

Infant Formula–Handling Education and Safety

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ABSTRACT

OBJECTIVES. Our goal was to assess the extent to which mothers learn about proper handling of infant formula from health professionals and package labels; mothers' beliefs about the likelihood of germs being in infant formula and the importance of following safe-use directions; whether they take measures while handling infant formula to prevent foodborne illnesses and injury to their infants; and maternal characteristics associated with unsafe infant formula–handling practices.

PARTICIPANTS AND METHODS. The study cohort consisted of mothers participating in the 2005–2007 Infant Feeding Practices Study II who fed their infant formula. We conducted frequency and multiple logistic regression analyses. Sample sizes for the analyses ranged from 860 to 1533.

RESULTS. The majority of formula-feeding mothers did not receive instruction on formula preparation (77%) or storage (73%) from a health professional. Thirty percent did not read some of the safe-use directions on the formula package label; an approximately equal percentage (38%) thought that both powdered (which is not sterile) and ready-to-feed (which is sterile) formula were unlikely to contain germs; and 85% believed that following safe-storage directions was very important. Among the mothers of the youngest infants analyzed, 55% did not always wash their hands with soap before preparing infant formula, 32% did not adequately wash bottle nipples between uses, 35% heated formula bottles in a microwave oven, and 6% did not always discard formula left standing for >2 hours. The prevalence of these unsafe practices was similar among mothers of older infants. No consistent pattern of maternal characteristics was associated with unsafe practices.

CONCLUSIONS. Many mothers do not follow safe practices when preparing infant formula. Additional research is needed to understand why more mothers do not follow safe formula-handling recommendations. *Pediatrics* 2008;122:S85–S90

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Key Words

infant formula, food handling, food labeling

Abbreviations

IFPS—Infant Feeding Practices Study
FDA—Food and Drug Administration

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COMMERCIAL INFANT FORMULA is the only safe source of food for nonbreastfed infants up to 6 months old and an important food source for nonbreastfed infants through their first year.¹ Although the majority of US infants begin breastfeeding, most receive formula at some point by 6 months, either instead of or as a supplement to breast milk.²

In the United States, infant formulas are available in 3 types: ready-to-feed, liquid concentrate, and powdered. Liquid concentrates and powders require appropriate dilution with clean water. Adding too much water may lead to inadequate intake of calories and nutrients, whereas adding too little water may lead to dehydration, diarrhea, and excessive intake of calories. The safety of liquid concentrate and powdered formulas can be compromised if they are diluted with water of poor quality.¹ Unlike ready-to-feed and liquid concentrates, powdered formulas are not sterile when purchased and could contain bacteria. To reduce the risk of infant illness caused by bacteria in powdered formula,³ the World Health Organization urges caregivers to use water no less than 158°F when reconstituting powdered formula.⁴

Four safe-handling practices for all types of infant formula have been recommended as means of reducing infants' risk of being burned or infected with foodborne pathogens: (1) wash hands with soap before preparing formula; (2) wash bottles and bottle nipples thoroughly between uses; (3) discard formula left at room temperature for >2 hours; and (4) never heat formula bottles in a microwave oven.^{1,5}

In this study, we sought to determine (1) whether mothers learn about proper handling of infant formula from health professionals and package-label information, (2) mothers' beliefs about the safety of infant formula and the importance of following safe-storage directions, (3) the percentage of mothers who fail to follow each of the 4 safe formula-handling practices described above, and (4) the maternal characteristics associated with lack of adherence to these practices.

PARTICIPANTS AND METHODS

Data for this analysis are from the 2005–2007 Infant Feeding Practices Study II (IFPS II). The IFPS II is a longitudinal mail survey of mothers from pregnancy through their infants' first birthday. The study sample was limited to adult mothers of healthy, term singletons. The study was approved by the US Food and Drug Administration (FDA) Research Involving Human Subjects Committee. The methodologic details of the IFPS II are described elsewhere in this supplement.⁶

The cohort for this analysis consisted of IFPS II participants who reported that their infant was fed any formula in the previous 2 weeks on 4 questionnaires sent when the infant was between 2 and 9 months old. Regardless of what the mother reported feeding her infant on 1 questionnaire, she was asked whether she was feeding formula on subsequent questionnaires. The number of mothers who reported feeding their infant formula declined throughout the study as a result of diminishing survey response rates, which were 83% for the month 2 questionnaire but dropped to 67% for the month 9 questionnaire.

