Impact of a Baby-Friendly–Aligned Pacifier Policy on Pacifier Use at 1 Month of Age

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ABSTRACT

OBJECTIVE: Pacifier use decreases the risk of sudden infant death syndrome, but its impact on breastfeeding remains controversial. We evaluated the impact of a pacifier policy aligned with the World Health Organization and United Nations Children's Fund Baby-Friendly Hospital Initiative on subsequent pacifier use and breastfeeding at 1 month of age.

METHODS: We conducted a prospective 2-stage (pre- and post-implementation) cohort study of newborns at a birth hospital before and after implementation of a Baby-Friendly–aligned pacifier policy. Consecutive mothers of newborns admitted to the nursery participated in a telephone survey when the infants were 1 month of age.

RESULTS: In total, 342 mothers participated (190 before and 152 after implementation of the policy). Pacifier adoption was delayed in the post-implementation group, but pacifier use by 1 month of age was comparable (78.9% pre-implementation vs 77.6% post-implementation; $P = .793$). In the pre-implementation group, female and male infants used pacifiers at comparable rates; however, in the post-implementation group, females

were significantly less likely to use a pacifier compared to males after controlling for insurance, race, parity, and delivery mode (adjusted odds ratio, 0.35; 95% confidence interval, 0.15–0.83; $P = .02$). In the post-implementation group, exclusive breastfeeding rates at discharge increased significantly (from 40% to 51.3%; $P = .04$), but rates were not different at 1 month (23.7% pre-implementation vs 24.3% post-implementation; $P = .89$).

CONCLUSION: A Baby-Friendly–aligned pacifier policy delayed pacifier adoption but did not impact overall pacifier use or breastfeeding rates at 1 month of age. The finding of lower pacifier use rates among female infants post-intervention requires verification in other populations before evaluating public heath relevance.

KEYWORDS: Baby-Friendly; breastfeeding; pacifier; sudden infant death syndrome; newborns

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WHAT'S NEW?

A Baby-Friendly–aligned pacifier policy delayed pacifier adoption but did not affect overall pacifier use at 1 month of age; however, there was a differential impact by sex, with significantly lower pacifier use among females compared to males.

PACIFIERS ARE FREQUENTLY used to soothe a fussy baby.[1,2] Nationwide, the majority of infants (77.5%) use a pacifier by 2 months of age.[3] In addition to its soothing effect, pacifier use at bedtime has been shown to be a protective factor against sudden infant death syndrome (SIDS).[4−6] Prevention of SIDS is a compelling public health issue, especially among racial/ethnic minorities, who experience the highest SIDS rates.[7] Meta-analyses and reviews have shown that pacifier use at bedtime decreases the risk of SIDS by up to 90%.[8,9] This risk is reduced even in unfavorable infant sleep environments, such as prone or side-lying positioning and bedsharing.[4]

Based on this evidence, the 2011 American Academy of Pediatrics (AAP) Task Force on SIDS recommended offering infants a pacifier at nap and bedtime.[10]

Studies have also shown that breastfeeding is protective against SIDs, and the effect is stronger with exclusive breastfeeding.[11] The impact of pacifier use on breastfeeding outcomes, however, remains controversial. The AAP Section on Breastfeeding recommends that parents of "healthy term breastfed infants should be instructed to delay pacifier use until breastfeeding is well-established, usually about 3 to 4 weeks after birth."[12] This recommendation is also supported by the Baby-Friendly Hospital Initiative (BFHI), a global program sponsored by the World Health Organization (WHO) and the United Nations Children's Fund. The BFHI recognizes hospitals that offer an optimal level of care for lactation based on its Ten Steps to Successful Breastfeeding.[13] Baby-Friendly USA is the accrediting body for the BFHI in the United States. Baby-Friendly USA Step 9 reads: "Give no pacifiers or artificial nipples to breastfeeding infants."[14]

This recommendation comes from observational studies showing a strong association between pacifier use and decreased breastfeeding duration.[13,15] More recent randomized control trials (RCTs) and evidence-based reviews have not shown a causal relationship between pacifier use and decreased breastfeeding duration or exclusivity.[16–19] In April 2018, WHO revised Step 9 to read, "Counsel mothers on the use and risks of feeding bottles, teats and pacifiers," rather than calling for restriction.[20] To date, this revision has not been adopted by Baby-Friendly USA.

