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Primary Care Interventions to Support Breastfeeding
Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

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IMPORTANCE Although 80% of infants in the United States start breastfeeding, only 22% are exclusively breastfed up to around 6 months as recommended by a number of professional organizations.

OBJECTIVE To systematically review the evidence on the benefits and harms of breastfeeding interventions to support the US Preventive Services Task Force in updating its 2008 recommendation.

DATA SOURCES MEDLINE, PubMed, Cumulative Index for Nursing and Allied Health Literature, Cochrane Central Register of Controlled Trials, and PsycINFO for studies published in the English language between January 1, 2008, and September 25, 2015. Studies included in the previous review were re-evaluated for inclusion. Surveillance for new evidence in targeted publications was conducted through January 26, 2016.

STUDY SELECTION Review of randomized clinical trials and before-and-after studies with concurrent controls conducted in a developed country that evaluated a primary care–relevant breastfeeding intervention among mothers of full- or near-term infants. Of 211 full-text articles reviewed, 52 studies met inclusion criteria. Thirty-one studies were newly identified, and 21 studies were carried forward from the previous review.

DATA EXTRACTION AND SYNTHESIS Independent critical appraisal of all provisionally included studies. Data were independently abstracted by one reviewer and confirmed by another.

MAIN OUTCOMES AND MEASURES Child and maternal health outcomes, rates and duration of breastfeeding, and harms related to interventions as prespecified before data collection.

RESULTS Fifty-two studies (n = 66 757) in 57 publications were included. Six trials (n = 2219) reported inconsistent effects of the interventions on infant health outcomes; no studies reported maternal health outcomes. Pooled estimates based on random-effects meta-analyses using the DerSimonian and Laird method indicated beneficial associations between individual-level breastfeeding interventions and any breastfeeding for less than 3 months (risk ratio [RR], 1.07 [95% CI, 1.03-1.11]; 26 studies [n = 11 588]), at 3 to less than 6 months (RR, 1.11 [95% CI, 1.04-1.18]; 23 studies [n = 8942]), and for exclusive breastfeeding for less than 3 months (RR, 1.21 [95% CI, 1.11-1.33]; 22 studies [n = 8246]), 3 to less than 6 months (RR, 1.20 [95% CI, 1.05-1.38]; 18 studies [n = 7027]), and at 6 months (RR, 1.16 [95% CI, 1.02-1.32]; 17 studies [n = 7690]). Absolute differences in the rates of any breastfeeding ranged from 14.1% in favor of the control group to 18.4% in favor of the intervention group. There was no significant association between interventions and breastfeeding initiation (RR, 1.00 [95% CI, 0.99-1.02]; 14 studies [n = 9428]). There was limited mixed evidence of an association between system-level interventions and rates of breastfeeding from well-controlled studies as well as for harms related to breastfeeding interventions, including maternal anxiety scores, decreased confidence, and concerns about confidentiality.

CONCLUSIONS AND RELEVANCE The updated evidence confirms that breastfeeding support interventions are associated with an increase in the rates of any and exclusive breastfeeding. There are limited well-controlled studies examining the effectiveness of system-level policies and practices on rates of breastfeeding or child health and none for maternal health.

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Breastfeeding is associated with beneficial health outcomes for both the child and mother.[1-11] Multiple US-based and international organizations recommend exclusive breastfeeding up to or around 6 months, followed by continued breastfeeding for at least 1 year as mutually desired by mother and infant.[12-15] Despite 80% of infants in the United States ever having been breastfed, only 21.9% of infants born in 2012 were exclusively breastfed through 6 months, and substantial disparities in rates of breastfeeding exist.[16] A number of health care interventions may support breastfeeding, including prenatal education, individual-level support provided by health care professionals or peer counselors at or around the time of delivery and postpartum, and system-level policies and maternity care practices, including the Baby-Friendly Hospital Initiative (BFHI).

In 2008, the US Preventive Services Task Force (USPSTF) recommended interventions during pregnancy and after birth to promote and support breastfeeding (B recommendation).[17] The recommendation was based on 2 separate systematic reviews: a 2007 review on the relationship between breastfeeding and infant and maternal health outcomes[1] and a 2008 review on the effectiveness of interventions to support breastfeeding.[18] The purpose of the current review was to update the 2008 review on interventions to support breastfeeding to help the USPSTF update their recommendation.

Methods

Scope of Review

This review addressed 3 key questions (KQs) as shown in **Figure 1**. Methodological details (including search strategies, detailed study inclusion criteria, excluded studies, and description of data analyses) as well as more detailed results are publicly available in the full evidence report available at http://www.uspreventiveservicestaskforce.org/Page/Document/final-evidence-review141/breastfeeding-primary-care-interventions.

Data Sources and Searches

Forty-one studies (in 42 articles) included in the 2008 review[18,20] were re-evaluated, and the following databases were searched for new relevant English-language literature published between January 1, 2008, and September 25, 2015: MEDLINE, PubMED (for publisher-supplied records only), PsycINFO, CINAHL (Cumulative Index for Nursing and Allied Health Literature), and CENTRAL (Cochrane Central Register of Controlled Trials) (eMethods in the Supplement). The database searches were supplemented by reviewing bibliographies from other relevant literature and from expert suggestions. ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform were searched for ongoing trials. Since October 2015, ongoing surveillance was conducted through article alerts and targeted searches of high-impact journals to identify major studies published in the interim that may affect the conclusions or understanding of the evidence and therefore the related USPSTF recommendation. The last surveillance was conducted on January 26, 2016, and identified no new studies.

Study Selection

Two reviewers independently reviewed all identified titles and abstracts and then relevant full-text articles against prespecified inclusion and exclusion criteria (eTable 1 in the Supplement). Discrepancies were resolved through discussion and consensus. Fair- and good-quality randomized clinical trials (RCTs) and before-and-after studies with concurrent controls among mothers of full- or near-term infants, as well as members of the mother-infant support system (eg, partners, grandparents, or friends), were eligible. Included studies targeted the effects of prenatal, peripartum, or postpartum breastfeeding interventions initiated in, feasible for, or referable from primary care settings. Infant health outcomes included, but were not limited to, gastrointestinal illness, otitis media, respiratory illness, asthma, atopic dermatitis, and infant health care utilization (as a proxy for health outcomes). Maternal health outcomes included those such as postpartum weight loss and incidence of breast cancer. Breastfeeding outcomes included self-reported or observed initiation of breastfeeding, or the prevalence and duration of any or exclusive breastfeeding. For adverse events, harms that could be related to a breastfeeding intervention (eg, feeling criticized by the interventionist, guilt related to not starting breastfeeding or stopping breastfeeding) were included; harms related to breastfeeding itself (eg, mastitis, nipple pain) were excluded. Studies were required to take place in developed countries, defined as "very high" (>0.9) on the 2014 United Nations Human Development Index[21] to ensure that the evidence was applicable to a US setting.

