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1 **Best Practices on Fluoride Therapy**

2

3 **Review Council**

4 Council on Clinical Affairs

5 **Latest Revision**

6 2014\* 2018

7 *\*The 2014 revision was limited to use of fluoridated toothpaste in young children*

8

9 **Purpose**

10 The American Academy of Pediatric Dentistry (AAPD) intends ~~this guideline~~ these recommendations to  
11 help practitioners and parents make decisions concerning appropriate use of fluoride as part of the  
12 comprehensive oral health care for infants, children, adolescents, and persons with special health care  
13 needs.

14

15 **Methods**

16 This guideline was originally developed by the Council on Clinical Affairs Committee and adopted in  
17 1967. This document is a revision of the previous version, last revised in ~~2013~~2014. To update this  
18 guidance, an electronic search from 2012 to 2017 pertaining to ~~A thorough review of the scientific~~  
19 ~~literature in the English language pertaining to~~ regarding the use of systemic and topical fluoride was  
20 conducted, completed to revise and update this guideline. Database searches were conducted using the  
21 terms: fluoride caries prevention, fluoridation, fluoride gel, fluoride varnish, fluoride toothpaste, fluoride  
22 therapy, and topical fluoride. Because ~~over two million~~ 720 papers were identified through these  
23 electronic searches, an alternate strategy strategies of limiting the information gathering to systematic  
24 reviews using term “fluoride caries prevention” yielded 95 papers since 2012. Nine well conducted  
25 systematic reviews and their references primarily were used for this update <sup>1-9</sup>. ~~such as appraisal of~~  
26 ~~references from recent evidence based reviews and meta analyses, as well as hand searches, were~~  
27 ~~performed. This strategy yielded 105 manuscripts, primarily related to randomized clinical trials and~~  
28 ~~evidence based reviews, that were evaluated further by abstract. Of those, 45 manuscripts each had full~~  
29 ~~examination and analysis in order to revise this guideline.~~ Expert opinions and best current clinical  
30 practices also were relied upon for ~~this guideline~~ these recommendations.

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## 32 Background

33 Widespread use of fluoride has been a major factor in the decline in prevalence and severity of dental  
34 caries in the U.S. and other economically developed countries. ~~When used appropriately, fluoride is both~~  
35 ~~safe and effective in preventing and controlling dental caries. Decisions concerning the administration of~~  
36 ~~fluoride are based on the unique needs of each patient, including the risks and benefits (i.e., risk of mild~~  
37 ~~or moderate fluorosis versus the benefits of decreasing caries increment and, in some cases preventing,~~  
38 ~~devastating dental disease).~~

39  
40 Fluoride has several caries-protective mechanisms of action. Topically, low levels of fluoride in plaque  
41 and saliva inhibit the demineralization of sound enamel and enhance the re-mineralization of  
42 demineralized enamel. Fluoride also inhibits dental caries by affecting the metabolic activity of cariogenic  
43 bacteria<sup>10</sup>. High levels of fluoride, such as those attained with the use of topical gels or varnishes,  
44 produce a temporary layer of calcium fluoride-like material on the enamel surface. The fluoride is  
45 released when the pH drops in response to acid production and becomes available to remineralize enamel  
46 or affect bacterial metabolism<sup>11</sup>. The original belief was that fluoride's primary action was to inhibit  
47 dental caries when incorporated into developing dental enamel (i.e., the systemic route), but the fluoride  
48 concentration in sound enamel does not fully explain the marked reduction in dental caries. It is  
49 oversimplification to designate fluoride simply as systemic or topical. Fluoride that is swallowed, such as  
50 fluoridated water and dietary supplements, may contribute to a topical effect on erupted teeth (before  
51 swallowed, as well as a topical effect due to increasing salivary and gingival crevicular fluoride levels).  
52 Additionally, elevated plasma fluoride levels can treat the outer surface of fully mineralized, but  
53 unerupted, teeth topically. Similarly, topical fluoride that is swallowed may have a systemic effect<sup>12</sup>.

54  
55 Fluoridation of community drinking water is the most equitable and cost-effective method of delivering  
56 fluoride to all members of most communities<sup>13</sup>. Water fluoridation at the level of 0.7-1.2 mg fluoride  
57 ion/L (ppm F) was introduced in the U.S. in the 1940s. Since fluoride from water supplies is now one of  
58 several sources of fluoride, the Department of Health and Human Services ~~recently has proposed~~  
59 ~~recommended to not have~~ having a fluoride range, but rather to limit the recommendation to the lower  
60 standardize all water to the limit of 0.7 ppm F level. The rationale is to balance the benefits of preventing  
61 dental caries while reducing the chance of fluorosis<sup>1</sup>.