In the questionnaire sent when their infants were ~2 months old, formula-feeding mothers ($n = 1533$) were asked about their use of the package labels on infant formula and their perceptions of the importance of following formula directions and the likelihood that germs were in the formula. In questionnaires sent at 2 and 5 months postpartum, formula-feeding mothers were asked whether a health professional had instructed them on formula preparation and storage ($n = 1446$). For the analysis of these once- or twice-asked questions, we were interested in responses regardless of the exact age of the infant at the time that the mother responded.

Questions about formula-handling practices were repeated on 4 questionnaires, which were sent when the infants were ~2, 5, 7, and 9 months old. For the analysis of handling practices, we were interested in evaluating differences in the mothers' behavior as their infants aged. To do this we limited the sample of formula-feeding mothers to those who responded when their infant was within a certain age range. We used the age of the infant at the time the mother completed each questionnaire to set up 4 mutually exclusive age groups. The age groups and sample sizes of formula feeding mothers for the 2-, 5-, 7-, and 9-month questionnaire data were 1.5 to 4.5 months ($n = 1527$), >4.5 to 6.5 months ($n = 1392$), >6.5 to 8.5 months ($n = 1364$), and >8.5 to 10.5 months ($n = 1323$), respectively.

With SAS software (SAS Institute, Inc, Cary, NC), we analyzed the data cross-sectionally by using frequency procedures. We used 16 multiple logistic regression models to evaluate whether maternal characteristics were independently associated with the likelihood that the mothers of infants in each of the 4 age groups did not follow each of the 4 safe-use recommendations described previously. The characteristics that we evaluated were whether mothers received relevant instruction on formula use from a health professional; whether they read relevant package-label information; whether their annual income was no more than 185% of the federal

poverty level; whether they had more than a high school education; whether they were aged ≤ 30 years; whether they were white; whether they had other children; and whether they fed their infant at least as much breast milk as formula. Because of missing data, the sample sizes for logistic regression models fell from 1527 to 1336 for the 1.5- to 4.5-month data, from 1392 to 972 for the >4.5- to 6.5-month data, from 1364 to 911 for the >6.5- to 8.5-month data, and from 1323 to 860 for the >8.5- to 10.5-month data.

RESULTS

Infant Formula Use

The majority of mothers of infants in all age groups reported that their infant was fed some amount of formula. The distribution of demographic characteristics among mothers who fed formula was similar to that among all IFPS II participants⁶ except that the mothers who fed formula to infants younger than 4.5 months old were less likely to be college educated than mothers who did not (32% vs 40%).

The percentage of mothers who reported that their infant was fed formula in the previous 2 weeks increased with infant age, from 62% among mothers with infants aged 1.5 to 4.5 months to 72% among mothers with infants aged >8.5 to 10.5 months. When their infants were aged 1.5 to 4.5 months, 70% of mothers who used formula reported feeding their infant a milk-based formula with docosahexaenoic acid (DHA) and arachidonic acid (ARA), 88% reported feeding them powdered formula from a can, and 98% reported feeding them an iron-fortified formula. These percentages remained relatively consistent across age groups. Of 881 mothers who reconstituted powdered formula mixed with tap water for infants aged 1.5 to 4.5 months, 30% boiled the water first; and of 790 who mixed powdered formula with bottled water, 17% boiled the water first. Lower percentages of mothers boiled either type of water as infant age increased.

Receipt of Instructions on Preparation and Storage of Infant Formula

Most mothers did not receive instruction on formula preparation or storage from a health professional. In the 2-month questionnaire, 88% of the mothers reported not having received instruction on formula preparation, and 82% reported not having received instruction on formula storage from a doctor, other health professional, or birthing class instructor. By the 5-month questionnaire, 77% of the mothers who reported having fed formula on the 2-month questionnaire indicated that they still had not received instruction on formula preparation from any of these sources, and 73% reported not having received instruction on formula storage ($n = 1118$).

Although a majority of the mothers did read the various categories of safe-handling information on the formula-package label, a substantial minority did not (Table 1). Of 1420 mothers who read any information on the formula label, 3% found the information difficult

TABLE 1 Mothers Who Did Not Read Various Categories of Label Information on the Package of the Formula They Used Most Often (Month 2 Questionnaire, *n* = 1533)

Label Information	%
Ingredient list	44.8
Pictures on the container showing how to prepare	34.1
Directions for storing formula package after opening	30.5
Directions for what do with formula left over after feeding	30.0
Directions for storing formula after it is prepared	25.1
Directions for preparing formula	11.7

to understand, and 9% found the print size too small to read easily (data not shown).

