

Review Article

Impact of the Baby-friendly Hospital Initiative on breastfeeding and child health outcomes: a systematic review

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Abstract

The Baby-friendly Hospital Initiative (BFHI) is a key component of the World Health Organization/United Nations Children's Fund Global Strategy for Infant and Young Child Feeding. The primary aim of this narrative systematic review was to examine the impact of BFHI implementation on breastfeeding and child health outcomes worldwide and in the United States. Experimental, quasi-experimental and observational studies were considered eligible for this review if they assessed breastfeeding outcomes and/or infant health outcomes for healthy, term infants born in a hospital or birthing center with full or partial implementation of BFHI steps. Of the 58 reports included in the systematic review, nine of them were published based on three randomized controlled trials, 19 followed quasi-experimental designs, 11 were prospective and 19 were cross-sectional or retrospective. Studies were conducted in 19 different countries located in South America, North America, Western Europe, Eastern Europe, South Asia, Eurasia and Sub-Saharan Africa. Adherence to the BFHI *Ten Steps* has a positive impact on short-term, medium-term and long-term breastfeeding (BF) outcomes. There is a dose-response relationship between the number of BFHI steps women are exposed to and the likelihood of improved BF outcomes (early BF initiation, exclusive breastfeeding (EBF) at hospital discharge, any BF and EBF duration). Community support (step 10) appears to be essential for sustaining breastfeeding impacts of BFHI in the longer term.

Keywords: Baby-Friendly Hospital Initiative, breastfeeding protection, promotion and support, child health.

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Introduction

Infant and young child feeding practices have a strong impact on the nutrition status of children under 2 years of age as well as on their risk for infectious diseases and mortality. The World Health Organization (WHO) recommends that breastfeeding be initiated within 1 h after birth, that breastfeeding be practised exclusively for the first 6 months of life followed by the introduction of safe nutritious complementary foods and that breastfeeding be continued until the child is at least 2 years old (WHO 2002). The WHO guidelines are backed up by a strong body of evidence indicating that optimal breastfeeding behaviours are strongly associated with lower incidence of gastrointestinal

and respiratory tract infections as well as with child survival (Sankar *et al.*, 2015). Furthermore, breastfeeding may protect children against otitis media (Bowatte *et al.*, 2015), malocclusions (Peres *et al.*, 2015), dental caries (Tham *et al.*, 2015), obesity and type 2 diabetes (Horta *et al.*, 2015a) and has been consistently associated with improved cognitive development (Horta *et al.*, 2015b). Benefits to the mother include prolonged lactational amenorrhea and a reduced risk of post-partum (pp) haemorrhage, ovarian and breast cancer, and type 2 diabetes (Chowdhury *et al.* 2015). Thus, it is not surprising that the WHO Global Strategy on Infant and Young Child Nutrition specifically calls for strong government commitment to protecting, promoting and supporting breastfeeding (WHO/UNICEF 2003).

The Baby-friendly Hospital Initiative (BFHI) launched in 1991 is a key component of the WHO/UNICEF Global Strategy for Infant and Young Child Feeding (de Oliveira *et al.*, 2003, UNICEF 1990, WHO/UNICEF 2003). BFHI is based on adherence to the Ten Steps to Successful Breastfeeding (*Ten Steps*; WHO 1989) and the 1981 WHO Code for Marketing of Breast Milk Substitutes (Kyenkyia-Isabirye, 1992; Naylor, 2001, UNICEF/WHO 2009) and endorses the integration of facility-level and community-level services (UNICEF/WHO 2009).

The *Ten Steps* can be considered a quality assessment and improvement system based upon specific actions in five breastfeeding domains (Table 1; UNICEF/WHO 2009, WHO 1989). (1) Policy: includes written breastfeeding (BF) policies endorsing the *Ten Steps* and the 1981 WHO Code; not accepting infant formula for free or at reduced cost; and forbidding direct or indirect marketing of infant formula to mothers. (2) Development of human resources: BF training of maternity ward staff. (3) Promotion and support: prenatal BF education; in-hospital support including early BF initiation and on demand BF; and community support including referrals and in-house support groups. (4) Protection: no infant formula; avoiding teats or pacifiers. (5) Structural changes to maternity ward workflow in the form of rooming-in throughout the hospital stay.

It is estimated that as of 2010 there were 21 328 maternity hospitals or birthing centres that had ever received the Baby-friendly Hospital (BFH) designation worldwide (Labbok, 2012, UNICEF/WHO 2009, Baby Friendly USA, 2010). The BFHs are distributed across 160 countries with approximately 31% of maternity facilities in developing countries and 8.5% in developed countries having ever received the BFH certification (Labbok, 2012). Currently, the United States has 166

hospitals and birthing centres with the baby-friendly designation, distributed across 41 states and the District of Columbia and accounting for 7% of annual births nationwide (Baby Friendly USA 2012).

Objectives

The primary aim of this review was to examine the impact of the BFHI package on breastfeeding and child health outcomes worldwide and in the United States. This is relevant because previous reviews have focused largely on the impact of individual BFHI steps (Perez-Escamilla *et al.*, 1994; WHO 1998; Dyson *et al.*, 2005; Jaafar *et al.*, 2011; Jaafar *et al.*, 2012; Moore *et al.*, 2012). Because the United States is in the midst of major policy decisions regarding future strategies and investments in breastfeeding protection, promotion and support (National Academies of Sciences, Engineering, and Medicine, 2015), findings specific to the United States are also examined.

Methods

The specific research questions were designed, and the literature search was conducted using the PICOS (Participants, Interventions, Comparators, Outcomes, Study Design) model for evidenced-based medical research (Table 2; Liberati *et al.*, 2009).

