

**Evidence-Based Clinical Recommendations on the Prescription of Dietary Fluoride Supplements for Caries Prevention: A Report of the American Dental Association Council on Scientific Affairs**

R. Gary Rozier, Steven Adair, Frank Graham, Timothy Iafolla, Albert Kingman, William Kohn, David Krol, Steven Levy, Howard Pollick, Gary Whitford, Sheila Strock, Julie Frantsve-Hawley, Krishna Aravamudhan and Daniel M. Meyer  
*J Am Dent Assoc* 2010;141;1480-1489

---

*The following resources related to this article are available online at [jada.ada.org](http://jada.ada.org) ( this information is current as of March 8, 2011 ):*

**Updated information and services** including high-resolution figures, can be found in the online version of this article at:

<http://jada.ada.org/cgi/content/full/141/12/1480>

Information about obtaining **reprints** of this article or about permission to reproduce this article in whole or in part can be found at:

<http://www.ada.org/prof/resources/pubs/jada/permissions.asp>

# Evidence-based clinical recommendations on the prescription of dietary fluoride supplements for caries prevention

A report of the American Dental Association Council on Scientific Affairs

**R. Gary Rozier, DDS, MPH; Steven Adair, DDS, MS; Frank Graham, DMD; Timothy Iafolla, DMD, MPH; Albert Kingman, PhD; William Kohn, DDS; David Krol, MD, MPH; Steven Levy, DDS, MPH; Howard Pollick, BDS, MPH; Gary Whitford, PhD, DMD; Sheila Stroock, DMD, MPH; Julie Frantsve-Hawley, RDH, PhD; Krishna Aravamudhan, BDS, MS; Daniel M. Meyer, DDS**

**D**ental caries remains the most prevalent chronic disease in children. The Centers for Disease Control and Prevention<sup>1</sup> (CDC) reported that from 1999 through 2004, 42 percent of children aged 2 to 11 years experienced dental caries in their primary teeth, the trend in younger children aged 2 to 4 years has increased over time, and 59 percent of adolescents aged 12 to 19 years experienced dental caries in their permanent teeth.

A series of epidemiologic studies conducted during the 1930s and 1940s led to experimental studies in Grand Rapids, Mich., and other locations in which investigators documented the benefits of fluoride in drinking water.<sup>2</sup> Since then, fluoride has played a dominant role in caries-prevention programs for both children and adults.<sup>3</sup> Fluoride has two known classifications of effects in controlling dental caries: topical and systemic.<sup>4-11</sup> Although it now is believed that the topical effect is predominant, the maximum benefit likely is achieved when a person

## ABSTRACT

**Background.** This article presents evidence-based clinical recommendations for the prescription of dietary fluoride supplements. The recommendations were developed by an expert panel convened by the American Dental Association (ADA) Council on Scientific Affairs (CSA). The panel addressed the following questions: when and for whom should fluoride supplements be prescribed, and what should be the recommended dosage schedule for dietary fluoride supplements?

**Types of Studies Reviewed.** A panel of experts convened by the ADA CSA, in collaboration with staff of the ADA Center for Evidence-based Dentistry, conducted a MEDLINE search to identify publications that addressed the research questions: systematic reviews as well as clinical studies published since the systematic reviews were conducted (June 1, 2006).

**Results.** The panel concluded that dietary fluoride supplements should be prescribed only for children who are at high risk of developing caries and whose primary source of drinking water is deficient in fluoride.

**Clinical Implications.** These recommendations are a resource for practitioners to consider in the clinical decision-making process. As part of the evidence-based approach to care, these clinical recommendations should be integrated with the practitioner's professional judgment and the patient's needs and preferences. Providers should carefully monitor the patient's adherence to the fluoride dosing schedule to maximize the potential therapeutic benefit.

**Key Words.** Fluoride; supplements; caries prevention; fluorosis; evidence-based dentistry; clinical recommendations.

*JADA 2010;141(12):1480-1489.*

receives both topical and systemic fluoride.<sup>7-9</sup> Topical fluoride inhibits the demineralization of sound enamel and enhances its remineralization.<sup>12,13</sup> When fluoride is absorbed by the enamel along with calcium and phosphate during the remineralization process, it establishes an improved enamel crystal structure that, in comparison with its state before mineralization, is more acid resistant and contains more fluoride and less carbonate.<sup>11,12,14-17</sup> A second topical mechanism of action is antimicrobial; by this mechanism, fluoride inhibits carbohydrate metabolism and acid production and affects bacterial production of adhesive polysaccharides.<sup>18,19</sup>

Evidence supports fluoride's systemic mechanism of caries inhibition when it is incorporated into the tooth pre-eruptively.<sup>6,20</sup> Ingested fluoride is absorbed systemically by calcified tissues, including developing enamel.<sup>21</sup> Therefore, a person's teeth may benefit from early-life exposure to systemic fluoride.<sup>6,20</sup> The mineralization period varies, in terms of age of initiation and duration, across people and among the different teeth for a given person.<sup>22-26</sup> Also, ingested fluoride can exert a topical mechanism of action when it is redistributed to the oral environment by means of saliva.<sup>27,28</sup>