As more birth hospitals in the United States pursue the Baby-Friendly designation, pacifiers may no longer be routinely offered to newborn infants. The relationship between restriction of pacifier use in the birth hospital and later adoption of pacifiers is not well known. A theoretical concern with restricting pacifier use in the birth hospital is that it may lead to an overall decrease in pacifier use.[21] A recent study found that initiation of pacifier use in the newborn nursery was the strongest predictor (odds ratio, 1.75) of pacifier use in infants.[22] A decrease in the use of pacifiers could place infants at a higher risk for SIDS. In 2012, the study hospital began the journey to achieve Baby-Friendly status, and implementation of a new restrictive pacifier policy was planned to fulfill the Ten Steps. Doing so offered a quasi-experimental design to prospectively explore the effect of this policy on pacifier adoption by infants.

The primary objective of this study was to evaluate the impact of implementation of a Baby-Friendly–aligned pacifier policy in a birth hospital on infant pacifier use at 1 month of age. A secondary objective was to evaluate the impact of this policy on breastfeeding rates at 1 month of age.

METHODS

STUDY DESIGN AND SETTING

We conducted a prospective 2-stage (pre- and post-implementation) cohort study of newborns at an academic hospital in Philadelphia, Pennsylvania. The hospital serves as a major provider of care in an urban, low-income, minority community. This hospital delivers 3000 infants per year, and the patient demographics include 60% African American and 80% covered by Medicaid.

PARTICIPANTS AND RECRUITMENT

All infants admitted to the nursery were eligible for participation. Criteria for admission to the newborn nursery include gestational age ≥ 36 weeks, birth weight ≥ 2000 grams, clinically stable, and no major malformations. Infants were excluded from the study if they were transferred from the nursery to the neonatal intensive care unit, if they were not discharged to their biological parents, or if the mother did not speak English. A research assistant approached all eligible mothers during the birth hospitalization and invited them to participate in a follow-up telephone survey of infant feeding and sleeping practices at 1 month after discharge; pacifier use was not mentioned. The age of 1 month was selected following the AAP Section on Breastfeeding recommendation to avoid pacifier use until 3 to 4 weeks of age. Recruitment was limited by staff availability. The pre-intervention group was recruited between June and September 2016. The post-intervention group was recruited beginning in July 2017, to allow for a 3-month washout period after implementation of the new Baby-Friendly pacifier policy in February 2017. Mothers were offered a $20 gift card as incentive for completion of the survey. The research assistant and gift cards were funded by a grant from the hospital's foundation.

INTERVENTION

Beginning in 2012, the study hospital embarked on the Baby-Friendly journey. Changes implemented prior to putting the new pacifier policy in place in February 2017 included the following: 1) establishing a multidisciplinary breastfeeding taskforce (2012); 2) training nursing staff on breastfeeding knowledge and practical skills based on the Pennsylvania Department of Health's Keystone 10 Initiative[23] (2012–2013); 3) mother and infant skin-to-skin contact immediately after birth (2013); and 4) mother and infant rooming in, with blood draws and pulse oximetry screening, all physician and nursing exams, and hearing screens being performed in the room (2014–2015).

Before the new Baby-Friendly–aligned pacifier policy went into effect in February 2017, all babies received a pacifier on admission to the nursery, regardless of parental feeding intentions. The pacifiers were routinely placed in the bassinets. Lactation consultants in the nursery recommended against pacifier use by breastfed infants, but no uniform recommendations for or against pacifier use were given by other staff.

Since February 2017, pacifiers are no longer placed in the bassinets, regardless of parental feeding intentions. On admission to the postpartum floors, nurses deliver an educational message to mothers who intend to breastfeed, following a script that was approved by the Baby-Friendly committee. The educational messages include the following: 1) avoid pacifier use until breastfeeding is well established; 2) use alternative ways to soothe a fussy baby (eg, skin-to-skin contact, rocking, singing); 3) feed the baby on demand; and 4) after breastfeeding is well established, offer the infant a pacifier at sleep time to prevent SIDS. Pacifiers are provided to parents who still request one after receiving education. The use of pacifiers is allowed during painful procedures (circumcision and lumbar punctures), but pacifiers are removed at completion of the procedure. Parents are not restricted from bringing pacifiers into the birth hospital. No signs restricting pacifier use are posted in rooms or hallways. Mothers who do not intend to breastfeed are not given the education on pacifier avoidance and are only given pacifiers upon request. Ongoing evaluation of the intervention was done by the nurse manager and nurse educator of the postpartum unit by periodic patient interviews and chart audits.

