# The Case for Reducing the Current Council on Dental Therapeutics Fluoride Supplementation Schedule

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**Abstract**

*The milder forms of dental fluorosis have increased in prevalence since the original epidemiologic surveys of the 1930s. Most studies of fluorosis have identified the use of supplements as a major risk factor. Fluorosis could be prevented, in part, by stopping the improper prescription of fluoride supplements in optimally fluoridated areas and by lowering the dosage currently recommended by the Council on Dental Therapeutics supplemental fluoride schedule. At a 1991 workshop at the University of North Carolina, five alternatives to the present ADA Council on Dental Therapeutics schedule were suggested; however, no consensus on dosage was reached. Recently, the Fédération Dentaire International adopted a dosage schedule of 0.25 mg F from birth to 3 years of age, 0.5 mg F from 3 to 5 years, and 1 mg F thereafter. At a 1992 Canadian workshop it was proposed that supplements should not be started until age 3, should be given only to those "at high risk" of caries, and only 0.25 mg F should be prescribed from 3 to 5 years of age. Similarly, in some European countries supplements are not recommended until 3 years, at which time 0.5 mg F is prescribed, but only "for children at risk." Australia is considering a dosage schedule starting with 0.25 mg F at 6 months, again only for those "particularly at risk of caries." Serious problems exist in limiting fluoride supplementation only to high-caries-risk children because they are not easily identifiable at a young age. Ideally, a dosage schedule should be based on body surface area or weight rather than simply age, and supplements should be in the form of lozenges for children over 2 years of age. A reduced fluoride supplement dosage schedule is proposed. [J Public Health Dent 1999;59(4):263-68]*

*Key Words: fluoride, dietary fluoride supplements, fluorosis, fluoride intake, dosage schedule.*

Previous speakers in this workshop have documented amply the efficacy of systemic fluoride in caries reduction (1), discussed the fluoride intake from dietary and other sources (2,3), and reviewed the current prevalence and severity of dental fluorosis (4). The points that I wish to bring to this workshop are as follows: First, the use of fluoride supplements has been identified as a risk factor for dental fluorosis. Second, the present dosage schedule of the Council on Dental Therapeutics (CDT) of the American Dental Association exceeds the total maximal fluoride intake recommended to limit dental fluorosis, based on 0.05 mg/kg, for children aged from birth to 6 months and 3 to 5 years, and also increases more rapidly than would a dosage based on body surface area. Third, many different dosage schedules are currently in use throughout the world and most of these schedules, even in North America, are lower than that recommended by the CDT. Fourth, it is time we agreed on a new, lower dosage schedule that will reduce the risk of fluorosis while maintaining adequate caries-preventive benefits.

## Fluorosis Related to Use of Supplements: Epidemiologic Data

The prevalence of dental fluorosis, predominantly the milder forms, has increased since the original epidemiologic surveys of the 1930s (5,6), particularly during the 1970s (7). Some data indicate that the prevalence of fluorosis has now stabilized in the United States (8,9). Most, but not all, studies of fluorosis have identified the use of supplements as a major risk factor (others include the use of fluoride toothpaste at an early age, prolonged use of infant formulas, and higher than optimal concentrations of fluoride in the water supply). The association between use of fluoride supplements and prevalence of dental fluorosis has been reviewed extensively (10,11) and has been reconfirmed by additional reports published since these reviews (12-14). Most of these studies are based on cross-sectional surveys that rely on anamnestic data regarding dosage and frequency of intake of the supplement. Such data are of questionable accuracy. Prospective studies avoid this problem. In one such study of compliance with use of fluoride supplements, individual use varied substantially (~70% of the children) and only 24 percent of the children used the tablets daily over the 10-year study period (15). In one case-control study of children 7 to 9 years of age who showed relatively good compliance in daily supplement use, a considerably greater prevalence of fluorosis (56%) was observed in comparison with the no-supplement control subjects (31%) (Leverett D, personal communication, 1993). To place these data in perspective, when 0 and 1 TSIF scores were combined, 93 percent of control children and 79 percent of experimental children fell in that range.