Eligibility criteria

The specific inclusion and exclusion criteria are listed in Table 3. In brief, observational, quasi-experimental and experimental studies of both primiparous and multiparous women were included if they assessed BF

Key messages

- The *Ten Steps* that form the basis of Baby-friendly Hospital Initiative (BFHI) serve as a quality assurance system based on highly interrelated specific actions at the facility and community level.
- Adherence to the BFHI *Ten Steps* has a positive impact on short-term, medium-term and longer-term BF outcomes.
- There is a dose–response relationship between the number of BFHI steps women are exposed to and the likelihood of improved breastfeeding outcomes.
- Community support (step 10) is key for sustaining the short-term breastfeeding benefits obtained from the BFHI steps requiring implementation only at the maternity ward.
- Avoiding in-hospital supplementation appears to be a key step for breastfeeding success, perhaps reflecting adequate implementation of the rest of *Ten Steps*.

Table 1. WHO/UNICEF *Ten Steps* to successful breastfeeding. Baby-Friendly Hospital Initiative systematic review

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in the skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within a half-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 newborn infants no food or drink other than breast milk, unless medically indicated.
7. Practice rooming-in: allow mothers and infants to remain together 24 h a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

WHO, World Health Organization; UNICEF, United Nations Children's Fund.

The *Ten Steps* can be considered a quality assessment and improvement system based upon specific actions in five breastfeeding domains. (1) *Policy*: includes written BF policies endorsing the *Ten Steps* and the 1981 WHO Code, not accepting infant formula for free or at reduced cost and forbidding direct or indirect marketing of infant formula to mothers. (2) *Development of human resources*: BF training of maternity ward staff. (3) *Promotion and support*: prenatal BF education, in-hospital support including early BF initiation and on demand BF and community support including referrals and in-house support groups. (4) *Protection*: no infant formula, avoiding teats or pacifiers. (5) *Structural changes* to maternity ward workflow in the form of rooming-in throughout the hospital stay. The *Ten Steps* are highly interrelated with each other. If the maternal-newborn dyad is separated immediately after birth, it is not possible to comply with step 4 (early skin-to-skin contact and initiation of BF). If the maternal-newborn dyad is not rooming-in 24 h a day (step 7), it becomes very difficult to adhere to step 6 (no breast milk supplements) and step 8 (BF on demand). If adequate prenatal education (step 3) and BF support in the maternity ward (step 5) are not available, it is unreasonable to expect that women will be able to breastfeed exclusively and on demand throughout the hospital stay. If direct or indirect marketing of infant formula is allowed, it may become extremely difficult for women to remain motivated to follow optimal BF practices even if several measures supportive of BF are in place. If there is no community support for BF once the mothers leave the maternity facility (step 10), it is unlikely that they will be able to breastfeed exclusively once they are back home and when many return work. *Ten Steps* implementation relies on having a well-qualified workforce in place (step 2), and this is unlikely to happen unless there are clear written policies in place (step 1).

outcomes and/or infant health outcomes for healthy, term infants born in facilities designated as baby friendly or implementing at least three or all of the BFHI steps but not designated as baby friendly. Studies that assessed the impact of community-based initiatives connected to BFHs were also included (i.e. Baby-friendly Primary

Table 2. PICOS model for evidence-based medical research questions. Baby-Friendly Hospital Initiative systematic review

Population
Women who deliver a healthy, full-term infant in a hospital or birthing centre.
Intervention
Research question: Is there an impact of BFHI on breastfeeding and infant health outcomes globally and in the USA?
Comparison
Women not exposed to the <i>Ten Steps</i> ; degree of exposure to the <i>Ten Steps</i> .
Outcomes
Exclusive breastfeeding at discharge through 6 months post-partum. Any breastfeeding at discharge through 12 months post-partum. Onset of lactation. Infant health outcomes: gastrointestinal infection, upper and lower respiratory tract infection, otitis media, allergies, asthma, obesity and intelligence.
Study designs
Randomized controlled trials quasi-experimental designs (with or without a parallel reference group), prospective studies cross-sectional studies

Care Units and referral to home-based peer counselling at discharge from BFH).

Information sources

MEDLINE, EMBASE, Global Health, CINAHL, PUBMED and Web of Science were searched from their dates of inception to December 2012. Hand searches were conducted of the bibliographies of each of the manuscripts considered eligible for the study as well as of relevant background articles.

Search strategy

Literature searches were conducted by two of the authors (JM and RPE). Databases were searched using different combinations of the terms 'baby friendly', 'Ten Steps' and 'hospital practices' as text words. The Medical Subject Heading (MeSH) term 'breastfeeding' was exploded (i.e. expanded to include all sub-terms) and combined with the text word searches to obtain the final set of articles (i.e. infant health outcomes were extracted from the literature identified through this search approach). Infant health outcomes examined were gastrointestinal infection, upper and lower respiratory tract infection, otitis media, allergies, asthma, obesity and intelligence.

Table 3. Study inclusion and exclusion criteria. Baby-Friendly Hospital Initiative systematic review

Inclusion criteria
Studies that
1. Assessed <i>breastfeeding outcomes</i> for women who delivered a healthy term infant in a baby friendly-designated hospital or birthing centre
2. Assessed <i>breastfeeding outcomes</i> for women who were exposed to a combination of at least three BFHI steps
3. Assessed <i>breastfeeding outcomes</i> for women who were exposed to Baby Friendly Community initiatives or community support linked to a baby friendly hospital
4. Assessed <i>infant health outcomes</i> for women who delivered a healthy term infant in a Baby Friendly-designated hospital or birthing centre
5. Assessed <i>infant health outcomes</i> for women who were exposed to a combination of BFHI steps
6. Assessed <i>infant health outcomes</i> for women who were exposed to Baby Friendly Community initiatives or community support linked to a Baby Friendly hospital
7. Study conducted in low-income, middle-income and high-income countries
Exclusion criteria
Studies that
1. Had an ecological design
2. Included women who delivered a preterm/sick infant
3. Included women who were HIV positive
4. Included women who delivered at home
5. Included women and infants with breastfeeding contraindications
6. Were published in languages other than English, Spanish or Portuguese

Study selection

All records were imported into EndNote X6. Duplicates were removed, followed by a review of titles and abstracts. Once articles were removed based on titles and abstracts, a full text review was conducted of the remaining articles.

