Comparative Effectiveness Review
Number 210

Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries

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Agency for Healthcare Research and Quality

Effective Health Care Program

Comparative Effectiveness Review

Number 210

Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries

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Key Messages

Purpose of Review

To summarize the effectiveness of community, workplace, and health care system–based programs and policies aimed at supporting and promoting breastfeeding, and to determine the association between breastfeeding and maternal health

Key Messages

- Baby-Friendly Hospital Initiative (BFHI) is associated with improved rates of breastfeeding initiation and duration.
- Health care staff education combined with postpartum home visits may be effective for increasing breastfeeding duration.
- Health care staff education alone (with no additional breastfeeding support services) may not be effective for increasing breastfeeding initiation rates.
- For women enrolled in the WIC Program, peer-support interventions offered by WIC agencies may improve rates of breastfeeding initiation and duration.
- Breastfeeding is associated with reduced maternal risk of breast and ovarian cancer, hypertension, and type 2 diabetes.
- Workplace, school-based, and community-based interventions and underlying socioeconomic factors need further research.

This report was funded by the Office on Women's Health at the Office of the Assistant Secretary for Health (OASH) and the Centers for Disease Control and Prevention (CDC) through an interagency agreement with the Agency for Healthcare Research and Quality (AHRQ) and is based on research conducted by the RTI International–University of North Carolina Evidence-based Practice Center (EPC) under contract to AHRQ, Rockville, MD (Contract No. 290-2015-00011-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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This report may periodically be assessed for the currency of conclusions. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at www.effectivehealthcare.ahrq.gov. Search on the title of the report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States.

The Office on Women's Health at the Office of the Assistant Secretary for Health (OASH) and the Centers for Disease Control and Prevention (CDC) requested this report from the EPC Program at AHRQ. AHRQ assigned this report to the following EPC: RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (Contract No. 290-2015-00011-I).

The reports and assessments provide organizations with comprehensive, evidence-based information on common medical conditions and new health care technologies and strategies. They also identify research gaps in the selected scientific area, identify methodological and scientific weaknesses, suggest research needs, and move the field forward through an unbiased, evidence-based assessment of the available literature. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review and public comment prior to their release as a final report.

AHRQ expects that the EPC evidence reports and technology assessments, when appropriate, will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

If you have comments on this evidence report, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

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Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries

Structured Abstract

Objectives. To summarize the effectiveness of community, workplace, and health care system–based programs and policies aimed at supporting and promoting breastfeeding and determine the association between breastfeeding and maternal health.

Data sources. We searched PubMed®/MEDLINE®, the Cochrane Library, and CINAHL® from January 1, 1980, to October 12, 2017, for studies relevant to the effectiveness of health care system–based, workplace, and community breastfeeding programs and policies. For evidence on breastfeeding and maternal health, we updated the 2007 Agency for Healthcare Research and Quality report on this topic and searched the same databases from November 1, 2005, to October 12, 2017. For studies of breastfeeding programs and policies, trials, systematic reviews, and observational studies with a control group were eligible; we excluded primary care–based programs delivered as part of routine care. For studies related to breastfeeding and maternal health, we included systematic reviews, case-control studies, and cohort studies.

Review methods. Pairs of reviewers independently selected, extracted data from, and rated the risk of bias of relevant studies; they graded the strength of evidence (SOE) using established criteria. We synthesized all evidence qualitatively.

Results. We included 128 studies (137 publications) and 10 systematic reviews. Of these, 40 individual studies were relevant to the effectiveness of breastfeeding programs or policies, and the remainder were relevant to one or more maternal health outcomes. Based on evidence from one large randomized controlled trial (RCT) (Promotion of Breastfeeding Intervention Trial [PROBIT], N=17,046) enrolling mothers who intended to breastfeed and nine cohort studies (1,227,182 women), we graded the SOE for the Baby-Friendly Hospital Initiative (BFHI) as moderate for improving rates of breastfeeding duration. Evidence from eight cohort studies of BFHI (135,983 women) also demonstrates improved rates of breastfeeding initiation (low SOE). Low SOE (k=4 studies; 1,532 women) supports the conclusion that health care education or training of staff alone (without additional breastfeeding support services) does not improve breastfeeding initiation rates. Women, Infants and Children (WIC, a Federal supplemental nutrition program) interventions that focus on peer support are effective in improving rates of breastfeeding initiation and duration (low SOE). We found limited evidence for other (community-based) interventions and no comparative studies on workplace or school-based interventions or harms associated with interventions.

For maternal health outcomes, low SOE supports the conclusion that ever breastfeeding or breastfeeding for longer durations may be associated with lower rates of breast cancer, epithelial ovarian cancer, hypertension, and type 2 diabetes, but not fractures. Because of heterogeneity and inconsistent results, we found insufficient evidence on whether breastfeeding is associated with postpartum depression, cardiovascular disease, or postpartum weight change.

Conclusions. The body of evidence for breastfeeding programs and policies was diverse in terms of interventions and settings. Current evidence supports the benefit of BFHI for improving rates of breastfeeding initiation and duration; however, evidence from one large RCT (PROBIT) has limited applicability, and observational studies do not clearly establish the magnitude of benefit. For women enrolled in WIC, low SOE supports peer-support interventions for improving breastfeeding outcomes. The identified associations between breastfeeding and improved maternal health outcomes are supported by evidence from observational studies, which cannot determine cause-and-effect relationships.

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Evidence Summary

Background

In reproductive physiology, lactation follows pregnancy; a growing body of evidence supports the association between breastfeeding and better health outcomes for both infants and mothers.[1-3] A 2007 Agency for Healthcare Research and Quality (AHRQ) review by Ip and colleagues concluded that breastfeeding was associated with reduced maternal type 2 diabetes, breast cancer and ovarian cancer, but not fractures.[2] For other outcomes (e.g., postpartum depression), the authors concluded that the relationship between breastfeeding and maternal health was unclear. Since 2007, several new studies have reported on maternal outcomes not addressed in the 2007 AHRQ review, including hypertension, rates of myocardial infarction, and other cardiovascular outcomes.[4-7]

In 2014, an estimated 82.5 percent of infants born in the United States were breastfed at birth, meeting Healthy People 2020 targets for the percentage of infants who are ever breastfed (81.9%). However, rates of breastfeeding duration fell short of Healthy People 2020 targets. In 2014, only 55.3 percent of women breastfed at 6 months and 33.7 percent at 12 months[8] (falling short of the 2020 targets of 66.6 and 34.1 percent, respectively, for 6 and 12 months).[9] Rates of exclusive breastfeeding through 3 and 6 months were 46.6 and 24.9 percent, respectively; these measures are close to Health People 2020 targets (46.2 and 25.5%, respectively).[8] Women would prefer to breastfeed longer: in a national survey, 45 percent of U.S. women who initiated breastfeeding reported early, undesired weaning.[10] Despite rising breastfeeding initiation and duration rates in the United States, racial and ethnic differences persist. From 2000 to 2014, the percentage of women who initiated breastfeeding went up from 47.4 to 68.0 percent for blacks, 71.8 to 85.7 percent for whites, and 77.6 to 84.8 percent for Hispanics.[11, 12]

In addition to setting targets for breastfeeding initiation rates and duration of breastfeeding, other Healthy People 2020 objectives related to breastfeeding include (1) increasing the proportion of live births that occur in facilities that provide recommended care for lactating mothers and their babies and (2) increasing the proportion of employers that have worksite lactation support programs.[9] These community, workplace, and health care system–based programs and policies may be promising strategies to support initiation and increase duration of breastfeeding.

Health care system–based interventions may include maternity staff education or the Baby-Friendly Hospital Initiative (BFHI). The BFHI is a global program sponsored by the World Health Organization (WHO) and United Nations Children's Fund to encourage and recognize hospitals and birth centers that create an environment supporting breastfeeding. In each country, a BFHI Coordination Group is charged with designating facilities as Baby-Friendly;[13] there are likely country-specific differences in the process for determining final accreditation (or certification) status. As a result, details of implementation vary from country to country. The Baby-Friendly USA "Ten Steps to Successful Breastfeeding" for hospitals and birthing facilities are listed in Table A. Insurance coverage for lactation support is another strategy that may enable women to achieve their breastfeeding goals. Costs associated with breastfeeding support (e.g., comprehensive lactation support and counseling, breastfeeding equipment) are currently covered by health insurance marketplace plans and private nongrandfathered health plans under the 2010 Patient Protection and Affordable Care Act.[14] It is not clear whether certain lactation benefit packages (e.g., type of breastfeeding supplies offered, number of visits provided, or qualifications of intervention delivery personnel) are more or less effective than others in increasing breastfeeding initiation and duration. In addition, a key program relevant to breastfeeding is the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), which serves 53 percent of infants born in the United States.[15] Because WIC reaches more than half of U.S. infants, its programs have considerable influence on population health.

Although there is broad appeal and interest in workplace interventions to increase duration and exclusivity of breastfeeding, their effectiveness and harms are uncertain.[16]

Table A. Baby-Friendly Hospital Initiative's 10 steps to successful breastfeeding[a]

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within 1 hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation even if they should be separated from their infants.
6. Give infants no food or drink other than breast milk, unless medically indicated.
7. Practice rooming in—allow mothers and infants to remain together 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

[a] Baby-Friendly USA "Ten Steps to Successful Breastfeeding"[17]

Existing Guidelines

Multiple clinical guidelines and health-related organizations recommend exclusive breastfeeding up to (or around) 6 months, including the American Academy of Pediatrics,[18] the American Congress of Obstetrics and Gynecology,[19] the WHO,[20, 21] and others.[22, 23] These organizations recommend continued breastfeeding through the first year of life and beyond; the WHO recommends continued breastfeeding through the second year of life and beyond.[24]

Rationale for Evidence Review

The purpose of this review is to develop an evidence report that summarizes the effectiveness of community, workplace, and health care system–based programs and policies aimed at supporting and promoting breastfeeding. Such knowledge is needed to inform allocation of resources to enable more women to achieve their infant feeding goals. The U.S. Preventive Services Task Force (USPSTF) recommends providing interventions during pregnancy and after birth to support breastfeeding as part of routine primary care (B recommendation).[25] To avoid duplication, this review will not address the effectiveness of individual-level primary care interventions to support breastfeeding covered in the recent systematic review to support the USPSTF recommendation.[26]

In addition, this review will address the association between breastfeeding and maternal health. Substantial time has elapsed since the last AHRQ review on this topic in 2007, and the body of literature focused on the maternal health benefits of breastfeeding has grown.[1, 27-29] This review will conduct a partial update of the 2007 AHRQ review focused on the relationship between breastfeeding and various maternal health outcomes. This review will inform the extent to which breastfeeding may be an effective primary prevention strategy for improving women's health.

Key Questions

Key Question 1:

1a. What are the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding?

1b. To what extent do the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding differ for subpopulations of women defined by sociodemographic factors (e.g., age, race, ethnicity, socioeconomic status)?

1c. To what extent do intervention-related characteristics (e.g., type of breast pump provided—manual or electric; delivery personnel) influence the initiation, duration, and exclusivity of breastfeeding?

Key Question 2:

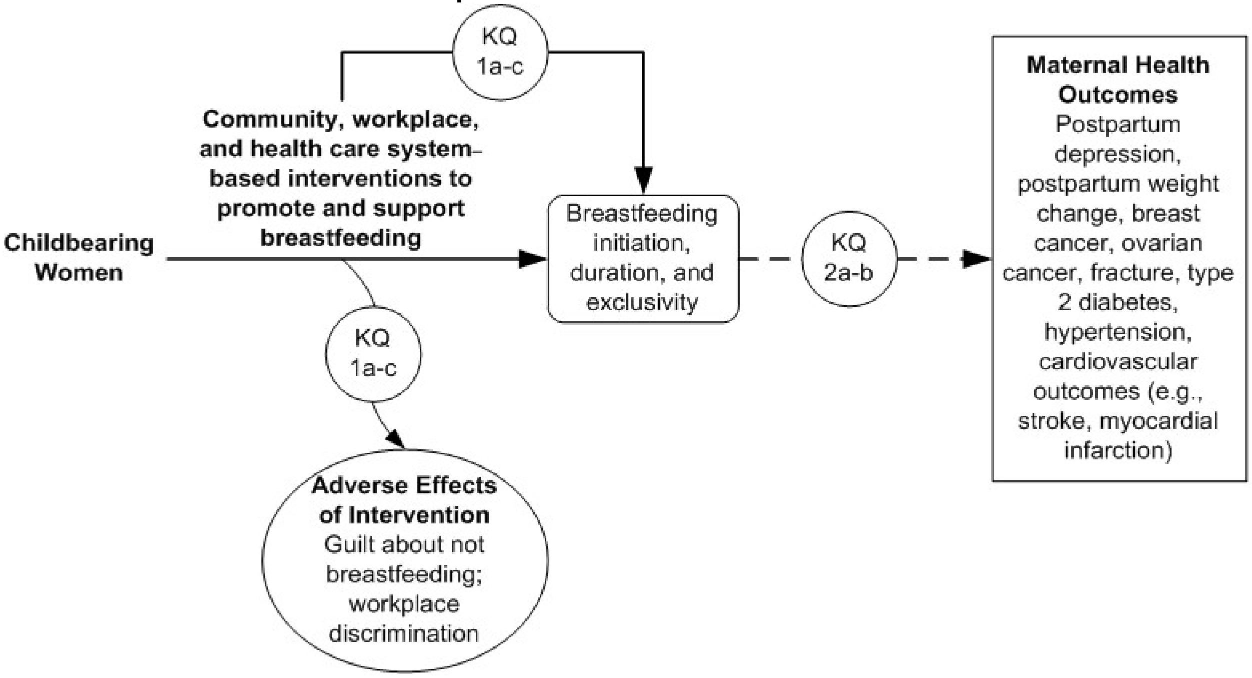
2a. What are the comparative benefits and harms for maternal health outcomes among women who breastfeed for different intensities and durations?

2b. To what extent do benefits and harms for maternal health outcomes differ for subpopulations of women defined by age, race, ethnicity, and comorbidity?

Analytic Framework

We developed an analytic framework to guide the systematic review process (Figure A). The analytic framework illustrates the population, interventions, outcomes, and adverse effects that guided our literature search and synthesis.

Figure A. Analytic framework for breastfeeding programs and policies, breastfeeding uptake, and maternal health outcomes in developed countries



KQ = Key Question.

Methods

The initial Key Questions (KQs) were provided by AHRQ and developed in collaboration with partners from the Centers for Disease Control and Prevention (CDC) and National Institutes of Health Office of Women's Health. The Evidence-based Practice Center further refined the KQs. We sought input from a Technical Expert Panel on the final research protocol, which was posted on the AHRQ Web site on March 20, 2017, at https://effectivehealthcare.ahrq.gov/topics/breastfeeding/research-protocol/; our PROSPERO registration number is CRD42017079125.

Literature Search Strategy

Search Strategy

For KQ 1, we searched PubMed/MEDLINE, the Cochrane Library, and CINAHL from January 1, 1980, to October 12, 2017, to ensure that evidence is applicable to current breastfeeding policies and practices. For KQ 2, we searched PubMed/MEDLINE, the Cochrane Library, and CINAHL from November 1, 2005 (6 months prior to the search date of the 2007 AHRQ review searches) to October 12, 2017. A full description of the search strategy is provided in the methods section of the full report.

Inclusion and Exclusion Criteria

Interventions of interest for KQ 1 included any community, workplace, or health care system–based interventions aimed at promoting and supporting breastfeeding. Included studies for KQ 1 had to have a concurrent control group or (for single-group pre-post studies) include multiple pre- and post-measures of breastfeeding rates. For KQ1, we included studies conducted in countries categorized as “very high” and “high” human development index per the United Nations Development Programme.[30]

Eligibility criteria for KQ 2 were based on criteria used in the 2007 AHRQ review by Ip and colleagues for maternal health outcomes (postpartum depression, postpartum weight change, breast cancer, ovarian cancer, osteoporotic fracture, and type 2 diabetes). For this update, we also included hypertension and cardiovascular disease. Eligible studies compared groups of women exposed to breastfeeding with those who did not breastfeed (or breastfed for shorter duration and/or less intensity). To maintain consistency with the 2007 review, we limited to studies enrolling women from countries categorized as “very high” human development index per the United Nations Development Programme.[30] A detailed search strategy is provided in the methods section of the full report.

Risk of Bias Assessment of Individual Studies

We adapted existing tools (ROBINS-I[31] for observational studies, and the Cochrane tool[32] for trials) and used predefined criteria based on the AHRQ *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*. Criterion details are included in the full report, including Appendix C.[33]

Risk of Bias Assessment of Systematic Reviews

We assessed the relevance of systematic reviews published within the past 5 years using predefined criteria. For reviews determined to be relevant, we rated the risk of bias (ROB) as low, unclear, or high ROB using the ROBIS tool.[34] Appendix C of the full report lists the specific questions used for evaluating the ROB of all relevant reviews.

Data Synthesis

For those KQ 2 outcomes for which we included a recent published systematic review rated low or unclear ROB, we first described the results of the review and then summarized data from primary studies published after the latest search date of those reviews. We included systematic reviews for some outcomes (breast cancer, ovarian cancer, and type 2 diabetes) that had conducted meta-analyses. If individual studies identified in our database searches were generally consistent with the pooled results reported by existing systematic reviews, we did not conduct new meta-analyses.

Strength of the Body of Evidence

We graded the strength of evidence (SOE) based on guidance established for the Evidence-based Practice Center Program.[35] This approach incorporates five key domains: study limitations (aggregate ROB), consistency, directness, precision, and reporting bias.

Applicability

We assessed applicability following guidance from the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[36] For individual studies, we examined conditions that may limit applicability of evidence such as race or ethnicity of enrolled populations, setting of enrolled populations, geographic setting, time period of enrollment, and availability of health insurance and other health-related employment benefits.

Peer Review and Public Commentary

This report was posted for public comment and peer reviewed. We addressed all comments in the final report, making revisions as needed; a disposition of comments report will be publicly posted 3 months after release of the final report.

Results of Literature Searches

Searches of all sources identified a total of 11,006 potentially relevant citations. We included 128 unique individual studies (described in 137 publications) and 10 systematic reviews. Of these, 40 individual studies (from 44 publications) were relevant to KQ 1, and 88 individual studies (from 93 publications) and 10 systematic reviews were relevant to KQ 2. Of the KQ 2 included studies, 18 were studies from a prior 2007 AHRQ review addressing the maternal health benefits of breastfeeding.[2] The remaining 34 studies from the 2007 review were included in at least 1 of our 10 systematic reviews or superseded by a new included study. Appendix B in the full report provides a complete list of articles excluded at the full-text screening stage, with reasons for exclusion.

Effectiveness and Harms of Breastfeeding Programs and Policies

The 40 studies that met our inclusion criteria evaluated a range of strategies to improve rates of breastfeeding initiation and duration. No included studies assessed the benefit of workplace interventions or the potential harms of interventions. To aid in synthesizing results of similar studies, we categorized interventions primarily based on intervention type: BFHI, other (non-BFHI) health care system–based interventions (e.g., residency curriculum related to breastfeeding), WIC-based interventions, and community-based interventions (not primarily delivered as part of the health care system). In addition to categorizing interventions by intervention type, we also summarized results for breastfeeding initiation and duration separately when we had similar studies reporting on multiple breastfeeding outcome types. Below, we provide a summary of our main conclusions related to the effectiveness of programs and policies for improving rates of breastfeeding initiation and duration organized by intervention type.

BFHI Interventions

Twelve included studies (described in 13 publications) assessed the effectiveness of BFHI interventions.[37-50] Studies were conducted in diverse country settings including the United States (2 studies);[39, 40] Taiwan (2 studies);[46, 50] and one each in the Republic of Belarus,[37] Hong Kong,[41] Czech Republic,[42] Russia,[51] Brazil,[44] Croatia,[45] Brazil,[49] United Kingdom (multiple regions),[47] and Scotland.[52] Table B presents key findings and SOE related to the benefit of BFHI interventions. Overall, the evidence supports the effectiveness of BFHI for improving rates of breastfeeding initiation and duration.

Table B. Summary of key findings and strength of evidence: Studies assessing BFHI

Breastfeeding Outcome Intervention Versus Comparator	**N Studies; N Subjects Study Limitations**	**Outcome and Results**	**Strength of Evidence**
Initiation BFHI certified/accredited vs. no BFHI status	9 cohorts;[39, 40, 42, 43, 46-50] 1,227,532 Medium	Any BF initiation (k=6): higher rates of BF at discharge among BFHI-accredited hospitals than control hospitals (by 0.5% to 10%); differences between groups were not statistically significant in 4 studies Exclusive BF initiation (k=5): significantly higher rates of exclusive BF at discharge among BFHI-accredited hospitals than control hospitals; magnitude varied, ranging from 3 to 56%	Low for benefit (consistent, imprecise)
Duration BFHI vs. no BFHI intervention (evidence from RCTs) Duration BFHI certified/accredited vs. no BFHI status (evidence from observational studies)	1 RCT;[37, 38] 17,046 8 cohorts;[39-41, 43, 46, 47, 49, 50] 136,983 Medium	One RCT found significantly higher rates of exclusive BF among women at BFHI hospitals at 3 mos (43% vs. 6%; p<0.001) and 6 mos postpartum (7.9% vs. 0.6%; p=0.01), and lower odds of weaning (from any BF) at 3, 6, 9, and 12 mos postpartum than women in control hospitals Any BF duration (k=8 cohort studies): higher rates of BF 1 to 12 mos postpartum among women at BFHI hospitals (by approximately 0.6% to 15%) than women at control hospitals; one study found slightly higher BF rates at 1 mo among women in control hospitals than BFHI hospitals (by 0.4% to 7%) Exclusive BF duration (k=5 cohort studies): higher rates of exclusive BF over 1 to 2 mos among infants born in BFHI hospitals than control hospitals (by approximately 4% to 25%)	Moderate for benefit (consistent, imprecise)
Breastfeeding Outcome Intervention Versus. Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Duration Six or more BFHI steps vs. fewer than six steps	1 cohort;[41] 1,417 Medium	Significantly higher odds of weaning at or before 8 wks postpartum among women giving birth in hospitals practicing ≤ four BFHI steps than women giving birth in hospitals practicing six BFHI steps (ORs ranged from 2.08 and 3.13); no difference between women exposed to five vs. six steps	Low for benefit (consistent[a] precise)

[a] Although only one study compared groups of women based on number of BFHI steps practiced by hospitals, we considered evidence on duration from studies comparing BFHI implementation (or accreditation) with nonaccredited hospitals. As shown in the table, we concluded that moderate SOE supports the effectiveness of BFHI for improving breastfeeding duration.

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; HV = home visits; k = number of studies; N = number; OR = odds ratio; RCT = randomized controlled trial; SOE = strength of evidence.

For breastfeeding initiation, evidence from nine cohort studies (1,227,532 women) comparing women giving birth in BFHI-certified (or accredited) hospitals with noncertified hospitals supports the effectiveness of BFHI (low SOE). Although the included studies consistently found higher rates of initiation at accredited hospitals, results were imprecise and the magnitude of benefit varied by breastfeeding measure and country setting (Table B).

Based on evidence from one large RCT (Promotion of Breastfeeding Intervention Trial [PROBIT], N=17,046) and five cohort studies (62,834 women), we concluded that BFHI increases rates of breastfeeding duration through 12 months postpartum (moderate SOE). In the PROBIT trial, women in the intervention group had significantly higher rates of exclusive breastfeeding and lower rates of weaning across various multiple time points (1 to 12 months postpartum). Although the eight observational studies were mostly consistent in finding benefit for BFHI, results were imprecise, and the magnitude of benefit varied by breastfeeding measure and country setting. One cohort study (N=1,417) compared rates of breastfeeding at 6 months among women discharged from hospitals that differed in the number of BFHI steps implemented; low SOE supports the conclusion that implementation of four or more BFHI steps is associated with lower rates of weaning than implementation of fewer than four steps.

Other (Non-BFHI) Health Care System–Based Interventions

Fifteen studies (described in 16 publications) assessed the effectiveness of other (non-BFHI) health care system–based interventions.[44, 53-67] Studies were conducted in diverse country settings including the United States (3 studies),[59, 66, 68] Canada (1 study),[64] Sri Lanka (1 study),[61] Brazil (2 studies),[65, 69] China (1 study),[58] and various European countries (6 studies).[53, 56, 57, 60, 62, 63] Studies assessed a variety of intervention types; the majority focused on health care provider education or training related to breastfeeding, with or without additional services offered (e.g., breastfeeding groups, home visits). Table C presents key findings and SOE conclusions. Overall, the evidence supports the effectiveness of three intervention types for improving the duration of exclusive breastfeeding: modified BFHI policy implementation in outpatient setting (e.g., development of a breastfeeding policy, staff training, outcome assessment, and quality improvement initiatives), continuous nursing care during the perinatal period (the same nurse provides routine perinatal care to the mother and infant), and health care provider education combined with a series of home visits (low SOE). In addition, the evidence suggests that health care provider education and training alone (without additional breastfeeding support services) are not effective in improving rates of breastfeeding initiation (low SOE). As a result of methodological limitations and imprecise and inconsistent findings, we rated the SOE as insufficient for other intervention types.

Table C. Summary of key findings and strength of evidence: Non-BFHI health care system–based interventions

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation Education/staff training related to BF alone vs. usual practice	4 (2 RCTs,[55, 56, 61] 2 NRCTs[59, 64]); 1,532[a] Medium	No significant difference between intervention and control groups in rates of any or exclusive BF initiation	Low for no benefit (consistent, imprecise)
Initiation Education and staff training plus additional individual services vs. usual care	4 (2 RCTs,[60, 63] 1 NRCT,[57] 1 pre-post study[53]); 34,018 Medium	Inconsistent findings across four studies assessing heterogeneous interventions	Insufficient (inconsistent, imprecise)
Duration Education and staff training related to BF only vs. usual practice	3 (2 RCTs,[55, 56, 65] 1 NRCT[59]); 1,526[a] Medium	Inconsistent findings across three studies for duration of any and exclusive BF	Insufficient (inconsistent, imprecise)

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Duration Education and staff training plus additional individual services vs. usual care	4 RCTs;[44, 60, 62, 63] 21, 253 Medium	Two RCTs assessing staff education combined with a series of postpartum HVs found improved rates of any BF duration Two RCTs assessing staff education combined with different clinic-based patient education strategies found no significant difference between groups	Staff education plus HVs: Low for benefit (consistent, precise) Staff education plus clinic-based education/support: Insufficient (inconsistent, imprecise)
Duration Adaptation of the BFHI for integration into routine primary care (maternal and child health centers) vs. usual care	1 NRCT;[67] 3,948 Medium	Significantly higher rates of exclusive BF in the intervention group than controls at 6 mos (OR, 1.33; 95% CI, 1.03 to 1.72); no difference between groups in rates of any BF at 5 or 12 mos	Low for benefit (unknown consistency, precise)
Initiation/duration Continuous primary nursing care (same nurse through perinatal period for mother/infant) vs. usual care (task-oriented nursing)	1 RCT;[58] 470 Medium	Significantly higher rates of exclusive BF during hospitalization (99% vs. 88%; p=0.001) and higher rates of exclusive BF 6 wks (72% vs. 94%; p=0.001) among women in the intervention group than controls	Low for benefit (unknown consistency, precise)

[a] Number here includes participants enrolled from three studies; one study focused on 13 residency programs did not report the number of women included in analyses of breastfeeding outcomes.[59]

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; CI = confidence interval; HV = home visit; N = number; NRCT = non-randomized controlled trial; OR = odds ratio; RCT = randomized controlled trial.

WIC-Based Interventions

Eight included studies assessed changes in breastfeeding rates associated with a WIC program or policy.[70-77] Although all studies were set in the United States, they included women from diverse States. Included studies assessed heterogeneous interventions and policies; key findings and SOE assessments are shown in Table D. Overall, low SOE supports the effectiveness of WIC-based peer-support programs for improving rates of any breastfeeding initiation and duration from 6 weeks to 6 months postpartum. We found insufficient evidence (primarily because of unknown consistency and imprecision) to make a conclusion on the benefit of other WIC programs or policies for improving breastfeeding outcomes, including policy changes related to WIC food packages, provision of different types of breast pumps (electric vs. manual), tailored counseling, cash incentives, and peer-support programs targeted at fathers.

Table D. Summary of key findings and strength of evidence: WIC-based interventions

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation/duration Mother peer support vs. control	3 (1 RCT,[73] 1 NRCT,[74] 1 cohort[75]); 2,480 Medium	Two studies of in-person peer support resulted in significantly higher rates of BF initiation and increased BF duration; one telephone-based peer-support study found significantly higher rates of any BF at 3 and 6 mos than controls	Low for benefit (consistent, precise)
Initiation/duration BF rates post-2007 policy revising the WIC food package vs. pre-policy implementation	1 (3 pop. cohorts);[71] PRAMS (127,477) NIS (73,991) PedNSS (744 infants): 744 High	No association between the policy change and rates of BF;[a] BF rates increased overall with no difference between women receiving WIC benefits and similar groups of women not receiving WIC benefits	Insufficient (high ROB, unknown consistency, imprecise)
Duration Provision of electric breast pump vs. manual pump	1 RCT;[70] 280 Medium	No difference in BF duration among women assigned to an electric vs. manual breast pump; median duration of BF was 12 vs. 11 mos, respectively (HR,1.13; 95% CI, 0.79 to 1.50)	Insufficient (unknown consistency, imprecise)
Initiation/duration Peer-support program for fathers (in addition to mother peer support) vs. peer support for mothers alone	1 NRCT;[72] 200 Medium	Mothers in the intervention group had slightly higher rate of any BF at 6 mos than controls (63% vs. 55%) that was not statistically significant (p=0.20)	Insufficient (unknown consistency, imprecise)
Duration Cash incentives vs. usual WIC services	1 RCT;[77] 36 Medium	BF rates in the intervention group were significantly higher than controls at 1, 3, and 6 months (89% vs. 44%, 89% vs. 17%, and 72% vs. 0%, respectively)	Insufficient (unknown consistency; precise)
Duration Tailored BF counseling and support based on BAPT survey	1 cohort;[76] 826 High	Significantly higher rates of exclusive BF in the intervention group at 7 and 30 days than controls; no difference between groups at 2 mos	Insufficient (high ROB, unknown consistency, imprecise)

[a] All three databases measured rates of "ever-breastfeeding"; in addition, PRAMS measured rates of breastfeeding for at least 4 weeks, NIS measured rates of breastfeeding for at least 3 months, and PedNSS measured rates of breastfeeding for at least 1 month. Conclusions were consistent across the different measures.

BAPT = Breastfeeding Attrition Prediction Tool; BF = breastfeeding; CI = confidence interval; HR = hazard ratio; N = number; NIS = National Immunization Survey; NRCT = non-randomized controlled trial; PedNSS = Pediatric Nutrition Surveillance System; PRAMS = Pregnancy Risk Assessment Monitoring System; RCT = randomized controlled trial; ROB= risk of bias; WIC = Special Supplemental Nutrition Program for Women, Infants and Children.

Community-Based Interventions

Five included studies (described in 7 publications) assessed the effectiveness of a community-based intervention;[78-84] key findings and SOE assessments are shown in Table E. Studies were conducted in diverse country settings including one each in Italy,[79] Australia,[80] Mexico,[82] Chile,[84] and Canada.[83] No studies assessed the same intervention type, which limited our ability to make conclusions on the SOE for most intervention types. Low SOE supports the benefit of community-based interventions that provide mothers with peer-support (via home visits). In addition, access to a community-based breastfeeding drop-in center among women receiving early home-based breastfeeding support does not increase breastfeeding duration (low SOE).

Table E. Summary of key findings and strength of evidence: Community-based interventions

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation/duration Community-based policy aimed at promoting BF in nonhospital-based health and community centers vs. no intervention	1 NRCT;[78, 79] 5,094 Medium	No significant difference in rates of exclusive BF at discharge, 3 and 6 mos, or rates of any BF at 5 and 12 mos between groups	Insufficient (unknown consistency, imprecise)
Duration Access to community-based BF drop-in centers (plus early BF support) vs. early BF support alone vs. usual care	1 RCT;[80, 81] 9,675 Low	No difference between groups in rates of any BF at 3, 4, or 5 mos.	Low for no benefit (unknown consistency, precise)
Duration Community-based peer support vs. usual care	1 RCT;[82] 130 Low	Significantly higher rates of exclusive BF at 3 mos among intervention groups (50% to 67%) than control group (12%), $p<0.001$; rates of any BF were significantly longer in intervention groups (combined) than in the control group at 3 mos (but not 6 mos)	Low for benefit (unknown consistency, precise)
Duration Peer-led BF support class vs. Nurse-led BF support class	1 cohort;[83] 109 High	No significant difference between groups in rates of any BF at 1 and 6 mos postpartum	Insufficient (high ROB, unknown consistency, imprecise)
Duration Integrated postpartum program (BF education and support, maternal/infant health care) vs. usual care	1 NRCT;[84] 392 High	Significantly higher rates of exclusive BF at 6 mos among the intervention group than control group (74% vs. 10%; $p=0.001$)	Insufficient (high ROB, unknown consistency, precise)

BF = breastfeeding; N = number; NRCT = nonrandomized controlled trial; ROB = risk of bias; RCT = randomized controlled trial.

Effectiveness and Harms of Breastfeeding Programs and Policies for Subpopulations of Women

Few studies reported on subgroups of women. Of the four included studies reporting on subgroups of women, two focused on BFHI and reported on differences by education status,[39, 40] one focused on a WIC peer-support intervention and reported on subgroups by language spoken (Spanish only vs. English),[73] and one prospective cohort study assessed a tailored breastfeeding counseling intervention.[76] Table F shows our key findings and SOE related to subgroups of women. Low SOE supports the conclusion that BFHI effectiveness may vary among women who differ by education status. For WIC interventions, we found insufficient evidence to make a conclusion on whether benefit of telephone peer support varies by subgroups of women based on language spoken (Spanish only vs. English) or whether benefit of tailored breastfeeding counseling intervention varies by race/ethnicity, primarily because of unknown consistency (and inconsistency across time points) and imprecision.

Table F. Summary of key findings and strength of evidence: KQ 1 studies reporting on subgroups

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation (subgroups: education status) BFHI certified/accredited vs. no BFHI status	2 cohort;[39, 40] 27,341 Medium	Higher rates of BF initiation found among women with lower education (≤12 yrs) at BFHI hospitals compared with control hospitals, but no difference in rates among women with higher education (≥13 yrs)	Low (consistent, imprecise)
Duration (subgroups: education status) BFHI certified/accredited vs. no BFHI status	2 cohort;[39, 40] 27,341 Medium	Two studies found mixed results.	Insufficient (inconsistent, imprecise)
Initiation/duration (subgroups: language spoken) Mother peer support vs. control	1 RCT;[73] 1948 Medium	One RCT of telephone peer support found mixed results for subgroups of women defined by language (English-speaking vs. Spanish-speaking only)	Insufficient (unknown consistency, imprecise)
Duration (subgroups: race/ethnicity) Tailored BF counseling and support based on BAPT survey	1 cohort;[76] 826 High	Significantly higher rates of exclusive BF among non-Hispanic black and Hispanic women in the intervention group than controls at 1 and 2 mos; no significant difference in exclusive BF rates among white women at any time point	Insufficient (high ROB, unknown consistency, precise)

BAPT= Breastfeeding Attrition Prediction Tool; BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; KQ = Key Question; N = number; RCT = randomized controlled trial; ROB = risk of bias.

Effect of Intervention Characteristics on Breastfeeding Outcomes

This KQ focused on the extent to which intervention-related characteristics (e.g., type of breast pump provided—manual or electric, delivery personnel) influence the initiation, duration, and exclusivity of breastfeeding. We found no evidence to address this KQ.

Maternal Health Outcomes Associated With Breastfeeding

Table G summarizes our key findings related to KQ 2, including evidence for subpopulations of women, by outcome. Low SOE supports the conclusion that ever breastfeeding, as well as longer durations of breastfeeding, may be associated with a reduced risk of developing (any) breast cancer, luminal breast cancer, or triple-negative breast cancer. Despite a large body of observational evidence, study and participant characteristics and methodological limitations did not explain the significant heterogeneity of results. Low SOE supports the association between ever breastfeeding, as well as longer versus shorter durations of breastfeeding, and a reduced risk of developing epithelial ovarian cancer. The body of evidence is relatively large and includes one systematic review of 41 studies and 8 additional studies (39,618 women); however, we rated SOE as low because the results included significant heterogeneity not explained by study and participant characteristics and methodological limitations.

Table G. Summary of key findings and strength of evidence: Maternal health outcomes

Maternal Health Outcome	N Studies; N Subjects Study Limitations	Outcome and Results[a]	Strength of Evidence
Breast cancer	1 SR of 98 cohort/case-control studies;[1] NR[b]	Consistent association in one SR (98 observational studies) between ever BF and	Low for beneficial

Maternal Health Outcome	N Studies; N Subjects Study Limitations	Outcome and Results[a]	Strength of Evidence
	19 cohort/case-control studies; [85-103] 256,891 women Medium	lower rates of breast cancer compared with never BF (pooled OR 0.78, 95% CI 0.74 to 0.82); longer durations of BF was also associated with significantly lower rates of breast cancer than never BF. Results of individual studies were generally consistent in direction of effect (although results were imprecise); magnitude varied significantly across all studies and pooled results were associated with significant heterogeneity, only partially explained by subgroup analyses.	association (consistent, imprecise)
Breast cancer: *BRCA1/2* carriers	1 case-control study;[104] 5,708 women Medium	Unclear association between BF and breast cancer among *BRCA* carriers.	Insufficient (unknown consistency, imprecise)
Breast cancer: In situ	3 cohort/case-control studies;[96, 99, 105] 67,234 women Medium	Unclear association between BF and breast cancer in situ.	Insufficient (inconsistent, imprecise)
Breast cancer: Hormone receptor subtypes	1 SR of 11 cohort/case-control studies;[106] 169,879 women for luminal, 14,266 women for HER2, and 176,430 women for triple-negative analyses 7 cohort/case-control studies;[91, 95, 102, 107-110] 592,558 women Medium	Consistent association between ever BF or longer duration of BF and lower rates of luminal and triple negative breast cancer (although magnitude of association varies); for HER2, pooled estimates show unclear association between BF and lower rates of breast cancer (results are imprecise and pooled estimate is not statistically significant).	Low for beneficial association (luminal, triple-negative; consistent, imprecise); insufficient (HER2, inconsistent, imprecise)
Breast cancer: Mortality	1 cohort study;[111] 250,470 parous women Medium	Unclear association; one study found no significant association between BF and breast cancer mortality (HR,1.01; 95% CI, 0.79 to 1.29).	Insufficient (unknown consistency, imprecise)
Ovarian cancer	1 SR of 41 cohort/case-control studies;[1] NR[c] 9 cohort/case-control studies; [112-121] 42,611 women Medium	Consistent association between ever BF and longer durations of BF and lower risk of ovarian cancer; magnitude of association varies across studies by BF exposure definition.	Moderate for beneficial association (inconsistent, precise)

Intervention type	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Hypertension	5 cohort studies;[4, 5, 122-124] 441,989 women Medium	Consistent association between longer duration of BF (>6-12 mos) and lower rates of HTN; magnitude of association varies by BF exposure comparisons and study design.	Low for beneficial association (consistent, imprecise)
CVD	3 cohort studies;[4, 6, 125] 301,989 women Medium	Unclear association between BF and CVD; three studies conclude an association between longer BF duration and lower CVD rates, each using a different composite outcome. Magnitude of association varies by exposure comparisons, age at cohort enrolment, and study design.	Insufficient (unknown consistency, imprecise)
CVD mortality	1 cohort study;[126] 15,000 women Medium	Unclear association between BF and CVD mortality. One study found mixed results: parous women ≤65 yrs at enrollment who had never BF had higher CVD mortality over 14 yrs of followup than women who BF ≥24 mos (HR 2.77; 95% CI, 1.28 to 5.99). No clear associations were observed among women ≤65 yrs at enrollment.	Insufficient (unknown consistency, imprecise)
Type 2 diabetes	1 SR of 6 cohort studies;[127] 273,961 women 5 cohort studies;[4, 128-132] 325,815 women Medium	Consistent association between ever BF and longer durations of BF and lower rates of type 2 diabetes (among women with and without gestational diabetes); magnitude of association varies by BF exposure duration and study design.	Low for beneficial association (consistent, imprecise)
Fractures	11 cohort/case-control studies);[133-143] 101,726 women Medium	Consistent lack of association between BF and fractures. Magnitude varies by exposure and outcome measure, but only 1 high ROB study reported statistically significant differences.	Low for no association (consistent, imprecise)
Postpartum depression	1 SR of 48 cohort studies;[144] 71,245 women 14 cohort studies;[145-158] 39,372 women Medium	Unclear association between BF and postpartum depression. Magnitude of association and direction of effect unclear; studies are heterogeneous in design and results inconsistent.	Insufficient (unknown consistency, imprecise)
Postpartum weight change	16 cohort studies;[159-177] 47,655 women Medium	Unclear association between BF and postpartum weight change. Magnitude of postpartum weight change varies by BF exposure and outcome measure.	Insufficient (inconsistent, imprecise)

[a] We marked outcomes as indirect for long-term maternal health outcomes primarily due to uncertainty of the relative contribution of breastfeeding to risk (given that many other potential factors also contribute to outcomes such as hypertension, fracture, and breast cancer); for short-term maternal health outcomes (e.g., postpartum depression) there is uncertainty in the direction of effect between breastfeeding and health outcomes.

[b] Per authors, there were 52 studies with >1,500 women, 31 studies with 500-1,499 women, and 15 studies with <500 women. Exact number of participants is unclear.

[c] Per authors, there were 22 studies with >1,500 women, 12 studies with 500-1,499 women, and 7 studies with <500 women. Exact number of participants is unclear.

BF = breastfeeding; CI = confidence interval; CVD = cardiovascular disease; HER2 = human epidermal growth factor receptor 2; HR = hazard ratio; HTN = hypertension; N = number; NR = not reported; ROB = risk of bias; SR = systematic review.

For both hypertension and type 2 diabetes, studies varied in terms of outcomes and case definition; however, evidence was consistent in finding an association between longer duration of breastfeeding and lower rates of hypertension and type 2 diabetes (low SOE for both outcomes).

Eleven studies reported on the association between breastfeeding using different measures (e.g., ever versus never and duration per child) and hip, vertebral, and forearm fracture risk. Apart from two studies (rated high ROB), no study reported a statistically significant association between breastfeeding and fracture. We rated the SOE as low for no association.

Because of significant heterogeneity in study design, breastfeeding exposure definitions, outcomes, and inconsistency in results, we found insufficient evidence on whether breastfeeding is associated with postpartum depression or postpartum weight change. For postpartum depression, current evidence does not establish the direction of relationship between breastfeeding and higher or lower rates of postpartum depression.

Discussion and Findings in Context

For KQ 1, our findings related to the benefit of BFHI for improving breastfeeding initiation and duration support continued efforts to implement this policy. Because of heterogeneity in study design, country setting, and outcome measures, we were not able to pool results. The absolute difference in rates of breastfeeding initiation and duration vary by setting and are likely influenced by a range of factors, such as intervention fidelity, social factors, and others. Although our scope is narrower (in terms of eligible country setting and study design), our conclusions are consistent with a recent narrative review[178] focused on BFHI; the authors concluded that adherence to the BFHI Ten Steps has a positive influence on breastfeeding outcomes. In terms of other health care interventions, staff training alone (without other breastfeeding support components) did not lead to improved breastfeeding outcomes. However, health care interventions that pair staff education with other services, such as a series of home visits, lead to improved rates of exclusive breastfeeding duration. For workplace interventions, we looked for both trials and observational studies with a control group and still found no eligible studies; the absence of eligible evidence precludes us from commenting on the effectiveness of workplace breastfeeding interventions. In 2012 the Affordable Care Act required large employers to provide reasonable break time and a private place for expressing breastmilk, and mandated insurance coverage of lactation support services and equipment without cost-sharing for new health insurance policies. Without adequate time to express breastmilk in the workplace, working mothers would face significant barriers to breastfeeding. Future studies (as noted below) could address whether certain workplace interventions are more effective than others in improving breastfeeding duration among working mothers.

For other intervention types, our results show that WIC programs providing in-person or telephone peer support improve breastfeeding outcomes. We also identified evidence on a range of other WIC programs (e.g., cash incentives, provision of different types of breast pumps, and changes in food package policies); however, primarily as a result of unknown consistency and imprecision, we had insufficient evidence to make a conclusion regarding the benefit of these interventions. We identified no eligible studies assessing workplace breastfeeding interventions; other reviews have highlighted the lack of controlled trials of workplace interventions for promoting breastfeeding in employed women.[16]

Our conclusions related to the maternal benefits of breastfeeding (KQ 2) suggest that breastfeeding is associated with lower rates of breast cancer, ovarian cancer, hypertension, and type 2 diabetes. The potential to improve maternal health could be highlighted as a rationale for improving rates of breastfeeding by health care and public health practitioners. For cardiometabolic outcomes, it has been hypothesized that lactation "resets" maternal metabolism after pregnancy, thereby reducing cardiovascular disease risk.[179] Our conclusions related to hypertension and type 2 diabetes support this hypothesis. Results of our current review are, in general, consistent with those in previous reviews with respect to conclusions about the limitations of the evidence base. As was the case in 2007, we are not able to make a conclusion about the association between breastfeeding and postpartum weight change or postpartum depression (because of study limitations and imprecise and inconsistent results). For this review, we added two additional maternal health outcomes: hypertension and cardiovascular disease. We concluded that low SOE supports the association between breastfeeding and reduced hypertension; however, primarily because of heterogeneity in outcome measures and study limitations, we concluded that evidence was insufficient to reach a conclusion about cardiovascular disease.

Limitations of the Review Process

For KQ 1, we looked for and included a broad range of interventions to promote and support breastfeeding. At the same time, we specifically excluded primary care–relevant interventions delivered to individual women (to avoid duplicating a recent review conducted for the USPSTF).[26] The studies that met our inclusion criteria assessed a variety of different intervention types. As a result of the inclusion criteria we used, we may have excluded some interventions that could be considered system level or community based. The breadth of our eligibility criteria was also a limitation in terms of evidence synthesis; included studies may have been categorized in different ways. We chose to focus on intervention type and setting because these may be important factors for decisionmakers who plan to implement breastfeeding programs and policies. For KQ 2, we chose to include recent, relevant systematic reviews in our evidence synthesis. Although including these reviews may improve efficiency, this approach has limitations. Some included systematic reviews do not fully report details related to methods (particularly ROB assessment). Because KQ 2 was an update of the 2007 Ip review, we limited our search to very high-income countries; as a result, a secondary analysis of maternal obesity and hypertension from the PROBIT study was excluded from the KQ 2 review.

Limitations of the Evidence Base

For KQ 1, we found no evidence on certain types of interventions (e.g., workplace and school-based interventions), limited evidence for subgroups of women, and no included studies reported on potential harms of interventions. Studies used various definitions of breastfeeding initiation and exclusivity, which may limit the comparability of findings. In addition, because of heterogeneity across studies, we were not able to assess whether certain characteristics of interventions have a greater influence on breastfeeding initiation, duration, and exclusivity. We were also not able to determine whether heterogeneity within some categories of interventions such as BFHI is due to study design, differences in outcome measures, or country setting (since variation exists across all these factors). Factors most likely to limit the applicability of the evidence include country setting, community breastfeeding rates, variation in usual maternity care practices (including other policies and practices to support breastfeeding), and potentially socioeconomic factors.

For KQ 2, although we found a large volume of evidence supporting the association between breastfeeding and improved maternal health, methodological limitations specific to observational study designs limit the ability to determine the magnitude of effect that lactation has on maternal health outcomes. Although a growing literature documents protective associations between lifetime lactation and improved maternal health, these findings do not establish that breastfeeding prevents poor maternal health. Several other factors may be at work. First, women in very high income countries who choose to and successfully breastfeed are typically better educated, wealthier, and more likely to engage in other beneficial health behaviors.[180, 181] Moreover, it is plausible that, rather than breastfeeding preventing poor maternal health, poor maternal health may prevent breastfeeding. One limitation of the evidence is related to time frame of enrollment. Many observational studies (including data from Women's Health Initiative participants[4]) enrolled women who breastfed decades ago. In 1970, only 26.5 percent of women initiated breastfeeding[182] compared with more than 80 percent of women today. Because of these secular changes, confounders of the association between breastfeeding and maternal health have changed over time, and evidence on the association between breastfeeding from older cohorts of women may or may not reflect the strength of association for women currently breastfeeding. Women who chose to breastfeed when breastfeeding rates in the United States were lower could be different in ways that affect risk of adverse maternal health outcomes.

Future Research Needs

For KQ 1, future research should assess the benefit of workplace, school-based, and other community-based interventions for improving rates of breastfeeding. Authors of future studies should more clearly describe characteristics of usual care and what other breastfeeding support services are available. For studies conducted in the United States, future research should address whether certain interventions are more effective for groups of women who differ by socioeconomic factors in order to assess the consistency of current evidence suggesting a difference by education status. In addition, studies are needed to compare types of support, such as manual versus electric pumps or interventions delivered by International Board Certified Lactation Consultants versus Certified Lactation Consultants, to tailor support to the needs of each woman. Study designs with a concurrent control group (e.g., trials or prospective cohort studies) would be helpful in reducing bias and informing the benefit of breastfeeding programs or policies implemented in a wide range of settings, particularly workplace programs.

For KQ 2, observational studies will likely remain the major source of evidence on the association between breastfeeding and maternal health. Use of standardized breastfeeding definitions and clear reporting of how participants were selected could help minimize bias. In terms of analyses, authors should adequately address known confounders, such as breastfeeding intention, birth complications, diet, physical activity, tobacco use, mental health, and social support, and they should clearly report a rationale for why certain factors were chosen. Further studies might also consider the extent to which adverse lactation outcomes, like adverse pregnancy outcomes,[183] may be a window to maternal health.

More generally, standardized definitions of breastfeeding, as well as consistent methods of collecting these data, are needed to facilitate future systematic reviews and meta-analyses.

Conclusions

The body of evidence for breastfeeding programs and policies was diverse in terms of interventions and settings. Current evidence supports the effectiveness of BFHI for improving rates of breastfeeding initiation and duration; however, evidence from one large RCT (PROBIT) has limited applicability, and observational studies do not clearly establish the magnitude of benefit. For U.S. women enrolled in WIC, peer-support interventions have low SOE for improving breastfeeding outcomes. The identified associations between breastfeeding and improved maternal health outcomes are supported by evidence from observational studies, which cannot determine cause and effect relationships.

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Chapter 1. Introduction

Background

In reproductive physiology, lactation follows pregnancy; evidence supports the association between breastfeeding and better health outcomes for both infants and mothers.[1-3] A 2007 Agency for Healthcare Research and Quality (AHRQ) review by Ip and colleagues concluded that breastfeeding was associated with reduced maternal type 2 diabetes, breast cancer, and ovarian cancer, but not fracture.[2] For other outcomes (e.g., postpartum depression), the authors concluded that the relationship between breastfeeding and maternal health was unclear. Since 2007, several new studies have reported on maternal outcomes not addressed in the 2007 AHRQ review, including hypertension, rates of myocardial infarction, and other cardiovascular outcomes.[4-7]

Breastfeeding initiation rates are increasing, and 2014 estimates for the percentage of infants breastfed at birth in the United States (82.5%)[8] met the Healthy People 2020 target for the percentage of infants ever breastfed (81.9%).[9] However, rates of breastfeeding duration did not meet Healthy People 2020 targets. In 2014, only 55.3 percent were breastfed at 6 months and 33.7 percent at 12 months,[8] falling short of Healthy People 2020 targets of 66.6 and 34.1 percent, respectively, for 6 and 12 months.[9] Rates of exclusive breastfeeding through 3 and 6 months were 46.6 and 24.9 percent, respectively; these measures are close to Health People 2020 targets (46.2 and 25.5%, respectively).[8] Women would prefer to breastfeed longer: in a national survey, 45 percent of U.S. women who initiated breastfeeding reported early, undesired weaning.[10] Despite rising breastfeeding initiation (starting) and duration (continuing) rates in the United States, racial and ethnic differences persist. From 2000 to 2014, the percentage of women who initiated breastfeeding went up from 47.4 percent to 68.0 percent for blacks, 71.8 percent to 85.7 percent for whites, and 77.6 percent to 84.8 percent for Hispanics.[11, 12] Sociodemographic factors associated with an increased likelihood of breastfeeding initiation and continuation include older maternal age, being married, Asian or white race, Hispanic ethnicity, higher maternal education, and access to private insurance.[12-15]

In addition to setting targets for breastfeeding initiation rates and duration of breastfeeding, other Healthy People 2020 objectives related to breastfeeding include (1) increasing the proportion of live births that occur in facilities that provide recommended care for lactating mothers and their babies and (2) increasing the proportion of employers that have worksite lactation support programs.[9] These community, workplace, and health care system–based programs and policies may be promising strategies to support initiation and increase duration of breastfeeding.

Health care system–based interventions may include maternity staff education or the Baby-Friendly Hospital Initiative (BFHI). The BFHI is a global program sponsored by the World Health Organization and United Nations Children's Fund to encourage and recognize hospitals and birth centers that create an environment that supports breastfeeding; the "Ten Steps to Successful Breastfeeding" are listed in Table 1. In each country, a BFHI Coordination Group is charged with designating facilities as Baby-Friendly;[16] there are likely country-specific differences in the process for determining final accreditation (or certification) status. As a result, details of implementation vary from country to country. For U.S. hospitals, Baby-Friendly accreditation is awarded to facilities that successfully implement the 10 steps and the International Code of Marketing of Breast-Milk Substitutes[17] and pass an intensive site visit.[18] Site visits and certification are adjudicated by Baby-Friendly USA, a 501c3 nonprofit organization.[19] In addition to certification by Baby-Friendly USA, State departments of public health have encouraged implementation of the Ten Steps through local programs such as the Texas Ten Step Program,[20] the North Carolina Maternity Center Breastfeeding-Friendly Designation Program,[21] and others. On a national level, the Centers for Disease Control and Prevention has audited maternity care practices during the past 10 years with a biennial maternity care practice survey of all U.S. facilities where births occur, results of which are distributed to each facility.[22]

Table 1. Baby-Friendly Hospital Initiative's 10 steps to successful breastfeeding[a]

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within 1 hour of birth.
5. Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants.
6. Give infants no food or drink other than breast milk, unless medically indicated.
7. Practice rooming in—allow mothers and infants to remain together 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

[a] Baby-Friendly USA "Ten Steps to Successful Breastfeeding"[23]

Insurance coverage for lactation support is another strategy that may enable women to achieve their breastfeeding goals. Costs associated with breastfeeding support (e.g., comprehensive lactation support and counseling and breastfeeding equipment) are currently covered by health insurance marketplace plans and private nongrandfathered health plans under the 2010 Patient Protection and Affordable Care Act.[24] It is not clear whether certain lactation benefit packages (e.g., type of breastfeeding supplies offered, number of visits provided, or qualifications of intervention delivery personnel) are more or less effective than others in increasing breastfeeding initiation and duration. In addition, a key system-based program relevant to breastfeeding is the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), which serves 53 percent of infants born in the United States.[25] Because WIC reaches more than half of U.S. infants, its programs have considerable impact on population health.

There is broad appeal and interest in workplace interventions to increase duration and exclusivity of breastfeeding. If they are not supported by their employers, working mothers may have difficulty expressing and storing milk and thus may not be able to maintain breastfeeding. At the same time, there is limited evidence assessing these interventions,[26] and the benefits and harms associated with workplace breastfeeding interventions are uncertain. The 2010 Patient Protection and Affordable Care Act included a provision aimed at workplace breastfeeding policies by amending Section 7 of the Fair Labor Standards Act to require employers to provide reasonable break time and a private space (other than a bathroom) for breastfeeding women to express breast milk for at least 1 year after childbirth.[27]

Existing Guidelines

Multiple clinical guidelines and health-related organizations recommend exclusive breastfeeding up to (or around) 6 months, including the American Academy of Pediatrics,[28] the American Congress of Obstetrics and Gynecology,[29] World Health Organization,[17, 30] and others.[31, 32] These organizations recommend continued breastfeeding through the first year of life and beyond; the WHO recommends continued breastfeeding through the second year of life and beyond.

Rationale for Evidence Review

Programs and policies to support breastfeeding are quite diverse and often complex.[33-35] The purpose of this review is to develop an evidence report that summarizes the effectiveness of community, workplace, and health care system–based programs and policies aimed at supporting and promoting breastfeeding. This review will describe the effectiveness of programs or policies in supporting breastfeeding and whether effectiveness varies for subgroups of women defined by important sociodemographic factors (e.g., maternal age, education, and income; family and social support). The U.S. Preventive Services Task Force (USPSTF) recommends providing interventions during pregnancy and after birth to support breastfeeding as part of routine primary care (B recommendation).[36] To avoid duplication, this review will not address the effectiveness of individual-level primary care interventions to support breastfeeding covered in the recent systematic review to support the USPSTF recommendation.[37]

In addition, this review will address the association between breastfeeding and maternal health. Substantial time has elapsed since the last AHRQ review on this topic in 2007, and the body of literature focused on the maternal health benefits of breastfeeding has grown.[1, 38-40] This review will conduct a partial update of the 2007 AHRQ review focused on the relationship between breastfeeding and various maternal health outcomes.

Key Questions

Key Question 1:

1a. What are the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding?

1b. To what extent do the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding differ for subpopulations of women defined by sociodemographic factors (e.g., age, race, ethnicity, socioeconomic status)?

1c. To what extent do intervention-related characteristics (e.g., type of breast pump provided—manual or electric; delivery personnel) influence the initiation, duration, and exclusivity of breastfeeding?

Key Question 2:

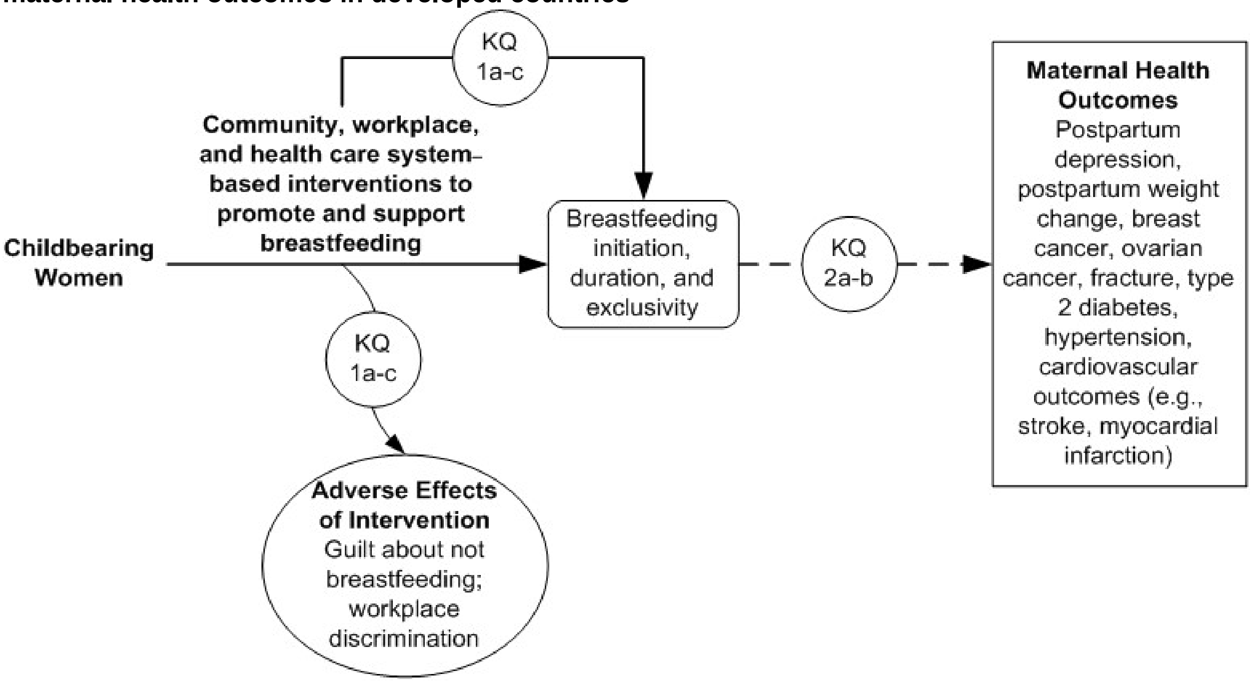
2a. What are the comparative benefits and harms for maternal health outcomes among women who breastfeed for different intensities and durations?

2b. To what extent do benefits and harms for maternal health outcomes differ for subpopulations of women defined by age, race, ethnicity, and comorbidity?

Analytic Framework

We developed an analytic framework to guide the systematic review process (Figure 1). The analytic framework illustrates the population, interventions, outcomes, and adverse effects that guided our literature search and synthesis.

Figure 1. Analytic framework for breastfeeding programs and policies, breastfeeding uptake, and maternal health outcomes in developed countries



KQ=Key Question.

Organization of This Report

The remainder of the review describes our methods in detail and presents the results of our synthesis of the literature by Key Question (KQ), with summary tables and the strength of evidence (SOE) grades for intervention types (KQ 1) or eligible maternal health outcomes (KQ 2). The discussion section offers our conclusions, summarizes our findings, and provides other information relevant to interpreting this work for practice and future research.

Appendix A contains the exact search strings we used in our literature searches. Appendix B contains the PRISMA and provides a summary of evidence and search selection. Appendix C provides the specific questions used for evaluating the risk of bias of all included studies and documents risk of bias ratings for each study and explains the rationale for high or medium ratings. Appendix C also provides questions used for evaluating risk of bias and relevance of included systematic reviews and documents relevance and risk of bias ratings for each review. Appendix D presents information about our grading of the strength of the various bodies of evidence (tables for individual domain assessments and overall SOE grades for each intervention type or outcome). Appendix E lists studies excluded at the stage of reviewing full-text articles with reasons for exclusion. Appendix F contains the breast cancer evidence tables. Appendix G lists references cited across all appendixes.

Chapter 2. Methods

Protocol Review

The initial Key Questions (KQs) were provided by Agency for Healthcare Research and Quality (AHRQ) and developed in collaboration with partners from the Centers for Disease Control and Prevention and National Institutes of Health Office of Women's Health. The RTI International–University of North Carolina at Chapel Hill (RTI-UNC) Evidence-based Practice Center further refined the KQs. We sought guidance from a Technical Expert Panel on the final research protocol, which was posted on the AHRQ Web site on March 20, 2017, at https://effectivehealthcare.ahrq.gov/topics/breastfeeding/research-protocol/; our PROSPERO registration number is CRD42017079125.

Literature Search Strategy

Search Strategy

We conducted two separate search strategies, one for KQ 1 and a second for KQ 2. Appendix A presents the full search strategies for each KQ. For KQ 1, we searched PubMed/MEDLINE, the Cochrane Library, and CINAHL from January 1, 1980, to October 12, 2017. Its start date (January 1, 1980) was chosen to ensure that evidence is applicable to current breastfeeding policies and practices. For KQ 2, we searched PubMed/MEDLINE, the Cochrane Library, and CINAHL from November 1, 2005 (6 months prior to the search date of the 2007 AHRQ review searches) to October 12, 2017.

For both searches, we used either Medical Subject Headings or major headings as search terms when available or key words when appropriate, focusing on terms to describe the relevant population and interventions of interest. We reviewed our search strategy with the Technical Expert Panel and incorporated their input into our search strategy. An experienced information scientist (a librarian at the Evidence-based Practice Center) conducted the searches. The literature search will be updated concurrent with the peer review process.

We searched for unpublished studies relevant to this review using ClinicalTrials.gov. On our behalf, the AHRQ Scientific Resource Center solicited scientific information packages via Federal Register notices or informational requests.

We also manually searched reference lists of pertinent reviews and included trials and background articles on this topic to look for any relevant citations that our searches might have missed. We imported all citations into an EndNote® X7.5 electronic database.

Inclusion and Exclusion Criteria

We developed eligibility (inclusion and exclusion) criteria with respect to PICOTS (populations, interventions, comparators, outcomes, time frames, settings), study designs, and study durations for each KQ (Table 2). Both KQs focused on populations of childbearing women (adults and adolescents).

Table 2. Eligibility criteria

PICOTS	Inclusion	Exclusion
Population	KQs 1 and 2: Childbearing women and adolescents[a]; we will also search for evidence on subgroups of women defined by age, race, ethnicity, comorbidity, and socioeconomic status (including insurance status and payer type).	KQs 1 and 2: Men; nulliparous women; children
Intervention/ Exposure	KQ 1: Community, workplace, and health care system–based interventions aimed at promoting and supporting BF, including the following: health plan benefits; State and Federal policies or programs (e.g., WIC programs); workplace and school-based programs; BFHI implementation, including full or partial implementation (defined as three or more steps) KQ 2: Exposure to BF[b]	KQ 1: Interventions delivered in primary care settings as part of pre- or postnatal care; interventions specific to NICU care KQ 2: All other exposures
Comparator	KQ 1: No intervention (or usual practice); comparisons of two interventions that differ in content or intensity KQ 2: No BF; shorter duration (e.g., BF for 1 month vs. 12 months) and/or less intensive BF (e.g., exclusive BF vs. mixed feeding or formula feeding)	KQs 1 and 2: All other comparisons; no comparisons
Outcomes	KQ 1: Rates of BF initiation, duration, and exclusivity of BF; harms of interventions (e.g., guilt about not BF, workplace discrimination, and other reported harms) KQ 2: Postpartum depression (any measure), postpartum weight change,[c] breast cancer, ovarian cancer, osteoporotic fracture,[d] type 2 diabetes, hypertension, cardiovascular outcomes (e.g., stroke, myocardial infarction, cardiovascular disease specific mortality, and composite outcomes)	KQ 1: Any other outcome not specified, including compliance with policies or practices and attitudes toward BF and complications of lactation KQ 2: Any other outcome not specified, including complications of lactation (e.g., mastitis) and other maternal outcomes (e.g., lung cancer)
Country setting	KQ 1 and 2: Studies conducted in a developed country ("very high" [KQs 1 and 2][e] and "high" [KQ 1] human development index per the United Nations Development Programme)[41]	KQs 1 and 2: Studies conducted in other countries
Study designs	KQ 1: RCTs; CCTs; prospective cohort studies with concurrent control groups; systematic reviews; for studies assessing policy or system-level interventions, pre-post studies with repeated outcome measures before and after the intervention are also eligible KQ 2: RCTs, CCTs, cohort studies,[f] case-control studies, systematic reviews	KQs 1 and 2: All other designs
Publication language	KQs 1 and 2: English	KQs 1 and 2: Languages other than English

[a] Childbearing women and adolescents are our population of interest; however, for KQ 1, interventions may include or be targeted toward the woman's partner or family.

[b] This includes women who breastfeed their infant at the breast and/or express milk.

[c] The prior 2007 review on this topic for AHRQ[2] restricted results to prospective cohort studies reporting on women for whom the exclusivity or amount of breastfeeding was known. Studies reporting on weight change needed to control for gestational weight gain or prepregnancy weight and have at least 3 months of followup. All included studies for the update met these criteria.

[d] We excluded studies with surrogate measures of fracture (e.g., fracture risk score or index) or bone turnover markers or with measures of osteoporosis only.

[e] The United Nations does not recognize Taiwan (i.e., Republic of China) as a sovereign state and did not include it in the 2015 Human Development Index report. However, Taiwan's government calculated its human development index to be 0.882, based on 2014 data and using the same methodology as the United Nations. This human development index value would place Taiwan among countries in the "very high" human development category, so it will be included in this report.[42]

[f] For all KQ 2 outcomes, we included cohort studies that report on the incidence of eligible health outcomes prospectively regardless of whether women were classified into categories based on breastfeeding exposure prospectively (i.e., at study enrollment) or retrospectively. Additionally, for long-term outcomes for which no prospective studies of outcomes exist, we included cohort studies that collected information on exposure and outcomes at a single time point (retrospectively). Such studies provide evidence on associations rather than on causal relationships.

AHRQ = Agency for Healthcare Research and Quality; BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; CCT = controlled clinical trial; KQ = Key Question; NICU = neonatal intensive care unit; PICOTS = population, intervention/exposure, comparator, outcomes, time frames, country settings, study design; RCT = randomized controlled trial; WIC = Special Supplemental Nutrition Program for Women, Infants and Children.

The focus of KQ 1 is on providing an overall synthesis of community, workplace, or health care system–based interventions aimed at promoting and supporting breastfeeding. We specifically excluded studies assessing individual-level primary care interventions to support and promote breastfeeding to avoid duplicating a recent review conducted for the U.S. Preventive Services Task Force.[37] For KQ 1, we included studies conducted in countries categorized as "very high" and "high" on the human development index per the United Nations Development Programme, given the relatively small body of literature on the Baby-Friendly Hospital Initiative and other community-based breastfeeding interventions.[43] Eligible outcomes include rates of breastfeeding initiation, duration and exclusivity of breastfeeding (based on any definition, as described by study authors), and potential harms of interventions (e.g., guilt about not breastfeeding, workplace discrimination).

Our eligibility criteria for KQ 2 are based on those used in the 2007 AHRQ review by Ip and colleagues for maternal health outcomes. Eligible studies are those that compare groups of women exposed to breastfeeding with those who did not breastfeed (or breastfed for shorter duration and/or less intensity). For this update, we also expanded to include additional outcomes including hypertension and cardiovascular disease (e.g., stroke and myocardial infarction). For outcomes relevant to osteoporotic fracture, we limited to studies reporting on fractures and excluded intermediate outcomes such as bone mineral density.

Study Selection

Two members of the research team independently reviewed all titles and abstracts of individual studies and published systematic reviews (identified through searches) for eligibility against our inclusion and exclusion criteria (Table 2). We retrieved any publications marked for inclusion by either reviewer for evaluation of the full text. For titles and abstracts that lacked adequate information to determine inclusion or exclusion, we retrieved the full text for review. Then, two investigators independently reviewed the full text to determine final inclusion or exclusion. The reviewers resolved any disagreements by discussion and consensus or by consulting a third member of the review team.

All results in both review stages were tracked in an EndNote database. We recorded the principal reason that each excluded full-text publication did not satisfy the eligibility criteria (see Appendix B).

Data Extraction

For studies that met our inclusion criteria, we designed and used structured data extraction forms to gather pertinent information from each article, including characteristics of study populations, settings, interventions, comparators, study designs, methods, and results. One investigator extracted the relevant data from each included article; all data abstractions were reviewed for completeness and accuracy by a second member of the team. We recorded intention-to-treat results if available. For KQ 2, we abstracted results relevant to the association between breastfeeding and health outcomes that were adjusted for potential confounders rather than unadjusted results (when both were provided). All data abstraction was performed using Microsoft Excel® software.

Risk of Bias Assessment of Individual Studies

To assess the risk of bias (ROB) (i.e., internal validity) of individual studies, we adapted existing tools (ROBINS-I[44] for observational studies and the Cochrane tool[45] for trials) and used predefined criteria based on the AHRQ *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*. These criteria included questions to assess selection bias, confounding, performance bias, detection bias, and attrition bias; concepts covered include those about adequacy of randomization, similarity of groups at baseline, masking, attrition, whether intention-to-treat analysis was used, method of handling missing data, validity and reliability of outcome measures, and treatment fidelity.[46] Appendix C lists the specific questions used for evaluating the ROB of all included studies. It also includes a table showing the responses to these questions and ROB ratings for each study and explains the rationale for all ratings that were either high or medium. When tools use the term “some concerns” for final ROB assessments in Appendix B, we changed this to “medium” for consistency in our summary tables and text; a final rating of “medium” or “some concerns” refers to the same level of concern regarding ROB.

In general terms, results from a low ROB study are considered to be valid. A study with medium (i.e., some concerns in Appendix C) ROB is susceptible to some risk of bias but probably not enough to invalidate its results. A study assessed as high ROB has significant ROB (e.g., stemming from serious errors in design, conduct, or analysis) that may invalidate its results. To assess publication bias, we looked for evidence of unpublished literature through searches of gray literature (clinicaltrials.gov).

We evaluated the ROB from selection, confounding, measurement of exposure, missing data, measurement of outcomes, and reporting. Based on multiple signaling questions, we rated the ROB for each domain as high, some concerns, or low and provided justification for the rating. Studies with a high ROB in any domain received an overall high ROB rating. Studies with one or more domains with some concerns received an overall rating of medium ROB (i.e., some concerns in Appendix C). Studies with low ROB in all domains received an overall low ROB rating. We describe the results of all included studies regardless of the ROB rating. ROB for individual studies influences the aggregate ROB rating for the overall strength of evidence (SOE) for each outcome.

Two independent reviewers assessed ROB for each study. Disagreements between the two reviewers were resolved by discussion and consensus or by consulting a third member of the team.

Risk of Bias Assessment of Systematic Reviews

For both KQs, we capitalized on the availability of existing systematic reviews and meta-analyses; these were captured in our database searches and identified during the literature review. One systematic review was identified for KQ 1 but was rated as not relevant, primarily due to ineligible country settings and study designs of the included studies (Appendix Table C-1). For KQ 2, we assessed the relevance of recent systematic reviews (published within the past 5 years) using predefined criteria. Appendix Table C-17 shows our assessment of each potentially relevant review identified during our database searches. For reviews determined to be relevant, we rated the ROB as low, unclear, or high using the ROBIS tool;[47] we excluded reviews rated as high ROB. Appendix C lists the specific questions used for evaluating the ROB of all relevant reviews.

Data Synthesis

We summarized all included studies in narrative form and in summary tables that tabulate the important features of the study populations, design, intervention, outcomes, and results for KQ 1 and KQ 2.

KQ 2 is a partial update of the 2007 AHRQ review by Ip and colleagues; we synthesized evidence from that review with newly identified evidence and did not report results from that review separately from the body of literature published since. As noted above, we included other recent (published within the past 5 years) relevant systematic reviews rated low or unclear ROB using the ROBIS tool[47] for KQ 2. Conclusions from systematic reviews rated high ROB may not be valid because of bias stemming from uncertain study eligibility criteria, lack of dual-review during identification and selection of studies, and other factors. For those KQ 2 outcomes for which we included a recent published systematic review, we first describe the results of the review and then summarize data from primary studies not included in the review (i.e., those published after the latest search date of those reviews or identified by searching reference lists of relevant articles).

When recent, relevant existing systematic reviews were identified for a particular outcome, we assessed whether newly identified primary studies were likely to change judgments about conclusions made in existing reviews using an SOE framework (i.e., assessment of study limitations, consistency, precision, directness, and reporting bias). If we deemed their results likely to change the conclusions, we considered conducting a new quantitative synthesis if appropriate (i.e., if conclusions made in existing reviews are based on a pooled analysis of studies). If the new studies were consistent with prior syntheses and would not change the conclusion of the review, we presented the results of the existing review along with an updated qualitative synthesis including the newly identified studies and an explanation of how they are consistent with the prior findings. We conducted a new SOE for each outcome and did not use SOE grading from existing reviews.

We considered performing meta-analyses when we had at least three unique studies of low or medium risk of bias that we deemed sufficiently similar (in population, interventions, comparators, and outcomes), because of the potential biases of meta-analyses that include a small number of studies.[48] We planned to consider heterogeneity carefully before calculating a pooled summary estimate in a meta-analysis, we carefully considered the heterogeneity across studies. As described above, in cases where we identified a recent eligible meta-analysis for an eligible outcome, we assessed whether to update the analysis by considering how the results of recently published primary studies would change the conclusions of the meta-analyses using a SOE framework. For KQ 1, we did not conduct meta-analyses of studies assessing the benefit of interventions to improve rates of breastfeeding initiation and duration because we identified few studies that were similar in population, setting, intervention type and design. For KQ 2, the size of the literature and heterogeneity varied across outcomes. For postpartum depression and cardiovascular disease, we did not conduct meta-analyses primarily due to significant heterogeneity in terms of study designs and outcome measures. For type 2 diabetes, breast and ovarian cancer, we included recent existing systematic reviews with meta-analyses; individual studies identified in our database searches were generally consistent with the pooled results reported by existing systematic reviews and so we did conduct new meta-analyses for these outcomes.

We synthesized and described results of all studies regardless of the risk of bias rating. When possible, we describe whether results of studies rated high risk of bias differ from those rated low or medium risk of bias (narratively, or by noting whether existing systematic reviews or meta-analyses found inconsistent results for studies that varied by risk of bias).

Strength of the Body of Evidence

We graded the SOE of the accumulated evidence on a given issue to answer the specific KQs on the benefits and harms of the interventions in this review; we used the guidance established for the Evidence-based Practice Center Program.[49] Developed to grade the overall strength of a body of evidence, this approach now incorporates five key domains: ROB (including study design and aggregate ROB); consistency, directness, and precision of the evidence; and reporting bias. It also considers other optional domains that may be relevant for some scenarios, such as plausible confounding that would decrease the observed effect and strength of association (i.e., magnitude of effect) or factors that would increase the strength of association (i.e., dose-response effect).

Table 3 describes the grades of evidence that can be assigned. Grades reflect the strength of the body of evidence to answer the KQs on the comparative effectiveness, efficacy, and harms of the interventions in this review and on associations between breastfeeding and health outcomes. Two reviewers assessed each domain for each key outcome, and differences were resolved by consensus. For each assessment, one of the two reviewers was always an experienced Evidenced-based Practice Center investigator. We graded the SOE for all included outcomes.

Table 3. Definitions of the grades of overall strength of evidence

Grade	Definition
High	**We are very confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has few or no deficiencies. We believe that the findings are stable (i.e., another study would not change the conclusions).
Moderate	**We are moderately confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	**We have limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	**We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome.** No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

Source: Berkman et al.[49]

An unfavorable assessment for any one of the five key domains (e.g., inconsistency, indirectness, imprecision, high or medium aggregate ROB, or evidence of reporting bias) typically resulted in downgrading from high to moderate SOE. Two unfavorable assessments typically resulted in downgrading to low SOE. When only one study reported an outcome of interest (with unknown consistency and imprecision arising from nonsignificant results or wide confidence intervals spanning the null), we usually graded the SOE as insufficient. Insufficient ratings also applied to evidence bases with multiple studies with inconsistent results. When aggregate ROB was high or uncertain, we usually graded the SOE as low or insufficient (depending on responses to other key domains). Appendix D presents tables showing our assessments for each domain and the resulting SOE grades for outcomes organized by KQ and then intervention type (for KQ 1) and outcome category (for KQ 2).

Applicability

We assessed applicability following guidance from the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[50] For individual studies, we examined conditions that may limit applicability based on the PICOTS structure. Some factors identified a priori that may limit the applicability of evidence include the following: race or ethnicity of enrolled populations, setting of enrolled populations, geographic setting, and availability of health insurance and other health-related employment benefits. We also paid close attention to secular trends when interpreting the evidence. Such trends are of concern in that breastfeeding initiation rates in the United States have changed dramatically in the past 40 years, from a nadir of less than 25 percent in 1971[51] to more than 80 percent in 2014.[8] This is important because the time period between exposure to breastfeeding and some outcomes of interest (e.g., cancer, cardiovascular disease) may be decades, and secular trends in social determinants of infant feeding may confound observed associations. Findings linking breastfeeding to maternal health among women feeding their infants decades ago may not be generalizable to contemporary women.

Peer Review and Public Commentary

This report was posted for public comment and was peer reviewed. We addressed all comments in the final report, making revisions as needed; a disposition of comments report will be publicly posted 3 months after release of the final report.

Chapter 3. Results

Results of Literature Search and Screening

Searches of all sources identified a total of 11,006 potentially relevant citations. We included 128 unique individual studies (described in 137 publications) and 10 systematic reviews. Of these, 40 individual studies (from 44 publications) were relevant to Key Question (KQ) 1, and 88 individual studies (from 93 publications) and 10 systematic reviews were relevant to KQ 2. Of the KQ 2 included studies, 18 were studies from a prior 2007 Agency for Healthcare Research and Quality (AHRQ) review addressing the maternal health benefits of breastfeeding.[2] The remaining 34 studies from the 2007 review were included in at least one 1 of our 10 systematic reviews or superseded by a new included study. Appendix E provides a complete list of articles excluded at the full-text screening stage, with reasons for exclusion.

Effectiveness and Harms of Breastfeeding Programs and Policies

To aid in synthesizing results of similar studies, we categorized interventions primarily based on intervention type: Baby-Friendly Hospital Initiative (BFHI), other (non-BFHI) health care system–based interventions (e.g., residency curriculum related to breastfeeding), Special Supplemental Nutrition Program for Women, Infants and Children (WIC)–based interventions, and community-based interventions (not primarily delivered as part of the health care system). Key points and strength of evidence (SOE) assessments are summarized below by intervention category.

Key Points: Baby-Friendly Hospital Initiative

- Twelve studies set in diverse country settings assessed the effectiveness of BFHI interventions; no study reported on potential harms associated with the intervention.
- Based on results from nine cohort studies (1,227,532 women), rates of any and exclusive breastfeeding at discharge is higher among women giving birth in BFHI-certified facilities than control facilities (low SOE).
- Based on evidence from one large randomized controlled trial (RCT) (Promotion of Breastfeeding Intervention Trial [PROBIT], N=17,046) and eight cohort studies (136,983 women), we concluded that BFHI is associated with increased breastfeeding duration (moderate SOE).
- Low SOE supports the conclusion that implementation of four or more BFHI steps is associated with lower rates of weaning than implementation of fewer than four steps (1 cohort study; 1,417 women).

Key Points: Non-BFHI Health Care System–Based Interventions

- Fifteen studies assessed the effectiveness of other (non-BFHI) health care system–based interventions. Included studies assessed heterogeneous interventions; no study reported on potential harms associated with the interventions.
- Overall, low SOE evidence supports the effectiveness of three intervention types for improving the duration of exclusive breastfeeding: modified BFHI policy implementation in outpatient setting (e.g., development of a breastfeeding policy, staff training, outcome

assessment, and quality improvement initiatives), continuous nursing care during the perinatal period (the same nurse provides routine perinatal care to the mother and infant), and health care provider education combined with a series of home visits.

- Interventions assessing health care provider education and training alone (without additional breastfeeding support services) are not effective in improving rates of breastfeeding initiation (low SOE); 4 studies (1,532 women) found no significant difference between groups.

Key Points: Women, Infants and Children–Based Interventions

- Eight included studies assessed a WIC program or policy; studies evaluated heterogeneous interventions. Although all studies were set in the United States, they included women from diverse States. None reported on potential harms.
- Based on 4 studies (2,480 women), low SOE supports the effectiveness of WIC-based peer-support programs for improving rates of any breastfeeding initiation (exclusive or nonexclusive) and breastfeeding duration.
- We found insufficient evidence (primarily because of unknown consistency and imprecision) to make a conclusion on the benefit of other WIC programs or policies for improving breastfeeding outcomes, including policy changes related to WIC food packages, provision of different types of breast pumps (electric vs. manual), tailored counseling, cash incentives, and peer-support programs targeted at fathers.

Key Points: Community-Based Interventions

- Five studies assessed the effectiveness of community-based interventions (not associated with the health care system or delivered as part of routine maternity care). Interventions were heterogeneous; we found no eligible studies evaluating workplace breastfeeding programs or policies.
- Low SOE supports the benefit of community-based interventions that provide mothers with peer support (via home visits) for improving rates of breastfeeding duration.
- Based on evidence from one large RCT, access to a community-based breastfeeding drop-in center among women receiving early home-based breastfeeding support does not increase breastfeeding duration (low SOE).
- We found insufficient evidence to draw a conclusion on the effectiveness of other community-based interventions, primarily because of unknown consistency, imprecision, and study limitations.

Baby-Friendly Hospital Initiative Interventions

Characteristics

Twelve included studies (described in 13 publications) assessed the effectiveness of BFHI interventions (Table 4).[52-64] All focused on postpartum women enrolled from hospital wards or birth facilities soon after delivery. Studies were conducted in diverse country settings including the United States (two studies);[54, 55] Taiwan (two studies);[60, 64] and one each in the Republic of Belarus,[52] Hong Kong,[56] Czech Republic,[57] Russia,[65] Croatia,[59] Brazil,[63] United Kingdom (multiple regions),[61] and Scotland.[66] All studies focused on multiple hospitals (>4) or clusters of hospitals. The majority of studies focused on women giving birth between 2000 and 2009 (Table 4); two enrolled women in the late 1990s.[52, 62]

One included study was an RCT,[52] 10 were prospective cohort studies,[54-58, 60-62, 64, 67] and 1 was a single-group pre-post study.[59] The RCT (PROBIT)[52] was a cluster-randomized trial of BFHI (34 hospitals were randomized to BFHI or routine practice). The majority of observational studies compared cohorts of women giving birth in hospitals that had implemented BFHI with women giving birth in hospitals that had not implemented BFHI (or were not accredited). Most assessed the implementation of all 10 steps; one study set in Hong Kong compared breastfeeding initiation rates at hospitals that had implemented at least 6 steps with those that had implemented fewer than 6 steps.[56] For observational studies comparing outcomes among women giving birth in BFHI-certified hospitals versus control hospitals, studies differed in the extent to which they described whether control hospitals had implemented any BFHI steps or whether they were planning to become certified. For example, one study compared outcomes among women giving birth in fully accredited hospitals (those that had implemented all 10 steps, had completed an annual audit of compliance and progress monitoring visits, and had completed a reassessment 24 months after the initial award), certified hospitals (those that adopted a policy covering all 10 steps and had an action planning visit from United Nations Children's Fund (UNICEF) UK Baby Friendly but were not yet fully accredited), and control hospitals.[62]

In terms of population characteristics, seven studies reported on maternal age and generally enrolled women in their 20s and 30s.[52, 54, 56, 58, 60, 61, 63] Three studies (set in the United States and United Kingdom) reported on race; the percentage of nonwhite participants enrolled ranged from 3 to 47 percent.[54, 55, 61] In the six studies reporting on the percentage of enrolled women who were primiparous, the range was 38 to 67 percent.[54, 56, 58, 60, 61, 63] One study (PROBIT) reported on the percentage of women who previously breastfed a child for 3 months or longer (25%),[52] and one reported on the percentage of included women who had previously breastfed for any duration (34%).[56] Six studies reported on the rate of cesarean delivery among enrolled participants; rates ranged from 10 to 48 percent.[52, 56, 58, 60, 61, 63]

Included studies varied in terms of whether they had other specific inclusion criteria for mothers or hospitals or clusters (Table 4). Notably, the PROBIT RCT included only mothers who initiated breastfeeding,[52] and another study recruited only women who were willing to breastfeed or experienced in breastfeeding.[60] Three included studies were limited to women giving birth to healthy singletons.[52, 56, 61]

The majority (9 studies) were rated medium risk of bias (ROB) and three were rated high ROB.[59, 60, 64] Common methodological limitations included selection bias, high or unclear rates of attrition, and baseline differences between groups that were not accounted for in analyses.

