EDITORIAL

Interventions Intended to Support Breastfeeding
Updated Assessment of Benefits and Harms

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In this issue of *JAMA*, the US Preventive Services Task Force (USPSTF) has updated its recommendations on primary care interventions to support breastfeeding.[1] Based on the accompanying evidence review by Patnode and colleagues,[2] who evaluated studies conducted in settings classified as having very high human development,[1,2] the USPSTF concluded that, based on fair- to good-quality studies, there is adequate evidence to recommend primary care interventions to support breastfeeding (B recommendation).

However, the evidence review[2] may generate controversy because only individual-level interventions demonstrated effectiveness at improving breastfeeding, whereas system-level interventions, including the World Health Organization's Baby-Friendly Hospital Initiative (BFHI),[3] did not. The evidence review also highlighted other areas in which more attention is needed: few studies with a randomized design or with a before-and-after design with concurrent controls have examined the effect of primary care interventions on health outcomes or adverse events. To improve breastfeeding rates in the United States, new evidence-based strategies may be needed. To strengthen the research on effective interventions to increase breastfeeding, several key issues need to be carefully considered, along with their clinical and research implications and their broader potential social and cultural repercussions.

The evidence review included 43 studies evaluating the effectiveness of individual-level primary care interventions to support breastfeeding. The studies reported the positive effect that individual-level support provides to a breastfeeding dyad, particularly if support is given at multiple time points, and reinforce the USPSTF recommendation to provide interventions during pregnancy and after birth. Although breastfeeding is a natural process, mothers and infants sometimes have difficulty breastfeeding and need instruction and assistance from trained personnel. The USPSTF estimated that for every 30 dyads provided breastfeeding support, 1 dyad will breastfeed for up to 6 months. Ensuring that prenatal, perinatal, postpartum, and pediatric personnel have appropriate training in breastfeeding support is thus an integral component of primary care.

In contrast to the evidence supporting individual-level interventions, the evidence review included 9 fair- to good-quality studies evaluating the effectiveness of system-level primary care interventions to support breastfeeding and reported that there was no consistent association between system-level interventions and any beneficial outcomes. Certification by BFHI was specifically evaluated in 2 studies[4,5] with concurrent control groups from 5 US states and was not associated with increased breastfeeding duration; a study from Australia,[6] not included in the evidence review, reported similar results. The evidence review by Patnode and colleagues noted that many before-and-after studies without a concurrent control group show an association between system-level interventions and breastfeeding outcomes; the authors excluded these because of their study design.

One included study presented good-quality evidence that BFHI certification may be beneficial for mothers of low educational attainment, although it was ineffective for mothers overall.[5] Thus, BFHI may be beneficial for specific groups of mothers. Using clinical judgment individualized for each mother and infant may result in better outcomes than following a rigid system of practices. Because so many public health and medical resources are being directed to system-level interventions to support breastfeeding, this area is of high importance for future research.

Any intervention, no matter how well-intentioned, carries a risk of adverse events. The USPSTF attempted to evaluate adverse events from primary care interventions to support breastfeeding. However, only 2 studies were identified as reporting any adverse events, and both focused on maternal outcomes. This limited evidence, especially for infants, should prompt additional research; all federally funded studies require collecting data on adverse events, and these should be reported.

In addition, 2 controversial areas (counseling mothers to avoid pacifiers and to avoid feedings other than breast milk) could present potential risk associated with primary care interventions to support breastfeeding.

Counseling to avoid the use of pacifiers in the newborn period is an intervention commonly used to support breastfeeding. However, evidence has been building that infant use of a pacifier may be associated with a reduced risk of sudden infant death syndrome,[7] the most common cause of postneonatal death in the United States. The evidence review showed that avoiding pacifiers was not associated with any breastfeeding outcomes assessed in the evidence review. A recent Cochrane systematic review reached the same conclusion.[8] Thus, routine counseling to avoid pacifiers may very well be ethically problematic.

