

# THE FLUORIDE DIALOGUE: CDHA POSITION STATEMENTS

By The Canadian Dental Hygienists Association

## INTRODUCTION

Historically, the Canadian Dental Hygienists Association (CDHA) has not developed a fluoride position relating to oral health promotion and disease prevention. However, as experts in disease prevention and health promotion, dental hygienists champion issues that are in keeping with these approaches. This paper presents a summary of the fluoride research that assisted the CDHA Board of Directors in developing fluoride position statements. The report presents the arguments and assesses the evidence on the positive and negative effects of fluoride use.

The report is based on an Internet search of fluoride research and policy position statements of various government and oral health organizations. The question of fluoride effectiveness is explored primarily by reviewing meta-analysis research, which is a collection of statistical methods designed to examine and summarize a series of investigations. Papers are included in the meta-analysis when they meet well-defined methodological selection criteria. Appendix A contains the grading system used in the meta-analysis for determining the quality of research and the strength of the recommendations. It is based on the United States Preventive Services Task Force's *Guide to Clinical Preventive Services*.<sup>1</sup> The report also includes individual research studies.

There are two opposing arguments in the fluoride debate. On the one hand, fluoride proponents claim that fluoridated water and the addition of fluoride to oral health products such as gels, varnishes, rinses, dentifrices, and supplements reduce the caries rates. They argue that, without optimal exposure to fluoride, the level of public oral health would deteriorate significantly. On the other hand, fluoride opponents claim it does not reduce dental caries and has a detrimental impact on general health.

The research and articles referred to in this paper are collated into fluoride information binders for future reference. The report did not examine the following areas since these considerations were outside the scope of the review: environmental and ecological impacts, legal issues, floss impregnated with fluoride, chewing gum containing fluoride, and intra-oral fluoride-releasing devices.



## WHAT IS FLUORIDE?

In 1996, Health Canada changed the classification of fluoride from an element that is essential for growth and reproduction to an element that has a “beneficial effect on dental caries.”<sup>2</sup> The Food and Nutrition Board of the National Academy of Sciences – National Research Council (NAS/NRC) expresses a stronger view of fluoride’s anti-caries properties when it states, “fluorine is essential for the prevention of dental caries and possibly osteoporosis.”<sup>3</sup>

## FEDERAL AND PROVINCIAL RESPONSIBILITIES

At the federal level, Health Canada endorses the fluoridation of drinking water but does not participate in the decision to fluoridate water supplies. Usually the provincial and territorial governments in conjunction with municipalities make this decision. In March 2001, the federal, provincial, and territorial governments developed a *Summary of Guidelines for Canadian Drinking Water Quality*<sup>4</sup> that indicates the **maximum acceptable concentration (MAC)** of fluoride in drinking water is 1.5 mg/L. In 2002, Health Canada reported that an **optimal fluoride concentration** of 0.8 to 1.0 mg/L of fluoride concentration is recommended for water supply.<sup>5</sup> In addition, Health Canada has established labelling requirements for dental products containing fluoride and has limited the amount of fluoride that can be added to bottled water or pre-packaged ice under the Food and Drugs Act.<sup>6</sup>

## FLUORIDE MECHANISMS OF ACTION

Researchers' understanding of fluoride mechanisms of action in reducing dental caries has changed over time. Although it was initially thought that fluoride was effective through its incorporation into enamel before the teeth erupted, thereby reducing the solubility of the enamel, this effect is likely to be minor. Instead, its primary mechanism of action is post-eruptive. It is now understood that topical application or the constant supply of fluoride in the mouth is the most important factor in preventing dental decay.<sup>7</sup>

Fluoride has five principal topical mechanisms of action:

- It inhibits demineralization or protects the tooth against acids that dissolve tooth minerals.<sup>8</sup>
- It promotes remineralization of tooth enamel that has been demineralized by acids that cause tooth decay. Tooth decay is a result of mineral loss in teeth and fluoride helps to replace these minerals.<sup>9,10,11</sup>
- It inhibits bacterial metabolism or enzyme activity in dental plaque by reducing the ability of plaque organisms to produce acid that causes tooth decay. Fluoride stops the bacteria from producing acids that cause tooth decay.<sup>12</sup>
- It aids in post-eruptive maturation of enamel.<sup>13</sup>
- It reduces enamel solubility.<sup>14</sup>

## SOURCES OF FLUORIDE

Canadians are exposed to fluorides in food, water, dental products, soil, and the air. Dental products contain two forms of fluoride, topical and systemic. Topical fluorides act on the teeth already present in the mouth and include toothpastes, mouth rinses, and professionally applied fluoride gels, varnishes, and rinses. At least 95 per cent of toothpastes in North America contain fluoride, making it the most commonly used fluoride-containing dental product.<sup>15</sup> Systemic fluorides are ingested into the body and become incorporated into forming tooth structures; systemic fluorides also give topical protection. They include fluoride found in supplements, water supplies, food, and beverages.

Some fluorides occur naturally in rocks and soil and are released into the environment by weathering processes and volcanic activity. In addition, approximately 23,500 tons are released into the Canadian environment each year from human activities, such as phosphate fertilizer production, aluminum smelting, and chemical manufacturing.<sup>16</sup> This amount does not include fluoride that is added to drinking water. All vegetation and virtually all foods contain at least trace amounts of fluorides. Foods that contain the highest levels of fluorides include fish, shellfish, meat, and tea.<sup>17</sup>

## FLUOROSIS

Dental fluorosis is a permanent hypomineralization of tooth enamel due to a fluoride-induced disruption of tooth development.<sup>18</sup> In the mildest forms, the outer layer of enamel is affected, producing white opaque lines across the tooth surface. Bleaching with 10 per cent carbamide peroxide can treat this.<sup>19</sup> In more severe forms, deeper layers are affected and the enamel becomes porous and has a chalky white appearance. Chewing erodes the surface enamel, producing pits that

become stained. Significant enamel erosion due to fluorosis can lead to tooth pain and impairment of chewing ability and require complex restorative procedures.<sup>20</sup> These may include placing resin or porcelain veneers or crowns on the teeth.