Data collection process

Structured forms were developed to extract key information from each article including study design, outcomes and results. Data extraction was carried out by the first author (RPE).

Quality assessment

The quality of the studies was assessed using a modified version of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology (Table 4; Guyatt *et al.*, 2011). Studies were

classified as being of either high, moderate, low or very low quality, taking into account the study design and key design features including sample size, exposure and outcome measures, random allocation procedures (when applicable), inclusion of control or reference group and statistical analyses. RCTs were initially considered to be of high quality and quasi-experimental studies of medium quality but could be downgraded based on study design limitations. Prospective studies were considered to be of moderate quality but could be downgraded or upgraded up to moderate quality. Cross-sectional and retrospective studies were considered to be of low quality but could be downgraded or upgraded. Quality assessment was performed by two authors (RPE and SSP) based on independent rankings and a consensus process.

Results

Results are presented below by geographic location (global vs. United States only) and by study design. From the 834 records originally identified, 58 articles were included in the final review (Fig. 1). Data extracted for each study are presented in WebAppendix Tables 1–4 in Supporting Information.

Randomized controlled trials

Study quality

Nine of the 58 articles identified were derived from three RCTs conducted in Belarus and Brazil. The Promotion of Breastfeeding Trial (PROBIT) was rated as high quality for all outcomes (Kramer *et al.*, 2001; Kramer *et al.*, 2002; Kramer *et al.*, 2007a; Kramer *et al.*, 2007b; Kramer *et al.*, 2008a; Kramer *et al.*, 2008b) except oral health as there was a high degree of measurement clustering by polyclinic (Kramer *et al.*, 2007c). The two Brazilian studies were of medium (Taddei *et al.*, 2000) and high (Coutinho *et al.*, 2005a) quality.

Studies' description and findings

The large-scale clustered RCT PROBIT found that the implementation of the *Ten Steps* had a positive impact on exclusive breastfeeding (EBF)

Table 4. Summary of study quality by outcome, study design and location. Baby-Friendly Hospital Initiative systematic review.

Outcome	Study design	Quality	Global	USA
Breastfeeding	Cross-sectional/retrospective	Very low	Narchi <i>et al.</i> (2009)	Dabritz <i>et al.</i> (2009)
			Shilpa <i>et al.</i> (2009)	
			Vieira <i>et al.</i> (2006)	Declercq <i>et al.</i> (2009)
			Ojofeitimi <i>et al.</i> (2000)	
			Bartington <i>et al.</i> (2006)	Rosenberg <i>et al.</i> (2008)
		Weng <i>et al.</i> (2003)		
		Rivera-Lugo <i>et al.</i> (2007)		
		Silva <i>et al.</i> (2008)		
		Low	Sampaio <i>et al.</i> (2011)	Merewood <i>et al.</i> (2005)
			Venancio <i>et al.</i> (2002)	
	Moderate	Broadfoot <i>et al.</i> (2005)		
		Helsing <i>et al.</i> (2002)		
		Mydlilova <i>et al.</i> (2009)		
	Prospective	Very Low	De Oliveira <i>et al.</i> (2003)	—
			Merten <i>et al.</i> (2005)	
			Venancio <i>et al.</i> (2012)	
		Low	Chien <i>et al.</i> (2007)	—
Giovannini <i>et al.</i> (2005)				
Moderate		Dulon <i>et al.</i> (2003)		
		Pincombe <i>et al.</i> (2008)	Kuan <i>et al.</i> (1999)	
Quasi-experimental <i>without</i> parallel comparison group	Very Low	Tarrant <i>et al.</i> (2011)	Murray <i>et al.</i> (2007)	
		—	Nickel <i>et al.</i> (2012)	
		—	DiGirolamo <i>et al.</i> (2001)	
		—	DiGirolamo <i>et al.</i> (2008)	
		—	Perrine <i>et al.</i> (2012)	
	Low	Caldeira and Goncalves (2007)	—	
		Bosnjak <i>et al.</i> (2004)		
		Coutinho <i>et al.</i> (2005b)		
		Duyan Camurdan <i>et al.</i> (2007)		
		Dasgupta <i>et al.</i> (1997)		
Quasi-experimental <i>with</i> parallel comparison group	Moderate	Braun <i>et al.</i> (2003)	Wright <i>et al.</i> (1996)	
		Cattaneo and Buzzetti (2001)	Philipp <i>et al.</i> (2001)	
		Garcia-de-Leon-Gonzalez <i>et al.</i> (2011)	Philipp <i>et al.</i> (2003)	
	Very Low	Ingram <i>et al.</i> (2011)		
		Zakarija-Grkovic <i>et al.</i> (2012)		
		Valdes <i>et al.</i> (1993)	—	
		Martens (2000)	—	
RCT	Low	Abolyan (2006)	—	
	High	Gau (2004)		
		Lutter <i>et al.</i> (1997)	—	
Child health	RCT	Moderate	Kramer <i>et al.</i> (2001)	—
			Kramer <i>et al.</i> (2002)	—
		High	Kramer <i>et al.</i> (2007a)	
			Kramer <i>et al.</i> (2007b)	
			Kramer <i>et al.</i> (2008a)	
	Moderate	Kramer <i>et al.</i> (2007c)		
		Kramer <i>et al.</i> (2008b)		

