
CLINICAL PRACTICE GUIDELINES
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Appropriate uses of fluorides for children: guidelines from the Canadian Workshop on the Evaluation of Current Recommendations Concerning Fluorides

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Objective: To prevent fluorosis caused by excessive fluoride ingestion by revising recommendations for fluoride intake by children.

Options: Limiting fluoride ingestion from fluoridated water, fluoride supplements and fluoride dentifrices.

Outcomes: Reduction in the prevalence of dental fluorosis and continued prevention of dental caries.

Evidence: Before the workshop, experts prepared comprehensive literature reviews of fluoride therapies, fluoride ingestion and the prevalence and causes of dental fluorosis. The papers, which were peer-reviewed, revised and circulated to the workshop participants, formed the basis of the workshop discussions.

Values: Recommendations to limit fluoride intake were vigorously debated before being adopted as the consensus opinion of the workshop group.

Benefits, harms and costs: Decrease in the prevalence of dental fluorosis with continuing preventive effects of fluoride use. The only significant cost would be in preparing new, low-concentration fluoride products for distribution.

Recommendations: Fluoride supplementation should be limited to children 3 years of age and older in areas where there is less than 0.3 ppm of fluoride in the water supply. Children in all areas should use only a "pea-sized" amount of fluoride dentifrice no more than twice daily under the supervision of an adult.

Validation: These recommendations are almost identical to changes to recommendations for the use of fluoride supplements recently proposed by a group of European countries.

Sponsors: The workshop was organized by Dr. D. Christopher Clark, of the University of British Columbia, and Drs. Hardy Limeback and Ralph C. Burgess, of the University of Toronto, and funded by Proctor and Gamble Inc., Toronto, the Medical Research Council of Canada and Health Canada (formerly the Department of National Health and Welfare). The recommendations were formally adopted by the Canadian Dental Association in April 1993.

Objectif : Prévenir la fluorose causée par une ingestion excessive de fluorure en révisant les recommandations relatives à l'absorption de fluorure par les enfants.

Options : Limiter l'ingestion de fluorure contenu dans l'eau fluorée, les suppléments de fluorure et les dentifrices au fluorure.

Résultats : Réduction de la prévalence de la fluorose dentaire et maintien de la prévention des caries dentaires.

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Preuves : Avant l'atelier, des experts ont préparé des recensions détaillées des écrits portant sur les traitements au fluorure, l'ingestion de fluorure et la prévalence et les causes de la fluorose dentaire. Les documents, qui ont fait l'objet d'un examen par les pairs et ont été révisés et distribués aux participants à l'atelier, ont servi de base aux discussions.

Valeurs : Les recommandations visant à limiter l'ingestion de fluorure ont fait l'objet d'un débat animé avant d'être adoptées comme avis consensuel de l'atelier.

Avantages, préjudices et coûts : Baisse de la prévalence de la fluorose dentaire et maintien des effets préventifs du fluorure. Le seul coût important sera celui qu'entraînerait la préparation, pour la distribution, de nouveaux produits à faible concentration de fluorure.

Recommandations : Les suppléments de fluorure devraient être limités aux enfants de 3 ans et plus dans les régions où l'eau potable contient moins de 0,3 ppm de fluorure. Les enfants de toutes les régions devraient utiliser au maximum un volume de dentifrice au fluorure de «la grosseur d'un pois», au plus deux fois par jour, sous la surveillance d'un adulte.

Validation : Ces recommandations sont presque identiques aux modifications des recommandations relatives à l'utilisation de suppléments au fluorure proposées récemment par un groupe de pays européens.

Commanditaires : L'atelier a été organisé par le Dr D. Christopher Clark, de l'Université de la Colombie-Britannique, et les Drs Hardy Limeback et Ralph C. Burgess, de l'Université de Toronto, et financé par Proctor and Gamble Inc., de Toronto, le Conseil de recherches médicales du Canada et Santé Canada (auparavant Ministère de la Santé nationale et du Bien-être social). L'Association dentaire canadienne a adopté officiellement les recommandations en avril 1993.

