Overview of the History and Current Status of Fluoride Supplementation Schedules

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Abstract

Clinical trials of dietary fluoride supplements began in the 1940s in an effort to bring the benefits of fluoride to those who did not receive it through their drinking water. Following the early success of these trials, the Council on Dental Therapeutics of the American Dental Association (ADA) published its first recommendations for fluoride supplementation in 1958. The American Academy of Pediatrics (AAP) followed with its own recommendations in 1972. During the 1970s a variety of alternative schedules appeared in the literature, most in reaction to the findings of unexpectedly high levels of enamel fluorosis in children being supplemented with the AAP schedule. In 1979 the ADA and AAP agreed on essentially identical schedules. During the 1980s, however, the prevalence of enamel fluorosis continued to increase, and fluoride supplements were found in some studies to be a risk factor for fluorosis. This finding prompted another round of dosage schedule recommendations in the early 1990s. This paper presents a history of fluoride dosage recommendations and reviews the recent proposals for reducing supplement dosage. [J Public Health Dent 1999;59(4):252-58]

Key Words: fluoride, fluoride supplementation, dosage schedules.

Interest in administering fluoride as a dietary supplement grew from the desire to provide the caries-protective effect of fluoride to those who did not receive it in their drinking water. For years after this effect of water fluoridation was discovered, it was believed that fluoride reduced caries susceptibility by becoming incorporated in the enamel of the developing teeth. The trials of controlled water fluoridation were not designed to determine the existence of any other mode of action for fluoride. As a result of the success of these early trials, investigators began to seek ways to bring the benefits of systemically ingested fluoride to children in fluoride-deficient communities. The purpose of this paper is to review fluoride supplementation dosage schedules used or proposed over the past three and one-half decades.

History

Beginning in the 1940s, dietary fluoride supplements were tested as cariostatic agents (1-3). Without reviewing the strengths and weaknesses in study design of the various trials, it can be said that caries reductions were found to be significant for both the primary and the permanent dentitions. With the notable exception of Bibby (4), who evaluated fluoride mouthrinses and lozenges, the investigators uniformly assumed a systemic mode of action for fluoride. This assumption led to the conclusion that fluoride supplement dosages should mimic previous estimates of dietary fluoride intake of individuals in optimally fluoridated communities (5). An example of this conclusion can be found in the 1960 study by Arnold et al. (6), in which concentrated sodium fluoride solutions or fluoride tablets were to be added to the participants' drinking water to approximate a daily fluoride intake of 1.0 mg. This method of supplementation had been proposed in 1958 in the first fluoride dosage schedule of the American Dental Association (7). This schedule required dissolving a 2.2 mg sodium fluoride tablet in 1 quart of water, which was then to be used in the preparation of food or as drinking water for children under the age of 2 years. Supplementation was recommended only in those areas with less than 0.7 mg F^-/L, with the full supplementation dose applicable to those whose water supplies contained <0.2 mg F^-/L. For older children, the ADA schedule called for the addition of fluoride to juice or water that the child would drink at one time. Children aged 2–3 years were to receive 1.0 mg F^- every other day, while those older than 3 years were to receive 1.0 mg daily. Instructions were given also for prescribing a 0.05 percent solution of NaF, delivering approximately 1.0 mg F^- per teaspoon. This solution would provide the necessary fluoride to be added to juice or water. The fluoride concentration of this solution was to be decreased by 10 percent for each 0.1 mg F^-/L in the drinking water.

The Council on Dental Therapeutics (CDT) echoed the prevailing assumption of a systemic mode of action for fluoride in its recommended mode of delivery of fluoride and in its statement that "... it appears that dietary fluoride provides its greatest benefit during the period of tooth development...." Supplementation was recommended "until at least 8 to 10 years of age," after which the enamel of the permanent second molars would be completed.

Nikiforuk and Fraser (8) in 1964 presaged a number of future recommendations with their supplementation schedule, shown in Table 1. Their scheme divided age into four categories, beginning at birth and ending at age 12 years. The drinking water category included four categories, with no supplementation recommended with water fluoride levels in excess of 0.75 mg/L.

