

# Fluoride Therapy

## Latest Revision

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### Abstract

*This best practice provides information for practitioners regarding the use of fluoride as an aid in preventing and controlling dental caries in pediatric dental patients. These recommendations address systemic fluoride (water fluoridation, dietary fluoride supplements), topical fluoride delivery via professional application (acidulated phosphate fluoride gel or foam, sodium fluoride varnish, silver diammine fluoride), and home-use products (toothpastes, mouthrinses) as well as the associated risks of fluoride agents. The standard level for community water fluoridation (0.7 ppm fluoride) helps balance the risk of caries and the possibility of dental fluorosis from excessive fluoride ingestion during the early years of tooth development. Specific recommendations for dietary supplementation of fluoride for children ages 6 months through 16 years are based on fluoride levels in the drinking water, other dietary sources of fluoride, use of a fluoridated toothpaste, and caries risk. The specific needs of each patient determine the appropriate use of systemic and topical fluoride products, whether delivered in a professional clinical or a home setting. Fluoride has proven to be an effective therapy in reducing the prevalence of dental caries in infants, children, adolescents, and persons with special needs.*

*Through a collaborative effort of the American Academy of Pediatric Dentistry Councils on Clinical Affairs and Scientific Affairs, this best practice was revised to offer updated information and recommendations to assist health care practitioners and parents in using fluoride therapy for management of caries risk in pediatric patients.*

**KEYWORDS:** ADOLESCENT; CHILD; FLUORIDATION; FLUORIDE; ORAL HEALTH; SILVER DIAMMINE FLUORIDE; TOOTHPASTE

### Purpose

The American Academy of Pediatric Dentistry intends these recommendations to help practitioners make decisions concerning appropriate use of fluoride as part of the comprehensive oral health care for infants, children, adolescents, and persons with special health care needs.

### Methods

This document was initially developed by the Liaison with Other Groups Committee, adopted in 1967<sup>1</sup>, and last revised by the Council on Clinical Affairs in 2018<sup>2</sup>. To update this guidance, an electronic search of the PubMed/MEDLINE database was conducted using the terms: *fluoride caries prevention, fluoridation, fluoride gel, fluoride varnish, fluoride toothpaste, fluoride therapy, silver diamine fluoride, and topical fluoride*; fields: all; limits: within last 5 years, English. Because 4077 papers were identified through these electronic searches, an alternate strategy of limiting the information gathering to systematic review using the term fluoride caries prevention yielded 116 new systematic reviews or trials since 2017. Expert opinions and clinical practices also were relied upon for these recommendations.

### Background

Fluoride has been a major factor in the decline in prevalence and severity of dental caries in the US and other economically developed countries. It has several caries-protective mechanisms of action. Topically, low levels of fluoride in plaque and saliva inhibit the demineralization of sound enamel and enhance the remineralization of demineralized enamel.<sup>3,4</sup> The

topical effect may be enhanced when combined with good oral hygiene practices at home and use of a fluoride dentifrice.<sup>5</sup> Fluoride also inhibits dental caries by affecting the metabolic activity of cariogenic bacteria.<sup>6</sup> High levels of fluoride, such as those attained with the use of topical gels or varnishes, produce a temporary layer of calcium fluoride-like material on the enamel surface. The fluoride is released when the pH drops in response to acid production and becomes available to remineralize enamel or affect bacterial metabolism.<sup>7</sup> Although fluoride-rich enamel is less acid-soluble than enamel with less fluoride, the topical and remineralization effects of fluoride have been found to have a greater impact on caries prevention than incorporation of fluoride into developing teeth.<sup>8</sup>

### Community water fluoridation

Fluoridation of community drinking water is the most equitable and cost-effective method of delivering fluoride to all members of most communities.<sup>9</sup> As of 2018, 73% of the US population on community water systems had access to fluoridated water.<sup>10</sup> Water fluoridation at the level of 0.7-1.2 mg fluoride ion (F) per liter (ie, ppm F) was introduced in the US in the 1940s. Since community water is now one of several sources of fluoride, the US Department of Health