In 1962, the U.S. Public Health Service<sup>29</sup> established the optimum concentration for fluoride in the water in the United States in the range of 0.7 to 1.2 parts per million to reduce dental caries while minimizing the occurrence of dental fluorosis. The optimum level depends on the annual average of the maximum daily air temperature in the geographic area; this is based on the assumption that the amount of water, and thus fluoride, that people consume will vary according to temperature.<sup>29</sup> As early as the 1940s, investigators began clinical trials of dietary fluoride supplements in an effort to bring the caries-preventive benefits of fluoride to children living in areas without fluoridated water.<sup>30</sup>

Although use of fluoride has been important in the prevention and control of dental caries, fluoride ingestion also may be associated with increased risk of developing enamel fluorosis. Enamel fluorosis is a type of hypomineralization of tooth enamel that results from excess fluoride intake during critical periods of tooth development early in life. Milder forms of the condition are characterized by paper-white opacities that can vary from minor striations to larger areas of affected enamel.<sup>31</sup> Often, the milder changes in

the enamel are visible only when the enamel is dried and viewed with careful observation under direct lighting.

The prevalence of enamel fluorosis apparently has increased in U.S. children in recent decades. CDC<sup>32</sup> reported an increase of nine percentage points in the prevalence of "mostly mild" enamel fluorosis among U.S. children and adolescents aged 6 to 19 years between the 1986-1987 period (23 percent) and the 1999-2002 period (32 percent). The apparent increase in enamel fluorosis prevalence may stem from an increase in the number of sources of exposure to fluoride, including ingestion of water, toothpastes, dietary fluoride supplements, beverages, foods and professional dental products,<sup>26</sup> and it is relatively greater in those living in communities with fluoride-deficient water supplies.<sup>33,34</sup> The severity and distribution of enamel fluorosis in permanent teeth depends on the amount, duration and timing of fluoride intake, the stage of tooth development at exposure and individual susceptibility.<sup>31</sup> Very mild, mild and moderate enamel fluorosis is associated with lower caries prevalence and severity.<sup>32,35,36</sup>

In studies of the public's perceptions of enamel fluorosis, researchers have found that the level of enamel fluorosis about which most people express concern is moderate to severe.<sup>37,38</sup> According to a 2010 review of the few studies examining oral health-related quality of life, none of those studies' results showed mild enamel fluorosis to have negative effects.<sup>37</sup> In fact, one study's researchers found that the condition was associated with improved oral health-related quality of life.<sup>38</sup> The majority of enamel fluorosis cases in the United States are mild or very mild and do not adversely affect a person's oral health-related quality of life. Nonetheless, recommendations regarding fluoride supplementation should take into account both fluoride's caries-preventive effects and its risk of causing fluorosis. The goal should be to find an optimal balance between benefit of and risk associated with fluoride use. To address this need, the American Dental Association (ADA) Council on Scientific Affairs (CSA) convened an expert panel to revise the dietary fluoride supplement schedule.

---

**ABBREVIATION KEY.** ADA: American Dental Association. CDC: Centers for Disease Control and Prevention. CSA: Council on Scientific Affairs. sb: subset. tw: text word.

## SCOPE AND PURPOSE OF THE RECOMMENDATIONS

This report focuses on the prescription of dietary fluoride supplements for infants and children aged 6 months to 16 years who live in communities without fluoridated water or with water of low fluoride content. In July 2008, the ADA CSA convened an expert panel to develop recommendations addressing the following questions:

- When and for whom should fluoride supplements be prescribed?
- What should be the recommended dosage schedule for dietary fluoride supplements?

The clinical recommendations that ensued and are published here are intended as a resource for use by dentists and other health care providers. The recommendations must be balanced with the practitioner's professional judgment and the individual patient's needs and preferences. The scope of review for this panel did not include recommendations for school-based or other dental public health programs such as the federal Head Start program.

## METHODS

**Expert panel.** The ADA CSA convened a panel of 10 experts to evaluate systematically the collective scientific evidence related to the clinical questions listed above and develop evidence-based clinical recommendations for the prescription of dietary fluoride supplements.

The Council selected panelists on the basis of their expertise in the relevant subject matter. The expert panel convened at a workshop held July 16-18, 2008, at the ADA Headquarters in Chicago. The panelists continued their work by means of conference calls to finalize the recommendations and develop this report.

**Conflict-of-interest disclosures.** The panel comprised 10 members who represented a broad range of expertise in dentistry, children's oral health or both. All panelists completed a standard conflict-of-interest questionnaire.

**Search strategies. Systematic reviews.** ADA staff conducted a literature search for systematic reviews published in English as of May 14, 2008, by using PubMed and the following search terms: "fluoride supplements," "vitamin" OR "fluoride supplements," "tablet" OR "fluoride supplements," "chewable" OR "fluoride supplements," "drop" OR "fluoride supplements," "lozenges" AND "dental caries" OR "demineralization" OR "remineralization" OR "cariostatic" OR

"anticaries" (tw) OR "anticaries" (tw) OR "fluorosis," "dental" OR "fluorosis," "enamel" OR "mottled" AND "systematic" (sb). (Note: "tw" means "text word"; "sb" means "subset.")

Two investigators on the ADA staff (S.S. and another investigator) conducted the search on May 14, 2008. The initial search yielded 136 articles. The same two investigators conducted a title review for relevance to the clinical questions. They identified 46 articles. They also screened abstracts of these 46 articles, which yielded 23 articles for consideration. They conducted a full-text review of the 23 articles. Their reviews included systematic reviews that either included or did not include meta-analyses, as evidenced by use of the terms in the publication, or that had key features of a systematic review such as a comprehensive literature search and two independent reviewers. Inclusion criteria were as follows:

- human participants;
- publication in the English language;
- patients who had been exposed to fluoride supplements;
- evidence provided to answer the clinical questions;
- reported outcomes of either caries or enamel fluorosis;
- examination of patients to determine presence of caries or enamel fluorosis;
- for caries-prevention studies, a study design that included both control and experimental groups.

