

# LINKAGES BETWEEN BREAST MILK SUBSTITUTE LIMITING INTERVENTIONS AND BREASTFEEDING OUTCOMES: A SCOPING REVIEW

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## ABSTRACT

**Background:** The initiation of infants to human milk within the first hour of delivery, exclusive breastfeeding for 180 days and continued breastfeeding up to 24 months or beyond are standard breastfeeding recommendations. However, globally, the majority of infants do not experience optimal breastfeeding for many reasons including the unethical and inappropriate commercial marketing strategies that expose children to breast milk substitutes (BMS).

**Research Aim:** To identify and categorise published interventions that promote, protect and support breastfeeding while limiting exposure to and use of BMS, globally.

**Methods:** Arksey and O'Malley's (2005) scoping review process guided this review. An initial search of peer-reviewed health-related literature databases was updated by searching through CINAHL, Google Scholar, Pubmed, PSYCHINFO, and SCOPUS. WHO and UNICEF's websites. Keywords used included human milk, breastfeeding, breast milk substitute, formula feeding and interventions. Full-text, peer-reviewed research articles published in the English language between 1990-2022 were eligible for the review. Thematic data analysis was done.

**Results:** We identified 447 records and of these, there were seven articles that were eligible for inclusion in this review. Seven themes were discovered as key intervention strategies to facilitate breastfeeding and limit BMS use, globally. The interventions included health worker training programs and educational strategy; implementation and revitalisation of the Baby-Friendly Hospital Initiative; formula payment policy; diaper bag donation (not containing BMS); government-owned breastfeeding programs; enforcement of the International Code of Breastmilk Substitutes and implementation of other enabling factors.

**Conclusion:** Globally, there are few facility-and community-based strategies to mitigate the marketing and use of BMS. The adoption of the identified BMS interventions can be leveraged to protect, promote and support optimal breastfeeding.

**Keywords:** Exclusive breastfeeding, breast milk substitutes, breastfeeding outcomes, breast milk substitute interventions, and the International Code of Breastmilk Substitutes

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## INTRODUCTION

The first 180 days of infants' lives are critical periods for growth and development. The initiation of infants to human milk within the first sixty minutes, exclusive breastfeeding (EBF) for the first 180 days and continued breastfeeding up to 24 months or beyond is recommended, globally (United Nations Children's Fund [UNICEF], 2021). EBF refers to the feeding of infants with human milk only, without solids or supplemental liquids, except for liquid vitamins, medicines or mineral supplements during the first 180 days of life (World Health Organization [WHO], 2021). This is recommended because human milk provides nutritional and health benefits to mothers, infants and society.

Globally, only four out of every ten infants below 180 days are exclusively breastfed and 48% of infants are introduced to human milk within the first hour of birth (Pérez-Escamilla *et al.*, 2023; Victora *et al.*, 2016; UNICEF, 2021; WHO & UNICEF, 2021). The suboptimal breastfeeding rates can be associated with diverse factors, including exposure to BMS (WHO, 2022a).

The unethical and multifaceted strategies used for marketing BMS expose infants and mothers to significant adverse health impacts, BMS thus denying children of the benefits of breastfeeding which include reduced risk of infectious disease, undernutrition, maternal cancers, and obesity (Rollins *et al.*, 2016). Some of the marketing strategies employed by the BMS industries include deliberate misinformation through diverse media inclusive of various digital/social media platforms that influence maternal feeding decisions (Franco-Lares *et al.*, 2023; Green *et al.*, 2021; Mota-Castillo *et al.*, 2023; Rollins *et al.*, 2016; WHO, 2021; WHO, 2022a, b).

United Nations Children's Fund (UNICEF) and World Health Organisation (WHO) introduced the Baby-Friendly Hospital Initiative (BFHI)

and at the 33<sup>rd</sup> World Health Assembly both organizations endorsed the implementation of the International Code of Marketing of Breastmilk Substitutes (the Code) strategies to improve breastfeeding practice (WHO and UNICEF, 2018; WHO, 2017). Subsequently, some countries that have adopted the code have developed national policies/legislations that guide implementation of the principles of the code. The Code seeks to limit aggressive and unethical marketing strategies used by BMS manufacturers and marketers (Lutter *et al.*, 2022). We summarized reports of the Code violations from eight studies using the WHO/UNICEF NetCode protocol. Among 3,124 pregnant women and mothers with young children, in eight countries, 64% reported exposure to promotion of products covered under the Code in the previous 6 months, primarily from advertisements seen outside of health facilities (62%; WHO, 2017). For instance, the Code restricts the promotion of BMS (WHO, 1981; WHO, 2017). Despite these policies, BMS manufacturers continue to create and utilise new and sophisticated strategies to bypass the existing policies and reach target populations. Recently, WHO and UNICEF reported that 51% of pregnant women from multiple countries have been exposed to BMS information and products through various marketing channels and tactics including digital marketing (WHO, 2022).

In this scoping review, we identified and categorised published interventions that explicitly decrease the use of BMS and promote breastfeeding globally. This evidence will support decision-making for promoting, protecting and supporting EBF globally by limiting inappropriate exposure and use of BMS. Additionally, this scoping review will be added to available literature and provide a compilation of information on existing interventions that limit BMS use globally.

## METHODOLOGY

### Design and Sample (Defining the Articles Reviewed)

Using a scoping review approach, peer-reviewed published interventions that were designed to either explicitly decrease BMS promotion or use and intended to promote, protect and support breastfeeding were identified and included in the review.