Healthy adults excrete about 90 per cent of the fluorides they consume. Young children, however, may retain up to half of the fluorides they ingest, storing it in the skeleton and the teeth.<sup>21</sup> Enamel fluorosis can occur when young children ingest higher than optimal amounts of fluoride, from any source, during the period of tooth formation. Some researchers consider the risk for enamel fluorosis to be limited to children up to five to six years of age, following development of the maxillary central incisors;<sup>22</sup> others consider the risk to be for children up to the age of eight, when the posterior teeth have developed.<sup>23</sup>

Over time, studies show an increase in the rate of fluorosis. A 1993 study shows the amount of very mild and mild fluorosis was quite high, 15 to 60 per cent, in both fluoridated and non-fluoridated communities in Canada and the amount of moderate fluorosis was still very low.<sup>24</sup> However, a recent study conducted between 1999 and 2000 reports that 14 per cent of 7-year-olds and 12.3 per cent of 13-year-olds in Toronto had moderate dental fluorosis.<sup>25</sup> In 1994, C. Clark conducted a literature review and found the prevalence of dental fluorosis is now between 35 and 60 per cent in fluoridated communities and between 20 and 45 per cent in non-fluoridated areas. While the increase in this study represents primarily very mild and mild fluorosis, there is also some evidence that the prevalence is increasing in the moderate and severe classifications as well.<sup>26</sup> A 1999 federal-Ontario report shows very mild and mild dental fluorosis has increased to 20 to 75 per cent in fluoridated communities and 12 to 45 per cent in non-fluoridated communities.<sup>27</sup> Finally, a meta-analysis from the NHS Centre for Reviews and Dissemination (NHS CRD) at the University of York, England, reports approximately 48 per cent of the population shows fluorosis at fluoridation levels of 1.0 ppm; however, the studies were of low quality, level C (see Appendix B).<sup>28</sup>

Silva and Reynolds agree that fluorosis has increased in both optimally fluoridated and non-fluoridated areas in the United States and Australia.<sup>29</sup> This may be attributed to the "halo" effect, in that drinks and foods that manufactured in fluoridated areas using fluoridated water are also available in non-fluoridated areas.<sup>30</sup> It may also be due to increased availability of fluoridated dental products, inadvertent ingestion of fluoride toothpaste, and the inappropriate use of dietary supplements.<sup>31</sup>

Knowledge of the halo effect and the increase in dental fluorosis have prompted studies on the total intake of fluoride to determine the benefits and risks. In 1994, Levy conducted a study on children's intake of fluoride from all sources, including food, beverages, fluoride dentifrice, and dietary fluoride supplements. Mouth rinses and professionally applied topical fluorides were not included. A calculation of the mean daily ingestion of fluoride shows that some children probably ingest sufficient fluoride from a single source that exceeds the optimal fluoride intake recommended from all sources and they are therefore at risk for fluorosis.<sup>32</sup>

A study by Jones, Riley, Couper, and Dwyer also examined total intakes of fluoride in Canada. The report indicates that children aged seven months to four years consuming the maximum dose (water fluoridated at 1.6 ppm) are at risk of moderate levels of dental fluorosis and are consuming amounts

only 20 per cent less than that at which skeletal fluorosis is possible, if maintained over long periods of time.<sup>33</sup>

Optimum exposure to fluoride is expressed in milligrams per kilogram of body weight and is based on the amount of fluoride necessary to obtain a maximum reduction in caries with a minimum occurrence of dental fluorosis. Some researchers estimate optimum exposure is 0.05 to 0.07 milligrams per kilogram of body weight per day;<sup>34</sup> others suggest that it may be an even lower level of 0.03 to 0.04.<sup>35</sup> The Canadian Dental Association points out that the threshold at which fluoride causes dental fluorosis is not known precisely but has been estimated at 0.10 mg fluoride/kg body weight, and the most frequently used standard of 0.05 to 0.07 mg fluoride/kg body weight has generally been accepted as the upper limit intake for minimizing dental fluorosis.<sup>36</sup>

A number of recent studies indicate that the increase in fluorosis may be due to the ingestion of infant formula prepared with fluoridated water. Fluoride intake is nil for infants receiving formula prepared with non-fluoridated water; however, infants receiving formula prepared with fluoridated water may be ingesting 0.08 milligrams per kilogram of body weight per day.<sup>37</sup> These infants are clearly receiving higher than optimal levels of fluoride in their diet.

In 2001, the Centers for Disease Control and Prevention (CDC) in the United States reported two studies confirming that consumption of infant formula beyond the age of 10 to 12 months is a risk factor for enamel fluorosis, especially when formula concentrate was mixed with fluoridated water.<sup>38</sup> Similar results were found in an Australian study that concludes prolonged consumption beyond 12 months of age of infant formula prepared with optimally fluoridated water may be a risk factor for dental fluorosis.<sup>39</sup> Levy, Kiritsy, and Warren reviewed a number of studies of fluoride intake in children and concluded that the fluoride content of foods and beverages, particularly infant formulas and water used in their reconstitution, should be monitored closely in an effort to limit excessive fluoride intake.<sup>40</sup> In a 1993 study of 350 children from birth to age four years, similar concerns were raised regarding the consumption of infant formula. This study concludes that the elimination of fluoride from infant formula would contribute significantly to reducing the prevalence of fluorosis.<sup>41</sup>

Health Canada reports that higher than optimal levels of fluorides consumed for a very long period of time may lead to skeletal fluorosis.<sup>42</sup> Skeletal fluorosis is a progressive disease in which bones increase in density and become more brittle. In mild cases, the symptoms may include pain and stiff joints. In more severe cases, the symptoms may include difficulty in moving, deformed bones, and an increased risk of bone fractures.

## WATER FLUORIDATION

In the 1930s, initial observations that people living in communities served by naturally fluoridated water had lower dental caries led to the prevention studies of the 1940s and 1950s that compared communities with fluoridated water to control communities with trace amounts of fluoride. The success of these studies led to the widespread adoption of community water fluoridation in the United States.<sup>43</sup>

In Canada, there is a wide disparity in access to fluoridated water across different populations and geographical locations.

Although an estimated 40 per cent of Canadians are now exposed to fluoridated water,<sup>44</sup> less than 10 per cent of First Nations people living on reserves are exposed to fluoridated water.<sup>45</sup> There is also a great disparity between provinces regarding access to fluoridated water. For example, British Columbia has the lowest rate in Canada, at 6 per cent of the population, while 78 per cent of Alberta's population has access.<sup>46</sup> In the United States, about 145 million people or 62 per cent of the population served by public water supplies consume fluoridated water.<sup>47</sup>

The American Dental Association estimates the cost of water fluoridation at 50 cents (US\$) per person per year in an average community.<sup>48</sup> Similar findings are reported in a 1992 study that estimates the cost at 31 cents (US\$) per person per year in communities in the United States with populations of more than 50,000, to a mean of \$2.12 (US\$) per person in communities with fewer than 10,000.<sup>49</sup> Health Canada reports that the costs for water fluoridation are approximately \$1 per person per year.<sup>50</sup> The CDC estimate the per capita cost savings from one year of fluoridation range from negligible amounts in low caries risk communities to \$53 (US\$) among communities with a high risk of caries.<sup>51</sup>

Nearly 100 national and international organizations and governments endorse the fluoridation of drinking water to prevent dental decay, including the Canadian Public Health Association, the Canadian Dental Association, the Canadian Medical Association, the World Health Organization, the Canadian Paediatric Society, the American Medical Association, the International Association for Dental Research, and the American Dental Association.<sup>52,53,54,55,56,57</sup>

Statements from a number of organizations and government departments show unequivocal support for water fluoridation. The CDC state, "water fluoridation is one of the great public health achievements of the twentieth century, and it is a major factor responsible for the decline in dental caries during the second half of the 20th century."<sup>58</sup> The Canadian Dental Association expresses a similar sentiment with the following statement: "The appropriate use of fluorides in the prevention of dental caries is one of the most successful preventive health measures in the history of health care."<sup>59</sup> The United States Surgeon General's report of 2000, *Oral Health in America*, states "community water fluoridation is an effective safe public health measure that benefits individuals of all ages and socioeconomic strata."<sup>60</sup> Finally, Health Canada states "current scientific data indicate that communities with a dental decay rate (DMFT/deft rate) of 3.0 per six-year-old child would benefit from implementation of a community fluoridation system."<sup>61</sup>