Data Extraction and Quality Assessment

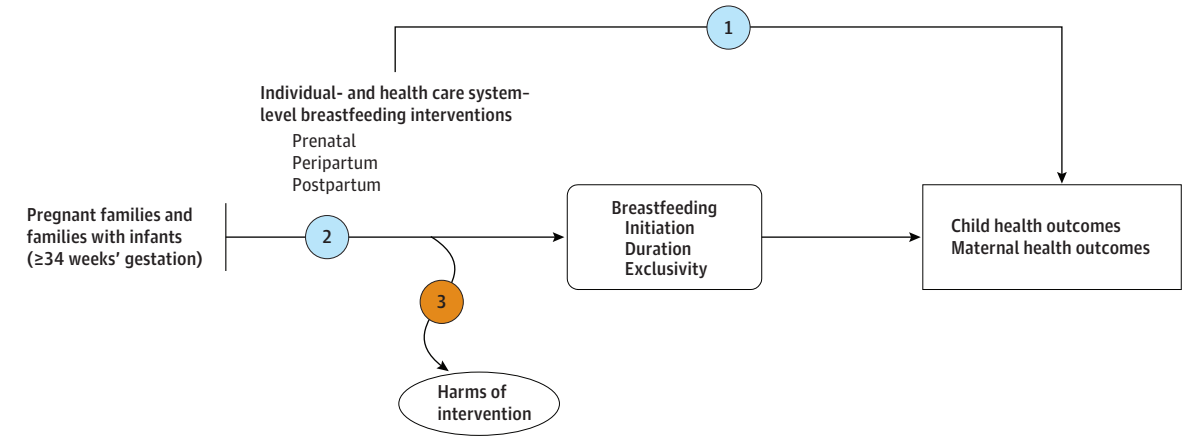
Two reviewers independently assessed the methodological quality of all eligible studies, including the original studies, using the USPSTF study design–specific criteria (eTable 2 in the Supplement).[22] Each study was assigned a final quality rating of good, fair, or poor; disagreements between the investigators were resolved through discussion. Studies were rated as poor quality and excluded if there were several major risks of bias (eg, evidence of selection bias or confounding, attrition greater than 40%, differential attrition higher than 20% and not accounting for missing data, inadequate assessor blinding) that could invalidate the results.[22] One reviewer completed primary data abstraction, and a second reviewer checked all data for accuracy and completeness.

Data Synthesis and Analysis

Summary tables were created for study characteristics, population characteristics, intervention characteristics, and outcomes separately for each KQ. The data on health outcomes (KQ1) and adverse events (KQ3) did not allow for pooled analyses and so were summarized descriptively. For breastfeeding outcomes (KQ2), the results of studies among adolescents or young adults (ie, women 21 years or younger) and those among adults were synthesized separately. The results for adults were organized by the level of intervention (individual vs system) and, owing to the clinical heterogeneity between them, were not pooled across these intervention types. Individual-level interventions included individual or group counseling provided by professionals, peer support, and structured education, whereas system-level interventions included hospital staff training and hospital policies (eg, the BFHI). Because of the small number of studies available for system-level interventions, those results are reported narratively and without pooling the data.

For individual-level interventions with breastfeeding outcomes, the raw number of events (prevalence of breastfeeding initiation, any breastfeeding, or exclusive breastfeeding) in each

Figure 1. Analytic Framework



Key questions

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

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

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

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

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

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

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

USPSTF indicates US Preventive Services Task Force.

Evidence reviews for the US Preventive Services Task Force (USPSTF) use an analytic framework to visually display the key questions that the review will address to allow the USPSTF to evaluate the effectiveness and safety of a preventive service. The questions are depicted by linkages that relate interventions and outcomes. Dashed line indicates a health outcome that follows an intermediate outcome. Further details are available from the USPSTF procedure manual.[19]

treatment group and the total number of participants randomized for each group were entered into random-effects meta-analyses using the DerSimonian and Laird method[23] to calculate a pooled risk ratio (RR) (with the RR indicating the risk of still breastfeeding). The breastfeeding results were grouped into 5 distinct cross-sectional time points to correspond with US Healthy People 2020 objectives[24]: breastfeeding initiation (at birth up through 1 week postpartum) and breastfeeding less than 3 months (2 through 11 weeks), 3 to less than 6 months (12 through 23 weeks), 6 months (24 through 26 weeks), and 12 months (52 weeks). Each study could be included within more than 1 meta-analysis if it reported corresponding data. Within each study, however, the data from the longest time point within a given time category was chosen if more than 1 time point was reported (eg, if a study reported both 12- and 20-week outcomes, the 20-week results were pooled); with this approach, an individual trial never contributed to more than 1 data point for a given pooled estimate. The specific definition of breastfeeding initiation, any breastfeeding, and exclusive breastfeeding was noted as described by each individual study.

Statistical heterogeneity among the pooled studies was examined using standard χ^2 tests, and the proportion of total variability in point estimates was approximated using the I^2 statistic. Sensitivity analyses using a restricted maximum-likelihood model with the Knapp-Hartung modification were run for all meta-analyses that resulted in substantial heterogeneity ($I^2 > 50\%$).[25] All statistically significant results remained within the restricted maximum-likelihood model, so the results using the DerSimonian and Laird method are shown. To evaluate small-study effects, funnel plots were generated and the Peters test was run to assess statistical significance of imbalance in study size and findings that suggested a pattern.[26]

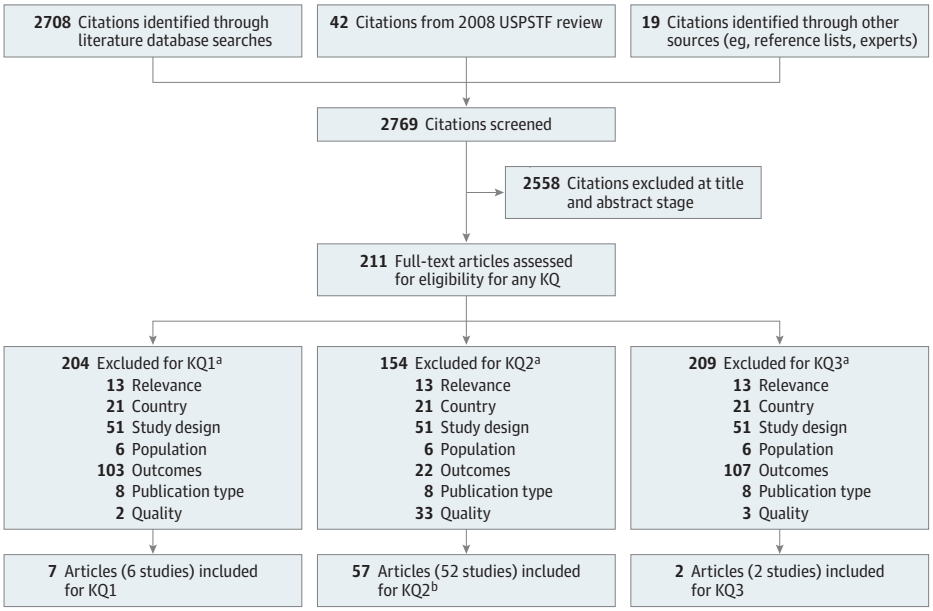
Visual displays were first used to investigate whether the heterogeneity among the results was associated with any prespecified population or intervention characteristics; then, where indicated, meta-regression and subgroup analyses were used.