We identified, retrieved, and screened full-text peer-reviewed articles (mixed methods, qualitative and quantitative studies) published

in the English language between 1990 and 2022 from databases. All duplicate documents were removed. The documents that reported on interventions that promote breastfeeding and breastfeeding outcomes but provided no evidence on association between breastfeeding and BMS were excluded. Seven full-text, peer reviewed articles from different countries remained eligible for the review (Figure 1). Of the seven articles, one study used a mixed methods design and the other six used quantitative designs.

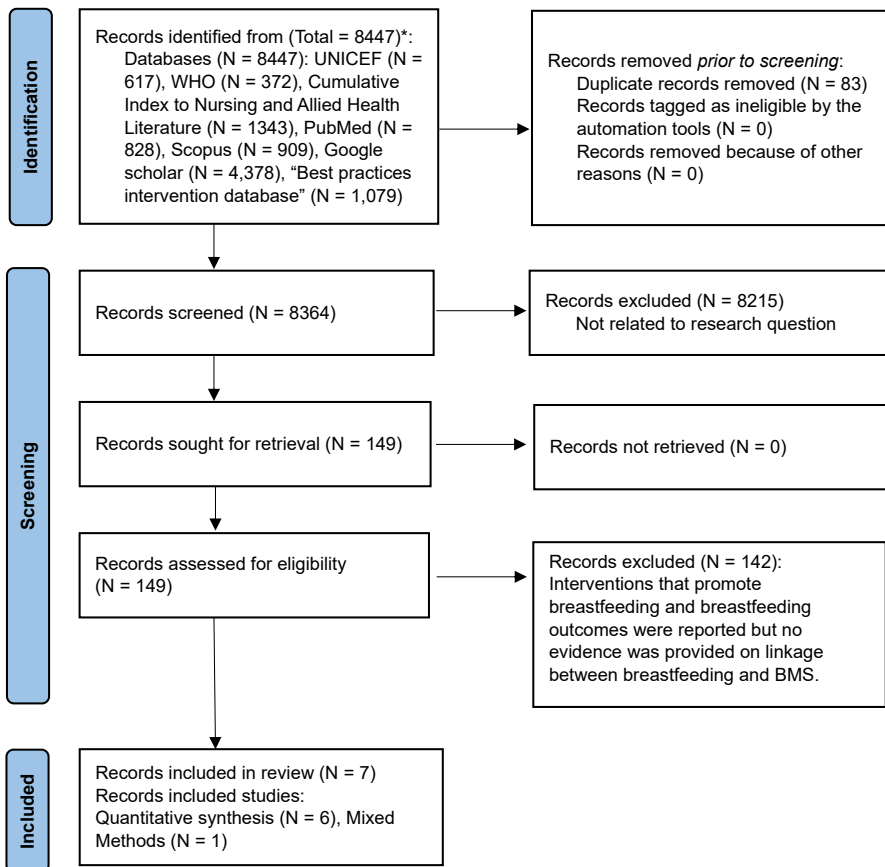


Figure 1: PRISMA Flowchart for Identification of Studies via Databases

## **Data Collection: The Search Strategy and Process**

This review was conducted between August 01, 2022 – December 31, 2022, guided by Arksey and O'Malley's scoping review process (Arksey and O'Malley, 2005). Namely: (1) identification of the research question; (2) identification of relevant studies; (3) selection of studies; (4) data charting; (5) results collation, summary, and reporting and (6) consultation. Additionally, the review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) (Peters *et al.*, 2020). Moreso, eligible articles were assessed by the Joanna Briggs Institute Critical Appraisal Tools for qualitative and quantitative studies (Joanna Briggs Institute, 2020). Five literature databases, CINAHL, Google Scholar, PubMed, Scopus, UNICEF, and WHO, were searched and the retrieved citations were used to complement the citations from an earlier search conducted as part of the "Best Practices Intervention Project". First, a PubMed syntax was developed and used for the online database search; the search syntax was Human milk OR breastfeeding AND breast milk substitute OR formula feeding AND interventions, Human milk OR breast milk OR breastfeeding AND breast milk substitutes OR formula feeding, Human milk OR breast milk OR breastfeeding AND breast milk substitutes OR formula feeding, Formula feeding AND breastfeeding. This syntax was modified as appropriate for the other databases (CINAHL, Google Scholar, Scopus, UNICEF, and WHO).

## **Data Extraction**

We identified and defined interventions that addressed the linkage between breastfeeding and BMS globally based on findings from eligible records. Extracted data included:

- Socio-demographics of infants and caregivers (mother – age, religion, education, mother tongue, type and place of work, marital status, gestation at birth, type of delivery; child – age in months).
- Maternal and infant obstetric characteristics (e.g., parity, gender of infant, type of delivery, medication given during labour and delivery, dates of birth and discharge, micronutrient supplementation, birth weight, and maternal first nation status).
- Infant feeding data (e.g., breastfeeding initiation, whether the infant was given BMS during the first week of life, EBF history, breastfeeding technique records).
- Implementation of the International Code of Breastmilk Substitutes (the strength of the Code legislation and enforcement, and the extent of restrictions to infant formula sales across countries).
- Exposure to the 10 steps to successful breastfeeding.

## **Data Analysis**

Documents were iteratively read to identify eligible full-text articles reporting interventions that explicitly decrease BMS use and promote breastfeeding. Subsequently, an excel template with data abstraction fields was developed for each article and used to retrieve the following information: author, publication year, study (site, aim and design), sample, instruments, variables, reliability, validity and trustworthiness (Table 1).