Although this shows strong support primarily within Canada and the United States, internationally the picture is somewhat different. There are approximately as many countries advocating fluoridation to address dental caries as there are countries rejecting it. Water fluoridation proponents point out that water fluoridation is used not only in Canada and the United States but also in Australia, Brazil, Hong Kong, Malaysia, the United Kingdom (England, Scotland, and Northern Ireland), Singapore, Chile, New Zealand, Israel, Columbia, Costa Rica, South Africa, and Ireland.<sup>62</sup> Water fluoridation opponents point out that 98 per cent of Western Europe has rejected water fluoridation, including Germany, France, Belgium, Luxembourg, Finland, Denmark, Norway, Sweden, the Netherlands, Austria, and the Czech Republic.<sup>63</sup>

There are numerous domestic and international epidemiolog-



ical studies verifying the efficacy of water fluoridation. The report *Oral Health in America* identifies a number of studies from the last five decades supporting the effectiveness of water fluoridation in preventing coronal and root caries in children and adults.<sup>64</sup> This report identifies two large reviews of fluoride research. The first review of 95 studies, conducted between 1945 and 1978, found that caries were reduced by 40 to 50 per cent for primary teeth, and 50 to 60 per cent for permanent teeth.<sup>65</sup> Studies in the United States, Australia, Britain, Canada, Ireland, and New Zealand also demonstrate the effectiveness of water fluoridation. These studies show reductions in dental caries range between 15 and 40 per cent in the fluoridated communities compared with the non-fluoridated.<sup>66</sup>

The American Dental Association publishes a fluoridation facts information sheet highlighting the results of 113 water fluoridation studies in 23 countries. The most frequently reported decay reductions observed were 40 to 49 per cent for primary teeth and 50 to 59 per cent for permanent teeth.<sup>67</sup> This publication also mentions a second review of studies conducted from 1976 to 1987. Reduction rates in fluoridated communities were 30 to 60 per cent in the primary dentition, 20 to 40 per cent in the mixed dentition, and 15 to 35 per cent in the permanent dentition.<sup>68</sup>

The following six studies examine the efficacy of water fluoridation and health benefits and risks. In September 2000, the NHS CRD published a meta-analysis of water fluoridation studies. The report used international studies including 45 before-and-after studies, 102 cross-sectional studies, 47 ecological studies, 13 cohort studies, and 7 case-control studies. The studies were rated for quality using a level A, B, and C hierarchy (see Appendix B). They suggest that water fluoridation does reduce caries in children and withdrawal of it from water supplies results in an increase in caries rates.<sup>69</sup> The report concludes that it is difficult to interpret from this data the degree to which water fluoridation works, since the studies were of moderate quality (level B), and of limited quantity.<sup>70</sup> In addition, early studies lacked appropriate analysis.<sup>71</sup> Statistical research analysis has developed significantly over time, limiting the usefulness of the older results. In addition, in later studies the estimates of effects could be biased due to poor adjustment for the effects of potential confounding factors. The report also suggests water fluoridation reduces the differences in severity of tooth decay between classes among 5- and 12-year-old children. However, the report cautions that this topic needs further clarification, since the evidence was based on level C studies (see Appendix B).<sup>72</sup>

The negative effects of fluoride were also examined. No link was found between water fluoridation and bone fractures or cancers; however, these studies were primarily low quality, level C (see Appendix B).<sup>73</sup> Overall, the NHS CRD report found a lack of high-quality research in the area of water fluoridation. In addition, because of the potential toxicity of very high doses of fluoride, the report called for research that measures total fluoride exposure including fluoride obtained through sources such as water, food, toothpaste, and gels.

Cohen and Locker arrive at conclusions similar to the NHS CRD report regarding the quality of fluoride research. Following a review of three studies from 1999 to 2000, they conclude that although current studies indicate that water fluoridation continues to be beneficial, the quality of the evidence is poor.<sup>74</sup> They also indicate, “studies of the benefits to

adults are largely absent, and there is little evidence that water fluoridation has reduced social inequalities in dental health.”<sup>75</sup> Finally, they argue that, in the absence of high-quality evidence for the benefits of water fluoridation, advocating for water fluoridation could perhaps be considered immoral.<sup>76</sup>

In 1999, Health Canada and Environment Canada conducted a meta-analysis of 50 international water fluoridation studies and concluded there is no consistent evidence of an association between the consumption of “fluoridated” drinking water and increased morbidity due to cancer.<sup>77</sup> However, since conclusions were based on ecological or geographical correlation studies, their limitations preclude them from providing conclusive evidence for or against an exposure-response relationship.<sup>78</sup>

In 2001, the Centers for Disease Control (CDC) conducted a meta-analysis of the published research on community water fluoridation and found that the quality of evidence from the studies is rated at Grade II-1 (see Appendix A), defined as evidence obtained from one or more controlled clinical trials without randomization. It should be noted that it is not possible to design a randomized community water fluoridation clinical trial, which is rated as the highest-grade study, since the whole community is exposed to the fluoridated water. Although water fluoridation studies cannot receive a Grade I rating, the CDC report that research limitations are counterbalanced by broadly similar results from numerous well-conducted field studies with thousands of persons throughout the world.<sup>79</sup> In conclusion, the CDC recommend community water fluoridation for all populations and the strength of this recommendation is given a Grade A code, the highest code (see Appendix A).

Although the CDC support community water fluoridation, they also call for a re-evaluation of the method of determining optimal fluoride concentration of community drinking water, since the present method depends on the average maximum annual ambient air temperature and does not take into account the recent social and environmental changes that have occurred.<sup>80</sup> In addition, the CDC support additional research into consumption patterns of water, processed beverages, and processed foods.

In 1999, the federal and Ontario governments produced a joint report providing an update on the 1996 Federal-Provincial Subcommittee Report concerning fluoride in the water supply. This report reviews numerous studies, published between 1994 and 1999, on the risks and benefits of fluoridation and makes the following four significant conclusions.<sup>81</sup> Although current studies of the effectiveness of water fluoridation have design weaknesses and methodological flaws, tooth decay is found to be less common in communities where there is fluoridation. However, “the magnitude of the effect is not large in absolute terms, is often not statistically significant and may not be of clinical significance.” It also concludes, “Canadian studies do not provide systematic evidence that water fluoridation is effective in reducing decay in contemporary child populations.” In addition, water fluoridation withdrawal studies do not suggest significant increases in dental caries.

This report makes the following additional conclusions and recommendations.<sup>82</sup> There are inconsistent findings in relation to the contribution of fluoride to the treatment of osteoporosis. Fluoride toxicity cannot be achieved by drinking fluoridated water. Additional bone fracture research with bet-

ter designs is needed. There is no link between fluoridated water and cancer, lowered IQ level, and skeletal fluorosis. The main recommendation is that further research is needed to assess the balance between reductions in decay and increases in dental fluorosis. The report argues that more information is needed on the actual advantages to quality of life from fluoridation and that “the absence of this data undermines the credibility of water fluoridation as a public health initiative.”