Stata version 13.1 (Stata Corp) was used for all quantitative analyses. All significance testing was 2-sided, and results were considered statistically significant if the *P* value was .05 or less.

Results

In total, 2769 titles and abstracts and 211 articles were reviewed against the prespecified inclusion criteria, and 52 studies (n = 66 757 participants [including 50 RCTs, with n = 39 416 participants]) reported in 57 publications were included (**Figure 2**).[27-83] Only 21 studies (in 22

Figure 2. Literature Flow Diagram



KQ indicates key question.

[a] Details about reasons for exclusion are as follows. Relevance: Study aim was not relevant. Country: Study was not conducted in a country relevant to US practice. Design: Study did not use an included design. Population: Study was not conducted in an included population. Outcomes: Study did not have relevant outcomes or had incomplete outcomes. Publication type: The study design was not an included type. Quality: Study was poor quality.

[b] Two studies were reported in a single publication.

articles[28,30,31,33,36,38,41,43,46,49,52,58,59,61-63,65,69,71,75,78,79]) were carried forward from the previous review and were synthesized with the new evidence. The main reason for exclusion for the previously included studies was poor quality (the previous review included poor-quality studies). Thirty-one studies were identified as part of the update. The included studies were highly variable in terms of their country setting, study population, intervention and control conditions, specific outcome measures and timing of those measures, and methodological quality (eTable 3 in the Supplement).

Effects of Interventions on Health Outcomes

Key Question 1. What are the effects of prenatal, peripartum, and postpartum individual- and health care system–level interventions to promote and support breastfeeding on short- and long-term child and maternal health outcomes?

Key Question 1a. Does the effectiveness of breastfeeding interventions differ by the population subgroups based on age, race/ethnicity, and socioeconomic status?

Key Question 1b. Are there intervention characteristics that influence the effectiveness of breastfeeding interventions?

Six of the 52 included studies (n = 2219) reported the effects of a breastfeeding intervention on infant health outcomes, with mixed results.[28,30,32,35,43,51] For gastrointestinal outcomes, 1 trial (n = 182) found that the control group was more likely to have 1 or more diarrheal episodes during the 3-month follow-up period compared with the intervention group (RR, 2.15 [95% CI, 1.16 to 3.97]), and this was supported by higher rates of exclusive breastfeeding in the intervention group.[28] A second trial (n = 338), however, did not report a statistically significant difference in the rates of gastrointestinal tract illnesses between intervention vs control groups at 1 year (22.7% vs 25.7%), despite the women in the intervention group breastfeeding for a statistically significant longer duration than the women in the control group.[30] Likewise, within this same trial, there was no statistically significant between-group difference in the rates of otitis media (43.6% vs 54.9%) or the number of health care visits for respiratory tract illnesses (76.7% vs 83.4%) for intervention vs control participants.[30]

Three of 4 trials[32,35,43,51] that reported rates of infant health care utilization found higher use among those in the usual care control groups (within-group rates ranging from 2.8% to 36.0%) than among those who received intervention (within-group rates ranging from 1.2% to 25.0%). None of these 3 trials, however, reported an effect of the intervention on the rates of breastfeeding. The data were too sparsely reported to examine whether the effectiveness of the interventions varied by population subgroup or intervention characteristics. No studies were identified that reported the effects of a breastfeeding intervention on maternal health outcomes.

Effects of Interventions on Breastfeeding

Key Question 2. What are the effects of prenatal, peripartum, and postpartum individual- and health care system–level interventions to promote and support breastfeeding on initiation, duration, and exclusivity of breastfeeding?

Key Question 2a. Does the effectiveness of breastfeeding interventions differ by the population subgroups based on age, race/ethnicity, and socioeconomic status?

Key Question 2b. Are there intervention characteristics that influence the effectiveness of breastfeeding interventions?

All 52 studies (n = 66 757) reported the effect of a breastfeeding intervention on rates of any or exclusive breastfeeding, with time points ranging from initiation shortly after birth to 52 weeks (eTable 4 in the Supplement). Forty-three trials (n = 21 973) evaluated individual-level support and education interventions provided by professionals or peers (39 trials among adults and 4 trials among adolescents or young adults),[27-30,32,34-44,46,49,51,54,56-58,60-63,65-67,69,71,73-80,82,83] whereas 9 studies (7 trials and 2 before-after studies) (n = 44 784) examined the association between a system-level policy or practice and rates of breastfeeding.[33,45,47,48,50,52,55,59,72]

Table 1. Pooled Results of Any and Exclusive Breastfeeding Among Adults, for Individual-Level Breastfeeding Support and Education Interventions (Key Question 2)

	No. of Studies	No.	RR (95% CI)	I^2, %
Any Breastfeeding				
Follow-up time point, mo				
Initiation	14	9428	1.00 (0.99-1.02)	22.8
<3	26	11 588	1.07 (1.03-1.11)	72.0
3 to <6	23	8942	1.11 (1.04-1.18)	46.5
6	20	9715	1.07 (0.98-1.16)	57.5
12	3	1957	Not pooled	Not pooled
Exclusive Breastfeeding				
Follow-up time point, mo				
<3	22	8246	1.21 (1.11-1.33)	52.4
3 to <6	18	7027	1.20 (1.05-1.38)	44.6
6	17	7690	1.16 (1.02-1.32)	14.3
12	0	NA	NA	NA

Abbreviations: NA, not applicable; RR, risk ratio.

