

From Maine to Mississippi

Hospital Distribution of Formula Sample Packs Along the Eastern Seaboard

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Objectives: To determine the proportion of hospitals distributing free infant formula sample packs in 21 eastern states and the District of Columbia, to investigate any regional trends or timelines associated with discontinuation of formula pack distribution, and to catalog in 2 states the take-home items given to new mothers in addition to, or instead of, formula sample packs.

Design: Data were collected between October 1, 2006, and March 31, 2007, over the telephone by research assistants using a prepared script. We determined whether hospitals distributed a “formula company–sponsored diaper discharge bag” to new mothers.

Setting: Our sample comprised all mainland states in the US Department of Health and Human Services Health Resources and Services Administration regions 1 through 4.

Participants: We contacted 1295 hospitals in 21 eastern states and the District of Columbia.

Intervention: Hospital distribution of an infant formula sample pack.

Main Outcome Measure: The proportion of hospitals that distributed formula sample packs.

Results: Ninety-four percent of hospitals distributed formula sample packs. Regional trends were evident. The proportion of distributing hospitals ranged from 70.4% (New Hampshire) to 100.0% (4 states—New Jersey, Maryland, Mississippi, and West Virginia—and Washington, DC). The proportion of hospitals that do not distribute sample packs has risen significantly between 1979 and 2006 ($P < .01$).

Conclusion: Most eastern US hospitals distributed formula sample packs to new mothers at hospital discharge, contrary to recommendations from the major medical organizations, but the practice is changing significantly.

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UNITED STATES EXCLUSIVE breastfeeding rates among newborns fall far short of national goals. Although the American Academy of Pediatrics recommends exclusive breastfeeding for 6 months,¹ only 11% of US infants are exclusively breastfed at 6 months.² Studies³⁻⁷ have demonstrated that hospital-based distribution of formula sample packs undermines exclusive breastfeeding, is associated with inappropriately early introduction of complementary foods in infants, and is most likely to affect vulnerable populations.

Per the US Preventive Services Task Force, “Commercial discharge packs provided by hospitals that include samples of infant formula and/or bottles and nipples are associated with reducing the rates of exclusive breastfeeding.”⁸ One study³ ran-

domly assigned 448 breastfeeding new mothers to receive or not to receive a formula sample pack on hospital discharge. When telephoned at 3 months post partum, sample recipients were less likely to be breastfeeding at 1 month (78% vs 84%, $P = .07$) and were more likely to have introduced solid foods by 2 months (18% vs 10%, $P = .01$). Trends were most significant among primiparas, less educated mothers, and mothers who had been ill post partum. These findings, as well as those described in a review by Pérez-Escamilla et al,⁹ contributed to concerns and to an assessment of formula company marketing practices by the Government Accountability Office.¹⁰ The Government Accountability Office report stated,

A majority of the studies we reviewed found lower breastfeeding rates among women receiving formula samples in discharge packs,

[and] WIC [Women, Infants, and Children program] mothers who received formula discharge packs also had lower breastfeeding rates.^{10(p30)}

The most recent study⁵ to examine the effect of formula sample packs on a large scale used Oregon data from the Centers for Disease Control and Prevention Pregnancy Risk Assessment Monitoring System to determine whether breastfeeding practices of 2684 new mothers were affected by the distribution of formula sample packs given on discharge from the hospital. Rosenberg et al⁵ found that women who received formula sample packs at hospital discharge were less likely to breastfeed exclusively than women who did not receive formula sample packs and that the relationship between receiving a sample pack and diminished exclusive breastfeeding was significant every week throughout the first 10 weeks post partum, with the strongest significance being at approximately 3 weeks. After controlling for maternal age, race/ethnicity, educational level, and family income, women who received formula samples were more likely to exclusively breastfeed their infants for less than 10 weeks than women who did not receive formula samples (adjusted odds ratio, 1.39; 95% confidence interval, 1.05-1.84).