The CDT continued to recommend "creating" fluoridated water for consumption by children under the age of 2 years in subsequent editions of Accepted Dental Remedies and Accepted

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Dental Therapeutics through the 1960s and into the late 1970s. In 1966 the ADA altered its recommendation for children aged 2–3 years by calling for the daily administration of 0.5 mg F^- as opposed to 1.0 mg every other day (9). Downward adjustments were recommended for water supplies with 0.2, 0.4, and 0.6 mg F^-/L. Accepted fluoride tablet formulations did not accommodate the resultant dosages, but additional instructions were given for preparing a solution that would deliver 0.1 mg F^- per drop. No specific allowance was recommended for children under age 2 years except for the use of water containing 1.0 mg F^-/L for drinking and preparation of formula. Supplementation was recommended to age 12–14 years.

In 1975 the ADA suggested an acceptable alternative of 0.25 mg F^- per day for children under 2 years of age (10). In that edition of "Accepted Dental Therapeutics," the council suggested that no supplementation be provided in regions with a water fluoride level >60 percent of the optimum for that geographic area. Supplementation was suggested to "approximately age 13." Perhaps the most important change in the recommendations was in the sample prescription for the use of sodium fluoride tablets, in which the instructions now called for the tablet to be chewed and swished prior to swallowing. With the exception of the simple use of fluoride tablets in areas devoid of waterborne fluoride, all of the recommendations proposed by the council were cumbersome and difficult to implement.

In 1972 the American Academy of Pediatrics classified fluoride as a nutrient and stated that "Physicians ... should see that sufficient fluoride is prescribed to provide an intake of 0.5 mg per day for children up to 3 years of age and 1.0 mg per day after age 3 years" (11). No upper age limit was specified for discontinuing supplementation, and no supplementation was recommended in areas with water fluoride levels in excess of 0.5 mg/L. This schedule became the AAP's fluoride supplementation regimen until 1979.

During the 1970s, a multitude of dietary fluoride regimens proliferated. Several of these new proposals were prompted by the 1974 study by Aasenden and Peebles (12) that demonstrated unexpectedly high rates of

TABLE 1
Daily Fluoride Supplementation Regimen (mg/day) Proposed by Nikiforuk and Fraser (1964)

	Water Fluoride Concentration (mg/L)			
Child's Age	0–0.25	0.25–0.50	0.50–0.75	>0.75
Birth–12 mos	0.25	0	0	0
1–4 years	0.50	0.25	0	0
4–8 years	0.75	0.50	0.25	0
8–12 years	1.00	0.75	0.50	0

TABLE 2
Daily Fluoride Supplementation Regimen (mg/day) by Ripa (1974)

	Water Fluoride Concentration (mg/L)	
Child's Age	0–0.3	0.4–0.6
Birth–24 mos	0.30*	0.20†
2–3 years	0.50	0.30–0.50
3–12 years	1.00	0.50

*Or use of water containing 1.0 mg F^-/L for drinking and preparation of formula.
†Or use of water containing 0.5 mg F^-/L for drinking and preparation of formula.

TABLE 3
Daily Fluoride Supplementation Regimen (mg/day) Proposed by the International Workshop on Fluorides (1974)

Age (Years)	Mg F^-
0–1	0.25
2–3	0.50
4–5	0.75
6–7	1.00
8–9	1.25
10–11	1.20
12–13	1.75
14–16	2.00
17 and older	2.25

TABLE 4
Daily Fluoride Supplementation Regimen (mg/day) Proposed by Wei et al. (1977)

	Water Fluoride Concentration (mg/L)				
Child's Age	<0.2	0.2–0.4	0.4–0.6	0.6–0.8	>0.8
Birth–6 mos	0	0	0	0	0
6–8 mos	0.25	0*	0*	0*	0*
18–36 mos	0.50	0.25	0	0	0
3–6 years	0.75	0.50	0.25	0	0

*0.25 mg/day for breast-fed infants aged 6–12 months.

