BREASTFEEDING, COMPLEMENTARY FEEDING AND HEALTH

DOI: 10.12957/DEMETRA.2019.43555

DEMETRA Alimentação, Nutrição & Saúde

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Study from the Doctoral Thesis "The cost-effectiveness of the Baby-Friendly Hospital Initiative in breastfeeding promotion and late neonatal infant mortality reduction", by Osvaldinete Lopes de Oliveira Silva, Faculty of Public Health at the Universidade de São Paulo, 2018.

Association between infant formula and pacifier supply in maternity and breastfeeding in the first six months of life

Associação entre oferta de fórmulas infantis e chupetas na maternidade e amamentação nos primeiros seis meses de vida

Abstract

Introduction: Breastfeeding (BF) provides the basis for health, food and nutrition supply. It should be promoted at the maternity hospital through practices such as the 6th step (avoid any food or fluid supplements) and 9th step (avoid feeding bottles, teats and pacifiers) of the Baby-Friendly Hospital Initiative (BFHI). *Purpose*: To assess the compliance with BFHI steps 6 and 9 among patients in public hospitals and its association with BF in the first six months of life. *Methodology*: Prospective cohort of patients enrolled in six hospitals in Sao Paulo municipality (three Baby-Friendly Hospitals, BFHs, and three non-BFHs). Mothers were interviewed at maternity ward, and by phone 30 and 180 days after child birth. Compliance with steps 6 and 9 of BFHI, and BF practices were investigated. Associations were analyzed through logistic regression adjusted for confounding variables, determined by the directed acyclic graph (DAG). *Results*: Sample comprised of 969 mothers in the first interview, 902 in the second and 814 in the third with steps 6 and 9 observed in both groups. Non-compliance of step 6 reduced exclusive breastfeeding (EBF) at 30 days (aOR=1.82; CI=1.19-2.77) and at 180 days (aOR=1.79; CI=1.15-2.78). Non-compliance of step 9 reduced EBF at 30 days (aOR=2.33, CI=1.30-4.19). *Conclusion*: The

possibility of EBF in the first month of life was reduced by the offer of infant formula and pacifier in the maternity ward. At six months, breastfeeding was reduced by the introduction of infant formula in the maternity ward. The results emphasize the importance of complying with the International Code of Marketing of Breastmilk Substitutes, providing a safe environment that encourages women to choose to breastfeed.

Keywords: Breastfeeding. Pacifiers. Infant formulas. Baby-Friendly Hospital Initiative.

Resumo

Introdução: Amamentação (AM) é base para a segurança alimentar e saúde. Deve ser promovida na maternidade por práticas como os passos 6 (não oferecer suplementos) e 9 (não oferecer bicos) da Iniciativa Hospital Amigo da Criança (IHAC). *Objetivo*: Avaliar o cumprimento dos passos 6 e 9 da IHAC e sua associação com a AM nos primeiros seis meses de idade. *Metodologia*: Coorte prospectiva em seis hospitais do município de São Paulo, sendo três Hospitais Amigos da Criança (HAC) e três não HAC. Mães foram entrevistadas na maternidade e por telefone aos 30 e 180 dias. Investigaram-se o cumprimento dos passos 6 e 9 e as práticas de AM. As associações foram analisadas por regressão logística ajustada para as variáveis de confusão determinadas pelo gráfico acíclico direcionado (DAG). *Resultados*: Amostra de 969 mães na primeira entrevista, 902 na segunda e 814 na terceira. Os passos 6 e 9 foram cumpridos nos dois grupos de hospitais. O não cumprimento do passo 6 reduziu o AME aos 30 dias (aOR=1,82; IC=1,19-2,77) e a AM aos 180 dias (aOR=1,79; IC=1,15-2,78). O descumprimento do passo 9 reduziu o AME aos 30 dias (aOR=2,33; IC=1,30-4,19). *Conclusão*: A chance do AME no primeiro mês foi reduzida pela oferta de fórmula infantil e chupeta na maternidade. Aos seis meses, a amamentação foi reduzida pela introdução de fórmula na maternidade. Os resultados reforçam a importância do cumprimento das disposições do Código Internacional de Comercialização de Substitutos do Leite Materno, propiciando um ambiente seguro que incentive a mulher a escolher amamentar.

