### 1. What maternal factors (other than dietary intake or nutritional status) have been documented to affect lactation initiation and success (incorporating both duration and intensity)?

**Rationale:** A number of factors may impact directly or indirectly on the initiation and success of lactation (Dewey, 2003; Nommsen-Rivers, 2010). Recent studies have emphasized such factors as delivery mode (C-section versus vaginal, pre-term versus term), and such maternal inflammatory conditions as obesity, impaired glucose tolerance, and mastitis. Other factors include could include the influence of the post-natal hospital environment (e.g., providing formula, rooming in) and pharmaceutical drug use during the peripartum period (including anti-inflammatory drugs). Any of these factors can impact positively or negatively on initiation or success of lactation leading to a child not being fed human milk as recommended; thus, better understanding of the various factors that potentially affect breastfeeding performance is needed to inform future guidance targeting this age group and their mothers/caregivers. A systematic assessment of these myriad factors will help women and their caregivers in making informed decisions about best feeding choices for them and their infants.

**PICO:**
- **Population:** Lactating women.
- **Intervention/Exposure:** Delivery mode (C-section versus vaginal), maternal inflammatory conditions (e.g., eclampsia, diabetes, and mastitis), breast irregularities (e.g., inverted nipples), post-natal hospital environment (e.g., providing formula, rooming in) and pharmaceutical drug-use during the peripartum period (including anti-inflammatory drugs). [NOTE: Higher priority exposures are those that are modifiable, as well as those that are related to overweight/obesity.].
- **Comparator:** Delivery mode (C-section versus vaginal), maternal inflammatory conditions (e.g., eclampsia, diabetes, and mastitis), breast irregularities (e.g., inverted nipples), post-natal hospital environment (e.g., providing formula, rooming in) and pharmaceutical drug-use during the peripartum period (including anti-inflammatory drugs).
- **Outcomes:** Infant: 1) growth and development and 2) immune system development, infection, or inflammation.

**Systematic Review Questions:**
- What impact does delivery mode (C-section versus vaginal) have on lactation initiation and sustainability?
- What impact do maternal inflammatory conditions (e.g., eclampsia, diabetes, and mastitis) have on lactation initiation and sustainability?
- What impact do breast irregularities (e.g., inverted nipples) have on lactation initiation and sustainability?
- What impact does the post-natal hospital environment (e.g., not providing formula, having access to lactation specialist, making rooming-in available) have on lactation initiation and sustainability?
- What impact does pharmaceutical drug-use during the peripartum period (including anti-inflammatory drugs) have on lactation initiation and sustainability?
1. **What maternal factors (other than dietary intake or nutritional status) have been documented to affect lactation initiation and success (incorporating both duration and intensity)?**

   - What impact do maternal factors, such as 1) delivery mode (C-section versus vaginal), 2) maternal inflammatory conditions (e.g., eclampsia, diabetes, and mastitis), 3) post-natal hospital environment (e.g., not providing formula, making rooming-in available) have on infant growth and physical development?

**Data and Research Priorities:**

- What impact do maternal factors, such as 1) breast irregularities (e.g., inverted nipples) and 2) pharmaceutical drug-use during the peripartum period (including anti-inflammatory drugs) have on infant growth and physical development?

- What impact do maternal factors, such as 1) delivery mode (C-section versus vaginal), 2) maternal inflammatory conditions (e.g., eclampsia, diabetes, and mastitis), 3) breast irregularities (e.g., inverted nipples), 4) post-natal hospital environment (e.g., not providing formula, making rooming-in available), and 5) pharmaceutical drug-use during the peripartum period (including anti-inflammatory drugs) have on infant immune system development, infection, or inflammation?