Packaged as smart diaper bags, the commercial sample packs contain formula, coupons, advertisements, and baby products. Typically, they are given free to the hospital by the relevant infant formula manufacturer and are distributed to patients by clinicians when mother and newborn are discharged from the hospital. Institutions that have voiced opposition to hospital distribution of formula sample packs in addition to the Government Accountability Office¹⁰ include the Centers for Disease Control and Prevention,¹¹ the American Academy of Pediatrics,¹ the American College of Obstetricians and Gynecologists,¹² the US Office on Women's Health,¹³ and the World Health Organization.¹⁴

Efforts have been made to remove formula sample packs from hospitals in specific parts of the nation. The New York City Department of Health and Mental Hygiene launched a major breastfeeding initiative in 2006, which included efforts to reduce the influence of the formula industry and led to the elimination of sample packs from all 11 public hospitals operated by the New York City Health and Hospitals Corporation.¹⁵ In 2007, the New York City Health and Hospitals Corporation created 22 000 alternative hospital discharge bags, each bearing the relevant hospital's name, as replacements. The Massachusetts Breastfeeding Coalition, working with the Massachusetts Department of Public Health, attempted to remove formula sample packs in all Massachusetts hospitals through statewide perinatal regulations in 2006. The effort was thwarted by Gov Mitt Romney's office, but the resultant publicity sparked an ethical debate, and subsequently many hospitals eliminated sample packs on their own initiative.¹⁶ More recently and since the original data for the present study were collected, Portland, Oregon, became the first US city in which formula sample hospital discharge packs were eliminated from every hospital.¹⁷

Companies such as Nestlé began offering free "baby milk" samples to new mothers as early as the turn of the

20th century, and distribution of formula sample packs via hospital clinicians began in the 1960s.¹⁸ However, the current extent of this practice is unknown. The goals of the present study were (1) to determine the proportion of hospitals distributing free infant formula sample packs in 21 eastern states and the District of Columbia, (2) to investigate any regional trends or timelines associated with discontinuation of formula pack distribution, and (3) to catalog in 2 states the take-home items given to new mothers in addition to, or instead of, formula sample packs.

METHODS

Between October 1, 2006, and March 31, 2007, we obtained information directly from 1295 hospitals in 21 states and the District of Columbia. Our sample comprised all mainland states in the US Department of Health and Human Services Health Resources and Services Administration regions 1 through 4. We obtained names and telephone numbers of birthing hospitals by contacting hospital organizations and state departments of public health.

Initially, the survey instrument was tested in Massachusetts because we already knew which hospitals in our state had eliminated formula sample packs as a result of the work of the Massachusetts Breastfeeding Coalition. After telephoning the maternity service at each hospital, a research assistant (R.F. and T.N.) (using a prepared script) asked the person who answered the telephone whether the service distributed a "formula company-sponsored diaper discharge bag" to new mothers. This specific language was used to distinguish between a formula sample pack (usually referred to within the hospital as a formula company "diaper bag") and any alternative discharge bag or gift the hospital may have created separately for mothers and newborns. At the test stage, we added a second question for respondents who initially said no such bags were distributed. The clarification question was "Do you give formula company bags to any mothers?" This question was added because we learned that some providers said that formula company bags were not distributed, but when questioned in more depth, they clarified that "some mothers" or "non-breastfeeding mothers" received bags. In this study, only hospitals that distributed no formula sample packs at all were considered sample pack free.

Subsequently, researchers (R.F. and T.N.) telephoned the maternity service at every hospital in all 21 states and the District of Columbia, with a response rate of 100.0% after persistent calling. If the respondent stated that a formula company diaper bag was distributed, the hospital was counted as a distributor of sample packs. If the respondent did not know the answer, we asked to be transferred to a provider who knew the answer. If the respondent remained uncertain or stated that no formula sample packs were distributed, a second independent researcher called and confirmed the information with the lactation department or nurse manager of the maternity service. Therefore, all hospitals stating that they did not distribute formula sample packs received 2 independent telephone calls. When known, the date when the hospital ended sample pack distribution was also recorded. Significance of changes in practice among all hospitals over time was calculated using commercially available software (STATS/SE version 8; StataCorp LP, College Station, Texas) and the Pearson product moment correlation test for trend.