62  
63 Community water fluoridation has been associated with the decline in caries prevalence in adolescents  
64 from 90 percent in at least one permanent tooth in U.S. 12-17 years-olds in the 1960s, to 60 percent in a

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65 1999-2004 survey<sup>14</sup>. When used appropriately, fluoride is both safe and effective in preventing and  
66 controlling dental caries. Although adverse health effects, such as decreased cognitive ability, endocrine  
67 disruption and cancer, have been ascribed to the use of fluoride over the years, the preponderance of  
68 evidence from large cohort studies and systematic reviews does not support an association of such health  
69 issues and consumption of fluoridated water<sup>1</sup>. Regarding cognitive ability, a recent study of mothers'  
70 urinary fluoride levels and their child's IQ levels suggested an association with exposure levels greater  
71 than those recommended in the U.S. for water fluoridation<sup>15</sup>. However, a prospective study in New  
72 Zealand did not support an association between fluoridated water and IQ measurements<sup>16</sup>, and a national  
73 sample in Sweden found no relationship between fluoride levels in water supplies and cognitive ability,  
74 non-cognitive ability, and education<sup>17</sup>. Consumption of fluoride during the mineralization of teeth,  
75 however, can cause fluorosis (children 1-3 years of age being most susceptible for fluorosis of the  
76 permanent incisors). The NHANES 1999-2004 study found 23 percent of the U.S. population had very  
77 mild or mild fluorosis<sup>18</sup>. Decisions concerning the administration of fluoride are based on the unique  
78 needs of each patient, including the risks and benefits (e.g., risk of mild or moderate fluorosis versus the  
79 benefits of decreasing caries increment and, in some cases preventing, devastating dental disease).

80  
81 Fluoride supplements also are effective in reducing prevalence of dental caries and should be considered  
82 for children at high caries risk who drink fluoride-deficient (less than 0.6 ppm F) water<sup>19</sup> (see Table).  
83 Determination of dietary fluoride before prescribing supplements can help reduce intake of excess  
84 fluoride. Sources of dietary fluoride may include drinking water from home, day care, and school;  
85 beverages such as soda<sup>20</sup>, juice<sup>21</sup>, and infant formula<sup>22</sup>; prepared food<sup>23</sup>, and toothpaste. Concentrated  
86 infant formulas requiring reconstitution with water have raised concerns regarding especially powdered  
87 formulas that have been reconstituted with fluoridated water, have been associated with an increased risk  
88 of fluorosis<sup>24</sup>. Infants may be particularly susceptible because of the large consumption of such liquid in  
89 the first year of life, while the body weight is relatively low<sup>12</sup>. ~~However, a recent~~ An evidence-based  
90 review found that consumption of suggests that reducing fluoride intake from reconstituted infant formula  
91 can be associated with an increased risk of mild fluorosis, but recommended the continued use of  
92 fluoridated water<sup>25</sup>. One study has shown that dental fluorosis levels do not vary in fluoridated areas  
93 regardless of premixed versus reconstituted formula<sup>26</sup>. Standardization of the optimal fluoride levels in  
94 drinking water to 0.7 ppm F, however, makes this issue mute. alone will not eliminate the risk of fluorosis  
95 development. Fluorosis is associated with cumulative fluoride intake during enamel development, with  
96 the severity dependent on the dose, duration, and timing of intake. Findings from a national survey report  
97 that eight percent of 12-15 year-olds have mild fluorosis and five percent have moderate fluorosis.

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**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 mo 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

100

101 Professionally-applied topical fluoride treatments are efficacious in reducing prevalence of dental caries.

102 The most commonly used agents for professionally-applied fluoride treatments are ~~five~~ 5 percent sodium

103 fluoride varnish (**NaFV**; 2.26%F, 22,600 ppm F) and ~~1.23 percent~~ acidulated phosphate fluoride (**APF**;

104 1.23%F 12,300 ppm F). ~~The efficacy of~~ Meta-analyses of 23 clinical trials, most with twice yearly

105 application, favors the use of fluoride varnish in primary and permanent teeth <sup>2</sup>. Unit doses of fluoride

106 varnish are the only professional topical fluoride agent that are recommended for children younger than

107 age six <sup>2</sup>. ~~when used at least twice a year has been reported in at least four randomized controlled trials.~~

108 ~~The efficacy of fluoride varnish in permanent teeth, applied at three or six month intervals, also has been~~

109 ~~reported in at least four randomized controlled trials.~~ Meta-analyses of 14 placebo-controlled trials show

110 that fluoride gels, applied at three month to one year intervals, also are efficacious in reducing caries in

111 permanent teeth <sup>27</sup>. Some topical fluoride gel and foam products are marketed with recommended

112 treatment times of less than four minutes, but there are no clinical trials showing efficacy of shorter than

113 four-minute application times <sup>28</sup>. There also is limited evidence that topical fluoride foams are efficacious

