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Trends in US Hospital Distribution of Industry-Sponsored Infant Formula Sample Packs



WHAT'S KNOWN ON THIS SUBJECT: Industry-sponsored distribution of infant formula samples in hospitals is associated with decreases in breastfeeding exclusivity and duration. The vast majority of US hospitals distribute industry-sponsored formula sample packs in violation of recommendations from the major medical authorities.



WHAT THIS STUDY ADDS: This is the first study to examine whether the proportion of hospitals that distribute industry-sponsored formula sample packs has changed over time. On the basis of data from 20 states, significantly fewer hospitals distributed these packs in 2010 than in 2007.

abstract

OBJECTIVE: To describe trends in the proportion of US hospitals that distribute industry-sponsored formula sample packs between 2007 and 2010.

METHODS: This is a follow-up of a 2007 study. In 2007, we surveyed all 50 US states to determine the proportion of hospitals that distributed infant formula samples to new mothers. In 2010, we selected the 10 best-record and 10 worst-record states with regard to industry-sponsored formula sample-pack distribution in 2007. We called all hospitals in these 20 states and asked if the maternity service distributed a “formula company-sponsored diaper discharge bag” to new mothers. We also recorded the respondent’s job title.

RESULTS: We contacted 1239 hospitals in 20 states. In 2007, 14% of these hospitals were sample-pack-free. In 2010, 28% of the same hospitals were sample-pack-free; the proportion of sample-pack-free hospitals per state ranged from 0% (5 states) to 86% (Rhode Island). In the 10 best-record states, the weighted proportion of sample-pack-free hospitals increased by a mean difference of 18% between 2007 and 2010 ($P < .0001$). In the 10 worst-record states, the weighted proportion of sample-pack-free hospitals increased by a mean difference of 6% ($P < .01$).

CONCLUSION: Most US hospitals continue to distribute industry-sponsored formula sample packs, but trends indicate a significant change in practice; increasing proportions of hospitals eliminate these packs. Change was more significant in states where higher proportions of hospitals had already eliminated packs in 2007. *Pediatrics* 2011;128:702–705

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KEY WORDS

breastfeeding, infant feeding, infant formula, samples, hospital policy

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Hospital-based distribution of industry-sponsored formula sample packs, packaged as diaper discharge bags, to new mothers violates the World Health Organization's International Code of the Marketing of Breast-milk Substitutes, and is widely criticized by leading pediatric and preventive health care organizations, including the Centers for Disease Control and Prevention,¹ the American Academy of Pediatrics,² the American College of Obstetricians and Gynecologists,³ and the Government Accountability Office.⁴ Distribution of industry-sponsored formula sample packs undermines breastfeeding, especially the duration of exclusive breastfeeding.⁵⁻¹⁰ Nonetheless, formula company manufacturers frequently use this marketing technique in the United States. In 2007, our nationwide study found that only 9% of US hospitals did not distribute these packs.¹¹ In recent years, especially after a 2009 Institute of Medicine report on conflict of interest in medicine,¹² pressure has mounted in clinical and research settings to decrease ties with industry and to stem the tide of free samples distributed in medical settings. Specific to industry-sponsored formula sample packs, a national campaign, Ban the Bags, was launched that includes a Web site from which hospitals can obtain resources on practice discontinuation and can self-report discontinuation of the practice.¹³ The goal of this study was to determine if any significant changes in practice occurred in the prevalence of industry-sponsored formula sample-pack distribution to new mothers in the maternity setting at US hospitals between 2007 and 2010.

METHODS

In our 2007 national study, we contacted all US maternity hospitals.¹¹ In this study, we called all hospitals in 20 selected states: the 10 states with the best and worst records for pack distri-