At 10 randomly selected hospitals that gave out sample packs, we also asked which person on the unit distributed the samples. In addition, we asked all hospitals in a convenience sample of 2 states, New Hampshire and Pennsylvania, if they gave alter-

Table. Proportion of Hospitals Distributing Formula Sample Packs by State and by US Department of Health and Human Services Health Resources and Services Administration (HRSA) Region

State	Hospitals Giving Bags, No. (%)
HRSA region 1	
Connecticut	28/30 (93.3)
Massachusetts	37/51 (72.5)
Maine	29/35 (82.9)
New Hampshire	19/27 (70.4)
Rhode Island	5/7 (71.4)
Vermont	9/12 (75.0)
HRSA region 2	
New Jersey	69/69 (100.0)
New York	226/245 (92.2)
HRSA region 3	
Delaware	6/7 (85.7)
Maryland	36/36 (100.0)
Pennsylvania	116/118 (98.3)
Virginia	52/54 (96.3)
Washington, DC	6/6 (100.0)
West Virginia	35/35 (100.0)
HRSA region 4	
Alabama	54/55 (98.2)
Florida	108/113 (95.6)
Georgia	88/90 (97.8)
Mississippi	47/47 (100.0)
North Carolina	81/85 (95.3)
Kentucky	52/54 (96.3)
South Carolina	41/45 (91.1)
Tennessee	72/75 (96.0)

native items to new mothers at hospital discharge instead of, or in conjunction with, formula sample packs. Because no personal-level data were collected and because all data were publicly available, the study was exempt from institutional review board approval.

RESULTS

In March 2007, 93.8% (1215 of 1295) of hospitals in the eastern United States were distributing formula sample packs to new mothers. Patterns varied by state and by region. The proportion of hospitals distributing formula sample packs per state ranged from 70.4% (New Hampshire) to 100.0% (4 states—New Jersey, Maryland, Mississippi, and West Virginia—and Washington, DC) (**Table** and **Figure 1**).

Of 80 hospitals that were sample pack free, 34 gave a specific date for discontinuation of the practice, 45 gave a specific year, and 1 hospital stated “before 2000.” Twenty hospitals reported eliminating sample packs before 2000, and 60 hospitals reported discontinuation of the practice since 2000. The proportion of bag-free hospitals has risen significantly between 1979 and 2006 ($P < .01$) (**Figure 2**). Elimination was regionally focused. For example, of 15 hospitals that removed sample packs in 2006, 5 were in New England and 5 in New York State. Based on the random sample of 10 hospitals, the patient’s nurse distributed the formula sample packs at 7 hospitals, and “the nurse or an aide” distributed the bags at the remaining 3 hospitals.

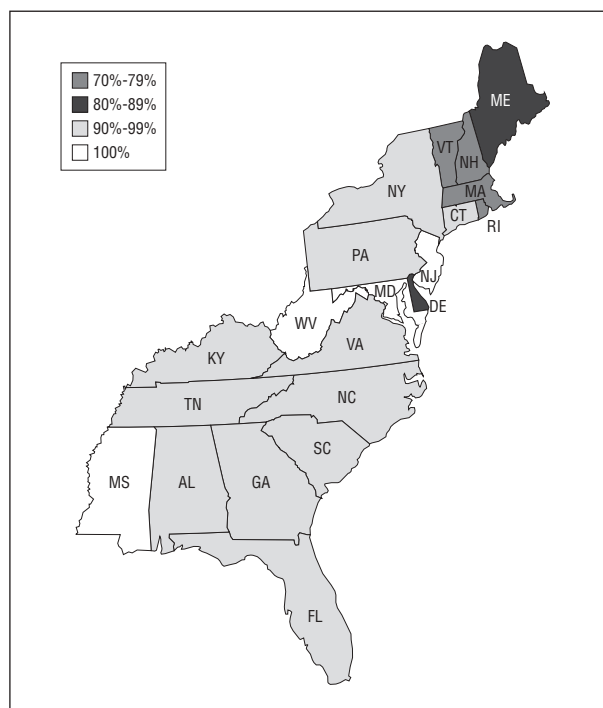


Figure 1. Percentage of hospitals distributing formula sample packs by state.

Regarding distribution of alternatives to formula sample packs, 25 of 118 hospitals (21.2%) in Pennsylvania gave out an alternative bag created by the hospital, with 24 of 118 (20.3%) giving out the alternative bag and a formula company sample pack. In New Hampshire, 12 of 27 hospitals (44.4%) gave out their own hospital bags, with 6 of 27 (22.2%) giving out this bag and a formula company sample pack. The most popular items in hospital bags were breast pads, baby blankets, and water bottles for the mother.