A workshop was held Apr. 9 to 11, 1992, in Toronto to review existing recommendations for the use of fluorides in Canada; it was organized by me along with Drs. Hardy Limeback and Ralph C. Burgess, of the University of Toronto. More than 30 participants attended, representing the scientific community, national, provincial and local dental public health authorities, and associations of dentists and dental hygienists. Representatives of commercial interests and Health Canada (formerly the Department of National Health and Welfare) attended as observers. The workshop group's primary goal was to revise recommendations for fluoride use to limit exposure to the lowest possible level of fluoride that will control dental caries. Specifically, revised recommendations are intended to decrease the prevalence of dental fluorosis by reducing ingestion of fluoride by Canadian children. Participants recognized that the fluoride concentrations in water and dentifrices and the dosages for fluoride supplements established when fluoridation was introduced may no longer be appropriate. They also recognized that further revisions to the recommendations may be needed as conditions change in the future.

The recommendations of the workshop participants change existing guidelines on the use of fluorides for the general population. However, practitioners are encouraged to use their best clinical judgement in providing preventive care in unusual conditions of fluoride use.

Methods

As a backdrop to the workshop, experts from Canada and the United States were asked to review literature on selected topics on fluorides.¹⁻⁷ These reviews were peer-reviewed before the workshop and, after further

peer review, have been accepted for publication in *Community Dentistry and Oral Epidemiology* (Copenhagen). They are supported by proceedings from other recent symposia and workshops and other major reviews.⁸⁻¹⁵

The workshop participants accepted the findings of major reviews on the risks of fluorides, which demonstrated the absence of any significant safety concerns about their appropriate use.^{13,15} Participants agreed with the conclusion of Lewis and Banting.⁵

Water fluoridation continues to have unique advantages from the perspectives of distribution, equity, compliance and cost-effectiveness over other fluoride technologies. Therefore, it would be a backward step to consider abandoning or de-emphasizing water fluoridation without first eliminating most other sources of fluoride, many of which are used or consumed on an elective basis.

The review and subsequent discussion focused on five questions: How do fluorides work? Is the prevalence of dental fluorosis increasing? Does a particular fluoride therapy put children at risk of having dental fluorosis? How much fluoride are children ingesting? How effective are particular therapies?

Two working groups held preliminary discussions in which participants assessed selected fluoride therapies' risk of causing fluorosis and effectiveness in preventing dental caries. Separate reports were prepared by the two groups and distributed to participants before the final plenary session. Following vigorous discussion, participants within each working group and in the plenary session reached consensus on new recommendations. These recommendations have been adopted and distributed by the Canadian Dental Association and several provincial dental associations.

How do fluorides prevent dental caries?

Traditional thinking about how fluorides prevent dental caries has changed.¹⁶⁻¹⁸ Fluorides were once thought primarily to increase the resistance of the tooth to demineralization by acids if incorporated into the outer surface of the enamel.¹⁹ They were also thought to play an important role in inhibiting bacterial enzymes. Because fluorides were thought to be fully beneficial only if incorporated into the tooth surface, it was recommended that they be administered by supplementation in infancy, before the teeth erupted. Likewise, early topical fluoride systems were designed to incorporate fluoride into the outer surface of the enamel. Although fluorides were considered beneficial even after the teeth had erupted, the primary goal was to add fluoride to the tooth as fluorapatite (a naturally occurring calcium fluorophosphate).