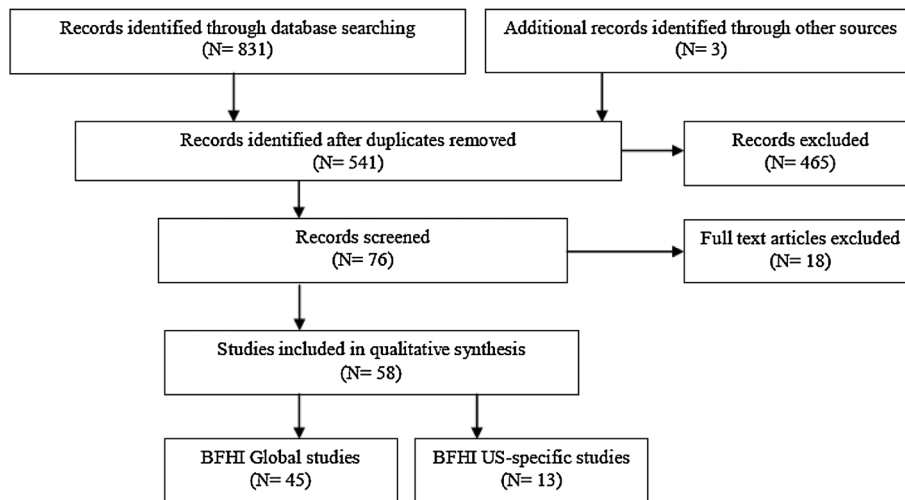


Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. BFHI, Baby-friendly Hospital Initiative.

and any breastfeeding (ABF) duration and a significant decrease in the incidence of gastrointestinal infections and atopic eczema at 1 year of age (Kramer *et al.*, 2001). However, the intervention did not have an impact on respiratory tract infections (Kramer *et al.*, 2001), infant weight outcomes or head circumference at 12 months (Kramer *et al.*, 2002). PROBIT's 6.5-year pp follow-up study found a positive intervention effect on children's IQ and academic performance (Kramer *et al.*, 2008a) but not on anthropometry or blood pressure outcomes (Kramer *et al.*, 2007b), asthma and allergy risk (Kramer *et al.*, 2007a), dental health (Kramer *et al.*, 2007c), child behaviour or maternal adjustment (Kramer *et al.*, 2008b). Interestingly, PROBIT had a positive impact on the likelihood that the mother would breastfeed her subsequent child for at least 3 months (Kramer *et al.*, 2008b).

The RCT conducted by Coutinho *et al.* in Brazil found that strengthening step 10 by adding home peer counselling had a significant positive impact of the intervention on the prevalence of EBF and ABF among 0- to 6-month-old infants (Coutinho *et al.*, 2005a). Taddei *et al.* did not find an impact of BFHI on ABF duration among Brazilian women delivering in eight hospitals that were randomly assigned to *Ten Steps* training or to continue the standard of care (Taddei *et al.*, 2000).

Experimental evidence conclusions

High-quality RCTs indicate that BFHI implementation leads to improvements in EBF and ABF and health benefits among infants and school-aged children. Long-term sustainability of breastfeeding improvements is likely to rely on the strong implementation of step 10. This is based on three important findings: (1) the success of PROBIT and the fact that the trial involved strong implementation of BF promotion and support by *trained* polyclinic personnel; (2) the findings from Coutinho *et al.* (2005a) regarding the addition of home peer counselling to step 10; and (3) the lack of BF benefits shown in an RCT with weak step 10 implementation (Taddei *et al.*, 2000).

Quasi-experimental

Eighteen quasi-experimental studies conducted in Brazil, Canada, Chile, Croatia, India, Italy, Russia, Spain, Taiwan, Turkey, United States and the UK have examined the association between BFHI and BF outcomes.

Quasi-experimental with parallel comparison group

Study quality. Four quasi-experimental studies conducted in Brazil (Lutter *et al.*, 1997), Canada (Martens, 2000), Russia (Abolyan, 2006) and Taiwan (Gau, 2004) included a parallel comparison group. The quality of

these studies was very low (Martens, 2000), low (Gau, 2004; Abolyan, 2006) and moderate (Lutter *et al.*, 1997).

Studies' description and findings. In Taiwan, delivering in BFHs was associated with higher BF initiation and a higher prevalence of EBF and ABF across time (Gau, 2004). In a Canadian hospital serving a predominantly aboriginal population, in-hospital EBF rates increased significantly after exposure to a brief in-service BFHI maternity staff training (Martens, 2000). Women delivering in a BFH in Santos, Brazil with strong step 10 implementation had significantly higher EBF duration compared with their counterparts delivering in a hospital with partial implementation of the *Ten Steps* that did not include step 10 (Lutter *et al.*, 1997). Russian women giving birth in four certified BFHs had better in-hospital BF behaviours (earlier BF initiation and higher EBF prevalence at hospital discharge) than their counterparts delivering in non-certified hospitals (Abolyan, 2006).

Pre-post BFHI implementation without parallel comparison group

Study quality. Fourteen pre-post studies without a parallel comparison group were conducted in Brazil, Chile, Croatia, India, Italy, Spain, Turkey, UK and the United States. Five studies were of very low quality (Dasgupta *et al.*, 1997; Bosnjak *et al.*, 2004; Coutinho *et al.*, 2005b; Caldeira & Goncalves, 2007; Duyan Camurdan *et al.*, 2007), eight of low quality (Wright *et al.*, 1996; Cattaneo & Buzzetti, 2001; Philipp *et al.*, 2001; Braun *et al.*, 2003; Philipp *et al.*, 2003; Garcia-de-Leon-Gonzalez *et al.*, 2011; Ingram *et al.*, 2011; Zakarija-Grkovic *et al.*, 2012) and one of moderate quality (Valdes *et al.*, 1993).

