1980)
  • Study participants
  • Health status of study participants
Next Steps

• Next set of **Dietary Patterns** questions:
  • Human milk composition and quantity
  • Developmental milestones
  • Micronutrient status

• Next set of **Dietary Supplements and Fortified Foods** questions:
  • Vitamin B12
  • Omega-3 fatty acids
  • Vitamin D
  • Iodine
# 2020 Dietary Guidelines Advisory Committee: Pregnancy and Lactation Subcommittee

## Members:
- Sharon Donovan
- Kathryn Dewey
- Rachel Novotny
- Jamie Stang
- Elsie Taveras
- Ron Kleinman

## Support Staff:
- Jean Altman
- Kripa Raghavan
- Maureen Spill
- Julia Kim
- Julie Nevins
- Julie Obbagy
- Nancy Terry
- Janet deJesus (DFO Rep)

### Intervention/Exposure time period for the systematic review questions

<table>
<thead>
<tr>
<th>Systematic Review questions</th>
<th>Before pregnancy</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; trimester</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; trimester</th>
<th>3&lt;sup&gt;rd&lt;/sup&gt; trimester</th>
<th>Postpartum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dietary Patterns</strong></td>
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<tr>
<td>Gestational weight gain</td>
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<tr>
<td>Postpartum weight loss</td>
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<tr>
<td><strong>Dietary Supplements and Fortified Foods</strong></td>
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<tr>
<td>Micronutrient status</td>
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<td>Gestational diabetes mellitus</td>
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<tr>
<td>Hypertensive disorders of pregnancy</td>
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<td>Human milk composition</td>
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<td>Developmental milestones</td>
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