Individual-Level Support

Among adults, individual-level support and education interventions were associated with a statistically significant higher likelihood of any and exclusive breastfeeding for less than 3 months and at 3 to less than 6 months and for exclusive (but not any) breastfeeding at 6 months in pooled analyses (**Table 1**). The meta-analysis pooling the 26 trials that reported the prevalence of any breastfeeding for less than 3 months among adults found a statistically significant pooled RR for mothers assigned to a breastfeeding support or education intervention, compared with women in the usual care control groups (1.07 [95% CI, 1.03 to 1.11]; I^2 = 72.0%; n = 11 588) (**Figure 3**). The range in the absolute difference in rates of any breastfeeding was 6.4 percentage points in favor of the control group to 17.5 percentage points in favor of the intervention group. The pooled RR for exclusive breastfeeding for less than 3 months was also statistically significant (RR, 1.21 [95% CI, 1.11 to 1.33]; I^2 = 52.4%; 22 studies [n = 8246]; range in absolute difference, −2.5% to 22.4%) (eFigure 1 in the Supplement). Results were generally consistent for any breastfeeding at 3 to less than 6 months (RR, 1.11 [95% CI, 1.04 to 1.18]; I^2 = 46.5%; 23 studies [n = 8942]; range in absolute difference, −5.8% to 18.4%) (**Figure 4**) and for exclusive breastfeeding at 3 to less than 6 months (RR, 1.20 [95% CI, 1.05 to 1.38]; I^2 = 44.6%; 18 studies [n = 7027]; range in absolute difference, −4.6% to 19.2%) (eFigure 2 in the Supplement).

Twenty trials among adults (n = 9715) reported the proportion of women performing any breastfeeding at 6 months with a lack of consistent effects across the individual trials. When pooled, the association was not statistically significant but did not rule out potential benefit (RR, 1.07 [95% CI, 0.98 to 1.16]; I^2 = 57.5%; range in absolute difference, −14.1% to 12.3%) (**Figure 5**). In contrast, the pooled RR demonstrated a positive association between individual-level support interventions and exclusive breastfeeding at 6 months (RR, 1.16 [95% CI, 1.02 to 1.32]; 17 studies[n = 7690]), with less evidence of statistical heterogeneity (I^2 = 14.3%) (eFigure 3 in the Supplement). Absolute differences in the rates of exclusive breastfeeding at 6 months ranged from 2.9 percentage points in favor of the control group (5.2% vs 8.1% of women in the intervention and control groups, respectively) to 21.0 percentage points (47.7% vs 26.7% of women in the intervention and control groups, respectively). Only 3 trials reported breastfeeding rates at 1 year, and none found a statistically significant difference between treatment groups. The funnel plots for exclusive breastfeeding at less than 3 months and at 6 months revealed asymmetric patterns, and the results of the Peters test for small study effects was statistically significant (P = .047 for <3 months and P = .02 for 6 months).

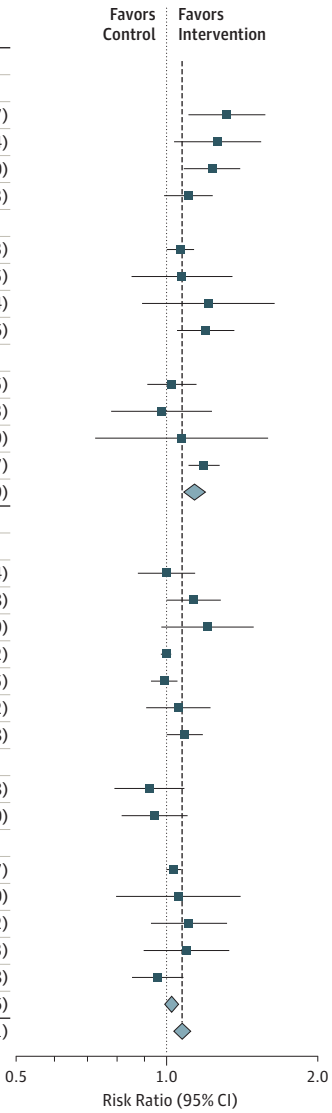
There was no evidence of a relationship between individual-level support and education interventions and breastfeeding initiation after pooling 14 trials (RR, 1.00 [95% CI, 0.99 to 1.02]; I^2 = 22.8%; n = 9428) (eFigure 4 in the Supplement). Despite nearly all 14 trials showing higher rates of breastfeeding initiation among intervention group mothers compared with control group mothers, none of the individual trials found a statistically significant benefit. The breastfeeding initiation rate was relatively high in these studies, ranging from 53.1% to 98.7%. In addition, in all but 4 of these trials, more than 80% of enrolled women intended to initiate breastfeeding (range, 51.6%-100%).

There was some evidence of a differential effect of individual-level interventions on the rates of any breastfeeding for less than 3 months (Figure 3) and 3 to less than 6 months (Figure 4), based on the periods in which the interventions were delivered. For instance, the pooled RR for interventions delivered at more than 1 period (eg, prenatal and postpartum) showed a statistically significant association with any breastfeeding for less than 3 months (RR, 1.14 [95% CI, 1.08 to 1.19]), whereas those delivered at 1 period only (eg, postpartum only) did not show a statistically significant relationship (RR, 1.02 [95% CI, 0.99 to 1.06]) (test for subgroup difference, P = .001) (Figure 3). There was no evidence, however, of effect modification based on the specific type of intervention (professional support, peer support, or education), number of sessions, presence of face-to-face support, or presence of telephone support. The interventions were too variable to determine whether there were any differences by interventionist type or group vs individual session format.

Additionally, there was no evidence that the effectiveness of the interventions varied by specific population characteristics, including by country (United States vs other), breastfeeding status at baseline (whether the trial only included women who had already attempted or established breastfeeding), intention to breastfeed, and previous breastfeeding experience. Demographic variables such as race, ethnicity, and socioeconomic status were too sparsely re-

Figure 3. Pooled Analysis of Randomized Clinical Trials for Any Breastfeeding for Less Than 3 Months