Palavras-chave: Aleitamento materno. Chupetas. Fórmulas infantis. Iniciativa Hospital Amigo da Criança.

INTRODUCTION

Breastfeeding ensures food and nutritional supply in the early years with unmatched health and well-being effects throughout the individual's lifetime.[1] Its benefits reach high-, medium- and low-income populations, and extend to infants, mothers, society and the planet;[1,2] therefore, being the most lasting investment in physical, cognitive and social capacity of future generations.[3]

Yet, the prevalence or breastfeeding worldwide still remains low.[1,4] Increasing the number of breastfed children is key to achieve the objectives set by the Sustainable Development Goals, which recommend reducing neonatal mortality and ending preventable deaths of children under five years by 2030.[5-7] Promoting this practice requires a combination of social efforts, addressing various socioeconomic, cultural, family and individual aspects that influence women's choice of breastfeeding.[2,4,8-11]

Among these factors, the early supply of breast milk substitutes (BMS) and pacifiers have been suggested as possible promoters of nipple confusion, increasing risk of early discontinuation and/or reducing likelihood of EBF in numerous studies.[12-19] However, there are other studies challenging the evidence on negative relationship between pacifier supply in the maternity ward and breastfeeding.[20-22]

Among the global initiatives to promote breastfeeding, the Baby-Friendly Hospital Initiative (BFHI) advocates the reorganization of pre-delivery, childbirth and postpartum practices in order to support women who want to breastfeed. The initiative is based on the *Ten steps to successful breastfeeding*, which were recently reviewed by the World Health Organization and the United Nations Children's Fund (WHO/UNICEF),[23] reinforcing the practical steps that governments should take to protect, promote and support breastfeeding in maternity hospitals.[24]

The recent review of the BFHI steps maintained the step 6 recommendation, stating that it is recommended to "*Do not provide breastfed newborns any food or fluids other than breast milk, unless medically indicated*". On the other hand, the step 9 has undergone major change. It originally indicated that should "*Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants*"; however, it was reviewed and changed to "*Counsel mothers on the use and risks of feeding bottles, teats and pacifiers*".[23]

Therefore, given the lack of consensus on the association between supply of infant formula (step 6) and pacifier (step 9) in the maternity ward with breastfeeding, this study aimed to assess the compliance of these steps in the sample and its association with breastfeeding practices in the first six months of life.

METHODOLOGHY

A six-month prospective cohort study was conducted with children born in six hospitals, three Baby-Friendly Hospitals (BFHs) and three non-Baby-Friendly Hospital (nBFH), in São Paulo municipality from 2016 to 2018. This study presents part of the data gathered in the cohort conducted for cost-effectiveness analysis of the BFHI, which will be published later.

The hospitals were chosen through convenience sampling, based on criterion for selection of BFHs: compliance with all the requirements recommended by the BFHI, according to an online monitoring survey conducted by the Brazilian Ministry of Health in 2015. The study included the three hospitals with the largest number of specialized maternity beds (gynecology, obstetrics, neonatal ICU, intermediate neonatal ICU, Kangaroo Mother Care and Neonatology). A nBFH matching the characteristics of each BFH selected was also included in the study to comprise comparison group: being located in the same urban region (similar patients profile), having the same administrative level (state or municipal) and equivalent number of specialized beds.

The sample of mothers was calculated with a confidence level of 95%, test power of 80%, and estimating a difference of +28% in exclusive breastfeeding (EBF) among children born in a BFH. This estimate was based on the difference observed between the prevalence of EBF in children under six months born in a BFH in Brazil (49.9%) and the prevalence found in São Paulo (39.1%) in the II Breastfeeding Prevalence Survey (IIPPAM), performed in 2008,[25] which are the latest nationally representative data available in the literature on children born in BFHs. The initial sample estimate consisted of 686 mothers with additional 40% to compensate for follow-up losses (960 mothers).

