

Organizational factors that promote or inhibit the adoption and implementation of the
Baby Friendly Hospital Initiative in the United States

By

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To my family, Joe, Ned, and Delia

Thank you for believing in me when I didn't believe in myself

To my father, Jim Howe

I wish you could have seen me finish this

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TABLE OF CONTENTS

DEDICATION	iii
ACKNOWLEDGEMENTS	iv
LIST OF TABLES	vii
LIST OF FIGURES	viii
LIST OF ABBREVIATIONS.....	ix
Chapter	
1. Introduction and Background	1
Overview	1
Significance.....	1
Purpose of study and research questions.....	6
Theoretical framework: The Synthesized Model of Organizational Adoption and Implementation.....	6
Dissertation chapters	11
References	12
2. The Baby-Friendly Hospital Initiative as an Intervention to Improve Breastfeeding Outcomes: A Review of the Literature.....	17
Background	17
The BFHI.....	18
Methods.....	20
Description of the studies	55
Findings of the studies.....	59
Discussion	67
Conclusion.....	69
References	70
3. Development of a Survey to Identify Barriers and Facilitators to Implementing the Baby-Friendly Hospital Initiative.....	76
Background.....	76
Review of the Literature	79
Methods.....	87
Discussion.....	99
Conclusion	101
References.....	103

4.	Identifying the Key Barriers and Facilitators to the Adoption and Implementation of the Baby-Friendly Hospital Initiative	113
	Background	113
	Methods	115
	Results	117
	Discussion	131
	Conclusion	136
	References	137
5.	Conclusion and Implications for Research	144
	Meaning of findings in relation to research questions	144
	Significance in light of prior research findings	144
	Limitations	145
	Recommendations for future research	146
	Conclusion	149

LIST OF TABLES

Table	Page
Chapter 1	
1. The Ten Steps to Successful Breastfeeding	3
Chapter 2	
1. The Ten Steps to Successful Breastfeeding	19
2. Studies that Evaluated the Effect of the BFHI on Breastfeeding Initiation, Duration, and Exclusivity	22
Chapter 3	
1. Psychometric Evaluation of Instruments that Measure Implementation	82
2. Examples of Survey Sections and Items in Final Survey	94
Chapter 4	
1. Personal Characteristics of Respondents	118
2. Characteristics of Respondents' Hospitals.....	120
3. Factors that Influence Adoption of the BFHI	123
4. Factors that Influence Implementation of the BFHI.....	128

LIST OF FIGURES

Figure	Page
Chapter 1	
1. Synthesized Conceptual Model.....	7
2. Synthesized Conceptual Model with Areas of Interest for Current Study.....	10
Chapter 2	
1. Prisma Diagram for Search Method	55
2. Breastfeeding Outcomes in Included Studies	59
Chapter 3	
1. The Ten Steps to Successful Breastfeeding.....	77
2. Synthesized Conceptual Model with Areas of Interest for Current Study.....	87
3. Response Choices for the Initial Version of the Survey.....	91
Chapter 4	
1. Clinicians Perceived to be Most Supportive of the BFHI.....	126
2. Clinicians Perceived to be Least Supportive of the BFHI	126

CHAPTER 1

INTRODUCTION AND BACKGROUND

Overview

This doctoral research explores the organizational factors that influence the adoption and implementation of the Baby Friendly Hospital Initiative (BFHI) in the United States (US).

Although other researchers have conducted single-site studies describing the adoption and implementation experience, this project fills a gap in the literature by exploring the influencing factors with a multi-state, quantitative approach.

Significance

The importance of breastfeeding

Breastfeeding rates remain persistently low in the United States, despite a large body of evidence documenting the many benefits of breastfeeding to infants and mothers (US Department of Health and Human Services, 2014; US Department of Health and Human Services Office of Disease Prevention and Health Promotion). Infants who breastfeed for nine months have 30% lower odds of childhood obesity compared to infants who were never breastfed (Harder, Bergmann, Kallischnigg, & Plagemann, 2005). Additionally, breastfeeding has been shown to reduce the risk of otitis media, atopic dermatitis, gastroenteritis, severe lower respiratory tract infections, asthma, types 1 and 2 diabetes mellitus, childhood leukemia, sudden infant death syndrome and necrotizing enterocolitis (Ip et al., 2007). For mothers, the benefits include reducing the risk of breast and ovarian cancer (Ip et al., 2007).

Given the strength of the data, multiple public health and professional organizations have positions promoting breastfeeding. The American Academy of Pediatrics recommends exclusive breastfeeding for the first six months of life, with continued breastfeeding through at least the

first year of life (Gartner et al., 2005). The World Health Organization's (WHO) guidelines are similar, but recommend breastfeeding through two years of age (Kramer & Kakuma, 2002). The Surgeon General of the United States issued a Call to Action to Support Breastfeeding in 2011, which outlines the barriers to breastfeeding and gives specific guidelines to improve rates throughout the nation (U.S. Department of Health and Human Services, 2011).

In spite of this evidence and support, in 2013, 81.1% of American women breastfed in the early postpartum period, but by 3 months only 44.4% were breastfeeding exclusively, and at six months only 22.3% were breastfeeding exclusively (Centers for Disease Control and Prevention, 2016). Additionally, 17.1% of breastfed infants were supplemented with formula by two days of life (Centers for Disease Control and Prevention, 2016).

In an attempt to improve breastfeeding rates, WHO/UNICEF has developed a hospital-based program called the Baby Friendly Hospital Initiative (BFHI) (World Health Organization & UNICEF, 2009). The BFHI has developed guidelines, called the Ten Steps. All Steps must be met in order for hospitals to qualify for Baby-Friendly Hospital status. The Ten Steps are grounded in evidence and have been shown to improve both short-term and long-term breastfeeding rates (Murray, Ricketts, & Dellaport, 2007). However, in the United States there are only 460 Baby-Friendly hospitals, less than 1% of the hospitals certified globally (Baby-Friendly USA, 2017). Currently, only 22.1% of infants born in the United States are born in Baby-Friendly facilities (Baby-Friendly USA, 2017). This means that more than 77 % of infants born in the United States are not guaranteed the opportunity to be born in an environment that could optimize their chances of being breastfed, a known mechanism to improve their overall health. The same is true for women who may not receive the level of support needed to encourage breastfeeding and therefore miss the health benefits for themselves, as well.

The value of the Baby Friendly Hospital Initiative

An intervention that has demonstrated a statistically significant influence on breastfeeding rates both in the US and internationally is the BFHI (Carvalho, Boccolini, Oliveira, & Leal, 2016; Hawkins, Stern, Baum, & Gillman, 2014; Kramer et al., 2001; Merewood, Mehta, Chamberlain, Philipp, & Bauchner, 2005; Merten, Dratva, & Ackermann-Liebrich, 2005; Philipp et al., 2001; Renfrew, McCormick, Wade, Quinn, & Dowswell, 2012). The BFHI is a program through which hospitals adopt a package of ten interventions that have each been shown to improve rates of breastfeeding initiation, duration and exclusivity. This package, known as The Ten Steps, requires hospitals to implement the following policies:

Table 1. The Ten Steps to Successful Breastfeeding

The Ten Steps to Successful Breastfeeding (Baby-Friendly Hospital Initiative in the US, 2012)
1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within one hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they are 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 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

When all Ten Steps are implemented, hospitals may become certified as Baby Friendly, a designation that provides recognition to a hospital and that is publicly available to consumers and policy makers. The BFHI is supported by Healthy People 2020, the Surgeon General and

endorsed by the American Academy of Pediatrics ("Breastfeeding and the use of human milk," 2012; U.S. Department of Health and Human Services, 2011; US Department of Health and Human Services, 2014)

The BFHI has been studied extensively both in the US and internationally. Research has focused on a variety of outcomes, including initiation, short-term duration, long-term duration and exclusive breastfeeding. A detailed review of the literature regarding the effectiveness of the BFHI follows in Chapter 2, but overall, the body of literature indicates that the BFHI does positively influence breastfeeding outcomes. Despite the effectiveness of the intervention, implementation of the BFHI in the US lags far behind the rest of the world (Baby-Friendly Hospital Initiative in the US, 2012).

The role of implementation science

Implementation research seeks to address the lack of routine translation of research findings into clinical practice through the scientific study of the methods to promote uptake of clinical treatments, practices, and organizational interventions to improve health outcomes (Editorial Board). Implementation science includes the study of the influence of research on patient outcomes, healthcare professional behaviors, and organizational change in the healthcare setting (Editorial Board). In the context of this study, implementation will refer to the accreditation process to become a Baby-Friendly Hospital. Full BFHI accreditation will be considered equivalent to full implementation.

The reasons for the lack of implementation of the BFHI remain elusive. The Ten Steps require organizations to change their policies and practices, but it is likely that some of these changes are more difficult than others. Organizational change and the implementation of new research are complicated processes. But through improved understanding of the implementation

process and its barriers and facilitators, future interventions can be developed to support this implementation process and increase use of the BFHI.

A majority of the published studies to date on implementation of the BFHI have been qualitative case studies or have used before-after designs (Bartick, Edwards, Walker, & Jenkins, 2010; Crivelli-Kovach & Chung, 2011; Daniels & Jackson, 2011; Hannon, Ehlert-Abler, Aberman, Williams, & Carlos, 1999; Hofvander, 2005; Lundeen, Sorensen, Bland, George, & Snyder, 2016; McKeever & Fleur, 2012; Merewood & Philipp, 2001; Sadacharan et al., 2012; Schmied, Gribble, Sheehan, Taylor, & Dykes, 2011; Tran, 2017; Vasquez & Berg, 2012; Ward, Williamson, Burke, Crawford-Hemphill, & Thompson, 2017; Weddig, Baker, & Auld, 2011; Wieczorek, Marent, Dorner, & Dur, 2016; Wright, Rice, & Wells, 1996; Zakarija-Grkovic et al., 2012). While this work provides a useful basis for the understanding of the barriers and facilitators of the implementation process, the results are, by their nature, not generalizable. Factors that have been identified as facilitators to implementation at the organizational level include: leadership, organizational culture, human and financial resources, audit and feedback mechanisms, breastfeeding policies and breastfeeding training (Semenic, Childerhose, Lauziere, & Groleau, 2012). Other work has highlighted barriers to implementation at the individual level or at the social-political level (Semenic et al., 2012). The list of potential barriers and facilitators is vast. But a long list of factors that may influence implementation does not provide a framework for the development of interventions to enhance the process. No hierarchy has been created that could identify the most significant factors influencing implementation of the program. In addition, a significant number of studies have been conducted outside the United States (Daniels & Jackson, 2011; Garcia-de-Leon-Gonzalez et al., 2011; Hofvander, 2005; Kramer et al., 2001; Merten, Dratva, & Ackermann-Liebrich, 2005; Schmied, Gribble, Sheehan,

Taylor, & Dykes, 2011; Weng, Hsu, Gau, Chen, & Li, 2003; Zakarija-Grkovic et al., 2012).

The unique qualities of the US healthcare system pose specific challenges to implementation that merit special attention. Therefore, a quantitative descriptive study that highlights the key factors in the implementation process in the US can lay the groundwork for future interventions and prioritize the needs of institutions.

Purpose of Study and Research Questions

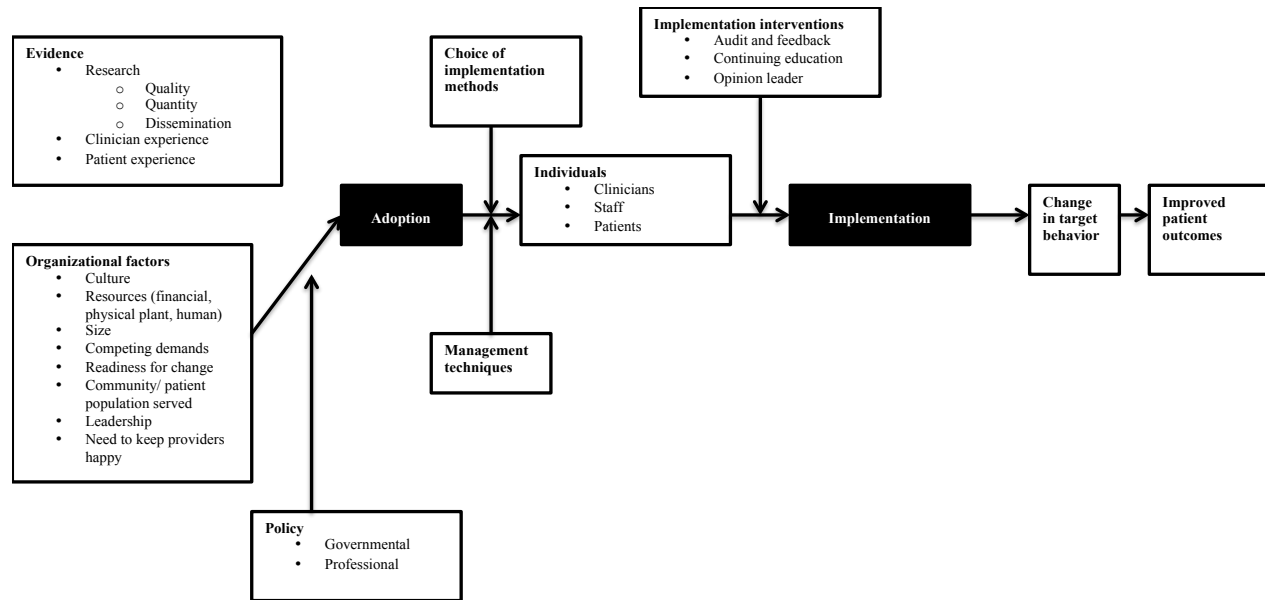
In light of this weak record of implementation, a descriptive study to explore the factors that facilitate or act as barriers to the implementation of the BFHI in the US was conducted. This study focused on answering the following specific questions:

- 1. What are the organizational factors that promote the successful implementation of the Baby Friendly Hospital Initiative in the United States?*
- 2. What are the organizational factors that inhibit the successful implementation of the Baby Friendly Hospital Initiative in the United States?*

Theoretical Framework: The Synthesized Model of Organizational Adoption and Implementation

This synthesized model (Figure 1) was developed from many sources, but relies most heavily on the work of Damschroder et al. (2009) and the CFIR meta-theory in conjunction with the systematic review of barriers and facilitators to implementation presented by Flottorp et al. (2013). However, neither of these prior works attempt to explain the relationship that each of these concepts has with one another, nor do they identify predictor variables, moderating variables, or dependent variables.

Figure 1. Synthesized Conceptual Model



In this synthesized model, two predictor variables are the starting point for the adoption process. The evidence itself, is one predictor variable. Evidence is defined as research, patient experience, and clinician experience. This definition is in line with the definitions employed by a number of implementation scientists (Rycroft-Malone et al., 2004; Titler, 2008) and incorporates the value of high quality research with the professional experiences of the clinician and the lived experiences of the patient. Additionally, the model accounts for the idea that research quantity plays an important part in the adoption process, as one study rarely leads to changes in practice, but usually requires a critical mass of research support before practices change (Puddy & Wilkins, 2011). Dissemination is a modifying variable for the adoption of evidence, as it influences clinicians' and administrators' knowledge of the evidence. Without effective dissemination techniques, research findings will remain in journals and not adopted and

implemented into clinical practice.

The second predictor variable in the model is the concept of the organization and the factors at play in the internal setting. Factors that influence an organization's ability and willingness to adopt an innovation include both environmental factors and resource factors. These include the context and climate, the culture and readiness for change, leadership styles, evaluation methods used in the organization, professional interactions, the size, resources, competing demands, information system, continuing education system, and support for clinicians. If an organization's setting is not amenable to change for one or more of the listed reasons, adoption will not occur. This makes the organization one of the two key predictor variables within this framework.

The influence of external factors is a moderating variable that influences the organization's interest in and ability to adopt a new policy. If legislative policy requires that a new program or practice be adopted, or malpractice cases in the area have inhibited changes in practice, then the organization may be more or less willing to adopt the program. External factors include: economic constraints on the total healthcare budget or its growth, contracts, legislation, payer or funder policies, malpractice liability, influential people, corruption, and political stability (Flottorp et al., 2013)

Adoption in the model is defined as the decision to pursue a new program or practice. The opposite of adoption is rejection (Rogers, 2003) and will occur if the strength of a barrier to adoption is greater than the facilitating factors. Once the decision to adopt an innovation has been made, the organization moves into the implementation phase of the model. It is an intermediate outcome, or dependent variable in the model. If adoption is not achieved, the process has ended.

At this phase in the process, the organization begins to shape the way the program will be implemented through its management techniques, a moderating variable. Management techniques include: leadership, planning, engaging, executing, reflecting, evaluating, capacity-building, coaching, creating implementation teams, recruiting staff, building capacity, communicating the vision, eliminating obstacles (Flottorp et al., 2013; Kotter, 1995; Lutenbacher, 2009; Meyers, Durlak, & Wandersman, 2012; Rycroft-Malone, 2004). The success or failure of the implementation phase will be greatly influenced by the effects of these techniques and their reception by the individuals in the next phase.

Once the program or practice has been adopted and introduced within the organization, individuals are tasked with the work of making the change in practice take hold. Clinicians and staff have the primary responsibility for implementing the program or practice and their individual characteristics are a predictor variable for success of the implementation process. Clinician characteristics are comprised of knowledge, attitudes, autonomy of practice, and professional training (Flottorp et al., 2013; Likis, 2006). In addition to the characteristics of the clinician, patients are important individuals in the implementation process. If they decline the new program or practice, then implementation will cease. Patient characteristics include: needs, knowledge, attitudes, and cultural beliefs (Flottorp et al., 2013; Likis, 2006; Minnick, Roberts, Young, Kleinpell, & Marcantonio, 1997).

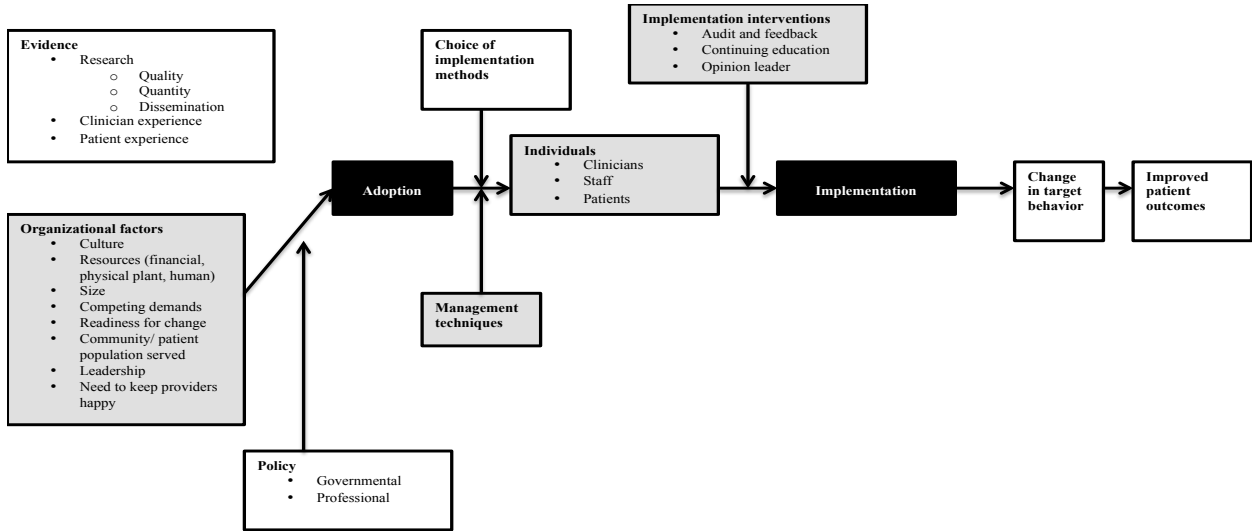
The type of implementation intervention is the final moderating variable in the model. A variety of methods exist to facilitate implementation, most relying on some form of evaluation, such as audit and feedback (Chou, Vaughn, McCoy, & Doebbeling, 2011; Meyers et al., 2012; Rycroft-Malone, 2004). Other interventions are the use educational methods to facilitate implementation, or the use of an opinion leader (Chaillet et al., 2006; Rogers, 2003). The

selection of the type of implementation intervention can have a significant impact on the success of implementation efforts.

The model concludes with two levels of outcomes, an intermediate outcome, defined as a change in the target behavior, and a terminal outcome, improved patient outcomes. This framework presents the process from research finding to improved patient outcomes and attempts to fill the gaps in frameworks in the body of published literature on the topic. By considering factors that determine how and why evidence is adopted, along with organizational and external influences on adoption, the model helps to define the initial barriers and facilitators to adoption. The relationship between adoption and implementation is also defined, as are the influences of management techniques, individuals within the organization, and implementation techniques. Ultimately, the model requires that implementation outcomes and patient outcomes be considered, as both are necessary for success.