Beliefs About Infant Formula Safety

Although 30% of the mothers did not read the package directions on what to do with leftover formula, 85% believed that it was very important for their infant's health to follow the label directions to refrigerate or discard prepared formula. Another 14% believed this practice was somewhat important (data not shown).

Thirty-eight percent of the mothers thought it was unlikely that either ready-to-feed or powdered formula contained germs, and 32% thought it was unlikely that liquid concentrate formula contained germs (data not shown).

Infant Formula Handling

Many mothers of infants aged 1.5 to 4.5 months did not follow safe formula-handling recommendations to prevent foodborne illness and burns. The percentages of those who did not follow specific recommendations (shown in Table 2 and highlighted below) were generally similar to corresponding percentages among mothers of older infants, unless otherwise noted. Fifty-five percent of these mothers said that they did not always wash their hands with soap before preparing formula (vs 63% among mothers of infants aged >8.5–10.5 months), and <3% of those who did not always wash their hands reported always using hand sanitizer before preparing infant formula. In addition, 33% reported that their infant's bottle nipples were at least sometimes only rinsed with water before being reused, 5% reported that the nipples were at least sometimes not cleaned in any way before being reused. Thirty-five percent reported that bottles were at least sometimes heated in a microwave oven, and almost 20% reported that bottles were always heated this way. However, only 6% reported that

TABLE 2 Mothers Who Reported That Formula for Their 1.5- to 4.5-Month-Old Infant Was Sometimes or More Frequently Handled With Various Unsafe Practices

Unsafe Practice	<i>n</i> (%)
Did not wash hands with soap before preparing formula	1469 (55.0)
Reused bottle nipples after just rinsing with water	1399 (33.1)
Reused bottle nipples without cleaning in any way	1399 (5.1)
Left formula at room temperature for >2 h	1483 (6.0)
Heated bottle in microwave oven	1488 (35.3)

prepared formula was kept at room temperature for >2 hours, and only 17% to 23% of all the mothers, depending on the age of the infant, said prepared formula was never kept at room temperature. The majority of those who did report sometimes keeping formula at room temperature reported doing so for <1 hour.

Maternal Characteristics Associated With Unsafe Formula-Use Practices

Results from the multiple logistic regression analyses indicated that no maternal characteristic was consistently associated with failing to follow all of the safe formula-handling recommendations while controlling for the other characteristics in the models (Table 3). In our analysis of whether bottles of formula were left standing at room temperature for >2 hours, the likelihood-ratio test indicated that the group of maternal characteristics was not a good predictor of this practice. Therefore, this practice is not included in Table 3.

White mothers were more likely than nonwhite mothers to not always wash their hands with soap before preparing formula. Mothers who were <30 years old and those with more than a high school education were more likely to not always wash their hands with soap when feeding infants older than 4.5 months than were older mothers and those with less education.

Mothers of infants aged 1.5 to 8.5 months who fed at least as much breast milk as formula were less likely than those who fed less or no breast milk to inadequately clean formula bottle nipples between uses. Mothers at <185% of the federal poverty line were more likely than those with a higher family income to inadequately clean formula bottle nipples for infants aged 1.5 to 4.5 and >6.5 to 8.5 months.

Two maternal characteristics were associated with microwave heating of formula bottles in all 4 infant age groups: mothers with other children were more likely than those with no other children to do so, whereas mothers who fed breast milk at least as often as formula were less likely to heat bottles of formula in a microwave oven.

DISCUSSION

This analysis suggests that there are gaps in mothers' education on safe infant formula-handling practices that could reduce the risk of infant illness and injury. To help protect infants, the FDA requires that formula labels include directions for proper formula handling and a warning statement that cautions caregivers that their infant's health depends on carefully following the directions.⁷ The results of our analysis showed that many mothers do not read this information. However, the analysis also showed no association between mothers' instruction on safe formula handling from a package label or a health professional and the likelihood of handling formula properly. Package-label use and instruction on formula handling from a health professional may not impact mothers' behaviors. Alternatively, the data may not adequately capture the relationship for some of the practices. Although the mothers were asked to report only on their own hand-washing practices, they

TABLE 3 Adjusted Odds Ratios Associated With 3 Unsafe Formula-Handling Practices, According to Infant Age Group