#### ABBREVIATIONS

**CaF:** Calcium fluoride. **F:** Fluoride. **FSIQ:** Full scale intelligent quotient. **IQ:** Intelligence quotient. **NaFV:** Sodium fluoride varnish. **SDF:** Silver diammine fluoride.

and Human Services revised these recommendations in 2015 to a standardized level of 0.7 ppm F to balance the benefits of preventing dental caries while reducing the chance of fluorosis.<sup>11</sup>

Community water fluoridation has been associated with the decline in caries prevalence in US adolescents, from 90% in at least 1 permanent tooth in 12-17-year-olds in the 1960s, to 60% in a 1999-2004 survey,<sup>12,13</sup> with more recent estimates of 35% caries reduction in primary teeth and 26% in permanent teeth of children<sup>14</sup>. Additionally, a Cochrane review found that water fluoridation led to a 15% increase in caries-free children in primary dentition and 14% increase in caries-free children with permanent dentition.<sup>14</sup>

Consuming fluoridated drinking water is both safe and effective in preventing and controlling dental caries. Although adverse health effects (eg, decreased cognitive ability, endocrine disruption, cancer) have been ascribed to the use of fluoride over the years, the preponderance of evidence from large cohort studies and systematic reviews does not support an association of such health issues and consumption of fluoridated water at the recommended concentration.<sup>11</sup> Regarding cognitive ability, a recent study of mothers' urinary fluoride levels and their child's intelligence quotient (IQ) levels suggested an association with exposure levels much greater than those recommended in the US for water fluoridation.<sup>15</sup> Also utilizing maternal urinary fluoride levels, a multicenter prospective cohort study<sup>16</sup> followed children born in Canada between 2008 and 2012. Forty-one percent of followed patients lived in fluoridated communities. This study assessed IQ at ages 3 and 4 years using the Wechsler Preschool and Primary Scale of Intelligence with Full Scale Intelligence Quotient (FSIQ) as the primary outcome.<sup>16</sup> Results indicated that a 1 mg increase in daily fluoride intake (eg, an extra 6 cups of optimally-fluoridated water each day) during pregnancy was associated with a 4.49 point lower FSIQ score in boys but did not significantly impact girls.<sup>16</sup> The study results suggested maternal exposure to high fluoride levels was associated with lower IQ scores in boys and girls; however, it overlooked confounding variables that did not adjust for differences in socioeconomic status or maternal IQ, and there was no IQ difference when evaluating the full population.<sup>16</sup> Moreover, a prospective study in New Zealand did not support an association between fluoridated water and IQ measurements,<sup>17</sup> and a national sample in Sweden found no relationship between fluoride levels in water supplies and cognitive ability, noncognitive ability, and education<sup>18</sup>. The current evidence does not support that consuming water fluoridated at the level 0.7 ppm F is associated with reductions in IQ.

Repeated consumption of fluoride at levels higher than those recommended in this document during enamel development, however, can cause dental fluorosis (children 15-30 months of age being most susceptible for fluorosis of the permanent incisors).<sup>19</sup> The National Health and Nutrition Examination Survey (NHANES) 1999-2004 study found 23% of the US population aged 6 through 49 had very mild

or mild fluorosis.<sup>20</sup> Very mild and mild levels of fluorosis are associated with decreased caries experience and present clinically as an increase in diffuse or lacy appearing white opacities of the enamel and generally are not considered an esthetic problem.<sup>21,22</sup> The Iowa Fluoride Study was a longitudinal study that gathered data on fluoride intake from multiple sources (water, beverages, foods, fluoride supplements, and dentifrices) on subjects from birth to 36 months.<sup>23</sup> Those subjects were examined at about age 9 to assess permanent incisors and first molars for fluorosis using the Fluorosis Risk Index.<sup>24</sup> This study found the prevalence of mild fluorosis was 13% among those children with average fluoride intakes of 0.04 mg/kg body weight and increased to 23 percent when intakes were between 0.04 to 0.06 mg/kg.<sup>24</sup> When fluoride intakes average 0.06 mg/kg or more per day, mild fluorosis prevalence was 38%.<sup>24</sup> A more recent study found mild fluorosis levels increased to over 60% for adolescents ages 16 and 17 in 2011-2012 compared to 29.4% in 2001-2002; this is a greater than 31% increase.<sup>25</sup>