TABLE 5
Daily Fluoride Supplementation Regimen (mg/day) Proposed by Parkins (1977)

	Water Fluoride Concentration (mg/L)		
Child's Age	0–0.3	0.3–0.7	>0.7
6 mos–2 years	0.25	0	0
2–4 years	0.50	0.25	0
4–6 years	0.75	0.50	0.25
6–8 years	1.00	0.75	0.50
>8 years	1.00	1.00	1.00

dental fluorosis among children supplemented with the AAP's dosages. Some, such as Ripa's (13) 1974 schedule (Table 2), bore little resemblance to either the ADA's or the AAP's regimens, but obviously sought to reduce the fluoride dose to infants younger than 24 months, and to adjust the doses to children who consumed fluoride-deficient water. At the International Workshop on Fluorides and Dental Caries Reductions in 1974, a weight-based schedule was proposed that was based on the assumption that a 70 kg adult in an optimally fluoridated community would consume 2.25 mg F⁻ per day (14). The published schedule (Table 3), however, used an age-based category and did not state the water fluoride level above which supplementation would not be necessary. The resultant doses were too unwieldy to make the schedule usable.

Wei et al. (15) in 1977 proposed the schedule shown in Table 4. This scheme began supplementation at birth, and divided the water fluoride level of the recipient into five ranges. The age ranges were compressed at the lower end, covering birth–6 months, 6–18 months, 18–36 months, and 36 months–6 years, beyond which no supplementation was recommended. No supplementation was suggested for infants aged 6–18 months in areas with water fluoride levels ≥0.2 mg/L except for 6–12-month-olds who were breast fed. A few months later in the same journal, Parkins (16) proposed another regimen (Table 5), this time subdividing the drinking water fluoride into ranges of <0.3, 0.3–0.7, and >0.7 mg F⁻/L. The four age ranges were expanded to five, and the onset of supplementation was delayed until 6 months of age. In 1978 Adair and Wei (17), prompted by the levels of fluoride in some infant formulas, proposed the schedule shown in Table 6. This schedule essentially was identical to the one by Wei et al. (15), except that 0.25 mg F⁻ was recommended for fully breast-fed infants from birth to 18 months of age, regardless of the drinking water fluoride status.

Various other schemes appeared in the literature during the 1970s, including regimens for developmentally disabled patients who were considered at higher risk for dental caries. The schedule proposed by Nowak (18) (Table 7) began supplementation at birth and continued with the final age category "Over 18 years." The change from 0.25 mg to 0.5 mg F⁻ took place at 6 months of age instead of 2 years, and there was an intermediate dose of 0.75 mg F⁻ for ages 3 to 6 years. The 1.0 mg F⁻ dose was not initiated until age 6. Downward revisions were suggested for children residing in areas with water fluoride levels of <0.3 mg/L.

These alternative schemes were largely empirical derivations of the then-current ADA or AAP regimens. They attempted to take into consideration fluoride intake from other sources, primarily food and dentifrice, that might be contributing to unexpectedly high levels of dental fluorosis. In general, the caries-preventive efficacy of these alternative schedules was not proven in clinical trials.

The 1979 supplementation schedule appeared in "Accepted Dental Therapeutics" (19) (Table 8). This schedule called for the administration of fluoride from birth for children living in areas with 0.3 mg F⁻/L in the drinking water. The upper limit of drinking water fluoride for supplementation

TABLE 6
Daily Fluoride Supplementation Regimen (mg/day) Proposed by Adair and Wei (1978)

	Water Fluoride Concentration (mg/L)				
Child's Age	<0.2	0.2–0.4	0.4–0.6	0.6–0.8	>0.8
Birth–6 mos	0*	0*	0*	0*	0*
6–18 mos	0.25	0*	0*	0*	0*
18–36 mos	0.50	0.25	0	0	0
3–6 years	0.75	0.50	0.25	0	0
>6 years	1.00	0.75	0.50	0.25	0

*0.25 mg/day for fully breast-fed infants.