The calculation of sample to be interviewed in each hospital was proportionally stratified, considering the monthly average of births and the average percentages of cesarean sections (CS). The selection of mothers interviewed in each hospital was performed by consecutive sampling process. All mothers who met the inclusion criteria and agreed to participate were included upon signing the Informed Consent prior to interview, and the process of selection continued until the completion of the sample calculated for each hospital.

Inclusion criteria were: mother admitted to a rooming-in apartment, delivery occurrence 24 hours or more prior to the interview, maternal age of 18 years or older, single fetus, absence of problems that prevented breastfeeding, and mothers who were breastfeeding at the period of the interview (even if the child was in the neonatal unit). The exclusion criterion was childbirth performed outside the hospital (home delivery or during transfer to hospital).

Data were collected through three structured interviews. The first interview took place in the rooming-in apartment. The second and third interviews were conducted by telephone 30 and 180 days postpartum, respectively. Socioeconomic and reproductive data were obtained in the first interview, as well as data concerning the conditions of birth, and regarding absence of supply of infant formula (step 6), and pacifiers (step 9) in the maternity ward. In the following interviews, mothers were asked about their children's dietary intake in the last 24 hours previous to the call, the use of pacifiers and the difficulties faced in breastfeeding.

The BFHI steps were considered fulfilled in the cases that met the WHO recommendation[26] of being experienced by at least 80% of mothers.

The exposure factors included in this study were non-compliance with step 6 (provision of food supplement) and step 9 (provision of pacifier). Although step 9 originally referred to artificial teats also, this study only included use of pacifier in the maternity ward.

Breastfeeding indicators, as defined by WHO, were considered as outcomes.[27]

1. Breastfeeding (BF): defined as the child having received breast milk (direct from the breast or milked), regardless of the provision of any other foods.
2. Exclusive breastfeeding (EBF): defined as offering only breast milk with no other liquid or solid. Exception: oral rehydration salts, medicines, syrups and vitamin or mineral supplements.

Statistical analyzes were performed using Stata software (v.13.1). The distribution of cohort characteristics between exposed and non-exposed groups was analyzed by Pearson's Chi-Squared Test. Logistic regression was used to estimate odds ratios (OR) with a 95% confidence interval between the exposure factors and outcomes. First, the gross OR was estimated, and then the OR was adjusted for potential confounding factors (aOR), which were selected based on a preliminary assessment suggested by directed acyclic graph (DAG)[28,29] designed in the DAGitty3.0 (Figure 1.2).

Figure 1. Directed acyclic graph showing hypotheses on the relationship between infant formula and EBF in the maternity ward. São Paulo, 2018.