Characteristic	Not Always Wash Hands With Soap			Not Adequately Clean Bottle Nipples			Heat Bottles in a Microwave Oven					
	1.5–4.5 mo (n = 1336)	4.5–6.5 mo (n = 972)	6.5–8.5 mo (n = 911)	8.5–10.5 mo (n = 875)	1.5–4.5 mo (n = 1336)	4.5–6.5 mo (n = 972)	6.5–8.5 mo (n = 911)	8.5–10.5 mo (n = 875)	1.5–4.5 mo (n = 1326)	4.5–6.5 mo (n = 965)	6.5–8.5 mo (n = 906)	8.5–10.5 mo (n = 860)
Received instruction on formula handling	0.87	1.03	1.02	1.01	0.82	0.90	1.00	1.01	0.84	1.02	1.01	1.04
Read label directions	1.10	1.05	1.23	1.11	0.96	0.76	1.10	1.18	0.87	0.89	0.74	0.99
≤185% of federal poverty	1.05	0.99	0.92	0.94	1.36 ^a	1.23	1.46 ^a	1.35	1.24	1.21	1.04	1.03
≤High school	0.83	0.63 ^a	0.62 ^a	0.65 ^a	1.23	0.91	0.88	0.97	1.01	0.84	1.08	0.80
Aged ≤30 y	1.19	1.35 ^a	1.65 ^a	1.64 ^a	1.00	1.53 ^a	1.23	1.25	0.99	1.13	0.96	0.99
White	1.59 ^a	1.49 ^a	2.10 ^a	1.80 ^a	1.00	1.03	0.93	1.06	0.99	1.39	1.40	1.44
Has other children	0.69 ^a	0.85	1.08	1.18	0.94	1.13	1.26	1.17	1.46 ^a	1.53 ^a	1.62 ^a	1.79 ^a
Fed at least as much breast milk as formula	1.06	1.35	0.82	0.77	0.51 ^a	0.44 ^a	0.43 ^a	0.57	0.56 ^a	0.60 ^a	0.60 ^a	0.47 ^a

^a Statistically significant at the <.05 level.

were asked about other handling practices by anyone who feeds their infant. To the extent that mothers were reporting on the practices of other caregivers, rather than their own, it is the education of these other caregivers that would be expected to predict formula-handling practices.

The data on mothers' beliefs about germs in formula suggest that consumers are not aware that there are different risks associated with powdered formulas, which are not sterile when purchased, compared with ready-to-feed and liquid concentrates, which are commercially sterile. The IFPS II data do not have enough detail to know whether mothers who prepared powdered formula followed the World Health Organization recommendation to use water warmer than 158°F. The data do indicate that most mothers did not boil tap (70%) or bottled (83%) water used to reconstitute formula. We assume that even fewer who do boil water mix the formula when the water is hotter than 158°F, because some may use water that was boiled and then cooled before reconstituting the formula.

The incidence of infection with pathogens often associated with food, such as *Salmonella*, *Yersinia enterocolitica*, and *Campylobacter*, is significantly higher for children <1 year of age than for older age groups.⁸ This increased incidence may largely be attributable to the vulnerability of a developing intestinal system and the increased likelihood among parents to report and seek care for infant illness versus illness observed in older children or adults. Infants who are fed formula, rather than breast milk, have been shown to be at increased risk for infection with *Salmonella*, which may be a result of the protective effects of breast milk or contamination of formula during its handling.⁹

Risk of foodborne illness in infants should be reduced when caregivers wash their hands with soap before preparing food, including formula; do not feed formula held at room temperature for >2 hours; and adequately wash bottle nipples between uses. This analysis suggests that most mothers believe it is very important to refrigerate or discard prepared formula, and almost all follow the recommendation to never leave formula standing for >2 hours. However, over half of the mothers, of even young infants, did not always wash their hands with soap before preparing formula, and one third did not always adequately wash bottle nipples between uses, thereby increasing their infant's risk of being exposed to a foodborne pathogen and suffering an illness.

Some mothers may not wash their hands or adequately wash bottle nipples because they do not perceive these actions to be a threat to their infant's health. Although such unsafe food-handling practices increase infants' risk for illness, they do not always lead to an illness, and even when they do, the relationship between these unsafe practices and the illness is not always obvious. As a result, mothers may incorrectly attribute their infant's illness to a cause other than foodborne pathogens and, thus, not recognize the need to improve their food-handling hygiene.