Table 1. Characteristics of Articles included in the Scoping Review

Authors, year, study site	Study aim	Sample size, design, study instrument	Variables	Trustworthiness	Reliability or validity
Ekström <i>et al.</i> , 2012 Sweden	Effects of process oriented training in supportive breastfeeding counselling for postnatal nurses and midwives on the time lapse between breastfeeding initiation, the introduction of BMS and solids, and breastfeeding duration were evaluated.	480 mothers. Quantitative. Questionnaire was used.	Sociodemographic background, initial breastfeeding period, and if baby was given BMS during week one.	Not applicable	Pilot test of questionnaire
Feldman-Winter <i>et al.</i> , 2012 United States of America	Effectiveness of an intervention to change the practice around sample pack distribution was measured. Also, there were assessments on whether hospital-relevant changes associated with practice occurred when during sample packs elimination and if discontinuation of samples of formula packs distribution was linked to changes in breastfeeding practices.	527 breastfeeding women (284 control; 243 intervention) Quantitative Questionnaire	Maternal demographics feeding patterns and practices (maternal and infant characteristics, data collected from mothers at weeks 1 and 10)	Not applicable	Not stated

Authors, year, study site	Study aim	Sample size, design, study instrument	Variables	Trustworthiness	Reliability or validity
Martens, 2000 Canada	Effectiveness of a breastfeeding education intervention strategy in a Canadian hospital within a small rural community was evaluated.	75 charts (41 in Pine Falls and 34 in Arborg) and 38 staff (18 from Pine Falls and 20 from Arborg) Quantitative (staff survey and retrospective chart audits). BFHI compliance, Breastfeeding Beliefs, Breastfeeding Attitude and Bottle Feeding Beliefs scales. The BFHI Compliance scales were derived from diverse sources – two WHO/UNICEF appraisal tools for assessors, BFHI compliance tool developed by Kovach and a survey developed for Manitoba provincial maternity hospitals.	Chart audit: obstetric, demographics, and infant-feeding information within the hospital. Gender of infant, parity, type of delivery, drugs given in labour and delivery, initiation to human milk, EBF, breastfeeding technique records, dates of birth, date of discharge, supplement given, birth weight, and the mother's First Nation's status.	Not applicable	Use of validated instruments, expert panel review and pilot testing. Content validity, intra-rater reliability were assessed. Breastfeeding Attitude, Breastfeeding Beliefs, and Bottle Feeding Beliefs scales were considered internally consistent, with Cronbach's alpha scores of 0.95, 0.92 and 0.92, respectively, during the pilot test and 0.89, 0.84 and .86, and .89 during the actual study.

Authors	Study aim	Sample size, design, study instrument	Variables	Trustworthiness	Reliability or validity
Robinson <i>et al.</i> , 2019 India, Vietnam and China	To (i) explore the relationships among the legislation and enforcement of the Code, infant formula sales and EBF practice within China, India and Vietnam; (ii) identify best practices for Code operationalization; and (iii) identify pathways by which the implementation of the Code may influence EBF.	Six key informants were interviewed and the number of secondary data records were not stated. Mixed methods (secondary descriptive analysis from available data at the national-level and key informant interviews Semi-structured interview guides and World Breastfeeding Trends Initiative reports; EBF data from UNICEF's Global Database on the Infant and Young Child Feeding, within 2014-2015 (Vietnam), 2015-2016 (India) and 2013 (China); EBF data at the national level, inclusive of Rapid Survey on Children, Demographic and Health Surveys and Infant formula sales were gathered from comprehensive Euromonitor data within 2014.	Exclusive Breastfeeding (EBF) rates; Prevalence of EBF, the Code implementation; strength of the Code legislation and the enforcement, and sales of infant formula sales across the globe.	Key informant interview lasting 39-47 minutes (Prolong engagement); audio recording and transcription; reached point of saturation.	Not stated
Tarrant <i>et al.</i> , 2015a Hong Kong	To (1) compare new mothers' exposure to Baby-Friendly steps pre and post public hospitals implemented a policy of paying for infants' formula and (2) assess association between new a mother's exposure to Baby-Friendly steps and duration of EBF and any breastfeeding.	2560 mother–infant pairs Quantitative (repeated prospective cohort design) Questionnaire and medical records (intake and output records for newborns, kept which were the bedside) review.	Baseline demographics, infant and maternal data inclusive of infant feeding, exposure to six of the ten Baby-Friendly steps (except Step 10) plus in-hospital infant feeding data.	Not applicable	Not stated

Authors	Study aim	Sample size, design, study instrument	Variables	Trustworthiness	Reliability or validity
Tarrant et al., 2015b Hong Kong	Effect of ceasing free infant formula within public hospitals as related to the following was assessed: (i) number of supplementary feeds given to breastfeeding babies in-hospital (ii) proportion of infants fed with formula supplements in-hospital and (iii) overall duration and EBF. Additionally, the overall effect of the quantity of in-hospital infant formula supplementation on the duration of EBF and any breastfeeding was assessed in a pooled analysis.	2560 mother–infant pairs Quantitative Prospective cohort design No study instrument was stated	Socio-demographics; breastfeeding status [EBF, partial breastfeeding, or exclusive formula feeding]. (i) baseline demographics; (ii) infant and maternal data; (iii) within-hospital infant feeding data; (iv) follow-up data on infant feeding at months 1, 2, 3, 6, 9 and 12 during postpartum or until participant ceased breastfeeding completely; and (v) data on the final breastfeeding status.	Not applicable	Not stated