**Supporting Documents:**


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| 2. What predicts the following maternal feeding choices: A) to feed human milk at the breast or with a bottle and B) to feed on demand or on schedule? | These maternal feeding choices are linked with infant health outcomes (reviewed by Work Group 1) and knowledge of maternal characteristics associated with these choices will allow targeting of education/intervention to mothers who are least likely to adhere to best feeding practices. | **Population:** Lactating women.  
**Intervention/Exposure:** Predictors related to maternal choice to feed human milk via breast or in bottle: 1) Maternal employment/return to work/use of child care, 2) household income, and 3) infant birth weight.  
**Comparator:** Variations in maternal employment, including return to work, use of child care, levels of household income, ND infant’s birth weight  
**Outcomes:** Feeding human milk from the breast and 2) feeding human milk from the bottle. | Insufficient evidence/data exist to support systematic reviews at this time. | • What predicts the maternal feeding choice to feed human milk at the breast or with a bottle?  
• What predicts the maternal feeding choice to feed on demand or on schedule?  
• What is the prevalence of feeding human milk in a bottle? |
3. **What are the relationships of maternal feeding practices and styles (including control, pressure, restriction, responsive/intrusive/indulgent, and responsiveness to satiety and hunger cues) to infant growth and physical development, overweight/obesity, and eating behaviors?**

**Rationale:** Feeding styles and approaches differ greatly between women and across cultures (Birch, 1998; Lumeng, 2012; Thompson, 2013). The impact of different feeding styles assumes greater importance in light of a reported 9.7% of infants and toddlers in 2009–2010 NHANES have weight-for-recumbent length >95th percentile (Ogden, 2012). Further, numerous reports have documented that excessive infant weight gain predicts childhood obesity (Taveras, 2009; Taveras, 2011; Druet, 2012). Finally, childhood overweight and obesity predict multiple health and social outcomes in adolescence and adulthood.

**PICO:**

**Population:** Mothers.

**Intervention/Exposure:** Feeding style, including control, pressure, restriction, and responsive/pressuring/indulgent styles.

**Comparator:** Differing degrees of control, pressure, restriction, and responsive/pressuring/indulgent styles. [Note: Most literature focuses on comparing different degrees of an individual feeding style and few studies make comparisons between styles.]

**Outcomes:** Infant/toddler 1) growth and physical development (including rapid weight gain, weight-for-length, and BMI or BMI-Z), 2) overweight/obesity, and 3) infant feeding/eating behaviors (e.g., speed of eating, Baby Eating Questionnaire subscales).

**Systematic Review Questions:**

- What is the relationship between maternal feeding style (including control, pressure, restriction, responsive/pressuring/indulgent styles, and responsiveness to satiety and hunger cues) and infant/toddler growth and physical development (including rapid weight gain, weight-for-length, and BMI or BMI-Z)?
- What is the relationship between maternal feeding style (including control, pressure, restriction, responsive/pressuring/indulgent styles, and responsiveness to satiety and hunger cues) and infant, toddler, and childhood overweight/obesity?
- What is the relationship between maternal feeding style (including control, pressure, restriction, responsive/pressuring/indulgent styles, and responsiveness to satiety and hunger cues) and infant/toddler infant feeding/eating behaviors (e.g., speed of eating, Baby Eating Questionnaire subscales)?

**Data and Research Priorities:**

- Research on impacts of other caregivers’ feeding styles on infant/toddler outcomes.
- Longitudinal studies and randomized, controlled trials of interventions to increase parenting that is authoritative (i.e., high in responsivity and appropriate limit-setting).

**Supporting Documents:**

3. What are the relationships of maternal feeding practices and styles (including control, pressure, restriction, responsive/intrusive/indulgent, and responsiveness to satiety and hunger cues) to infant growth and physical development, overweight/obesity, and eating behaviors?


4. What is the evidence for any benefit or harm of maternal fish consumption during lactation?

**Rationale:** Awareness has been raised about the potential risks and benefits of seafood consumption in the context of maternal and child health (Lando, 2012). Consequent to the concerns raised, a systematic review of the extant evidence with regard to risk/benefit of maternal seafood consumption is needed to further refine existing recommendations. A specific need is the review of the evidence related to lactating mothers and breastmilk content and infant health outcomes.

**PICO:**
- **Population:** Lactating women.
- **Intervention/Exposure:** Maternal fish consumption.
- **Comparator:** Greater versus lesser fish consumption. Fish consumption, according to current federal guidelines (between 0oz and 12oz/340g per week) versus less (0) or more (≥12oz weekly).
- **Outcomes:** 1) Breast milk composition (n-3 LCPUFA, mercury), 2) infant neurodevelopment, 3) linear growth, weight gain and adiposity, and 4) asthma/atopy.