Recent studies have altered this view by demonstrating that fluorides prevent dental caries predominantly through remineralization (primarily after teeth have erupted).^{17,18} Thylstrup¹⁷ suggested that the most important period for exposure to fluorides is from tooth emergence to the establishment of interproximal contact and full occlusion. Also, he demonstrated that benefits from systemic and from long-term topical administrations are similar. After following populations in areas with fluoridated water and nonfluoridated water, Groeneveld, Van Eck and Backer-Dirks¹⁸ found that the number of incipient carious lesions among people living in both areas was similar at the beginning of their investigation, but after several years fewer of the incipient lesions had formed dental cavities in populations living in the com-

munities with fluoridated water. Thus, the primary effect of fluorides is inhibition of dental caries after the teeth have erupted, not before, and is more therapeutic than preventive. These findings support changes in the use of fluoride supplementation to prevent dental caries.

What is dental fluorosis?

Dental fluorosis is caused by high tissue fluoride concentrations from excessive fluoride ingestion during tooth formation and results in hypoplasia or hypomineralization of the dental enamel and dentin. The effect of hypoplastic enamel and dentin on tooth appearance ranges from barely perceptible white striations to confluent pitting and staining. These effects probably result from a breakdown in enamel maturation because of a fluoride-induced change in the composition or rheologic features of the enamel matrix or because of a disturbance of the cellular processes. Apparently, high tissue fluoride concentrations interfere with calcium homeostasis.⁶ However, there is no evidence that increased ingestion of fluorides after teeth have formed has any effect on enamel appearance.

Prevalence and causes of dental fluorosis

The prevalence of dental fluorosis has increased in recent years; in most areas of Canada it probably ranges between 35% and 60% of the population in communities with fluoridated water and 15% to 45% in communities with nonfluoridated water (Tables 1 and 2), depending on the extent of water fluoridation, proximity to water fluoridation and consistency of the recommended con-

Table 1: Results of studies of dental fluorosis prevalence in areas with optimally fluoridated water*

Study and year of examination	Age, yr	Fluoride intake period	Type of case; prevalence, %			
			None	Very mild/mild	Moderate/severe	Total
Driscoll et al, 1980 ²⁰	8-16	1964-78	84.5	15.5	0.0	15.5
Heifetz et al, 1980 ²¹	8-10	1970-78	81.1	18.7	0.1	18.8
Leverett, 1981 ²²	13-15	1965-73	88.6	11.4	0.0	11.4
Segreto et al, 1984 ²³	7-17	1964-80	73.1	-†	-†	26.9
Heifetz et al, 1985 ²¹	7-18	1962-78	39.6	60.1	0.3	60.4
Szpunar and Burt, 1986 ²⁴	8-10	1975-83	72.0	28.0	0.1	28.1
Williams and Zwemer, 1988 ²⁵	13-15	1970-78	70.7	29.3	0.0	29.3
Ismail et al, 1991 ²⁶	6-12	1974-84	51.0	49.0	0.0	49.0
Clark et al, 1991 ²⁷	12-14	1974-82	19.1	66.9	14.0	80.9
	10-12	1979-87	31.8	-†	-†	69.2
	6-14	1977-91	35.0	55.0	10.0	65.0

*Adapted from Clark.¹

†Cases were not classified according to severity.

centration of fluoride in water systems.¹ Although the increase in prevalence has occurred primarily in very mild and mild forms of dental fluorosis, there is also some evidence that the prevalence of moderate and severe fluorosis is increasing as well.¹ Furthermore, this increase has been associated with the use of fluoridated dentifrices, fluoride supplements, infant formula and water fluoridation.^{2,3,5,7}

Although none of the indices of dental fluorosis assess its cosmetic effects, there is some evidence that very mild and mild dental fluorosis poses no esthetic problems.³² Furthermore, dental fluorosis, however severe, has not been shown to pose any health risks beyond the possible esthetic concern.¹⁵

How much fluoride are children ingesting?