bution in 2007. "Best-record" states were those with the lowest prevalence of distribution in 2007, and "worst-record" states were those with the greatest prevalence of distribution in 2007. Contact information was obtained from the 2007 study, and the same survey and methodology was used as in previous studies:^{11,14} namely, a research assistant called the facility and determined that the hospital had a maternity service. The research assistant then asked the respondent on the maternity service their position at the hospital, and if "a formula company-sponsored diaper discharge bag" was given to any mothers. This terminology was used because these packs are commonly called "diaper discharge bags"; however, we wanted to distinguish between hospital-funded diaper discharge bags, which do not violate the World Health Organization code, and products sponsored by the infant formula industry. When the answer was "no," the research assistant called back and confirmed this information with a more senior source such as the nurse manager or lactation consultant. We only called back "no" respondents for 2 reasons: it was not financially viable to make 2 telephone calls to >1200 hospitals, and in our experience of the previous survey, respondents were more likely to be confused about a "no" answer. For example, when we tested the question for the original survey, respondents often said, "No, we don't distribute formula diaper bags, only to formula-feeding women." We considered it critical to determine if any mothers received the packs (rather than, for example, only formula-feeding mothers), and the call back was primarily to verify this. This is based on our clinical knowledge that if industry-sponsored formula sample packs are present in the hospital, they are likely to be distributed to many women, not just to a particular group

for whom they are theoretically designated. For the consistency of our research, a facility is not considered to be sample-pack-free unless all industry-sponsored formula sample packs are removed. The study was exempt from institutional review board review because it collected data about routing hospital practices with no privacy or confidentiality issues.

SAS 9.1 (SAS Institute, Inc, Cary, NC) was used to conduct all statistical analyses. Some maternity services had closed since 2007; because of the change in the number of hospitals with maternity services between 2007 and 2010, to have paired data, the hospitals that had discontinued maternity services as of 2010 were treated as missing data in 2010. χ^2 analyses were used to describe the difference in proportion of sample-pack-free hospitals in each state between 2007 and 2010. The paired *t* test was used to calculate the mean difference in weighted proportions of sample-pack-free hospitals between 2007 and 2010. The proportions of sample-pack-free hospitals among the best-record and worst-record groups were based on an aggregation of state proportions of sample-pack-free hospitals, and weighting was used to account for the varying number of hospitals per state: states with more hospitals were given more weight in the analyses. This was done to ensure that smaller states such as Rhode Island with 7 hospitals, 6 of which are sample-pack-free, did not exert a greater influence in the analysis compared with a state such as California, with 255 hospitals, 117 of which are sample-pack-free. The interpretation of the mean difference in weighted proportions is the change in proportion of sample-pack-free hospitals from 2007 to 2010 in the 10 best- and 10 worst-record states. A 95% confidence interval that did not include 0% represents a significant dif-

ference in the proportion of sample-pack-free hospitals from 2007 to 2010. *P* values were reported; *P* < .05 was considered significant.

RESULTS

Between January and April 2010, we contacted 1323 hospitals in 19 states and Washington, DC. Of the 1323 hospitals, 1239 had maternity services in 2010. The proportion of sample-pack-free hospitals in the 20 states increased from 14% (181 of 1323) in 2007, to 28% (349 of 1239) in 2010. In 2010, the proportion of sample-pack-free hospitals ranged from 0% (Maryland, Mississippi, Arkansas, South Dakota, and DC) to 86% (Rhode Island) (Table 1).

Among the 10 best-record states, the average proportion of sample-pack-free hospitals rose from 25% (2007) to 46% (2010), and the mean difference in weighted proportions of sample-pack-free hospitals rose by 18% (*P* < .0001 [95% confidence interval: 12%–23%]). All 10 best-record states had significant increases in the proportion of

sample-pack-free hospitals. In 5 of these states, >50% of hospitals had eliminated industry-sponsored formula packs. In the 10 worst-record states, the average percentage of sample-pack-free hospitals rose from <1% (2007) to 7% (2010), and the mean difference in weighted proportions of sample-pack-free hospitals rose by 6% (*P* = .01 [95% confidence interval: 2%–11%]). Five of these states experienced significant increases in the proportion of sample-pack-free hospitals.

On the basis of self-identification, staff who answered the question were registered nurses (46.6%), nurse managers or head nurses (14.7%), secretaries (12%), unit directors (9.9%), nursing assistants (7.1%), lactation consultants (3.5%), and 6.3% other.