While the model could likely be applied to many healthcare settings, the focus of this study was the BFHI. In addition, this study focused primarily on the organizational factors and their influence on the adoption and implementation processes as demonstrated in Figure 2. The modified model highlights the areas of interest for the proposed study, as highlighted in grey

Figure 2 Synthesized Conceptual Model with areas of interest for the current study highlighted



Dissertation Chapters

This project was conducted in three steps: a review of the literature regarding the effectiveness of the BFHI, the development of a survey tool to identify the barriers and facilitators using the e-Delphi method, and the collection and analysis of the data collected from 256 perinatal professionals. Each step built on the one before it; taken as whole, the chapters provide a broad review of the BFHI and its place in perinatal care in the US. Chapters Two-Four represent three separate manuscripts that have been published or are currently under review. The final chapter summarizes this work and lays the framework for next steps and further research.

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CHAPTER 2

THE BABY-FRIENDLY HOSPITAL INITIATIVE AS AN INTERVENTION TO IMPROVE BREASTFEEDING RATES: A REVIEW OF THE LITERATURE

This chapter describes a review of the literature regarding the effectiveness of the BFHI to improve the rates of breastfeeding initiation, duration, and exclusivity. The results of this investigation led to identification of gaps in the literature and recommendations for further study on this important public policy initiative. The content below was published in *The Journal of Midwifery and Women's Health*, 61:1, January/February 2016, pp 77-102 (Howe-Heyman & Lutenbacher, 2016) and is republished with permission.

Background

Breastfeeding rates remain persistently low in the United States, despite a large body of evidence documenting the many benefits of breastfeeding for both infants and women (US Department of Health and Human Services, 2014). Infants who breastfeed for 9 months or more have 30% lower odds of childhood obesity compared to infants who were never breastfed (Harder, Bergmann, Kallischnigg, & Plagemann, 2005). Breastfeeding has been associated with a decreased risk of otitis media, atopic dermatitis, gastroenteritis, severe lower respiratory tract infections, asthma, types 1 and 2 diabetes mellitus, childhood leukemia, sudden infant death syndrome and necrotizing enterocolitis (Ip et al., 2007). For breastfeeding women, the benefits include a reduction in the risk of breast and ovarian cancer (Ip et al., 2007).

However, in 2011, although 79.2% of women in the United States breastfed in the early postpartum period, only 40.7% were breastfeeding exclusively by 3 months, and at 6 months the rate of exclusive breastfeeding decreased to 18.8% (Centers for Disease Control, 2014a). By 2 days of life, 19.4% of breastfed infants received supplemental formula (Centers for Disease

Control, 2014a). In comparison, the Healthy People 2020 goal is that 81.9% of infants should be breastfed at least once, 60.6% should be breastfed for 6 months, and 34.1% should be breastfed for one year. The goals for breastfeeding exclusivity are 46.2% at 3 months, and 25.5% at 6 months; the goal for the maximum number of infants who receive supplementation within the first 2 days of life is 14.2%.

The Baby Friendly Hospital Initiative (BFHI) has been widely promoted as an intervention that improves breastfeeding rates. This article reviews the research that has evaluated the effectiveness of the BFHI as an intervention to improve breastfeeding initiation, duration and exclusivity.

The BFHI

The BFHI is a quality improvement program designed by World Health Organization/ United Nations International Emergency Children's Fund (WHO/UNICEF) and is intended to improve breastfeeding initiation, duration, and exclusivity. The program provides certification to institutions meeting the Ten Steps (Table 1), as evaluated by a panel of outside observers (Baby-Friendly USA, 2010). Since the launch of the program in 1991, more than 20,000 hospitals have been certified as Baby-Friendly world-wide (Baby Friendly USA, 2014a). In the United States, of the 3281 facilities that provide maternity care, 203 are certified as Baby-Friendly. Only 8.4% of infants born in the United States are born in Baby-Friendly facilities (Baby-Friendly USA, 2014).

Table 1: The Ten Steps to Successful Breastfeeding
1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within one hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they are 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 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

Source: World Health Organization, Unicef.

WHO/UNICEF states that the benefits of the BFHI are improved health outcomes for women and infants and increased maternal-infant bonding (Baby Friendly USA, 2014c). According to Baby Friendly USA, which is the certifying organization for the BFHI in the United States, the intended benefits to hospitals are: the delivery of patient-centered care, improved maternal-child health outcomes, improved patient satisfaction, elevated reputation and standards of the facility, development of a professional environment of competence, strengthening of leadership and teamwork skills, improved hospital scores on the national *Maternity Practices in Infant Nutrition and Care (m-PINC)* survey conducted by the Centers for Disease Control and Prevention (CDC), compliance with Joint Commission maternity care standards and corporate compliance requirements, and achievement of Healthy People 2020 goals (Baby Friendly USA, 2014b). There are no reports in the literature that document BFHI-certified hospitals have accrued these benefits.

A majority of the literature regarding the BFHI has focused on the implementation of this program. Fewer studies have evaluated the influence of the program on breastfeeding outcomes, namely breastfeeding initiation, duration, and exclusivity. Thus, the purpose of this review is to critique the literature and synthesize findings to determine the effectiveness of the BFHI as an intervention to improve breastfeeding initiation, duration, and exclusivity.

Methods

A search using the electronic databases MEDLINE, CINAHL, PsycINFO and Web of Science for the years 1991 (when the BFHI started) to October, 2014 was conducted in late 2014 using the PRISMA guidelines for literature collection. The search term was *Baby-Friendly Hospital Initiative*. This search returned 724 titles. Titles were screened according to the predetermined inclusion criteria that articles had to appear in English, include primary research, and be available electronically or via interlibrary loan. PubMed currently catalogs articles published back to 1947. Thus, we were able to include articles that were not originally published electronically in 1991. Published and grey literature were included. Grey literature refers to literature not published in an academic journal (eg, poster presentations at conferences, graduate research housed in academic libraries). By using grey literature, publication bias can be reduced (Rothstein & Hopewell, 2009).

Studies were excluded if they explicitly stated that they had omitted specific portions of the BFHI or did not fully implement the intervention; breastfeeding, rather than the BFHI, was used as an intervention to improve infant or maternal outcomes; the BFHI was used to improve NICU outcomes; or the study measured different outcomes than breastfeeding initiation, duration, or exclusivity.

After identification of the appropriate articles, each was reviewed for BFHI definition

adherence, design, methods, results, and limitations. When considering the outcomes measured, only breastfeeding initiation, duration, and exclusivity were evaluated. The length of time measured for breastfeeding duration and exclusivity was noted. Methods were categorized by the type of data collection employed such as interview, questionnaire, medical record review, observation, or a standardized tool. The source of the breastfeeding data was also noted in the review and included mother, health care provider, infants' medical records, or national data sets. The timing of the data collection in each study was noted, as some authors collected data one time, while others collected data over multiple encounters. All of these categories were organized and are presented in Table 2.

Table 2.

Studies that Evaluated the Effect of the Baby-Friendly Hospital Initiative on Breastfeeding Initiation, Duration, and Exclusivity

Author (Date of Publication), Setting	N	Design	Outcome Measured	Data Collection: Method ^a (Source ^b) Timing	Findings	Do results support the BFHI? ^c	Study Limitations
Abrahams and Labbok (2009), 14 developing nations	National data from Demographic and Health Surveys from 1986-2006. Data was collected from the 14 countries that could provide data regarding breastfeeding rates in 2 surveys prior to BFHI implementation and 2 surveys after BFHI implementation.	Retrospective cohort	Exclusivity (2 months, 6 months)	I (ND) 2 months postpartum 6 months postpartum	No statistically significant difference in trends of exclusive breastfeeding rates before and after implementation of the BFHI.	Initiation: N/M Duration: N/M Exclusivity: No (LT)	International setting limits generalizability to the United States.
Alam et al. (2002) Bangladesh	209	Prospective longitudinal	Exclusivity (30, 150,	I (M) In-hospital	Mean duration of exclusive	Initiation: N/M	International setting limits

					<p>among women who gave birth at a Baby-Friendly hospital vs. 48.4 days among women who gave birth at a non- Baby-Friendly hospital ($P < .001$).</p> <p>Exclusive breastfeeding rate at 30 days was 82% among women giving birth at BFHI hospitals vs. 50% among women giving birth at non-BFHI hospitals (no P value reported).</p> <p>Exclusive breastfeeding rate at 150 days was 16% among women giving birth at BFHI hospitals vs. 6% among</p>	<p>Exclusivity: Yes (LT)</p>	<p>States.</p> <p>No P values reported for many statistics inhibits the ability to interpret the statistical significance of the findings.</p>
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					women giving birth at non-BFHI hospitals (no <i>P</i> value reported). Exclusive breastfeeding rate at > 150 days was 8% among women giving birth at BFHI hospitals vs. 6% among women giving birth at non-BFHI hospitals (no <i>P</i> value reported).		
Bartington et al. (2006), United Kingdom	17,359	Retrospective cohort	Initiation Exclusivity (1 month)	I (M) 9 months pp	Women who gave birth in a BFHI accredited hospital were 10% (95% CI, 1.05-1.15) more likely to initiate breastfeeding than those who gave birth in a non-certified hospital. No statistically	Initiation: Yes Duration: No (ST) Exclusivity: N/M	International setting limits generalizability to the United States.

					significant difference in the likelihood of any breastfeeding at one month between women giving birth at a BFHI-certified hospital and those giving birth at a non-BFHI hospital (aOR, 0.96; 95% CI, 0.84-1.09).		
Bosnjak et al. (2004), Croatia	7414	Retrospective cohort	Duration (1,3,6,9,12 months)	MR (I) 1,3,6, 9, 12 months pp	No statistically significant difference in 1 and 3 month breastfeeding rates between infants born at the same institution before and after Baby-Friendly certification. Breastfeeding rates increased at 6 months	Initiation: N/M Duration: No at 1 (ST) and 3 months, Yes at 6, 9, 12 months (LT) Exclusivity: N/M	International setting limits generalizability to the United States.

					(from 11.46% to 28.36%), 9 months (from 6.14% to 14.71%), and 12 months (from 2.24% to 3.48%) between infants born at the same institution before and after Baby-Friendly certification ($P < .05$).		
Braun et al. (2003), Brazil	437	Before-after	Duration (4 months) Exclusivity (1 month)	I (M) In-hospital 1, 2, 4, 6 months pp	Women who gave birth at a BFHI hospital were 45% more likely to breastfeed at 4 months than those who gave birth at non-BFHI hospital (Cox hazard ratio 1.55; 95% CI, 1.16-2.07). Women who gave birth at a BFHI hospital	Initiation: N/M Duration: Yes (LT) Exclusivity: Yes (ST)	International setting limits generalizability to the United States. Use of one hospital is a source of possible selection bias. Before-after design limits causal inference.

					were 33% more likely to exclusively breastfeed at 1 month than those who gave birth at non-BFHI hospital (Cox hazard ratio, 1.66; 95% CI, 1.40-1.98).		
Broadfoot et al. (2005), Scotland	464,246	Cross-sectional	Duration (7 days)	MR (I) 6-7 days of life	Breastfeeding at 7 days was higher among women who gave birth at a certified hospital than at a non-certified hospital (49.4% vs. 42.0%). aOR for breastfeeding at 7 days: 1.28 (95% CI, 1.24-1.31).	Initiation: N/M Duration: Yes (ST) Exclusivity: N/M	International setting limits generalizability to the United States. Cross-sectional design limits causal inference. Measurement of breastfeeding outcomes at 6-7 days of life provides limited information about breastfeeding

							outcomes.
Brodribb et al. (2013), Australia	6752	Retrospective cohort	Initiation Duration (1, 4 months) Exclusivity (1, 4 months)	Q (M) 4 months pp	Breastfeeding initiation rates did not differ between women giving birth in Baby-Friendly and non-Baby-Friendly hospitals. Women who gave birth in a Baby-Friendly hospital had statistically significantly lower odds of breastfeeding at 1 and 4 months [OR of breastfeeding at one month, 0.74; 95% CI, 0.63-0.88; OR of breastfeeding at 4 months, 0.81; 95% CI, 0.72-0.92]. After adjusting for significant univariate	Initiation: No Duration: No (BFHI had a negative association with duration) (ST and LT) Exclusivity: No (ST and LT)	International setting limits generalizability to the United States.

					<p>variables, women who gave birth in a BFHI hospital continued to have lower odds of breastfeeding at one month [aOR, 0.72; 95% CI, 0.58-0.90], but there was no difference in the odds of breastfeeding at 4 months [aOR, 0.90; 95% CI, 0.76-1.07].</p> <p>Women who gave birth in a Baby-Friendly hospital had statistically significantly higher odds of exclusively breastfeeding at 1 month, though there was no difference</p>		
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					<p>between the groups at 4 months [OR of exclusive breastfeeding at one month, 1.26; 95% CI, 1.11-1.42; OR of breastfeeding at 4 months, 0.99; 95% CI, 0.87-1.12]. After adjusting for significant univariate variables, there was no difference in 1 month or 4-month exclusive breastfeeding rates [aOR for 1 month exclusivity, 1.14; 95% CI, 0.97-1.34; aOR for 4 month exclusivity, 1.17; 95% CI, 0.99-1.38].</p>		
Budin et al.	113	Non-	Duration	Q (M)	88% of women	Initiation:	Small sample

(2010), United States		comparative descriptive design	(2-3 weeks) Exclusivity (2-3 weeks)	2-3 weeks pp	were breastfeeding at 2-3 weeks after discharge. 60% of women were exclusively breastfeeding at 2-3 weeks after discharge.	N/M Duration: Unclear (ST) Exclusivity: Unclear (ST) (In the absence of a comparator, the results are not interpretable as being related to the BFHI)	size at one hospital limits causal inference. Lack of comparator limits the ability to interpret the study's findings.
Caldeira and Goncalves (2007), Brazil	2128	Before-after	Duration (median) Exclusivity (median)	I (M) Up to 2 yrs pp	Breastfeeding duration increased from 8.9 months pre-intervention to 11.6 months post-intervention ($P < .001$). Exclusive breastfeeding duration increased from 27 days pre-intervention to 3.5 months	Initiation: N/M Duration: Yes (LT) Exclusivity: Yes (LT)	International setting limits generalizability to the United States. Before-after design limits causal inference. Sample included 3 hospitals in one region of Brazil with no information

					post-intervention ($P < .001$).		regarding their selection criteria or other hospitals in the region. Possible selection bias.
DeJong and Lynne (2012), United States	842	Cross-sectional	Duration (3 months)	Q (M) 3 months pp	No statistically significant difference in 3-month breastfeeding rates between women who gave birth at a BFHI hospital and those who gave birth at a hospital with a mature breastfeeding program.	Initiation: N/M Duration: No (LT) Exclusivity: N/M	Convenience sample: possible selection bias.
DiGirolamo, Grummer-Strawn, and Fein (2008), ^d United States	1085	Longitudinal time series	Duration (6 weeks)	Q (M) "neonatal" period 2 months pp	Women who experienced no Baby-Friendly practices at the time of delivery were more likely to terminate breastfeeding early than women who	Initiation: N/M Duration: Yes (LT) Exclusivity: N/M	Data collection method of surveying postpartum women allowed for collection of data regarding only 5 of the 10 steps.

					experienced 5 Baby-Friendly practices (32.1% early termination vs. 5.1% early termination).		
Duyan Camurdan et al. (2007), Turkey	555	Before-after	Duration (2, 4, 6 months) Exclusivity (15 days)	I (M) 15 days 2, 4, 6, 9, 12, 18, 24 months pp	There was a statistically significant increase in cumulative breastfeeding rates (breastfeeding duration) between the before-BFHI and after-BFHI groups from a mean of 17.83 ± 0.6 months to 21.17 ± 0.42 months ($P=.0036$) The difference in 15-day exclusive breastfeeding rates at pre and post intervention was not	Initiation: N/M Duration: Yes (LT) Exclusivity: No (ST and LT)	International setting limits generalizability to the United States. The use of one hospital for data collection is a possible source of selection bias. Before-after design limits causal inference.

					<p>statistically significant (93.1% vs. 97.4%, $P > .05$).</p> <p>The difference in 2-month exclusive breastfeeding rates at pre and post intervention was not statistically significant (67.2% vs. 76.1%, $P > .05$).</p> <p>The difference in 4 month exclusive breastfeeding rates at pre and post intervention was not statistically significant (45.6% vs. 53.7%, $P > .05$).</p> <p>The difference in 6-month</p>		
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					<p>exclusive breastfeeding rates at pre and post intervention was not statistically significant (9.8% vs. 9.3%, $P > .05$). The difference in 15 day exclusive breastfeeding rates at pre and post intervention was not statistically significant (93.1% vs. 97.4%, $P > .05$).</p>		
Figueredo et al. (2013), Brazil	261	Cross-sectional study with no control group	Exclusivity (1 week, 1 month, 2 months, 3 months, 4 months, 5 months, 6 months)	Q (M) 1 week I (M) 2 months, 3 months, 4 months, 5 months, 6 months	<p>99% exclusive breastfeeding rate at discharge. 92% exclusive breastfeeding rate at one week. 75% exclusive breastfeeding</p>	<p>Initiation: N/M Duration: N/M Exclusivity: Unclear (ST and LT) (In the absence of a comparator,</p>	<p>International setting limits generalizability to the United States. Use of one hospital is a source of possible</p>

					<p>rate at one month. 67% exclusive breastfeeding rate at 2 months. 52% exclusive breastfeeding rate at 3 months. 33% exclusive breastfeeding rate at 4 months. 20% exclusive breastfeeding rate at 5 months. 6% exclusive breastfeeding rate at 6 months.</p>	<p>the results are not interpretable as being related to the BFHI)</p>	<p>selection bias. Descriptive, non-comparative design limits causal inference.</p>
Garcia-de-Leon-Gonzalez et al. (2011), Spain	1273	Time series	Initiation	Q, MR (P) Hospital discharge, 1 month pp, 2 months pp, 3 months pp, 5 months pp,	Women who gave birth post intervention were 20% more likely to breastfeed at the time of discharge than those who gave birth pre-intervention	<p>Initiation: Yes Duration: Yes (ST and LT) Exclusivity: N/M</p>	<p>International setting limits generalizability to the United States. The use of one hospital for data collection is a possible source of</p>

				7 months pp	<p>(95% CI, 0.12-0.33). Women who gave birth post intervention were 55% more likely to breastfeed at 1 month postpartum than those who gave birth pre-intervention (95% CI, 0.38-0.79). Women who gave birth post intervention were 43% more likely to breastfeed at 2 months postpartum than those who gave birth pre-intervention (95% CI, 0.31-0.6). Women who gave birth post intervention were 29% more likely to</p>		selection bias.
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					<p>breastfeed at 3 months postpartum than those who gave birth pre-intervention (95% CI, 0.21-0.4). Women who gave birth post intervention were 22% more likely to breastfeed at 5 months postpartum than those who gave birth pre-intervention (95% CI, 0.16-0.3). Women who gave birth post intervention were 14% more likely to breastfeed at 7 months postpartum than those who gave birth pre-intervention (95% CI, 0.09-</p>		
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					0.2).		
Hawkins et al. (2014), United States	25,327	Longitudinal matched cohort	Initiation Duration (4 weeks) Exclusivity (4 weeks)	Q- PRAMS (M) 4 months pp	No differences in breastfeeding initiation rates among women giving birth in BFHI institutions and non-BFHI institutions (adjusted coefficient, 0.024; 95% CI, 0.0-0.52). Breastfeeding initiation rates did increase by 3.8% among women with lower education who gave birth at a BFHI institution (adjusted coefficient, 0.038; 95% CI, 0.0-0.8), but not among women with higher education	Initiation: No (Yes for women with lower education) Duration: No (ST) Exclusivity: No (Yes for women with lower education) (ST)	States selected based on their participation in PRAMS and their ability to identify hospitals' BFHI status. Possible selection bias.