The two main sources of ingested fluoride are fluoridated water and dentifrices. Ingestion of fluoride from water can occur by drinking tap water, eating foods cooked in such water or consuming soups, juices or other types of drinks reconstituted or prepared with fluoridated water. Armstrong, Holliday and Schrecker³³ showed that on average children under 3 years of age consumed 0.61 L of water per day. Ten percent consumed 0.14 L per day, and 90% consumed 0.87 L per day. For children between 3 and 5 years of age, daily intake of water was reported to be 0.87 L on average, 10% consuming 0.37 L per day and 90% consuming 1.5 L per day. If these liquids contained 1 ppm of fluoride, the

mean daily intake of fluoride from tap water and tap-water-based beverages would be about 0.14 mg for 10% and 0.87 mg for 90% of children under 3 years and 0.37 mg for 10% and 1.5 mg for 90% of children 3 to 5.

In areas with nonfluoridated water, intake of fluoride from tap water alone would be negligible. A recent study³⁴ found that the average dietary fluoride intake for 6-year-old children in areas with nonfluoridated water was 0.86 mg/d, which is considered nearly optimal.³⁵ Beverages and drinking water contributed to 75% of this total. Another study found that the mean daily fluoride intake from prepared beverages alone was 0.36 mg in children 2 to 3 years of age, 0.54 mg in those 4 to 6, and 0.60 mg in those 7 to 10.³⁶ On average, a Canadian boy aged 5 years and weighing 19 kg ingests 0.028 mg of fluoride per kilogram of body weight daily from beverages alone.³⁷ These findings suggest that the use of fluoridated water to process soft drinks and juices is largely responsible for fluoride ingestion in those living outside of communities with water fluoridation.

In areas with fluoridated water and with nonfluoridated water, however, ingestion of fluoride will vary depending on the concentrations of fluoride in the available products. As Levy² pointed out, these concentrations not only vary in the same product over time but are often not reported on product labels. Levy also noted wide variations in the pattern of soft-drink consumption and in the concentration of fluoride in different products; although the average amount of fluorides ingested from beverages is less than optimal, in combination with additional

Table 2: Results of studies of dental fluorosis prevalence in areas with nonfluoridated water

Study and year of examination	Age, yr	Fluoride intake period	Type of case; prevalence, %			
			None	Very mild/mild	Moderate/severe*	Total*
Segreto et al, 1980 ²³	7-18	1962-79	74.6	25.4	0.0	25.4
Driscoll et al, 1980 ²⁰	8-16	1964-78	94.1	5.9	0.0	5.9
Leverett, 1981 ²²	7-17	1964-80	95.6	-†	-†	4.4
Szpunar and Burt, 1986 ²⁴	6-12	1974-86	87.8	12.2	0.0	12.2
Woolfolk et al, 1987 ²⁸	9-13	1974-84	77.7	22.4	0.0	22.4
Ismail et al, 1987 ²⁹	11-17‡	1970-82	68.9	-†	-†	31.1
	11-17§	1970-82	69.9	-†	-†	30.1
Hargreaves et al, 1987 ³⁰	6-13	1974-87	85.0	-†	-†	15.0
Pendrys et al, 1988 ³¹	11-14	1974-83	74.8	-†	-†	25.2
Ismail et al, 1991 ²⁶	10-12	1979-87	58.5	-†	-†	41.5
Clark et al, 1991 ²⁷	6-14	1977-91	45.0	48.0	7.0	55.0

*Presented to enable comparison with future data and with Table 1. Adapted from Clark.¹

†Cases were not classified according to severity.

‡Students in public schools.

§Students in private schools.

sources of fluorides (water, foods and dentifrices) it could increase the amount ingested to above optimal levels.

A literature review revealed that children under 6 years of age ingest a significant amount of fluorides from dentifrices (Table 3). The mean amount of fluoride ingested per brushing is 0.40 mg for a 2-year-old child and 0.18 mg for a 3-year-old child.^{2,7} Given that a 2-year-old may brush twice a day, the mean intake per child from dentifrice alone could meet the optimal daily requirement.² Similarly, the mean amount of fluoride ingested from dentifrice may be 0.12 mg per brushing for children 6 to 7 years of age or 0.39 mg per brushing for children 3 to 6. Again, if children brush twice daily these levels could account for a considerable proportion of the optimal daily requirement.^{2,7}

A greater concern is the range of fluoride ingested. Levy² suggested that a significant number of children exceed their optimal daily requirement through the use of dentifrice alone.

