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# Hospital Discharge Bags and Breastfeeding at 6 Months: Data from the Infant Feeding Practices Study II

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## Abstract

**Background:** Distribution of industry-sponsored formula sample packs to new mothers undermines breastfeeding.

**Objective:** Using data from the Infant Feeding Practices Study II (IFPS II), we aimed to determine whether receipt of 4 different types of bags was associated with exclusive breastfeeding during the first 6 months of life.

**Methods:** We extracted data from IFPS II questionnaires. Type of discharge bag received was categorized as “formula bag,” “coupon bag,” “breastfeeding supplies bag,” or “no bag”. We examined exclusive breastfeeding status at 10 weeks (post hoc) and at 6 months using univariate descriptive analyses and multivariate logistic regression models, controlling for sociodemographic and attitudinal variables.

**Results:** Overall, 1868 (81.4%) of women received formula bags, 96 (4.2%) received coupon bags, 46 (2.0%) received breastfeeding supplies bags, and 284 (12.4%) received no bag. By 10 weeks, recipients of breastfeeding supplies bags or no bag were significantly more likely to be exclusively breastfeeding than formula bag recipients. In the adjusted model, compared to formula bag/coupon bag recipients, recipients of breastfeeding supplies bag/no bag were significantly more likely to breastfeed exclusively for 6 months (odds ratio = 1.58; 95% confidence interval, 1.06–2.36).

**Conclusion:** The vast majority of new mothers received formula sample packs at discharge, and this was associated with reduced exclusive breastfeeding at 10 weeks and 6 months. Bags containing breastfeeding supplies or no bag at all were positively associated with exclusive breastfeeding at 10 weeks and 6 months.

## Keywords

breastfeeding, discharge bags, formula samples, Infant Feeding Practices Study II

## Well Established

*Hospital distribution of industry-sponsored formula sample packs to new mothers at discharge shortens duration of any and exclusive breastfeeding up to 10 weeks postpartum.*

## Newly Expressed

*At 6 months, formula sample packs were associated with lowered exclusive breastfeeding compared to breastfeeding supplies bags or no bag. At 10 weeks, formula packs were associated with earlier discontinuation of exclusive breastfeeding compared to breastfeeding supplies bags or no bag.*

## Background

Hospital-based distribution of infant formula sample packs to new mothers at discharge is widespread in the US,<sup>1–4</sup> even though this practice is in opposition to the World Health Organization’s International Code of the Marketing of

Breast-milk Substitutes<sup>5</sup> and to statements from the Centers for Disease Control and Prevention (CDC),<sup>6,7</sup> the American Academy of Pediatrics (AAP),<sup>8</sup> the American College of Obstetricians and Gynecologists,<sup>9</sup> and the Government Accountability Office.<sup>10</sup> In most US hospitals, women receive discharge bags containing formula samples.<sup>2</sup> However, sometimes women receive other types of bags containing coupons or breastfeeding supplies, or they may not receive any bag at all.<sup>2</sup>

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Sample packs containing formula, packaged as attractive diaper bags, have been shown to undermine breastfeeding duration, especially duration of exclusive breastfeeding.<sup>11-15</sup> Recently, our study looking at the real-life effect of removing formula sample packs from a New Jersey urban hospital found an impact on any breastfeeding at 10 weeks, but no impact on exclusivity<sup>16</sup>; the intervention was heavily contaminated by illicit staff distribution of formula samples after formula sample packs were removed from the maternity service. Whereas our study<sup>16</sup> and a study by Rosenberg<sup>14</sup> examined 10-week outcomes, most researchers investigating effects of sample pack distribution have studied relatively small groups of women over shorter periods of time. Studies generally have compared sample pack receipt either with alternative discharge bags provided by the study team or with no bags.