Ultimately, the two investigators included two systematic reviews for consideration by the expert panel.<sup>39,40</sup> The investigators also included for the panel's review a systematic review by Ismail and colleagues<sup>41</sup> that had been accepted for publication but not yet published.

Appendix 1 in the supplemental data to the online version of this article (available at "http://jada.ada.org") provides the complete list of the excluded publications.

One of the authors (J.F.H.) updated the literature search for systematic reviews to include only articles published between May 14, 2008, and Dec. 11, 2009. She used the same search terms as described above. She and another independent reviewer (K.A.) identified and screened 23 citations (full text and abstract). They did not identify any new systematic reviews. Then she conducted the search again to include only articles published between Dec. 11, 2009, and June 16, 2010, using the same search terms as described

above. She and the other independent reviewer (K.A.) identified and screened the abstracts of three citations. They did not identify any new systematic reviews.

**Clinical studies.** Two researchers (S.S. and another investigator) searched for recently published clinical studies related to the clinical questions. They conducted their search on the basis of the search date used in the most recent systematic review, which Ismail and Hasson<sup>41</sup> published in 2008. In that systematic review, the authors conducted a literature search on June 1, 2006. Thus, the researchers limited their search to articles published from June 1, 2006, through May 14, 2008. The two researchers conducted a literature search for clinical studies published in English by using PubMed and the following search terms: “fluoride supplements,” “vitamin” OR “fluoride supplements,” “tablet” OR “fluoride supplements,” “chewable” OR “fluoride supplements,” “drop” OR “fluoride supplements,” “lozenges” AND “dental caries” OR “demineralization” OR “remineralization” OR “cariostatic” OR “anti-caries” (tw) OR “anticaries” (tw) OR “fluorosis,” “dental” OR “fluorosis,” “enamel” OR “mottled.” The initial search yielded 987 articles. The researchers screened titles and reduced the number to 51 clinical studies that related to the clinical questions. Screening of the abstracts yielded 25 articles for full-text review, two of which the researchers included for consideration by the expert panel but which, ultimately, the panel excluded because they were not relevant to the clinical question.<sup>42,43</sup>

The inclusion criteria were as described earlier for the systematic review search.

Appendix 2 in the supplemental data to the online version of this article (found at “<http://jada.ada.org>”) provides the complete list of excluded publications.

One of the authors (J.F.-H.) updated the literature search for clinical studies to include only articles published between May 14, 2008, and Dec. 11, 2009. She used the same search terms as described above. She and another independent reviewer (K.A.) identified and screened 754 citations (titles and abstracts). They selected three articles<sup>44-46</sup> for full-text review. Of these, the panel

considered only one study that met the inclusion criteria.<sup>45</sup> The panel became aware of one additional report that had been accepted for publication, but not yet published, by The Journal of the American Dental Association.<sup>47</sup> The panel included these two studies.

Then the same author (J.F.-H.) updated the literature search for clinical studies published between Dec. 11, 2009, and June 16, 2010. She used the same search terms as described above. She and the other independent reviewer (K.A.) identified and screened 222 citations (titles and abstracts). They identified no additional studies.

#### **Grading the evidence and classifying the strength of the clinical recommendations.**

The panel performed a qualitative assessment of the strengths and limitations of each included systematic review or clinical study to determine the quality of the evidence. The panel developed evidence statements that were based on the literature, then graded the evidence according to a system modified by Shekelle and colleagues<sup>48</sup> (Table 1). The panel then developed the clinical recommendations according to the evidence statements. Using the same modified system (Table 1), the panel classified the clinical recommendations on the strength of the evidence reviewed. Al-

**TABLE 1**

### **Shekelle system for grading evidence.\***

<b>LEVEL</b>	<b>CATEGORY OF EVIDENCE</b>
<b>Ia</b>	Evidence from systematic review of randomized controlled trials
<b>Ib</b>	Evidence from at least one randomized controlled trial
<b>IIa</b>	Evidence from at least one controlled study without randomization
<b>IIb</b>	Evidence from at least one other type of quasi-experimental study, such as time series analysis or studies in which the unit of analysis is not the individual
<b>III</b>	Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case-control studies
<b>IV</b>	Evidence from expert committee reports or opinions or clinical experience of respected authorities
<b>CLASSIFICATION</b>	<b>STRENGTH OF RECOMMENDATIONS</b>
<b>A</b>	Directly based on category I evidence
<b>B</b>	Directly based on category II evidence or extrapolated recommendation from category I evidence
<b>C</b>	Directly based on category III evidence or extrapolated recommendation from category I or II evidence
<b>D</b>	Directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence
* Amended with permission of BMJ Publishing Group from Shekelle and colleagues. <sup>48</sup>	