					<p>(adjusted coefficient, 0.002; 95% CI, -0.04 to 0.05). No differences in 4-week breastfeeding rates among women giving birth in BFHI institutions and non-BFHI institutions (adjusted coefficient, 0.006; 95% CI, -0.01 to 0.03. No difference in 4 week breastfeeding rates among women with lower education levels (adjusted coefficient, 0.027; 95% CI, -0.02 to 0.07). No difference in 4-month exclusivity rates among women giving</p>		
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					<p>birth in BFHI institutions and non-BFHI institutions (adjusted coefficient, 0.012; 95% CI, -0.01 to 0.03). 4-week exclusivity rates did increase by 4.5% among women with lower education who gave birth at a BFHI institution (adjusted coefficient, 0.045; 95% CI, 0.01-0.08), but not among women with higher education (adjusted coefficient, -0.023; 95% CI, -0.05 to 0.01).</p>		
Hofvander (2005), Sweden	National level statistics- no N	Time series	Duration (4, 6	MR (ND) Timing not	4-month duration rates	Initiation: N/M	International setting limits

	provided. All hospitals in Sweden became BFHI-certified between 1993-1996, so national breastfeeding rates are compared before, during, and after this time period.		months) Exclusivity (1 week)	provided.	were higher post intervention than pre-intervention (83.2% vs. 67.9%). 6 month duration rates were higher post intervention than pre-intervention (72.2% vs. 50.7%). 1 week exclusive breast feeding rates were minimally higher post-intervention than pre-intervention (92.6% vs. 91.6%).	Duration: Yes (LT) Exclusivity: Yes (ST)	generalizability to the United States.
Kramer et al. (2001), Belarus	17,046	Cluster randomized control trial	Duration (3, 6, 9, 12 months) Exclusivity (3, 6	I, MR (M, I) 1, 2, 3, 6, 9, 12 months pp	3-month breastfeeding rates were higher for women who gave birth at	Initiation: N/M Duration: Yes (LT) Exclusivity: Yes (LT)	International setting limits generalizability to the United States.

			months)		<p>BFHI certified hospitals than for those who gave birth at control hospitals (72.7% vs. 60%; aOR, 0.52; 95% CI, 0.40-0.69). 6-month breastfeeding rates were higher for women who gave birth at BFHI certified hospitals than for those who gave birth at control hospitals (49.8% vs. 36.1%; aOR, 0.52; 95% CI, 0.39-0.71). 9-month breastfeeding rates were higher for women who gave birth at BFHI certified</p>		<p>Only women who intended to breastfeed were eligible for enrollment. Possible selection bias.</p> <p>1-week inpatient postpartum stay may have influenced breastfeeding outcomes.</p>
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					<p>hospitals than for those who gave birth at control hospitals (36.1% vs. 24.4%; aOR, 0.51; 95% CI, 0.36-0.73).</p> <p>12 month breastfeeding rates were higher for women who gave birth at BFHI certified hospitals than for those who gave birth at control hospitals (19.7% vs. 11.4%; aOR, 0.47; 95% CI, 0.32-0.69).</p> <p>Exclusive 3 month breastfeeding rates were higher for women who gave birth at BFHI certified</p>		
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					<p>hospitals than for those who gave birth at control hospitals (43.3% vs. 6.4%; $P < .001$).</p> <p>Exclusive 6 month breastfeeding rates were higher for women who gave birth at BFHI certified hospitals than for those who gave birth at control hospitals (7.9% vs. 0.6%; $P = .01$)</p>		
Merewood et al. (2005), United States	29 hospitals- All 29 hospitals that were BFHI-certified in 2003 were surveyed regarding their initiation and exclusive	Cross-sectional	Initiation Exclusivity (in-hospital)	MR (I) In-hospital	Breastfeeding initiation rates were higher at BFHI certified hospitals than at all US hospitals (83.% vs. 69.5%). Exclusive breastfeeding	Initiation: Yes Duration: N/M Exclusivity: Yes (ST)	Small sample size (due to small available sample of BFHI certified hospitals at the time of the study), limits causal inference.

	breastfeeding rates then these rates were compared to the national norms.				rates during the hospital stay were higher at BFHI certified hospitals than at all US hospitals (78.4% vs. 46.3%).		Data source for breastfeeding outcomes was the Ross Mothers' Survey, a data source collected and stored by a formula manufacturer. Possible sampling or data reporting bias. Measurement of breastfeeding outcomes in the hospital only provides limited information about breastfeeding outcomes.
Merten et al. (2005), Switzerland	3032	Cross-sectional and retrospective cohort	Duration (3, 5 months) Exclusivity	Q(M) 24 hour recall 3, 5 months	3 month breastfeeding rates were higher for women who	Initiation: N/M Duration: Yes (LT) Exclusivity:	International setting limits generalizability to the United States.

			(3, 5 months)		<p>gave birth at BFHI certified hospitals than for those who gave birth at non-BFHI hospitals (72% vs. 60%, $P = .012$)</p> <p>5 month breastfeeding rates were higher for women who gave birth at BFHI certified hospitals than for those who gave birth at non-BFHI hospitals (51% vs. 42%, $P = .015$)</p> <p>Exclusive 3 month breastfeeding rates were higher for women who gave birth at BFHI certified hospitals than for those who</p>	Yes (LT)	
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					gave birth at non-BFHI hospitals (60% vs. 49%, $P = .033$) Exclusive 5 month breastfeeding rates were higher for women who gave birth at BFHI certified hospitals than for those at non-BFHI hospitals (51% vs. 42%, $P = .015$).		
Mydlilova et al. (2009), Czech Republic	660,355	Retrospective cross-sectional	Exclusivity (in-hospital)	MR (I) Hospital discharge	Exclusive breastfeeding was higher in BFHI certified hospitals than non-certified hospitals for each year measured. While the number of certified hospitals grew nationally each	Initiation: N/M Duration: N/M Exclusivity: Yes (ST)	International setting limits generalizability to US. Measurement of breastfeeding outcomes at hospital discharge provides limited information

					year, the overall national rates of breastfeeding declined slightly over the study period.		regarding breastfeeding.
Philipp et al. (2001), United States	200	Retrospective cohort	Initiation Exclusivity (in-hospital)	MR (I) In-hospital	Breastfeeding initiation increased from pre-intervention to post-intervention (58% vs. 86.5%, $P < 0.001$). Exclusive breastfeeding in hospital increased from pre-intervention to post-intervention (5.5% vs. 33.5%, $P < .001$).	Initiation: Yes Duration: N/M Exclusivity: Yes (ST)	Setting in one hospital for data collection is a source of possible selection bias. Measurement of breastfeeding outcomes in the hospital provides limited information regarding breastfeeding.
Pincombe et al ^e , 2008 ³⁴ Australia	317	Cross-sectional	Initiation, Duration.	I (M) See note to right	Duration of breastfeeding was not associated with	Initiation: N/M Duration: Unclear	International hospital limits the generalizability

					<p>early initiation of breastfeeding, breastfeeding on demand, or rooming in. Duration of breastfeeding was associated with exclusive breastfeeding and not being offered artificial nipples. Authors measured “risk of weaning” rather than specific duration or exclusivity time frames.</p>	<p>(measured outcome unclear) Exclusivity: N/M</p>	<p>of findings to the United States.</p> <p>The use of one hospital for data collection is a source of possible selection bias.</p> <p>Non-comparative design limits causal inference.</p> <p>Breastfeeding outcomes reported as “risk of weaning” rather than standard methods of measuring breastfeeding outcomes. This inhibits the ability to relate these findings to other publications.</p>
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van der Merwe (2012), South Africa	435	Cross-sectional	Exclusivity (<1, 1-2, 2-3, 3-4, 4-5, 5-6 months)	I/Q (M) one interview between 0-6 months pp	Exclusive breastfeeding rates were 60.1% among 'women giving birth in BFHI institutions vs. 47.5% in non-BFHI institutions. (no <i>P</i> -value reported). The age of the infants whose mothers were interviewed varied considerably from newborns- age 6 months.	Initiation: N/M Duration: N/M Exclusivity: Unclear (no statistical significance reported)	International setting limits generalizability to United States. Cross-sectional design limits causal inference. No statistical significance reported for exclusive breastfeeding rates prevents the interpretation of the findings.
Venancio et al. (2012), Brazil	65,936	Longitudinal cohort	Exclusivity (1 hour; first day home; 60, 90, 180 days)	Q (M) 24 hour recall used 1, 60, 90, 180 days pp	1 hour exclusive breastfeeding rates were higher among women who gave birth at BFHI hospitals than among those who gave	Initiation: N/M Duration: N/M Exclusivity: Yes (ST and LT)	International setting limits generalizability to the United States.

					<p>birth at non-BFHI hospitals (71.7% vs. 65.1%, $P = .0001$).</p> <p>First day of life exclusive breastfeeding rates were higher among women who gave birth at BFHI hospitals than among those who gave birth at non-BFHI hospitals (87.2% vs. 82.3%, $P = .0001$).</p> <p>60 day exclusive breastfeeding rates were higher among women who gave birth at BFHI hospitals than among those who gave birth at non-BFHI hospitals (68.9% vs.</p>	
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					<p>61.4%, $P = .0002$). 90 day exclusive breastfeeding rates were higher among women who gave birth at BFHI hospitals than among those who gave birth at non-BFHI hospitals (63.3% vs. 59.7%, $P = .0454$). 180 day exclusive breastfeeding rates were higher among women who gave birth at BFHI hospitals than among those who gave birth at non-BFHI hospitals (49.9% vs. 47.1%, $P = .0286$).</p>		
Wright et al.	584	Before-after	Initiation	I (M)	Breastfeeding	Initiation:	Timing of

(1996), ^f United States			Duration (1 and 4 months)	In hospital, 1 and 4 months	in hospital 73.6% post-intervention vs. 69.9%% pre-intervention ($P > .01$). Not statistically significant. Duration was measured in association with the number of BFHI practices experienced by women. No duration data was available for the pre-BFHI group.	No Duration: Unclear (no comparator) Exclusivity: Unclear (no comparator)	study pre-dates BFHI program, therefore the setting was not BFHI certified. Setting in one hospital in the United States limits the generalizability of findings. Before After design limits causal inference. Survey tools were not the same at the 2 data collection points. Possible instrumentation bias.
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^a Codes used for data collection methods: I= interview, Q= questionnaire, MR= medical record review, CK= Crivelli Kovach tool, O= observation., ^b Codes used for data source: M= mother, P= provider, I= infant medical record, ND= national database.

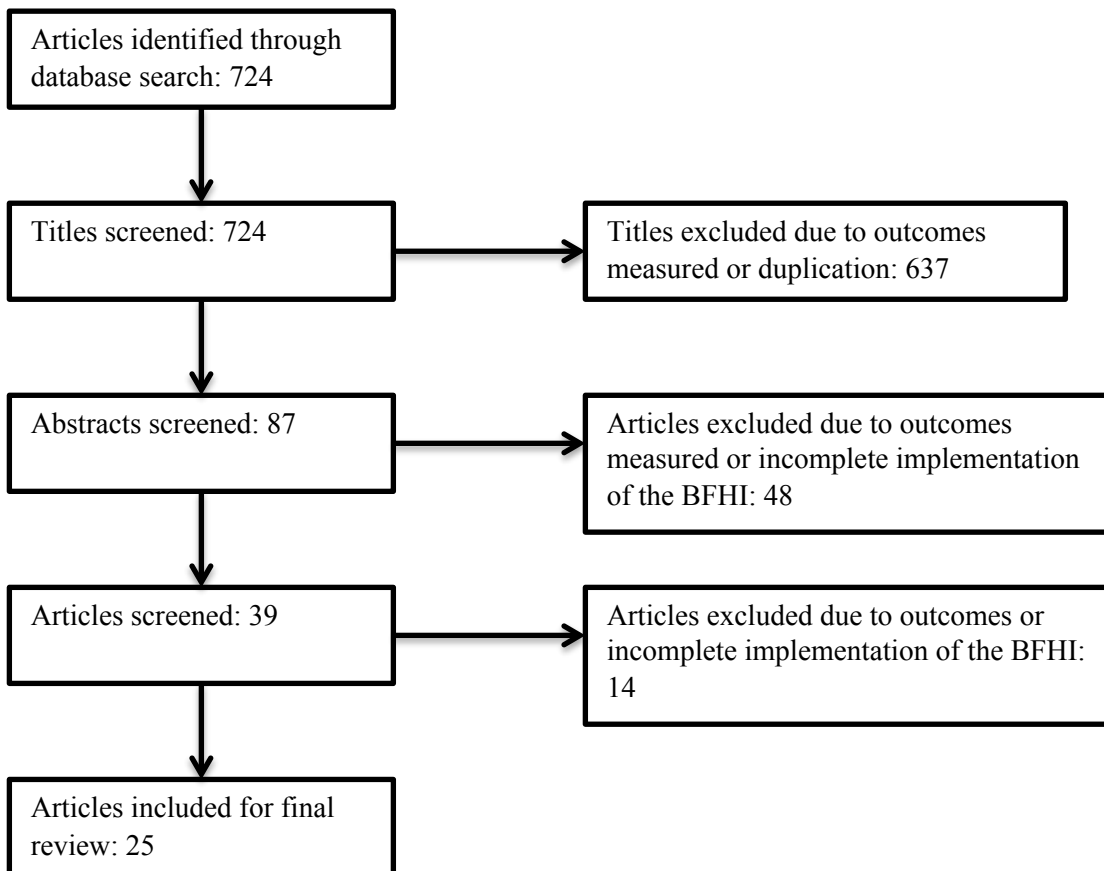
^c Codes used for interpretation of results: N/M= not measured; ST= short-term; LT= long-term. ^d Steps 4, 6-9 were measured.

^e Steps 4-9 were measured^f Steps 1-10 were implemented, but the facility was not yet BFHI certified.

Description of the Studies

A diagrammatic representation of the search strategy is presented in Figure 1. A total of 637 articles were excluded as duplicates or by title review, and another 48 articles were removed after abstract review, leaving 39 articles for full review. Fourteen articles were excluded at this level because they did not specifically measure the targeted outcomes of breastfeeding initiation, duration, or exclusivity or did not fully implement the intervention, leaving 25 primary research studies of the BFHI as an intervention that were included for review.

Figure 1. PRISMA Diagram for search method



Most (n=22) studies used the standard definition of the BFHI, in that the BFHI intervention included all Ten Steps (Abrahams & Labbok, 2009; Alam, Rahman, & Rahman, 2002; Bartington, Griffiths, Tate, Dezateux, & Millennium Cohort Study Health, 2006; Bosnjak, Batinica, Hegedus-Jungvirth, Grguric, & Bozikov, 2004; Braun et al., 2003; Broadfoot, Britten, Tappin, & MacKenzie, 2005; Brodribb, Kruske, & Miller, 2013; Budin et al., 2010; Caldeira & Goncalves, 2007; DeJong & Lynne, 2012; Duyan Camurdan et al., 2007; Figueredo, Mattar, & Abrao, 2013; Garcia-de-Leon-Gonzalez et al., 2011; Hawkins, Stern, Baum, & Gillman, 2014; Hofvander, 2005; Kramer et al., 2001; Merewood, Mehta, Chamberlain, Philipp, & Bauchner, 2005; Merten, Dratva, & Ackermann-Liebrich, 2005; Mydlilova, Sipek, & Vignerova, 2009; Philipp et al., 2001; van der Merwe, 2012; Venancio, Saldiva, Escuder, & Giugliani, 2012). Researchers usually checked the WHO/UNICEF database to see if a hospital was certified as Baby-Friendly; this database is readily available online. Two groups of researchers, however, used maternal reporting of hospital practices to define which institutions were Baby-Friendly (DiGirolamo, Grummer-Strawn, & Fein, 2001; Pincombe et al., 2008). When evaluating a hospital via maternal reporting, the administrative steps cannot be assessed (eg, Step 1: Have a written breastfeeding policy that is routinely communicated to all health care staff). One group measured the influence of all implemented Ten Steps on breastfeeding outcomes, although the hospital was not yet BFHI certified (Wright, Rice, & Wells, 1996). This study, authored by Wright et al was conducted between 1990 and 1993, as the BFHI was first being developed. Although researchers in these 3 studies (DiGirolamo et al., 2001; Pincombe et al., 2008; Wright et al., 1996) did not document full Baby-Friendly certification, they have been included in the review because they evaluate the influence of Baby Friendly practices on the outcomes of interest and the lack of documented full-certification is explained by the methods and timing of

the study, rather than by a lack of implementation of the full intervention.

Designs

Among the 25 studies that assessed the full BFHI as an intervention to improve breastfeeding initiation, duration, and exclusivity, the authors of one study employed a cluster randomized control design (Kramer et al., 2001). The majority of authors used a quasi-experimental design with a control group or a cohort design (Abrahams & Labbok, 2009; Alam et al., 2002; Bartington et al., 2006; Bosnjak et al., 2004; Brodribb et al., 2013; Hawkins et al., 2014; Philipp et al., 2001; Venancio et al., 2012); a time series design (DiGirolamo et al., 2001; Garcia-de-Leon-Gonzalez et al., 2011; Hofvander, 2005); or a before-after or cross-sectional design (Braun et al., 2003; Broadfoot et al., 2005; Budin et al., 2010; Caldeira & Goncalves, 2007; DeJong & Lynne, 2012; Duyan Camurdan et al., 2007; Figueredo et al., 2013; Merewood et al., 2005; Merten et al., 2005; Mydlilova et al., 2009; Pincombe et al., 2008; van der Merwe, 2012; Wright et al., 1996).

Setting

Seven studies among the 25 were conducted in the United States (Budin et al., 2010; DeJong & Lynne, 2012; DiGirolamo et al., 2001; Hawkins et al., 2014; Merewood et al., 2005; Philipp et al., 2001; Wright et al., 1996), with the remaining 18 conducted in a variety of nations worldwide, including: Bangladesh (Alam et al., 2002), United Kingdom (Bartington et al., 2006; Broadfoot et al., 2005), Croatia (Bosnjak et al., 2004), Brazil (Braun et al., 2003; Caldeira & Goncalves, 2007; Figueredo et al., 2013; Venancio et al., 2012), Australia (Brodribb et al., 2013; Pincombe et al., 2008), Turkey (Duyan Camurdan et al., 2007), Spain (Garcia-de-Leon-Gonzalez et al., 2011), Sweden (Hofvander, 2005), Belarus (Kramer et al., 2001), Switzerland (Merten et al., 2005), Czech Republic (Mydlilova et al., 2009), South Africa (van der Merwe, 2012), and a

group of 14 developing countries (Abrahams & Labbok, 2009).

Measures and Sources of Data

Researchers used an assortment of methods to measure outcomes. Questionnaires (paper-and-pencil and electronic); interviews; review of medical records, including birth certificate and newborn screening data; and review of national public health databases were employed. One set of researchers used a standardized tool, the Krivelli- Covach tool, although the reliability and validity of this instrument have not been published (Rosenberg, Stull, Adler, Kasehagen, & Crivelli-Kovach, 2008). Sources of breastfeeding data included maternal report, hospital staff, and infants' medical records.

The timing of data collection ranged from 1 day postpartum to 24 months postpartum. Most commonly, data were collected in the hospital, either on the postpartum unit or in the pediatric outpatient clinic. Some studies included data collection by trained researchers or medical personnel in patients' homes.

The scope of the included studies varied greatly. Some researchers evaluated the impact of the BFHI on outcomes at one hospital, while others assessed the influence of the BFHI on city-wide, state-wide or national breastfeeding indicators.

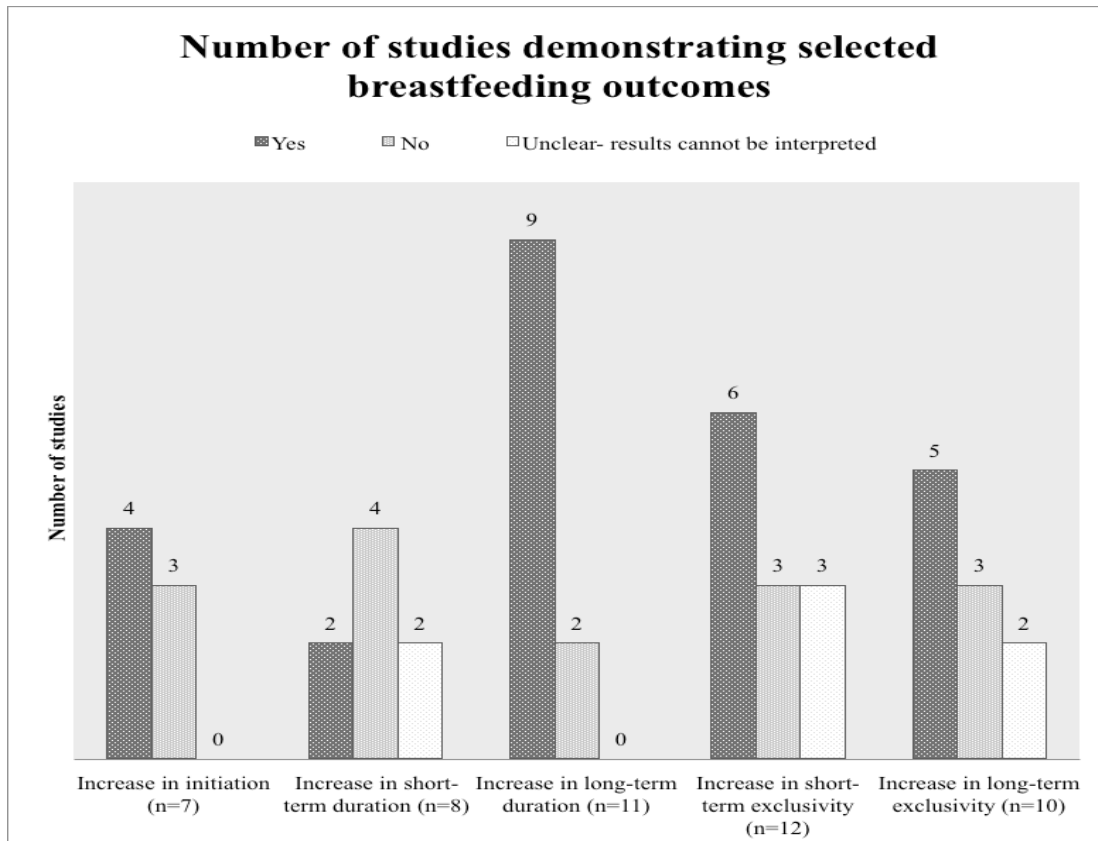
Only 2 studies attempted to present evidence that their methods had been validated. Hawkins et al used an existing data set, the Pregnancy Risk Assessment Monitoring System (PRAMS) of the CDC survey, rather than collecting new data (Hawkins et al., 2014). When using a large data set such as this, the validity of the survey is publicly reported. In this case, the CDC states that the 95% confidence interval for the accuracy of this data is $\pm 3.5\%$ (Centers for Disease Control, 2014b). The study by Kramer et al reported validating data collected via questionnaires by comparing questionnaire answers to findings in medical records or at maternal

interview (Kramer et al., 2000). The fact that no other study included this kind of safeguard against human error or fabrication of findings minimizes the reliability of many studies' findings.

