Water and formula fluoride concentrations: significance for infants fed formula

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Abstract

The independent contributions of formula and water to the total fluoride (F) intake from the diet of formula-fed infants is not fully documented. Although the precise timing and mechanism by which dental fluorosis occurs has not been fully defined, water F levels can be an important consideration in the risk of dental fluorosis for formula-fed infants. An assessment of 1,308 participants younger than 2 years old revealed that: 81% of homes received public water; 19% received well water; 26% of participants used bottled water; and 11% used some kind of filtration system. In this study, virtually all formulas consumed by the birth cohort and water sources used in the reconstitution of these formulas were assayed for F using a F ion specific electrode and direct read method, except for soy-based formulas, which were analyzed by microdiffusion (modified Taves). Among 78 commercially available bottled waters in Iowa, F levels ranged from 0.02 to 1.36 ppm (mean 0.18 ppm), 83% from 0.02 to 0.16 ppm, 7% from 0.34 to 0.56 ppm, 1% had a F level of 0.88, and 9% had F levels > 1.0 ppm. Among 47 casein (milk)-based formulas, 16 ready-to-feed (RTF) formulas had levels of 0.04–0.55 ppm F (mean 0.17 ppm), 14 liquid concentrates (LC) reconstituted with distilled water had levels of 0.04-0.19 ppm F (mean 0.12 ppm), and 17 powdered concentrates (PC) reconstituted with distilled water had levels of 0.05-0.28 ppm F (mean 0.14 ppm). The 17 soy-based formulas had a range of 0.04– 0.47 ppm F (mean 0.26 ppm). These 1992-93 findings generally are consistent with results of studies conducted in the 1980s. Type of formula and the water used could be an important consideration in fluorosis risk assessment and dietary fluoride supplementation recommendations. (Pediatr Dent 17:305-10, 1995)

I imited data are available from studies designed to comprehensively consider multiple sources of fluoride (F) ingestion, such as from water, diet, dentifrice and dietary fluoride supplements.^{1, 2} Longitudinal assessment of the relationships between such exposures and dental caries and dental fluorosis would better predict age-specific risks and benefits² and help define appropriate recommendations. The small number of studies of F metabolism in infants have shown high rates of fluoride absorption from infant formulas and supplements.^{3,4}

Studies reporting high F concentration in commercially available formulas in the 1970s prompted the voluntary reduction by manufacturers in their formulas' F levels.⁵⁻⁷ However, F levels in soy-based formulas in the 1980s continued to be about twice as high as the casein (milk) -based formulas.^{8,9} The F intake of infants varies with their feeding pattern. Breast milk is very low in F, and intake from formula feeding is determined by the F levels of the formula and water used in reconstitution (public supply, individual or community well, bottled, or filtered).²

Evidence currently supports the local presence of F in the fluids of the oral cavity being more important than the previous belief that cariostatic effects of F were due to F incorporation into the tooth structure (during development).¹⁰ Although the caries rate has declined, the prevalence of fluorosis has increased in both fluoridated and nonfluoridated areas, leading to the recent revision of the dosage schedule recommended by the American Dental Association.¹⁰⁻¹³ It is, therefore, important for pediatric dentists and other prescribers of dietary F supplements to assess individuals' needs for F supplements based on current knowledge of the F levels already in their diets.

The long-term goal of the Iowa Fluoride Study is to estimate the levels of total ingested F associated with various levels of dental caries and dental fluorosis among a birth cohort in Iowa. Information is being collected longitudinally on F levels of infant formulas and water sources used by study participants, along with data on quantities of intake from these sources. The purpose of this paper is to report F levels of infant formulas and water sources.

Methods

Mothers of newborns were recruited from postpartum wards at eight hospitals in eastern and central Iowa for this longitudinal study. They completed mailed questionnaires and 3-day food and beverage diaries describing the infants' F intake from diet, dietary F supplements, and dentifrice. This information was obtained when the infants were 6 weeks and 3 months old, and every 3–4 months thereafter. At age 3 to 4, dental exams will assess caries and fluorosis prevalence and severity of the primary dentition, and the results will be related to F exposures and ingestion during tooth development. All formulas and water sources reported in the food diaries from this ongoing, larger study constitute the data for this paper.