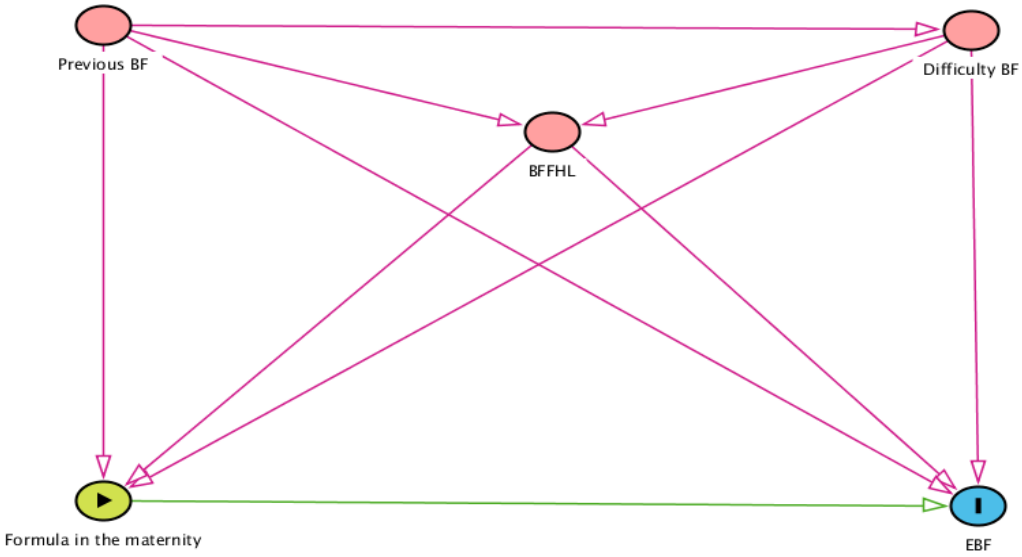
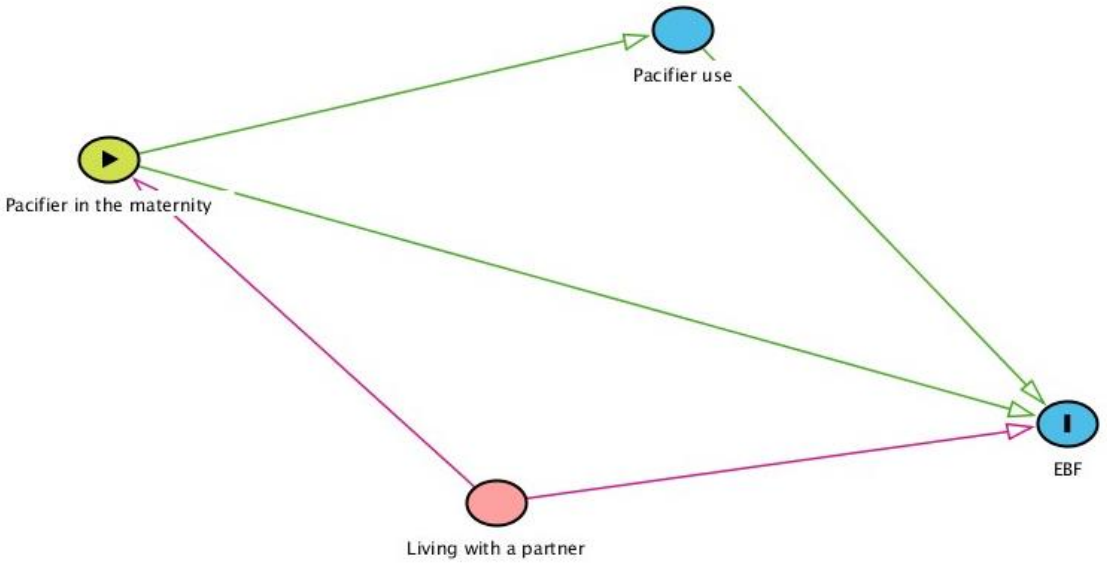


Figure 2. Directed acyclic graph showing hypotheses on the relationship between infant formula and EBF in the maternity ward. São Paulo, 2018.



The adjustment variables were those related to both exposure and outcome:

- For exposure to infant formula in the maternity ward: previous breastfeeding, breastfeeding in the first hour of life, and difficulty in breastfeeding.
- For exposure to pacifier in the maternity ward: living with a partner, and pacifier use.

The study complied with all ethical requirements established on Resolution nr. 466/2012 and was approved by the Research Ethics Committee (CEP) of the School of Public Health at University of São Paulo under nr. 1.811.327, and by the Research Ethics Committee of the Municipal Health Department of São Paulo, under nr. 1,687,649. All participants included in the study signed the Informed Consent after being invited, informed and have agreed to participate.

RESULTS

The initial sample consisted of 969 mothers, 56% from BFHs and 44% from nBFH. On the second interview (30th. day), 902 mothers participated, while 814 mothers were interviewed on 180th. day, which represents a 16% loss from initial sample. Despite the loss of follow-up, which is common in cohort studies, the characteristics of the final sample had no statistical differences in relation to the initial sample.