### Fluoride supplements and infant formula

Fluoride supplements are effective in reducing prevalence of dental caries and may be considered for children at high caries risk who drink fluoride-deficient (less than 0.6 ppm F) water<sup>26</sup> (see Table). Fluoride supplementation schedules were last revised in the early 1990s<sup>27</sup> and have not been adjusted since 1) fluoride concentration in municipal water was standardized and 2) recommendations to use fluoridated toothpaste with the eruption of the first tooth were promulgated.

Before prescribing supplements, determination of dietary fluoride intake from all sources can help reduce intake of excess fluoride. Sources of dietary fluoride may include drinking water from home, day care, and school; beverages such as soda<sup>28</sup>, juice<sup>29</sup>, and infant formula<sup>30</sup>; prepared food<sup>31</sup>; and toothpaste. Concentrated infant formulas requiring reconstitution with water have raised concerns regarding an increased risk of fluorosis.<sup>32</sup> Infants may be particularly susceptible because of the large consumption of such liquid while the body weight is relatively low<sup>4</sup> and the enamel is mineralizing. An evidence-based review found that consumption of reconstituted infant formula can be associated with an increased risk of mild

**Table. DIETARY FLUORIDE SUPPLEMENTATION SCHEDULE**

Age	<0.3 ppm F	0.3 to 0.6 ppm F	>0.6 ppm F
Birth to 6 months	0	0	0
6 months to 3 years	0.25 mg	0	0
3 to 6 years	0.50 mg	0.25 mg	0
6 to at least 16 years	1.00 mg	0.50 mg	0

Abbreviations in this table: ppm F=Parts per million fluoride; mg=milligram.

*Note:* The recommendations in this table have not been revised since fluoride concentration in municipal water was standardized and use of fluoridated toothpaste for dentate infants was promulgated. All dietary sources of fluoride should be taken into consideration before recommending fluoride supplements for patients with fluoride-deficit community water.

fluorosis but recommended the continued use of fluoridated water.<sup>33</sup> One study has shown that dental fluorosis levels do not vary in fluoridated areas regardless of premixed versus reconstituted formula.<sup>34</sup> Nevertheless, over-supplementation of fluoride, even for patients residing in areas with unfluoridated water, can cause fluorosis.<sup>35</sup> Since standardization of the optimal fluoride levels in drinking water to 0.7 ppm F in 2015, dental fluorosis is less likely to occur. However, caution is indicated when considering the use of fluoride supplements for children under age 6 due to their continued dental development and consumption of fluoride from a variety of sources.

### Professionally-applied fluoride varnish, gel, and foam

Professionally-applied topical fluoride treatments are efficacious in reducing prevalence of dental caries. The most commonly used agents for professionally-applied fluoride treatments are 5% sodium fluoride varnish ([NaFV]; 2.26% F, 22,600 ppm F) and acidulated phosphate fluoride ([APF]; 1.23% F, 12,300 ppm F). Meta-analyses of 23 clinical trials, most with twice yearly application, favors the use of fluoride varnish in primary and permanent teeth to prevent decay.<sup>36</sup> Fluoride varnish appears to be effective at preventing caries in higher-risk children younger than 5 years.<sup>37</sup> Unit doses of 5% fluoride varnish are the only professional topical fluoride agent recommended for children younger than age 6 for safety reasons.<sup>36</sup> Meta-analyses of placebo-controlled trials show that fluoride gels, applied at 3-months to 1-year intervals, also are efficacious in reducing caries in permanent teeth.<sup>38,39</sup> Some topical fluoride gel and foam products are marketed with recommended treatment times of less than 4 minutes, but there are no clinical trials showing efficacy of shorter than 4-minute application times.<sup>40</sup> Evidence that topical fluoride foams are efficacious in children is limited.<sup>36</sup> Children at risk for caries should receive a professional fluoride treatment at least every 6 months.<sup>40</sup> In 2014, the US Preventive Services Task Force recommended a schedule for fluoride varnish application specifically by non-dental personnel to provide this preventive strategy to children in medical settings, especially when children are more likely to see a medical provider rather than a dental provider.<sup>41,42</sup> Recent meta-analyses tried to determine whether professionally-applied fluoride can reverse incipient/white spot caries lesions<sup>43-45</sup> but, due to heterogeneity of studies included in the systematic review coupled with home use of fluoride dentifrices by research subjects, a valid conclusion could not be made<sup>43</sup>. Yet another study has shown that incipient enamel lesions (International Caries Detection and Assessment System Code 2) can be arrested with semiannual applications of 5% NaFV.<sup>46</sup>