Water sources being used other than unfiltered public water supplies (all filtered water, well supplies, and bottled waters) were assayed for F. The participants were sent the results of the analysis and information regarding recommended dietary F supplementation dosage. Ethical considerations necessitated subjects being encouraged to consult their health-care providers to assess needs for any F supplementation. If the participant's water source had a F level > 2 ppm, they were contacted by phone to inform them that consumption of water by their child at this F level could result in dental fluorosis. Water F assay of bottled waters was done for two sets of samples purchased about one year apart from stores in Iowa City (1992-1993). All water samples obtained were analyzed using a F ion specific electrode by a direct reading (DR).

All formulas that appeared on the food diaries were purchased in Iowa City and analyzed for F. The same brands were purchased a year later and analyzed for consistency of F levels. During preliminary studies, 19 milk- and soy-based formulas were analyzed using both the DR method and a modified Taves¹⁴ method of microdiffusion (MD). For the milk-based formulas, the DR results and the MD results differed by less than 10%. In contrast, for some soy-based formulas the DR and MD F values were inconsistent. Therefore, milkbased formulas were analyzed by DR and soy-based formulas by the MD method.

Direct read method

F was measured using a F ion specific electrode (Model #9609) and the model #920 Ionalyzer® (Orion Research Inc, Boston, MA). Powdered concentrate (PC) and liquid concentrate (LC) infant formulas were reconstituted with distilled water following the manufacturers' directions. The samples of formula and water and standards were mixed with equal amounts of a total ionic strength adjustment buffer (TISAB II buffer #940909, Orion, Boston, MA) to provide constant ionic strength, decomplex F, and adjust the pH. Random samples were read again at the end of each day to verify accuracy of the electrode. Standards were read at the beginning of each set and after 1–2 hr of use to confirm the standard curve. All samples were read at 5 min. Since F levels were unknown, those samples not measuring in the range of the standard curve were reanalyzed using more appropriate standards. More than 20% of the total number of samples were analyzed in duplicate. The mean reproducibility (mg %) for the DR method was 99%. Recovery of F in concentrated milk-based formulas using fluoridated water for reconstitution was 91%.

The microdiffusion method

For soy-based formulas, F was measured by microdiffusion using a modified Taves method.¹⁴ PC and LC formulas were reconstituted with distilled water following manufacturers' directions. Standards were prepared by serial dilution of 100 ppm fluoride standard from sodium fluoride (Orion #940907) and diffused in duplicate concurrently with the samples and blanks. A 2-ml sample or standard was placed into a petri dish, 2 ml of a 5 M hexamethyldisiloxsane (HMDS) saturated perchloric acid was added and the petri dishes were sealed. Hydrogen fluoride was absorbed onto the inner surface of the petri dish previously prepared with 50 μ l of 0.5 M NaOH solution. After 6 hr of diffusion, the lids were inverted and dried in a vacuum desiccator overnight. The dried layer was then dis-

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				Fluoride Levels					
	Number	Fluoride		Percentage					
Type of Supply	(%)	Number	Range	<0.3	0.3–0.7	0.71–1.0	>1.0	Mean	Median
Unfiltered wells	196 (15)	139	0.06-7.22	57	34	2	7	0.45	0.27
Filtered wells	52 (4)	44	0.02 - 1.00	61	27	9	3	0.32	0.23
Filtered public supply	92 (7)	53	0.01–3.29	41	2	32	25	0.67	0.87
Unfiltered public supply [†]	968 (74)		—		—		_	_	
Bottled	340 (26)	78	0.02-1.36	83	7	1	9	0.18	0.06

TABLE 1. HOME WATER SOURCES OF PARTICIPANTS BY TYPE OF SUPPLY AND FLUORIDE LEVELS (PPM)*

• (N = 1308).