The Infant Feeding Practices Study II (IFPS II) was a national US-based longitudinal mail-in survey conducted from 2005 to 2007 by the Food and Drug Administration in collaboration with the CDC and other US government agencies. Large numbers of women were enrolled in IFPS II, and very specific questions were included detailing the type of bag women received and its contents, at hospital discharge after giving birth. The goal of our study was to explore the association between receipt of different types of discharge bags and exclusive breastfeeding for the first 6 months of life. The AAP recommends exclusive breastfeeding until 6 months<sup>8</sup>; as far as we are aware, no other study has investigated discharge bags and outcomes as distal as 6 months postpartum.

## Methods

We extracted data on demographics from the IFPS II prenatal questionnaire and obtained information on additional questions of interest from monthly postnatal questionnaires up to 6 months. The detailed methodology behind the IFPS II has been described elsewhere.<sup>17</sup> Briefly, women were recruited from a nationally distributed consumer opinion panel in the third trimester of pregnancy, and data were collected on women and their healthy term singletons, with regard to infant feeding and care practices, prenatally, and then throughout year 1 of life. Maternal participation in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), smoking status, and all other sociodemographic data were collected at the time of the prenatal survey. Maternal overweight is defined as a body mass index (BMI) greater than or equal to 25.0 kg/m<sup>2</sup>, based on maternal report of pre-pregnancy weight and height. Attitudinal data were collected in the prenatal questionnaires. The only attitudinal question we used in our analysis was, "Infant formula as good as breast milk: Answer agree/disagree or unsure."

To obtain data on the type of bag that new mothers received at discharge, we analyzed responses to the following questions: (1) Did you receive a gift pack or diaper bag from the hospital or birth center? (Yes/No) (2) Were any of the following included in the gift pack? (choices: infant formula, infant formula coupons, breastfeeding supplies). We categorized responses in order to make them mutually exclusive. If a mother said she received formula in the bag, she was placed in the formula bag category, regardless of whether she also received formula coupons or breastfeeding supplies. If a mother did not receive formula in the bag but did receive formula coupons, she was placed in the coupon bag category, regardless of whether she also received breastfeeding supplies. If she received only breastfeeding supplies, she was placed in the breastfeeding supplies bag category. We used this hierarchical system because we are aware that industry-sponsored sample packs often contain formula, coupons, and breastfeeding supplies. However, anecdotally, staff may remove the samples, which would result in a bag containing only coupons; thus, we would be assuming that, in general, bags with only coupons were still formula industry sponsored. Similarly, if a bag contained breastfeeding supplies as well as formula, it would most likely be industry sponsored, as many industry-sponsored packs include breastfeeding-related materials or supplies. However, a bag containing only breastfeeding supplies with no formula and no coupons would most likely be an alternative bag created by the hospital. These terms are used throughout this article to describe each mutually exclusive category: formula bag, coupon bag, breastfeeding supplies bag, or no bag. The study was exempted from ethical approval by the Boston University Medical School Institutional Review Board, as it was a secondary data analysis from a publicly available dataset (the IFPS II).

## Statistical Analysis

In the initial analysis, we examined exclusive breastfeeding status at 6 months with combined categories (formula bag/coupon bag vs breastfeeding supplies bag/no bag) because our focus was on the effect of distributing formula company-sponsored diaper discharge bags. We then performed an additional, post-hoc analysis at 10 weeks. We chose 10 weeks for the post-hoc analysis because we assumed that fewer subjects had been lost to follow-up at earlier time points, and we hypothesized that choosing an earlier point in time would allow us to look at the 4 groups separately. In addition, 10 weeks was the time point selected in 2 recent studies examining the association between distribution of discharge bags and duration of any and exclusive breastfeeding.<sup>14,16</sup>

All analyses were performed with SAS version 9.1.2. Sociodemographic and attitudinal data were extracted from

the prenatal questionnaire. Data on subjects were analyzed at 6 months, defined as 24 weeks of exclusive breastfeeding.