114 in children <sup>2</sup>. Children at ~~increased risk for caries~~ risk should receive a professional fluoride treatment at

115 least every six months <sup>28</sup>. ~~As the risk categories may change over time, the type and frequency of~~

116 ~~preventive interventions should be adjusted.~~

117

118 Silver diamine fluoride (SDF; 5%F 44,800 ppm F) recently has been approved by the U.S. Food and

119 Drug Administration and currently is used most frequently to arrest dentinal caries. SDF arrests caries by

120 the antibacterial effect of silver and by remineralization of enamel and dentin <sup>9</sup>. Some clinical trials show

121 a caries arrest rate greater than 80 percent <sup>7</sup>, but such studies have a high risk of bias and a wide variation

122 of results, leading to conditional recommendations at this time <sup>29</sup>. Although the product is highly

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123 concentrated, less than a drop is needed to treat several caries lesions. The only reported side effect of the  
124 SDF is that caries lesions stain black after treatment, and will temporarily stain skin with contact.

125  
126 ~~Other topical fluoride products, such as 0.2 percent sodium fluoride (NaF) mouthrinse (900 ppm~~  
127 ~~F)(*Torell; Horowitz; Heifetz*) and brush-on gels/pastes (e.g., 1.1 percent NaF; 5,000 ppm F) also have~~  
128 ~~been shown to be effective in reducing dental caries in permanent teeth.~~ Home use of fluoride products  
129 for children should focus on regimens that maximize topical contact, in lower-dose higher-frequency  
130 approaches <sup>30</sup>. Meta-analyses of more than 70 randomized or quasi-randomized controlled clinical trials  
131 show that fluoride toothpaste is efficacious in reducing prevalence of dental caries in permanent teeth,  
132 with the effect increased in children with higher baseline level of caries ~~and by with~~ higher concentration  
133 of fluoride in the toothpaste, greater frequency of use, and supervision of brushing <sup>31,32</sup>. A meta-analysis  
134 of eight clinical trials on caries increment in preschool children also shows that tooth brushing with  
135 fluoridated toothpaste significantly reduces dental caries prevalence in the primary dentition <sup>6</sup>. Using no  
136 more than a smear or rice-size amount of fluoridated toothpaste for children less than three years of age  
137 may decrease risk of fluorosis. Using no more than a pea-size amount of fluoridated toothpaste is  
138 appropriate for children aged three to six <sup>8</sup> (see Figure). To maximize the beneficial effect of fluoride in  
139 the toothpaste, ~~teeth supervised toothbrushing should be brushed done~~ twice a day, and rinsing after  
140 brushing should be kept to a minimum or eliminated altogether <sup>4</sup>. Other topical fluoride products (e.g.,  
141 prescription strength, home-use 0.5 percent fluoride gels and pastes; prescription-strength, home-use 0.09  
142 percent fluoride mouthrinse have benefit in reducing dental caries in children six years or older <sup>2</sup>.

143

## 144 Recommendations

- 145 1. There is confirmation from evidence-based reviews that fluoride use for the prevention and  
146 control of caries is both safe and highly effective in reducing dental caries prevalence.
- 147 2. There is evidence support from ~~randomized clinical trials and~~ evidence-based reviews that  
148 fluoride dietary supplements are effective in reducing dental caries and should be considered for  
149 children at caries risk who drink fluoride-deficient (less than 0.6 ppm) water.
- 150 3. There is evidence support from ~~randomized controlled trials and meta-analyses~~ evidence-based  
151 reviews that professionally applied topical fluoride treatments as ~~five~~2.26 percent NaFV or 1.23  
152 percent F gel preparations are efficacious in reducing caries in children at caries risk.
- 153 4. There is evidence support from ~~meta-analyses~~ evidence-based reviews that fluoridated toothpaste  
154 is effective in reducing dental caries in children with the effect increased in children with higher

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155 baseline level of caries, higher concentration of fluoride in the toothpaste, greater frequency in  
156 use, and supervision. Using no more than a smear or rice-size amount of fluoridated toothpaste  
157 for children less than three years of age may decrease risk of fluorosis. Using no more than a pea-  
158 size amount of fluoridated toothpaste is appropriate for children aged three to six.

159 5. There is evidence support from randomized clinical trials evidence-based reviews that prescription  
160 strength, home-use 0.5 percent fluoride gels and pastes and prescription-strength, home-use 0.09  
161 percent fluoride mouthrinse 0.2 percent NaF mouthrinse and 1.1 percent NaF brush-on gels/pastes  
162 also are effective in reducing dental caries in children.

163 6. There is support from evidence-based reviews to recommend the use of 38% silver diamine  
164 fluoride for the arrest of cavitated caries lesions in primary teeth as part of a comprehensive caries  
165 management program.

166



167

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

169

170

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