⁺ Monthly mean water fluoride levels are gathered from the Iowa Department of Public Health¹⁷ for the public water supplies used by study participants. Thus, water fluoride assay of these sources is not part of the study.

solved with 50 μ l of 0.5 M hydrochloric acid and 100 μ l of 0.25 M acetic acid buffer. The F concentration of the solution was measured as described in the DR method using a standard curve of correlation coefficient not less than 0.999. More than 20% of the samples were done in duplicate. The mean reproducibility for the MD method was 98%. Recovery of F from soy-based concentrated formulas when reconstituted with fluoridated water was 98%.

Results

Data on the types of home water sources and their F levels are summarized in Table 1. Seventy-four percent of subjects received unfiltered public water supplies, both fluoridated and nonfluoridated. Individual and community wells (such as in subdivisions or mobile home parks) without individual filtration were used by 15% of the subjects. Much variation in F levels was evident in the F assay of participants' home water sources (wells and all filtered supplies).

The percentages of home water sources with F levels < 0.3 ppm ranged from 41% of filtered public water supplies to 57% of unfiltered wells and 61% of filtered wells (54% overall). Among unfiltered and filtered wells, 34% and 27%, respectively, were in the 0.3–0.7 ppm range. Fifty-seven percent of filtered public water supplies were > 0.7 ppm. Seven percent of unfiltered well water sources had F levels of > 1 ppm. The highest well water F was 7.22 ppm and the highest F level of a filtered public water supply was 3.29. Many of the 1,308 participants received water from multiple sources such as home, childcare, a relative's home, and bottled water.

Eleven percent of subjects reported using some type of filtration at home. The types of filters used included charcoal/carbon (generally does not remove

TABLE 2. BOTTLED WATERS CONTAINING >0.3 PPM FLUORIDE				
Brand Name	Fluoride (ppm)•			
Eagle Reverse Osmosis	0.34			
HyVee Drinking Water (1993) [†]	0.41			
Crystal Geyser Natural Spring	0.52			
S and S Meat and Grocery Dispenser	0.56			
Spring Valley	0.56			
Humboldt Springs Drinking Water (2.5 Gal)	0.88			
Flavorite Drinking	1.02			
Great Value Distilled Water (Walmart)	1.06			
Hinkley and Schmidt Nursery Water	1.07			
Humboldt Springs Drinking Water Shur-Fine Family Facedo Distilled	1.14 1.22			
HyVee Drinking Water (1992) ⁺	1.29			

• (N = 13). Based on mean of 1992 and 1993 assay results.

[†] Analysis showed F level of 0.41 ppm in 1993 and 1.36 ppm in 1992. Contact with the company revealed that the supplier and water source had changed.

F), reverse osmosis (RO, removes 65–95% F), and distillation (removes 100% F). Other types of water treatments such as water softeners (does not remove F)^{15, 16} and use of boiled water were reported, but are not included in the results. Some homes reported multiple treatments; for example, RO water for formula preparation and drinking, but water treated with water softener used for cooking.

Average values from the two assays of separate purchases of bottled waters are shown in Tables 1 and 2. Among 78 commercial bottled waters, 83% were < 0.3 ppm and 9% were found to be > 1 ppm. Bottled waters (N = 13) > 0.3 ppm F are listed in Table 2. All bottled waters analyzed were in plastic containers and none had F levels declared on the label. Many bottled waters were obtained from RO and other dispensers at the grocery stores; the rest were prepackaged. For most

TABLE 3. FLUORIDE LEVELS[•] (PPM) FOR MILK-BASED FORMULAS (N = 47)