Undoubtedly, the inappropriate prescribing of fluoride supplements for children living in optimally fluoridated communities has contributed to the increased prevalence of fluorosis (11). In the largest US survey of children 5 to 17 years old, 8 percent were taking drops and 7 percent reported

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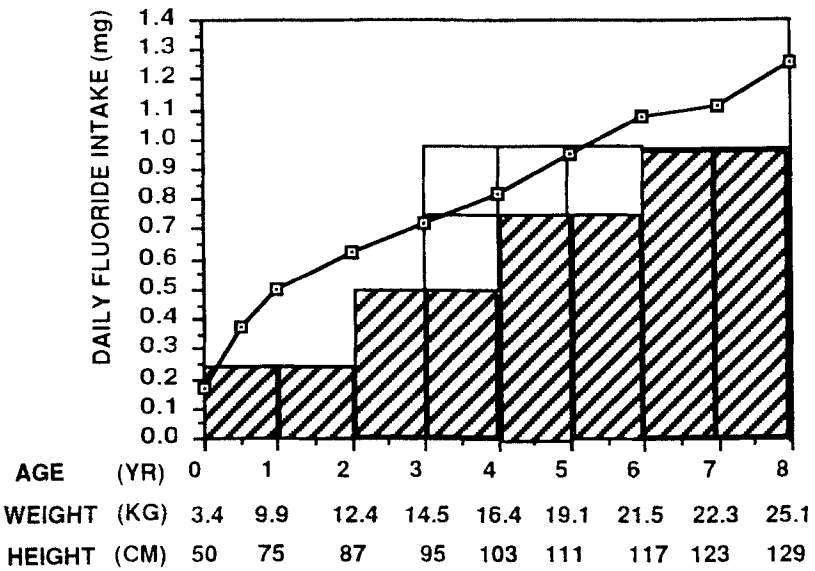
FIGURE 1
**Linear plot shows maximum daily fluoride intake to limit risk of dental fluorosis, based on a threshold dose of 0.05 mg/kg body weight. Bars show the currently used CDT dosage schedule of fluoride supplements for areas with <0.3 ppm F in the water supply. Clear bars show that CDT dosage exceeds the maximum daily suggested intake at ages between birth and 6 months and 3 to 5 years.**




using tablets while living in optimally fluoridated areas (16).

### Fluorosis Related to Use of Supplements: Biological Basis for Reducing the Currently Used CDT Dosage Schedule

At the workshop on Changing Patterns of Fluoride Intake held at the University of North Carolina at Chapel Hill, in 1991, we showed that if one assumes a threshold of 0.05 mg/kg of body weight as the maximum fluoride intake to avoid the risk of dental fluorosis, the currently used supplemental dosage from birth to about 6 months of age and for ages 3 to 5 years exceeds that threshold (Figure 1) (11). It allows little leeway for additional intake from the diet, which could be significant for children living in a nonfluoridated community surrounded by predominantly fluoridated communities. Moreover, it does not allow for unintentional ingestion of topical fluoride agents, particularly dentifrices (17,18). Only about 5 percent of children younger than 2 1/2 years of age spit out after brushing, and only 32 percent of those aged 2 1/2 to 4 years do so. Based on a recent survey of tap water consumption, investigators estimated that the mean fluoride intake from water (assuming a fluoride concentration of 1 ppm) by children from birth to 7 years of age was 0.04 mg/kg (19). These authors concluded that the present CDT fluoride supplementation schedule resulted in a daily fluoride intake rate 76 percent higher than that obtained from optimally fluoridated water.