We evaluated the effect of sociodemographics and work and feeding attitudes on any observed associations between type of bag received in-hospital and exclusive breastfeeding status at 6 months, and post hoc at 10 weeks, using a multivariate logistic regression model. Building on the DiGirolamo et al 2008 *Pediatrics* article,<sup>18</sup> which also analyzed IFPS II data, we included the following variables in our analysis: maternal age at time of birth, maternal education, poverty level, race, having breastfed a previous child, receiving WIC within the month prior to birth, mother's weight classification based on BMI, maternal smoking status, delivery type, child gender, exposure to friends or family who had breastfed a child, prenatal intent to work for pay after delivery, prenatal attitudes toward the best way to feed an infant, and prenatal intent to breastfeed. Recipients of formula bags and coupon bags were collapsed and compared with recipients of breastfeeding supplies bags/no bag for the 6-month analysis. We also evaluated exclusive breastfeeding at a post-hoc 10-week outcome using logistic regression. Four bag-type groups were left as separate entities in the 10-week models.

IFPS II data defined exclusive breastfeeding through the postnatal monthly questionnaires asking mothers questions about what their babies had received for nutrition in the past 7 days and in the past 2 weeks. Mothers were asked to check off foods and liquids that their babies had received, including breast milk, formula, dairy and non-dairy milks, fruit and vegetable juices, "sweet drinks," a variety of foods, and "other (please specify)." Water was not specifically mentioned. Mothers were also asked whether they had completely stopped breastfeeding and/or pumping. Based on these questions, it was determined whether an infant was exclusively breastfed. It is possible that an infant received water and was still considered exclusively breastfed if the mother did not write this under "other."

Likewise, duration of exclusive breastfeeding was assessed through these same postnatal monthly questionnaires asking about infant feeding, using a cumulative estimate of variable responses. For example, mothers were asked about infant feeding in the past 7 days and in the past 2 weeks, which was thought to be an appropriate measure of whether the baby had received anything but breast milk in the past month. However, because there was no direct question to the mother that asked if the infant received anything but breast milk/only breast milk, it is possible that an infant could have received formula more than 2 weeks before the mother had filled out the survey, although the previous monthly questionnaire completed should account for this. When the mother had introduced any other foods or formula as per the report on the questionnaire, this was considered an endpoint of exclusive breastfeeding. If the mother reported that the infant received formula in the

hospital on the neonatal questionnaire, this would exclude the infant from being exclusively breastfed.

## Results

Complete data were available on 2294 women. Overall, 1868 (81.4%) of women received formula bags, 96 (4.2%) received coupon bags, 46 (2.0%) received breastfeeding supplies bags, and 284 (12.4%) received no bag. Demographics of the sample are presented in Table 1.

The unadjusted logistic regression model for exclusive breastfeeding at 6 months yielded a significant difference between mothers who received formula bags/coupon bags in-hospital and mothers who did not. Controlling for possible confounding sociodemographic and attitudinal variables, women who did not receive formula bags/coupon bags were significantly more likely to breastfeed exclusively for 6 months, compared to women who received formula bags/coupon bags (odds ratio [OR] = 1.58; 95% confidence interval [CI], 1.06-2.36; Table 2).

## Post-Hoc Results

In a post-hoc analysis, and analyzing each of the original 4 bag categories as mutually exclusive, receiving either no bag or a bag with only breastfeeding supplies was significantly associated with exclusive breastfeeding at 10 weeks, compared to receiving a formula bag. Women who received breastfeeding supplies were more likely to be exclusively breastfeeding at 10 weeks (OR = 1.77; 95% CI, 1.29-2.41), and women who received no bag were also significantly more likely to be exclusively breastfeeding at 10 weeks, compared to women who received a formula bag (OR = 2.18; 95% CI, 1.07-4.42). There was no significant difference in exclusive breastfeeding at 10 weeks between women who received a bag with formula coupons, compared to women who received a formula bag (OR = 1.16; 95% CI, 0.71-1.90; Table 3).