Table 4. Characteristics of included studies assessing BFHI interventions

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primi-parous % Previously BF	% Cesarean Birth
Abolyan, 2006[58] Medium	Prospective cohort 8 hospitals 741 women	Russia 2004	Mothers with no mental illness who had healthy infants (Apgar >7, weight >2,500 g)	Mothers giving birth in hospitals with BFHI certification	Mothers giving birth in "not-as yet Baby-Friendly"[a] hospitals	26	NR	63-67 NR	15-16
Bartington, 2006[61] Medium	Prospective cohort 496 maternity units; 17,359 mother-infant parts	United Kingdom 2000-2002	Women with singleton live births	Birth in a BFHI-accredited hospital or certified unit	Birth in a hospital that was not BFHI accredited or certified	Median age: 28-29	6-13	43-44 NR	22-23
Bosnjak, 2004[59] High	Single-group, pre-post study 14 primary care sites 7,414 infants	Croatia 1990-2000	NR	Implementa-tion of BFHI (1994-1998) and, later, establishment of community-based BF support groups (1999-2000)	Period before intervention implementation (1990-1993)	NR	NR	NR NR	NR
Broadfoot, 2005[62] Medium	Prospective cohort 33 maternity units 445,623 births	Scotland 1995-2002	Maternity units: those with >50 births/year	Hospitals that held a UNICEF U.K. BFHI standard award	Hospitals without BFHI accreditation	NR	NR	NR NR	NR
Gau, 2004[60] High	Prospective cohort 12 hospitals 4,614 mothers	Taiwan 2000-2002	Women giving birth at participating hospitals	Hospital lactation intervention focused on BFHI initiation and accreditation	Control hospitals not participating in intervention (and pre-post comparisons)	30-31	NR	49-53 NR	24-30

Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primi-parous % Previously BF	% Cesarean Birth
Hawkins, 2014[54] Medium	Prospective cohort 32 birth facilities in 5 U.S. States 25,327 women	United States 1999-2009	Facilities: data[b] from 5 States participating in PRAMS monitoring (1999-2009) Mothers giving birth at facilities with ≥ 100 births during study period who had information on BF initiation	Mothers giving birth in a BFHI-accredited birth facility/hospital	Mothers giving birth in a nonaccredited birth facility/hospital	% by age category: ≤19: 9 20-24: 24 25-29: 29 30-34: 24 ≥35: 15	49	42 NR	NR
Hawkins, 2014[55] Medium	Prospective cohort 10 birth facilities in 1 U.S. State (Maine) 2,014 women	United States 2004-2008	Mothers giving birth in Maine at a hospital where at least 100 births occur	Mothers giving birth in an accredited or becoming accredited BFHI facility	Mothers giving birth in a facility that is not BFHI accredited	NR	≤7% across all facili-ties	NR NR	NR
Kramer, 2001[52]; Yang, 2014[53] (PROBIT) Medium	Cluster RCT 31 maternity hospitals/ polyclinics 17,046 mother/infant pairs	Republic of Belarus 1996-1997	Mothers with healthy singleton infants (≥37 wks, birth weight ≥2,500 g) who initiated BF during their postpartum stay	Maternity care in a BFHI facility, included staff training (18 hours) and implementa-tion of all 10 steps	Standard maternity care (non-BFHI-accredited facilities)	% by age category: <20: 14 20-34: 81-83 ≥35: 4	NR	% with no other children in household: 56-60 % BF previous child ≥3 mos: 24-25	11-13

Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primi-parous % Previously BF	% Cesarean Birth
Mydlilova, 2009[57] Medium	Prospective cohort 112 hospitals 660,355 births	Czech Republic 2000-2006	Mothers giving birth in a maternity hospital with a living infant at discharge	Mothers giving birth in a BFHI-accredited hospital	Mothers giving birth in a non-BFHI-accredited hospital	NR	NR	NR NR	NR
Tarrant, 2011[56] Medium	Prospective cohort 4 hospitals 1,417 mother/infant pairs	Hong Kong 2006-2007	Healthy mothers intending to BF with healthy singleton births (≥37 wks, ≥2,500 g)	Completion of steps 6 out of 6 steps (4, 6, 7, 8, 9, 10)	Completion of <6 of 6 of the identified BFHI steps	% by age category: 18-24: 7 25-29: 23 30-34: 46 ≥35: 24	NA	59 34	12
Venancio, 2011[63] Medium	Prospective cohort 64 municipalities 65,936 infants	Brazil 2008	Participants of a 2008 nationwide survey related to child health	Birth in a BFHI-accredited facility	Birth in a hospital that was not BFHI accredited	% by age category: <20: 16 ≥20: 84	NR	50 NR	48
Weng, 2003[64] High	Prospective cohort 56 hospitals 7,563 women	Taiwan 2000-2001	Women giving birth in hospitals registered for BFHI appraisal	Hospitals that passed BFHI appraisal	Hospitals that did not pass BFHI appraisal	NR[c]	NR	NR NR	NR

[a] Per authors, the "not-as-yet BFHI" maternity hospitals of the control group were similar to the maternity hospitals of the experimental group in terms of quality indices of obstetrical services, number of deliveries, and level of participation.
[b] Per authors, data from Alaska, Maine, Nebraska, Ohio, and Washington were used because these States had at least one birth facility that received BFHI accreditation during 1999 through 2009 when PRAMS data were collected, and the State released hospital identifiers. The years of PRAMS data varied across States as did the timing of hospitals' BFHI accreditation.
[c] Characteristics of mothers were not reported; there were geographic differences in the percentage of hospitals that passed the BFHI appraisal. Per authors, more hospitals passed the appraisal in the northern region than other regions of Taiwan, which may be due to more resources or earlier adoption of BFHI practices.

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; g = gram; HV = home visits; N = number; NA = not applicable; NR = not reported; NRCT = nonrandomized controlled trial; PRAMS = Pregnancy Risk Assessment Monitoring System; PROBIT = Promotion of Breastfeeding Intervention Trial; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation; U.K. = United Kingdom; UNICEF = United Nations Children's Fund; wks = weeks.

Results

Breastfeeding Initiation

Nine studies reported on rates of breastfeeding initiation at hospitals that were BFHI accredited (or certified) compared with nonaccredited hospitals (Table 5).[54, 55, 57, 58, 60-64] Six of these reported on rates of any breastfeeding initiation (exclusive or nonexclusive) at hospital discharge;[54, 55, 60-62, 64]overall, rates of breastfeeding initiation were higher at BFHI hospitals than control hospitals, but the magnitude of benefit varied across studies. Two studies (by the same author) compared hospitals in the United States enrolling women from similar time periods (1999-2009); one evaluated data from five U.S. States[54] and the other focused on hospitals in one State (Maine).[55] In both studies, estimated rates of initiation were approximately 2.4 to 7.0 percent higher in BFHI-accredited facilities than nonaccredited facilities; however, the differences were not statistically significant in either study (Table 5).[54, 55] Similarly, two studies set in the United Kingdom (one of which was limited to Scotland[62]) found higher rates of breastfeeding initiation in BFHI-accredited hospitals than nonaccredited hospitals (ranging from 0.5 to 7.4%); however, the differences were not statistically significant (Table 5).[61, 62] Finally, two studies set in Taiwan found significantly higher rates of in-hospital breastfeeding at BFHI hospitals compared with control hospitals.[60, 64] One of these compared hospitals that passed with those that did not pass BFHI appraisal and found initiation rates of 88.1 percent and 78.1 percent respectively ($p<0.001$).[64] The second measured breastfeeding rates over a four year period (1999-2002), trends in breastfeeding rates were significantly higher at BFHI certified hospitals than controls ($p<0.001$).[60]

Five studies set in various country settings (Czech Republic,[57] Russia,[58] Taiwan,[60, 64] and Brazil[63]) found significantly higher rates of exclusive breastfeeding initiation at discharge in BFHI-certified or -accredited hospitals than control hospitals (Table 5). The absolute difference in breastfeeding initiation between BFHI hospitals and control hospitals varies widely. In three studies, the difference between groups ranged from approximately 3 to 8 percent.[57, 63, 64] Two studies found a larger difference between groups; one study set in Russia found a 56 percent higher rate of exclusive breastfeeding among mothers giving birth in BFHI- and non-BFHI-certified hospitals in a single year (2004), and the second (set in Taiwan) found a 23 to 27 percent higher rate of exclusive breastfeeding initiation in BFHI hospitals than controls over a 4-year period.[60]

Table 5. BFHI studies reporting on breastfeeding initiation

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation
Abolyan, 2006[58] Medium	G1: Mothers giving birth in BFHI-certified hospitals G2: Mothers giving birth in “not-yet Baby-Friendly” hospitals	Prospective cohort 741 women 8 sites	Exclusive BF at discharge, % (N) G1: 88.9 (383) G2: 32.6 (358) p<0.0001

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation
Bartington, 2006[61] Medium	G1: Birth in BFHI-accredited maternity unit G2: Birth in BFHI-certified maternity unit G3: Birth in maternity unit with neither award	Prospective cohort 496 maternity units 17,359 women	BF initiation (full sample), % G1: 71.3 G2: 70.8 G3: 69.5 RR[a] (G1 vs. G3): 1.10 (1.05 to 1.15) RR[a] (G2 vs. G3): 1.02 (0.99 to 1.05)
Broadfoot, 2005[62] Medium	G1: Birth in BFHI-accredited[b] maternity unit G2: Birth in BFHI-certified[c] unit G3: Birth in maternity unit with neither award	Prospective cohort 33 sites 445,623 births	Initiation of any BF at 7 days (%) G1: 49.4 G2: 43.4 G3: 42.0 OR[c] (G1 vs. G3); 1.28 (1.24 to 1.31) OR[c] (G2 vs. G3): 1.04 (1.02 to 1.06)
Gau, 2004[60] High	G1: Mothers giving birth in BFHI-certified hospitals G2: Mothers giving birth in control hospitals	Prospective cohort 12 sites 4,614 mothers	Rates of exclusive BF during hospitalization by year, G1 vs. G2, % (SD) 1999: 0.30 (0.24) vs. 0.24 (0.006) 2000: 0.34 (0.24) vs. 0.22 (0.007) 2001: 0.46 (0.21) vs. 0.23 (0.05) 2002: 0.50 (0.16) vs. 0.23 (0.25) p<0.001 for all years Total BF rate (any BF): 1999: 0.92 (0.03) vs. 0.82 (0.08) 2000: 0.94 (0.03) vs. 0.82 (0.04) 2001: 0.95 (0.03) vs. 0.94 (0.07) 2002: 0.95 (0.04) vs. 0.95 (0.02) p<0.001 for all years
Hawkins, 2014[54] Medium	G1: Mothers giving birth in a BFHI-accredited facility G2: Mothers giving birth in a nonaccredited facility	Prospective cohort 32 birth facilities in 5 U.S. States 25,327 women	No overall differences in rates of BF initiation between facilities that received BFHI accreditation and those without accreditation: (adjusted coefficient[d]=0.024; 95% CI, -0.00 to 0.51)
Hawkins, 2014[55] Medium	G1: Mothers giving birth in a BFHI-accredited facility G2: Mothers giving birth in a nonaccredited facility	Prospective cohort 10 birth facilities in 1 U.S. State (Maine) 2,014 women	No effect of BFHI on BF initiation between facilities that were accredited and those that were nonaccredited: (adjusted coefficient[d]=0 0.070; 95% CI, -0.04 to 0.18; p=0.2)

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation
Mydlilova, 2009[57] Medium	G1: Mothers giving birth in a BFHI-accredited hospital G2: Mothers giving birth in a non-BFHI hospital	Prospective cohort 112 hospitals 660,355 women	Risk of not being exclusively BF was higher in non-BFHI than in BFHI hospitals (by year): Year: RR (95% CI) 2000: 1.09 (1.08 to 1.10) 2004: 1.54 (1.48 to 1.61) 2006: 1.32 (1.27 to 1.37) Avg. rate of exclusively BF infants for 2000-2006 (%): G1: 90.32 G2: 87.53 p<0.001
Venancio, 2011[63] Medium	G1: Birth in BFHI-accredited facility G2: Birth in a nonaccredited facility	Prospective cohort 64 municipalities 65,936 infants	Adjusted[e] prevalence ratio of exclusive BF on first day after hospital discharge (G1 vs. G2): 1.06 (1.04 to 1.09) Unadjusted prevalence of exclusive BF on first day after hospital discharge: G1: 87.2 G2: 82.3 p=0.0001
Weng, 2003[64] High	G1: Births in hospitals that passed BFHI appraisal G2: Births in hospitals that passed BFHI appraisal	Prospective cohort 56 hospitals 7,563 women	In-hospital exclusive BF rate, weighted % (SD) G1: 31.43 (22.40) G2: 23.18 (24.65) p<0.01 In-hospital BF rate (exclusive and nonexclusive), weighted % (SD) G1: 88.08 (15.91) G2: 78.11 (14.62) p<0.001

[a] RRs adjusted for ward type, socioeconomic status, ethnicity, academic qualifications, maternal age, parity, and lone parent status.
[b] Fully-accredited hospitals had implemented all Ten Steps, completed an annual audit of compliance and progress monitoring visits, and completed a reassessment 24 months after the initial award. Certified hospitals where those that adopted a policy covering all Ten Steps, had an action planning visit from UNICEF UK Baby Friendly, but were not yet fully accredited.
[c] OR adjusted for Carstairs deprivation category, mother's age, number of births in hospital, and year of birth.
[d] All models include a birth fixed effect and an interaction between year and whether a birth facility received accreditation.
[e] Adjusted for infant age (at time of survey), low birth weight, mode of delivery, firstborn, maternal age, and maternal education.

Avg.= average; BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; CI = confidence interval; G = group; N = number; NR = not reported; OR = odds ratio; ROB = risk of bias; RR = risk ratio; SD = standard deviation; U.K. = United Kingdom.

Breastfeeding Duration

Ten studies reported on breastfeeding duration (Table 6); nine compared women giving birth in BFHI-certified or -accredited hospitals and control hospitals,[52, 54, 58-61, 63, 64, 68] and one study compared hospitals based on the number of BFHI steps implemented.[56]

Of the nine studies comparing hospitals with and without a BFHI status, one was an RCT (PROBIT),[69] and eight were observational studies (one single group pre-post study,[59] and the rest were prospective cohort studies). In the PROBIT RCT, women giving birth at intervention hospitals had higher rates of exclusive breastfeeding at 3 months postpartum (43% vs. 6%; p<0.001), 6 months postpartum (7.9% vs. 0.6%; p=0.01), and lower odds of having been weaned (from any breastfeeding) at 3, 6, 9, and 12 months (Table 6).[52]

Findings from eight observational studies reporting on breastfeeding duration were mostly consistent in finding benefit; however, results were often imprecise and varied by setting and outcome timing.[54, 58-61, 63, 64, 68] Two studies set in the United States found slightly higher rates of any breastfeeding and exclusive breastfeeding for at least 4 weeks at BFHI than control hospitals (by approximately 0.5 to 6.8%); however, differences between groups were not statistically significant.[54, 55] One study evaluating Scottish hospitals found no significant difference between women giving birth in BFHI-accredited hospitals, and non-accredited hospitals in rates of any breastfeeding at 1 month; rates were slightly lower at BFHI-accredited hospitals (44.6%) than hospitals that were certified (i.e., had adopted a BFHI policy but were not yet audited for compliance) or had neither status (49.9% vs. 49.5%, respectively).[61] A study set in Russia found higher rates of any breastfeeding at 6 to 12 months among women giving birth in BFHI hospitals than non-BFHI-certified hospitals; however, authors did not clearly report the sample size or whether differences are statistically significant (percentage change from baseline: 10.5 vs. 3.7; p-value not reported).[58] Four studies set in Taiwan,[60, 64] Croatia,[59] and the Czech Republic found significantly higher rates of any or exclusive breastfeeding over 1 to 12 months of followup. Studies reported different outcome measures, which limits the ability to compare the magnitude of differences between groups.

Table 6. BFHI studies reporting on breastfeeding duration and exclusivity

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Abolyan, 2006[58] Medium	G1: Birth in BFHI- certified hospitals G2: Birth at “not-yet Baby-Friendly” hospitals	Prospective cohort 741 women (survey); N for BF rates at 6-12 months NR 8 sites	Increase in BF rates (%) at 6-12 mos among infants born during implementation of BFHI Baseline (1999-2003): G1: 20.7 to 31.2 (+10.5%) G2: 15.6 to 19.3 (+3.7%)	NR
Bartington 2006[61] Medium	G1: Birth in a BFHI-accredited maternity unit[a] G2: Birth in BFHI-certified unit[a] G3: Birth in unit with neither award	Prospective cohort 496 maternity units 17,359 women	Any BF at 1 mo, % G1: 44.6 G2: 49.9 G3: 49.5 RR (G1 vs. G3): 0.96 (0.84 to 1.09) RR (G2 vs. G3): 0.96 (0.91 to 1.01)	NR

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Bosnjak, 2004[59] High	G1: Implementation of BFHI (1994-1998) and, later, establishment of community-based BF support groups (1999-2000) G2: Period before intervention implementation (1990-1993)	Single-group, pre-post study 14 primary care sites 7,414 infants	Increase in BF prevalence compared with 1990-1993 (preintervention): BFHI implementation (1994-1998), G2 vs. G1: 1 mo: 68% vs. 87% 3 mos: 30% vs. 54% 6 mos: 11.5% vs. 28% 11-12 mos: 2% vs. 3.5% p<0.05 Implementation of BF support groups (1999–2000), G2 vs. G1: 1 mo: 68% vs. 87% 3 mos: 30% vs. 66% 6 mos: 11.5% vs. 49% 11-12 mos: 2% vs. 23 p<0.05	NR
Gau, 2004[60] High	G1: Mothers giving birth in BFHI-certified hospitals G2: Mothers giving birth in control hospitals	Prospective cohort 12 sites 4,614 mothers	Total BF rate (any BF), by year, G1 vs. G2, % (SD) 1 mo 1999: 0.36 (0.05) vs. 0.30 (0.05) 2000: 0.35 (0.01) vs. 0.30 (0.01) 2001: 0.38 (0.02) vs. 0.30 (0.05) 2002: 0.44 (0.05) vs. 0.34 (0.02) p<0.001 for all comparisons 2 mos 1999: 0.19 (0.03) vs. 0.14 (0.02) 2000: 0.11 (0.03) vs. 0.07 (0.02) 2001: 0.16 (0.05) vs. 0.08 (0.02) 2002: 0.21 (0.05) vs. 0.13 (0.02) p<0.001 for all comparisons	Exclusive BF rate, by year, G1 vs. G2, % (SD): 1 mo 1999: 0.16 (0.04) vs. 0.06 (0.02) 2000: 0.15 (0.03) vs. 0.08 (0.02) 2001: 0.18 (0.03) vs. 0.06 (0.01) 2002: 0.23 (0.05) vs. 0.03 (0.02) p<0.001 for all comparisons 2 mos 1999: 0.09(0.03) vs. 0.03 (0.02) 2000: 0.06(0.02) vs. 0.05 (0.02) 2001: 0.08 (0.03) vs.0.03 (0.004) 2002: 0.12 (0.04) vs. 0.0 (0.00) p<0.001 for all comparisons
Hawkins, 2014[54] Medium	G1: Mothers giving birth in a BFHI-accredited facility G2: Mothers giving birth in a nonaccredited facility	Prospective cohort 32 birth facilities in 5 U.S. States 25,327 women	Any BF for ≥4 wks after delivery: coefficient[b]=0.006 (-0.01 to 0.033); p=0.6	Exclusive BF for ≥4 wks after delivery: coefficient[b]=0.012 (-0.01 to 0.03); p=0.3
Hawkins, 2014[55] Medium	G1: Mothers giving birth in a BFHI-accredited facility G2: Mothers giving birth in a nonaccredited facility	Prospective cohort 10 birth facilities in 1 U.S. State (Maine) 2,014 women	Any BF for ≥4 wks after delivery: coefficient[b]=0.068 (-0.02 to 0.08); p=0.2	Exclusive BF for ≥4 wks after delivery: coefficient[b]=0.025 (-0.07 to 0.12); p=0.6

First Author, Year **ROB**	**Intervention** **Comparison**	**Study Design** **N Sites** **N Participants**	**Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)**	**Exclusive Breastfeeding Duration**
First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Kramer 2001;[52] Yang, 2014[53] PROBIT Medium	G1: Intervention modeled on BFHI G2: Usual maternity care	Cluster RCT 31 maternity hospitals 17,046 mother/infant pairs	Any BF (% of women), OR[c] (95% CI) for having been weaned: 3 mos: G1: 72.7 vs. G2: 60.0 OR (95% CI): 0.52 0.40 to 0.69 6 mos: G1: 49.8 vs. G2: 36.1 OR (95% CI): 0.52 (0.39 to 0.71) 9 mos: G1: 36.1 vs. G2: 24.4 OR (95% CI): 0.51 (0.36-0.73) 12 mos: G1: 19.7 vs. G2: 11.4 OR (95% CI): 0.47 (0.32 to 0.69)	Prevalence of exclusive BF (% of women), as defined by WHO: 3 mos: G1: 43.3 G2: 6.4 p<0.001 6 mos: G1: 7.9 G2: 0.6 p=0.01
Tarrant, 2001[56] Medium	G1: Mothers giving birth in hospitals with 6 or more BFHI steps/practices G2: Mothers giving birth in hospitals with <6 BFHI steps/practices	Prospective cohort 4 hospitals 1,417 mother/infant pairs	Association between exposure to number of BFHI practices and infant being weaned in ≤8 wks, No. BFHI practices: OR[d] (95% CI): 0-1: 3.13 (1.41 to 6.95) 2: 2.03 (1.05 to 3.94) 3: 2.31 (1.21 to 4.42) 4: 2.08 (1.08 to 4.00) 5: 1.45 (0.70 to 2.99) 6: 1.00 (referent)	NR
Venancio, 2011[63] Medium	G1: Birth in BFHI-accredited facility G2: Birth in a nonaccredited facility	Prospective cohort 64 municipalities 65,936 infants	NR	Adjusted prevalence ratio of exclusive BF by infant age (G1 vs. G2): <2 mos:[e] 1.13 (1.07 to 1.20 <3 mos:[f] 1.08 (1.03 to 1.13) 6 mos:[g] 1.06 (1.01 to 1.11) Median duration of exclusive BF, days (95% CI) G1: 60.2 (95% CI, 56.5 to 64.2) G2: 48.1 (95% CI, 45.3 to 50.8)
Weng, 2003[64] High	G1: Births in hospitals that passed BFHI appraisal G2: Births in hospitals that passed BFHI appraisal	Prospective cohort 56 hospitals 7,563 women	Any BF at 1 mo (exclusive and nonexclusive), weighted % (SD) G1: 67.68 (20.65) G2: 59.43 (21.19) p<0.001	Exclusive BF at 1 mo, weighted % (SD) G1: 26.11 (13.05) G2: 18.79 (14.74) p<0.01

[a] Fully accredited hospitals had implemented all 10 steps, completed an annual audit of compliance and progress monitoring visits, and completed a reassessment 24 months after the initial award. Certified hospitals where those that adopted a policy covering all 10 steps and had an action planning visit from UNICEF UK Baby Friendly but were not yet fully accredited.
[b] All models include a birth fixed effect and an interaction between year and whether a birth facility received accreditation.
[c] All ORs adjusted for birth weight, maternal age, and previous breastfeeding history.

[d] Adjusted for Baby-Friendly hospital practices, maternal age, maternal education, household income, emergency cesarean section, return to work, whether mother was breastfed as a child, mother's previous breastfeeding experience, and husband's feeding preference.
[e] Adjusted for infant age, low birth weight, maternal age, maternal education.
[f] Adjusted for infant age, gender, maternal age, and maternal education
[g] Adjusted for infant age, gender, low birth weight, mode of delivery, firstborn, maternal age, maternal education, and maternal employment.

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; CI = confidence interval; G = group; N = number; NR = not reported; OR = odds ratio; PROBIT = Promotion of Breastfeeding Intervention Trial; RCT = randomized controlled trial; ROB = risk of bias; RR = risk ratio; SD = standard deviation; wks = weeks; WHO = World Health Organization.

One study set in Hong Kong assessed breastfeeding rates by degree of BFHI implementation.[56] Women giving birth in hospitals practicing four or fewer BFHI steps had higher odds of weaning at or before 8 weeks postpartum compared with women giving birth in facilities practicing six BFHI steps (Table 6).[56]

Other (Non-BFHI) Health Care System–Based Interventions

Characteristics

Fifteen included studies (described in 16 publications) assessed the effectiveness of other health care system–based interventions (non-BFHI interventions) (Table 7).[68, 70-84] All enrolled women from routine maternity care settings (prenatal clinics, maternity hospitals, or postpartum care settings). Studies were conducted in diverse country settings including the United States (3 studies),[73, 80, 82] Canada (1 study),[78] Sri Lanka (1 study),[75] Brazil (2 studies),[79, 85] China (1 study),[72] and various European countries (6 studies).[68, 71, 74, 76, 77, 83] Most were RCTs, 4 were nonrandomized controlled trials,[68, 73, 78, 81] and two were single-group pre-post studies.[80, 82] Most studies enrolled women prior to 2009; the majority (10 studies) enrolled women during the 2000s, and 5 studies enrolled women during the 1990s.[78-80, 82]

In terms of population characteristics, two studies were limited to primiparous women only,[71, 72] and others included primiparous or multiparous women. Of the 13 studies enrolling both primiparous and multiparous women, 3 reported on the percentage of women who had previously breastfed (39% to 60%, across groups).[68, 71, 75, 76, 81, 83, 84]Three studies did not report on the age of enrolled mothers;[73, 76, 78, 82] across the remaining studies, the mean age of women in the study samples ranged from approximately 27 to 34 years. Five studies reported on cesarean births, with rates ranging from 0 to 29 percent;[68, 71, 78, 83, 84] 1 study excluded mothers who had a cesarean delivery.[80]

Studies assessed the effectiveness of diverse interventions. Five assessed the effectiveness of education and training for health care professionals only (with no mention of additional individual-level services offered to women).[71, 73, 75, 78, 79] Of these, one targeted training to midwives and postnatal nurses in Swedish municipalities,[71] one focused on U.S. residency programs (pediatrics, OBGYN, and family medicine),[73] and three focused on hospital staff (one focused on nursing staff only,[78] and two included nurses, midwives, and physicians[75, 79]). Length of training and content varied across studies (Table 7).

Seven studies assessed a multicomponent health system intervention that combined education (or skills training) to providers with expanded breastfeeding support services for mothers (or families).[68, 74, 76, 77, 82-84] The intensity of training and range of providers included in staff training differed across studies (Table 7). Several studies included expanded patient education activities delivered in diverse health care settings, including hospitals or maternity units,[82] prenatal classes,[82] Web sites,[68] and outpatient settings.[77] One intervention targeted women who were expected to be discharged early and provided a multicomponent breastfeeding intervention during the hospital stay (emphasizing extended skin-to-skin contact, breastfeeding at least 8

Table 7. Characteristics of studies evaluating non-BFHI health care system–based interventions

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Baerug, 2016[81] Medium	NRCT 54 municipalities 3,948 mothers	Norway 2009-2012	Women with a singleton birth >2,000 g	Implementing the BFHI in routine antenatal and child care services at the community level (staff training and demonstration of practical skills)	Routine antenatal and preventive health care[a]	% by age category: 16-24: 15 25-29: 34 30-34: 32 35-44: 19	NR	44 NR	NR
Coutinho, 2005[84] Low	RCT 2 hospitals 350 women	Brazil 2001	Healthy mothers with singleton births	Staff training (modeled after BFHI training); all mothers assigned 10 postnatal HVs specific to BF support	Staff training alone (with no added HV)	% by age group: <20: 33 ≥20: 67	NR	38 NR	29
Ekstrom, 2014[70]; Ekstrom, 2012[71] Medium	Cluster RCT 10 municipalities 540 women (480 analyzed)	Sweden 2000-2002	Primiparous healthy mothers of singleton full-term infants receiving care from health professionals in the intervention or control municipalities	Process-oriented training in supportive BF counseling for midwives and postnatal nurses (7 days of lectures)	Usual care, women were sampled from clusters not receiving the intervention at two time points, before the intervention and at the same time as the intervention sample	27 (NR)	NR	100 NA	14-18

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Feldman-Winter, 2010[73] Medium	NRCT 13 residency programs (417 residents) N women NR	United States 2006-2008	Residency programs (pediatrics, OBGYN, and family medicine) with low or unknown BF rates at hospitals lacking Baby-Friendly certification Medical records of women giving birth at included sites were randomly sampled at study initiation and 6m later	Targeted BF curriculum for residents in pediatrics, family medicine, and OBGYN, including lectures, skills workshops, discussions, participation in newborn nursery rotation assisting mothers with BF, and community outreach and care coordination (field trip or presentation to local BF support group)	No curriculum (usual care)	NR[b]	NR	NR NR	NR
Hannula, 2014[68] High	NRCT 3 maternity hospitals 705 mothers	Finland 2007-2008	Mothers giving birth to singleton infants at included maternity hospitals	Access to long-term intensified counseling on BF and parenthood support (via Web pages), in maternity hospital, and after childbirth (20th week gestation to 1 year)	Normal counseling and support at maternity health care[c]	31 NR	NR	47-62 39-52	12-17

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Hoddinott, 2009[74] Medium	Cluster RCT 14 general practices ('localities') 18,603	Scotland 2002	Clusters: general practices that routinely collected BF data through a national surveillance program Women: no specific criteria other than women attending participating practices	Adoption of a BF group policy: localities were asked to double the amount of BF group activity, set up a minimum of 2 new groups and ensure all centers had access to a group; individual BF groups were to be offered weekly to women only and at least 50% of the group meeting was to be social and interactive	Practices without a new BF group policy[d]	28-29	NR	NR NR	NR
Kools, 2005[77] Medium	Cluster RCT 10 maternity and child health centers 781 mothers	Netherlands 2000-2002	Women who gave birth to infants >2,000 g	Health care provider training to deliver a BF promotion and support program (health counseling, early signaling of BF problems, continuity of care, and free access to lactation consultancy)	Usual care	NR; % by age group <25 yrs: 8-10 25 to 30 yrs: 44-45 ≧31 yrs: 46-47	NR	55-56 NR (66-71% intended to BF)	NR

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Kronborg, 2007[76] Medium	Cluster RCT 22 municipalities 1,595 mothers	Denmark 2004	Mothers living in eligible municipalities who gave birth to a single full-term child	Health visitors received an 18-h course (related to providing BF support and counseling); 1 to 3 HVs were provided within 5 wks of birth and addressed BF techniques, education, maternal and infant care, and need for support	Usual care (health visitor service, including one or more nonstandardized HVs within 5 wks of birth)	NR; % by age group: 15-24: 10-12 25-32: 63-66 33-46: 25	NR	40-41 60	NR
Madden, 2003[80] Medium	Single-group, pre-post 14 health centers 20,366 mother-infant pairs	United States 1990-1998	Mother-infant pairs identified from HMO[e] medical records who had given birth during 7.5 yrs before and after two LOS policy changes; excluded pairs whose deliveries involved cesarean sections, >4 nights' LOS, or unequal mother and infant LOS	Introduction of a new HMO protocol of 1 postpartum overnight hospitalization followed by a nurse HV for normal vaginal deliveries (1994- 1996), then MA[f] State 48h minimum coverage mandate (effective 1996)	Mothers giving birth during a 4-yr period before the first policy change	NR; % by age group: <22: 4.5 22-29: 31.2 30-34: 39.2 35+: 25.1	31	45 NR	NA (excluded)

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Martens, 2000[78] High	NRCT 2 rural hospitals 75 births	Canada 1997	Mothers giving birth at participating hospitals	Mandated 1.5-h hospital staff BF education session for all nursing staff; optional tutorial related to BF education, support and hospital policy completed individually	Usual care	NR	NR; 27 to 76% were First Nations clients	9.8-23.5 NR	0
Nilsson, 2017[83] Medium	Cluster RCT 9 maternity settings 3,541 women	Denmark 2013-2014	Women expecting a single infant, intending to BF and expected to be discharged within 50 hrs postpartum	Multicomponent BF program emphasizing extended skin-to-skin contact, BF at least 8 times per day, BF position guidance, and acknowledgement of equal roles between parents	Usual care	30 (5)	NR	40 NR	13-16

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Senarath, 2007[75] High	Cluster RCT 5 hospitals 892 women	Sri Lanka 2003-2004	Healthy mother-newborn pairs (singleton births only) who received care from the 5 study hospitals	Training program (4 days) for hospital obstetric service staff (midwives, nurses, and doctors) to increase knowledge and essential newborn care skills; approximately 5 h spent on BF topics	Usual care (no additional training)	NR; % by age group: ≦19: 8-11 20-34: 80-87 ≧ 35: 5-9	100 (Sri Lankan ethnic-i-ties)	36-46 NR	NR

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Taddei, 2000[79] Medium	Cluster RCT 8 hospitals 970 infants	Brazil 1992	Hospitals located near Sao Paulo, Brazil with at least 2 births per day in the maternity ward; no previous exposure to a similar intervention	3-wk intensive BF promotion program designed to train multidisciplinary teams in lactation management (pediatricians, obstetricians, and nurses)	No exposure to staff training[g]	26-29	NR	34-37 NR (90-96% intended to BF)	NR
Wagner, 2002[82] Medium	Single group, pre-post 1 health care system 13,039 infants	United States 1993-1999	All mothers and their infants admitted to the Medical University of South Carolina 1993-1999	Mandated BF education for all medical and nursing staff (including residents) emphasizing the benefits of BF for mothers and infants offered in a range of forums[h] patient education offered via prenatal classes and postnatal care	Usual care (pre-intervention)	NR	69	NR NR	NR

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Wan, 2011[72] Medium	RCT 1 hospital (2 obstetric units) 470 pregnant women	China 2008-2009	Pregnant women ≥20 yrs having their first delivery	Continuous primary nursing care: individualized continuous holistic primary nursing care starting 8 wks prior to delivery (outpatient setting), during admission and 2 wks post discharge (to mother and infants) by the same nurse	Task-centered nursing care: women received the same care for the same duration, but task centered (not individualized), and by different nurses who carried out different services	27-28	NR	100 NA	NR

[a] Per authors, routine preventive health care for infants includes a home visit between 0 and 2 wks and consultations at 6 wks and at 3, 4, 5, 6, 7–8, 10, and 11–12 mos for vaccination, anthropometric measurements, screening, and lactation counseling.

[b] All characteristics provided in study are for the residents who were exposed to the educational curriculum, not for the women/infants whose BF rates were being measured.

[c] Described as personal advice from midwives and nurses according to the mother's wishes and a possibility to watch a BF video on the ward; no additional staff training and the families did not have access to more individualized BF support.

[d] At baseline, 10 BF groups were offered in the intervention and control localities. The number of BF groups increased to 27 in intervention localities and remained at 10 in control localities.

[e] The HMO included 14 health centers of the Harvard Vanguard Medical Associates in eastern Massachusetts.

[f] The Massachusetts law established a "minimum stay" of 48 hours, with shorter stays permitted if a mother gave consent and was offered a home visit. A federal law effective January 1998 extended the 48-hour coverage mandate to other States and health plans but did not change the policy environment for the study population.

[g] At the time of the study, few Brazilian hospitals had rooming-in, and approximately 30% of all deliveries were via cesarean section.

[h] The learning forum included a yearly didactic conference for pediatric residents and twice yearly seminar for staff (pediatrics, obstetrics and nursing, bedside teaching, case conferences journal club).

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; g = gram; HMO = health maintenance organization; h = hour; HV = home visit; LOS = length of stay; MA = Massachusetts; N = number; NA = not applicable; NR = not reported; NRCT = nonrandomized controlled trial; OBGYN = obstetrician/gynecologist; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation; wks = weeks.

times per day, and education targeted at both parents).[83] Three studies combined staff training with expanded access to breastfeeding groups[74] or additional postpartum home visits.[76, 84]

Three studies assessed changes in health service delivery or policies that relate to breastfeeding. One RCT compared two different types of perinatal nursing care: continuous primary nursing care (the same nurse provided care during prenatal appointments, during admission, and 2 weeks postdischarge to both mothers and infants) or usual task-centered nursing (women and infants received the same care, but different nurses carried out different tasks).[72] The second study was a single group pre-post study assessing the effect of changes in maternity length of stay policies in one U.S. State (Massachusetts) among women enrolled in a large health maintenance organization.[80] The third study assessed the benefit of implementing an adapted BFHI intervention in outpatient maternal and child health centers (e.g., developing a breastfeeding policy, staff training, outcome assessment, and quality improvement initiatives).[81]

The majority of studies (11) were rated as medium ROB, 1 was rated low ROB,[84] and 3 were rated high ROB.[68, 75, 78] Common sources of bias included selection bias, high attrition, and baseline differences between groups that were not controlled for in the analyses.

Results

Breastfeeding Initiation

Ten studies assessing non-BFHI health care system interventions reported on rates of breastfeeding initiation (Table 8). Studies generally measured breastfeeding initiation during a maternity stay or at discharge. Three studies assessed the initiation of any breastfeeding (exclusive and nonexclusive) only,[71, 74, 80] two assessed the initiation of exclusive breastfeeding only,[68, 72] and the others reported on both measures.

Table 8. Non-BFHI health care system–based interventions reporting on breastfeeding initiation

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results
Ekstrom, 2014[70]; Ekstrom, 2012[71] Medium	G1: BF training program for health care professionals G2: Usual care (control group A)[a] G3: Usual care (control group B)	Cluster RCT 10 municipalities 480 women	Assessed via questionnaire (3 days postpartum), % initiated BF (N total): G1: 100 (172) G2: 97 (148) G3: 97 (160) G1 vs. G2: p=0.863 G1 vs. G3: p=0.838

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results
Feldman-Winter, 2010[73] Medium	G1: Residency BF curriculum G2: Usual care	NRCT 13 sites (residency programs) N women NR	Initiation of exclusive BF, % (n/N total): G1 pre: 15.5 (78/504) G1 post: 23.1 (114/493) G1 pre-post % change: 7.5; p=0.002 G2 pre: 27.5 (193/701) G2 post: 30.5 (214/701) G2 pre-post % change: 3.0; p=0.239 Initiation of any BF (% (n/N total): G1 pre: 76.0 (383/504) G1 post: 80.7 (398/493) G1 pre-post % change: 4.7; p=0.071 G2 pre: 64.8 (454/701) G2 post: 66.6 (467/701) G2 pre-post % change: 1.8; p=0.500
Hannula, 2014[68] High	G1: Intensified perinatal family BF support G2: Usual care	NRCT 3 maternity hospitals 705 mothers	Exclusive BF at hospital discharge, % (N): G1: 76 (431) G2: 66 (274) p=0.0099
Hoddinott, 2009[74] Medium	G1: Adoption of a policy to provide BF groups for pregnant and BF women G2: Usual care (no new policy)	Cluster RCT 14 general practices (“localities”) 18,603[b]	Initiation of any BF at birth, mean difference (95% CI) between intervention and control groups at postintervention (adj. for preintervention rate): -0.009 (-0.045 to 0.027); p=0.58
Kools, 2005[77] Medium	G1: BF promotion and support program G2: Usual care	Cluster RCT 10 maternity and child health centers 781 mothers	Exclusive BF at birth, % (N): G1: 61 (371) G2: 67 (330) OR (95% CI): 0.80 (0.57 to 1.11) Total BF at birth (exclusive or nonexclusive), % (N): G1: 68 (371) G2: 72 (330) OR (95% CI): 0.84 (0.61 to 1.16)
Madden, 2003[80] Medium	Changes in maternity length of stay policy (pre-post)[c]	Single-group, pre-post 14 health centers 20,366 births	BF initiation rates increased an estimated 0.4% per quarter over time: 70.1% in the 4th quarter of 1990 to 81.9% in the 1st quarter of 1998 (p<0.0001); no statistically significant changes in BF rates were found at either of the 17 policy intervention points. Subgroups: no reductions in BF rates were associated with the changes in LOS policies for the following subgroups: maternal age, primiparous status, Medicaid enrollment, living in a low-income neighborhood, black race, Asian race, and Hispanic nonblack race.
Martens, 2000[78] High	G1: Nursing staff BF education G2: Usual care	NRCT 2 rural hospitals 75 births	Any BF initiation, % (N)[d]: G1 pre: 62 (21) G1 post: 65 (20) G2 pre: 74 (74) G2 post: 64 (14) p>0.05 for pre-post change in both groups

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results
Senarath, 2007[75] High	G1: Obstetric staff training on essential newborn care G2: Usual care	Cluster RCT 5 hospitals 892 women	Exclusive BF at discharge (mothers self-report), % (N): G1 pre: 97.8 (233) G1 post 97.3 (233) G2 pre: 99.6 (233) G2 post: 98.7 (223) Difference in pre-post change between intervention and control groups NS
Wagner, 2002[82] Medium	Mandated medical and nursing staff BF education and expanded patient education (pre-post)	Single-group, pre-post 1 health care system 13,039 infants	Any BF initiation (at the time of feeding initiation during first 24-hour period), % (N BF/N total) Pre (1993-1994): 18.9 (816/4,315) Post (1996-1999): 47.1 (4,107/8, 724) p<0.0001
Wan, 2011[72] Medium	G1: Continuous primary nursing care G2: Task-centered nursing care	RCT 1 hospital (2 obstetric units) 470 pregnant women	Exclusive BF during hospitalization, % (N): G1: 98.69 (230) G2: 87.92 (240) p=0.001

[a] Women were sampled from clusters not receiving the intervention at two time points: before the intervention (control group A) and at the same time as the intervention sample (control group B).
[b] The population refers to eligible birth records in all randomized clusters with valid feeding data considered in ITT analysis.
[c] This study period spanned the 17 interventions of interest: (1) the introduction of a new HMO protocol of one postpartum overnight hospitalization followed by a nurse home visit for normal vaginal deliveries and then (2) Massachusetts State minimum coverage legislation.
[d] Rates of any BF initiation obtained from chart audits before and after intervention (at both intervention and control hospitals). All breastfed babies born at the control site from June 1997 to the end of September were supplemented with additional fluids.

BF = breastfeeding; BFHI = Baby-Friendly Health Initiative; CI = confidence interval; G = group; HMO = health maintenance organization; ITT = intent-to-treat; LOS = length of stay; N = sample size; NR = not reported: NRCT = nonrandomized controlled trial; NS = not sufficient; RCT = randomized controlled trial; ROB = risk of bias.

Four studies assessing the effectiveness of education and training for health care professionals only (with no mention of additional individual-level services offered to women) reported on breastfeeding initiation; overall, studies found no difference between intervention and control groups.[71, 73, 75, 78] Two of these were RCTs enrolling populations with a high rate of breastfeeding initiation before and after implementation of the intervention, at both intervention and control sites (>97%).[71, 75] One NRCT assessed the effectiveness of a residency breastfeeding curriculum; at intervention sites, initiation of exclusive breastfeeding increased (pre-post % change, 7.5; p=0.002), however, control sites also had an increase in breastfeeding initiation (pre-post % change, 3.0; p=0.239) and authors do not note whether differences between groups are statistically significant.[73]

Four studies assessed a health-system intervention that combined education (or skills training) to providers with expanded breastfeeding support services and reported on breastfeeding initiation rates.[68, 74, 77, 82] Of these studies, two did not find benefit; one was an RCT assessing adoption of a policy to provide increased access to breastfeeding groups (mean difference between groups in breastfeeding initiation rates, -0.009; 95% confidence interval [CI],

-0.045 to 0.027),[74] and the other assessed a multicomponent breastfeeding promotion and support program and found no difference in initiation of any or exclusive breastfeeding at birth (Table 8).[77] Two other studies found benefit.[68, 82] One found increased rates of exclusive breastfeeding initiation at hospitals implementing an intensified perinatal family breastfeeding support intervention compared with controls (75 vs. 66%; p=0.0099),[68] and the other found increased initiation of any breastfeeding after a mandated medical and nursing staff educational intervention paired with increased pre- and postnatal breastfeeding support (19% vs. 48%; p<0.0001).[82]

Two studies assessing changes in different health service delivery methods or policies that relate to breastfeeding reported on initiation rates with inconsistent results.[72, 80] One study was a single-group pre-post study assessing the relationship between changes in maternity length-of-stay policies among women belonging to one Massachusetts health maintenance organization (HMO); the study period spanned two separate interventions: (1) the introduction of a new protocol of one postpartum overnight hospitalization for women who had normal vaginal deliveries (followed by a nurse home visit) and (2) Massachusetts State law mandating minimum 48-hour coverage legislation.[80] Breastfeeding initiation rates increased an estimated 0.4 percent per quarter over time with no statistically significant changes at either of the two policy intervention time points.[80] The RCT comparing continuous primary nursing care with usual care (task oriented nursing) among Chinese women found higher rates of exclusive breastfeeding during hospitalization among the intervention group than in the controls (99% vs. 88%; p=0.001).[72]

Breastfeeding Duration

Table 9 shows results of the 11 non-BFHI health care system intervention studies reporting on breastfeeding duration. Two measured duration of exclusive breastfeeding only,[72, 76] 2 measured the duration of any breastfeeding only,[74, 80] and 5 measured both exclusive and nonexclusive breastfeeding duration.

Table 9. Non-BFHI health care system–based interventions reporting on breastfeeding duration

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Baerug, 2016[81] Medium	G1: Implementing the BFHI into routine antenatal and child care services at the community level G2: Usual care	NRCT 54 municipalities 3,948 mothers	Any BF, % (N) 6 mos G1: 72 (969) G2: 68 (898) OR[a]: 1.24 (0.99-1.54); p=0.06 12 mos G1: 28 (224/807) G2: 27 (204/732) OR NR; p=0.43	Exclusive BF, % (N) 5 mos G1: 41 (971) G2: 36 (900) OR[a]: 1.39 (1.09 to 1.77); p=0.018 6 mos G1: 18 (174/971) G2: 14 (127/900) OR[a]: 1.33 (1.03 to 1.72); p=0.03

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Coutinho, 2005[84] Low	G1: BFHI staff training + 10 HVs providing BF support and promotion G2: BFHI staff training alone	RCT 2 sites 350 women	Mean rate of any BF 10-180 days after discharge, % (N) G1: 78 (174) G2: 62 (175) p<0.001	Mean rate of exclusive BF 10-180 days after discharge, % (N) G1: 45 (174) G2: 13 (175) p<0.0001
Ekstrom, 2014[70]; Ekstrom, 2012[71] Medium	G1: BF training program for health care professionals G2: Usual care (control group A)[b] G3: Usual care (control group B)	Cluster RCT Antenatal and child health centers in 10 municipalities 480 women	Total BF duration[c] (exclusive plus partial BF) assessed at 9 mos, mean mos (SD) G1: 7.5 (4.7) G2: 7.1 (4.6) G3: 7.0 (4.5) p=NS per authors	Duration of exclusive[c] BF (mos), mean (SD) G1: 3.9 (2.2) G2: 3.2 (1.7) G3: 3.5 (2.0) G1 vs. G2= p=0.02 G1 vs. G3= NS per authors
Feldman-Winter, 2010[73] Medium	G1: Residency BF curriculum G2: Usual care	NRCT 13 sites[d] (residency programs)	Any BF at 6 mos, % (N): G1 pre: 25.3 (300) G1 post: 28.7 (300) pre-post change: 3.4; p=0.291 G2 pre: 26.9 (499) G2 post: 25.3 (550) pre-post % change: -1.6; p=0.574	Exclusive BF at 6 mos, % (N): G1 pre: 2.3 (300) G1 post: 9.0 (300) pre-post % change: 6.7; p=0.001 G2 pre: 11.6 (499) G2 post: 6.2 (550) pre-post % change: -5.4; p=0.002
Hoddinott, 2009[74] Medium	G1: Adoption of a policy to provide BF groups for pregnant and BF women G2: Usual care (no new policy)	Cluster RCT 14 general practices ("localities") 18,603	Any BF at 6-8 wks postpartum, mean difference (95% CI) between intervention and control groups at postintervention (adj. for preintervention rate): -0.017 (-0.036 to 0.002); p=0.08 Any BF at 8-9 mos postpartum, mean difference (95% CI) between intervention and control groups at postintervention (adj. for preintervention rate): 0.007 (-0.056 to 0.070); p=0.82	NR
Kools, 2005[77] Medium	G1: BF promotion and support program G2: Usual care	Cluster RCT 10 maternity and child health centers 781 mothers	Any BF 3 mos postpartum, % (N): G1: 32 (371) G2: 38 (330) OR (95% CI): 0.79 (0.58 to 1.08)	Exclusive BF 3 mos postpartum, % (N): G1: 27 (371) G2: 32 (330) OR (95% CI): 0.79 (0.57 to 1.10)

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Kronborg, 2007[76] Medium	G1: Health visitor education and delivery of BF support intervention (1-3 HVs) G2: Usual care	Cluster RCT 22 municipalities 1,595 mothers	NR	Exclusive BF 6 mos postpartum, % (N): G1: 7.7 (780) G2: 4.9 (815) Cessation rate of exclusive BF at 6 mos postpartum (intervention vs. control): HR (95% CI) 0.86 (0.75 to 0.99) p=0.04
Madden, 2003[80] Medium	Changes in maternity length-of-stay policy (pre-post)	Single-group, pre-post 14 health centers 20,366 births	Rates of BF continuation within 90 days of birth among BF initiators remained constant at an estimated 72.6% throughout the study period.	NR
Nilsson, 2017[83] Medium	G1: Multicomponent BF intervention in early-discharge maternity settings G2: Usual care	Cluster RCT 9 maternity settings 3,541 women	NR	Exclusive BF 5-7 days postpartum, %: G1: 82 G2: 82 AOR (95% CI) 1.01 (0.88 to 1.14) Exclusive BF 1 mo postpartum, %: G1: 74 G2: 76 AOR (95% CI) 0.87 (0.64 to 1.18) Exclusive BF 6 mo postpartum, %: G1: 7 G2: 5 AOR (95% CI) 1.36 (1.02 to 1.81)
Taddei, 2000[79] Medium	G1: Intensive staff BF training (3-wk course) G2: Usual care (no staff training)	Cluster RCT 8 hospitals 970 infants	Full BF duration (days),[e] measured at 6 mos, adj. HR (95% CI) of before-after cohort: G1: 0.80 (0.67 to 0.97) G2: 1.16 (0.93 to 1.45) p=0.0019 Total BF duration (age at which BF was terminated, days), measured at 6 mos, adjusted[f] HR (95% CI) of before-after cohort: G1: 1.01 (0.83 to 1.22) G2: 1.55 (1.23 to 1.96) p=0.0019	Exclusive BF duration (days), measured at 6 mos, adjusted[f] HR (95% CI) of before-after cohort: G1: 0.71 (0.59 to 0.85) G2: 0.98 (0.79 to 1.22) p=0.0020

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Wan, 2011[72] Medium	G1: Continuous primary nursing care G2: Task-centered nursing care	RCT 1 hospital (2 obstetric units) 470 pregnant women	NR	Exclusive BF at 6 wks postpartum, % (N): G1: 93.91 (230) G2: 72.08 (240) p=0.001

[a] Adjusted for cluster effects, breastfeeding at hospital discharge, maternal education, age, parity and smoking habits.
[b] Women were sampled from control clusters at two time points: before the intervention (control group A) and at the same time as the intervention sample (control group B).
[c] Exclusive breastfeeding was defined as breastfeeding with occasional use of water, breastmilk substitutes (not more than a few times), and/or solids (not more than 1 tablespoon per day). Partial breastfeeding was defined as infants who received breastmilk and breastmilk substitutes (every day) and/or solids (more than 1 tablespoon per day).
[d] Residency programs in pediatrics, obstetrics, and family medicine were enrolled; eligible programs had to have low or unknown breastfeeding rates, serve a diverse patient population and varied geographical regions, and lack a Baby-Friendly certification.
[e] Full breastfeeding refers to age at introduction of any other milk.
[f] Adjusted for hospital of birth, mother's age, parity, delivery (normal vs. other), birth weight, and sex; p-value refers to the interaction term of control-exposed and before-after variables from the model that included both cohorts from all hospitals (N=970).

AOR = adjusted odds ratio; BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; CI = confidence interval; G = group; HR = hazard ratio; HV = home visit; N = number; NR = not reported; NRCT = nonrandomized controlled trial; NS = not sufficient; OR = odds ratio; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation; wks = weeks.

Three studies assessed the effectiveness of an intervention providing education and training to health care professionals (with no additional individual-level services offered to women); the results did not consistently demonstrate benefit.[71, 73, 79] In the cluster RCT comparing breastfeeding training to Swedish midwives and postnatal nurses,[71] women in the intervention and control groups had similar durations of any breastfeeding (7.5, 7.1, and 7.0 months, respectively) and exclusive breastfeeding durations (3.9, 3.2, and 3.5 months, respectively);[71] only one comparison was significant: mean exclusive BF duration among women in intervention municipalities versus women from control group municipalities measured before the start of the intervention (3.9 vs. 3.2 months; p=0.02). The NRCT enrolling U.S. residency programs (pediatrics, OBGYN, and family medicine) reported on breastfeeding rates at 6 months following implementation of a breastfeeding residency curriculum; there was no difference in the pre-post change among intervention sites (3.4%; p=0.291) or control sites (1.6%; p=0.574) for rates of any breastfeeding at 6 months.[73] For rates of exclusive breastfeeding at 6 months, intervention sites had improved rates (6.7%; p=0.001), while control sites had decreased rates (-5.4; p=0.002) during the study period.[73] Authors provide only p-values for pre-post comparisons and not sufficient data to calculate differences between intervention and control groups. The cluster RCT assessing staff education (nurses, midwives, and physicians) found lower rates of weaning for exclusive breastfeeding, full breastfeeding (age at introduction of another milk), and total (any) breastfeeding among women in the intervention group compared with controls (Table 9).[79]

Four studies assessed a health system intervention that combined education (or skills training) to providers with expanded individually delivered breastfeeding support services; results were mixed (two studies found benefit and two did not).[74, 76, 77, 84] At 3 months, the RCT set in The Netherlands found no difference in rates of any and exclusive breastfeeding between groups randomized to the health care provider training and support program (counseling, identification of breastfeeding problems, and free access to lactation consultants) and control sites (Table 9).[77] One cluster RCT assessing a policy to provide breastfeeding groups found no difference in rates of any breastfeeding among intervention and control practices 6 to 8 weeks postpartum and 8 to 9 months postpartum.[74] The two studies providing staff education along with expanded or new home visits found benefit.[76, 84] One evaluated breastfeeding education to health visitors plus expanded home visits (1 to 3 within 5 weeks of birth) to support breastfeeding; mothers in the intervention group had a lower cessation rate of any breastfeeding than controls (hazard ratio [HR], 0.86; 95% CI, 0.75 to 0.99).[76] The second was an RCT set in Brazil that compared staff training (modeled after BFHI training) plus 10 postpartum home visits providing breastfeeding support with staff training alone; women receiving home visits had higher rates of any breastfeeding over 6 months post-discharge (78% vs. 62%; p=0.001) and higher rates of exclusive breastfeeding (45% vs. 13%; p<0.001).[84]

Three studies assessed changes in health service delivery or policies that relate to breastfeeding and reported on breastfeeding duration; the studies did not consistently demonstrate benefit. The RCT comparing continuous primary nursing care with usual care (task-oriented nursing) among Chinese women found higher rates of exclusive breastfeeding at 6 weeks postpartum among the intervention group than in the controls (94% vs. 72%; p=0.001).[72] One nonrandomized trial set in Norway adapted BFHI for implementation into routine antenatal and child services; there was no difference between the intervention and control groups in rates of any breastfeeding at 6 months (OR, 1.24; 95% CI, 0.99 to 1.54) or at 12 months. For rates of exclusive breastfeeding, the intervention group had a significantly higher rate than controls at 5 months and 6 months postpartum (OR, 1.33; 95% CI, 1.03 to 1.72).[81] The single-group pre-post study assessing the relationship between changes in maternity length-of-stay policies among women belonging to one Massachusetts HMO found that rates of breastfeeding 90 days after birth among initiators remained constant at an estimated 73 percent throughout the study period.[80]

Women, Infants and Children–Based Interventions

Characteristics

Eight included studies assessed changes in breastfeeding rates associated a Special Supplemental Nutrition Program for Women, Infants and Children (WIC) program or policy.[86-93] Although all studies were set in the United States, they included women from diverse States (Table 10). Studies generally enrolled a population of women with mean ages in the 20s to 30s. Two studies focused on populations of women enrolled during the 1990s,[90, 91] and the other four enrolled women from 2002 to 2016.

Included studies assessed heterogeneous interventions and policies. One study used three separate U.S. population cohorts to assess breastfeeding rates before and after a 2007 policy revising the WIC food package (implemented by States in 2009):[87] (1) the Pregnancy Risk Assessment Monitoring System (PRAMS), women from 19 States between 2004 to 2010; (2) the Pediatric Nutrition Surveillance System (PedNSS), women/infants from 16 States from 2007 to 2010; and (3) the National Immunization Survey (NIS), infants from all 50 States and the District of Columbia from 2004 to 2010. One goal of the food package revision was to provide a greater economic incentive for women to breastfeed (e.g., by providing mothers of infants exclusively breastfed with additional milk, cheese, eggs, canned fish, and whole wheat bread).[87]

The other seven studies assessed various individual-level interventions implemented in individual States or WIC agencies (Table 10). One RCT assessed whether an electric breast pump (vs. a manual pump) would increase breastfeeding duration in mothers returning to full-time work or school.[86] One RCT compared cash incentives contingent on demonstrating breastfeeding to research staff with usual WIC services among Puerto Rican women.[93] One prospective cohort study compared use of the Breastfeeding Attrition Prediction Tool (BAPT) with usual WIC services.[92] Four studies assessed a type of peer support intervention. One nonrandomized trial compared a Peer Dad program (plus Peer Support for Mothers) with Peer Support for Mothers alone among Hispanic participants at a single WIC agency in Texas.[88] One RCT compared telephone peer counseling with standard care (no peer counseling) at four WIC agencies in Oregon.[89] Two compared a peer counseling program with usual care (no peer counseling) at different agencies in Iowa (8 counties)[90] and Tennessee (9 health departments).[91]

Results

Results of the eight included studies are presented in Table 11. Most studies reported on both breastfeeding duration and initiation, and we present results together below grouped by intervention type. Overall, peer-support interventions targeted to mothers were effective for improving breastfeeding rates. We found insufficient evidence (primarily due to unknown consistency and imprecision) to make a conclusion on the benefit of other WIC programs or policies for improving breastfeeding outcomes.

One study assessing breastfeeding rates in relationship to the 2007 Federal rule revising WIC food packages found no association between the policy change and rates of breastfeeding.[87] Data from all three sources (PRAMS, PedNSS, and NIS) showed steady upward trends in rates of ever breastfed infants on WIC during the study period; in neither PRAMS nor NIS data were trends in breastfeeding after implementation of the new food package statistically different from trends in breastfeeding among low-income women not on WIC (Table 11).[87] Similarly, there was no change in monthly breastfeeding rates by birth cohort associated with the new food package in the PedNSS data (pre- vs. postimplementation of the new policy).[87]

In the RCT (N=280) enrolling Hawaiian mothers on WIC who planned to return to work or school, there was no difference in breastfeeding duration among mothers assigned to an electric or manual breast pump (median duration of breastfeeding: 12 vs. 11 months, respectively; HR, 1.13; 95% CI, 0.79 to 1.50).[86] The RCT comparing monthly cash incentives for breastfeeding with usual WIC services among Puerto Rican women found significantly higher rates of any breastfeeding at 1, 3, and 6 months postpartum (Table 11); there was no difference between groups for self-reported exclusive breastfeeding.[93] In one prospective cohort study, women who agreed to participate in a tailored breastfeeding counseling and support intervention (based on responses to the BAPT tool) had higher rates of exclusive breastfeeding at 1 week and 1 month postpartum than women who declined to participate (Table 11); there was no difference in rates of exclusive breastfeeding between groups at 2 months.

Table 10. Characteristics of studies assessing WIC-based interventions

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Edmunds, 2017[92] High	Prospective cohort 12 WIC clinics (NY) 826	United States 2013-2016	Women ≥18 yrs, enrolled in WIC during the first trimester who intended to BF or were undecided	Use of the Breastfeeding Attrition Prediction Tool to inform tailored BF counseling targeting attitudes, social /professional support, and BF confidence	Women who declined to participate and received usual WIC services	29 (6.0)	89	75 NR	NR
Hayes, 2008[86] Medium	RCT 13 WIC sites (Hawaii) 280 women	United States 2002-2003	Women who planned to return to work or school full time after delivery and had no medical conditions that prevented or limited BF	Provision of an electric breast pump (loaned)	Provision of a manual breast pump (loaned)	NR: % by age group: <20: 11-18 20-29: 64-59 30-44: 18-30	NR	50-55 NR	NR

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous %Previously BF	% Cesarean Birth
Joyce, 2015[87] High	Prospective cohort NA (3 population cohorts: PRAMS, NIS, and PedNSS) PRAMS (WIC): 85,458 PRAMS (Non-WIC): 42,019 NIS (WIC): 62,289 NIS (Non-WIC): 11,702 PedNSS (infants): 744	United States 2004-2010	**PRAMS:** WIC participants and women w/ low SES[a] who did not participate in WIC **NIS:** Children who ever received WIC benefits and children who did not but had family income ≤250% of the Federal poverty level **PedNSS[b]:** All participants 2007-2011 (pre- and post-policy change)	WIC food package policy change (2007 rule implemented by States in 2009): vouchers available to BF women with monetary value comparable to vouchers received by mothers not exclusively BF; restrictions on issuance of formula to BF infants in first mo.; infants exclusively BF eligible to receive extra commercially prepared fruits and vegetables	Mothers/infants not receiving WIC benefits (PRAMS and NIS); or pre-implementation of WIC policy change (PedNSS)	PRAMS: <20: 6-17 20-29: 61-62 ≥30: 21-31 NIS: <20:1-5 20-29: 35-54 ≥30: 41-63 PedNSS: NR	PRAMS: 56 (WIC); 34 (non-WIC) NIS:67 (WIC and non-WIC) PedNSS: NR	NR NR	NR
Lovera, 2010[88] Medium	NRCT 1 WIC agency in Texas 200 women	United States 2005-2006	Program participation; mother had initiated BF of the index child; current WIC program participation; Hispanic; ≥18 yrs	Peer Dad Program (plus Peer Counseling Program for Mothers): Peer Dad volunteers acted as role models and provided counseling and classes pre- and postnatally for WIC father	Peer counseling program for Mothers only: Experienced BF women serve as role models	NR; % by age group, Mother: 20-35 yrs: 84-86% 36-50 yrs: 14-16% Father: 20-35 yrs: 73-78% 36-55 yrs: 22-27%	NR (100% Hispanic)	29-30 72-78	46-54

First Author, Year **ROB**	**Study Design** **N Sites** **N Participants**	**Country** **Year(s) of Enrollment**	**Inclusion Criteria**	**Intervention Description**	**Comparator(s)**	**Age, Mean (SD)**	**% Non-white**	**% Primiparous** **%Previously BF**	**% Cesarean Birth**
First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Reeder, 2014[89] Medium	RCT 4 WIC agencies in Oregon 1,948 women	United States 2005-2007	Women attending a WIC new pregnancy appointment who indicated an intention to BF or were undecided about BF	Telephone peer counseling program: delivered through WIC agencies[c]	Standard WIC BF promotion and support (no contact with a peer counselor)	27	44-47	NR NR	26-30
Schafer, 1998[90] High	NRCT 8 counties (Iowa) 241 women	United States 1994-1996	Rural, low-income pregnant and postpartum women who qualified for WIC	Peer counseling program: trained volunteer peer counselors from the community met one-on-one with women and presented lessons on nutrition, BF and provided support	Usual care (6 counties without peer counseling program)	23-25	0-19	NR NR	NR
Shaw, 1999[91] Medium	Prospective cohort 9 health departments (Tennessee) 291 women	United States 1996-1997	Pregnant women who had registered antepartum for WIC at 1 of 9 health departments in West Tennessee	Peer counseling program: trained peer counselors held individualized sessions with participants based on need	Usual care	22-23	16-29	37-47 21-35	21-24

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Washio, 2017[93] Medium	RCT 2 WIC offices (Philadelphia, PA) 36 women	United States 2015-2016	Puerto Rican women enrolled in WIC who initiated BF	Cash incentive contingent on demonstrating BF in front of research staff ($20 at end of 1st mo. and increase by $10 every mo. until end of 6 mos) in addition to usual WIC services)	Usual WIC services (on-site lactation consultant, peer counseling and support meetings, free breast pump, enhanced food package)	23-24 (5)	100	39-44 47-50	NR

[a] Included women with a family income of less than $50,000 per year or whose prenatal care was covered by Medicaid.
[b] Approximately 85% of cohort participated in WIC; data from all participants from 2007 to 2011 were used to describe changes in the percentage of women ever breastfeeding or breastfeeding for at least 1 month.
[c] Low-frequency (4 calls) protocol or high-frequency protocol (8 calls) but analyzed together (see comments).

BF = breastfeeding; N = number; NA = not applicable; NIS = National Immunization Survey; NR = not reported; NRCT = nonrandomized controlled trial; PedNSS = Pediatric Nutrition Surveillance System; PRAMS = Pregnancy Risk Assessment Monitoring System; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation; SES = socioeconomic status; WIC = Special Supplemental Nutrition Program for Women, Infants and Children.

Table 11. WIC interventions reporting on breastfeeding initiation and duration

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Edmunds, 2017[92] High	G1: Tailored BF counseling and support based on Breastfeeding Attrition Prediction Tool G2: Usual WIC BF and nutritional counseling	Prospective cohort 12 WIC clinics (NY) 826	NR	NR	AOR[a] (95% CI) exclusive BF at 7 days: 1.6 (1.1 to 2.5); p<0.05 AOR (95% CI) exclusive BF at 1 mo: 1.6 (1.0 to 2.5); p<0.05 AOR (95% CI) exclusive BF at 2 mos: 1.3 (0.8 to 2.1); p=NS
Hayes, 2008[86] Medium	G1: Provision of an electric breast pump (loaned) G1: Provision of a manual breast pump (loaned)	RCT 13 WIC sites (Hawaii) 280 women	NR	% of women (N) who BF for at least 6 mos: G1: 72.3 (94/130) G2: 76.8 (76/88) Adjusted OR (95% CI),[b] electric vs. manual: 0.85 (0.45 to 1.60) Median duration (95% CI) of BF (mos): G1: 12 (8 t162) G2: 11 (9 to 14) Adjusted HR (95% CI)[c] 1.13 (0.79 to 1.50)	NR

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Joyce, 2015[87] High	G1: Pre-WIC policy change G2: Post-WIC policy change	Prospective cohort NA (3 population cohorts: PRAMS, NIS, and PedNSS) PRAMS (WIC): 85,458 PRAMS (Non-WIC): 42,019 NIS (WIC): 62,289 NIS (Non-WIC): 11,702 PedNSS (infants): 744	Trends in rates of ever BF (2008 to 2010), Adjusted difference[d] between WIC and non-WIC groups: PRAMS: 1.2 %; p=NS NIS: -1.3%; p=NS PedNSS: pre-post difference in proportion of children ever BF after the new food package (adjusted for trends in BF) =-0.1%	Trends in BF for at least 4 wks (2008 to 2010), adjusted difference between WIC and non-WIC groups, PRAMS: 0.3%; p=NS Trends in BF for at least 3 mos (2008 to 2010), adjusted difference between WIC and non-WIC groups, NIS: 0.4%; p=NS PedNSS: Pre-post difference in proportion of children BF for ≥1 mo after the new food package (adjusted for trends in BF) = 0.5%	NR
Lovera, 2010[88] Medium	G1: BF peer-support program for fathers (in addition to mother peer-support program) G2: Mother participation in peer-support program only	NRCT 1 WIC site (Texas) 200 women	NA (only mothers who initiated BF were eligible)	% (N) of women who BF for 6 mos or longer: G1: 63.4 (64/101) G2: 54.5 (54/99) p=0.20 OR (95% CI) 1.44 (0.82 to 2.54)	NR
Reeder, 2014[89] Medium	G1: Telephone peer counseling program G2: Usual care	RCT 4 WIC agencies in Oregon 1948 women	No association between telephone peer counseling and BF initiation rates (per authors, results not shown)	Adjusted[e] RR (95% CI) of nonexclusive BF (vs. nontreatment group): 1 mo: 1.19 (1.10 to 1.27) 3 mos: 1.22 (1.10 to 1.34) 6 mos: 1.18 (1.03 to 1.34)	Adjusted[e] RR (95% CI) of exclusive BF (vs. nontreatment group): 1 mo: 1.07 (0.97 to 1.18) 3 mos: 1.09 (0.95 to 1.24) 6 mos: 1.01 (0.85 to 1.20)

Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Schafer, 1998[90] High	G1: WIC peer counseling program G2: Usual care	NRCT 8 counties 241 women	BF initiation, % (N/N total): G1: 82 (59/72) G2: 31 (20/64)	Average BF duration (wks): G1: 5.7 G2: 2.5 % of women BF at 12 wks: G1: 43 (31/72) G2: 0 (0/64) p<0.001	NR
Shaw, 1999[91] Medium	G1: WIC peer counseling program G2: Usual care	Prospective cohort 9 health departments (Tennessee) 291 women	BF initiation (any attempt to BF), % (N/N total): G1: 53 (82/156) G2: 33 (45/135) p<0.01 Adjusted OR (95%): 2.43 (1.23 to 4.67) BF at hospital discharge, % (N/N total): G1: 44 (69/156) G2: 26 (35/136) p<0.01	Any BF at ≥6 wks, % (N/N total): G1: 26 (41/156) G2: 13 (18/135) p<0.01 Adjusted OR (95% CI): 2.78 (1.31 to 5.91)	NR

Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Washio, 2017[93] Medium	G1: Monthly cash incentive contingent on demonstrating BF in addition to usual WIC services G2: Usual WIC services	RCT 2 WIC offices (Philadelphia, PA) 36 women	NA (only women who initiated BF were eligible)	Effect size (Cohen's h) G1 vs. G2 (95% CI) 1 mo: 1.03 (0.15 to 1.87) 3 mos: 1.99 (0.32 to 3.67) 6 mos: 2.15 (0.62 to 3.72) % of BF mothers, G1 vs. G2, p-value 1 mo: 89 vs. 44, p=0.01 3 mos: 89 vs. 17, p<0.001 6 mos: 72 vs. 0, p<0.001	No significant differences at any time point between groups for self-reported exclusive BF rates

[a] Adjusted for race/ethnicity, mother's age, parity, and number of nutrition education sessions.
[b] Adjusted for mother's age, race/ethnicity, education, marital status, and parity.
[c] Adjusted for education, age, race/ethnicity, marital status, and parity.
[d] All models include State and year fixed effects. Additional covariates include indicators for age, race/ethnicity, parity, marital status, family income, mother's schooling, and whether prenatal care was paid for by Medicaid.
[e] Adjusted for age, education, race, language, marital status, month in pregnancy enrolled, family income, cesarean delivery, and LWA.

AOR = adjusted odds ratio; BF = breastfeeding; CI = confidence interval; G = group; HR = hazard ratio; LWA =local WIC agency; N = number; NA = not applicable; NIS = National Immunization Survey; NR = not reported; NRCT = nonrandomized controlled trial; NS = not significant; OR = odds ratio; PedNSS = Pediatric Nutrition Surveillance System; PRAMS = Pregnancy Risk Assessment Monitoring System; RCT = randomized controlled trial; ROB = risk of bias; RR = risk ratio; WIC = Special Supplemental Nutrition Program for Women, Infants and Children; wks = weeks.

Four studies assessed a type of WIC peer-support program: three assessing peer support for mothers found benefit, and one (assessing added peer support for fathers) did not. Of the three studies assessing peer support for mothers, two compared in-person peer support to mothers with usual care.[90, 91] One was an NRCT assessing a volunteer peer counselor program at eight Iowa county WIC agencies; women in the intervention group had a higher rate of breastfeeding initiation than in the controls (82% vs. 31%, respectively) and a higher rate of breastfeeding at 12 weeks (43% vs. 0%; $p<0.001$).[90] Similarly, the cohort study assessing a WIC peer-support program at nine Tennessee health departments found higher rates of breastfeeding at hospital discharge in the intervention group than in the controls (44% vs. 26% of women, $p<0.01$) and higher rates of any breastfeeding at 6 weeks postpartum (26% vs. 13%, $p<0.01$).[91] One RCT compared telephone-delivered breastfeeding support among women enrolled at four Oregon WIC agencies with usual care: there was no difference between groups in terms of breastfeeding initiation (per authors, data not provided).[89] However, in the overall sample, rates of nonexclusive breastfeeding were greater in the intervention than controls at 3 months and 6 months (RR, 1.18; 95% CI, 1.03 to 1.34).[89] There was no significant difference in rates of exclusive breastfeeding in the overall sample at 3 and 6 months postpartum.[89]

The NRCT comparing a peer-support program for fathers (in addition to peer support for mothers) with peer support for mothers alone found a slightly higher rate of any breastfeeding at 6 months, but the difference was not statistically significant (63 vs. 55%, respectively; $p=0.20$).[88]

Community-Based Interventions

Characteristics

Five included studies (described in seven publications) assessed the effectiveness of a community-based intervention (Table 12). Studies were conducted in diverse country settings including one each in Italy,[94]Australia,[95] Mexico,[96] Chile,[97] and Canada.[98] Two were cluster RCTs,[95, 96] two were NRCTs,[94, 97] and one was a prospective cohort study.[98] Two studies enrolled women between 1991 and 1996,[96, 97] and all others enrolled women after 2005.

In terms of populations, two studies enrolled a majority of primiparous women[94, 98] and three enrolled a minority of primiparous women. Rates of cesarean births ranged from 27 to 40 percent in three studies, and two did not report on the rate of cesarean birth.[97, 98] Most studies enrolled women living in a community in which the intervention was implemented; one Australian study targeted women who were considered at risk of early breastfeeding cessation (e.g., infant received formula in the early postpartum period or mother asked for help with breastfeeding).[95]

No studies assessed the same intervention type; details of intervention and comparators are shown in Table 12. Briefly, one Italian study assessed a community-based policy (Baby Friendly Community Initiative) aimed at promoting breastfeeding in nonhospital-based health and community centers (including workplaces and day care centers).[94] The Australian cluster RCT evaluated an early home-based breastfeeding intervention in local health authorities with and without access to a community-based breastfeeding drop-in center.[95] The cluster RCT set in Mexico compared community-based breastfeeding peer support to usual care (peer counselors were trained and supervised by staff of La Leche League of Mexico).[96] The study set in Chile evaluated an integrated postpartum health care program that featured multiple components, including education, maternal and infant health care, support for the mother, and active participation of women from the community served.[97] Finally, one prospective cohort study set in Canada compared peer-led breastfeeding education classes with standard nurse-led classes.[98]

Table 12. Characteristics of studies assessing community-based interventions

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Alvarado, 1999[97] High	NRCT 2 neighborhoods with extreme poverty in Santiago, Chile 392 women	Chile 1991-1992	Pregnant women living in a defined area close to the nongovernment organization implementing the intervention	Community-based integrated postpartum health care program focusing on BF education and support,[a] and maternal/infant health care	Mothers in a nearby neighborhood with similar socioeconomic characteristics attending a public clinic	25-26	NR	34-46 NR	NR
Cattaneo, 2016;[94] Macaluso, 2013[99] Medium	NRCT 18 local health authorities (9 regions of Italy) 5,094 mother/infant pairs	Italy 2009-2012	Mothers giving birth to a healthy infant in hospitals within eligible local health authorities	Early implementation of BFCI, a policy promoting BF in nonhospital health facilities, day care centers, public locations, and businesses	Later implementation of BFCI	32 (NR)	NR; (96-67% Italian)	54-57 41-44	27-29

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
MacLachlan, 2016;[95] Cramer, 2017[100] Medium	Cluster RCT 10 LGAs, with 99 maternal child centers 9,675 women	Australia 2012-2013	Clusters: LGAs in Victoria, Australia, with >450 births per year and lower rates of any BF at discharge from hospital than the Victoria state average Mothers: those BF at discharge; mothers considered at risk of early BF cessation were targeted for HVs[b]	Early home-based nursing BF support for women identified as at risk of BF cessation, with or without access to a community-based BF drop-in center (offering women the opportunity to discuss BF concerns with nurse and/or trained peer supporter, meet and learn from other mothers, and access other BF support)	Usual care: hospital midwife visit 1-2 days after discharge; home visit 10-14 days after birth	31 (NR)	NR	39-41 NR	32-36

First Author, Year ROB	Study Design N Sites N Participants	Country Year(s) of Enrollment	Inclusion Criteria	Intervention Description	Comparator(s)	Age, Mean (SD)	% Non-white	% Primiparous % Previously BF	% Cesarean Birth
Morrow, 1999[96] Low	Cluster RCT 36 clusters (composed of 2 to 4 city blocks) 130 women	Mexico 1995-1996	Pregnant women residing in the study area who agreed to participate	Community-based[c] BF peer counselor support via home visits (3 or 6)	Standard care (mothers with lactation problems were referred to their own physicians)	NR	NR	21-30 NR	23-40
Rempel, 2012[98] High	Prospective cohort 1 hospital 109 women	Canada 2005-2006	NR; participants sampled from those who had participated in classes	Peer-led BF class (2 hours) providing education and support facilitated by 2 volunteer Breast-feeding Buddies (who BF for 6 mos and completed 18 hours of BF training)	Standard nurse-led prenatal BF class	28-31	NR	97 2	NR

[a] Exclusive BF on demand was promoted for the first 6 months postpartum, education focused on the nutritional and health benefits of BF.
[b] Women were considered at risk of early breastfeeding cessation if their infant received any formula (in addition to breast milk) in the early postpartum period and if a woman was distressed about breastfeeding or asked for help with breastfeeding when telephoned.
[c] Peer counselors were trained and supervised by staff of La Leche League of Mexico and the physician study coordinator (trained in lactation management). The peer-counselor training consisted of 1 week of classes, 2 months in lactation clinics and with mother-to-mother support groups, and 1 day of observation and demonstration by visiting experts. The peer counselors practiced in a neighborhood near the study site for 6 months before the intervention trial, during which the content of messages and problem-solving skills were refined.

BF = breastfeeding; BFCI = Baby Friendly Community Initiative; HV = home visit; LGA = local governmental agency; N = number; NR = not reported; NRCT = nonrandomized controlled trial; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation.

Results

Results of studies are shown in Table 13. All studies reported on at least one measure of breastfeeding duration, and one also reported on rates of breastfeeding initiation.[96] The studies generally did not demonstrate benefit, with the exception of one study that reported a benefit at 3 months but not at 6 months.

The study assessing a community-based policy aimed at promoting breastfeeding in nonhospital-based health and community centers[94] found no differences in outcomes between intervention and control regions at any time point; rates of exclusive breastfeeding at discharge, 3 and 6 months, and of any breastfeeding at 5 and 12 months increased during the study period in both groups.[94] The cluster RCT assessing an early home-based breastfeeding intervention in local health authorities with and without access to a community-based breastfeeding drop-in center[95] found no difference between groups in the rate of any breastfeeding at 4 months.[95] The cluster RCT set in Mexico compared community-based breastfeeding peer support to usual care;[96] at 3 months, more women in the intervention groups were exclusively breastfeeding than in the controls (67% of the six-visit group, 50% of the three-visit group, vs. 12% of controls; p<0.001), and rates of any breastfeeding were significantly longer in intervention groups (combined) than in control groups at 3 months, but not 6 months (Table 13).[96] The multicomponent integrated postpartum program in Chile found a higher rate of full breastfeeding at 6 months in the intervention group than in the control group (74% vs. 10%; p=0.0001).[97] Finally, in the prospective cohort study set in Canada comparing peer-led breastfeeding education classes with standard nurse-led classes,[98] there was no difference between groups in rates of any breastfeeding at 1 and 6 months postpartum (Table 13).

Effectiveness and Harms of Breastfeeding Programs and Policies for Subpopulations of Women

Key Points

- Few eligible studies reported on subgroups of women.
- Low SOE supports the conclusion that BFHI effectiveness may vary among women who differ by education status; two cohort studies (27,341) found higher rates of breastfeeding initiation among women with lower education (≤12 years) at BFHI hospitals compared with control hospitals, but no difference in rates among women with higher education (≥13 years).
- We found insufficient evidence to make a conclusion on whether the benefit of WIC peer support interventions varies by subgroups of women based on language spoken (Spanish only vs. English) or whether benefit of tailored breastfeeding counseling intervention varies by race/ethnicity, primarily because of unknown consistency and imprecision.

Table 13. Results of studies assessing community-based interventions

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
Alvarado, 1999[97] High	G1: Integrated postpartum program (BF education and support, maternal/infant health care) G2: Usual care at a public clinic	NRCT 2 neighborhoods with extreme poverty in Santiago, Chile 392 women	NR	% of women who weaned by 6 mos postpartum: G1: 7 G2: 50 p=0.0001	% of women exclusively[a] BF at 6 mos: G1: 74 G2: 10 p=0.0001
Cattaneo, 2016[94]; Macaluso, 2013[99] Medium	G1: Early implementation of BFCI G2: Later implementation of BFCI	NRCT 18 local health authorities (9 regions of Italy) 5,094 mother/ infant pairs	NR	Any BF 6 mos, % (data collected on 3 separate cohorts of women): G1: Round 1: 67.6 Round 2: 66.7 Round 3: 69.0 G2: Round 1: 62.4 Round 2: 63.4 Round 3: 65.4 Any BF, 12 mos, %: G1: Round 1: 32.4 Round 2: 34.9 Round 3: 36.2 G2: Round 1: 26.6 Round 2: 30.8 Round 3: 34.9	Exclusive BF 3 mos (24-hour recall), % (data collected on 3 separate cohorts of women): G1: Round 1: 58.1 Round 2: 57.5 Round 3: 62.3 G2: Round 1: 52.8 Round 2: 53.6 Round 3: 57.9 6 mos (24-hour recall): G1: Round 1: 9.0 Round 2: 7.7 Round 3: 7.6 G2: Round 1: 7.1 Round 2: 8.4 Round 3: 9.6

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation Outcome Results	Breastfeeding Duration (Any, Nonexclusive Plus Exclusive)	Exclusive Breastfeeding Duration
MacLachlan, 2016;[95] Cramer, 2017[100] Medium	G1: Early home-based maternal and child health nurse BF support G2: Early home-based maternal and child health nurse BF support (plus community-based BF drop-in center) G3: Usual care	Cluster RCT 10 LGAs, with 99 maternal child centers 9,675 women	NR	Any breast milk feeding at 4 mos, % (N): G1: 62.7 (2,281) G2: 54.4 (2,344) G3: 53.9 (2,414) Adjusted[b] OR (95% CI) G1 vs. G3: 1.04 (0.84 to 1.29) G2 vs. G3: 0.92 (0.78 to 1.08) Authors also report no difference at 3 or 6 mos between groups and no difference before or after the intervention in any LGA.	NR
Morrow, 1999[96] Low	G1: Community-based BF peer counselor support G1: Usual care	Cluster RCT 36 clusters, (comprising 2 to 4 city blocks) 130 women	BF initiation, % (N/N total): G1 (6-visit): 100 (44/44) G1 (3-visit): 98 (51/52) G2: 94 (32/34) p=NS	Duration of any BF, % (N) ≥3 mos: G1: 95 (92) G2: 85 (33) p=0.039 ≥6 mos: G1: 87 (75) G2: 76 (29) p=0.09	Duration of exclusive BF % (N), 3 mos: G1 (6-visit): 67 (42) G1 (3-visit): 50 (50) G2: 12 (33) G1 (6-visit) vs. G1 (3-visit): p=0.015 G1 (6-visit) vs. G3: p<0.001 G1 (3-visit) vs. G3: p<0.001
Rempel, 2012[98] High	G1: Peer-led BF support class G2: Nurse-led BF support class	Prospective cohort 1 hospital 109 women	NR	Women BF at 1 mos, % (N): G1: 84 (38) G2: 70 (37) p=NS Women BF at 6 mos, % (N): G1: 61 (31) G2: 49 (35) p=NS	NR

[a] Authors use the term "fully breastfeeding" to indicate mothers who provided only breastmilk as a source of nutrients for the first 4 months of life, then breastmilk as the only source of milk thereafter.
[b] Adjusted for baseline breastfeeding rates in the local government areas, gestational age, maternal age, cesarean births, age in weeks at 4-mo Key Ages and Stages visit, and the potential effect of clustering in the maternal and child health centers.