In posology several rules have been proposed for computing the correct dosage for children, based either on the ratio of the child's weight to that of an adult (Clark's rule) or on the ratio of the child's age to that age plus 12 (Young's rule). However, a more accurate method is based on the ratio of the child's surface area to that of an adult. The child's surface area is extrapolated from nomograms representing the relationships among height, weight, and surface area (20). Because there is no specific dosage of fluoride supplementation for adults, we have used an intake of 0.35 mg fluoride for 3- to 4-year-old children (see below). This approach gives a value of 0.53 mg F/$m^2$. Using this value, the corresponding supplement dosage from birth to 8 years of age would be 0.12 mg to 0.50 mg (Table 1). This dosage schedule is very conservative and should not be considered as a recommendation to this workshop; nevertheless, it makes the point that a more gradual increase in supplement dosage would be appropriate. Between

TABLE 1
**Fluoride Dosage Based on Body Surface Area**

| Age (Years) | Surface Area ($m^2$) | F Dose (mg) |
|---|---|---|
| Birth | 0.22 | 0.12 |
| 0.5 | 0.36 | 0.20 |
| 1 | 0.46 | 0.25 |
| 2 | 0.55 | 0.29 |
| 3 | 0.63 | 0.33 |
| 4 | 0.69 | 0.37 |
| 5 | 0.77 | 0.41 |
| 6 | 0.84 | 0.45 |
| 7 | 0.87 | 0.46 |
| 8 | 0.94 | 0.50 |

birth and 2 years of age, stature of the infant increases approximately twofold, surface area threefold, and body weight fourfold. Clearly, if the present 0.25 mg F supplement is the correct dosage for a 2-year-old child, it cannot be the correct dosage for a newborn or a 6-month-old infant. The options are to give no supplements until at least 1 year of age or to give a lower dosage, such as 0.125 mg F (i.e., half the present dosage), for the first 2 years.

### Fluoride Intake by Children Measured by Actual Analysis of Foods and Beverages

One approach to determining what should be the fluoride supplement dosage has been to estimate the total fluoride intake from water, other beverages, and solid foods by analyzing representative foods from "market basket surveys." However, the data from such estimates imply relatively higher intakes than have been observed by direct analysis of duplicate meal and beverage collection. For example, Ophaug et al. (21), using the market basket method, reported a fluoride intake of 0.61 mg/day by 2-year-old children in a region with 1 ppm of fluoride, whereas duplicate meal analysis of 3- to 4-year-old children in similarly fluoridated communities found intakes of 0.33 and 0.36 mg/day exclusive of any fluoride from dentifrice ingestion (22,23). When these estimates were compared with fluoride intake from food and beverages in a nonfluoridated community, the differences were 0.21 mg for 3- to 4-year old children and 0.20

**TABLE 2**
**ADA Council on Dental Therapeutics' Fluoride Supplement Dosage Schedule (mg F/day) (Ref. 25)***

| Age (Years) | F Concentration in Water (ppm) | | |
|---|---|---|---|
| | <0.3 | 0.3–0.7 | >0.7 |
| Birth–2 | 0.25 | 0 | 0 |
| 2–3 | 0.5 | 0.25 | 0 |
| >3 | 1.0 | 0.5 | 0 |

*2.2 mg sodium fluoride contains 1 mg fluoride.

**TABLE 3**
**Swiss Fluoride Supplement Dosage Schedule (mg F/Day) (Ref. 28)**

| Age (Years) | Dosage |
|---|---|
| 0–2 | 0.25 |
| 2–4 | 0.50 |
| 4–6 | 0.75 |
| >6 | 1.00 |

**TABLE 4**
**Canadian Fluoride Supplement Dosage Schedule (mg F/Day) (Ref. 30)**

| Age (Years) | Water F Concentration <0.3 ppm |
|---|---|
| Birth–3 | 0 |
| 3, 4, 5 | 0.25 |
| From 6 | 1.0 |

mg for 7- to 8-year-olds (23). These findings would suggest that for 3- to 4-year-old children living in a suboptimally fluoridated community, a supplement of about 0.20 to 0.25 mg fluoride would be adequate. Clearly, additional data on fluoride intake for ages 2 to 3 years and 4 to 5 years would be desirable to best devise a supplement schedule. In this same study the 3- to 4-year-old children ingested an additional 0.3 mg fluoride from dentifrice use (23). Urinary excretion of fluoride was 0.42 mg over 24 hours by children 4 years of age living in optimally fluoridated Newcastle upon Tyne and using fluoridated dentifrices (24). In children who are in balance, fluoride excretion is a good indicator of fluoride intake (22).