## Discussion

We believe this is the first study to look at the association between formula sample packs and exclusive breastfeeding status at 6 months, and the first study to differentiate between 4 different types of discharge bag/no bag, which was done post hoc at the 10-week time point. Exclusive breastfeeding to 6 months was significantly reduced among new mothers who received a discharge bag containing formula/formula coupons, compared to women who received discharge bags containing breastfeeding supplies/no bag. In addition, women who received a bag containing formula at discharge were less likely to be exclusively breastfeeding at 10 weeks than women who received breastfeeding supplies or no bag. These findings are in line with the 2000 Cochrane review,

**Table 1.** Characteristics of Infant Feeding Practices Study II Sample Based on Period of Exclusive Breastfeeding for 6 Months and for Less Than 6 Months.

Variable	Exclusively Breastfed for 6 Months, No. (%)	Exclusively Breastfed for Less Than 6 Months, No. (%)
Bag type <sup>a</sup>		
No bag	37 (20.2)	247 (11.7)
Breastfeeding supplies only	4 (2.2)	42 (2.0)
Formula coupons only	7 (3.8)	89 (4.2)
Formula in bag	135 (73.8)	1733 (82.1)
Child sex		
Male	87 (47.5)	1032 (48.9)
Female	96 (52.5)	1079 (51.1)
Maternal education <sup>a</sup>		
High school or less	19 (10.4)	439 (20.8)
Some college	76 (41.5)	851 (40.3)
College grad or more	88 (48.1)	821 (38.9)
Poverty level <sup>b</sup>		
< 185%	76 (41.5)	851 (40.3)
185%-349.9%	61 (33.3)	770 (36.5)
≥ 350%	46 (25.1)	490 (23.2)
Race		
Caucasian	169 (92.4)	1831 (86.7)
African American	2 (1.1)	90 (4.3)
Hispanic	9 (4.9)	133 (6.3)
Asian/Pacific Islander	3 (1.6)	57 (2.7)
Previous breastfeeding experience <sup>a</sup>		
First child	39 (21.3)	618 (29.3)
Breastfed a previous child	144 (78.7)	1226 (58.1)
Did not breastfeed a previous child	0 (0.0)	267 (12.6)
Maternal body mass index <sup>a</sup>		
< 25.0	152 (83.1)	1542 (73.0)
≥ 25.0	31 (16.9)	569 (27.0)
Prenatal WIC status <sup>a,c</sup>		
Yes	39 (21.3)	592 (28.0)
No	144 (78.7)	1519 (72.0)
Marital status <sup>a</sup>		
Married	168 (91.8)	1673 (79.3)
Separated/divorced	7 (3.8)	82 (3.9)
Never married	8 (4.4)	356 (16.9)
Number of friends and relatives who breastfed <sup>a</sup>		
1 or 2	23 (12.6)	468 (22.2)
3-5	34 (18.6)	611 (28.9)
> 5	119 (65.0)	745 (35.3)
None breastfed	0 (0.0)	66 (3.1)
None have children	1 (0.6)	6 (0.3)
Unsure	6 (3.3)	215 (10.2)
Best way to feed an infant <sup>a</sup>		
Breastfeed	177 (96.7)	1420 (67.3)
Formula feed	0 (0.0)	251 (11.9)
Breastfeed and formula feed	3 (1.6)	53 (2.5)
Equally good	3 (1.6)	387 (18.3)
Plan to feed the baby in first few weeks <sup>a</sup>		
Breastfeed only	174 (95.1)	1240 (58.7)
Formula feed only	0 (0.0)	293 (13.9)
Both	7 (3.8)	506 (24.0)
Don't know yet	2 (1.1)	72 (3.41)

(continued)

Table 1. (continued)

Variable	Exclusively Breastfed for 6 Months, No. (%)	Exclusively Breastfed for Less Than 6 Months, No. (%)
Plan to work for pay in baby's first year <sup>a</sup>		
Yes	81 (44.3)	1285 (60.9)
No	102 (55.7)	826 (39.1)
Maternal age, mean (SD), y	30.0 (4.8)	29.0 (5.3)
Delivery type <sup>a</sup>		
Vaginal	151 (82.5)	1511 (71.6)
Cesarean	32 (17.5)	600 (28.4)

<sup>a</sup>Significantly different between exclusively breastfed and not exclusively breastfed at 6 months.