Findings of the Studies

When taken as a whole, the majority of research included for review supports the BFHI as an intervention to increase breastfeeding initiation, long-term breastfeeding duration, and increased breastfeeding exclusivity rates (Figure 2). However, it is notable that most research did not support the BFHI as an intervention which improves short-term breastfeeding duration rates. In addition, there is only a small difference in the number of studies showing that the BFHI increases breastfeeding initiation rates and those showing that it does not have an effect on initiation (4 vs 3, respectively)

Figure 2. Breastfeeding outcomes in included studies



The seminal study that assessed the effectiveness of the BFHI was published by Kramer et al. in 2001. A cluster-randomized design was used to randomly assign 31 hospitals in the Republic of Belarus to either the BFHI intervention group or standard care. Once hospitals were assigned to a group, mother-infant pairs (n=17,046) were enrolled in the study if the newborns were full-term singleton infants weighing 2500 grams or more, and the woman intended to breastfeed. Data were collected from mother-infant pairs' medical records during the postpartum visit and then at 1, 2, 3, 6, 9, and 12 months after birth. The outcomes of interest were numerous and focused on both breastfeeding and infant health. Those that are relevant to this review were the prevalence of any breastfeeding at 3, 6, 9, and 12 months of age and the prevalence of exclusive and predominant breastfeeding at 3 and 6 months. At 3 months, more women in the BFHI group were breastfeeding compared to the number of women in the control group who were breastfeeding (72.7% vs 60.0%; adjusted odds ratio [aOR], 0.52; 95% confidence interval [CI], 0.40-0.69). Similar findings were noted for any breastfeeding at 6 months (49.8% vs 36.1%; aOR, 0.52; 95%, CI 0.39-0.71). At 9 months the breastfeeding rates were 36.1% vs 24.2% (aOR 0.51; 95% CI 0.36-0.73) and at 12 months the breastfeeding rates were also higher among the women who gave birth at a BFHI institution compared to those who gave birth in a control hospital (19.7% vs 11.4%; aOR, 0.47; 95% CI, 0.32-0.69). The proportion of women exclusively breastfeeding at 3 months was 7-times higher in the experimental group (43.3% vs. 6.4%; $P < .001$ by unpaired t -test) and more than 12-times higher at 6 months (7.9% vs. 0.6%; $P = .01$) than the control group.

Another large and well designed study by Venancio et al. published in 2012 used national level public health data collected from 65,936 infants in Brazil to examine breastfeeding in the first hour of life, exclusive breastfeeding on the first day after hospital discharge, exclusive

breastfeeding in infants younger than 2, 3, and 6 months of age, and pacifier use in infants younger than 6 months of age. Data were collected through interviews of the infants' guardians when they were brought to a site for vaccinations. This study found that infants born at BFHI facilities were 9% more likely to be breastfed in the first hour of life than were infants born in a non-BFHI facility (prevalence ratio [PR], 1.09; 95% CI, 1.06-1.11) and 6% more likely to be breastfed in the first day home from the hospital (PR, 1.06; 95% CI, 1.04 to 1.09). Infants less than 2 months of age were 13% more likely to be exclusively breastfed if born in a BFHI institution than if born at a non-BFHI institution (PR, 1.13; 95% CI, 1.07-1.20). Infants younger than 3 months of age were 8% more likely to be exclusively breastfed (PR, 1.08; 95% CI, 1.03- 1.13) and infants younger than 6 months of age were 6% more likely to be exclusively breastfed (PR, 1.06; 95% CI, 1.01-1.11) when they were born at a BFHI facility. The findings of these 2 very large studies appear compelling. However, a careful look at the full body of research regarding the effectiveness of the BFHI and its impact on the outcomes of breastfeeding initiation, duration, and exclusivity reveals a more nuanced interpretation.

Breastfeeding Initiation

Seven studies specifically measured breastfeeding initiation as an outcome. Among them, 4 found a statistically significant increase in breastfeeding initiation after implementation of the BFHI (Bartington et al., 2006; Garcia-de-Leon-Gonzalez et al., 2011; Merewood et al., 2005; Philipp et al., 2001). These 4 studies vary in terms of the strength of their designs, sample sizes, and settings; they include a small cross-sectional survey of BFHI hospitals in the US and a large retrospective cohort study in Scotland. No significant change in breastfeeding initiation rates after BFHI implementation as compared to pre-implementation rates was noted in 3 of the studies, among which, 2 were large cohort studies (Brodribb et al., 2013; Hawkins et al., 2014;

Pincombe et al., 2008).

A recent longitudinal matched cohort study published in 2014 by Hawkins et al. used data from the PRAMS survey. This work stands apart from previous studies on breastfeeding initiation, as it used a large population based sample, which allowed the authors to directly associate BFHI-certification with breastfeeding outcomes. Additionally, participants were compared based on educational attainment and race/ethnicity, allowing for a more detailed interpretation of the findings. In order to be included in the study, states had to release hospital identifiers to the researchers, which allowed them to match breastfeeding outcomes with the BFHI certification status of the hospitals where women gave birth; 5 states met the inclusion criteria. The final sample included 11,723 women who gave birth in thirteen BFHI institutions and 13,604 women who gave birth in 19 matched non-BFHI institutions. This large sample from 5 diverse states in the United States (Alaska, Maine, Nebraska, Ohio, and Washington) may provide the most internally and externally valid data about the impact of the BFHI on breastfeeding initiation and short-term duration in the United States. The researchers found no difference in breastfeeding initiation rates between women who gave birth at BFHI institutions and non-BFHI institutions (adjusted coefficient 0.024; 95% CI, 0.00- 0.51). They did note that breastfeeding initiation rates increased by 3.8% among women with lower education who gave birth at BFHI institutions when compared with non-BFHI institutions (adjusted coefficient, 0.38; 95% CI, 0.00-0.08) but not among women with higher education (adjusted coefficient, 0.002; 95% CI, -0.04 to 0.05).

Breastfeeding duration

When measuring breastfeeding duration, researchers differed significantly in the time periods they used to define “breastfeeding duration” and varied in methods of measurement.

Some measured short-term duration, while others measured breastfeeding duration up to one year. One study used the median to measure duration of breastfeeding (Caldeira & Goncalves, 2007), and one measured a ‘likelihood of weaning’ calculated as an estimated hazard ratio using Kaplan-Meier curves for each Baby-Friendly practice (Pincombe et al., 2008).

Among studies considering breastfeeding duration for one month or less ($n = 8$), results varied considerably. Four studies found no statistically significant differences in breastfeeding duration among women who gave birth in a BFHI institution and women who gave birth in a non-BFHI institution, including the large study from the United States by Hawkins, et al (Bartington et al., 2006; Bosnjak et al., 2004; Brodribb et al., 2013; Hawkins et al., 2014). Two studies found an increase in 1 month breastfeeding rates after exposure to the intervention including the one by Broadfoot et al. in which the authors evaluated 33 maternity units in Scotland (Broadfoot et al., 2005; Garcia-de-Leon-Gonzalez et al., 2011), and one lacked the clarity of statistics that would allow a conclusion to be reached regarding the influence of the BFHI (Budin et al., 2010).

One study, authored by Brodribb et al. (2013) found a negative association between the BFHI and short-term breastfeeding duration. These authors used a retrospective cohort design and mailed a survey to all women who had a live birth in Queensland, Australia between February 1, 2010 and May 31, 2010. The sample included 6572 women out of a possible 20,056 who replied to the survey either by paper and pencil, online, or telephone interview responses. The outcomes of interest were breastfeeding initiation and any and exclusive breastfeeding rates at 1 and 4 months of age. Breastfeeding initiation rates did not differ between women who gave birth at BFHI facilities versus those who gave birth at non-BFHI facilities (96.2% vs. 95.9%; odds ratio [OR], 0.92; 95% CI, 0.69-1.24). They also found that women who gave birth at BFHI

facilities had significantly lower odds of any breastfeeding at 1 month (81.1% vs. 84.8%; OR, 0.77; 95% CI, 0.66-0.90) and 4 months (62.9% vs. 67.4%; OR, 0.82; 95% CI, 0.73-0.93) than those who gave birth at non-BFHI facilities. After adjusting for non-modifiable maternal and infant characteristics, women who gave birth at a BFHI hospital continued to have statistically significant lower odds of any breastfeeding at 1 month (aOR, 0.72; 95% CI, 0.58-0.90), but there was no difference in breastfeeding at 4 months between the groups (aOR, 0.90; 95% CI, 0.76-1.07). The authors offered some possible reasons for these negative findings including: the BFHI may be less effective in nations where breastfeeding is already the norm; there may be a ceiling effect; or women who give birth at BFHI institutions may initiate breastfeeding without intent to continue.

Among studies that examined breastfeeding durations of longer than 1 month ($n = 11$), a majority supported an increase either in breastfeeding duration at a designated period in time (e.g. 60 days, 3 months, 6 months) or an increase in the number of months of breastfeeding (Bosnjak et al., 2004; Braun et al., 2003; Caldeira & Goncalves, 2007; DiGirolamo et al., 2001; Duyan Camurdan et al., 2007; Garcia-de-Leon-Gonzalez et al., 2011; Hofvander, 2005; Kramer et al., 2001; Merten et al., 2005). All but one of these studies were conducted outside the United States, though many used rigorous designs and large sample sizes. Two studies found no statistically significant differences between breastfeeding duration by women who gave birth at a BFHI institution versus women who gave birth at a non BFHI institution, one of which was the large Australian study by Brobribb et al. (2013) and the other a dissertation that looked at breastfeeding rates in counties of New York State (DeJong & Lynne, 2012).

Bosnjak et al. (2004) found no statistically significant difference in 3-month breastfeeding rates between infants born at the same institution before and after Baby-Friendly

certification; but they did find statistically significant differences in rates of breastfeeding duration at 6, 9, and 12 months.

Two different designs were used by the studies conducted by Caldeira et al. (2007) and Pincombe et al. (2008). Caldeira et al. measured median duration of breastfeeding in a study that compared breastfeeding rates before and after implementation of BFHI, rather than duration to a specific time frame. These authors found median duration was longer among women who gave birth at BFHI-institutions rather than non-BFHI institutions. Pincombe et al measured the “likelihood of weaning” over time and associated that likelihood with a woman’s experience with 6 of the Ten Steps. They found that the duration of breastfeeding was not associated with early initiation of breastfeeding (Step 4), breastfeeding on demand (Step 8), or rooming-in (Step 7). They did find that the duration of breastfeeding was associated with exclusive breastfeeding and not being offered artificial nipples (Step 9).

Exclusive Breastfeeding

Exclusive breastfeeding was an outcome measure of several of the studies. As with the duration outcome, a wide variety of timeframes were used to consider exclusive breastfeeding and ranged from exclusive breastfeeding in the hospital immediately after birth to 6 months after birth. One study reported the mean number of days of exclusive breastfeeding (Alam et al., 2002). In addition, the methods for assessing exclusivity varied and were not well-defined. Breastfeeding exclusivity information was collected from mothers, medical records, or by collecting data from providers. Among studies considering exclusive breastfeeding up to one month (n = 12), the majority, including the before-after study by Braun et al. (2003) and the cross-sectional studies by Merewood et al. (2005) and Mydlilova et al. (2009), demonstrated some positive effect of the BFHI on short-term exclusive breastfeeding (Hofvander, 2005;

Philipp et al., 2001; Venancio et al., 2012). Three, including the large studies by Brodribb et al. (2013) (N= 6752) and Hawkins et al. (2014) (N=25,327), found no difference between the BFHI and non-BFHI groups (Bartington et al., 2006; Duyan Camurdan et al., 2007), and 3 studies lacked enough information to make an assumption about the influence of the BFHI on short-term exclusive breastfeeding (Budin et al., 2010; Figueredo et al., 2013; van der Merwe, 2012).

Hawkins et al. (2014) found no difference overall in 4-week exclusive breastfeeding rates between women who gave birth at a BFHI institution and a non-BFHI institution in the United States. However, there was a statistically significant 4.5% increase in breastfeeding exclusivity rates among women with lower educational attainment who gave birth at BFHI institutions compared to women with the same educational attainment who gave birth at non- BFHI institutions (adjusted coefficient, 0.045; 95% CI, 0.01-0.08). Brodribb et al. (2013) found that women in Australia who gave birth at BFHI-hospitals had higher odds of exclusive breastfeeding at one month (OR, 1.24; 95% CI, 1.10-1.39) but after adjusting for non-modifiable characteristics, there was no difference in the odds of exclusive breastfeeding between women who gave birth at BFHI and non-BFHI hospitals at 1 month (aOR, 1.14; 95% CI, 0.97-1.34).

Ten studies considered long-term (longer than 1 month) exclusive breastfeeding rates. Among these articles, 5, including the seminal works by Kramer et al. (2001) and Merten et al. (2005), noted a positive influence of the BFHI on long-term rates (Alam et al., 2002; Caldeira & Goncalves, 2007; Venancio et al., 2012). Three studies found no difference in long-term exclusivity rates between women giving birth at a BFHI institution and those giving birth elsewhere (Abrahams & Labbok, 2009; Brodribb et al., 2013; Duyan Camurdan et al., 2007), and 2 studies offered ambiguous results that inhibited interpretation (Figueredo et al., 2013; van der Merwe, 2012). Kramer et al. had the strongest results documenting the influence of the BFHI on

long-term exclusive breastfeeding rates. This cluster randomized-controlled study found statistically significant increases in 3 and 6 -month exclusive breastfeeding rates among women who gave birth in BFHI institutions in Belarus. Meanwhile, the other large population based study from Australia conducted by Brodribb et al. (2013) found no statistically significant difference between 4-month exclusive breastfeeding rates between women giving birth at BFHI vs. non-BFHI institutions both with unadjusted and adjusted odds ratios. Both the Kramer et al. and Brodribb et al. studies were well-designed and included a large sample-size. It is notable that none of the studies regarding long-term breastfeeding duration were conducted in the United States.

Discussion

Considerable heterogeneity in definitions, design, methods, analysis, and outcomes was noted among studies, and thus it is not surprising that the results also are heterogeneous. Although it is difficult to reach definitive conclusions about the effectiveness of the BFHI based on the variety of research efforts to-date, some trends do emerge.

A majority of the studies that assessed the effect of BFHI did find BFHI had a positive influence on breastfeeding outcomes. Of note, however, is that an increase in exclusive breastfeeding in the hospital is a criteria for Baby Friendly certification. Thus, concluding that the intervention increases breastfeeding initiation employs circular logic, as the intervention itself cannot also be a measured outcome. It is more appropriate to consider the influence of the BFHI on breastfeeding duration. Duration and exclusivity, while more difficult to measure, are the outcomes that appear to have the greatest influence on health outcomes for women and children.

Prior reviews have considered studies that employed parts of the BFHI. This review

attempted to restrict articles for consideration to only those implementing the full intervention. Three studies that evaluated the influence of full BFHI implementation but without having BFHI certification were included. Inclusion of studies found in the grey literature (Budin et al., 2010; DeJong & Lynne, 2012; van der Merwe, 2012) along with published literature is a strength, as bias is reduced. In addition, the inclusion of a recent work by authors who employed rigorous designs helps to provide a current and more thorough review of the BFHI.

This review has some limitations. Although an attempt was made to consider all primary research on the BFHI as an intervention, some studies may have been overlooked. The use of a single reviewer raises the possibility of bias or error. Many of the studies supporting the intervention have weak designs, which may inappropriately influence the interpretation of the findings as a whole.

Although studies assessing full or parts of the BFHI are plentiful, many areas remain open to exploration before recommending widespread efforts to increase BFHI adoption among hospitals in the United States. More research utilizing quasi-experimental or experimental designs conducted in the United States would help to generalize findings to the unique healthcare setting in this county. A meta-analysis that weighs the impact of the findings based on design, sample size, and methods of data analysis would be a valuable addition to the literature.

Clinical Implications

Many midwives, nurses, and physicians are active participants in the adoption and implementation of the BFHI at their institutions, in the interest of improving breastfeeding outcomes and, in turn, health outcomes for infants and women. However, given the lack of certainty about the impact of the program, some clinicians may find that their efforts to improve breastfeeding might be better focused on other methods of improving breastfeeding initiation,

duration, and exclusivity rates. Findings from reviews published by Cochrane and the Agency for Healthcare Research and Quality (AHRQ) suggest that peer support, formal prenatal breastfeeding education, and needs-based informal postpartum support may be more effective methods of encouraging long-term breastfeeding success than the BFHI (Chung, Raman, Trikalinos, Lau, & Ip, 2008; Dyson, McCormick, & Renfrew, 2005; Renfrew, McCormick, Wade, Quinn, & Dowswell, 2012).

Conclusion

Although research that has evaluated the effectiveness of the BFHI as an intervention to improve breastfeeding rates has been conducted, many of these studies have been hampered by weak designs or methodologic limitations. Research conducted in the United States and employing experimental designs would help to support the BFHI as an effective intervention for the improvement of breastfeeding rates.

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CHAPTER 3

DEVELOPMENT OF A SURVEY TO IDENTIFY BARRIERS AND FACILITATORS TO IMPLEMENTING THE BABY-FRIENDLY HOSPITAL INITIATIVE

This chapter presents the development and pilot testing of a survey tool regarding specific barriers and facilitators to adoption and implementation of the BFHI in the US. The instrument developed in this phase was then used to collect data for the dissertation research project. This manuscript is currently under review at the Journal of Obstetric, Gynecologic, and Neonatal Nursing.

Background

Breastfeeding rates remain persistently low in the United States (US), despite a large body of evidence documenting the many benefits of breastfeeding for infants and women (Amitay & Keinan-Boker, 2015; Aune, Norat, Romundstad, & Vatten, 2014; Chowdhury et al., 2015; Horta, Loret de Mola, & Victora, 2015; Ip et al., 2007; Kramer & Kakuma, 2012; Lodge et al., 2015; Sankar et al., 2015). In 2013, 81.1% of American women breastfed in the early postpartum period, but by 3 months only 44.4% were breastfeeding exclusively, and at six months the exclusive breastfeeding rate decreased to 22.3% (Centers for Disease Control, 2016). By two days of life, 17.1% of breastfed infants received supplemental formula (CDC, 2016).

In an attempt to improve breastfeeding rates, the World Health Organization (WHO) and United Nations International Children's Emergency Fund (UNICEF) have developed a hospital-based program called the Baby-Friendly Hospital Initiative (BFHI), which includes guidelines for implementation, called the Ten Steps (WHO & UNICEF, 2009). The Ten Steps are grounded in evidence and have been shown to improve short-term and long-term breastfeeding rates both in the US and internationally (Carvalho, Boccolini, Oliveira, & Leal, 2016; Hawkins, Stern,

Baum, & Gillman, 2014; Kramer et al., 2001; Merewood, Mehta, Chamberlain, Philipp, & Bauchner, 2005; Merten, Dratva, & Ackermann-Liebrich, 2005; Philipp et al., 2001; Renfrew, McCormick, Wade, Quinn, & Dowswell, 2012). The Ten Steps require hospitals to implement the practices indicated in Figure 1. When all Ten Steps are implemented, hospitals may become certified as Baby-Friendly, a designation that provides recognition to a hospital and that is publicly available to consumers and policy makers (Baby-Friendly USA, 2016). Healthy People 2020 and the Surgeon General support the BFHI, and it is endorsed by the American Academy of Pediatrics (Takach, 2012; U.S. Department of Health and Human Services, 2011; US Department of Health and Human Services Office of Disease Prevention and Health Promotion).

Figure 1. The Ten Steps to Successful Breastfeeding

The Ten Steps to Successful Breastfeeding (World Health Organization & UNICEF, 2009)
1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within one hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they are 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 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

Of the 3281 facilities that provide inpatient maternity care in the US, only 393 are certified as Baby-Friendly (Baby-Friendly USA, 2016). Only 19.4% of infants born in the US are born in Baby-Friendly facilities (Baby-Friendly USA, 2016). This means that more than 80% of US-born infants are denied the opportunity to be born in an environment that could optimize

their chances of being breastfed, a known mechanism to improve their overall health. In addition, 80% of women who give birth in the US are not guaranteed the support associated with giving birth in a Baby-Friendly facility and may miss out on the inherent health benefits for themselves that are related to breastfeeding.