TABLE 7
Daily Fluoride Supplementation Regimen (mg/day) Proposed by Novak (1978) for Developmentally Disabled Patients

	Water Fluoride Concentration (mg/L)		
Patient's Age	<0.3	0.3–0.7	>0.7
Birth–6 mos	0.25	0	0
6 mos–3 years	0.50	0.25	0
3–6 years	0.75	0.50	0.25
6–18 years	1.00	0.75	0.50
> 18 years	1.00	1.00	1.00

TABLE 8
1979 Fluoride Supplementation Schedule (ADA/AAP/AAPD)

	Water Fluoride Concentration (mg/L)		
Child's Age	<0.3	0.3–0.7	>0.7
Birth*–2 years	0.25	0	0
2–3 years	0.50	0.25	0
3–13 years†	1.00	0.50	0

*AAP schedule begins at 2 weeks of age.
†AAP schedule ends at 16 years of age.

TABLE 9
Daily Fluoride Supplementation Regimens (mg/day) Recommended for Use in Fluoride-deficient Areas in Various Countries [Ref. (46) and Marthaler T, Personal communication, 1994]

	Child's Age											
Country	Birth	2 wks	6 mos	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	12 yrs	13 yrs	14 yrs
Australia	0	0.25		0.5	1.0							
Austria	0		0.25	0.5		0.75	1.0					
Britain	0	0.25		0.5		1.0						
Canada	0				0.25			1.0				
Denmark	0		0.25	0.5						0		
Finland	0		0.25	0.5					1.0			
Germany	0.25			0.5	0.75			1.0				
Italy	0.25			0.5		0.75	1.0					
Netherlands	0.25			0.5	0.75	1.0						
N. Zealand	0		0.25	0.5		1.0						0
Norway	0		0.25	0.5				0.75		1.0		
Sweden	0				0.5				0.75		1.5	
Switzerland	0.25			0.5		0.75		1.0				

was changed from 60 percent of optimum back to 0.7 mg F⁻/L. The daily fluoride recommendations for children in the three age ranges remained the same; however, specific dose recommendations were made for children residing in areas with 0.3–0.7 mg F⁻/L. This new regimen also was adopted by the American Academy of Pediatric Dentistry.

By this time the differences between the schedules proposed by the ADA and the AAP became more obvious. Newbrun (20), writing in *Pediatrics* in 1978, explored the differences between the two schedules and suggested that the lower-dosage ADA schedule should reduce the likelihood of enamel fluorosis. In 1979 the AAP (21) adopted the ADA's schedule, with the exceptions of a starting age of 2 weeks and a maximum age of 16 years. The two organizations restated their recommendations in separate publications in 1986 (22,23).

During this time a number of supplementation regimens were developed in other parts of the world, notably Europe, Canada, New Zealand, and Australia. These recommendations (Table 9) vary in the age at which supplementation is to start, with some advocating supplementation from birth, others delaying until 3 years of age. In some instances supplementation is intended only for individuals with high caries activity or those with risk factors that cannot be eliminated. In the United States, further recommendations for disabled patients proposed by the National Foundation of Dentistry for the Handicapped (24) in 1981 were identical to the current ADA/AAP/AAPD recommendations, regardless of the caries status of the disabled individual. In contrast to Nowak's recommendations, supplementation was not advocated beyond the age of 13.

TABLE 10
Proposed Revision of Daily Fluoride Supplementation by North Carolina Workshop (1992)

	Water Fluoride Concentration (mg/L)		
Child's Age	<0.3	0.3–0.7	>0.7
Birth–3 years	0.25	0	0
3–5 years	0.50	0.25	0
>5 years	1.0	0.50	0

Compliance

In general, compliance with supplementation regimens has been poor. The initial ADA regimen was complicated for dentists and cumbersome for parents, and the resultant doses did not always coincide with available fluoride preparations.