TABLE 2

Evidence statements for caries prevention, enamel fluorosis and dosage schedule.		
TOPIC	EVIDENCE STATEMENTS	LEVEL OF EVIDENCE
<b>Caries Prevention</b>	On the basis of studies conducted mostly in the 1960s and 1970s in the United States, in children younger than 6 years, dietary fluoride supplements reduce the incidence of dental caries in primary teeth*	Ia
	On the basis of studies conducted mostly in the 1970s in the United States, in school-based programs, chewable dietary fluoride supplements reduce the incidence of dental caries in permanent teeth†	Ia
	Adherence to a daily prescription regimen enhances the caries-preventive benefit of dietary fluoride supplements‡	IV
<b>Enamel Fluorosis of the Permanent Dentition</b>	The use of dietary fluoride supplements during tooth development increases the likelihood of developing enamel fluorosis, predominantly of the very mild to mild form§	III
	Inappropriate prescription of dietary fluoride supplements during the first years of life in an area with optimally fluoridated water is associated with mild to moderate enamel fluorosis¶	III
<b>Schedule</b>	In children aged 6 months to 3 years who are exposed to suboptimal levels of fluoride in water, receiving dietary fluoride supplements at 0.25 to 1.00 milligrams per day reduces the incidence of dental caries#	Ib
	In children aged 3 to 6 years who are exposed to suboptimal levels of fluoride in water, receiving dietary fluoride supplements at 0.5 to 1.0 mg per day reduces the incidence of dental caries**	Ib
	In children aged 6 to 16 years who are exposed to suboptimal levels of fluoride in water, receiving dietary fluoride supplements at 0.5 to 1.0 mg per day reduces the incidence of dental caries††	Ib

\* Sources: Bader and colleagues,<sup>39</sup> Hennon and colleagues,<sup>49</sup> Hennon and colleagues<sup>50</sup> and Hennon and colleagues.<sup>51</sup>  
 † Sources: Stephen and Campbell,<sup>10</sup> Ismail and Hasson,<sup>41</sup> Driscoll and colleagues<sup>52</sup> and Driscoll and colleagues.<sup>53</sup>  
 ‡ Sources: Bader and colleagues,<sup>39</sup> Ismail and Bandekar<sup>40</sup> and Ismail and Hasson.<sup>41</sup>  
 § Sources: Ismail and Bandekar,<sup>40</sup> Ismail and Hasson,<sup>41</sup> Spencer and Do<sup>45</sup> and Pendrys and colleagues.<sup>47</sup>  
 ¶ Source: Pendrys and Katz.<sup>54</sup>  
 # Source: Hennon and colleagues,<sup>49</sup> Hamberg,<sup>55</sup> Hu and colleagues<sup>56</sup> and Lin and Tsai.<sup>57</sup>  
 \*\* Sources: Hennon and colleagues,<sup>49</sup> Hennon and colleagues,<sup>50</sup> Hennon and colleagues,<sup>51</sup> Hennon and colleagues<sup>58</sup> and Margolis.<sup>59</sup>  
 †† Sources: DePaola and Lax,<sup>4</sup> Driscoll and colleagues,<sup>5</sup> Stephen and Campbell,<sup>10</sup> Hennon and colleagues,<sup>49</sup> Driscoll and colleagues,<sup>52</sup> Driscoll and colleagues,<sup>53</sup> Allmark and colleagues,<sup>60</sup> Driscoll and colleagues<sup>61</sup> and Driscoll and colleagues.<sup>62</sup>

though the classification of the recommendation may not directly reflect the importance of the recommendation, it does reflect the quality of scientific evidence that supports the recommendation.

Appendix 3 in the supplemental data online (found at “http://jada.ada.org”) lists the numerous scientific experts and organizations that reviewed this document. The panelists evaluated all com-

ments received and made appropriate revisions. The CSA approved the final clinical recommendations.

**Role of the funding source.** The CSA commissioned the panel’s work, which was funded by the ADA.

**RESULTS**

**Published evidence.** The panel included in its evaluations three systematic reviews and two clinical studies related to the clinical questions.<sup>39-41,45,47</sup> Appendix 4 in the supplemental data to the online version of this article (found at “http://jada.ada.org”) presents a summary of these publications, along with a critical appraisal of the strengths and weaknesses of the evidence they offer.

The panelists also analyzed the individual studies in the systematic reviews in which investigators addressed caries prevention, looking for evidence related to specific schedules according to age group and level of fluoride in the community water supply.<sup>39,41</sup> Appendix 5 in the supplemental data to the online version of this article (found at “http://jada.ada.org”) lists the studies that contained evidence regarding the specific schedule of dosages the panel considered. The included studies were not limited to the United States and were conducted in areas with varying levels of fluoride in the community water supply. Appendixes 1, 2 and 6 in the supplemental data to the online version of this article (found at “http://jada.ada.org”) list the excluded publications. The panelists considered the body of evidence and drafted the evidence statements listed in Table 2.<sup>4,5,10,39-41,45,47,49-62</sup> Although investigators in many of the included studies addressed the clinical questions, many of the studies had methodological limitations. Also, some are from an earlier era of fluoride supplement research, during which caries incidence was higher and there were fewer sources of fluoride exposure than there are now. The panel developed clinical recommendations and a dosing schedule for the use of dietary fluoride supplements based on the available evidence (Table 3).