Table 1 shows the characteristics of the sample at baseline and the groups exposed to non-compliance with step 6 (those who received infant formula in the maternity ward) and step 9 (those who received pacifier in the maternity ward). It is noteworthy the association of non-compliance of step 6 with the variables "cesarean birth", "preterm birth", "low birth weight", "maternal race", "primiparity", "no previous BF" and "difficulty breastfeeding". Pacifier use in the maternity ward was initially associated only with "mother who lives without a partner".

Table 1. Distribution of the total sample characteristics and exposed groups. São Paulo, 2018.

Variables	Total		Provision of infant formula in maternity ward (n=142)		Provision of pacifier in maternity ward (n=55)	
	n	%	%	p[a]	%	p[a]
Type of Delivery (n)	969					
Normal		67.3	10.0	<0.001	5.1	
Cesarean birth		32.7	25.0		7.0	0.233
Gender (n)	964					
Male		52.0	14.8	0.885	5.2	0.502
Female		48.0	14.5		6.2	
Gestational age (n)	959					

Table 1. Distribution of the total sample characteristics and exposed groups. São Paulo, 2018.(Continues)

Variables	Total		Provision of infant formula in maternity ward (n=142)		Provision of pacifier in maternity ward (n=55)	
	n	%	%	p[a]	%	p[a]
Full-term		95.1	12.9	<0.001	5.9	0.086
Preterm		4.9	46.8		0.0	
Birth weight (n)	960					
≥2,500g		92.8	12.6	<0.001	6.0	0.292
<2,500g		7.2	43.5		2.9	
BFFHL	966					
Yes		60.2	8.7	<0.001	5.0	0.320
No		39.8	23.4		6.5	
Pacifier use at 30 days	901					
Yes		38.3	14.8	0.762	10.4	<0.001
No		61.7	14.1		2.9	
Characteristics of mothers						
Race	940					
Black		23.2	20.4	0.025	6.0	0.824
Mixed		39.0	13.1		5.2	
White		37.8	13.3		6.2	
Lives with a partner	957					
Yes		77.4	14.5	0.765	4.7	0.012
No		22.6	15.3		9.3	
Has a paid job	967					
Yes		45.9	14.9	0.761	5.2	0.443
No		54.1	14.2		6.3	
Previous pregnancies	966					
Yes		65.9	11.3	<0.001	5.2	0.344
No		34.1	21.0		6.7	
Previous BF	922					
Yes		62.2	10.5	<0.001	5.2	0.339
No		37.9	19.5		6.6	
BF Intention[b]	951					
Yes		60.3	15.0	0.673	6.0	0.429
No		39.7	14.0		4.8	
Difficulty BF[c]	892					
Yes		33.5	21.7	<0.001	5.0	0.515
No		66.5	10.3		6.1	
Age range	968					
18-20 years old		16.5	15.0	0.192	5.6	0.322
21-30 years old		55.0	13.0		6.6	
≥31 years old		28.5	17.8		4.0	
Education level	963					
1-9 years		23.0	14.5	0.971	6.8	0.633
10-12 years		66.9	14.6		5.6	
≥13 years		10.1	15.5		4.1	
Family income per capita	824					
Up to ½ MW		72.3	13.6	0.308	5.2	0.571
½ -1 MW		22.1	13.8		7.2	
>1MW		5.6	21.7		4.4	

Note: [a]Chi-Squared Test; [b]mothers intending to breastfeed for as long as the child wishes; [c]variable obtained in the second interview; BFFHL= breastfeeding in the first hour of life; BF= breastfeeding; MW= minimum wage. Variations in the sample size in the variables are due to the lack of response from the mothers.

The compliance of BFHI steps were high in both hospital groups (Table 2), with step 6 (avoiding infant formulas) and step 9 (avoiding teats) being reported by more than 80% of the participants.

Table 2. Distribution of the compliance degree of BFHI Steps, according to birth in BFH and nBFH. São Paulo, 2018.