Source	Country	Duration of Intervention, wk	No. Breastfeeding/Total (%)		Risk Ratio (95% CI)
			Intervention	Control	
Timing of intervention: combination of prenatal, peripartum, or postpartum					
Prenatal, peripartum, or postpartum					
Bonuck et al,[30] 2006	United States	68	99/137 (72.3)	85/155 (54.8)	1.32 (1.10-1.57)
Bonuck et al,[29] 2014 (BINGO)	United States	24	172/226 (76.1)	44/73 (60.3)	1.26 (1.03-1.54)
Bonuck et al,[29] 2014 (PAIRINGS)	United States	24	108/124 (87.1)	92/130 (70.8)	1.23 (1.08-1.40)
Chapman et al,[35] 2013	United States	30	71/76 (93.4)	66/78 (84.6)	1.10 (0.99-1.23)
Peripartum and postpartum					
Abbass-Dick et al,[27] 2015	Canada	3	102/104 (98.1)	94/102 (92.2)	1.06 (1.00-1.13)
McQueen et al,[67] 2011	Canada	2	43/61 (70.5)	48/73 (65.8)	1.07 (0.85-1.35)
Pollard,[74] 2011	United States	6	30/41 (73.2)	26/43 (60.5)	1.21 (0.89-1.64)
Su et al,[78] 2007	Singapore	2	108/128 (84.4)	96/136 (70.6)	1.20 (1.05-1.36)
Prenatal and postpartum					
Graffy et al,[46] 2004	United Kingdom	NR	218/336 (64.9)	213/336 (63.4)	1.02 (0.91-1.15)
Jolly et al,[56] 2012	United Kingdom	13	170/271 (62.7)	194/301 (64.5)	0.98 (0.77-1.23)
Muirhead et al,[69] 2006	Scotland	4	35/112 (31.3)	33/113 (29.2)	1.07 (0.72-1.59)
Reeder et al,[76] 2014	United States	42	839/1065 (78.8)	312/470 (66.4)	1.19 (1.10-1.27)
Subtotal: I^2 = 38.6%, P = .08					1.14 (1.08-1.19)
Timing of intervention: only prenatal, peripartum, or postpartum					
Postpartum					
Bunik et al,[32] 2010	United States	2	110/149 (73.8)	122/165 (73.9)	1.00 (0.88-1.14)
Dennis et al,[36] 2002	Canada	26	112/132 (84.8)	93/124 (75.0)	1.13 (1.00-1.28)
Fu et al,[42] 2014	Hong Kong	4	153/261 (58.6)	127/260 (48.8)	1.21 (0.97-1.49)
Gagnon et al,[43] 2002	Canada	1 d	247/252 (98.0)	243/247 (98.4)	1.00 (0.97-1.02)
Hopkinson et al,[51] 2009	United States	1 d	202/226 (89.4)	218/241 (90.5)	0.99 (0.93-1.05)
Labarere et al,[62] 2005	France	1 d	87/112 (77.7)	84/114 (73.7)	1.05 (0.91-1.22)
Paul et al,[73] 2012	United States	2	367/509 (72.1)	326/491 (66.4)	1.09 (1.00-1.18)
Peripartum					
Henderson et al,[49] 2001	Australia	1 d	60/79 (75.9)	65/79 (82.3)	0.92 (0.79-1.08)
Wallace et al,[79] 2006	United Kingdom	1 d	111/172 (64.5)	114/167 (68.3)	0.95 (0.81-1.10)
Prenatal					
Kronborg et al,[60] 2012	Denmark	5	503/535 (94.0)	478/525 (91.0)	1.03 (1.00-1.07)
Lavender et al,[63] 2005	United Kingdom	1 d	332/644 (51.6)	297/605 (49.1)	1.05 (0.79-1.40)
Mattar et al,[65] 2007	Singapore	1 d	79/112 (70.5)	86/135 (63.7)	1.11 (0.93-1.32)
Noel-Weiss et al,[71] 2006	Canada	1 d	40/47 (85.1)	35/45 (77.8)	1.09 (0.90-1.33)
Wong et al,[83] 2014	Hong Kong	1 d	160/233 (68.7)	169/236 (71.6)	0.96 (0.85-1.08)
Subtotal: I^2 = 40.7%, P = .056					1.02 (0.99-1.06)
Overall: I^2 = 72.0%, P <.001					1.07 (1.03-1.11)



Error bars indicate 95% confidence intervals. Significant difference in risk ratios between groups (b = 1.11 [95% CI, 1.05-1.17], SE = 0.03, P = .001). BINGO indicates Best Infant Nutrition for Good Outcomes; PAIRINGS, Provider Approaches to Improved Rates of Infant Nutrition and Growth Study.

ported to examine possible differential effects. The 4 trials limited to adolescents or young adults found beneficial effects consistent with the results among adults.[37,39,75,80]

System-Level Support

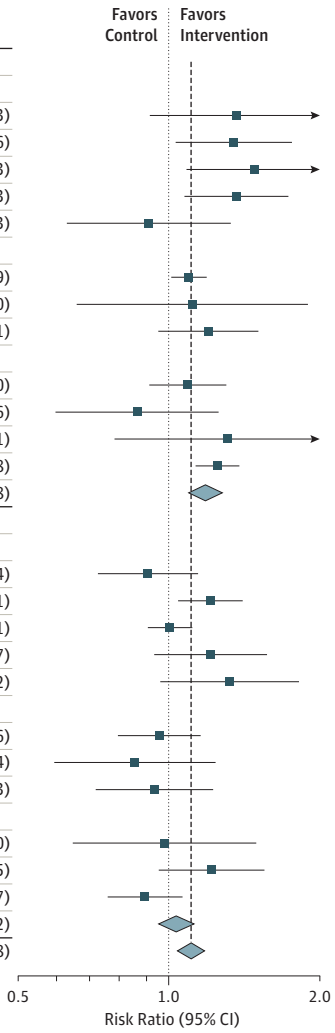
There was no consistent association with the rate of any or exclusive breastfeeding from 9 studies of system-level policy or maternity care practices.[33,45,47,48,50,52,55,59,72] The system-level interventions that were evaluated within these 9 studies included receiving accreditation for the BFHI,[47,48] a clinic policy to provide breastfeeding support groups for pregnant women and breastfeeding mothers,[50] and establishing maternity care practices for maintaining mother and infant contact following delivery[33,45,72] or restricting or delaying pacifier use.[52,55,59] Across these 9 studies (7 RCTs and 2 before-after studies), there was no consistent evidence of an association between system-level changes and the rate of any or exclusive breastfeeding at up to 16 weeks' postpartum. One large observational study (n = 25 327) found a statistically significant higher rate of breastfeeding initiation and exclusive breastfeeding at 4 weeks among women with lower education but not among women overall or among those with higher education after implementation of the BFHI. For example, breastfeeding initiation increased by 3.8 percentage points among mothers who gave birth following BFHI accreditation among women with lower education but only increased by 0.02 percentage points following accreditation among women with higher education.[47]

Harms of Interventions

Key Question 3. Are there adverse events associated with interventions to promote and support breastfeeding?