Counseling to avoid pacifiers is listed in step 9 of the "Ten Steps of Successful Breastfeeding" of the BFHI.[3] The Ten Steps

were established in 1991, and although their implementation has been updated, the steps apparently cannot be changed. Therefore, US institutions will need to disengage from the Ten Steps if they conclude that the scientific evidence that conflicts with them is valid.

A second potentially controversial area involves use of feedings other than breast milk. Counseling mothers to avoid giving infants any food or drink other than breast milk during the newborn period is step 6 of the BFHI and one of the primary care interventions most commonly used to support breastfeeding. Three randomized trials have specifically examined the effectiveness of counseling to avoid giving newborns any food or drink other than breast milk[9-11]; none showed a beneficial effect of such counseling on breastfeeding duration. Studies examining counseling to avoid giving newborns any food or drink other than breast milk were not included in the evidence review. The authors did include several studies examining the effectiveness of multiple-component interventions that incorporated such counseling.[4,5,12] These studies also did not show a beneficial effect on breastfeeding outcomes.

Lack of proven efficacy for exclusive breastfeeding during the newborn period to improve breastfeeding duration is important, because exclusivity during the newborn period may not be free of potential harm. For example, the onset of copious breast milk production varies.[13] For women who have scant colostrum and no copious milk production for 4 to 7 days, exclusive breastfeeding in the first few days after birth is associated with increased risk of hyperbilirubinemia, dehydration, and readmission.[14-16] Although these conditions are generally mild and often resolve rapidly, their frequency is high; 1% to 2% of all US newborns require readmission in the first week after birth, and the risk is approximately doubled for those exclusively breastfed.[15,17] If counseling to avoid food and drink other than breast milk is not an effective method to support breastfeeding, the frequent low morbidity and rare high morbidity outcomes could potentially be avoided without reducing breastfeeding duration. In combination with the new recommendations to introduce allergenic foods by age 4 to 6 months for certain infants,[18] these data emphasize that individual clinical judgment may be more valuable than a single rigid rule for exclusive breastfeeding for the first 6 months.

The scope of the USPSTF review of primary care interventions to support breastfeeding did not extend to the effect of such interventions on social issues, such as gender equity in parenting and employment, but the authors noted that policy decisions regarding this topic involve considerations in addition to clinical benefits and harms. In deciding whether to breastfeed, mothers face an evolving social and economic landscape. Working men and women born 1980-2000 (millennials) have near equity in salaries at the start of their working lives.[19] As they begin families, however, historical difficulties for women in the workplace may continue to emerge. In a 2013 survey of working parents with children younger than 18 years, 51% of 479 women reported that being a working mother makes it more difficult to advance in their career, whereas 16% of 561 men reported that being a working father makes it difficult to advance.[19]

Interventions such as pumping breast milk when mothers are separated from their infants have the potential to contribute to women's employment-related decisions and could potentially aggravate the trend toward gender disparities in employment. This effect may be ameliorated by emerging factors such as the increasing availability of paternity leave. However, it will remain true that women have a unique, time-specific responsibility with respect to provision of breast milk. Therefore, when primary care interventions are successful in encouraging breastfeeding, a disproportionate burden will continue to be placed on women until and perhaps even when progressive policies become commonplace. Workplace accommodations are needed for lactating mothers, and the importance of social factors should be considered when making policy decisions.

Based on the evidence review by Patnode and colleagues,[2] individual-level interventions to support breastfeeding, such as professional lactation support and peer support, have been demonstrated to be effective, even though system-level interventions, such as BFHI or hospital policies, have not. An approach to breastfeeding support with decisions tailored to the individual patient may be effective at promoting individual breastfeeding duration, whereas a single, uniform approach is ineffective at improving breastfeeding duration of the population. To improve breastfeeding rates in the United States, further implementation of system-level interventions such as the BFHI for the general population should be reconsidered until good-quality evidence emerges that these interventions are safe and effective. Implementation of ineffective strategies, potentially those not based on evidence, may divert resources from effective interventions at the individual level and risk causing unnecessary harm.

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