	Ready- to-Feed	Liquid Concentrate*	Powder Concentrate*
Brand Name	(N = 16)	(N = 14)	(N = 17)
1. Alimentum	0.55		
2. Carnation Good Start	0.20	0.12	0.12
3. Carnation Follow-Up	0.13	0.05	0.05
4. Enfamil Low Iron	0.14	0.13	0.11
5. Enfamil With Iron	0.07	0.04	0.09
6. Gerber	—		0.05
7. Gerber Low Iron	0.10	0.04	0.08
8. Gerber With Iron	0.09	0.09	0.08
9. Gerber With Iron			0.09
10. Investigational 06 ⁺		0.15	
11. Investigational 10 ⁺	_		0.25
12. Investigational 11 ⁺	0.11		
13. Investigational 48 ⁺		0.14	_
14. Investigational 49 ⁺		0.15	_
15. Investigational 50 ⁺	_	0.16	_
16. Investigational	0.15	_	_
Infant Formula N ⁺			
17. Investigational			0.25
Rice Based ⁺			
18. Lacto-free	_		0.25
19. Nutramigen		_	0.28
20. Nutrilon Premium	0.04		0.18
21. Pediasure	0.05		
22. Similac Low Iron	0.19	0.19	0.08
23. Similac With Iron	0.35	0.08	0.25
24. Similac With Iron/6pl	k 0.06		
25. SMA Low Iron	0.21	0.10	0.07
26. SMA With Iron	0.20	0.17	0.06
Range	0.04-0.5	5 0.04-0.19	0.050.28
Mean	0.17	0.12	0.14

 All powder and liquid concentrates were reconstituted with distilled water (0 ppm F).

[†] Investigational formulas used by subjects participating in pediatric metabolic study at the University of Iowa Hospitals and Clinics.

of the 78 bottled waters, the F levels for the two separate purchases and analyses did not vary by more than 0.03 ppm. The exceptions and their differences were: Sedona Springs (0.05 ppm), Hy-Vee Purified Baby Water (0.07 ppm), Eagle RO (0.15 ppm), Humboldt Springs Drinking Water (0.18 ppm), Flavorite (0.29 ppm), Hy-Vee Baby Water Distilled (0.25 ppm), and Hy-Vee Drinking Water (0.95 ppm). This last bottled water also gave the highest F level among the bottled waters analyzed (1.36 ppm in 1992).

In this study, 64 infant

TABLE 4. FLUORIDE LEVELS (PPM) FOR SOY-BASED FORMULAS (N = 17)

Brand Name	Ready- to-Feed (N = 5)	$\begin{array}{c} Liquid\\ Concentrate \\ (N = 6) \end{array}$	Powder • Concentrate (N = 6)
1. Gerber	0.17	0.15	0.25
2. Investigational Nurse	oy [†] —	_	0.19
3. Isomil	0.35	0.28	0.21
4. Isoyalac	0.38	0.47	0.26
5. Nursoy	0.35	0.23	0.28
6. Nutri-soya w/Fe	_	0.04	
7. Prosobee	0.23	0.24	0.25
Range	0.17-0.3	38 0.04-0.47	7 0.19–0.28
Mean	0.30	0.24	0.24

 All powder and liquid concentrates reconstituted with distilled water (0 ppm F) and all soy-based formulas assayed by microdiffusion (modified Taves).

⁺ Investigational formulas used by subjects participating in pediatric metabolic study at the University of Iowa Hospitals and Clinics.

formulas were analyzed for F, including commercial brands and nine investigational formulas. There were 47 milk-based (Table 3) and 17 soy-based (Table 4) formulas. Mean F levels for milk-based formulas were 0.17 ppm for RTF, 0.12 ppm for LC (reconstituted with distilled water), and 0.14 ppm for PC (distilled water). Mean F concentrations for RTF, LC, and PC soy-based formulas (reconstituted with distilled water) were 0.30, 0.24, and 0.24 ppm, respectively. The results in Tables 3 and 4 are the mean F levels of the two separately purchased and assayed sets of samples. The F assay results for the two sets were in close agreement for most formulas. Formulas that showed a difference of ≥ 0.10 ppm were: Alimentum (RTF), Similac With Iron (RTF), Similac With Iron (PC), Carnation Follow-up (PC), Carnation Good Start (RTF), Enfamil With Low Iron (LC), Enfamil With Low Iron (PC), and Nutramigen 16 oz (PC). All Gerber formulas were found to have very consistent F levels. For investigational formulas consumed by subjects participating concurrently in a pediatric metabolic study at the University of Iowa Hospitals and Clinics, information on the type of base (casein or soy) also was obtained for selection of appropriate method of analysis (MD or DR).