**Systematic Review Questions:**
- What are the effects of maternal fish consumption on milk composition and infant growth, immune function, and neurological development?

**Data and Research Priorities:**
- Randomized trials of interventions to change fish consumption (amount/composition) among pregnant/lactating women.
- Observational studies including information on all three factors of interest (fish intake, mercury intake/levels, and n-3 LCPUFA intake/levels in mothers, their milk, and their infants) and infant outcomes.

**Supporting Documents:**
5. **What is the relationship between lactating mothers' energy balance (energy intake, energy expenditure, and postpartum weight loss) on breast milk volume and composition, as well as infant growth and body composition?**

**Rationale:** Over two-thirds of women in their childbearing years are overweight or obese. In addition, over half of women gain more weight during pregnancy than recommended by IOM. A bi-directional relationship exists between body composition and lactating performance, i.e., body composition impacts lactation and vice versa (Winkvist, 1999; Amir, 2007; Wojcicki, 2011). Approaches to addressing these relationships during pregnancy (e.g., exercise, weight loss, diet, etc.; Cohen, 2013) and lactation (McCrorry, 1999; Lovelady, 2000) have been explored. Concerns about these relationships may lead to practices that might be counterproductive in terms of both maternal needs and lactation success. Thus, women need guidance on how to lose excess weight during lactation, without compromising breastmilk volume or composition and, ultimately, infant growth.

**Population:** Lactating women.

**Intervention/Exposure:** Energy intake, energy expenditure, and postpartum weight loss; independently and in combination.

**Comparator:** Different levels of energy intake, energy expenditure, and postpartum weight loss; independently and in combination.

**Outcomes:** 1) Breastmilk volume and composition and 2) infant growth and body composition.

**Systematic Review Questions:**

- What is the relationship between lactating mothers’ energy intake (including “dieting”), energy expenditure (including exercise), and postpartum weight loss (independently and in combination) with human milk volume?
- What is the relationship between lactating mothers’ energy intake (including “dieting”), energy expenditure (including exercise), and postpartum weight loss (independently and in combination) with human milk composition?
- What is the relationship between lactating mothers’ energy intake (including “dieting”), energy expenditure (including exercise), and postpartum weight loss (independently and in combination) with infant growth or body composition?

**Supporting Documents:**

6. Maternal and caregiver predictors of infant dietary quality (i.e., what do we know about maternal and caregiver adherence to dietary recommendations for infants and how can we increase the number of infants and toddlers who would benefit from improved adherence to dietary recommendations, especially low-income/high risk?)

**Rationale:** Disparities have been reported, irrespective of setting, between national dietary recommendations and actual dietary intakes of women, infants, and children (Dubois, 2011; Thorisdottir, 2013). Evidence exists to explain how and why mothers/caregivers might be able to effectively implement and adhere to dietary recommendations (Wojcicki, 2009). There is also a growing appreciation of the potential impact of child care providers (beyond parents) on infant and young child diet and nutrition (Kim, 2008; Pearce, 2010). A need exists for analyses to inform policy makers, practitioners, and educators about which mothers/caregivers are most at risk for not adhering to dietary guidelines or best practices and how to intervene to increase adherence. This topic is a needed research agenda topic after the 2020 Dietary Guidelines for Americans are implemented.

**PICO:**

**Population:** Mothers, caregivers and child care providers.

**Intervention/Exposure:** Maternal and caregiver predictors of infant diet quality; diet quality/adherence to the Dietary Guidelines.

**Comparator:** Maternal and caregiver predictors of diet quality; poor diet quality/less adherence to the Dietary Guidelines.

**Outcomes:** Growth and physical development, diet quality and dietary intake.

**Systematic Review Questions:**

- Insufficient evidence/data exist to support systematic reviews at this time.

**Data and Research Priorities:** (These questions should be investigated in the future after guidelines are developed and data can be generated in response to that guidance in relevant target groups.)

- What are the maternal and caregiver predictors of infant diet quality or adherence to the Dietary Guidelines?
- Does maternal/caregiver/child care provider adherence to dietary guidelines/best practices impact the infant/toddler’s:
  - Diet quality or dietary intake?
  - Growth and physical development?
- What are the modifiable mediators (i.e., potential intervention targets) in addition to parental socio-economic status and education, nutrition knowledge, self-efficacy, and motivational variables?