Figure 4. Pooled Analysis of Randomized Clinical Trials for Any Breastfeeding at 3 to Less Than 6 Months

Source	Country	Duration of Intervention, wk	No. Breastfeeding/Total (%)		Risk Ratio (95% CI)
			Intervention	Control	
Timing of intervention: combination of prenatal, peripartum, or postpartum					
Prenatal, peripartum, or postpartum					
Anderson et al,[28] 2005	United States	14	31/63 (49.2)	26/72 (36.1)	1.36 (0.92-2.03)
Bonuck et al,[30] 2006	United States	68	62/117 (53.0)	55/140 (39.3)	1.35 (1.03-1.76)
Bonuck et al,[29] 2014 (BINGO)	United States	24	127/226 (56.2)	28/74 (37.8)	1.49 (1.09-2.03)
Bonuck et al,[29] 2014 (PAIRINGS)	United States	24	76/125 (60.8)	57/128 (44.5)	1.37 (1.07-1.73)
Chapman et al,[35] 2013	United States	30	26/57 (45.6)	31/62 (50.0)	0.91 (0.63-1.33)
Peripartum and postpartum					
Abbass-Dick et al,[27] 2015	Canada	3	100/104 (96.2)	92/105 (87.6)	1.10 (1.01-1.19)
Pollard,[74] 2011	United States	6	17/41 (41.5)	16/43 (37.2)	1.11 (0.65-1.90)
Su et al,[78] 2007	Singapore	2	71/122 (58.2)	65/134 (48.5)	1.20 (0.95-1.51)
Prenatal and postpartum					
Graffy et al,[46] 2004	United Kingdom	NR	143/310 (46.1)	131/310 (42.3)	1.09 (0.91-1.30)
Kools et al,[58] 2005	The Netherlands	3	119/368 (32.3)	124/330 (37.6)	0.86 (0.59-1.26)
Muirhead et al,[69] 2006	Scotland	4	26/112 (23.2)	20/113 (17.7)	1.31 (0.78-2.21)
Reeder et al,[76] 2014	United States	42	672/1065 (63.1)	237/470 (50.4)	1.25 (1.13-1.38)
Subtotal: I^2 = 31.1%, P = .14					1.18 (1.10-1.28)
Timing of intervention: only prenatal, peripartum, or postpartum					
Postpartum					
Bunik et al,[32] 2010	United States	2	64/130 (49.2)	78/144 (54.2)	0.91 (0.72-1.14)
Dennis et al,[36] 2002	Canada	26	107/132 (81.1)	83/124 (66.9)	1.21 (1.04-1.41)
Elliott-Rudder et al,[40] 2014	Australia	1 d	137/154 (89.0)	156/176 (88.6)	1.01 (0.91-1.11)
Fu et al,[42] 2014	Hong Kong	4	124/261 (47.5)	102/260 (39.2)	1.21 (0.94-1.57)
Labarere et al,[62] 2005	France	1 d	52/112 (46.4)	40/114 (35.1)	1.32 (0.96-1.82)
Peripartum					
Henderson et al,[49] 2001	Australia	1 d	56/78 (71.8)	57/76 (75.0)	0.96 (0.79-1.16)
Labarere et al,[61] 2003	France	1 d	32/93 (32.4)	39/97 (40.2)	0.86 (0.59-1.24)
Wallace et al,[79] 2006	United Kingdom	1 d	64/173 (37.0)	66/167 (39.5)	0.94 (0.71-1.23)
Prenatal					
Lavender et al,[63] 2005	United Kingdom	1 d	202/644 (31.4)	192/605 (31.7)	0.98 (0.64-1.50)
Mattar et al,[65] 2007	Singapore	1 d	64/112 (57.1)	61/130 (46.9)	1.22 (0.95-1.55)
Wong et al,[83] 2014	Hong Kong	1 d	116/233 (49.8)	131/236 (55.5)	0.90 (0.75-1.07)
Subtotal: I^2 = 38.0%, P = .10					1.04 (0.95-1.12)
Overall: I^2 = 46.5%, P = .008					1.11 (1.04-1.18)



Error bars indicate 95% confidence intervals. Significant difference in risk ratios between groups (b = 1.14 [95% CI, 1.02-1.29], SE = 0.06, P = .03). BINGO indicates Best Infant Nutrition for Good Outcomes; PAIRINGS, Provider Approaches to Improved Rates of Infant Nutrition and Growth Study.

Only 2 trials[36,43] reported adverse events related to a breastfeeding intervention. One trial reported no significant difference in maternal state anxiety among women receiving a postpartum home visit vs those receiving usual care (mean difference in score, 0.3 [95% CI, −0.5 to 1.1]).[43] The other trial reported that 2 mothers expressed feelings of anxiety, decreased confidence, or concerns about confidentiality during a peer support intervention and that no such feelings were reported by women receiving usual care.[36]

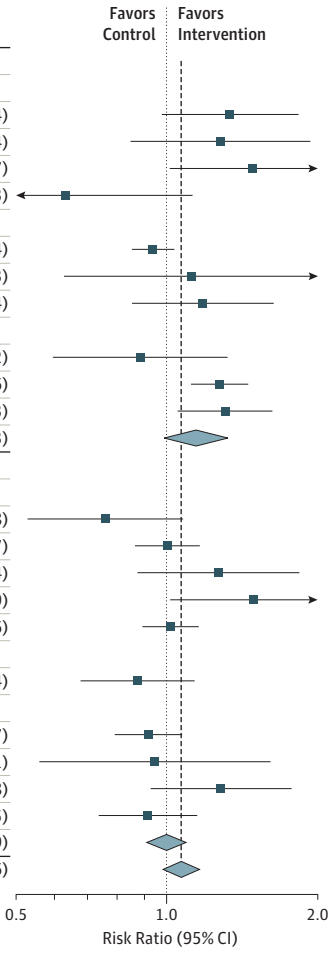
Discussion

This review included 52 fair- to good-quality studies that examined the effectiveness of breastfeeding interventions on rates of breastfeeding. A summary of evidence for all KQs is presented in **Table 2**. Only 6 studies reported results related to infant health outcomes with mixed effects of the interventions. None of the included studies reported the intervention effect on short- or long-term maternal health outcomes. Individual-level breastfeeding support and education interventions increased the relative likelihood of women breastfeeding up to 6 months and exclusively breastfeeding up to and at 6 months relative to those receiving usual care. The size of the treatment effects varied in magnitude and precision in different trials, and average treatment effects may not be applicable in different settings. This updated review failed to find a statistically significant relationship between individual-level breastfeeding interventions and initiation of breastfeeding or any breastfeeding at 6 months.

The relatively modest effect seen within and across trials may be a result of the breastfeeding support provided as part of standard or usual care within many of these countries and specific clinical settings, and the magnitude of effect should be interpreted as an incremental benefit above usual care. Most studies indicated that there was a good level of breastfeeding support within the birthing

Figure 5. Pooled Analysis of Randomized Clinical Trials for Any Breastfeeding at 6 Months