Authors	Study aim	Sample size, design, study instrument	Variables	Trustworthiness	Reliability or validity
Grguric' et al., 2016 Croatia	A description of the successful reintroduction of BFHI in Croatia between 2007-2015, inclusive of challenges encountered was provided to benefit other countries.	All public maternity facilities (32). Quantitative The Ten of the BFHI Preliminary version of 2006's expanded, revised, and updated BFHI was translated by UNICEF Croatia. Adapted versions of BFHI self-assessment tool, the 20-hour course and other external assessment forms.	Socio-demographics; breastfeeding status [EBF, partial breastfeeding or exclusive formula feeding]. (i) baseline demographics; (ii) infant and maternal data; (iii) within-hospital infant feeding data; (iv) follow-up data on infant feeding at months 1, 2, 3, 6, 9 and 12 during postpartum or until participant ceased breastfeeding completely; and (v) data on the final breastfeeding status.	Not applicable	Used a validated instrument (Preliminary version of 2006's expanded, revised, and updated BFHI was translated by UNICEF Croatia. Adapted versions of BFHI self-assessment tools).

NB: NB: BFHI = Baby-Friendly Hospital Initiative, EBF = Exclusive breastfeeding;

The completed data abstraction template was used to extract all the relevant aspects of each eligible record. In addition, each of the reviewed documents was assessed critically guided by the Joanna Briggs Institute Critical Appraisal Tool (Joanna Briggs Institute, 2020) and the seven records were considered appropriate for this review.

Subsequently, the data fields were categorised into themes based on Krippendorff's (2019) content analysis. Then, two researchers worked independently and both of them iteratively read all the seven articles which were included in the review to facilitate an in-depth understanding of the contents. Afterwards, both researchers worked independently to identify and tease out keywords and phrases from the results section of each included document. Words and phrases which had similar meanings were grouped; then, themes were identified. The researchers compared and thoughtfully discussed the themes until they agreed on the themes. Co-authors with expertise in human milk and lactation verified the identified themes to promote trustworthiness. Seven themes emerged as interventions that explicitly decrease BMS use and promote breastfeeding (Tables 2 and 3). Also, a detailed audit trail was kept on the data analysis process.

## **RESULTS**

### **Characteristics of the sample**

A total of 8447 peer-reviewed articles and other policy documents were retrieved: subsequently, seven of the documents were considered eligible and included in the review (Figure 1). The included articles were based on either primary research and/or secondary data analysis. Study sites were either global or in specific countries including Canada, China, Croatia, Hong Kong, India, Sweden, United States of America and Vietnam. Participants for the studies were

mother-infant dyads and diverse categories of health professionals. Most of the authors of the articles that were used for the scoping review did not have any conflict of interest. Information on the authors' declaration of conflict of interest was present in four of the eligible records.

### **Breastmilk Substitute Interventions and Outcomes**

Seven categories of BMS interventions were identified (Table 2). These interventions included the International Code of Breastmilk Substitutes, health worker training programs and educational strategy, Baby-Friendly Hospital Initiative (BFHI), formula payment policy, government-owned breastfeeding programs, diaper bag donation and other enabling factors (Robinson *et al.*, 2019; Ekström *et al.*, 2012; Grguric' *et al.*, 2016; Martens 2000; Robinson *et al.*, 2019; (Grguric' *et al.*, 2016; Tarrant *et al.*, 2015a; Tarrant *et al.*, 2015b; (Feldman-Winter *et al.*, 2012)

### **International Code of Breastmilk Substitutes**

Legislation and implementation of the Code at national levels was reported to improve breastfeeding outcomes (Robinson *et al.*, 2019). For instance, a comparison of India and China confirmed that stronger enforcement of the Code is linked with increased EBF prevalence and reduced infant BMS marketing. The Code was implemented between 1983 and 2006 in China, India and Vietnam although China abandoned implementation of the Code in 2017. Vietnam banned BMS marketing for children less than two years in 2013. The successful legislation and implementation of the Code required communication, advocacy, national and regional legislation, monitoring and inspection systems, proportional sanctions, pre-and in-service training on the Code for all health professionals, coordination, research and evaluation.

Table 2. BMS Interventions

Author(s)	Training program or educational strategy	Diaper bag	International Code of Breastmilk Substitutes	Other enabling factors	Government-owned breastfeeding programs	Baby-Friendly Hospital Initiative (BFHI)*	Formula payment policy.
Ekström et al., 2012	A training program which was process-oriented was conducted for postnatal nurses and midwives.						
Feldman-Winter et al., 2012		The Cooper University Hospital (CUH) CUH-sponsored diaper bag rather than industry-sponsored sample formula pack.					

Author(s)	Training program or educational strategy	Diaper bag	International Code of Breastmilk Substitutes	Other enabling factors	Government-owned breastfeeding programs	Baby-Friendly Hospital Initiative (BFHI)*	Formula payment policy.
Martens 2000	The Pine Falls hospital educational strategy entailed a mandatory 90 minutes' hospital personnel in-service, then a voluntary written tutorial which was completed individually over the following month.						

