

## SHORT COMMUNICATION

## Home preparation of powdered infant formula: is it safe?

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Breastfeeding is the natural way of feeding infants and young children. WHO recommends, as a public health measure, exclusive breastfeeding for 6 months and continued breastfeeding up to 2 years and beyond (1). Yet a large proportion of infants worldwide is formula fed (2,3). Of these, the largest majority is fed with powdered infant formula (PIF). In Italy in 1998, an estimated 15% of newborns were given PIF at discharge, up to 35% at 2 weeks and 90% at 5 months (4). A recent judicial inquiry estimated a consumption of about 11.7 kg of PIF per infant in 2004 (5). PIF is not a sterile product; it can be intrinsically, that is before the tin is opened for use, contaminated with bacteria (6). This has become a concern after the recent increase in the notification of serious cases and outbreaks of disease caused by *Enterobacter sakazakii* (7). This problem may be even more serious in selected groups (infants small for gestational age, preterm, immunocompromised, in the first 2 months of life) and in low-income countries where adequate diagnostic facilities are lacking (8). To address the problem, WHO has recently issued guidelines for the safe preparation, storage and handling of PIF (9). The objective of this study was to assess the practices of a sample of parents using PIF against the WHO guidelines.

The study was carried out in Trieste on a sample of 131 infants recruited between April and July 2006 in immunisation centres. The infants were 1 week to 12 months old and to be enrolled had to take PIF, exclusively or as a supplement of breast milk and/or solid food, at the time of the interview. The sample size was based on the 95% probability of finding a 50%  $\pm$  10% prevalence of using water at  $\geq 70^\circ\text{C}$  for the preparation of PIF. Data were analysed with SPSS and statistical associations were tested with Chi-square and Fisher's exact test.

A total of 124 mothers and 7 fathers were interviewed; 76% were married, 2% single and 22% were living with a partner; 47% were older than 35 years, 34% were 30–34 years and 19% were 20–29 years old; 19% had a university and 62% a secondary school degree; 72% were working outside home, mostly full time; 67% had no other children. The

131 infants were evenly distributed by age; 12% had a birth weight less than 2500 g, 8% more than 4000 g; there were 7 couples of twins. PIF had been started at age 0–4 weeks in 37%, 5–12 in 47%, 13–40 in 16%; 33% were exclusively formula fed, 37% were still breastfed. Sixty-two percent of parents had been instructed on PIF preparation by health professionals, mostly in the hospital; the remaining parents were using the instructions found in the labels to prepare the product. Tables 1 and 2 show the practices reported by parents. After preparing a feed, 10% of parents store the bottle at room temperature and 3% in a bottle warmer; 16% use the stored feed within 4 h. Tests carried out during the study showed that bottle warmers reach a temperature of  $70^\circ\text{C}$  in about 20 min; none of the parents using such a device was aware of this. Forty parents (31%) fill the bottle with cereals. Based on the four criteria set by WHO (sterilize the bottle at each feed, wash hands with warm water and soap before preparation, warm water at  $\geq 70^\circ\text{C}$  then add PIF, use immediately and discard the remaining), only 15 parents (11%) prepare PIF safely. No association was found between safe PIF preparation and infant and parental variables.

The fact that just over 10% of 131 parents with a medium to high level of education comply with the safety criteria set by WHO is a matter of concern. On the other hand, how could parents act differently if those were the instructions they got from health professional and/or read in the labels, despite the fact that guidelines similar to the WHO ones had been issued by the European Food Safety Authority (EFSA) and by the Italian National Institute of Health 2 years before? (8,10) Manufacturers also ignored a directive of the Ministry of Health issued on 15 March, 2006 and asking them to update the labels (11). Most labels instruct to prepare the feed with water at  $40\text{--}45^\circ\text{C}$ ; some labels do not even mention the temperature and generically say to use warm water. These temperatures do not inactivate *Enterobacter sakazakii* (12). Manufacturers probably pay attention to the warnings of both EFSA (8) and ESPGHAN (13) about the possible loss of nutritional value of using water at  $80\text{--}90^\circ\text{C}$ .

**Table 1** Parental practices before preparing PIF

	Always/often		Sometimes		Seldom/never	
	N.	% (95% CI)	N.	% (95% CI)	N.	% (95% CI)
Wash hands	107	82 (74–88)	7	5 (2–11)	17	13 (8–20)
Wash bottle	63	48 (39–57)	12	9 (5–15)	56	43 (34–52)
Sterilize the bottle	93	71 (62–79)	16	12 (7–19)	22	17 (11–24)

**Table 2** Parental practices for the preparation, handling and administration of PIF

	Yes	
	N.	% (95% CI)
Warm up water before adding PIF	103	79 (71–85)
Mix water and PIF then warm up	34	26 (19–34)
Method of warming up water (n = 103, more than one answer possible)		
Pan	48	47 (37–57)
Microwave	40	39 (29–49)
Bottle warmer	16	15 (9–24)
Other	7	7 (3–13)
Water ≥ 70°C when adding PIF	29	22 (15–30)
New PIF bottle at every meal	117	89 (83–94)

ESPGHAN puts also more emphasis on the discard of the left formula than on reconstitution.

Unfortunately, it is difficult to compare our results with other populations. A systematic review published in 2003 identified only five studies carried out in UK (3), USA and Australia and aiming at assessing the correct dilution of feeds, not their safety (14). The only comparable study was carried out in South Africa to assess the safety of PIF preparation in a population with high prevalence of HIV infection (15). Out of 94 highly educated mothers, 72% owning a refrigerator but 34% without running water at home, the majority prepared feeds incorrectly and 38% of formula samples were contaminated with enterobacteria; interestingly, the samples prepared with water that had just been boiled had lower levels of contamination. Even in Australia a study found that 22% of formula samples from 274 mothers was contaminated with enterobacteria (16). Adding cereals to reconstituted PIF is also a practice to be discouraged as it increases the risk of contamination with *Enterobacter sakazakii* (17).

To conclude, safety guidelines would not be needed if all infants were breastfed as recommended by WHO (1). Meanwhile

- Codex Alimentarius and national health authorities should revise the microbiological standards for the production of PIF;
- health authorities should issue and disseminate guidelines on safe preparation, storage and handling in health care facilities and at home;
- manufacturers should change and standardize their instructions on labels and indicate clearly that PIF is not a sterile product;

- paediatricians and other health professionals should be made aware of the potential risks of PIF in order to give correct advice to parents;
- finally, the public, and in particular parents with lower levels of education, should be informed not only of the risks associated with PIF, but also of the change in guidelines for preparation, storage and handling.

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