BFHI Steps (N=968)	Total (%)	BFH (%)	nBFH (%)	P[a]
Step 6 No infant formula in maternity ward	85.3	86.6	83.8	0.223
Step 9 No pacifier use in maternity ward	94.3	96.1	92.0	0.006

Note: [a]Chi-squared test with 95% significance; BFH= Baby-Friendly Hospital; NHAC= non-Baby-Friendly Hospital

Adjusted OR analyzes showed that the chances of breastfeeding in the first month were reduced by non-compliance of step 6 or 9. The provision of infant formula in maternity ward also reduced the chances of breastfeeding at six months of age in the adjusted analysis (Table 3).

Table 3. Association between exposure and outcome, according to gross odds ratio (OR) and adjusted odds ratio (aOR). São Paulo, 2018.

Age	Endpoint	Exposure	N	%	OR (CI 95%)	aOR (CI 95%)
30 days	No BF	Provision of infant formula (Step 6)				
		No	772	2.20	1	1
		Yes	129	10.1	4.98 (2.35-10.52)	2.31 (0.93-5.75)
		Pacifier use (Step 9)				
		No	848	3.3	1	-
		Yes	52	3.9	1.17 (0.27-5.06)	
	No EBF	Provision of infant formula (Step 6)				
		No	772	23.3	1	1
		Yes	129	41.1	2.29 (1.55-3.38)	1.82 (1.19-2.77)
		Pacifier use (Step 9)				
		No	848	24.3	1	1
		Yes	52	50.0	3.11 (1.77-5.49)	2.33 (1.30-4.19)

Table 3. Association between exposure and outcome, according to gross odds ratio (OR) and adjusted odds ratio (aOR). São Paulo, 2018.

Age	Endpoint	Exposure	N	%	OR (CI 95%)	aOR (CI 95%)
180 days	No BF	Provision of infant formula (Step 6)				
		No	702	22.4	1	1
		Yes	112	39.3	2.24 (1.48-3.41)	1.79 (1.15-2.78)
		Pacifier use (Step 9)				
		No	765	24.2	1	1
		Yes	48	33.3	1.57 (0.84-2.92)	0.93 (0.47-1.80)
	No EBF	Provision of infant formula (Step 6)				
		No	702	79.2	1	
		Yes	112	85.7	1.58 (0.90-2.76)	
		Pacifier use (Step 9)				
		No	759	79.5	1	-
		Yes	54	87.5	1.79 (0.75-4.29)	

Note: BF= breastfeeding; EBF = exclusive breastfeeding. Adjustment variables for infant formula in maternity ward were as follows: previous breastfeeding, breastfeeding in the first hour of life and difficulty breastfeeding; while the adjustment variables for pacifier use in maternity ward were: living with a partner and pacifier use

DISCUSSION

This study considered the interpretation of the BFHI steps in the original version prior to the last review. Steps 6 and 9 presented high compliance in both groups of hospitals, indicating a significant homogeneity in breastfeeding promotion practices in Brazilian public hospitals. These results indicate the incorporation of the BFHI recommendations by various hospitals, in observance to WHO recommendations, which guide governments to adopt hospital birth and delivery routines that promote breastfeeding.[30,31]

Step 6, which sates "*Do not provide breastfed newborns any food or fluids other than breast milk, unless medically indicated*", was also observed in other national studies concerning the BFHI.[32-36] However, among children for whom step 6 was not respected, the negative effect of infant formula provision extended to the sixth month of life, in line with other previous studies conducted in Brazil,[14,16] Vietnam,[15] United States,[12,37] and Australia.[13] Chantry et al.[12] suggested that the risk of breastfeeding interruption at two months was three times higher with the provision of infant formula in the maternity ward, and a recent systematic review found no benefits in the early introduction of BMS, thus reinforcing the importance of exclusive breastfeeding.[38]

It should be noted that during the interviews of this study at 30th. days after birth, the supply of infant formula to children in the hospital was spontaneously mentioned by some mothers as an attempt to "legitimize" the mixed (or artificial) feeding. These reports confirm the

findings of Nguyen et al.,[15] suggesting that the use of infant formula within the first three days after birth increased the subsequent use of non-human milk and the risk of early interruption of breastfeeding.