In 1999, Jones, Riley, Couper, and Dwyer conducted a qualitative overview of 18 population studies examining the association between water fluoridation and fracture risk at a population level. The overview concludes that water fluoridation both at levels aimed at preventing dental caries and, possibly, at higher naturally occurring levels appears to have little effect on fracture risk, either protective or deleterious.<sup>83</sup> However, the authors suggest that further research is required to confirm these findings in large studies on individuals, not just populations.

A number of studies suggest that due to the halo effect, the usefulness of water fluoridation alone is now difficult to determine since there are a number of other sources of fluoride. Lewis and Banting’s 1994 study concludes that compared with early fluoridation studies, the differences in dental caries and fluorosis prevalence between fluoridated and non-fluoridated areas have narrowed markedly.<sup>84</sup> They recommend that, since water fluoridation has distribution, equity, compliance, and cost-effectiveness advantages, the other sources of fluoride should be examined for changes in fluoride content. A 2001 study arrives at similar conclusions: multiple sources of fluoride besides water fluoridation have made it more difficult to detect changes in the epidemiological profile of a population with generally low caries experience.<sup>85</sup>

### Water fluoridation opponents

The Fluoride Action Network, one of the largest organizations opposing water fluoridation, posted a web site article by Dr. P. Connett, “50 Reasons to Oppose Fluoridation.”<sup>86</sup> Highlights of the arguments follow:

- The accumulation of fluoride, which is poisonous in high doses, is of concern for the following reasons: only 50 per cent of ingested fluoride is excreted through the kidneys;<sup>87</sup> it is impossible to control the amount of water ingested; intake varies widely from one individual to another; and there are many other sources of fluoride, including food, beverages, and dental products.
- Most Western European countries are not fluoridated and according to the World Health Organization’s study on levels of tooth decay in Europe, United States, New Zealand, and Australia, they have experienced the same decline in dental decay as the United States.<sup>88</sup>
- The largest survey conducted, by the United States’ National Institute of Dental Research (now the National Institute of Dental and Craniofacial Research), with over 39,000 children, showed little difference in tooth decay among children in fluoridated and non-fluoridated communities.<sup>89</sup>
- Three studies are cited showing that when water fluoridation has been discontinued in communities in Canada, Germany, Cuba, and Finland, dental decay has not increased, but decreased.<sup>90,91,92</sup>

- Since fluoride’s benefits are mainly topical, not systemic, it doesn’t have to be swallowed to protect teeth and it makes more sense to deliver the fluoride directly to the tooth in the form of toothpaste.
- The United States’ fluoridation program has failed to achieve one of its key objectives—to lower dental decay rates while minimizing dental fluorosis.
- Fluoride use is associated with chromosome damage, enzyme activity disruption in the area of DNA repair and the reproductive system, hormonal and neuro-chemical interference, bone cancer, increased susceptibility to hip fractures, and reduced thyroid gland activity.<sup>93</sup>
- Despite evidence that fluorosis is increasing and we are exposed to far more fluoride in 2000 than we were in 1945 when fluoridation began, the optimal fluoridation level is still 1 part per million, the same level deemed optimal in 1945.<sup>94</sup>
- Fluorosilicic acid is the chemical used for the fluoridation of drinking water in more than 90 per cent of the major cities in the United States.<sup>95</sup> This chemical is a toxic waste byproduct from the phosphate fertilizer industry and contains heavy metals such as arsenic, a known carcinogen, as well as lead and mercury.<sup>96,97</sup>
- A study comparing different geographical areas in the United States found that the states with the highest percentage of their population using fluoridated water also had the highest percentage of edentulous elderly.<sup>98</sup> This means that fluoridation may not have protected against tooth loss, as intended. Limeback proposes two possible explanations for these results.<sup>99</sup> The first explanation is that the lead in fluorsilicic acid is deposited in the teeth and increases the risk for caries. A second explanation is that fluoridated water contributes to periodontal disease through a mechanism that has not yet been examined carefully.

### Bioethics

A discussion of the use of water fluoridation would not be complete without a discussion of bioethics and how it relates to water fluoridation. Cohen and Locker explore this topic and conclude that an unresolved conflict exists between the principles of beneficence and autonomy.<sup>100</sup> Advocates of water fluoridation argue that water fluoridation promotes social equity since it benefits everyone, regardless of socio-economic status. However, since it is impossible for individuals to opt out of water fluoridation, it takes away the freedom to choose. This violates the ethics principle of autonomy and may be regarded as “involuntary medication of populations.”<sup>101</sup> Dr. P. Connett also considers fluoridation unethical because individuals do not give their informed consent prior to medication.<sup>102</sup>

### FLUORIDE SUPPLEMENTATION

Fluoride supplements were initially introduced to provide fluoride to communities without water fluoridation. Unfortunately, these supplements were overprescribed<sup>103</sup> and a number of studies show a clear association between fluoride supplements and the risk of fluorosis.<sup>104,105</sup> In response to this, recent changes in the dosage schedule were recom-

mended. Further evaluation over time will determine the results from these changes.

CDC's 2001 literature review on fluoride supplementation makes the following recommendations:<sup>106</sup>

- Fluoride supplements are not recommended for pregnant women, since there is Grade I evidence of no benefit for their children.
- No specific recommendation is made for fluoride supplements for children younger than six years, since the research is significantly flawed.
- Fluoride supplements for high-risk children aged 6 to 16, in areas with fluoride-deficient drinking water, are supported by high-quality studies. The dosage requires consideration of other sources of fluoride including water (community fluoridated water and bottled water), toothpaste, or mouth rinse.

Health Canada makes the following recommendation for minimizing health risks in relation to fluoride supplements. No fluoride supplements should be given if fluoridated drinking water is consumed or if there is naturally occurring fluoride in the water supply.<sup>107</sup>

The Canadian Dental Association (CDA) re-visited their protocol on fluoride supplements for the following reasons: investigators presented sound arguments for restricting the use of fluoride supplements in children, due to fluorosis;<sup>108</sup> Health Canada's Medical Services Branch does not recommend fluoride supplements;<sup>109</sup> and there is a worldwide trend to lower fluoride supplement dosages to minimize the risk of dental fluorosis.<sup>110</sup> In March 2002, the CDA issued a new policy statement with the following significant changes.<sup>111</sup> First, fluoride supplementation is no longer recommended for children prior to the eruption of the first permanent tooth, since it will cause fluorosis of permanent teeth. Second, it cautions that levels of fluoride intake should be assessed prior to making a recommendation, given that exposure to more fluoride than is required can cause dental fluorosis. Chewable tablets/lozenges containing 1 mg fluoride are recommended for those at high risk for dental caries.