BF = breastfeeding; BFCI = Baby Friendly Community Initiative; CI = confidence interval; G = group; LGA= local governmental agency; N = number; NR = not reported; NRCT = nonrandomized controlled trial; NS = not significant; OR = odds ratio; RCT = randomized controlled trial; ROB = risk of bias.

Characteristics and Results

Few eligible studies reported on subgroups of women; we found no studies reporting on subgroups defined by maternal age, comorbidity, and other factors. Of the four studies reporting on subgroups of women, two focused on BFHI and reported on differences by education status.[54, 55] The other two focused on a WIC intervention; one peer-support intervention reported on subgroups by language spoken (Spanish only versus English),[89] and one counseling intervention reported outcomes by race/ethnicity.[92]

The two studies assessing BFHI (by the same author) focused on hospitals in the United States enrolling women from similar time periods (1999-2009); one of these evaluated data from five U.S. States[54] and the other focused on hospitals in one State (Maine).[55] Characteristics are described above in KQ 1a and shown in Table 4. Neither study found a significant difference in breastfeeding initiation rates between facilities that received BFHI accreditation and nonaccredited facilities in the overall sample, but both offer some evidence of differences in effectiveness by education level, with benefits accruing to those with lower levels of education.[54, 55] Both studies found higher rates of breastfeeding initiation among women with lower education (≤12 years) at BFHI facilities compared with nonaccredited facilities, but no difference in rates among women with higher education (≥13 years).[54, 55] For breastfeeding duration, the study enrolling women from five U.S. States found increased rates of exclusive breastfeeding for 4 or more weeks among women with lower education in the intervention arm when compared with the control arm (p=0.02), but no difference for women with higher education (Table 14); no difference was seen for rates of any breastfeeding by education status.[54] The study evaluating women giving birth in Maine hospitals found no difference in rates of exclusive or any breastfeeding at 4 or more weeks postpartum among women who differed by education status.[55]

Two studies assessing a WIC intervention reported on subgroups relevant to race/ethnicity.[89, 92] One RCT compared telephone peer counseling with standard care at four WIC agencies in Oregon; in the overall sample, the intervention group had significantly higher rates of any breastfeeding at 3 and 6 months than controls. In subgroups of women based on language (English speaking and Spanish speaking only), results were significant at 3 months for both groups, but for Spanish speaking only at 6 months (Table 14). There was no significant difference in rates of exclusive breastfeeding in the overall sample or by language at 3 or 6 months postpartum.[89] The second WIC intervention reporting on subgroups was a prospective cohort study evaluating a tailored breastfeeding counseling and support intervention (based on responses to the BAPT tool).[92] Women participating in the intervention had higher rates of exclusive breastfeeding at 1 week and 1 month postpartum than women who declined to participate; however, the benefit was significant only in black and Hispanic mothers at 1 month (but not white mothers).[92]

Effect of Intervention Characteristics on Breastfeeding Outcomes

This KQ focused on the extent to which intervention-related characteristics (e.g., type of breast pump provided—manual or electric, delivery personnel) influence the initiation, duration, and exclusivity of breastfeeding. We had insufficient evidence to address this KQ. As noted above (KQ 1a), few studies assessed similar interventions among similar groups of women (or settings).

Table 14. KQ 1 studies reporting on eligible subgroups

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation	Breastfeeding Duration
Hawkins, 2014[54] Medium	G1: Mothers giving birth in a BFHI-accredited facility G2: Mothers giving birth in a nonaccredited facility	Prospective cohort 32 birth facilities in 5 U.S. States 25,327 women	BF initiation increased by 3.8% among mothers with less education (≤12 yrs) who delivered in BFHI facilities (p=0.05), but not among mothers with more education (≥13 yrs) (p=0.9)	BF initiation increased exclusive BF for ≥4 wks by 4.5% (p=0.02) among mothers with lower education who delivered in BFHI facilities (p=0.1) No significant difference seen in subgroups based on education for rates of any BF for ≥4 wks
Hawkins, 2014[55] Medium	G1: Mothers giving birth in a BFHI-accredited facility G2: Mothers giving birth in a nonaccredited facility	Prospective cohort 10 birth facilities in 1 U.S. State (Maine) 2,014 women	Among mothers with less education (≤12 yrs), the BFHI increased BF initiation by 8.6% (adjusted coefficient, 0.086; 95% CI, 0.01 to 0.16) No significant change in BF initiation rates for mothers with more education (≥13 yrs); p=0.9	No significant change in exclusive BF for ≥4 wks among mothers with less education (≤12 yrs; p=0.5) or more education (≥13 yrs; p=0.3) No significant change in any BF for ≥4 wks among mothers with less education (≤12 yrs; p=0.5) or more education (≥13 yrs; p=0.3)
Edmunds, 2017[92] High	G1: Tailored BF counseling and support based on Breastfeeding Attrition Prediction Tool G2: Usual WIC BF and nutritional counseling	Prospective cohort 12 WIC clinics (NY) 826	NR	Results shown in figure only. White women: No significant difference in exclusive BF at 7, 30, or 60 days between groups. Black women: No significant difference at 7 days; higher rate of exclusive BF among intervention group than control at 30 and 60 days (p=0.01 and p=0.02, respectively) Hispanic women: No significant difference at 7 days; higher rate of exclusive BF among intervention group than control at 30 and 60 days (p=0.4 and p=0.002, respectively)

First Author, Year ROB	Intervention Comparison	Study Design N Sites N Participants	Breastfeeding Initiation	Breastfeeding Duration
Reeder, 2014[89] Medium	G1: Telephone peer counseling program G2: Usual care	RCT 4 WIC agencies in Oregon 1,948 women	NR	Adjusted[a] RR (95% CI) of nonexclusive BF (vs. nontreatment group): Spanish only subgroup: 1 mo: 1.16 (1.06 to 1.28) 3 mos: 1.29 (1.13 to 1.48) 6 mos: 1.29 (1.10 to 1.51) English only subgroup: 1 mo: 1.22 (1.09 to 1.36) 3 mos: 1.19 (1.02 to 1.38) 6 mos: 1.10 (0.88 to 1.37) Adjusted[a] RR (95% CI) of exclusive BF (vs. nontreatment group): Spanish-only subgroup: 1 mo: 1.13 (1.00 to 1.29) 3 mos: 1.20 (1.02 to 142) 6 mos: 1.17 (0.94 to 1.44) English-only subgroup: 1 mo: 1.04 (0.90 to 1.19) 3 mos: 1.02 (0.84 to 1.24) 6 mos: 0.91 (0.70 to 1.19)

[a] Adjusted for age, education, race, language, marital status, month in pregnancy enrolled, family income, cesarean delivery, and LWA.

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; CI = confidence interval; G = group; LWA=local WIC agency; N = number; NRCT = nonrandomized controlled trial; NY = New York; ROB = risk of bias; RR = risk ratio; U.K. = United Kingdom; WIC = Special Supplemental Nutrition Program for Women, Infants and Children; wks = weeks.

Maternal Health Outcomes Associated With Breastfeeding

Key Points

- Based on evidence from one systematic review (98 studies) and 19 individual studies (256,891 women), we concluded that ever breastfeeding, as well as longer durations of breastfeeding, is associated with lower rates of overall breast cancer (low SOE). Similarly, consistent evidence from one systematic review (11 studies) and 7 individual studies supports the association between ever breastfeeding and longer duration of breastfeeding and lower rates of breast cancer defined by two hormone receptor subtypes: luminal and triple-negative (low SOE).
- We rated the evidence as insufficient (primarily due to unknown consistency and imprecision) for the association between breastfeeding and subtypes of breast cancer defined by tumor behavior (i.e., in situ breast cancer), subgroups of women who are *BRCA1/2* mutation carriers, HER2 hormone receptor subtype, and mortality due to breast cancer.
- Based on evidence from one systematic review (41 studies) and 9 individual studies (42,611 women), we concluded that ever breastfeeding, as well as longer durations of breastfeeding, is associated with reduced risk of developing epithelial ovarian cancer (moderate SOE).
- Based on consistent evidence from five cohort studies (441,989 women), we concluded that a longer duration of breastfeeding is associated with reduced risk of hypertension (low SOE). We found insufficient evidence for an association between breastfeeding and cardiovascular disease (CVD) because few studies assessed the same outcome among similar cohorts of women.
- Based on one systematic review (6 studies) and five individual studies (325,815 women) with consistent findings, we concluded that a longer duration of lifetime breastfeeding is associated with a reduced risk of developing type 2 diabetes (low SOE).
- Eleven studies (101,726 women) reported on the association between breastfeeding and hip, vertebral, and forearm fracture risk. Apart from one study of self-reported vertebral fractures (rated high ROB), no study reported a statistically significant association between breastfeeding and fracture. We rated the evidence as low for no association.
- For postpartum depression, we found insufficient evidence on whether breastfeeding is associated with postpartum depression. Studies were heterogeneous in design and varied in how breastfeeding exposure and depression outcomes were assessed and categorized; studies do not establish the direction of relationship between breastfeeding and depression.
- We rated the SOE on the association between breastfeeding and postpartum weight change as insufficient; results from 16 cohort studies are inconsistent and studies used heterogeneous measures of both exposure and outcomes limiting the ability to compare findings.

Breast Cancer and Ovarian Cancer

Background

Breast cancer is the most frequently diagnosed cancer among women, with an estimated 266,120 new diagnoses in 2018; an estimated 40,920 women will die as a result of breast cancer in 2018, making it the second most deadly cancer diagnosis among women behind lung cancer.[101] Ovarian cancer is substantially rarer than breast cancer, with an estimated 22,240 new diagnoses in 2018 but is the fifth most deadly cancer among women (estimated 14,070 deaths).[101] Family history of breast or ovarian cancer, increased age, obesity, smoking, and postmenopausal hormone use are known or suspected risk factors of both breast and ovarian cancer. Reproductive factors that shorten a women's menstrual history, such as oral contraceptive use and parity, are associated with a decreased risk of both breast and ovarian cancer. Because breastfeeding is also associated with a shortened menstrual history, we examined the association between it and breast and ovarian cancer.[102]

Methods

We included systematic reviews published within the past 5 years that were rated low or unclear ROB. For breast cancer, we additionally included the three systematic reviews that were included in the 2007 report.[2] We (1) compared multiple systematic reviews to identify the extent of overlapping studies and homogeneity of results, (2) summarized all included reviews in tables, and (3) described the most recent or comprehensive systematic review in detail and considered it in the SOE assessment. We also included and summarize eligible primary studies not captured in the recent systematic reviews. In terms of outcomes, we included studies reporting on overall breast or ovarian cancer, as well as subtypes of cancer, defined by molecular or histopathologic features. Additionally, we included studies enrolling populations with *BRCA1* and *BRCA2* mutation carriers who are at increased risk of both breast and ovarian cancer.

Breast Cancer: Systematic Reviews and Meta-Analyses

Overall Breast Cancer

We included one recent systematic review on the relationship between breastfeeding and breast cancer.[103] In addition, we briefly describe three other systematic reviews included in the 2007 AHRQ report[2] since the overlap of included studies (described below) is not complete; the reviews were originally published in 2000[104, 105] and 2002[106] These four reviews are summarized in Table 15.[106]

The recent systematic review (98 studies), rated unclear ROB,[1] examined the association between ever breastfeeding, as well as duration of breastfeeding, and subsequent (overall) breast carcinoma; 73 percent of the studies were conducted in high-income countries (Table 15, Appendix Tables C-13 to C-18). The authors did not perform a formal ROB assessment of included articles but did assess 67 percent of the studies as adequate (i.e., had none or one of selection, measurement, or confounding bias or attrition of 20 percent as assessed by the review authors). They used random effects meta-analysis to estimate pooled ORs; when heterogeneity was high (I^2>60% or p for heterogeneity<0.010), reasons for heterogeneity were explored with subgroup analyses and meta-regression for the main comparison of ever versus never breastfed.

Table 15. Breastfeeding and overall breast cancer: Summary of published systematic reviews and meta-analyses

Author, Year ROB	Number of Studies (Number of Participants; Number of Cases) Included Study Designs	Overlap With Other Published SRs	Search Dates Databases	Results
Bernier, 2000[104] Medium[a]	23 studies (70,871; 25,871) Case-control	Included in the 2007 AHRQ report[2] 19 of 23 studies included in Chowdhury, 2015[1]	1980-1998 Medline, Embase	Ever vs. never BF OR, 0.84 (95% CI, 0.78 to 0.91) Total BF duration (mos) vs. never BF <6: OR, 1.00 (95% CI, 0.86 to 1.16) 6-<12: OR, 0.97 (95% CI, 0.86 to 1.09) ≥12: OR, 0.72 (95% CI, 0.65 to 0.80)
Chowdhury, 2015[1] Unclear	98 studies (NR) Cohort, case-control	34 (35 articles) of 98 studies were previously included in at least one of the SRs included in the 2007 AHRQ report[2]	Inception through February 2015 PubMed, Cochrane, CABI	Ever vs. never BF OR, 0.78 (95% CI, 0.74 to 0.82), I^2=72, k=98 Total BF duration (mos) vs. never BF <6: OR, 0.93 (95% CI, 0.88 to 0.99), I^2=59, 39 studies 6-12: OR, 0.91 (95% CI, 0.87 to 0.96), I^2=23, 36 studies >12: OR, 0.74 (95% CI, 0.69 to 0.79), I^2=62, 50 studies
Collaborative Group on Hormonal Factors in Breast Cancer, 2002[106] Low[a]	47 studies (147,275; 50,302) Cohort, case-control	Included in the 2007 AHRQ report[2] 16 (17 studies) of 47 studies included in Chowdhury, 2015[1]	1983-2001 NA[b]	Ever vs. never BF RR=0.96 (95% SE: 0.2), p=0.04 Reduction in relative risk of breast cancer per 12 mos BF 4.3% (99% SE: 0.8) Lifetime duration of BF (mos) vs. never BF ≤6: RR=0.98 (99% SE: 0.017) 7-18: RR=0.94 (95% SE: 0.016) 19-30: RR=0.89 (95% SE: 0.025) 31-54: RR=0.88 (95% SE: 0.033) ≥55: RR=0.73 (95% SE: 0.049)
Lipworth, 2000[105] Medium[a]	27 studies (57,109; 19,482) Case-control	Included in the 2007 AHRQ report[2] 23 of 27 studies included in Chowdhury, 2015[1]	1966-1998 Medline	No details or quantitative results were reported. Authors provided only a qualitative synthesis: “The evidence with respect to ‘ever’ breast-feeding remains inconclusive, with results indicating either no association or a rather weak protective effect against breast cancer.” “An inverse association between increasing cumulative duration of breastfeeding and breast cancer risk among parous women has been reported in some, but not all, studies.”

[a] Risk of bias rating carried forward from the 2007 AHRQ report[2]
[b]Authors pooled 45 studies published between 1983 and 2001 and two unpublished studies in a collaborative analysis. Authors did not describe how studies were identified and included in the collaborative analysis.

AHRQ = Agency for Healthcare Research and Quality; BF = breastfeeding; CABI = Centre for Agriculture and Biosciences International database; CI = confidence interval; NA = not applicable; NR = not reported; OR = odds ratio; ROB = risk of bias; RR = relative risk; SE = standard error; SR = systematic review.

The authors found evidence of publication bias, as evidenced by (1) an asymmetrical funnel plot, (2) significant Egger's test ($p<0.001$), and (3) significant Begg's test ($p<0.001$); authors did not describe the potential impact of the publication bias.

Using data from all 98 included studies, the authors reported a pooled OR for ever versus never breastfeeding of 0.78 (95% CI, 0.74 to 0.82). The substantial heterogeneity (I^2=72) of these results could not be completely explained in subgroup analyses. The reviewers found statistically significantly different results when studies were categorized according to number of participants (meta-regression p-value=0.009) and method of adjustment for parity (meta-regression p-value = 0.037); they continued, however, to find substantial residual heterogeneity within those subgroups (I^2 ranged from 23 to 77). Among 52 studies that included at least 1,500 participants, the pooled OR was 0.83 (95% CI, 0.80 to 0.88; I^2=72); the association was stronger among 31 studies of 500 to 1,499 participants and 15 studies of fewer than 500 participants, but the CIs were wider (pooled OR, 0.74; 95% CI, 0.66 to 0.83; I^2=67 and pooled OR, 0.50; 95% CI, 0.37 to 0.66; I^2=59, respectively). Among 60 studies that did not adjust for parity, the pooled OR was 0.73 (95% CI, 0.68 to 0.79; I^2=77); the pooled ORs were attenuated among 19 studies that crudely adjusted for parity (0.86; 95% CI, 0.81 to 0.90; I^2=23) and 19 studies that finely adjusted for parity (0.92; 95% CI, 0.88 to 0.96; I^2=55).

Authors also conducted pooled analyses to evaluate the association between different total durations of breastfeeding (compared with women who never breastfed) and breast cancer among a subset of studies with duration data. They reported a numeric decrease in the pooled ORs with increasing duration of breastfeeding. For total breastfeeding duration of less than 6 months, the pooled OR was 0.93 (95% CI, 0.88 to 0.99; I^2=59); the pooled ORs for 6 to 12 months and greater than 12 months, respectively, were 0.91 (95% CI, 0.87 to 0.96; I^2=23) and 0.74 (95% CI, 0.69 to 0.79; I^2=62).

As described above, the 2007 AHRQ report[2] included 2 systematic reviews[104, 105] and 1 meta-analysis from the Collaborative Group on Hormonal Factors in Breast Cancer (CGHFBC)[106] (Table 15). We found a substantial overlap of included studies (i.e., 80%) among the 2 systematic reviews and the recent systematic review by Chowdhury et al.[1] We found, however, less overlap between the CGHFBC meta-analysis of 47 studies (2 unpublished)[106] and the recent meta-analysis;[1] only 16 studies (17 articles) were included in both.[1] Regardless of overlap (or lack thereof), all systematic reviews and meta-analyses included in the 2007 AHRQ report[2] reported a nonsignificant reduced risk of breast cancer among women who had ever breastfed. The authors also reported varying degrees of an inverse association between increasing duration of breastfeeding and breast cancer risk. The results are generally consistent in direction and magnitude with pooled results reported by Chowdhury et al.[1]

Tumor Subtypes of Breast Cancer Defined by Hormone Receptor Status

One recent systematic review rated unclear ROB examined the association between ever breastfeeding and subsequent tumor subtypes of breast cancer, defined by hormone receptor status (Appendix Tables C-13 to C-18).[107] They defined the breast cancer subtypes as (1) luminal (HR+ and HER2+/-), (2) HER2 (HR- and HER2+), or (3) triple negative (HR- and HER2-).

All 11 included studies, except for 2 case-control studies from China and Japan, were conducted in the United States; the studies were published between 2008 and 2014. The pooled OR for the association between ever breastfeeding and luminal breast cancer from 9 studies (169,870 women) was 0.77 (95% CI, 0.66 to 0.88; I^2=79). The pooled OR for the HER2 and triple-negative subtypes were 0.78 (95% CI, 0.59 to 1.03; I^2=46; 8 studies of 14,266 women) and

0.79 (95% CI, 0.6 to 0.94; I^2=65; 11 studies of 176,340 women), respectively. The authors reported that ORs were lower among case-control than among cohort or population-based case-control studies; there were only 2 case-control studies and 1 cohort study in the subgroup analysis compared to 6 population-based case-control studies.

Breast Cancer: Individual Studies

Overall Breast Cancer

Characteristics

Three cohort studies[108-110] and 16 case-control studies,[111-126] published since the 2007 AHRQ report[2] and not included in the recent systematic review by Chowdhury et al.[1] evaluated the association between ever breastfeeding or duration of breastfeeding and overall breast cancer rates (Table 16, Table 17, Appendix Tables C-19 to C-23 and F1). One medium-rated ROB cohort study was conducted in Japan and compared mixed feeding (breastfeeding and formula feeding) and formula-only feeding with exclusive breastfeeding.[109] Over 26,000 of these women in the Ohsaki National Health Insurance Cohort Study were followed for 11 years; 148 incident breast cancer cases were identified.[109] Another medium-rated ROB cohort study combined the hormone trial and the observational study of the Women's Health Initiative (WHI) into one cohort for analysis; 24,095 women in the hormone trial and 45,263 women in the observational study were followed for a median duration of 7.9 years. The WHI evaluated the association between both ever breastfed and duration of breastfeeding and breast cancer, and it presented results for each group of women, defined by which WHI study they participated in and which hormone therapy group they were members of.[108] Finally, the Nurses' Health cohort Study (NHS), also rated medium risk of bias, identified 8,421 cases of incident invasive breast cancer over 2,424,778 person-years; the authors did not evaluate duration of breastfeeding in their analyses.[110]We rated eight of the case-control studies as medium ROB; the studies were conducted in the United States,[113, 119, 121, 122, 124, 125] Spain,[114] Sweden,[117] and Poland.[123] The remaining case-control studies were rated high ROB and were conducted in the United Kingdom,[124] Saudi Arabia,[111, 112] Germany,[116, 126] Greece,[115] Italy,[120] and Poland.[118, 124] For the most part, ever breastfeeding was not defined further with the exception of one study that described it as ≥1 month of breastfeeding.[113] In analyses that examined duration, never breastfed was the referent group, with a few exceptions. Some studies used durations up to 3 months[124] and 12 months[112] as the referent group; one study in Spain actually grouped women into two categories where women reported whether they met a 2007 recommendation (from the World Cancer Research Fund and the American Institute of Cancer Research) of cumulatively breastfeeding for at least 6 months.[114] In the Swedish study by Holm and colleagues, the referent group for the duration analysis was nulliparous women, which is slightly different from a referent group of parous women who have never breastfed.[117] One medium ROB case-control study in the United States evaluated the risk of histologic subtypes of breast cancer that included ductal, lobular, and mixed ductal/lobular breast cancers; histologic subtype was determined by centralized pathology review for a vast majority of the cases.[113] Finally, another medium ROB case-control study in the United States evaluated the risk of breast cancer among *BRCA* mutation carriers and noncarriers; the *BRCA* genes of only the cases were sequenced.[119]

Results

The WHI[125] and NHS[110] cohort studies reported no statistically significant association between ever breastfeeding and breast cancer,[125] but in the Ohsaki National Health Insurance Cohort Study in Japan, investigators reported that women who only formula-fed their children had an 80 percent increased risk of breast cancer compared with women who exclusively breastfed their children (HR, 1.80; 95% CI, 1.14 to 2.86). The hazard was numerically increased but not statistically significant, for women who both breast- and formula-fed their children.[109] Beaber et al.[113] reported a statistically significant decrease in risk of ductal breast cancer (OR, 0.7; 95% CI, 0.5 to 0.9) but not lobular or mixed ductal/lobular breast cancers, and two other studies found varying magnitudes in the statistically significant decrease of odds of breast cancer with ever breastfeeding.[122, 127] The Italian case-control study reported an 82 percent increased risk of breast cancer when comparing women who never breastfed with women who had[120] and the Swedish case-control study reported a 59 percent increased risk for the same comparison.[117] T[128]wo other studies reported a higher prevalence of breastfeeding among controls than cases, but results were not significant. There was one study in Germany in which more cases than controls reported ever breastfeeding.[116] Finally, Lee and colleagues reported that the prevalence of breastfeeding among controls and cases who were *BRCA* mutation carriers was 88 percent; the prevalence of breastfeeding among cases who were not *BRCA* carriers was 79 percent (Table 16, Appendix Table F1).[119]

Although the direction of effect is generally consistent with pooled results from systematic reviews, seven of 14 studies reported at least one significant inverse association between an increased duration of breastfeeding and breast cancer risk (Table 17, Appendix F1); however, confidence intervals were often wide and overlapping. Not all studies provided results from regression analyses and referent groups varied among the studies. Women in a small case-control study in Saudi Arabia were 44 percent less likely to develop breast cancer if they breastfed for ≥12 months (compared with breastfeeding for <12 months), but results were unadjusted for any potential confounders (OR=0.56; 95% CI, 0.35 to 0.88).[112] Two other case-control studies did report a significant trend between decreased risk of breast cancer and increased duration[121] and with ≥12 months of breastfeeding (but not 4 to 11 months).[124] In the German study where more cases reported breastfeeding, multiple linear regression indicated that women with breast cancer had a significantly longer duration of breastfeeding, but specific details were not provided.[116] Among cases who were not *BRCA* carriers, there was a significant trend (p=0.002) of decreased breast cancer risk associated with increased duration of breastfeeding; there was no trend of decreased breast cancer risk with increased breastfeeding duration among cases who were *BRCA* carriers (p=0.83).[119]

Table 16. Ever breastfeeding and overall breast cancer

Author, Year Country	Study Design ROB	Results for Ever Versus Never Breastfeeding[a]
Al-Amri, 2015[111] Saudi Arabia	Case-control High	OR, 0.30 (95% CI, 0.13 to 0.69)
Beaber, 2008[113] United States	Case-control Medium	Ductal BC: OR, 0.7 (95% CI, 0.5 to 0.9)[b] Lobular BC: OR, 0.9 (95% CI, 0.7 to 1.3)[b] Ductal/lobular BC: OR, 0.9 (95% CI, 0.6 to 1.4)[b]
Ge, 2015[126] Germany	Case-control High	Cases: 63% Controls: 67%
Hadji, 2007[116] Germany	Case-control High	Cases: 69% Controls: 52%
Holm, 2017[117] Sweden	Case-control Medium	Cases: 96% Controls: 97% OR, 1.59 (95% CI, 1.23 to 2.03)[c]
Lee, 2008[119] United States	Case-control Medium	*BRCA* cases: 88%[d] Non-*BRCA* cases: 79%[d] Controls: 88%[d]
Lumachi, 2010[120] Italy	Case-control High	OR, 1.82 (95% CI, 1.20 to 2.77)[c]
Phillips, 2009[122] United States	Case-control Medium	OR, 0.77 (95% CI, 0.67 to 0.89)
Ruszczyk, 2016[125] United States	Case-control Medium	Cases: 59% Controls: 66%
Stendell-Hollis, 2013[108] United States	Cohort Medium	WHI hormone trial CEE HR, 0.72 (0.50, 1.06) CEE placebo HR, 1.12 (0.80, 1.57) CEE/MPA HR, 1.06 (0.83, 1.36) CEE/MPA placebo HR, 0.92 (0.70, 1.21) WHI observational study CEE HR, 1.11 (0.89, 1.39) CEE/MPA HR, 1.16 (0.91, 1.47) No prior HT HR, 1.00 (0.86, 1.18) Prior HT HR, 0.97 (0.78, 1.22)
Sugawara, 2013[109] Japan	Cohort Medium	Mixed feeding: HR, 1.12 (95% CI, 0.92 to 1.37)[e] Formula feeding: HR, 1.80 (95% CI, 1.14 to 2.86)[e] p for trend=0.014
Tamimi, 2016[110] United States	Cohort Medium	RR, 1.05 (95% CI, 1.00 to 1.10), P=0.07 PAR, 1.6% (95% CI, 0.1% to 3.4%)

[a] Never breastfed is the referent group for all comparisons, except when otherwise footnoted.
[b] Ever breastfed was defined as ≥1 month.
[c] Referent group is ever breastfed.
[d]Analysis is among women who had a full-term pregnancy.
[e] Referent group is exclusively breastfed.

BC = breast cancer; CEE = conjugated equine estrogen; CI = confidence interval; HR = hazard ratio; HT = hormone therapy; MPA = medroxyprogesterone acetate; OR = odds ratio; PAR = population attributable risk; ROB = risk of bias; RR = relative risk; WHI = Women's Health Initiative Study.

Table 17. Duration of breastfeeding and breast cancer

Author, Year Country	Study Design ROB	Results for Duration of Breastfeeding[a]
Al-Amri, 2015[111] Saudi Arabia	Case-control High	>2 yrs: OR, 1.68 (95% CI, 0.98 to 4.53)[b] Referent group is unclear
Al-Qutub, 2013[112] Saudi Arabia	Case-control High	≥12 mos: OR, 0.56 (95% CI, 0.35 to 0.88)[b] Referent group≤12 mos
Beaber, 2008[113] United States	Case-control Medium	Ductal breast cancer <1 mos: OR, 1.1 (95% CI, 0.6 to 1.9) 1.0-5.9 mos: OR, 0.7 (95% CI, 0.5 to 0.9) 6.0-11.9 mos: OR, 0.8 (95% CI, 0.5 to 1.2) 12.0-23.9 mos: OR, 0.8 (95% CI, 0.5 to 1.3) ≥24.0 mos: OR, 0.6 (95% CI, 0.3 to 1.0) p for trend=0.43 Lobular breast cancer <1 mos: OR, 1.0 (95% CI, 0.5 to 1.9) 1.0-5.9 mos: OR, 0.9 (95% CI, 0.6 to 1.3) 6.0-11.9 mos: OR, 1.0 (95% CI, 0.6 to 1.6) 12.0-23.9 mos: OR, 1.1 (95% CI, 0.7 to 1.8) ≥24.0 mos: OR, 0.8 (95% CI, 0.4 to 1.6) p for trend=0.85 Ductal/lobular breast cancer <1 month: OR, 1.4 (95% CI, 0.7 to 3.0) 1.0-5.9 mos: OR, 0.7 (95% CI, 0.4 to 1.2) 6.0-11.9 mos: OR, 0.8 (95% CI, 0.4 to 1.5) 12.0-23.9 mos: OR, 1.1 (95% CI, 0.6 to 2.0) ≥24.0 mos: OR, 1.9 (95% CI, 1.0 to 3.6) p for trend=0.11
Castello, 2015[114] Spain	Case-control Medium	OR, 0.95 (95% CI, 0.70 to 1.28)[c]
Dalamaga, 2011[115] Greece	Case-control High	>6 mos BF Cases: 44% Controls: 50%
Hadji, 2007[116] Germany	Case-control High	Multiple linear regression showed that women with breast cancer had a significantly longer duration of BF; no other details were provided.
Holm, 2017[117] Sweden	Case-control Medium	>0-1.5 yrs: OR, 0.70 (95% CI, 0.61 to 0.80) >1.5 yrs: OR, 0.63 (95% CI, 0.54 to 0.75) Referent group is nulliparous women
Kruk, 2014[118] Poland	Case-control High	Compared with case subjects, controls reported a longer duration of BF; no other details were provided.
Lee, 2008[119] United States	Case-control Medium	*BRCA* cases <1-6 mos: OR, 1.31 (95% CI, 0.45 to 3.82) 7-23 mos: OR, 0.73 (95% CI, 0.23 to 2.30) ≥24 mos: OR, 1.29 (95% CI, 0.36 to 4.61) p for trend=0.83 Non-*BRCA* cases <1-6 mos: OR, 0.66 (95% CI, 0.43 to 1.02) 7-23 mos: OR, 0.52 (95% CI, 0.33 to 0.81) ≥24 mos: OR, 0.49 (95% CI, 0.29 to 0.81) p for trend=0.002

Author, Year Country	Study Design ROB	Results for Duration of Breastfeeding[a]
Ma, 2006[121] United States	Case-control Medium	<1 month: OR, 0.99 (95% CI, 0.56 to 1.77) 1-6 mos: OR, 0.58 (95% CI, 0.37 to 0.91) 7-23 mos: OR, 0.52 (95% CI, 0.33 to 0.82) ≥24 mos: OR, 0.51 (95% CI, 0.30 to 0.86) p for trend=0.001
Pieta, 2008[123] Poland	Case-control Medium	Mean duration of BF[d] Cases: 8.3 mos Controls: 6.8 mos
Press, 2010[124] United Kingdom/United States	Case-control High	United Kingdom 4-11 mos: OR, 1.05 (95% CI, 0.84 to 1.31)[b] ≥12 mos: OR, 0.49 (95% CI, 0.38 to 0.64)[b] United States 4-11 mos: OR, 0.91 (95% CI, 0.78 to 1.07)[b] ≥12 mos: OR, 0.81 (95% CI, 0.68 to 0.96)[b] Referent group=0 to 3 mos
Ruszczyk, 2016[125] United States	Case-control Medium	0-12 mos: OR, 0.76 (95% CI, 0.49 to 1.19)[e] >12 mos: OR, 0.61 (95% CI, 0.37 to 1.02)[e] p trend = 0.07
Stendell-Hollis, 2013[108] United States	Cohort Medium	WHI hormone trial CEE 1-3 mos: HR, 0.70 (95% CI, 0.41 to 1.20) 4-12 mos: HR, 0.78 (95% CI, 0.48 to 1.26) 13-23 mos: HR, 0.72 (95% CI, 0.35 to 1.46) ≥24 mos: HR, 0.64 (95% CI, 0.27 to 1.49) CEE placebo 1-3 mos: HR, 0.86 (95% CI, 0.52 to 1.42) 4-12 mos: HR, 1.41 (95% CI, 0.95 to 2.08) 13-23 mos: HR, 1.15 (95% CI, 0.64 to 2.06) ≥24 mos: HR, 0.71 (95% CI, 0.30 to 1.64) CEE/MPA 1-3 mos: HR, 1.13 (95% CI, 0.81 to 1.59) 4-12 mos: HR, 1.02 (95% CI, 0.75 to 1.39) 13-23 mos: HR, 1.17 (95% CI, 0.79 to 1.72) ≥24 mos: HR, 0.89 (95% CI, 0.54 to 1.45) CEE/MPA placebo 1-3 mos: HR, 0.87 (95% CI, 0.59 to 1.30) 4-12 mos: HR, 1.00 (95% CI, 0.71 to 1.40) 13-23 mos: HR, 1.00 (95% CI, 0.65 to 1.54) ≥24 mos: HR, 0.70 (95% CI, 0.40 to 1.24) WHI observational study CEE 1-3 mos: HR, 1.08 (95% CI, 0.80 to 1.46) 4-12 mos: HR, 1.15, (95% CI, 0.87 to 1.51) 13-23 mos: HR, 1.19 (95% CI, 0.81 to 1.76) ≥24 mos: HR, 0.96 (95% CI, 0.55 to 1.68) CEE/MPA 1-3 mos: HR, 1.11 (95% CI, 0.79 to 1.55) 4-12 mos: HR, 1.06 (95% CI, 0.79 to 1.43) 13-23 mos: HR, 1.38 (95% CI, 0.97 to 1.97) ≥24 mos: HR, 1.32 (95% CI, 0.84 to 2.06)

Author, Year Country	Study Design ROB	Results for Duration of Breastfeeding[a]
Stendell-Hollis, 2013[108] (continued)		No prior HT 1-3 mos: HR, 0.99 (95% CI, 0.79 to 1.24) 4-12 mos: HR, 0.96 (95% CI, 0.78 to 1.18) 13-23 mos: HR, 1.01 (95% CI, 0.77 to 1.32) ≥24 mos: HR, 1.22 (95% CI, 0.90 to 1.66) Prior HT 1-3 mos: HR, 0.94 (95% CI, 0.68 to 1.29) 4-12 mos: HR, 0.92 (95% CI, 0.69 to 1.23) 13-23 mos: HR, 1.15 (95% CI, 0.79 to 1.67) ≥24 mos: HR, 1.05 (95% CI, 0.64 to 1.72)

[a] Never breastfed is the referent group for all comparisons, except when otherwise noted.
[b] Results are unadjusted.
[c] OR is for women who met a recommendation of cumulative breastfeeding ≥6 months compared to women who did not meet a recommendation. The recommendation was issued by the World Cancer Research Fund and the American Institute of Cancer Research in 2007.
[d] A nonsignificant OR greater than the null is reported, but it is unclear if the analysis compared malignant breast cancer cases to controls or if the benign neoplasm group of 'cases' was included somehow.
[e] Cases were diagnosed with invasive ductal carcinoma.

CEE = conjugated equine estrogen; CI = confidence interval; HR = hazard ratio; HT = hormone therapy; MPA = medroxyprogesterone acetate; OR = odds ratio; ROB = risk of bias; WHI = Women's Health Initiative Study.

Breast Cancer Among *BRCA1* and *BRCA2* Mutation Carriers

Characteristics

We included one case-control study of 2,854 women with invasive breast cancer and 2,854 women without invasive breast cancer who were matched to the cases on *BRCA* mutation type, year of birth, and country of residence; the study was rated medium ROB (Appendix Tables C-19 to C-23). The study was nested within a cohort study that recruited women who sought testing for *BRCA1* and *BRCA2* mutations because of a family history of breast or ovarian cancer; the women were recruited from 70 centers in 12 countries.[129] The results presented here supersede (1) results presented in the 2007 AHRQ report[2] from a 2004 article by Jernstrom et al.[130] that included only 965 matched pairs of cases and controls from 53 centers in six countries and (2) results published in 2012 by Kotsopoulos et al.[131] that included 1,665 matched pairs from 62 centers in seven countries. Authors estimated ORs and 95 percent CIs for the association between multiple durations of breastfeeding and invasive breast cancer using conditional logistic regression, adjusting for age at menarche, parity, and oral contraceptive use.

A majority of the women (72%) were *BRCA1* carriers, and the mean age at interview was 47 years; the mean age at diagnosis among cases was 40 years, indicating that at least some of the cases were prevalent. Cases breastfed for a mean of 9.6 months (range: 0 to 147 months); 79 percent of cases were parous. Controls breastfed for a mean of 7.5 months (range: 0 to 102 months); 80 percent of controls were parous.

Results

The study found a significant inverse relationship between duration of breastfeeding and breast cancer risk among *BRCA1* mutation carriers (p for trend<0.0001) but not *BRCA2* mutation carriers (p for trend=0.68).[129] Among 1,847 *BRCA1* carrier pairs, the ORs for ≤1 year, 1 to ≤2 years, 2 to ≤3 years, and >3 years compared with never breastfeeding were 0.81 (95% CI, 0.66 to 1.00), 0.65 (95% CI, 0.50 to 0.85), 0.51 (95% CI, 0.35 to 0.75), and 0.45 (95% CI, 0.30 to 0.68), respectively. Among 714 *BRCA2* carrier pairs, the ORs were 1.03, 1.04, 1.33, and 1.02 for the same duration categories, respectively; all 95 percent CIs included the null.

Breast Cancer In Situ

Characteristics

We included one cohort and two population-based case-controls studies, all rated medium ROB, that evaluated the association between breastfeeding and incident ductal carcinoma in situ (DCIS)[122, 132] or incident breast cancer defined by a mix of invasive ductal carcinoma and DCIS[125] confirmed by pathology (Table 18, Appendix Tables C-19 to C-23 and F1). The cohort study included 64,060 women originally enrolled in the WHI clinical trials that were followed for a median of 12 years.[132] All studies were conducted in the United States, and the percentage of nonwhite participants ranged from 17 percent[132] to 63 percent.[125] The Women's Circle of Health Study (WCHS) was a multicenter case-control study of breast cancer in 2,270 African-American and European American women in metropolitan New York City and seven counties in New Jersey; the high percentage of African-American women in the study (56% of cases and 63% of controls) was reported to be representative of the general community regarding education, income, marital status, and obesity status.[125]

Table 18. Breastfeeding and breast cancer in situ

Author, Year Study Design ROB	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results[a]	Confounders Adjusted for
Kabat, 2011[132] Cohort Medium	Cohort of women, 50 to 79 years of age, originally randomized in the WHI clinical trial and followed for a median of 12 yrs (64,060) Incident diagnosis of DCIS, verified by centralized review of medical records and pathology reports (664)	Mean age (yrs) Cases: 62 Noncases: 63 Nonwhite Cases: 17% Noncases: 18% Parous Cases: 89% Noncases: 89%	Ever BF Cases: 54% Noncases: 52% Duration of BF 1-6 mos: HR, 1.05 (95% CI, 0.86 to 1.28) 7-12 mos: HR, 1.04 (95% CI, 0.80 to 1.36) >12 mos: HR, 1.01 (95% CI, 0.80 to 1.29)	Age, education, hormone therapy, family history of breast cancer, history of breast biopsy, mammograms in past 2 yrs, age at menarche, age at menopause, and parity
Phillips, 2009[122] Case-control Medium	Population-based case-control study; cases were rapidly ascertained and controls were frequency matched to cases on race and age (904) First diagnosis of DCIS, pathology confirmed (446)	Mean age (yrs) Cases: 55 Controls: 55 Nonwhite Cases: 22% Controls: 15% Parous Cases: 85% Controls: 88%	Ever BF DCIS OR, 1.02 (95% CI, 0.78 to 1.34) High-grade DCIS OR, 0.82 (95% CI, 0.57 to 1.20) Medium/low-grade DCIS OR, 1.02 (95% CI, 0.72 to 1.42)	Age, race, and frequency matching offset terms

Author, Year Study Design ROB	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results[a]	Confounders Adjusted for
Ruszczyk, 2016[125] Case-control Medium	Population-based case-control study of African-American and white women, 20 to 75 yrs; cases were rapidly ascertained through hospitals and cancer registries and controls were frequency-matched to cases by telephone prefixes (2,270)[c] Histologically confirmed incident mixed breast cancer, defined by a mix of IDC and DCIS (650)	Mean age (yrs) Cases: 51 Controls: 50 Nonwhite Cases: 56% Controls: 63% Parous Cases: 77% Controls: 78%	Ever BF IDC/DCIS cases: 67% Controls: 66% Duration of BF >0-12 mos: OR, 1.15 (95% CI, 0.88 to 1.50)[b] >12 mos: OR, 0.94 (95% CI, 0.70 to 1.27)[b]	Age, race, birthplace, family history, composite screening score, education, OC use, age at menarche, parity, age at first birth, and menopausal status

[a] Compared to never breastfed, unless otherwise specified.
[b] Among parous women only.
[c] Study enrolled 1,620 controls, 181 pure IDC cases, and 650 cases with mixed IDC and DCIS; only the 1,620 controls and 650 mixed cases are reported here.

BF = breastfeeding; CI = confidence interval; DCIS = ductal carcinoma in situ; HR = hazard ratio; IDC = invasive ductal carcinoma; N = number; OC = oral contraceptive; OR = odds ratio; ROB = risk of bias; WHI = Women's Health Initiative Study.

Tumor Subtypes of Breast Cancer Defined by Hormone Receptor Status

Characteristics

We included three medium ROB cohort studies[110, 133, 134] and four case-control studies (three rated medium ROB[117, 121, 135] and one rated high ROB,[136]) that evaluated the association between breastfeeding and breast cancer subtypes defined by hormone receptor status (i.e., estrogen receptor [ER], progesterone receptor [PR], and human epidermal growth factor receptor [HER2]) (Table 19, Appendix Tables C-19 to C-23 and F1). One study pooled data from two cohort studies [Black Women's Health Study (BWHS) and Nurses' Health Study II (NHSII)] and evaluated the association between duration of breastfeeding (<6 months and ≥6 months) and ER+ breast cancer; there were 140,194 women, with 1,506 confirmed-by-pathology ER+ breast cancer cases from over 1.5 million person-years of followup.[134] The European Prospective Investigation into Cancer and Nutrition (EPIC) study followed women from 10 western European countries for a median of 11 years and evaluated the association between ever breastfeeding and duration of breastfeeding with ER+/PR+ and ER-/PR- breast cancer.[133] The NHS, described above in the overall breast cancer section, determined the estrogen receptor status for 6,646 cases (79% of the cases identified over 2.4 million person-years) and compared ever to never breastfeeding; a majority of the cases (81%) were positive for the estrogen receptor.[110]

Table 19. Breastfeeding and tumor subtypes of breast cancer defined by hormone receptor status

Author, Year Study Design ROB	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever[a] or Duration	Confounders Adjusted for
Atkinson, 2016[136] Case-control High	Hospital-based case-control study in Texas cancer center; controls were undergoing routine mammography screening (620) Incident inflammatory breast cancer[b] (224)	Mean age (yrs): Cases: 51 Controls: 51 Nonwhite: Cases: 23% Controls: 0%	Triple-negative IBC[c] Ever BF[d]: OR, 0.30 (95% CI, 0.15 to 0.62) HER2neu+ IBC[c] Ever BF[d]: OR, 1.01 (95% CI, 0.55 to 1.87) Luminal IBC[c] Ever BF[d]: OR, 0.35 (95% CI, 0.18 to 0.68)	Age at menarche, menopausal status, number of children, age at first pregnancy, BF history, BMI, smoking history, breast cancer family history
Holm, 2017[117] Case-control Medium	Case-control analysis of women from two cohort studies in Sweden; controls were frequency-matched to cases on age (18,577) Primary invasive breast cancer with information on immunohistochemical stains diagnosed 2005 to 2015 (2,632)	Mean age (SD), range: Cases: 61 (10.3), 27-88 Controls: 58 (9.7), 25-88	<u>Luminal A[e]</u> Never BF[d,f]: OR, 1.49 (95% CI, 1.12 to 1.98) >0-1.5 yrs: OR, 0.69 (95% CI, 0.59 to 0.82) >1.5 yrs: OR, 0.63 (95% CI, 0.52 to 0.76) <u>Luminal B[e]</u> Never BF[d,f]: OR, 1.71 (95% CI, 0.81 to 3.53) >0-1.5 yrs: OR, 0.55 (95% CI, 0.37 to 0.81) >1.5 yrs: OR, 0.59 (95% CI, 0.37 to 0.95) <u>HER2-overexpressing[e]</u> Never BF[d,f]: OR, 0.90 (95% CI, 0.37 to 2.22) >0-1.5 yrs: OR, 0.72 (95% CI, 0.49 to 1.07) >1.5 yrs: OR, 0.64 (95% CI, 0.40 to 1.02) <u>Basal-like[e]</u> Never BF[d,f]: OR, 4.20 (95% CI, 2.20 to 7.99) >0-1.5 yrs: OR, 1.02 (95% CI, 0.59 to 1.76) >1.5 yrs: OR, 0.81 (95% CI, 0.43 to 1.60)	Country of birth, age, education level, parity, age at first birth, BMI
Ma, 2006[121] Case-control Medium	Population-based case-control study of cases identified by the CSP and neighborhood controls matched on age and race (2,238) First primary invasive breast cancer, histologically confirmed (1,794)[g]	Mean age (yrs): Cases: 43 Controls:43 Nonwhite: Cases: 12% Controls: 8%	ER+/PR+ <1 mo[d]: OR, 1.01 (95% CI, 0.53 to 1.90) 1-6 mos[d]: OR, 0.57 (95% CI, 0.34 to 0.94) 7-23 mos[d]: OR, 0.52 (95% CI, 0.31 to 0.87) 24+ mos[d]: OR, 0.49 (95% CI, 0.27 to 0.87) p for trend=0.002 ER-/PR- <1 mo[d]: OR, 1.19 (95% CI, 0.59 to 2.39) 1-6 mos[d]: OR, 0.72 (95% CI, 0.41 to 1.27) 7-23 mos[d]: OR, 0.55 (95% CI, 0.31 to 0.98) 24+ mos[d]: OR, 0.62 (95% CI, 0.32 to 1.21) p for trend=0.03	Race, age, education, breast cancer family history, age at menarche, full-term pregnancies (number and age at), BMI, OC use, alcohol use, menopausal status, and HRT use

Author, Year Study Design ROB	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever[a] or Duration	Confounders Adjusted for
Ma, 2017[135] Case-control Medium	Pooled analysis of women from 3 population-based studies of breast cancer, predominantly in Los Angeles; controls[h] were frequency-match to controls on age, race, and geographic area of residence (5,106) Newly diagnosed *in situ* and invasive breast cancer; some were first primary diagnoses and were histologically confirmed (2,658)	Mean age (SD), range Cases: 47 (8.1), 22-64 Controls: 48 (8.3), 24-64 African-American Race Cases: 26% Controls: 37%	Triple-negative[i]: OR (95% CI) Ever: 0.80 (0.63 to 1.02) <6 mos: 0.96 (0.74 to 1.26) 6-11 mos: 0.55 (0.37 to 0.82) ≥12 mos: 0.69 (0.50 to 0.96) P for trend=0.006 Luminal A-like[i]: OR (95% CI) Ever: 0.78 (0.65 to 0.94) <6 mos: 0.83 (0.68 to 1.02) 6-11 mos: 0.76 (0.59 to 0.99) ≥12 mos: 0.71 (0.56 to 0.90) P for trend=0.004 Luminal B-like[i]: OR (95% CI) Ever: 0.89 (0.65 to 1.23) <6 mos: 0.99 (0.70 to 1.41) 6-11 mos: 0.70 (0.44 to 1.12) ≥12 mos: 0.85 (0.56 to 1.30) P for trend=0.28 HER2-enriched[i]: OR (95% CI) Ever: 0.91 (0.63 to 1.32) <6 mos: 0.68 (0.43 to 1.07) 6-11 mos: 1.28 (0.78 to 2.09) ≥12 mos: 1.10 (0.69 to 1.75) P for trend=0.36	Sub-study (CARE, BCIS, LIFE), study site (Los Angeles, Detroit), race, reference age, education, first-degree breast cancer family history, BMI, menopausal status, hormone therapy use, lifetime recreational physical activity, alcohol intake, smoking status, age at menarche, completed pregnancies, oral contraceptive use, age at first completed pregnancy
Ritte, 2013[133] Cohort Medium	Cohort study of women enrolled in the EPIC study, recruited from 23 centers in 10 western European countries, and followed for a median of 11 yrs (311,097) First primary invasive breast cancer (9,456)[i]	Median age at recruitment (yrs): 51 Ever BF: 84% Median duration of BF: 6 mos	ER+/PR+ Ever[d]: HR, 0.99 (95% CI, 0.89 to 1.09) 1-3 mos[k]: HR, 1.04 (95% CI, 0.89 to 1.20) 4-6 mos[k]: HR, 0.97 (95% CI, 0.83 to 1.14) 7-12 mos[k]: HR, 0.97 (95% CI, 0.83 to 1.13) 13-17 mos[k]: HR, 0.92 (95% CI, 0.75 to 1.12) ≥18 mos[k]: HR, 1.11 (95% CI, 0.92 to 1.33) ER-/PR- Ever[d]: HR, 0.98 (95% CI, 0.81 to 1.17) 1-3 mos[k]: HR, 0.91 (95% CI, 0.69 to 1.21) 4-6 mos[k]: HR, 0.99 (95% CI, 0.74 to 1.32) 7-12 mos[k]: HR, 0.91 (95% CI, 0.68 to 1.23) 13-17 mos[k]: HR, 1.12 (95% CI, 0.79 to 1.60) ≥18 mos[k]: HR, 1.07 (95% CI, 0.75 to 1.51)	Age, EPIC center, BMI, height, menopausal status, HRT use, physical activity, smoking status, alcohol use, and education

Author, Year Study Design ROB	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever[a] or Duration	Confounders Adjusted for
Tamimi, 2016[110] Cohort Medium	Female registered nurses 30 to 55 years enrolled in the Nurses' Health Cohort Study (112,951 postmenopausal women; 2,424,778 person-years) Incident invasive breast cancer confirmed through review of medical records (8,421 cases: 5,376 ER+ and 1,270 ER-)	Mean age (SD), range: 48 (6.9), NR Post-menopausal: 100% Current use HRT: 34%	ER+ Ever[d]: RR, 0.96 (95% CI, 0.91 to 1.02), P=0.24; PAR, 0 (95% CI, 2.2% to 2.2%) ER- Ever[d]: RR, 1.07 (95% CI, 0.94 to 1.21), P=0.30; PAR, 2.4 (95% CI, 2.1% to 6.8%)	Age in months, calendar year, age at menarche, BMI at age 18 years, height in inches, parity/age at first birth, benign breast disease history, family history of breast cancer, age at menopause, weight change since age 18 years, menopausal hormone use, alcohol consumption, physical activity
Warner, 2013[134] Cohort Medium	Two cohorts of 103,508 white and 37,406 African-American women enrolled in the BWHS and NHSII studies, with 1,582,083 person-yrs of followup (140,194) ER+ breast cancer, confirmed by pathology reports (1,506)	Mean age (yrs): Black: 39 White: 40 Parous: Black: 73% White: 79% Ever BF: Black: 44% White: 81% PR+ status: Black: 79% White: 86%	<6 mos[d]: HR, 0.85 (95% CI, 0.70 to 1.03) ≥6 mos[d]: HR, 0.95 (95% CI, 0.81 to 1.10)	Age, time, age at first birth, parity, age at menarche, menopausal status, age at menopause, family history, BMI, weight change since age 18, history of benign breast disease, alcohol use, OC use, and post-menopausal hormone use

[a] Compared with never breastfed, unless otherwise footnoted.
[b] Confirmed according to World IBC Consortium or AJCC criteria. The main characteristics of IBC include breast erythema and edema, with or without an underlying palpable mass.
[c] Triple negative breast cancer was defined by ER-/PR-/HER2neu- receptor status. HER2neu+ breast cancer was defined as any ER/PR receptor status and HER2neu+ receptor status. Luminal breast cancer was defined as ER+ and/or PR+ and HER2neu- receptor status.
[d] Among parous women.
[e] Luminal A breast cancer was defined by low Ki167 (proliferation marker) and ER+/PR-/HER2- receptor status. Luminal B breast cancer was defined by (a) high Ki167 and ER+ receptor status or (b) low Ki167 and ER+/HER2+ receptor status. HER2-overexpressing breast cancer was defined by ER-/PR-/HER2+ receptor status. Basal-like breast cancer, also referred to as triple negative breast cancer, was defined by ER-/PR-/HER2- receptor status.
[f] Compared to never breastfed.
[g] Of the 1,794 breast cancer cases, 881 were ER+/PR+; 92 were ER+/PR-; 41 were ER-/PR+; 405 were ER-/PR-; 91 were borderline or undecided ER/PR status; and 284 had no information on hormone receptor status. Only the cases identified as ER+/PR+ or ER-/PR- were included in the hormone receptor-specific analyses and in this table.
[h] The BCIS study shared controls from the CARE study.
[i] Triple negative breast cancer was defined by ER-/PR-/HER2- receptor status. Luminal A-like breast cancer was defined by HER2-/ER+ and/or PR+ receptor status. Luminal B-like breast cancer was defined by HER2+/ER+ and/or PR+ receptor status. HER2-enriched breast cancer was defined by ER-/PR-/HER2+ receptor status.
[j] A total of 5,843 breast cancer cases had information on both ER and PR status (3,567 were ER+/PR+; 1,078 were ER+/PR-; 200 were ER-/PR+; and 998 were ER-/PR-).
[k] Analysis is among parous women who breastfed; the referent group is women who breastfed for <1 month.

AJCC = American Joint Committee on Cancer; BF = breastfeeding; BMI = body mass index; BWHS = Black Women's Health Study; CI = confidence interval; CSP = LA Cancer Surveillance Program; EPIC = European Prospective Investigation into Cancer and Nutrition study; ER = estrogen receptor; HER2/HER2nue = human epidermal growth factor receptor 2; HR = hazard ratio; HRT = hormone replacement therapy; IBC = inflammatory breast cancer; N = number; NHSII = Nurses' Health Study II; OC = oral contraceptive; OR = odds ratio; PAR = population attributable risk; PR = progesterone receptor; ROB = risk of bias.

A population-based case-control study in Sweden,[117] also described above in the overall breast cancer section, and a pooled analysis of three population-based case-control studies in the United States[135] evaluated the association between both ever breastfeeding and duration of breastfeeding and breast cancer; breast cancer diagnoses in both studies were similarly defined as luminal, HER2, and triple negative (or basal-like) subtypes. A population-based case-control study of 2,238 women in Los Angeles County, California, included women with ER+/PR+ and ER-/PR- breast cancer but evaluated only duration of breastfeeding.[121] Finally, a small hospital-based case-control study, rated high risk of bias, at the MD Anderson Cancer Center in Texas evaluated the association between ever breastfeeding and inflammatory breast cancer further defined by hormone receptor status: (1) triple negative breast cancer (ER-/PR-/HER2neu-), (2) HER2neu breast cancer (any ER/PR status/HER2neu+), and (3) luminal breast cancer (ER+/any PR/HER2neu-).[136] The mean age of women enrolled in these seven studies ranged from 39[134] to 61 years.[117]

Results

All three cohort studies reported no association between breastfeeding and breast cancer, regardless of the cancer subtype, with effect estimates close to and on both sides of the null.[110, 133, 134] In a US-based case control study,[133]Ma and colleagues[121] reported an inverse association between both ER+/PR+ and ER-/PR- breast cancer and increasing duration of breastfeeding (p for trend=0.002 and 0.03, respectively). The ORs for ≥24 months of breastfeeding were 0.49 (95% CI, 0.27 to 0.87) and 0.62 (95% CI, 0.32 to 1.21) for ER+/PR+ and ER-/PR- breast cancer, respectively.[121] Results were mixed in three case-control studies that evaluated similarly defined luminal, HER2, and triple negative breast cancer cases. The Swedish study reported significantly decreased odds of luminal A, luminal B, and basal-like (i.e., triple negative), but not HER2 breast cancers; estimates for most comparisons were below the null.[117] In the pooled analysis of three studies, there was a numerically decreased risk of all breast cancer subtypes with any breastfeeding. For triple negative and luminal A-like subtypes, there was a significant inverse association between increasing duration of breastfeeding and cancer risk; the p-values for trend were 0.006 and 0.004, respectively.[135]Finally, from a case-control study rated high risk of bias, Atkinson et al.[136] reported a decreased risk of triple-negative (OR, 0.30; 95% CI, 0.15 to 0.62) and luminal (OR, 0.35; 95% CI, 0.18 to 0.68) but not HER2neu+ (OR, 1.01; 95% CI, 0.55 to 1.87) breast cancers with ever breastfeeding.[136]

Two studies evaluated the relationship between breastfeeding and breast cancer risk among subgroups of women (Appendix Table F2).[134, 135] Both studies reported results stratified by race (white and black) and the pooled analysis of three case-control studies additionally evaluated age (20-44 years and 45-64 years of age). Ma and colleagues reported a significant inverse association between both triple negative and luminal A-like subtypes and any breastfeeding among African-American women (ORs of 0.67 and 0.78, respectively) but not white women, though the odds of cancer were still numerically decreased; there was a similar trend of decreased cancer risk with increased duration of breastfeeding for African-American women but not white women.[135] In a pooled analysis of two cohort studies, there was a nonsignificant decrease in the risk of ER+ breast cancer with both <6 months and ≥6 months of breastfeeding.[134] When the authors stratified by race, they found a nonsignificant increase in ER+ breast cancer risk among black women, regardless of duration. For white women, the authors found an inverse association between <6 months breastfeeding and ER+ breast cancer (HR, 0.76; 95% CI, 0.60 to 0.98) but not ≥6 months. Notably, although 81 percent of the white women in the two cohort studies reported ever breastfeeding, only 44 percent of the black women reported the same.[134] In the pooled analysis of three case-control studies, there was a significant trend of decreased risk of triple negative breast cancer among younger women (20-44 years; p for trend=0.02) but not older women (45-64 years; p for trend=0.17). There was a significant trend of decreased luminal A-like breast cancer among the older women (p for trend=0.03) but not the younger women (p for trend=0.0.12). All effect estimates were below the null and some confidence intervals were wide.[135, 136]

All-Cause and Breast Cancer-Specific Mortality

Characteristics

We included one medium ROB study of women in the EPIC prospective cohort study that evaluated the association between breastfeeding and mortality (all cause and breast cancer specific) after a mean followup of 12.9 years (standard deviation=2.3 years) (Appendix Tables C-19 to C-23 and F1).[137] The study included 322,972 (250,470 parous) women who were 25 to 70 years of age when they were recruited from 23 centers in 10 European countries between 1992 and 2000. Exposure and confounder data were collected at enrollment via questionnaires; mortality data were primarily ascertained from cancer registries, boards of health, and death indices.

Results

Among parous women, ever breastfeeding was associated with a decreased risk of all-cause mortality (fully adjusted HR, 0.92; 95% CI, 0.87 to 0.97), but duration of breastfeeding was not associated with all-cause mortality (p for trend=0.85). A total of 749 deaths were attributed to breast cancer; the confidence intervals for the association with ever breastfeeding spanned the null (fully adjusted HR, 1.01; 95% CI, 0.79 to 1.29), and the study reported no statistically significant trend between duration of breastfeeding and death due to breast cancer (p for trend=0.35).

Ovarian Cancer: Systematic Reviews

Four recent systematic reviews rated low[138] or unclear ROB[1, 128, 139] examined the association between breastfeeding and subsequent ovarian cancer (Table 20, Appendix Tables C-13 to C-18). The number of studies included in the recent systematic reviews ranged from 15[139] to 41.[1] Most of the studies included in the systematic reviews were conducted in the United States, Europe, and Australia; seven studies were conducted in countries not categorized by the United Nations Development Programme[41] as very high or high human development (Mexico, China, Thailand, Vietnam, and the Philippines) that contributed to one or more of the systematic reviews. All four systematic reviews evaluated the association between ovarian cancer and ever breastfeeding, and the duration of breastfeeding. Two reviews, both rated unclear ROB, performed a quality assessment of included articles according to the Newcastle-Ottawa Scale (NOS). In one review, approximately two-thirds of the studies were considered high quality but only 12 studies had a NOS score of 7. The remaining studies had NOS scores ranging from 4 to 6.[128] In the other review, only 4 of the 15 studies were considered high quality (i.e., NOS score ≥

“8”); the NOS scores for all studies ranged from “5” to “9.”[139] The other two systematic reviews[1, 138] did not do a formal quality or ROB assessment but did perform a number of stratified analyses by factors related to potential biases (e.g., known confounders, aspects of study design).

Table 20. Breastfeeding and ovarian cancer: Summary of published systematic reviews

Author, Year ROB	Number of Studies (Number of Participants; Number of Cases) Included Study Designs	Overlap with Prior AHRQ Report[2] Overlap with Other Published SRs	Search Dates Databases	Results
Chowdhury, 2015[1] Unclear	41 studies (NR) Cohort, case-control	9 studies 40 of 41 studies are included in SRs by Ip,[2] Li,[128], Luan,[138] or Sung[139]	Inception through February 2015 PubMed, Cochrane, CABI	Ever vs. never BF OR, 0.70 (95% CI, 0.64 to 0.77), I^2=70, 41 studies Total BF duration (mos) vs. never BF <6: OR,0.83 (95% CI, 0.78 to 0.89), I^2=3, 20 studies 6-12: OR, 0.72 (95% CI, 0.66 to 0.78), I^2=22, 19 studies >12: OR, 0.63 (95% CI, 0.56 to 0.71), I^2=52, 29 studies
Li, 2014[128] Unclear	40 studies (415,949; 17,139) Cohort, case-control	9 studies 38 of 40 studies are included in SRs by Ip,[2] Chowdhury,[1] Luan,[138] or Sung[1, 138, 139]	Inception through March 2013 PubMed, Embase	Ever vs. never BF RR=0.70 (95% CI, 0.64 to 0.76), I^2=76, 40 studies[a] Total BF duration (mos) vs. never BF <6: RR, 0.85 (95% CI, 0.77 to 0.93), I^2=38, 16 studies 6-12: RR, 0.73 (95% CI, 0.65 to 0.82), I^2=37, 15 studies >12: RR, 0.64 (95% CI, 0.56 to 0.73), I^2=62, 20 studies p_{trend}=0.00, 29 studies
Luan, 2013[138] Low	35 studies (720,617; 14,465) Cohort, case-control	10 studies All 35 studies are included in SRs by Ip,[2] Chowdhury,[1] Li,[128] or Sung[1, 138, 139]	Inception through December 2012 PubMed	Ever vs. never BF RR, 0.76 (95% CI, 0.69 to 0.83), I^2=55, 32 studies Total BF duration (per 5-month increase) RR, 0.92 (95% CI, 0.90 to 0.95), I^2=68, 26 studies Longest vs. shortest duration of BF categories RR, 0.65 (95% CI, 0.55 to 0.78), I^2=64, 26 studies
Sung, 2016[139] Unclear	15 studies (527,051; 7,639) Cohort, case-control	5 studies All 15 studies are included in SRs by Ip,[2], Chowdhury,[1] Li,[128] or Luan[138]	Inception through December 2015 PubMed, Embase	Total breastfeeding duration (mos) <6: RR, 0.79 (95% CI, 0.72 to 0.87), I^2=25.5, 15 studies 6-12: RR, 0.72 (95% CI, 0.64 to 0.81), I^2=19.6, 15 studies ≥13: RR, 0.67 (95% CI, 0.56 to 0.79), I^2=64.4, 15 studies

[a] When restricted to parous women, RR=0.76 (95% CI, 0.64 to 0.76), I^2=76, 32 studies.

AHRQ = Agency for Healthcare Research and Quality; BF = breastfeeding; CABI = Centre for Agriculture and Biosciences International database; CI = confidence interval;; NR = not reported; OR = odds ratio; ROB = risk of bias; RR = relative risk; SR = systematic review.

Because of substantial overlap among the four recent systematic reviews, results from pooled analyses were very similar (Table 20). As such, we describe in detail the most comprehensive systematic review by Chowdhury, published in 2015 and rated unclear ROB; the review included 41 studies and reported pooled results for both ever compared to never breastfeeding and different durations of breastfeeding.[1]

Chowdhury et al.[1] included 5 cohort and 36 case-control studies in their systematic review; 9 of the 41 included studies were also included in the 2007 AHRQ review.[2] The authors rated 27 (66%) of the studies as being of adequate quality, defined as having only one or none of the following: selection bias, measurement bias, confounding bias, or attrition of 20 percent. They used random effects meta-analysis to estimate pooled ORs when heterogeneity was high (I^2>60% or p for heterogeneity<0.010); reasons for heterogeneity were explored with subgroup analyses and meta-regression for the main comparison of ever versus never breastfed. Authors reported no evidence of publication bias using Begg's test, Egger's test, or funnel plot inspection.

Using data from all 41 included studies, the study reported a pooled OR for ever versus never breastfeeding of 0.70 (95% CI, 0.64 to 0.77); the substantial heterogeneity (I^2=70) of results could not be explained in subgroup analyses. The authors noted that among 35 studies in high-income countries, the association was significantly attenuated (pooled OR=0.74; 95% CI, 0.68 to 0.80) when compared with 6 studies in lower mid-income countries (pooled OR=0.48; 95% CI, 0.29 to 0.77), but the pooled estimates for two subgroups had substantial heterogeneity. The inverse association between ever breastfeeding and ovarian cancer was also attenuated but remained significant among cohort studies (pooled OR, 5 studies=0.87; 95% CI, 0.78 to 0.98), studies that finely adjusted for parity (pooled OR, 16 studies=0.80; 95% CI, 0.75 to 0.86), and studies that thoroughly adjusted for confounders (pooled OR, 14 studies=0.76; 95% CI, 0.67 to 0.85) compared with case-control studies, studies with crude or no adjustment for parity, and studies with partial or no adjustment for confounders, respectively.

Authors also conducted pooled analyses to evaluate the association between different total durations of breastfeeding (compared with women who never breastfed) and ovarian cancer among a subset of studies with duration data. There was a numeric decrease in the pooled ORs with increasing duration of breastfeeding. For total breastfeeding duration of <6 months, the pooled OR was 0.83 (95% CI, 0.78 to 0.89); the pooled ORs for 6 to 12 months and >12 months, respectively, were 0.72 (95% CI, 0.66 to 0.78) and 0.63 (95% CI, 0.56 to 0.71).

Ovarian Cancer: Individual Studies

Characteristics

We included four case-control studies[140-143] of 2,131 women who were included in the 2007 AHRQ report by Ip[2] but not included in subsequent systematic reviews (Table 21, Appendix Tables C-24 to C-28); these older studies were conducted as early as 1959 in the United States and Canada. One study was a pooled analysis of seven independent case-control studies[140] among 465 black women. Three studies included cases with nonmalignant (i.e., low malignant potential or borderline) tumors,[140, 141, 143] and one study enrolled women with benign ovarian tumors as controls.[142] The two oldest studies, published in the 1960s, were rated high ROB by the authors of the 2007 AHRQ report.[2] Two studies[140, 143] evaluated the association between ever breastfeeding and ovarian cancer, and three studies[140-142] analyzed the association between different durations of breastfeeding and ovarian cancer.

Table 21. Breastfeeding and ovarian cancer: Summary of individual studies

Author, Year Study Design ROB	Description of Study (N) Description of Ovarian Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed[a]	Results: Duration of Breastfeeding[a]	Confounders Adjusted for
Cook, 2017[144] Case-control Medium	Population-based case-control study in British Columbia and Calgary, Canada, with controls frequency-matched to cases on age (2,993) Women with histologically confirmed incident epithelial ovarian cancer (first primary) and reported to cancer registries (2,139)	Mean age (yrs): 50-69 Nonwhite: 14% Post-menopausal: 75% Current or prior use of HRT: 27%	Cases: 73% Controls: 80%	<10 months Cases: 45% Controls: 41% ≥10 months Cases: 28% Controls: 39%	None
Gay, 2015[145] Cohort Medium	Women, 50-64 yrs of age, enrolled in the Singapore Breast Cancer Project (28,107) Women diagnosed with incident ovarian cancer and reported to the Singapore Cancer Registry through 2012 (107)	Mean age (yrs): 57 Postmenopausal: 90% Current or prior use of HRT: 13%	HR=0.97 (95% CI, 0.63 to 1.51)[b]	≤1 year HR=1.09 (95% CI, 0.66 to 1.81)[b] >1 year HR=1.20 (95% CI, 0.72 to 2.01)[b]	Age, housing type, family history of breast cancer, race, BMI status, smoking status
Gierach, 2006[146] Case-control Medium	Population-based case-control study in the Delaware Valley, USA, with controls frequency-matched to cases on age and study area (1,151) Incident epithelial ovarian cancer, confirmed by pathologic review (521)	Mean age (yrs): 40-59 Nonwhite: 16%	Cases: 44% Controls: 51% p=0.04	NR	None
John, 1993[140] Case-control Medium[c]	Pooled analysis of 7 case-control studies conducted in the USA between 1971 and 1986 (465) Epithelial ovarian cancer (72), ovarian tumors of low malignant potential (borderline cases) (35), and ovarian tumors of unknown behavior (3)	Mean age (yrs) Invasive cases: 53 Borderline cases: 37 Controls: NR Nonwhite: 100%	OR=0.90 (95% CI, 0.42 to 1.90)[d] Per month of BF OR=0.99 (p=0.57)[d]	1-5 mos OR=1.00 (95% CI, 0.39 to 2.60)[d] ≥6 mos OR=0.85 (95% CI, 0.36 to 2.00)[d]	Study, year of birth, age, parity

Author, Year Study Design ROB	Description of Study (N) Description of Ovarian Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed[a]	Results: Duration of Breastfeeding[a]	Confounders Adjusted for
Jordan, 2008;[147] Nagle, 2008[148] Case-control Medium	Population-based case-control study in Australia, with controls frequency-matched to cases on age and State of residence (2,309)[147] and (1,740)[148] Invasive serous epithelial ovarian cancer, confirmed by histopathology reports (801)[147] Invasive endometrioid and clear cell epithelial ovarian cancers, confirmed by histopathology reports (232)[148]	Mean age (yrs) Serous cases: 60[147] Endometrioid and clear cell cases: 57-59[148] Controls: 56 Nonwhite: 4%[147] Current or prior HRT use Serous cases: 41%[147] Endometriod and Clear cell cases: 27-31%[148] Controls: 32-35%	Serous ovarian cancer[147] Per month of BF OR=0.98 (95% CI, 0.97 to 0.99)[147] Endometrioid ovarian cancer[148] OR=0.6 (95% CI, 0.4 to 1.0)[e] Clear cell ovarian cancer[148] OR=0.8 (95% CI, 0.4 to 1.4)[e]	Serous ovarian cancer[147] ≤6 mos OR=0.93 (95% CI, 0.68 to 1.28) 7-12 mos OR=0.66 (95% CI, 0.47 to 0.94) 13-24 mos OR=0.66 (95% CI, 0.47 to 0.93) 25-35 mos OR=0.63 (95% CI, 0.40 to 0.99) ≥36 mos OR=0.26 (95% CI, 0.13 to 0.54) p for trend<0.0001	Parity, hormonal contraceptive use, history of breast or ovarian cancer in first-degree relatives, tubal ligation, hysterectomy, education[f]
Kotsopoulos, 2015[149] Case-control High	Nested case-control study within cohort of women with *BRCA1* and *BRCA2* mutations from 72 participating centers in 20 countries with controls frequency-matched on *BRCA* mutation type, year of birth, country of residence, and previous diagnosis of breast cancer (6,596) Invasive epithelial ovarian cancer (1,329)[g]	Mean age (yrs) Cases: 54 Controls: 55 Nonwhite: 3%	*BRCA1* carriers OR=0.75 (95% CI, 0.61 to 0.93) *BRCA2* carriers OR=0.67 (95% CI, 0.45 to 1.00)	*BRCA1* carriers ≤12 mos: OR=0.83 (95% CI, 0.67 to 1.04) >12 mos: 0.62 (95% CI, 0.48 to 0.79) p for trend=0.0002 *BRCA2* carriers ≤12 mos: OR=0.79 (95% CI, 0.51 to 1.23) >12 mos: OR=0.50 (95% CI, 0.29 to 0.84) p for trend=0.009	Age at menarche, parity, OC use, tubal ligation, ethnicity

Author, Year Study Design ROB	Description of Study (N) Description of Ovarian Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed[a]	Results: Duration of Breastfeeding[a]	Confounders Adjusted for
Risch, 1994[141] Case-control Medium[c]	Population-based case-control study conducted in Canada from 1989 to 1992, with controls frequency-matched to cases by age (1,014) Incident epithelial ovarian cancer, based on histology (450)	Mean age (yrs) Cases: 57 Controls: 58 Used noncontraceptive estrogens: 18%	NR	Mean total duration of lactation (yrs) Cases: 0.51 Controls: 0.65 OR=0.89 (95% CI, 0.75 to 1.05)[h] Average duration of lactation per pregnancy (mos) Cases: 2.24 Controls: 2.72 OR=0.87 (95% CI, 0.76 to 0.99)[h]	Age, duration of OC use, number of full-term pregnancies
West, 1966[142] Case-control High[c]	Hospital-based case-control study where ovarian cancer cases and controls with benign ovarian tumors, matched to cases on age, residence, and date of surgery, were ascertained from 50 hospitals in the Boston, MA, area (194) Malignant ovarian cancer based on pathology (97)	Mean age (yrs) Cases: 45-64 Controls: 40-59	NR	Duration of lactation (mos) Cases: 6.6 Controls: 5.8 p>0.03	None
Wynder, 1969[143] Case-control High[c]	Hospital-based case-control study where ovarian cancer cases were matched to controls on age (450) Malignant ovarian cancer, based on pathology; a vast majority (89%) were epithelial (150)	Mean age (yrs) Cases: 52 Controls: NR Nonwhite Cases: 9% Controls: 6%	No difference between cases and controls for never nursing	NR	None

[a] Compared with never breastfed, unless otherwise specified.
[b] Among parous women only (25,975 women).
[c] This study was included in the prior 2007 AHRQ review by Ip and colleagues.[2] We did not reassess ROB for individual studies included in that review; this rating represents the decisions of the authors of that review.
[d] Among parous women only (80 cases, 310 controls).
[e] Among parous women only (109 endometrioid ovarian cancer cases, 59 clear cell ovarian cancer cases, 1,328 controls).
[f] Jordan et al. (2008)[147] adjusted for all confounders list; Nagle et al. (2008)[148] adjusted only for parity, hormonal contraceptive use, and education.
[g] Among cases, the mean age at diagnosis was 49.99 yrs, while mean age at interview was 53.85, indicating that some portion of cases were prevalent (as opposed to incident); ascertainment of cancer diagnoses was self-report.
[h] Among parous women (77% of cases, 89% of controls).

BF = breastfeeding; BMI = body mass index; CI = confidence interval; HR = hazard ratio; MA = Massachusetts; N = number; NR = not reported; OC = oral contraceptive; OR = odds ratio; ROB = risk of bias.

We also included one cohort study and four case-control studies published after the most recent systematic review (Table 21, Appendix Tables C-24 to C-28).[144-149] The cohort study followed 28,107 women, ages 50 to 64 years, participating in the Singapore Breast Cancer Project from 1994 to 1997; the Singapore Cancer Registry identified 107 ovarian cancer cases after an average 17 years of followup. The mean age of cases was 57 years and 90 percent of women were postmenopausal at the time of enrollment in the cohort. Information on breastfeeding was collected in 1994 to 1997; total duration of breastfeeding was calculated as the sum of breastfeeding duration for each child that was breastfed. More than 90 percent of women were parous at the time of enrollment, and 69 percent of them reported ever breastfeeding; the average total duration of breastfeeding was 1.88 years.[145]

Three recent, population-based case-control studies were conducted in the United States,[146] Canada,[144] and Australia.[147, 148] The SHARE Study in the United States enrolled cases that were identified prior to surgery for ovarian cancer.[146] Both the Australian Ovarian Cancer Study,[147, 148] which contributed cases to two separate analyses, and the recent Canadian study,[144] recruited incident cases that had been reported to population-based cancer registries;[147, 148] population-based controls were recruited using random-digit dialing, Health Care Financing Administration or provincial health rosters, and electoral rolls; some controls from the Canadian study were also recruited from a mammography screening program. Information on parity, breastfeeding, and other risk factors for ovarian cancer was collected at enrollment during either an in-person interview[146] or questionnaire.[144, 147, 148] The Australian Ovarian Cancer Study published two analyses, one including invasive serous ovarian cancer cases[147] and the other including invasive endometrioid and clear cell ovarian cancer cases;[148] both analyses compared the breastfeeding exposure of cases to that of 1,508 controls. We also included a high ROB case-control study, nested within a cohort of *BRCA1* and *BRCA2* mutation carriers, that recruited women from 72 participating centers across 20 countries; cases with self-reported invasive ovarian cancer (n=1,329) were frequency-matched to women without ovarian cancer on *BRCA* mutation type, year of birth, and country of residence. For cases, the mean age at diagnosis was 50 years and the mean age at enrollment in the study was 54 years, indicating that a proportion of the ovarian cancer cases were enrolled with prevalent disease.[149]

With the exception of the SHARE, and recent Canadian[144] studies, which only presented frequencies of ever breastfeeding or duration of breastfeeding among cases and controls only,[146] the recent studies used regression analysis to estimate relative measures of association (i.e., hazard or odds ratios) for ever breastfeeding and different durations of breastfeeding, compared with never breastfeeding; regression models were adjusted for potential confounders including age, race/ethnicity, BMI, age at menarche, parity, oral contraceptive use, tubal ligation, hysterectomy, and family history of breast or ovarian cancer.

Results

The case-control studies, conducted across multiple countries and among women at both average and increased risk of ovarian cancer (i.e., *BRCA1* and *BRCA2* mutation carriers), generally reported an association between breastfeeding and reduced risk of ovarian cancer (Table 21). The SHARE Study reported that 51 percent of controls, compared with 44 percent of cases, reported ever breastfeeding;[146] Prevalence of ever breastfeeding was high in the recent Canadian study overall and higher among controls (80%) than among cases (73%).[144] ORs in the other studies ranged from 0.60 for endometrioid ovarian cancer (95% CI, 0.4 to 1.0)[148] to 0.80 for clear cell ovarian cancer (95% CI, 0.4 to 1.4)[148] to 0.90 (95% CI, 0.42 to 1.90) for ovarian cancer among black women.[140] A hospital-based case-control study, published in 1969, described no difference between groups with respect to ever breastfeeding but did not report specific frequencies.[143] The cohort study in Singapore reported an adjusted HR of 0.97 (95% CI, 0.63 to 1.51); the wide CI could be partially attributed to only 107 ovarian cancer cases being identified.

An association between various durations of breastfeeding and reduced rates of ovarian cancer was also reported across most studies. In a pooled analysis of black women from seven case-control studies, the OR for ovarian cancer among women who breastfed 6 months or more was significantly lower (0.85; 95% CI, 0.36 to 2.00) but not for women who breastfed 1 to 5 months (OR, 1.00, 95% CI, 0.39 to 2.60) when compared with no breastfeeding.[140] A Canadian population-based study published in 1994 reported a higher mean total duration of breastfeeding and average duration of breastfeeding per pregnancy, respectively, among controls (0.65 years and 2.72 months) than among cases (0.51 years and 2.24 months);[141] the more recent Canadian study reported that among women who breastfed, 49 percent of controls and 38 percent of cases breastfed for 10 or more months.[144] Cases had a higher mean duration of breastfeeding (6.6 months) than controls with benign ovarian tumors (5.8 months) in a study published in 1966, but the difference was not statistically significant.[142] The Australian Ovarian Cancer Study reported a significant trend ($p<0.0001$) of decreasing odds of invasive serous ovarian cancer with increasing duration of breastfeeding; for 6 or fewer months of breastfeeding, the reported OR was 0.93 (95% CI, 0.68 to 1.28), and 0.26 for 3 or more years of breastfeeding, it was 0.26 (95% CI, 0.13 to 0.54).[147] One study reported similar results among *BRCA1* and *BRCA2* mutation carriers,[148] with an OR per month of breastfeeding for invasive serous ovarian cancer of 0.98 (95% CI, 0.97 to 0.99).[147] The only study to report increased odds of ovarian cancer with increasing duration of breastfeeding was the cohort study in Singapore; because of the small number of cases, CIs were wide and overlapping, however, and included no difference.[145]

Cardiovascular Disease and Hypertension

Background

Physiologic changes associated with breastfeeding (e.g., increased plasma levels of oxytocin) have been associated with lower blood pressure.[150] In addition, observational studies suggest that lactation has a beneficial effect on glucose and lipid metabolism that persists long after weaning.[151] For these reasons, it is possible that breastfeeding leads to lower rates of CVD and hypertension in women. Commonly considered confounders in studies of the relationship between CVD and breastfeeding are diet, physical activity, cholesterol levels, and smoking status.

Methods

We included both case-control and cohort studies that examined the link between breastfeeding and incidence of CVD and hypertension. Although recent systematic reviews (published within the last 5 years) were eligible, we did not find one that was relevant to the scope of this review. We excluded metabolic markers associated with CVD (e.g., lipid levels and C-reactive protein) and measures of vascular characteristics (e.g., carotid artery intima media thickness) that could not be used to establish a diagnosis of CVD. For hypertension, we excluded changes in blood pressure levels that did not establish a diagnosis of hypertension.

