WHAT IS THE RELATIONSHIP BETWEEN BEVERAGE CONSUMPTION DURING LACTATION AND HUMAN MILK COMPOSITION AND QUANTITY?: SYSTEMATIC REVIEW PROTOCOL

This document describes the protocol for a systematic review to answer the following question: What is the relationship between beverage consumption during lactation and human milk composition and quantity?

This systematic review is being conducted by the 2020 Dietary Guidelines Advisory Committee, Beverages and Added Sugars 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 includes details about the methodology as it will be applied to the systematic review as follows:
- 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. 2) 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. 6) 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: 09/19/2019.

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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 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
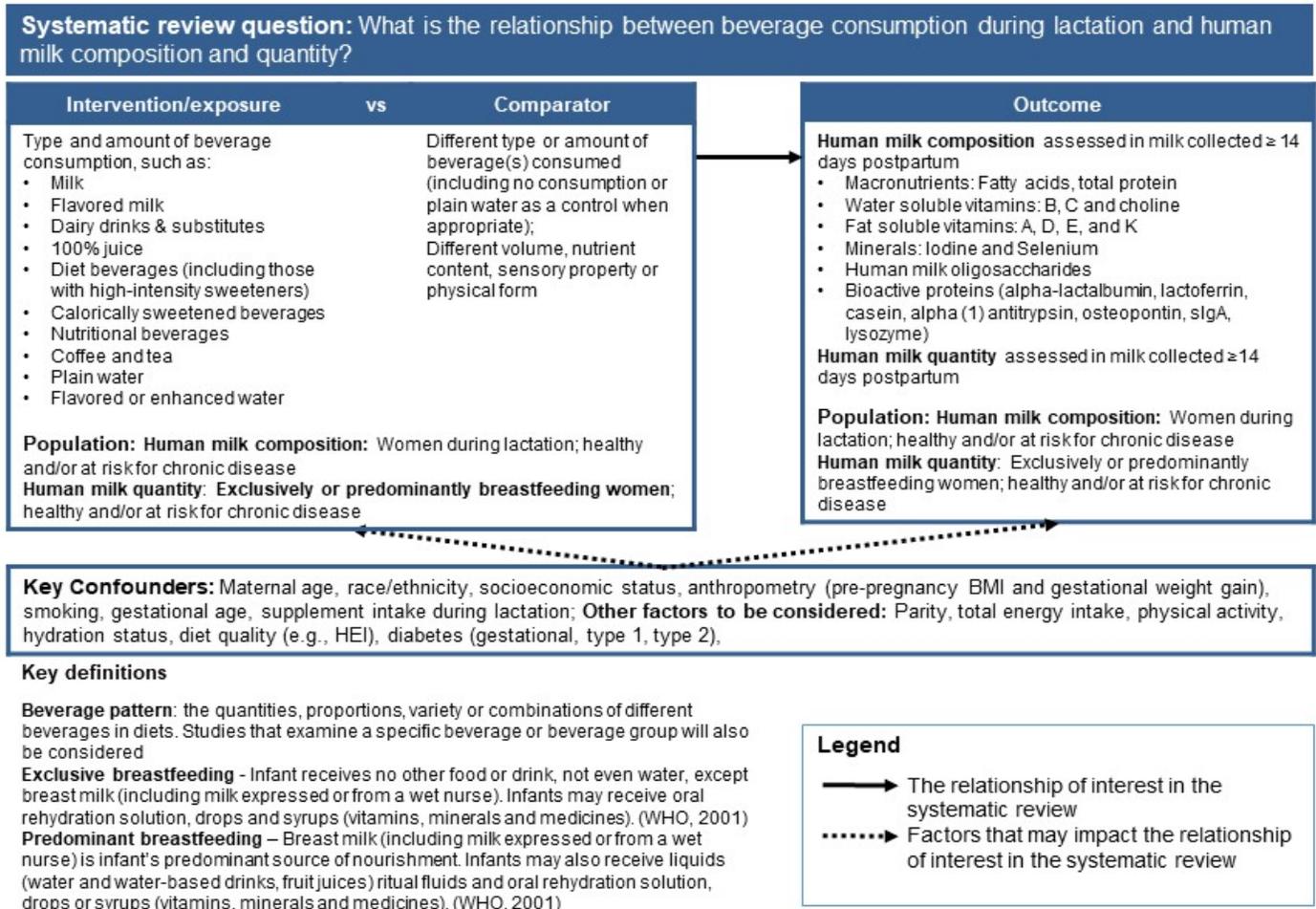
LITERATURE SEARCH AND SCREENING PLAN

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**

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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.