Studies' description and findings. A Brazilian study found that a 18-h BFHI training of maternity staff led to improvements in adherence to some of the *Ten Steps* (early skin-to-skin contact, BF positioning support and not offering supplements or pacifiers) and to EBF (Coutinho *et al.*, 2005b). However, EBF rates remained very low suggesting the need to strengthen step 10 (Coutinho *et al.*, 2005b). A study conducted in Brazil found a positive adjusted association of BFHI implementation in one hospital with EBF duration and breastfeeding continuation at 4 months pp (Braun

et al., 2003). Another Brazilian study with a pre/post cross-sectional design also found a positive association of BFHI with increased EBF, full breastfeeding (FBF) and ABF duration (Caldeira & Goncalves, 2007).

In a hospital in India, women delivering vaginally or via caesarean section 6 months after BFHI certification began breastfeeding earlier compared with women who delivered 6 months before the hospital was certified as baby friendly (Dasgupta *et al.*, 1997). The study, however, did not document pre-post group equivalence and did not adjust findings for potential confounders. A study conducted in eight Italian hospitals distributed across two regions found a positive association between BFHI implementation, EBF at hospital discharge, EBF at 3 months and ABF at 6 months (Cattaneo & Buzzetti, 2001). A medical records study conducted in one Turkish hospital covering the first 24 months pp found that BFHI implementation was associated with a 1.5 times increase in breastfeeding duration, but there was no association with EBF across time pp (Duyan Camurdan *et al.*, 2007). In agreement with this study, a maternity records study conducted in one hospital in Spain found that the median breastfeeding duration increased progressively across time after BFHI programme implementation (Garcia-de-Leon-Gonzalez *et al.*, 2011).

A UK study involving Baby Friendly Initiative training of home-visiting staff in a primary care trust found that the likelihood of breastfeeding initiation and ABF at 8 weeks pp was significantly higher in the year following (vs. 2 years before) implementation of the intervention (Ingram *et al.*, 2011). Chilean women attending a post-natal outpatient BF support clinic linked with a BFH who delivered after BFHI implementation had higher in-hospital EBF and FBF rates at 6 months and a lower likelihood of weaning from the breast by 6 months compared with their counterparts delivering before BFHI implementation. Women delivering post-BFHI implementation were also more likely to remain amenorrhoeic at 6 months pp (Valdes *et al.*, 1993).

A study conducted in Arizona, USA, found that BFHI implementation was associated with greater likelihood of breastfeeding initiation within 1 h of birth and lower likelihood of in-hospital formula supplementation (Wright *et al.*, 1996). In this study, after adjusting for potential confounders, breastfeeding duration was

longer among those not receiving in-hospital supplementation, not given formula discharge/coupons and rooming-in >60% of time. A study conducted in Boston, USA (Philipp *et al.*, 2001) found that in-hospital BF outcomes improved in a maternity hospital after implementation of BFHI and these improvements remained in place 2 years post-accreditation (Philipp *et al.*, 2003).

A national study conducted in Croatia found that ABF rates improved from pre to post BFHI implementation, and ABF rates increased even further after community-based support groups were introduced as part of the national breastfeeding programme strategy (Bosnjak *et al.*, 2004). A more recent study conducted in a maternity ward in Croatia that assessed BFHI steps 4 to 9 found that exposing maternity staff to the 20-h UNICEF/WHO BFHI training led to greater adherence to some steps 4 (early contact), 7 (rooming-in) and 8 (BF on demand) (Zakarija-Grkovic *et al.*, 2012). The intervention increased EBF during the first 48 h after birth but was not associated with longer-term benefits in breastfeeding outcomes. This was not surprising as post-training, 79% of infants were still receiving in-hospital supplementation.

Quasi-experimental evidence conclusions

Consistent but limited quality quasi-experimental studies suggest that BFHI is associated with improved in-hospital and post-discharge BF outcomes. Because studies were collected in 12 different countries, these findings strengthen the external validity of the high-quality RCTs reported previously. Consistent but limited quality quasi-experimental studies suggest that step 10 needs to be well implemented for BFHI to have longer-term impacts on breastfeeding outcomes (Lutter *et al.*, 1997; Coutinho *et al.*, 2005b).

Observational

Prospective

Study quality. Eleven of the studies identified in this systematic review were prospective. Six were conducted in the United States and one each in Taiwan, Italy, Germany, Australia and Hong Kong. Three studies were classified as being of very low quality (Dulon *et al.*, 2003; Giovannini *et al.*, 2005; Chien *et al.*, 2007), five

of low quality (Kuan *et al.*, 1999; Murray *et al.*, 2007; Pincombe *et al.*, 2008; Tarrant *et al.*, 2011 Nickel *et al.*, 2012) and three of medium quality (DiGirolamo *et al.*, 2001; DiGirolamo *et al.*, 2008; Perrine *et al.*, 2012).