**Supporting Documents:**

7. What are the effects of dietary patterns (such as vegan, vegetarian, macrobiotic diets) on breastmilk composition?

**Rationale:** Although a basic knowledge of the nutrient and bioactive components of human milk exists (Ballard, 2013), our understanding of the factors that influence that composition is still evolving. It is clear that maternal intake can affect the concentrations of some nutrients in human milk (e.g., lipids and some vitamins), while other nutrients are unaffected (e.g., protein, lactose, and most minerals). Certain restricted or “unconventional” dietary patterns (e.g., vegetarianism, vegan diets, macrobiotic diets, etc.) may impact these relationships (Dagnelie, 1992; Baatenburg de Jong, 2005). Because of the intimate relationship between maternal diet/practices on human milk composition, guidance is needed with regard to the impact of restricted dietary patterns on maternal and infant nutrition during lactation.

**PICO:**

**Population:** Lactating women.

**Intervention/Exposure:** Dietary patterns (such as vegan, vegetarian, and macrobiotic diets).

**Comparator:** Different dietary patterns.

**Outcomes:** Human milk composition.

**Systematic Review Questions:**

- What is the relationship between maternal vegan dietary pattern during lactation and human milk composition?
- What is the relationship between maternal vegetarian dietary pattern during lactation and human milk composition?
- What is the relationship between maternal macrobiotic diet during lactation and human milk composition?

**Data and Research Priorities:**

- Prevalence of specific dietary patterns in the general population of women of reproductive age.
- Behavioral/ethnic/cultural predictors.
- Impact of special dietary patterns on maternal body composition and health during pregnancy/lactation.
- Impact of maternal special dietary patterns on nutritional status of infants (not just dietary quality).
- Impact on infant body composition and neurological development.

**Supporting Documents:**

8. What is the influence of maternal dietary intake on micronutrients (including fat-soluble and water-soluble vitamins) and macronutrients (including total fat, n-3 PUFA, n-6 PUFA, and trans fats) on human milk composition?

**Rationale:** A basic understanding exists on the nutrient and bioactive component composition of human milk (Ballard, 2013) and the impact of maternal diet and nutritional status on infant nutrient intake (Chapman, 2012). Of the dietary essential nutrients, human milk content of lipids (total and fatty acid composition; Rudolph, 2007) and specific water-soluble and fat-soluble vitamins (Allen, 2012; Dawodu, 2012) are most affected by maternal diet. Hence, breastfeeding mothers will need guidance to assure optimal human milk composition.

**PICO:**

**Population:** Lactating mothers.

**Intervention/Exposure:** Maternal intake of fat-soluble vitamins, water-soluble vitamins, and fat (i.e., total fat, trans fats, n-3 PUFA, and n-6 PUFA).

**Comparator:** Different levels of intake of fat-soluble vitamins, water-soluble vitamins, and fat (i.e., total fat, trans fats, n-3 PUFA, and n-6 PUFA).

**Outcomes:** Human milk composition (i.e., fat-soluble and water-soluble vitamins and fat (i.e., total fat, trans fats, n-3 PUFA, and n-6 PUFA).

**Systematic Review Questions:**

- What is the relationship between maternal dietary water-soluble vitamin intake and human milk water-soluble vitamin composition?
- What is the relationship between maternal dietary fat-soluble vitamin intake and human milk fat-soluble vitamin composition?
- What is the relationship between maternal dietary fat intake and human milk fat composition?

**Supporting Documents:**

9. **What are infants/children aged 0–24 months being fed and what are they consuming in non-parental child care settings?**

**Rationale:** A large number of children in the United States are cared for outside of the home and receive at least one or more meals and snacks in non-parental child care settings. Today, roughly 40% of infants and toddlers cared for outside of the home for (on average) 30 hours per week (US Department of Education, National Center for Education Statistics). A body of evidence is emerging to document the impact of differing childcare settings on infant/toddler diet and nutrition (Nicklas, 2001; Fleischhacker, 2006; Erinosho, 2011). Efforts have been made to provide guidance for dietary/nutritional care in child care settings (Benjamin Neelon, 2011). A need exists for a systematic review of the evidence to in order to provide evidence-based guidance to parents and caregivers and to provide a better understanding of the impact of this important trend.

