



November 5, 2014

United States Preventive Services Task Force
540 Gaither Road
Rockville, MD 20850

To Whom It May Concern:

We, the undersigned organizations, appreciate the opportunity to provide comments on the United States Preventive Services Task Force “Draft Research Plan for Breastfeeding: Primary Care Interventions”, released for public comment on October 9, 2014. We hope you find our comments helpful and we look forward to your response in the forthcoming Draft Recommendations. We are submitting a letter from the signatories at the end of this letter, under the joint auspices of...

...The **United States Breastfeeding Committee** (USBC) is an independent nonprofit coalition of over 50 nationally influential professional, educational and governmental organizations. The United States Breastfeeding Committee and member organizations work to advance breastfeeding on our nation’s agenda through collaboration, leadership and advocacy.

...The **Coalition for Quality Maternity Care** (CQMC), a group of national professional, consumer and human rights organizations that promote high-quality maternity care for all women and newborns.

Conceptual Perspective:

We suggest USPSTF acknowledge that breastfeeding/human milk provision by infant’s mother is different from most interventions in that it is the natural, physiologically designed intervention to provide the infant with antibodies and optimal nutrition. In fact, there is some evidence that a mother’s milk is customized for her infant.¹ The questions then arise around the ability to quantify the benefits to the infant of receiving human milk, the health benefits to the mother of providing breast milk to her infant, any contraindications to the infant in receiving human milk (distinguishing between milk from the infant’s mother and donated milk), and the efficacy of individual and system wide interventions/supports to promote the initiation, exclusivity, and duration of breastfeeding/human milk provision. Quantifiable short and long-term positive effects on the health of infants and mothers, in the absence of contraindications, would support and guide the direction of recommendations for commitment of resources in primary care.

Proposed Analytic Framework:

We acknowledge that since 2008, when USPSTF first reviewed the breastfeeding evidence base, breastfeeding is now recognized as both an intervention and an outcome. The actions taken by clinicians occur in a rich context of cultural, family, and community influencers. This is among the reasons we urge the inclusion of prospective

¹ Smilowitz JT, O’Sullivan A, Barile D, German JB, Lonnerdal B, & Slupsky CM (2013). J Nutr., 2013 Nov;143(11):1709-18. doi: 10.3945/jn.113.178772. Epub 2013 Sep 11

observational cohort design studies, rather than only controlled trials. While randomized controlled trials are possible for interventions that may affect the outcomes of breastfeeding and the use of human milk, it is unethical to use RCT's to study the outcome of health and disease as they may be affected by breastfeeding and the use of human milk. Several studies stemming from the widely recognized RCT in Belarus² have examined not only the outcomes of breastfeeding intensity, but also differences in disease patterns that may be explained by breastfeeding (as a result of the intervention). Using the intent to treat analysis such studies may be deemed the highest quality, but it is recognized that residual confounding effects of feeding choice may still affect them.

Breastfeeding initiation, exclusivity, and duration are often variously defined across studies. It is, therefore, important to note the definitions used in a given study. We urge the adoption and use of the following definitions as a baseline:

- **Initiation:** The act of providing one's own milk to an infant.
- **Exclusivity:** Exclusive breast milk feeding is defined as a newborn/infant receiving only breast milk and no other liquids (including water) or solids except for drops of syrups consisting of vitamins, minerals, or medicines. Breast milk feeding includes expressed mother's milk as well as donor human milk, both of which may be fed to the infant by means other than suckling at the breast. [Distinctions between the provision of the mother's milk and donor milk should be noted in the review.]
- **Duration:** The total length of time an infant/child receives any human milk.

Although it is understood that USPSTF is concerned with clinical interventions rather than implementation and advocacy, we support explicit inclusion of the baby as a distinct beneficiary/entity in the Proposed Analytic Framework. Though this may seem subtle, it has large implementation and advocacy implications as to who receives required covered services.

We strongly encourage USPSTF to take note of research funding for every study included in the review. Commercial influence, both direct and indirect, is a vital consideration and complication in this field. We recommend it be both a component of the process and the published conclusions.