The relationship of step 6 with other factors related to breastfeeding outcomes should also be highlighted. Biggs et al,[39] in the United Kingdom, noted the relationship between step 6 and 4: the lack of skin-to-skin contact within one hour of delivery increased the prevalence of BMS provision. Barbosa et al.[16] reported that the supply of any food supplement to children at the maternity ward more than doubled the chances of the mother having breast problems in the postpartum period, which may difficult to maintain breastfeeding for a long period.

On the other hand, the effect of the non-compliance with step 9 nearly tripled the chances of non-EBF at 30 days, possibly favoring the continuity in pacifier use after discharge, and thus interfering with breastfeeding exclusivity, as noted by Kair & Colaizy.[40] According to the authors, pacifier use during hospitalization was independently associated with lower chances of breastfeeding and EBF in the first four months of life.

Similarly, other studies also indicate the use of pacifiers as factor potentially promoting nipple confusion, increasing the risk of early breastfeeding interruption or reducing the likelihood of breastfeeding.[15-19] Such evidence was supported by recent guidelines published for organization of comprehensive and humanized care of women and newborns in the rooming-in setting in the Brazilian Unified Health System (SUS), recommending to avoid artificial teats in the maternity ward.[41]

On the other hand, different studies have questioned this evidence. A recent systematic review[21] found that pacifier use, even when started soon after birth, did not affect significantly the prevalence or duration of exclusive and partial breastfeeding until four months of age, reinforcing the findings of O'Connor et al.[20] Lubbe and Ham-Baloyi[22] further report that the supply of pacifiers in the maternity ward provides benefits in some justifiable situations, such as the use of pacifiers for non-nutritive sucking in premature infants who require oral stimulation to develop, maintain and mature the sucking reflex.

The lack of consensus on the impact of pacifier supply shortly after birth on breastfeeding led to a review of WHO/UNICEF with respect to the interpretation of the step 9 of the BFHI,[24] which decided for a less prescriptive and more suggestive guidance on the subject.[23]

However, WHO recommendations on the need for health institutions and their professionals to comply with the provisions of the International Code of Marketing of Breastmilk Substitutes remain unchanged. This implies in not providing bottles and teats, nor accepting any

form of BMS promotion, in order to provide a safe environment that encourages women to make the choice of breastfeeding, given the special vulnerability of breastfeeding women to commercial promotion and marketing, as well as the risks involved in the use of these products.[30]

The findings of this study reiterate the negative effect of infant formula and pacifier supply on maternity ward in breastfeeding indicators in the first months of life. These data reinforce the importance of incorporating the WHO recommendations in all delivery and postpartum services in order to enhance the success in continuity and exclusivity of breastfeeding.

CONCLUSION

Steps 6 and 9 were observed in both groups of hospitals, thus indicating the incorporation of the BFHI recommendations by various hospitals. The provision of infant formula in the maternity ward had a negative effect, reducing the chances of exclusive breastfeeding in the first month of life and the continued breastfeeding in the first six months of life. The use of pacifiers in the maternity ward also reduced the exclusive breastfeeding in the first month of life.

The results emphasize the importance healthcare providers in compliance with the International Code of Marketing of Breastmilk Substitutes, thus avoiding infant formula and feeding bottles or any form of BMS promotion. These measures can provide a safe environment that favors the choice of women to breastfeed and enhance the continuity and exclusivity of breastfeeding.

ACKNOWLEDGMENTS

Financial Support: São Paulo Research Foundation (FAPESP)

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Conflicts of interest: the authors declare no conflicts of interest.

Received: June 29, 2019
Reviewed: August 19, 2019
Accepted: September 2, 2019