Individual Studies

Characteristics

Eight cohort studies were identified (Table 22); five reported on hypertension,[4, 5, 152-154] three reported on composite measures of CVD (e.g., myocardial infarction [MI] or stroke),[4, 6, 155] and one reported on death from CVD.[156] All studies were based on population cohorts. Four were set in the United States,[4-6, 155] two were set in Korea,[152, 154] and one each was set in Australia[153] and Norway.[156] Of the four studies set in the United States, two focused on women enrolled in the WHI,[4, 155] one enrolled participants from the Nurses' Health Study I,[6] and one enrolled participants from the Nurses' Health Study II.[5] No study followed participants from the time of exposure; all assessed exposure based on self-report at cohort enrollment. The majority of studies enrolled women in their 20s or 30s through menopause; two studies (enrolling participants from the WHI) enrolled postmenopausal women only (mean ages 63 to 64 years).[4, 155] Most studies reported on smoking; rates ranged from 32 to 60 percent in six studies but were lower in the two studies enrolling Korean women (<1 to 9%).[152, 154] All studies measured self-reported lifetime duration of lactation but used different categories (Table 22). Outcome ascertainment varied significantly and included self-report only,[153] self-reported treatment or physical exam,[154] biennial physical exams,[152] and use of medical records or other means to confirm cardiovascular outcomes.[6, 155]

Results: Hypertension

Five studies reported on the association between breastfeeding duration and hypertension; all reported some statistically significant association (Table 22).[4, 5, 152-154] Most studies (4) compared women by categories of breastfeeding duration (in months) with parous women who never breastfed; one study compared women who breastfed for less than 5 months with women who breastfed at least 6 months (or longer).[154] Four studies found a consistent pattern of lower rates of hypertension across all categories of breastfeeding duration.[4, 5, 152, 154] In one Australian cohort study, women who breastfed for longer than 6 months per lifetime (or greater than 3 months per child), on average, had significantly lower odds of having hypertension when compared with women who never breastfed (Table 22); however, results were only significant for women less than 64 years of age at cohort enrollment.[153]

Table 22. Breastfeeding and CVD or hypertension: Summary of individual studies

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Outcome Definition Timing of Followup	Results	Confounders Adjusted for
Choi, 2017[154] High	Parous women in the 2010-2013 Korean National Health and Nutrition Examination Survey (KNHANES) ages 19-50 yrs	Mean age (SD): 40 (NR) % nonwhite: NR % current smokers (by BF duration): ≤5 mos: 9 6-11 mos: 5 12-23 mos: 5 24+ mos: 3	Self-reported lifetime BF duration	Elevated BP defined as measured SBP≥130 mmHg, DBP≥85 mmHg, or self-reported treatment with HTN	Adjusted OR (95% CI) of elevated BP by BF duration: 6-11 mos vs. ≤ 5 mos: 0.67 (0.51 to 0.89) 12-23 mos vs. ≤5 mos: 0.68 (0.54 to 0.86) 24+ mos vs. ≤ 5 mos: 0.82 (0.65 to 1.03)	Age, BMI, household income, education, marriage status, smoking status, alcohol, physical activity, age at menarche, menopause, parity, and use of OCs

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Outcome Definition Timing of Followup	Results	Confounders Adjusted for
	4,724 women	% with type 2 DM (by BF duration): ≤5 mos: 2 6-11 mos: 1 12-23 mos: 2 24+ mos: 2		medication NA: Cross-sectional data from cohort study	p for trend=0.015	
First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Outcome Definition Timing of Followup	Results	Confounders Adjusted for
Lee, 2005[152] Medium	Women >20 yrs through menopause without HTN at baseline enrolled in the Korean Women's Cohort Study 177,749 (106,585 ever pregnant)	Mean age (SD): 32.2 (7.1) % nonwhite: NR (presumably all S. Korean) % current or former smokers: 0.3 to 0.9% (across BF categories)	Self-reported history of BF any or all children (lactation records of up to a maximum of 5 children per mother were recorded); duration of lactation was defined by total duration for all children	SBP ≥140 mmHg, DBP ≥90 mmHg or current use of HTN treatment (determine during biennial physical exam) 6 yrs (BP measured twice)	RR (95% CI), mean duration of lifetime lactation (mos): 1-3: 0.90 (0.87 to 0.93) 4-6: 0.92 (0.87 to 0.98) 7-9: 0.93 (0.86 to 0.99) 10-12: 1.00 (0.91 to 1.11) >12: 1.06 (0.99 to 1.14) RR (95% CI), effect of combination obesity and lactation history (ever vs. never) on incident HTN (reference = BMI <23.05 and +lactation) BMI <23.05/no lactation: 1.06 (1.02 to 1.11) BMI ≥23.05/lactation: 1.65 (1.58 to 1.72) BMI ≥23.05/no lactation: 1.85 (1.75 to 1.90)	Age, obesity, smoking, alcohol drinking, exercise, number of children, and age at first pregnancy

First Author, Year **ROB**	**Study Description** **N Participants**	**Population**	**Definition of Exposure**	**Outcome Definition** **Timing of Followup**	**Results**	**Confounders Adjusted for**
Lupton, 2013[153] Medium	Nested case- control study of women >45 yrs participating in an Australian population-based cohort study without HTN during pregnancy 74,785 (64,199 parous women)	% of cases in each age category: 45 to <54: 35 54 to <64: 33 ≥64: 32 % of cases who were current or former smokers: 35	Self-reported total lifetime BF duration (and average BF duration per child)	Self-reported current treatment of HTN (onset after age of first birth) NA (recruited from 2006 to 2009)	OR (95% CI), lifetime BF category (mos) vs. never BF in parous women: Age 45 to <54 yrs: 1 to <3: 0.88 (0.63 to 1.24) 3 to <6: 0.87 (0.62 to 1.20) 6 to <12: 0.74 (0.55 to 0.98) 12 to <18: 0.71 (0.53 to 0.95) 18 to <24: 0.57 (0.41 to 0.79) >24: 0.58 (0.44 to 0.77) 54 to <64 yrs: 1 to <3: 0.97(0.78 to 1.20) 3 to <6: 0.84 (0.69 to 1.02) 6 to <12: 0.81 (0.68 to 0.96) 12 to <18: 0.78 (0.64 to 0.94 18 to <24: 0.71 (0.57 to 0.89) >24: 0.60 (0.50 to 0.73) >64 yrs: 1 to <3: 1.08 (0.89 to 1.31) 3 to <6: 1.11 (0.94 to 1.31) 6 to <12:1.04 (0.90 to 1.20) 12 to <18: 1.06 (0.91 to 1.24) 18 to <24: 1.07 (0.90 to 1.28) >24: 1.03 (0.88 to 1.22)	Country of origin (Australia or other), income level, BMI, smoking status, alcohol consumption, physical activity, family history of HTN, history of OC use, and history of HRT use
First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Outcome Definition Timing of Followup	Results	Confounders Adjusted for
Natland Fagerhaug, 2013[156] Medium	Norwegian population-based cohort enrolling women ages 30 to 85 who attended a health survey followup in 1995-1997[a] 21,889 (15,000 parous women)	Age: Ever lactated: 52.1 (14.1) Never lactated: 52.5 (12.5) Nulliparous: 55.9 (16.8) % nonwhite: NR % current or former smokers: 51.2 % post-menopausal : NR	Self-reported lactation history, ever and lifetime lactation (defined as sum of lactation duration for all births)	Death from CVD (MI or stroke) defined by ICD 9: 390-459 and ICD-10: 100-99 Median 14.5 yrs after enrollment	HR (95% CI): never vs. ever lactation in parous women <65 yrs: 2.86 (1.51 to 5.39) 45-64 yrs: 3.15 ((1.66 to 5.00) >65 yrs: 1.11 (0.77 to 1.69) HR (95% CI) by lifetime lactation duration in parous women <65 yrs: Never vs. >24 mos: 2.77 (1.28 vs. 5.99) 7-12 mos vs. >24 mos: 0.55 (0.27 to 1.09) HR (95% CI), lifetime lactation duration in parous women 45 to 64 yrs:	Age, smoking status, physical activity, education, marital status, parity

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Outcome Definition Timing of Followup	Results	Confounders Adjusted for
		% with type 2 diabetes: 2.9%			Never vs. >24 mos: 3.03 (1.38 to 6.70) 7-12 mos vs. >24 mos: 0.45 (0.21 to 0.97)	
Parikh, 2016[155] Medium	U.S. women participating in the WHI observational cohort study who had no prior history of CHD 72,982	Mean age (SD): 63.2 (7.3) % nonwhite: 14 % postmeno-pausal: 100 % using HRT: 30 % current or former smokers: 49 % with type 2 diabetes: 4.7	Self-reported lifetime BF duration assessed at WHI enrollment	Physician-adjudicated fatal and nonfatal CHD[b] Median 12 yrs	HR (95% CI), BF for at least 1 mo vs. <1 mo: 0.90 (0.85-0.96)	Menstrual irregularity, age at first birth, still births, miscarriages, age, medication use for high cholesterol, medication use for HTN, log of systolic blood pressure, current smoker, and diabetes mellitus

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Outcome Definition Timing of Followup	Results	Confounders Adjusted for
Schwarz, 2009[4] Medium	Cohort study (WHI) enrolling generally healthy post-menopausal women from the United States who reported at least 1 live birth 139,681	Mean age: 63-64 (SD NR) % nonwhite; 14-19 % with GDM: NR	Self-reported lifetime BF duration assessed at WHI enrollment Median 7.9 yrs	Self-reported HTN and history of CVD[c] prior to enrollment; incident CVD[d] over 7.9 yrs of WHI (validated by physician adjudication)	OR (95% CI), lifetime duration (mos) vs. never BF: Prevalent HTN: 1-6: 0.95 (0.92 to 0.98) 7-12: 0.88 (0.84 to 0.91) 13-23: 0.89 (0.84 to 0.93) 24+: 0.87 (0.82 to 0.93) >13: 0.88; p<0.001 Prevalent CVD: 1-6: 1.03 (0.97 to 1.08) 7-12: 0.94 (0.87 to 1.01) 13-23: 0.92 (0.85 to 1.00) 24+: 0.86 (0.89 to 0.98) p for trend: 0.003 >13: 0.91; p=0.0008 Incident CVD, HR (95% CI): 1-6: 1.03 (0.98 to 1.08) 7-12: 0.97 (0.90 to 1.03) 13-23: 0.98 (0.91 to 1.05) 24+: 0.93 (0.85 to 1.02) p for trend: 0.10 Subgroup of women from WHI cohort study who provided information on their weight at age 18 and whether they were BF (N=78,825) Prevalent HTN: 1-6: 0.95 (0.91 to 0.99) 7-12: 0.87 (0.82 to 0.93) 13-23: 0.90 (0.85 to 0.97) 24+: 0.88 (0.81 to 0.95) p for trend<0.001 Prevalent CVD: 1-6: 1.06 (0.99 to 1.13) 7-12: 0.97 (0.88 to 1.06) 13-23: 0.98 (0.88 to 1.09) 24+: 0.94 (0.82 to 1.07) p for trend=0.26	Age; race; parity; age at menopause; education; income; family history (of diabetes mellitus; MI or stroke); physical activity; energy, cholesterol, fat, fiber, and sodium intakes; tobacco history; HRT use, aspirin use; and MVI use

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Outcome Definition Timing of Followup	Results	Confounders Adjusted for
Stuebe, 2009[6] High	Participants from the Nurses' Health Study I who were parous with no history of MI, angina, or CABG before 1986 89,326	Age: 30-55 yrs at enrollment (mean NR) % nonwhite: NR % with type 2 diabetes: 1.7-2.1 % with HTN: 18.5 to 23.3 % past or current smoker: 60.4 to 44.1	Self-reported total duration of lactation for all pregnancies (via questionnaire in 1986)	Incident CHD (nonfatal MI[e] and mortality due to CHD) confirmed by medical records (from 1986 to 2002)[f] 16 yrs	HR (95% CI), lifetime BF duration (mos) vs. never: <3: 1.01 (0.91 to 1.11) 3-6: 1.0 (0.88 to 1.14) 6-11 1.02 (0.88 to 1.18) 11-23: 0.93 (0.8 to 1.07) >23: 0.77 (0.62 to 0.94) p for trend: 0.02	Age; parity; history of stillbirth; BMI at age 18 yrs; birthweight of subject; parental history of MI before age 60 yrs; diet quintile; physical activity; smoking; menopausal status; and use of aspirin, alcohol, MVI, and HRT
Stuebe, 2011[5] Medium	Participants from the Nurses' Health Study II without HTN,[g] self-reported diabetes, CVD, hyperlipidemia, or cancer (1991-2005) 55,636	Age: 25-42 yrs at enrollment (mean=35.7) in 1989) % nonwhite: 6.2 % current or former smokers: 32.3	Self-reported total duration and exclusive duration of lactation (for first 4 children)	Incident self-reported HTN (excluding pregnancy) NA: Cross-sectional data from cohort study	HR (95% CI), duration of BF for first child (mos), referent=≥12 Never: 1.27 (1.18 to 1.36) >0-3: 1.29 (1.20 to 1.39) >3, <6: 1.16 (1.08 to 1.25) 6, <9: 1.11 (1.03 to 1.19) 9, <12: 1.03 (0.95 to 1.11) p for trend <0.001 HR (95% CI), exclusive duration of BF for first child (mos), referent=≥6 Never BF: 1.29 (1.20 to 1.39) BF, never exclusively: 1.11 (1.03 to 1.19) >0-3: 1.08 (0.99 to 1.18) >3, <6: 1.03 (0.95 to 1.12) p for trend <0.001 HR (95% CI), mean total duration of BF per child (mos), referent=≥12 Never: 1.20 (1.10 to 1.29) >0-3: 1.14 (1.06 to 1.23) >3, <6: 1.14 (1.06 to 1.22) 6, <9: 1.07 (0.99 to 1.15) 9, <12: 1.07 (0.99 to 1.16) p for trend<0.001	Age and inverse probability weights (derived from models including maternal BMI at age 18, year of first birth, self-reported history of preeclampsia, gestational HTN, gestational diabetes, birth of an infant at <37 wks, birth of an infant weighing <2,500 g, miscarriage or stillbirth at >12 wks, smoking status, vigorous physical activity, alcohol consumption, DASH diet score quintile, family history of HTN, current OC use, current nonnarcotic analgesic use, and self-reported race)

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Outcome Definition Timing of Followup	Results	Confounders Adjusted for
Stuebe, 2011[5] (continued)					HR (95% CI), exclusive duration of BF per child (mos), referent=≥6 Never BF: 1.14 (1.04 to 1.26) BF, never exclusively: 1.10 (1.01 to 1.20) >0-3: 1.06 (0.97 to 1.15) >3, <6: 1.03 (0.95 to 1.13) p for trend=0.001	

[a] Exclusion criteria included the following: nonresponse to the second questionnaire; current pregnancy; less than 30 or greater than 85 years old; nonattendance at the clinical examination; self-report of MI, stroke, angina pectoris, or diabetes prior to the first birth; unknown parity; less than 1 year since their last child birth; and unknown lactation history.
[b] Composite outcome defined as clinical MI, CHD death, or coronary artery revascularization in the form of coronary artery bypass surgery or percutaneous coronary intervention.
[c] Prevalent CVD defined as self-reported history of MI, angina, congestive heart failure, peripheral arterial disease, revascularization, carotid angioplasty, carotid endarterectomy, or stroke.
[d] Incident CVD defined as coronary heart disease, stroke, congestive heart failure, angina, peripheral vascular disease, carotid artery disease, and coronary revascularization.
[e] Confirmed cases met World Health Organization criteria for MI (symptoms associated with diagnostic electrocardiographic changes or elevations in cardiac enzymes). Cause of death was determined from hospital records or autopsy, when available.
[f] Incident cases of MI were examined from 1986, when cohort members were ages 40-65 years, to 2002, at which point they were 56-81 years of age.
[g] Women were excluded if they reported a diagnosis of hypertension prior to 1991 or reported elevated blood pressure (median systolic blood pressure >120 mm Hg or diastolic blood pressure >80 mm Hg) or antihypertensive medications in 1989. Also excluded women with diabetes, CVD, hyperlipidemia, or cancer.

BF = breastfeeding; BMI = body mass index; BP = blood pressure; CABG = coronary artery bypass graft; CHD = coronary heart disease; CI = confidence interval; CVD = cardiovascular disease; DASH = Dietary Approaches to Stop Hypertension; DBP = diastolic blood pressure; DM = diabetes mellitus; GDM = gestational diabetes mellitus; HR = hazard ratio; HRT = hormone replacement therapy; HTN = hypertension; ICD = International Classification of Diseases; KNHANES = Korean National Health and Nutrition Examination Survey; MI = myocardial infarction; MVI = Multivitamin; N = number; NA = not applicable; NR = not reported; OR = odds ratio; ROB = risk of bias; RR = relative risk; SBP = systolic blood pressure; SD = standard deviation; WHI = Women's Health Initiative.

Results: Cardiovascular Disease

Three studies reported on CVD using a composite measure,[4, 6, 155] and one reported on death due to CVD.[156] Two assessed outcomes among women enrolled in the WHI; one focused on women enrolled in the observational study only,[155] and the other included women enrolled in the RCT and observational study.[4] The analysis of women in the WHI observational study (N=72,982) reported on incidence of fatal and nonfatal coronary heart disease (defined as clinical MI, coronary heart disease death, or coronary artery revascularization in the form of coronary artery bypass surgery or percutaneous coronary intervention); women who breastfed for at least 1 month had fewer incident coronary heart disease over 12 years (median) than women who breastfed for less than 1 month (HR, 0.30; 95% CI, 0.85 to 0.96).[155] The study enrolling women participating in the WHI RCT and observational study (N=139,681) reported on the association between lifetime duration of breastfeeding and presence of CVD at enrollment (composite of self-reported MI, angina, congestive heart failure, peripheral arterial disease, revascularization, carotid angioplasty, carotid endarterectomy, or stroke); women with a cumulative lifetime duration of breastfeeding equal to or greater than 13 months were less likely to have CVD than women who breastfed for less than 13 months (OR, 0.91; p=0.008).[4] The same study also reported on incident CVD (after WHI enrollment); over an average of 7.9 years of followup there was no significant difference in CVD incidence between women based on lifetime breastfeeding duration in adjusted models (Table 22). Finally, an analysis of participants from the Nurses' Health Study 1 who were parous with no history of CVD prior to enrollment (N=89,326) found that women who had breastfed for greater than 23 months had lower rates of incident MI (defined as fatal or nonfatal MI) over 16 years of followup (HR, 0.77; 95% CI, 0.62 to 0.94).[6] Women who breastfed for shorter durations (<23 months) did not have a significantly different rate of MI compared with women who never breastfed (Table 22).

One Norwegian population-based cohort study (N=15,000 parous women) compared incident CVD mortality among women ages 30 to 85 years at enrollment over approximately 14 years of followup.[156] Parous women younger than 65 at enrollment who had never lactated had higher CVD mortality than women who lactated 24 months or more (HR 2.77; 95% CI, 1.28 to 5.99). No clear associations were observed among women 65 years of age or older at cohort enrollment (Table 22).

Type 2 Diabetes

Background

Observational studies suggest that lactation has a beneficial effect on glucose and lipid metabolism that persists long after weaning.[151] For women with gestational diabetes, evidence suggests that lactation is associated with improved pancreatic beta-cell function and glucose levels.[157] Studies have reported that mothers who do not breastfeed (or breastfeed for shorter durations) have less visceral fat than mothers who breastfed for at least 3 months. Thus, it is plausible that lactation could reduce the risk of the development of type 2 diabetes. Commonly considered confounders in studies of relationship between maternal type 2 diabetes and breastfeeding are parity, BMI, diet, physical activity, family history of diabetes, and smoking status.

Methods

We included both case-control and cohort studies that examined the association between breastfeeding and incidence of type 2 diabetes, in addition to recent systematic reviews (published within the past 5 years). We excluded measures of glucose metabolism that could not be used to establish a diagnosis of diabetes (e.g., changes in mean levels of fasting blood glucose in women without known diabetes) and other laboratory markers of abnormal glucose metabolism (e.g., measures of insulin levels). We included studies enrolling women with a history of gestational diabetes that reported on the incidence of type 2 diabetes.

Systematic Reviews

One systematic review rated low ROB examined the association between breastfeeding and maternal risk of subsequent type 2 diabetes (Table 23).[158] The authors identified six prospective cohort studies (described in 5 publications) that evaluated the association between breastfeeding and incident type 2 diabetes. Three studies were set in the United States, and one each was set in Germany, China, and Australia. One study focused on women with gestational diabetes (N=304), and the others focused on an unselected sample of women with no diabetes at enrollment (sample sizes ranged from 1,829 to 83,585 participants). All studies defined exposure as duration of breastfeeding, and most (5 of 6) reported on multiple categories of breastfeeding exposure defined in months or years of breastfeeding. All studies controlled for a range of known confounders; however, specific measures varied across studies; most studies adjusted for age, smoking, alcohol, BMI, physical activity, and family history of diabetes, and some had further adjusted for income, education, and parity. Systematic review authors assessed the ROB of individual studies using the Newcastle-Ottawa Scale, rating it on a 0 to 9-point scale (with higher values indicating better quality); four studies were rated a 6, one was rated a 7, and one was rated an 8.[158]

Table 23. Breastfeeding and type 2 diabetes: Summary of published systematic review

First Author, Year	Number of Studies (N Participants) Study Design	Search Date (Databases)	Study Characteristics	Definition of Exposure	Definition of Outcome	Timing of Followup	Results	ROB
Aune, 2014[158]	6 (273,961); prospective cohort studies	Inception through September 2013 (PubMed, Embase, Ovid)	Three studies set in the U.S. and one each in Germany, China, and Australia; studies enrolled women between 1989 and 2008 One focused on women with GDM; the others focused on women without known diabetes	Measures of BF duration (lifetime and per-child categories)	NR: any measure of type 2 diabetes appears eligible	Unclear; studies assessed lifetime duration of BF	Pooled RR (95% CI): highest vs. lowest BF duration: 0.68 (0.57-0.82) 3-mo increase in BF duration per child: 0.89 (0.77-1.04) 1-year increase in total BF duration: 0.91 (0.86-0.96)	Low

BF = breastfeeding; CI = confidence interval; GDM = gestational diabetes mellitus; N = number; NR = not reported; ROB = risk of bias; RR = risk ratio.

The review authors conducted meta-analyses using random effects models to calculate summary risk ratios (RRs) for different durations of breastfeeding.[158] Authors first pooled studies based on comparisons of the highest versus lowest breastfeeding duration reported by each study; all included a comparison of "no breastfeeding," longest duration included >3 months (1 study), ≥ 6 months (2 studies), >23 months' total duration (2 studies), and ≥ 4 years (study). The pooled RR for high versus low breastfeeding (6 studies, 273,961 participants) was 0.68 (95% CI, 0.57 to 0.82; I^2 74.7%). To explore heterogeneity, authors conducted sensitivity analyses excluding individual studies. When excluding results from the Nurses' Health Study I,[6] the pooled RR (5 studies) was 0.62 (95% CI, 0.56 to 0.69) and heterogeneity was lower (I^2 0%). Authors also reported on subgroup and meta-regression analyses and reported no significant heterogeneity between subgroups of studies based on country setting, number of cases, study quality scores, or extent to which individual studies adjusted for confounding factors. There was no evidence of publication bias with Egger's test, p=0.27.

Authors also conducted pooled analyses that examined the dose-response of different levels of breastfeeding duration across four studies (by computing study-specific linear trends across categories of breastfeeding duration); the summary RR was 0.91 (95% CI, 0.86 to 0.96; I^2 80.9%) per 12 months' increase in lifetime duration of breastfeeding, and 0.89 (95% CI, 0.77 to 1.04; I^2 92.9%) per 3 months' increase in duration of breastfeeding per child.[158] No further sensitivity analyses were conducted, presumably because of the small number of studies available.

Individual Studies

Characteristics

We identified five cohort studies not included in the systematic review described above (Table 24).[4, 159-163] Two were limited to women with gestational diabetes,[159, 160, 163] two included women who had no history of diabetes prior to delivery,[4, 162] and one reported on subgroups of women with and without gestational diabetes.[161]

Table 24. Breastfeeding and type 2 diabetes: Summary of individual studies

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Type 2 Diabetes Timing of Followup	Results	Confounders Adjusted for
Chamberlain, 2016[159] High	Cohort study of women with GDM who gave birth at a regional Australian hospital from 2004-2010 289	Age category (y), %: <25: 9 25-29: 20 30-34: 28 35+: 44 % nonwhite: 32[a]	BF status at hospital discharge, defined as fully BF, partially BF, or no BF	Positive OGTT 7 yrs postpartum	HR (95% CI) Partial vs. full BF (ref): 2.34 (1.23 to 4.47) No vs. full BF (ref): HR 1.33 (0.40 to 4.37)	None

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Type 2 Diabetes Timing of Followup	Results	Confounders Adjusted for
Gunderson, 2012[163]; Gunderson, 2015[160] Medium	Cohort study of women with GDM who gave birth at Kaiser Northern CA hospitals from 2008-2011 959	Mean age: 33-34 (SD NR) % nonwhite: 77 % with GDM: 100[c]	BF duration/ intensity assessed prospectively via feeding diaries, phone calls, in-person exams, and monthly mailed questionnaires Intensity represents cumulative amount of formula and breast milk fed since delivery and the intensity for the past 7 days (measured at 6-9 wks after delivery)	Positive OGTT or diagnosis obtained from EMRs[b] 2 yrs post-partum	Adjusted HR (95% CI), BF group compared with exclusive formula feeding: Exclusive lactation: 0.47 (0.25 to 0.91) Mostly lactation: 0.53 (0.31 to 0.91) Mostly formula: 0.65 (0.37 to 1.13) p for trend=0.017 Adjusted HR (95% CI), BF duration group compared with 0-2 mos duration: >2-5 mos: 0.43 (0.23 to 0.82) >5-10 mos: 0.50 (0.25 to 0.99) >10 mos: 0.55 (0.31 to 1.01) p for trend=0.007	Age, race/ethnicity, education, prepregnancy BMI, GDM treatment, sum of prenatal oral glucose tolerance test Z score, gestational age at GDM diagnosis, subsequent birth (0 vs. 1) during 2-yr followup, large for gestational age vs. not large for gestational age (reference), hospital stay >3 days, and neonatal intensive care unit admission

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Type 2 Diabetes Timing of Followup	Results	Confounders Adjusted for
Martens, 2016[161] Medium	Cohort study of women who gave birth in Manitoba Canada (1987-2011), without diabetes before pregnancy 180,107 women (334,553 deliveries)	Mean age (at delivery): 26-28 (6) % with GDM: 3-4	BF initiation before hospital discharge (from hospital administrative database, recorded by nurses)	One hospital-ization or two outpatient visits with a diabetes diagnosis code in a 3- year period (using ICD codes) Maximum of 24 yrs	Adjusted HR (95% CI) for incident DM, BF vs. not-BF: With GDM: First Nations: 0.82 (073 to 0.92) Non-First Nations: 0.78 (0.69 to 0.82) Without GDM: First Nations: 0.89 (0.81 to 0.98) Non-First Nations: 0.73 (0.68 to 0.79)	Age at birth of child, parity, rurality, income quintile, year of delivery
Schwarz, 2009[4] Medium	Cohort study (WHI) enrolling generally healthy, postmeno-pausal women from the U.S. starting in 1994 who reported at least one live birth 139,681	Mean age: 63-64 (SD NR) % nonwhite: 14-19 % with GDM: NR	Self-reported lifetime BF duration assessed at WHI enrollment	Self-reported need to use medication to control “sugar diabetes”[d] Average of 35-year post-lactation (at WHI enrollment)	OR (95% CI), lifetime duration (mos) vs. never BF: 1-6: 0.92 (0.85 to 0.99) 7-12: 0.87 (0.78 to 0.97) 13-23: 0.74 (0.65 to 0.84) 24+: 0.89 (0.77 to 1.02) p for trend<0.0001 ≥13: 0.80 (NR); p<0.001 Subgroup of women from WHI cohort study who provided information on their weight at age 18 and whether they were BF (N=78,825): OR (95% CI), lifetime duration (mos) vs. never BF: 1-6: 0.94 (0.84 to 1.04) 7-12: 0.91 (0.78 to 1.06) 13-23: 0.69 (0.58 to 0.84) 24+: 0.99 (0.82 to 1.19) p for trend=0.02	Age; race; parity; age at menopause; education; income; family history (of diabetes mellitus, MI or stroke); physical activity; energy, cholesterol, fat, fiber, and sodium intakes; tobacco history; HRT use; aspirin use; and MVI use

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Type 2 Diabetes Timing of Followup	Results	Confounders Adjusted for
Zong, 2016[162] High	Cohort study enrolling parous women without diabetes before delivery who completed the NHANES survey (1999-2006) 4,779	Mean age 46-51 at enrollment (SD NR) % nonwhite: 27-34 % with GDM: NR	Self-reported BF (ever vs. never), and duration of BF per child	Self-report physician-diagnosed diabetes, current use of diabetes medication or HbA1c ≥6.5% NA: Cross-sectional data from cohort study	OR (95% CI), ever vs. never BF: 0.75 (0.58 to 0.97) OR (95% CI), by N children BF for ≥1 mo: 1-2 vs. 0: 0.84 (0.63 to 1.13) 3+ vs. 0: 0.61 (0.41 to 0.89)	Age, survey yrs, ethnicity, country of birth, education, family history of chronic disease, smoking, alcohol, physical activity, and BMI

[a] Refers to percentage of population that was indigenous, defined as self-identification as Aboriginal, Torres Strait Islander, or Aboriginal and Torres Strait Islander.
[b] Per authors, data from health plans were also used to identify incident diabetes-based clinical laboratory testing (fasting, 2-hour OGTT, random glucose, or HbA1c); self-report of diabetes with health care provider diagnosis was allowed for women receiving care from outside facilities.
[c] To be included, women identified with gestational diabetes during pregnancy had to have a normal blood sugar measurement 6-9 wks postpartum.
[d] Per authors, medication use was validated on enrollment by nurse examination of medication bottles. Women with type 1 diabetes were not eligible to participate in the WHI.

BF = breastfeeding; BMI = body mass index; CA = California; CI = confidence interval; DM = diabetes mellitus; EMR = electronic medical record; GDM = gestational diabetes mellitus; HR = hazard ratio; HRT = hormone replacement therapy; ICD = International Classification of Diseases; MI = myocardial infarction; MVI = multivitamin; N = number; NHANES = National Health and Nutrition Examination Survey; NR = not reported; OGTT = oral glucose tolerance test; OR = odds ratio; ROB = risk of bias; SD = standard deviation; WHI = Women's Health Initiative.

In the three studies reporting on incident diabetes among women with gestational diabetes, two included women giving birth during a similar time frame (approximately 2004 to 2011),[159, 160, 163] and one enrolled women who gave birth between 1987 and 2011.[161] One study each was set in the United States,[160, 163]Australia,[159]and Canada.[161] Two measured incident type 2 diabetes based on an oral glucose tolerance test;[159, 160, 163] one of these also searched an electronic medical record for diagnoses made on other criteria (e.g., hemoglobin A1c).[160, 163] The third relied on administrative databases to determine incident diabetes (using hospital and outpatient diagnosis codes).[161] Ascertainment of breastfeeding exposure and length of followup differed across studies. One study measured breastfeeding duration and exclusivity prospectively (via feeding diaries, telephone interviews, in-person exams, and monthly mailed questionnaires) and categorized breastfeeding exposure based on interviews at 6 to 9 weeks postpartum (exclusive formula, mostly formula, mostly lactation, and exclusive lactation); incident diabetes was measured at 2 years.[160] The two other studies measured breastfeeding status at hospital discharge and followed women over a longer time frame; one followed women for 7 years postpartum[159] and the other followed women for up to 24 years.[161]

Three studies reported on incident diabetes among women without known gestational diabetes.[4, 161, 162] Two studies were set in the United States[4, 162] and one was set in Canada.[161] Of the two studies set in the United States, one enrolled parous women participating in the WHI (an average of 35 years postlactation),[4] and the other enrolled women participating in the National Health and Nutrition Examination Survey (NHANES) survey (1999-2006) with a mean age of 46 to 51 years.[162] Both assessed breastfeeding exposure based on self-reported lifetime breastfeeding duration. In the WHI, diabetes status was measured based on self-reported need to take medication for "sugar diabetes"; although the study did not make a distinction between whether women had been treated for type 1 or type 2 diabetes, women with type 1 diabetes were not eligible to participate in the WHI.[164] The study enrolling women participating in the NHANES study ascertained diabetes status based on self-report, use of medications for diabetes, or measured hemoglobin A1c greater than 6.5 percent.[162] The study set in Canada relied on administrative databases to categorize breastfeeding status at discharge and incident diabetes.[161]

Two studies were rated high ROB[159, 162] (primarily due to selection bias and no adjustment for potential confounding factors), and the other studies were rated medium ROB. The two studies enrolling women who had gestational diabetes followed women for a relatively short period of time (2 to 7 years postpartum), which may be inadequate followup to determine a difference in the incidence of type 2 diabetes.[159, 160]

Results

Despite differences in study design, breastfeeding definition, and outcome ascertainment, all studies found a lower incidence of diabetes among women who initiated breastfeeding or breastfed for longer durations or increased intensity (Table 24). Results were consistent with the findings of the published systematic review described above.[158]

In the three studies reporting outcomes among women with gestational diabetes, two followed women for 2 years postpartum and categorized breastfeeding exposure based on duration and exclusivity.[159, 160] One of these followed women prospectively and found a lower rate of incident type 2 diabetes among women who reported exclusive breastfeeding at 6 to 9 weeks postpartum than women who exclusively formula fed (HR, 0.47; 95% CI, 0.24 to 0.93).[160] Women who mostly lactated or mostly formula fed had a lower incidence of type 2 diabetes than women who exclusively formula fed, but the difference was not statistically significant (Table 24). The second study ascertained breastfeeding exposure via hospital discharge records (as fully, partially, or no breastfeeding); compared with women who fully breastfed, women who partially breastfed at discharge had a higher rate of incident type 2 diabetes over 2 years (HR 2.34; 95% CI, 1.23 to 4.47); however, there was no significant difference in incident type 2 diabetes between women not breastfeeding and those fully breastfeeding at discharge (HR 1.33; 95% CI, 0.40 to 4.37).[159]One Canadian study categorized women as breastfeeding or not breastfeeding at hospital discharge and reported outcomes separately for women with gestational diabetes who were First Nations or Non-First Nations; incident diabetes was measured over a variable time frame postpartum depending on year of enrollment (to a maximum followup of 24 years).[161] Incident diabetes was lower among women breastfeeding at discharge than those not breastfeeding in both First Nations women (HR 0.82; 95% CI, 0.73 to 0.92) and Non-First Nations women (HR 0.78; 95% CI, 0.69 to 0.82).[161]

Of the three studies enrolling women without known gestational diabetes, two reported outcomes based on lifetime duration of breastfeeding.[4, 162] The study enrolling women participating in the WHI found that increasing duration of breastfeeding was associated with lower prevalence of diabetes (p for trend<0001);[4] women reporting a cumulative lifetime duration of lactation equal to or greater than 13 months were less likely to have diabetes than those who did not breastfeed (OR=0.80, p<0.001).[4] Similarly, the study enrolling women participating in the NHANES survey found a lower rate of diabetes among women who breasted one or two infants for at least 1 month each (OR, 0.83; 95% CI, 0.61 to 1.13) and those who breastfed three or more infants for at least 1 month each (OR, 0.63; 95% CI, 0.44 to 0.91) than women who did not breastfeed.[162] Finally, in the Canadian study (described above), there was a lower rate of incident diabetes among both First Nations and Non-First Nations women who breastfed at discharge than those who were not breastfeeding at discharge.[161]

Fracture

Background

Pregnancy and lactation lead to changes in bone metabolism. During lactation, the body can meet the burden of demand of calcium by increasing resorption from maternal bones. However, such losses typically reverse themselves over time.[165] Additionally, increased weight during gestation and consequent bone strengthening (and expansion) in response to greater loads on the maternal skeleton may also serve to counteract the effects of loss of bone mass.[166] This review focuses on the long-term and clinically relevant implications of lactation by evaluating the risk of fractures rather than the risk of loss in bone mass. Other variables that could influence the relationship between lactation and fractures include age, hormone replacement therapy, physical activity, parity, and BMI.[165]

Methods

We included all studies that examined the link between breastfeeding and fracture (case-control or cohort studies). Although recent systematic reviews (published within the last 5 years) were eligible, we did not find one that was relevant to the scope of this review rated low or unclear risk of bias. We excluded studies with surrogate measures of fracture (e.g., fracture risk score or index), bone turnover markers, or with measures of osteoporosis only.

Individual Studies

Characteristics

We included a total of six case-control studies[167-172] and five cohort studies[165, 173-176] that examined the risk of fractures in relation to a history of breastfeeding (Table 25). The case-control studies included 1,609 cases with hip, forearm, or vertebral fractures and 2,967 controls. The five cohort studies (constructed from cross-sectional data in two cases)[173, 174] included 97,150 participants, with most (92,980) from a single study.[176] Mean ages of enrolled women ranged from 58 to 75. Five studies were conducted in the United States; one study each was conducted in Australia, Greece, Hong Kong, Spain, South Korea, and Sweden. Four studies were rated high ROB and the rest were rated medium. Two cohort studies did not report the number of cases; the rate of fractures in the other two studies was reported as 15.6 percent in one study[175] and 1.2 percent in a second study.[173] A fifth cohort study reported the rate of incident hip fractures as 1.27% over the followup period of 7.9 years.[176]

Table 25. Breastfeeding and fractures: Summary of individual studies

First Author, Year ROB	Study Description N of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) Timing of Followup	Results	Confounders Adjusted for
Alderman, 1986[167] Medium[b]	Case-control study of women between 50 and 74 yrs of age in King County, Washington; cases seeking orthopedic care, controls from general population (door-to-door recruitment) Cases: 355 women who sought care from orthopedists between 1976 and 1980; controls: 562 unmatched women from the same county	Age range: 50-74 yrs	Duration of lactation: sum of the number of mos of lactation associated with each birth, categorized as 0, 1 to 12, 13 to 24, or more than 24 mos[a]	Hip or forearm fractures NA: Case-control	OR (95% CI) for duration of lactation versus 0 mos 1-12 mos: 1.2 (0.73 to 1.95) 13-24 mos: 0.7 (0.34 to 1.29) >24 mos: 0.8 (0.38 to 1.51)	Age, relative weight, and exogenous estrogen use

First Author, Year ROB	Study Description N of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) Timing of Followup	Results	Confounders Adjusted for
Chan, 1996[168] Medium[b]	Case-control study of Chinese women ages 70-79 yrs who were living in three housing blocks under a Geriatric Priority Housing Scheme in Shatin, Hong Kong Cases: 144 women with one or more definite fractures; controls: 163 women with no fractures	Mean age: 75 yrs	Duration of lactation: categorized as 0, 1 to <24, or ≥24 mos	Diagnosis of vertebral fracture (when any of the 3 vertebral ratios [anterior to posterior, middle to posterior and posterior to posterior ratios] compare with the vertebral bodies above and below the vertebra of interest) was 3 SD or more away from the mean NA: Case-control	OR (95% CI) for duration of lactation vs. 0 mos 1 to <24 mos: 0.7 (0.4 to 1.3) ≥24 mos: 0.6 (0.3 to 1.0)	Age

First Author, Year ROB	Study Description N of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) Timing of Followup	Results	Confounders Adjusted for
Crandall, 2017[176] Medium	Cohort study, using data from the WHI observational study, of 92,980 postmenopausal participants ages 50-79 yrs 92,980	Mean age (SD): 64 (7.4) yrs	Average duration of BF per child, categorized as 0, 1-6, 7-12, 13-23, and ≥24 mos	Physician-adjudicated hip fractures Self-reported incident clinical fractures Within 7.9 yrs	Incident hip fractures: HR (95% CI) for average duration of BF vs. 0 mos 1-6 mos: 0.85 (0.71 to 1.01) 7-12 mos: 0.77 (0.60 to 0.99) 13-23 mos: 0.88 0.68 to 1.15) ≥24 mos: 0.92 (0.67 to 1.27) Incident clinical fractures: HR (95% CI) for average duration of BF vs. 0 mos 1-6 mos: 0.96 (0.84 to 1.10) 7-12 mos: 0.92 (0.76 to 1.11) 13-23 mos: 0.93 (0.76 to 1.15) ≥24 mos: 1.12 (0.88 to 1.42)	Age; race–ethnicity; education; smoking status; alcohol consumption; hysterectomy; bilateral oophorectomy; years since menopause; previous fracture age 55 yrs or older; parental history of fracture; number of falls in the past 12 mos; estrogen use, route of delivery, and recent use; use of prescription osteoporosis medication, aromatase inhibitors, tamoxifen, antidepressants, corticosteroids, proton pump inhibitors, antiepileptics, antineoplastics, and thiazolidinedione; BMI; total energy expenditure per week from physical activities; total calcium intake; total vitamin D intake at baseline; and weight change since age 35 yrs

First Author, Year ROB	Study Description N of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) Timing of Followup	Results	Confounders Adjusted for
Cumming, 1993[170] Medium[b]	Case-control study of women ages 65 yrs or older living in a defined region in Sydney, Australia, during 1990-1991 Cases: 174 women were from 12 hospitals; controls: 137 selected using an area probability sampling method, with additional sampling from nursing homes	Mean age NR	Ever BF vs. never BF Average duration of BF per child, categorized as 0, 0.5-3, 3-6, 6-9, and >9 mos	Hip fractures presenting to the hospitals NA: Case-control	OR (95% CI) for ever BF vs. never BF 0.55 (0.10 to 2.90) OR (95% CI) for average duration of BF vs. never BF 0.5-3 mos: 0.64 (0.13 to 3.06) 3-6 mos: 0.79 (0.18 to 3.51) 6-9 mos: 0.41 (0.09 to 1.82) >9 mos: 0.24 (0.04 to 1.53)	Age, BMI, history of HRT use, current slate of psychotropic medications, current smoking status, current dairy product consumption, score on mental state questionnaire, current physical activity (number of hours of work in the house or garden per week), and health status (number of self-reported illnesses)
Hoffman,1993[169] Medium[b]	Case-control study of women ages 45 or older in New York and Philadelphia between 1987-89 174 cases, with radiologically confirmed first hip fracture, from 30 hospitals in New York and Philadelphia (103 parous); 174 controls from general surgical and orthopedic services during the same time period and were frequency-matched to cases by age and hospital (123 parous)	71% over age 75	Ever BF vs. never BF Lactated ≤12 mos or >12 mos	Radiologically confirmed first hip fracture NA: Case-control	OR (95% CI for ever vs. never BF All women: 0.87 (0.47 to 1.61) Parous women: 0.66 (0.41 to 1.05) OR (95% CI) for duration of BF vs. never BF All women >12 mos: 0.64 (0.32 to 1.29) ≤12 mos: 0.67 (0.39 to 1.13) Parous women >12 mos: 1.08 (0.45 to 2.60) ≤12 mos: 0.80 (0.42 to 1.55)	Hospital of recruitment, age group, and age for models that included all women; additionally, adjusted for number of live births for models restricted to parous women

First Author, Year ROB	Study Description N of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) Timing of Followup	Results	Confounders Adjusted for
Hwang, 2016[173] High	Cohorts constructed from the KHANES, a nationwide, population-based, cross-sectional survey 1,222	Mean age (SD): 63 (8.8) yrs	BF for 7-18 mos, 19-36 mos, and ≥37 mos vs. 0-6 mos	Self-reported lumbar spine fracture or hip fracture NA: Cross-sectional data from cohort study	p=0.026 for trend of positive correlation between BF duration and lumbar spine fractures p=0.322 for trend of positive correlation between BF duration and hip fractures	None
Kreiger, 1982[171] High[b]	Case-control study of women between 45 and 74 yrs of age in Connecticut recruited from 1977-79 Cases: 98 women with hip fractures; controls: 83 trauma cases from the same hospitals	Age range: 45-74 yrs	BF (12 mos increase)	First hip fracture confirmed by radiography identified from hospital record NA: Case-control	OR, 0.50 (95% CI, 0.20 to 0.90)	Age, Quetelet index, bilateral ovariectomy, and estrogen replacement therapy
Lambrinoudaki, 2015[174] High	Cohort constructed from cross-sectional survey of all postmenopausal women who presented in a menopause clinic between August 2007 and July 2013 in Greece 454	Mean age (SD): 57 (7.1) yrs	Months of lactation	Radiologically assessed vertebral fracture NA: Cross-sectional data from cohort study	OR (95% CI) for presenting with at least one vertical fracture 1.03 (0.99 to 1.06), p=0.127	None

First Author, Year ROB	Study Description N of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) Timing of Followup	Results	Confounders Adjusted for
Michaelsson, 2001[172] Medium[b]	Case-control study of Swedish postmenopausal women ages 50-81 yrs between October 1993 and February 1995 Cases: 664 women with hip fractures; controls: 1,848 women randomly selected from the population register	Age range: 50-81 yrs,	BF (3 mos increase) Total months of BF, categorized as 6-10 mos 11-16 mos >16 mos vs. 1-5 mos	Hip fracture based on clinical or register records NA: Case-control	OR (95% CI) for BF (3 mos increase) 0.98 (0.95 to 1.01) OR (95% CI) for total months BF vs. 1-5 mos 6-10 mos: 0.87 (0.68 to 1.11) 11-16 mos: 0.86 (0.66 to 1.12) >16 mos: 0.86 (0.67 to 1.12)	Age, HRT use, OC use, and BMI
Mori, 2015[165] High	Cohort study of pre- or early perimenopausal women from the Study of Women's Health Across the Nation (United States): ages 42-52 yrs 2,239	Age range: 42-52 yrs Median age (IQR): 46 (44-48) yrs	Accumulated length of lactation before age 42	Self-reported nondigital noncraniofacial fractures after age 42 (95% of them confirmed by medical records) Median 15.7 yrs	HR, 0.97 (95% CI, 0.92 to 1.02) per every additional 6 mos of lactation (p=NS)	Race/ethnicity, BMI, smoking status, smoking pack-years, alcohol consumption, physical activity, employment status, diabetes, hyperthyroidism, supplementary calcium, supplementary vitamin D, use of sex steroid hormone pill/patch injection, birth control pills, depo-provera injection, oral corticosteroids, proton pump inhibitors, other bone-adverse medications, study site

First Author, Year ROB	Study Description N of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) Timing of Followup	Results	Confounders Adjusted for
Naves, 2005[175] Medium	Cohort of women ages 50 or over, randomly selected from a Spanish population that had participated in a study of prevalence of vertebral fractures 255	Mean age (SD): 65 (9) yrs	BF for >3 mos vs. ≤3 mos	Radiologically assessed vertebral osteoporotic fracture (includes Colles, vertebral, ankle, rib, pelvis, humerus) 8 yrs	OR, 3.05 (95% CI, 0.94 to 9.90)	Age, handgrip strength, femoral neck BMD, prevalent vertebral fracture, and the history of falls during followup

[a] The authors note that "[s]imilar results were obtained when lactation was treated as a continuous variable" but do not provide results.
[b] This study was included in the prior 2007 AHRQ review by Ip and colleagues.[2] We did not reassess ROB for individual studies included in that review; this rating represents the decisions of the authors of that review.

BF = breastfeeding; BMD =bone mineral density; BMI = body mass index; HR = hazard ratio; IQR = interquartile range; KHANES = Korean National Health and Nutrition Examination Survey; HRT = hormone replacement therapy; N = number; NA = not applicable; NR = not reported; OC = oral contraceptive; OR = odds ratio; ROB = risk of bias; SD = standard deviation; WHI = Women's Health Initiative.

All except two studies reported on hip, vertebral, or forearm fractures identified from hospital or clinical records (with or without radiography confirmations). One study relied on recall for fracture outcomes. A second relied on adjudication by physicians to confirm hip fractures and recall for nonhip fractures.[176] Of the six case-control studies, two identified matched or unmatched general population controls living in the same area [167, 172] and three studies used hospital controls.[169-171] In the sixth study,[168] women with vertebral fractures (classified according to the radiological diagnoses) were defined as definite or doubtful cases, and the remaining enrolled subjects without fractures were classified as control subjects; our analysis is restricted to comparisons of definite cases versus controls. Assessments of breastfeeding history were based on subjects' long-term recalls in all studies.

Studies defined exposures as ever versus never breastfeeding, total breastfeeding, and duration of breastfeeding per child. For studies reporting on duration of breastfeeding, results were reported as categorical variables with cut points that varied by study or as a continuous variable. No study reported on exclusive breastfeeding.

Results

With the exception of two high ROB studies,[171, 173] no study reported a statistically significant association between breastfeeding and fracture. The majority of studies reported lower odds of fractures with greater breastfeeding duration, but the results were generally not statistically significant. We rated the SOE as low for no association.

Postpartum Depression

Background

According to 2012 data from the PRAMS, nearly 12 percent of postpartum women reported a history of postpartum depressive symptoms.[177] Women with postpartum depression are at increased risk of maternal suicide, infanticide, and impaired maternal sensitivity and attachment with the infant.[178-181] Women with depression are also less likely to engage in enriching interactions (e.g., reading, singing) with their children.[182] Prevention of postpartum depression is thus a major public health priority. Breastfeeding is thought to affect depression risk through the hormone oxytocin, which is implicated in maternal bonding, and through modulation of the hypothalamic pituitary adrenal axis.

Elucidating the relationship between breastfeeding and postpartum depression is challenging, because women with depression may have difficulty initiating and sustaining breastfeeding, and women who experience breastfeeding difficulties may develop depression. Some of the potential confounders thought to be important in studies of depressive symptoms and feeding practices include prior depression history, marital status, employment status, pregnancy intention, and intention to breastfeed.

Methods

We included both case-control and cohort studies that examined the link between breastfeeding and postpartum depression, in addition to recent systematic reviews (published within the past 5 years). All methods of assessment of depression were included (e.g., the Edinburgh Postnatal Depression Scale and other questionnaires). The prior AHRQ systematic review[2] was also limited to studies that had at least 100 nursing mothers; for this update, all newly included individual studies had a sample size greater than 100 (i.e., we did not exclude any studies because of inadequate sample size).

Systematic Reviews

A recent systematic review[183] identified 48 articles on associations among breastfeeding, prenatal, and postpartum depression (Table 26). The review included studies from 12 very high-income countries (Australia, Canada, Norway, Finland, Iceland, Italy, Japan, Portugal, Sweden, United Arab Emirates, United Kingdom, and United States) and 7 other countries (Brazil, Barbados, China, Congo, Mexico, Pakistan, and Turkey). No exclusion criteria were based on study design.[2, 184]

The authors explored the relationship between depression and breastfeeding and, in doing so, accounted for the temporal relationship in an effort to address causal direction.[183] They reported associations between postpartum depression and breastfeeding in 18 included studies; shorter breastfeeding duration was associated with higher rates of depressive symptoms. However, the causal direction of this association was unclear. In longitudinal studies that measure depression symptoms and breastfeeding status over time, the authors reported that three studies in very high-income countries found no association between early breastfeeding cessation or bottle-feeding and subsequent depression; two studies found that breastfeeding pain or low breastfeeding self-efficacy predicts depression. The authors concluded that breastfeeding difficulties predict postpartum depression.

Notably, they also concluded that depression symptoms during pregnancy and postpartum depression are associated with early cessation of lactation. Given the potential confounding between these variables, authors reported mixed results in studies that include prenatal and postpartum assessment of maternal mood as well as longitudinal assessment of breastfeeding outcomes. Among seven studies that measured the association between prenatal depression and breastfeeding duration, two found no association, and five found an inverse association. Shorter breastfeeding duration was associated with postpartum depression in four studies but not in three other studies. The authors concluded that approaches are needed to identify and assist women with prenatal depression or early breastfeeding problems to improve both breastfeeding outcomes and maternal mood.

Table 26. Breastfeeding and postpartum depression: Summary of published systematic review

Author, Year	Number of Studies (N Participants Study Design	Search Date (Databases)	Study Characteristics	Definition of Exposure	Definition of Outcome	Timing of Followup	Results	ROB
Dias, 2015[183]	48 (71,245); cohort studies	1980 through December 2013 (MEDLINE, Web of Science, PsycINFO)	Most studies were conducted in the U.S. (n=15) and U.K. (n=6), with others in Australia, Brazil, Canada, Barbados, Norway, Pakistan, Turkey, China, Congo, Finland, Iceland, Italy, Japan, Mexico, Portugal, Sweden, and the UAE	BF exposure defined according to different criteria: Labbok and Krasovec criteria (n=5), WHO criteria (n=1), as a dichotomous variable (n=10), as a 3- or 4-group variable (n=5), with the inclusion of solids (n=2), exclusive BF status (n=7), and not specified (n=13); duration was assessed at different time points: before the 6-mo public recommendations (n=26) and at 6 mos (n=12)	Pregnancy depression, PPD (any measure)	Three studies assessed depression only during pregnancy, 35 measured symptoms postpartum, and nine assessed depression both during pregnancy and post-partum; postpartum followup ranged from 1 wk to 2 yrs	No meta-analyses: authors conclude BF duration is associated with PPD; PPD predicts and is predicted by BF cessation in several studies; pregnancy depression and PPD are associated with shorter BF duration, BF may mediate the association between pregnancy and PPD; pregnancy depression predicts shorter BF duration and that may increase depressive symptoms during postpartum	Unclear

BF = breastfeeding; N = number; ROB = risk of bias; PPD= postpartum depression; UAE = United Arab Emirates; U.K. = United Kingdom; WHO = World Health Organization; wks = weeks.

Individual Studies

Characteristics

We included 14 individual prospective cohort studies not included in the systematic review described above (Table 27); 13 were newly identified, and 1 study was included in the prior 2007 review.[184] Sample size ranged from 119 to 14,541 participants. Studies generally included women in their 20s and 30s. Eleven studies described the proportion of enrolled women with prior depression; of these, 2 excluded women who had a previous or current history of depression,[185, 186] and others enrolled a minority of women with previous or current depression (5 to 45% of participants). Three studies did not describe whether women had a prior history of depression.[184, 187, 188] Three studies were conducted in the United States;[189-191] 2 in Canada;[192, 193] 2 in the United Kingdom;[184, 194] and 1 each in Europe,[195] Australia,[196] Denmark,[197] Hong Kong,[198] Spain,[199]Sweden,[200] and the United Arab Emerites.[201] In general, studies followed women over time (6 weeks to 8 months postpartum) and measured both depression symptoms and breastfeeding duration/exclusivity. Studies varied in terms of whether they focused on any versus exclusive breastfeeding measures (Table 27); 7 studies compared women who were not breastfeeding with those who were currently breastfeeding. Two studies compared women who had never breastfed, women who had initiated but stopped, and women who were still breastfeeding,[197, 198] and 5 studies used other comparisons: women who did or did not initiate breastfeeding,[188, 194, 195] women who were exclusively breastfeeding, mixed feeding, or formula feeding,[185, 194] and women who were predominantly breastfeeding or predominantly formula feeding at 6 months.[189]

Thirteen studies evaluated outcomes using the Edinburgh Postnatal Depression Scale (EPDS). In nine studies, a threshold score was used to identify women with depression symptoms (thresholds ranged from ≥10 to ≥13 across studies); one study used a threshold score ≥10 and a positive answer to question 8, “I have felt sad or miserable,”[195] and three studies analyzed EPDS scores as continuous variables.[185, 189, 198] Two studies used other instruments in addition to the EPDS, one assessed depression using the Mini International Neuro-psychiatric interview to establish a diagnosis of depression among women with an EPDS ≥10,[201] and another assessed self-reported history of postpartum depression diagnosis or treatment.[196]

Of the 13 new studies, we rated 4 as medium ROB and the remainder as high ROB. Common methodological limitations included lack of information on the temporality of breastfeeding cessation and onset of depression symptoms, recall bias, lack of adjustment for potential confounding factors, and high rate of missing data.

Table 27. Breastfeeding and postpartum depression: Summary of individual studies

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Postpartum Depression Timing of Followup	Results	Confounders Adjusted for
Ahn, 2015[189] High	Prospective cohort enrolling women with vaginal birth, no postpartum hemorrhage, discharged within 72 hours of delivery 152 (119 completed 6-month followup)	Age, mean: 29-31 yrs % with prior depression: 21-23	Predominantly BF or predominantly bottle-feeding at 6 mos postpartum	Continuous EPDS score Assessed day 7, day 14, mos 1-6	EPDS at 6 mos, mean (SE): Breast: 3.35 (0.34) Bottle: 3.39 (0.60) p=0.94 No association at all time points, p=0.33-0.94	None
Borra, 2015[194] Medium	Prospective cohort (Avon Longitudinal Survey of Parents and Children [ALSPAC]) enrolling pregnant women from the Bristol area of England in the early 1990s 14,541 pregnant women (14,062 live births)	Age, mean (SD): 28 (4.8) yrs % antenatal depression (EPDS >14) at 18 wks pregnancy: 7 % antenatal depression (EPDS >14) at 32 wks pregnancy: 8	Initiation (putting the baby to the breast at least once) Any BF for at least 1, 2, and 4 wks Exclusive BF for at least 1, 2, and 4 wks	Depressive symptomatology defined as EPDS>12 in postpartum assessments at 8 weeks, and 8, 21, and 33 months 8 wks and 8, 21, and 33 mos	OR (95% CI) for EPDS >12 at 8 wks BF initiated: 1.10 (0.89 to 1.37)[a] Any BF by outcome timing: ≥1 wk: 1.08 (0.88 to 1.33) ≥2 wks: 0.98 (0.81 to 1.19) ≥4 wks: 0.88 (0.74 to 1.06) Exclusive BF by outcome timing: ≥1 wk: 0.99 (0.82 to 1.19) ≥2 wks: 0.89 (0.74 to 1.06) ≥4 wks: 0.81 (0.68 to 0.97) OR (95% CI) for EPDS >12 at 8 mos BF initiated: 0.99 (0.79 to 1.24) Any BF by outcome timing: ≥1 wk: 1.15 (0.93 to 1.43) ≥2 wks: 1.02 (0.84 to 1.25) ≥4 wks: 1.05 (0.87 to 1.28) Exclusive BF by outcome timing: ≥1 wk: 1.12 (0.92 to 1.36) ≥2 wks: 0.93 (0.77 to 1.12) ≥4 wks: 1.02 (0.84 to 1.23)	Child's sex, parental education, socio-demographic and socioeconomic variables, BF attitudes, child characteristics at birth, information on pregnancy and birth, mother's health (physical and mental) in pregnancy, interpersonal relationships, and stressful life events

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Postpartum Depression Timing of Followup	Results	Confounders Adjusted for
Chojenta, 2016[196] High	Population cohort study of Australian women born 1973-1978 with one or more children born before 2009 5,219	Age 31-36 yrs at assessment of pregnancy history % with prior PPD: 26	Any BF <6 months vs. ≥6 for each child born	Retrospective self-report for each child born: “Were you diagnosed or treated for postnatal depression?” NA (age 31-36 yrs at cohort enrollment)	OR (95% CI) of PPD for pregnancy followed by BF <6 mos vs. ≥6: 1.29 (1.12 to 1.50)	Pregnancy complications, social support, proportion of stressful life events, SF-36 mental health index, SF-36 general health index, income stress, education, partner status, mean stress, LOT-R optimism, history of pregnancy, birth and postpartum events, history of self-harm, violent relationship, depression, anxiety, tobacco use
Davey, 2011[192] Medium	Secondary analysis of RCT enrolling pregnant women 2,015 (1,403 completed 8-week followup)	Age: % <25: 18 ≥25: 82 % with prior depression: No PPD: 20 Subclinical PPD: 37 Major PPD: 45	Any BF at 8 wks postpartum (yes or no)	EPDS score, categorized by score indicating risk of PPD: None: <10 Subclinical: 10-12 Major: 13+ 8 wks postpartum	BF status at 8 wks was not associated with subclinical PPD (OR not reported; p>0.05) Not BF at 8 wks was associated with an increased risk of major PPD, OR (95% CI): 2.12 (1.21 to 3.70) No information on temporality of depression symptom onset and BF cessation	History of depression, country where mother was born, depressive symptoms during pregnancy

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Postpartum Depression Timing of Followup	Results	Confounders Adjusted for
Fiala, 2017[195] High	Prospective cohort study 7,589 (3,233 included in analysis)	Age, mean (SD): 26 (4.8) yrs % with prior depression: 5.2	Any BF vs. no BF	EPDS score ≥10 and positive answer to question number 8, "I have felt sad or miserable" 6 wks and 6 mos postpartum	Multivariate-adjusted OR were reported for association between not BF and PPD OR of PPD (95% CI); p value 6 wks: 1.2 (0.8-1.9); 0.39 6 mos: 1.5 (1.0-2.3); 0.07	Personal history of depression, mother or father of expectant mother had history of depression, unintentional pregnancy, mother unhappy about being pregnant, primiparity, gender of child, preterm birth, C-section, ICU, mother<18 yrs, education, family savings, mother living alone, psychosocial stressors

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Postpartum Depression Timing of Followup	Results	Confounders Adjusted for
Hamdan, 2012[201] High	Prospective cohort study of women recruited during pregnancy in UAE 137	Age, %: <30: 74 30+: 26 Prior depression: NR	Any BF vs. no BF, 2 and 4 mos postpartum	PPD diagnosis: women with EPDS≥10 were assessed using the Mini International Neuro-psychiatric interview 2 and 4 mos postpartum	Unadjusted results were reported for cross-sectional and longitudinal associations between BF status and PPD. N (%) BF at 2 mos x PPD at 2 mos: Any breast: 11 (9) No breast: 3 (17.7) p=0.38 PPD at 2 mos x BF at 4 mos: Any breast: 8 (7) No breast: 6 (31.6) p<0.01 BF at 2 mos x PPD at 4 mos: Any breast: 6 (5.1) No breast: 3 (17.7) p=0.05 BF at 4 mos x PPD at 4 mos: Any breast: 4(3.3) No breast: 5 (26.3) p<0.01	Multiple confounders measured, no adjusted results reported

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Postpartum Depression Timing of Followup	Results	Confounders Adjusted for
Illiadis, 2015[200] High	Longitudinal cohort study among Swedish-speaking women age 18+ enrolled during pregnancy 365 enrolled 181 included in analysis	Age, %: 20-34: 73 ≥35: 27 % with prior depression: 27	Any BF vs. no BF, 6 wks postpartum	Depressive symptoms, defined as EPDS≥10 Healthy women: no EPDS≥10 Symptoms, but not PPD: Depression symptoms before/during pregnancy, but EPDS<10 postpartum PPD: EPDS≥10 6 wks postpartum	Association with BF status at 6 wks postpartum: EPDS≥10, N (%): Any BF: 21 (15.4) No BF: 11 (25) History of depression symptoms, but not postpartum, N (%) Any BF: 37 (27.2) No BF: 15 (34.0) No depression symptoms, N (%) Any BF: 78 (57) No BF: 11 (40) p=0.14	None
Lau, 2006[198] High	Prospective cohort enrolling Chinese women in Hong Kong with no personal or family psychiatric history 2,178 enrolled (598 completed 6-wk followup)	Age, %: >25: 89 Prenatal depression: EPDS score, mean (SD) 18 wks: 8.28 (4.63) 32 wks: 7.55 (4.79)	Ever BF vs. never BF Among those who initiated, duration ≤3 wks vs. >3 wks	Continuous EPDS score 6 wks postpartum	Unadjusted EPDS score at 6 wks, mean (SD) Did not initiate BF: 7.13 (5.30) Initiated BF: 7.25 (4.90 p=0.854 BF, ≤3 wks: 7.21 (4.55) BF, >3 wks: 7.26 (5.01) p=0.943 Odds of BF outcome, by EPDS score at 6 wks, OR (95% CI) Ever BF vs. never BF: 1.00 (0.96, 1.05) BF >3 wks vs. ≤3 wks: 0.95 (0.87, 1.03)	Age, educational level, ≥1 year in Hong Kong, married, length of marriage ≥1 yr, housewife or part-time work, family income <$5K, private housing, size of residence ≥500 ft^2, living with parents, living with parents-in-law

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Postpartum Depression Timing of Followup	Results	Confounders Adjusted for
Maimburg, 2015[197] High	Secondary analysis of RCT enrolling primiparous Danish women between 10+0 and 21+6 days gestation, singleton pregnancy 1,138	Age, mean 29-30 yrs % with prior psychiatric history: 11-12	Never BF BF: < 6 wks BF: ≥6 wks	EPDS score ≥12 6 wks postpartum	EPDS score ≥12 at 6 wks vs. BF ≥6 wks, OR (95% CI): BF: <6 wks: 3.10 (1.65, 5.85) Never BF: 6.41 (1.92, 21.44)	None
McCoy, 2008[186] High	Cohort study (chart review) enrolling women who attended a 4-wk postpartum visit and had a documented EPDS score, not already taking antidepressants 588	Age, % <21: 35 ≥21: 65 % with depression documented in chart: 2	Any BF vs. not BF	EPDS score ≥13 4 wks postpartum	EPDS≥13 at 4 wks, by infant feeding at 4 wks, N (%) Any BF: 14 (7) Not BF: 33 (9) p=0.48	None
Reifsnider, 2016[185] Medium	Secondary analysis of RCT enrolling women of Mexican origin, pregravid BMI ≥25 kg/m^2, age 18 to 45, no previous serious medical or psychological disease 150	Age, mean (SD) 30 (5.9) yrs % with prior depression: 0 (not eligible)	Exclusive BF, nonexclusive BF, no BF	Continuous EPDS score 1 mo and 6 mos postpartum	EPDS score by feeding group, mean (SD): 1 mo Exclusive: 3.64 (5.56) Nonexclusive: 3.04 (4.42) No BF: 5.18 (6.97) 6 mos Exclusive: 5.43 (6.79) Nonexclusive: 3.04 (3.77) No BF: 4.39 (6.99) p (for mixed model): 0.313	Mixed model adjusted for food stamps and having no money for food

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Postpartum Depression Timing of Followup	Results	Confounders Adjusted for
Sword, 2011[188] Medium	Prospective cohort study, enrolling Canadian women, >16 yrs delivering singleton at >37 wks gestation 2,560	Age, mean (SD): 31 (5.3) yrs % with prior depression: NR	BF initiated vs. not initiated	EPDS≥12 6 wks postpartum	EPDS≥12 at 6 wks postpartum (BF initiated vs. not initiated), OR (95% CI): 2.07 (1.02 to 4.21) p=0.0449	Maternal age <25 yrs, first pregnancy, MacArthur SES score, number of unmet learning needs, maternal hospital readmission, health since delivery, SF-12 mental component score, SF-12 physical component score, urinary incontinence, mode of delivery, low social support, exhaustion/ extreme fatigue, previous depression, household income, country of birth
Trevino-Juarez, 2016[187] Medium	Prospective cohort enrolling Spanish-speaking primiparas in Madrid with healthy singleton infants (36-42 wks gestation) not admitted to NICU 364	Age, mean (SD): 32 (5.3) yrs % with prior depression: NR	Any BF vs. artificial milk feeding	EPDS≥11 6 wks and 6 mos	EPDS≥11 at 6 wks, N (%) Any BF: 35 (13.2) No BF: 7 (16.7) p=0.538 At 6 mos, N (%) Any BF: 11 (6.1) No BF: 3 (2.3) p=0.118	Infant sex, mode of birth, “baby does not sleep well,” “baby does not eat well,” use of emergency medical services for baby’s health, mother’s employment status, socioeconomic level, age at childbearing

First Author, Year ROB	Study Description N Participants	Population	Definition of Exposure	Definition of Postpartum Depression Timing of Followup	Results	Confounders Adjusted for
Warner, 1996[184] Medium[b]	Prospective cohort recruited from postnatal wards, followed up with home interview 6-8 wks postpartum 2,375	Mean age (range): 28 (15 to 46) % with prior depression: NR	Not BF vs. BF at home interview	EPDS≥13 6-8 wks postpartum	OR (95% CI), EPDS≥13 at 6 wks, not BF vs. BF: 1.52 (1.12 to 2.06)	Unplanned pregnancy, maternal unemployment, head of household unemployed

[a] Authors also assessed outcomes at 21 and 33 months postpartum and conclude that the association between breastfeeding and postpartum depression is weak at both timepoints. In subgroup analyses, authors note the association between breastfeeding and depression is mediated by whether women had planned to breastfeed and depression during pregnancy.
[b] This study was included in the prior 2007 AHRQ review by Ip and colleagues.[2] We did not reassess ROB for individual studies included in that review; this rating represents the decisions of the authors of that review.

BF = breastfeeding; BMI = body mass index; CI = confidence interval; EPDS = Edinburgh Postnatal Depression Scale; ICU = intensive care unit; kg = kilogram; LOT-R = Life Orientation Test-Revised; m^2 = square meter; N = number; NA = not applicable; NICU = neonatal intensive care unit; NR = not reported; OR = odds ratio; PPD = postpartum depression; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation; SF-36 = Short Form-36; UAE = United Arab Emirates; wks = weeks.

Results

Thirteen studies measured postpartum depression using the EPDS scale; however, studies varied in terms of how scores were analyzed and interpreted (Table 27). Overall, results were mixed.

Nine studies reported on the association between breastfeeding and EPDS scores above and below a set threshold.[184, 186-188, 192, 194, 197, 200, 201] Only one study verified EPDS scores using a diagnostic instrument.[201] Enrolled women (N=137) completed the EPDS and reported on breastfeeding status at 2 and 4 months postpartum; women with an EPDS ≥10 underwent further assessment with the Mini International Neuro-psychiatric interview to establish a diagnosis of depression. In unadjusted analyses, feeding status at 2 months was not associated with postpartum depression diagnosis; however, postpartum depression at 2 months predicted not breastfeeding at 4 months ($p < 0.01$), and not breastfeeding at 2 months predicted postpartum depression at 4 months ($p=0.05$).[201]

Three studies accounted for prior history of depression or depressive symptoms in the analysis and found inconsistent results.[192, 195, 200] One of these analyzed data separately for women with and without a prior history of depression symptoms; enrolled women (N=181) reported data on breastfeeding status at 6 weeks (any vs. none) and were grouped by prior history of depression symptoms (none, prepregnancy, or prenatal depression, but EPDS <10 postpartum; and EPDS ≥10 postpartum, regardless of previous history). Breastfeeding status at 6 weeks did not differ significantly by depression symptom history ($p=0.14$).[200] The second study was a secondary analysis of women enrolled in an RCT of an unsuccessful prenatal support intervention to reduce postpartum depression.[192] At 8 weeks postpartum, current breastfeeding status (any breastfeeding vs. no breastfeeding) was not associated with subclinical postpartum depression (EPDS scores 10-12); however, in a prediction model adjusting for history of depression, country where the mother was born, and depressive symptoms during pregnancy, not breastfeeding at 8 weeks was associated with a higher risk of major postpartum depression (EPDS≥13, adjusted OR, 2.12; 95% CI, 1.21 to 3.70).[192] The third study found that a history of depression was associated with prenatal depression and depression at 6 weeks but not 6 months; not breastfeeding was not associated with postnatal depression (EPDS ≥10 and a positive response to question 8; OR at 6 weeks 1.2, 95% CI, 0.8 to 1.9; at 6 months, OR 1.5, 95% CI, 1.0 to 2.3).[195] Six additional studies did not specifically account for depression symptoms before or during pregnancy.[186-188, 194, 197, 202] Three found an association between breastfeeding status at 6 to 8 weeks postpartum and three did not.[186, 187, 194] Of those that found an association, one focused on nulliparous women enrolled in an RCT (N=1,138) evaluating a prenatal care education and support intervention (“Ready for Child”); postpartum depression was assessed at 6 weeks postpartum and categorized as EPDS score ≥12. In the whole sample, 1 percent of participants had never breastfed, and 8 percent had stopped breastfeeding at 6 weeks postpartum. In unadjusted analyses, compared with women who were breastfeeding at 6 weeks, never breastfeeding was associated with increased risk of depression (OR, 6.41; 95% CI, 1.93 to 21.44) as was cessation of breastfeeding by 6 weeks (OR, 3.10; 95% CI, 1.65 to 5.85).[197] The second study (N=2,560) followed women from birth through 6 weeks postpartum; never initiating breastfeeding was associated with an increased risk of postpartum depression (EPDS≥12) at 6 weeks compared with initiating breastfeeding (adjusted OR, 2.07; 95% CI, 1.02 to 4.21, $p=0.0449$).[188] The third study that found an association enrolled women (N=2,375) 6 to 8 weeks postpartum and assessed both current feeding status and EPDS. In models adjusted for unplanned pregnancy, maternal employment, and head of household employment, not breastfeeding was associated with an increased risk of EPDS≥13 compared with breastfeeding (adjusted OR, 1.52; 95% CI, 1.12 to 2.06).[202] The three studies that found no difference in depression scores and breastfeeding status measured outcomes at a similar time point (4 to 8 weeks postpartum). In one (N=551) unadjusted analyses showed no association between current breastfeeding (at 4 weeks) and EPDS scores ≥13 (7% vs. 9%, respectively; p=0.48).[186] The second study (N=364) breastfeeding was categorized as any breastfeeding or no breastfeeding and collected at 6 weeks and 6 months postpartum; in unadjusted analyses, there were no associations between infant feeding status and EPDS≥11 at 6 weeks or 6 months.[187] The third study found no association between various definitions of breastfeeding (e.g., initiation, any, or exclusive breastfeeding for 1, 2, and 4 or more weeks) and EPDS>12 at both 8 weeks and 8 months.[194]

Three studies assessed the relationship between breastfeeding status and mean EPDS scores; all three found no association between breastfeeding status and depressive symptoms.[185, 189, 198] One (N=119) followed participants who had an uncomplicated vaginal birth and measured EPDS scores at multiple time points (7 days, 14 days, and monthly from 1 to 6 months); there was no association between breastfeeding status at 6 months (classified as predominantly breastfeeding vs. predominantly bottle-feeding) and EPDS scores at any time point (p-value range: 0.33 to 0.94).[189] The second enrolled pregnant women (N=2,178) who had no personal or family psychiatric history; at 6 weeks postpartum, there was no association between EPDS scores and breastfeeding initiation and noninitiation (p=0.85) and no difference in scores among those who breastfed for 3 weeks or less and those who breastfed for longer than 3 weeks (p=0.94).[198] The third study enrolled Mexican-American participants (N=150) from an RCT focused on preventing childhood obesity; there was no significant associations were found between feeding status (categorized as exclusive breastfeeding, nonexclusive breastfeeding, or not breastfeeding) and EPDS score or EPDS score trajectory (at 1 and 6 months).[185]

Finally, one Australian population cohort study (the Australian Longitudinal Study on Women's Health) assessed self-reported breastfeeding and postpartum depression for each birth (at ages 31 to 36 years).[196] Postpartum depression was ascertained with the question, "Were you diagnosed or treated for postnatal depression?"; breastfeeding was categorized as less than 6 months vs. more than 6 months or more for each child. The authors found a modest association between breastfeeding less than 6 months and self-reported diagnosis or treatment of postpartum depression (adjusted OR, 1.29; 95% CI, 1.12 to 1.50). Interpretation of this result is limited by lack of information on the temporal sequence of depression and breastfeeding cessation.[196]

Return to Prepregnancy Weight or Postpartum Weight Change

Background

The relationship between breastfeeding and weight retention is not clearly understood; a host of related factors influence weight, making it difficult to isolate the effect of breastfeeding on weight change. These factors include prepregnancy weight, parity, activity level, nutritional intake, socioeconomic status, and ethnicity, among others.[203] Unmeasured confounding could also arise from an underlying propensity that may influence both the decision to breastfeed and maintain other health behaviors[204] that might influence weight changes.

Methods

Our eligibility criteria follow that of the previous systematic review;[2] we limited our review to prospective cohort studies conducted in developed countries that directly compared weight changes of nonlactating women with weight changes of lactating women and for whom the exclusivity or the amount of breastfeeding was clear. Studies of the relationship between postpartum weight change and breastfeeding needed to control for subjects' gestational weight gain or prepregnancy weight and have at least 3 months postpartum followup to be included. The previous review[2] also restricted inclusion to studies with at least 50 women per feeding group in the final analyses (e.g., lactating vs. nonlactating); however, all eligible studies for the update met this sample size criterion (in other words, we did not exclude studies because of inadequate sample size). For each included publication that reported multiple time points, we focused on the furthest time point available. Although recent systematic reviews (published within the last 5 years) were eligible, we did not find one that was relevant to the scope of this review.

Individual Studies

Characteristics

In total, the evidence base includes 47,655 women in 16 studies (described in 19 publications), predominantly from the United States (exceptions include studies or analyses from Canada,[205] Taiwan,[206] Sweden,[207] Australia,[208] and Norway[203]). Of these, 7 cohort studies that examined postpartum weight changes in relation to exclusive breastfeeding were included in the prior 2007 AHRQ review;[205, 207, 209-215] short-[212, 215] and long-term[207] outcomes were reported for the Stockholm Pregnancy and Women's Nutrition Study (SPAWN) in three publications. The searches for this update review identified 10 additional relevant publications.[203, 204, 206, 208, 216-221] Of these, 2 reported on the same cohort from the Infant Feeding Practices Study II (IFPSII),[216, 220] and one, from the WHO Multicentre Growth Reference Study (MGRS), reported analyses from Norway and the United States.[203] Despite the substantial breadth of this evidence base, its heterogeneity precluded meta-analysis.

Studies varied in their definition of exposure, using duration, duration and intensity, or duration and exclusivity. Studies also varied in how they reported outcomes. All reported a change in weight, but the time points that marked the beginning and the end of the measurement varied. Start times for outcome measurement included a fixed time point (e.g., 1989), before the index pregnancy, at the first prenatal visit, at the point of the highest pregnancy weight, within 1 to 2 days of delivery, or at 14 days after delivery. Stop times for outcome measurement were similarly varied, ranging from a fixed time point (e.g., 1993), just before a second pregnancy, and at a postpartum date ranging from 6 months to 15 years after the index delivery. In addition to the heterogeneity in PICOTS, this database spans publication of results starting in 1989. This period of time also covers secular changes in breastfeeding practices and women's weight.

We present results below by definition of exposure first and then by the time frame of the weight change outcome. Table 28 summarizes characteristics and results for individual studies.

Table 28. Breastfeeding and postpartum weight change: Summary of individual studies

First Author, Year ROB	Study Description Number of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) (Start to End of Followup)	Results	Confounders Adjusted for
Brewer, 1989[214] Medium[a]	Pregnant women recruited through mail and telephone contacts before delivery with assistance from a local woman's hospital in Louisiana 56	Prepregnancy weight, kg (SD) Exclusive BF: 59.8 (13.1) Formula feed: 54.9 (6.0) Mixed feed: 57.3 (7.5)	Exclusive formula feed or mixed feed at 6 mos	Change in weight and weight-height index from 1-2 days to 6 mos postpartum	No statistically significant differences between groups	Age, parity, prepregnancy weight, socioeconomic data, energy intake, energy expenditure exclusive of lactation (physical activity)
Endres, 2015[219] Medium	Women ages 18-40 with a live birth at 20 wks of gestation or longer from a 5-site prospective cohort NICHD study 774	Prepregnancy weight, lbs (SD) 161.5 (46.2)	Partial or exclusive BF at 6 mos vs. no BF at 6 mos	Weight retention of 20 lbs or more from prepregnancy weight to 1 yr postpartum	OR (95% CI): 0.46 (0.24 to 0.87)	Age, race, type of insurance, marital status, poverty level, GWG, prepregnancy BMI, BF, working outside the home, and hours of nightly sleep
Haiek, 2001[205] Medium[a]	Mothers recruited at the immunization clinics while waiting for their child's visit in 2 public health clinics in Montreal, Canada 236	Mean prepregnancy BMI (SD): 22.5 (3.4)	Mixed-feeding (i.e., average daily intake of formula and breast milk of >4 oz) or predominantly bottle-feeding (i.e., exclusive bottle-feeding or average daily intake of breast milk of 4 oz or less) vs. predominantly BF (i.e., exclusive BF or average daily intake of formula of 4 oz or less) (time-varying measurement of exposure)	Average monthly rate of weight change from delivery to up to 9 mos	No statistically significant differences	GWG, postpartum smoking, infant's solid intake, maternal place of birth

First Author, Year ROB	Study Description Number of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) (Start to End of Followup)	Results	Confounders Adjusted for
Janney, 1997[211] Medium[a]	Pregnant nulliparous and primiparous women ages 20-40 yrs in their third trimester recruited from birthing education classes and obstetric practices in the Ann Arbor, Michigan, area 110	Prepregnancy mean BMI (SD): 22.2 (3.4)	Fully BF,[b] partially BF, bottle-feeding	Weight change from prepregnancy weight to weight at 18 mos (time varying)	Duration of lactation practice was a significant predictor of postpartum weight retention over time (p<0.001)	GWG, months since parturition, marital status, age
Jarlenski, 2014;[216] Sharma, 2014[220] Medium	Infant Feeding Practices Study II (IFPSII) following women from last trimester through 12 mos; sampled from a national consumer opinion panel[216] Women who had no additional births after participating in the IFPSII were followed through 6 yrs[220] 2,102[216] (726 followed through 6 yrs)[220]	Original cohort[216] Exclusive BF (%): Underweight: 2.8 Healthy weight: 46.4 Overweight: 28.6 Obese: 22.3 Nonexclusive or no BF (%): Underweight: 2.0 Healthy weight: 44.0 Overweight: 29.5 Obese: 24.5 Followup cohort's prepregnancy BMI by adherence categories[220] Never initiated BF **(%)** Normal: 15.8 Overweight: 16.2 Obese: 23.7	Exclusive BF for ≥3 mos vs. nonexclusive BF for ≥3 mos or never BF[216] (1) Initiated BF, did not exclusively BF for ≥4 mos, (2) adhered to exclusivity for ≥4 mos, BF duration <12 mos, (3) adhered to exclusivity for ≥4 mos, duration ≥12 mos vs. never BF[220]	Postpartum weight loss (highest pregnancy weight to her postpregnancy weight) at 12 mos postpartum[216] Return to prepregnancy BMI category at 12 mos postpartum[216] Return to prepregnancy weight at 12 mos postpartum[216] Weight change from prepregnancy to 6 yrs postpartum[220]	Postpartum weight loss[216] Difference in weight loss of -3.2 pounds (95% CI, 1.7 to 4.7 pounds, p<0.05) Return to prepregnancy BMI[216] 6.0 percentage point increase (95% CI, 2.3 to 9.7), p<0.01 Return to prepregnancy weight[216] 6.1 percentage-point increase (95% CI, 1.0 to 11.3), p<0.05	Cohort matched based on propensity score that included the following covariates: maternal age, race/ethnicity, parity, education, WIC enrollment, prepregnancy obesity, prenatal insurance coverage, postpartum smoking, C-section, infant in ICU postpartum, and BF support[216] Maternal age, race or ethnicity, education, poverty income ratio, marital status, parity, GWG, smoking status, physical activity[220]

First Author, Year ROB	Study Description Number of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) (Start to End of Followup)	Results	Confounders Adjusted for
Jarlenski, 2014;[216] Sharma, 2014[220] (continued)		Initiated BF, did not exclusively BF for ≥4 mos **(**%**)** Normal: 55.4 Overweight: 60.8 Obese: 60.8 Adhered to exclusivity for ≥4 mos, BF duration <12 mos **(**%**)** Normal: 8.9 Overweight: 5.9 Obese: 5.4 Adhered to exclusivity for ≥4 mos, BF duration <12 mos **(**%**)** Normal: 19.9 Overweight: 17.2 Obese: 10.2[c]			No statistically significant differences for any category of prepregnancy weight by any category of adherence on weight retention, with the exception of the most adherent obese women (N=19, mean change in kg: -8.0 [95% CI, -15.4 to -0.7])[220]	
Lyu, 2009[206] Medium	Women over 20 yrs old with Han ethnicity, living in North Taiwan for more than 10 yrs and being less than 20 wks pregnant with singleton gestations 130 at 6 mos, 122 at 12 mos	Mean prepregnancy weight: 53.4 kg (SD=7.97)	BF duration in months	Weight retention from prepregnancy to 12 mos postpartum	Regression coefficient in multiple models is not statistically significant	Model with the most variables includes age, socioeconomic status, BF, parity, physical activity, prepregnancy BMI, GWG, 1-mo postpartum energy intakes, 6-mo weight retention, postpartum average energy intakes and energy consumption

First Author, Year ROB	Study Description Number of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) (Start to End of Followup)	Results	Confounders Adjusted for
Ng, 2014[208] High	Women who planned to give birth at one of three participating hospitals in Australia and were over age 16 (Environments for Healthy Living cohort) 1,316	Prepregnancy BMI (%) Underweight: 8.3 Normal weight: 52.4 Overweight: 21.4 Obese: 17.9	BF for at least 3 mos vs. BF for <3 mos or no BF	High postpartum weight retention from prepregnancy to 12 mos (within the top quintile)	Adjusted OR: 0.673 (95% CI, 0.471 to 0.961), p=0.03	Maternal age, employment and education, alcohol intake and smoking during pregnancy, nonmedical drug use, primaparity, preexisting hypertension, marital status, paternal employment and education, household ownership, number of children under age 16, and year of recruitment
Ohlin, 1990;[212] Ohlin, 1996;[215] Linne, 2003[207] Medium[212, 215] and high[207a]	Stockholm Pregnancy and Women's Nutrition Study (SPAWN) 1,423 followed to 1 yr postpartum[212, 215] and 563 followed to 15 yrs postpartum[207]	Prepregnancy BMI: 21.5	Lactation score (scale 0-48): Every mo with full lactation was given 4 points, and every mo with mixed feeding was given 2 points	Weight change from prepregnancy to 1 yr[212, 215] or 15 yrs[207] postpartum	Correlation between weight change through 1 yr postpartum and lactation score, r=-0.09, p<0.01, multiple stepwise regression analysis had a regression coefficient of -0.04, p<0.001[212, 215] Those women who became overweight had lower lactation scores than women who remained normal weight at 15 yrs followup (21.7 vs. 24.0, p<0.05 for t test)[207]	GWG, age, prepregnancy BMI, and parity[212, 215] None[207]

First Author, Year ROB	Study Description Number of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) (Start to End of Followup)	Results	Confounders Adjusted for
Olson, 2003[209] Medium[a]	Prospective cohort study of healthy adult women who gave birth to singleton infants and were followed from early pregnancy until 1 yr postpartum. Women were registered for obstetrical care over a 2-yr period in a hospital and primary care clinic system serving a 10-county area of upstate New York 540	BMI <19.8 (low) 48 (8.9%) 19.8-26.0 (normal) 273 (50.6%) 26.1-29.0 (overweight) 83 (15.4%) >29.0 (obese) 136 (25.2%)	BF at 1 yr vs. no BF BF score to capture intensity and duration (not described in detail)	Weight change from early pregnancy (first prenatal visit) to 1 yr postpartum	BF at 1 yr vs. no BF Regression coefficient: -1.20 SE: 0.52, p=0.02 BF score to capture intensity and duration Results NR, not statistically significant	BF at 1 yr vs. no BF: Age, single status, income, gestational weight gain, food intake, exercise often BF score: NR
Onyango, 2011[203] Medium	WHO Multicentre Growth Reference Study (MGRS) in (Norway and USA data reported here) USA: 172 Norway: 262	Prepregnancy weight not reported	BF for ≥4 mos vs. BF <3 mos, stratified by prepregnancy BMI	Weight change between 14 days and 24 mos postpartum	No statistically significant differences for normal, overweight, or obese women	NR
Ostbye, 2010[221] High	North Carolina WIC recipients at least 18 yrs of age and had more than one pregnancy available for analysis 32,920	Prepregnancy BMI (SD): 26.4 (6.9)	BF 1-4 wks, 5-19 wks, or ≥20 wks vs. no BF	Weight retention from prepregnancy weight for the first pregnancy to the beginning of the second pregnancy (mean time between pregnancies: 2.8 yrs)	No statistically significant differences for any exposure other than 20 or more wks of BF; β (SE): -0.39 (0.18), p=0.03	Age, race, ethnicity, education, parity, GWG, smoking status, and prepregnancy BMI

First Author, Year ROB	Study Description Number of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) (Start to End of Followup)	Results	Confounders Adjusted for
Palmer, 2015[217] High	Women from the Black Women's Health Study who gave birth for the first time from 1995 to 2003 3,147	Mean prepregnancy BMI (SD) No BF: 27.5 (6.8) <3 mos: 27.5 (7.0) 3-5 mos: 26.2 (5.6) 6-11 mos: 25.2 (5.0) ≥12 mos: 25.4 (5.0)	Duration of BF (<3, 4-7, 8-11, and ≥12 mos) vs. no BF	Weight change from baseline (year of first birth) to an average of 4 and 8 yrs postpartum	No differences by duration of lactation	Age, GWG, preterm birth, vigorous physical activity, dietary pattern, years of education, number of additional births during followup, and mean duration of lactation for the additional births during followup
Sicheiri, 2003[210] Medium[a]	Nurse's Health Study II, with analysis restricted to women who were ages 24 to 40 yrs at baseline (1989), who had a history of no more than one past full-term pregnancy at baseline, gave birth to one child between 1990 and 1991 but had no other pregnancies during the followup Nulliparous: 1,538; Primiparous: 2,810	BMI >25 kg/m^2 in 1989 (%) Never: 27.8 <3 mos:18.4 4-7 mos:15.8 8-11 mos:17.9 >12 mos:10.7	Exclusive BF[d] vs. no BF, stratified by parity and BMI Duration of exclusive BF (<3, 4-7, 8-11, and ≥12 mos)[d] vs. no BF	Weight change from baseline (prepregnancy, 1989) to 1-2 yrs postpartum (1993)	Exclusive BF was associated with a weight gain of approximately 1 kg (statistically significantly greater only for nulliparous women with a baseline BMI <25 who BF 1-3 and 4-7 mos (p<0.05) and for primiparous women with a baseline BMI ≥25 who BF ≥12 mos (p=0.04) when compared with women who did not BF Duration of lactation was unrelated to the magnitude of weight change (p>0.40 for all comparisons)	Exclusive BF: Age, physical activity, BMI, GWG Duration: NR

First Author, Year ROB	Study Description Number of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) (Start to End of Followup)	Results	Confounders Adjusted for
Straub et al., 2016[218] High	Women ages 18-40 yrs old with a live birth of 20+ wks of gestation who self-identified as black/African American, white/Caucasian, or Hispanic/Latino; excluded women who underwent permanent sterilization; had more than 4 children; could not provide morning and evening saliva samples; were currently pregnant, currently used steroids, were ≥350 lbs, or were missing prepregnancy or postpartum weights 696	Prepregnancy BMI, N (%): >25: 299 (43) 25-30: 185 (26.6) 30-35: 116 (16.7) 35-40: 41 (5.9) >40: 55 (7.9)	Still BF at the 6-mo interview vs. not BF	Weight retention between prepregnancy weight and weight at 6 mos postpartum, evaluated as both a categorical variable (<10, 10-20, >20 lbs) and as a continuous variable	OR for categorical outcomes=0.53 (95% CI, 0.36 to 0.79) *β* for continuous outcome = -3.29 (95 % CI, -4.88 to -1.76).	Prepregnancy BMI, age, cortisol slope, public health insurance status, race/ethnicity, cortisol covariates (tobacco use, birth control pill usage, wake time)
Stuebe, 2010[204] Medium	Project Viva participants were recruited from a multispecialty group in eastern Massachusetts and had to be fluent in English, <22 wks gestation at study entry, and have a singleton pregnancy 579	Mean prepregnancy BMI (SD) Overall: NR No lactation: 26.8 (6.0) <3 mos: 26.9 (7.3) 3-<6 mos: 24.9 (5.0) 6-<12 mos: 24.8 (5.2) 12+ mos: 23.7 (3.8)	Lactation <3, 3-<6 ,6-<12, 12+ mos	Weight retention at 3 yrs postpartum	Not statistically significant for any category of lactation	Smoking status, intention to lose weight, dietary intake, physical activity

First Author, Year ROB	Study Description Number of Participants	Population	Definition of Exposure(s)	Definition of Outcome(s) (Start to End of Followup)	Results	Confounders Adjusted for
Walker, 2004[213] Medium[a]	Austin New Mothers Study (ANMS), a longitudinal study of a low-income, tri-ethnic sample of postpartum women that incorporated serial assessment of weight and behavioral and psychosocial variables 382	Mean prepregnancy BMI (SD) White: 24.23 ± 5.78 African American: 25.39 ± 5.40 Hispanic: 26.75 ± 6.19[222]	Partial BF or full bottle-feeding vs. full (exclusive BF) (time-varying measurement of exposure)	Postpartum BMI over time (delivery to 12 mos)	Infant feeding method was not associated with postpartum BMI (p=0.140)	Ethnicity, maternal education, parity, smoking, physical activity, time of weight measurement, interaction of ethnicity and time, prepregnant BMI, GWG, energy intakes, fat intake, contraception, emotional eating, depressive symptoms

[a] This study was included in the prior 2007 AHRQ review by Ip and colleagues.[2] We did not reassess ROB for individual studies included in that review; this rating represents the decisions of the authors of that review.
[b] Fully BF was defined as providing at least two-thirds of the needed energy intake per kilogram of the infant's weight in breast milk.
[c] Underweight is defined is <18.5 kg/m^2. Healthy or normal weight is defined as 18.5-24.9 kg/m^2. Overweight is defined as 25-29.9 kg/m^2. Obese is defined as ≥30 kg/m^2.
[d] Introduction of daily formula/milk was assumed to represent the end of exclusive BF period.