Author(s)	Training program or educational strategy	Diaper bag	International Code of Breastmilk Substitutes	Other enabling factors	Government-owned breastfeeding programs	Baby-Friendly Hospital Initiative (BFHI)*	Formula payment policy.
Robinson et al., 2019	Breastfeeding training for health professionals.		Legislation and implementation of the Code (need for communication, advocacy, legislation at national and regional levels, monitoring and inspection systems, proportional sanctions, pre-service and in-service trainings on the Code for health staff, research and evaluation, coordination and evaluation).	Other enabling factors (adequate maternity leave [6 months], and breastfeeding related counseling for mothers against strategies adopted by infant formula industries).	Transitioning breastfeeding programs in countries from donor-led to government-owned is vital to sustain the Code implementation and enforcement in the long term.	India has no BFHI certified hospitals; 0.4% of births occur in BFHI facilities in Vietnam and 12% of births occur in BFHI hospitals in China. Availability of health systems strengthening towards BFHI	

Author(s)	Training program or educational strategy	Diaper bag	International Code of Breastmilk Substitutes	Other enabling factors	Government-owned breastfeeding programs	Baby-Friendly Hospital Initiative (BFHI)*	Formula payment policy.
Grguric' et al., 2016	Six-year "Young Child Development Program," entailing positive parenting, optimal infants feeding, with much emphasis on renewing BFHI. Preliminary version of 2006's expanded, revised, and updated BFHI was translated by UNICEF Croatia and training for coordinators, assessors and trainers was held for staff using the UNICEF/WHO 20-hour course.			Hospitals shared model policies and available breastfeeding promotional materials. Mother-Friendly Hospital Initiative (MFHI) in National Breastfeeding Program within 2014 - 2016, because "Baby-Friendly" care should include maternal wellbeing. Breastfeeding support groups (BSGs) to promote continued infant feeding after hospital discharge. In 1995, BSGs became established in Croatia. Experienced mothers and community health nurses led the BSGs. In this Croatian model, the mothers met regularly in community facilities or private homes. By early 2007, 16 BSGs had registered with Croatian Association of BSG; in 2016, Croatia had 166 BSGs and others to emerge, especially after workshops organized for community health nurses by UNICEF-sponsored on breastfeeding recently.		Revitalization of the BFHI. Nurses proficient in Baby-Friendly practices payed visits. Some hospitals shared their experiences with colleagues. Before the formal assessment, regional coordinator visited the hospital once or more to conduct informal assessment as well as discuss with staff challenges associated with the implementation of the ten steps to BFHI and possible solutions. Self-appraisal and self-monitoring tools of BFHI were found to be very useful.	

Author(s)	Training program or educational strategy	Diaper bag	International Code of Breastmilk Substitutes	Other enabling factors	Government-owned breastfeeding programs	Baby-Friendly Hospital Initiative (BFHI)*	Formula payment policy.
Tarrant et al., 2015a							Implementation of infant formula payment as a policy.
Tarrant et al., 2015b							Policy implementation related to the payment of market price for infant formula.

Table 3. Breastfeeding Outcomes

Author(s)	Breastfeeding initiation	Exclusive breastfeeding (EBF)	Breastmilk substitute (BMS) quantity	Any breastfeeding (duration, rooming-in, feeding on demand)	Removal of formula samples	Education or knowledge	BMS policy
Ekström et al., 2012	All groups had a high breastfeeding initiation rate: 90% initiated breastfeeding during the first 24 hours and 97% initiated breastfeeding during the first 72 hours.	IG infants who received BMS in week one without medical reasons were fewer (10%) compared with Control Group A (CGA_ infants (20%) and Control Group B (CGB) (14%) (v2 = 5.04, df = 1, p = 0.01, for all three groups). Infants fed with BMS without medical reasons had a significantly shorter duration of EBF when compared with infants who were not fed with BMS in all groups: IG, df = 152, t = 2.4,	p = 0.02; CGA, df = 116, t = 3.03, p = 0.01; CGB, df = 130, t = 2.48, p = 0.01. In the IG group, fewer infants received BMS on one occasion within week one compared to infants in the two control groups (IG, 0.3%; CGA, 2.3%; CGB, 2.6%; p = 0.005).				



Author(s)	Breastfeeding initiation	Exclusive breastfeeding (EBF)	Breastmilk substitute (BMS) quantity	Any breastfeeding (duration, rooming-in, feeding on demand)	Removal of formula samples	Education or knowledge	BMS policy
Feldman-Winter et al., 2012	There was no significant difference between intervention and control groups in terms of EBF. Mean duration of EBF was 44 days (control) and 47 days (intervention; $P = .46$ ).	During the control period, 35% of mothers reported feeding their infants with formula from the industry-sponsored formula sample pack in the first week postpartum, and in the intervention period, 19% of women reported feeding formula from the Cooper University Hospital (CUH), CUH-sponsored diaper bag in the first week ( $P = .001$ ).	Breastfeeding outcomes were based on survival analysis. The observed mean duration for any breastfeeding was as follows: 58 days (during the control period) versus 62 days (during the intervention period).	Formula sample packs were removed completely from the hospital.	Staff were educated on the change in practice.	Marketing department of the hospital agreed to continue to support he costalways when the study ended. Thus, CUH-sponsored diaper bags become the new and acceptable standard of care. CUH implemented revised procedures and policies for all pharmaceutical industry representatives, CUH restricted their access to the patient areas and required them to book appointments, to eliminate direct contact with all students and trainees, as well as wear specific identification.	