<sup>b</sup>Percentage of federal poverty level was defined as a ratio of household income to the poverty thresholds by household size produced by the latest available data from the US Census Bureau. Because household income was collected in ranges, we used the midpoint of each category for estimating percentage of poverty.

<sup>c</sup>WIC, the Special Supplemental Nutrition Program for Women, Infants, and Children, is a federally funded health and nutrition program. Participants must meet income guidelines and be pregnant women, new mothers, infants, or children younger than 5 years.

which analyzed 9 randomized controlled trials and found that “commercial discharge packs” containing “artificial formula or promotional material for artificial formula” were associated with reduced rates of women who exclusively breastfed at 6 and 13 weeks postpartum. The control groups in these studies included “no intervention, non-commercial pack[s]” (from which formula was removed and/or replaced with breastfeeding supplies) “and combinations of these.”<sup>19</sup> Also in line with data from other studies,<sup>2,4</sup> we found that the vast majority of US women received formula sample packs at discharge.

The 6-month outcome is important because it indicates that formula sample packs distributed at discharge are associated with a decreased likelihood of women meeting the recommended AAP guidelines of breastfeeding exclusively for 6 months. Reasons for these outcomes were not explored, but as early feeding is obviously predictive of later success, initial interference resulting from formula sample packs, as has been reported in multiple studies,<sup>11-15</sup> may be predictive of less success later in the breastfeeding relationship. It is logical to assume that distribution of formula samples led to early supplementation, which can undermine duration of both exclusive and any breastfeeding.

### Limitations

The study has several limitations. The women included in IFPS II were not representative of the US population and had higher breastfeeding rates than is typical in the US. Infant formula sample packs are known to impact vulnerable groups more than others<sup>20</sup>; thus, this study may have underestimated their effect compared to any effect in the general US population. In addition, due to use of a secondary data analysis

design, we used certain assumptions with regard to categorization of bags, and it is possible that there is some crossover. For example, because we categorized all bags containing formula as formula bags regardless of additional bag content, it is probable that some bags containing formula samples also contained coupons and maybe even breastfeeding supplies. In addition, it is possible that the types of breastfeeding supplies varied, and potentially some of these could have been found in discharge bags created by the infant formula industry. However, to our knowledge, all formula company-sponsored bags with breastfeeding supplies contain either formula or formula coupons as well; thus, we believe that this categorization virtually eliminated the possibility that a mother received only breastfeeding supplies from a formula company bag.

Very few hospitals appear to provide bags containing breastfeeding supplies. Given this, the few that do potentially have a mission that incorporates breastfeeding promotion, and thus outcomes associated with bags containing breastfeeding supplies are possibly reflective of additional supportive practices at the hospital, and not just with the contents of the discharge bag.

### Conclusion

In 2005-2007, the vast majority of US hospitals distributed formula sample packs to new mothers at discharge, despite recommendations to the contrary and a mounting body of literature demonstrating adverse associations with breastfeeding. Sample pack distribution is negatively associated with exclusive breastfeeding even at 6 months postpartum. Further research that samples sociodemographically diverse populations and separates the effect of discharge bags from maternity care practice is needed to expand upon these results.