Some hospitals volunteered information on how this alternative bag was financed. Financing sources included volunteer donations, funding from a public health institution, and the hospital’s nursing and maternity budgets.

COMMENT

We found that most hospitals in the eastern United States distributed formula sample packs to new mothers and infants on hospital discharge. We also found that increasing numbers of hospitals were discontinuing the practice, with evidence of regional differences. Distribution was least prevalent in New England and was most prevalent in the District of Columbia and neighboring states. Given the widespread condemnation of this practice by major medical authorities and by groups such as the Government Accountability Office, it is disturbing to note its continued prevalence.

Elimination of sample packs was ongoing, with clusters of activity in certain regions such as New York City and Massachusetts. In both of these regions, we hypothesize that activity was associated with the aforementioned public health efforts to eliminate formula sample packs, led respectively by the New York City Depart-

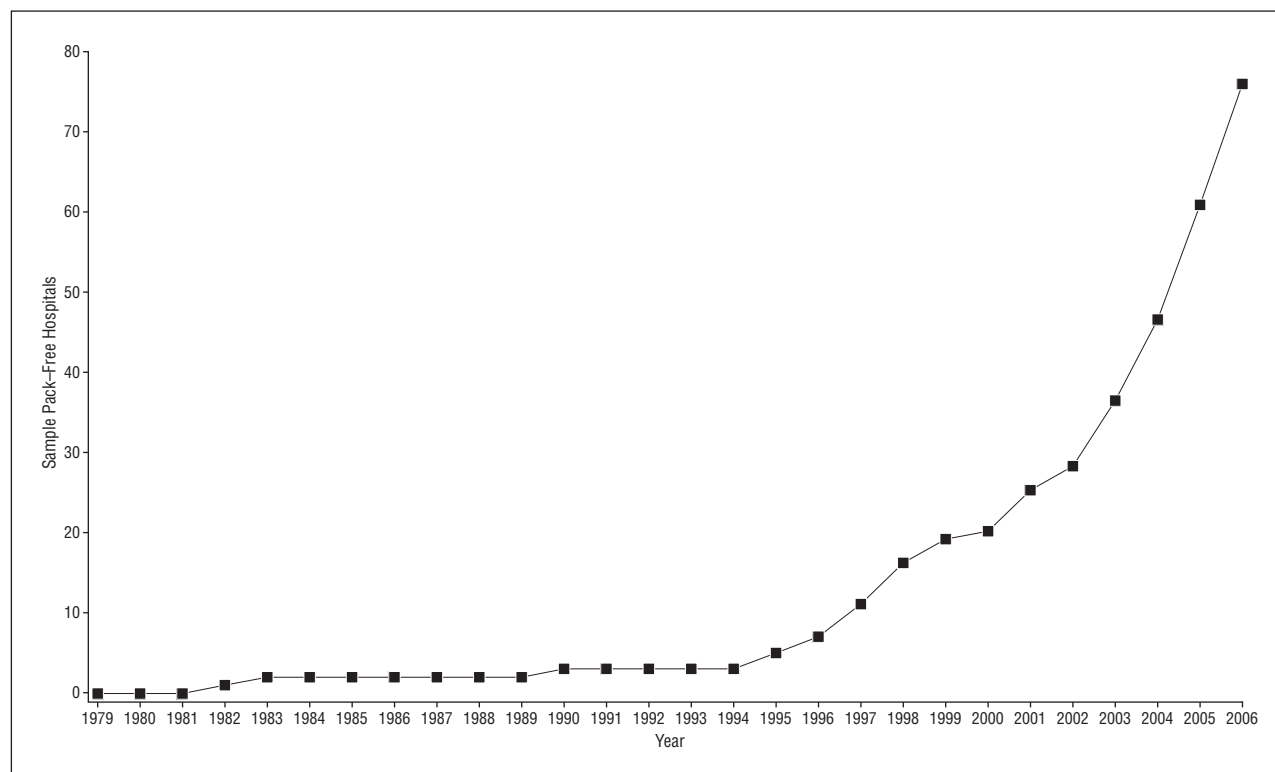


Figure 2. Total number of hospitals that do not distribute formula sample packs, 1979 to 2006. A significant upward trend was noted in the proportion of hospitals that do not distribute formula sample packs ($P < .01$).

ment of Health and Mental Hygiene and by the Massachusetts Department of Public Health with the Massachusetts Breastfeeding Coalition.