While the study was in process, additional training of staff took place between March and September 2017. All physicians completed a 3-hour online continuing medical education module on breastfeeding.[24] All nurses received a 5-hour competency-based breastfeeding training given by 2 trained educators and based on the Pennsylvania Department of Health's Keystone 10 Initiative.[23] The study hospital achieved the Baby-Friendly designation in August 2018, after completion of this study.

DATA COLLECTION

We collected maternal, obstetrical, infant, and feeding data. Maternal data included age, ethnicity and race, parity, and insurance status. Obstetrical data included type of delivery and complications during delivery. Infant data included birth weight, gestational age, and medical conditions. Feeding data included initial feed (breast or formula), feeding in nursery (breast, formula, or both), and feeding at discharge (feeding for the last 12 hours before discharge and classified as exclusive breastfeeding, exclusive formula feeding, or both breast and formula feeding). All data were extracted from the electronic medical record.

When infants were 1 month of age, a 10-minute telephone survey was administered by a trained research assistant. At least 3 attempts were made on different days and times to reach all consented participants. The survey was adapted from the validated Infant Feeding Practices Survey[25] and included questions on participation in the Special Supplemental Nutrition Program for Women, Infants, and Children; feeding practices over the last 7 days (exclusive breastfeeding, exclusive formula feeding, or both breast and formula feeding); pacifier use (ever used, use in last 7 days, age at start); and sleep practices (sleep position, co-sleeping). We also collected information on the hospital experience, including whether a pacifier was provided and whether the mother received pacifier-related advice. The survey was pilot tested in the pediatric clinic among parents of 1- to 2-month-old infants and was modified based on parents' feedback and health literacy level.

OUTCOME MEASURES

The primary outcome was pacifier use at 1 month of age, before and after the new pacifier policy. The secondary outcomes were breastfeeding rates (any and exclusive) at hospital discharge and at 1 month of age.

VALIDATING THE INTEGRITY OF THE INTERVENTION

To validate the actual intervention, the research assistant observed if there was a pacifier in the bassinet at the time of recruitment and, if so, whether it was provided by the hospital or brought from home.

STATISTICAL ANALYSIS

Previous RCTs attempting a restriction in pacifier use achieved a 15% to 25% reduction in pacifier use post-

intervention.[16,17,26] To detect a 15% difference in pacifier use at 1 month, with an alpha = 0.05 and a power of 0.80, we needed a sample size of 176 infants. To detect a 10% difference in breastfeeding rates at 1 month of age, with an alpha = 0.05 and a power of 0.80, we needed a sample size of 598 infants. Our study was not powered to detect differences in breastfeeding. Analyses include descriptive statistics for breastfeeding and pacifier use rates at 1 month of age. We used Fisher's exact and chi-square tests (for categorical variables) and independent sample t-test (for continuous variables) to determine if the pre- and post-intervention groups were significantly different from each other. To determine factors affecting pacifier use at 1 month of age, we conducted a multivariate logistic regression controlling for maternal ethnicity, insurance status, parity, mode of delivery, and infant gender, and we then repeated the analysis stratified by pre- and post-intervention. Analysis was done using SPSS Statistics Version 25 (IBM Corp.; Armonk, NY).

INSTITUTIONAL REVIEW BOARD

The study was approved by the study hospital's institutional review board, and written informed consent was obtained from all participants.

RESULTS

For the pre-intervention group, we approached 333 mothers, of whom 283 (84.9%) consented; of these, 190 (67.1%) completed the telephone survey. For the post-intervention group, we approached 308 mothers, of whom 276 (89.6%) consented; of these, 152 (55%) completed the telephone survey. Participants were mostly African American with public insurance (Table 1). A comparison of Zip Code areas with the US Census Bureau's 2012 −2016 American Community Survey showed that the median household income in the study population was $34,720, with a median poverty rate of 30% (at or below 100% of federal poverty level).[27] Compared to those completing the survey, mothers who were lost to follow-up were not significantly different with regard to age, race/ethnicity, or insurance status, both overall and in the pre- and post-intervention groups.

VALIDITY OF THE INTERVENTION

The number of pacifiers observed in the bassinets decreased significantly after the new policy. Mothers in the post-intervention group were less likely to report the birth hospital offering a pacifier and more likely to report education on pacifier avoidance (Table 2).