**PICO:**

**Population:** Out-of-home child care providers.

**Intervention/Exposure:** Foods provided by out-of-home caregivers to children while in child care (including all types of child care, such as licensed centers, licensed in-home providers, informal neighbor/relative care); behaviors/practices used by out-of-home caregivers when providing food to children while in child care (including the “food environment”).

**Comparator:** Different food provided to children while in child care; different types of child care or caregivers.

**Outcomes:** Toddler (aged 12–24 months) 1) dietary intake, 2) diet quality, and 3) dietary behaviors/food environment.

**Systematic Review Questions:**

- What is the relationship between out-of-home feeding and infant/toddler dietary intake?
- What is the relationship between out-of-home feeding and infant/toddler diet quality?
- What is the relationship between out-of-home feeding and infant/toddler dietary behaviors?

**Data and Research Priorities:**

- Description of what children are fed at out-of-home care settings [Note: Existing data sets can provide some information (NHANES), but additional sources of data are also needed.].
- Research on more informal types of child care is limited.
- Research on dietary intake of infants in non-parental child care settings is extremely limited.
- Are there data to assess potential differences in health outcomes in infants/children in “out-of-home” child care settings?

**Supporting Documents:**

10. Effects of maternal alcohol consumption during lactation on milk production, milk composition, and infant outcomes

**Rationale:** Many perceptions exist about the impact of alcohol on various aspects of lactation (Mennella, 2001). A need exists to amalgamate the extant evidence to address the validity of these perceptions.

**PICO:**
- **Population:** Lactating women.
- **Intervention/Exposure:** Alcohol consumption.
- **Comparator:** Different levels or types of alcohol consumption.
- **Outcomes:** 1) Infant/toddler growth and physical development, 2) infant/toddler cognitive, behavioral, or neuromotor development, and 3) breast milk composition.

**Systematic Review Questions:**
- What are the effects of (or associations between) maternal alcohol consumption during lactation on human milk alcohol concentration?
- What are the effects of (or associations between) maternal alcohol consumption during lactation on human milk volume (or infant milk consumption)?
- What are the effects of (or associations between) maternal alcohol consumption during lactation on infant (birth to 6 months) behavior (specifically suckling and sleep)?

**Data and Research Priorities:**
- What data exist with regard to the use of alcohol by lactating women in the US?
- Are there groups at greater risk of alcohol use:
  - Behavioral characteristics?
  - Ethnic/cultural influence?
  - Use of other recreational drugs?
- Are there common perceptions about the use of alcohol and what is their prevalence?
- What are the effects of maternal alcohol consumption during lactation on: 1) human milk composition (other than alcohol), 2) infant and toddler (aged 0–24 months) growth and physical development, and 3) infant and toddler (0–24 months) cognitive, behavioral, and neuromotor development?
- Is there a dose response, safe dose, or upper limit of alcohol that imparts any benefit?

**Supporting Documents:**
11. Effects (or lack thereof) of maternal caffeine consumption during lactation on milk production, milk composition, and infant outcomes

**Rationale:** Caffeine exposure continues to rise in the general population. The potential impact of maternal caffeine consumption on infant health has not been clearly delineated (Nehlig, 1994; Santos, 2012). A need exists to assess the impact of caffeine exposure on various aspects of lactation as well as relevant health outcomes in infants.

**PICO:**
- **Population:** Lactating women.
- **Intervention/Exposure:** Caffeine consumption.
- **Comparator:** Different levels or types of caffeine consumption.
- **Outcomes:** Infant/toddler growth and physical development, 2) infant/toddler cognitive, behavioral, or neuromotor development, and 3) breast milk composition.

**Systematic Review Questions:**
- What are the effects of (or associations between) maternal caffeine consumption during lactation on human milk caffeine concentration?
- What are the effects of (or associations between) maternal caffeine consumption during lactation on human milk volume (or infant milk consumption)?
- What are the effects of (or associations between) maternal caffeine consumption during lactation on infant (birth to 6 months) behavior (specifically suckling and sleep), as well as growth?