ANMS = Austin New Mothers Study; BF = breastfeeding; BMI = body mass index; CI = confidence interval; GWG = gestational weight gain; ICU = intensive care unit; IFPSII = Infant Feeding Practices Study II; kg = kilogram; lbs = pounds; MGRS = Multicentre Growth Reference Study; N = number; NICHD = ; NR = not reported; OR = odds ratio; ROB = risk of bias; SD = standard deviation; SE =standard error; SPAWN = Stockholm Pregnancy and Women's Nutrition Study; WHO = World Health Organization; WIC = Special Supplemental Nutrition Program for Women, Infants and Children; wks = weeks.

Results

Duration

Ten studies defined breastfeeding in terms of duration,[203, 204, 206, 208, 209, 213, 217-219, 221] but their measurement of outcomes varied. Three of 10 studies reported weight change between an early postpartum period (1 to 14 days after delivery) to later in the postpartum period (12 to 24 months).[203, 208, 213] Only 1 of these 3 studies, set in Australia, reported statistically significant differences. Breastfeeding for at least 3 months predicted lower odds of having postpartum weight retention from prepregnancy to 12 months within the top quintile, when compared with breastfeeding for less than 3 months or not breastfeeding.[208] One of 10 studies reported on weight change between early pregnancy (first prenatal visit) and 1 year postpartum and found a greater and statistically significant weight reduction.[209] The remaining 6 of 10 studies reported on weight change from prepregnancy weight to postpartum weight measured at time points ranging from 6 months to 8 years postpartum.[204, 206, 217-219, 221] Of these, 3 reported no statistically significant differences,[204, 206, 217] and 1 reported a difference only for the group with the longest period of exposure (20 weeks or more).[221] Two studies, set in the United States, reported differences by exposure. Specifically, 1 study reported a lower risk of weight retention of 20 pounds or more among those who partially or exclusively breastfed for 6 months or more when compared with those who did not,[219] and a second reported lower weight retention among those who were still breastfeeding at 6 months postpartum compared with those who were not.[218]

Duration and Intensity

Four studies, reported in six publications, reported on duration and intensity.[205, 207, 209, 211, 212, 215] Of these, two publications reported on 1 year postpartum outcomes[212, 215] and a third reported on 15-year outcomes from the Swedish SPAWN Study.[207] One study, evaluating weight change from immediately after delivery to 9 months postpartum, found no difference. A second, evaluating weight change from the first prenatal visit to 1 year postpartum, also found no differences.[209] The two studies that evaluated weight change from a prepregnancy measure to weight at 1 year,[212, 215] 18 months,[211] and 15 years[207] all reported statistically significant differences favoring greater intensity of breastfeeding.

Duration and Exclusivity

Four publications reported on duration and exclusivity of breastfeeding from three studies[210, 214, 216, 220] (2 publications reported on the Infant Feeding Practices Study II but chose different weight change measures).[216, 220] Of the three studies, one study that evaluated weight change from the highest pregnancy weight to 12 months postpartum reported a difference in postpartum weight loss return to prepregnancy BMI and BMI category among those who were exclusively breastfeeding for 3 or more months compared with those who did not.[216] Another publication using a subset of participants from the same study, but evaluating change in weight from a prepregnancy measure to 6 years postpartum, found benefit only for obese women who were most adherent to breastfeeding guidelines in terms of duration and exclusivity.[220] A second study that evaluated change in weight and weight-height index from 1 to 2 days to 6 months postpartum found no statistically significant differences,[214] and a third that stratified results by BMI, parity, and intensity generally found no differences in weight from a prepregnancy measurement to weight at 1 to 2 years postpartum, with some exceptions (i.e., higher weight retention in underweight nulliparous women who breastfed exclusively for up to 7 months vs.

those who did not; obese primiparous women who breastfed exclusively ≥12 months vs. those who did not).[210]

Chapter 4. Discussion

Key Findings and Strength of Evidence

For this report, we conducted a systematic review to evaluate the evidence for community, workplace, and health care system–based programs and policies aimed at supporting and promoting breastfeeding. In addition, we also updated the evidence on the association between breastfeeding and maternal health. Below, we summarize the main findings by each Key Question (KQ), including giving the strength of evidence (SOE) for the bodies of evidence pertaining to the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding (KQ 1) and association between breastfeeding and maternal health (KQ 2).

Effectiveness and Harms of Breastfeeding Programs and Policies

The 40 studies that met our inclusion criteria evaluated a range of strategies to improve rates of breastfeeding initiation and duration. We categorized interventions primarily based on intervention type and delivery setting: Baby-Friendly Hospital Initiative (BFHI), non-BFHI health care system–based interventions, Women, Infants and Children (WIC)-based interventions, and community-based interventions. No included studies assessed workplace interventions or potential harms of interventions. Results are discussed below by intervention category.

Baby-Friendly Hospital Initiative Interventions

Results from 12 included studies assessing BFHI interventions support the effectiveness of BFHI for improving rates of breastfeeding initiation and duration. Table 29 summarizes key findings and SOE. For breastfeeding initiation, evidence from 9 cohort studies (1,227,532 women) comparing women giving birth in BFHI-certified (or accredited) hospitals with noncertified hospitals supports the effectiveness of BFHI (low SOE); although the included studies consistently found higher rates of initiation at BFHI hospitals, results were imprecise and the magnitude of benefit varied across studies. For breastfeeding duration, evidence from 1 large randomized controlled trial (RCT) (Promotion of Breastfeeding Intervention Trial [PROBIT], N=17,046 women) and 8 cohort studies (N=62,834 women) supports the effectiveness of BFHI for increasing rates of breastfeeding duration (moderate SOE). In the PROBIT trial, women in the intervention group had significantly higher rates of exclusive breastfeeding and lower rates of weaning across multiple time points (1 to 12 months postpartum). Although the 8 observational studies were mostly consistent in finding benefit, results were imprecise and the magnitude of benefit varied. One cohort study compared rates of breastfeeding at 6 months among women discharged from hospitals that differed in the number of BFHI steps implemented; low SOE supports the conclusion that implementation of four or more BFHI steps is associated with lower rates of weaning than implementation of fewer than four steps.

Table 29. Summary of key findings and strength of evidence: Studies assessing BFHI

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation BFHI certified/accredited vs. no BFHI status	9 cohorts;[54, 55, 57, 58, 60-64] 1,227,532 Medium	Any BF initiation (k=6): higher rates of BF at discharge among BFHI-accredited hospitals than control hospitals (by 0.5% to 10%); differences between groups were not statistically significant in 4 studies Exclusive BF initiation (k=5): significantly higher rates of exclusive BF at discharge among BFHI-accredited hospitals than control hospitals; magnitude varied, ranging from 3 to 56%	Low for benefit (consistent, imprecise)
Duration BFHI vs. no BFHI intervention (evidence from RCTs) Duration BFHI certified/accredited vs. no BFHI status (evidence from observational studies)	1 RCT;[52, 53] 17,046 8 cohorts;[54-56, 58, 60, 61, 63, 64] 136,983 Medium	One RCT found significantly higher rates of exclusive BF among women at BFHI hospitals at 3 mos (43% vs. 6%; p<0.001) and 6 mos postpartum (7.9% vs. 0.6%; p=0.01), and lower odds of weaning (from any BF) at 3, 6, 9, and 12 mos postpartum than women in control hospitals Any BF duration (k=8 cohort studies): higher rates of BF 1 to 12 mos postpartum among women at BFHI hospitals (by approximately 0.6% to 15%) than women at control hospitals; one study found slightly higher BF rates at 1 mo among women in control hospitals than BFHI hospitals (by 0.4% to 7%) Exclusive BF duration (k=5 cohort studies): higher rates of exclusive BF over 1 to 2 mos among infants born in BFHI hospitals than control hospitals (by approximately 4% to 25%)	Moderate for benefit (consistent, imprecise)
Duration Six or more BFHI steps vs. fewer than six steps	1 cohort;[56] 1,417 Medium	Significantly higher odds of weaning at or before 8 wks postpartum among women giving birth in hospitals practicing ≤ four BFHI steps than women giving birth in hospitals practicing six BFHI steps (ORs ranged from 2.08 and 3.13); no difference between women exposed to five vs. six steps	Low for benefit (consistent[a] precise)

[a] Although only one study compared groups of women based on number of BFHI steps practiced by hospitals, we considered evidence on duration from studies comparing BFHI implementation (or accreditation) with nonaccredited hospitals. As shown in the table, we concluded that moderate SOE supports the effectiveness of BFHI for improving breastfeeding duration.

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; HV = home visits; k = number of studies; N = number; OR = odds ratio; RCT = randomized controlled trial; SOE = strength of evidence.

Other (Non-BFHI) Health Care System–Based Interventions

Fifteen studies (described in 16 publications) assessed the effectiveness of other (non-BFHI) health care system–based interventions.[68, 70-85, 223] Studies assessed a variety of intervention types; the majority focused on health care provider education or training related to breastfeeding, with or without additional services offered (e.g., breastfeeding groups, home visits). Table 30 presents key findings and SOE conclusions. Overall, the evidence supports the effectiveness of three intervention types for improving the duration of exclusive breastfeeding: modified-BFHI policy implementation in outpatient settings (e.g., development of a breastfeeding policy, staff training, outcome assessment, and quality improvement initiatives), continuous nursing care during the perinatal period (the same nurse provides routine perinatal care to the mother and infant), and health care provider education combined with a series of home visits (low SOE). In addition, the evidence suggests that health care provider education and training alone (without additional breastfeeding support services) are not effective in improving rates of breastfeeding initiation (low SOE). Because of methodological limitations and imprecise and inconsistent findings, we rated the SOE as insufficient for other intervention types.

Table 30. Summary of key findings and strength of evidence: Non-BFHI health care system–based interventions

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation Education/staff training related to BF alone vs. usual practice	4 (2 RCTs,[70, 71, 75] 2 NRCTs[73, 78]); 1,532[a] Medium	No significant difference between intervention and control groups in rates of any or exclusive BF initiation	Low for no benefit (consistent, imprecise)
Initiation Education and staff training plus additional individual services vs. usual care	4 (2 RCTs,[74, 77] 1 NRCT,[68] 1 pre-post study[82]); 34,018 Medium	Inconsistent findings across four studies assessing heterogeneous interventions	Insufficient (inconsistent, imprecise)
Duration Education and staff training related to BF only vs. usual practice	3 (2 RCTs,[70, 71, 79] 1 NRCT[73]); 1,526[a] Medium	Inconsistent findings across three studies for duration of any and exclusive BF	Insufficient (inconsistent, imprecise)
Duration Education and staff training plus additional individual services vs. usual care	4 RCTs;[74, 76, 77, 84] 21, 253 Medium	Two RCTs assessing staff education combined with a series of postpartum HVs found improved rates of any BF duration Two RCTs assessing staff education combined with different clinic-based patient education strategies found no significant difference between groups	Staff education plus HVs: Low for benefit (consistent, precise) Staff education plus clinic-based education/support: Insufficient (inconsistent, imprecise)
Duration Adaptation of the BFHI for integration into routine primary care (maternal and child health centers) vs. usual care	1 NRCT;[81] 3,948 Medium	Significantly higher rates of exclusive BF in the intervention group than controls at 6 mos (OR, 1.33; 95% CI, 1.03 to 1.72); no difference between groups in rates of any BF at 5 or 12 mos	Low for benefit (unknown consistency, precise)
Initiation/duration Continuous primary nursing care (same nurse through perinatal period for mother/infant) vs. usual care (task-oriented nursing)	1 RCT;[72] 470 Medium	Significantly higher rates of exclusive BF during hospitalization (99% vs. 88%; p=0.001) and higher rates of exclusive BF 6 wks (72% vs. 94%; p=0.001) among women in the intervention group than controls	Low for benefit (unknown consistency, precise)

[a] Number here includes participants enrolled from three studies; one study focused on 13 residency programs did not report the number of women included in analyses of breastfeeding outcomes.[73]

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; CI = confidence interval; HV = home visit; N = number; NRCT = non-randomized controlled trial; OR = odds ratio; RCT = randomized controlled trial.

WIC-Based Interventions

Eight included studies assessed changes in breastfeeding rates associated with a WIC program or policy;[86-93] studies enrolled women from diverse States and assessed heterogeneous interventions; key findings and SOE assessments are shown in Table 31. Few studies assessed the same intervention type. Low SOE supports the effectiveness of WIC-based peer-support programs for improving rates of any breastfeeding initiation and duration from 6 weeks to 6 months postpartum. We found insufficient evidence (primarily due to unknown consistency and imprecision) to make a conclusion on the benefit of other WIC programs or policies for improving breastfeeding outcomes, including policy changes related to WIC food packages, provision of different types of breast pumps (electric vs. manual), cash incentives, and peer-support programs targeted at fathers.

Table 31. Summary of key findings and strength of evidence: WIC-based interventions

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation/duration Mother peer support vs. control	3 (1 RCT,[89] 1 NRCT,[90] 1 cohort[91]); 2,480 Medium	Two studies of in-person peer support resulted in significantly higher rates of BF initiation and increased BF duration; one telephone-based peer-support study found significantly higher rates of any BF at 3 and 6 mos than controls	Low for benefit (consistent, precise)
Initiation/duration BF rates post-2007 policy revising the WIC food package vs. pre-policy implementation	1 (3 pop. cohorts);[87] PRAMS (127,477) NIS (73,991) PedNSS (744 infants): 744 High	No association between the policy change and rates of BF;[a] BF rates increased overall with no difference between women receiving WIC benefits and similar groups of women not receiving WIC benefits	Insufficient (high ROB, unknown consistency, imprecise)
Duration Provision of electric breast pump vs. manual pump	1 RCT;[86] 280 Medium	No difference in BF duration among women assigned to an electric vs. manual breast pump; median duration of BF was 12 vs. 11 mos, respectively (HR,1.13; 95% CI, 0.79 to 1.50)	Insufficient (unknown consistency, imprecise)
Initiation/duration Peer-support program for fathers (in addition to mother peer support) vs. peer support for mothers alone	1 NRCT;[88] 200 Medium	Mothers in the intervention group had slightly higher rate of any BF at 6 mos than controls (63% vs. 55%) that was not statistically significant (p=0.20)	Insufficient (unknown consistency, imprecise)
Duration Cash incentives vs. usual WIC services	1 RCT;[93] 36 Medium	BF rates in the intervention group were significantly higher than controls at 1, 3, and 6 months (89% vs. 44%, 89% vs. 17%, and 72% vs. 0%, respectively)	Insufficient (unknown consistency; precise)
Duration Tailored BF counseling and support based on BAPT survey	1 cohort;[92] 826 High	Significantly higher rates of exclusive BF in the intervention group at 7 and 30 days than controls; no difference between groups at 2 mos	Insufficient (high ROB, unknown consistency, imprecise)

[a] All three databases measured rates of "ever-breastfeeding"; in addition, PRAMS measured rates of breastfeeding for at least 4 weeks, NIS measured rates of breastfeeding for at least 3 months, and PedNSS measured rates of breastfeeding for at least 1 month. Conclusions were consistent across the different measures.

BAPT = Breastfeeding Attrition Prediction Tool; BF = breastfeeding; CI = confidence interval; HR = hazard ratio; N = number; NIS = National Immunization Survey; NRCT = non-randomized controlled trial; PedNSS = Pediatric Nutrition Surveillance System; PRAMS = Pregnancy Risk Assessment Monitoring System; RCT = randomized controlled trial; ROB= risk of bias; WIC = Special Supplemental Nutrition Program for Women, Infants and Children.

Community-Based Interventions

Five included studies (described in five publications) assessed the effectiveness of a community-based intervention;[94-100] key findings and SOE assessments are shown in Table 32. No studies assessed the same intervention type, which limited our ability to make conclusions on the SOE for most intervention types. Low SOE supports the benefit of community-based interventions that provide mothers with peer support (via home visits). In addition, access to a community-based breastfeeding drop-in center among women receiving early home-based breastfeeding support does not increase breastfeeding duration (low SOE).

Table 32. Summary of key findings and strength of evidence: Community-based interventions

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation/duration Community-based policy aimed at promoting BF in nonhospital-based health and community centers vs. no intervention	1 NRCT;[94, 99] 5,094 Medium	No significant difference in rates of exclusive BF at discharge, 3 and 6 mos, or rates of any BF at 5 and 12 mos between groups	Insufficient (unknown consistency, imprecise)
Duration Access to community-based BF drop-in centers (plus early BF support) vs. early BF support alone vs. usual care	1 RCT;[95, 100] 9,675 Low	No difference between groups in rates of any BF at 3, 4, or 5 mos.	Low for no benefit (unknown consistency, precise)
Duration Community-based peer support vs. usual care	1 RCT;[96] 130 Low	Significantly higher rates of exclusive BF at 3 mos among intervention groups (50% to 67%) than control group (12%), p<0.001; rates of any BF were significantly longer in intervention groups (combined) than in the control group at 3 mos (but not 6 mos)	Low for benefit (unknown consistency, precise)
Duration Peer-led BF support class vs. Nurse-led BF support class	1 cohort;[98] 109 High	No significant difference between groups in rates of any BF at 1 and 6 mos postpartum	Insufficient (high ROB, unknown consistency, imprecise)
Duration Integrated postpartum program (BF education and support, maternal/infant health care) vs. usual care	1 NRCT;[97] 392 High	Significantly higher rates of exclusive BF at 6 mos among the intervention group than control group (74% vs. 10%; p=0.001)	Insufficient (high ROB, unknown consistency, precise)

BF = breastfeeding; N = number; NRCT = nonrandomized controlled trial; ROB = risk of bias; RCT = randomized controlled trial.

Effectiveness and Harms of Breastfeeding Programs and Policies for Subpopulations of Women

Few studies reported on subgroups of women. Of the four included studies reporting on subgroups of women, two focused on BFHI and reported on differences by education status, and two focused on WIC interventions and reported on differences relevant to race/ethnicity. Table 33 summarizes our conclusions below by intervention type. Low SOE supports the conclusion that BFHI effectiveness may vary among women who differ by education status. For WIC interventions, we found insufficient evidence to make a conclusion on whether benefit of telephone peer support varies by subgroups of women based on language spoken (Spanish only vs. English) or whether benefit of tailored breastfeeding counseling intervention varies by race/ethnicity, primarily due to unknown consistency (and inconsistency across time points) and imprecision.

Table 33. Summary of key findings and strength of evidence: KQ 1 studies reporting on subgroups

Breastfeeding Outcome Intervention Versus Comparator	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Initiation (subgroups: education status) BFHI certified/accredited vs. no BFHI status	2 cohort;[54, 55] 27,341 Medium	Higher rates of BF initiation found among women with lower education (≤12 yrs) at BFHI hospitals compared with control hospitals, but no difference in rates among women with higher education (≥13 yrs)	Low (consistent, imprecise)
Duration (subgroups: education status) BFHI certified/accredited vs. no BFHI status	2 cohort;[54, 55] 27,341 Medium	Two studies found mixed results.	Insufficient (inconsistent, imprecise)
Initiation/duration (subgroups: language spoken) Mother peer support vs. control	1 RCT;[89] 1948 Medium	One RCT of telephone peer support found mixed results for subgroups of women defined by language (English-speaking vs. Spanish-speaking only)	Insufficient (unknown consistency, imprecise)
Duration (subgroups: race/ethnicity) Tailored BF counseling and support based on BAPT survey	1 cohort;[92] 826 High	Significantly higher rates of exclusive BF among non-Hispanic black and Hispanic women in the intervention group than controls at 1 and 2 mos; no significant difference in exclusive BF rates among white women at any time point	Insufficient (high ROB, unknown consistency, precise)

BAPT= Breastfeeding Attrition Prediction Tool; BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; KQ = Key Question; N = number; RCT= randomized controlled trial; ROB = risk of bias .

Effect of Intervention Characteristics on Breastfeeding Outcomes

This KQ focused on the extent to which intervention-related characteristics (e.g., type of breast pump provided—manual or electric, delivery personnel) influence the initiation, duration, and exclusivity of breastfeeding. We found no evidence to address this KQ.

Maternal Health Outcomes Associated With Breastfeeding

Table 34 summarizes our key findings related to KQ 2, including evidence for subpopulations of women, by outcome. Low SOE supports the conclusion that ever breastfeeding, as well as longer durations of breastfeeding, may be associated with a reduced risk of developing (any) breast cancer, luminal breast cancer, or triple-negative breast cancer.

Table 34. Summary of key findings and strength of evidence: Maternal health outcomes

Maternal Health Outcome	N Studies; N Subjects Study Limitations	Outcome and Results[a]	Strength of Evidence
Breast cancer	1 SR of 98 cohort/case-control studies;[1] NR[b] 19 cohort/case-control studies;[108-126] 256,891 women Medium	Consistent association in one SR (98 observational studies) between ever BF and lower rates of breast cancer compared with never BF (pooled OR, 0.78, 95% CI, 0.74 to 0.82); longer durations of BF was also associated with significantly lower rates of breast cancer than never BF. Results of individual studies were generally consistent in direction of effect (although results were imprecise); magnitude varied significantly across all studies and pooled results were associated with significant heterogeneity, only partially explained by subgroup analyses.	Low for beneficial association (consistent, imprecise)
Breast cancer: *BRCA1/2* carriers	1 case-control study;[129] 5,708 women Medium	Unclear association between BF and breast cancer among *BRCA* carriers.	Insufficient (unknown consistency, imprecise)
Breast cancer: In situ	3 cohort/case-control studies;[122, 125, 132] 67,234 women Medium	Unclear association between BF and breast cancer in situ.	Insufficient (inconsistent, imprecise)
Breast cancer: Hormone receptor subtypes	1 SR of 11 cohort/case-control studies;[107] 169,879 women for luminal, 14,266 women for HER2, and 176,430 women for triple-negative analyses 7 cohort/case-control studies;[110, 117, 121, 133-136] 592,558 women Medium	Consistent association between ever BF or longer duration of BF and lower rates of luminal and triple negative breast cancer (although magnitude of association varies); for HER2, pooled estimates show unclear association between BF and lower rates of breast cancer (results are imprecise and pooled estimate is not statistically significant).	Low for beneficial association (luminal, triple-negative; consistent, imprecise); insufficient (HER2, inconsistent, imprecise)
Breast cancer: Mortality	1 cohort study;[137] 250,470 parous women Medium	Unclear association; one study found no significant association between BF and breast cancer mortality (HR,1.01; 95% CI, 0.79 to 1.29).	Insufficient (unknown consistency, imprecise)
Ovarian cancer	1 SR of 41 cohort/case-control studies;[1] NR[c] 9 cohort/case-control studies;[140-149] 42,611 women Medium	Consistent association between ever BF and longer durations of BF and lower risk of ovarian cancer; magnitude of association varies across studies by BF exposure definition.	Moderate for beneficial association (inconsistent, precise)
Hypertension	5 cohort studies;[4, 5, 152, 153, 224] 441,989 women Medium	Consistent association between longer duration of BF (>6-12 mos) and lower rates of HTN; magnitude of association varies by BF exposure comparisons and study design.	Low for beneficial association (consistent, imprecise)
CVD	3 cohort studies;[4, 6, 155] 301,989 women Medium	Unclear association between BF and CVD; three studies conclude an association between longer BF duration and lower CVD rates, each using a different composite outcome; magnitude of association varies by exposure comparisons, age at cohort enrolment, and study design.	Insufficient (unknown consistency, imprecise)

Intervention type	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
CVD mortality	1 cohort study;[156] 15,000 women Medium	Unclear association between BF and CVD mortality. One study found mixed results: parous women ≤65 yrs at enrollment who had never BF had higher CVD mortality over 14 yrs of followup than women who BF ≥24 mos (HR, 2.77; 95% CI, 1.28 to 5.99). No clear associations were observed among women ≤65 yrs at enrollment.	Insufficient (unknown consistency, imprecise)
Type 2 diabetes	1 SR of 6 cohort studies;[158] 273,961 women 5 cohort studies;[4, 159-163] 325,815 women Medium	Consistent association between ever BF and longer durations of BF and lower rates of type 2 diabetes (among women with and without gestational diabetes); magnitude of association varies by BF exposure duration and study design.	Low for beneficial association (consistent, imprecise)
Fractures	11 cohort/case-control studies);[165, 167-176] 101,726 women Medium	Consistent lack of association between BF and fractures. Magnitude varies by exposure and outcome measure, but only 1 high ROB study reported statistically significant differences.	Low for no association (consistent, imprecise)
Postpartum depression	1 SR of 48 cohort studies;[183] 71,245 women 14 cohort studies;[184-189, 192, 195-198, 200, 201, 225] 39,372 women Medium	Unclear association between BF and postpartum depression. Magnitude of association and direction of effect unclear; studies are heterogeneous in design and results inconsistent.	Insufficient (unknown consistency, imprecise)
Postpartum weight change	16 cohort studies;[203-221] 47,655 women Medium	Unclear association between BF and postpartum weight change. Magnitude of postpartum weight change varies by BF exposure and outcome measure.	Insufficient (inconsistent, imprecise)

[a] We marked outcomes as indirect for long-term maternal health outcomes primarily due to uncertainty of the relative contribution of breastfeeding to risk (given that many other potential factors also contribute to outcomes such as hypertension, fracture, and breast cancer); for short-term maternal health outcomes (e.g., postpartum depression) there is uncertainty in the direction of effect between breastfeeding and health outcomes.
[b] Per authors, there were 52 studies with >1,500 women, 31 studies with 500-1,499 women, and 15 studies with <500 women. Exact number of participants is unclear.
[c] Per authors, there were 22 studies with >1,500 women, 12 studies with 500-1,499 women, and 7 studies with <500 women. Exact number of participants is unclear.

BF = breastfeeding; CI = confidence interval; CVD = cardiovascular disease; HER2 = human epidermal growth factor receptor 2; HR = hazard ratio; HTN = hypertension; N = number; NR = not reported; OR = odds ratio; ROB = risk of bias; SR = systematic review.

We rated the evidence as insufficient (primarily due to unknown consistency) for the association between breastfeeding and subtypes of breast cancer defined by tumor behavior (i.e., in situ breast cancer) or hormone receptor status, breast cancer among *BRCA1/2* mutation carriers, and mortality due to breast cancer. Low SOE supports the association between ever breastfeeding, as well as longer versus shorter durations of breastfeeding, and a reduced risk of developing epithelial ovarian cancer.

For both hypertension and type 2 diabetes, studies consistently found an association between longer duration of breastfeeding and lower rates of hypertension and type 2 diabetes (low SOE for both outcomes). Because of heterogeneous outcome measures and imprecision, we were not able to make a conclusion on the association between breastfeeding and other cardiovascular outcomes.

Eleven studies reported on the association between breastfeeding using different measures (e.g., ever vs. never and duration per child) and hip, vertebral, and forearm fracture risk. Apart from two studies (rated high ROB), no study reported a statistically significant association between breastfeeding and fracture. We rated the SOE as low for no association.

Because of significant heterogeneity in study design, breastfeeding exposure definitions, outcomes, and inconsistency in results, we found insufficient evidence on whether breastfeeding is associated with postpartum depression or postpartum weight change. For postpartum depression, current evidence does not establish the direction of relationship between breastfeeding and higher or lower rates of postpartum depression.

Deficiencies in Methods

Many included studies for KQ 1 have methodological limitations. Studies often did not adequately describe the flow of participants or facilities; this was particularly true of those that randomized or assigned interventions at the hospital or other systems level. Many studies do not adequately describe or define breastfeeding outcome measures. Among studies that described breastfeeding outcome measures, studies vary in terms of definitions used (particularly for breastfeeding exclusivity) and also measure initiation rates using different criteria (e.g., self-reported initiation of any breastfeeding, breastfeeding status at hospital discharge). Selection bias is also a concern for observational studies. Overall attrition was high in several studies, and many did not conduct an intention-to-treat analysis (i.e., they analyzed only completers). In general, authors did not describe the potential for contamination (from other concurrent programs and policies to promote and support breastfeeding). None of the included studies assessed potential harms of interventions. We found no eligible studies of workplace breastfeeding interventions. Studies describing workplace breastfeeding interventions identified in our literature searches did not have an eligible comparator (i.e., no concurrent control group or, for pre-post studies, no multiple pre- and post-outcome measures). For KQ 2, the evidence base comprises observational studies only (cohorts and case-controls). For outcomes such as depression and weight gain, the direction of causality is unclear and the evidence does not offer definitive guidance. For other outcomes (e.g., cardiovascular disease), confounding and selection bias pose threats to causal inference, and existing studies cannot rule out residual confounding. For most outcomes, the vast majority of studies rely on self-report to categorize breastfeeding exposure. In studies that enroll women decades after giving birth, differential recall (particularly for outcomes where women are aware of the purported benefits of breastfeeding) can result in misclassification of the duration of exposure.

Findings in Relation to What Is Already Known

For KQ 1, our findings related to the benefit of BFHI for improving breastfeeding initiation and duration support continued efforts to implement this policy. Because of heterogeneity in study design, country setting, and outcome measures, we were not able to pool results. The absolute difference in rates of breastfeeding initiation and duration vary by setting and are likely influenced by a range of factors such as intervention fidelity, social factors, and others. Although our scope is narrower (in terms of eligible country setting and study design), our conclusions are consistent with a recent narrative review[226] focused on BFHI; the authors conclude that adherence to the BFHI Ten Steps has a positive influence on breastfeeding outcomes. In terms of other health care interventions, staff training alone (without other breastfeeding support components) did not lead to improved breastfeeding outcomes. However, health care interventions that pair staff education with other services, such as a series of home visits, lead to improved rates of exclusive breastfeeding duration.

For other intervention types, our results show that WIC programs providing in-person or telephone peer support improve breastfeeding outcomes. We also identified evidence on a range of other WIC programs (e.g., cash incentives, provision of different types of breast pumps, and changes in food package policies); however, primarily as a result of unknown consistency and imprecision, we had insufficient evidence to draw a conclusion regarding the benefit of these interventions. We identified no eligible studies assessing workplace breastfeeding interventions; other reviews have highlighted the lack of controlled trials of workplace interventions for promoting breastfeeding in employed women.[26, 226] We looked for both trials and observational studies with a control group and still found no eligible studies. The absence of evidence on this topic precludes us from commenting on the effectiveness of workplace breastfeeding interventions. In 2012, the Affordable Care Act required large employers to provide reasonable break time and a private place for expressing breastmilk and mandated insurance coverage of lactation support services and equipment without cost-sharing for new health insurance policies. Without adequate time to express breastmilk in the workplace, working mothers would face significant barriers to breastfeeding. Future studies (as noted below) could address whether certain workplace interventions are more effective than others in improving breastfeeding duration among working mothers.

Our conclusions related to the maternal benefits of breastfeeding (KQ 2) suggest that breastfeeding is associated with lower rates of breast cancer, ovarian cancer, hypertension, and type 2 diabetes. The potential to improve maternal health could be highlighted as a rationale for improving rate of breastfeeding by health care and public health practitioners. For cardiometabolic outcomes, it has been hypothesized that lactation “resets” maternal metabolism after pregnancy, thereby reducing cardiovascular disease risk.[151] Our conclusions related to hypertension and type 2 diabetes support this hypothesis. Results of our current review are, in general, consistent with those in previous reviews with respect to conclusions about the limitations of the evidence base. As was the case in 2007, we are not able to draw a conclusion about the association between breastfeeding and postpartum weight change or postpartum depression (due to study limitations and imprecise and inconsistent results). For this review, we added two additional maternal health outcomes: hypertension and cardiovascular disease. We concluded that low SOE supports the association between breastfeeding and hypertension; however, primarily as a result of heterogeneity in outcome measures and study limitations, we concluded that evidence was insufficient to reach a conclusion about cardiovascular disease.

Overall, given the benefit associated with health care system–level interventions, WIC peer-support programs for improving breastfeeding outcomes, and the maternal health benefits associated with breastfeeding, our results support continued efforts to ensure that mothers have adequate breastfeeding support. This support includes provisions contained in the Affordable Care Act[227] that aim to support breastfeeding, such as requirements of insurers to provide coverage of breastfeeding supplies and support services and workplace policies supporting breastfeeding.

Applicability

For KQ 1, several factors may limit the applicability of findings. Although most studies enrolled women of a similar age (20s to 30s), many had other specific inclusion criteria related to parity or health status (of the mother, infant, or both); a few enrolled only women who intended to breastfeed or were undecided.[52, 89] In general, the findings are applicable to healthy women who have access to routine maternity care and gave birth to healthy infants. Interventions focused on critically ill infants were beyond the scope of this review. Factors most likely to limit the applicability of the evidence include country setting, variation in usual maternity care practices (including other policies and practices to support breastfeeding), and (potentially) socioeconomic factors. For example, usual maternity care in one Danish study included at least one home visit within the first 5 weeks of birth,[76] which may reflect a higher level of support than other country settings. Other studies evaluated interventions in resource-poor settings, such as one intervention that enrolled mothers from neighborhoods in Santiago, Chile, with a high rate of poverty.[97] In terms of subgroups of women, limited data from the United States suggest that the magnitude of benefit for BFHI policies may be greater among women with less education than women with more education.[54, 55] Although the PROBIT trial, conducted in the Republic of Belarus, demonstrated benefit for increasing breastfeeding duration, results may not be applicable to the United States. Only women who initiated breastfeeding were enrolled in PROBIT. At the time of enrollment, for example, mothers in Belarus often stayed in the hospital close to 1 week postpartum and infant formula was costly (up to 20% of an average yearly salary).[52] The benefit demonstrated in PROBIT for BFHI may represent a best-case scenario.

For KQ 2, similar concerns about applicability apply. However, for KQ 2, we did limit to studies conducted in very high income countries (to be consistent with the 2007 AHRQ review). One limitation of the evidence related to time frame of enrollment. Many observational studies (including data from WHI participants[4]) enrolled women who breastfed decades ago. In 1970, only 26.5 percent of women initiated breastfeeding,[228] compared with more than 80 percent of women today. Because of these secular changes, confounders of the association between breastfeeding and maternal health have changed over time, and evidence on the association between breastfeeding from older cohorts of women may or may not reflect the strength of association for women currently breastfeeding. Women who chose to breastfeed when breastfeeding rates in the United States were lower could be different in ways that affect risk of adverse maternal health outcomes.

Limitations of the Review Process

For KQ 1, we looked for and included a broad range of interventions to promote and support breastfeeding. At the same time, we specifically excluded primary care–relevant interventions delivered to individual women (to avoid duplicating a recent review conducted for the U.S. Preventive Services Task Force).[37] The studies that met our inclusion criteria assessed a variety of different intervention types but did not fully span all interventions potentially relevant to policymakers. Because of our inclusion criteria, we may have excluded some interventions that could be considered systems level or community based. The breadth of our eligibility criteria was also a limitation in terms of the evidence synthesis; included studies may have been categorized in different ways. We chose to focus on intervention type and setting because these may be important factors for decisionmakers who plan to implement breastfeeding programs and policies. Despite our broad intervention inclusion criteria, we identified no eligible studies assessing workplace interventions (primarily due to no control group of women who did not receive the intervention).

Publication bias and selective reporting of outcomes are potential limitations. Although we searched for unpublished trials and unpublished outcomes, we did not find direct evidence of either of these biases. However, the majority of included studies are not trials (and were published before trial registries became available); these factors limit our certainty about the potential for publication bias. Finally, for this review, we excluded non-English-language studies based largely on limitations of time and resources.

For KQ 2, we chose to include recent, relevant systematic reviews in our evidence synthesis. Although this approach may improve efficiency, it has limitations. Some included systematic reviews do not fully report details related to methods (particularly ROB assessment). In addition, reporting of study characteristics was often lacking. Among the included systematic reviews that conducted meta-analyses, strategies to assess clinical and statistical heterogeneity were not always clearly described.

The scope of outcomes evaluated for KQ 2 was limited to an update of the 2007 review,[2] with the addition of hypertension and cardiovascular disease outcomes. These outcomes represent common conditions that contribute significantly to burden of disease in very high income countries. However, studies have linked lactation with other maternal health outcomes, including reduced risk of endometrial cancer, multiple sclerosis,[229] endometriosis,[230] rheumatoid arthritis,[231] and short-interval pregnancy.[232, 233] These outcomes and others may be of interest for future systematic reviews.

Limitations of the Evidence Base

For KQ 1, we found no evidence on certain types of interventions (e.g., workplace and school-based interventions), limited evidence for subgroups of women, and no included studies reported on potential harms of interventions. Studies used various definitions of breastfeeding initiation and exclusivity, which may limit the comparability of findings. In addition, as a result of the heterogeneity across studies, we were not able to assess whether certain characteristics of interventions have a greater influence on breastfeeding initiation, duration, and exclusivity. We were also not able to determine whether heterogeneity within some categories of interventions such as BFHI is due to study design, differences in outcome measures, fidelity of implementation, or country setting (given that variation exists across all these factors).

For KQ 2, although we found a large volume of evidence supporting the association between breastfeeding and improved maternal health, methodological limitations specific to observational study designs limit the ability to determine the magnitude of the effect that lactation has on maternal health. Although a growing literature documents protective associations between lifetime lactation and improved maternal health, these findings do not establish that breastfeeding prevents poor maternal health. Several other factors may be at work. First, women in very high income countries who choose to breastfeed and succeed in doing so are typically better educated, wealthier, and more likely to engage in other beneficial health behaviors.[234, 235] Moreover, it is plausible that, rather than breastfeeding preventing poor maternal health, poor maternal health may prevent the initiation or continuation of breastfeeding. This is of particular concern for studies of postpartum depression, in that preexisting depression or anxiety may disrupt breastfeeding, leading to early weaning;[4, 155, 236, 237] moreover, there is evidence that early breastfeeding difficulties are associated with depressive symptoms.[238] Similarly, emerging evidence similarly suggests that women who are insulin resistant are more likely to experience breastfeeding difficulties,[239] potentially leading to shorter breastfeeding durations. In this context, rather than breastfeeding preventing cardiometabolic disease, early weaning may be a marker for maternal risk.[240] One limitation of the evidence is related to time frame of enrollment. Many observational studies (including data from Women's Health Initiative participants[4]) enrolled women who breastfed decades ago. In 1970, only 26.5 percent of women initiated breastfeeding[228] compared with more than 80 percent of women today. Because of these secular changes, confounders of the association between breastfeeding and maternal health have changed over time, and evidence on the association between breastfeeding from older cohorts of women may or may not reflect the strength of association for women currently breastfeeding. Women who chose to breastfeed when breastfeeding rates in the United States were lower could be different in ways that affect risk of adverse maternal health outcomes.

Future Research Needs

For KQ 1, future research should assess the benefit of workplace, school-based, and other community-based interventions for improving rates of breastfeeding. Studies are also needed to inform context-specific types of professional and material support (e.g., double-electric vs. manual breast pumps) that enable women to achieve their infant feeding goals. Authors of future studies should more clearly describe characteristics of usual care and other breastfeeding support services are available. For studies conducted in the United States, future research could address whether certain interventions are more effective for groups of women who differ by socioeconomic factors in order to assess the consistency of current evidence suggesting a difference by education status. Study designs with a concurrent control group (e.g., trials or prospective cohort studies) would be helpful in reducing bias and informing the benefit of breastfeeding programs or policies implemented in a wide range of settings, particularly workplace programs. Methods to address selection bias, confounding, and measurement bias should also be considered in future research related to breastfeeding programs and policies. In addition, future studies assessing breastfeeding interventions should collect outcomes related to potential harms of interventions. In addition, studies are needed to compare types of support, such as manual versus electric pumps or interventions delivered by International Board Certified Lactation Consultants vs. Certified Lactation Consultants, to tailor support to the needs of each woman.

For KQ 2, observational studies will likely remain the major source of evidence on the association between breastfeeding and maternal health. Long-term followup of prospectively assessed breastfeeding duration may eliminate or significantly reduce potential of recall bias. Use of standardized breastfeeding definitions and clear reporting of how participants were selected would help minimize bias. In terms of analyses, authors should adequately address known confounders, such as breastfeeding intention, birth complications, diet, physical activity, tobacco use, mental health, and social support and clearly report a rationale for why certain factors were chosen. Future studies might also consider the extent to which adverse lactation outcomes, like adverse pregnancy outcomes,[241] may be a window to maternal health.

More generally, standardized definitions of breastfeeding, as well as consistent methods of collecting these data, are needed to facilitate future systematic reviews and meta-analyses.

Conclusions

The body of evidence for breastfeeding programs and policies was diverse in terms of interventions and settings. Current evidence supports the effectiveness of BFHI for improving rates of breastfeeding initiation and duration; however, evidence from one large RCT (PROBIT) has limited applicability, and observational studies do not clearly establish the magnitude of benefit. For U.S. women enrolled in WIC, low SOE supports peer-support interventions for improving breastfeeding outcomes. The identified associations between breastfeeding and improved maternal health outcomes are supported by evidence from observational studies, which cannot determine cause and effect relationships.

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Appendix A. Literature Search Strategies and Yields

Breastfeeding Original Searches KQ 1

FINAL

PubMed

Searched February 8, 2017
Results:
RCTs and other study designs: 2,632 (Line 14)
2,632 imported, no duplicates
SRs: 193 (Line 19)
144 imported, 49 duplicates

PubMed Search Strategy

Search	Query	Items Found
#1	Search “Infant Nutritional Physiological Phenomena”[Mesh] OR “Milk, Human”[Mesh] OR “Breast Feeding”[Mesh] OR “breast feeding”[All Fields] OR “human milk”[All Fields] OR (human[tiab] AND milk[tiab]) OR “breast milk”[All Fields] OR breastmilk OR breastfeed* OR (breast[tiab] AND fed[tiab]) OR breastfed OR “Lactation”[Mesh] OR lactating OR lactation	130104
#2	Search (((Absenteeism[Mesh] OR “Affordable Care Act” OR ACA[tiab] OR “Baby friendly Hospital Initiative” OR BFHI OR (break*[tiab] AND (express* AND milk)) OR “Breast Milk Expression”[Mesh] OR “breast pump”[All Fields] OR “Child Day Care Centers”[Mesh] OR “Employment”[Mesh] OR (employ* AND (polic* OR program*)) OR “Health Knowledge, Attitudes, Practice”[Mesh] OR “Health Promotion”[Mesh] OR “Insurance Benefits”[Mesh] OR (“lactation consultant” OR “lactation consultants”) OR “Maternal Health Services”[Mesh] OR “Mothers/psychology”[Majr] OR “Nurseries, Hospital”[Mesh] OR “Occupational Health Services”[Mesh] OR “Parental Leave”[Mesh] OR “Program Evaluation”[Mesh] OR “Salaries and Fringe Benefits”[Mesh] OR “Social Support”[Mesh] OR “Women, Working”[Mesh])))	460877
#3	Search (“baby friendly”[All Fields] OR “hospital practices”[All Fields] OR “Ten Steps”[All Fields] OR Counseling[Mesh] OR WIC OR “Women, Infants, and Children Program” OR SNAP OR “Food Stamps”[All Fields] OR “Food Assistance”[Mesh] OR “Food assistance”[All Fields] OR “Health Education”[Mesh] OR “House Calls”[Mesh] OR “Organizational Policy”[Mesh] OR “Patient Education as Topic”[Mesh] OR “Promotion of Breastfeeding Intervention Trial”[All Fields] OR PROBIT[All Fields] OR “Postnatal Care”[Mesh] OR “Social Support”[Mesh] OR 'Ten Steps to Successful Breastfeeding'[All Fields] OR “Workplace”[Mesh])	281167
#4	Search (((“schools”[MeSH] OR “schools”[All Fields] OR “school”[All Fields] OR “universities”[MeSH] OR “universities”[All Fields] OR “university”[All Fields]) AND (“wellness programmes”[All Fields] OR “health promotion”[MeSH Terms] OR (“health”[All Fields] AND “promotion”[All Fields] OR “health promotion”[All Fields]) OR (“wellness”[All Fields] AND “programs”[All Fields]) OR “wellness programs”[All Fields]) OR (“school health services”[MeSH] OR (“school”[All Fields] AND “health”[All Fields] AND “services”[All Fields]) OR “school health services”[All Fields])) OR ((“workplace”[MeSH] OR “workplace”[All Fields]) AND (“wellness programmes”[All Fields] OR “health promotion”[MeSH] OR (“health”[All Fields] AND “promotion”[All Fields]) OR “health promotion”[All Fields] OR (“wellness”[All Fields] AND “programs”[All Fields]) OR “wellness programs”[All Fields] OR programs[All Fields])))	175566
#5	Search (#2 OR #3 OR #4)	732183
#6	Search (#1 AND #5)	12024

Search	Query	Items Found
#7	Search ((((randomized[title/abstract] OR randomised[title/abstract]) AND controlled[title/abstract] AND trial[title/abstract]) OR (controlled[title/abstract] AND trial[title/abstract]) OR “controlled clinical trial”[publication type] OR “Randomized Controlled Trial”[Publication Type] OR “Single-Blind Method”[MeSH] OR “Double-Blind Method”[MeSH] OR “Random Allocation”[MeSH]))	662215
#8	Search (#6 AND #7)	820
#9	Search (“Cohort Studies”[Mesh] OR “Epidemiologic Studies”[Mesh] OR “Follow-up Studies”[Mesh] OR “prospective cohort” OR “prospective studies”[MeSH] OR (prospective*[All Fields] AND cohort[All Fields] AND (study[All Fields] OR studies[All Fields])))	1979868
#10	Search (#6 AND #9)	2248
#11	Search (#8 OR #10)	2849
#12	Search (#8 OR #10) Filters: Publication date from 1980/01/01 to 2017/12/31	2836
#13	Search (#8 OR #10) Filters: Publication date from 1980/01/01 to 2017/12/31; Humans	2774
#14	Search (#8 OR #10) Filters: Publication date from 1980/01/01 to 2017/12/31; Humans; English	2632
#15	Search (((“systematic review”[ti] OR “meta-analysis”[pt] OR “meta-analysis”[ti] OR “systematic literature review”[ti] OR “this systematic review”[tw] OR (“systematic review”[tiab] AND review[pt]) OR meta synthesis[ti] OR “meta synthesis”[ti] OR “cochrane database syst rev”[ta])))	148009
#16	Search (#6 AND #15)	218
#17	Search (#6 AND #15) Filters: Publication date from 1980/01/01 to 2017/12/31	218
#18	Search (#6 AND #15) Filters: Publication date from 1980/01/01 to 2017/12/31; Humans	200
#19	Search (#6 AND #15) Filters: Publication date from 1980/01/01 to 2017/12/31; Humans; English	193

CINAHL

Searched February 8, 2017
Excluded Medline citations
Results: 79
79 imported, no duplicates

#	Query	Limiters/Expanders	Results
S1	MH “Infant Nutritional Physiological Phenomena” OR MH “Milk, Human” OR MH “Breast Feeding” OR “breast feeding” OR “human milk” OR (human AND milk) OR “breast milk” OR breastmilk OR breastfeed* OR (breast AND fed) OR breastfed OR MH “Lactation” OR lactating OR lactation	Search modes - Boolean/Phrase	29,283
S2	(((MH “Absenteeism” OR “Affordable Care Act” OR ACA OR “Baby friendly Hospital Initiative” OR BFHI OR (break* AND (express* AND milk)) OR MH “Breast Milk Expression” OR “breast pump” OR MH “Child Day Care Centers” OR MH “Employment” OR (employ* AND (polic* OR program*)) OR MH “Health Knowledge, Attitudes, Practice” OR MH “Health Promotion” OR MH “Insurance Benefits” OR (“lactation consultant” OR “lactation consultants”) OR MH “Maternal Health Services” OR “Mothers/psychology” OR MH “Nurseries, Hospital” OR MH “Occupational Health Services” OR MH “Parental Leave” OR MH “Program Evaluation” OR MH “Salaries and Fringe Benefits” OR MH “Social Support” OR MH “Women, Working”)))	Search modes - Boolean/Phrase	149,444
S3	“baby friendly” OR “hospital practices” OR “Ten Steps” OR MH Counseling OR WIC OR “Women, Infants, and Children Program” OR SNAP OR “Food Stamps” OR MH “Food Assistance” OR “Food assistance” OR MH “Health Education” OR MH “House Calls” OR MH “Organizational Policy” OR MH “Patient Education as Topic” OR “Promotion of Breastfeeding Intervention Trial” OR PROBIT OR MH “Postnatal Care” OR MH “Social Support” OR “Ten Steps to Successful Breastfeeding” OR MH “Workplace”	Search modes - Boolean/Phrase	47,284
S4	((MH “schools” OR “schools”[All Fields] OR “school”[All Fields] OR MH “universities” OR “universities”[All Fields] OR “university”[All Fields]) AND (“wellness programmes”[All Fields] OR MH “health promotion” OR (“health”[All Fields] AND “promotion”[All Fields] OR “health promotion”[All Fields]) OR (“wellness”[All Fields] AND “programs”[All Fields]) OR “wellness programs”[All Fields]) OR (MH “school health services” OR (“school”[All Fields] AND “health”[All Fields] AND “services”[All Fields]) OR “school health services”[All Fields])) OR ((MH “workplace” OR “workplace”[All Fields]) AND (“wellness programmes”[All Fields] OR MH “health promotion” OR (“health”[All Fields] AND “promotion”[All Fields]) OR “health promotion”[All Fields] OR (“wellness”[All Fields] AND “programs”[All Fields]) OR “wellness programs”[All Fields] OR programs[All Fields]))	Search modes - Boolean/Phrase	7,888
S5	S2 OR S3 OR S4	Search modes - Boolean/Phrase	194,378
S6	S1 AND S5	Search modes - Boolean/Phrase	4,156
S7	(randomized OR randomised) AND controlled AND trial) OR (controlled AND trial) OR “controlled clinical trial” OR “Randomized Controlled Trial” OR MH “Single-Blind Method” OR MH “Double-Blind Method” OR MH “Random Allocation”	Search modes - Boolean/Phrase	112,810
S9	MH “Cohort Studies” OR MH “Epidemiologic Studies” OR MH “Follow-up Studies” OR “prospective cohort” OR MH “prospective studies” OR (prospective* AND cohort AND (study OR studies))	Search modes - Boolean/Phrase	306,067
S10	S6 AND S9	Search modes - Boolean/Phrase	307
S11	S8 OR S10	Search modes - Boolean/Phrase	450

#	Query	Limiters/Expanders	Results
S12	S11	Limiters - Published Date: 19800101-20171231; English Language; Exclude MEDLINE records Search modes - Boolean/Phrase	79

Cochrane Library

Total results: 1,611; 1,602 imported, 9 duplicates

Cochrane Reviews: 774; all imported, no duplicates
Other Reviews: 6; all imported, no duplicates
Trials: 810; 801 imported, 9 duplicates
Methods Studies: 2; all imported, no duplicates
Technology Assessments: 1; all imported, no duplicates
Economic Evaluations: 13; all imported, no duplicates
Cochrane Groups: 5; all imported, no duplicates

ID	Search	Hits
#1	[mh “Infant Nutritional Physiological Phenomena”] or [mh “Milk, Human”] or [mh “Breast Feeding”] or “breast feeding” or “human milk” or (human and milk) or “breast milk” or breastmilk or breastfeed* or (breast and fed) or breastfed or [mh Lactation] or lactating or lactation	9220
#2	[mh Absenteeism] or “Affordable Care Act” or ACA or “Baby friendly Hospital Initiative” or BFHI or (break* and (express* and milk)) or [mh “Breast Milk Expression”] or “breast pump” or [mh “Child Day Care Centers”] or [mh Employment] or (employ* and (polic* or program*)) or [mh “Health Knowledge, Attitudes, Practice”] or [mh “Health Promotion”] or [mh “Insurance Benefits”] or (“lactation consultant” or “lactation consultants”) or [mh “Maternal Health Services”] or [mh Mothers/psychology] or [mh “Nurseries, Hospital”] or [mh “Occupational Health Services”] or [mh “Parental Leave”] or [mh “Program Evaluation”] or [mh “Salaries and Fringe Benefits”] or [mh “Social Support”] or [mh “Women, Working”]	26093
#3	“baby friendly” or “hospital practices” or “Ten Steps” or [mh Counseling] or WIC or “Women, Infants, and Children Program” or SNAP or “Food Stamps” or [mh “Food Assistance”] or “Food assistance” or [mh “Health Education”] or [mh “House Calls”] or [mh “Organizational Policy”] or [mh “Patient Education as Topic”] or “Promotion of Breastfeeding Intervention Trial” or PROBIT or [mh “Postnatal Care”] or [mh “Social Support”] or “Ten Steps to Successful Breastfeeding” or [mh Workplace]	19417
#4	((([mh schools] or “schools” or “school” or [mh universities] or “universities” or “university”) and (“wellness programmes” or [mh “health promotion”] or (“health” and “promotion”) or “health promotion” or (“wellness” and “programs”) or “wellness programs”)) or ([mh “school health services”] or (“school” and “health” and “services”) or “school health services”)) or (([mh workplace] or “workplace”) and (“wellness programmes” or [mh “health promotion”] or (“health” and “promotion”) or “health promotion” or (“wellness” and “programs”) or “wellness programs” or programs))	10257
#5	#2 or #3 or #4	40711
#6	#1 and #5	1919
#7	((controlled:ti or controlled:ab) and (trial:ti or trial:ab)) or “controlled clinical trial” or “randomized controlled trial”:pt or “randomized controlled trial as topic”:pt or “single-blind method”:pt or “double-blind method”:pt or “random allocation”:pt	618067
#8	#6 and #7	1552
#9	[mh “Cohort Studies”] or [mh “Epidemiologic Studies”] or [mh “Follow-up Studies”] or “prospective cohort” or [mh “prospective studies”] or (prospective* and cohort and (study or studies))	146506
#10	#6 and #9	521
#11	#8 or #10 Publication Year from 1980 to 2017	1611

Breastfeeding Original Searches KQ 2
FINAL
PubMed
Searched February 2, 2017
Results:
Case control studies and other study types: 6,660 (Line 10)
6,659 imported, 1 duplicate
SRs: 660 (Line 12)
508 imported, 152 duplicates

Search	Query	Items found
#1	Search (“Infant Nutritional Physiological Phenomena”[Mesh] OR “Milk, Human”[Mesh] OR “Breast Feeding”[Mesh] OR “breast feeding”[All Fields] OR “human milk”[All Fields] OR (human[tiab] AND milk[tiab]) OR “breast milk”[All Fields] OR breastmilk OR breastfeed* OR (breast[tiab] AND fed[tiab]) OR breastfed OR “Lactation”[Mesh] OR lactating OR lactation)	130094
#2	Search (“HIV Infections”[Mesh] OR HIV OR “Fatty Acids”[Majr] OR “Amino Acids”[Majr])	936134
#3	Search (#1 NOT #2)	120404
#4	Search (“Case-Control Studies”[MeSH] OR “Cohort Studies”[MeSH] OR “Epidemiologic Studies”[MeSH] OR “Cross-Sectional Studies”[MeSH] OR “Organizational Case Studies”[MeSH] OR “Cross-Over Studies”[MeSH] OR “Follow-Up Studies”[MeSH] OR “Seroepidemiologic Studies”[MeSH] OR “Evaluation Studies”[Publication Type] OR “observational study” OR “observational studies” OR “Comparative Study”[MeSH] OR “prospective studies”[MeSH] OR (prospective*[All Fields] AND cohort[All Fields] AND (study[All Fields] OR studies[All Fields]) OR “Longitudinal Studies” OR cohort*)	2384206
#5	Search (#3 AND #4)	14133
#6	Search (Addresses[pt] OR Autobiography[pt] OR Bibliography[pt] OR Biography[pt] OR “Case Reports”[pt] OR Congresses[pt] OR “Consensus Development Conference”[pt] OR “Consensus Development Conference, NIH”[pt] OR Dictionary[pt] OR Directory[pt] OR Editorial[pt] OR Festschrift[pt] OR “Government Publications”[pt] OR Interview[pt] OR Lectures[pt] OR “Legal Cases”[pt] OR Legislation[pt] OR Letter[pt] OR News[pt] OR “Newspaper Article”[pt] OR Overall[pt] OR “Patient Education Handout”[pt] OR “Periodical Index”[pt])	3486139
#7	Search (#5 NOT #6)	13859
#8	Search (#5 NOT #6) Filters: Publication date from 2005/01/11 to 2017/12/31	8356
#9	Search (#5 NOT #6) Filters: Publication date from 2005/01/11 to 2017/12/31; Humans	7084
#10	Search (#5 NOT #6) Filters: Publication date from 2005/01/11 to 2017/12/31; Humans; English	6660
#11	Search (“systematic review”[ti] OR “meta-analysis”[pt] OR “meta-analysis”[ti] OR “systematic literature review”[ti] OR “this systematic review”[tw] OR (“systematic review”[tiab] AND review[pt]) OR meta synthesis[ti] OR “meta synthesis”[ti] OR “cochrane database syst rev”[ta]) Filters: Publication date from 2005/01/11 to 2017/12/31; Humans; English	97194
#12	Search (#3 AND #11) Filters: Publication date from 2005/01/11 to 2017/12/31; Humans; English	660

CINAHL

Searched February 2, 2017
Results: 304
304 imported

#	Query	Limiters/Expanders	Results
S1	S1 MH “Infant Nutritional Physiological Phenomena” OR MH “Milk, Human” OR MH “Breast Feeding” OR “breast feeding” OR “human milk” OR (human AND milk) OR “breast milk” OR breastmilk OR breastfeed* OR (breast AND fed) OR breastfed OR MH “Lactation” OR lactating OR lactation	Search modes - Boolean/Phrase	29,240
S2	MH “HIV Infections” OR HIV OR MH “Fatty Acids” OR MH “Amino Acids”	Search modes - Boolean/Phrase	94,304
S3	S1 NOT S2	Search modes - Boolean/Phrase	27,700
S4	MH “Case-Control Studies” OR MH “Cohort Studies” OR MH “Epidemiologic Studies” OR MH “Cross-Sectional Studies” OR MH “Organizational Case Studies” OR MH “Cross-Over Studies” OR MH “Follow-Up Studies” OR MH “Seroepidemiologic Studies” OR “Evaluation Studies” OR “observational study” OR “observational studies” OR MH “Comparative Study” OR MH “prospective studies” OR (prospective* AND cohort AND (study OR studies)) OR “Longitudinal Studies” OR cohort*	Search modes - Boolean/Phrase	367,212
S5	S3 AND S4	Search modes - Boolean/Phrase	3,524
S6	S5	Limiters - Published Date: 20050301-20171231; English Language; Exclude MEDLINE records; Human Search modes - Boolean/Phrase	304

Cochrane Library

Searched February 2, 2017
Results:
Cochrane Reviews: 572
Other Reviews: 29
Trials: 818
Methods Studies: 1
Technology Assessments: 2
Economic Evaluations: 13
Cochrane Groups: 4

1,428 imported, 11 duplicates

ID	Search	Hits
#1	[mh "Infant Nutritional Physiological Phenomena"] or [mh "Milk, Human"] or [mh "Breast Feeding"] or "breast feeding" or "human milk" or (human and milk) or "breast milk" or breastmilk or breastfeed* or (breast and fed) or breastfed or [mh Lactation] or lactating or lactation	9214
#2	[mh "HIV Infections"] or HIV or [mh "Fatty Acids"] or [mh "Amino Acids"]	52102
#3	#1 not #2	7659
#4	[mh "Case-Control Studies"] or [mh "Cohort Studies"] or [mh "Epidemiologic Studies"] or [mh "Cross-Sectional Studies"] or [mh "Organizational Case Studies"] or [mh "Cross-Over Studies"] or [mh "Follow-Up Studies"] or [mh "Seroepidemiologic Studies"] or "Evaluation Studies" or "observational study" or "observational studies" or [mh "Comparative Study"] or [mh "prospective studies"] or (prospective* and cohort and (study or studies)) or "Longitudinal Studies" or cohort*	202770
#5	#3 and #4 Publication Year from 2005 to 2017	1439

Breastfeeding Update Searches KQ 1

PubMed

September 2, 2016, to October 12, 2017
Results:
RCTs and other study designs: 129 (Line 14)
129 imported, no duplicates
SRs: 15 (Line 19)
10 imported, 5 duplicates

Search	Query	Items found
#1	Search "Infant Nutritional Physiological Phenomena"[Mesh] OR "Milk, Human"[Mesh] OR "Breast Feeding"[Mesh] OR "breast feeding"[All Fields] OR "human milk"[All Fields] OR (human[tiab] AND milk[tiab]) OR "breast milk"[All Fields] OR breastmilk OR breastfeed* OR (breast[tiab] AND fed[tiab]) OR breastfed OR "Lactation"[Mesh] OR lactating OR lactation	134155
#2	Search (((Absenteeism[Mesh] OR "Affordable Care Act" OR ACA[tiab] OR "Baby friendly Hospital Initiative" OR BFHI OR (break*[tiab] AND (express* AND milk)) OR "Breast Milk Expression"[Mesh] OR "breast pump"[All Fields] OR "Child Day Care Centers"[Mesh] OR "Employment"[Mesh] OR (employ* AND (polic* OR program*)) OR "Health Knowledge, Attitudes, Practice"[Mesh] OR "Health Promotion"[Mesh] OR "Insurance Benefits"[Mesh] OR ("lactation consultant" OR "lactation consultants") OR "Maternal Health Services"[Mesh] OR "Mothers/psychology"[Majr] OR "Nurseries, Hospital"[Mesh] OR "Occupational Health Services"[Mesh] OR "Parental Leave"[Mesh] OR "Program Evaluation"[Mesh] OR "Salaries and Fringe Benefits"[Mesh] OR "Social Support"[Mesh] OR "Women, Working"[Mesh])))	479351
#3	Search (("baby friendly"[All Fields] OR "hospital practices"[All Fields] OR "Ten Steps"[All Fields] OR Counseling[Mesh] OR WIC OR "Women, Infants, and Children Program" OR SNAP OR "Food Stamps"[All Fields] OR "Food Assistance"[Mesh] OR "Food assistance"[All Fields] OR "Health Education"[Mesh] OR "House Calls"[Mesh] OR "Organizational Policy"[Mesh] OR "Patient Education as Topic"[Mesh] OR "Promotion of Breastfeeding Intervention Trial"[All Fields] OR PROBIT[All Fields] OR "Postnatal Care"[Mesh] OR "Social Support"[Mesh] OR 'Ten Steps to Successful Breastfeeding'[All Fields] OR "Workplace"[Mesh]))	289089
#4	Search ((("schools"[MeSH] OR "schools"[All Fields] OR "school"[All Fields] OR "universities"[MeSH] OR "universities"[All Fields] OR "university"[All Fields]) AND ("wellness programmes"[All Fields] OR "health promotion"[MeSH Terms] OR ("health"[All Fields] AND "promotion"[All Fields] OR "health promotion"[All Fields]) OR ("wellness"[All Fields] AND "programs"[All Fields]) OR "wellness programs"[All Fields]) OR ("school health services"[MeSH] OR ("school"[All Fields] AND "health"[All Fields] AND "services"[All Fields]) OR "school health services"[All Fields])) OR (("workplace"[MeSH] OR "workplace"[All Fields]) AND ("wellness programmes"[All Fields] OR "health promotion"[MeSH] OR ("health"[All Fields] AND "promotion"[All Fields]) OR "health promotion"[All Fields] OR ("wellness"[All Fields] AND "programs"[All Fields]) OR "wellness programs"[All Fields] OR programs[All Fields])))	191440
#5	Search (#2 OR #3 OR #4)	765688
#6	Search (#1 AND #5)	12574
#7	Search ((((randomized[title/abstract] OR randomised[title/abstract]) AND controlled[title/abstract] AND trial[title/abstract]) OR (controlled[title/abstract] AND trial[title/abstract]) OR "controlled clinical trial"[publication type] OR "Randomized Controlled Trial"[Publication Type] OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]))	687174
#8	Search (#6 AND #7)	892
#9	Search ("Cohort Studies"[Mesh] OR "Epidemiologic Studies"[Mesh] OR "Follow-up Studies"[Mesh] OR "prospective cohort" OR "prospective studies"[MeSH] OR (prospective*[All Fields] AND cohort[All Fields] AND (study[All Fields] OR studies[All Fields]))	2085344
#10	Search (#6 AND #9)	2400
#11	Search (#8 OR #10)	3055
#12	Search (#8 OR #10) Filters: Publication date from 2016/09/02	169
#13	Search (#8 OR #10) Filters: Publication date from 2016/09/02; Humans	131
#14	Search (#8 OR #10) Filters: Publication date from 2016/09/02; Humans; English	**129**

Search	Query	Items found
#15	Search ("systematic review"[ti] OR "meta-analysis"[pt] OR "meta-analysis"[ti] OR "systematic literature review"[ti] OR "this systematic review"[tw] OR ("systematic review"[tiab] AND review[pt]) OR meta synthesis[ti] OR "meta synthesis"[ti] OR "cochrane database syst rev"[ta])	164355
#16	Search (#6 AND #15)	241
#17	Search (#6 AND #15) Filters: Publication date from 2016/09/02	25
#18	Search (#6 AND #15) Filters: Publication date from 2016/09/02; Humans	15
#19	Search (#6 AND #15) Filters: Publication date from 2016/09/02; Humans; English	**15**

CINAHL
KQ 1
Searched October 12, 2017
Limited to September 2016 to present
Excluded Medline citations
Results: 37
37 imported, no duplicates

#	Query	Limiters/Expanders	Results
S1	MH "Infant Nutritional Physiological Phenomena" OR MH "Milk, Human" OR MH "Breast Feeding" OR "breast feeding" OR "human milk" OR (human AND milk) OR "breast milk" OR breastmilk OR breastfeed* OR (breast AND fed) OR breastfed OR MH "Lactation" OR lactating OR lactation	Search modes - Boolean/Phrase	31,657
S2	(((MH Absenteeism OR "Affordable Care Act" OR ACA OR "Baby friendly Hospital Initiative" OR BFHI OR (break* AND (express* AND milk)) OR MH "Breast Milk Expression" OR "breast pump" OR MH "Child Day Care Centers" OR MH "Employment" OR (employ* AND (polic* OR program*)) OR MH "Health Knowledge, Attitudes, Practice" OR MH "Health Promotion" OR MH "Insurance Benefits" OR ("lactation consultant" OR "lactation consultants") OR MH "Maternal Health Services" OR "Mothers/psychology" OR MH "Nurseries, Hospital" OR MH "Occupational Health Services" OR MH "Parental Leave" OR MH "Program Evaluation" OR MH "Salaries and Fringe Benefits" OR MH "Social Support" OR MH "Women, Working")))	Search modes - Boolean/Phrase	159,128
S3	"baby friendly" OR "hospital practices" OR "Ten Steps" OR MH Counseling OR WIC OR "Women, Infants, and Children Program" OR SNAP OR "Food Stamps" OR MH "Food Assistance" OR "Food assistance" OR MH "Health Education" OR MH "House Calls" OR MH "Organizational Policy" OR MH "Patient Education as Topic" OR "Promotion of Breastfeeding Intervention Trial" OR PROBIT OR MH "Postnatal Care" OR MH "Social Support" OR "Ten Steps to Successful Breastfeeding" OR MH "Workplace"	Search modes - Boolean/Phrase	49,828

#	Query	Limiters/Expanders	Results
S4	((MH “schools” OR “schools”[All Fields] OR “school”[All Fields] OR MH “universities” OR “universities”[All Fields] OR “university”[All Fields]) AND (“wellness programmes”[All Fields] OR MH “health promotion” OR (“health”[All Fields] AND “promotion”[All Fields] OR “health promotion”[All Fields]) OR (“wellness”[All Fields] AND “programs”[All Fields]) OR “wellness programs”[All Fields]) OR (MH “school health services” OR (“school”[All Fields] AND “health”[All Fields] AND “services”[All Fields]) OR “school health services”[All Fields])) OR ((MH “workplace” OR “workplace”[All Fields]) AND (“wellness programmes”[All Fields] OR MH “health promotion” OR (“health”[All Fields] AND “promotion”[All Fields]) OR “health promotion”[All Fields] OR (“wellness”[All Fields] AND “programs”[All Fields]) OR “wellness programs”[All Fields] OR programs[All Fields]))	Search modes - Boolean/Phrase	8,254
S5	S2 OR S3 OR S4	Search modes - Boolean/Phrase	206,321
S6	S1 AND S5	Search modes - Boolean/Phrase	4,497
S7	(randomized OR randomised) AND controlled AND trial) OR (controlled AND trial) OR “controlled clinical trial” OR “Randomized Controlled Trial” OR MH “Single-Blind Method” OR MH “Double-Blind Method” OR MH “Random Allocation”	Search modes - Boolean/Phrase	128,349
S8	S6 AND S7	Search modes - Boolean/Phrase	211
S9	MH “Cohort Studies” OR MH “Epidemiologic Studies” OR MH “Follow-up Studies” OR “prospective cohort” OR MH “prospective studies” OR (prospective* AND cohort AND (study OR studies))	Search modes - Boolean/Phrase	329,266
S10	S6 AND S9	Search modes - Boolean/Phrase	344
S11	S8 OR S10	Limiters - Published Date: 20160901-20171231; English Language; Exclude MEDLINE records Search modes - Boolean/Phrase	**37**

KQ 1

Cochrane Library

Total results: 123; all imported, no duplicates
Cochrane Reviews: 101; all imported, no duplicates
Other Reviews: 0;
Trials: 21; all imported, no duplicates
Methods Studies: 0
Technology Assessments: 0
Economic Evaluations: 0
Cochrane Groups: 1; all imported, no duplicates

ID	Search	Hits
#1	[mh "Infant Nutritional Physiological Phenomena"] or [mh "Milk, Human"] or [mh "Breast Feeding"] or "breast feeding" or "human milk" or (human and milk) or "breast milk" or breastmilk or breastfeed* or (breast and fed) or breastfed or [mh Lactation] or lactating or lactation	10043
#2	[mh Absenteeism] or "Affordable Care Act" or ACA or "Baby friendly Hospital Initiative" or BFHI or (break* and (express* and milk)) or [mh "Breast Milk Expression"] or "breast pump" or [mh "Child Day Care Centers"] or [mh Employment] or (employ* and (polic* or program*)) or [mh "Health Knowledge, Attitudes, Practice"] or [mh "Health Promotion"] or [mh "Insurance Benefits"] or ("lactation consultant" or "lactation consultants") or [mh "Maternal Health Services"] or [mh Mothers/psychology] or [mh "Nurseries, Hospital"] or [mh "Occupational Health Services"] or [mh "Parental Leave"] or [mh "Program Evaluation"] or [mh "Salaries and Fringe Benefits"] or [mh "Social Support"] or [mh "Women, Working"]	27683
#3	"baby friendly" or "hospital practices" or "Ten Steps" or [mh Counseling] or WIC or "Women, Infants, and Children Program" or SNAP or "Food Stamps" or [mh "Food Assistance"] or "Food assistance" or [mh "Health Education"] or [mh "House Calls"] or [mh "Organizational Policy"] or [mh "Patient Education as Topic"] or "Promotion of Breastfeeding Intervention Trial" or PROBIT or [mh "Postnatal Care"] or [mh "Social Support"] or "Ten Steps to Successful Breastfeeding" or [mh Workplace]	20423
#4	((([mh schools] or "schools" or "school" or [mh universities] or "universities" or "university") and ("wellness programmes" or [mh "health promotion"] or ("health" and "promotion") or "health promotion" or ("wellness" and "programs") or "wellness programs")) or ([mh "school health services"] or ("school" and "health" and "services") or "school health services")) or ((([mh workplace] or "workplace") and ("wellness programmes" or [mh "health promotion"] or ("health" and "promotion") or "health promotion" or ("wellness" and "programs") or "wellness programs" or programs))	11032
#5	#2 or #3 or #4	43283
#6	#1 and #5	2075
#7	((controlled:ti or controlled:ab) and (trial:ti or trial:ab)) or "controlled clinical trial" or "randomized controlled trial":pt or "randomized controlled trial as topic":pt or "single-blind method":pt or "double-blind method":pt or "random allocation":pt	695356
#8	#6 and #7	1701
#9	[mh "Cohort Studies"] or [mh "Epidemiologic Studies"] or [mh "Follow-up Studies"] or "prospective cohort" or [mh "prospective studies"] or (prospective* and cohort and (study or studies))	154536
#10	#6 and #9 Publication Year from 2016 to 2017	**123**

Breastfeeding Update Searches KQ 2

PubMed
KQ 2
Searched October 12, 2017
Results:
Case control studies and other study types: 405 (Line 10)
315 imported, 90 duplicates
SRs: 53 (Line 12)
32 imported, 21 duplicates

Search	Query	Items found
#1	Search ((“Infant Nutritional Physiological Phenomena”[Mesh] OR “Milk, Human”[Mesh] OR “Breast Feeding”[Mesh] OR “breast feeding”[All Fields] OR “human milk”[All Fields] OR (human[tiab] AND milk[tiab]) OR “breast milk”[All Fields] OR breastmilk OR breastfeed* OR (breast[tiab] AND fed[tiab]) OR breastfed OR “Lactation”[Mesh] OR lactating OR lactation))	134155
#2	Search (“HIV Infections”[Mesh] OR HIV OR “Fatty Acids”[Majr] OR “Amino Acids”[Majr])	957218
#3	Search (#1 NOT #2)	124091
#4	Search (“Case-Control Studies”[MeSH] OR “Cohort Studies”[MeSH] OR “Epidemiologic Studies”[MeSH] OR “Cross-Sectional Studies”[MeSH] OR “Organizational Case Studies”[MeSH] OR “Cross-Over Studies”[MeSH] OR “Follow-Up Studies”[MeSH] OR “Seroepidemiologic Studies”[MeSH] OR “Evaluation Studies”[Publication Type] OR “observational study” OR “observational studies” OR “Comparative Study”[MeSH] OR “prospective studies”[MeSH] OR (prospective*[All Fields] AND cohort[All Fields] AND (study[All Fields] OR studies[All Fields]) OR “Longitudinal Studies” OR cohort*)	2513165
#5	Search (#3 AND #4)	14952
#6	Search (Addresses[pt] OR Autobiography[pt] OR Bibliography[pt] OR Biography[pt] OR “Case Reports”[pt] OR Congresses[pt] OR “Consensus Development Conference”[pt] OR “Consensus Development Conference, NIH”[pt] OR Dictionary[pt] OR Directory[pt] OR Editorial[pt] OR Festschrift[pt] OR “Government Publications”[pt] OR Interview[pt] OR Lectures[pt] OR “Legal Cases”[pt] OR Legislation[pt] OR Letter[pt] OR News[pt] OR “Newspaper Article”[pt] OR Overall[pt] OR “Patient Education Handout”[pt] OR “Periodical Index”[pt])	3567609
#7	Search (#5 NOT #6)	14672
#8	Search (#5 NOT #6) Filters: Publication date from 2016/09/02	822
#9	Search (#5 NOT #6) Filters: Publication date from 2016/09/02; Humans	421
#10	Search (#5 NOT #6) Filters: Publication date from 2016/09/02; Humans; English	**405**
#11	Search (“systematic review”[ti] OR “meta-analysis”[pt] OR “meta-analysis”[ti] OR “systematic literature review”[ti] OR “this systematic review”[tw] OR (“systematic review”[tiab] AND review[pt]) OR meta synthesis[ti] OR “meta synthesis”[ti] OR “cochrane database syst rev”[ta]) Filters: Publication date from 2016/09/02; Humans; English	9081
#12	Search (#3 AND #11) Filters: Publication date from 2016/09/02; Humans; English	**53**

CINAHL
KQ 2
Searched October 12, 2017
Results: 177
177 imported

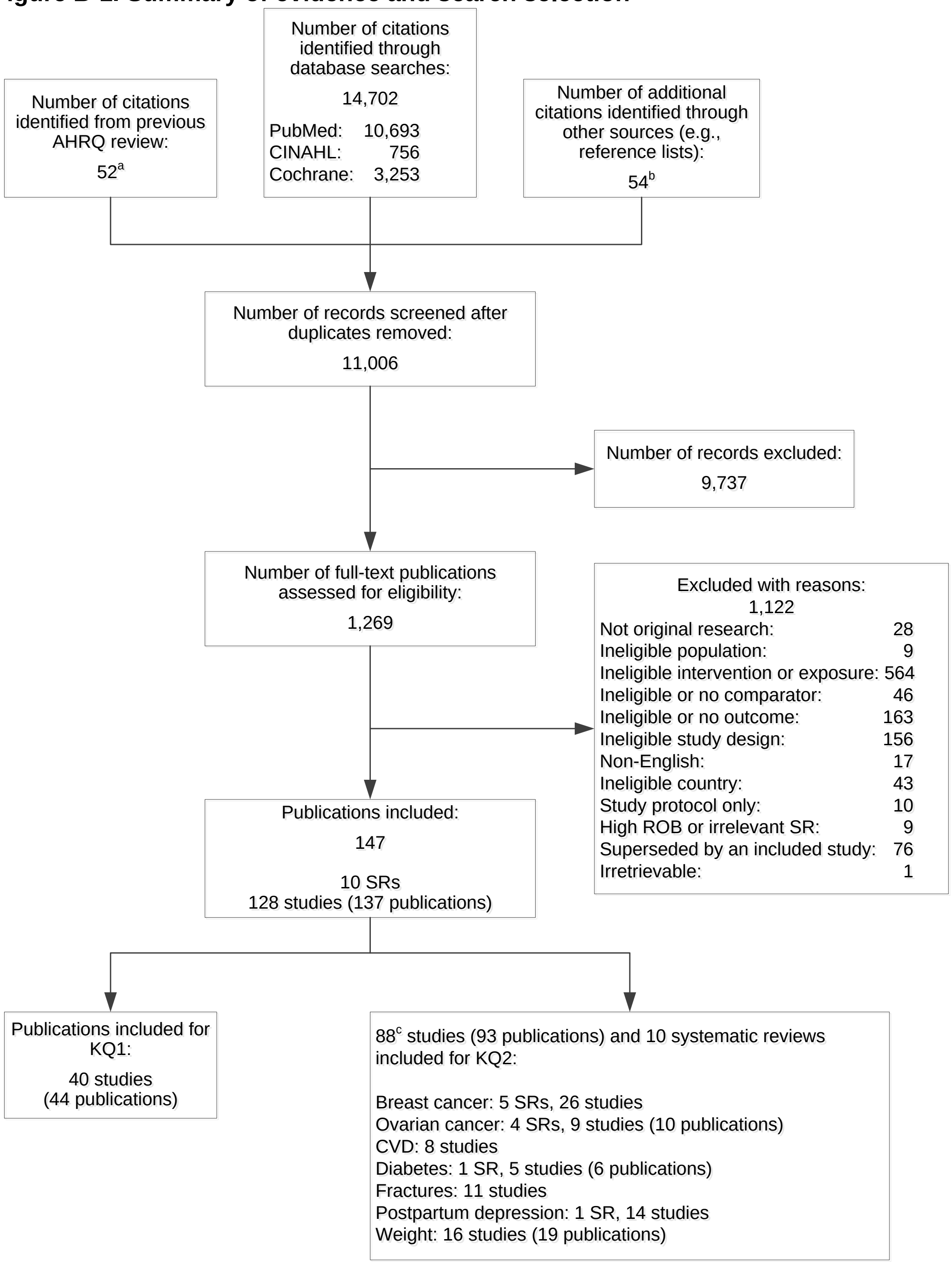
#	Query	Limiters/Expanders	Results
S1	MH “Infant Nutritional Physiological Phenomena” OR MH “Milk, Human” OR MH “Breast Feeding” OR “breast feeding” OR “human milk” OR (human AND milk) OR “breast milk” OR breastmilk OR breastfeed* OR (breast AND fed) OR breastfed OR MH “Lactation” OR lactating OR lactation	Search modes - Boolean/Phrase	31,679
S2	MH “HIV Infections” OR HIV OR MH “Fatty Acids” OR MH “Amino Acids”	Search modes - Boolean/Phrase	99,823
S3	S1 NOT S2	Search modes - Boolean/Phrase	30,014
S4	MH “Case-Control Studies” OR MH “Cohort Studies” OR MH “Epidemiologic Studies” OR MH “Cross-Sectional Studies” OR MH “Organizational Case Studies” OR MH “Cross-Over Studies” OR MH “Follow-Up Studies” OR MH “Seroepidemiologic Studies” OR “Evaluation Studies” OR “observational study” OR “observational studies” OR MH “Comparative Study” OR MH “prospective studies” OR (prospective* AND cohort AND (study OR studies)) OR “Longitudinal Studies” OR cohort*	Search modes - Boolean/Phrase	403,999
S5	S3 AND S4	Limiters - English Language Search modes - Boolean/Phrase	3,886
S6	S5	Limiters - Published Date: 20160901-20171231; English Language; Exclude MEDLINE records; Human Search modes - Boolean/Phrase	177

Cochrane Library
KQ 2
Searched October 12, 2017
Results: Total: 332
Cochrane Reviews: 175; 118 imported, 58 duplicates
Other Reviews: 0
Trials: 156; 131 imported, 25 duplicates
Methods Studies: 0
Technology Assessments: 0
Economic Evaluations: 0
Cochrane Groups: 1; 1 imported, no duplicates
250 imported, 83 duplicates

ID	Search	Hits
#1	[mh "Infant Nutritional Physiological Phenomena"] or [mh "Milk, Human"] or [mh "Breast Feeding"] or "breast feeding" or "human milk" or (human and milk) or "breast milk" or breastmilk or breastfeed* or (breast and fed) or breastfed or [mh Lactation] or lactating or lactation	10043
#2	[mh "HIV Infections"] or HIV or [mh "Fatty Acids"] or [mh "Amino Acids"]	54286
#3	#1 not #2	8401
#4	[mh "Case-Control Studies"] or [mh "Cohort Studies"] or [mh "Epidemiologic Studies"] or [mh "Cross-Sectional Studies"] or [mh "Organizational Case Studies"] or [mh "Cross-Over Studies"] or [mh "Follow-Up Studies"] or [mh "Seroepidemiologic Studies"] or "Evaluation Studies" or "observational study" or "observational studies" or [mh "Comparative Study"] or [mh "prospective studies"] or (prospective* and cohort and (study or studies)) or "Longitudinal Studies" or cohort*	219736
#5	#3 and #4 Publication Year from 2005 to 2017	**332**

Appendix B. PRISMA

Figure B-1. Summary of evidence and search selection



[a] This represents the number of studies relevant to maternal health only (not infant health).[1]

[b] Sources include reference lists of reviews and included studies, ClinicalTrials.gov, the World Health Organization International Clinical Trials Registry Platform, and suggestions from expert reviewers and public commentators.