Surveys of supplement use have shown compliance rates to be low. Woolfolk and co-workers (25) found that only 45 percent of parents in a low-fluoride area of Michigan had regularly administered supplements to their children. Studies from Britain (26), Canada (27), Sweden (28), and Australia (29) also have documented poor compliance with recommended regimens. Horowitz (30) in 1985 speculated on several causes for noncompliance: economic factors, low emphasis on dental prevention in medical and dental training, the complicated dosage schedule, and low levels of public knowledge about the benefits of supplementation. In addition, studies have documented improper prescribing practices by dentists and physicians (31,32). Pediatricians and family practitioners, of course, have the greatest opportunity to prescribe supplements for infants and young children; nevertheless, their compliance with the current regimen is apparently low in some parts of this

country, leading to both under- and oversupplementation.

Current Status

Surveys (33-35) conducted in the mid- and late 1980s demonstrated levels of dental fluorosis in fluoride-deficient communities that were higher than would have been predicted by the studies of Dean (36) conducted earlier in this century. Of greatest concern are the studies of Pendrys and Katz (37), Woolfolk et al. (25), Osuji et al. (38), and others showing a statistically significant relationship between fluoride supplementation and the presence of fluorosis. Not all studies (39,40) have found such a relationship; nevertheless, there is general concern that ingestion of fluoride from multiple sources may require reduction in the dosages of supplementation, delay in the onset of supplementation, and/or adjustment of the age ranges of supplementation.

The report on dietary fluoride supplements developed at the workshop on Changing Patterns of Fluoride Intake, held at the University of North Carolina in April 1991, proposed the schedule shown in Table 10 (41). This schedule maintains that supplementation should begin at or shortly after birth for children residing in regions with water containing less than 0.3 mg F^-/L, but extends the age range by one year for supplementation at the lowest level, 0.25 mg F^-. The dose increase to 0.50 mg F^- occurs at age 3 and continues to age 5, at which time the dose increases to 1.0 mg F^-. Supplementation is not suggested for locales with water fluoride levels above 0.7 mg/L, and it is reduced for children who consume water containing 0.3 to 0.7 mg F^-/L. This dose schedule was further echoed by Szpunar and Burt (42) in 1992 and by Burt (43) in 1993 as a basis for future consensus on a new supplementation schedule. The Fédération Dentaire Internationale also adopted this schedule.

In one of the published reports issued from the UNC workshop, Newbrun (44) proposed the supplementation regimen shown in Table 11, indicating that it coincides with a schedule used in Switzerland since 1966. This schedule uses both weight and age as guides for the various doses, although the schedule does not state which should be given higher priority. Again, no supplementation is recommended for children who consume water containing more than 0.7 mg F^-/L. This proposal delays the 1.0 mg dose until age 6, with an intermediate dose of 0.75 mg for children aged 4–6 years, but maintains the onset of the 0.5 mg dose at age 2 years.

TABLE 11
Fluoride Supplement Regimen Proposed for United States by Newbrun (1992)

		Water Fluoride Concentration (mg/L)		
Weight (kg)	Child's Age	<0.3	0.3–0.7	>0.7
3.4–12.4	Birth–2 years	0.25	0	0
12.4–16.4	2–4 years	0.50	0.25	0
16.4–21.5	4–6 years	0.75	0.50	0
>21.5	>6 years	1.00	0.75	0

TABLE 12
Fluoride Supplement Regimen Proposed by Riordan (1992)

	Water Fluoride Concentration (mg/L)	
Child's Age	<0.3	0.3<0.5
6 mos–4 yrs	0.25	0
4–8 years	0.50	0.25
≥8 years	1.00	0.50

TABLE 13
Fluoride Supplement Regimen Proposed by Toronto Workshop (1992) and Accepted in Canada

	Water Fluoride Concentration (mg/L)	
Child's Age	<0.3	>0.3
3–6 years	0.25*	0
≥6 years	1.00	0

*0.5 mg if fluoridated dentifrice is not regularly used.

Discussion of the use of fluoride supplements in various countries was held in 1991 at the Brussels Conference on a European View of Fluoride Supplementation (46). In general, supplemental fluoride in Europe is provided through school-based programs or through pediatricians' prescriptions to selected individuals. In Norway and Sweden, fluoride tablets are used only as a supplementary preventive measure for children and adults with high caries risk or activity. The conference reached the following consensus: (1) fluoride supplements have no place as a public health measure; (2) the maximum dose of 0.5 mg F^- per day should be used with caries-risk children above 3 years of age, and (3) fluoride supplements should be labeled to indicate their use before age 3 only on the prescription of a dentist.