The CDA policy statement recommends that total daily fluoride intake from all sources should not exceed 0.05 to 0.07 mg F/kg body weight in order to minimize the risk of dental fluorosis.<sup>112</sup> Although CDA suggests assessing fluoride intake levels prior to recommending fluoride supplements, it explains there is difficulty establishing these levels. Swan confirms this difficulty and states, "this assessment may be unrealistic, given the widespread exposure to multiple sources of fluoride." He concludes that when a confident assessment is not possible, fluoride supplements should not be given.<sup>113</sup>

The United States Surgeon General's report supports dietary fluoride supplements for children in the absence of optimally fluoridated drinking water.<sup>114</sup> The report includes the following fluoride supplement dosage schedule, which is also supported by the American Dental Association, the American Academy of Pediatric Dentistry, the American Academy of Pediatrics, the American Dietetic Association, and the Canadian Paediatric Society (Table 1).<sup>115,116,117</sup>

**Table 1. Dietary fluoride supplement dosage schedule**

Age of child	Fluoride dosage (milligrams per day) at fluoride in water concentration of:		
	<0.3 ppm	0.3 to 0.6 ppm	>0.6 ppm
Birth to 6 months	None	None	None
6 months to 3 years	0.25	None	None
3 to 6 years	0.50	0.25	None
6 to 16 years	1.00	0.50	None

In 1997, the Canadian Consensus Conference on the appropriate use of fluoride supplements for the prevention of dental caries in children recommended the use of chewable tablets/lozenges containing 1 mg fluoride for those at high risk for dental caries and even this may be unnecessary if patients are receiving adequate fluoride from other sources.<sup>118</sup> The Conference defined the term "high risk for dental caries" as those individuals who do not brush their teeth (or have them brushed) with a fluoridated dentifrice twice a day or those who are assessed as susceptible to high caries activity because of community or family history, etc.<sup>119</sup>

The Conference participants developed the following decision-making protocol and schedule for fluoride supplement usage.<sup>120</sup> The schedule differs somewhat from the above schedule, since it does not recommend any fluoride supplements for individuals consuming fluoridated water at a 0.3 to 0.6 ppm level.

First ask the following question: Does the child brush his or her teeth (or have teeth brushed by parent or guardian) using fluoridated toothpaste at least twice a day? If the answer is no, then supplemental topical fluoride exposure should be provided according to the table below. If the answer is yes, then ask this question: In your judgment, is the child susceptible to high dental caries activity?

If your answer is yes, then supplemental topical fluoride exposure should be provided according to Table 2.

**Table 2. Dosage of daily fluoride supplement based on fluoride in water supply**

Age of child	<0.3 ppm	0.3 to 0.6 ppm	>0.6 ppm
0 to 6 months	None	None	None
>6 months to 3 years	0.25 mg/day	None	None
>3 years to 6 years	0.50 mg/day	None	None
>6 years	1.00 mg/day	None	None

The Canadian Dental Association's concern for the link between fluoride supplements and fluorosis is voiced by a number of researchers. Some researchers also question the use of fluoride supplements, given the low quality of the efficacy research. Ismail and Bandekar reviewed 14 studies on fluoride supplements during the first six years of life, in non-fluoridated communities, and found a consistent and strong association between the use of fluoride supplements and dental fluorosis.<sup>121</sup> B.A. Burt draws a similar conclusion when he states, "fluoride supplements should no longer be used for

young children.”<sup>122</sup> He argues that the risks of fluorosis outweigh the benefits, fluoride prevents caries principally through post-eruptive effects or through topical action, and the quality of efficacy research on fluoride supplements is poor and does not meet the standard for acceptable clinical trials.<sup>123</sup> Riordan reiterates this concern regarding the quality of the research when he states, “there are very few scientifically good clinical trials of fluoride supplements, and those that may be considered methodologically adequate suggest that the contribution of fluoride supplements to caries prevention is slight.”<sup>124</sup> The low rate of effectiveness Riordan claims may be due to the fact that fluoride is much more widely available today than in the past. He also notes that compliance with fluoride supplement recommendations is generally poor over longer periods of time, making it a poor public health measure. Finally, Ismail also questions the need for fluoride supplements, given the availability of optimal levels of fluorides in beverages in non-fluoridated communities.<sup>125</sup>

## TOPICAL FLUORIDES

### (varnishes, gels, foams, and rinses)

Clinical trials from the 1940s through the 1970s documented the benefits of professionally applied fluoride in reducing dental caries.<sup>126,127,128</sup> The use of topical fluorides is now recognized as effective by several prominent oral health organizations, including the American Dental Association<sup>129</sup> and the Canadian Dental Association.<sup>130,131</sup>

### Gels and varnishes

Although the United States Food and Drug Administration (FDA) has not approved fluoride varnish for use as a caries-preventive agent since appropriate clinical trial evidence has not been submitted showing its effectiveness as an anti-caries agent, it has been used in Canada and Europe since the 1970s to prevent dental caries.<sup>132</sup>

Five literature reviews supporting the use of gels and varnishes and recommendations for various application protocols are outlined below.

1. The CDC report high-quality evidence from five studies conducted between 1987 and 1996 in Canada and Europe that showed fluoride varnish is efficacious in preventing dental caries in high-risk children.<sup>133</sup> These studies show mixed evidence regarding the application protocols, with some claiming semi-annually is best, others four times per year, and others reporting that three applications in one week, once per year, are most effective.<sup>134</sup>
2. In 2001, the Ontario Community Dental Health Services Research Unit reviewed 25 studies on fluoride solutions, gels, and varnishes. The review was carried out initially since pit and fissure caries account for between 74 to 77 per cent of all caries lesions in children. However, professionally applied topical fluoride (PATF) is more effective against smooth surface caries than against pit and fissure caries.<sup>135</sup> Recommendations are as follows (see Appendix A for information on the grading system):<sup>136</sup>
  - Children with one or more decayed surfaces should receive PATF (Grade I, Code B).

- PATF should be provided on a biannual basis (Grade I; Code A).
  - When considering caries prevention efficacy, both acidulated phosphate fluoride (APF) gel and fluoride varnish are recommended (Grade I; Code A); however, APF gel is preferred to fluoride varnish (Grade I; Code B).
3. A review of fluoride varnish studies conducted between 1984 and 1991 showed no benefit from annual application; 23 per cent caries reduction rate with applications four times per year; and 46 to 67 per cent caries reduction rate with three applications in one week, once per year.<sup>137</sup>
  4. A meta-analysis of eight randomized clinical trials with children using Duraphat varnish showed similar findings, with a 38 per cent reduction in the decayed, missing, or filled surfaces or DMFS index.<sup>138</sup> The quality of the evidence is considered Grade I, the highest possible level of evidence (see Appendix A). The study also indicates that fluoride varnish may be a better choice for young children, since it is less likely than gel to be swallowed.<sup>139</sup>
  5. Four studies conducted between 1985 and 1991, using semi-annual treatments of four minutes in duration with fluoride gel and foam, caused an average decrease of 26 per cent in caries rates in the permanent teeth of children residing in non-fluoridated areas.<sup>140</sup> The American Dental Association also recommends semi-annual use.<sup>141</sup>