Source	Country	Duration of Intervention, wk	No. Breastfeeding/Total (%)		Risk Ratio (95% CI)
			Intervention	Control	
Timing of intervention: combination of prenatal, peripartum, or postpartum					
Prenatal, peripartum, or postpartum					
Bonuck et al,[30] 2006	United States	68	51/115 (44.3)	45/136 (33.1)	1.34 (0.98-1.84)
Bonuck et al,[29] 2014 (BINGO)	United States	24	80/231 (34.6)	20/74 (27.0)	1.28 (0.85-1.94)
Bonuck et al,[29] 2014 (PAIRINGS)	United States	24	46/122 (37.7)	31/122 (25.4)	1.48 (1.01-2.17)
Chapman et al,[35] 2013	United States	30	13/55 (23.6)	20/53 (37.7)	0.63 (0.35-1.13)
Peripartum and postpartum					
McDonald et al,[66] 2010	Australia	6	267/428 (63.9)	286/421 (67.9)	0.94 (0.85-1.04)
Pollard,[74] 2011	United States	6	15/41 (36.6)	14/43 (32.6)	1.12 (0.62-2.03)
Su et al,[78] 2007	Singapore	2	48/119 (40.3)	43/126 (34.1)	1.18 (0.85-1.64)
Prenatal and postpartum					
Jolly et al,[56] 2012	United Kingdom	13	93/271 (34.3)	117/301 (38.9)	0.89 (0.59-1.32)
Reeder et al,[76] 2014	United Kingdom	42	512/1065 (48.1)	177/470 (37.7)	1.28 (1.12-1.46)
Wen et al,[82] 2011	Australia	53	117/278 (42.1)	91/283 (32.2)	1.31 (1.05-1.63)
Subtotal: I^2 = 67.8%, P = .001					1.15 (0.99-1.33)
Timing of intervention: only prenatal, peripartum, or postpartum					
Postpartum					
Bunik et al,[32] 2010	United States	2	35/125 (28.0)	49/132 (37.1)	0.75 (0.53-1.08)
Elliott-Rudder,[40] 2014	Australia	1 d	118/150 (78.7)	135/172 (78.5)	1.00 (0.86-1.17)
Fu et al,[42] 2014	Hong Kong	4	80/261 (30.7)	62/260 (23.8)	1.27 (0.87-1.84)
Labarere et al,[62] 2005	France	1 d	44/112 (39.3)	30/114 (26.3)	1.49 (1.02-2.19)
Paul et al,[73] 2012	United States	2	244/491 (49.7)	221/453 (48.8)	1.02 (0.89-1.16)
Peripartum					
Henderson et al,[49] 2001	Australia	1 d	42/75 (56.0)	48/75 (64.0)	0.88 (0.67-1.14)
Prenatal					
Forster et al,[41] 2004	Australia	2	146/293 (49.8)	162/299 (54.2)	0.92 (0.79-1.07)
Lavender et al,[63] 2005	United Kingdom	1 d	140/644 (21.7)	138/605 (22.8)	0.95 (0.56-1.61)
Mattar et al,[65] 2007	Singapore	1 d	48/112 (42.9)	43/129 (33.3)	1.29 (0.93-1.78)
Wong et al,[83] 2014	Hong Kong	1 d	87/233 (37.3)	96/236 (40.7)	0.92 (0.73-1.15)
Subtotal: I^2 = 32.0%, P = .15					1.00 (0.91-1.09)
Overall: I^2 = 57.5%, P = .001					1.07 (0.98-1.16)



Error bars indicate 95% confidence intervals. No test for subgroup differences performed, given lack of statistical significance in overall effect. BINGO indicates Best Infant Nutrition for Good Outcomes; PAIRINGS, Provider Approaches to Improved Rates of Infant Nutrition and Growth Study.

facility at or around the time of delivery from hospital staff, including support from lactation care providers, but failed to fully describe the minimal support for breastfeeding during the prenatal and postpartum periods.

For system-level intervention, there was limited, mixed evidence of an effect of BFHI accreditation, minimizing mother-infant separation following delivery, or delayed pacifier use on rates of breastfeeding initiation or the duration of any and exclusive breastfeeding from well-controlled trials. A number of studies, including 1 study included in this review,[48] have shown that the implementation of the individual steps (or mothers' perception of experiencing these steps) within the BFHI, rather than BFHI accreditation itself, influences rates of breastfeeding.

Limitations

Several limitations of the included evidence deserve special attention. First, most of the studies included a number of threats to internal validity, including possible selection bias, reporting bias, and relatively high attrition. Second, despite several calls over the 3 decades for standardizing breastfeeding definitions and indicators for both surveillance and program evaluation,[84,85] there was no uniform reporting of breastfeeding outcomes across the included studies regarding definitions of breastfeeding and timing of assessments. Most of the studies followed the World Health Organization definition for exclusive breastfeeding (which does not include water or water-based drinks),[86] but others used less robust definitions or did not report what counted as exclusive breastfeeding. In addition, there was a lack of clarity concerning the boundary point for many of the prevalence time points. That is, it was unclear if exclusive breastfeeding reported for 6 months was exclusive breastfeeding *at* 6 months or exclusive breastfeeding *to* 6 months, which is technically the recommendation (the introduction of something other than breast milk at or after 6 months among otherwise exclusively breastfed infants). Moreover, most of the studies did not fully describe the level of breastfeeding support given to women as part of usual care.

In addition to the limitations of the individual studies, there are limitations to the review methods worth noting. The review of system-level interventions was limited to RCTs, including cluster RCTs, and before-and-after designs with concurrent control groups.