PACIFIER USE

Pacifier adoption was significantly delayed among infants after implementation of the pacifier policy ($P <$ .01) (Figure). In the post-intervention group, 25.4% (32/126) of infants began using a pacifier after 3 weeks of age compared to 4.9% (8/164) of infants in the pre-intervention group ($P <$ .01). However, pacifier use at 1 month of

Table 1. Characteristics of Study Participants Before and After Baby-Friendly Pacifier Policy

	Pre-Intervention Group (n = 190)	Post-Intervention Group (n = 152)	P Value
Maternal age (y), mean ± SD	26.83 ± 6.15	27.01 ± 6.2	0.08
Maternal ethnicity, n (%)			.24
African American	116 (61.1)	97 (63.8)	
Hispanic	42 (22.1)	33 (21.7)	
Caucasian	24 (12.6)	21 (13.8)	
Other	8 (4.2)	1 (0.7)	
Mother on public insurance, n (%)	159 (83.7)	117 (77)	.13
Primiparity, n (%)	62 (32.6)	43 (28.5)	.48
Infant on WIC, n (%)	161 (84.7)	124 (81.6)	.48
C-section, n (%)	65 (34.2)	47.6 (31.3)	.64
Gestational age (wk), mean ± SD	38.9 ± 1.2	39.1 ± 1.2	.24
Birth weight (g), mean ± SD	3305 ± 453	3247 ± 448	.23
Screening for hypoglycemia, n (%)	44 (23.2)	27 (17.8)	.23
Male sex, n (%)	112 (58.9)	78 (51.3)	.19

SD indicates standard deviation; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children; C-section, caesarean section.

Table 2. Baby-Friendly Pacifier Policy: Pre- and Post-Intervention and Outcomes

	Pre-Intervention Group (n = 190)	Post-Intervention Group (n = 152)	P Value
Intervention: investigator observed			
Pacifier in basinet, n (%)	147 (77.4)	42 (27.6)	<.01
Pacifiers brought from home, n (%)	17/147 (11.6)	11/42 (26.2)	.02
Intervention: maternal recall (1-month survey)			
Pacifier offered at hospital, n (%)	155 (81.6)	44 (28.9)	<.01
Doctor/nurse at hospital advised pacifier avoidance, n (%)	22 (11.6)	43 (28.3)	<.01
Outcomes			
Pacifier use at 1 month, n (%)	150 (78.9)	118 (77.6)	.79
Any breastfeeding at 1 month, n (%)	101 (53.2)	81 (53.3)	1.00
Exclusive breastfeeding at 1 month, n (%)	45 (23.7)	37 (24.3)	.89
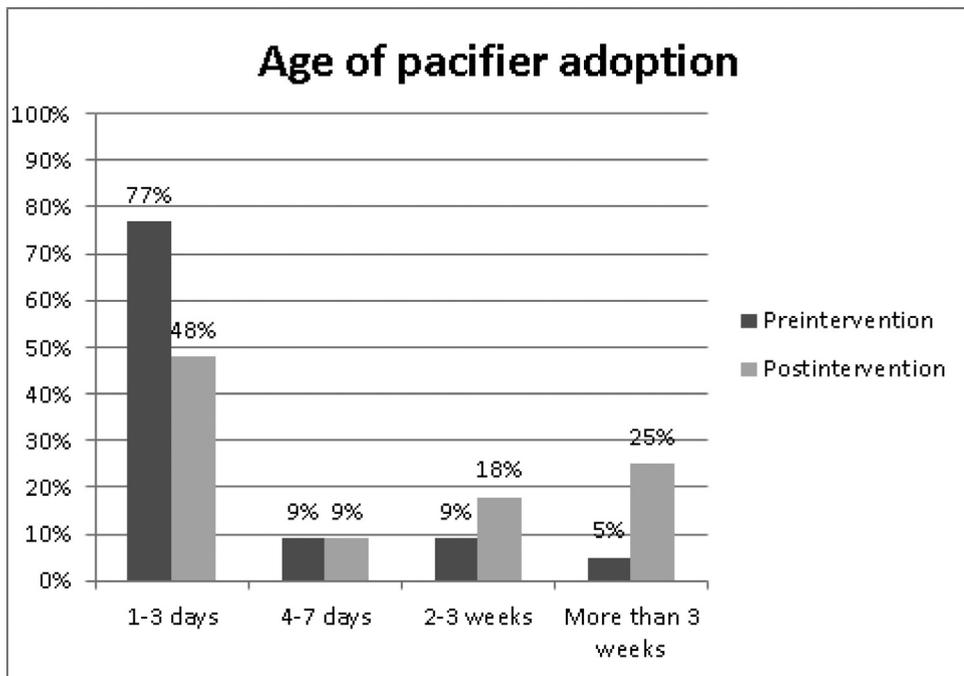
Figure. *Age of pacifier adoption.*