Author(s)	Breastfeeding initiation	Exclusive breastfeeding (EBF)	Breastmilk substitute (BMS) quantity	Any breastfeeding (duration, rooming-in, feeding on demand)	Removal of formula samples	Education or knowledge	BMS policy
Martens, 2000	No significant differences were found in initiation of breastfeeding.	Chart audits showed increases in EBF rates at intervention site and no differences in the breastfeeding initiation rates or breastfeeding frequency. Pine Falls indicated 23% increase in EBF (31% vs. 54%), whereas the control site showed 43% decrease (43% to 0%) from before intervention to after intervention (logistic regression model $\chi^2 = 10.15$ , 3 df, $P = .017$ , adjusted for birth weight).	No statistically significant differences were observed by site or time regarding the average quantity of supplements or the average number of supplements given to all the breastfed babies.			Staff Surveys: BFHI Compliance score increased and it was statistically significant at the intervention site (24.4-31.9, $P = .005$ ) and not the control site (20.2-22.5, ns). The increment was evident in scores for five steps (1, 5, 6, 9 and 10) of the Ten Steps.	

Author(s)	Breastfeeding initiation	Exclusive breastfeeding (EBF)	Breastmilk substitute (BMS) quantity	Any breastfeeding (duration, rooming-in, feeding on demand)	Removal of formula samples	Education or knowledge	BMS policy
Robinson et al., 2019		India had the highest EBF prevalence among infants low five months of age (54.9%), then Vietnam (24%), and China (20.8%). A comparison of Chinese and Indian infants confirmed expected pattern of strong enforcement of the Code is linked to higher EBF prevalence and reduced infant formula sales. For Vietnamese infants, this pattern was absent because EBF prevalence was low amidst a high Code implementation score.					

Author(s)	Breastfeeding initiation	Exclusive breastfeeding (EBF)	Breastmilk substitute (BMS) quantity	Any breastfeeding (duration, rooming-in, feeding on demand)	Removal of formula samples	Education or knowledge	BMS policy
Grgetic et al., 2016		EBF rates have increased. Current national data on EBF rates, published by the Croatian Public Health Institute, show an increase of 16% at 0 to 2 months (from 51% in 2007 to 67% in 2014) and a 14% increase at 3 to 5 months (from 32% in 2007 to 46% in 2014), which we credit primarily to the BFHI. The 10 steps were reintroduced to the primary health care setting in Croatia, aimed at primary care paediatricians and family doctors. This model of primary care has been included in the Republic of Croatia's National Health Strategy for the period 2012 to 2020.		During the BFHI implementation process, nine maternity facilities were renovated to facilitate 24-hour rooming-in.  Breastfeeding duration did not increase significantly after reintroduction of BFHI in Croatia.			

Author(s)	Breastfeeding initiation	Exclusive breastfeeding (EBF)	Any breastfeeding (duration, rooming-in, feeding on demand)	Education or knowledge
Tarrant et al., 2015a	<p>A higher and significant proportion of infants from Cohort 2 were initiated to breastmilk within one hour of birth (45% vs 28.7%; adjusted odds ratio [aOR] = 2.04; 95% CI, 1.61-2.59). A fully adjusted model showed that breastfeeding initiation within first hour following birth (Step 4) was significantly linked with lower risk of ceasing breastfeeding, and participants breastfed for about five additional weeks (15.5 weeks vs 10.9 weeks). The overall median time to initiation of the first breastfeeding decreased from 3.0 hours in Cohort 1 to 1.5 hours in Cohort 2 (<math>P &lt; .001</math>). Median time to initiation of the first breastfeed among participants undergoing vaginal delivery decreased from 2 hours to 1 hour (<math>P &lt; .001</math>) and for cesarean delivery reduced from 23 hours within Cohort 1 to four hours within Cohort 2 (<math>P &lt; .001</math>).</p>	<p>Cohort 1 participants were less likely to decide to plan to practice EBF. However, Cohort 1 participants' husbands were more likely to consider and prefer EBF practice for their infants. A higher and more significant proportion of the infants in Cohort 2 received only breastmilk in hospital (41.4% vs 17.9%; aOR = 1.45; 95% CI, 1.07-1.96), and the infants were given no artificial teats or nipples (78.1% vs 58.4%; aOR = 6.02; 95% CI, 4.06-8.94). A fully adjusted model showed that receiving only breastmilk while in hospital (Step 6) was significantly linked with lower risk of ceasing any and EBF. Participants who were exposed to Step 6 breastfed for about 10 additional weeks (19.8 weeks vs 10.2 weeks) when compared to participants who were not exposed. When compared to participants who were exposed to each of the six Baby-Friendly steps, duration of EBF was continuously shorter among participants who experienced fewer Baby-Friendly steps.</p>	<p>When compared to mothers who received all six Baby-Friendly steps, duration of any breastfeeding was continuously shorter among participants who experienced fewer Baby-Friendly steps. Also when compared to participants who experienced each of the six Baby-Friendly steps, participants who experienced 0 or only one step had nearly a double risk of weaning after any breastfeeding (hazard ratio [HR] = 1.78; 95% CI, 1.39-2.28) and about 50% increase in risk of weaning from EBF (HR = 1.42; 95% CI, 1.13-1.79). Participants exposed to each of the six Baby-Friendly steps breastfed three times longer when compared to participants who were exposed to <math>\leq 1</math> step (21 weeks vs 7.1 weeks). Rates of breastfeeding infants on demand and rooming-in showed no significant change within the two time periods.</p>	<p>Participants in Cohort 1 were more likely to have participated in antenatal breastfeeding classes. A highly significant proportion of mothers confirmed that they received information on breastfeeding support options following their discharge from the hospital (85.6% vs 75.8%; aOR = 2.14; 95% CI, 1.63-2.82).</p>