Discussion

The participants in our study reported using single (home) or multiple water sources (home, child care, home of relative, bottled water). Nineteen percent of our participants reported well water as the home source. Fifty-seven percent of the well water F levels were 0.06–0.28 ppm, 36% were 0.3–1.0 ppm, and 7% were 1.03–7.22 ppm. The consumption of 1 L of 7.22 ppm well water would provide about 29 times the newly recommended F supplement dose for a 6-month to 3-year-old infant.^{12,13} The participant who sent in this

sample confirmed the use of this water for the infant and 2-year-old sibling. Contact with other participants revealed that well water users generally assumed that there was no F in their water. However, before assessing supplemental F, well waters should be analyzed for F content. In the absence of F analysis, supplement prescription should include directions to use a low-F bottled water (distilled) for formula preparation. Patients probably should be advised not to change bottled water brands unless specific knowledge of the F levels is available.

Otherwise, the F supplement dose might be too high.

Contact with home filtration system manufacturers revealed various types and combinations of filters sold. The two types of RO filters remove approximately 65% or 90-95% of the F, respectively. Manufacturers reported that carbon-charcoal filters generally do not remove F, but were used alone to improve taste and odor or in combination with RO filters to protect the RO membrane from the detrimental effects of chlorine. However, some investigators have reported an uncommon, special application of activated alumina in some activated carbon filters that removes up to 81% of the F from water 18, 19 RO filtration systems also require regular maintenance, and their efficiency at removing solutes including F is affected by such factors as cleanliness of the filters and water pressure in the supply lines.¹⁸ Thus, when RO filters are not performing at optimal level, the water F levels will be higher than anticipated.

Bottled waters are marketed as a source of "uncontaminated" water and often their use is recommended during periods when a public water supply is considered unsafe. This recommendation is usually made for infants and pregnant women, but may support the erroneous assumption among general consumers that bottled waters are uniformly of a higher quality than are public water supplies. There is no requirement in the U.S. that F content be indicated on the label even though some are specifically marketed for infants. Hence, the two bottled waters used most frequently by study participants for formula preparation and juice dilution, Hy-Vee Purified Baby Water (0.05 ppm F) and Hinkley and Schmidt Nursery Water with F added (1.07 ppm F), show the variation in F intake that can result from choosing a particular brand. Our contact with participants revealed little consumer awareness

of the impact of such a choice for the child. New federal labeling regulations state that if F was added to the bottled water, then that fact can now be written on the label; however, labels can not list F as an ingredient if it is part of the original water source.²⁰

McFadyen et al.²¹ analyzed F content of 26 bottled waters in the United Kingdom and found levels as high as 5.8 ppm. Of the 76 bottled waters analyzed in our study, the highest was 1.36 ppm. McFadyen et al.²¹ concluded that two waters with F levels of 1.4 and 2.8 could result in fluorosis but recommended that others, including two with levels of 0.75 and 0.58, were acceptable for diluting infant foods. However, levels much lower than this could result in daily F intake above the "optimal" levels of 0.05–0.07 mg/kg body weight.^{1,2}

A 1991 study of 17 Canadian²² bottled waters found F levels from 0 ppm (distilled) to > 4 ppm (mineral). Twenty-two percent listed F levels on the labels whereas none did in an American study.²³ Weinberger ²² reported that 16 of the 17 Canadian bottled waters had F values that differed by 0.01–0.5 ppm from those listed on the labels by the manufacturer. In our study of bottled waters, we found differences as high as 0.29 and 0.95 ppm between samples of the same bottled water purchased one year apart. This could result in substantial differences in an infant's dietary intake of F. Similar dental health implications resulting from type of bottled water used also have been addressed in other investigations.^{24, 25}