The reasons for the lack of implementation of the BFHI in the US remain elusive. The Ten Steps require organizations to change their policies and practices, and it is likely that some of these changes are more difficult than others. Organizational change and the implementation of new research are complicated processes (Chandler, Rycroft-Malone, Hawkes, & Noyes, 2016; Damschroder et al., 2009; Dearing, 2009; Ilott, Gerrish, Booth, & Field, 2012; Innis, Dryden-Palmer, Perreira, & Berta, 2015; Rycroft-Malone et al., 2013; Schillinger, 2010; Weiner, Amick, & Lee, 2008). However, through improved understanding of the implementation process and its barriers and facilitators, future interventions can be developed to support this implementation process and increase the number of BFHI-certified facilities.

From an implementation science perspective, it is critical to learn more about the reasons for the lack of routine translation of research findings related to the BFHI. If organizational leaders and policy-makers understand which interventions are most effective in supporting organizations as they adopt and implement the BFHI, they can focus efforts on these factors. Additionally, if certain factors greatly impede adoption and implementation, these factors can be addressed at the outset of the process. Therefore, a quantitative descriptive study that highlights the key factors in the implementation process in the US can lay the groundwork for future interventions and prioritize the needs of institutions.

Thus, the purpose of this study was to develop and pilot test a survey tool for use in a larger study regarding barriers and facilitators to adoption and implementation of the BFHI in the

US. A secondary aim was to develop a survey that could be modified for use in evaluating organizational barriers and facilitators to adoption and implementation of other perinatal evidence-based programs. To this end, we began our work with a review of the current implementation, methodological, and theoretical literature.

Review of the Literature

Implementation of the BFHI

The majority of the published studies to date on implementation of the BFHI have been qualitative case studies or have used before-after designs (Bartick, Edwards, Walker, & Jenkins, 2010; Crivelli-Kovach & Chung, 2011; Daniels & Jackson, 2011; Hannon, Ehlert-Abler, Aberman, Williams, & Carlos, 1999; Hofvander, 2005; Lundeen, Sorensen, Bland, George, & Snyder, 2016; McKeever & Fleur, 2012; Merewood & Philipp, 2001; Sadacharan et al., 2012; Schmied, Gribble, Sheehan, Taylor, & Dykes, 2011; Tran, 2017; Vasquez & Berg, 2012; Ward, Williamson, Burke, Crawford-Hemphill, & Thompson, 2017; Weddig, Baker, & Auld, 2011; Wieczorek, Marent, Dorner, & Dur, 2016; Wright, Rice, & Wells, 1996; Zakarija-Grkovic et al., 2012). While the body of qualitative work provides useful examples that serve as a basis for the understanding of the barriers and facilitators of the implementation process, the results are, by their nature, not generalizable to other settings.

An integrative review by Semenic, Childerhose, Lauziere, and Groleau (2012) synthesized the findings of numerous qualitative studies regarding implementation of the BFHI and identified key themes experienced by hospitals as they try to adopt and implement the program. The authors identified organizational factors that may act as barriers or facilitators to implementation of the BFHI which include: organizational leadership, organizational culture, human and financial resources, audit and feedback mechanisms, breastfeeding policies, and

breastfeeding training (Semenic et al., 2012). In addition, socio-political factors such as national health policy, integration of health services, cultural norms, strength of the infant formula industry, legislation that supports breastfeeding, socioeconomic disparities, and pre-service training of healthcare providers influence implementation of the BFHI (Semenic et al., 2012). Semenik et al. (2012) also identified individual-level factors that influence the implementation of the BFHI from both the healthcare provider's perspective and the patient and her family's perspective.

The list of potential barriers and facilitators is vast and does not provide a framework for the development of interventions to enhance the process. No hierarchy has been created that could identify the most significant factors influencing implementation of the BFHI. In addition, a significant number of studies have been conducted outside the US (Daniels & Jackson, 2011; Garcia-de-Leon-Gonzalez et al., 2011; Hofvander, 2005; Kramer et al., 2001; Merten et al., 2005; Schmied et al., 2011; Weng, Hsu, Gau, Chen, & Li, 2003; Zakarija-Grkovic et al., 2012). The unique qualities of the US healthcare system, such as the array of state policies, the fee-for-service model, and the diversity of the patient population, pose specific challenges to implementation of the BFHI that merit special attention (Rice et al., 2013). Thus, we identified that there was a need to quantitatively measure the greatest barriers and facilitators to adoption and implementation of the BFHI in the US.

Existing tools

We endeavored to find an existing instrument that could be used to identify and quantify the barriers and facilitators to the adoption and implementation of evidence-based programs such as the BFHI. The use of standardized tools provides for continuous-level data that can be used for higher-level forms of statistical analysis and allows for comparisons between different studies

with different patient populations. A number of validated tools have been used to assess the implementation of research findings or evidence-based practice. A summary of instruments used to measure the factors that influence implementation is presented in Table 1. Two of these instruments, the Alberta Context Tool (ACT) (Estabrooks, Squires, Cummings, Birdsell, & Norton, 2009) and the Barriers to Research Utilization Scale (BARRIERS) (Funk, Champagne, Wiese, & Tornquist, 1991) were specifically considered for inclusion in this study, as they had been validated in other studies at the time survey development commenced (2014).

Table 1

Psychometric evaluation of instruments that measure implementation

Factor Analysis	Reliability	Validity	Comments
<u>BARRIERS (Funk, et. al., 1991)</u>			
<p><u>Factor 1</u>: eight items with loadings= .40-.78.</p> <p><u>Factor 2</u>: eight items with loadings= .41-.80.</p> <p><u>Factor 3</u>: six items with loadings = .41-.77.</p> <p><u>Factor 4</u>: six items with loadings= .40-.65.</p>	<p style="text-align: center;"><u>Internal Consistency</u></p> <p>Factor 1= .80 Factor 2= .80 Factor 3= .72 Factor 4= .65</p> <p style="text-align: center;"><u>Test-Retest</u></p> <p>.68 - .83 when test administered one week apart.</p>	<p>Validated using: dieticians, occupational therapists, physical therapists, speech therapists, nurses, nurse-administrators</p>	<p>Based on Rogers' Diffusion of Innovations conceptual framework.</p> <p>Used in >35 empirical studies to date. Findings tend to be consistent among studies that the greatest barriers are:</p> <p style="padding-left: 20px;"><i>Lack of time</i> <i>Lack of authority</i> <i>Organizational infrastructure</i> <i>Lack of support</i> <i>Lack of access</i> <i>Lack of evidence</i></p> <p>Questions are broad-specifying the instrument to the setting might provide more useful information.</p>
<u>Context Assessment Index (McCormack, McCarthy, Wright, Slater, & Coffey, 2009)</u>			
<p>Factor analysis explains 48.08% of the data variance:</p> <p>1- Collaborative practice= .40-.62</p> <p>2- Evidence-informed practice= .40-.57</p> <p>3- Respect for the person= .41-.55</p> <p>4- Practice boundaries= .41-.61</p> <p>5- Evaluation= .47-.62</p> <p>Confirmatory item analysis questions the five-factor model and suggests that fewer factors would be more appropriate.</p>	<p>Internal consistency for entire instrument- Cronbach's alpha= 0.93.</p> <p>Factor 1= .91 Factor 2= .88 Factor 3= .81 Factor 4= .80 Factor 5= .78</p> <p>Test-retest: .56 (p< 0.001) correlation from Time 1 to Time 2</p>	<p>14 nurses read and evaluated the initial items for clarity of statements, layout, and clarity of terminology. Items reduced from 88 to 83 in this process.</p> <p>Validated in Swedish study- minimized validity found in the second study, which concluded that further development and psychometric evaluation was needed to establish content and construct validity prior to wider use.</p>	<p>Based on the PARIHS conceptual framework. Focuses on organizational structure ("context") exclusively.</p> <p>Rigorous psychometric testing in initial development, but not supported by validation study.</p> <p>Used in one empirical study.</p>

Factor Analysis	Reliability	Validity	Comments
<u>Alberta Context Tool (ACT) (Estabrooks, et al., 2009)</u>			
13-factor solution accounting for 59.26% of the variance in data.	Internal consistency for overall instrument not reported.	Construct validity assessed by examining associations between each of the ACT factors and instrumental research utilization (scored on a 5-point frequency scale). All factors were statistically significantly correlated a p=.01 levels or higher, except for one factor, <i>organizational slack: human resources</i> .	Based on PARIHS framework. Used in 7 published empirical studies. The original developers of the tool are authors on 6/7 of the empirical studies and authors of 6/7 the validation studies.
Leadership= .75-.84 Culture= .39-.70 Evaluation= .77-.86 Social capita= .58-.68 Formal interactions= .37-.70 Informal interaction Non-direct care providers= .56-.77 Direct care providers= .34-.80 Formal resources = .44-.81 Traditional resources= .51-.72 Electronic resources= .60-.71 Organizational slack: Time= .61-.72 Space= .63-.81 Human resources= .76-.79	1= .91 2= .72 3= .91 4= .77 5= .60 6= .75 7= .70 8= .71 9= .60 10= .54 11= .74 12= .63 13=.83	Validated for use in Australia (no correlation coefficients are provided, simply states that instrument was valid for use in Australia). Validated in pediatric setting, residential long-term care setting, and with nurses across a variety of settings. Also validated in Germany and Sweden.	
<u>Organizational Readiness to Change Assessment (ORCA) (Helfrich, Li, Sharp, & Sales, 2009)</u>			
Overall variance is not reported 1- Facilitation= .62-.74 2- Context= .10-.88 3- Evidence= .24-.88	Internal consistency for overall instrument is not reported. 1= .95 2= .85 3= .74 Published protocol identifies a study currently underway to assess inter-rater reliability and internal consistency reliability.	No validity testing in initial instrument development. Published protocol identifies a study currently underway to assess content validity, predictive validity, concurrent validity, convergent validity, and discriminant validity.	Based on the PARIHS framework. Used in two empirical studies.

Alberta Context Tool. This tool was based on the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Rycroft-Malone, 2004) and has been used in seven published empirical studies to date. The strengths of the ACT are that it is grounded in implementation theory, specifically relates to organizational factors that influence implementation in the healthcare setting, and has undergone significant psychometric testing. However, the original authors have conducted the majority of the validation studies. In addition, the layout of the tool is somewhat confusing and the response set is not consistent throughout the instrument.

Barriers to Research Utilization Scale (BARRIERS). This tool identifies specific factors that act as barriers or facilitators to change (Funk et al., 1991). A strength of the BARRIERS tool is that it has been administered to nursing administrators to identify their attitudes toward the utilization of nursing research and demonstrated internal consistency in that setting, as well (Funk, Champagne, Tornquist, & Wiese, 1995). As this population was likely to overlap with our targeted respondents, its inclusion would provide construct validity for our project. The instrument has been used in 35 empirical studies. The greatest limitation of the instrument is that it focuses mainly on the use of research in nursing practice. While access to research findings is one factor that may influence adoption and implementation of the BFHI, it is not the only influencing factor and therefore, the BARRIERS instrument alone would not be sufficient alone when measuring the myriad barriers and facilitators to adoption and implementation.

After considering the qualitative literature and the review by Semenic et al. (2012), we did not find that the existing tools would comprehensively measure the spectrum of potential barriers and facilitators that could influence adoption and implementation of the BFHI. We decided that the best approach to filling this gap was to develop our own survey, along with the

possible inclusion of an existing tool.

Theoretical literature

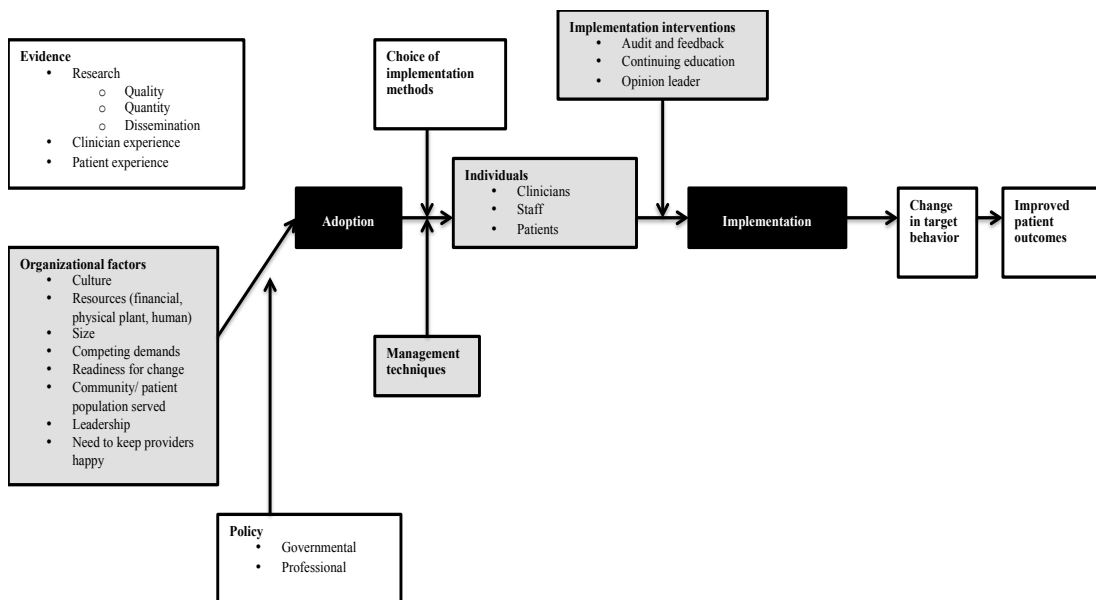
Our survey development was guided by the body of theoretical literature in implementation science that seeks to explain the organizational processes involved in the adoption and implementation of evidence-based practice. We specifically focused on the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009), a theory derived from a systematic review of theoretical approaches to the phenomenon. Damschroder et al. (2009) developed the CFIR by synthesizing the work of nineteen implementation theories, in an attempt to provide a comprehensive understanding of the implementation process. The CFIR is meta-theoretical and provides an understanding of the major constructs from published implementation theory. The meta-theory does not depict linear relationship between variables, although it does have a stated outcome: *successful implementation of an innovation*. The CFIR names five variables that can influence organizational implementation: *characteristics of the intervention, inner setting, outer setting individuals, and the implementation process*. The CFIR does not, however, explain how the interaction of these variables influences implementation. Instead, this meta-theory consolidates and names the many factors involved in implementation and leaves the task of describing and explaining the implementation process to future researchers (Damschroder et al., 2009).

A systematic review by Flottorp et al. (2013) provides an index of factors that have been identified in the literature as having and influence on the adoption and implementation processes. While their work is not theoretical, by analyzing the body of literature on the topic, the authors lay the groundwork for the development of a conceptual framework. They identify seven broad categories that act as barriers and facilitators of implementation of evidence-based programs and

guidelines: guideline factors; individual health professional factors; patient factors; professional interactions; incentives and resources; capacity for organizational change; and social, political, and legal factors (Flottorp et al., 2013).

From a theoretical standpoint, neither of these prior works fully meets the needs of researchers who seek a model to explain the relationship that each concept has with one another, nor do they identify predictor variables, moderating variables, or dependent variables. Therefore, taking into consideration the work by these two authors, we developed a synthesized conceptual framework (Figure 2). By also considering factors that determine adoption, the synthesized model expands beyond the concept of implementation. The model requires that implementation outcomes and patient outcomes be considered, as both are necessary for success. All aspects of the model are important, but for the goals of this study, we chose to focus primarily on the organizational factors and their influence on the adoption and implementation processes. Organizational factors were the ones most commonly noted in the Semenic et al. (2012) review. The areas of interest for this study are highlighted in grey in Figure 2.

Figure 2 Synthesized Conceptual Model with areas of interest highlighted



Methods

Design

An e-Delphi design was used for this project. The e-Delphi technique is a social research method designed to obtain a consensus opinion from a group of experts (Crisp, Pelletier, Duffield, Adams, & Nagy, 1997). Through the use of this method, individual opinions can become consolidated into a shared recommendation. Experts' opinions are collected in stages via electronic questionnaires until a majority of the experts agree (Keeney, 2011). The following steps were followed in the development of the survey: a review of the literature (described in the review of the literature), development of the initial draft, enrollment of experts, revision of initial survey based on experts' comments, second review by experts, and finalized survey.

Data for the survey development process were collected and stored using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at Vanderbilt University (Harris et al., 2009). "REDCap is a secure, web-based program designed to support data

collection for research studies. Because we intended to use REDCap for the finalized survey, we decided to use that environment for data collection during survey development.

Ethics

An application to the Vanderbilt University Medical Center Institutional Review Board (IRB) was made prior to any contact with potential reviewers. The IRB decided that this project did not require IRB approval, as it did not involve human subjects and was focused on survey development, rather than data collection.

Development of the Survey

The first draft of our survey was broad in scope. We included a large number of barriers and facilitators, with the intention of deleting the items that were deemed unnecessary by the experts as we went through the review process. Using the conceptual framework and the findings from the review by Semenic et al. (2012) as guides, we divided the survey into subsections of key barriers and facilitators identified in those two sources. These sections were: introduction (determining level of BFHI adoption/implementation); statewide policies; and a number of organizational factors: culture, resources, competing demands, readiness for change, leadership, policy changes, clinicians, ancillary staff, patients, and implementation interventions. We considered inclusion of the ACT and BARRIERS instruments in conjunction with our own survey and presented these tools to our experts for consideration.

Expert Reviewers

Experts were recruited from our professional contacts with expertise in the BFHI, breastfeeding research, or survey development. Using the snowballing method, we asked those experts to then recommend other experts. In addition to four of the primary author's dissertation committee members, 11 outside experts were invited to review the study in the first round. The

experts were nursing researchers with expertise in the BFHI or maternal-child health, hospital administrators, or clinicians with experience implementing the BFHI, as well as one survey design expert. Twelve of the total 15 invited experts completed the review of the survey in the first round of e-Delphi. In the second round of review, we invited one additional survey design expert to review the structure and design of the survey. One expert who completed the first round of e-Delphi did not complete the second round of review, for a total of twelve reviews in the second round of e-Delphi.

First e-Delphi Round

For our first e-Delphi round, we created a questionnaire that was specifically intended to solicit the opinions of the experts regarding the draft BFHI survey. We wanted the experts to visualize the survey as respondents would see it, therefore the questionnaire was developed and administered in the REDCap environment. The experts were asked to read each survey question and give their opinion regarding the meaning of the question, the feasibility of answering the question by the intended respondents, and the clarity of response choices. Response choices were binary. Experts selected the box, indicating a “yes” response, if they agreed with the statements, “The meaning of the question is clear,” “It is feasible for perinatal care professionals to answer this question,” and “The response choices provided are clear.” Not selecting the box indicated disagreement or a “no” response. The experts were also asked to evaluate the ACT and BARRIERS tools. They were asked to read each tool and then assess the relevancy, redundancy, and value of inclusion of the tools in the survey, by responding to the following questions: “Is the instrument relevant?” “Are the questions redundant?” “Do you think the instrument should be included with the survey?” Response choices were again binary with yes and no choices offered for each question. Finally, we asked the experts to provide general feedback regarding

any barriers or facilitators that had been omitted from the survey. We also solicited their opinions about any redundant questions and the length of the survey, and we provided a free text space for any further comments.

Findings from first e-Delphi review. After analysis of the feedback from the expert panel, consistent ideas and suggestions emerged regarding the utility, clarity, and feasibility of items and sections. In addition, we learned that we needed to clearly define our targeted respondent. The experts indicated that the response scale needed modification. Based on the length of the survey, recommendations for the elimination of some sections and one or both validated tools were common. In addition, the experts suggested some specific re-wording, clarification, or elimination of questions.

Deletion of Items. Based on the experts' recommendations, we eliminated the ACT, which most respondents found to be too long and redundant. Six of the 7 (85.7%) experts who responded (5 did not respond to this question) to the question, "Do you think the Alberta Context Tool should be included in the proposed study regarding the barriers and facilitators to implementing the BFHI?" replied with a "no" response. Comments from experts included the following: "too long and instructions are confusing," "this [ACT] is an endless questionnaire-seemed OK at first blush but goes on and on," "I don't think the information you obtain from this tool is any more valuable than rest of your survey. Plus you need to consider the length of your survey."

We also removed the section about the influence of ancillary staff on the implementation of the BFHI. Experts suggested that it would not be feasible for clinician respondents to accurately respond to the questions in this area. When asked if each question in the section titled "ancillary staff" was feasible to be answered by perinatal care professionals, 4 of 10 (40%) or 5

of 10 (50%) respondents replied, “yes,” depending on the specific question. This indicated that at least half of the experts found these questions to be inappropriate to ask perinatal clinicians and administrators. A comment that supported this theme was, “I am not sure most providers and professionals would have a good feel for these items for ancillary staff- I am worried that without data you would be learning about employee attitudes about ancillary staff, not their specific ability to engage in the BFHI.”