Proposed Key Question 1:

What are the effects of prenatal, peripartum, and postpartum individual and system-level interventions to promote and support breastfeeding on short and long-term child and maternal health outcomes?

The wording of this key question implies that individual and system-level interventions ultimately result in health outcomes that are related to breastfeeding, but it is also important to consider first the most current literature linking maternal and child health outcomes, with breastfeeding and the use of human milk. Several additional health outcomes have been identified since the 2008 review and should be further reviewed. Furthermore, these associations may require stratified analyses for breastfeeding, breast milk feeding, and donor milk feeding to fully understand the impact of different feeding patterns on maternal and child health outcomes. With this understanding, literature that defines interventions should identify the outcome as breastfeeding (overall and exclusive), breast milk feeding, and other use of human milk.

Baby-Friendly USA is actively engaged in developing a designation program for breastfeeding support in the NICU. The U.S. program will be modeled after the international initiative but will be modified for applicability to the U.S. health care system and maternity laws.

² Kramer MS, Chalmers B, Hodnett ED, et al., for the PROBIT Study Group. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. *JAMA*. 2001;285(4):413–420

Separate research for the pre-term versus the term infant will be helpful to the development of new guidelines for clinical practice for the preterm population.

Does the effectiveness of breastfeeding interventions differ by the population subgroups of age, race/ethnicity and socioeconomic status?

No specific comment.

Are there intervention characteristics that influence the effectiveness of breastfeeding interventions?

Research that provides more evidence regarding the timing of the provision of prenatal breastfeeding education as well as the method of delivery of said information will help inform clinical practice. In addition to an evaluation of traditional educational methods, such as written and verbal, an evaluation of the effectiveness and safety of new methods of reaching mothers through new technological opportunities will help guide education into the future.

Research that provides evidence of the effectiveness of prenatal breastfeeding education delivered at specific settings such as a prenatal service affiliated with a comprehensive health care institution compared to non-affiliated settings will help drive the creation of future programs.

Proposed Key Question 2:

What are the effects of prenatal, peripartum, and postpartum individual and system-level interventions to promote and support breastfeeding on initiation, duration and exclusivity of breastfeeding?

Does the effectiveness of breastfeeding interventions differ by the population subgroups of age, race/ethnicity and socioeconomic status?

No specific comment.

Are there intervention characteristics that influence the effectiveness of breastfeeding interventions?

We recommend specific examination of evidence for the effect of timing on the promotion of breastfeeding outcomes. In a large national qualitative study of the process by which women make infant feeding decisions, it was noted that women making a *confident commitment* to breastfeed in the prenatal period were able to achieve this goal despite lack of support or considerable obstacles. While this hypothesis needs to be tested quantitatively, it may be important in the evidence review to look at the achievement of breastfeeding outcomes in relation to the timing of interventions (prenatal vs postpartum periods).³

³ Avery, A., Zimmerman, K., Underwood, P., & Magnus, J.H. (2009). *Birth*, 36, 141-148. DOI: 10.1111/j.1523-536x.2009.00312x

We also recommend the specific mention of “provider” as a variable of intervention effectiveness. Existing studies have examined the use of clinicians as well as community peer coaches in supporting breastfeeding. In addition, newer studies are testing virtual support applications.

This review should include analyses that determine characteristics that influence effectiveness of breastfeeding interventions, particularly for disproportionately impacted populations. To further collective understanding of structural inequities that lead to breastfeeding disparities, we encourage USPSTF to review the evidence as well as highlight research gaps, and include evidence in the area of community-based participatory research (CBPR) in breastfeeding. CBPR equitably involves community members, organizational representatives and researchers working together to further the research agenda, particularly in topics of equity, such that all partners contribute expertise, share decision-making and ownership.

Proposed Key Question 3:

Are there adverse events associated with interventions to promote and support breastfeeding?

No specific comment.

Proposed Contextual Question:

What are the benefits and harms of breastfeeding, including using expressed or donated breast milk, on short and long-term health outcomes in children and mothers?