Our contacts with commercial bottled water companies revealed that some were only distributors, with little or no knowledge of the F levels or the sources or treatments of the waters they distributed. One brand sold under labels of "Drinking" and "Distilled" was erroneously reported by the distributor to be prepared by distillation for both types. While all "Drinking", "Infant," and "Distilled" products of another brand were reported by the company to have < 0.10 ppm F, our F assay results were 1.14, 0.06, and 0.03 ppm, respectively. The same company supplied three different waters under a grocery chain's label and the "Drinking" water F level was 1.36 ppm, "Baby" water was 0.05 ppm and "Distilled" water was 0.06 ppm F. Our follow-up efforts for one of these bottled waters that changed in F level from 1.36 (1992) to 0.41 (1993) revealed that the supplier had indeed changed, and hence it was really a different bottled water with the same label. Thus, the information regarding expected F levels of bottled waters obtained from the company representatives often did not agree with the results we obtained by analysis, and the label designations of such waters were not always helpful.

Infant formulas, although lower in F content than two decades ago, still often show considerable variations in F levels among different types (milk- or soybased; RTF, LC or PC) and brands. F levels of the soybased formulas are still higher than milk-based and RTF formulas, since RTF formulas are more affected by the F content of water at the manufacturing site. Clearly, PC and LC formulas have the additional potential to vary substantially depending on which type of water is used in reconstitution. Any use of water that is not distilled would result in PC and LC formulas with higher F levels than those we obtained in this study.

Both McKnight-Hanes et al.⁸ and Johnson and Bawden⁹ found soy-based formulas to have higher F levels than similar RTF, LC, and PC milk-based formulas. We obtained soy-based powder concentrate F levels that were much higher than those of McKnight-Hanes et al., but we found similar results for the LC and PC.⁸ Based on their results, Johnson and Bawden⁹ suggested that children using RTF, PC, and LC formulas prepared with nonfluoridated water would not receive sufficient F from these sources to be of concern for dental fluorosis, even when combined with a supplement. Their estimate, however, was based on lower mean F values obtained for milk-based formulas compared with our findings and, thus, may understate the potential for fluorosis.

There are many challenges facing the prescriber of dietary F supplements, including assessing patients' home water F levels, and educating patients' families on reporting changes in the use of and type of formula, or water source and filtration so that the need for F dosage can be reevaluated. This process could be facilitated by having F levels listed on bottled water and formula labels.²⁶

It should be noted that children who have a sensitivity to milk protein may be of particular concern. The formulas prescribed for these children, including soybased and enzymatically hydrolyzed milk-based (e.g., Alimentum RTF and Nutramigen PC) can supply F above optimum recommended levels, placing these children at risk for dental fluorosis.

However, even when considering the mean value for F obtained in our study for milk-based LC, the following example can show the impact of formula and water F levels on a formula-fed infant's total F intake. Assuming a 6-month-old infant at the 50th percentile for weight (7.6 kg)²⁷ consumes about 1 L of formula per day, with our average value for milk-based LC (0.12 ppm F) and reconstituted with water free of F, F intake per kg body weight would be 0.016 mg/kg. If this infant received a 0.25 mg F supplement, then they would get 0.049 mg/kg. If the 1 L of formula was reconstituted with 1 ppm F bottled or tap water, F intake would be 0.082 mg/kg/day. Adding the 0.25 mg F supplement, this child would receive 0.115 mg/kg/day, about twice the recommended "optimal" level of F for this infant.

Conclusions

Assessing the need for F supplementation for formula-fed infants is difficult because the substantial differences in F intake depend on both the particular formula chosen and the water used in reconstitution. Though formulas in our study showed F levels consistent with results from the 1980s and much lower than in the 1970s, soy-based formulas and enzymatically hydrolyzed casein-based formulas are still much higher than the milk-based formulas. Bottled waters do not indicate F levels on the labels and are subject to considerable variation. Use of water filtration systems also can have significant effects on F levels.

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