How effective is each therapy in preventing dental caries?

The workshop participants evaluated fluoride supplementation and fluoridated dentifrices to determine their effectiveness in preventing dental caries. (As noted above, water fluoridation was evaluated and considered the foundation of all fluoride therapy.) Effectiveness is the extent to which a specific intervention does what it is intended to do for a defined population; efficacy is the extent to which an intervention produces a beneficial result under ideal conditions.³⁸ The effectiveness of fluoride therapies is the aspect of interest to practitioners. For example, the workshop participants acknowledged that fluoride supplements are efficacious but not particularly effective because of compliance problems.³

Fluoride supplementation

The most significant change in recommendations to emerge from the workshop concerned fluoride supplementation. Traditionally, fluoride supplements have been recommended for all children living in areas where the water supply is not fluoridated.

The workshop participants recommended the following for children in areas with less than 0.3 ppm fluoride in the water.

- The use of chewable fluoride supplements may be appropriate for targeted individuals and groups of children 3 years and older.

- For children 3 to 6 years of age the recommended dosage is 0.25 mg of fluoride per day, unless the child is not using fluoridated toothpaste regularly, in which case the dosage is 0.5 mg/d.

- Children 6 years and older should receive a supplement of 1.0 mg/d.

These changes mean that children living in areas with fluoridated water or those under 3 years of age who have been advised to use supplements or are now using them should be instructed to stop. Faced with the difficult prospect of changing established practice and explaining this change to patients, practitioners require a clear understanding of why this change is needed.

To address these considerations practitioners should review how supplements work, how effective they are and whether they put children at risk for dental fluorosis. First, since the preventive effect from fluorides occurs primarily after the teeth erupt, the use of supplements starting at 3 years of age will still afford significant preventive effects. What exactly might preventive fluoride supplementation mean given the current prevalence of dental caries? For example, in a recent study the average 12-year-old in an area with nonfluoridated water had about six decayed or filled tooth surfaces.³⁹ On the basis of this level of dental caries and Groeneveld and associates' estimate of fluoride effectiveness before and after tooth eruption,¹⁸ the efficacy of a supplementation regimen started at birth could reduce this child's incidence of dental caries to about three decayed or filled tooth surfaces, whereas supplement use from 3 years of age would reduce it to about four tooth surfaces.

When compliance is considered, how effective is fluoride supplementation? Ismail³ noted that "use of fluoride supplements by young children is idiosyncratic and all of the studies which investigated the effectiveness of this regimen suffered from a significant drop in the number of participants receiving daily supplements." He further noted that "the scientific evidence supports the

Table 3: Dentifrice usage and ingestion by young children (per tooth brushing)*

Age, yr	Mean amount of dentifrice used, g	Mean % of dentifrice ingested	Mean fluoride intake, mg
2	0.62	65	0.40
3	0.50	36	0.18
4	0.45	49	0.22
6-7	0.44	27	0.12
7	0.50	34	0.16

*Adapted from Levy.²

efficacy of fluoride supplements but there is weaker support for their effectiveness in caries prevention." Both conclusions are supported by recent Canadian findings.³⁹ Parents who are most compliant with supplementation regimens may not be those whose children require the benefits of fluoride most, namely parents with low socioeconomic status living in areas with nonfluoridated water. Furthermore, the compliant parents are most likely to comply as well with daily brushing routines. It is exactly these compliant parents and their children who concerned workshop participants. Participants asked, will the small group of children who receive supplements before the age of three benefit from supplementation and are they at risk of dental fluorosis?