In the FDA's 2006 Food Safety Survey, a random-digit-dial survey of >4600 US adult consumers, 75% of

those surveyed reported that they always washed their hands with soap before preparing food (unpublished data). However, mothers who participated in the IFPS II were considerably less likely to report always washing their hands before preparing infant formula, despite infants being more vulnerable to foodborne illness than people over 1 year of age. Perhaps a reason for this disparity is that adults are unlikely to prepare food for themselves or for older children when away from a home or other venue with easy access to soap and water, because packing a nonperishable item or purchasing prepared food is often a convenient alternative. These options do not exist for mothers who are not breastfeeding and have an infant who is not yet eating complementary foods. Although hand sanitizer is recommended for cleaning hands when soap and water are unavailable,¹⁰ and alcohol gel hand sanitizers can be effective in reducing bacteria on hands that are free of debris,¹¹ very few mothers who did not always wash their hands reported always using hand sanitizer before preparing formula.

The widespread use of inadequately washed bottle nipples may be because consistent use of clean bottle nipples requires access to running water and soap or a supply of extra bottle nipples. Some mothers may heat bottles in a microwave oven despite the risk of burns to their infant's mouth simply because it is faster than alternative warming options. The association between feeding at least as much breast milk as formula and a decreased likelihood of inadequately cleaning bottle nipples between uses and heating bottles in a microwave oven may be because breastfeeding mothers can choose to feed formula only when they have a clean bottle nipple or the time to safely warm a bottle or because they are more likely to engage in other health behaviors than are nonbreastfeeding mothers. The results of previous research suggest that not smoking and participating in childbirth education classes are both positively associated with duration of breastfeeding.¹²

Although there remain shortfalls in mothers' reports of safe infant formula-handling practices, fewer mothers reported 2 risky behaviors in 2005–2007 than a decade earlier. When comparing data from the IFPS II with data from the IFPS I (a 1993–1994 study with similar design, sampling frame, and data-collection procedures), mothers were more careful about discarding formula and avoiding microwave heating in 2005–2007. In the 1993–1994 IFPS I, ~15% of the mothers left bottles at room temperature for >2 hours, whereas in 2005–2007 the estimate was 6%. The 1993–1994 study found that 39%, increasing with greater infant age to 48%, reported heating bottles in a microwave oven >50% of the time. In 2005–2007, approximately one quarter of the mothers reported that their infant's bottles were heated in a microwave oven approximately half of the time or more frequently.¹³

The question about washing bottle nipples that was asked in 1993–1994 is not directly comparable with the measure used in 2005–2007. In 1993–1994, mothers were asked whether bottles and nipples were usually sterilized, but no other questions about cleaning prac-

tices were asked. At 2 months postpartum, 38% of the mothers did not sterilize bottles and nipples; this number increased to 54% at month 5 and increased again to 60% at month 7. In 2005–2007, mothers were asked a series of questions about how often they washed nipples in several different ways. Although 74% of the mothers of the youngest infants (1.5–4.5 months), and increasing to 87% of those of the oldest infants (>8.5–10.5 months), said that they did not boil or sterilize bottle nipples regularly, these mothers had the opportunity earlier to indicate that nipples were adequately cleaned in a dishwasher or by hand with detergent. The 1993–1994 study did not include questions about mothers washing their hands before preparing formula.¹³

Despite lower rates of some unsafe-handling practices in 2005–2007, mothers were less likely than in 1993–1994 to have received instruction on formula preparation from a health care professional (12% of mothers responding to the 2-month postpartum questionnaire in 2005–2007% vs 21% of mothers responding to the 2-month postpartum questionnaire in 1993–1994 received such instruction).¹³

CONCLUSIONS

Although some formula-handling practices seem to have improved in the past decade, data from the IFPS II suggest areas for further progress to reduce the risk to infants of foodborne illness and burns. Unfortunately, our results do not suggest any obvious strategies that might be used to reduce the number of mothers who engage in unsafe practices or characteristics of mothers associated with unsafe practices that might be used to target interventions, because neither formula-use education nor any maternal characteristics were consistently associated with the likelihood of engaging in the unsafe-handling practices we examined. Although, as noted previously, the wording of the IFPS II questionnaires, in which mothers were asked to report on the behaviors of other caregivers, may have confounded our analyses, IFPS I results showed a similar lack of consistent association between improper formula-handling practices and maternal characteristics.¹³

The results of our analyses of IFPS II data suggest a need for additional research on why caregivers may not follow recommendations for safe infant formula handling. The results of such research could help to identify ways of increasing compliance with the recommendations designed to help protect infants.

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