Author(s)	Breastfeeding initiation	Breastmilk substitute (BMS) quantity	Any breastfeeding (duration, rooming-in, feeding on demand)	Education or knowledge
Tarrant et al., 2015b	<p>Participants in cohort 2 were more likely to exclusively breastfeed (<math>P &lt; 0.001</math>). The husbands of participants in cohort 2 were less likely to explicitly prefer EBF for the infant and more likely to have no particular infant feeding preference (both <math>P &lt; 0.001</math>). After the implementation of the infant formula policy, more mothers (41.3% v. 17.7%) exclusively breastfed during hospitalisation.</p>	<p>The mean number of infant formula supplements given to infants in the first 24 h of life was 2.70 (SD 3.11) before policy implementation and 1.17 (SD 1.94) after implementation (<math>P &lt; 0.001</math>). In the pooled sample, infants who were supplemented with infant formula had an increased risk of cessation of any EBF with higher levels of supplementation than infants who received no in-hospital formula supplementation (EBF). In the fully adjusted model, infants who received high partial breastfeeding during hospital stay (&lt;20% infant formula) had about 30% increased risk of breastfeeding cessation (HR = 1.29; 95% CI 1.15, 1.46) and infants who received medium-partial.</p>	<p>The median duration of breastfeeding increased from 8 to 12.5 weeks after policy implementation. The risk of breast-feeding cessation was significantly lower after the policy implementation (<math>P &lt; 0.001</math>), but there was no significant change in the risk of stopping EBF (<math>P = 0.58</math>). Even after adjusting for potential confounding variables, infants in Cohort 2 had about 20% lower risk of stopping any breastfeeding (hazard ratio [HR] = 0.81; 95% CI 0.73, 0.90) and showed no change associated with risk of stopping EBF (HR = 1.01; 95% CI 0.93, 1.11).</p>	<p>Cohort 2 participants were less likely to have attended antenatal breastfeeding classes.</p>

NB: BFHI = Baby-Friendly Hospital Initiative; EBF = Exclusive breastfeeding

### **Health Worker Training Program and Educational Strategy**

This entailed in-service training of hospital staff, including midwives and postnatal nurses on breastfeeding in both private and public sector facilities (Ekström *et al.*, 2012; Grguric' *et al.*, 2016; Martens 2000; Robinson *et al.*, 2019). The training was theory and practice-oriented. The duration of the training varied and it occurred over a period of one month. An adapted version of the UNICEF/WHO 20-hour course BFHI manual and facility was used for facilitation. The training programs were associated with a statistically significant increase in BFHI Compliance score (Martens 2000).

### **Baby-Friendly Hospital Initiative (BFHI)**

The implementation and revitalization of the BFHI were reported to be critical in the achievement of improved breastfeeding outcomes (Grguric' *et al.*, 2016; Robinson *et al.*, 2019). The revitalization of BFHI was positively associated with increased EBF rates. For instance, the Croatian Public Health Institute, reported of increased EBF rates – 16% points at 0-2 months (from 51% in 2007 to 67% in 2014) and 14% points increase at 3-5 months (from 32% in 2007 to 46% in 2014) (Grguric' *et al.*, 2016). Nurses, proficient in BFHI practices visited other hospitals and shared their experience with colleagues. In addition, the regional coordinator met with hospital staff to discuss any challenges in the implementation of the BFHI and recommendations were made to address the challenges (Grguric' *et al.*, 2016). Moreover, hospitals conducted informal assessments on compliance with the BFHI using self-appraisal tools and the monitoring tools of BFHI prior to the formal BFHI compliance by external evaluators Grguric' *et al.*, 2016).

### **Formula payment policy**

Clients at the study site had opportunities to learn about exclusive breastfeeding and support services available; and the hospital's formula payment policy. Implementation of the infant formula payment policy required clients to pay the prevailing market cost for infant formula use in health facilities (Tarrant *et al.*, 2015a; Tarrant *et al.*, 2015b). The implementation of the policy resulted in favourable breastfeeding outcomes (increased breastfeeding information and support, breastfeeding initiation, any breastfeeding duration and EBF).

### **Diaper bag donation**

The Cooper University Hospital (CUH) introduced CUH-sponsored diaper bags rather than industry-sponsored formula sample packs. Industry-sponsored formula sample pack had donations of free formula for all infants born at CUH. The CUH ceased the distribution of industry-sponsored sample packs with the introduction of the CUH-sponsored diaper bags. The implementation of CUH-sponsored diaper bags facilitated increased duration of breastfeeding (Feldman-Winter *et al.*, 2012).

### **Government-owned Breastfeeding Programs**

At the national level, various political leaders were encouraged to transition breastfeeding programs from prevailing donor-led programs to mainly government-owned programs (Robinson *et al.*, 2019). The transition process is vital for the long-term sustainability of Code enforcement and implementation at individual country levels.

### **Other Enabling Factors**

The implementation of other enabling factors was observed to be important in the achievement of favourable breastfeeding

outcomes (Grgurić *et al.*, 2016; Robinson *et al.*, 2019). The factors identified included adequate maternity leave (six months); breastfeeding counselling for lactating mothers against infant formula industries' marketing strategies; implementation of model policies and the exchange of breastfeeding promotional materials among hospitals. Additionally, mother-friendly care (Mother-Friendly Hospital Initiative) was recommended to be included in National Breastfeeding Programs (Grgurić *et al.*, 2016). Mother-Friendly Hospital Initiative ensured well-being of mothers during the implementation of BFHI (Grgurić *et al.*, 2016). Moreover, the establishment of BSGs assisted with infant feeding after hospital discharge (Grgurić *et al.*, 2016). The breastfeeding support groups were jointly led by experienced mothers and community health nurses; and the groups met regularly, in community facilities or private homes (Grgurić *et al.*, 2016).