Downloaded from jada.ada.org on March 8, 2011

TABLE 3

<b>Clinical recommendations for the use of dietary fluoride supplements.</b>						
The expert panel convened by the American Dental Association Council on Scientific Affairs developed the following recommendations. They are intended as a resource for dentists and other health care providers. The recommendations must be balanced with the practitioner's professional judgment and the individual patient's needs and preferences.						
Children are exposed to multiple sources of fluoride. The expert panel encourages health care providers to evaluate all potential fluoride sources and to conduct a caries risk assessment before prescribing fluoride supplements.						
<b>RECOMMENDATION</b>			<b>STRENGTH OF RECOMMENDATIONS</b>			
For children at low risk of developing caries, dietary fluoride supplements are not recommended and other sources of fluoride should be considered as a caries-preventive intervention			D			
For children at high risk of developing caries, dietary fluoride supplements are recommended according to the schedule presented in the table below			D			
When fluoride supplements are prescribed, they should be taken daily to maximize the caries-preventive benefit			D			
<b>RECOMMENDED AMERICAN DENTAL ASSOCIATION DIETARY FLUORIDE SUPPLEMENT DOSING SCHEDULE FOR CHILDREN AT HIGH RISK OF DEVELOPING CARIES</b>						
<b>Age (Years)</b>	<b>Amount of Fluoride Supplementation and Strength of Recommendations, According to Fluoride Concentration in Drinking Water (Parts per Million*)</b>					
	<b>&lt; 0.3</b>		<b>0.3-0.6</b>		<b>&gt; 0.6</b>	
	<b>Fluoride supplementation</b>	<b>Strength of recommendations</b>	<b>Fluoride supplementation</b>	<b>Strength of recommendations</b>	<b>Fluoride supplementation</b>	<b>Strength of recommendations</b>
<b>Birth to 6 months</b>	None	D	None	D	None	D
<b>6 months to 3 years</b>	0.25 milligrams per day	B	None	D	None	D
<b>3 to 6 years</b>	0.50 mg/day	B	0.25 mg/day	B	None	D
<b>6 to 16 years</b>	1.00 mg/day	B	0.50 mg/day	B	None	D
* 1.0 part per million = 1 milligram per liter.						

It also identified topics for which additional research is necessary (Box).

## DISCUSSION

Dental caries can be controlled by several strategies used either alone or in combination. These strategies include approaches that involve altering the bacterial flora in the mouth, modifying the diet, increasing the resistance of tooth enamel to acid attack or reversing the demineralization process. The use of fluorides has reduced the incidence of dental caries. On the other hand, ingestion of fluoride during critical periods of tooth development may result in enamel fluorosis. Therefore, as stated above, any recommendations for fluoride supplementation must be based on finding the optimal balance between the benefit of and the risk associated with fluoride use.

Available evidence indicates that the incidence of caries in both the primary and the permanent teeth of children can be reduced with the use of dietary fluoride supplements. Evidence also indicates that the use of dietary fluoride supplements

during tooth development increases the potential risk of developing very mild to mild enamel fluorosis. The panelists considered several factors that can affect the balance between the caries-preventive benefit of dietary fluoride supplementation and the risk of enamel fluorosis development. These factors include the child's age, the fluoride concentration of the child's primary sources of drinking water and the child's caries risk status.

The author of a systematic review conducted in 1999 concluded that the duration and amount of fluoride exposure during amelogenesis contributes to enamel fluorosis in the permanent teeth.<sup>22</sup> Studies have shown that a child's fluoride intake from birth to age 36 months may be associated with enamel fluorosis in his or her permanent anterior teeth.<sup>22,25,63,64</sup> However, exceeding the optimal intake of fluoride beyond this age range also may increase the risk of developing enamel fluorosis.<sup>25</sup> Because of the lack of new evidence, the age stratification as established in the ADA's 1994 recommendation schedule remains unchanged.<sup>65</sup>

## BOX

**Recommendations for research.**

- Develop and validate measures of the public health and individual effects of all degrees of enamel fluorosis and the balance with dental caries.
- Evaluate methods of translating evidence-based recommendations regarding the use of fluoride in caries prevention into the practice of both primary and allied health care professionals (such as physicians, dentists, pharmacists, physicians' assistants, nurse practitioners and dental hygienists).
- Evaluate the effectiveness and feasibility of the use of dietary fluoride supplements in adults.
- Investigate methods of assessing patients' total fluoride exposure and intake.
- Investigate valid and reliable methods of determining patients' risk of caries development and the effectiveness of preventive fluoride therapies.
- Evaluate the effectiveness of dietary fluoride supplements and potential risk of enamel fluorosis in U.S. children receiving fluoride supplements according to the current supplement schedule in the context of total fluoride exposure.
- Determine if and how fluoride metabolism—including fluoride bioavailability, intake and excretion—is influenced by environment, altitude, temperature, genetics, age, sex, nutritional status, pharmacological agents, physiological status and culture. Inherent in this broad scope of factors is the study of the precise molecular and genetic mechanisms involved in fluoride's role in caries and enamel fluorosis.
- For children younger than three years:
  - Determine the relative effectiveness and cost of dietary fluoride supplementation regimens as applied to different population groups.
  - Determine adherence to prescribed regimens by caregivers in different population groups.
  - Compare daily dietary supplementation with alternative fluoride therapies—such as professional applications of fluoride varnish, daily use of fluoridated toothpaste or a combination of these modalities—on the basis of the patient's risk of developing caries.
- Evaluate methods of effecting behavioral change in the motivation of parents or caregivers to adhere to recommendations for the use of dietary fluoride supplements.