[c] 1 systematic review and 1 individual study cover two eligible outcomes each: (breast and ovarian cancer,[2] CVD and diabetes,[3] respectively)

AHRQ = Agency for Healthcare Research and Quality; CVD = cardiovascular disease; KQ = Key Question; RCT = randomized controlled trial; ROB = risk of bias; SR = systematic review.

Appendix C. Relevance and Risk of Bias Assessments

Table C-1. Relevance assessment for systematic reviews evaluating an eligible KQ 1 outcome

Author, Year	KQ 1 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include studies from countries ranked "very high"[a] and "high"[b] development?	Did the review focus on the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of BF?	Did the review focus on RCTs, CCTs, prospective cohort studies with concurrent control groups, and case-control studies?[c]	Did the review focus only on relevant health outcomes[d]?	Overall, is the review directly relevant, providing an adequate answer to KQ 1 (for one or more outcome categories)?	Additional Comments about Relevance
Perez-Escamilla, 2017[4]	Breastfeeding	Yes; MEDLINE, Embase, Global Health, CINAHL, PUBMED and Web of Science through 2012	No; included low, middle, and high-income countries	Yes; review is focused on studies evaluating full or partial implementation of BFHI	No; RCTs, quasi-experimental designs (with or without a parallel reference group), prospective studies cross-sectional studies included	No; included health outcomes for children in addition to measure of breastfeeding initiation and duration	No	At least 20 of the 58 included studies were described as "cross-sectional or retrospective" and do not appear to meet our eligibility criteria. Other observational studies described as prospective do not provide multiple pre- and post- implementation measures of breastfeeding. Many studies were conducted in ineligible country settings.

[a]Very high: Andorra, Argentina, Australia, Austria, Bahrain, Belgium, Brunei Darussalam, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, China (SAR), Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan, United Arab Emirates, United Kingdom, United States

[b]High: Albania, Algeria, Antigua and Barbuda, Armenia, Azerbaijan, Bahamas, Barbados, Belarus, Belize, Bosnia and Herzegovina, Brazil, Bulgaria, China, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, Fiji, Georgia, Grenada, Iran (Islamic Republic of), Jamaica, Jordan, Kazakhstan, Lebanon, Libya, Malaysia, Maldives, Mauritius, Mexico, Mongolia, Oman, Palau, Panama, Peru, Romania, Russian Federation, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Samoa, Serbia, Seychelles, Sri Lanka, Suriname, Thailand, Tonga, Trinidad and Tobago, Tunisia, Turkey, Ukraine, Uruguay, Venezuela (Bolivarian Republic of), The former Yugoslav Republic of Macedonia

[c] For studies assessing policy or system-level interventions, pre-post studies with repeated outcome measures before and after the intervention are also eligible studies.

[d]Rates of breastfeeding initiation, duration, and exclusivity of breastfeeding; harms of interventions (e.g., guilt about not breastfeeding, workplace discrimination, and other reported harms).

BF = breastfeeding; BFHI = Baby-Friendly Hospital Initiative; CCT = controlled clinical trial; KQ = Key Question; RCT = randomized controlled trial.

Table C-2. KQ 1 risk of bias assessment: Randomized controlled trials, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of randomization adequate?	2. Was allocation concealment adequate?	3. Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Coutinho, 2005[5]	Low	NA	Yes	Yes	Yes	Low	NA
Ekstrom, 2012;[6] Ekstrom, 2014[7]	Some concerns	See individual domains. Authors report on a number of outcomes and subgroups, but the denominators for calculations are not always apparent.	No information	No information	Probably yes	Some concerns	Unclear what randomization methods were used and whether they were adequate given the small sample size.
Hayes, 2008[8]	Some concerns	No clear definition of BF reported, inadequate reporting on design elements and differences at baseline raise concerns about the success of randomization.	No Information	No Information	No Information	Uncertain	No information on how groups were randomized and there are several differences between arms.
Hoddinott, 2009[9]	Some concerns	Potential for co-interventions to explain the results.	Yes	Probably yes	No	Uncertain	No information on how groups were randomized and there are several differences between arms.
Kools, 2005[10]	Some concerns	Potential for co-interventions to explain the results.	Probably no	Probably no	Probably yes	Some concerns	Coin flip for randomization, and no evidence of allocation concealment, but baseline characteristics similar.
Kramer, 2001;[11] Yang, 2014[12]	Some concerns	See individual domains; bias related to missing data and potential deviations from intended intervention.[11] Differential attrition, failure to address missing data, outcomes not prespecified.[12]	Yes;[11] Probably yes[12]	NA;[11] Probably yes[12]	Yes	Low	Sites (clusters) were stratified based on important characteristics (e.g., urban vs. rural, etc.) prior to randomization. Final determination of group assignment (after individual sites were randomized) was based on a coin toss.
Kronborg, 2007[13]	Some concerns	No blinding; fidelity and sources of potential contamination are unclear; risk of measurement bias (home-visitors assessed and recorded outcomes, unclear how exclusive BF was defined and measured).	Probably yes	Probably no	Yes	Low	Maternal characteristics were balanced at baseline (shown in online appendix).

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of randomization adequate?	2. Was allocation concealment adequate?	3. Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
MacLachlan, 2016;[14] Cramer, 2017[15]	Some concerns	Differences between arms, differential and high overall attrition, and failure to address missing data.	Probably yes	Probably yes	Probably no	Some concerns	Allocation of clusters took place at a state-wide forum; an audience member chose opaque envelopes with cluster assignments. The proportion of Australian-born women was unequal across the arms.
Morrow, 1999[16]	Low	NA	Yes	No information	Yes	Low	NA
Nilsson, 2017[17]	Some Concerns	High overall attrition and unknown fidelity/possible contamination are sources of potential bias.	Yes	NA	Yes	Low	NA
Reeder, 2014[18]	Some concerns	Risk of selection bias; moderate rates of missing data (21% overall) and unclear handling of missing data.	No information	No information	Yes	Some concerns	Of 36 Oregon LWAs, 6 expressed interest in the study (5 were selected). Only women who indicated an intention to breastfeed or were undecided on their first WIC appointment were invited to participate.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of randomization adequate?	2. Was allocation concealment adequate?	3. Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Senarath, 2007[19]	High	High risk of selection bias (no description of randomization and women in intervention and control hospitals differed in ways that could affect rates of BF) and measurement bias.	No Information	No Information	No	High	Group characteristics differed by ethnicity, employment status, and parity; there also appear to be important baseline differences in hospital practices across intervention and control sites.
Taddei, 2000[20]	Some concerns	Unclear randomization and group selection; attrition is 16-19% overall, with no comment on differential attrition and no methods used to address missing data.	No information	Probably yes	No information	Uncertain	Randomization and allocation concealment not described; groups of women were similar at baseline, but there is no description on whether hospitals or staff were similar (intervention focuses on staff training).
Wan, 2011[21]	Some concerns	Unclear whether outcome assessors were blinded; fidelity to intervention not assessed.	No information	No information	Yes	Low	NA
Washio, 2017[22]	Some concerns	No blinding of participants or staff; women in the control group also received a small financial incentive to participate which may have affected reports of BF.	Yes	No information	Yes	Low	NA

BF = breastfeeding; KQ = Key Question; LWAs = local WIC agencies; NA = not applicable.

Table C-3. KQ 1 risk of bias assessment: Randomized controlled trials, part 2

Author, Year	4. What was the overall attrition and attrition by group?	5. Did the study have low attrition?	6. Are the proportion of participants and reasons for missing data similar across interventions?	7. For BF outcomes, was ITT analysis used?	8. Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Coutinho, 2005[5]	14/175 vs. 6/175=5%	Yes	Yes	Yes	Probably no	Low	Analysis appears to be focused on completers; given low rate of missing data, this publication was not downgraded based on lack of statistical methods to account for missing data.
Ekstrom, 2012;[6] Ekstrom, 2014[7]	3 days: G1: 17% (100-172/206) G2: 9% (100-148/162) G3: 7% (100-160/172) 3 months: G1: 16% (100-145/172) G2: 22% (100-126/148) G3: 17% (100-132/160) 9 months: G1: 24% (100-131/172) G2: 22% (100-116/148) G3: 22% (100-125/160)	Probably no	Probably yes	Probably yes	Probably no	Some concerns	It seems as if consent happened after randomization at 3 days postpartum; attrition calculations are based on the women who responded to the first questionnaire/signed consent. Authors reported that there were no significant differences between women who answered all 3 questionnaires and those who only answered the first. Authors do not specify ITT analyses, but given cluster RCT design, it seems likely.
Hayes, 2008[8]	NR	Yes	No information	Yes	Yes	Low	NA
Hoddinott, 2009[9]	NA	Yes	NA	NA	NA	Low	NA

Author, Year	4. What was the overall attrition and attrition by group?	5. Did the study have low attrition?	6. Are the proportion of participants and reasons for missing data similar across interventions?	7. For BF outcomes, was ITT analysis used?	8. Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Kools, 2005[10]	T1 (1 month postpartum) G1: 91% (371/408) G2: 88% (330/373) T2 (3 months postpartum) G1: 90% (368/408) G2: 88% (330/373) T3 (6 months postpartum) G1: 89% (364/408) G2: 86% (319/373)	Yes	No information	No	NA	Low	NA
Kramer, 2001;[11] Yang, 2014[12]	Sites: 6% (16/17 vs. 15/17 sites) Women: (8547/8865)-(7895/8930)=8%	Yes	No	Probably yes ;[11] No[12]	No information	Some concerns	One site (in the intervention group) was excluded owing to falsification of outcome data; this accounts for most of attrition. Analyses did not account for missing data.
Kronborg, 2007[13]	0%	Yes	Yes	Yes	NA	Low	No attrition for clusters (municipalities or health visitors). For mothers, 9% who were potentially eligible were not enrolled (declined or did not breast feed); of those enrolled, only 2 women had missing information on breastfeeding status and were not enrolled in the final analysis.

Author, Year	4. What was the overall attrition and attrition by group?	5. Did the study have low attrition?	6. Are the proportion of participants and reasons for missing data similar across interventions?	7. For BF outcomes, was ITT analysis used?	8. Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
MacLachlan, 2016;[14] Cramer, 2017[15]	G1: Comparison arm: 30.0% ([3,449-2,414]/3,449) G2: Home visit arm: 31.6% ([3,335-2,281]/23,335) G3: Home visit plus drop-in center arm: 18.9% ([2,891-2,344]/2,891)	No	No information	No	No	Some concerns	Relatively high overall attrition, and differential attrition, no controls for loss to followup.
Morrow, 1999[16]	G1: 2/44=4.5% G2: 2/52=3.8% G3: 1/34=2.9%	Yes	Yes	Yes	Yes	Low	NA
Nilsson, 2017[17]	For women who agreed to participate, attrition was 31% at 1 month and 44% at 6 months.	No	No information	Yes	Yes	Some concerns	Overall attrition is high, however authors conducted an ITT analysis using imputation of missing data.

Author, Year	4. What was the overall attrition and attrition by group?	5. Did the study have low attrition?	6. Are the proportion of participants and reasons for missing data similar across interventions?	7. For BF outcomes, was ITT analysis used?	8. Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Reeder, 2014[18]	G1: 25% G2: 14%	No	No information	No	No information	Some concerns	Women from one local WIC agency (n=179) were excluded mid-study when a peer counselor left and could not be replaced. These women are not accounted for in attrition calculations. Attrition as noted in the flow diagram is low; however, authors state later that up to 20% of participants were missing data on BF exclusivity. Unclear whether main analyses account for missing data.
Senarath, 2007[19]	Unclear	Probably yes	No information	Yes	NA	Some concerns	The number of mother-newborn pairs enrolled was based on sample size calculations; how sample was selected is not clear. Authors note that <1% of sample refused to be interviewed.

Author, Year	4. What was the overall attrition and attrition by group?	5. Did the study have low attrition?	6. Are the proportion of participants and reasons for missing data similar across interventions?	7. For BF outcomes, was ITT analysis used?	8. Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Taddei, 2000[20]	NR	Probably yes	No information	Yes	No	Some concerns	Rates of attrition are not described, however, authors make a case for why attrition is likely to be similar in intervention/control hospitals.
Wan, 2011[21]	0%	Yes	NA	NA	NA	Low	NA
Washio, 2017[22]	3%	Yes	NA	Yes	NA	Low	No blinding of participants or staff.

BF = breastfeeding; G = group; ITT = intent-to-treat; KQ = Key Question; NA = not applicable; NR = not reported; RCT = randomized controlled trial; T = treatment; WIC = Women, Infants, and Children.

Table C-4. KQ 1 risk of bias assessment: Randomized controlled trials, part 3

Author, Year	9. Were participants unaware of their intervention status?	10. Were the trial personnel and clinicians unaware of the intervention status of participants?	11. Were outcome assessors unaware of the intervention status of participants?	12. Was intervention fidelity adequate?	13. Were cross-overs or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Coutinho, 2005[5]	Probably no	Probably no	Probably yes	No information	Probably yes	Some concerns	Participants and clinicians unlikely to be blinded based on intervention type (systems-level, home visiting intervention); per authors, outcome assessors were blinded from intervention status. Fidelity to intervention unclear.
Ekstrom, 2012;[6] Ekstrom, 2014[7]	Yes	NA	Probably yes	No information	No information	Some concerns	The midwife in the hospital likely knew of the intervention status of the hospital; the child health nurse from the community health center may have been blinded to intervention status.
Hayes, 2008[8]	No	No	No information	No information	No information	Uncertain	None
Hoddinott, 2009[9]	No information	No	Yes	No information	No	Some concerns	Both arms had some BF certified hospitals, and results were different in these hospitals, unclear how the results overall were influenced by the potential competing intervention.
Kools, 2005[10]	No	No	No information	Probably no	Probably no	Some concerns	Potential for secular changes in both regions, on participant and organizational behavior.

Author, Year	9. Were participants unaware of their intervention status?	10. Were the trial personnel and clinicians unaware of the intervention status of participants?	11. Were outcome assessors unaware of the intervention status of participants?	12. Was intervention fidelity adequate?	13. Were cross-overs or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Kramer, 2001;[11] Yang, 2014[12]	Probably no;[11] No[12]	No	Probably no;[11] No information[12]	Probably yes;[11] No information[12]	No information	Some concerns	Participants, health professionals not blinded owing to the nature of the intervention. Given that one intervention site falsified outcome data and was excluded, outcome assessors were unlikely to be blinded. Insufficient information on intervention fidelity.
Kronborg, 2007[13]	No information	No	No	No information	Probably yes	Some concerns	No blinding of participants, staff or outcome assessors; home-visiting nurses assessed outcomes during mother interviews. Fidelity and potential contamination from other programs/polices unclear.
MacLachlan, 2016;[14] Cramer, 2017[15]	No	No	Yes	no	Uncertain because no information	Some concerns	The drop-in aspect of the home visit+drop-in intervention did not succeed in terms of implementation, and were “poorly attended, with one attendance per session on average, and in two, peer supporters to staff the drop-in centers could not be recruited.” As a result the two active intervention arms are likely not different from one another.

Author, Year	9. Were participants unaware of their intervention status?	10. Were the trial personnel and clinicians unaware of the intervention status of participants?	11. Were outcome assessors unaware of the intervention status of participants?	12. Was intervention fidelity adequate?	13. Were cross-overs or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Morrow, 1999[16]	No	No	No	No information	Probably no	Low	NA
Nilsson, 2017[17]	Probably yes	No	No information	No information	Probably yes	Some concerns	Mothers were not blinded (owing to the nature of the intervention); however, they were not informed whether their facility was randomized to the intervention or usual care. Health care providers at reference facilities were not informed about the content of the intervention (providers at intervention facilities participated in development of intervention). No assessment of intervention fidelity.
Reeder, 2014[18]	No	No	No information	Probably no	Probably yes	Some concerns	Fidelity was a concern, leading to no difference in contacts among those in the high and low frequency groups. These groups were analyzed together. No assessment was made of the type/quality of support provided to women and whether this differed across peer counselors. No description of the type of BF support/services received outside of WIC.

Author, Year	9. Were participants unaware of their intervention status?	10. Were the trial personnel and clinicians unaware of the intervention status of participants?	11. Were outcome assessors unaware of the intervention status of participants?	12. Was intervention fidelity adequate?	13. Were cross-overs or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Senarath, 2007[19]	NA	NA	No information	No information	Probably yes	Some concerns	Owing to design, contamination is not a major concern. Staff would be aware of intervention status (intervention focuses on staff training); unclear if outcome assessors were aware of status; fidelity to training intervention is not discussed but may not be a major concern.
Taddei, 2000[20]	NA	NA	No information	Probably yes	Probably yes	Some concerns	Owing to cluster-randomization, contamination and crossovers are not a concern. Intervention is focused on staff training, so blinding of staff/participants is not a major concern. Unclear whether outcome assessors were aware of intervention status.
Wan, 2011[21]	No	No	No information	No information	Probably yes	Some concerns	Fidelity was not described; unclear if outcome assessors were blinded.
Washio, 2017[22]	No	No	No	No information	No information	Some concerns	No blinding of participants or staff; control group also received some compensation for participation ($25 per visit, maximum of $100) which may have led to increased rates of BF among controls.

BF = breastfeeding; KQ = Key Question; NA = not applicable; WIC = Women, Infants, and Children.

Table C-5. KQ 1 risk of bias assessment: Randomized controlled trials, part 4

Author, Year	14. Were BF outcomes (e.g., duration, initiation, exclusivity) adequately described, prespecified, valid, and reliable?	15. Were similar techniques used among groups to ascertain BF outcomes?	Bias arising from measurement of breastfeeding outcomes?	Comments
Coutinho, 2005[5]	Yes	Yes	Low	NA
Ekstrom, 2012;[6] Ekstrom, 2014[7]	Probably yes	Yes	Some concerns	Authors provided definitions of outcomes, but it was not always clear what the denominators were in their calculations for the different outcomes.
Hayes, 2008[8]	No	Yes	Some concerns	BF measurement not clear
Hoddinott, 2009[9]	Yes	Yes	Low	NA
Kools, 2005[10]	Yes	Yes	Low	NA
Kramer, 2001;[11] Yang, 2014[12]	Yes;[11] No[12]	Probably yes;[11] Yes[12]	Low;[11] Uncertain because no information[12]	Yang uses discontinuation of exclusive BF (i.e., introducing any foods other than breast milk) before 3 months and discontinuation of BF to any degree (weaning) before 12 months. Kramer uses other outcomes. Neither describes which outcomes were prespecified.
Kronborg, 2007[13]	Probably yes	Probably yes	Some concerns	Outcome was exclusive breastfeeding, but little details are given in terms of how this was defined and operationalized.
MacLachlan, 2016;[14] Cramer, 2017[15]	Yes	Yes	Low	The measure was “any breastfeeding.”
Morrow, 1999[16]	Yes	Yes	Low	NA
Nilsson, 2017[17]	Probably yes	Yes	Low	NA
Reeder, 2014[18]	Probably yes	Probably yes	Some concerns	Outcomes assessed during regular WIC appointments (which did not differ by groups). Authors note lower rates of missing data among intervention participants than controls and theorize that having peer support may have led to women staying engaged in WIC for longer periods of time and/or keeping appointments.
Senarath, 2007[19]	No information	Yes	Some concerns	Authors note that “breastfeeding” was a practice that was measured, but do not indicate the type of measure/question used. Results include BF within the first half hour and exclusive BF (no note about how exclusivity was defined).
Taddei, 2000[20]	Probably yes	Yes	Low	A random sample of interviews on feeding practices were repeated by a second field supervisor to check for reliability.
Wan, 2011[21]	Yes	Probably yes	Low	NA
Washio, 2017[22]	Yes	Probably yes	Low	NA

BF = breastfeeding; KQ = Key Question; NA = not applicable; WIC = Women, Infants, and Children.

Table C-6. KQ 1 risk of bias assessment: Randomized controlled trials, part 5

Author, Year	16. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias arising from selection of reported results?	Comments
Coutinho, 2005[5]	Yes	Low	NA
Ekstrom, 2012;[6] Ekstrom, 2014[7]	Probably yes	Low	NA
Hayes, 2008[8]	No	Low	NA
Hoddinott, 2009[9]	No	Low	NA
Kools, 2005[10]	Yes	Low	NA
Kramer, 2001;[11] Yang, 2014[12]	Yes;[11] Probably yes[12]	Low;[11] Some concerns[12]	Unclear whether the timing of the reported outcome was determined a priori or was the result of selective reporting.
Kronborg, 2007[13]	Probably no	Low	NA
MacLachlan, 2016;[14] Cramer, 2017[15]	Low	Low	NA
Morrow, 1999[16]	No	Low	NA
Nilsson, 2017[17]	Yes	Low	NA
Reeder, 2014[18]	Probably yes	Low	NA
Senarath, 2007[19]	Probably yes	Low	NA
Taddei, 2000[20]	Yes	Low	NA
Wan, 2011[21]	Probably yes	Low	NA
Washio, 2017[22]	Yes	Low	NA

KQ = Key Question; NA = not applicable.

Table C-7. KQ 1 risk of bias assessment: Nonrandomized trials and observational studies, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Abolyan, 2006[23]	Some concerns	Although selection bias is a concern, baseline characteristics of women were very similar and unlikely to influence results. For data on BF prevalence over time, determining intervention status is a potential risk of bias. Some hospitals may have started changing maternity practice before becoming BF certified.	Probably yes	NA	NA	NA	Some concerns	This comparison of BFHI certification status and BF initiation rates obtains information in two ways: survey of mothers giving birth in hospitals, and use of administrative data to compare changes in BF practices over time. Selection is based only on where women give birth (and hence whether they were exposed to the intervention vs. control hospital maternity practice). Characteristics of women are very similar, other control group women having a slightly higher income.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Alvarado, 1999[24]	High	Selection bias, confounding and measurement bias are a concern and are not adequately addressed in analyses.	Probably yes	NA	Yes	NA	Some concerns	Participants were selected based on where they lived; a neighboring community was selected as the control. Pregnant women were invited into the intervention group and control women were selected based on public clinic records. There were differences between intervention and control women at baseline.
Bærug, 2016[25]	Some concerns	Potential for bias arising from high refusal rate overall, although the attrition rate does not differ between arms.	Yes	NA	Yes	NA	Low	NA
Bartington, 2006[26]	Some concerns	Potential for selection bias and confounding.	Probably yes	NA	NA	NA	Low	NA
Bosnjak, 2004[27]	High	standard definitions were not used, the study relied on recall in the pre-intervention period and in the first phase of the intervention.	NA	NA	Yes	No	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Broadfoot, 2005[28]	Some concerns	Potential for selection bias and confounding; up to 17% (or more) records had missing data on important confounders or outcomes.	Probably yes	NA	NA	NA	Low	NA
Edmunds, 2017[29]	High	High risk of selection bias and bias due to unmeasured confounding.	Probably no	Related to outcome	NA	NA	Some concerns	Of 96 NYS WIC local agencies invited, 31 responded and 12 were chosen to participate. Only women who planned to BF or were considering BF were eligible.
Feldman-Winter, 2010[30]	Some concerns	Potential for contamination, but the effect would be to reduce the difference between arms.	Probably yes	NA	Yes	NA	Low	NA
Gau, 2004[31]	High	Differential attrition, unclear whether there was a potential for confounding in the design, outcomes poorly defined (BF duration did not account for exclusivity).	Yes	NA	Yes	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Hannula, 2014[32]	High	Potential for selection bias and confounding, high and differential attrition.	Probably no	Related to intervention	No	No	High	The sample is limited to the women who agreed to participate, so high attrition between experiencing the intervention and participating in the study could potentially be associated with postintervention variables and result in a selection bias. Start of the intervention precedes start of followup.
Hawkins, 2014[33]	Some concerns	Poor compliance within BFHI accredited hospitals coupled with adoption of some BF initiatives in nonaccredited facilities make the distinction between study arms weak; absence of effects could potentially be attributed to poor intervention definition and contamination/co-interventions	Yes	NA	Yes	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Hawkins, 2014[34]	Some concerns	Poor compliance within BFHI accredited hospitals coupled with adoption of some BF initiatives in nonaccredited facilities make the distinction between study arms weak; absence of effects could potentially be attributed to poor intervention definition and contamination/co-interventions.	Yes	NA	Yes	NA	Low	NA
Joyce, 2015[35]	High	Potential for selection bias and measurement bias. Inadequate adjustment for confounding variables. Data sources used were not designed to measure BF rates and extent of missing data is unclear.	Probably no	Yes	NA	No	Some concerns	Authors use three separate population databases to contrast trends in BF pre- and post-WIC policy changes; two have a non-WIC control group. Adjustment for variables is limited. Some women may have applied for WIC post-intervention due to nonformula benefits.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Lovera, 2010[36]	Some concerns	See individual domains. Selection into the study groups is not clear. The response rate on the part of the fathers was poor, but outcome data were probably from the mother. There was no description of intervention departures, but given the response rate from the fathers, there is a concern about intervention fidelity and participation (which could bias the result toward the null).	Probably yes	NA	Yes	NA	Low	NA
Madden, 2003[37]	Some concerns	Pre-post data, unclear if other secular changes or cointerventions were occurring at the same time, unclear how study was implemented, study excluded complex deliveries, study used but did not provide information on validation of automation to identify outcome	Probably yes	NA	NA	NA	Low	Pre-post study looking at a policy intervention related to length of hospital stay.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Macaluso, 2013;[38] Cattaneo, 2016[39]	Some concerns	Potential for selection bias (at cluster level) and confounding.	Probably yes	NA	Probably no	Probably yes	Some concerns	Intervention steps were implemented in a phased way; the early intervention group may have been different from the late intervention group, leading to risk of selection bias (the early intervention group had already implemented some intervention steps before the start of the study).
Martens, 2000[40]	High	Baseline differences not adjusted in models	Probably yes	NA	Yes	NA	Low	NA
Mydlilova, 2009[41]	Some concerns	The authors did attempt to evaluate the presence of perinatal centers and neonatal intermediate care units. The percentage of missing newborn reports is very low but it is unclear how unbiased these reports are between non BFHI and BFHI hospitals. Does having BFHI certification result in inflated reported BF rates.	Yes	NA	Yes	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Rempel, 2010[42]	High	See individual domains. Selection into the study groups is not clear, nor is the pattern of missing data due to attendees not completing some or all of the study surveys at different points in time.	Probably yes	NA	Yes	NA	Low	NA
Schafer, 1998[43]	High	High and differential attrition between arms, weak measure of outcomes.	Yes	NA	Yes	NA	Low	NA
Shaw, 1999[44]	Some concerns	Baseline differences, not fully adjusted in models	Probably no	Related to outcome	Yes	No	Some concerns	Women needed to have been seen at least for prenatal care to be eligible for the study, this may have resulted in a cohort of women who are different from those who did not get seen before pregnancy.
Tarrant, 2011[45]	Some concerns	Despite the observational nature of this study and the lack of information on how BFHI is implemented in Hong Kong hospitals, this was a fairly well done study with minimal missing data and an appropriate analytic approach.	Yes	NA	Yes	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to intervention/ outcome?	2. Were post-intervention variables that influenced selection related to intervention/ outcome?	3. Do start of followup and start of intervention coincide?	4. Were adjustment techniques used to correct for presence of selection biases?	Bias arising from selection?	Comments
Venancio, 2011[46]	Some concerns	Potential for selection bias and measurement bias.	Probably no	Related to outcome and intervention	Yes	NA	Some concerns	There is no discussion of whether women who had a strong intention to breastfeed might choose to give birth at a BFHI certified hospital, nor was there any discussion of whether regions with higher BF rates might be more inclined to pursue BFHI certification.
Wagner, 2002[47]	Some concerns	No description of maternal characteristics or adjustment for potential confounders in analyses. Extent of missing data and adherence are not reported.	Yes	NA	NA	NA	Low	NA
Weng, 2003[48]	High	High risk of selection bias, no description of participant characteristics or adjustment for confounding factors, and potential for measurement bias (no description of how BF outcomes were defined or assessed).	Probably no	Related to outcome and intervention	Yes	NA	High	High risk of selection bias in relationship to the hospitals sampled; unclear whether the sample that applied for BFHI is different than those that did not apply. There are clear differences in hospital practices by region which were not accounted for in the analyses.

BF = breastfeeding; BFHI = Baby Friendly Hospital Initiative; KQ = Key Question; NA = not applicable; NYS = New York State; RCT = randomized controlled trial; WIC = Women, Infants, and Children.

Table C-8. KQ 1 risk of bias assessment: Nonrandomized trials and observational studies, part 2

Author, Year	5. Is confounding of the intervention effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-intervention variables?	5d. Were participants analyzed according to their initial intervention group throughout followup?	5e. Were intervention discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Abolyan, 2006[23]	Probably no	Probably no	NA	Yes	NA	Yes	Some concerns	Women giving birth in intervention and control hospitals (in 2004) who were surveyed had very similar baseline characteristics; for comparisons of BF rates over time, changes are given for both intervention and control (non-BFHI) hospitals which takes into account contamination from other policy (or cultural) changes in BF initiation rates.
Alvarado, 1999[24]	No	No	NA	Yes	Yes	Yes	High	Baseline characteristics of women differed in important ways (women in control group were less likely to be primiparous) and do not appear to have been addressed in analyses.
Bærug, 2016[25]	Yes	NA	NA	NA	NA	NA	Low	Clusters assigned by investigators.

Author, Year	5. Is confounding of the intervention effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-intervention variables?	5d. Were participants analyzed according to their initial intervention group throughout followup?	5e. Were intervention discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Bartington, 2006[26]	Probably no	Probably no	Probably yes	Yes	Yes	Yes	Some concerns	Individual level confounders were addressed. Women living in communities where BFHI was adopted may be different in other factors from women in communities were BFHI was not implemented yet.
Bosnjak, 2004[27]	NA	NA	NA	NA	NA	NA	NA	Single arm study, so confounding not applicable.
Broadfoot, 2005[28]	Probably no	Probably no	Probably yes	Yes	Yes	Yes	Some concerns	Potential for confounding; those adjusted for were limited to Carstaris deprivation category, mother's age, hospital size, and year of birth.
Edmunds, 2017[29]	No	No	Probably no	Yes	Yes	No	High	Authors compare outcomes among women who agreed to participate and those who declined to participate in the study; it is likely that those who did not participate may have been less likely to continue BF. Few factors were included in regression analyses aside from age, race, parity and number of nutrition education sessions.

Author, Year	5. Is confounding of the intervention effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-intervention variables?	5d. Were participants analyzed according to their initial intervention group throughout followup?	5e. Were intervention discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Feldman-Winter, 2010[30]	Probably yes	NA	NA	NA	NA	NA	Low	NA
Gau, 2004[31]	No information	NA	NA	NA	NA	NA	Uncertain because no information	Unclear how hospitals self-selected into intervention and control groups.
Hannula, 2014[32]	No	No	NA	Yes	Yes	NA	High	Groups of participants in intervention clusters appear to have different characteristics, suggesting that their choice of delivery institution (and therefore intervention group) could potentially have been influenced by underlying traits that also influence the outcome.
Hawkins, 2014[33]	No	Yes	Probably yes	Yes	Yes	NA	Low	NA
Hawkins, 2014[34]	No	Yes	Probably yes	Yes	Yes	NA	Low	NA
Joyce, 2015[35]	Probably no	No	Probably yes	NA	Yes	Yes	High	Unlikely that authors were able to adjust for all important confounding domains given limitations of population databases (which were designed for different purposes).

Author, Year	5. Is confounding of the intervention effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-intervention variables?	5d. Were participants analyzed according to their initial intervention group throughout followup?	5e. Were intervention discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Lovera, 2010[36]	Probably no	Probably yes	Yes	Yes	Yes	Probably yes	Low	Authors reported that none of the potential confounders they evaluated changed the overall effect estimate more than 10%.
Macaluso, 2013;[38] Cattaneo, 2016[39]	Probably no	Probably yes	Probably yes	Yes	Yes	NA	Some concerns	Authors adjust for individual level confounders; unclear whether there are population level differences between intervention and control communities that may affect outcomes.
Madden, 2003[37]	Probably yes	NA	NA	NA	NA	NA	Some concerns	Complex deliveries (23% were excluded, including mothers with C-sections and more than 4 nights postpartum LOS or unequal mother/infant LOS. This is a systems-level intervention that relies on administrative data. Mothers were not selected for participation by staff (or self-selected based on individual factors) based on factors associated with BF.

Author, Year	5. Is confounding of the intervention effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-intervention variables?	5d. Were participants analyzed according to their initial intervention group throughout followup?	5e. Were intervention discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Martens, 2000[40]	No	No	Yes	Yes	Yes	NA	High	Significant differences at baseline between groups, suggesting that some underlying factors may influence the selection of hospital and the outcome.
Mydlilova, 2009[41]	Probably no	Probably no	NA	Probably yes	Yes	NA	Some concerns	Authors did look at effect of intervention on BF rates stratified by perinatal center and neonatal intermediate care unit status, but there was no other attempt to consider potential confounders between the non BFHI and BFHI hospitals. Note that question 5e does not make sense in the context of this study design.
Rempel, 2010[42]	Probably no	No	NA	Yes	Yes	Probably no	Some concerns	Authors do not provide adjusted results; it is unlikely that a participant would have attended more than one of the prenatal classes or had access to PLCs (if in the NLC group).

Author, Year	5. Is confounding of the intervention effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-intervention variables?	5d. Were participants analyzed according to their initial intervention group throughout followup?	5e. Were intervention discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Schafer, 1998[43]	No	No information	No information	No	Yes	NA	Uncertain because no information	No information on important baseline characteristics for the intervention arms, so cannot judge the potential for confounding fully.
Shaw, 1999[44]	No	No	Probably yes	Yes	Yes	NA	Some concerns	Analysis did not adjust for the variables that were different between groups at baseline (i.e., age, marital status, Medicaid status), all which are associated with breastfeeding rates. Baseline differences could have masked a greater difference in outcomes between the groups.

Author, Year	5. Is confounding of the intervention effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-intervention variables?	5d. Were participants analyzed according to their initial intervention group throughout follow-up?	5e. Were intervention discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Tarrant, 2011[45]	Probably yes	NA	NA	NA	NA	NA	Low	Authors presented multiple models, adjusted for a number of factors related to the intervention and to the outcome and adequately interpreted the results. The one potential confounder that was not adjusted for was hospital (there were 4); however, adjustment for BFHI steps would probably account for most of the potential confounding from hospital site.
Venancio, 2011[46]	No	Probably yes	Probably yes	Yes	Yes	Probably yes	Some concerns	Maternal education and age are both associated with several outcomes of interest, and these are dichotomized, rather than measured in narrower categories, raising concerns regarding residual confounding. Maternal BF intention, a critical potential confounder, is not measured.

Author, Year	5. Is confounding of the intervention effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-intervention variables?	5d. Were participants analyzed according to their initial intervention group throughout followup?	5e. Were intervention discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Wagner, 2002[47]	Probably no	No	NA	Yes	Yes	Yes	Some concerns	Pre- and post-intervention variables were compared without any adjustment for possible confounders.
Weng, 2003[48]	No	No	NA	NA	Yes	NA	High	No sociodemographic data are provided on the mothers surveyed, nor is any adjustment for confounding performed (based on participant or hospital characteristics).

BF = breastfeeding; BFHI = Baby Friendly Hospital Initiative; KQ = Key Question; LOS = length of stay; NA = not applicable; NLC = nurse-led class; PLC = peer-led class.

Table C-9. KQ 1 risk of bias assessment: Nonrandomized trials and observational studies, part 3

Author, Year	6. Is intervention status well-defined?	7. Was information on intervention status recorded at the time of intervention?	8. Was classification of intervention status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of interventions?	Comments
Abolyan, 2006[23]	Probably yes	Yes	Yes	Some concerns	For measurement of BF prevalence in intervention/control groups over time, it is not clear how BFHI "status" coincided with changes in actual care delivered across hospitals. Some women giving birth in control hospitals (each year) may have had exposure to BFHI practices.
Alvarado, 1999[24]	Probably yes	Yes	Yes	Low	NA
Bærug, 2016[25]	Yes	Yes	Yes	Low	NA
Bartington, 2006[26]	Yes	Yes	Probably yes	Low	NA
Bosnjak, 2004[27]	no	No	No	High	"Standard WHO breastfeeding definitions were not used. It is possible that each doctor may have used his/her own definitions and recall period, especially in the research period without intervention and the first phase of the intervention period."
Broadfoot, 2005[28]	Yes	Yes	Probably yes	Low	NA
Edmunds, 2017[29]	Yes	Yes	Probably yes	Some concerns	Unclear whether other, similar interventions were available across WIC agencies.
Feldman-Winter, 2010[30]	Yes	Yes	Yes	Low	NA
Gau, 2004[31]	Yes	Yes	Yes	Low	NA
Hannula, 2014[32]	Yes	Yes	Yes	Low	None
Hawkins, 2014[33]	Probably no	No information	Yes	Some concerns	The definition of the intervention rests on accreditation, rather than the number of practices followed in accredited hospitals. As a result, accredited hospitals with low compliance and nonaccredited hospitals with some BF practices cannot be easily distinguished.

Author, Year	6. Is intervention status well-defined?	7. Was information on intervention status recorded at the time of intervention?	8. Was classification of intervention status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of interventions?	Comments
Hawkins, 2014[34]	Probably no	No information	Yes	Some concerns	The definition of the intervention rests on accreditation, rather than the number of practices followed in accredited hospitals. As a result, accredited hospitals with low compliance and nonaccredited hospitals with some BF practices cannot be easily distinguished.
Joyce, 2015[35]	Yes	Probably yes	NA	Low	Intervention is a change in WIC policy.
Lovera, 2010[36]	Yes	Probably yes	Yes	Low	NA
Macaluso, 2013;[38] Cattaneo, 2016[39]	Yes	Yes	Yes	Low	NA
Madden, 2003[37]	Probably yes	Probably yes	Yes	Some concerns	Intervention is a policy change; women were analyzed in a time-series before, during and after the intervention. There is clear timing regarding the policy change, however, details of implementation are not clear.
Martens, 2000[40]	Yes	Yes	Yes	Low	NA
Mydlilova, 2009[41]	Yes	Yes	Yes	Low	NA
Rempel, 2010[42]	Yes	Yes	Yes	Low	The difference between the two intervention groups is relatively clear (the selection into them is not).
Shaw, 1999[44]	Yes	Yes	Yes	Low	NA
Schafer, 1998[43]	Yes	Yes	Yes	Low	NA
Tarrant, 2011[45]	Probably no	Probably yes	Yes	Some concerns	Authors noted that data on exposure to the BFHI steps were available on the participants' hospital records (except for step 10, available through self-report at 1 month). However, no further details were available about how BFHI was implemented at the hospitals or why certain steps may or may not have been implemented, either at the hospital or the participant level. It seems as though implementation of BFHI in Hong Kong has not been done in any official capacity.

Author, Year	6. Is intervention status well-defined?	7. Was information on intervention status recorded at the time of intervention?	8. Was classification of intervention status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of interventions?	Comments
Venancio, 2011[46]	Yes	Yes	Yes	Low	NA
Wagner, 2002[47]	Yes	Yes	Yes	Low	NA
Weng, 2003[48]	Probably yes	Probably yes	Probably yes	Low	NA

BF = breastfeeding; BFHI = Baby Friendly Hospital Initiative; KQ = Key Question; NA = not applicable; WIC = Women, Infants, and Children; WHO = World Health Organization.

Table C-10. KQ 1 risk of bias assessment: Nonrandomized trials and observational studies, part 4

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on intervention status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across intervention groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising from Missing Data	Comments
Abolyan, 2006[23]	Probably yes	Probably yes	Probably yes	Yes	NA	Low	For administrative data on BF initiation, rates of missing data are likely very low. For survey of women giving birth in 2004, survey completion rates were high (95% and 89%, respectively, in intervention and control groups).
Alvarado, 1999[24]	Probably yes	Probably yes	Probably yes	No	No	Some concerns	Unclear rate of missing data for control sites; authors state that 20 (of 200) women had no information (but information was available for their infant). At intervention sites, missing data appears low but is not clearly reported by outcome.
Bærug, 2016[25]	No	Yes	No	Yes	Yes	Some concerns	Although authors used an ITT analysis and retained all the clusters (only 18/27 completed the intervention), a large proportion of participants refused to participate in the survey (740.3% in the intervention arm and 43.5% in the control arm).
Bartington, 2006[26]	Probably yes	Probably yes	Probably yes	No information	No information	Low	Missing data is unclear, however, due to population level databases information on most births appear to be accounted for.
Bosnjak, 2004[27]	Probably yes	No information	No information	NA	No	Uncertain because no information	Sample consisted of 90.3% of newborns.
Broadfoot, 2005[28]	No	Yes	Probably yes	No information	No information	Some concerns	Feeding status was missing on a small number of records (2.4-3.2%); Carstairs deprivation category was missing on 17.4% of records.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on intervention status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across intervention groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising from Missing Data	Comments
Macaluso, 2013;[38] Cattaneo, 2016[39]	Yes	Yes	Yes	Yes	No	Some concerns	Authors report no significant differences by intervention and control groups for missing data; missing data at 12 months ranged from 9-20% across community clusters. No methods appear to be used to account for missing data.
Edmunds, 2017[29]	Probably yes	Yes	Yes	Yes	No	Some concerns	Attrition ranged from 13-15%; only completers analysis was performed.
Feldman-Winter, 2010[30]	No information	No information	No information	No information	NA	Uncertain because no information	None
Gau, 2004[31]	Probably no	No information	No information	No	NA	High	Two of seven control hospitals dropped out because birth rates were so low that their caseloads went to zero eventually. This raises a larger question of whether the intervention and control hospitals were truly similar. Also, the text seems to suggest that a minimum threshold of cases was necessary to compile the data "Fifty cases were randomly sampled every month from each hospital, and all the cases were collected if the number was less than 50." Very little information on dropouts.
Hannula, 2014[32]	No	No	No information	No	No	High	High and differential attrition between arms, coupled with baseline differences in characteristics suggest the potential for bias due to missing data.
Hawkins, 2014[33]	No information	No information	No information	No information	No information	Uncertain because no information	Study does not disclose what proportion of PRAMS participants completed surveys.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on intervention status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across intervention groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising from Missing Data	Comments
Hawkins, 2014[34]	No information	No information	No information	No information	No information	Uncertain because no information	Study does not disclose what proportion of PRAMS participants completed surveys.
Joyce, 2015[35]	No information	No information	No information	No information	No information	Uncertain because no information	None
Lovera, 2010[36]	Probably yes	Yes	Probably yes	No information	No information	Some concerns	The outcome data and the confounder data came from the mothers' responses. Though it does not appear that any data (other than baseline characteristics) came from the father, it is important to note that only 53% of the intervention and 50% of the control group responded to paternal interviews.
Madden, 2003[37]	Probably yes	Yes	Yes	No information	NA	Some concerns	Per authors, they were able to categorize all but 0.5% of infants based on feeding patters (breastfeeding exposure). No other mention is made of missing data or other exclusions. Not clear if missing data is different for pre- vs. post-comparison.
Martens, 2000[40]	Yes	Yes	Yes	NA	NA	Low	NA
Mydlilova, 2009[41]	Yes	No	Probably yes	Probably yes	Probably yes	Low	Newborn reports were only missing for 1.5% of infants; authors didn't describe missingness by BFHI status. The rate of missing data is so small that any differential missingness is unlikely to impact the findings.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on intervention status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across intervention groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising from Missing Data	Comments
Rempel, 2010[42]	No	Probably no	Probably no	No information	No	High	Authors report that 54 PLC and 55 NLC attendees completed at least one study survey. It is not clear how many attendees did not complete at least one survey. The authors provided the number of participants completing each survey in table 2, but it seems to be inconsistent with some of the results text. It's clear that there is a lot of missing data due to attendees not completing surveys at each timepoint, but it's not clear how it tracks over the course of each attendee (e.g., is there anyone who completed all surveys). According to Table 2, only 24 PLC and 23 NLC participants completed the 6-month survey. According to text in the second column on page 77, 5 PLC and 7 NLC mothers stopped BF between 1 and 6 months. However, there is no way to tell what the denominators are for these two results. There are fewer mothers who completed the 6-month survey than the 1-month survey and we have no idea what the overlap between those groups are. According to text in the second column on page 77, 49% of the 35 NLC mothers and 61% of the 31 PLC mothers for whom duration data were available were still BF at six months. It’s not clear where the denominators of 31 (PLC) and 35 (NLC) came from!

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on intervention status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across intervention groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising from Missing Data	Comments
Schafer, 1998[43]	No	No	No	No information	No	High	Nearly one-half (71/143) participants in the intervention arm did not respond, the analysis could not account for such a high attrition.
Shaw, 1999[44]	No	Yes	Yes	No information	NA	Low	Low attrition rate: for the OR analysis, the minimum sample appears to be 287 of 293 (98%), so the failure to adjust for missing data probably does not have a big impact.
Tarrant, 2011[45]	Probably yes	Probably yes	Probably yes	No information	Probably yes	Low	1242/1417 (88%) of mother-infant pairs recruited were analyzed. Of the 31 participants lost-to-followup, 21 (68%) had provided enough data to analyze the main study outcome. Authors performed a sensitivity analysis of the 31 participants lost to followup and ultimately included them in analyses.
Venancio, 2011[46]	Yes	Yes	No information	No information	No information	Uncertain because no information	No information is provided on missing data.
Wagner, 2002[47]	No information	Probably yes	No information	NA	No information	Some concerns	No description of exclusions for missing data from the perinatal database.
Weng, 2003[48]	Probably yes	Probably no	NA	No information	No	Some concerns	No information provided on differences between those missing at 1 month and the full sample, and no information provided on the number of women approached for survey vs. the number who provided data.

BF = breastfeeding; BFHI = Baby Friendly Hospital Initiative; ITT = intent-to-treat; KQ = Key Question; NA = not applicable; NLC = nurse-led class; OR = odds ratio; PLC = peer-led class; PRAMS = Pregnancy Risk Assessment Monitoring System.

Table C-11. KQ 1 risk of bias assessment: Nonrandomized trials and observational studies, part 5

Author, Year	14. Were there no or minimal deviations from the intended intervention?	14a. Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?	15. Were important cointerventions balanced across intervention groups?	16. Was the intervention implemented successfully for most participants?	16a. Did the study measure adherence with the defined intervention?	Bias arising from departures from intended interventions	Comments
Abolyan, 2006[23]	Probably yes	NA	No information	NA	NA	Low	Study looks at a systems-level intervention; responses from survey indicates that (in 2004) more women giving birth in BF-certified hospitals received recommended practices (e.g., BF education, rooming-in) which could be considered a measure of adherence.
Alvarado, 1999[24]	No information	NA	No information	Probably yes	NA	Uncertain because no information	Level of fidelity unclear. Due to nature of intervention (systems level) adherence was not a major factor.
Bærug, 2016[25]	Yes	NA	No information	Yes	NA	Low	NA
Bartington, 2006[26]	No information	NA	Probably yes	NA	NA	Some concerns	Exposure is defined as giving birth in a BFHI accredited facility; unclear to what extent hospitals not accredited may have been offering similar policies/programs.
Bosnjak, 2004[27]	No information	NA	NA	No information	No information	Uncertain because no information	None
Broadfoot, 2005[28]	No information	NA	Probably yes	NA	NA	Some concerns	No formal assessment of fidelity or description of other community or health care interventions to support or promote breastfeeding.

Author, Year	14. Were there no or minimal deviations from the intended intervention?	14a. Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?	15. Were important cointerventions balanced across intervention groups?	16. Was the intervention implemented successfully for most participants?	16a. Did the study measure adherence with the defined intervention?	Bias arising from departures from intended interventions	Comments
Edmunds, 2017[29]	No information	NA	NA	No information	No	Uncertain because no information	No assessment or description of fidelity.
Feldman-Winter, 2010[30]	Probably no	NA	Probably no	No information	No	Some concerns	Potential for contamination between arms.
Gau, 2004[31]	Yes	No information	No information	Probably no	No	Some concerns	The structure of hospitals prevented implementation of early tactile contact and rooming in.
Hannula, 2014[32]	Probably no	Probably no	Probably no	No information	No	Some concerns	The co-interventions varied by arm but details of the control group are not described "support and care practices used in the intervention and control group differed from each other."
Hawkins, 2014[33]	Probably no	Probably yes	Probably no	No information	Yes	Some concerns	Study notes the potential for contamination between arms; nonaccredited facilities had BF practices.
Hawkins, 2014[34]	Probably no	Probably yes	Probably no	No information	No information	Some concerns	"At least half of the mothers from Maine reported experiencing 6–7 breastfeeding practices consistent with the BFHI, regardless of the birth facility's BFHI status."
Joyce, 2015[35]	Probably yes	NA	No information	NA	NA	Some concerns	Unclear whether implementation of WIC policy was consistent during timepoints measured.
Lovera, 2010[36]	No information	No information	No information	No information	No information	Uncertain because no information	None

Author, Year	14. Were there no or minimal deviations from the intended intervention?	14a. Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?	15. Were important cointerventions balanced across intervention groups?	16. Was the intervention implemented successfully for most participants?	16a. Did the study measure adherence with the defined intervention?	Bias arising from departures from intended interventions	Comments
Macaluso, 2013;[38] Cattaneo, 2016[39]	Probably yes	NA	Probably yes	NA	NA	Some concerns	No formal assessment of fidelity or detailed description of what other community or health care interventions to promote breastfeeding were available (aside from BFHI).
Madden, 2003[37]	Probably yes	NA	No information	NA	NA	Low	Intervention is a policy change; there is no information on whether the policy was amended or changed after implemented. Theoretically, there could be other breastfeeding interventions/ policy changes occurring in the post-intervention time period (but no specific co-intervention).
Martens, 2000[40]	Yes	NA	No information	No information	No	Low	NA
Mydlilova, 2009[41]	No information	No information	NA	No information	No information	Uncertain because no information	Authors do not report on the extent of BFHI status at the Baby Friendly hospitals other than to note that over time, a hospital may change from non BFHI to BFHI.
Rempel, 2010[42]	No information	No information	No information	No information	No information	Uncertain because no information	None
Schafer, 1998[43]	Yes	NA	No information	No information	No	Low	NA
Shaw, 1999[44]	Yes	NA	No information	Yes	Yes	Low	NA
Tarrant, 2011[45]	Probably yes	NA	Probably yes	No information	No information	Some concerns	See bias in intervention measurement domain.

Author, Year	14. Were there no or minimal deviations from the intended intervention?	14a. Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?	15. Were important cointerventions balanced across intervention groups?	16. Was the intervention implemented successfully for most participants?	16a. Did the study measure adherence with the defined intervention?	Bias arising from departures from intended interventions	Comments
Venancio, 2011[46]	Probably yes	No information	No information	Probably no	NA	Uncertain because no information	No description on compliance with BFHI steps for intervention group.
Wagner, 2002[47]	Probably yes	NA	No information	No information	No	Some concerns	No description of attendance, adherence or practice-change following intervention. Participation in patient BF groups was low (<10%) but unclear whether this was a change from pre-intervention.
Weng, 2003[48]	Probably yes	NA	No information	NA	Yes	Some concerns	Co-interventions are not discussed, although the authors note in the discussion that “some hospitals refused to accept on-the-job training and had no intention to improve their services; these hospitals failed the evaluation.” This suggests that failing BFHI evaluation may reflect staff resistance to breastfeeding promotion, which in turn may lower BF rates.

BF = breastfeeding; BFHI = Baby Friendly Hospital Initiative; KQ = Key Question; NA = not applicable; WIC = Women, Infants, and Children.

Table C-12. KQ 1 risk of bias assessment: Nonrandomized trials and observational studies, part 6

Author, Year	17. Was measurement of breastfeeding outcomes unlikely to have been influenced by knowledge of the intervention received?	18. Were methods of benefit outcome assessment comparable across groups?	Bias Arising from Measurement of Breastfeeding Outcomes	Comments	19. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?	Bias Arising from Selection of Reported Results	Comments
Abolyan, 2006[23]	Probably No	Probably yes	Some concerns	Whether women were aware of BFHI status in their hospital is not clear; however, it is unlikely that women or hospital staff were blinded. Unclear whether outcome assessors of BF prevalence data over time were blinded.	Probably yes	Low	NA

Author, Year	17. Was measurement of breastfeeding outcomes unlikely to have been influenced by knowledge of the intervention received?	18. Were methods of benefit outcome assessment comparable across groups?	Bias Arising from Measurement of Breastfeeding Outcomes	Comments	19. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?	Bias Arising from Selection of Reported Results	Comments
Alvarado, 1999[24]	No information	No	High	Owing to different methods of obtaining outcomes at intervention and control sites, measurement bias is a concern. Women receiving care at control sites had more frequent interactions with staff and outcome assessors do not appear to have been blinded.	Probably yes	Low	NA
Bærug, 2016[25]	No	Yes	Low	NA	No	Low	NA
Bartington, 2006[26]	Yes	Yes	Low	NA	Probably yes	Low	NA

Author, Year	17. Was measurement of breastfeeding outcomes unlikely to have been influenced by knowledge of the intervention received?	18. Were methods of benefit outcome assessment comparable across groups?	Bias Arising from Measurement of Breastfeeding Outcomes	Comments	19. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?	Bias Arising from Selection of Reported Results	Comments
Bosnjak, 2004[27]	Yes	NA	High	"Standard WHO breastfeeding definitions were not used. It is possible that each doctor may have used his/her own definitions and recall period, especially in the research period without intervention and the first phase of the intervention period."	No information	Uncertain because no information	None
Broadfoot, 2005[28]	Yes	Yes	Low	NA	Probably yes	Low	NA
Edmunds, 2017[29]	Probably no	Probably yes	Some concerns	No description of blinding.	Yes	Low	NA
Feldman-Winter, 2010[30]	No	Yes	Low	NA	No	Low	NA
Gau, 2004[31]	no	Yes	Low	NA	No	Low	NA
Hannula, 2014[32]	Yes	Yes	Low	NA	no	Low	NA
Hawkins, 2014[33]	Yes	Yes	Low	NA	No	Low	NA
Hawkins, 2014[34]	Yes	Yes	Low	NA	No	Low	NA
Joyce, 2015[35]	Probably yes	Probably yes	Low	NA	Probably yes	Low	NA
Lovera, 2010[36]	Probably yes	Yes	Low	NA	Probably yes	Low	NA

Author, Year	17. Was measurement of breastfeeding outcomes unlikely to have been influenced by knowledge of the intervention received?	18. Were methods of benefit outcome assessment comparable across groups?	Bias Arising from Measurement of Breastfeeding Outcomes	Comments	19. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?	Bias Arising from Selection of Reported Results	Comments
Macaluso, 2013;[38] Cattaneo, 2016[39]	Probably yes	Probably yes	Low	NA	Probably yes	Low	NA
Madden, 2003[37]	Yes	Probably yes	Some concerns	From automated medical records, using text-search algorithms, unclear how outcomes were validated.	No	Low	NA
Martens, 2000[40]	Yes	No information	Some concerns	Outcomes in the control group in the second time point look very different from the first time point and the author notes the potential for error in the small sample size. Unclear whether outcomes are recorded the same way in both units.	No	Low	NA

Author, Year	17. Was measurement of breastfeeding outcomes unlikely to have been influenced by knowledge of the intervention received?	18. Were methods of benefit outcome assessment comparable across groups?	Bias Arising from Measurement of Breastfeeding Outcomes	Comments	19. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?	Bias Arising from Selection of Reported Results	Comments
Mydlilova, 2009[41]	Probably no	Yes	Some concerns	Newborn reports are required of all hospitals but there is no discussion of whether the reports at BFHI hospitals are reported more positively because of their BFHI certification.	Probably yes	Low	NA
Rempel, 2010[42]	Probably yes	Probably yes	Low	NA	Probably yes	Low	NA
Schafer, 1998[43]	No	Yes	High	Outcomes based on self-report at 12 weeks, and any BF qualified as the outcome	No	Low	NA
Shaw, 1999[44]	No	Yes	Low	NA	No	Low	NA
Tarrant, 2011[45]	Probably yes	Yes	Low	NA	Probably yes	Low	NA
Venancio, 2011[46]	Probably yes	Probably yes	Some concerns	Data collection was not blinded, and social desirability bias may have affected responses.	Probably no	Low	NA

Author, Year	17. Was measurement of breastfeeding outcomes unlikely to have been influenced by knowledge of the intervention received?	18. Were methods of benefit outcome assessment comparable across groups?	Bias Arising from Measurement of Breastfeeding Outcomes	Comments	19. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?	Bias Arising from Selection of Reported Results	Comments
Wagner, 2002[47]	No information	Probably yes	Some concerns	Unclear whether documentation or data abstraction for the perinatal database may have changed after the intervention.	Probably yes	Low	NA
Weng, 2003[48]	No information	No information	Some concerns	No information is provided on how BF outcomes were defined or assessed, or whether outcome assessors were blinded.	Probably no	Low	NA

BF = breastfeeding; BFHI = Baby Friendly Hospital Initiative; KQ = Key Question; NA = not applicable; WHO = World Health Organization.

Table C-13. Relevance assessment for systematic reviews evaluating an eligible KQ 2 outcome

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked "very high" development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
Anothaisintawee, 2013[49]	Breast cancer	No; last search date was January 2011.	NA	NA	NA	NA	No	In addition to outdated search, only 39/69 (57%) were from very highly developed countries, and this review primarily relies on older SRs to identify relevant studies.

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked "very high" development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
Aune, 2014[50]	Type 2 diabetes	Yes; PubMed, Embase and Ovid searched through September 2013	No. 83% (5/6) articles are from U.S., Germany, or Australia, and one is from China. The subgroup analysis also includes the Chinese study.	Yes; includes highest vs. lowest level of exposure and duration of breastfeeding	Includes cohorts and case control studies	Yes; type 2 diabetes	Yes	This study includes the three studies in Jager, and then an additional three. It doesn't include the German data from Jager because those data came out after the publication of the Aune study; it also excludes cross-sectional studies, but it does include prospective cohort, case-cohort or nested case control design. That could possibly explain the discrepancy. Also, one of the included studies was entirely in women in gestational diabetes, but we haven't excluded such populations for type 2 either.

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked "very high" development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
Chowdhury, 2015[2]	Ovarian and breast cancer[d]	Yes; PubMed, Cochrane, CABI searched through February 2015	No; ovarian CA: 88% (35/40) according to Table A3 or 85% (35/41) according to Table 2 were from HIC;[e] 1 of the 41 references is an SR they updated.[51] Breast CA: 73% (72 of 98) were HIC. Analyses presented for HIC and LIC strata for both outcomes.	Yes; includes ever vs. never and breastfeeding duration (never, <6 months, 6-12 months, >12 months)	Yes: cohort and case-control	Yes: Ovarian and breast carcinoma (no other details provided)	Yes, though includes some ineligible countries	Breast cancer: 34 of 98 included studies were previously included in at least one of the other identified SRs included in the 2007 AHRQ report. Ovarian cancer: 40 of 41 included studies are included by other identified SRs.

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked "very high" development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
Dias, 2015[52]	Depression	Yes; Medline, Web of Knowledge and PsycInFO searched from 1980 to Dec 2013	No; 28% (5 of 18 relevant studies in Table 2) are from wrong country setting and 40% of studies from Table 3 (7 of 18).	Yes; this review is also broader and includes studies assessing the association between depression during pregnancy and rates of BF as well as other questions (see comments).	Not well described; methods note "associative studies" and "prospective studies" were included regardless of the study design."	Yes; however, measures of "depressive symptoms" were also included (in addition to changes in EPDS scores). Not clear how many studies look at validated measures of depression.	Yes; however, scope is broader than our KQ and presentation of data my limit usefulness in the data synthesis.	Review includes studies that address various questions related to depression and breastfeeding; only a subset of the results is relevant to our KQ.
Feng, 2014[53]	Ovarian cancer	Yes; Medline and Embase through December 2012	No; 79% (15/19) conducted in developed countries No subgroup analyses by country setting	Yes; includes ever (as defined by the study) vs never and duration (dose-response by month)	Yes: cohort and case-control (both hospital- and population-based)	Yes: Ovarian cancer incidence (no other details provided)	Yes, though includes some ineligible countries	Quality of included articles was assessed according to Newcastle-Ottawa Scale. Most studies were rated high quality (NOS 7 or 8; no 9 ratings) but there were a handful of low quality (NOS=6).

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked "very high" development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
He, 2015[54]	PPWR	Yes; Medline, Embase, Cochrane searched through Oct 2014	No; 27% (3 of 11 included studies) were from an ineligible country setting.	Yes; meta-analysis includes 2 subgroups: exclusive BF vs. formula-feeding and "mixed-feeding" vs. formula-feeding (and an overall summary effect that includes all studies, i.e., any BF vs. no BF presumably).	RCTs and cohort studies were included in meta-analysis but other study designs were identified (see notes).	Yes; however, outcomes had to have data on weight change or weight retention, report both mean and SD and include a measurement of weight (rather than self-reported weight).	Yes; however, relatively few relevant studies reporting on weight change appear to be included in the quantitative analysis.	Authors note 26 studies met inclusion criteria but 15 were "not eligible for the meta-analyses"; these are listed in an online supplement.[c] Three of 11 studies in the analysis are from a noneligible country; there is a sensitivity analysis that includes U.S. studies only (7).
Islami, 2015[55]	Breast cancer	Yes: PubMed and Scopus through 8/2014	No; 79% (15 of 19) case-control studies set in highly developed countries and 100% (8/8) prospective cohort studies set in highly developed countries.	Yes; included measures of ever/never, and various durations; in some cases, studies of shorter vs. longer duration were combined with studies reporting ever/never.	Yes; prospective cohort and case-control studies	Yes: review is limited to association between BF and specific cancer subtypes defined by hormone receptor status (e.g., luminal, nonluminal, triple negative).	Yes; though includes some ineligible countries.	Review is focused on a subset of the BF literature (studies reporting subtypes of cancer by BF status).

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked "very high" development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
Jager, 2014[56]	Type 2 diabetes	Yes; PubMed and Web of Science searched through March 2014	No; 75% (3/4 articles) from U.S. (2 articles, 1 study) and Germany (Germany data are not from an article but are from the other part of the article), 1 article from China; some subgroup analyses exclude the Shanghai study and so are in very high developed.	Yes; includes both yes/no and duration of breastfeeding	Not very clear, but appears to have included prospective cohort studies only.	Yes; type 2 diabetes	Yes	Although the article doesn't say so explicitly, the PRISMA figure makes clear that they excluded noncohort studies.
Jiang, 2017[57]	Osteoporotic fractures	Yes	No	Yes	Yes	Yes	Yes	3 of 12 included studies are not from very highly developed countries (2 China, 1 Mexico) but subgroup analysis is presented in supplemental material.
Lambertini, 2016[58, 59]	Breast cancer	Yes: PubMed and Embase through 10/2014	No; 91% (10 of 11) were from the U.S. and Japan (1 study was from China). Separate analyses performed for studies set in U.S. and Asia.	Yes; focused on measures of ever/never	Yes: cohort and case control studies were included (and 2 pooled analyses of cohort/ case-control studies).	Yes; Breast cancer subtypes defined by hormone receptor status (e.g., Luminal, HER2, triple negative).	Yes; though includes one study from China and a few pooled analyses.	None

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked "very high" development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
Li, 2014[60]	Ovarian cancer	Yes; Medline and Embase through March 2013	No; 83% (33/40) conducted in developed countries Subgroup analyses presented for North American (19), Asian (10), European (9), Australian (2) populations	Yes; includes ever vs never; total breastfeeding duration in months (<6; 6-12; >12; >24), and average breastfeeding duration in months (<6; 6-12; >12)	Yes: cohort and case-control (both hospital- and population-based)	Yes: Ovarian cancer confirmed by histology Subgroup analyses presented for invasive and borderline ovarian tumors, and histologic subtype (serous, mucinous, endometrioid/ clear cell).	Yes, though includes some ineligible countries	Quality of included articles was assessed according to Newcastle-Ottawa Scale. Approximately 2/3 of studies were considered high quality, but only 12 studies had a NOS score of 7; remaining NOS scores ranged from 4 to 6.
Luan, 2013[51]	Ovarian cancer	Yes; Medline through December 2012	No; 86% (30/35) conducted in developed countries Subgroup analyses presented for Asian, American, and European study populations.	Yes; includes measures of ever vs. never and total duration of breastfeeding (longest compared with shortest categories).	Yes: cohort and case-control	Yes: Incident epithelial ovarian cancer Subgroup analyses presented for invasive and borderline tumors and by histology (serous, mucinous, endometrioid, clear cell)	Yes, though includes some ineligible countries.	No quality assessment; relied on numerous subgroup and sensitivity analyses.

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked “very high” development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
Neville, 2014[61]	Postpartum weight change	Yes; 8 databases through June 2012	Most likely; criteria state studies conducted in “developing countries” were excluded. 32 included studies were from U.S., UK, Europe, Japan, Taiwan/Hong Kong, Canada and Australia.	Yes; results reported by exposure (including separately for studies reporting on measures of ever/never, vs. both intensity and duration of BF).	Yes; obs. studies were included (categorized as prospective vs. retrospective); case-control studies appear to be excluded.	Yes; review included any measure of postpartum weight change (measured and self-reported) but also other measures of body mass we would exclude (i.e., lean body mass, fat-free mass).	Yes; however, presentation of data my limit usefulness in the evidence synthesis (see comments).	No meta-analyses were performed. Main table is a summary and does not include results of weight change measures. Results are in an online appendix; however, data presentation is difficult to interpret.
Pan, 2013[62]	Breast cancer	Yes; PubMed searched through 2/2013	Yes; all 3 included studies enrolled women from highly developed countries.	Yes; ever/never and longer vs. shorter duration of BF	Yes; cohort studies (including pooled data from a consortium of observational studies) and case-control studies.	Yes: Breast cancer (no other details provided)	Yes	Only 3 included studies included (2 of those studies include women from various eligible, countries; this may not be surprising since genetic testing is likely more often done in developed countries.
Sung, 2016[63]	Ovarian cancer	Yes	Yes	Yes	Yes	Yes	Yes	None

Author, Year	KQ 2 Outcome(s)	Was the database search conducted in 2012 or later?	Did the review include only studies from countries ranked "very high" development[a]?	Did the review focus on benefits and harms of maternal exposure to breastfeeding (or different intensities/ duration of BF)?	Did the review focus on RCTs, CCTs, cohort studies, and case-control studies?	Did the review focus only on relevant health outcomes[b]?	Overall, is the review directly relevant, providing an adequate answer to KQ 2 (for one or more outcome categories)?	Additional Comments about Relevance
Unar-Munguia, 2017[64]	Breast cancer	Yes	No	Yes	Yes	Yes	No	28 (43%) of included studies were from Asia, 4 (6%) were from Africa, and 5 (8%) were from Latin America. There is no list that provides country but it's likely that a majority of the included studies are not from very highly development countries.
Zhou, 2015[65]	Breast cancer	Yes; PubMed searched from 1/2008 through 7/2014	No; 19% (5 of 27 studies) were from highly developed countries; most were from Middle Eastern or Western Asian countries. No subgroup analysis by country setting.	Yes; included Ever/Never and Longest/shortest duration (of total or average duration) comparisons.	Yes: cohort and case-control, though one of the included studies is classified as cross-sectional.	Yes; Breast Cancer (no other details provided)	No; a large majority of the studies are from countries that would not be eligible for our review.	Consider hand-searching this review to ensure that we've captured the included studies that would meet our country eligibility criteria.

[a]Very high: Andorra, Argentina, Australia, Austria, Bahrain, Belgium, Brunei Darussalam, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, China (SAR), Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan, United Arab Emirates, United Kingdom, United States

[b]Postpartum depression, breast cancer, ovarian cancer, osteoporosis, cardiovascular (CVD) outcomes [e.g., stroke, myocardial infarction (MI)], postpartum weight change, type 2 diabetes, hypertension

[c]Reasons for not being included in meta-analyses include no reporting of PPWR and no reporting of a standard deviation. Not clear whether authors tried to calculate these measures when individual studies reported other measures of weight change.

[d]Reasons we did not formally consider the relevance of Chowdhury for other outcomes we included: (1) Osteoporosis: Six studies (two from LMICs) countries were included. Only BMD was an included outcome (not fracture incidence). Chowdhury pooled four studies reporting on femoral neck and distal radius BMD. No description of study design, timing of BMD measurement, etc. At least one from HIC is a case-control study of BMD and BF (these were excluded by 2007 review). (2) Diabetes: No new studies; describes results from Aune et. al. (3) Postpartum Depression: No new studies; describes results from Dias et. al. (4) Postpartum weight change: Describes results from Neville et. al and five additional studies (no meta-analysis).
[e]High Income Country (HIC) setting defined according to 2014 World Bank data (add citation from Choudhry).

AHRQ = Agency for Healthcare Research and Quality; BF = breastfeeding; CA = cancer; CABI = Centre for Agriculture and Biosciences International; CCT = controlled clinical trial; CVD = cardiovascular; EPDS = Edinburgh Postnatal Depression Scale; HER2 = human epidermal growth factor receptor 2; HIC = High Income Country; KQ = Key Question; LIC = Low Income Country; MI = myocardial infarction; NA = not applicable; NOS = Newcastle-Ottawa Scale; obs = observational; PPWR = postpartum weight retention; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta- Analyses; RCT = randomized controlled trial; SD = standard deviation; SR = systematic review; UK = United Kingdom; U.S.= United States.

Table C-14. KQ 2 risk of bias assessment: Systematic reviews, part 1

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Aune, 2014[50] Diabetes	Low	Although no grey literature or unpublished studies were included, the potential for bias from other sources is low.	Yes	Yes	Yes	Yes	Yes	Low	NA

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Chowdhury, 2015[2] Breast and ovarian cancer	Unclear	Little description of individual studies is provided; no other methods were used to identify unpublished articles; analyses (funnel plot) showed evidence of publication bias for breast cancer. Unclear whether this is a potential bias for the group of studies relevant for our review. Whether data abstraction and ROB were dually assessed is not clear.	Yes	Yes	Probably yes	Probably yes	Yes	Low	Excluded non-English studies; authors note that RCTs were eligible but do not explain whether they would have included RCTs assessing BF interventions that report on health outcomes. All included studies appear to be observational.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Dias, 2015[52] Postpartum depression	Unclear	See individual domains; no assessment for included studies. Characteristics of studies are not well desribed and syntheses focuses on number of studies that found a postiive association grouped by study design.	Yes	Yes	Yes	Probably yes	Probably yes	Low	NA

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Feng, 2014[53] Ovarian cancer	High	See individual domains. Authors strongly suggested that their findings were supportive of multiple breastfeeding guidelines due to their dose-response analysis; authors acknowledged the substantial heterogeneity but said they didn't enough data to explore further, which is not true based on the study characteristics they provided.	Yes	Yes	Yes	Probably yes	Probably no	Unclear	Authors note that studies had to report a measure of effect (ORs) and 95% CI: unclear if some relevant studies might have been excluded due to availability of data (e.g., no CI reported) and not clear whether authors attempted to calculate measures (or obtained from authors of individual studies). Limited to English-language studies.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
He, 2015[54] Postpartum weight change	Unclear	See domain specific comments; no dual assessment of data abstraction. Unclear whether results of studies not included in quanitative synthesis support consculstions based on meta-analyses. Pooled studies had substantial heterogeneity that was oly partially explored. Inadequate description of study characteristics.	Yes	Probably yes	Yes	Probably yes	Probably yes	Low	Eligibility criteria is well defined; authors make restrictions on studies that could be included in quantitative analyses based on reporting of appropriate data, but summarize other relevant studies in an appendix (those that could not be included in quantitative synthesis).

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Islami, 2015[55] Breast cancer	High	See individual domains; unpublished reports were ineligible, unclear whether literature review and data abstraction were dually reviewed. No ROB of individual studies was described. However, some potential bias (confounding) is addressed by the evidence synthesis. Authors may have over-interpreted the importance of their findings given the results and the limitations.	Yes	Yes	Yes	Probably yes	Probably no	Unclear	Authors state that abstracts and unpublished studies were ineligible; some relevant measures of BF duration were also excluded (e.g., duration of BF per child). Non-English studies were excluded.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Jager, 2014[56] Diabetes	High	No grey literature or unpublished studies were included and authors required studies to report CIs, leading to a risk of publication bias (which the review found evidence of).	Yes	Yes	Yes	Yes	Probably no	Unclear	Authors restricted eligibility to studies reporting a RR and 95% CI; unclear if this meant that they would have excluded otherwise eligible studies that reported a different measure of diabetes risk associated with BF (e.g., OR).

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Jiang, 2017[57] Osteoporotic fractures	High	Exclusion of studies without effect sizes reporting, and no consideration of bias in primary studies.	Probably yes	Probably no	Yes	Probably no	Probably yes	High	The review restricted inclusion to studies that provided an effect size. Studies with the same underlying information, i.e., event rates and total sample size, for which effect sizes could be calculated, were excluded. This suggests a potential for excluding relevant studies.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Lambertini, 2016[58] Breast cancer	Unclear	Unclear reporting of whether literature review and data abstraction were dually reviewed. No ROB assessment of individual studies. Exclusion of studies that do not report an OR (or give sufficient information to calculate one) may lead to exclusion of some relevant studies. Analyses are appropriate; however, more may have been done to address substantial heterogeneity across studies.	Yes	Yes	Yes	Probably yes	Probably yes	Unclear	Authors specify that OR had to be reported (or computed from available data) for study to meet inclusion criteria. Unclear how many potentially relevant articles were excluded due to reporting of a different measure of association and/or no measure of variance. English-language only restriction.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Li, 2014[60] Ovarian cancer	Unclear	Unclear for several domains (including issues related to study selection and data collection). Evidence synthesis appears overall well done (aside from sensitivity analyses involving fixed effects), though substantial heterogeneity remained.	Yes	Yes	Yes	Probably yes	Probably yes	Unclear	Limited to studies reporting a RR/OR and measure of variation; however, authors note that they also attempted to calculate measures when data was available. Unclear how may potentially relevant studies were excluded due to availability of data. Limited to English studies.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Luan, 2013[51] Ovarian cancer	Low	Although only one database was searched, authors searched references of all included studies to identify publications that may have been missed in their Medline search. No ROB of individual studies was conducted, however analyses address a number of factors related to potential bias in this literature (e.g., known confounders, aspects of study design).	Yes	Yes	Yes	Probably yes	Probably yes	Low	Authors note that studies had to report a measure of effect and CI; however, unlike other studies, they at least note that any measure would be eligible (HR, RR and OR) and note they attempted to calculate measures when data was available. English-language only restriction.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Neville, 2014[61] Postpartum weight change	High	See individual domains; no dual review of abstracts/full texts or ROB assessment for included studies. Characteristics of studies are not well desribed and syntheses focuses on number of studies that found a postiive association grouped by study design and outcome.	Yes	Yes	Yes	Yes	Probably yes	Low	No specific restrictions on eligibility were reported based on sources of information, language or availability of data.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Pan, 2013[62] Breast cancer	High	See individual domains; unclear ratings for multiple categories and high risk of bias for data collection. Unclear whether literature review was dually assessed. No ROB of individual studies. Exclusion of studies based on specific type of outcome measure reported may bias study selection. Meta-analyses conducted on only 3 studies with limited assessment of heterogeneity.	Yes	Yes	Yes	Probably yes	Probably yes	Unclear	Authors specify that included studies had to report a RR and corresponding 95% CI; no note regarding whether they attempted to calculate this with sufficient data was available. English-language only restriction.

Author, Year Health Outcome	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	1.2 Were the eligibility criteria appropriate for the review question?	1.3 Were eligibility criteria unambi-guous?	1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g., date, sample size, study quality, outcomes measured)?	1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g., publication status or format, language, availability of data)?	Concerns Regarding Specifi-Cation of Study Eligibility Criteria	Rationale for Concern
Sung, 2016[63] Ovarian cancer	Unclear	See individual domains for details. Briefly, study selection methods were not reported, there was substantial heterogeneity that was unexplained, and several opportunities for additional analyses were not taken.	Yes	Yes	Yes	No	Yes	Low	NA

BF = Breastfeeding; CI = confidence interval; HR = hazard ratio; KQ = Key Question; NA = not applicable; OR = odds ratio; RCT = randomized controlled trial; ROB = risk of bias; RR = relative risk.

Table C-15. KQ 2 risk of bias assessment: Systematic reviews, part 2

Author, Year Health Outcome	2.1 Did the search include an appropriate range of databases/ electronic sources for published and unpublished reports?	2.2 Were methods additional to database searching used to identify relevant reports?	2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	2.4 Were restrictions based on date, publication format, or language appropriate?	2.5 Were efforts made to minimize error in selection of studies?	Concerns Regarding Methods Used to Identify and/or Select Studies	Rationale for Concern
Aune, 2014[50] Diabetes	Probably yes	Yes	Yes	Yes	No information	Unclear	Authors searched references of included articles to identify further studies but did not look for unpublished (grey) literature. Methods unclear whether abstracts and full-texts were dually reviewed.
Chowdhury, 2015[2] Breast and ovarian cancer	Probably yes	Yes	Probably yes	Yes	Yes	Low	Authors searched multiple databases and reference lists of relevant articles; I considered this sufficient.
Dias, 2015[52] Postpartum depression	Probably yes	No information	Probably yes	Yes	Yes	Low	Multiple databases were searched and review of abstracts and full-texts was conducted dually; unclear if grey/unpublished literature was searched. Only a brief description of search terms/strategy is provided.
Feng, 2014[53] Ovarian cancer	Yes	Yes	Probably yes	Probably no	No information	Unclear	As noted in Domain #1, unclear whether restrictions were made during study selection based on outcome measures. Unclear whether literature was dually reviewed. Authors searched conference proceedings and reference lists of included studies.

Author, Year Health Outcome	2.1 Did the search include an appropriate range of databases/ electronic sources for published and unpublished reports?	2.2 Were methods additional to database searching used to identify relevant reports?	2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	2.4 Were restrictions based on date, publication format, or language appropriate?	2.5 Were efforts made to minimize error in selection of studies?	Concerns Regarding Methods Used to Identify and/or Select Studies	Rationale for Concern
He, 2015[54] Postpartum weight change	Probably yes	Yes	Probably yes	Probably yes	Yes	Unclear	In addition to databases, authors assessed included studies to identify relevant citations missed in database searches. Dual review of abstract and full-texts was conducted. Methods state that RCTs were eligible but there is no note of whether studies of weight loss interventions were eligible.
Islami, 2015[55] Breast cancer	Probably yes	Yes	Probably yes	Probably no	Probably yes	Unclear	Searches were not designed to identify unpublished reports (unpublished abstracts/reports were not eligible); authors did look at references from relevant studies to identify articles database searches may have missed. Methods note that three authors "independently" performed the search and evaluated articles (unclear if each article was dually reviewed).
Jager, 2014[56] Diabetes	Probably no	Yes	Yes	Yes	Yes	Unclear	No grey literature search; this, in addition to requirement that studies report CIs could elevate publication bias.
Jiang, 2017[57] Osteoporotic fractures	Yes	Yes	Yes	Yes	Probably no	High	Studies without reported effect sizes were excluded (studies with relevant data that allowed calculation of effect size data were potentially excluded).

Author, Year Health Outcome	2.1 Did the search include an appropriate range of databases/ electronic sources for published and unpublished reports?	2.2 Were methods additional to database searching used to identify relevant reports?	2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	2.4 Were restrictions based on date, publication format, or language appropriate?	2.5 Were efforts made to minimize error in selection of studies?	Concerns Regarding Methods Used to Identify and/or Select Studies	Rationale for Concern
Lambertini, 2016[58] Breast cancer	Probably yes	Yes	Probably yes	Probably yes	No information	Unclear	Unclear whether literature review was conducted dually or by one of two authors (methods are ambiguous). Inclusion criteria based on type of outcome measure available may exclude some potentially relevant studies. Restricted to English-language publications.
Li, 2014[60] Ovarian cancer	Yes	Yes	Probably yes	Probably yes	No information	Unclear	No information on whether literature review was dually assessed; as noted in Domain #1, studies were excluded if they did not report an OR/RR and 95% CI (or data sufficient to calculate these). Authors searched reference lists of included studies.
Luan, 2013[51] Ovarian cancer	Probably no	Yes	Probably yes	Probably yes	Probably yes	Unclear	Only searched MEDLINE, but did search the reference lists of all included studies for additional publications; no unpublished sources were evaluated; unclear whether dual or singular screening of titles/abstracts (full-text review was dual).
Neville, 2014[61] Postpartum weight change	Probably yes	Yes	Probably yes	Probably yes	Probably no	Unclear	Multiple databases were searched; authors also reviewed additional relevant citations from articles retrieved via database searches. One reviewer screened all abstracts/full-texts, and a second reviewer was consulted for questions about eligibility.

Author, Year Health Outcome	2.1 Did the search include an appropriate range of databases/ electronic sources for published and unpublished reports?	2.2 Were methods additional to database searching used to identify relevant reports?	2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	2.4 Were restrictions based on date, publication format, or language appropriate?	2.5 Were efforts made to minimize error in selection of studies?	Concerns Regarding Methods Used to Identify and/or Select Studies	Rationale for Concern
Pan, 2013[62] Breast cancer	Probably no	Yes	Probably yes	Probably yes	No information	Unclear	Only one database was searched. Unclear whether literature review was conducted dually or by one of two authors (methods are ambiguous). Inclusion criteria based on type of outcome measure available (RR and 95% CI) may exclude some potentially relevant studies. Searched reference lists of included studies and reported that they did not identify any unpublished data (though didn't describe their search methods).
Sung, 2016[63] Ovarian cancer	Probably yes	Yes	Probably yes	Yes	No information	Unclear	450 of 489 articles identified for the breastfeeding analysis were excluded at title/abstract review, which is a very high rate of exclusion. Authors did not describe whether title/abstract or full-text review was dual.

CI = confidence interval; KQ = Key Question; OR = odds ratio; RCT = randomized controlled trial; RR = relative risk.

Table C-16. KQ 2 risk of bias assessment: Systematic reviews, part 3

Author, Year Health Outcome	3.1 Were efforts made to minimize error in data collection?	3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	3.3 Were all relevant study results collected for use in the synthesis?	3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria?	3.5 Were efforts made to minimize error in risk of bias assessment?	Concerns Regarding Methods Used to Collect Data and Appraise Studies	Rationale for Concern
Aune, 2014[50] Diabetes	Yes	Yes	Yes	Yes	No information	Unclear	Methods state that two authors independently abstracted data from studies, but it is unclear whether risk of bias of included studies was dually assessed.
Chowdhury, 2015[2] Breast and ovarian cancer	No information	Probably no	Probably yes	Yes	No information	Unclear	Unclear whether data abstraction was checked by a second author. Very few study characteristics were presented/described, and only then on an aggregate level, probably due to the scope of the review (i.e., multiple outcomes). Authors cited the ACROBAT-NRSI tool as a measure of study quality, explaining that study quality was used in subgroup analyses; no additional details were provided, including whether the assessment was performed dually.
Dias, 2015[52] Postpartum depression	Probably yes	Probably no	Probably yes	No	No information	Unclear	No sample characteristics were reported, effect sizes were not reported, and risk of bias was only determined based on two criteria: (1) women should be clearly identified as postpartum women, and (2) studies should identify the outcome measurements.
Feng, 2014[53] Ovarian cancer	No information	Probably yes	Probably yes	Yes	Yes	Unclear	Unclear whether data abstractions for each article were reviewed by two authors. Description of database searches is limited.