Table 2. Overall Summary of Evidence by Key Question

No. of Studies, Study Design, No. of Observations (No.)	Study Quality	Major Limitations (Includes Reporting Bias)	Consistency	Applicability[a]	Summary of Findings (Includes Precision)
Key Question 1: What Are the Effects of Prenatal, Peripartum, and Postpartum Individual- and Health Care System–Level Interventions to Promote and Support Breastfeeding on Short- and Long-term Child and Maternal Health Outcomes?					
6 RCTs (n = 2219)	Good: 1 Fair: 5	No studies reported maternal health outcomes. Most outcomes based on maternal recall. Follow-up ranged from 4 to 52 weeks.	Inconsistent	High Applicable to a predominantly Hispanic and black low-income population.	Mixed results for the effects on infant gastrointestinal outcomes (2 studies): 1 trial (n = 182) found greater risk of ≥1 diarrheal episodes over 3 mo among those in usual care vs intervention groups (RR, 2.15 [95% CI, 1.16-3.97]), while the other trial (n = 338) found no difference between intervention and control groups at 1 y (22.7% vs 25.7%). One trial (n = 338) found no difference in risk of otitis media (43.6% vs 54.9%) or the number of health care visits for respiratory tract illnesses (76% vs 83.4%) at 1 y. Three of 4 trials that reported rates of infant health care utilization found higher use among those in the usual care control groups (2.8%-36.0%) than among those who received intervention (1.2%-25.0%). No studies reported the effects on maternal health outcomes.
Key Question 2: What Are the Effects of Prenatal, Peripartum, and Postpartum Individual- and Health Care System–Level Interventions to Promote and Support Breastfeeding on Initiation, Duration, and Exclusivity of Breastfeeding?					
Individual-level interventions 43 RCTs (n = 21 973)	Good: 14 Fair: 29	Statistical heterogeneity moderate or substantial in most analyses and considerable clinical variation. Lack of detail regarding measurement of breastfeeding, including recall period and definition of exclusivity. Sparse reporting of breastfeeding at 12 mo. Indication of small study effects for exclusive breastfeeding for less than 3 mo and at 6 mo.	Consistent	Moderate US trials (15 studies) applicable to a predominantly Hispanic and black low-income population. Non-US trials have low applicability, given differences usual care and underlying social and cultural differences.	Statistically significant associations between individual-level breastfeeding interventions and any breastfeeding for less than 3 mo (RR, 1.07 [95% CI, 1.03-1.11] [26 studies; n = 11 588]) and at 3 to less than 6 mo (RR, 1.11 [95% CI, 1.04 to 1.18] [23 studies; n = 8942]) and for exclusive breastfeeding for less than 3 mo (RR, 1.21 [95% CI, 1.11-1.33] [22 studies; n = 8246]), 3 to less than 6 mo (RR, 1.20 [95% CI, 1.05-1.38] [18 studies; n = 7027]), and at 6 mo (RR, 1.16 [95% CI, 1.02-1.32] [17 studies; n = 7690]). No significant association between individual-level interventions and breastfeeding initiation (RR, 1.00 [95% CI, 0.99-1.02] [14 studies; n = 9428]). Absolute differences in the rates of any breastfeeding ranged from 14.1 percentage points in favor of the control group to 18.4 percentage points in favor of the intervention group. Interventions delivered over more than 1 time point (eg, prenatal and postpartum) may be more effective than those delivered at only 1 time point (eg, postpartum only).
System-level interventions 9 studies (7 RCTs, 2 before-after with matched control group) (n = 44 784)	Good: 6 Fair: 3	Only 1 cluster RCT evaluating system-level policy change; 2 studies were controlled before-after designs. Limited number of studies evaluating specific maternity care practices related to breastfeeding.	Consistent	High applicability for studies of policy changes (3 studies). Moderate applicability for studies of maintaining mother-baby contact following delivery (3 studies). Low applicability for studies of restricted pacifier use (3 studies).	No consistent evidence of an association between system-level changes (BFHI accreditation and policies for breastfeeding support groups, minimizing mother and baby separation postdelivery, and restricting or delaying pacifier use) and the rate of any or exclusive breastfeeding at up to 16 weeks' postpartum. One large observational study (n = 25 327) found a statistically significant higher rate of breastfeeding initiation and exclusive breastfeeding at 4 wk among women with a lower education (initiation increased by 3.8 percentage points) but not among women overall or among those with higher education (initiation increased by 0.02 percentage points) after implementation of the BFHI.
Key Question 3: Are There Adverse Events Associated With Interventions to Promote and Support Breastfeeding?					
2 RCTs (n = 844)	Good: 0 Fair: 2	Only 2 trials reported adverse events related to the interventions.	NA	High	One trial (n = 586) reported no difference in maternal state anxiety at 2 wk postpartum between those receiving a home visit from a nurse vs those receiving usual care (mean difference, 0.3 [95% CI, −0.5 to 1.1]). Another trial (n = 258) reported that 2 mothers expressed feelings of anxiety, decreased confidence, or concerns about confidentiality during a peer support intervention.

Abbreviations: BFHI, Baby Friendly Hospital Initiative; NA, not applicable; RCT, randomized clinical trial; RR, risk ratio.

[a]Applicability or external validity to US primary care.

There are a number of other observational examinations of the BFHI and system-level policies and practices, but they are limited to before-and-after comparisons within single hospitals or retrospective designs and were not included in this update. These studies, however, generally show higher rates of breastfeeding following system-level changes (for example, Philipp et al[87] and Corriveau et al[88]).

Only studies taking place in countries listed as "very high" on the 2014 United Nations Human Development Index were included, to ensure that the evidence was applicable to a US setting.[21] This criterion led to the exclusion of one of the most widely cited trials on the effectiveness of a system-wide intervention on infant health outcomes as well as breastfeeding outcomes. The Promotion of Breastfeeding Intervention Trial (PROBIT) in Belarus (n = 17 046) found that infants born to mothers at sites randomized to an intervention modeled after the BFHI were significantly more likely than control infants to be breastfed at 12 months and to be exclusively breastfed at both 3 and 6 months.[89] The intervention also resulted in a significant reduction in the risk of gastrointestinal tract infection and the incidence of rashes, including atopic eczema, but no significant differences in risk of respiratory tract infections or otitis media in the first year of life[89] and no differences in a host of child health outcomes at 6.5 years of follow-up.[90-93]

In addition, 2 of the funnel plots presented asymmetry, and the tests for small-study effects were significant; therefore, potential publication bias cannot be ruled out.

Conclusions

The updated evidence confirms that breastfeeding support interventions are associated with an increase in the rates of any and exclusive breastfeeding. There are limited well-controlled studies examining the effectiveness of system-level policies and practices on rates of breastfeeding or child health and none for maternal health.

ARTICLE INFORMATION

Correction: This article was corrected online to clarify section headings in figures 3, 4, and 5, on November 3, 2016.

Author Contributions: Dr Patnode had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Patnode, Senger, Whitlock.
Acquisition, analysis, or interpretation of data: Patnode, Henninger, Senger, Perdue.
Drafting of the manuscript: Patnode.
Critical revision of the manuscript for important intellectual content: Patnode, Henninger, Senger, Perdue, Whitlock.
Statistical analysis: Patnode, Perdue.
Obtained funding: Whitlock.
Administrative, technical, or material support: Patnode, Henninger, Senger, Perdue, Whitlock.
Study supervision: Patnode.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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Role of the Funder/Sponsor: Investigators worked with USPSTF members and AHRQ staff to develop the scope, analytic framework, and key questions for this review. AHRQ had no role in study selection, quality assessment, or synthesis. AHRQ staff provided project oversight; reviewed the report and manuscript to ensure that the analysis met methodological standards; and distributed the draft for peer review. Otherwise, AHRQ had no role in the conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript findings.

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Additional Information: A draft version of this evidence report underwent external peer review from 7 content experts (Karen Bonuck, PhD [Albert Einstein College of Medicine], Roslyn Giglia, PhD, MPH [Telethon Kids Institute], Lucy Hope, RM, PhD [University of Worcester], Ann Kellams, MD, IBCLC [University of Virginia Health System], Miriam Labbok, MD [University of North Carolina], Anne Merewood, PhD, MPH, IBCLC [Boston University], and Ann Witt, MD [Senders Pediatrics]) and 2 federal partners (the Centers for Disease Control and Prevention [CDC] and the Indian Health Service [HIS]). Comments were presented to the USPSTF during its deliberation of the evidence and were considered in preparing the final evidence review.

Editorial Disclaimer: This evidence report is presented as a document in support of the accompanying USPSTF Recommendation Statement. It did not undergo additional peer review after submission to *JAMA*.

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