Studies' description and findings. Maternal rating of in-hospital breastfeeding support experience was positively associated with meeting prenatal-intended breastfeeding duration in the United States (Kuan *et al.*, 1999). In a sub-sample of women who received breastfeeding support at home from a visiting nurse, both the rating of breastfeeding support experience in the maternity ward and at home were associated with breastfeeding success (Kuan *et al.*, 1999). The US Infant Feeding Practices Study (IFPS I) found an inverse dose-response association between the number of BFHI steps that women were exposed to and the likelihood of stopping BF by 6 weeks pp (DiGirolamo *et al.*, 2001). Multivariate analyses also documented that, of the five BFHI steps women were asked to recall, initiating BF >1 h pp and in-hospital formula supplementation were the strongest risk factors for stopping BF by 6 weeks pp. A replication study conducted by the same group with IFPS II confirmed these findings with data collected 11 years later (DiGirolamo *et al.*, 2008). Another IFPS II analysis also found a dose-response relationship between exposure to the six BFHI steps as recalled by mothers and median BF duration (Nickel *et al.*, 2012). Lack of exposure to steps 6, 4 and 9 together or 8 and 9 together was associated with the greatest decrease in BF duration. Another US study examining the six BFHI practices recalled by participants in the IFPS II found that women whose infants were not provided with in-hospital formula supplementation were more likely to meet their prenatal EBF duration intention (Perrine *et al.*, 2012).

A prospective Italian study found that lack of exposure to steps 6 (in-hospital supplementation), 7 (rooming-in) or 8 (BF on demand) increased the odds of practising predominant breastfeeding (vs. EBF) in the maternity ward and that in-hospital predominant breastfeeding (vs. EBF) was associated with shorter FBF duration (Giovannini *et al.*, 2005). A German study found that women delivering in hospitals with a high (vs. low) breastfeeding promotion *Ten Steps* index were more likely to breastfeed at 4 months pp (Dulon *et al.*, 2003). A mailed questionnaire study conducted

in Colorado, USA, found that five out of nine breastfeeding practices examined (breastfeeding within 1 h pp, no infant feeding supplements, rooming-in, no pacifier and pp phone contact) were associated with an increased likelihood of breastfeeding at 8 weeks (Murray *et al.*, 2007). Women exposed to these five hospital practices had longer breastfeeding durations after adjusting for socio-economic status. Hong Kong women exposed to six of the *Ten Steps*, as documented in their hospital records, were three times more likely than those exposed to none or only one of the steps to breastfeed for more than 8 weeks pp after adjusting for confounders (Tarrant *et al.*, 2011). Multivariate analyses also showed that feeding only breast milk in the maternity ward and providing information on breastfeeding support after hospital discharge were the only steps that independently predicted longer breastfeeding duration. An Australian study with primiparous women found that breastfeeding on demand was the only practice, out of six, associated with increased breastfeeding duration (Pincombe *et al.*, 2008). *Summary of prospective evidence.* Consistent but limited evidence suggests that exposure to BFH step(s) is associated with improved BF outcomes. There is a dose-response synergistic association between the number of steps women recall being exposed to and improved BF outcomes. Findings support that even a partial implementation of steps (vs. all or none approach) improves breastfeeding outcomes. Consistent with one quasi-experimental study, four studies found lack of compliance with step 6 to be a risk factor for poor breastfeeding outcomes.

Cross-sectional/retrospective

Study quality. Twenty cross-sectional/retrospective studies were identified. Seven were conducted in Brazil, four in the United States and one each in Scotland, the UK, Russia, Puerto Rico, the Czech Republic, India, Nigeria, Switzerland and Taiwan. Eleven studies were classified as being of very low quality (Ojofeitimi *et al.*, 2000; Weng *et al.*, 2003; Bartington *et al.*, 2006; Vieira *et al.*, 2006; Rivera-Lugo *et al.*, 2007; Rosenberg *et al.*, 2008; Silva *et al.*, 2008; Dabritz *et al.*, 2009; Declercq *et al.*, 2009; Narchi *et al.*, 2009; Shilpa *et al.*, 2009), six of low quality (Helsing *et al.*, 2002; Venancio *et al.*, 2002; Broadfoot *et al.*, 2005; Merewood *et al.*,

2005; Mydlilova *et al.*, 2009; Sampaio *et al.*, 2011) and three of moderate quality (de Oliveira *et al.*, 2003; Merten *et al.*, 2005; Venancio *et al.*, 2012).

Studies' description and findings. A retrospective study that interviewed women at 9 months pp found that UK women delivering at BFH units were more likely to initiate breastfeeding but were not more likely to continue breastfeeding by 1 month pp (Bartington *et al.*, 2006). Consistent with RCT findings (Coutinho *et al.*, 2005a), this study suggested that step 10 was weak and would need to be strengthened to increase BF duration. A Scottish study that reviewed clinical screening records from 33 maternity wards found that the prevalence of breastfeeding at 7 days pp was higher among women delivering in hospitals certified as baby friendly vs. not certified (Broadfoot *et al.*, 2005). A retrospective study conducted in California, USA, found that among women with 6- to 8-month-old infants who had returned to work, 'almost' EBF at 6 months (defined as breast milk as the sole source of milk allowing for occasional intake of other water-based fluids) was positively associated with in-hospital EBF, and receipt of a phone number from staff for pp BF support, and inversely associated with receipt of hospital discharge packs (Dabritz *et al.*, 2009).

Brazilian mothers with <6-month-old infants attending Primary Health Care Units (PHCUs) with fair baby friendly performance, as determined by a 10-item baby friendly primary health care unit score, had higher EBF rates compared with their counterparts attending PHCUs with poor baby friendly performance (de Oliveira *et al.*, 2003).

Russian women delivering in a BFH had a higher likelihood of initiating breastfeeding earlier and a lower likelihood of the infant receiving infant formula supplements (Helsing *et al.*, 2002). A national retrospective phone and internet survey found that US women delivering in hospitals that followed six to seven steps (vs. none to one) were more likely to meet their late pregnancy EBF intentions (Declercq *et al.*, 2009). Among primiparae, the specific steps associated with meeting prenatal EBF intentions were as follows: help with breastfeeding initiation, no in-hospital formula/water supplementation, community resources and no pacifiers. Among multiparae, the corresponding steps were as follows: no in-hospital formula/water supplementation and breastfeeding on demand.