There are several studies providing support for the efficacy of PATF with a low pH level. A study by Cruz and Rolla shows that acidulated topical fluoride (2 per cent NaF solutions) with a pH of 3.5 was almost twice as effective in depositing calcium fluoride compared with acidulated topical fluoride with a pH of 5.5.<sup>142</sup> Similar results are reported in two other research studies by Rolla and Saxegaard<sup>143</sup> and Ogaard<sup>144</sup> who conclude that increased deposition of calcium fluoride can be obtained with a decrease in pH fluoride solution. A third study, which manipulated pH levels in sodium monofluorophosphate, found that by adjusting the pH to 4.0, an optimal reduction of enamel solubility was obtained.<sup>145</sup> Support for the pH 4.0 level is also found in four other studies that demonstrate its enhanced ability to produce fluoride uptake and anti-caries effectiveness.<sup>146,147,148,149</sup> Studies examining pH above 4.0 indicate that it compromises the enamel uptake of fluorides.<sup>150,151</sup>

Acidulated phosphate fluoride (APF) is not recommended for all types of teeth, as it can damage porcelain and composite restorations by causing dulling or etching.<sup>152,153,154,155</sup> It is also not recommended for those with reduced salivary flow or for those who cannot tolerate acidic fluorides (e.g., clients with bulimia).<sup>156</sup> In these cases, a neutral sodium fluoride solution, gel, or foam is recommended.

In contrast to the above findings, the following two studies indicate additional research may be needed on fluoride varnish and gels. In 2001, Bader, Shugars, and Bonito conducted a literature review of 27 studies and concluded that not enough is known to determine the efficacy of topical fluorides.<sup>157</sup> In addition, a 1998 meta-analysis of clinical studies on the caries-inhibiting effect of fluoride gel treatment in 6- to 15-year-old children concluded that from the standpoint of cost-effectiveness, the additional effect of fluoride gel treat-



ment in current low and even moderate caries incidence child populations must be questioned.<sup>158</sup>

In clinical practice, it is common to apply fluoride gel for one minute<sup>159</sup> and scientific evidence for the efficacy of this practice is found in one *in vitro* study using APF solutions.<sup>160</sup> However, the Centers for Disease Control report that, as of August 2001, the efficacy of this shorter time period has not been tested in human clinical trials.<sup>161</sup>

The CDC report that fluoride gel can be used with children under six years, since its infrequent application results in little risk for dental fluorosis and proper application technique reduces the possibility of clients swallowing the gel during application.<sup>162</sup> In addition, no published evidence indicates that professionally applied fluoride varnish is a risk factor for enamel fluorosis, even among children younger than six years.<sup>163</sup>

One literature review examined the appropriate conditions for topical fluoride application in periodontal therapy. It shows that the use of fluoride applications should be restricted to maintenance recall visits rather than at scaling, root planing, and surgical visits.<sup>164</sup> In particular, it recommends that fluoride should be avoided during root preparation in open-flap surgery, since fluoride may damage the healing ability of the periodontal tissues.

## Rinses

The following two studies point to the efficacy of self-applied fluoride rinses. The U.S. Surgeon General's report of 2000 indicates that 13 randomized controlled clinical trials were conducted between 1974 and 1998 on school-based fluoride mouth rinse programs for children in grades one and up. These trials found that caries reduction ranged from 20 to 50 per cent, firmly establishing the efficacy of 0.2 per cent solutions.<sup>165</sup> Although these programs were successful, the U.S. Surgeon General suggests they should now target only students at high risk for caries, since a declining prevalence of dental caries would reduce the cost-effectiveness of these programs. A CDC review of the literature also provides support for the use of rinses with high-risk populations.<sup>166</sup> The evidence quality was Grade 1, the highest rating and the strength of the recommendation was Code A, the strongest recommendation (see Appendix A).

In contrast to the above findings, a large National Preventive Dentistry Demonstration Program conducted in 10 cities in the United States from 1976 to 1981 questions the success of fluoride rinse programs. Fluoride mouth rinse was found to have little effect among schoolchildren, either among first-grade students with high and low caries rates or among all second- and fifth-grade students.<sup>167,168</sup>

The appropriate age for the introduction of rinses in children is explored in the following research. Although there are no studies of enamel fluorosis associated with the use of fluoride mouth rinses, there is a study showing that children aged three to five might swallow substantial amounts of fluoride mouth rinse.<sup>169</sup> Horowitz and Horowitz also raise concern that inadvertent swallowing of the fluoride rinse can cause acute fluoride toxicity in a child.<sup>170</sup> The fact that children younger than six are not at risk for enamel fluorosis suggests that fluoride mouth rinse may be appropriate for children older than six. A statement from Health Canada supports this starting age: "Children under six years of age should never be

given fluoridated mouthwash or mouth rinses, as they may swallow it."<sup>171</sup>

## DENTIFRICES

A Canadian Dental Association (CDA) Patient Information Sheet on Fluoride and Dentistry, dated 2001, states that fluoridated toothpastes are given continued recognition and support for their contribution to cavity prevention.<sup>172</sup> Dr. Hardy Limeback also supports fluoridated toothpaste when he states "the major reasons for the general decline of tooth decay worldwide, both in non-fluoridated and fluoridated areas, is the widespread use of fluoridated toothpaste, improved diets, and overall improved general and dental health."<sup>173</sup>

The CDC recommend the use of fluoride toothpaste, based on evidence from a review of 10 studies, each two to three years in duration, conducted from 1959 to 1996.<sup>174</sup> The review concludes that fluoride toothpaste reduces caries among children by a median of 15 to 30 per cent.<sup>175</sup> Although this reduction is modest compared with the effect found in some water fluoridation studies, the research was high-quality, Grade 1, Code A (see Appendix A).

Although the literature shows support for fluoridated dentifrice, it also suggests that the use of fluoride toothpaste by young children is a risk factor in fluorosis. The following are highlights of the reports indicating a connection between fluoride toothpaste use by young children and fluorosis.

- Three studies note the risk of fluorosis is higher if fluoride toothpaste is used in children younger than three years of age.<sup>176,177,178</sup>
- A 1997 study of infants 6, 9, and 12 months old shows that fluoride dentifrice use among infants can be a risk factor for dental fluorosis.<sup>179</sup>
- A 1997 study of 325 children concludes that toothpaste swallowing might be a factor in the production of fluorosis.<sup>180</sup>
- H.S. Horowitz draws our attention to several studies indicating that preschool-aged children inadvertently ingest sizable proportions of toothpaste during tooth brushing and that the findings of at least four studies support the dentifrice-fluorosis connection in young children.<sup>181</sup>
- A CDC review of eight studies, conducted between 1988 and 1998, found that children who begin using fluoride toothpaste below the age of two are at higher risk for enamel fluorosis than children who begin later or who do not use fluoride toothpaste at all.<sup>182</sup> This may be due to a swallowing reflex in this age group, particularly in children younger than three, that is less well controlled compared with children over the age of six.<sup>183,184</sup>
- Four studies showed a link between the use of fluoride toothpaste and dental fluorosis.<sup>185</sup> It should be noted that these studies suggest the risk of dental fluorosis from toothpaste is not as high as from fluoride supplements.
- Two studies indicate that the amount of fluoridated toothpaste ingested by young children may cause them to intake more than the upper limit established by the CDA, of 0.05 to 0.07 mg fluoride/kg body weight. For example, the CDC reviewed five studies<sup>186</sup> indicating that



children aged younger than six can inadvertently swallow as much as 0.8g of fluoride (800 mg). A similar concern is expressed by Burt who reports that children aged six months to three years who live in fluoridated areas and swallow some toothpaste once per day take in approximately 0.06 to 0.08 milligrams per kilo per day.<sup>187</sup>