The increase in the prevalence of enamel fluorosis may stem from an increase in the number of sources of exposure to fluoride.<sup>26</sup> These sources include water, toothpastes, dietary fluoride supplements, beverages, foods and professional dental products. It is estimated that nearly two-thirds of the cases of mild to moderate enamel fluorosis observed in people living in an area with nonfluoridated water could be attributed to the use of supplements with the supplementation schedules that were in place before 1994.<sup>66</sup> An estimated 13 percent of cases of fluorosis in a community with fluoridated water may stem from the inappropriate use of supplements,<sup>41</sup> and the inappropriate prescription of fluoride supplements during a child's first years of life in an area with optimally fluoridated water is associated with mild to moderate enamel fluorosis.<sup>39</sup> Although information is not easy to assess comprehensively, the practitioner should consider all sources of a patient's fluoride intake and use his or her clinical judgment when prescribing fluoride supplements for children whom he or she suspects of receiving significant amounts of fluoride from other sources and whose teeth are undergoing amelogenesis.

Although there is evidence from systematic

reviews of randomized controlled trials (level I) to support the use of fluoride supplements for caries prevention,<sup>39-41</sup> the panel did not identify studies that supported its use specifically in populations at high or low risk of developing caries. However, in balancing the risks of caries versus those of enamel fluorosis, the panel concluded that concern about caries outweighs concern about enamel fluorosis in children at high risk of developing caries. Therefore, the panel suggested that fluoride supplements should be prescribed only for children at high risk of developing dental caries and whose primary source of drinking water is deficient in fluoride. Because the decision to limit use of fluoride supplements to high-caries-risk children is based on expert opinion, the panel assigned this recommendation a classification level of D (Table 1).

In addition to its systemic effect on developing enamel, ingested fluoride exerts a direct topical effect and an indirect topical effect when it is redistributed to the oral environment by means of saliva.<sup>27,28</sup> Fluoride supplements exert a direct topical effect via exposure to the oral environment when fluoride lozenges or tablets are used. Thus, fluoride supplements can affect caries prevention beyond the ages at which amelogenesis occurs. For this reason, the expert panel recommended prescription of fluoride supplements, when indicated, for children who are up to 16 years of age.

The clinician should conduct a caries risk assessment to determine the appropriateness of prescribing dietary fluoride supplements. There is no exact definition of high risk of developing caries; rather, it can be a continuum.

When determining a patient's caries risk, clinicians can use several tools, including those developed by the ADA,<sup>67,68</sup> the American Academy of Pediatric Dentistry<sup>69</sup> and other health care agencies.<sup>70,71</sup> For physicians, information about caries risk assessment is available from the dental agency of Bright Futures, a national health promotion initiative launched in 1990 by the Health Resources and Services Administration's Maternal and Child Health Bureau (now the National Center for Education in Maternal and Child Health).<sup>72</sup> Providers should repeat caries

risk assessment at frequent intervals, because risk status can be affected by changes in the child's development, personal and family situations, and behavioral factors such as dietary regimen and oral hygiene practices. Because of known increases in exposure to fluoride from multiple sources and the increased prevalence of enamel fluorosis in permanent teeth, the panel emphasized the need for caries risk assessment, weighing the benefits and risks of dietary fluoride supplement use, and judicious prescription of dietary fluoride supplements.

Health care providers should evaluate a child's other sources of fluoride exposure, including fluoride from water, when deciding whether to prescribe supplements. They can contact local, county or state health departments for information on the fluoride content of public water sources or to be referred to a certified laboratory that can provide a fluoride test for private wells. Bottled drinking water containing fluoride is commercially available in some parts of the country and may substitute for fluoridated tap water.

Compliance with the daily prescription regimen enhances the caries-preventive benefit of dietary fluoride supplements.<sup>43,44</sup> As with all prescriptions, the provider should explain to the patient the potential benefits and risks of dietary fluoride supplements. The provider also should instruct the parents or caregivers and the patient, as developmentally appropriate, about the use of fluoride supplements. To maximize the topical effect of fluoride, patients should chew tablets or suck lozenges for one to two minutes before swallowing them.<sup>28</sup> For infants, supplements are available in liquid form to be used with a dropper.<sup>28</sup> Dentists, physicians and other health care workers should ensure that caregivers and patients understand the importance of adhering to the supplement regimen.<sup>73</sup> The expert panel suggested that, when prescribed, fluoride supplements should be used as directed to maximize their caries-preventive benefit. Furthermore, providers should monitor the patient's adherence to the schedule carefully to maximize the potential therapeutic benefit. If the clinician has concern about lack of adherence to the fluoride supplement schedule, he or she should consider other sources of fluoride exposure, such as bottled water containing fluoride.

## CONCLUSION

The panel concluded that fluoride supplements are effective in preventing caries. Owing to

known increases in exposure to fluoride from multiple sources and the increased prevalence of enamel fluorosis, the panel recommended fluoride supplement use for children at high risk of developing caries. These recommendations emphasize the need for caries risk assessment and judicious prescription of dietary fluoride supplements with consideration of total fluoride intake. ■

Dr. Rozier is the chair and a professor of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina at Chapel Hill.

Dr. Adair is a professor emeritus, Department of Pediatric Dentistry, School of Dentistry, Medical College of Georgia, Augusta; and the chief dental officer, FORBA Dental Management, Nashville, Tenn.

Dr. Graham maintains a private practice in orthodontics in Teaneck, N.J.; and is a senior attending dentist in orthodontics, Department of Dentistry, Montefiore Medical Center, Bronx, N.Y. He also is the immediate past chair, American Dental Association Council on Dental Practice, and represented the council on the expert panel.