Author, Year Health Outcome	3.1 Were efforts made to minimize error in data collection?	3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	3.3 Were all relevant study results collected for use in the synthesis?	3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria?	3.5 Were efforts made to minimize error in risk of bias assessment?	Concerns Regarding Methods Used to Collect Data and Appraise Studies	Rationale for Concern
He, 2015[54] Postpartum weight change	No information	Probably no	Probably yes	Yes	Yes	Unclear	Unclear whether data abstraction was dually reviewed. Authors assessed study quality using predefined criteria; however, tool appears to be developed by authors and may not address all potential risks of bias. There is limited description of study characteristics.
Islami, 2015[55] Breast cancer	Probably yes	Probably no	Probably yes	Probably no	No information	High	Unclear whether data abstractions for each article were reviewed by two authors. ROB assessment for individual studies was not mentioned in the methods or results.
Jager, 2014[56] Diabetes	No information	Yes	Yes	Yes	No information	Unclear	Unclear whether data abstraction and risk of bias assessment was dually reviewed. Authors rate risk of bias and show assessments in an appendix; questions appear appropriate. Tool used was adapted from another existing systematic review on a related topic.
Jiang, 2017[57] Osteoporotic fractures	Yes	Yes	Probably yes	No	No information	Unclear	No assessment of risk of bias, unclear whether an assessment would have altered findings.

Author, Year Health Outcome	3.1 Were efforts made to minimize error in data collection?	3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	3.3 Were all relevant study results collected for use in the synthesis?	3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria?	3.5 Were efforts made to minimize error in risk of bias assessment?	Concerns Regarding Methods Used to Collect Data and Appraise Studies	Rationale for Concern
Lambertini, 2016[58] Breast cancer	Probably yes	Probably no	Probably yes	Probably no	No information	High	Unclear how data extraction discrepancies were resolved. Insufficient information is provided for study characteristics in terms of how BF exposure was measured and then classified by authors in ever/never analyses. Authors do not appear to have conducted a ROB assessment of included studies.
Li, 2014[60] Ovarian cancer	Yes	Probably yes	Probably yes	Yes	Probably yes	Unclear	Study characteristics are limited. There was dual data abstraction and ROB assessment, though it is unclear how ROB discrepancies were reconciled.
Luan, 2013[51] Ovarian cancer	Probably yes	Probably no	Probably yes	No	NA	High	Methods suggest data abstraction was dually reviewed but description is ambiguous. There are very few study characteristics described. Authors do not describe the definition of ever/never breastfed nor explain about the role of parity in the analyses. Authors did not formally assess ROB of included studies. However, some characteristics abstracted (and analyses performed) do address issues of confounding.

Author, Year Health Outcome	3.1 Were efforts made to minimize error in data collection?	3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	3.3 Were all relevant study results collected for use in the synthesis?	3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria?	3.5 Were efforts made to minimize error in risk of bias assessment?	Concerns Regarding Methods Used to Collect Data and Appraise Studies	Rationale for Concern
Neville, 2014[61] Postpartum weight change	No information	Probably no	Probably no	Probably no	Probably no	High	No formal risk of bias/ quality assessment of included studies is described in the methods or tables. A few (brief) remarks are made in the discussion regarding study rigor and heterogeneity of outcome measures. Unclear whether data abstraction was dually reviewed. Minimal study characteristics were described; unclear whether all relevant results were collected. Results reporting is minimal.
Pan, 2013[62] Breast cancer	Probably yes	Probably no	Probably yes	Probably no	No information	High	Data abstraction likely dually reviewed but methods are ambiguous (state that two authors independently abstracted data and differences were addressed by consensus). Study characteristics are limited (e.g., no country setting described). No ROB of individual studies performed.
Sung, 2016[63] Ovarian cancer	Yes	Probably yes	Probably yes	Probably yes	Yes	Low	Dual data extraction and dual quality assessment using the NOS.

ACROBAT-NRSI = A Cochrane Risk of Bias Assessment Tool for Non-Randomized Studies of Interventions; BF = breastfeeding; KQ = Key Question; NOS = Newcastle-Ottawa Scale; ROB = risk of bias.

Table C-17. KQ 2 risk of bias assessment: Systematic reviews, part 4

Author, Year Health Outcome	4.1 Did the synthesis include all studies that it should?	4.2 Were all pre-defined analyses reported or departures explained?	4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	4.6 Were biases in primary studies minimal or addressed in the synthesis?	Concerns regarding the synthesis and findings	Rationale for Concern
Aune, 2014[50] Diabetes	Probably yes	Yes	Yes	Yes	Yes	Yes	Low	NA
Chowdhury, 2015[2] Breast and ovarian cancer	Probably yes	Yes	Probably yes	Probably yes	Probably yes	Probably yes	Unclear	For ovarian cancer, authors described thresholds for heterogeneity and explained that random-effects models were used if present; authors conducted various subgroup analyses and evaluated within group and between subgroups with meta-regression; authors suggest that approximately 80% of the heterogeneity was explained in meta-regression. For breast cancer, authors reported evidence of publication bias (asymmetry in funnel plot as well as statistically significant Egger and Begg tests) suggesting findings may not be robust.

Author, Year Health Outcome	4.1 Did the synthesis include all studies that it should?	4.2 Were all pre-defined analyses reported or departures explained?	4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	4.6 Were biases in primary studies minimal or addressed in the synthesis?	Concerns Regarding the Synthesis and Findings	Rationale for Concern
Dias, 2015[52] Postpartum depression	Probably yes	Yes	Probably yes	No information	No information	No information	Unclear	Evidence synthesis focuses on a range of questions related to breastfeeding and post-partum depression. No quantitative synthesis was performed and results (including outcome measures) appear heterogeneous. Criteria used to group outcomes is not reported.
Feng, 2014[53] Ovarian cancer	Probably yes	Probably yes	Probably yes	Probably no	No information	Probably yes	High	Authors describe I-squared in random effects meta-analysis, but do not adequately address the substantial between-study variation in the synthesis. They report fixed effects meta-analyses as a way to assess the robustness of their findings which does not seem appropriate, especially given the substantial heterogeneity. Quality of included articles was assessed according to Newcastle-Ottawa Scale; most studies were rated high quality (NOS 7 or 8; no 9 ratings) but there were a handful of low quality (NOS=6) and no subgroup analysis done by rating. There was no evidence of publication bias as reported by the authors.

Author, Year Health Outcome	4.1 Did the synthesis include all studies that it should?	4.2 Were all pre-defined analyses reported or departures explained?	4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	4.6 Were biases in primary studies minimal or addressed in the synthesis?	Concerns Regarding the Synthesis and Findings	Rationale for Concern
He, 2015[54] Postpartum weight change	Probably yes	Probably yes	Probably yes	Probably no	Probably no	Probably yes	Unclear	Some relevant studies were identified but not included in the quantitative synthesis for various reasons (e.g., inadequate outcome reporting). Reasons are described in text and studies are noted in an Appendix. Not clear whether results of these studies were congruent with the meta-analyses. Analyses had significant heterogeneity across studies, only partially addressed by subgroup analyses. No assessment of publication bias.
Islami, 2015[55] Breast cancer	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes	No information	Unclear	Authors address heterogeneity primarily through subgroup analyses (and focus on differences in study design); publication bias was addressed via funnel plot (even though unpublished studies were not eligible). No formal ROB of individual studies was described. Authors do address some potential bias by performing subgroups based on whether estimates from individual studies were adjusted for known confounders.

Author, Year Health Outcome	4.1 Did the synthesis include all studies that it should?	4.2 Were all pre-defined analyses reported or departures explained?	4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	4.6 Were biases in primary studies minimal or addressed in the synthesis?	Concerns Regarding the Synthesis and Findings	Rationale for Concern
Jager, 2014[56] Diabetes	Probably yes	Yes	Probably yes	Probably yes	Yes	Yes	Low	Meta-analyses included few (3 studies); however, heterogeneity across studies which was addressed in the text and I-squared was reported.
Jiang, 2017[57] Osteoporotic fractures	Yes	No information	Yes	Yes	Probably yes	no information	Unclear	No assessment of risk of bias, unclear whether an assessment would have altered findings.
Lambertini, 2016[58] Breast cancer	Probably yes	Probably yes	Probably yes	Probably no	Probably yes	Probably yes	Unclear	Authors report a clear description of analyses and conduct subgroup analyses to address heterogeneity. However, there was substantial heterogeneity even among the subgroups, some of which were defined by correlated variables.
Li, 2014[60] Ovarian cancer	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes	Low	Although authors conducted several subgroup analyses and meta-regression to address heterogeneity (based on important study and population characteristics), there was residual heterogeneity within subgroups. Publication bias was also addressed.

Author, Year Health Outcome	4.1 Did the synthesis include all studies that it should?	4.2 Were all pre-defined analyses reported or departures explained?	4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	4.6 Were biases in primary studies minimal or addressed in the synthesis?	Concerns Regarding the Synthesis and Findings	Rationale for Concern
Luan, 2013[51] Ovarian cancer	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes	Low	Multiple subgroup analyses performed to address potential heterogeneity, in addition to meta-regression. Authors also conducted analyses removing one study at a time. Publication bias was addressed. There was residual heterogeneity within subgroups.
Neville, 2014[61] Postpartum weight change	Probably yes	No information	Probably no	Probably no	No information	No information	High	No meta-analyses; results are described by study design and outcome timing of measure (in relation to postpartum period). Unclear whether different study designs that measured the same weight outcome found similar results. Synthesis primarily focuses on number of studies that had statistically significant results. No formal assessment of heterogeneity per specific outcomes or publication bias.
Pan, 2013[62] Breast cancer	Probably yes	Probably yes	Probably yes	Probably no	Probably yes	Probably no	Unclear	Small number of studies (three) were pooled, which may not be appropriate given heterogeneity; analyses seem appropriate and well described, but very limited attention to heterogeneity.

Author, Year Health Outcome	4.1 Did the synthesis include all studies that it should?	4.2 Were all pre-defined analyses reported or departures explained?	4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	4.6 Were biases in primary studies minimal or addressed in the synthesis?	Concerns Regarding the Synthesis and Findings	Rationale for Concern
Sung, 2016[63] Ovarian cancer	Probably yes	Yes	Probably yes	Probably no	Probably yes	Probably no	Unclear	Substantial heterogeneity of results, even after subgroup analysis was performed;73% of the included studies were rated “low-quality” according to the NOS, and even though authors performed subgroup analysis by quality, they did not go further. While most studies did adjust for a number of confounders, not all did. Additionally, authors do not report on the types of case-control studies (i.e., population- or hospital-based).

KQ = Key Question; NA = not applicable; NOS = Newcastle Ottawa Scale; ROB = risk of bias.

Table C-18. KQ 2 risk of bias assessment: Systematic reviews, part 5

Author, Year Health Outcome	A. Did the interpretation of findings address all of the concerns identified in Domains 1 to 4?	B. Was the relevance of identified studies to the review's research question appropriately considered?	C. Did the reviewers avoid emphasizing results on the basis of their statistical significance?
Aune, 2014[50] Diabetes	Probably yes	Yes	Yes
Chowdhury, 2015[2] Breast and ovarian cancer	Probably yes	Yes	Probably yes
Dias, 2015[52] Postpartum depression	Probably no	Yes	No
Feng, 2014[53] Ovarian cancer	Probably no	Yes	Probably no
He, 2015[54] Postpartum weight change	Probably yes	Yes	Yes
Islami, 2015[55] Breast cancer	Probably yes	Yes	Probably no
Jager, 2014[56] Diabetes	Probably yes	Yes	Yes
Jiang, 2017[57] Osteoporotic Fractures	No	Yes	No
Lambertini, 2016[58] Breast cancer	Probably no	Yes	Probably yes
Li, 2014[60] Ovarian cancer	Probably yes	Yes	Probably no
Luan, 2013[51] Ovarian cancer	Probably yes	Yes	Yes
Neville, 2014[61] Postpartum weight change	No	Yes	No
Pan, 2013[62] Breast cancer	Probably no	Yes	Probably yes
Sung, 2016[63] Ovarian cancer	No	Yes	Probably yes

KQ = Key Question.

Table C-19. KQ 2 risk of bias assessment: Breast cancer, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Al-Amri, 2015[66]	High	High risk of measurement bias (exposure status and confounding variables); unclear analysis regarding adjustment for potential confounders. Women (cases and controls) are relatively young and duration may not be sufficient to determine a difference in breast cancer outcomes.	NA	NA	NA	NA	Yes	Low	NA
Al-Qutub, 2013[67]	High	High risk for measurement bias for exposure (recall bias); lack of adjustment for any confounders in analyses, dissimilarity between cases and controls at baseline not accounted for in analyses.	NA	NA	NA	NA	Probably no	Some concerns	Controls were recruited from communities and from the same hospitals as cases, but little additional information is provided about control selection.
Atkinson, 2016[68]	High	High risk of selection bias (dissimilar criteria used to select cases and controls); risk of recall bias for BF exposure and confounding (differences between groups at baseline not fully addressed in analyses).	NA	NA	NA	NA	No	High	Although cases and controls were recruited from the same clinical setting, they were recruited for two different studies with different racial eligibility criteria—controls were only Caucasian and cases were not restricted by race/ethnicity.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Beaber, 2008[69]	Some concerns	Breastfeeding history was assessed after diagnosis of breast cancer among cases, resulting in concern for differential recall bias.	NA	NA	NA	NA	Yes	Low	NA
Castello, 2015[70]	Some concerns	Risk of recall bias in breastfeeding measurement, lack of adequate adjustment for confounders (and some adjustment for postexposure variables).	NA	NA	NA	NA	Probably yes	Low	Controls were selected from cases' in-law relatives, friends, neighbors, or work colleagues residing in the same town and were matched on age. No other eligibility criteria are listed for controls.
Dalamaga, 2011[71]	High	Risk of selection bias; analyses did not adjust for potential confounders; risk of recall bias (including differential recall bias).	NA	NA	NA	NA	Probably yes	Some concerns	Cases and controls were selected from the same hospital; controls were women from outpatient clinics who came for an annual checkup and had a negative mammogram.
Ge, 2015[72]	High	Risk of recall bias and lack of precision in breastfeeding measurement, lack of adjustment for any potential confounders.	NA	NA	NA	NA	Probably yes	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/outcome?	1a. Were post-exposure variables that influenced selection related to exposure/outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Hadji, 2007[73]	High	Risk of recall bias, ascertainment of breast cancer outcome not described, and lack of adjustment for potential confounders.	NA	NA	NA	NA	Probably yes	Low	NA
Holm, 2017[74]	Some concerns	Potential selection bias; cases were recruited from two cohort studies of different time periods while controls came from a mammography cohort from one-time period. BF exposure broadly defined and reported many years after the exposure.	NA	NA	NA	NA	Probably no	Some concerns	Controls were sampled from a mammography screening cohort from 2001-2008 while some cases were sampled from a cohort from 2011-2013; geographic regions overlapped.
Kabat, 2011[75]	Some concerns	Risk of inception bias, residual confounding, and recall bias.	Probably no	NA	No	NA	NA	Some concerns	Potential inception bias; women were postmenopausal at enrollment and generally healthy.
Kotsopoulos, 2012[76]	Some concerns	Risk of selection bias, residual confounding and recall bias (breastfeeding duration).	NA	NA	NA	NA	Probably yes	Low	Although controls were likely sampled from different populations, they were matched to cases on several key variables and selected from similar countries and timepoints.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Kruk, 2014[77]	High	Risk of selection bias, recall bias (including differential recall bias on BF exposure measures) and lack of adjustment for potential confounders.	NA	NA	NA	NA	Probably no	High	Controls were recruited from a variety of clinical settings (similar geographic setting as controls), including those visiting ambulatory clinics for "health controlling" or a cold, from hospitals being treated for fractures, CVD, back pain, and other diseases. Response rates for questionnaires sent in both cases and controls was relatively low at 74% and 69% respectively.
Lee, 2008[78]	Some concerns	Recall bias and testing for numerous effect modifiers are concerns.	NA	NA	NA	NA	Yes	Low	NA
Lumachi, 2010[79]	High	Breastfeeding history was assessed after diagnosis of breast cancer among cases, resulting in concern for differential recall bias. Analyses did not adjust for any potential confounders.	NA	NA	NA	NA	Probably no	Some concerns	Controls were women who had undergone mammograms twice. Depending on screening guidelines in the source population, this could have selected for women who were more likely to follow medical recommendations, and thus more likely to breastfeed, than the general population.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Ma, 2006[80]	Some concerns	Risk of selection bias, residual confounding and recall bias (breastfeeding duration).	NA	NA	NA	NA	Probably yes	Low	NA
Ma, 2017[81]	Some concerns	Investigators pooled data from 3 studies that did not occur at the same time. Potential confounding or recall bias.	NA	NA	NA	NA	Probably yes	Some concerns	Study pooled women from three different population-based studies. Two studies shared controls from the same time and geographic area. The third study recruited neighborhood controls and was conducted after the other two studies.
Merritt, 2015[82]	Some concerns	Risk of selection bias, measurement bias, and residual confounding.	Probably no	Probably no	Probably no	NA	NA	Some concerns	Only those with complete data on lifestyle and breastfeeding were included from the larger cohort (women who BF may have been more likely to complete expose data).
Phillips, 2009[83]	Some concerns	Recall bias with respect to breastfeeding history is a concern.	NA	NA	NA	NA	Probably yes	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/outcome?	1a. Were post-exposure variables that influenced selection related to exposure/outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Pieta, 2008[84]	Some concerns	Risk of recall bias and selection bias, particularly with respect to differences in ages of cases and controls.	NA	NA	NA	NA	Probably no	Some concerns	Controls were women who had had a breast exam and normal mammogram. They were younger than cases, and it was unclear whether cases were similarly screened and then diagnosed, or referred from a different clinic/patient population. Moreover, secular trends in breastfeeding rates may be driving differences by age, rather than association with cancer risk.
Press, 2010[85]	High	Cases and controls sampled from different populations, no adjustment for potential confounders; potential recall bias and measurement bias (for BF exposure).	NA	NA	NA	NA	No	Some concerns	Controls sampled from women admitted to the hospital for another disease, or applying for outpatient care.
Ritte, 2013[86]	Some concerns	Risk of recall bias for breastfeeding exposure, residual confounding, and adjusted analyses included several post-exposure variables.	Yes	NA	Probably no	NA	NA	Some concerns	Women were recruited into the cohort between the ages of 25 and 70 years; for most women, this would have been after breastfeeding exposure.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Ruszczyk, 2016[87]	Some concerns	Risk of recall bias for breastfeeding exposure, unclear amount of missing data, risk of residual confounding.	NA	NA	NA	NA	Probably yes	Some concerns	Some controls recruited with random digit dialing of residential telephone numbers. However, some recruited through community-based efforts that were not well described.
Stendell-Hollis, 2013[88]	Some concerns	Risk of residual confounding and some post-exposure variables were included in the adjusted analyses.	Yes	NA	No	NA	NA	Low	NA
Sugawara, 2013[89]	Some concerns	Risk of inception bias, residual confounding, and measurement bias.	Probably no	Probably yes	No	No	NA	Some concerns	Potential inception bias; women were generally 50–60 years old at cohort enrollment and only those who were cancer-free were followed.
Tamimi, 2016[90]	Some concerns	Potential selection bias, recall bias, and confounding bias; moderate missing data for a number of covariates.	Yes	NA	Probably no	NA	NA	Low	NA
Warner, 2013[91]	Some concerns	Risk of selection bias and residual confounding; some post-exposure variables were included in adjusted analyses.	Yes	Probably yes	No	Probably yes	NA	Some concerns	Healthy user bias in participants from Nurses Health Study may lead to selection bias.

BF = breastfeeding; CVD = cardiovascular disease; KQ = Key Question; NA = not applicable.

Table C-20. KQ 2 risk of bias assessment: Breast cancer, part 2

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Al-Amri, 2015[66]	Probably no	Probably yes	No information	No	Probably no	NA	Some concerns	Baseline differences were adjusted for during statistical analyses, however statistical analyses were not well described. Validity/reliability of measurement of confounders was also not well described; results potentially adjusted for post-exposure variables (HRT use).
Al-Qutub, 2013[67]	No	No	NA	Yes	NA	NA	High	The analysis of BF and cancer outcomes did not adjust for any confounders. Groups are dissimilar in regards to parity and other factors at baseline.
Atkinson, 2016[68]	Probably no	Probably yes	No information	No	NA	NA	Some concerns	Race/ethnicity is a likely confounder and was not adjusted for; validity of covariate measures unclear. Some potential post-exposure variables were considered in analyses (BMI, smoking status).
Beaber, 2008[69]	Probably no	Probably yes	Probably yes	Probably yes	Yes	Yes	Low	NA
Castello, 2015[70]	Probably no	Probably no	Probably yes	No	NA	NA	Some concerns	Adjusted analyses included some factors that are post exposure (total calorie intake, smoking, history of breast problems). History of breast problems is unclear in terms of clinical significance; could indicate BF problems or factors related to cancer.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Dalamaga, 2011[71]	Probably no	No	NA	NA	NA	NA	High	Main analyses look at association between serum vistatin and breast cancer; analysis reporting on association between BF exposure and cancer is not adjusted for potential confounders.
Ge, 2015[72]	Probably no	No	NA	NA	NA	NA	High	The analysis of BF and cancer outcomes did not adjust for potential confounders.
Hadji, 2007[73]	No	No	NA	NA	NA	NA	High	Analysis did not adjust for any potential confounders; authors report a multiple linear regression analysis but provide no details or quantitative results.
Holm, 2017[74]	Probably no	Yes	Probably yes	Yes	NA	NA	Some concerns	Analysis controlled for multiple factors, but residual confounding may be of concern.
Kabat, 2011[75]	Probably no	Probably no	Probably yes	No	NA	NA	Some concerns	Analysis controlled for multiple factors, but residual confounding may be of concern.
Kotsopoulos, 2012[76]	Probably no	Probably yes	Probably yes	Probably yes	NA	NA	Some concerns	Analysis controlled for multiple confounders, but residual confounding may be of concern.
Kruk, 2014[77]	Probably no	No	NA	NA	NA	NA	High	The analysis of BF and cancer outcomes did not adjust for any potential confounders.
Lee, 2008[78]	Probably no	Probably yes	Probably yes	Probably no	Yes	Yes	Low	NA

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Lumachi, 2010[79]	No	No	NA	NA	NA	NA	High	Analysis did adjust for any potential confounders.
Ma, 2006[80]	Probably no	Probably no	Probably yes	No	NA	NA	Some concerns	Some adjustment was made for variables related to exposure and outcome (BMI).
Ma, 2017[81]	Probably no	Yes	Probably yes	Yes	NA	NA	Some concerns	Investigators included a substantial number of potential confounders in the models but did not quantitatively assess confounding; there is a potential for over-adjustment or residual confounding.
Merritt, 2015[82]	Probably no	No	Probably yes	No	NA	NA	Some concerns	Analyses adjusted for multiple potential confounders; some (BMI) were likely related to both exposure and outcome.
Phillips, 2009[83]	Probably no	Probably yes	Probably yes	Probably yes	Probably yes	NA	Low	No confounders met the 10% threshold for inclusion, so only adjusted for age and race.
Pieta, 2008[84]	No	No	NA	Probably no	Probably yes	NA	High	Only unadjusted odds ratios for breastfeeding are presented.
Press, 2010[85]	No	No	NA	NA	Yes	Yes	High	Analyses do not adjust for any potential confounding factors.
Ritte, 2013[86]	Probably no	Yes	Probably yes	No	Probably yes	NA	Some concerns	Adjusted results included post-exposure variables, including BMI (at enrollment), HRT use, smoking and alcohol consumption, and others.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Ruszczyk, 2016[87]	Probably no	Probably yes	Probably yes	Probably yes	NA	NA	Low	NA
Stendell-Hollis, 2013[88]	Probably no	Probably yes	Probably yes	No	Probably yes	NA	Some concerns	Analysis adjusted for some post-exposure variables, including BMI, smoking status, and use of HRT.
Sugawara, 2013[89]	Probably no	Probably yes	Probably yes	No	Yes	NA	Some concerns	Analysis adjusted for BMI, number of deliveries, and other health behaviors potentially associated with both exposure and outcome.
Tamimi, 2016[90]	Probably no	Probably no	Probably no	Probably yes	Probably yes	NA	Some concerns	Multiple analyses adjusted for a number of potential confounders; the specific confounders varied by model. Data were self-reported via surveys.
Warner, 2013[91]	Probably no	Probably yes	Probably yes	No	Yes	NA	Some concerns	Models included some post-exposure covariates (alcohol consumption, postmenopausal HRT, weight change since age 18).

BF = breastfeeding; BMI = body mass index; HRT = hormone replacement therapy; KQ = Key Question; NA = not applicable.

Table C-21. KQ 2 risk of bias assessment: Breast cancer, part 3

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Al-Amri, 2015[66]	No	No	No	High	Measurement of BF exposure is not well described (and there was no assessment of duration/intensity). Potential for recall bias (and differential recall bias among cases).
Al-Qutub, 2013[67]	No	No	Probably yes	Some concerns	Risk of recall bias due to amount of time between BF and data collection. BF measure not well-defined (greater than or less than 12 months of lifetime BF).
Atkinson, 2016[68]	No	No	Probably no	Some concerns	Risk of recall bias due to amount of time between breastfeeding and data collection. BF measure (ever/never) does not take into account duration or intensity.
Beaber, 2008[69]	Probably yes	No	No	Some concerns	BF history was assessed after diagnosis of breast cancer among cases, resulting in concern for differential recall bias.
Castello, 2015[70]	Yes	No	No	Some concerns	Risk of recall bias due to amount of time between breastfeeding and data collection.
Dalamaga, 2011[71]	No	No	No	High	No description of how BF exposure status was measured; potential for recall bias and differential recall among cases vs. controls.
Ge, 2015[72]	No	No	Probably yes	Some concerns	Risk of recall bias due to length of time between breastfeeding and data collection. Breastfeeding measure not well-defined (ever vs. never).
Hadji, 2007[73]	Probably yes	No	Probably no	Some concerns	Risk of recall bias due to length of time between breastfeeding and data collection for poorly defined analysis of BF duration.
Holm, 2017[74]	Probably yes	No	Probably no	Some concerns	Potential for recall bias, though exposure is broadly defined. BF exposure was measured decades later in most women.

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Kabat, 2011[75]	Probably yes	No	Probably yes	High	Risk of recall bias; BF exposure was measured decades later in most women. Risk of recall bias for BF duration.
Kotsopoulos, 2012[76]	Yes	No	Probably no	Some concerns	Recall bias may be present due to the length of time between exposure and assessment.
Kruk, 2014[77]	Probably no	No	No	Some concerns	Risk of recall bias due to amount of time between breastfeeding and data collection. BF measure not well-defined (0, less than 6 months, greater than 6 months).
Lee, 2008[78]	Probably yes	No	No	High	BF history was assessed after diagnosis of breast cancer among cases, resulting in concern for differential recall bias.
Lumachi, 2010[79]	No	No	No	Some concerns	BF history was assessed after diagnosis of breast cancer among cases, resulting in concern for differential recall bias.
Ma, 2006[80]	Probably yes	No	Probably yes	Some concerns	Potential recall bias (BF duration), and differential recall among cases.
Ma, 2017[81]	Yes	No	Probably no	Some concerns	Potential for recall bias since exposure occurred long before the outcome; information ascertained after the outcome occurred. Ever/never BF is likely to be accurate but the duration of BF may have been more difficult to accurately recall.
Merritt, 2015[82]	Yes	No	Yes	Some concerns	Risk of recall bias for some of the participants who were older at baseline due to amount of time between BF and data collection.
Phillips, 2009[83]	No	No	No	High	BF history was assessed after diagnosis of breast cancer among cases, resulting in concern for differential recall bias. Furthermore, assessment was limited to “ever vs. never.”

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Pieta, 2008[84]	No	No	No	High	BF history was assessed after diagnosis of breast cancer among cases, resulting in concern for differential recall bias. Details regarding how breastfeeding was assessed were not provided.
Press, 2010[85]	Probably yes	No	No	High	BF history was assessed after diagnosis of breast cancer among cases, resulting in concern for differential recall bias.
Ritte, 2013[86]	Probably yes	No	Probably yes	Some concerns	Risk of recall bias due to amount of time between BF and data collection.
Ruszczyk, 2016[87]	Yes	No	Probably yes	Some concerns	Risk of recall bias due to amount of time between BF and data collection.
Stendell-Hollis, 2013[88]	Yes	No	Probably yes	Some concerns	Risk of recall bias due to amount of time between BF and data collection.
Sugawara, 2013[89]	Probably no	No	Yes	Some concerns	Authors note that women were asked to choose one of three categories (BF only, mixed feeding, and formula feeding only); category of “mixed feeding” does not account for BF duration or intensity. Potential recall bias (although unlikely due to categorical nature of BF exposure classification).
Tamimi, 2016[90]	Probably no	Probably no	Probably yes	Some concerns	Amount of time between BF and seld-report varied but could have been a couple of decades; potential for recall bias. Broad categorization (ever/never) of BF was likely accurate.
Warner, 2013[91]	Probably yes	No	Probably yes	Some concerns	Risk of recall bias due to amount of time between BF and data collection.

BF = breastfeeding; KQ = Key Question.

Table C-22. KQ 2 risk of bias assessment: Breast cancer, part 4

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Al-Amri, 2015[66]	Probably yes	Probably yes	Probably yes	NA	NA	Low	NA
Al-Qutub, 2013[67]	No information	No information	No information	No information	No information	Uncertain because no information	None
Atkinson, 2016[68]	No information	No information	No information	No information	No information	Uncertain because no information	None
Beaber, 2008[69]	Yes	Probably yes	Probably yes	Probably yes	NA	Low	NA
Castello, 2015[70]	Yes	Probably yes	Probably yes	No information	Yes	Some concerns	Number of participants with missing data unclear; however, analyses do include imputation for missing data specific to some variables in analyses.
Dalamaga, 2011[71]	Yes	Probably yes	Probably yes	No information	NA	Low	NA
Ge, 2015[72]	Yes	No information	No information	No information	No information	Uncertain because no information	Authors note “participants with missing values in any of the adjustment variables were excluded”, but the rates of missing values are not reported.
Hadji, 2007[73]	No information	No information	No information	No information	No information	Uncertain because no information	Number of participants with missing data unclear.
Holm, 2017[74]	Yes	Probably yes	Probably yes	No information	No information	Some concerns	No details were provided about extent of missing data or how the analytic approach dealt with missing data. Over 99% of parous participants reported breastfeeding status.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Kabat, 2011[75]	Yes	Yes	Yes	No information	No information	Low	NA
Kotsopoulos, 2012[76]	Probably yes	Probably yes	Probably yes	No information	No information	Low	NA
Kruk, 2014[77]	Probably yes	No information	Yes	No information	No information	Uncertain because no information	NA
Lee, 2008[78]	Probably yes	Probably yes	Probably yes	Probably yes	NA	Low	NA
Lumachi, 2010[79]	Yes	No information	No information	No information	No information	Uncertain because no information	Information on missing data not provided.
Ma, 2006[80]	Probably yes	Probably yes	Probably no	No information	Probably yes	Some concerns	Extent of missing data unclear; analyses appear to impute values for some variables.
Ma, 2017[81]	Yes	Yes	Yes	Probably yes	Probably no	Low	Very few participants were excluded due to missing data, but a majority of those missing data were cases. Investigators used a complete-case analysis rather than employing methods like multiple imputation.
Merritt, 2015[82]	Yes	Yes	Yes	NA	Probably no	Low	NA
Phillips, 2009[83]	Yes	Probably yes	Probably yes	No information	No information	Low	NA
Pieta, 2008[84]	Yes	No information	No information	No information	NA	Uncertain because no information	No information on missing data provided.
Press, 2010[85]	Yes	No	NA	No information	No	Some concerns	Missing exposure data for >10% of control births in United States study.
Ritte, 2013[86]	Yes	Yes	Yes	No information	No information	Low	NA

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Ruszczyk, 2016[87]	No information	Probably yes	No information	No information	No information	Uncertain because no information	Amount of missing data is unclear; discussion notes that up to 30% otherwise eligible cases were excluded due to missing data on histology.
Stendell-Hollis, 2013[88]	No information	No information	No information	No information	Probably no	Uncertain because no information	Analysis was limited to those with “known duration of lactation” but the number of participants missing on that variable is not reported.
Sugawara, 2013[89]	Yes	Yes	Yes	No information	Probably no	Low	NA
Tamimi, 2016[90]	Probably yes	Probably no	Probably no	No information	Probably no	Some concerns	More than 99% of breast cancer cases were confirmed; ER status was only defined for 79% of cases. Over 13% of parous participants were missing total breastfeeding duration. Several covariates were moderately missing data (>10% missing). Authors used a missing covariate indicator method in analyses.
Warner, 2013[91]	Probably yes	No information	No information	No information	No information	Uncertain because no information	None

ER = estrogen receptor; KQ = Key Question; NA = not applicable.

Table C-23. KQ 2 risk of bias assessment: Breast cancer, part 5

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcome	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Al-Amri, 2015[66]	Yes	NA	Probably no	Some concerns	Mean (and median) age of sample is 48–49; this may not be sufficient duration to detect a difference in breast cancer outcomes.	Probably yes	Low	NA
Al-Qutub, 2013[67]	Probably yes	Probably yes	Probably no	Some concerns	Mean age of cases and controls (40 years) may not be sufficient to determine risk of breast cancer.	Probably yes	Low	NA
Atkinson, 2016[68]	Yes	Probably yes	Yes	Low	NA	Probably yes	Low	NA
Beaber, 2008[69]	Probably yes	Probably yes	NA	Low	NA	Probably yes	Low	NA
Castello, 2015[70]	Probably yes	Probably yes	Probably yes	Some concerns	Age of women at cohort enrollment unclear, close to 50% are classified as pre-menopausal. Duration may not be adequate to fully assess BF outcomes.	Probably yes	Low	NA

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcome	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Dalamaga, 2011[71]	Probably yes	NA	Probably yes	Some concerns	Unclear if outcome assessors were blinded.	Uncertain because no information	Uncertain because no information	Main outcome is not relationship between BF and cancer; unclear whether authors considered or obtained additional information (or conducted other analyses) related to the association between BF and cancer.
Ge, 2015[72]	Probably yes	Probably yes	Probably yes	Some concerns	Enrolled cases were between 50 and 74 years of age; unclear how many women were in their 50s vs. older. Unclear whether duration is adequate across both cases and controls to assess outcome.	Probably yes	Low	NA
Hadji, 2007[73]	Probably yes	No information	Probably yes	Some concerns	Ascertainment of breast cancer status was not described.	Probably yes	Low	NA

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcome	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Holm, 2017[74]	Yes	Probably yes	Yes	Low	NA	Probably yes	Low	NA
Kabat, 2011[75]	Yes	Yes	Probably yes	Low	NA	Yes	Low	NA
Kotsopoulos, 2012[76]	Yes	Probably yes	Probably yes	Low	NA	Yes	Low	NA
Kruk, 2014[77]	Yes	Probably yes	Yes	Low	NA	Probably yes	Low	NA
Lee, 2008[78]	Probably yes	Probably yes	NA	Low	NA	Probably no	Some concerns	Multiple effect modifiers were tested with no correction for multiple testing.
Lumachi, 2010[79]	Yes	Yes	NA	Low	NA	Probably yes	Low	The association between BF and cancer was not the primary outcome of the study, and adjusted odds ratios were not reported.
Ma, 2006[80]	No	Probably yes	NA	Low	NA	Probably yes	Low	NA
Ma, 2017[81]	Yes	Probably yes	Yes	Low	NA	Yes	Low	NA

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcome	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Merritt, 2015[82]	Yes	Yes	Probably yes	Some concerns	Outcome assessment varied by country; duration of outcome assessment may not be sufficient for younger women.	Probably yes	Low	NA
Phillips, 2009[83]	Probably yes	Probably yes	NA	Low	NA	Probably yes	Low	NA
Pieta, 2008[84]	Yes	Probably yes	NA	Some concerns	Control participants were considerably younger than cases, resulting in (essentially) differential followup time—controls might go on to get breast cancer if they were followed into the Postmenopausal period.	Probably no	Some concerns	Authors report an increased risk of breast cancer with “breast problems needing intervention in the puerperium” - unclear what data were collected and to what extent this finding reflects multiple testing.
Press, 2010[85]	Yes	Yes	NA	Low	NA	Probably yes	Low	NA
Ritte, 2013[86]	Yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Ruszczyk, 2016[87]	Yes	NA	Probably no	Some concerns	Mean age of participants was in the 50s, which may not be adequate to assess outcomes.	Probably yes	Low	NA

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Stendell-Hollis, 2013[88]	Yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Sugawara, 2013[89]	Yes	Yes	Probably yes	Some concerns	Unclear whether 10 years sufficient duration to measure outcomes among all women (age varied from 50–60s at enrolment).	Probably yes	Low	NA
Tamimi, 2016[90]	Yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Warner, 2013[91]	Yes	Yes	Probably no	Some concerns	Twelve years may not be sufficient duration to assess outcomes among younger women (age at enrollment ranged from 39 to 40 years).	Probably yes	Low	NA

BF = breastfeeding; KQ = Key Question; NA = not applicable.

Table C-24. KQ 2 risk of bias assessment: Ovarian cancer, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Cook, 2017[92]	Some concerns	Potential confounding and recall bias as well as potential selection bias related to ascertainment of controls.	NA	NA	NA	NA	Probably no	Some concerns	Controls were identified from provincial health rosters and a mammography screening program. These two groups may only represent a portion of the source population; the provincial health rosters only cover people with public insurance.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Gay, 2015[93]	Some concerns	Potential for recall bias and confounding (as noted in individual domains).	Probably yes	Probably yes	No	No	NA	Some concerns	Postmenopausal women interested in breast cancer screening comprise the cohort and were then followed for an average of 17 years. Women who choose to enter a breast cancer screening trial may reflect a higher than average risk pool for ovarian cancer, especially if family history of breast or ovarian cancer is present.
Gierach, 2006[94]	Some concerns	Potential recall bias and poor definition of exposure.	NA	NA	NA	NA	Yes	Low	NA
Jordan, 2008[95]	Some concerns	Potential bias could arise from recall bias, residual confounding, and missing data (not completely at random).	NA	NA	NA	NA	Yes	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Kotsopoulos, 2015[96]	High	High risk of selection bias, recall bias (for exposure status), and bias related to outcome assessment.	No	Probably yes	No	No	Yes	High	The average age of cases at diagnosis is several years younger than the average age at interview/ enrollment in study, suggesting that cases are prevalent. BRCA1/2 mutation carriers are at higher than average risk of ovarian cancer to begin with.
Nagle, 2008[97]	Some concerns	Potential bias could arise from recall bias, residual confounding, and missing data (not completely at random).	NA	NA	NA	NA	Yes	Low	NA

BRCA = breast cancer gene; KQ = Key Question; NA = not applicable.

Table C-25. KQ 2 risk of bias assessment: Ovarian cancer, part 2

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Cook, 2017[92]	No	No	NA	NA	Yes	NA	High	Authors only provide unadjusted frequencies of BF exposure by outcome status.
Gay, 2015[93]	Probably no	Probably yes	No	Probably yes	Yes	NA	Some concerns	Authors did not adjust for a couple of key risk factors for ovarian cancer (oral contraceptive use, tubal ligation). Data were self-reported at the beginning of followup; some information (e.g., BMI) may have changed over the course of followup.
Gierach, 2006[94]	Probably no	NA	NA	NA	NA	NA	Some concerns	Only frequency data for breastfeeding are reported; no modeling was applied.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Jordan, 2008[95]	Probably no	Probably yes	Probably yes	Probably yes	NA	NA	Some concerns	Authors adjusted for a number of ovarian cancer risk factors that are related (but not affected) by BF; some residual confounding may remain. Other potential confounders, though not described, did not change the effect estimate by more than 10% and were not included in final adjusted models. Analyses of breastfeeding were appropriately restricted to women who had at least one live birth.
Kotsopoulos, 2015[96]	Probably no	Probably yes	Probably yes	Probably yes	Yes	Yes	Some concerns	Analysis of BF was not restricted to parous women but models were adjusted for parity; methods are unclear.
Nagle, 2008[97]	Probably no	Probably yes	Probably yes	Probably yes	NA	NA	Some concerns	Authors adjusted for a number of ovarian cancer risk factors that are related (but not affected) by BF; some residual confounding may remain.

BF = breastfeeding; BMI = body mass index; KQ = Key Question; NA = not applicable.

Table C-26. KQ 2 risk of bias assessment: Ovarian cancer, part 3

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Cook, 2017[92]	Probably no	No	Probably no	Some concerns	Potential for recall bias since exposure occurred long before the outcome. BF was only measured by ever/never and a dichotomous duration variable; though the variables do not provide details of BF history, they are likely to be reported relatively accurately.
Gay, 2015[93]	Probably yes	No	Probably yes	Low	Recall bias regarding the ever/never status is likely to be minimal; exposure data was collected prior to the outcome occurring.
Gierach, 2006[94]	No	No	No	Some concerns	BF status was only defined as ever/never (no additional information) and was collected at the time of outcome (case or control), possibly decades after the exposure happened. Recall bias is not likely to be a big issue since the exposure is broadly defined.
Jordan, 2008[95]	Probably yes	No	No	Some concerns	There is unlikely to be recall bias associated with an ever/never BF status, but there may be some recall bias associated with duration of breastfeeding; investigators suggested that the question was asked for each live birth which may support more accurate recall.

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Kotsopoulos, 2015[96]	Probably yes	No	No	High	Women suspected/knew they were BRCA1/2 mutation carriers at the time of study enrollment (and thus, that they were at higher risk of ovarian cancer). Recall bias is also a concern in this study as BF exposure was, for the most part, years prior to the interview. Ever/never status of BF is not as susceptible to recall bias, but duration may be more so.
Nagle, 2008[97]	Yes	No	No	Low	Recall bias regarding the ever/never exposure status is likely to be minimal.

BF = breastfeeding; BRCA = breast cancer gene; KQ = Key Question.

Table C-27. KQ 2 risk of bias assessment: Ovarian cancer, part 4

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Cook, 2017[92]	Yes	Yes	Yes	Probably yes	No	Low	NA
Gay, 2015[93]	Yes	Yes	Probably yes	No information	No information	Low	NA
Gierach, 2006[94]	Yes	Yes	Yes	Probably yes	No	Some concerns	Complete case analysis was performed (i.e., no imputation); only 1% of women were excluded due to missing offspring gender or demographic data.
Jordan, 2008[95]	Probably yes	Probably yes	Probably yes	Probably yes	Probably no	Some concerns	Though investigators only performed a complete case analysis, the amount of missing data for the exposure and confounders is minimal.
Kotsopoulos, 2015[96]	Yes	Probably no	Probably yes	Probably yes	Probably no	Some concerns	Approximately 10% of participants were missing BF status and a similar amount were missing tubal ligation status; a complete case analysis was performed rather than multiple imputation.
Nagle, 2008[97]	Probably yes	Probably yes	Probably yes	Probably yes	Probably no	Some concerns	Though investigators only performed a complete case analysis, the amount of missing data for the exposure and confounders is minimal.

BF = breastfeeding; KQ = Key Question.

Table C-28. KQ 2 risk of bias assessment: Ovarian cancer, part 5

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Cook, 2017[92]	Yes	Probably yes	Probably yes	Low	NA	Yes	Low	NA
Gay, 2015[93]	Yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Gierach, 2006[94]	Yes	Yes	Yes	Low	NA	NA	Low	NA
Jordan, 2008[95]	Yes	Yes	Yes	Low	NA	Yes	Low	NA
Kotsopoulos, 2015[96]	No	Yes	Probably yes	Some concerns	Methods were not described, but it appears as though cancer diagnoses were self-reported; no information was provided about confirming diagnosis. Self-report of outcome among women known to be at higher risk of the outcome may be susceptible to bias.	Probably yes	Low	NA
Nagle, 2008[97]	Yes	Yes	Yes	Low	NA	Yes	Low	NA

KQ = Key Question; NA = not applicable.

Table C-29. KQ 2 risk of bias assessment: Cardiovascular disease, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Choi, 2017[98]	High	Multiple concerns across all ROB domain, including potential for selection bias, measurement bias, attrition bias, and bias arising from selection of reported outcomes.	Probably yes	NA	No	No	NA	Some concerns	Participants were selected from the Korean National Health and Nutrition survey if they had a prior history of pregnancy (but were not currently pregnant) and data on breastfeeding exposure.
Lee, 2005[99]	Some concerns	Potential for confounding, selection bias, and recall bias	Probably yes	No	No	No	Yes	Some concerns	Data collection of exposure information follows data collection on outcomes. Because the study excludes those with high BP at baseline, which merges 1992 and 1994 data, it is possible that some outcome data were inappropriately excluded.
Lupton, 2013[100]	Some concerns	Potential for recall bias and confounding.	NA	NA	NA	NA	Yes	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Natland Fagerhaug, 2013[101]	Some concerns	Very low rate of "never breastfeeding," suggesting unique factors that might have led to this group of women not initiating breastfeeding. Recall bias is also a concern.	Yes	Probably yes	No	No	NA	Some concerns	Concern for immortal person-time bias—limited to individuals who were alive at enrollment, which occurred remote from breastfeeding, especially among older participants.
Parikh, 2016[102]	Some concerns	Potential for recall and attrition bias, immortal person time bias, and confounding.	Probably no	Probably yes	No	NA	NA	Some concerns	Women were enrolled after menopause, and women with prevalent CHD were excluded. Thus, to be eligible for the observational cohort study women had to have had a period of disease-free survival that creates immortal person-time bias.
Schwarz, 2009[3]	Some concerns	Potential for immortal person time bias, confounding, recall bias and measurement bias (of prevalent HTN and CVD at WHI enrollment).	Probably no	Probably yes	No	Probably yes	NA	Some concerns	Concern for immortal person-time bias - limited to individuals who were alive at enrollment, which occurred remote from breastfeeding, especially among older participants.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Stuebe, 2009[103]	High	Potential for selection bias, confounding, recall bias, attrition.	Probably no	Yes	No	No	Yes	High	Risk of selection bias from a healthy cohort of nurses. The study excluded participants with cardiovascular issues or events (MI, angina, CABG) between the start of the study in 1976 and the collection of lactation history in 1986, which was the starting point for evaluating cardiovascular outcomes.
Stuebe, 2011[104]	Some concerns	Potential for recall and attrition bias.	Probably no	Yes	No	Yes	Yes	Some concerns	Risk of selection bias from a healthy cohort of nurses. The study excluded participants with hypertension, elevated BP, and other conditions between the start of the study in 1989 and the collection of dietary history in 1991.

BP = blood pressure; CABG = coronary artery bypass grafting; CHD = coronary heart disease; CVD = cardiovascular disease; HTN = hypertension; KQ = Key Question; MI = myocardial infarction; NA = not applicable; ROB = risk of bias; WHI = Women's Health Initiative.

Table C-30. KQ 2 risk of bias assessment: Cardiovascular disease, part 2

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Choi, 2017[98]	No	Probably yes	Probably yes	No	NA	Probably yes	Some concerns	Postexposure variables associated with BF and metabolic outcomes were controlled for in analyses (e.g., BMI).
Lee, 2005[99]	No	Yes	Yes	No	Yes	NA	Some concerns	Authors adjust for potential confounders, but include parity which can be a collider variable.
Lupton, 2013[100]	No	Yes	Probably no	Yes	Yes	NA	Some concerns	The authors adjusted for lifestyle variables at the time of enrollment, which was, by definition, after the exposure. This is of particular concern for body mass index, which may be a mediator of any association between breastfeeding and subsequent hypertension.
Natland Fagerhaug, 2013[101]	Probably no	Probably yes	Probably yes	Probably no	Yes	NA	Some concerns	Worry about residual confound by perinatal events that led moms not to breastfeed. Only 3% of population had “never breastfed,” suggesting it is highly atypical for women not to initiate BF in this population. Some confounding variables e.g., (smoking status- current, former or “ever”) may have reflected post exposure health behavior.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Parikh, 2016[102]	No	Yes	Yes	Probably no	Yes	NA	Some concerns	Models adjusted for CVD risk factors (hypertension, diabetes, BMI) that may mediate associations between breastfeeding history and disease outcome.
Schwarz, 2009[3]	Probably no	Probably yes	Probably yes	Probably yes	Yes	NA	Some concerns	Authors adjust for lifestyle (diet) which is both pre and post exposure (but measured post exposure).
Stuebe, 2009[103]	No	Yes	Yes	No	No	NA	High	Although the study controls for potential confounders, the likelihood of a healthy user effect likely results in unmeasured confounding. The study also adjusts for supplement use, which could potentially be a post-exposure variable that arises from breastfeeding and could influence cardiovascular outcomes.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Stuebe, 2011[104]	No	Yes	Yes	Yes	Yes	NA	Some concerns	Although the study controls for potential confounders, the likelihood of a healthy user effect likely results in unmeasured confounding. The study did use inverse probability weights in the analysis. To address the risk of bias from parity as a collider, the authors limited analysis to the first child and incident hypertension.

BF = breastfeeding; BMI = body mass index; CVD = cardiovascular disease; KQ = Key Question; NA = not applicable.

Table C-31. KQ 2 risk of bias assessment: Cardiovascular disease, part 3

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Choi, 2017[98]	Probably yes	No	Probably yes	Some concerns	BF duration was measured by participant self-report; women varied in age and recall bias is a potential concern. Exposure is based on months of total BF and does not take into consideration intensity or BF duration per child.
Lee, 2005[99]	No	No	Probably no	Some concerns	Potential recall bias.
Lupton, 2013[100]	No	No	Probably no	Some concerns	Potential recall bias. To the extent that there is some evidence for validity of duration data for BF this addresses some concerns.
Natland Fagerhaug, 2013[101]	Probably yes	No	Probably yes	Some concerns	Potential recall bias.
Parikh, 2016[102]	No	No	Probably no	Some concerns	Potential recall bias, variable categorized as yes/no, but yes is 1 or more months. To the extent that there is some evidence for validity of duration data for BF this addresses some concerns.
Schwarz, 2009[3]	Probably yes	No	Probably no	Some concerns	Potential for recall bias (and differential recall bias) given that exposure and outcomes were assessed remote from BF status.
Stuebe, 2009[103]	No	No	Probably no	Some concerns	Potential recall bias from 10-year lag between baseline and collection of lactation history, some births occurred prior to 1976, and so total recall period was likely longer; one study (Primoslow) suggests no difference between recall and prospective recording for duration of BF.
Stuebe, 2011[104]	No	No	Probably no	Some concerns	Potential recall bias from 10-year lag between baseline and collection of lactation history, some births occurred prior to 1976, and so total recall period was likely longer; one study (Primoslow) suggests no difference between recall and prospective recording for duration of BF. Extent of bias for yes/no outcome unclear and could potentially be high risk of bias for that exposure variable because of the risk of misclassification.

BF = breastfeeding; KQ = Key Question.

Table C-32. KQ 2 risk of bias assessment: Cardiovascular disease, part 4

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Choi, 2017[98]	Probably yes	Probably no	Probably no	No information	No	Some concerns	Approximately 19% of the sample (n=881) were excluded due to incomplete analytic data; unclear whether this was primarily data on exposure or other outcomes.
Lee, 2005[99]	Yes	Yes	Yes	No information	No	Low	Total excluded for missing data=0.3%.
Lupton, 2013[100]	No	No	No	No information	No	Some concerns	Missing data: 8.7%.
Natland Fagerhaug, 2013[101]	Probably yes	Probably yes	No information	No information	No information	Low	NA
Parikh, 2016[102]	No	No	No	No information	No	Some concerns	Missing data >18.9%, possibly up to 22.1%.
Schwarz, 2009[3]	Probably yes	Probably yes	No	No information	No	Some concerns	A minority of participants were excluded due to no information on parity (N=973) or duration of lactation (N=1,705).
Stuebe, 2009[103]	No	No	No	No information	No	Some concerns	17% of the sample excluded for missing exposure data.
Stuebe, 2011[104]	No	No	No	No information	No	Some concerns	Missing data ranges from 5.5% to 13.9%.

KQ = Key Question; NA = not applicable.

Table C-33. KQ 2 risk of bias assessment: Cardiovascular disease, part 5

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Choi, 2017[98]	Probably yes	Yes	Probably no	Some concerns	Followup after BF likely varies by age; women 19 to 40 years were eligible (mean age: 39 to 40 years). Strength of association for younger versus older women may vary based on several factors.	Probably no	Some concerns	Authors report history of type 2 DM diagnosis in the description of characteristics, but only report mean blood sugar levels in adjusted analyses.
Lee, 2005[99]	Probably no	Yes	Yes	Low	Outcomes based on self-report, but authors report that validation of self-report has been done (94% sensitivity, 85% specificity)	Probably no	Low	NA
Lupton, 2013[100]	Probably yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Natland Fagerhaug, 2013[101]	Probably yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Parikh, 2016[102]	Yes	Yes	Yes	Low	NA	Yes	Low	NA

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Schwarz, 2009[3]	Probably no	Yes	Probably yes	Some concerns	Outcomes primarily based on self-report (for prevalent HTN and CVD at enrollment); incident CVD during WHI study period was verified using standard protocols.	Probably no	Low	NA
Stuebe, 2009[103]	Probably no	Yes	Yes	Some concerns	Some outcomes (angina, CABG) based on self-report.	Probably no	Low	NA
Stuebe, 2011[104]	Probably no	Yes	Yes	Low	Outcomes based on self-report, but authors report that validation of self-report has been done (94% sensitivity, 85% specificity).	Probably no	Low	NA

BF = breastfeeding; CABG = coronary artery bypass grafting; CVD = cardiovascular disease; DM = diabetes mellitus; HTN = hypertension; KQ = Key Question; NA = not applicable; WHI = Women's Health Initiative.

Table C-34. KQ 2 risk of bias assessment: Diabetes, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Chamberlain, 2016[105]	High	Risk of selection bias due to method of outcome assessment (selection of women with postpartum lab testing documented); high risk of measurement bias for exposure status (BF status determined at hospital discharge only) and high risk of bias due to confounding.	Probably no	Probably no	Yes	No	NA	Some concerns	Only women who had postpartum laboratory assessments were included in the analysis; women without lab testing may have been less concerned about type 2 diabetes and could have deferred testing (or testing may not have been recommended).

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Gunderson, 2012[106]; Gunderson, 2015[107]	Some concerns	Lack of adjustment for important confounders, including baseline metabolic status and SES, raises concern about residual confounding; duration (2 years) may not be sufficient to assess incident type 2 diabetes among younger women.	No	Probably yes	No	No	NA	Some concerns	Women were screened during pregnancy, but enrolled based on BF status at 4–6 weeks after delivery; women who were mixed feeding at 4-6 weeks were ineligible. Thus, feeding behavior (the exposure) was an exclusion criteria for the study. Women who had stopped BF by 3 weeks, potentially due to failure of lactogenesis, were classified as formula feeding.
Martens, 2016[108]	Some Concerns	Risk of measurement bias and bias due to unmeasured confounding.	Probably yes	NA	Yes	NA	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Schwarz, 2009[3]	Some concerns	Potential for immortal person-time bias, confounding, recall bias, and measurement bias (of prevalent HTN and CVD at WHI enrollment).	Probably no	Probably yes	No	Probably yes	NA	Some concerns	Concern for immortal person-time bias limited to individuals who were alive at enrollment, which occurred remote from breastfeeding, especially among older participants.
Zong, 2016[109]	High	High risk of selection bias and measurement of exposure.	Probably no	Probably yes	No	No	NA	High	Participants were selected from the NHANES survey if they had completed a medical exam, had a pregnancy resulting in a live birth, were not currently pregnant or BF, or had prevalent cardiovascular disease or cancer. Both cardiovascular disease and cancer may be associated with BF duration (exposure) and diabetes (outcome).

BF = breastfeeding; CVD = cardiovascular disease; KQ = Key Question; NA = not applicable; NHANES = National Health and Nutritional Examination Survey; SES = socioeconomic status.

Table C-35. KQ 2 risk of bias assessment: Diabetes, part 2

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Chamberlain, 2016[105]	No	No	NA	Yes	Yes	Yes	High	Breastfeeding at discharge is primary handled as a confounder for increased rates of type 2 diabetes in this population; authors do not appear to have addressed confounding in the analysis of type 2 diabetes incidence by breastfeeding status (e.g., obesity).
Gunderson, 2012[106]; Gunderson, 2015[107]	No	Probably no	Probably yes	No	Yes	NA	Some concerns	No adjustment for some important confounding factors related to SES (e.g., use of WIC). Unclear how the confounders included in the adjusted analyses were selected.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Martens, 2016[108]	Probably no	Probably yes	Probably yes	Yes	NA	Probably yes	Some concerns	Some potentially confounding factors were not considered in the analyses, such as pre-pregnancy BMI.
Schwarz, 2009[3]	Probably no	Probably yes	Probably yes	Probably yes	Yes	NA	Some concerns	Authors adjusted for lifestyle (diet), which is both pre- and postexposure (but measured postexposure).
Zong, 2016[109]	No	Probably yes	Probably yes	No	NA	Probably yes	Some concerns	Exposure and outcome data collected at same time (exposure based on recall); domains that were adjusted for may reflect postexposure variables associated with both BF and diabetes (e.g., SES, other health behaviors).

BF = breastfeeding; KQ = Key Question; NA = not applicable; OGTT = oral glucose tolerance test; SES = socioeconomic status; WIC = Women, Infants, and Children.

Table C-36. KQ 2 risk of bias assessment: Diabetes, part 3

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Chamberlain, 2016[105]	No	Probably no	Yes	High	Exposure status is measured and defined only in terms of BF status at hospital discharge; whether women who were fully or partially breastfeeding continued with their recorded behavior is unclear.
Gunderson, 2012[106]; Gunderson, 2015[107]	Yes	Yes	Probably yes	Low	NA
Martens, 2016[108]	Probably no	Yes	Yes	Some concerns	Exposure is defined as BF initiation only (at time of hospital discharge). A small% of mothers may initiate BF after discharge; among those who did initiate, duration and intensity of BF was not considered.
Schwarz, 2009[3]	Probably yes	No	Probably no	Some concerns	Potential for recall bias (and differential recall bias) given that exposure and outcomes were assessed remote from BF status.
Zong, 2016[109]	Probably no	No	Probably yes	High	BF exposure was measured by asking whether participants had ever breastfed then whether they breastfed for more than one month per child. No assessment of BF intensity and no information on duration for longer than one month per child.

BF = breastfeeding; KQ = Key Question; NA = not applicable.

Table C-37. KQ 2 risk of bias assessment: Diabetes, part 4

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Chamberlain, 2016[105]	Probably no	Probably no	NA	No information	No	High	Authors report on association between BF and type 2 diabetes only in the subsample of women who had a chart review (289 births out of 483 births with a postpartum screening test). This is less than the size noted by authors in the methods section for detecting a 10% difference in diabetes among indigenous and nonindigenous women.
Gunderson, 2012[106]; Gunderson, 2015[107]	Probably yes	Probably yes	Yes	No information	No information	Low	NA
Martens, 2016[108]	Probably yes	No information	Probably yes	No information	NA	Some concerns	Approximately 4% of total deliveries were excluded due to no information on prepregnancy diabetes or breastfeeding data. Degree of missing outcome data is unclear; measurement was based on hospitalization and outpatient visit codes only.
Schwarz, 2009[3]	Probably yes	Probably yes	No	No information	No	Some concerns	A minority of participants were excluded due to no information on parity (N=973) or duration of lactation (N=1,705).
Zong, 2016[109]	Probably no	Probably no	Probably no	No information	No	High	4,779 women were ultimately included (of 10,701 women older than 20 potentially eligible); women were excluded due to incomplete data (n=919), currently pregnant or breastfeeding (n=800), prevalent CVD or cancer (n=1,211), and other reasons.

BF = breastfeeding; KQ = Key Question; NA = not applicable.

Table C-38. KQ 2 risk of bias assessment: Diabetes, part 5

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Chamberlain, 2016[105]	Yes	Yes	Probably yes	Low	Seven years may or may not be adequate to determine risk of type 2 diabetes in some groups of women (i.e., those who are younger).	Probably yes	Low	NA
Gunderson, 2012[106]; Gunderson, 2015[107]	Probably yes	Yes	Probably no	Some concerns	Two years may not be sufficient to adequately assess outcomes.	Yes	Low	NA
Martens, 2016[108]	Probably yes	Yes	Yes	Some concerns	Measurement of outcomes was equal across groups but validity of using chart review alone is unclear; data came from hospitalizations and outpatient visit codes.	Probably yes	Low	NA

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Schwarz, 2009[3]	Probably no	Yes	Probably yes	Some concerns	Outcomes primarily based on self-report (for prevalent HTN and CVD at enrollment); incident CVD during WHI study period was verified using standard protocols.	Probably no	Low	NA
Zong, 2016[109]	Probably yes	Yes	Probably yes	Some concerns	Duration of followup after BF exposure likely varies by age; women 20 years and older were eligible. Older women are likely different from younger women not only in terms of parity but also other factors related to the exposure and outcome.	Probably yes	Low	NA

BF = breastfeeding; CVD = cardiovascular disease; HTN = hypertension; KQ = Key Question; NA = not applicable; WHI = Women’s Health Initiative.

Table C-39. KQ 2 risk of bias assessment: Fracture, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure /outcome?	1a. Were post-exposure variables that influenced selection related to exposure /outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Crandall, 2017[110]	Some Concerns	Some concerns arising from recall bias of exposure and from recall of nonhip fractures.	Yes	Probably no	Yes	NA	NA	Low	NA
Hwang, 2016[111]	High	Potential risk of recall bias leading to misclassification, high attrition rate.	Probably no	Yes	No	No	NA	Some concerns	Some concern that those with poor health (including those with fractures) who did not remain in the study were selectively excluded.
Lambrinoudaki, 2015[112]	High	Potential risk of recall bias leading to misclassification, risk of confounding.	Probably yes	NA	No	NA	NA	Low	NA
Mori, 2015[113]	High	Potential risk of recall bias leading to misclassification of exposure, some risk of recall bias from fracture outcomes (confirmed in 67% of cases), fracture outcomes are not specific to or completely representative of low trauma.	Probably yes	NA	No	NA	NA	Low	Although start of followup and start of exposure do not coincide, followup occurs in a period succeeding exposure, and so there's no risk of selection into the study for followup based on outcome status.
Naves, 2005[114]	Some concerns	Potential risk of recall bias leading to misclassification. Amount of missing data is unclear.	No	NA	No	NA	NA	Low	Although start of followup and start of exposure do not coincide, followup occurs in a period succeeding exposure, and so there's no risk of selection into the study for followup based on outcome status.

KQ = Key Question; NA = not applicable.

Table C-40. KQ 2 risk of bias assessment: Fracture, part 2

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Crandall, 2017[110]	No	Yes	Yes	Yes	Yes	NA	Low	NA
Hwang, 2016[111]	No	Yes	Probably yes	No	Yes	Probably yes	Some concerns	There's some adjustment for variables (reproductive status, medication status) that could have arisen from factors common to exposure and those variables, that also predict outcomes
Lambrinoudaki, 2015[112]	No	No	NA	Yes	Yes	NA	High	No controls for confounding. With a cross-sectional design and measurement of prevalent fractures, there's a risk of confounding arising from common prognostic variables that influenced both exposure and outcome (e.g., health status or other issues that may have led to early menopause).
Mori, 2015[113]	No	Yes	Probably yes	No	Yes	Probably yes	Some concerns	Some adjustment for variables (health, medication status) that could have arisen from factors common to BF exposure and those variables, that also predict outcomes.
Naves, 2005[114]	Probably yes	NA	Yes	Yes	Yes	NA	Low	NA

BF = breastfeeding; KQ = Key Question; NA = not applicable.

Table C-41. KQ 2 risk of bias assessment: Fracture, part 3

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Crandall, 2017[110]	Probably yes	No	Yes	Some concerns	Some recall bias likely present due to length of time between exposure and BF self-report (women were between 50–79).
Hwang, 2016[111]	No	No	Probably no	High	Duration of lactation is collected retrospectively over a potentially long period of recall, and did not account for intensity of BF.
Lambrinoudaki, 2015[112]	No	No	Probably no	High	Duration of lactation is collected retrospectively over a potentially long period of recall, and did not account for intensity of BF.
Mori, 2015[113]	No	No	Probably no	High	Duration of lactation is collected retrospectively over a potentially long period of recall, and did not account for intensity of BF.
Naves, 2005[114]	Yes	No	Yes	Some concerns	BF information was collected retrospectively (at age 50 or older) which may introduce recall bias.

BF = breastfeeding; KQ = Key Question.

Table C-42. KQ 2 risk of bias assessment: Fracture, part 4

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Crandall, 2017[110]	Probably yes	Probably yes	Probably no	No information	No	Low	The proportion excluded due to missing outcome or exposure data is very low (>1%).
Hwang, 2016[111]	No	No	No	No information	Yes	High	Only 1,222 of 2,105 women in the original sample were retained, suggesting a high attrition owing to missing data (although the details of reasons for exclusion are not clearly specified).
Lambrinoudaki, 2015[112]	No information	No information	No information	No information	No information	Uncertain because no information	None
Mori, 2015[113]	Yes	Yes	Yes	No information	Yes	Low	NA
Naves, 2005[114]	Probably yes	No information	No information	No information	No	Uncertain because no information	17% of the sample dropped out (208/250) for the fracture analysis, differences by exposure not specified, leading to some uncertainty.

KQ = Key Question; NA = not applicable.

Table C-43. KQ 2 risk of bias assessment: Fracture, part 5

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Crandall, 2017[110]	Yes	Yes	Yes	Low	Self-report included for nonhip fractures, so likely to undercount vertebral fractures, but there's no reason to think that the risk of underreporting would vary by exposure status.	Yes	Low	NA
Hwang, 2016[111]	Yes	Yes	Yes	Low	NA	Yes	Low	NA
Lambrinoudaki, 2015[112]	Yes	Yes	Yes	Low	NA	Yes	Low	NA
Mori, 2015[113]	Yes	Yes	Yes	High	Outcome measures not specific to or entirely representative of low trauma/osteoporosis (they include “nondigital, noncranio-facial” fractures and exclude nonclinical vertebral fractures.	Yes	Low	NA
Naves, 2005[114]	Yes	Yes	Yes	Low	NA	Yes	Low	NA

KQ = Key Question; NA = not applicable.

Table C-44. KQ 2 risk of bias assessment: Postpartum depression, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Ahn, 2015[115]	High	High risk of bias due to confounding and measurement bias. The outcome (depression scores at 7 days to 6 months) was assessed before the exposure, defined as predominant breast vs. bottle feeding at 6 months. No adjusted results were presented, despite differences in depression risk factors at baseline.	No	Yes	Yes	No	NA	Some concerns	Limited to uncomplicated vaginal birth, limiting generalizability
Borra, 2015[116]	Some concerns	High attrition, potential for confounding	Yes	NA	Yes	NA	NA	Low	NA
Chojenta[117]	High	High risk of recall bias, for both exposure and outcome. Measurement of BF duration may lead to misclassification.	Yes	NA	Yes	NA	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Davey, 2011[118]	Some concerns	Substantial loss to followup and lack of temporality with respect to stopping BF and onset of depression symptoms.	Yes	NA	Yes	NA	NA	Low	NA
Fiala, 2017[119]	High	Unclear definition of exposure and unvalidated measurement of outcomes, >50% loss to followup.	Yes	NA	Yes	NA	NA	Low	NA
Hamdan, 2012[120]	High	No adjustment for confounding.	Yes	NA	Yes	NA	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Illiadis, 2015[59]	High	High risk of selection bias, high rate of attrition/missing data, no adjustment for potential confounders; unclear temporal sequence of BF exposure and depression.	Yes	NA	Yes	NA	NA	Low	NA
Lau, 2006[121]	High	Risk of selection bias due to high attrition; only 38% of the sample returned postpartum questionnaires. Women who chose not to complete the followup survey may differ in exposure and/or outcome.	Yes	NA	Yes	NA	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Maimburg, 2015[122]	High	The analysis only controlled for food insecurity and did not assess or control for history of depression; unclear whether mothers who were more predisposed to depression were also more likely to stop BF.	Yes	NA	Yes	NA	NA	Some concerns	Sample comprised of participants in an RCT, in which about half of women approached agreed to participate. This may limit generalizability.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
McCoy, 2008[123]	High	Risk of selection bias due to high attrition; only 38% of the sample returned postpartum questionnaires. Women who chose not to complete the mailed followup survey may differ in exposure and/or outcome. No adjustment for potential confounders. Duration (4 weeks) may be insufficient to detect outcome.	No	Yes	No	No	NA	High	Approximately 25% of the eligible sample did not return for PP visit and only half of the target population of women had EPDS screeners in their medical charts, even though it is supposed to be routinely conducted. Authors list potential reasons for the large number of missing screeners, all of which may have biased the sample.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Reifsnider, 2016[124]	Some concerns	Risk of bias due to confounding (not addressed by analyses) and potential for selected outcome reporting.	Yes	NA	Yes	NA	NA	Low	NA
Sword, 2012[125]	Some concerns	Risk of bias due to confounding, adjustment for potential mediators in the association between BF and depression.	Yes	NA	Yes	NA	NA	Low	NA
Trivino-Juarez, 2016[126]	Some concerns	Missing information on loss to followup, no statistical adjustment for attrition, unclear adjustment methods for potential confounding.	Yes	NA	Yes	NA	NA	Low	NA

BF = breastfeeding; EPDS = Edinburgh Postnatal Depression Scale; KQ = Key Question; NA = not applicable; PP = postpartum; RCT = randomized controlled trial.

Table C-45. KQ 2 risk of bias assessment: Postpartum depression, part 2

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Ahn, 2015[115]	No	No	NA	NA	NA	NA	High	The authors measured the association between feeding status at 6 months and mood; in table 2, they present mean EPDS scores at multiple times from 7 days to 6 months postpartum according to feeding status at 6 months. These data suggest that mood does not predict feeding behavior, but does not address the stated objective of the study, to test if feeding behavior affects mood. Moreover, no data are presented with adjustment for pregnancy mood or consideration of timing of or reasons for discontinuing BF.
Borra, 2015[116]	Probably no	No information	No information	Yes	Yes	NA	Some concerns	Model C adjusts for “antenatal depression” scores according to the text, but Table 6 in the appendix says that these antenatal measures came from 18 and 33 months of pregnancy. It is possible that Table 6 contains a typo, but otherwise, the potential for confounding is high.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Chojenta, 2016[117]	No	Probably yes	Probably no	Yes	Yes	NA	Some concerns	It looks like PND was only assessed at the 5-year follow up for each child, and asks mothers to recall “were you diagnosed or treated for postnatal depression.” This does not seem like it would be a valid measure considering the potentially long recall time. Also, this only measures diagnosis/ treatment, and more women may have experienced PND than were actually diagnosed, so access to care plays a part here as well which may be a confounder (women with more access to care may have more assistance BF and more screening for PND).

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Davey, 2011[118]	No	Probably yes	Yes	Probably yes	No	No	High	Depression is measured during pregnancy and then at 8 weeks postpartum, and BF is measured at 8 weeks postpartum. Data regarding the temporality of weaning and onset of depression symptoms is not provided, so it is not possible to determine whether women stopped BF and became depressed, or became depressed and stopped BF. In the final model for clinical depression symptoms, no confounders that occurred after the exposure were included, but multiple measures at 8 weeks were tested for inclusion in the model.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Fiala, 2017[119]	No	Probably no	Probably yes	No	Probably yes	No information	Some concerns	BF exposure is poorly defined and it is unclear when it was measured; no information is provided on which variables were included in the adjusted analyses.
Hamdan, 2012[120]	No	No	NA	NA	No	No	High	Women with depression during pregnancy were less likely to breastfeed, but the authors did not adjust/account for pregnancy depression or anxiety in their analyses. Moreover, although they report that women who were depressed at 2 months were less likely to breastfeed at 4 months, they do not adjust for 2-month depression in their 4-month results. It is highly plausible that depression symptoms cause women to change exposure groups (e.g., stop BF) but this is not accounted for in the analysis.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Illiadis, 2015[59]	No	No	Probably yes	NA	No	No	High	No adjustment for covariates in association between depression and BF status; temporal sequence of BF cessation and depression not known for PPD group.
Lau, 2006[121]	No	No	No	NA	NA	NA	High	Multivariate adjusted results were not presented.
Maimburg, 2015[122]	No	Probably no	Yes	Yes	Yes	NA	High	The analysis only controlled for intervention arm, and did not assess or control for history of depression before or during pregnancy.
McCoy, 2008[123]	No	No	NA	NA	Probably yes	NA	High	Although they assessed prior history of depression, they did not include it (or any other variables) in a model with BF because BF did not predict PPD individually.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Reifsnider, 2016[124]	No	Probably no	Yes	Probably yes	Probably no	Probably no	High	The analysis only controlled for food insecurity (the main outcome of the analysis and parent RCT was weight), and did not assess or control for history of depression before or during pregnancy. There is no way to tell whether mothers who were more depressed were also more likely to stop BF.
Sword, 2012[125]	No	Probably no	Yes	Probably yes	Yes	NA	Some concerns	As exposure was whether BF was initiated, concerns regarding changing exposure category due to depression are lessened. However, it appears that confounders were only included in the model if they independently predicted the outcome, w/o consideration of whether they materially changed effect estimates for exposures of interest.
Trivino-Juarez, 2016[126]	No	Probably yes	Probably yes	Yes	NA	NA	Low	The way they describe confounders is confusing so I am not confident about this rating.

BF = breastfeeding; EPDS = Edinburgh Postnatal Depression Scale; KQ = Key Question; NA = not applicable; PND = postnatal depression; PPD = postpartum depression; RCT = randomized controlled trial.

Table C-46. KQ 2 risk of bias assessment: Postpartum depression, part 3

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Ahn, 2015[115]	Probably no	Yes	No information	Some concerns	Timing of stopping breastfeeding / introducing formula was not considered in the analysis of EPDS scores.
Borra, 2015[116]	Probably yes	Probably yes	Probably yes	Some concerns	Potential for recall bias for duration of BF because BF status was collected at 8 weeks and 8, 18, and 24 months. Other outcomes (initiation; BF at 1, 2, and 4 weeks; and exclusivity at those times) are likely to have less recall bias if women responded at the 8-week survey.
Chojenta, 2016[117]	Probably yes	No	Probably yes	Some concerns	Breastfeeding was assessed annually for each child born during the year, and the measure is imprecise (BF<6m: someone BF for 5.5 months is very different from someone who did not initiate).
Davey, 2011[118]	No	No	No information	Some concerns	Because timing of weaning was not collected, the temporal order of depression symptoms and breastfeeding cessation is not known.
Fiala, 2017[119]	No	No information	No information	High	It is not clear whether the exposure is never breastfeeding vs ever breastfeeding or not breastfeeding vs breastfeeding at 6 weeks or 6 months.
Hamdan, 2012[120]	Probably yes	Probably yes	Probably yes	Low	NA
Illiadis, 2015[59]	No	Yes	No	Some concerns	Unclear whether breastfeeding classified as exclusive (yes) vs. nonexclusive or not at all (no), or whether yes/no references to any current breastfeeding.
Lau, 2006[121]	No	Yes	No	Some concerns	Validity of obstetric chart review for breastfeeding status is not clear.
Maimburg, 2015[122]	Probably yes	Yes	Probably yes	Some concerns	Breastfeeding was assessed at the same time as EPDS.

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
McCoy, 2008[123]	Probably yes	Yes	Probably yes	Some concerns	Breastfeeding was assessed at the same time as EPDS.
Reifsnider, 2016[124]	Yes	Yes	Probably yes	Low	NA
Sword, 2012[125]	Yes	No	No information	Some concerns	It is odd that breastfeeding initiation was not assessed during the postpartum stay, and raises concerns that infant illness / other complications that might predispose to depression confound the observed associations. It is also difficult to interpret the results in the absence of any information on the proportion of women who did not breastfeed - based on the large confidence intervals reported, this was likely a small number of women.
Trivino-Juarez, 2016[126]	Yes	Yes	Probably yes	Low	NA

BF = breastfeeding; EPDS = Edinburgh Postnatal Depression Scale; KQ = Key Question; NA = not applicable.

Table C-47. KQ 2 risk of bias assessment: Postpartum depression, part 4

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Ahn, 2015[115]	No	No	No	No information	No	High	20% of participants did not complete the 6-month visit, and no information is provided on differences between the baseline population and the women who completed the 6-month visit. Furthermore, information on missing data points are not provided.
Borra, 2015[116]	No	No	Yes	No information	NA	Some concerns	Proportion of missingness in analyses ranges from 58% (8,172 in the fully adjusted model) to 63% (8,805 in the model with the least adjustment) using the 1-year denominator of 13,988).
Chojenta, 2016[117]	Yes	Yes	Probably yes	Yes	NA	Low	NA
Davey, 2011[118]	No	No	No	No information	No	Some concerns	30% of women did not complete the 8-week evaluation, and data are not provided regarding differences in pregnancy depression/anxiety or infant feeding intention.
Fiala, 2017[119]	No	No	No	No information	No information	High	Only 3,233 (42%) of 7589 completed questionnaires at all three time points and were included in the analysis.
Hamdan, 2012[120]	No information	No information	No information	No information	No information	Uncertain because no information	No information reported on loss to followup.
Illiadis, 2015[59]	No	No	No	No information	No	High	181/365 women were included in the analytic sample.
Lau, 2006[121]	Probably yes	Yes	No information	No information	No	Some concerns	Complete case analysis limited to charts that had no missing data; no information provided on the number of charts w/incomplete data.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Maimburg, 2015[122]	Yes	Yes	Yes	No information	No information	Low	NA
McCoy, 2008[123]	Yes	Yes	Probably yes	Probably yes	Probably no	Low	NA
Reifsnider, 2016[124]	No information	No information	No information	No information	No information	Uncertain because no information	None
Sword, 2012[125]	No	No	No	No information	No	Some concerns	Substantial LTFU, with no information on whether there was differential LTFU by exposure or outcome group.
Trivino-Juarez, 2016[126]	Yes	Probably yes	Probably yes	No information	No information	Low	NA

KQ = Key Question; LTFU = loss to followup; NA = not applicable.

Table C-48. KQ 2 risk of bias assessment: Postpartum depression, part 5

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Ahn, 2015[115]	No information	Probably yes	Probably yes	Low	NA	No	Some concerns	Reported differences in IL 6 and AM cortisol appear to be post-hoc findings.
Borra, 2015[116]	Yes	Probably yes	Yes	Low	NA	Yes	Low	NA
Chojenta, 2016[117]	Probably yes	Yes	Yes	Low	NA	Yes	Low	NA
Davey, 2011[118]	No information	Probably yes	Probably yes	Low	NA	Probably no	Low	Of note, in table 5, there appears to be an error, in that the labels for “yes” and “no” for breastfeeding at 8 weeks appear to be reversed.

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Fiala, 2017[119]	Probably yes	Yes	Yes	High	Investigators modified the EPDS and did not provide information on reliability/validity of this method: "we conditioned the determination of depressive symptoms on a positive answer to question number eight, which refers to mood problems (a score of at least two means the participants have felt sad or miserable at least quite often). This condition was added to a threshold of ten points among the original ten questions."	Probably yes	Low	NA

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Hamdan, 2012[120]	No information	Probably yes	Probably yes	Uncertain because no information	Unclear whether individuals performing the MINI were aware of breastfeeding status.	No	Some concerns	No adjusted analysis is performed, and authors emphasize the hypothesized association between breastfeeding and lower depression risk, with far less emphasis on depression and lower breastfeeding likelihood.
Illiadis, 2015[59]	No information	Probably yes	Probably yes	Low	NA	NA	Uncertain	Association between breastfeeding & depression was not the goal of the paper; we are extracting data from the table to look at the association.
Lau, 2006[121]	No	Yes	No	Some concerns	Four weeks postpartum may be insufficient followup for a depression assessment.	Probably no	Low	NA

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Maimburg, 2015[122]	Probably yes	Yes	No	Some concerns	EPDS should have been assessed after 6 weeks in order to reflect causality from breastfeeding.	Yes	Low	NA
McCoy, 2008[123]	Probably yes	Yes	No	Some concerns	EPDS should have been assessed after 4 weeks in order to reflect causality from breastfeeding.	Yes	Low	NA
Reifsnider, 2016[124]	Probably yes	Yes	Yes	Low	NA	Yes	Low	NA
Sword, 2012[125]	Probably no	Probably yes	Probably yes	Low	NA	Yes	High	The authors report that not breastfeeding was a significant predictor of depression status, but the confidence interval for this effect estimate crosses 1 and the p value exceeds the a priori alpha of 0.05.

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Trivino-Juarez, 2016[126]	No information	Yes	Yes	Uncertain because no information	None	Yes	Low	NA

AM = morning; EPDS = Edinburgh Postnatal Depression Scale; IL = inflammatory cytokines; KQ = Key Question; MINI = Mini International Neuro-psychiatric Interview; NA = not applicable.

Table C-49. KQ 2 risk of bias assessment: Postpartum weight change, part 1

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Endres, 2014[127]	Some concerns	Potential for selection bias, attrition and residual confounding.	No	Probably yes	Yes	No	NA	Some concerns	Selected into sample on the basis of having prepregnancy weight, to the extent that such variables are correlated with BF or eventual weight, potential for selection.
Jarlenski, 2014;[128] Sharma, 2014[129]	Some concerns	Substantial loss to followup, however sensitivity analyses conducted; potential for residual confounding.	Yes	NA	Yes	Yes;[128] No[129]	NA	Low	NA
Lyu, 2009[130]	Some concerns	Potential for confounding, self-reported weight.	Yes	NA	Yes	No	NA	Low	NA
Ng, 2014[131]	High	Potential for attrition and residual confounding.	Yes	NA	Yes	No	NA	Some concerns	Selected into sample on the basis of having prepregnancy weight, to the extent that such variables are correlated with BF or eventual weight, potential for selection.
Onyango, 2011[132]	Some concerns	Potential for residual confounding.	Yes	NA	Yes	No	NA	Low	NA
Ostbye, 2010[133]	High	Potential for bias from attrition and selection bias.	Yes	NA	Probably yes	Probably yes	NA	Low	NA

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Palmer, 2015[134]	High	Potential for confounding, self-reported weight, attrition	Yes	NA	Yes	No	NA	Some concerns	Selected into sample on the basis of having prepregnancy weight, to the extent that such variables are correlated with BF or eventual weight, potential for selection.
Straub, 2016[135]	High	Potential for selection bias, confounding, and attrition bias	No	Probably yes	Yes	No	NA	Some concerns	Selected into sample on the basis of having salivary samples and not missing prepregnancy weights, to the extent that such variables are correlated with BF or eventual weight, potential for selection.

Author, Year	Overall Risk of Bias Rating	Overall Rationale for Risk of Bias Rating	1. Was method of selection unrelated to exposure/ outcome?	1a. Were post-exposure variables that influenced selection related to exposure/ outcome?	2. Do start of followup and start of exposure coincide?	3. Were adjustment techniques used to correct for presence of selection biases?	4. Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	Bias arising from selection?	Comments
Stuebe, 2010[136]	Some concerns	Potential for residual confounding and attrition bias.	No	Probably yes	Yes	No	NA	Some concerns	Risk of selection bias: “women who recertified prior to 20 weeks and were still breastfeeding at the time were not included in the analysis, since an accurate duration of breastfeeding could not be reasonably ascertained”. To the extent that these early recertifiers had different weight retention outcomes, the results can be biased, but not clear in which direction the bias could operate.

BF = breastfeeding; KQ = Key Question; NA = not applicable.

Table C-50. KQ 2 risk of bias assessment: Postpartum weight change, part 2

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Endres, 2014[127]	No	Probably yes	Probably yes	Yes	Yes	NA	Some concerns	Potential for residual confounding.
Jarlenski, 2014;[128] Sharma, 2014[129]	No	Probably yes	Probably yes	Yes	Yes	NA	Low;[128] Some concerns[129]	Conducted propensity score analysis; potential for residual confounding.
Lyu, 2009[130]	No	Probably no	Probably yes	No	Yes	NA	Some concerns	One of the models adjusted for postexposure variables of 1-month energy intake, but other models did not.
Ng, 2014[131]	No	Probably yes	Probably yes	Yes	Yes	NA	Some concerns	Potential for residual confounding.
Onyango, 2011[132]	No	Probably yes	Probably yes	Yes	Yes	NA	Some concerns	Potential for residual confounding.
Ostbye, 2010[133]	No	Probably yes	Probably yes	Yes	Yes	NA	Some concerns	Potential for residual confounding.
Palmer, 2015[134]	No	Probably yes	Probably yes	No	Yes	NA	High	Adjusted for postexposure variables of additional births and subsequent lactation.

Author, Year	5. Is confounding of the exposure effect unlikely?	5a. Did the authors use an appropriate analysis to adjust for confounders?	5b. Were confounding domains that were controlled for measured validly and reliably?	5c. Did the authors avoid adjusting for post-exposure variables?	5d. Were participants analyzed according to their initial exposure group throughout followup?	5e. Were exposure discontinuations or switches unlikely to be related to factors prognostic for the outcome?	Bias arising from confounding?	Comments
Straub, 2016[135]	No	Probably no	Probably yes	Yes	Yes	NA	Some concerns	Potential for residual confounding, did not control for prior pregnancies.
Stuebe, 2010[136]	No	Probably yes	Probably yes	Yes	Yes	NA	Some concerns	Potential for residual confounding.

KQ = Key Question; NA = not applicable.

