

# WHAT IS THE RELATIONSHIP BETWEEN SEAFOOD CONSUMPTION DURING PREGNANCY AND LACTATION AND NEUROCOGNITIVE DEVELOPMENT OF THE INFANT?: SYSTEMATIC REVIEW PROTOCOL

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This document describes the protocol for a systematic review to answer the following question: What is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant? This systematic review is being conducted by the 2020 Dietary Guidelines Advisory Committee, Dietary Fats and Seafood Subcommittee and staff from USDA's Nutrition Evidence Systematic Review (NESR).

NESR methodology for answering a systematic review question involves:

- searching for and selecting articles,
- extracting data and assessing the risk of bias of results from each included article,
- synthesizing the evidence,
- developing a conclusion statement,
- grading the evidence underlying the conclusion statement, and
- recommending future research.

More information about NESR's systematic review methodology is available on the NESR website: <https://nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews>.

This document describes the protocol, or plan, for how the systematic review will be conducted. The protocol provides:

- The [analytic framework](#) (p. 2) illustrates the overall scope of the question, including the population, the interventions and/or exposures, comparators, and outcomes of interest.
- The [literature search and screening plan](#) (p. 3) details the electronic databases and [inclusion and exclusion criteria](#) (p. 3) that will be used to search for, screen, and select articles to be included in the systematic review.
- The [literature search and screening results](#) (p. 7) includes a list of included articles, and a list of excluded articles with the rationale for exclusion.

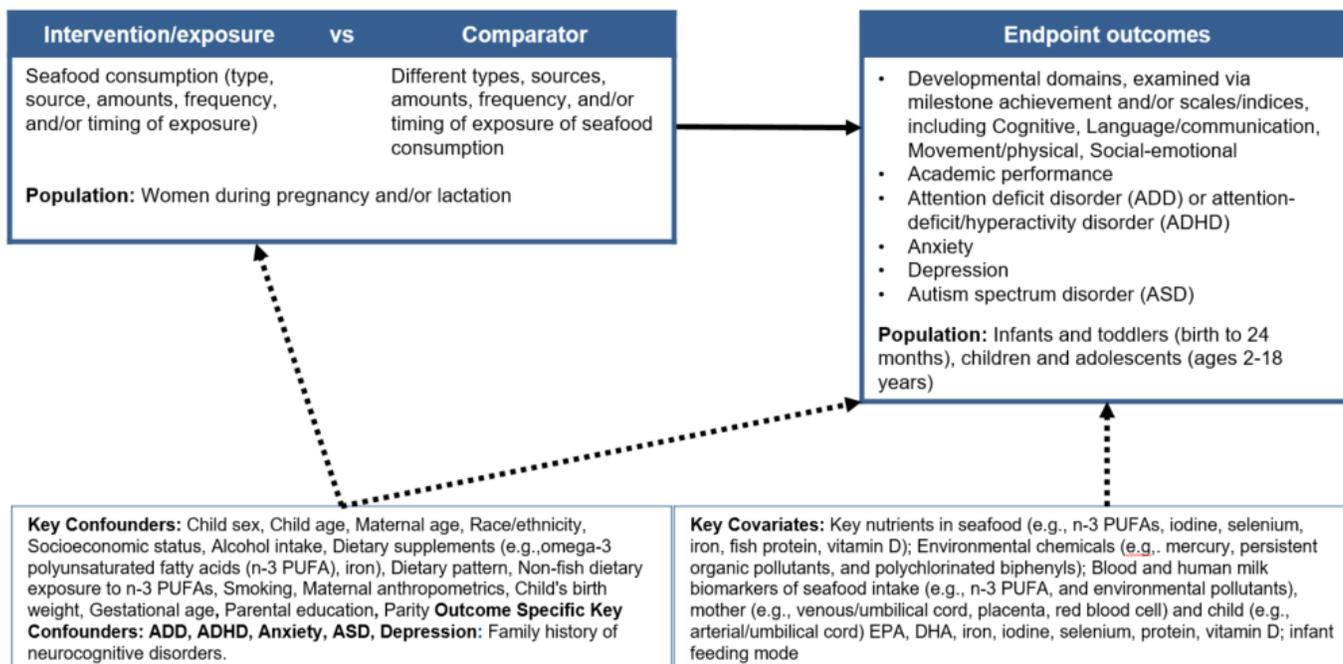
This protocol is up-to-date as of: 07/02/2019.

## ANALYTIC FRAMEWORK

The analytic framework (**Figure 1**) illustrates the overall scope of the systematic review, including the population, the interventions and/or exposures, comparators, and outcomes of interest. It also includes definitions of key terms and identifies key confounders and covariates considered in the systematic review. The inclusion and exclusion criteria that follow provide additional information about how parts of the analytic framework will be defined and operationalized for the review.