Dr. Iafolla is a public health analyst, Office of Science Policy and Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, Md.

Dr. Kingman is the chief biostatistician, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, Md.

Dr. Kohn is the director, Division of Oral Health, Centers for Disease Control and Prevention, Atlanta.

Dr. Krol is the team director and the senior program officer, Human Capital, Robert Wood Johnson Foundation, Princeton, N.J.

Dr. Levy is the Wright-Bush-Shreves Endowed Professor of Research, Department of Preventive and Community Dentistry, College of Dentistry, and a professor, Department of Epidemiology, College of Public Health, University of Iowa, Iowa City.

Dr. Pollick is a clinical professor, Department of Preventive and Restorative Dental Sciences, School of Dentistry, University of California San Francisco.

Dr. Whitford is a Regents Professor, Department of Oral Biology, School of Dentistry, Medical College of Georgia, Augusta.

Dr. Strock is the senior manager, Council on Access, Prevention and Interprofessional Relations, American Dental Association, Chicago.

Dr. Frantsve-Hawley is the director, Research Institute, and the director, Center for Evidence-based Dentistry, Division of Science, American Dental Association, Chicago. Address reprint requests to Dr. Frantsve-Hawley at Center for Evidence-based Dentistry, Division of Science, American Dental Association, 211 E. Chicago Ave., Chicago, Ill. 60611, e-mail "frantsvej@ada.org".

Dr. Aravamudhan is the assistant director, Center for Evidence-based Dentistry, Division of Science, American Dental Association, Chicago.

Dr. Meyer is the director, Division of Science, and the senior vice president, Science and Professional Affairs, American Dental Association, Chicago.

**Disclosures.** Dr. Adair is the chief dental officer, FORBA Dental Management, Nashville. None of the other authors reported any disclosures.

The American Dental Association Council on Scientific Affairs and the members of the expert panel thank Dr. Amid Ismail; Dr. David G. Pendrys; Ms. Jane McGinley; Mazhar Said, PhD; and Cliff Whall, PhD, for their contributions to this project.

1. Dye BA, Tan S, Smith V, et al. Trends in oral health status: United States, 1988-1994 and 1999-2004. *Vital Health Stat* 11 2007(248):1-92.

2. From the Centers for Disease Control and Prevention. Achievements in public health, 1900-1999: fluoridation of drinking water to prevent dental caries. *Morbidity and Mortality Weekly Report (MMWR)* 1999;48(41):933-940.

3. Dean HT. Fluorine and dental caries. *Ill Med J* 1949;95(1):33-37.

4. DePaola PF, Lax M. The caries-inhibiting effect of acidulated phosphate-fluoride chewable tablets: a two-year double-blind study. *JADA* 1968;76(3):554-557.

5. Driscoll WS, Heifetz SB, Korts DC. Effect of chewable fluoride tablets on dental caries in schoolchildren: results after six years of use. *JADA* 1978;97(5):820-824.