Table C-51. KQ 2 risk of bias assessment: Postpartum weight change, part 3

Author, Year	6. Is exposure status well-defined?	7. Was information on exposure status recorded at the time of exposure?	8. Was classification of exposure status unaffected by knowledge of the outcome or risk of the outcome?	Bias arising from measurement of exposures?	Comments
Endres, 2014[127]	Yes	Yes	Yes	Low	NA
Jarlenski, 2014;[128] Sharma, 2014[129]	Yes	Yes	Yes	Low	NA
Lyu, 2009[130]	No	Probably no	No information	Some concerns	Breastfeeding is measured in number of months. Because the analysis also includes BF>6 months in a correlation analysis of weight retention at 6 months, it's not clear whether the BF exposure variable was appropriately cut off to include months of BF that occurred before the 6-month weight retention variable only or whether it included all months of BF duration.
Ng, 2014[131]	No	No	Probably yes	Some concerns	Recall
Onyango, 2011[132]	Yes	Yes	Yes	Low	NA
Ostbye, 2010[133]	Yes	Yes	Yes	Low	NA
Palmer, 2015[134]	Yes	No	Probably yes	Some concerns	Recall bias
Straub, 2016[135]	Yes	Yes	Yes	Low	NA
Stuebe, 2010[136]	Yes	Yes	Yes	Low	NA

BF = breastfeeding; KQ = Key Question; NA = not applicable.

Table C-52. KQ 2 risk of bias assessment: Postpartum weight change, part 4

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Endres, 2014[127]	No	Yes	Yes	No information	Yes	Some concerns	Only 774 of 2,510 women had baseline and followup weight information. The authors note that they "we compared demographic characteristics between women with and without a prepregnancy BMI and found no statistically significant differences." Nonetheless, this high rate of exclusion could result in biased results.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Jarlenski, 2014;[128] Sharma, 2014[129]	No	Probably no;[128] no[129]	Probably no;[128] no[129]	No information	Probably yes;[128] no[129]	Some concerns	The study evaluated baseline characteristics between those with and without data (15%) and found differences; implications of missing data were not provided in detail. Response rate was 65% at 12 months.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Lyu, 2009[130]	Yes	No information	No information	No information	No	Some concerns	130 of 151 available at 6 months and 122 at 12 months, but no analysis of implications of missing data.
Ng, 2014[131]	No	Probably no	Probably no	No information	No	High	Analysis on 1,213 of 2,254 women, no sensitivity analysis.
Onyango, 2011[132]	Yes	No information	Probably no	No information	No	Some concerns	Analysis of 172/208 in the U.S. and 262/300 in Norway, but no analysis of implications of missing data.
Ostbye, 2010[133]	No	No	No	No information	No	High	Analysis on 32,920/70,353 (47%); no analysis of implications of missing data.
Palmer, 2015[134]	No	No	Yes	No information	No	High	Data available for only 70% of the sample, others are missing exposure or outcome data, no analysis of the implications of missing data.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Straub, 2016[135]	No	Yes	No	No information	No	High	Only women who returned morning and evening salivary samples were included; women were then excluded if there were data errors (n=81), if they were currently pregnant (n=20) or using steroids (n=5), or if they lacked pre-pregnancy or postpartum weights (n=349). Additionally, one woman was excluded for weighing more than 350 pounds (due to scale limitations). Authors do not comment on the missing data that resulted in selection of patients for the analysis.

Author, Year	9. Were outcome data available for all, or nearly all, participants?	10. Were few or no participants excluded because of missing data on exposure status?	11. Were few or no participants excluded due to missing data on other variables?	12. Was the proportion of participants and reasons for missing data similar across exposure groups?	13. Were appropriate statistical methods used to account for missing data or assess robustness to presence of missing data?	Bias Arising From Missing Data	Comments
Stuebe, 2010[136]	Yes	Yes	Yes	No information	Probably no	Some concerns	557 of 611 eligible with blood samples included in the analysis (91%), but no analysis of the implications of missing data.

BMI = body mass index; KQ = Key Question; U.S.= United States.

Table C-53. KQ 2 risk of bias assessment: Postpartum weight change, part 5

Author, Year	14. Was measurement of outcomes unlikely to have been influenced by knowledge of the exposure received?	15. Were methods of outcome assessment comparable across groups?	16. Was the duration of followup adequate to assess outcomes?	Bias Arising From Measurement of Outcomes	Comments	17. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias Arising From Selection of Reported Results	Comments
Endres, 2014[127]	Yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Jarlenski, 2014;[128] Sharma, 2014[129]	Probably no	Yes	Yes	Some concerns	Self-reported weight	Probably yes	Low	NA
Lyu, 2009[130]	Probably no	Yes	Yes	Some concerns	Self-reported weight	Probably yes	Low	NA
Ng, 2014[131]	Probably no	Yes	Yes	Some concerns	Self-reported weight	Probably yes	Low	NA
Onyango, 2011[132]	Yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Ostbye, 2010[133]	Probably no	Yes	Yes	Some concerns	Self-reported weight	Probably yes	Low	NA
Palmer, 2015[134]	Probably no	Yes	Yes	Low	Although weight was self-reported, authors noted that "In a validation study conducted among 115 participants, self-reported height and weight were highly correlated with technician-measured height and weight."	Probably yes	Low	NA
Straub, 2016[135]	Yes	Yes	Yes	Low	NA	Probably yes	Low	NA
Stuebe, 2010[136]	No information	Yes	Yes	Low	NA	Probably yes	Low	NA

KQ = Key Question; NA = not applicable.

Appendix D. Strength of Evidence Tables

Table D-1. KQ 1a/b: Studies assessing Baby Friendly Hospital Initiative

BF Outcome Intervention vs. Comparator	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Initiation BFHI certified/ accredited vs. no BFHI status	9; 1,227,532	9 prospective cohort;[23, 26, 28, 31, 33, 34, 41, 46, 48] medium to high	Consistent	Direct	Imprecise	Any BF initiation (k=65): higher rates of breastfeeding at discharge among BFHI-accredited hospitals than control hospitals (by 0.5% to 10%); differences between groups were not statistically significant in 4 studies Exclusive BF initiation (k=5): significantly higher rates of exclusive BF at discharge among BFHI-accredited hospitals than control hospitals; magnitude varied, ranging from 3% to 56%.	Low
Duration BFHI vs. no BFHI intervention) evidence from RCTs) BFHI certified/ accredited vs. no BFHI status (evidence from observational studies)	1 RCT; 17,046 8 cohorts; 136,983	1 RCT;[11, 12] medium 8 cohorts;[23, 26, 31, 33, 34, 45, 46, 48] medium to high	Mostly consistent	Direct	Precise for RCT evidence; imprecise for obs-ervational evidence	One RCT found significantly higher rates of exclusive BF among women at BFHI hospitals at 3 mos (43% vs. 6%; p<0.001) and 6 mos postpartum (7.9% vs. 0.6%; p=0.01), and lower odds of weaning (from any BF) at 3, 6, 9, and 12 mos postpartum than women in control hospitals Any BF duration (k=8 cohort studies): higher rates of BF 1 to 12 mos postpartum among women at BFHI hospitals (by approximately 0.6% to 15%) than women at control hospitals; one study found slightly higher BF rates at 1 mo among women in control hospitals than BFHI hospitals (by 0.4% to 7%) Exclusive BF duration (k=5 cohort studies): higher rates of exclusive BF over 1 to 2 mos among infants born in BFHI hospitals than control hospitals (by approximately 4% to 25%).	Moderate

Intervention vs. Comparison Outcome	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Initiation (subgroups: education status) BFHI certified/ accredited vs. no BFHI status	2; 27,341	2 prospective cohorts;[33, 34] medium	Consistent	Direct	Imprecise	Both studies found higher rates of BF initiation among women with lower education (≤12 years) at BFHI hospitals compared with nonaccredited hospitals, but no difference in rates among women with higher education (≥13 years).	Low
Duration (subgroups: education status) BFHI certified/ accredited vs. no BFHI status	2; 27,341	2 prospective cohorts;[33, 34] medium	Inconsistent	Direct	Imprecise	One study enrolling women from five U.S. states found significantly increased rates of exclusive BF for ≥4 weeks among women with lower educational attainment (p=0.02), but no difference for women with higher education; no difference was seen for rates of any BF for ≥4 weeks by education. The study evaluating women giving birth in Maine hospitals found no difference in rates of exclusive or any breastfeeding for ≥4 weeks postpartum among women who differed by education status.	Insufficient
Duration Six or more BFHI steps vs. less than six steps	1; 1,417	1 prospective cohort;[45] medium	Unknown[a]	Direct	Precise	Women giving birth in hospitals practicing ≤4 BFHI steps had higher odds of weaning at or before 8 weeks postpartum than women giving birth in facilities practicing six BFHI steps (ORs ranged from 2.08 and 3.13); no difference between women exposed to five vs. six steps.	Low

[a] Although only one study compared groups of women based on number of BFHI practiced by hospitals, we considered evidence on duration from studies comparing BFHI accreditation with nonaccredited hospitals that reported on duration.

BF = breastfeeding; BFHI = Baby Friendly Hospital Initiative; KQ = Key Question; N = number; OR = odds ratio; RCT = randomized controlled trial; ROB = risk of bias; SOE = strength of evidence; U.S.= United States

Table D-2. KQ 1a/b: Studies assessing Non-Baby Friendly Hospital Initiative health care system–based interventions

Intervention vs. Comparison (Outcome)	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Initiation Education/ staff training related to BF alone vs. usual practice	4; 1,532[a]	2 RCTs;[6, 7, 19] medium 2 NRCT;[30, 40] medium to high	Consistent	Direct	Imprecise	Three studies assessing maternity staff or nursing education/training found no benefit for rates of BF initiation. One NRCT assessing a residency BF curriculum found similar increases in BF initiation rates at intervention and control programs.	Low
Initiation Education and staff training plus additional individual services vs. usual care	4; 34,018	2 RCTs;[9, 10] medium 1 NRCT;[32] high 1 pre-post study;[47] medium	Inconsistent	Direct	Imprecise	Two RCTs assessed interventions combining staff training plus additional BF support services (expanding access to BF groups, and provision of additional HVs); neither found benefit. Two studies assessed staff training additional individual-level BF counseling and support services and both found significant benefit in favor of the intervention.	Insufficient
Duration Education and staff training related to BF only vs. usual practice	3; 1,526[a]	2 RCTs;[6, 7, 20] medium 1 NRCT;[30] medium	Inconsistent	Direct	Imprecise	Two RCTs assessing maternity staff education/training found inconsistent results: one found similar durations of any BF in intervention and control groups (7.5, 7.1, and 7.0 months; p=NS) and higher exclusive BF duration among the intervention vs. one control group (3.9 vs. 3.2 months; p=0.002) but not the other (3.9 vs. 3.6 months; p=NS); the second RCT found significantly lower rates of weaning in the intervention group (exclusive BF, full BF and any BF) than controls). One NRCT of a BF residency curriculum found higher pre-post increases in any BF at intervention vs. control programs at 6 months. (3.4% vs. 1.6%) and exclusive BF at 6 months. (6.7% vs. -5.4%); no measure of various provided for difference between groups.	Insufficient

Intervention vs. Comparison (Outcome)	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Duration Education and staff training plus additional individual services vs. usual care	4; 21, 253	4 RCTs;[5, 9, 10, 13] medium	Inconsistent	Direct	Imprecise	One RCT found no difference in rates of any or exclusive BF at 3 months between the intervention (health care provider training, increased individual support: counseling, free access to lactation consultants) and usual care; one cluster RCT assessing a policy to provide BF groups found no difference in rates of any BF among intervention and control practices 6 to 8 weeks and 8 to 9 months postpartum. Two RCTs assessing staff education combined with expanded or new home visits found consistent benefit; both provided staff training, one provided an additional 1-3 HVs for BF support and found a lower rate of BF cessation rate HR, 0.86; 95% CI, 0.75 to 0.99), the other compared staff training plus 10 HVs with staff training alone and found higher rates of any BF and exclusive BF over 6 months postpartum.	Low (interventions combining staff training and home visits) Insufficient (other intervention types)
Duration BFHI adaptation and implementation in antenatal and child health (outpatient) practices vs. usual care	1; 3,948	1 NRCT;[25] medium	Unknown	Direct	Precise	No difference between the intervention and control group in rates of any BF at 6 months (OR, 1.24; 95% CI, 0.99 to 1.54) or at 12 months (p=0.43). Rates of exclusive BF were higher in the intervention group than controls at 5 months (OR, 1.39; 95% CI, 1.09 to 1.77) and at 6 months (OR, 1.33; 95% CI, 1.03 to 1.72).	Low

Intervention vs. Comparison (Outcome)	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Initiation/ Duration Continuous primary nursing care (same nurse through perinatal period for mother/infant) vs. usual care (task oriented nursing)	1; 470	1 RCT;[21] medium	Unknown	Direct	Precise	Women in the intervention group had higher rates of exclusive BF during hospitalization than women in the control group (99% vs. 88%; p=0.001) and higher rates of exclusive BF 6 weeks than women in the control group (72% vs. 94%; p=0.001).	Low

[a] Number here includes participants enrolled from three studies; one study focused on 13 residency programs did not report the number of women included in analyses of breastfeeding outcomes.[30]

BF = breastfeeding; CI = confidence interval; HR = hazard ratio; HV = home visits; KQ = Key Question; N = number; NRCT = nonrandomized controlled trial; NS = not significant; OR = odds ratio; RCT = randomized controlled trial; ROB = risk of bias; SOE = strength of evidence; UK = United Kingdom; U.S.= United States.

Table D-3. KQ 1a/b: Studies assessing Women, Infants and Children–based interventions

Intervention vs. Comparison (Outcome)	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Initiation/ Duration BF rates post 2007 policy revising the WIC food package vs. pre-policy implementation (all sources: ever-BF; PRAMS: BF for least 4 weeks; NIS: BF for at least 3 months; PedNSS: BF for at least 1 month)	1 (3 population cohorts); PRAMS (WIC): 85,458 PRAMS (Non-WIC): 42,019 NIS (WIC): 62,289 NIS (Non-WIC): 11,702 PedNSS (infants): 744	1 prospective cohort[35]; high	Unknown	Indirect[a]	Imprecise	No association between the policy change and rates of BF; data from all showed steady upward trends in rates of ever breastfed infants on WIC during the study period; in neither PRAMS nor NIS data were trends in BF after implementation statistically different from trends in BF among low-income women not on WIC	Insufficient
Duration Provision of electric breast pump vs. manual pump	1; 280	1 RCT;[8] medium	Unknown	Direct	Imprecise	For Hawaiian mothers on WIC who planned to return to work/school, no difference in BF duration among women assigned to an electric vs. manual breast pump: median duration of BF 12 vs. 11 months, respectively; HR, 1.13; 95% CI, 0.79 to 1.50	Insufficient

Intervention vs. Comparison (Outcome)	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Initiation/ Duration Mother peer support vs. control	3; 2,480	1 RCT;[18] medium 1 NRCT;[43] high 1 cohort;[44] medium	Mostly consistent	Direct	Precise	Two studies of in-person peer support for mothers found significant benefit; in one, women in the intervention group had a higher rate of BF initiation than controls (82% vs. 31%) and a higher rate of any BF at 12 weeks (43% vs. 0%; p<0.001). The other RCT found higher rates of BF at hospital discharge in the intervention group than controls (44% vs. 26%, p<0.01) and higher rates of any BF at 6 weeks (26% vs. 13%, p<0.01). One RCT comparing telephone BF support, there was no difference between groups in BF initiation rates and rates of exclusive BF rates at 3 and 6 months postpartum; rates of any BF were higher in the intervention group than controls at 3 and 6 months (RR, 1.18; 95% CI, 1.03 to 1.34)	Low
Initiation/ Duration (subgroups: language spoken) Mother peer support vs. control	1; 1,948	1 RCT;[18] Medium	Unknown	Direct	Imprecise	One RCT (telephone peer support) reported on subgroups of women defined by language (English-speaking vs. Spanish-speaking only), results for any BF at 3 months were significant for both groups; at 6 months, benefit for any BF was significant only for the Spanish-speaking subgroup. There was no significant difference in rates of exclusive BF in either subgroup at 3 or 6 months.	Insufficient

Intervention vs. Comparison (Outcome)	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Initiation/ Duration Peer support program for fathers (in addition to mother peer support) vs. peer support for mothers alone	1; 200	1 NRCT;[36] medium	Unknown	Direct	Imprecise	Mothers in the intervention group had slightly higher rate of any BF at 6 months, but the difference was not statistically significant (63% vs. 55%; p=0.20).	Insufficient
Duration Cash incentives vs. usual WIC services	1: 36	1 RCT;[22] Medium	Unknown	Direct	Precise	Breastfeeding rates in the intervention group were significantly higher than controls at 1, 3, and 6 months (89% vs. 44%, 89% vs. 17%, and 72% vs. 0%, respectively)	Insufficient
Duration Tailored BF counseling and support based on BAPT survey	1; 826	1 cohort;[29] High	Unknown	Direct	Imprecise	Significantly higher rates of exclusive BF in the intervention group at 7 and 30 days than controls; no difference between groups at 2 months	Insufficient
Duration (subgroups: race/ethnicity) Tailored BF counseling and support based on BAPT survey	1; 826	1 cohort;[29] High	Unknown	Direct	Imprecise	Significantly higher rates of exclusive BF among non-Hispanic black and Hispanic women in the intervention group than controls at 30 and 60 days; no significant difference in exclusive BF rates among white women at any timepoint	Insufficient

[a] Databases not designed to collect information on breastfeeding status; unclear to what extent data reflects true rate of breastfeeding in women enrolled in WIC and those not enrolled who are similar in socioeconomic status.

BAPT = Breastfeeding Attrition Prediction Tool; BF = breastfeeding; CI = confidence interval; HR = hazard ratio; HV = home visit; KQ = Key Question; N = number; NIS = National Immunization Survey; NRCT = nonrandomized controlled trial; PedNSS = Pediatric Nutrition Surveillance System; PRAMS = Pregnancy Risk Assessment Monitoring System; RCT = randomized controlled trial; ROB = risk of bias; RR = risk ratio; SOE = strength of evidence; U.S.= United States; WIC = Special Supplemental Nutrition Program for Women, Infants, and Children.

Table D-4. KQ 1a/b: Studies assessing community-based interventions

Intervention vs. Comparison (Outcome)	N Studies; N Subjects	Design; ROB	Consistency	Direct-ness	Precision	Magnitude of Effect (Summary Effect Size, 95% Confidence Interval)	SOE
Initiation/ Duration Community-based policy aimed at promoting BF in nonhospital-based health and community centers vs. no intervention	1; 5,094	1 NRCT;[38, 39] medium	Unknown	Direct	Imprecise	The rate of exclusive BF at discharge, 3 and 6 months, and of any BF at 5 and 12 months increased during the study period in both groups (with no significant differences between groups).	Insufficient
Duration Access to community-based BF drop-in centers (plus early BF support) vs. early BF support alone vs. usual care	1; 9,675	1 RCT;[14, 15] low	Unknown	Direct	Precise	No difference between groups in rates of any breast milk feeding at 3, 4, or 5 months.	Low
Duration Community-based peer support vs. usual care	1; 130	1 RCT;[16] low	Unknown	Direct	Precise	More women in the intervention groups were exclusively BF than controls at 3 months postpartum (67% of the 6-visit group, 50% of the 3-visit group, vs. 12% of controls; p<0.001); rates of any BF were significantly longer in intervention groups (combined) than in the control group at 3 months, but not 6 months.	Low
Duration Peer-led BF support class vs. nurse-led BF support class	1; 109	1 prospective cohort;[42] high	Unknown	Direct	Imprecise	No significant difference between groups in rates of any breastfeeding at 1 and 6 months postpartum.	Insufficient
Duration Integrated postpartum program (BF education and support, maternal/ infant health care) vs. usual care	1;392	1 NRCT;[24] high	Unknown	Direct	Precise	Significantly higher rates of exclusive BF at 6 mos among the intervention group than control group (74% vs. 10%; p=0.001)	Insufficient

BF = breastfeeding; KQ = Key Question; N = number; NRCT = nonrandomized controlled trial; RCT = randomized controlled trial; SOE = strength of evidence.

Table D-5. SOE for KQ 2 summarized by outcome

Outcome	N Studies; N Subjects	Design; Risk of Bias	Consistency	Directness[a]	Precision	Magnitude of effect (Summary Effect Size, 95% Confidence Interval)	SOE
Breast cancer	1 SR of 98 studies;[2] NR[b] 19 individual studies;[66, 67, 69-74, 77-80, 83-85, 87-90] 256,891 women	Cohort and case-control; high to medium	Mostly consistent	Indirect	Imprecise	In one SR (k=98), ever BF was associated with lower rates of breast cancer compared with never BF (pooled OR 0.78, 95% CI 0.74 to 0.82); women who BF for longer durations also had significantly lower rates of breast cancer than women who did not BF. Results of individual studies were generally consistent in direction of effect (although results were imprecise); magnitude varied significantly across all studies and pooled results were associated with significant heterogeneity, only partially explained by subgroup analyses.	Low
Breast Cancer: *BRCA1/2* Carriers	1;[76] 5,708 women	Case-control; medium	Unknown	Indirect	Imprecise	Association between BF duration and lower rates of breast cancer among *BRCA1* mutation carriers (p for trend<0.0001), but not *BRCA2* mutation carriers (p for trend=0.68).	Insufficient
Breast cancer: In situ	3;[75, 83, 87] 67,234 women	1 cohort and 2 case-control; medium	Inconsistent	Indirect	Imprecise	One case-control study found no association between BF and DCIS and the other found no association between BF duration and diagnosis of DCIS or invasive ductal carcinoma; one cohort study found no association between BF duration and incident DCIS.	Insufficient
Breast cancer: Hormone receptor subtypes	1 SR of 11 studies;[58] 169,879 women for luminal, 14,266 women for HER2, and 176,430 women for triple-negative analyses 7 individual studies;[68, 74, 80, 81, 86, 90, 91] 592,558 women	Cohort and case-control; high to medium[c]	Luminal, triple-negative: consistent HER2: inconsistent	Indirect	Imprecise	Consistent association between ever BF or longer duration of BF and lower rates of luminal and triple- negative breast cancer (although magnitude of association varies); for HER2, pooled estimates show unclear association between BF and lower rates of breast cancer (results are imprecise and pooled estimate is not statistically significant)	Low (luminal, triple-negative; inconsistent, consistent, imprecise); Insufficient (HER2, inconsistent, imprecise)
Breast Cancer: Mortality	1;[82] 250,470 parous women	Cohort; medium	Unknown	Indirect	Imprecise	HR=1.01 (95% CI: 0.79 to 1.29)	Insufficient

Outcome	N Studies; N Subjects	Design; Risk of Bias	Consistency	Directness[a]	Precision	Magnitude of effect (Summary Effect Size, 95% Confidence Interval)	SOE
Ovarian cancer	1 SR of 41 studies;[2] NR[e] 9 individual studies;[92-97, 137-140] 42,611 women	Cohort and case-control; high to medium	Consistent	Indirect	Precise	Results from included systematic review: Ever breastfed Pooled OR=0.70 (95% CI: 0.64 to 0.77), I^2=70 <6 months Pooled OR=0.83 (95% CI: 0.78 to 0.89), I^2=3 6-12 months Pooled OR=0.72 (95% CI: 0.66 to 0.78), I^2=22 >12 months Pooled OR=0.63 (95% CI: 0.56 to 0.71), I^2=52.	Moderate
Hypertension	5;[3, 99, 100, 104, 141] 441,989 women	Cohort; medium to high	Consistent	Indirect	Imprecise	Consistent association between longer duration of BF (>6-12 months) and lower rates HTN; magnitude of association varies by BF exposure comparisons and study design.	Low
CVD	3;[3, 102, 103] 301,989 women	Cohort; medium	Unknown	Indirect	Imprecise	Three studies conclude an association between longer BF duration and lower CVD rates, each using a different composite outcome; magnitude of association varies by exposure comparisons, age at cohort enrolment, and study design	Insufficient
CVD mortality	1;[101] 15,000	Cohort; medium	Unknown	Indirect	Imprecise	Parous women ≤65 years at enrollment who had never lactated had higher CVD mortality over 14 years of followup than women who lactated ≥24 months (HR 2.77; 95% CI, 1.28 to 5.99). No clear associations were observed among women ≤65 years at enrollment.	Insufficient
Type 2 diabetes	1 SR of 6 studies;[50] 273,961 women 5 individual studies;[3, 105-109] 325,815 women	Cohort: medium	Consistent	Indirect	Imprecise	Consistent association between ever BF and longer durations of BF and lower rates of type 2 diabetes (among women with and without gestational diabetes); magnitude of association varies by BF exposure duration and study design.	Low

Outcome	N Studies; N Subjects	Design; Risk of Bias	Consistency	Directness[a]	Precision	Magnitude of effect (Summary Effect Size, 95% Confidence Interval)	SOE
Fractures	11;[110-114, 142-147] 101,726 women	6 case-control and 5 cohort studies; medium to high	Consistent	Indirect	Imprecise	Magnitude varies by exposure and outcome measure	Low
Postpartum depression	1 SR of 48 studies;[52] 71,245 women 14 individual studies;[59, 115, 117-126, 148, 149] 39,372 women	Cohort; high to medium	Inconsistent	Indirect	Imprecise	Magnitude of association and direction of effect unclear; studies are heterogeneous in design and results inconsistent.	Insufficient
Postpartum weight change	16;[127-136, 150-158] 47,655 women	Prospective cohort studies; medium	Inconsistent	Indirect	Imprecise	Magnitude varies by exposure and outcome measure	Insufficient

[a] We marked outcomes as indirect for long-term maternal health outcomes primarily due to uncertainty of the relative contribution of breastfeeding to risk (given that many other potential factors also contribute to outcomes such as hypertension, fracture and breast cancer); for short-term maternal health outcomes (e.g., postpartum depression) there is uncertainty in the direction of effect between breastfeeding and health outcomes.

[b] Per authors, there were 52 studies with >1,500 women, 31 studies with 500-1,499 women, and 15 studies with <500 women. Exact number of participants is unclear.

[c] The systematic review was rated unclear risk of bias and did not provide quality ratings for the included studies. Of the four additional studies, 3 were rated medium risk of bias and one was rated high risk of bias.

[d] Results from 4 additional individual studies were generally consistent in direction and magnitude of effect.

[e] There were 22 studies with >1,500 women, 12 studies with 500-1,499 women, and 7 studies with <500 women.

BF = breastfeeding; *BRCA* = breast cancer gene; CI = confidence interval; CVD = cardiovascular disease; DCIS = ductal carcinoma in situ; HER2 = human epidermal growth factor receptor 2; HR = hazard ratio; HTN = hypertension; KQ = Key Question; N = number; NR = not reported; OR = odds ratio; SOE = strength of evidence; SR = systematic review.

Appendix E. Excluded Studies

Exclusion codes:

X1: Not original research
X2: Wrong population
X3: Wrong exposure or intervention
X4: Wrong or no comparator
X5: Wrong or no outcome
X6: Wrong study design
X7: Non-English
X8: Wrong country
X9: Study protocol only
X10: Superseded by an included systematic review
X11: Irrelevant or high risk of bias systematic review

1. Independent study module for lactation consultants. J Hum Lact. 2012;28(2):251-3. doi: 10.1177/0890334412436722. PMID: 104555631. Exclusion Code: X1.
2. 04 'Who Loves Their Wives and Children More?': Vietnamese Fathers' Support Improves Early and Exclusive Breastfeeding. J Nutr Educ Behav. 2012;44(4S1):S14-S. PMID: 108143853. Exclusion Code: X9.
3. Counselling sessions increased duration of exclusive breastfeeding: a randomized clinical trial with adolescent mothers and grandmothers. Essentially MIDIRS. 2014;5(10):47-. PMID: 103915666. Exclusion Code: X3.
4. Research evidence. Community Practitioner. 2014;87(10):12-. PMID: 103806569. Exclusion Code: X2.
5. Evaluation of the Healthy Start Voucher Scheme in UK: a natural experiment using the Growing Up in Scotland record linkage study and the Infant Feeding Survey (Project record). Health Technology Assessment Database: Health Technology Assessment; 2015. Exclusion Code: X6.
6. Cochrane Pregnancy and Childbirth Group. About The Cochrane Collaboration: John Wiley & Sons, Ltd; 2016. Exclusion Code: X1.
7. Abbass-Dick J, Xie F, Koroluk J, et al. The Development and piloting of an eHealth breastfeeding resource targeting fathers and partners as co-parents. Midwifery. 2017;50:139-47. doi: 10.1016/j.midw.2017.04.004. PMID: 123257423. Exclusion Code: X3.
8. Abdulwadud OA, Snow ME. Interventions in the workplace to support breastfeeding for women in employment. Cochrane Database Syst Rev. 2012 Oct 17;10:Cd006177. doi: 10.1002/14651858.CD006177.pub3. PMID: 23076920. Exclusion Code: X5.
9. Abrahams RR, MacKay-Dunn MH, Nevmerjitskaia V, et al. An evaluation of rooming-in among substance-exposed newborns in British Columbia. J Obstet Gynaecol Can. 2010 Sep;32(9):866-71. PMID: 21050520. Exclusion Code: X3.
10. Adams IK, Okoli CT, Dulin Keita A, et al. Breastfeeding Practices among Native Hawaiians and Pacific Islanders. J Obes. 2016;2016:2489021. doi: 10.1155/2016/2489021. PMID: 27774314. Exclusion Code: X3.
11. Adedinsewo DA, Fleming AS, Steiner M, et al. Maternal anxiety and breastfeeding: findings from the MAVAN (Maternal Adversity, Vulnerability and Neurodevelopment) Study. J Hum Lact. 2014 Feb;30(1):102-9. doi: 10.1177/0890334413504244. PMID: 24065719. Exclusion Code: X3.

12. Adolfsson A, Linden K, Sparud-Lundin C, et al. A web-based support for pregnant women and new mothers with type 1 diabetes mellitus in Sweden (MODIAB-Web): study protocol for a randomized controlled trial. Trials. 2014 Dec 29;15:513. doi: 10.1186/1745-6215-15-513. PMID: 25543854. Exclusion Code: X3.

13. Agampodi SB, Agampodi TC. Effect of low cost public health staff training on exclusive breastfeeding. Indian J Pediatr. 2008 Nov;75(11):1115-9. doi: 10.1007/s12098-008-0185-4. PMID: 18810343. Exclusion Code: X6.

14. Aghdas K, Talat K, Sepideh B. Effect of immediate and continuous mother-infant skin-to-skin contact on breastfeeding self-efficacy of primiparous women: a randomised control trial. Women Birth. 2014 Mar;27(1):37-40. doi: 10.1016/j.wombi.2013.09.004. PMID: 24216342. Exclusion Code: X3.

15. Ahlqvist-Bjorkroth S, Vaarno J, Junttila N, et al. Initiation and exclusivity of breastfeeding: association with mothers' and fathers' prenatal and postnatal depression and marital distress. Acta Obstet Gynecol Scand. 2016 Apr;95(4):396-404. doi: 10.1111/aogs.12857. PMID: 26826608. Exclusion Code: X3.

16. Ahluwalia IB, Tessaro I, Grummer-Strawn LM, et al. Georgia's breastfeeding promotion program for low-income women. Pediatrics. 2000 Jun;105(6):E85. PMID: 10835098. Exclusion Code: X6.

17. Ahmed A, Ouzzani M. Development and assessment of an interactive web-based breastfeeding monitoring system (LACTOR). Matern Child Health J. 2013 Jul;17(5):809-15. doi: 10.1007/s10995-012-1074-z. PMID: 22791207. Exclusion Code: X3.

18. Ahmed AH, Roumani AM, Szucs K, et al. The Effect of Interactive Web-Based Monitoring on Breastfeeding Exclusivity, Intensity, and Duration in Healthy, Term Infants After Hospital Discharge. J Obstet Gynecol Neonatal Nurs. 2016 Mar-Apr;45(2):143-54. doi: 10.1016/j.jogn.2015.12.001. PMID: 26779838. Exclusion Code: X3.

19. Ahnfeldt AM, Stanchev H, Jorgensen HL, et al. Age and weight at final discharge from an early discharge programme for stable but tube-fed preterm infants. Acta Paediatr. 2015 Apr;104(4):377-83. doi: 10.1111/apa.12917. PMID: 25545824. Exclusion Code: X3.

20. Ajmera V, Terrault N, VanWagner L, et al. Longer lactation duration is associated with decreased non-alcoholic fatty liver disease in the cardia cohort study. Hepatology. Conference: 67th annual meeting of the american association for the study of liver diseases: the liver meeting 2016. United states. Conference start: 20161111. Conference end: 20161115; 2017. p. 590a. Exclusion Code: X5.

21. Akhter M, Inoue M, Kurahashi N, et al. Reproductive factors, exogenous female hormone use and colorectal cancer risk: the Japan Public Health Center-based Prospective Study. Eur J Cancer Prev. 2008 Nov;17(6):515-24. doi: 10.1097/CEJ.0b013e3282f521f8. PMID: 18941373. Exclusion Code: X5.

22. Akman I, Kuscu MK, Yurdakul Z, et al. Breastfeeding duration and postpartum psychological adjustment: role of maternal attachment styles. J Paediatr Child Health. 2008 Jun;44(6):369-73. doi: 10.1111/j.1440-1754.2008.01336.x. PMID: 18476931. Exclusion Code: X5.

23. Aksu H, Kucuk M, Duzgun G. The effect of postnatal breastfeeding education/support offered at home 3 days after delivery on breastfeeding duration and knowledge: a randomized trial. J Matern Fetal Neonatal Med. 2011 Feb;24(2):354-61. doi: 10.3109/14767058.2010.497569. PMID: 20608806. Exclusion Code: X3.

24. Al Mamun A, O'Callaghan MJ, Williams GM, et al. Breastfeeding is protective to diabetes risk in young adults: a longitudinal study. Acta Diabetol. 2015 Oct;52(5):837-44. doi: 10.1007/s00592-014-0690-z. PMID: 25539880. Exclusion Code: X5.

25. Albernaz E, Araujo CL, Tomasi E, et al. Influence of breastfeeding support on the tendencies of breastfeeding rates in the city of Pelotas (RS), Brazil, from 1982 to 2004. J Pediatr (Rio J). 2008 Nov-Dec;84(6):560-4. doi: doi:10.2223/JPED.1823. PMID: 18923797. Exclusion Code: X3.

26. Albernaz E, Victora CG, Haisma H, et al. Lactation counseling increases breast-feeding duration but not breast milk intake as measured by isotopic methods. J Nutr. 2003 Jan;133(1):205-10. PMID: 12514291. Exclusion Code: X3.

27. Alex MR, MacLellan-Peters J. The Relationship Among Skin-to-Skin Contact, Breastfeeding, and Mother-Infant Interaction: Implications for Nursing. JOGNN: Journal of Obstetric, Gynecologic & Neonatal Nursing. 2013;42:S88-9. doi: 10.1111/1552-6909.12181. PMID: 104179300. Exclusion Code: X4.

28. Alexander GR, Hulsey TC, Foley K, et al. An assessment of the use and impact of ancillary prenatal care services to Medicaid women in managed care. Matern Child Health J. 1997 Sep;1(3):139-49. PMID: 10728237. Exclusion Code: X3.

29. Allen J, Hector D. Benefits of breastfeeding. N S W Public Health Bull. 2005 Mar-Apr;16(3-4):42-6. PMID: 16106271. Exclusion Code: X6.

30. Almeida H, Venancio SI, Sanches MT, et al. The impact of kangaroo care on exclusive breastfeeding in low birth weight newborns. J Pediatr (Rio J). 2010 May-Jun;86(3):250-3. doi: doi:10.2223/JPED.1974. PMID: 20424798. Exclusion Code: X4.

31. Alshaikh B, Kostecky L, Blachly N, et al. Effect of a Quality Improvement Project to Use Exclusive Mother's Own Milk on Rate of Necrotizing Enterocolitis in Preterm Infants. Breastfeed Med. 2015 Sep;10(7):355-61. doi: 10.1089/bfm.2015.0042. PMID: 26230909. Exclusion Code: X3.

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33. Amir LH, Cullinane M, Garland SM, et al. The role of micro-organisms (Staphylococcus aureus and Candida albicans) in the pathogenesis of breast pain and infection in lactating women: study protocol. BMC Pregnancy Childbirth. 2011 Jul 22;11:54. doi: 10.1186/1471-2393-11-54. PMID: 21777483. Exclusion Code: X3.

34. Amissah EA, Kancherla V, Ko YA, et al. Validation Study of Maternal Recall on Breastfeeding Duration 6 Years After Childbirth. J Hum Lact. 2017 May;33(2):390-400. doi: 10.1177/0890334417691506. PMID: 28418809. Exclusion Code: X3.

35. Andaya E, Bonuck K, Barnett J, et al. Perceptions of primary care-based breastfeeding promotion interventions: qualitative analysis of randomized controlled trial participant interviews. Breastfeed Med. 2012 Dec;7(6):417-22. doi: 10.1089/bfm.2011.0151. PMID: 22621223. Exclusion Code: X5.

36. Anderson AK, Damio G, Chapman DJ, et al. Differential response to an exclusive breastfeeding peer counseling intervention: the role of ethnicity. J Hum Lact. 2007 Feb;23(1):16-23. doi: 10.1177/0890334406297182. PMID: 17293547. Exclusion Code: X3.

37. Anderson AK, Damio G, Young S, et al. A randomized trial assessing the efficacy of peer counseling on exclusive breastfeeding in a predominantly Latina low-income community. Arch Pediatr Adolesc Med. 2005 Sep;159(9):836-41. doi: 10.1001/archpedi.159.9.836. PMID: 16143742. Exclusion Code: X3.

38. Anderson KN, Schwab RB, Martinez ME. Reproductive risk factors and breast cancer subtypes: a review of the literature. Breast Cancer Res Treat. 2014 Feb;144(1):1-10. doi: 10.1007/s10549-014-2852-7. PMID: 24477977. Exclusion Code: X1.

39. Andrieu N, Goldgar DE, Easton DF, et al. Pregnancies, breast-feeding, and breast cancer risk in the International BRCA1/2 Carrier Cohort Study (IBCCS). J Natl Cancer Inst. 2006 Apr 19;98(8):535-44. doi: 10.1093/jnci/djj132. PMID: 16622123. Exclusion Code: X10.

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41. Anothaisintawee T, Wiratkapun C, Lerdsitthichai P, et al. Risk factors of breast cancer: a systematic review and meta-analysis. Asia Pac J Public Health. 2013 Sep;25(5):368-87. doi: 10.1177/1010539513488795. PMID: 23709491. Exclusion Code: X11.

42. Antonakou A, Papoutsis D, Panou I, et al. Role of exclusive breastfeeding in energy balance and weight loss during the first six months postpartum. Clin Exp Obstet Gynecol. 2013;40(4):485-8. PMID: 24597239. Exclusion Code: X4.

43. Aragon M, Chhoa E, Dayan R, et al. Perspectives of expectant women and health care providers on birth plans. J Obstet Gynaecol Can. 2013 Nov;35(11):979-85. PMID: 24246397. Exclusion Code: X3.

44. Arikpo D, Edet ES, Chibuzor MT, et al. Educational interventions for improving complementary feeding practices. Cochrane Database of Systematic Reviews: John Wiley & Sons, Ltd; 2015. Exclusion Code: X3.

45. Arlotti JP, Cottrell BH, Lee SH, et al. Breastfeeding among low-income women with and without peer support. J Community Health Nurs. 1998;15(3):163-78. doi: 10.1207/s15327655jchn1503_4. PMID: 9747023. Exclusion Code: X3.

46. Armenta RF, Kritz-Silverstein D, Wingard D, et al. Association of breastfeeding with postmenopausal visceral adiposity among three racial/ethnic groups. Obesity (Silver Spring). 2015 Feb;23(2):475-80. doi: 10.1002/oby.20956. PMID: 25522135. Exclusion Code: X5.

47. Arora A, Manohar N, Hayen A, et al. Determinants of breastfeeding initiation among mothers in Sydney, Australia: findings from a birth cohort study. International Breastfeeding Journal. 2017;12:1-10. doi: 10.1186/s13006-017-0130-0. PMID: 125191819. Exclusion Code: X3.

48. Artieta-Pinedo I, Paz-Pascual C, Grandes G, et al. Antenatal education and breastfeeding in a cohort of primiparas. J Adv Nurs. 2013 Jul;69(7):1607-17. doi: 10.1111/jan.12022. PMID: 23013265. Exclusion Code: X3.

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52. Avoa A, Fischer PR. The influence of perinatal instruction about breast-feeding on neonatal weight loss. Pediatrics. 1990 Aug;86(2):313-5. PMID: 2371108. Exclusion Code: X5.

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63. Barlow A, Varipatis-Baker E, Speakman K, et al. Home-visiting intervention to improve child care among American Indian adolescent mothers: a randomized trial. Arch Pediatr Adolesc Med; 2006. p. 1101-7. Exclusion Code: X5.

64. Barlow J, Smailagic N, Bennett C, et al. Individual and group based parenting programmes for improving psychosocial outcomes for teenage parents and their children. Cochrane Database of Systematic Reviews: John Wiley & Sons, Ltd; 2011. Exclusion Code: X3.

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66. Barros F, Halpern R, Victora C, et al. [Promotion of breast-feeding in urban localities of southern Brazil: a randomized intervention study]. Rev Saude Publica; 1994. p. 277-83. Exclusion Code: X7.

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68. Bartick MC, Jegier BJ, Green BD, et al. Disparities in Breastfeeding: Impact on Maternal and Child Health Outcomes and Costs. J Pediatr. 2017 Feb;181:49-55.e6. doi: 10.1016/j.jpeds.2016.10.028. PMID: 27837954. Exclusion Code: X6.

69. Bartick MC, Stuebe AM, Schwarz EB, et al. Cost analysis of maternal disease associated with suboptimal breastfeeding. Obstet Gynecol. 2013 Jul;122(1):111-9. doi: 10.1097/AOG.0b013e318297a047. PMID: 23743465. Exclusion Code: X3.

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Appendix F. Breast Cancer Evidence Tables

Table F-1. Breastfeeding and breast cancer: Summary of individual studies

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Al-Amri, 2015[66] Case-control High	Case-control study of Saudi Arabian women screening for a mammogram; five age comparable controls with normal mammogram results were selected from the same mobile clinic as cases (348) Diagnosed during mammogram screening and confirmed by clinical and pathological examination (58)	Mean age (SD): Cases: 49 (7.1) Controls: 49 (6.9) Postmenopausal: Cases: 55% Control: 38%	Cases: 45 (78%) Controls: 273 (94%) OR, 0.30 (95% CI 0.13 or 0.69), p=0.004	Total duration of all breastfeeding periods for all children >2 years cases: 31 (36%) >2 years controls: 231 (80%) >2 years vs. ≤2 years: OR, 1.68 (95% CI, 0.98 to 4.53), p=0.073	Ever breastfed analysis: Age at marriage, menopausal age, number of pregnancies, breastfeeding, family history of breast cancer were controlled for in adjusted analysis Duration analysis: Unadjusted
Al-Qutub, 2013[67] Case-control High	Case-control study of Saudi women ages 19–50 recruited at three government hospitals in Jeddah city, with controls recruited from community and hospital settings (317) Breast cancer diagnosis during the previous 2 years (151)	Mean age (SD): Cases: 40 (6.3) Controls: 39 (7.0) Use of exogenous hormones and/or contraception: Cases: 8% Controls: 2% Current smokers: Cases: 6% Controls: 13%	NR	Sum of breastfeeding duration in months for each baby born to the participant ≥12 months Cases: 81 (54%) ≥12 months Controls: 112 (68%) ≥12 months: OR, 0.56 (95% CI, 0.35 to 0.88), p=0.01	NR

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Atkinson, 2016[68] Case-control High	Case-control study of women at a Texas cancer center with no prior history of cancer except for nonmelanoma skin cancer or cervical cancer in situ; controls underwent routine mammography screening at the cancer center between 2005-2006 (620) Newly diagnosed inflammatory breast cancer at MD Anderson cancer center between 2004-2012 (224)	<u>Mean age (SD), range:</u> Cases: 51 (NR), 23-80 Controls: 51 (NR), 24-68 <u>Nonwhite:</u> Cases: 23% Controls: 0% <u>Postmenopausal:</u> Cases: 67% Controls: 62% <u>Ever smoker:</u> Cases: 42% Controls: 33%	Among parous women: <u>Triple-negative</u> OR, 0.30 (95% CI, 0.15 to 0.62) <u>HER2neu+</u> OR, 1.01 (95% CI, 0.55 to 1.87) <u>Luminal</u> OR, 0.35 (95% CI, 0.18 to 0.68)	NR	Age at menarche, menopausal status, number of children, age at first pregnancy, breastfeeding history, BMI, smoking history, breast cancer family history
Beaber, 2008[69] Case-control Medium	Population-based case-control study in the U.S., with controls frequency matched to cases on age (5-year age groups) and reference year (898 parous) Ductal and lobular tumors; based on histology review by study pathologists (when tissue available) or review of pathology reports by trained abstractors (when not) (469 parous)	<u>Mean age (SD):</u> NR <u>% Nonwhite:</u> Cases: 17% Controls: 16% <u>Current or prior HRT use:</u> Cases: 74% Controls: 74% <u>Postmenopausal:</u> Cases: 66% Controls: 73%	Ever breastfed ≥1 month <u>Ductal</u> Cases: 240 Controls: 264 OR, 0.7 (95% CI, 0.5 to 0.9), $p<0.05$ <u>Lobular</u> Cases: 167 Controls: 264 OR, 0.9 (95% CI, 0.7 to 1.3), p=NS	<u>Ductal</u> <1 month (37 exposed cases, 27 controls): OR, 1.1 (95% CI, 0.6 to 1.9) 1.0-5.9 months (96 exposed cases, 112 controls): OR, 0.7 (95% CI, 0.5 to 0.9) 6.0-11.9 months (61 exposed cases, 62 controls): OR, 0.8 (95% CI, 0.5 to 1.2) 12.0-23.9 months (58 exposed cases, 56 controls): OR, 0.8 (95% CI, 0.5 to 1.3) ≥24.0 months (25 exposed cases, 34 controls): OR, 0.6 (95% CI, 0.3 to 1.0) p for trend=0.43	Reference age, Reference year, number of live births

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Beaber, 2008[69] (continued)		-	<u>Ductal-Lobular</u> Cases: 97 Controls: 264 OR, 0.9 (95% CI, 0.6 to 1.4), p=NS *Analysis excluded 97 women who BF<1 month*	<u>Lobular</u> <1 month (17 exposed cases, 27 controls): OR, 1.0 (95% CI, 0.5 to 1.9) 1.0-5.9 months (65 exposed cases, 112 controls): OR, 0.9 (95% CI, 0.6 to 1.3) 6.0-11.9 months (43 exposed cases, 62 controls): OR, 1.0 (95% CI, 0.6 to 1.6) 12.0-23.9 months (42 exposed cases, 56 controls): OR, 1.1 (95% CI, 0.7 to 1.8) ≥24.0 months 17 exposed cases, 34 controls): OR, 0.8 (95% CI, 0.4 to 1.6) p for trend=0.85 <u>Ductal-Lobular</u> <1 month (14 exposed cases, 27 controls): OR, 1.4 (95% CI, 0.7 to 3.0) 1.0-5.9 months (43 exposed cases, 112 controls): OR, 0.7 (95% CI, 0.4 to 1.2) 6.0-11.9 months (19 exposed cases, 62 controls): OR, 0.8 (95% CI, 0.4 to 1.5) 12.0-23.9 months (24 exposed cases, 56 controls): OR, 1.1 (95% CI, 0.6 to 2.0) ≥24.0 months (22 exposed cases, 34 controls): OR, 1.9 (95% CI, 1.0 to 3.6) p for trend=0.11 *Analysis excluded 97 women who BF<1 month*	

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Castello, 2015[70] Case-control Medium	Case-control study of women diagnosed with incident cases of breast cancer in the oncology departments of 23 hospital members of the Spanish Breast Cancer Group located in 9 of 17 regions in Spain; matched healthy controls of similar age (+/- 5 years) were selected from cases' in-law relatives, neighbors, or work colleagues residing in same town (1,946) Incident breast cancer diagnosed in oncology department (973; sample size for BF analysis unclear)	Mean age (SD): NR Postmenopausal: Cases: 43% Controls: 47% Current or former smokers: Cases: 59% Controls: 60%	NR	Cumulative BF duration <6 months, overall sample (n=1,946; OR is for lack of compliance with guideline to BF up to 6 months) Cases: 394 Controls: 386 OR, 0.95 (95% CI, 0.70 to 1.27) Cumulative BF duration <6 months, premenopausal (n=1,064) Cases: 217 Controls: 210 OR, 0.89 (95% CI, 0.61 to 1.30) Cumulative BF duration ≥6 months, postmenopausal Cases: 177 Controls: 176 OR, 1.00 (95% CI, 0.69 to 1.45)	Total calorie intake, smoking habit, age at first delivery, education, history of breast problems, family history of breast cancer, menopausal study and composite score derived from adherence to WCRF/AICR[a] recommendations (excluding BF recommendation)

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Dalamaga, 2011[71] Case-control High	Case-control study of women at the Army Share Fund Hospital, Veteran's Hospital, with cases admitted in the Internal Medicine Department and controls randomly selected from women with negative mammograms and matched to cases based on age and proximity of the outpatient visit to the case's time of diagnosis (204) Diagnosed with invasive breast cancer between October 2003 and September 2010 (102)	Mean age (SD), range: Cases: 62 (8.2), NR Controls: 63 (8.9), NR Postmenopausal: 100% Current or prior HRT: Cases: 5% Controls: 1% Current or former smokers: Cases: 38% Controls: 27%	NR	>6 months breastfeeding: Cases: 45 (44%) Controls: 51 (50%) p=0.9	Analysis is unadjusted

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Ge, 2015[72] Case-control High	Population-based case-control study of postmenopausal German women ages 50-74 recruited between 2001-2005 (8,399); each case was frequency matched by birth year and study region with 2 controls drawn from random lists provided by resident registries (8,399) Diagnosed with histologically confirmed primary breast cancer (2,887)	<u>Mean age (SD):</u> NR <u>Postmenopausal:</u> 100% <u>Current or former smoker:</u> Cases: 45% Controls: 46%	Cases: 63% Controls: 67% Article reports "Cases had BF their children less frequently", but statistical tests NR	NR	NR
Hadji, 2007[73] Case-control High	Case-control study of German women consecutively recruited from a university gynecological oncology and endocrinology clinic for routine gynecological checkup (2,492) Incident breast operation (mean duration since operation 10±5 days) including a clear histological diagnosis of breast cancer (242)	<u>Mean age (SD), range:</u> 54 (10.3), 22-88 <u>Postmenopausal:</u> Cases: 71% Controls: 67% <u>On HRT:</u> Cases: 29% Controls: 42% <u>Current smoker:</u> Cases: 16% Controls: 21%	Cases: 69% Controls: 52% p<0.001 *Only unadjusted analysis available for ever BF; adjusted analysis matched cases and controls for BF.*	Multiple linear regression showed that women with breast cancer had a significantly longer duration of breastfeeding (p<0.05)	NR

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Holm, 2017[74] Case-control Medium	Case-control analysis of women from two cohort studies in Sweden: the KARolinska MAmmography Project for Risk Prediction of Breast Cancer (KARMA) from 2001-2008 and the Libro-1 cohort of breast cancer cases from 2011-2013; controls were frequency-matched to cases on age (18,577) Primary invasive breast cancer with information on immunohistochemical stains diagnosed 2005 to 2015 (2,632) Luminal A: estrogen receptor (ER+) and progesterone receptor (PR-) and HER2- and Ki167 low Luminal B: ER+ and Ki167 high or ER+ and Ki167 low and HER2+ HER2-overexpressing: ER- and PR- and HER2+ Basal-like: ER- and PR- and HER2-	Mean age (SD), range: Cases: 61 (10.3), 27-88 Controls: 58 (9.7), 25-88	Cases: 96% Controls: 97% Any breast cancer [a]: OR, 1.59 (95% CI, 1.23 to 2.03) Luminal A breast cancer [a]: OR, 1.49 (95% CI, 1.12 to 1.98) Luminal B breast cancer [a]: OR, 1.71 (95% CI, 0.81 to 3.53) HER2-overexpressing breast cancer [a]: OR, 0.90 (95% CI, 0.37 to 2.22) Basal-like breast cancer [a]: OR, 4.20 (95% CI, 2.20 to 7.99)	Any breast cancer [b]: >0-1.5 years: OR, 0.70 (95% CI, 0.61 to 0.80) >1.5 years: OR, 0.63 (95% CI, 0.54 to 0.75) Luminal A breast cancer [b]: >0-1.5 years: OR, 0.69 (95% CI, 0.59 to 0.82) >1.5 years: OR, 0.63 (95% CI, 0.52 to 0.76) Luminal B breast cancer [b]: >0-1.5 years: OR, 0.55 (95% CI, 0.37 to 0.81) >1.5 years: OR, 0.59 (95% CI, 0.37 to 0.95) HER2-overexpressing breast cancer [b]: >0-1.5 years: OR, 0.72 (95% CI, 0.49 to 1.07) >1.5 years: OR, 0.64 (95% CI, 0.40 to 1.02) Basal-like breast cancer [b]: >0-1.5 years: OR, 1.02 (95% CI, 0.59 to 1.76) >1.5 years: OR, 0.81 (95% CI, 0.43 to 1.60)	Country of birth, age, education level, parity, age at first birth, BMI

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Kabat, 2011[75] Case-control Medium	Case-control analysis of parous women ages 50-79 from the Women's Health Initiative Study, recruited from 40 clinical centers in the U.S.; controls were not matched with cases (63,396) Incident diagnosis of ductal carcinoma in situ breast cancer (664)	<u>Mean age (SD), range:</u> Cases: 62 (6.8), NR Controls: 623 (7.0), NR <u>Nonwhite:</u> Cases: 17% Controls: 18% <u>Postmenopausal:</u> 100% <u>Current or prior HRT:</u> Cases: 59% Controls: 52%	NR	<u>HR (95% CI)</u> 1-6 months: 1.05 (0.86 to 1.28) 7-12 months: 1.04 (0.80 to 1.36) >12 months: 1.01 (0.80 to 1.29) p for trend=0.94	Age, education, hormone therapy, family history of breast cancer, history of breast biopsy, and mammograms, age at menarche, age at menopause
Kotsopoulos, 2012[76] Case-control Medium	Case-control study of women who sought BRCA mutation testing from one of 70 participating centers in 12 countries and were confirmed as carriers of deleterious mutations in the *BRCA1* or *BRCA2* genes, with controls matched to cases on mutation in the same gene), year of birth (within 1 year), and country of residence (5,708) Diagnosis of invasive breast cancer (2,854)	<u>Mean age (SD), range:</u> Cases: 47 (NR), 21-85 Controls: 47 (NR), 18-86 <u>Postmenopausal:</u> Cases: 14% Controls: 7%	NR	<u>Mean months breastfed</u> Cases: 7.5 (0-102) Controls: 9.6 (0-147) p<0.0001 <u>*BRCA1* Carriers: OR (95% CI)</u> ≤ 1 year: 0.81 (0.66 to 1.00), p=0.05 1 to ≤2 years: 0.65 (0.50 to 0.85), p=0.001 2 to ≤3 years: 0.51 (0.35 to 0.75), p=0.0006 >3 years: 0.45 (0.30 to 0.68), p=0.0002 <u>*BRCA2* Carriers: OR (95% CI)</u> ≤ 1 year: 1.03 (0.76 to 1.40), p=0.85 1 to ≤2 years: 1.04 (0.70 to 1.53), p=0.86 2 to ≤3 years: 1.33 (0.76 to 2.32), p=0.31 >3 years: 1.02 (0.56 to 1.88), p=0.94	Age at menarche, parity, and oral contraceptive use

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Kruk, 2014[77] Case-control High	Case-control study of women ages 28-79 identified from the Szczecin Regional Cancer Registry in the Region of Western Pomerania; controls were randomly recruited from outpatient clinics and frequency matched to cases by age (5-year interval) and residence (urban, rural) (1,943) Diagnosed with histologically confirmed invasive breast cancer (858)	Mean age (SD), range: Cases: 55 (9.7), NR Controls: 55 (9.5), NR	NR	Compared with case subjects, controls reported a longer duration of breastfeeding (P-value and values by group NR)	Analysis is unadjusted

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Lee, 2008[78] Case-control Medium	Population-based case-control study in the U.S., with controls matched on race and age (within 5 years and ages 20-49) to a subset of case patients diagnosed between 7/2000-3/2003, and met the same eligibility criteria as cases (2,238) Histologically confirmed first primary invasive breast cancer identified through the Los Angeles County Cancer Surveillance Program, a population-based registry sponsored by the NCI Seer program (1,794)	<u>Mean age (SD):</u> Cases, *BRCA* carriers: 41 (6.4) Cases, *BRCA* noncarriers: 43 (5.1) Controls: 43 (4.9) <u>% Nonwhite:</u> 9% <u>Current or prior HRT use:</u> NR <u>Postmenopausal</u>: 20%	NR	<u>*BRCA* Carriers: OR (95% CI)</u> <1-6 months (22 exposed cases, 104 controls): 1.31 (0.45 to 3.82) 7-23 months (16 exposed cases, 111 controls): 0.73 (0.23 to 2.30) ≥24 months (11 exposed cases, 64 controls): 1.29 (0.36 to 4.61) p for trend=0.83 <u>*BRCA* Non-carriers: OR (95% CI)</u> <1-6 months (326 exposed cases, 104 controls): 0.66 (0.43 to 1.02) 7-23 months (264 exposed cases, 104 controls): 0.52 (0.33 to 0.81) ≥24 months (147 exposed cases, 104 controls): 0.49 (0.29 to 0.81) p for trend=0.002	Age at reference date, education, family history of breast or ovarian cancer, race, self-identified Ashkenazi Jewish origin, number of full-term pregnancies, age at first full-term pregnancy

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Lumachi, 2010 [79] Case-control High	Cases were identified by retrospective review of 404 consecutive women undergoing curative surgery for BC. Women were excluded who had a history pf previous cancer, BC onset during follow-up, had used estrogen + progestin therapy, or were non-OC users. (238) Randomly selected age-matched healthy women from the same region, who had undergone screening mammography twice and were followed up for 2 years. (255)	Mean age (SD): Cases: 62 (9.6) Controls: 61 (8.4) Postmenopausal: 100% Current or prior HRT: Cases: 58% Controls: 36% Current or former smokers: Cases: 18% Controls: 18%	Cases: 103 (57%) Controls: 145 (70%) OR, 1.82 (95% CI, 1.20 to 2.77), p=0.006	Mean (SD) Months of breastfeeding Cases: 10.2 (8.6) Controls: 13.9 (10.0) p<0.001	Bivariate analyses reported. Multivariate analysis conducted with years between menarche and menopause, BF, OC and HRT use, but only a cumulative OR (rather than BF specific) was reported: 4.55 (95% CI, 2.13 to 9.71).

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Ma, 2006[80] Case-control Medium	Case-control study among white or African American cases age 20-49 at time of diagnosis identified through LA Cancer Surveillance Program (CSP) and SEER registry, and controls from the same neighborhoods matched on age and race (within 5 years) (2,165) Diagnosis of first primary invasive ER and PR breast cancer (1,725)	<u>Mean age (SD):</u> Cases (known receptor): 423 (5.4) Cases (borderline/undecided receptor): 43 (5.2) Cases (no info on receptor): 44 (4.6) Controls: 43 (4.9) <u>Nonwhite:</u> Cases (known receptor): 12% Cases (borderline/undecided receptor): 7% Cases (no info on receptor): 14% Controls: 8%	NR	<u>All participants: OR (95% CI)</u> <1 month: 0.99 (0.56 to 1.77) 1-6 months: 0.58 (0.37 to 0.91) 7-23 months: 0.52 (0.33 to 0.82) 24+ months: 0.51 (0.30 to 0.86) p for trend=0.001 <u>ER+PR+: OR (95% CI)</u> <1 month: 1.01 (0.53 to 1.90) 1-6 months: 0.57 (0.34 to 0.94) 7-23 months: 0.52 (0.31 to 0.87) 24+ months: 0.49 (0.27 to 0.87) p for trend=0.002 <u>ER-PR-: OR (95% CI)</u> <1 month: 1.19 (0.59 to 2.39) 1-6 months: 0.72 (0.41 to 1.27) 7-23 months: 0.55 (0.31 to 0.98) 24+ months: 0.62 (0.32 to 1.21) p for trend=0.03	Race, age, education, first-degree breast cancer family history, age at menarche, gravidity, number of full-term pregnancies, BMI 1 year before reference date, COC use, average alcoholic drinks per week in recent 5 years, and a variable combining menopausal status and hormone therapy usage. Age at first full-term pregnancy and duration of BF mutually adjusted for each other.

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Ma, 2017[81] Case-control Medium	Pooled analysis of women from 3 population-based studies of breast cancer, predominantly in Los Angeles: Women's Contraceptive and Reproductive Experiences (CARE), Women's Breast Carcinoma in situ (BCIS), and Women's Learning the Influence of Family and Environment (LIFE). Controls were frequency-match to controls on age, race, and geographic area of residence (5,106) Newly diagnosed in situ and invasive breast cancer; some were first primary diagnoses and were histologically confirmed (2,658) Triple-negative: ER-, PR-, HER2- Luminal A-like: ER+ and/or PR+, HER2- Luminal B-like: ER+ and/or PR+, HER2+ HER2-enriched: ER-, PR-, HER2+	<u>Mean age (SD), range</u> Cases: Overall: 47 (8.1), 22-64 CARE: 49 (8.6), 35-64 BCIS: 52 (7.3), 35-64 LIFE: 43 (5.4), 22-49 Controls: Overall: 48 (8.3), 24-64 CARE: 49 (8.4), 35-64 BCIS: NA[c] LIFE: 43 (4.9), 24-49 <u>African-American Race</u> Cases: Overall: 26% CARE: 43% BCIS: 16% LIFE: 11% Controls: Overall: 37% CARE: 43% BCIS: NA[c] LIFE: 8%	<u>OR (95% CI)</u> Triple-negative: 0.80 (0.63 to 1.02) Luminal A-like: 0.78 (0.65 to 0.94) Luminal B-like: 0.89 (0.65 to 1.23) HER2-enriched: 0.91 (0.63 to 1.32)	<u>Triple-negative: OR (95% CI)</u> <6 months: 0.96 (0.74 to 1.26) 6-11 months: 0.55 (0.37 to 0.82) ≥12 months: 0.69 (0.50 to 0.96) p for trend=0.006 <u>Luminal A-like: OR (95% CI)</u> <6 months: 0.83 (0.68 to 1.02) 6-11 months: 0.76 (0.59 to 0.99) ≥12 months: 0.71 (0.56 to 0.90) p for trend=0.004 <u>Luminal B-like: OR (95% CI)</u> <6 months: 0.99 (0.70 to 1.41) 6-11 months: 0.70 (0.44 to 1.12) ≥12 months: 0.85 (0.56 to 1.30) p for trend=0.28 <u>HER2-enriched: OR (95% CI)</u> <6 months: 0.68 (0.43 to 1.07) 6-11 months: 1.28 (0.78 to 2.09) ≥12 months: 1.10 (0.69 to 1.75) p for trend=0.36	Sub-study (CARE, BCIS, LIFE), study site (Los Angeles, Detroit), race, reference age, education, first-degree breast cancer family history, BMI, menopausal status, hormone therapy use, lifetime recreational physical activity, alcohol intake, smoking status, age at menarche, completed pregnancies, oral contraceptive use, age at first completed pregnancy

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Merritt, 2015[82] Cohort Medium	Cohort study of women from the European Investigation into Cancer and Nutrition (EPIC) study, recruited from 23 study centers in 10 European countries (Denmark, France, Germany, Greece, Italy, the Netherlands, Norway, Spain, Sweden, United Kingdom; inclusion criteria varied slightly between centers). (212,041 included in breast cancer mortality analysis) Cases were women with breast cancer-specific mortality; vital status was collected via data linkages with cancer registries, boards of health, and death indices (484)	Mean age (SD): 50 (9.6) Postmenopausal: 46% Current smoker: 20%	Among parous women: HR (95% CI) of breast cancer mortality: 1.01 (0.79 to 1.29)	HR (95% CI) of breast cancer mortality: >1 to ≤3 months (102 exposed cases, 41,583 controls): 0.87 (0.62 to 1.21) >3 to ≤6 months (82 exposed cases, 43,445 controls): 0.68 (0.48 to 0.96) >6 to ≤12 months (101 exposed cases, 49,920 controls): 0.69 (0.49 to 0.97) >12 to ≤ 18 months (63 exposed cases, 24,239 controls): 0.88 (0.60 to 1.27) >18 months (74 exposed cases, 29,149 controls): 0.94 (0.65 to 1.37) p for trend=0.35 *BF info only available for first three and last full-term pregnancies. BF duration calculated as sum of these pregnancies. For women with > 4 full term pregnancies, duration calculated as # of pregnancies x mean duration of BF per child.*	BMI, physical activity, smoking, education level, menopausal status

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Phillips, 2009[83] Case-control Medium	Population-based case-control study of Caucasian and African-American women ages 20-74; cases were enrolled from the North Carolina Central Cancer Registry, and controls from the Department of Motor Vehicles and Health Care Finance Administration and frequency-matched based on race and 5-year age intervals (4,276; 904 DCIS, 3,372 IBC) First breast cancer diagnoses (in situ or invasive) (2254; 446 DCIS, 1,808 IBC)	Mean age (SD), range: DCIS cases: 55 (11.1), 27-74 DCIS controls: 55 (10.3), 22-74 IBC Phase 1 cases: 51 (11.8), 21-74 IBC Phase 2 cases: 52 (11.3), 24-74 IBC controls: 52 (11.5), 21-74 Nonwhite: 39% Postmenopausal HRT: 29%	OR (95% CI) DCIS All 1.02 (0.78 to 1.34) DCIS Comedo 0.82 (0.57 to 1.20) DCIS Non-comedo 1.02 (0.72 to 1.42) IBC 0.77 (0.67 to 0.89)	NR	Age, race, and frequency-matching offset terms

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Pieta, 2008[84] Case-control Medium	Case-control study of Polish women ages 35-70; control women had no changes in mammary glands revealed by examination and mammography and/or ultrasound imaging (555) Malignant breast neoplasms according to pathological examination of breast tissue from biopsy or surgery (79)	<u>Mean age (SD), range:</u> Malignant cases: 53 (9.0), 32-73 Controls: 48 (7.96), 35-71	NR	Mean BF duration (months) Cases with malignant neoplasms: 8.3 Cases with benign neoplasms: 6.3 Controls: 6.8 p=NS BF ≥6 months OR, 1.65 (95% CI, 0.78 to 3.48) *Cases are those with malignant neoplasms; unclear whether those with benign neoplasms are considered controls in this analysis*	NR
Press, 2010[85] Case-control High	Reanalysis of a 1926 case-control study in the UK and a 1931 case-control study in the U.S., designed to replicate the earlier study). In both studies, cases were women diagnosed with breast cancer from area hospitals and controls were recruited from the same hospitals (2,263) Women diagnosed with breast cancer (1,187)	<u>Postmenopausal:</u> UK cases: 65% UK controls: 65% U.S. cases: 59% U.S. controls: 59%	NR	<u>UK: OR (95% CI)</u> 4-11 months: 1.05 (0.84 to 1.31) 12+ months: 0.49 (0.38 to 0.64) <u>U.S.: OR (95% CI)</u> 4-11 months: 0.91 (0.78 to 1.07) 12+ months: 0.81 (0.68 to 0.96)	NR

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Ritte, 2013[86] Cohort Medium	Cohort study of women, mostly ages 25-70, enrolled in the EPIC Study with no prior history off cancer, enrolled between 1992-2000 at 23 regional and national research centers in 10 western European countries (311,097) Women with first primary invasive breast cancer; breast tumor receptor status was standardized across EPIC centers (9,456)	Mean age (SD), range: 62 (NR), 21-102 Postmenopausal: 47%	Parous women only: ER+PR+ HR, 0.99 (95% CI, 0.89 to 1.09), p=0.76 ER-PR- HR, 0.98 (95% CI, 0.81 to 1.17), p=0.74	Parous women who breastfed only: ER+PR+: HR (95% CI) 1-3 months: 1.04 (0.89 to 1.20) 4-6 months: 0.97 (0.83 to 1.14) 7-12 months: 0.97 (0.83 to 1.13) 13-17 months: 0.92 (0.75 to 1.12) ≥18 months: 1.11 (0.92 to 1.33) ER-PR-: HR (95% CI) 1-3 months: 0.91 (0.69 to 1.21) 4-6 months: 0.99 (0.74 to 1.32) 7-12 months: 0.91 (0.68 to 1.23) 13-17 months: 1.12 (0.79 to 1.60) ≥18 months: 1.07 (0.75 to 1.51) ER+PR-: HR (95% CI) 1-3 months: 1.04 (0.79 to 1.37) 4-6 months: 1.08 (0.81 to 1.44) 7-12 months: 0.86 (0.64 to 1.16) 13-17 months: 1.09 (0.77 to 1.54) ≥18 months: 0.83 (0.58 to 1.19) ER-PR+: HR (95% CI) 1-3 months: 0.96 (0.52 to 1.77) 4-6 months: 0.89 (0.47 to 1.70) 7-12 months: 1.07 (0.57 to 2.04) 13-17 months: 0.72 (0.29 to 1.82) ≥18 months: 1.33 (0.59 to 2.99) ER or PR missing: HR (95% CI) 1-3 months: 0.91 (0.79 to 1.04) 4-6 months: 0.91 (0.78 to 1.06) 7-12 months: 0.88 (0.76 to 1.02) 13-17 months: 0.92 (0.77 to 1.10) ≥18 months: 0.93 (0.79 to 1.10)	Age at recruitment and center, and further adjusted for BMI, height, menopausal status at recruitment, HRT use, physical activity, smoking status, alcohol consumption, and attained level of education

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Ritte, 2013[86] Cohort Medium (continued)				<u>ER+: HR (95% CI)</u> 1-3 months: 1.01 (0.90 to 1.14) 4-6 months: 0.89 (0.77 to 1.04) 7-12 months: 0.98 (0.87-1.11) 13-17 months: 0.91 (0.81-1.03) ≥18 months: 1.01 (0.88-1.17) <u>ER-: HR (95% CI)</u> 1-3 months: 0.88 (0.69 to 1.11) 4-6 months: 1.06 (0.78 to 1.42) 7-12 months: 0.93 (0.73 to 1.19) 13-17 months: 0.92 (0.72 to 1.18) ≥18 months: 1.10 (0.83 to 1.47) <u>PR+: HR (95% CI)</u> 1-3 months: 1.04 (0.90 to 1.20) 4-6 months: 0.91 (0.75 to 1.11) 7-12 months: 0.97 (0.83 to 1.13) 13-17 months: 0.98 (0.84 to 1.14) ≥18 months: 1.12 (0.94 to 1.34) <u>PR-: HR (95% CI)</u> 1-3 months: 0.98 (0.81 to 1.20) 4-6 months: 1.13 (0.88 to 1.45) 7-12 months: 1.05 (0.86 to 1.28) 13-17 months: 0.90 (0.73 to 1.11) ≥18 months: 0.96 (0.75 to 1.23)	

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Ruszczyk, 2016[87] Case-control Medium	Case-control study of African American and white women 20-75 from 12 targeted NY hospitals and the NJ State Cancer Registry through rapid case ascertainment; controls were identified through random digit dialing and community-based events, frequency matched to cases by telephone prefixes (1,912 parous) Primary, newly diagnosed, histologically confirmed breast cancer (642 parous)	Mean age (SD): Pure IDC cases: 51 (9.9) Mixed IDC/DCIS cases: 51 (10.5) Controls: 50 (9.4) Nonwhite: 44% Current/former smokers: 43% Postmenopausal: 47% Postmenopausal HRT use (among postmenopausal women): 32%	NR	Among parous women: Pure IDC Cases: OR (95% CI) 0-12 months (28.0% cases exposed, 31.6% controls): 0.76 (0.49 to 1.19) >12 months (19.6% cases exposed, 25.3% controls: 0.61 (0.37 to 1.02) p for trend=0.07 Mixed IDC/DCIS Cases: OR (95% CI) 0-12 months (34.3% cases exposed, 31.6% controls): 1.15 (0.88 to 1.50) >12 months (23.0% cases exposed, 25.3% controls): 0.94 (0.70 to 1.27) p for trend=0.49	Age, race, birthplace, family history, composite screening score, education, OC use, age at menarche, parity and menopausal status

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Stendell-Hollis, 2013[88] Cohort Medium	Cohort study of healthy parous women in the Women's Health Initiative (WHI) Hormone Trial (HT) and Observational Study (OS). OS participants were included in this analysis if the woman was post-hysterectomy at enrollment and using the same daily 0.625 mg CEE (conjugated equine estrogen preparation) as studied in the clinical trial, or had an intact uterus and was using the same daily CEE/MPA (0.625 CEE + 2.5 mg medroxyprogesterone acetate) combination as women in the clinical trial; if the woman had previously used postmenopausal hormones but was not currently using these preparations, or if the woman had never used Postmenopausal hormones (69,358)	Nonwhite: 15% Postmenopausal: 100% Current or prior HRT: 51% Current or former smokers: 49%	Breastfed for ≥1 month: Hormone Trial: HR (95% CI) CEE: 0.72 (0.50 to 1.06) CEE Placebo: 1.12 (0.80 to 1.57) CEE/MPA: 1.06 (0.83 to 1.36) CEE/MPA Placebo: 0.92 (0.70 to 1.21) Observational Study: HR (95% CI) CEE: 1.11 (0.89 to 1.39) CEE/MPA: 1.16 (0.91 to 1.47) No prior HT: 1.00 (0.86 to 1.18) Prior HT: 0.97 (0.78 to 1.22) P-values for trends were all NS	Cumulative lifetime months Hormone Trial: HR (95% CI) CEE 1-3 months: 0.70 (0.41 to 1.20) 4-12 months: 0.78 (0.48 to 1.26 13-23 months: 0.72 (0.35 to 1.46) ≥24 months: 0.64 (0.27 to 1.49) CEE Placebo 1-3 months: 0.86 (0.52 to 1.42) 4-12 months: 1.41 (0.95 to 2.08) 13-23 months: 1.15 (0.64 to 2.06) ≥24 months: 0.71 (0.30 to 1.64) CEE/MPA 1-3 months: 1.13 (0.81 to 1.59) 4-12 months: 1.02 (0.75 to 1.39) 13-23 months: 1.17 (0.79 to 1.72) ≥24 months: 0.89 (0.54 to 1.45) CEE/MPA Placebo 1-3 months: 0.87 (0.59 to 1.30) 4-12 months: 1.00 (0.71 to 1.40) 13-23 months: 1.00 (0.65 to 1.54) ≥24 months: 0.70 (0.40 to 1.24)	HT: age, race/ethnicity, BMI, family history of breast cancer, age at first birth, age at menarche, and participation in WHI extension study. Observational Study: age, race/ethnicity, BMI, smoking, family history of breast cancer, number live births, age at first birth (except in models for age first breastfed), years since menopause, duration of prior HRT use, and participation in WHI extension study.

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Stendell-Hollis, 2013[88] (continued)	Invasive breast cancer, verified by medical record and pathology reports, centrally reviewed by study physicians (743)	-		Observational Study: HR (95% CI) CEE 1-3 months: 1.08 (0.80 to 1.46) 4-12 months: 1.15, (0.87 to 1.51) 13-23 months: 1.19 (0.81 to 1.76) ≥24 months: 0.96 (0.55 to 1.68) CEE/MPA 1-3 months: 1.11 (0.79 to 1.55) 4-12 months: 1.06 (0.79 to 1.43) 13-23 months: 1.38 (0.97 to 1.97) ≥24 months: 1.32 (0.84 to 2.06) No Prior HT 1-3 months: 0.99 (0.79 to 1.24) 4-12 months: 0.96 (0.78 to 1.18) 13-23 months: 1.01 (0.77 to 1.32) ≥24 months: 1.22 (0.90 to 1.66) Prior HT 1-3 months: 0.94 (0.68 to 1.29) 4-12 months: 0.92 (0.69 to 1.23) 13-23 months: 1.15 (0.79 to 1.67) ≥24 months: 1.05 (0.64 to 1.72)	

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Sugawara, 2013[89] Cohort Medium	Analysis of data on parous women ages 40-70 years with no history of cancer who were enrolled in the Ohsaki National Health Insurance (NHI) Cohort Study in northeastern Japan (19,848) Incident breast cancer cases ascertained from the Miyagi Prefactural Cancer Registry (148)	<u>Mean age (SD), range:</u> Overall: NR (NR), 40-79 Breastfeeding only: 64 (8.4), NR Mixed feeding: 56 (9.8), NR Formula feeding only: 55 (9.3), NR <u>Postmenopausal</u>: 71% <u>Current or prior use HRT</u>: 7%	NR	Duration NR <u>Exclusivity</u> Mixed feeding HR=1.12 (95% CI, 0.92 to 1.37), p=0.014 Formula feeding HR=1.80 (95% CI, 1.14 to 2.86), p=0.014	Age (continuous), BMI, family history of cancer, education, job status, smoking status, alcohol consumption, time spent walking, total calorie intake, menopausal status, age at menarche, age at first delivery, number of deliveries, history of oral contraceptive drug use, history of HRT use

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Tamimi, 2016[90] Cohort Medium	Female registered nurses between the ages of 30 and 55 years enrolled in the Nurses' Health Cohort Study in 1976 and followed up between 1980 and 2010 through biennial questionnaires (112,951 postmenopausal women; 2,424,778 person-years) Incident invasive breast cancer identified through self-report and confirmed through review of medical records (8,421 cases: 5,376 ER+ and 1,270 ER-)	Mean age (SD), range: 48 (6.9), NR Postmenopausal: 100% Current use HRT: 34%	Among parous women: Invasive breast cancer RR, 1.05 (95% CI, 1.00 to 1.10), p=0.07; PAR, 1.6% (95% CI, 0.1% to 3.4%) ER+ invasive breast cancer RR, 0.96 (95% CI, 0.91 to 1.02), p=0.24; PAR, 0 (95% CI, 2.2% to 2.2%) ER- invasive breast cancer RR, 1.07 (95% CI, 0.94 to 1.21), p=0.30; PAR, 2.4 (95% CI, 2.1% to 6.8%)	NR	Age in months, calendar year, age at menarche, BMI at age 18 years, height in inches, parity/age at first birth, benign breast disease history, family history of breast cancer, age at menopause, weight change since age 18 years, menopausal hormone use, alcohol consumption, physical activity

Author, Year Study Design Risk of Bias	Description of Study (N) Description of Breast Cancer Cases (N)	Population Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding	Confounders Adjusted for
Warner, 2013[91] Cohort Medium	Two cohort studies contributed to a sample of healthy women followed to track breast cancer incidence: 1) Nurse's Health Study II, enrolling registered nurses ages 25-42 in 1989 (followup for this study began in 1995, to synchronize with BWHS cohort); 2) Black Women's Health Study (BWHS), enrolling African-American women ages 21-69 in 1995, from communities in all regions of the U.S.. Women were excluded if they did not identify as white or African-American. (BWHS: 35,338 NHS II: 105,576) Self-reported, invasive ER+ breast cancer diagnosis; pathology data from hospital or cancer registry records were centrally reviewed by study staff to confirm diagnosis. ER status was determined by biochemical or immunohistochemical assays (1,506)	Race Black women: 27% White women: 73% Mean age (SD): Black women: 39.0 (5.5) White women: 40.2 (4.7) Postmenopausal: Black women: 9% White women: 7% Current or past Postmenopausal HRT use: Black women: 74% White women: 91%	NR	Among parous women: HR (95% CI) <6 months: 0.85 (0.70 to 1.03) ≥6 months: 0.95 (0.81 to 1.10)	Age, time, age at first birth, parity, lactation, age at menarche, menopausal status, age at menopause, first degree family history, BMI at age 18, weight change since age 18, history of benign breast disease, alcohol consumption, OC use, and Postmenopausal hormone use

[a] Comparison was never breastfed compared with ever breastfed (referent).
[b] Referent group is nulliparous women.
[c] The BCIS study shared controls from the CARE study.

AICR = American Institute of Cancer Research; BC = breast cancer; BCIS = Women's Breast Carcinoma in situ; BF = breastfeeding; BMI = body mass index; BRCA = BrCa gene mutations; BWHS = Black Women's Health Study; and; CEE = conjugated equine estrogen; CI = confidence interval; COC = combined oral contraceptive; CSP = Cancer Surveillance Program; DCIS = ductal carcinoma in situ; EPIC = European Prospective Investigation into Cancer and Nutrition; ER = estrogen receptor; HR = hazard ratio; HRT = hormone replacement therapy; HT = hormone trial; IBC = inflammatory breast cancer; IDC = invasive ductal carcinoma; LA = Los Angeles; LIFE CARE = Women's Learning the Influence of Family and Environment Women's Contraceptive and Reproductive Experiences; MPA = medroxyprogesterone acetate; NCI = National Cancer Institute; NHI = National Health Insurance; NHS = National Health Service; NJ = New Jersey; NR = not reported; NS = not statistically significant; NY = New York; OC = oral contraceptive; OR = odds ratio; OS = observational study; PAR = population attributable risk; PR = progesterone receptor; SD = standard deviation; SEER = Surveillance, Epidemiology, and End Results; UK = United Kingdom; U.S. =United States; WCRF = World Cancer Research Fund; WHI = Women's Health Initiative.

Table F-2. Breastfeeding and breast cancer: Summary of results among subgroups (KQ 2b)

Author, Year Study Design Risk of Bias	Description of Breast Cancer Outcome	Subgroup Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding
Ma, 2017[81] Case-control Medium	Incident in situ and invasive breast cancer, categorized by ER, PR, and HER2 status Triple-negative: ER-, PR-, HER2- Luminal A-like: ER+ and/or PR+ plus HER2-	Mean age (SD), range: Cases: 47 (8.1), 22-64 Controls: 48 (8.3), 24-64 African-American Race: Cases: 26% Controls: 37%	Younger women (20-44 years old): OR (95% CI)[a] Triple-negative: 0.75 (0.50 to 1.12) Luminal A-like: 0.70 (0.50 to 0.99) Older women (45-64 years old): OR (95% CI)[a] Triple-negative: 0.85 (0.62 to 1.17) Luminal A-like: 0.83 (0.67 to 1.03): White women: OR (95% CI)[a] Triple-negative: 0.97 (0.68 to 1.02) Luminal A-like: 0.81 (0.64 to 1.02) African-American women: OR (95% CI)[a] Triple-negative: 0.67 (0.47 to 0.96) Luminal A-like: 0.78 (0.57 to 1.06)	Younger women (20-44 years old): OR (95% CI)[a] Triple-negative <6 months: 0.93 (0.60 to 1.44) 6-11 months: 0.49 (0.27 to 0.89) ≥12 months: 0.60 (0.35 to 1.01) p for trend=0.02 Luminal A-like <6 months:0.72 (0.49 to 1.05) 6-11 months: 0.68 (0.44 to 1.07) ≥12 months: 0.68 (0.44 to 1.05) p for trend=0.12 Older women (45-64 years old): OR (95% CI)[a] Triple-negative <6 months: 0.97 (0.67 to 1.39) 6-11 months: 0.62 (0.35 to 1.10) ≥12 months: 0.68 (0.44 to 1.05) p for trend=0.17 Luminal A-like <6 months: 0.90 (0.70 to 1.16) 6-11 months: 0.84 (0.60 to 1.17) ≥12 months: 0.71 (0.53 to 0.96) p for trend=0.03 White women: OR (95% CI)[a] Triple-negative <6 months: 1.14 (0.78 to 1.38) 6-11 months: 0.62 (0.37 to 1.05) ≥12 months: 0.88 (0.56 to 1.39) p for trend=0.27

Author, Year Study Design Risk of Bias	Description of Breast Cancer Outcome	Subgroup Characteristics	Results: Ever Breastfed	Results: Duration of Breastfeeding
Ma, 2017[81] Case-control Medium (continued)				Luminal A-like <6 months: 0.85 (0.66 to 1.10) 6-11 months: 0.75 (0.54 to 1.02) ≥12 months: 0.77 (0.57 to 1.04) p for trend=0.07 <u>African-American women: OR (95% CI)[a]</u> Triple-negative <6 months: 0.79 (0.52 to 1.19) 6-11 months: 0.54 (0.26 to 1.09) ≥12 months: 0.55 (0.32 to 0.94) p for trend=0.01 Luminal A-like <6 months: 0.82 (0.57 to 1.18) 6-11 months: 1.06 (0.63 to 1.77) ≥12 months: 0.57 (0.36 to 0.90) p for trend=0.04
Warner, 2013[91] Cohort Medium	Invasive ER+ breast cancer	<u>Race:</u> Black women: 27% White women: 73%	NR	Among parous women: HR (95% CI)[b] <u>Black women</u> <6 months: 1.31 (0.96 to 1.80) ≥6 months: 1.27 (0.90 to 1.80) <u>White women</u> <6 months: 0.76 (0.60 to 0.98) ≥6 months: 0.90 (0.76 to 1.07)

[a]Confounders adjusted for: sub-study, study site (Los Angeles, Detroit), race, reference age, education, first-degree breast cancer family history, BMI, menopausal status, hormone therapy use, lifetime recreational physical activity, alcohol intake, smoking status, age at menarche, completed pregnancies, oral contraceptive use, age at first completed pregnancy

[b]Confounders adjusted for: age, time, age at first birth, parity, lactation, age at menarche, menopausal status, age at menopause, first degree family history, BMI at age 18, weight change since age 18, history of benign breast disease, alcohol consumption, OC use, and Postmenopausal hormone use

BMI = body mass index; CI = confidence interval; ER = estrogen receptor; HER2 = human epidermal growth factor receptor 2; HR = hazard ratio; KQ = Key Question; NR = not reported; OR = odds ratio; PR = progesterone receptor; SD = standard deviation.

Appendix G. References for All Appendixes

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