A study conducted in Puerto Rico found that maternal perception of compliance with the *Ten Steps* was positively associated with a higher likelihood of in-hospital FBF (vs. partial BF) (Rivera-Lugo *et al.*, 2007). A US study that reviewed medical records or birth certificate data from 28 hospitals that had received the BFHI accreditation in 2001 and had retained it by 2003 found that the in-hospital rates of BF initiation and EBF were higher compared with national data (Merewood *et al.*, 2005). A national Swiss cross-sectional study that interviewed women who had given birth within 9 months preceding the survey documented that delivering in a BFH was associated with longer EBF, FBF and ABF duration (Merten *et al.*, 2005). The steps associated with longer ABF duration in multivariate analyses were rooming-in, first BF within 1 h pp, BF on demand and no pacifier use.

A national cross-sectional chart review conducted in the Czech Republic found higher likelihood of EBF at the time of hospital discharge in BFH vs. non-BFH hospitals (Mydlilova *et al.*, 2009). A small retrospective cohort study from Brazil that recruited women who attended all breastfeeding education sessions offered at a primary health care centre found that EBF between 60 and 180 days pp was more likely among women that gave birth in BFH vs. non-BFH (Narchi *et al.*, 2009). In that study, rooming-in was associated with an increased likelihood of EBF. Giving birth in a BFH in Nigeria was associated with higher likelihood of having initiated breastfeeding within 30 min pp and of EBF at the time of the survey (Ojofeitimi *et al.*, 2000).

A cross-sectional review of metabolic screening forms conducted in Oregon, USA, among women delivering in 57 hospitals found that a higher (vs. lower) *Ten Steps* adherence score was associated with higher likelihood of BF at 2 days and 2 weeks pp (Rosenberg *et al.*, 2008). In this study, the only individual step associated with breastfeeding success was the hospital having a written breastfeeding policy. This step may be a proxy for better adherence to *Ten Steps* as strong collinearity was found among individual steps. A cross-sectional Brazilian study that interviewed women with infants <5-month-old attending five community centres found that those delivering in BFHs (vs. non-BFHs) had longer breastfeeding duration (Sampaio *et al.*,

2011). A very low quality retrospective study conducted in India found no differences in prelacteal feedings or EBF among women who gave birth in a BFH vs. in non-BFHs (Shilpa *et al.*, 2009).

A cross-sectional Brazilian study with mothers of infants <1-year old attending immunization clinics found that birth in a BFH was associated with a higher prevalence of EBF among infants <4 months and ABF among infants <1 year (Venancio *et al.*, 2002). Consistent with these findings, a more recent national immunization campaign Brazilian survey found that being born in a BFH was associated with timely breastfeeding initiation and longer EBF duration (Venancio *et al.*, 2012). A retrospective study conducted in Brazil also targeting women with infants <1-year old attending immunization clinics documented that women who delivered in BFHs were less likely to self report having had experienced mastitis (Vieira *et al.*, 2006). A study from Pelotas, Brazil, found that infants born in a BFH were more likely to be doing EBF at 1 month pp compared with their counterparts born in non-BFHs, although this association was only marginally significant (Silva *et al.*, 2008). Findings from a cross-sectional Taiwanese study indicate that women delivering in BFHs had higher rates of EBF and ABF both in the hospital and at 1 month pp (Weng *et al.*, 2003).

Cross-sectional/retrospective evidence conclusions. Consistent but limited quality evidence from 19 out of 20 cross-sectional/retrospective studies suggests that infants born in BFHs (vs. non BFHs) are more likely to be exclusively breastfed and to be breastfed for longer. Evidence from one medium quality study (de Oliveira *et al.*, 2003) suggests that Baby Friendly Primary Health Care Units are likely to increase the chances of EBF. Study findings were subsequently confirmed by an RCT in the same population (Coutinho *et al.*, 2005a).

United States results

Thirteen out of the 58 studies that met the inclusion criteria of this systematic review were conducted in the United States (Wright *et al.*, 1996; Kuan *et al.*, 1999; DiGirolamo *et al.*, 2001; Philipp *et al.*, 2001; Philipp *et al.*, 2003; Merewood *et al.*, 2005; Murray *et al.*, 2007; DiGirolamo *et al.*, 2008; Rosenberg *et al.*, 2008; Dabritz *et al.*, 2009; Declercq *et al.*, 2009; Nickel

et al., 2012; Perrine *et al.*, 2012). None of the studies were RCTs and thus none were classified as high quality (Table 4). Nevertheless all studies support the acceleration of the implementation of the Baby Friendly Initiative nationwide. No studies conducted in the United States examined the impact of BFHI on child health outcomes.

Conclusion

The global evidence consistently supports the conclusion that adherence to the BFHI *Ten Steps* has a positive impact on short-term, medium-term and longer-term BF outcomes across geographies. Of the 58 studies that met the systematic review criteria, 55 support this relationship, and none suggest a negative impact of BFHI on BF outcomes. The vast majority of the research identified and reviewed herein is observational in nature given the moral and ethical considerations inherent in randomly assigning infants to breastfeed or not. Per the study quality definitions then, most of the evidence could not be ranked as high quality. However, we found that the observational evidence fully supports the experimental (e.g. randomization to the Ten Steps) and quasi-experimental findings reviewed. Our findings are in full agreement with a previous review supporting the implementation of 'structured programmes' to improve breastfeeding initiation as well as duration of any BF and EBF (Beake *et al.*, 2012). The authors of that review defined a 'structured programme' as 'a multifaceted approach to support breastfeeding that targeted change at organizational, service delivery and individual behaviour levels, for example, implementation of the 10 steps of the BFHI' (Beake *et al.*, 2012).