### Silver diammine fluoride

Thirty-eight percent silver diammine fluoride ([SDF]; 5% F, 44,800 ppm F) has been cleared by the US Food and Drug Administration as a dentin desensitizer in adults.<sup>47</sup> It currently is used frequently to arrest cavitated caries lesions. SDF is thought to arrest caries by the antibacterial effect of silver and

remineralization of enamel and dentin by fluoride.<sup>48</sup> Silver ions have an antimicrobial effect mainly in the treated carious dentin<sup>49</sup>, and the combination of silver and fluoride in an alkaline solution have a synergistic effect that creates an unfavorable environment for collagen enzyme activation, thereby reducing dentin degradation.<sup>50</sup> Clinical trials show caries arrest rates ranging from 35% to 80%<sup>51</sup>, but such studies have a high risk of bias and a high heterogeneity between them, leading to conditional recommendations for its use.<sup>52</sup> Numerous clinical trials conclude that biannual application of SDF results in higher caries arrest in dentin caries lesions as compared to fluoride varnish.<sup>47,53</sup> Thus, SDF is an important adjunct therapy in the individualized comprehensive care plan for children and adolescents for whom access to definitive dental restorative care may be limited for a variety of reasons or preferentially postponed. As the product is highly concentrated, less than a drop is needed to treat several caries lesions, making it cost-effective. SDF is best used as part of an ongoing caries management plan within the context of a dental home.<sup>54,55</sup>

SDF is safe to use in children and adults when delivered in accordance with dosing and application criteria.<sup>56</sup> While current data on the systemic effects of silver is limited<sup>47</sup>, data supports a cytotoxic effect to the dental pulp cells when applied directly on pulp tissue<sup>57-59</sup>. SDF solution, when applied to deep caries lesions (0.25-0.5 mm dentin thickness remaining), can be rapidly absorbed into dentin and produce a mild inflammation.<sup>60</sup> Whether tertiary dentin formation is a response to cariogenic bacteria or to the SDF remains undetermined.<sup>60</sup> Two investigations<sup>61,62</sup> have evaluated SDF as an indirect pulp therapy medicament. One study<sup>62</sup> found application of SDF arrested further caries progression but did not significantly increase the amount of reparative dentin radiographically. Similarly, the other found no significant difference between SDF, SDF combined with potassium iodide, and the control (resin-modified glass ionomer) at preventing secondary caries.<sup>61</sup> The absence of postoperative pain and maintenance of tooth vitality indicated that SDF did not adversely affect the pulp when applied as an indirect pulp therapy agent.<sup>61</sup> The other reported side effects of SDF are that caries lesions stain black after treatment and that skin and gingiva temporarily stain with contact.

### Home-use fluoride products

The goal of home-use fluoride products for children is to maximize the time fluoride is in direct contact with the tooth surface, in lower-dose higher-frequency approaches.<sup>63</sup> In children having higher baseline levels of caries, utilizing higher concentrations of fluoride in the toothpaste, brushing with greater frequency, and having supervision of brushing were efficacious in reducing the prevalence of dental caries in permanent teeth.<sup>64,65</sup> A meta-analysis of 8 clinical trials on caries increment in preschool children also shows that toothbrushing with fluoridated toothpaste significantly reduces dental caries prevalence in the primary dentition.<sup>66</sup> Using no more than a smear or rice-sized amount of fluoridated