DISCUSSION

We found a significant increase in the proportion of hospitals that had eliminated industry-sponsored formula sample packs between 2007 and 2010. This increase was far more prevalent

in states with higher proportions of sample-pack-free hospitals at baseline, which suggests that in states where activity was already under way, institutions removed industry-sponsored formula sample packs at a more accelerated pace than in states where little or no activity was evident in 2007. This implies that patterns in pack removal may be influenced by “peer pressure” or changing cultures at surrounding institutions, as sample-pack-free institutions become more normal. Examples of regionally mediated pressure include grassroots campaigns from breastfeeding advocacy groups to eliminate samples, such as those launched by the Breastfeeding Coalition of Oregon, the New Mexico Breastfeeding Task Force, and the Massachusetts Breastfeeding Coalition. In California, changes in culture occurred at major health maintenance organizations; Kaiser Permanente removed these packs from large groups of its hospitals, region by region, thereby creating large numbers of sample-pack-free institutions in a short time frame. In Texas, where we saw the biggest change in practice of any state we surveyed between 2007 and 2010, the Texas Ten Steps Program, operated by the Texas Department of State Health Services, encourages hospitals to promote breastfeeding and decrease reliance on formula samples and industry. To the best of our knowledge, while hospitals have discontinued distribution of these packs, the vast majority continue to receive free infant formula for in-hospital use from the industry.

In addition, and potentially related to differing practices in the distribution of industry-sponsored sample packs, differences exist in breastfeeding prevalence between the best-record and worst-record states. According to the Centers for Disease Control and Prevention’s Breastfeeding Report

TABLE 1 Proportion of Hospitals in 20 States That Have Eliminated Industry-Sponsored Formula Sample Packs

State	2007, % (n/N)	2010, % (n/N)
Best-record states		
Washington ^a	18 (12/65)	33 (21/64)
Minnesota ^a	20 (18/92)	34 (30/89)
California ^a	22 (63/283)	46 (117/255)
Vermont ^a	25 (3/12)	58 (7/12)
Massachusetts ^a	27 (14/51)	64 (32/50)
Wisconsin ^a	29 (30/102)	44 (44/100)
New Mexico ^a	31 (9/29)	40 (10/25)
New Hampshire ^a	32 (8/25)	62 (13/21)
Oregon ^a	33 (17/51)	59 (30/51)
Rhode Island ^a	43 (3/7)	86 (6/7)
Worst-record states		
Arkansas	0 (0/46)	0 (0/44)
Washington, DC	0 (0/7)	0 (0/7)
Maryland	0 (0/36)	0 (0/34)
Mississippi	0 (0/46)	0 (0/43)
New Jersey ^a	0 (0/62)	4 (2/56)
Oklahoma ^a	0 (0/49)	6 (3/49)
South Dakota	0 (0/25)	0 (0/25)
West Virginia ^a	0 (0/33)	6 (2/32)
Iowa ^a	1 (1/82)	4 (3/77)
Texas ^a	1 (3/220)	15 (30/198)

^a Significant difference in proportion comparing before and after; significance was defined as *P* < .05.

Card for 2010, average breastfeeding initiation in the best-record states was 81.5%, compared with 67.0% in the worst-record states. In the best-record states, at 6 months the average prevalence of any breastfeeding was 52.7%, compared with 37.0% in the worst-record states.¹⁵ A relationship seems to exist between hospital policy and breastfeeding prevalence, although the temporality of the relationship is not clear.

A limitation of this study is that we only considered distribution of industry-sponsored sample packs within the hospital's maternity service. It is possible that other areas of the hospital distribute these packs and that staff on the maternity service are unaware of this practice. One industry response to widespread efforts to change this practice has been to increase distribu-

tion of samples in other health care settings, for example, via the obstetrician's office, or direct to the home. It is possible that distribution of free samples has increased in other areas as it decreases in the hospital, but our study was not able to measure such changes. Another limitation is that we selected 20 states and compared prevalence only in those states. It is possible that these 20 states were not representative of all 50 states, especially as trends seem to be geographically mediated. However, we specifically chose the best-record and worst-record states because we hypothesized that these states represented the areas most and least likely to change according to their previous history. Given that change was highly significant in the best-record states, and less significant in the worst-record states, we believe our hypothe-

sis was borne out, and that the remaining states fall between the 2 extremes we researched.

CONCLUSIONS

Trends indicate that increasing numbers of US hospitals are eliminating industry-sponsored formula sample packs from their maternity service. In regions where this is already becoming a norm, institutions are eliminating packs at a more rapid rate, and in some states, more than half of hospitals have eliminated industry-sponsored formula sample packs. The majority of hospitals in 20 states surveyed continue to distribute industry-sponsored formula sample packs, but our research suggests that over time this will change, and that potentially, elimination of these packs will become the norm.

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