Observational studies suggest that there is a dose-response relationship between the number of BFHI steps women are exposed to and the likelihood of improved BF outcomes. The high-quality PROBIT RCT conducted in Belarus also supports a positive impact of BFHI on some but not all infant and child health outcomes examined. Unfortunately, there were no additional moderate or high-quality studies examining these relationships. It is noteworthy that with the exception of one study examining the

association between BFHI and mastitis (Vieira *et al.*, 2006) and one study examining lactational amenorrhea (Valdes *et al.*, 1993), studies did not report maternal health outcomes.

All of the United States BFHI evidence comes from observational studies, the vast majority of which are of very low or low quality. Although there is consistent empirical evidence that BFHI has led to improvements in breastfeeding outcomes in the very short and short terms, its impact on BF outcomes in the long term remains unclear. Stronger study designs (e.g. RCTs and/or quasi-experimental with a baseline equivalent parallel reference group) need to be implemented in the United States to better understand the impact of the BFHI on BF and child health outcomes. The external validity of BFHI studies conducted abroad to the United States is indeed limited because of the major differences in social, cultural and regulatory environments that influence breastfeeding behaviours (Giovannini *et al.*, 2005; Perez-Escamilla, 2012; Perez-Escamilla & Chapman, 2012).

An important finding from this systematic review is that community support (step 10) appears to be key for long-term sustainability of the short-term breastfeeding gains obtained as a result of BFHI efforts focusing solely in maternity facilities. The PROBIT trial, for example, focused not only on the maternity hospitals but also on the polyclinics providing post-natal paediatric care. The RCT by Coutinho in Brazil (Coutinho *et al.*, 2005a) found that adequate implementation of step 10 (defined as home visits by peer counsellors) is needed for long-term impacts on ABF and EBF. Also in Brazil, De Oliveira *et al.* (2003) documented that greater adherence to Primary Health Care Unit Baby Friendly steps was associated with improved EBF and ABF rates during the first 6 months pp. Additional quasi-experimental and observational studies also provide indirect evidence in support of this finding (i.e. low ABF rates in the short term in the absence of a well-implemented step 10) (de Oliveira *et al.*, 2003; Silva *et al.*, 2008; Coutinho *et al.*, 2005b; Lutter *et al.*, 1997). The central importance of step 10 calls for increasing investments on structured programmes at the community level such as the Baby Friendly Primary Health Care initiative from Brazil (de Oliveira *et al.*, 2003) and the Supplemental Nutrition Program for Women,

Infants and Children (WIC) breastfeeding peer counselling programme in the United States [National Academies of Sciences, Engineering, and Medicine (2015)].

Findings from studies measuring degree of exposure to the *Ten Steps* are encouraging but need to be interpreted with caution because of possible maternal recall (e.g. successful BF women may be more likely to recall having received in-hospital BF support) or indication (women receiving help on BF may have been those experiencing BF difficulties) biases.

Even though this systematic review excluded studies focusing on a single BFHI step, several articles (Chien *et al.*, 2007; DiGirolamo *et al.*, 2001; DiGirolamo *et al.*, 2008; Giovannini *et al.*, 2005; Tarrant *et al.*, 2011; Zakarija-Grkovic *et al.*, 2012) reported that lack of adherence to step 6 (in-hospital supplementation) was a major risk factor for poor BF outcomes. However, it is not possible to conclude that step 6 regardless of how the remaining steps are implemented should be the sole focus of BF promotion and support in maternity wards. Step 6 is indeed likely to be a reflection of adequate implementation of steps 1 thru 9 because each of the *Ten Steps* is indeed highly interconnected with the others, structurally and physiologically, and the steps are statistically correlated with each other (Merewood *et al.*, 2005, UNICEF/WHO 2009, Wright *et al.*, 1996).

Breastfeeding is a behaviour that is influenced by a multitude of internal and external motivational factors. It is recommended that future research takes into account psychosocial constructs that can help to explain these motivational influences and simultaneously fill the knowledge void between intentions and behaviours in healthy lifestyles research (Perez-Escamilla, 2012; Perez-Escamilla & Chapman, 2012; Schwarzer, 2008; Venancio *et al.*, 2012).

A limitation of our review is that we were unable to compare the impact of partial vs. full implementation of the *Ten Steps*. We did not undertake this comparison because there was a high degree of variability in terms of which combinations of steps were implemented across studies and also because recall studies can only probe for those steps that mothers can be expected to remember (i.e. steps 3 thru 10) but not others [step 1 (written policy), step 2 (training of health facility staff)].

A second limitation of our systematic review is that it examined primiparous and multiparous women together, however, both groups of women have different BF protection, promotion and support needs. It was not possible to analyse the differential impact of BFHI based on parity as most studies included both groups of women and did not report the findings by parity. In spite of this limitation, our findings have strong policy implications for the general population of women and infants (see Key messages box). This review strongly supports additional investments in the expansion and financing of quality implementation of BFHI globally. Although there may be other structured approaches to protection, promotion and support of breastfeeding that may be as efficacious as the BFHI, the global political commitment to the BFHI makes it an obvious structured evidence-based approach to pursue.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Contributions

RPE was responsible for conception of study. RPE and JM designed the review strategy and conducted electronic searches. RPE and SSP extracted studies' data and assessed quality of studies. RPE drafted initial version of manuscript. All co-authors participated in manuscript preparation and critically reviewed all sections

of the text. Final approval of the version to be published was given by RPE and JM.

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