Some experts stated that overall the survey was too long; 5 of 10 (50%) respondents to the question, “Is the survey too long” replied “yes.” An example was this comment, “...I’m afraid that if you make your survey too long, potential participants may not be willing or able to take the time to complete it.” The experts reported that completion of the first review took between 10 and 50 minutes. Mindful of this, we also eliminated some items in sections throughout the survey.

Modification of the Response Scale. Based on comments in the text boxes, some respondents found the original response scale confusing or difficult to apply to each item. In developing our response set, we created a scale that we hoped would allow the respondent to identify the degree to which a factor was a facilitator or barrier to implementation of the BFHI. The original response scale is presented in Figure 3.

Figure 3. Response choices in the initial version of the survey

Response choices for respondents working at Baby-Friendly certified institutions	
-2	This was a major obstacle in the process toward certification
-1	This was a minor obstacle in the process toward certification
0	This was present but had no effect on our certification process
1	This helped facilitate our certification process
2	This was essential to our certification process
N/A	We did not experience this issue

An example of a comment from an expert, “The scale did not work well for [me] because many of the content areas were presented as phrases and I found that difficult to then align with the barrier language. To answer the question, I ended [up] rewording it in my head as a statement and thinking of the scale as how much I agree or disagree rather than how much of a barrier. Bottom line, I found it very difficult to flow between the content and the scale.” We took this critique and rewrote the stems and responses throughout the survey.

We decided that before we could collect continuous-level data, we needed to first collect descriptive data from respondents. Therefore, we changed the format of every question to ask if respondents had experienced each factor and then followed up by asking them to rank the greatest barrier and greatest facilitator of implementation for each category. This led to a more streamlined survey with simpler response choices.

General Revisions. Based on other recommendations, we made changes to a variety of items. We added a category for hospitals that began to pursue Baby-Friendly certification but did not finish. We revised our language regarding leaders to focus instead on leadership qualities. Modifications to the demographic section were made based on our targeted respondents’ ability to answer and provided clear definitions for each item.

Clarifying the Targeted Respondent. The initial intention of the survey was to use hospitals as the unit of analysis. This would have allowed us to directly compare one hospital to another. However, it became clear through our conversations with statewide breastfeeding and perinatal organizations that many hospitals have more than one person who leads the BFHI adoption and implementation process. Selecting a single key informant would have eliminated differing perspectives. Therefore, we decided to target our questions and responses to any health care professional who self-identified as being familiar with the adoption and implementation

process in their hospitals.

Second e-Delphi Review

In the second round of the e-Delphi, a revised survey was sent to the experts who were asked to take the survey as if they were respondents in the study. The following text was included at the end of the survey, “This survey has been modified based on comments from experts. After the revisions, do you feel that this survey is ready to be distributed to perinatal care coordinators for data collection? Do you have any feedback or suggestions about how to modify this survey to make it clearer or more usable? Please provide any comments below.” A free text box was provided for these comments. Because consensus was reached at the end of the second e-Delphi, no further rounds of data collection were required.

Findings from the second e-Delphi review. Although the experts approved of the revisions to the response scale, many stated that the survey was still too long. Because the experts completed the survey as respondents would see it, we were able to measure the time it took for survey completion via the REDCap application. The range of response times was 13-44 minutes, with a median response time of 29.5 minutes. In addition, in the free text boxes at the end of the survey, many said that the inclusion of the BARRIERS scale, and the wording of the items in the BARRIERS scale made the survey cumbersome and biased. Thus, we decided to eliminate the BARRIERS instrument from the final survey.

Per suggestions from the reviewers, we also modified a few items regarding the demographics of the respondents and their organizations. We added an “I don’t know” or “other” response for each question and changed the survey settings to require a response on each item.

Finalized Survey

Upon completion of the development and face validation portion of the e-Delphi process, the

final version of the survey was comprised of 170 items. The survey was separated into four sub-sections: personal profile, Baby-Friendly implementation survey, profile of the participant's organization, and additional comments. Examples of questions from each section are presented in Table 2. The survey has been deemed to have face validity after achieving consensus via the e-Delphi technique. The finalized survey was piloted tested with seven people. The time to complete the survey ranged from 6-49 minutes, with a median time of 9 minutes for completion. The full survey is available to researchers via contact with the primary author.

Table 2

Examples of Survey Sections and Items in Final Survey

Section 1: Personal Profile

For how many years have you employed at your hospital?

- < 1 year
- 1-2 years
- 3-4 years
- 5-8 years

What is your discipline?

- Medicine: Pediatrics
- Medicine: OB/GYN
- Medicine: Anesthesia
- Medicine: Family Medicine
- Medicine: Other
- Nursing: Pediatrics
- Nursing: OB/GYN
- Nursing: Anesthesia
- Nursing: Administration
- Nurse-Midwife/ Certified Midwife
- Other type of midwife
- Physician Assistant
- Lactation Consultant
- Social Worker
- Other-please specify

Which of these job titles best describes your position?

- Mother-Baby Unit manager/supervisor
- Labor and Delivery Unit manager/supervisor
- Maternity care services director/manager
- Lactation services coordinator
- Clinical nurse specialist
- Director of obstetrics and gynecology
- Director of perinatal care
- Director of pediatrics
- Medical Director
- NICU nurse manager
- Staff physician
- Staff midwife
- Staff nurse
- Lactation consultant
- Other- please specify

Section 2: Baby-Friendly Implementation Survey

(This section defines each factor, asks about the presence of each factor at the respondent's institution, and then asks respondents to identify which is the greatest barrier and which is the greatest facilitator of implementation. Examples are truncated here due to space constraints.)

Which of these categories best describes your role in deciding whether or not to pursue Baby-Friendly certification at your hospital?

- 1- I am the person who makes the final decision.
 - 2- I am one of a group of people who makes the final decision.
 - 3- I am one of a group of people who has participated in the process, but I do not have a role in the final decision.
-

-
- 4-I have not participated in the decision- making process, but I am aware of how the decisions were made.
 - 5- I do not know how the decisions were made.
 - 6- Other- please specify:

Statewide policies

The following questions address statewide policies regarding the BFHI and their impact on your hospital.

1. Does your hospital participate in a statewide perinatal quality improvement program (e.g. TIPQ-C, OPQC, NYSPQC)? (YES/NO/ I DON'T KNOW)
2. Does your hospital receive financial support from a statewide perinatal quality improvement program? (YES/NO/ I DON'T KNOW)
3. Does your state have laws that encourage or require Baby-Friendly certification? (YES/NO/ I DON'T KNOW)

Which of these statewide policies is the *greatest barrier* to implementation of the BFHI at your hospital?

- 1- level of participation in a statewide perinatal quality improvement program
- 2- level of financial support from a statewide perinatal quality improvement program
- 3- state laws re: Baby-Friendly
- 4- other

Which of these statewide policies is the *greatest facilitator* of implementation of the BFHI at your hospital?

- 1- level of participation in a statewide perinatal quality improvement program
- 2- level of financial support from a statewide perinatal quality improvement program
- 3- state laws re: Baby-Friendly
- 4- other

Organizational Culture

Which of these elements of organizational culture is the *greatest barrier* to implementation of the BFHI at your hospital?

- 1- level of support for breastfeeding employees
- 2- emphasis on patient safety
- 3- emphasis on evidence-based practice
- 4- interdisciplinary communication
- 5- sense of responsibility for improving patient care
- 6- cooperation to improve patient care
- 7- innovation to improve patient care
- 8- level of receptiveness to change among staff members
- 9- other

Organizational Resources

Which element of organizational resources is the *greatest facilitator* of implementation of the BFHI at your hospital?

- 1- quantity of nurses available to support breastfeeding
- 2- quantity of lactation consultants available to support breastfeeding mothers
- 3- stability of the workforce
- 4- availability of funds for the physical changes required for the BFHI
- 5- availability of funds for the workforce training required for the BFHI
- 6- free formula from formula companies
- 7- availability of neonatal equipment in maternal rooms
- 8- use of well-baby nursery for routine newborn care
- 9- availability of funds for certification process with Baby-Friendly USA
- 10- availability of BFHI research articles
- 11- other

Competing Demands

Which of these competing demands the *greatest barrier* to implementation of the BFHI at your hospital?

- 1- focus on other perinatal quality improvement programs
- 2- focus on other quality improvement programs outside of perinatal care
- 3- compliance with regulatory requirements
- 4- other

Organizational Readiness for Change

Which of these elements of organizational readiness for change is the *greatest facilitator* of implementation at your hospital?

-
- 1- staff commitment to implementing the BFHI
 - 2- staff motivation to implement the BFHI
 - 3- level of belief in the benefits of the BFHI
 - 4- level of belief in the capability of the hospital to implement the BFHI
 - 5- level of belief in the hospital's resources to implement the BFHI
 - 6- other

Organizational Leaders- General

Which of these elements of leadership is the *greatest barrier* to implementation of the BFHI at your hospital?

- 1- emphasis on innovation to improve patient care
- 2- focus on the opinions of clinical staff when making decisions about improving patient care
- 3- defined areas of responsibility for managers and staff
- 4- emphasis on team building
- 5- emphasis on communication among clinical services and units
- 6- other

Organizational Leaders- Specific to the BFHI

Which of these elements of BFHI leadership is the *greatest facilitator* to implementation of the BFHI at your hospital?

- 1- management for the BFHI
- 2- goals for implementing the BFHI
- 3- schedule for implementation of the BFHI
- 4- other

Organizational policies

Which of these organizational policies is the *greatest barrier* to implementation of the BFHI at your hospital?

- 1- formal, written breastfeeding policy
- 2- clinicians' access to pacifiers
- 3- clinicians' access to formula
- 4- postpartum discharge policies
- 5- influence of other areas of the hospital
- 6- policy for non-nipple feeding for newborns requiring supplementation
- 7- availability of prenatal breastfeeding education
- 8- amount of obstetric interventions that reduce breastfeeding initiation
- 9- visiting hours
- 10- policies re: separation of mothers and infants
- 11- skin-to-skin contact policy
- 12- rooming-in policy
- 13- continuity of care from birth to postpartum
- 14- other

Clinicians

Which of these clinician factors is the *greatest facilitator* of implementation of the BFHI at your hospital?

- 1- knowledge of breastfeeding
- 2- level of support for breastfeeding
- 3- level of support for the BFHI
- 4- resistance to change at work
- 5- engagement in BFHI implementation
- 6- concerns re: making women feel forced to breastfeed
- 7- concerns re: making women feel guilty about breastfeeding choice
- 8- level of use of breastfeeding aides
- 9- level of use of formula
- 10- level of use of pacifiers
- 11- knowledge of BFHI research
- 12- other

Patients

Which of these patient factors is the *greatest barrier* to implementation of the BFHI at your hospital?

- 1- level of knowledge of breastfeeding
-

-
- 2- level of knowledge of the BFHI
 - 3- opinion of breastfeeding
 - 4- opinion of rooming-in
 - 5- feelings about exposing breasts
 - 6- cultural beliefs about breastfeeding
 - 7- ability to learn about breastfeeding in the immediate postpartum period
 - 8- involvement with breastfeeding support groups
 - 9- ability to afford a breast pump
 - 10- language
 - 11- level of support from family
 - 12- level of family encouragement of formula use
 - 13- availability of breastfeeding education for families
 - 14- other

Implementation Interventions

(This group of questions is only seen by respondents whose institutions have implemented the BFHI)

Which of these implementation interventions is the *greatest facilitator* of implementation of the BFHI at your hospital?

- 1- audit and feedback
- 2- BFHI training for nursing staff
- 3- availability of paid time off for nurses to attend BFHI training
- 4- BFHI training for physicians
- 5- availability of paid time off for physicians to attend BFHI training
- 6- use of a champion who enlists support for the BFHI from co-workers
- 7- use of a champion who works cooperatively with senior leadership
- 8- other

Section 3: Profile of Your Organization

What percentage of the patients in your hospital exclusively breastfeeds at discharge?

- < 20%
- 20-39%
- 40-59%
- 60-79%
- 80% or more
- I don't know

What is the average nurse: mother/infant couplet ratio on your unit?

- 1 nurse: 1-2 couplets
- 1 nurse: 3 couplets
- 1 nurse: 4 couplets
- 1 nurse: 5 couplets
- 1 nurse: 6 or more couplets

We do not utilize couplet assignments for nursing care

Thinking about the community your hospital serves, what are the *three* most predominant cultures or ethnic groups of the *patients*? (e.g. African American, Caucasian, Hmong, Puerto Rican, Chinese, etc.)

Section 4: Additional Comments

Are there any barriers or facilitators to implementing the BFHI that we have omitted from this survey? Please feel free to provide any comments or feedback in the space provided.

Discussion

The BFHI is a multi-faceted intervention that requires a team approach and changes in professional and organizational behavior on many levels. Although there are some validated instruments that address organizational change and implementation in the health care setting, none of them were applicable to the research questions of this project. Based on the published literature and our initial feedback from experts, it became clear that there are myriad potential barriers and facilitators to the adoption and implementation of the program. Thus, in order to identify the key factors in this process, we needed to develop our own survey. To date there have not been published studies that have tried to quantify the challenges faced by hospitals that are adopting and implementing the BFHI. We expect that the findings of the data collected from this survey will lay the foundation for further research into this area of study.

Our conceptual framework and associated survey provide a guide for evaluating the organizational factors that influence adoption and implementation of the BFHI, as well as other hospital-based programs. We identified the following key factors that play a role in adoption and implementation processes: statewide policies, organizational culture, organizational resources, competing demands, organizational readiness for change, organizational policies, leadership, clinicians, families, and implementation interventions. The experts guided our work to ensure that we comprehensively considered a broad group of influencing factors. We anticipate that this model and survey will be helpful to future researchers who seek to identify barriers and facilitators to the adoption and implementation of any hospital-based program. Although the specific factors within these categories may change based on the program and its target populations, these general factors are likely applicable to all organizations.

Additionally, the design of our survey, which asks respondents to first identify their

experience with an individual factor and then to identify a factor as a barrier or facilitator, is a novel approach to considering barriers and facilitators in a single survey. This approach allowed us to provide neutral language that did not bias responses with positive or negative language. We expect that this format will be useful to researchers in a variety of areas of implementation science.

For researchers who are specifically interested in the implementation of the BFHI, we have also provided a framework that can allow for deeper exploration into explicit factors. For example, for researchers interested in the role that clinicians play in implementation of the BFHI, the identification here of eleven clinician-based factors can help guide a deeper exploration of this specific area (Koopman, Callaghan-Koru, Alaofin, Argani, & Farzin, 2016; Lundeen, Sorensen, Bland, George, & Snyder, 2016; Pound et al., 2016; Wieczorek, Marent, Dörner, & Dur, 2016). In turn, this can lead to targeted interventions to improve adoption and implementation on specific areas of influence.

Balance of Complete Data vs. Time Constraints

Researchers must balance the competing goals of collecting the maximum amount of data while considering the desirability of participation for potential participants. Most research regarding survey length and response rate shows that there is a negative predictive relationship between the two factors (Dykema, Jones, Piche, & Stevenson, 2013; Hardigan, Popovici, & Carvajal, 2016). Therefore, we sacrificed some questions that we wanted to ask, in the interest of making our survey's length feasible.

Strengths of Methods and Final Survey

Many of our experts had personal experience with adopting and implementing the BFHI. These experiences helped to add content to the survey and helped us to prioritize certain areas

over others. The inclusion of two survey design experts helped to fine tune the design and execution of the survey. Using a literature review and conceptual framework in survey development helps ensure that the data collected will be relevant and applicable. The use of the e-Delphi technique supports the consensus that this survey includes the key factors involved in the adoption and implementation process. We anticipate that the data collected will be informative and lead to further research in this area. Additionally, because the survey is based in the body of implementation science literature and theoretical literature, we expect that the framework developed here can be useful to researchers who are interested in implementation in a variety of settings.

Limitations of Methods and Final Survey

Based on expert consensus, we eliminated the standardized tools that we initially included. By omitting these tools from our survey, we have eliminated continuous-level data from the survey. This omission will prevent us from using multivariate statistical methods in our data analysis, which in turn prevents the ability to predict or explain the value of one variable in relation to others. In seeking to develop a survey that was so expansive, we started out with a cumbersome instrument. Even for our experts, the length was long and the time taken was significant. If we had shortened our initial survey, we might have successfully enrolled more experts, which would have further bolstered our conclusions.

Conclusion

The process of survey development was lengthy and labor intensive. It required the synthesis of theoretical constructs, previously published accounts, opinions of BFHI and breastfeeding experts, and suggestions of survey design experts. The ultimate product, however, has balanced the need to collect complete and thorough information with the need to have a

usable survey. The findings from this survey will lead to a set of quantitative data regarding the barriers and facilitators that influence adoption and implementation of the BFHI in the US. We anticipate that the results will be informative and will guide future interventions to facilitate implementation of the BFHI program. There is also potential for our survey to be of use to researchers who seek to evaluate adoption and implementation in other settings, or for those who seek to more deeply explore specific influencing factors on the BFHI.

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CHAPTER 4

IDENTIFYING THE KEY BARRIERS AND FACILITATORS TO THE ADOPTION AND IMPLEMENTATION OF THE BABY FRIENDLY HOSPITAL INITIATIVE

This chapter describes the methods and results of the research project and specifically addresses aims 1 and 2. The manuscript has been prepared for submission and will be submitted for review in the coming weeks.

Background

The Baby-Friendly Hospital Initiative (BFHI) encourages hospitals to promote and support breastfeeding (World Health Organization & UNICEF, 2009). The BFHI designates facilities that comply with their guidelines, known as the Ten Steps to Healthy Breastfeeding, as Baby-Friendly (Baby Friendly USA, 2017b). Based on a number of studies that support the efficacy of the program for promoting breastfeeding (Kramer et al., 2001; Perez-Escamilla, Martinez, & Segura-Perez, 2016), the BFHI has broad support from multiple entities (American College of Obstetricians and Gynecologists, 2016; Association of Women's Health Obstetric and Neonatal Nurses, 2007; U.S. Department of Health and Human Services, 2011). Healthy People 2020 sets national goals for 8.1% of US hospitals to attain designation, and California law mandates that hospitals in the state with perinatal units adopt the Ten Steps by January 1, 2025 ("SB-402 Breastfeeding," 2013; US Department of Health and Human Services Office of Disease Prevention and Health Promotion). Despite this public policy push, the program has been slow to take hold in the US. As of October 2017, there are currently 454 US hospitals designated as Baby-Friendly, representing 21.9% of all maternity-care hospitals in the country (Baby Friendly USA, 2017a).

Adoption and Implementation

Adoption and implementation of any new program, including the complex and multi-faceted BFHI, pose challenges for an organization and are affected by a variety of factors. Facilitators are factors that help advance the use of a new innovation, whereas barriers are factors that inhibit the uptake of an innovation (Flottorp et al., 2013). When facilitators outweigh barriers, adoption and implementation efforts are more likely to succeed (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005).

Adoption is the decision by an organization to pursue a new program or practice, in this case, the BFHI (Dearing, 2009; Gaglio, Shoup, & Glasgow, 2013). The presence or absence of organizational factors (e.g., culture, resources, competing demands, readiness for change, and leadership) and policies can influence adoption of a new program (Flottorp et al., 2013).

Once the decision to adopt an innovation is made, the organization moves into the implementation phase where a change in the target behavior within an organization occurs (Damschroder et al., 2009). In this case, implementation refers to successful designation as Baby-Friendly. Implementation may be influenced by management techniques, organizational policies, efforts of clinicians, buy-in from patients, and choice of implementation interventions (Flottorp et al., 2013; Meyers, Durlak, & Wandersman, 2012; Rycroft-Malone et al., 2004).

The present study

There is a substantial body of qualitative literature and some single-site before-after design studies that describe the challenges faced by institutions as they attempt to adopt and implement the BFHI (Lundeen, Sorensen, Bland, George, & Snyder, 2016; Tran, 2017; Ward, Williamson, Burke, Crawford-Hemphill, & Thompson, 2017; Wiczorek, Marent, Dorner, & Dur, 2016). In

addition, one integrative review of the literature highlighted the myriad barriers and facilitators to implementation of the program (Semenic, Childerhose, Lauziere, & Groleau, 2012).

However, little is known about which barriers and facilitators most greatly impact adoption and implementation of the BFHI.

Clinicians and administrators who seek to guide their institutions to achieve BFHI designation have had little clarity regarding where to best focus their efforts. By understanding which barriers and facilitators are the most frequently experienced across the US, those seeking to begin or expedite the BFHI designation process can identify potential challenges and supports that exist in their own institutions. Therefore, the purpose of this study was to identify which organizational factors promote or inhibit the adoption and implementation of the BFHI in the US.

Methods

Design

We used a cross-sectional design to collect descriptive data from perinatal health specialists regarding their experiences with adoption and implementation of the BFHI. Cross-sectional designs are best suited to identifying a problem, forming a hypothesis, and guiding future research (Goldberg, McManus, & Allison, 2013; Silverman, 2009), which was congruent with our aims of identifying the experiences of our participants. Approval for the study was obtained through *blinded for review* Institutional Review Board (IRB).