**TABLE 5**
**Fédération Dentaire International Fluoride Supplement Dosage Schedule (mg F/Day) (Ref. 33)**

| Age (Years) | Water F Concentration (ppm) | | |
|---|---|---|---|
| | <0.3 | 0.3–0.7 | >0.7 |
| Birth–3 | 0.25 | 0 | 0 |
| 3–5 | 0.5 | 0.25 | 0 |
| From 5 | 1.0 | 0.5 | 0 |

**TABLE 6**
**Fluoride Supplement Dosage Schedule (mg F/Day) (Ref. 34)**

| Age Interval | Domestic Water F Concentration (ppm) | |
|---|---|---|
| | <0.3 | 0.3–0.5 |
| 6 mos–4 yrs | 0.25 | — |
| 4–8 years | 0.50 | 0.25 |
| 8+ years | 1.00 | 0.50 |

## Other Currently Used Dosage Schedules

The present CDT dosage schedule for fluoride supplementation (Table 2) was a compromise between the need for pediatricians to have a practical, easily memorized schedule and the previous, more precise, but decidedly impractical, drop regimen (11,25). At the University of North Carolina workshop, a consensus was reached that this present schedule be reduced to lower the risk of dental fluorosis. Five different alternative dosage schedules were discussed, but no agreement reached on any specific one. In the interim, several different dosage schedules have been adopted or proposed in various countries as well as in the United States. All have in common a lower dosage. Some recommend postponing supplementation until 6 months or even 3 years of age and several propose limiting supplementation to children deemed at risk.

A meeting of European experts was convened in Brussels in autumn 1991 to explore the possibility of reaching a consensus on a common dosage regimen of fluoride tablets and drops for Europe. Reportedly there was "unanimous agreement" that: (1) fluoride supplements have no application as a public health measure; (2) a dose of 0.5 mg/day should be prescribed for "at-risk individuals" from the age of 3 years; and (3) labeling should advise that fluoride supplements not be used before 3 years of age unless prescribed by a dentist (26). In fact, no uniform European policy existed before or after this meeting. In the United Kingdom a daily supplement schedule of 0.25 mg F from 6 months to 2 years of age, 0.5 mg F from 2 to 4 years, and 1 mg F thereafter was adopted in 1988 (27). In Switzerland a dosage schedule of 0.25 mg F from birth to 2 years, 0.5 mg F from 2 to 4 years, 0.75 mg F from 4 to 6 years and 1.0 mg F thereafter (Table 3) has been in use since 1966 and remains unchanged (28). In Germany a similar schedule has been in use since 1982 and continues to be endorsed by the Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde (29).

The Canadians also held a workshop of dental scientists in Toronto in April 1992 to determine whether currently recommended dosages need to be adjusted to ensure optimal intake of fluoride from all sources sufficient to sustain the current level of caries prevention without increasing the risk of dental fluorosis (30). The revised dosage schedule agreed upon by the Canadian workshop is as follows: no supplement for children younger than 3 years old; 0.25 mg F for ages 3, 4, and 5 years; and 1.0 mg F for 6 years and older in areas with <0.3 ppm F in the water (Table 4). Furthermore, supplements were recommended "only for individuals or groups at high risk of dental caries." These proposed fluoride supplementation guidelines were adopted subsequently by the Canadian Dental Association (30,31), but have not been endorsed by Canadian pediatricians (32). Since 1992 the School of Dentistry at the University of North Carolina has taught a modified dose schedule of 0.25 mg F from birth to 3 years, 0.5 mg F from 3 to 5 years, and 1.0 mg F from 5 years onward (Bawden, personal communication, 1994). This dosage schedule (Table 5)

also has been adopted by the Fédération Dentaire International (33).