**Table 2.** Predictors of Exclusive Breastfeeding for 6 Months.

Variable	Exclusively Breastfed for 6 Months, Adjusted OR (95% CI)
Bag type	
Breastfeeding supplies or no bag	1.58 (1.06-2.54)
Formula bag or formula coupons	1.00
Child sex	
Male	1.13 (0.82-1.55)
Female	1.00
Maternal education	
College grad or more	1.40 (0.78-2.52)
Some college	1.39 (0.80-2.42)
High school or less	1.00
Poverty level	
≥ 350%	0.87 (0.53-1.42)
185%-349.9%	0.69 (0.46-1.04)
< 185%	1.00
Race	
African American	0.47 (0.11-2.02)
Hispanic	1.09 (0.52-2.29)
Asian/Pacific Islander	0.60 (0.18-2.00)
Caucasian	1.00
Previous breastfeeding experience	
Breastfed a previous child	0.40 (0.90-2.16)
Did not breastfeed a previous child	< 0.01 (0.01-10.00)
First child	1.00
Maternal BMI	
≥ 25	0.56 (0.37-0.86)
< 25	1.00
Prenatal WIC status	
Yes	1.05 (0.67-1.66)
No	1.00
Marital status	
Separated/divorced	1.20 (0.50-2.87)
Never married	0.44 (0.20-0.96)
Married	1.00
Number of friends and relatives who breastfed	
At least 1	2.25 (1.01-4.99)
None	1.00
Best way to feed an infant	
Breastfeed only	4.15 (1.77-9.76)
Not breastfeed only	1.00
Plan to feed the baby in first few weeks	
Breastfeed only	5.8 (2.86-11.76)
Other <sup>a</sup>	1.00
Plan to work for pay in baby's first year	
No	1.51 (1.08-2.11)
Yes	1.00
Delivery type	
Cesarean	0.64 (0.42-0.97)
Vaginal	1.00

Abbreviations: BMI, body mass index; CI, confidence interval; OR, odds ratio; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.

<sup>a</sup>“Other” included formula feed, both breastfeed/formula feed, and don't know yet.

**Table 3.** Predictors of Exclusive Breastfeeding at 10 Weeks Post Hoc.

Variable	Exclusively Breastfed for at Least 10 Weeks, Adjusted OR (95% CI)
Bag type	
Breastfeeding supplies only	1.77 (1.29-2.41)
No bag	2.18 (1.07-4.42)
Formula coupons	1.16 (0.71-1.90)
Formula bag	1.00
Child sex	
Male	1.17 (0.95-1.45)
Female	1.00
Maternal education	
College grad or more	1.53 (1.06-2.21)
Some college	1.18 (0.84-1.66)
High school or less	1.00
Poverty level	
≥ 350%	0.86 (0.61-1.20)
185%-349.9%	0.70 (0.53-0.92)
< 185%	1.00
Race	
African American	0.35 (0.14-0.86)
Hispanic	1.12 (0.69-1.80)
Asian/Pacific Islander	0.58 (0.29-1.16)
Caucasian	1.00
Previous breastfeeding experience	
Breastfed a previous child	1.54 (1.17-2.03)
Did not breastfeed a previous child	0.21 (0.07-0.59)
First child	1.00
Maternal BMI	
≥ 25	0.74 (0.58-0.96)
< 25	1.00
Prenatal WIC status	
Yes	0.74 (0.54-1.00)
No	1.00
Marital status	
Separated/divorced	0.84 (0.45-1.58)
Never married	0.53 (0.35-0.80)
Married	1.00
Number of friends and relatives who breastfed	
At least 1	1.11 (0.76-1.64)
None	1.00
Best way to feed an infant	
Breastfeed only	1.93 (1.35-2.76)
Not breastfeed only	1.00
Plan to feed the baby in first few weeks	
Breastfeed only	7.27 (5.06-10.43)
Other <sup>a</sup>	1.00
Plan to work for pay in baby's first year	
No	1.29 (1.03-1.64)
Yes	1.00
Delivery type	
Cesarean	0.67 (0.52-0.86)
Vaginal	1.00

Abbreviations: BMI, body mass index; CI, confidence interval; OR, odds ratio; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.

<sup>a</sup>“Other” included formula feed, both breastfeed/formula feed, and don't know yet.

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