Setting

Participants were recruited by statewide perinatal quality improvement (PQI) partner organizations in Tennessee (TN), Ohio (OH), Indiana (IN), Texas (TX), Colorado (CO), and California (CA- Los Angeles county only). Data collection occurred between January and July

2017. Data were collected using REDCap (Research Electronic Data Capture), a secure, Web-based data collection system.

Sample

Each of the partner organizations has a program that supports hospitals in their state to pursue the Ten Steps and/or the BFHI designation, thus their contact lists contained perinatal professionals who were familiar with the BFHI. Partner organizations were responsible for sending the invitation to their members and for sending three subsequent reminder emails. This provided for anonymity of the respondents. Participants had access to the survey for six weeks. Those who completed the survey were eligible for a \$20 Amazon e-gift card. To be included in the study, participants had to currently work in a hospital that had considered pursuing Baby-Friendly designation; hold a minimum of an associate's degree and be at least 18 years of age to be eligible to participate.

Measurement

A survey developed for this study with the input of twelve experts via the e-Delphi process, was used to collect all study data. See *blinded for review* for details of the survey development, including pilot testing. The survey includes three sections: assessment of potential barriers and facilitators of adoption and implementation, hospital characteristics, and respondent characteristics.

Data Collection

The initial email invitation included information about the aims and procedures of the study, the expected time needed for completion of the survey, contact information for the primary investigator, and a Weblink to the survey.

Data Analysis

Frequency distributions (counts and percentages) were used to summarize the responses to each item. Chi-square tests of independence were used to investigate possible areas of personal characteristics differences between the respondents who completed the survey and those who completed only initial sections of the survey.

Results

Personal Characteristics

A total of 856 potential participants were invited to join the study, and 256 responded (29.9 % response rate). Respondents took a median of 20-25 minutes to complete the survey. Personal characteristics of the 256 respondents are depicted in Table 1. Almost all respondents were women (99.2%). Most respondents were lactation consultants (44.5%) or nurses (38.7%).

The full survey was completed by 188 respondents (i.e., “completers”); 68 respondents responded to some of the items but did not reach the end (i.e., “non-completers”). A statistically significant difference was noted between the respondents who completed the survey and those who did not related to the role that the respondent played in implementing the BFHI, a question asked only of those who had adopted the program ($N = 212, p = 0.028$). Completers had a higher percentage of respondents who oversaw implementation of the BFHI at the hospital level (29.1%) than non-completers (13.0%) and, correspondingly, a lower percentage who oversaw implementation of the BFHI on their units (3.2%) than non-completers (13.0%). Aside from this item, there were no statistically significant differences between completers and non-completers.

Table 1. *Personal characteristics of respondents* (N= 256)

Characteristic	n (%)
Years employed at hospital	
< 1	5 (2.0)
1-2	18 (7.0)
3-4	25 (9.8)
5-8	32 (12.5)
> 8	176 (68.8)
Years in position	
< 1	11 (4.3)
1-2	36 (14.0)
3-4	45 (17.6)
5-8	43 (16.8)
> 8	121 (47.3)
Highest level of education	
Associate's degree	36 (14.1)
Bachelor's degree	145 (56.8)
Master's degree	65 (25.4)
Doctorate degree	10 (3.9)
Gender	
Female	254 (99.2)
Male	2 (0.8)
Age (in years) ^a	
25-35	18 (7)
36-45	66 (25.9)
46-55	68 (26.7)
56-65	97 (38.0)
>65	6 (2.4)
Discipline ^b	
Lactation consultant	114 (44.5)
Nursing	99 (38.7)
Administration	30 (11.7)
Medicine	7 (2.7)
Other	6 (2.3)
Job title	
Lactation consultant	65 (25.4)
Lactation services coordinator	64 (25.0)
Maternity care services director/manager	33 (12.9)
Mother-Baby unit manager/supervisor	19 (7.4)
Staff nurse	17 (6.6)
Other ^c	58 (22.7)
Role in Baby-Friendly adoption ^d	
Main decision-maker	4 (1.6)
One of a group of decision-makers	92 (36.2)
Participant but not a decision-maker	119 (46.9)
Non-participant but aware of decision-making process	21 (8.3)

Unaware of decision-making process	12 (4.7)
Other	6 (2.4)
Role in Baby-Friendly implementation ^e	
Oversees implementation in the hospital	53 (25.0)
One of a group of implementers at hospital level	78 (36.8)
Oversees implementation on the unit	12 (5.7)
One of a group of implementers on the unit	34 (16.0)
Participant in implementation/ non-leader	26 (12.3)
Non-participant	5 (2.4)
Other	4 (1.9)

^a N = 256 for this item ^b When respondents entered two disciplines or two job titles in the “other” section, they were assigned to the first listed discipline or title. ^c Responses with fewer than 5% of responses have been removed from the table and grouped as Other. They include: NICU nurse manager, nursing education, Labor and Delivery unit manager/supervisor, clinical nurse specialist, director of perinatal care, patient education, director of obstetrics and gynecology, staff physician, medical director, chief nursing officer, other. ^d N = 254 for this item. ^e N = 212 for this item. Only respondents who indicated that their hospitals had adopted the BFHI were presented with this item.

Hospital Characteristics

Although participants were recruited in six states (TN, OH, IN, TX, CO, CA), we received responses from participants in twelve states (Table 2). This suggests that the survey was shared either through interpersonal communication or via a national listserv. Because our survey was not specific to the targeted states and because enrollment was not restricted to these states, we included the responses from all states in our data.

Most respondents worked in a community hospital (78.7%), although the setting for these hospitals varied, with 41% of respondents working in an urban setting, 39.9% in a suburban setting and 19.1% in a rural setting. The median number of annual births was 1500 (IQR = 800-3175, range = 1-8400). The hospitals varied in their levels of adoption and implementation of the BFHI and were distributed across five categories in the adoption/implementation continuum.

Table 2. *Characteristics of respondents' hospitals* (N=188)

Characteristic	n (%)
State	
Texas	45 (23.9)
Tennessee	44 (23.4)
Ohio	30 (16.0)
Colorado	23 (12.2)
California	22 (11.7)
Indiana	17 (9.0)
Other ^a	7 (3.7)
Percentage of patients who initiate breastfeeding	
<20%	1 (0.5)
20-39%	3 (1.6)
40-59%	17 (9.0)
50-79%	58 (30.9)
80% or more	106 (56.4)
Don't know	3 (1.6)
Percentage of patients who exclusively breastfeed at discharge	
<20%	8 (4.3)
20-39%	35 (18.6)
40-59%	68 (36.2)
50-79%	47 (25.0)
80% or more	26 (13.8)
Don't know	4 (2.1)
Type of hospital	
Community hospital	148 (78.7)
University-based teaching hospital	27 (14.4)
Other	13 (6.9)
Hospital setting ^b	
Urban	77 (41.0)
Suburban	75 (39.9)
Rural	36 (19.1)
Baby-Friendly Status N=256 ^c	
Considered but did not adopt	44 (17.2)
Pursuing some of the Ten Steps without full adoption	49 (19.1)
Began BFHI implementation but did not complete	15 (5.9)
In-process implementation	69 (26.9)
Fully designated at Baby-Friendly	79 (30.9)

^a States with fewer than five respondents included: AL, ID, KS, MI, NC, and WV, ^b For the purposes of this study, settings were defined as urban = 3000+ persons per square mile, suburban = 1000-3000 persons per square mile, rural = less than 1000 persons per square mile. ^c Most hospital questions were asked at the end of the survey, but we asked about Baby-Friendly status at the beginning of the survey; therefore, there were 256 responses to this item.

Factors Influencing Adoption

Potential facilitators and barriers of adoption of the BFHI are presented in Table 3.

Statewide policies. Participation in a statewide perinatal quality improvement (PQI) program was the greatest policy facilitator of BFHI adoption (58.9%) while a lack of financial support at the state level was the most often reported as a policy barrier (48.9%). Of note, 7.4% of respondents reported that none of these policies were facilitators and 19.3% reported that none were barriers.

Organizational culture. An organizational culture that emphasizes the value of evidence-based care was reported to be the greatest facilitator of BFHI adoption in this category (51.1%). A culture that does not encourage hospital staff to be receptive to change was reported as the greatest cultural barrier (62.2%). Some organizational cultural factors were not deemed to be influential as facilitators or barriers, including a cultural value of innovation (facilitator 5.9%, barrier 1.8%), emphasis on patient safety (facilitator 3.2%, barrier 0.9%), and level of support for breastfeeding staff (facilitator 4.5%, barrier 4.5%).

Organizational resources. Having a sufficient quantity of nurses was the most frequently selected resource facilitator (27.5%). A sufficient quantity of lactation consultants was also noted as an important facilitator (24.3%), as was a stable workforce (16.1%). The greatest reported resource barrier was a lack of funds to support the process with Baby-Friendly USA (14.7%). An insufficient quantity of lactation consultants (13.8%), a lack of funds for workforce BFHI training (13.3%), and the provision of free infant formula to hospitals (11.5%) were also reported as barriers to adopting the program.

Competing demands. Participation in other PQI programs, such as postpartum hemorrhage reduction, was the most frequently reported facilitator to BFHI adoption in this

category (57.0%). A hospital's involvement in quality improvement programs outside of the perinatal area, such as Magnet status, was reported as the greatest competing demand barrier (36.9%). Approximately one fifth stated that competing demands were not a barrier to adoption of the program.

Organizational readiness for change. The hospital staff's level of belief in the benefits of the BFHI was reported as the greatest facilitator in this category (31.9%) and the greatest barrier (28.4%). Responses were split among the remaining readiness facilitators: staff commitment to the BFHI (19.3%), staff belief in the hospital's ability to implement the BFHI (15.5%), staff belief in the hospital's resources to implement the BFHI (15.0%), and the staff's motivation to implement the BFHI (14.5%). Among readiness barriers, again responses were split between staff's motivation to implement the BFHI (23.1%), staff's belief in the hospital's resources to implement the BFHI (18.3%), and staff's commitment to the BFHI (14.9%).

Organizational leadership. Leaders who emphasize innovation were the most frequently cited facilitator of adoption in this category (52.2%). Respondents stated that leaders who emphasize interdisciplinary communication and inter-unit communication (24.4%), do not focus on the opinions of clinical staff (22.9%), or do not clearly define areas of responsibility for managers and staff (21.9%) can be barriers to BFHI adoption.

Table 3. *Factors That Influence Adoption of the Baby Friendly Hospital Initiative (BFHI)*

Facilitators	n (%)	Barriers	n (%)
<u>Statewide policies (N= 233) ^a</u>			
Participation in state perinatal QI program	136(58.9)	Lack of financial support	114(48.9)
Financial support	36 (15.6)	State laws	35 (15.0)
State laws	29 (12.6)	Non-participation in state perinatal QI program	23 (9.9)
Not a facilitator	17 (7.4)	Statewide policy is not a barrier	45 (19.3)
Other ^b	13 (5.6)	Other	16 (6.9)
<u>Organizational Culture (N=222) ^c</u>			
Emphasis on evidence-based care	113(51.1)	Staff's level of receptiveness to change	138(62.2)
Sense of responsibility for patient care	50 (22.6)	Interdisciplinary communication	18 (8.1)
Cooperation to improve patient care	20 (9.0)	Lack of cooperation to improve patient care	11 (5.0)
Innovation to improve patient care	13 (5.9)	Lack of support of breastfeeding staff	10 (4.5)
Support for breastfeeding staff	10 (4.5)	Sense of responsibility for patient care	9 (4.1)
Emphasis on patient safety	7 (3.2)	Emphasis on evidence-based care	5 (2.3)
Interdisciplinary communication	3 (1.4)	Lack of innovation to improve patient care	4 (1.8)
Staff's receptiveness to change	3 (1.4)	Emphasis on patient safety	2 (0.9)
Not a facilitator	0 (0.0)	Culture is not a barrier	22 (9.9)
Other	2 (0.9)	Other	3 (1.4)
<u>Organizational Resources (N=218)</u>			
Quantity of nurses	60 (27.5)	Funds for certification with BFUSA	32 (14.7)
Quantity of lactation consultants	53 (24.3)	Quantity of lactation consultants	30 (13.8)
Stability of the workforce	35 (16.1)	Funds for workforce training	29 (13.3)
Funds for workforce training	21 (9.6)	Free formula	25 (11.5)
Funds for certification with BFUSA	15 (6.9)	Quantity of nurses	24 (11.)
Availability of BFHI research articles	9 (4.1)	Stability of the workforce	22 (10.1)
Neonatal supplies in maternal rooms	8 (3.7)	Routine use of newborn nursery	15 (6.9)
Routine use of newborn nursery	4 (1.8)	Funds for physical changes	11 (5.0)
Funds for physical changes	2 (0.9)	Availability of BFHI research articles	3 (1.4)
Free formula	0 (0.0)	Neonatal supplies in maternal room	3 (1.4)

Facilitators	n (%)	Barriers	n (%)
<u>Competing Demands (N=214)</u>			
Other perinatal QI programs	122(57.0)	QI programs outside perinatal care	79 (36.9)
Compliance with regulatory rules	71 (33.2)	Compliance with regulatory rules	47 (22.0)
QI programs outside of perinatal care	10 (4.7)	Other perinatal QI programs	44 (20.6)
Not a facilitator	8 (3.7)	Not a barrier	41 (19.2)
Other	3 (1.4)	Other	3 (1.4)
<u>Organizational Readiness for Change (N=208)^d</u>			
Belief in the benefits of the BFHI	66 (31.9)	Belief in the benefits of the BFHI	59 (28.4)
Staff commitment to the BFHI	40 (19.3)	Staff motivation to implement the BFHI	48 (23.1)
Belief in the hospital's ability to implement	32 (15.5)	Belief in the hospital's resources	38 (18.3)
Belief in hospital resources	31 (15.0)	Staff commitment to the BFHI	31 (14.9)
Staff motivation to implement the BFHI	30 (14.5)	Belief in the hospital's ability to implement	20 (9.6)
Not a facilitator	7 (3.4)	Readiness for change is not a barrier	11 (5.3)
Other	1 (0.5)	Other	1 (0.5)
<u>Leadership- General (N=201)</u>			
Emphasis on innovation	105(52.2)	Focus on interdisciplinary communication	49 (24.4)
Focus on the opinions of clinical staff	29 (14.4)	Focus on the opinions of clinical staff	46 (22.9)
Emphasis on team building	25 (12.4)	Defined responsibilities for managers/ staff	44 (21.9)
Focus on interdisciplinary communication	21 (10.4)	Emphasis on team building	18 (9.0)
Defined responsibilities for managers/ staff	16 (8.0)	Emphasis on innovation	17 (8.5)
Not a facilitator	3 (1.5)	Leadership is not a barrier	18 (9.0)
Other	2 (1.0)	Other	9 (4.5)

^a N=231 for facilitators. ^b Respondents who chose not to answer, responded Don't know, or provided another barrier or facilitator have been grouped into an Other category. ^c N= 221 for facilitators. ^d N=207 for facilitators.

Factors Influencing Implementation

Potential facilitators and barriers of implementation of the BFHI are presented in Table 4.

BFHI-specific leadership. Only respondents who indicated that they had adopted the BFHI (N = 165) were asked to answer this section. Respondents indicated that leaders who have clear goals for implementing the BFHI were the greatest facilitator of implementation in this section (46.1%). Poor management of the BFHI process was the greatest leadership barrier reported (39.4%).

Organizational policies. Having a formal breastfeeding policy (36.6%) and a skin-to-skin policy (28.9%) were the most important policy facilitators of implementation of the BFHI. Clinicians' access to infant formula (n = 53, 27.3%) and a high rate of obstetric interventions that separate mothers and infants (18.0%) were the most commonly reported barriers. Some organizational policies were not deemed to be influential as facilitators or barriers. These included clinicians' access to pacifiers (dummies) (facilitator 0.0%, barrier 2.6%), postpartum discharge policies (facilitator 0.0%, barrier 2.1%), and influence of other areas of the hospital (facilitator 0.0%; barrier 5.2%).

Clinicians. Clinicians who support breastfeeding (49.5%) and are knowledgeable about breastfeeding (24.5%) were the greatest clinician facilitators of BFHI implementation. The top clinician barriers were distributed among clinicians who resist change at work (21.9%), are concerned about making women feel forced to breastfeed (16.1%), and use formula to manage breastfeeding difficulties (14.6%). Respondents were also asked to identify up to three professional groups of clinicians who are most supportive of the BFHI and three who are least supportive. These findings are presented in Figures 1 and 2. Lactation consultants were selected by 45% of the respondents as being most supportive of the BFHI. No respondents indicated that

lactation consultants were least supportive.

Figure 1. Clinicians perceived to be most supportive of the BFHI N=256 responses

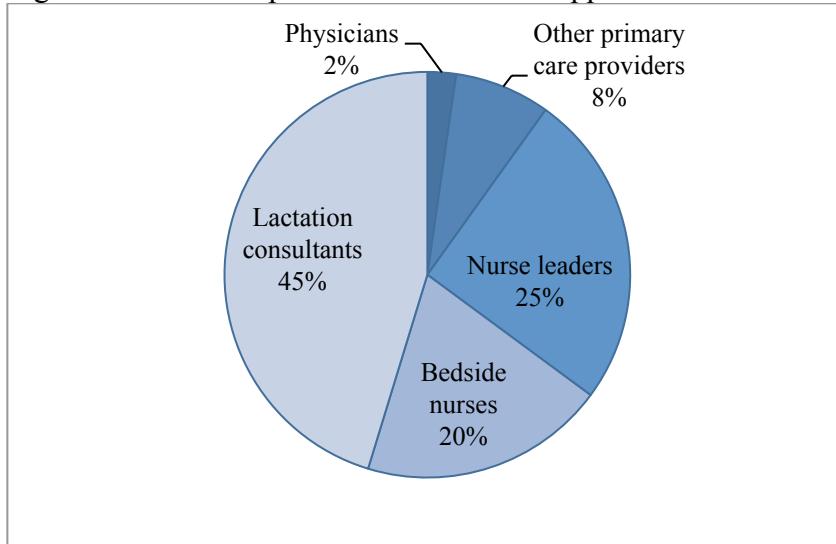
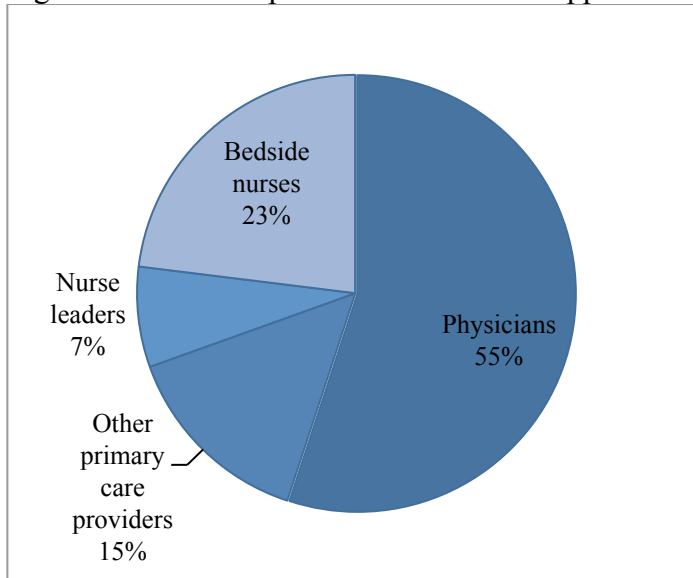


Figure 2. Clinicians perceived to be least supportive of the BFHI N=256 responses



Patients. Patient facilitators most often reported included patients who are able to learn about breastfeeding in the postpartum period (28.8%), are knowledgeable about breastfeeding (26.7), and have a positive opinion of breastfeeding (21.5%). Patients who do not have

knowledge of breastfeeding (20.9%), whose families encourage them to formula-feed their infants (16.8%), and whose cultural beliefs negatively influence their opinions of breastfeeding (15.7%) were considered the greatest patient barriers to BFHI implementation. Some patient factors were not deemed to be influential as facilitators or barriers. These included language differences between clinician and patient (facilitator 0.5%, barrier 0.5%), ability to afford a breastfeeding pump (facilitator 0.0%, barrier 0.5%), and feelings about exposing their breasts (facilitator 0.0%, barrier 1.6%).

Implementation interventions. The implementation intervention section was only presented to respondents who had adopted the BFHI (n = 160). The intervention facilitators of BFHI implementation most frequently selected by respondents were the provision of BFHI-specific training for nurses (33.8%) and the use of audit-and-feedback (27.5%). Respondents reported that BFHI training for physicians (28.1%) and a lack of paid time off for nurses to attend BFHI training (21.9%) were the greatest intervention barriers to implementation.