**Figure 1: Analytic framework**

**Systematic review question:** What is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development in infants?



**Key definition:**

**Seafood** - Marine animals that live in the sea and in freshwater lakes and rivers. Seafood includes fish (e.g., salmon, tuna, trout, and tilapia) and shellfish (e.g., shrimp, crab, and oysters) (Source: 2015-2020 DGA)

**Legend**

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

Question: What is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant?

## LITERATURE SEARCH AND SCREENING PLAN

### Electronic databases

Listed below are the databases that will be searched to identify all potentially relevant articles that have been published to address the systematic review question. Additional details regarding the search strategy will be published upon completion of the review, and are available upon request prior to publication.

- **Pubmed**
- **Cochrane**
- **Embase**
- **CINAHL**

### Inclusion and exclusion criteria

This table provides the inclusion and exclusion criteria for the systematic review. The inclusion and exclusion criteria are a set of characteristics used to determine which articles identified in the literature search will be included or excluded in the systematic review.

**Table 1. Inclusion and exclusion criteria**

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

Category	Inclusion Criteria	Exclusion Criteria
<b>Intervention/ exposure</b>	<ul style="list-style-type: none"> <li>• Seafood consumption measured prior to outcome assessment               <ul style="list-style-type: none"> <li>○ Type (e.g., salmon, tuna, bass)</li> <li>○ Source (e.g., sea, fresh water, farmed, wild)</li> <li>○ Amount/frequency of intake</li> <li>○ Timing of exposure (e.g., age at intake)</li> </ul> </li> <li>• Dietary intake (e.g., from food frequency questionnaires, dietary recall, fish/seafood screeners) may be validated with biomarkers for PUFA or MeHg, but not substituted.</li> </ul>	<ul style="list-style-type: none"> <li>• No measure of seafood consumption (i.e., studies that only examined biomarkers for consumption)</li> <li>• n-3 supplement studies which do not evaluate seafood consumption</li> <li>• Studies evaluating infant formula with added DHA and/or EPA</li> </ul>
<b>Comparator</b>	<ul style="list-style-type: none"> <li>• Different types, sources, amounts, frequency, and/or timing of exposure of seafood consumption</li> </ul>	<ul style="list-style-type: none"> <li>• No comparator</li> </ul>
<b>Outcomes</b>	<ul style="list-style-type: none"> <li>• Developmental milestones, including neurocognitive development               <ul style="list-style-type: none"> <li>○ Developmental domains examined via milestone achievement and/or scales/indices, including:                   <ul style="list-style-type: none"> <li>▪ cognitive,</li> <li>▪ language/communication,</li> <li>▪ movement/physical,</li> <li>▪ social/emotional</li> </ul> </li> </ul> </li> <li>• Academic performance</li> <li>• Attention deficit disorder (ADD) or attention deficit/hyperactivity disorder (ADHD)</li> <li>• Anxiety</li> <li>• Depression</li> <li>• Autism spectrum disorder (ASD)</li> </ul>	<ul style="list-style-type: none"> <li>• No measure of neurocognitive development</li> </ul>
<b>Date of publication</b>	<ul style="list-style-type: none"> <li>• January 2000 to June 2019</li> </ul>	<ul style="list-style-type: none"> <li>• Articles published prior to January 2000 or after June 2019</li> </ul>

Question: What is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant?

Category	Inclusion Criteria	Exclusion Criteria
<b>Publication status</b>	<ul style="list-style-type: none"> <li>Articles that have been peer-reviewed</li> </ul>	<ul style="list-style-type: none"> <li>Articles that have not been peer-reviewed and are not published in peer-reviewed journals, including unpublished data, manuscripts, reports, abstracts, and conference proceedings</li> </ul>
<b>Language of publication</b>	<ul style="list-style-type: none"> <li>Articles published in English</li> </ul>	<ul style="list-style-type: none"> <li>Articles published in languages other than English</li> </ul>
<b>Country<sup>i</sup></b>	<ul style="list-style-type: none"> <li>Studies conducted in countries ranked as high or very high human development</li> </ul>	<ul style="list-style-type: none"> <li>Studies conducted in countries ranked as medium or lower human development</li> </ul>
<b>Study participants</b>	<ul style="list-style-type: none"> <li>Human subjects</li> <li>At intervention/exposure <ul style="list-style-type: none"> <li>Females who are pregnant and/or lactating</li> </ul> </li> <li>At outcome <ul style="list-style-type: none"> <li>Males and females</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Non-human subjects (e.g., animal models or in-vitro models)</li> </ul>
<b>Age of study participants</b>	<ul style="list-style-type: none"> <li>Age at intervention or exposure: <ul style="list-style-type: none"> <li>Women during pregnancy and/or lactation</li> </ul> </li> <li>Age at outcome: <ul style="list-style-type: none"> <li>Infants and toddlers (0-24 months)</li> <li>Children (2-12 years)</li> <li>Adolescents (13-18 years)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Age at outcome: <ul style="list-style-type: none"> <li>Adults (ages 19-64 years)</li> <li>Older adults (ages 65 years and older)</li> </ul> </li> </ul>

Question: What is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant?