Riordan (46) in 1993 proposed the supplementation schedule shown in Table 12, which also was adopted by the New South Wales Health Department in Australia (47). This schedule specifically calls for no supplementation during the first 6 months of life. Supplementation for children who consume water with less than 0.3 mg F^-/L begins at 6 months with 0.25 mg F^-, with increases to 0.5 mg at age 4, and 1.0 mg at age 8. No upper age limit is specified. Riordan suggested that all supplements be formulated as lozenges with a maximum dose per lozenge of 0.5 mg.

The formulation of fluoride tablets as lozenges also was suggested by a Toronto workshop in 1992 (48). The participants further recommended that fluoride supplements be used only for groups or individuals at high risk for caries, only for individuals above the age of 3 years, and that supplements be packaged with a written dosage schedule. Their dosage recommendations, which were adopted by the Canadian Dental Association, appear in Table 13. Supplementation is recommended only for areas with less than 0.3 mg F^-/L. Children aged 3, 4, and 5 years are to receive 0.25 mg F^- daily, unless they do not regularly use fluoridated toothpaste, in which case a daily dose of 0.5 mg F^- was recommended. Individuals 6 years of age

and older are to receive 1.0 F daily. The workshop recommended that the prescribing dentist or physician estimate the individual's fluoride intake from fluids, including home and child care water sources and the possible effects of home filtration systems, prior to supplementation.

Conclusions

Fluoride supplementation regimens suffer from several shortcomings, the first of which may be their derivation from a time when the major effect of fluoride was thought to be systemic. Although evidence that fluoride exerts its effects mainly through topical contact with enamel is great, supplementation schemes still focus on the ingestion of fluoride. Fluoride tablets can be chewed and swished, of course; nevertheless, the need for systemic ingestion as the sole means of supplementation should be reconsidered. Secondly, if systemic ingestion is deemed advisable, the only practical means of estimating the dietary fluoride intake of the individual to be supplemented is through the fluoride content of that individual's drinking water. This source of fluoride may not be a significant one for many children, even those who live in optimally fluoridated communities. On the other hand, children in any community may ingest significant amounts of fluoride from foods and beverages processed in optimally fluoridated communities. Analysis of a given child's drinking water is important, especially to avoid prescribing fluoride supplements where unnecessary. In fluoride-deficient areas, however, water analysis alone may lead to an underestimation of the total fluoride consumed.

A third problem is that of age-based dosing. The optimum dose of fluoride should be based on weight or body surface area, a moving target in children that makes proper dosing serendipitous at best, especially when intake from other sources is unknown. Children at the lower end of an age range may be oversupplemented; those at the upper end will receive less fluoride on a body weight basis, although they, too, may receive more fluoride than necessary. Clearly, individualization of fluoride supplementation is at best difficult, and perhaps impossible on a public health basis.

The trends in recommendations for fluoride supplementation have been influenced largely by evidence of the increasing prevalence of fluorosis in optimally fluoridated and fluoride-deficient communities in the United States. Thus, the changes in supplementation schedules have focused on the age at which supplementation should begin, the initial dose, doses at subsequent ages, and the drinking water fluoride ranges. Some pediatricians believe that better compliance is obtained by beginning supplementation at or shortly after birth. Increased emphasis on the topical nature of fluoride's caries protective effect has prompted others to call for postponing the onset of supplementation or eliminating it entirely.

We must accept, too, that the current schedule and recent proposals are necessarily empirically derived. While they may not have been proven in controlled trials, they are nonetheless based on careful observation and consideration for the dental and overall health of the potential recipients. Time and resources, both human and fiscal, will not permit trials to compare the efficacies of the various proposals. Decisions regarding fluoride supplementation will have to be made on the basis of the best available evidence, with subsequent evaluation of the caries and fluorosis experience of large populations using the new recommendations.

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