Table 3. Multivariate Regression: Factors Impacting Pacifier Use at 1 Month of Age Before and After Baby-Friendly Pacifier Policy

Variable	Pre-Intervention			Post-Intervention		
	aOR	95% CI	P Value	aOR	95% CI	P Value
Gender						
Male	Ref	Ref	Ref	Ref	Ref	Ref
Female	0.82	0.40−1.69	0.59	0.35	0.15−0.83	0.02
Ethnicity						
African American	Ref	Ref	Ref	Ref	Ref	Ref
Hispanic	1.61	0.63−4.11	0.32	0.75	0.29−1.92	0.55
Caucasian	2.07	0.57−7.56	0.27	5.67	0.68−47.02	0.11
Other	1.01	0.19−5.41	0.99	NA	NA	1
Insurance						
Public	Ref	Ref	Ref	Ref	Ref	Ref
Private	1.24	0.46−3.35	0.67	0.86	0.32−2.34	0.77
Parity						
Primipara	Ref	Ref	Ref	Ref	Ref	Ref
Multipara	1.18	0.55−2.51	0.67	0.99	0.40−2.50	0.99
Mode of delivery						
Vaginal	Ref	Ref	Ref	Ref	Ref	Ref
C-section	0.79	0.38−1.64	0.52	0.74	0.52−0.74	0.50

aOR indicates adjusted odds ratio; CI, confidence interval; Ref, reference; NA, not available; C-section, caesarean section.

age in the pre-and post-intervention groups was comparable (78.9% pre-intervention vs 77.6% post-intervention; $P = .79$). Among mothers who initiated breastfeeding at the hospital, pacifier use at 1 month of age was 75.7% (106/140) in the pre-intervention group and 70.6% (77/109) in the post-intervention group ($P = .39$). On regression analysis, controlling for maternal insurance, ethnicity, parity, mode of delivery, and infant gender, infants in the post-intervention period had similar rates of pacifier use at 1 month of age (adjusted odds ratio [aOR], 0.97; 95% confidence interval [CI], 0.57−1.66; $P = .91$) as infants in the pre-intervention period.

We found a significant difference in pacifier use at 1 month of age by gender but only in the post-intervention group. In the pre-intervention group, 76.9% (60/78) of females and 80.4% (90/112) of males used a pacifier at 1 month of age ($P = 0.59$). However, post-intervention, pacifier use at 1 month of age was significantly lower in females (50/74, or 67.6%) compared to male infants (68/78, or 87.2%; $P < .01$). On regression analysis, controlling for maternal insurance, race, parity, and mode of delivery, female infants had significantly lower odds of using a pacifier compared to males (aOR, 0.35; 95% CI, 0.15−0.82; $P = .02$) in the post-intervention period (Table 3). Circumcision rates were similar in the pre-intervention (95/112, or 84.8%) and post-intervention groups (72/78, or 92.3%; $P = .17$). Pacifier use was not significantly different between circumcised males (138/167, or 82.6%) and uncircumcised males (20/23, or 87%; $P = .77$).

BREASTFEEDING RATES IN PRE- AND POST- INTERVENTION GROUPS

The post-intervention group had significantly higher rates of exclusive breastfeeding on day of discharge: 76/ 190 (40%) pre-intervention versus 78/150 (51.3%) post-intervention ($P = .04$). However, the rates of any and exclusive breastfeeding at 1 month of age were not significantly different: 101/190 (53.2%) any breastfeeding at 1 month pre-intervention versus 81/152 (53.3%) post-intervention ($p = 1$), and 45/190 (23.7%) exclusive breastfeeding at 1 month pre-intervention versus 37/152 (24.3%) post-intervention ($P = .89$) (Table 2).

DISCUSSION

In this quasi-experimental study, the implementation of a Baby-Friendly−aligned pacifier policy during birth hospitalization delayed pacifier adoption but did not result in a significant change in overall pacifier use at 1 month of age in a low-income minority population. Post-intervention, pacifier adoption was delayed until the third week of life in a quarter of the infants compared to 5% pre-intervention. By 1 month of age, the rate of pacifier use remained comparable to national averages.