There are a number of different methods currently employed for addressing the established link between ingested toothpaste and fluorosis. The United States Food and Drug Administration (FDA) responds by having toothpaste labelling requirements that direct parents of children younger than two to seek advice from a dentist or physician before using the toothpaste. The FDA also requires the following poison control label on fluoridated toothpaste: “If you accidentally swallow more than used for brushing, seek professional help or contact a poison control centre immediately.”<sup>188</sup> However, the American Dental Association objects to this label requirement and feel that the following labelling on all ADA-accepted toothpaste is adequate warning: “Do not swallow. Use only a pea-sized amount for children under six. To prevent swallowing, children under six years of age should be supervised in the use of toothpaste.”<sup>189</sup>

The Canadian Paediatric Society (CPS) suggests children should limit the amount of toothpaste used per brushing. They also suggest manufacturers including a warning about the dangers of excessive toothpaste use and sell tubes that make it more difficult to place excessive amounts of dentifrice on a toothbrush.<sup>190</sup> The CDA recommends children use only a small amount of toothpaste (the size of a pea) and avoid swallowing.<sup>191</sup> Similarly, the CDC recommends that children under age six should use only a pea-sized amount of fluoride toothpaste (0.25 g) and parents should consult their physician or oral health care practitioner concerning the use of fluoride under the age of two.<sup>192</sup> Health Canada recommends that children use no more than a pea-sized amount of toothpaste and be instructed not to swallow toothpaste. They also suggest that children under six years of age should be supervised while brushing, and children under the age of three should have their teeth brushed by an adult without using any toothpaste.<sup>193</sup>

Some researchers suggest that there may be benefits in developing child-strength toothpaste with lower fluoride concentrations, similar to those found in other countries including Australia and New Zealand.<sup>194,195</sup> The following study provides evidence that a slightly reduced concentration of fluoridated dentifrice shows no decreased efficacy. A three-year study in this area was conducted using a double-blind trial with more than 3,000 two-year-old children. Results from this study showed that toothpaste with 550 ppm fluoride had anticaries efficacy similar to that of the control toothpaste containing 1055 ppm fluoride.<sup>196</sup> The evidence of the efficacy of dentifrice with lower levels of fluoride prompted the CDC to agree that there may be benefits in a child-strength dentifrice.<sup>197</sup> H.S. Horowitz also calls for the production and marketing of fluoride toothpastes with 400–500 ppm fluoride for preschool-aged children, who are still at risk for developing fluorosis.<sup>198</sup> Similarly, a study of toothpaste use among 350 children, from birth to age four, concludes that a reduced fluoride concentration in toothpaste would contribute significantly to reducing the prevalence of fluorosis.<sup>199</sup>

## CONCLUSIONS

Over 50 years of extensive research worldwide has consistently demonstrated the efficacy of fluoride in preventing dental decay. As a result, numerous scientific bodies, oral health organizations, and government bodies have accepted the use of fluoride.

An understanding of fluoride’s mechanism of action has changed over time, from a belief that its beneficial effect was related to its systemic function, to an understanding of its primary topical action. This understanding is important in the use of fluoride as a disease prevention and oral health promotion measure, since it confirms that topical application of fluoride is of central importance in preventing dental decay.

Today, although there has been a decline in dental caries, “the burden of disease is still considerable in all age groups.”<sup>200</sup> It is vital that fluoride remains available to address this situation. There are, however, a number of challenges to the continued use of fluoride both as a public health measure and for individual use, including the issue of its safety.

## Water fluoridation

Since fluoride was first added to drinking water in the 1940s and 1950s, it has undergone scientific inquiry. Although some studies question the efficacy of water fluoridation, the balance of the evidence indicates that tooth decay is less common in communities with water fluoridation and the overwhelming majority of the health and scientific communities consider water fluoridation beneficial. The low cost for water fluoridation, combined with the estimated cost savings, make it a useful, cost-effective public health initiative.

The research indicates that reductions in dental caries ranged widely between 30 to 50 per cent in primary teeth and 15 to 60 per cent in permanent teeth in the fluoridated compared with the non-fluoridated communities. There is mixed evidence regarding the ability of water fluoridation to decrease the social inequities in dental health. While older research on fluoridated versus non-fluoridated communities shows a high level of caries reduction, the more recent studies show a lower caries reduction rate, likely due to the halo effect and increased use of fluoridated dental products. Research on communities where fluoride is withdrawn shows contradictory evidence. Some studies show an increase and others a decrease. One of the confounding factors in these studies may be the halo effect that is now making it difficult to properly assess the effects of water fluoridation.

There are several drawbacks to the efficacy research. Three of the large studies—by the NHS CRD, by Cohen and Locker, and the joint report by the federal and Ontario governments—indicate that the quality of the research is poor. The CDC are the only location to identify higher quality Grade II-1 research. Although the Surgeon General’s report does not identify the quality of the research, most of the research quoted is from 1945 to 1978, which suggests it is likely lacking in modern statistical methods of analysis. This concern for the quality of research warrants a call for further high-quality fluoride efficacy research.

There appears to be an increase in fluorosis in both fluoridated and non-fluoridated communities, with fluorosis rates at approximately 20 to 75 per cent in the former and 12 to 45 per cent in the latter. The evidence of the halo effect, the studies on total fluoride intake, the increased availability of fluo-

ridated dental products, and the link between fluoridated infant formula and fluorosis highlights the complexity of fluoride ingestion. There are two ways in which this evidence can be addressed while ensuring that both dental caries and fluorosis are reduced. First, an improved method is needed for determining the optimal fluoride concentration in community drinking water, which takes into account other sources of fluoride from air, food, and dental products. Second, parents should be instructed not to provide infants past the age of 12 months with formula made with fluoridated water.

Although fluoride opponents quote research showing fluoride is associated with a number of negative health effects, the balance of the evidence shows there is no link with health risks such as acute toxicity, skeletal fluorosis, and bone fractures. However, both the Health Canada and Environment Canada, and the NHS CRD reports indicated that the cancer research was limited, making it difficult to draw any definitive conclusions.

There is some evidence that the fluoride used in the United States public water systems may contain heavy metals. Although no research was found on the toxic content of the fluoride used in Canadian water systems, this information should be made available to the Canadian public.

### Fluoride supplements

A decision to use fluoride supplements should take into consideration the concern for fluorosis resulting from inappropriate use of fluoride supplements, as well as the evidence showing that the predominant cariostatic effect of fluoride is topical and that its effectiveness is not as clearly documented as other delivery systems. In addition, prior to a specific course of fluoride supplements, there should be an assessment of all sources of fluoride.