**Research or Data Needs:**
- What data exist with regard to the use of caffeine by lactating women in the US?
- Are there groups at greater risk of caffeine use:
  - Behavioral characteristics?
  - Ethnic/cultural influence?
  - Use of other recreational drugs?
- Are there common perceptions about the use of caffeine and what is their prevalence?
- What are the effects of maternal caffeine consumption during lactation on: 1) human milk composition, 2) infant caffeine levels (i.e., does caffeine get to the infant via human milk), 3) infant and toddler (aged 0–24 months) growth and physical development, and 4) infant and toddler (aged 0–24 months) cognitive, behavioral, or neuromotor development?
- Is there either a dose response, safe dose that imparts any benefit, or upper limit of caffeine intake?

**Supporting Documents:**
12. How can we assist women across the BMI spectrum to reach national goals for breastfeeding duration?

**Rationale:** Substantial literature exists that demonstrates an association between higher maternal BMI and difficulty initiating and sustaining breastfeeding in most (but not all) populations that have been studied (Lovelady, 2005; Amir, 2007; Nommsen-Rivers, 2010; Lepe, 2011; Turcksin, 2012). An evaluation of this literature is needed to provide guidance to mothers who are dealing with this issue.

**PICO:**
- **Population:** Lactating women.
- **Intervention/Exposure:** Maternal body composition (e.g., high versus low fat mass; pre-pregnancy, and post-delivery), including weight status (e.g., overweight and underweight).
- **Comparator:** Different maternal body composition (e.g., high versus low fat mass); weight status (e.g., overweight versus underweight).
- **Outcomes:**
  1) Growth and physical development of the 0- to 24-month-old,
  2) duration of breastfeeding (exclusive or any),
  3) breastmilk volume,
  4) breastmilk composition.

**Systematic Review Questions:**
- What are the effects of maternal body composition/weight status on initiation (ever breastfeeds) and duration of breastfeeding?

**Data and Research Priorities:**
- What is the relationship between maternal body composition/weight status and:
  - Human milk volume?
  - Human milk composition: Macronutrients (fat, protein), micronutrients (vitamins/minerals), and bioactive components (e.g., oligosaccharides, lactoferrin etc.)?
- What are the obstacles and how can women (particularly overweight and obese women) be assisted to achieve current breastfeeding goals (e.g., initiation, exclusive breastfeeding for up to six months, etc.)?
- What are the effects of maternal body composition/weight status on growth and development of infants and toddlers from birth to 24 months?
- What are the plausible biological mechanisms that might explain difficulties in initiating/sustaining breastfeeding in women with high BMI?
  - What is the role of inflammation?
  - How might such information be used to identify biomarkers of risk for poor breastfeeding performance?

**Supporting Documents:**
13. Effects of maternal probiotic consumption on human milk composition or infant outcomes

**Rationale:** The importance of the various human “microbiomes” (gastrointestinal, vaginal, oral, and milk) has emerged as a major focal point of activity, both clinically and from a research perspective. As these microbial populations are better characterized, a lot of information is learned about factors that might impact their growth, maintenance, and effect on host health. The role of maternal probiotic consumption during pregnancy/lactation and its influences on maternal and infant microbiomes remains undetermined. [Note: Because this is an emerging area of scientific inquiry, Work Group 4 (as did Work Group 1) has designated this as being part of a perceived “research agenda,” rather than high priority for a systematic literature review at this time. There is very little research on this and with the recent description of the human milk microbiome (Cabrera-Rubio, 2012) and its potential as both a pro-/prebiotic (Barile, 2013), this topic will likely assume a great importance to infant health.]

**PICO:**

**Population:** Lactating women.

**Intervention/Exposure:** Probiotic consumption.

**Comparator:** Different levels or types of probiotic consumption.

**Outcomes:** 1) Infant/toddler growth and physical development, 2) infant/toddler immune system development, infection, or inflammation, and 3) breastmilk composition.

**Systematic Review Questions:**
- Insufficient evidence/data exist to support systematic reviews at this time

**Data and Research Priorities:**
- What is the prevalence of probiotic use in lactating women in the US (i.e., use of any versus use of specific probiotics; if any, which ones?)
- What is the evidence to support the use of probiotic to:
  - Improve maternal gastrointestinal function?
  - Improve maternal overall health including immune function?
  - Improve lactation (performance/milk composition)?
  - Improve infant health (growth, immune function)?

**Supporting Documents:**