Our study findings contrast with previous randomized control trials of pacifier interventions in breastfeeding women that have shown significant reduction in pacifier use. Kramer et al[17] randomized mothers to nurse counseling on pacifier avoidance (experimental group) or pacifier use to comfort the baby (control group). Pacifier use in the experimental group was 61.4% compared to 84% in the control group, more than a twofold reduction (relative risk, 2.4; 95% CI, 1.5−3.8). Howard et al[26] randomized mothers to a pacifier at hospital discharge and early adoption or a pacifier by 4 weeks of age and delayed pacifier use. At 5 weeks, pacifier use was 70% in the late-pacifier group compared to 84% in the early pacifier group ($P = .002$). Jenik et al[16] randomized mothers to a pacifier and a pacifier guide (offerP group) or a guide on alternative methods to comfort a baby (not-offerP group). Only

40% of infants in the not-offerP group used a pacifier compared to 67% in the offerP group, a significant difference ($P < .001$). Our study differs from these RCTs by being a quasi-experimental design grounded in a real-life change to a Baby-Friendly environment. Mothers in our study received education on both pacifier avoidance for breastfeeding and the use of pacifiers as a protective factor against SIDS. This difference in intervention content may help explain our negative results.

Pacifier and breastfeeding counseling may affect outcomes differently in heterogeneous populations based on parental intent and values. It is also possible that the parental decisions to use a pacifier are made prenatally, and interventions in birth hospitals have a negligible effect on the parental decision. A recent qualitative study among African American mothers found parents had strong negative opinions about birth hospitals offering pacifiers to infants without parental knowledge or consent.[28]

An intriguing finding of our study is the differential in pacifier use among female and male infants after implementation of the policy. Previous studies have described higher rates of pacifier use by male infants.[15,29,30] A possible explanation is that male infants need more soothing than female infants. An observational study of 3-week infants found significant sex differences in infant behavior, with males sleeping 1 hour less a day, crying more often, and being fussier than females.[31] In this context, pacifier offering could be viewed as a maternal response to the infant's behavior. Conversely, pacifier adoption may be primarily infant driven. In a large study in Brazil, where pacifier use is considered socially desirable, pacifier use was higher among males than females, suggesting that pacifier adoption was largely an infant decision.[15] In our study, circumcision did not explain the findings; however, most male infants were circumcised, and the study lacks the power to compare pacifier use by circumcision.

In our hospital, exclusive breastfeeding rates at discharge increased significantly from 40% to 51% after implementation of the pacifier policy. This finding contrasts with the study by Kair et al[32] where restriction of pacifier use was followed by a decrease in exclusive breastfeeding rates from 79% to 68%. Our pacifier policy was more permissive than that described by Kair et al, and we used a scripted message for delivering pacifier and breastfeeding information. The study population in Kair et al's study also had a higher baseline breastfeeding rates compared to ours. These differences may explain the increase in exclusive breastfeeding rates at discharge observed in our study.

Our study has several limitations. This is a field study within the context of a Baby-Friendly journey and, hence, not truly experimental. Post-intervention higher breastfeeding rates may be due to the intensification of provider and nursing education after implementation of the pacifier policy. The study includes a small sample from a low-income, minority population, and follow-up rates were low, a common challenge in low-income communities.[33] We included only English-speaking postpartum mothers, and the findings cannot be generalized to other birth hospitals with different demographics. The level of pacifier restriction may be different across birth hospitals, and this could affect later pacifier adoption. The research assistant could have missed the presence of a pacifier in a bassinet at the time of recruitment. Responses to the telephone survey may be subject to recall bias. Despite these limitations, our study provides new and relevant information on an important topic. An additional strength is validation of the intervention by direct observation and maternal recall.

CONCLUSIONS

The implementation of a Baby-Friendly−aligned pacifier policy in a birth hospital delayed pacifier adoption but resulted in no significant change in the overall subsequent pacifier use at 1 month of age. The finding of lower pacifier use rates among female infants post-intervention requires verification in other populations before evaluating the public heath relevance. Additional investigations are needed on the impact of Baby-Friendly pacifier interventions on long-term pacifier and breastfeeding outcomes in other populations.

Our Baby-Friendly−aligned pacifier policy restricted pacifiers in the hospital but also focused on providing information on pacifiers, breastfeeding, and SIDS, thereby helping parents make an informed choice. With this policy, we had increased exclusive breastfeeding at discharge without affecting breastfeeding rates at 1 month. Our findings support the latest WHO revision of the Ten Steps to counsel mothers on the use and risks of pacifiers rather than restricting their use. The findings are highly relevant in the current environment where many US hospitals are striving to achieve Baby-Friendly status.

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