In Australia a new dosage schedule has been proposed (34), but as yet has not been accepted by the country's National Health and Medical Research Council. In essence this schedule defers supplementation until 6 months of age and also restricts it to persons considered "particularly at risk of caries." A dosage of 0.25 mg F is suggested from 6 months until 4 years, 0.5 mg F from 4 to 8 years, and 1.0 mg F from age 8 years onward (Table 6). Supplements are recommended only in lozenge form to extend the duration of the topical effect and prevent rapid swallowing. In addition, this proposal specifies that a dose of 0.5 mg F should be taken as two lozenges of 0.25 mg F each and a dose of 1.0 mg F should be taken as two lozenges of 0.5 mg F each "to reduce the maximum plasma fluoride level," but does not indicate at what times of the day.

## Discussion

Serious problems exist with the recommendation of limiting fluoride supplementation to children in low fluoride areas that are "at high risk," as it has not been specified how to determine high risk. Various caries risk factors have been identified (35-37), but all include past caries experience. With the possible exception of baby bottle caries, evaluating past caries experience in a child 3 years of age may be premature; yet, an arbitrary decision has to be made whether or not to start supplementation if caries risk is the determining factor. Because fluoride supplementation is a relatively low-cost preventive measure, a compelling case can be made for including all children (low-, moderate-, and high-risk) in suboptimally fluoridated areas before any information as to risk category is available.

Another problem in the Canadian and European schedules is the recommendation to postpone supplementation until 3 years of age, thereby sacrificing considerable benefit to the primary teeth and the first permanent molars (38). Some have argued that the benefits from preeruptive (systemic) use of fluoride are less than the topical benefits (39-41) and therefore are willing to forego these benefits. However, analysis of data from water fluoridation has shown that the extent of the relative preeruptive versus posteruptive benefit depends on the specific surface—the preeruptive effect accounted for 66 percent of the caries reduction on pit and fissure surfaces, approximately 50 percent of the reduction on interproximal surfaces, and 25 percent of the reduction on buccolingual smooth surfaces (42).

The assertion that fluoride supplements are not a public health measure belies the positive caries reduction found in numerous school-supervised distribution trials from the 1960s to the present time (43,44). Perhaps this idea was based on the poor compliance with regular tablet use when it depended on the individual parent or child. If so, it is somewhat of a self-fulfilling prophecy, as parents and children will not be motivated if the health provider is not enthusiastic or positive about the potential benefits accruing from regular tablet ingestion. For example, in Norway, after a concerted campaign by dental health professionals and others, as well as the change of fluoride to over-the-counter sale, estimated utilization based on sales was about 50 percent by 0- to 5-year-old children and 20 percent by 6- to 11-year-old children (45)—a far better compliance rate than has been observed in most studies (12,34). Nevertheless, even in Norway a nationwide survey showed that daily use of fluoride tablets declines with age; compliance is greater than 70 percent in early childhood, falls to between 50 percent and 60 percent in 4- to 7-year-old children, and drops to below 30 percent at age 10 years (15). The better compliance in early childhood has been attributed to more intensive counseling at maternal and child health care clinics during frequent visits for health control and vaccinations.

The recommendation that supplements should be dispensed only in lozenge or chewable-tablet form to prolong the topical exposure of erupted teeth to fluoride is not new, but certainly worth emphasis. Clearly, it cannot be applied to infants younger than 2 years old, for whom drops are the appropriate vehicle. In addition, it has been proposed that such supplements

**TABLE 7**
**Proposed Fluoride Supplement Dosage Schedule (mg F/Day)***

| | | F Concentration in Water (ppm) | | |
|---|---|---|---|---|
| Weight (kg) | Age (Years) | <0.3 | 0.3–0.7 | >0.7 |
| 3.4 | Birth–2 | 0.125 | 0 | 0 |
| 12.4 | 2–4 | 0.25 | 0.125 | 0 |
| 16.4 | 4–6 | 0.5 | 0.25 | 0 |
| 21.5 | >6 | 1.0 | 0.5 | 0 |

*2.2 mg sodium fluoride contains 1 mg fluoride.