We recommend two changes in relation to this question:

1. Divide it into two questions separating breastfeeding/provision of mother’s milk from donated milk. Donated milk/milk sharing has separate risks inherent in the quality, preservation and transport especially when it occurs outside of supervised/regulated process.
2. With respect to the separate question: *What are the benefits and harms of breastfeeding, including expressed milk?* We recommend a change in the word “harms”. Although benefits versus harms is the standard nomenclature for evidence review, the use of the word harms for a natural physiologic process seems both inappropriate and prejudicial. The term “contra-indications” might be more appropriate, because there are instances in which an infant should not be suckling or receiving its mother’s milk. In no other mammalian species do we raise the question of whether nursing the infant is harmful. While this comment may verge on the political rather than the strictly scientific, commercial enterprises are only too eager to misuse science to their own benefit and it is prudent to minimize the opportunity.

Proposed Research Approach:

Study design:

We strongly support the inclusion of prospective cohort design studies across settings, especially if repeated with same conclusions, and using statistical methods to address confounding such as propensity scoring.

We also recommend excluding case report series.

We strongly urge caution when examining conclusions of studies evaluating the sustainability of the evidence-based practices to support breastfeeding among Baby-Friendly designated hospitals. Annual monitoring procedures may vary from country to country. In 2012, Baby-Friendly USA implemented an annual quality improvement and monitoring program aimed at ensuring sustainability of the *Ten Steps to Successful Breastfeeding* among Baby-Friendly designated hospitals in the U.S. Studies evaluating data collected from Baby-Friendly designated hospitals prior to 2012 will not reflect this policy change.

Study aim:

We encourage that this be broadened to include adolescent, pre-conception care, exploring if we could impact clinical interventions that effect breastfeeding.

Condition:

We encourage that this be broadened to include donor human milk from HMBANA non-profit milk banks. Specifically of interest is the question, “Does exclusive breast milk feeding improve breastfeeding rates?” This is particularly pertinent in the NICU.

Population:

Given the NICHD definitions for late preterm as newborns 34 0/7 to 36 6/7 weeks gestation, we recommend adjusting population definition to: term and near-term newborns as well as late-preterm newborns with gestational age equal to or greater than 35 weeks, and birth weight >2500 grams.

Interventions:

Breastfeeding and use of human milk (consider expressed mothers milk and donor milk), and may suggest stratifying outcomes based on breastfeeding vs. provision of human milk via other means.

Add “*Ten Steps to Successful Breastfeeding*” specifically to the hospital interventions of interest.

Make it clearer that interventions that prepare breastfeeding mothers to return to work and primary care interventions that collaborate with community systems would be included in the review. This is especially important in view of healthcare system transitions to interprofessional practice and the emergence of Accountable Care Organizations, and medical homes, etc.

Setting:

No specific comment.

Comparators:

No specific comment.

Outcomes:

No specific comment.

Language:

No specific comment.

Quality:

No specific comment.

Again, thank you for providing us with this opportunity to comment on this very important research plan, which has the potential to inform and promote evidence-based breastfeeding interventions, and ultimately, to improve access to care for the majority of women. Should you have any questions, please feel free to contact Amelia Psmythe, Deputy Director of United States Breastfeeding Committee at apsmythe@usbreastfeeding.org or 202.367.1132 x23.

Signatory organizations:

Academy of Nutrition and Dietetics
American Academy of Pediatrics
American Association of Birth Centers
American College of Nurse-Midwives
American College of Osteopathic Pediatricians
Baby-Friendly USA
BirthingBliss
Breastfeeding Coalition of Oregon
California WIC Association
Carolina Global Breastfeeding Institute
Centering Healthcare Institute
International Center for Traditional Childbearing
International Childbirth Education Association
International Board of Lactation Consultant Examiners
La Leche League USA
Lamaze International
Midwives Alliance of North America
National Women's Health Network
National Association of Certified Professional Midwives
NYC Breastfeeding Leadership Council
New Mexico Breastfeeding Task Force
Wellstart International
Worksites for Wellness