Category	Inclusion Criteria	Exclusion Criteria
Study design	- 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 - Case-control studies - Cross-sectional studies, repeated cross-sectional studies	- Uncontrolled trials - Uncontrolled before-and-after studies - Narrative reviews - Systematic reviews - Meta-analyses
Intervention/ exposure	Type and amount of beverage consumption—all beverage types will be considered Example beverage categories include: - Milk - Flavored milk - Dairy drinks & substitutes 100% juice - Diet beverages (including those with high-intensity sweeteners [also known as artificial sweeteners], and juice diluted with water) - Calorically sweetened beverages (including sweetened juice) - Nutritional beverages (including meal replacements and protein shakes) - Coffee and tea - Plain water - Flavored or enhanced water	- Alcohol not within a beverage pattern - Soups

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Category	Inclusion Criteria	Exclusion Criteria
Comparator	• Different type or amount of beverage(s) consumed (including no consumption or plain water as a control when appropriate); • Different volume, nutrient content, sensory property or physical form	• No comparator

Outcomes	• Human milk composition assessed in milk collected ≥ 14 days postpartum
	
	   ○ Macronutrients: Fatty acids, total protein
	
	   ○ Water soluble vitamins: B, C, and choline
	
	   ○ Fat soluble vitamins: A, D, E, K
	
	   ○ Minerals: Iodine and Selenium
	
	   ○ Human milk oligosaccharides
	
	   ○ Bioactive proteins (alpha-lactalbumin, lactoferrin, casein, alpha (1) antitrypsin, osteopontin, sIgA, lysozyme)
	
	• Human milk quantity assessed in milk collected ≥14 days postpartum	

Date of publication	• January 2000 to August 2019	• Articles published before January 2000 or after July 2019
Publication status	• Articles published in peer-reviewed journals	• Articles that have not been peer-reviewed and are not published in peer-reviewed journals, including unpublished data, manuscripts, reports, pre-prints, abstracts, and conference proceedings
Language of publication	• Articles published in English	• Articles published in languages other than English

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Category	Inclusion Criteria	Exclusion Criteria
Country[i]	• Studies conducted in Very High or High Human Development Countries	• Studies conducted in countries ranked as medium or lower human development
Study participants	• Human milk composition: Women during lactation • Human milk quantity: Exclusively or predominantly breastfeeding women	• Animal and in vitro models • Human milk quantity outcome only: Studies that exclusively enroll multiple gestation pregnancies or exclusively present combined analyses of singleton and multiple gestations • Human milk from third parties (e.g., banked/donor milk)
Health status of study participants	• Studies that enroll mothers who are healthy and/or at risk for chronic disease • Studies that enroll some mothers diagnosed with a disease • Studies that enroll some mothers who were severely undernourished prior to pregnancy • Studies that enroll some or all mothers classified as underweight, or obese prior to pregnancy	• Studies that **exclusively** enroll mothers who gave birth to preterm (gestational age <37 weeks and 0/7 days) • Studies that **exclusively** enroll mothers diagnosed with a disease, including severe undernutrition, or hospitalized with an illness or injury

[i] The Human Development classification was based on the Human Development Index (HDI) ranking from the year the study intervention occurred or data was collected. 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 in 2018 or 2019, the most current HDI classification was applied. 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 is used instead.
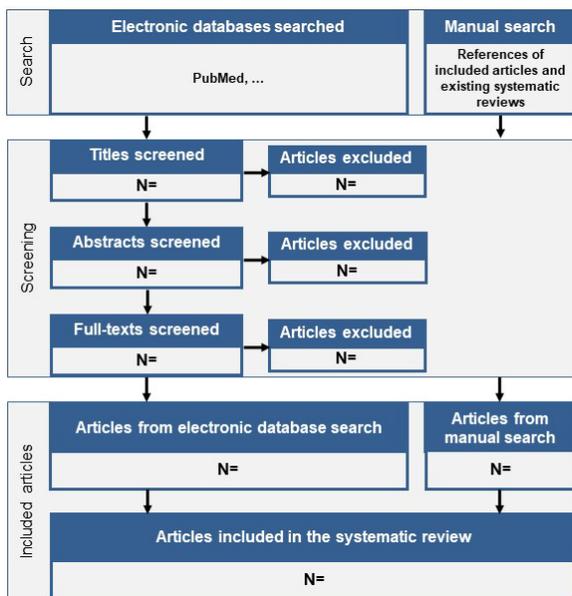
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LITERATURE SEARCH AND SCREENING RESULTS

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 1. Excluded articles

Citation	Rationale
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