Our subsample study in 2 states revealed that many hospitals are creating and distributing alternatives to formula sample discharge packs. This is of interest because anecdotally hospitals often state that they cannot eliminate sample packs because funding does not exist to replace them and new mothers expect a “gift pack” to take home. We found it surprising that in Pennsylvania 24 of 25 hospitals giving out alternative bags also gave out formula company sample packs, as did 6 of 12 New Hampshire hospitals. Funding sources vary at hospitals distributing alternative bags. An Alabama hospital described a complex arrangement whereby volunteers raised money through the hospital gift shop and other fundraising activities to buy items and bags, which were then assembled and distributed by lactation staff. In New York City, the Health and Hospitals Corporation funds the alternative bag at all 11 hospitals.

This study did not collect specific data on procedures surrounding elimination of formula sample packs, but we have experience with hospital policy in this area. Many hospitals tackle this issue when they make a decision to achieve World Health Organization Baby-Friendly status because a Baby-Friendly–designated hospital cannot distribute formula samples, as it is in violation of the World Health Organization’s *International Code of Marketing of Breast-Milk Substitutes*.¹⁴ Several considerations arise when an institution attempts to remove sample packs. Often, removal of the bags is opposed by staff because it is seen as denying patients a gift. Therefore, an

alternative “going home” bag may be substituted, but this can represent financial investment. Individual institutions attempting to change an embedded tradition often face internal opposition. Therefore, the practice is difficult to end without buy-in from key players in administration and clinical services who grasp the ethical concerns in a bigger picture. For example, when our inner-city institution (Boston Medical Center) eliminated sample packs before becoming Baby-Friendly, a key pediatrician complained that we were denying poor women a gift that was given to wealthier women in an institution across town. By contrast, our chief executive officer decided to remove sample packs for ethical reasons “because it was the right thing to do.”¹⁹

More effective ways of removing sample packs may be to tackle large numbers of hospitals at once through community-based initiatives, as with the Portland and New York City examples, where several hospitals decided to eliminate the packs together for ethical or health-based reasons. Future research on successful elimination policies is needed.

It is possible that recent trends toward elimination of formula samples are not specifically linked to breastfeeding promotion but reflect more general changes in attitude toward pharmaceutical company presence in the hospital. The Prescription Project, run by the Community Catalyst and by the Institute on Medicine as a Profession, is a national initiative to implement new guidelines surrounding industry funding and medical research. The project seeks to introduce policies outlined by Brennan et al²⁰ into hospitals and academic centers to curb aggressive marketing to physicians by pharma-

ceutical and device industries. The guidelines would require medical centers to adopt policies limiting financial ties between the medical profession and industry.²⁰

There are limitations to this study. No single source of public data catalogs all US birthing hospitals by name, and it is possible that we inadvertently omitted some institutions. In addition, our study was limited for practical and budgetary reasons to the eastern United States. Further studies should be performed to determine whether the practice is similar in other large US regions. Nevertheless, our sample included culturally and geographically diverse states such as Mississippi, New Jersey, and Maine. Our findings give us no cause to believe that general distribution would vary dramatically across the remainder of the United States, although we would expect to see local variations in practice.

CONCLUSIONS

Exclusive breastfeeding rates among young infants are discouragingly low.²¹ Formula sample packs have been shown to undermine breastfeeding, and their elimination from US hospitals may help to increase exclusive breastfeeding rates nationally. The prevalence of sample pack distribution is disturbing and incongruous given extensive opposition, but encouraging trends suggest that the practice may be curtailed in the future.

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Author Contributions: Ms Merewood had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Merewood, Grossman, and Navidi. *Acquisition of data:* Fonrose, Singleton, Navidi, and Pomales. *Analysis and interpretation of data:* Merewood, Grossman, and Cook. *Drafting of the manuscript:* Merewood. *Critical revision of the manuscript for important intellectual content:* Merewood, Fonrose, Singleton, Grossman, Navidi, Cook, and Pomales. *Statistical analysis:* Cook. *Obtained funding:* Merewood and Singleton. *Study supervision:* Merewood, Fonrose, Singleton, and Navidi.

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