The literature reports a number of different dosage schedules for fluoride supplements. Due to a recent report of increased risk of fluorosis, it may warrant implementing the CDA's and CDC's recommendations for no supplements prior to the eruption of the first permanent tooth, at approximately six years of age. For all other high caries risk individuals, it may be prudent to use the more conservative schedule proposed at the Canadian Consensus Conference on the appropriate use of fluoride supplements, since it is more conservative compared with the Surgeon General's schedule.

### Topical fluorides

Although some controversy surrounds fluoride application protocols, the majority of the evidence shows that PATF use has a significant positive impact on the oral health of individuals who are at high risk for dental caries. PATF with a pH of 3.1 to 4.0 appears to be favoured in the literature with a neutral pH recommended for porcelain and composite restorations, clients with reduced salivary flow and those who cannot tolerate acidic fluorides, such as clients with mucositis, stomatitis, eating disorders, or gastroesophageal reflux disorders. Professionally applied topical fluorides may be used, following an individualized caries and oral health risk assessment. There is mixed evidence around the choice of varnish or gel for young children; however, rinses are clearly not recommended for children under six years of age. In addition, there is not enough clinical research to support a one-minute over a four-minute exposure time.

### Fluoride dentifrice

There is a wide range of well-controlled studies on fluoride dentifrices and almost all of these demonstrate considerable reductions in dental decay. One drawback to the use of fluoride dentifrice is the risk of fluorosis for young children, due to a less well-controlled swallowing reflex. This warrants the development of better methods for addressing the fluorosis risk; one of these methods may include the development of low-concentration fluoride dentifrices.

### CANADIAN DENTAL HYGIENISTS ASSOCIATION POSITION STATEMENTS ON FLUORIDE

The following fluoride position statements of the Canadian Dental Hygienists Association were approved by the CDHA Board of Directors on October 26, 2002.

- The use of fluoride is an important oral health promotion and disease prevention approach.
- Water fluoridation should be maintained and extended to additional communities where feasible. Infants past the age of 12 months should not consume formula made with fluoridated water. Fluoridation research is needed in:
  - ♦ Developing an improved method for determining the optimal fluoride concentration in community drinking water, which takes into account other sources of fluoride from air, food, and dental products;
  - ♦ High-quality water fluoridation efficacy studies;
  - ♦ Developing recommendations for caries prevention and control using various combinations of fluoride modalities.
- CDHA advocates clean and toxin-free sources of fluoride for use in products and water supplies. Information should be made available to the public on the sources and quality of fluoride used in oral health products and water supplies.
- Fluoride supplements should be used in non-fluoridated areas, with high-risk children. Children under the age of six should not receive supplements and children older than six years of age should receive 1.00 mg/day, based on a water supply that is fluoridated at a level of less than 0.3 ppm. No supplement should be given to children in areas with water fluoridated at 0.3 ppm or greater. The dosage schedule should take into account the level of fluoride in the drinking water and exposure to other sources of fluoride, such as dental products.
- Professionally applied topical fluorides with a pH level of 3.1 to 4.0 should be used for high-risk clients, following an individualized caries and oral health risk assessment. PATFs with a neutral pH are recommended for clients with porcelain and composite restorations, those with reduced salivary flow, and clients who cannot tolerate acidic fluorides, such as clients with mucositis, stomatitis, eating disorders, or gastroesophageal reflux disorders. Safety and risk management procedures should be used to minimize ingestion and maximize tooth uptake of PATF.

"THE FLUORIDE DIALOGUE" ... continued on page 224

- Self-applied fluoride rinses are not recommended for children under six years of age.
- Fluoride dentifrice should be used widely, at least twice each day. Children younger than six years of age should be supervised and use only a thin smear of fluoridated dentifrice. Better methods should be developed for addressing the connection between ingested dentifrice by young children and fluorosis, including the development of low-concentration fluoride dentifrice for young children.

## APPENDIX A: DEFINITIONS

### Coding system used to classify recommendations for use of specific fluoride modalities to control dental caries:

- A. Good evidence to support the use of the modality
- B. Fair evidence to support the use of the modality
- C. Lack of evidence to develop a specific recommendation (i.e., the modality has not been adequately tested) or mixed evidence (i.e., some studies support the use of the modality and some oppose it)
- D. Fair evidence to reject the use of the modality
- E. Good evidence to reject the use of the modality

### Grading system used to determine the quality of evidence for a fluoride modality:

- I. Evidence obtained from one or more properly conducted randomized controlled trials (i.e., one using concurrent controls, double-blind design, placebos, valid and reliable measurements, and well-controlled study protocols)
- II-1. Evidence obtained from one or more controlled trials without randomization (i.e., one using systematic subject selection, some type of concurrent controls, valid and reliable measurements, and well-controlled study protocols)
- II-2. Evidence from one or more well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3. Evidence obtained from cross-sectional comparisons between times and places; studies with historical controls; or dramatic results in uncontrolled experiments (e.g., the results of the introduction of penicillin treatment in the 1940s)
- III. Opinions of respected authorities on the basis of clinical experience, descriptive studies, or reports of expert committees

Source: United States Preventive Services Task Force: Guide to clinical preventive services. 2nd ed. Alexandria, VA: International Medical Publishing, 1996

## APPENDIX B: QUALITY CRITERIA

### Level A (highest quality of evidence, minimal bias)

- Prospective studies that started within one year of either initiation or discontinuation of water fluoridation and

have a follow-up of at least two years for positive effects and at least five years for negative effects.

- Studies either randomized or address at least three possible confounding factors and adjust for these in the analysis where appropriate.
- Studies where fluoridation status of participants is unknown to those assessing outcomes.

### Level B (evidence of moderate quality, moderate risk of bias)

- Studies that started within three years of the initiation or discontinuation of water fluoridation, with a prospective follow-up for outcomes.
- Studies that measured and adjusted for less than three but at least one confounding factor.
- Studies in which fluoridation status of participants was known to those assessing primary outcomes, but other provisions were made to prevent measurement bias.

### Level C (lowest quality of evidence, high risk of bias)

- Studies of other designs (e.g., cross-sectional), prospective or retrospective, using concurrent or historical controls that meet other inclusion criteria.
- Studies that failed to adjust for confounding factors.
- Studies that did not prevent measurement bias.

Studies meeting two of the three criteria for a given evidence level were assigned the next level down. For example, if a study met the criteria for prospective design and blinding for Level A but was neither randomized nor controlled for three or more potential confounding factors, it was assigned Level B. Evidence rated below Level B was not considered in our assessment of positive effects. However, this restricted assessment of the evidence for Objective 3, so the best level of evidence relevant to this objective (from any study design) was included. In our assessment of possible negative effects, all levels of evidence were considered. Adjustment for confounding factors required analysis of data; simply stating that two study groups were similar on noted confounding factors was not considered adequate.

Source: McDonagh, M., Whiting, P., Bradley, M., Cooper, J., Sutton, A., Chestnutt, I., Misso, K., Wilson, P., Treasure, E., Kleijnen, J.: A systematic review of public water fluoridation [on-line]. NHS Centre for Reviews and Dissemination, University of York, September 2000. [Cited on May 12, 2002.] < [www.york.ac.uk/inst/crd/fluorid.pdf](http://www.york.ac.uk/inst/crd/fluorid.pdf) >

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