Category	Inclusion Criteria	Exclusion Criteria
<b>Health status of study participants</b>	<ul style="list-style-type: none"> <li>• Studies that enroll participants who are healthy and/or at risk for chronic disease, including those with obesity</li> <li>• Studies that enroll <b>some</b> participants diagnosed with a disease or with the neurocognitive development and/or health outcomes of interest</li> <li>• Studies that enroll infants born full-term (<math>\geq 37</math> weeks and 0/7 days gestational age)</li> <li>• Studies that enroll <b>some</b> infants born preterm (gestational age <math>&lt; 37</math> weeks and 0/7 days), infants with low birth weight (2500g), and/or infants born small for gestational age</li> </ul>	<ul style="list-style-type: none"> <li>• Studies that <b>exclusively</b> enroll participants diagnosed with a disease or hospitalized with an illness or injury. (For this criterion, studies that exclusively enroll participants with obesity will not be excluded.)</li> <li>• Studies that <b>exclusively</b> enroll participants with the neurocognitive development and/or health outcomes of interest</li> <li>• Studies that <b>exclusively</b> enroll infants born preterm (gestational age <math>&lt; 37</math> weeks and 0/7 days), infants with low birth weight (2500g), and/or infants born small for gestational age</li> </ul>

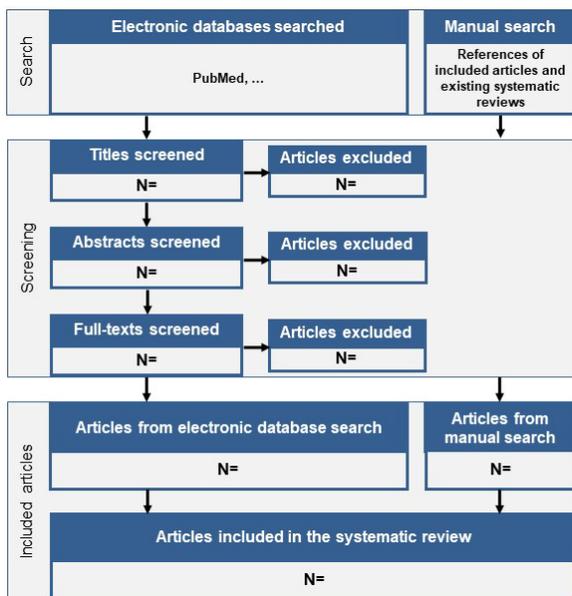
<sup>i</sup> The Human Development classification was based on the Human Development Index (HDI) ranking from the year the study intervention occurred or data were collected (UN Development Program. HDI 1990-2017 HDRO calculations based on data from UNDESA (2017a), UNESCO Institute for Statistics (2018), United Nations Statistics Division (2018b), World Bank (2018b), Barro and Lee (2016) and IMF (2018). Available from: <http://hdr.undp.org/en/data>). If the study did not report the year in which the intervention occurred or data were collected, the HDI classification for the year of publication was applied. HDI values are available from 1980, and then from 1990 to present. If a study was conducted prior to 1990, the HDI classification from 1990 was applied. When a country was not included in the HDI ranking, the current country classification from the World Bank was used instead (The World Bank. World Bank country and lending groups. Available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-country-and-lending-groups>).

## LITERATURE SEARCH AND SCREENING RESULTS

This protocol will be updated with the literature search and screening results after the search and screening plan has been finalized and implemented.

The flow chart (**Figure 2**) below illustrates the literature search and screening results for articles examining the systematic review question. The results of the electronic database searches, after removal of duplicates, were screened independently by two NESR analysts using a step-wise process by reviewing titles, abstracts, and full-texts to determine which articles met the inclusion criteria. A manual search was done to find articles that were not identified when searching the electronic databases; all manually identified articles are also screened to determine whether they meet criteria for inclusion.

**Figure 2: Flow chart of literature search and screening results (To be added)**



### Included Articles (To be added)

1. Ref

### Excluded Articles (To be added)

The table below lists the articles excluded after full-text screening. At least one reason for exclusion is provided for each article, which may not reflect all possible reasons. Information about articles excluded after title and abstract screening is available upon request.

**Table 2. Excluded articles**

Citation	Rationale
1	