

**Evidence Gaps Research Taxonomy Table**  
**Research to Address Evidence Gaps in Preventive Services for the USPSTF**  
**Topic: Primary Care Behavioral Counseling Interventions to Support Breastfeeding**

To fulfill its mission to improve health by making evidence-based recommendations for preventive services, the USPSTF routinely highlights the most critical evidence gaps for making actionable preventive services recommendations. As summarized in the research needs and gaps table (Table 2) in the recommendation statement, the USPSTF often needs additional evidence to create the strongest recommendations for everyone and especially for persons with the greatest burden of disease.

In this table, the USPSTF summarizes key bodies of evidence needed on primary care behavioral counseling interventions to support breastfeeding. For each of the evidence gaps listed below, the USPSTF provides guidance to researchers and funders on the types of studies needed.

The research taxonomy is intended to provide general guidance to investigators. Investigators are encouraged to develop research designs that are responsive to the research taxonomy outlined in the table, in collaboration with their research teams and areas of expertise and experience. The research developed will be reviewed according to standard USPSTF criteria for inclusion in its evidence report; inclusion criteria are summarized in the final Research Plan (<https://www.uspreventiveservicestaskforce.org/uspstf/document/final-research-plan/breastfeeding-interventions>) and Procedure Manual (<https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual>).

Research Gap	Key Questions* or Contextual Questions	Direct/ Indirect Pathway†	Type of Gap‡	Study Characteristics	Population	Intervention/Comparison	Outcomes/Timing	Setting
1. The direct effects of breastfeeding interventions on breastfeeding measures, short- and medium-term maternal and child health outcomes, and the relationship between breastfeeding measures and these health outcomes.	KQ1	Direct	Grade change	Randomized, controlled trials§	Adolescents or adults involved with or making decisions about feeding their child.  Studies should be representative of the people living in the United States and include populations who experience disparities in breastfeeding rates in sufficient numbers for preplanned subgroup analyses.	Interventions: Designed to support breastfeeding and the consumption of breast milk, including individual or group counseling, peer counseling, home visits, structured education, technology- or computer-based support, distribution of written materials, and support provided prenatally, at time of delivery, or postpartum.  Comparisons: Usual care, wait list control, no intervention, or attention control.	<u>Short- and medium-term maternal health outcomes</u> such as rates of diabetes mellitus, weight status, quality of life, or mental health symptoms.  <u>Short- and medium-term infant and child health outcomes</u> such as gastrointestinal symptoms, atopic dermatitis, respiratory symptoms, otitis media, asthma, or growth.  <u>Breastfeeding measures</u> may include duration, intensity, exclusivity, and mode of breast milk consumption.  <u>Relationship between breastfeeding measures and health outcomes.</u>	Any healthcare- or community-based setting, including services provided in-home or virtually/remotely, applicable to primary care in the United States.

Research Gap	Key Questions* or Contextual Questions	Direct/ Indirect Pathway <sup>†</sup>	Type of Gap <sup>‡</sup>	Study Characteristics	Population	Intervention/Comparison	Outcomes/Timing	Setting
2. Potential intervention harms, particularly those associated with maternal emotional well-being (e.g., feelings of depression, anxiety, guilt, failure, or shame) and quality of life.	KQ1, KQ3	Direct	Grade change Health disparities General	Randomized, controlled trials <sup>§</sup>	Adolescents or adults involved with or making decisions about feeding their child.  Studies should be representative of persons living in the United States and include populations who experience disparities in breastfeeding rates in sufficient numbers for preplanned subgroup analyses.	Interventions: Designed to support breastfeeding and the consumption of breast milk, including individual or group counseling, peer counseling, home visits, structured education, technology- or computer-based support, distribution of written materials, and support provided prenatally, at time of delivery, or postpartum.  Comparisons: Usual care, wait list control, no intervention, or attention control.	<u>Harms</u> potentially associated with breastfeeding intervention such as feelings of guilt, failure, or anxiety related to infant feeding, postpartum depression, and adverse newborn outcomes.	Any healthcare- or community-based setting, including services provided in-home or virtually/remotely, applicable to primary care in the United States.
3. Benefits and harms of breastfeeding support interventions in populations who experience challenges to breastfeeding.	KQs1–3	Both	Grade change Health disparities General	Randomized, controlled trials <sup>§</sup>	Adolescents or adults involved with or making decisions about feeding their child, who are members of groups that experience challenges to breastfeeding, such as:  Women who are Black, low-income, or living in rural locations.  Women returning to work or infants entering a new care situation (e.g., daycare, nanny).  Women contemplating breastfeeding or providing breast milk to their infant.	Interventions: Support interventions described above that are tailored to meet the needs of populations who experience challenges to breastfeeding.  Comparisons: Usual care, wait list control, no intervention, or attention control.	<u>Short- and medium-term maternal health outcomes</u> such as rates of diabetes mellitus, weight, quality of life, or mental health symptoms.  <u>Short- and medium-term infant and child health outcomes</u> such as gastrointestinal symptoms, atopic dermatitis, respiratory symptoms, otitis media, asthma, or growth.  <u>Breastfeeding</u> measures should be described by duration, intensity, exclusivity, and mode of breast milk consumption.  <u>Relationship between breastfeeding measures and health outcomes.</u>	Any healthcare- or community-based setting, including services provided in-home or virtually/remotely, applicable to primary care in the United States.

Research Gap	Key Questions* or Contextual Questions	Direct/ Indirect Pathway <sup>†</sup>	Type of Gap <sup>‡</sup>	Study Characteristics	Population	Intervention/Comparison	Outcomes/Timing	Setting
					Women intending to bottle feed expressed milk.			

\*Key questions are an integral part of the approach to conducting systematic reviews that the USPSTF uses in its recommendation process. Along with the analytic framework, these questions specify the logic and scope of the topic, and are critical to guiding the literature searches, data abstraction, and analysis processes. (<https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual>)

<sup>†</sup>The direct pathway is typically derived from RCTs of the targeted screening or preventive intervention that adequately measure the desired health outcomes in the population(s) of interest. If certainty for net benefit cannot be derived from the direct pathway, then the USPSTF determines if the evidence is sufficient across the key questions and linkages in the indirect pathway to determine overall certainty.

<sup>‡</sup>Types of gaps may include grade assignment (moving from an I statement to a letter grade), change in letter grade (e.g., from a C to B or C to D), health disparities (e.g., populations with a disproportionate burden of the condition), combined (e.g., grade assignment and health disparities), and general gap (e.g., uptake of a clinical preventive service).

<sup>§</sup>Randomized, controlled trials can include, but are not limited to, parallel, cluster, pragmatic, factorial, and stepped wedge trial designs, as appropriate.

**Abbreviations:** KQ=key question; RCT=randomized, controlled trial; USPSTF=US Preventive Services Task Force.