Table 4. *Factors that influence implementation of the Baby Friendly Hospital Initiative*

Facilitators	n (%)	Barriers	n (%)
<u>Leadership- BFHI specific (N=165)</u>			
Goals for implementing the BFHI	76 (46.1)	Management for the BFHI	65 (39.4)
Management for the BFHI	44 (26.7)	Schedule for implementation of the BFHI	54 (14.5)
Schedule for implementation of the BFHI	31 (18.8)	Goals for implementing the BFHI	24 (14.5)
BFHI leadership is not a facilitator	12 (7.3)	BFHI leadership is not a barrier	18 (10.9)
Other ^a	2 (1.2)	Other	4 (2.4)
<u>Organizational Policies (N=194)</u>			
Formal breastfeeding policy	71 (36.6)	Clinicians' access to formula	53 (27.3)
Skin-to-skin policy	56 (28.9)	Obstetric interventions	35 (18.0)
Continuity of care	19 (9.8)	Policy of non-nipple feeding	15 (7.7)
Rooming-in policy	16 (8.2)	Prenatal breastfeeding education	14 (7.2)
Prenatal breastfeeding education	16 (8.2)	Visiting hours	13 (6.7)
Policies re: separation of mothers and infants	9 (4.6)	Influence of other areas of the hospital	10 (5.2)
Obstetric interventions	2 (1.0)	Policies re: separation of mothers and infants	9 (4.6)
Visiting hours	1 (0.5)	Continuity of care	8 (4.1)
Clinicians' access to formula	1 (0.5)	Rooming-in policy	6 (3.1)
Clinicians' access to pacifiers	0 (0.0)	Clinicians' access to pacifiers	5 (2.6)
Postpartum discharge policies	0 (0.0)	Postpartum discharge policies	4 (2.1)
Influence of other areas of the hospital	0 (0.0)	Formal breastfeeding policy	2 (1.0)
Policy for non-nipple feeding	0 (0.0)	Skin-to-skin policy	1 (0.5)
Policy is not a facilitator	1 (0.5)	Policy is not a barrier	15 (7.7)
Other	2 (1.0)	Other	4 (2.1)
<u>Clinicians (N=194) ^b</u>			
Support for breastfeeding	95 (49.5)	Resistance to change at work	42 (21.9)
Knowledge of breastfeeding	47 (24.5)	Concern re: forcing breastfeeding	31 (16.1)
Engagement in BFHI implementation	16 (8.3)	Use of formula	28 (14.6)
Support for BFHI	12 (6.3)	Support for BFHI	20 (10.4)
Knowledge of BFHI research	10 (5.2)	Concern re: making women feel guilty	16 (8.3)

Facilitators	n (%)	Barriers	n (%)
Use of pacifiers	1 (0.5)	Knowledge of breastfeeding	12 (6.3)
Resistance to change at work	0 (0.0)	Knowledge of BFHI research	10 (5.2)
Use of formula	0 (0.0)	Use of breastfeeding aides	2 (1.0)
Concern re: making women feel guilty	0 (0.0)	Use of pacifiers	0 (0.0)
Clinicians are not a facilitator	4 (2.1)	Clinicians are not a barrier	3 (1.6)
Other	2 (1.0)	Other	1 (0.5)
<u>Patients (N=194) ^c</u>			
Postpartum ability to learn to breastfeed	55 (28.8)	Knowledge of breastfeeding	40 (20.9)
Knowledge of breastfeeding	51 (26.7)	Family encouragement of formula use	32 (16.8)
Opinion of breastfeeding	41 (21.5)	Cultural beliefs about breastfeeding	30 (15.7)
Opinion of rooming-in	15 (7.9)	Level of support from family	25 (13.1)
Access to breastfeeding education for families	12 (6.3)	Knowledge of BFHI	21 (11.0)
Involvement with peer support groups	6 (3.1)	Postpartum ability to learn to breastfeed	11 (5.8)
Level of support from family	4 (2.1)	Opinion of rooming-in	10 (5.2)
Knowledge of BFHI	1 (0.5)	Opinion of breastfeeding	9 (4.7)
Cultural beliefs about breastfeeding	1 (0.5)	Access to breastfeeding education for families	4 (2.1)
Language	1 (0.5)	Feelings about exposing breasts	3 (1.6)
Feelings about exposing breasts	0 (0.0)	Involvement with peer support groups	1 (0.5)
Ability to afford a breast pump	0 (0.0)	Ability to afford a breast pump	1 (0.5)
Family encouragement of formula use	0 (0.0)	Language	1 (0.5)
Patients are not a facilitator	3 (1.6)	Patients are not a barrier	2 (1.0)
Other	1 (0.5)	Other	1 (0.5)
<u>Implementation Interventions (N=160)</u>			
BFHI training for nurses	54 (33.8)	BFHI training for physicians	45 (28.1)
Audit and feedback	44 (27.5)	Paid time off for nurses to attend BFHI training	35 (21.9)
Champion who enlists support from co-workers	26 (16.3)	Audit and feedback	17 (10.6)
Champion who cooperates with senior leadership	18 (11.3)	Champion who cooperates with senior leadership	16 (10.0)
Paid time off for physicians to attend BFHI training	12 (7.5)	Paid time off for physicians to attend BFHI training	14 (8.8)

Facilitators	n (%)	Barriers	n (%)
BFHI training for physicians	2 (1.3)	BFHI training for nurses	13 (8.1)
Paid time off for physicians to attend BFHI training	0 (0.0)	Champion who enlists support from co-workers	12 (7.5)
Interventions are not a facilitator	3 (1.9)	Interventions are not a barrier	6 (3.8)
Other	1 (0.6)	Other	2 (1.0)

^a Respondents who chose not to answer, responded Don't know, or provided another barrier or facilitator have been grouped into an Other category. ^b N= 192 for facilitators. ^c N= 191 for barriers.

Discussion

This study identified key barriers to and facilitators of adoption and implementation of the BFHI. A number of unique themes emerged from the results. These findings help to elucidate our understanding of the uptake of the BFHI and the challenges facing hospitals in the US.

Adoption of the BFHI

Similar to studies investigating statewide PQI efforts in other clinical areas (Bingham, Lyndon, Lagrew, & Main, 2011; Lannon & Peterson, 2013; Miller & Miller, 2013; Simpson, Knox, Martin, George, & Watson, 2011), statewide support from PQI organizations was reported to be valuable in facilitating adoption of the BFHI. Because the sample frame for our study included respondents who were involved with a PQI collaborative or group, this would be expected. Additionally, respondents reported that being involved in other PQI programs, such as postpartum hemorrhage reduction or neonatal abstinence reduction, helped their organizations prepare for implementing the BFHI. Since these types of programs are frequently supported by statewide perinatal collaboratives, this further supports the role of these groups in advancing the BFHI. An emphasis on evidence-based care, a sense among the staff that they have personal responsibility for improving care, and a culture of cooperation to improve patient care were the key facilitators within organizational culture for successful adoption. Again, these are values espoused by statewide perinatal networks and support further research into their benefits and advancement of their missions.

Also at the statewide level, respondents stated that laws that encourage BFHI-designation were an important facilitator of adoption and a lack of these laws was a barrier. The case of California law, which requires full implementation of the Ten Steps by 2025, can serve as a

guide for other states who seek to increase the number of Baby-Friendly or Ten Steps-compliant facilities through policy initiatives ("SB-402 Breastfeeding," 2013).

Financial assistance at the state or local level was reported as a facilitator and the lack of these funds was a barrier. Additionally, a lack of funds to pay for designation with Baby-Friendly USA, workforce training, or infant formula was cited by many respondents as a barrier to adoption; the availability of these funds was a facilitator. Programs such as those in New Jersey and Los Angeles County, California may serve as models for funding to support adoption and implementation of the BFHI (Los Angeles County Department of Health, 2015; New Jersey Baby-Friendly Hospital Initiative, 2012). These programs have provided small grants to individual hospitals that seek to pursue Baby-Friendly designation.

A lack of receptiveness to change among staff was reported as the greatest cultural barrier to adoption of the BFHI. When considering organizational readiness for change, respondents selected a belief by staff in the benefits of the BFHI as the greatest readiness facilitator and a lack of this belief to be the greatest barrier. This suggests that there may be value in assessing baseline readiness for change and beliefs about the BFHI prior to deciding whether or not to pursue adoption of the program. There are a number of instruments that measure an organization's readiness for change for this purpose (Friedberg, Rodriguez, Martsof, Edelen, & Vargas Bustamante, 2016; Gagnon et al., 2014).

Some additional facilitators of adoption did not have a direct relationship with barriers but are worthy of mention, as they were frequently selected by respondents. These include having enough nurses and lactation consultants to provide the level of care required, as well as a stable workforce. Hospital leaders who emphasize innovation were also reported to be an important facilitator. These themes had also emerged in earlier qualitative research and merit

further exportation and attention (St Fleur & McKeever, 2014; VanDevanter, Gennaro, Budin, Calalang-Javiera, & Nguyen, 2014). Some additional barriers that were notable include the pursuit of Magnet status or other QI programs outside of perinatal care, leaders who emphasize interdisciplinary communication, and leaders who focus on the opinions of clinical staff. The ways in which a focus on other QI programs could negatively affect the adoption of the BFHI are understandable, but the leadership qualities that were identified as barriers are somewhat surprising and worthy of deeper exploration. Recent literature has begun to explore the influence that leaders have on adoption of the BFHI (Eganhouse, Gutierrez, Cuellar, & Velasquez, 2016; Feldman-Winter & Ustianov, 2016).

Implementation of the BFHI

Once the decision is made to pursue BFHI designation, hospitals enter into the implementation phase. At this level, managers, clinicians, and patients work together to advance the BFHI. The goal of successful designation requires a multi-faceted approach. Respondents reported that leaders who set goals for the process and clearly manage the process facilitate implementation, while leaders who lack management skills and a clear schedule impede the process. Leaders, in conjunction with clinicians, will need to focus on policy changes in their institutions that guide unit workflows and habits. Respondents reported that having a formal breastfeeding policy and a formal skin-to-skin policy were important policy facilitators. A lack of policies on clinicians' access to formula and non-nipple feeding were the greatest barriers. Programs such as Best Fed Beginnings (Feldman-Winter et al., 2017) may be effective in supporting hospital and unit leaders as they plan and organize the efforts toward designation.

Once these policy changes are put in place, the provision of BFHI-specific training and the use of audit-and-feedback were considered the most important implementation interventions

for supporting uptake of the program. The greatest barriers were BFHI-specific training for physicians and the availability of paid time-off for nurses to attend the trainings. The meaning of these barriers merits further investigation. The barrier may be the requirement that physicians attend training and the time required, or physicians' resistance to attending the training.

When asked which clinicians were most supportive and least supportive of the BFHI, respondents selected lactation consultants as the most supportive and physicians as the least supportive. Respondents cited clinicians' support for and knowledge of breastfeeding as the greatest clinician facilitators and their feelings of resistance to change and concerns about making women feel forced to breastfeed as the greatest barriers. The content of Baby-Friendly focused education may or may not change clinicians' attitudes and knowledge about breastfeeding, as two recent reviews have noted (Balogun et al., 2017; Gavine et al., 2016). Clearly, providing the twenty hours of dedicated time for training nurses and the three hours for physicians and other primary care providers requires a commitment of time and resources. This may be an area to target for researchers and policy-makers who seek to facilitate greater clinician buy-in, both through the provision of education and through a focus on the content of that education.

Lastly, patients themselves play an active role in the implementation of the BFHI. If they do not share in the values and practices of the program, implementation will not succeed. When patients are able to learn about breastfeeding in the immediate postpartum period, have knowledge of breastfeeding, and have a positive opinion of breastfeeding, respondents perceived that implementation was facilitated. Similar to studies identifying challenges to breastfeeding (Hedberg, 2013; Hinsliff-Smith, Spencer, & Walsh, 2014; Rozga, Kerver, & Olson, 2015; Tully & Ball, 2014), a lack of knowledge of breastfeeding, cultural beliefs around breastfeeding, and

families' provision of infant formula were noted as barriers. Culturally oriented breastfeeding education programs such as the It's Only Natural Program (Office on Women's Health, 2013), that involve family members in the prenatal and postpartum periods could be another area to target to bolster implementation of the BFHI (Johnson, Kirk, Rosenblum, & Muzik, 2015).

In addition to noting the most valuable facilitators and barriers of adoption and implementation of the BFHI, some factors were identified that were selected so infrequently that they appear to have little influence on adoption or implementation of the program either as barriers, facilitators, or both. In future versions of the survey, we will likely omit response choices where fewer than 5% of respondents selected an item. Some of these items are the cultural values of innovation, patient safety and support for breastfeeding staff; policies regarding clinicians' access to pacifiers (dummies), postpartum discharge, and influence of other areas of the hospital; and patient factors regarding language differences, ability to afford a breast pump, and feelings about exposing their breasts. This will help to streamline the survey, and allow for greater clarity of understanding regarding the hierarchy of barriers and facilitators.

Strengths

As the first multi-state quantitative inquiry into the barriers and facilitators of adoption and implementation of the BFHI, we have identified many challenges that are faced by hospitals. We have also identified factors that are not as significant, which may serve to narrow the focus for administrators and clinicians seeking to support their organizations as they pursue the BFHI. The 30% response rate is consistent with other online surveys of health care providers (Cho, Johnson, & Vangeest, 2013). By using a sample of respondents from multiple states, we have collected broad research from states with diverse patient populations, geographic settings, and public policy influences. Findings will provide guidance to researchers, policy-makers, and

administrators who seek to further support the efforts of hospitals in the US to increase the adoption and implementation of the BFHI.

Limitations

We were not able to identify respondents' hospitals; therefore, we were not able to eliminate the possibility that more than one respondent came from the same hospital. Although not likely, this could skew results if multiple respondents identified the same factors at their institutions. Additionally, because this was the first research project of this type, we had to focus solely on the collection of descriptive data, limiting our ability to make conclusions about associations between variables or predict which interventions will be most effective.

Conclusion

The BFHI is a complex program that requires resources, commitment, and a team effort in order to succeed. This study identifies a number of factors that can facilitate the processes of adoption and implementation as well as barriers that can impede the processes and filled a gap in the literature. We anticipate that policy-makers, administrators, and clinicians will find value in targeting their efforts on these main factors as they proceed through the process to Baby-Friendly designation.

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CHAPTER 5

CONCLUSION AND IMPLICATIONS FOR FUTURE RESEARCH

Meaning of findings in relation to research questions

The aim of this research project was to identify the key barriers and facilitators of adoption and implementation of the BFHI in the United States. Many administrators and clinicians struggle to achieve BFHI designation in order to improve patient outcomes, meet national policy goals, comply with regulatory standards, and, in some cases, abide by state laws. With information regarding the most effective and least effective ways to achieve designation, they can tailor their efforts and resources to the most efficient approaches to achieving BFHI designation. This project was conducted in three discrete phases: a review of the literature regarding the effectiveness of the BFHI; the development of a survey tool to identify the barriers and facilitators using the e-Delphi method; and the collection and analysis of the data collected from 256 perinatal professionals. The findings from these studies suggest several areas where further research is needed- these areas have been identified in each chapter and are further discussed here.

Significance in light of prior research findings

This is the first known project that has sought to quantify which of the barriers and facilitators are the most commonly experienced and the most influential on the processes of adoption and implementation. Each of the previous chapters has built on prior research and added new ideas and findings to the body of knowledge regarding the BFHI and implementation science, in general. In Chapter 1, a review of current conceptual frameworks regarding adoption and implementation identified the need for a clear framework to explain the relationships between adoption and implementation and the influence of evidence, policy, the organization,

and individuals. A newly developed conceptual model may serve as a guide for researchers interested in implementation science across a broad scope of settings. In Chapter 2, a review of the literature identified a number of gaps in the research regarding the effectiveness of the BFHI to improve breastfeeding outcomes. Research conducted in the US using rigorous designs and methods would greatly improve our understanding of the BFHI and its ability to influence breastfeeding outcomes in this country. In Chapter 3, a review of measures used to quantify factors that influence adoption and implementation noted that none of the existing measures comprehensively assessed all of the possible influencing factors for the BFHI. This led to the development of a survey instrument specifically tailored to the BFHI, but with themes that could translate to other settings and interventions. In Chapter 4, the findings identified some key themes that can help guide policy and implementation approaches. By providing a multi-state context, clear themes began to emerge that transcend one setting or one set of circumstances. Additionally, some potential barriers and facilitators were found to be less influential in our surveying of respondents; identification of these factors is also valuable, as it can help focus future research and interventions on alternative factors. Taken as a whole, this project adds new knowledge to the theoretical understanding of adoption and implementation; the ways in which barriers and facilitators can be measured; the synthesized findings regarding the effectiveness of the BFHI; and the factors that most greatly influence the adoption and implementation of the program at the national level.

Limitations

Because this was the first project to attempt to identify the greatest barriers and facilitators of adoption and implementation of the BFHI, the list of potential factors was expansive. This influenced the project in a number of ways. The initial survey development

included many items that likely made it burdensome for some expert reviewers and therefore limited the number of reviewers who were willing to participate in the e-Delphi process. Even after the culling of items and streamlining of the survey, the twenty- minute survey may have led to attrition or non-participation of potential respondents, leading to a possible response bias. Most importantly, the large quantity of items led to diffusion of responses and a lack of a clear hierarchy of influencing factors. The purely descriptive nature of the survey and its findings preclude the ability to make higher-level analyses that could identify relationships between factors or predict the influence of one factor over another.

Because the sample frame for this research project was established by participation in a statewide perinatal collaborative, selection bias was understood to be a limitation of this study. This may have led to skewed results related to the positive influence of the collaboratives on the adoption and implementation processes. And although this sample frame may have also led to a higher level of participants who had worked on the BFHI than a fully random sample would have, the partner organizations did maintain contacts with hospitals who had not pursued the BFHI, as evidenced by the 43% of responses that came from facilities that were not actively pursuing accreditation or currently accredited.

Recommendations for future research

In light of the broad scope of this project, there are a number of areas for future research that have been highlighted here.

Theoretical research

The synthesized conceptual model described in Chapter 1 has been applied to this project, from survey development through data analysis. Further refinement of the model and its application to research projects could lead to a more comprehensive and shared understanding of

the processes of adoption and implementation. The relatively new area of implementation science lacks a clear set of defined principles and frameworks and it is hoped that this model can add to the future understanding of multifactorial processes.

Baby-Friendly effectiveness research

There is a clear need for a well-designed cluster-randomized study set in the US to evaluate the influence of the BFHI on breastfeeding outcomes. The current body of literature is outdated, lacking in strong designs and methods, and mainly set in international settings that may not translate to the US population and private-market system. Given the large quantity of resources that are being allocated to the BFHI at the national and state levels, this type of research should be given high priority. Understanding the value of the program to women and infants in our country is important for the long-term goals of improving breastfeeding rates across all populations.

Methodological research

There is a clear need for measures of adoption and implementation that are conceptually grounded, provide quantitative understanding of barriers and facilitators, and apply to a variety of settings. Further refinement of the survey developed here and psychometric testing of the instrument would be valuable to implementation researchers across the spectrum of implementation science.

Baby-Friendly implementation research

This work has identified the most influential barriers and facilitators of adoption and implementation that are being currently faced by perinatal professionals. There is still much more to know. Future research projects should seek to develop a hierarchy of influencing factors. By considering only the most frequently reported barriers and facilitators in each category, the

list of potential factors would be much smaller, and respondents could order the factors from greatest to least. Correlating these kinds of figures with the level of adoption and implementation of respondents' facilities would deepen our understanding of the influence of factors at each phase of the BFHI adoption and implementation continuum.

Other factors that were explored for this project but have not yet been analyzed include the influence of race and ethnic-background on the adoption and implementation processes. Does the cultural background of patients, nurses, or physicians have an impact of the adoption and implementation process? Some have suggested that the cultural background of individuals within organizations may influence the process. Further consideration of these factors will be informative. Additionally, the influence of state laws and statewide perinatal collaboratives appear to be significant and merit further exploration. A recently publicized internet tool identifies which states have some level of legislative policy regarding the BFHI. Exploring the impact of these policies on the outcome of BFHI accreditation would be valuable for future health care policy. Most importantly, future research utilizing respondents from all 50 states would provide a truly national sample and would elucidate the barriers and facilitators faced by the diverse and varied populations in this country.

Health Services Research

Ultimately, considering whether or not the BFHI is a valuable program for hospitals in the US may be the most important research in this area. Given our fee-for service model of care, we must consider that an intervention at the hospital level should have some financial benefit for the institution. Do hospitals see any benefit from improved breastfeeding rates? While breastfeeding undoubtedly has health benefits for patients and correspondingly for the health care system in general, long-term health benefits do not have a clear benefit for hospitals that

profit from illness, not health. Do hospitals benefit from being accredited as Baby-Friendly? One of the stated benefits to hospitals of the BFHI has been purported to be improved marketing and an increase in patients. There is no research to support this idea, however, and it is not at all clear that patients select a hospital based on its Baby-Friendly status. Research regarding market influences of the program and cost-benefit analyses would substantively add to the body of knowledge regarding the BFHI.

Conclusion

This project has made significant contributions to science and nursing science in the areas of theoretical knowledge, understanding of the BFHI, methods to measure adoption and implementation, and specifically adoption and implementation of the BFHI. With the knowledge and information that was acquired, a new set of questions has arisen, with many areas yet to be explored.