Implementation of the aforementioned initiatives led to favourable breastfeeding outcomes (Table 3). These outcomes are namely, enhanced education and knowledge on breastfeeding, improved breastfeeding initiation, increased exclusive breastfeeding rates, exposure of infants to some quantity of human milk, any breastfeeding, limited use of BMS, removal of formula samples and the implementation of facility-specific BMS policy (Feldman-Winter *et al.*, 2012; Martens, 2000; Tarrant *et al.*, 2015a, 2015b; Ekström *et al.*, 2012; Tarrant *et al.*, 2015; Robinson *et al.*, 2019).

## **DISCUSSION**

In this review, we identified and categorised seven published interventions that explicitly decrease BMS use and promote breastfeeding.

The implementation of training programs

and educational strategies as an intervention that limits BMS use is consistent with previous recommendations (Green *et al.*, 2021; Leruth *et al.*, 2017; Pérez-Escamilla *et al.*, 2023; Pérez-Escamilla *et al.*, 1994; Rollins *et al.*, 2016; WHO, 2021; WHO 2022 a, b). There is the need to intensify breastfeeding promotion and communication programs at all levels of the healthcare system to promote optimal breastfeeding outcomes. The proposed breastfeeding education should be in simple language, and concise and use the language that is easily understood by various stakeholders involved, especially, pregnant women, lactating mothers and support persons/significant others. The educational sessions can occur during the prenatal and postnatal clinic visits and at birth (Pérez-Escamilla *et al.* 2023). Educational programs could be designed in a way that enables clinical assessment and addresses misconceptions about breastfeeding appropriately. The importance of EBF should also be emphasized through such educational programs.

Additionally, the identification of BFHI initiation and revitalization affirms earlier findings about the favourable effects of BFHI implementation on optimal breastfeeding outcomes (WHO and UNICEF, 2018). Thus, the adoption and compliance with BFHI in health facilities will be vital for the achievement of optimal breastfeeding (breastfeeding initiation, continued breastfeeding and EBF). Moreover, the vital role of legislation and implementation of the Code in promoting breastfeeding at the national level confirms previous findings from across the globe (Franco-Lares *et al.*, 2023; Mota-Castillo *et al.*, 2023; Rollins *et al.*, 2016; WHO, 1981; WHO, 2017; WHO 2022a). Therefore, there is a need for continued engagements with the government to regulate and implement the Code fully to facilitate optimal breastfeeding outcomes. Moreover, governments should be strategic and innovative in monitoring digital/social media advertisements on BMS



(Franco-Lares *et al.*, 2023; Mota-Castillo *et al.*). For instance, health facilities should not allow BMS companies to use their digital media platforms to contact, advertise and market BMS products to pregnant women, lactating mothers, caregivers and fathers of infants and /or young children. Additionally, health professionals should avoid conflicts of interest which promote BMS companies' activities. Currently, there are no global policies on how to address the online and social media marketing of BMS (WHO, 2022a). Efforts should be made to enact and enforce policies to restrict unethical and aggressive marketing on various digital and social media platforms. Furthermore, the monitory and regulatory agencies in various countries should be fair in sanctioning all individuals, groups and institutions when violations of the Code occur (Piaggio *et al.*, 2023).

Other novel interventions that limit BMS use were identified. Namely, implementation of a formula payment policy, diaper bag sans formula, government-owned breastfeeding programs, adequate maternity leave, exchange of breastfeeding promotional materials, breastfeeding support groups, and Mother-Friendly Hospital Initiative. Mothers with previous EBF success stories in the breastfeeding support groups in LMIC and other settings can be empowered to serve as breastfeeding champions or role models within their communities (Gyamfi *et al.*, 2022a and b). In addition, health facilities should enforce measures to cease the distribution of free sample formulas and implement policies where clients will pay for the full cost of the formula if medically prescribed. Moreover, in countries where the duration of paid maternity leave is less than six months, the governments should consider extending the paid maternity leave to six months to enable lactating mothers who opt to practice EBF to do so without interruption.

The collective efforts of all stakeholders,

inclusive of pregnant women, lactating mothers, the family, health professionals, policymakers, and governments are warranted to limit the aggressive marketing strategies of the BMS manufactures while promoting breastfeeding (Pérez-Escamilla *et al.*, 2023). The collective efforts of all stakeholders, implementation and sustainability of the aforementioned initiatives may favourably influence breastfeeding outcomes inclusive of increased breastfeeding initiation, EBF, and limited use of BMS. Future studies should consider conducting mixed methods studies to assess the interventions that can improve breastfeeding outcomes by limiting BMS supply.

## LIMITATION

The limitations of the study included the availability of few articles which were eligible for the review and the absence of any prior published protocol for this review process. Also, this review was limited to only published articles which were discoverable by the database searches as provided. Thus, the authors may have omitted important sources of unpublished records and/or virtually unavailable documents.

## CONCLUSIONS

Globally, there are only a few approaches to mitigate the use of breastmilk substitutes. These approaches may be facility-based, community-based based or nationally oriented. The identified interventions in this review can be adopted to promote, protect and support breastfeeding while limiting BMS use. Future studies may use a mixed methods research design to explore the linkages between breastfeeding and BMS limiting intervention at the community level.

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## Declaration of Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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