The evidence suggests that they will benefit very little.³ Concerning the risk of dental fluorosis for such children Ismail³ felt that the prevalence and severity of dental fluorosis may be affected by all fluoride ingestion during the period of calcification of the teeth. Also, "overall, fluoride supplements contribute little to total fluoride intake because of the small number of children using these products." He goes on to say, however, that use of fluoride supplements with fluoridated dentifrices and infant formula is associated with the occurrence of dental fluorosis. Thus, although few parents administer supplements to their children in the long term, if they do their children will probably have dental fluorosis. Evidence from numerous studies supports this conclusion.^{29,31,40-43}

The question then remains, if a child needs fluoride supplementation can the risk of dental fluorosis be reduced? Evans and Stamm⁴⁴ suggested that the developing maxillary anterior teeth are most susceptible to dental fluorosis between the ages of 18 and 26 months. Therefore, if fluoride supplementation begins at 3 years of age its full benefits will be realized, and the risk of dental fluorosis of the maxillary anterior teeth will be reduced significantly.

Further, it is likely that parents who give their children supplements also brush their children's teeth and coincidentally contribute to additional fluoride intake (Table 3). This likelihood provides support for eliminating supplementation for children less than 3 years of age.

However, why should we replace a therapy that provides a consistent and well-controlled dosage with one (fluoride dentifrice) that fails to control fluoride intake to the same extent? The foregoing discussion suggests that most children brush with a fluoride toothpaste, whereas compliance with supplementation is poor. If we continue to recommend supplements for children under 3 years of age, then those who comply and also use fluoride toothpaste will be at significant risk of dental fluorosis. Most parents should be encouraged to prevent dental caries only by brushing their children's teeth with a fluoride dentifrice.

In summary, workshop participants acknowledged

that the use of fluoride supplements in the new recommended dosage will probably result in a reduction in the prevalence of dental fluorosis in all classifications and a small increase in the incidence of caries in a small segment of school-aged children.

Although these Canadian recommendations on fluoride supplementation are more restrictive than those proposed in the United States⁹ they are validated by agreement with new European guidelines. Participants in a similar European meeting, results of which were published 1 month after the Canadian workshop, recommended that supplements be started at age 3 for high-risk children only.⁴⁵ Without any prior knowledge of the European conclusions, the Canadian group had revised the recommendations for supplementation in an almost identical way.

Fluoride dentifrices

Investigations of the effect on dental caries prevention of reducing the fluoride concentration in dentifrices have generally shown a dose response. In other words, for toothpastes with a reduced fluoride concentration, the caries-preventive effect seems to be diminished.^{46,47} However, a recent study involving young children did not show any difference in caries prevention between regular-strength and low-strength fluoride toothpastes.⁴⁸ In the future, a low-concentration dentifrice may be recommended for children under 6 years of age.

Virtually all dentifrices sold in Canada contain fluoride.⁷ Fluoride dentifrices have had a significant influence in the decline in the incidence of caries; however, it is difficult to quantify their effects or to separate them from those of fluoridated water.⁷ Fluoride dentifrices have clearly played a significant role in the increasing prevalence of dental fluorosis.^{2,3,7}

Recognizing the potential risk of dental fluorosis from the use of fluoride dentifrices, the workshop participants recommended that children under 6 years of age brush with a fluoride dentifrice twice a day, supervised by an adult. A "pea-sized" amount of toothpaste (or a single ribbon/strip of dentifrice not to exceed half the length of the head of a child-sized toothbrush) should be dispensed, preferably by the supervising adult. Swallowing should be discouraged (after brushing spit out, rinse with water and spit out the rinse).

The participants agreed that these recommendations alone may not remedy the problem of excessive fluoride intake. Therefore, the introduction of low-concentration dentifrice systems may eventually become necessary.

Considerable discussion focused on controlling fluoride ingestion from all sources. As part of a continuing re-evaluation, Health Canada has asked a panel of experts to study the question of fluoride ingestion with a view to recommending a total daily intake of inorganic fluoride that will maximize its benefits and minimize the risk of dental fluorosis. All fluoride sources will be con-

sidered in this review. It seems likely that there will be further recommendations on fluorides of interest to practitioners.

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