**TABLE 8**
**Fluoride Liquid Supplements**

| Product (Source) | Concentration (mg F/ml) | mg F/Drop | Drop Volume |
|---|---|---|---|
| Fluoritab Liquid (Fluoritab Corp.) | 5.90 | 0.250 | 0.055 |
| Flura-Drops (Kirkman Labs) | 5.50 | 0.250 | 0.045 |
| Karidium Liquid (Lorvic Corp.) | 2.00 | 0.125 | 0.062 |
| Sample prescription (CDT, 1984)* | 1.96 | 0.100 | 0.050 |
| Luride Drops (Colgate Oral Pharm)† | 0.50 | 0.25 mg/0.5 ml | NA |
| Pediafluor (Ross Labs) | 0.50 | 0.25 mg/0.5 ml | NA |

*Council on Dental Therapeutics. Accepted dental therapeutics. 40th ed. Chicago: American Dental Association, 1984:401.
†Prior to January 1994, Luride Drops were sold at a concentration of 2.25 mg F/ml.

be taken as a divided dose of two lozenges twice a day to minimize the transient high plasma fluoride concentration immediately after ingestion (34). This proposal was discussed at the North Carolina workshop, where data were presented to show that not only high fluoride plasma peaks, but also slightly elevated and constant plasma fluoride levels, can lead to dental fluorosis (46). The main problem with a divided dosage regimen requiring twice a day supplementation is, of course, compliance, because it doubles the chance of patients forgetting to take their supplement. The poor record of patient compliance with fluoride supplementation is well known [see reviews by Newbrun (47) and Riordan (34)]. An early 1990 US study of parents' behavior, knowledge, and attitudes towards fluoride found that although about 60 percent of parents thought that supplements were a good way for children to get fluoride, only 16 percent reported that their youngest child was currently taking a prescription supplement (48).

## Recommendations

Based on the foregoing discussion and to facilitate agreement at this workshop on a lowered fluoride supplement dosage, the schedule shown in Table 7 is proposed. It is more conservative than several debated at the North Carolina workshop, and is well below the level calculated as the threshold intake for dental fluorosis (0.05 mg F/kg). It recognizes that some unintentional swallowing of fluoride from dentifrices is inevitable by infants, and allows for that in the younger age groups. It approximates the total fluoride intake from dietary and beverage sources in optimally fluoridated communities calculated by body surface area. The dose for infants under 12.4 kg (from birth to 2 years) has been reduced to 0.125 mg F, a dose that would be taken in liquid form added to the infant's beverage during that age span.

Because sodium fluoride is highly soluble, concentrated solutions providing as much as 0.25 mg F per drop are marketed (Table 8). However, the volume of a drop is variable, depending on several factors such as viscosity, temperature, and the size of the orifice of the plastic dropper. A 5 percent to 10 percent error is considered acceptable; however, the more concentrated the liquid, the greater the size of the potential error. Furthermore, such concentrated solutions leave no margin for consumer error in administering the drops. Therefore, liquid fluoride should be dispensed in a more dilute form to contain 0.5 mg F in one milliliter, marketed with a graduated dropper to allow delivery of 0.5 ml (0.125 mg F) and 1.0 ml (0.25 mg F).

Rather than abandoning supplementation altogether for infants, it should be initiated at or shortly after birth, when mothers may be most cooperative and likely to get into the habit of regular supplementation. Because there is clear evidence of the value of preeruptive exposure to fluoride, beginning supplementation at birth provides greater caries-protective benefits to the primary dentition than providing only posteruptive exposure, as occurs when supplementation starts at 6 months or 3 years (49). Above age 2 years, all supplements should be in lozenge form, should be chewed or sucked before swallowing, and, for practical reasons, should be taken as a single dose.

All children living in communities with less than 0.7 ppm F should receive supplements because it is not practical and probably not cost effective to attempt to distinguish only those children who are at high caries risk. For an infant that is abnormally slow in growth, pediatricians should postpone prescribing a next higher fluoride dosage until the infant has reached the average body weight shown in Table 7.

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