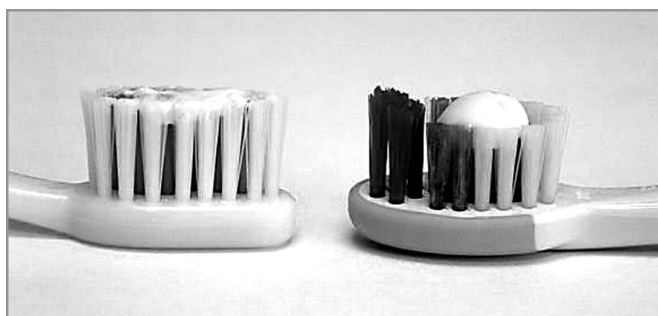


Figure. Comparison of a smear (left) with a pea-sized (right) amount of toothpaste.

toothpaste (0.1 mg F) for children less than 3 years of age may decrease risk of fluorosis. Using no more than a pea-sized amount of fluoridated toothpaste (0.25 mg F) is appropriate for children 3 to 6 years of age<sup>67,68</sup> (see Figure). To maximize the beneficial effect of fluoride in the toothpaste, supervised toothbrushing should be done twice a day, and rinsing after brushing should be kept to a minimum or avoided altogether.<sup>69</sup> Other topical fluoride products (eg, prescription-strength home-use 0.5% F gels and pastes; prescription-strength home-use 0.09% F mouthrinse) have benefit in reducing dental caries in those patients at higher risk, such as adolescents, adolescents with special health care needs, or patients with fixed orthodontic appliances; these products are recommended for use in children 6 years or older.<sup>36</sup> Having children spit after brushing and parents supervise the amounts administered to children will help avoid over-ingestion. Over-ingestion of fluoridated toothpaste combined with other dietary fluoride sources may lead to daily intake greater than the recommended amount and could lead to development of dental fluorosis.<sup>4</sup>

Over 20,000 reports per year regarding fluoride ingestion are received at poison control centers<sup>70</sup>, and over 80% of suspected cases occur in the under-6-years age group<sup>71</sup>. The probably-toxic dose for fluoride is 5 mg/kg body weight.<sup>72</sup> Lower dosage may result in gastrointestinal disturbances with higher doses producing central nervous system side effects such as seizures or tetany.<sup>73</sup> Fifteen mg/kg body weight of fluoride likely could be fatal for a small child.<sup>74</sup> Over-the-counter toothpastes approved by the American Dental Association contain at least 1000 ppm F and less than 1500 ppm F.<sup>75</sup> Currently available prescription strength toothpastes may contain 5000 ppm F<sup>75</sup> or 605 mg F per 100 milliliters<sup>76</sup>. Parental dispensing of toothpaste for use by children under the age of 3, supervised toothbrushing for all children unable to expectorate, and keeping prescription fluoride supplements and/or home-use fluoride products out of reach of young children can prevent unintended ingestion which has acute (toxicity) as well as chronic (fluorosis) implications.

## Recommendations

The AAPD recommends

- the use of fluoride for the prevention and control of caries as it is both safe and highly effective in reducing dental caries prevalence.
- consumption of optimally-fluoridated community water as a cost-effective method to prevent and control caries at the population level.
- toothbrushing at least twice daily with an age-appropriate amount of over-the-counter fluoride-containing toothpaste to prevent caries as first line for caries prevention.
- professionally-applied topical fluoride treatments such as 5% NaFV or 1.23% F gel preparations at least twice per year to reduce incidence of dental caries.
- 38% SDF be used to arrest cavitated caries lesions in primary teeth and permanent teeth as part of a comprehensive caries management program.
- prescription-strength home-use 0.5% F gels and pastes and 0.02-0.09% F mouth rinses to reduce dental caries in high-risk patients over 6 years of age.
- decisions concerning the administration of fluoride be based on the unique needs of each patient, including the risks and benefits (eg, risk of mild or moderate fluorosis versus the benefits of decreasing caries increment and, in some cases, preventing devastating dental disease).
- fluoride dietary supplements be cautiously considered for children at caries risk who drink less-than-optimally-fluoridated water as supplementation—in the face of all other sources of fluoride—could exceed the recommended amount of daily fluoride intake.

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