6. Groeneveld A, Van Eck AA, Backer Dirks O. Fluoride in caries prevention: is the effect pre- or post-eruptive? *J Dent Res* 1990;69(special issue):751-755.
7. Singh KA, Spencer AJ. Relative effects of pre- and post-eruption water fluoride on caries experience by surface type of permanent first molars. *Community Dent Oral Epidemiol* 2004;32(6):435-446.
8. Singh KA, Spencer AJ, Armfield JM. Relative effects of pre- and posteruption water fluoride on caries experience of permanent first molars. *J Public Health Dent* 2003;63(1):11-19.
9. Singh KA, Spencer AJ, Brennan DS. Effects of water fluoride exposure at crown completion and maturation on caries of permanent first molars. *Caries Res* 2007;41(1):34-42.
10. Stephen KW, Campbell D. Caries reduction and cost benefit after 3 years of sucking fluoride tablets daily at school: a double-blind trial. *Br Dent J* 1978;144(7):202-206.
11. Thylstrup A, Fejerskov O, Bruun C, Kann J. Enamel changes and dental caries in 7-year-old children given fluoride tablets from shortly after birth. *Caries Res* 1979;13(5):265-276.
12. Featherstone JD. Prevention and reversal of dental caries: role of low level fluoride. *Community Dent Oral Epidemiol* 1999;27(1):31-40.
13. Koulourides T. Summary of session II: fluoride and the caries process. *J Dent Res* 1990;69(special issue):558.
14. Chow LC. Tooth-bound fluoride and dental caries. *J Dent Res* 1990;69(special issue):595-600.
15. Ericsson SY. Cariostatic mechanisms of fluorides: clinical observations. *Caries Res* 1977;11(suppl 1):2-41.
16. Kidd EA, Thylstrup A, Fejerskov O, Bruun C. Influence of fluoride in surface enamel and degree of dental fluorosis on caries development in vitro. *Caries Res* 1980;14(4):196-202.
17. Thylstrup A. Clinical evidence of the role of pre-eruptive fluoride in caries prevention. *J Dent Res* 1990;69(special issue):742-750.
18. Hamilton IR. Biochemical effects of fluoride on oral bacteria. *J Dent Res* 1990;69(special issue):660-667.
19. Van Loveren C. The antimicrobial action of fluoride and its role in caries inhibition. *J Dent Res* 1990;69(special issue):676-681.
20. Murray JJ. Efficacy of preventive agents for dental caries: systemic fluorides—water fluoridation. *Caries Res* 1993;27(suppl 1):2-8.
21. Margolis HC, Moreno EC. Physicochemical perspectives on the cariostatic mechanisms of systemic and topical fluorides. *J Dent Res* 1990;69(special issue):606-613.
22. Bardsen A. "Risk periods" associated with the development of dental fluorosis in maxillary permanent central incisors: a meta-analysis. *Acta Odontol Scand* 1999;57(5):247-256.
23. Bardsen A, Klock KS, Bjorvatn K. Dental fluorosis among persons exposed to high- and low-fluoride drinking water in western Norway. *Community Dent Oral Epidemiol* 1999;27(4):259-267.
24. Pendrys DG, Stamm JW. Relationship of total fluoride intake to beneficial effects and enamel fluorosis. *J Dent Res* 1990;69(special issue):529-538; discussion 556-557.
25. Hong L, Levy SM, Broffitt B, et al. Timing of fluoride intake in relation to development of fluorosis on maxillary central incisors. *Community Dent Oral Epidemiol* 2006;34(4):299-309.
26. Mascarenhas AK. Risk factors for dental fluorosis: a review of the recent literature. *Pediatr Dent* 2000;22(4):269-277.
27. Rølla G, Ekstrand J. Fluoride in oral fluids and dental plaque. In: Fejerskov O, Ekstrand J, Burt BA, eds. *Fluoride in Dentistry*. 2nd ed. Copenhagen, Denmark: Munksgaard; 1996: 215-229.
28. Centers for Disease Control and Prevention. Recommendations for using fluoride to prevent and control dental caries in the United States. *MMWR Recomm Rep* 2001;50(RR-14):1-42.
29. U.S. Public Health Service. *Public Health Service Drinking Water Standards*. Washington: U.S. Department of Health, Education, and Welfare, Public Health Service; 1962.
30. Adair SM, Hanes CM, Russell CM, Whitford GM. Dental caries and fluorosis among children in a rural Georgia area. *Pediatr Dent* 1999;21(2):81-85.
31. Cutress TW, Suckling GW. Differential diagnosis of dental fluorosis. *J Dent Res* 1990;69(special issue):714-720; discussion 721.
32. Beltran-Aguilar ED, Barker LK, Canto MT, et al. Surveillance for dental caries, dental sealants, tooth retention, edentulism, and enamel fluorosis: United States, 1988-1994 and 1999-2002. *MMWR Surveill Summ* 2005;54(3):1-43.
33. Beltran-Aguilar ED, Griffin SO, Lockwood SA. Prevalence and trends in enamel fluorosis in the United States from the 1930s to the 1980s. *JADA* 2002;133(2):157-165.
34. U.S. Department of Health and Human Services, Committee to Coordinate Environmental Health and Related Programs, Ad Hoc Subcommittee on Fluoride. *Review of Fluoride Benefits and Risks: Report of the Ad Hoc Subcommittee on Fluoride of the Committee to Coordinate Environmental Health and Related Programs*. Washington: U.S. Public Health Service, Department of Health and Human Services; 1991: 48-62.
35. Eklund SA, Burt BA, Ismail AI, Calderone JJ. High-fluoride drinking water, fluorosis, and dental caries in adults. *JADA* 1987; 114(3):324-328.
36. Iida H, Kumar JV. The association between enamel fluorosis and dental caries in U.S. schoolchildren. *JADA* 2009;140(7):855-862.
37. Chankanka O, Levy SM, Warren JJ, Chalmers JM. A literature review of aesthetic perceptions of dental fluorosis and relationships with psychosocial aspects/oral health-related quality of life. *Community Dent Oral Epidemiol* 2010;38(2):97-109.
38. Do LG, Spencer A. Oral health-related quality of life of children by dental caries and fluorosis experience. *J Public Health Dent* 2007; 67(3):132-139.
39. Bader JD, Rozier RG, Lohr KN, Frame PS. Physicians' roles in preventing dental caries in preschool children: a summary of the evidence for the U.S. Preventive Services Task Force. *Am J Prev Med* 2004;26(4):315-325.
40. Ismail AI, Bandekar RR. Fluoride supplements and fluorosis: a meta-analysis. *Community Dent Oral Epidemiol* 1999;27(1):48-56.
41. Ismail AI, Hasson H. Fluoride supplements, dental caries and fluorosis: a systematic review. *JADA* 2008;139(11):1457-1468.
42. Ollila P, Larmas M. A seven-year survival analysis of caries onset in primary second molars and permanent first molars in different caries risk groups determined at age two years. *Acta Odontol Scand* 2007;65(1):29-35.
43. Wennhall I, Matsson L, Schroder U, Twetman S. Outcome of an oral health outreach programme for preschool children in a low socioeconomic multicultural area. *Int J Paediatr Dent* 2008;18(2):84-90.
44. Do LG, Spencer AJ, Ha DH. Association between dental caries and fluorosis among South Australian children. *Caries Res* 2009;43(5): 366-373.
45. Spencer AJ, Do LG. Changing risk factors for fluorosis among South Australian children. *Community Dent Oral Epidemiol* 2008; 36(3):210-218.
46. Warren JJ, Levy SM, Broffitt B, Cavanaugh JE, Kanellis MJ, Weber-Gasparoni K. Considerations on optimal fluoride intake using dental fluorosis and dental caries outcomes: a longitudinal study. *J Public Health Dent* 2009;69(2):111-115.
47. Pendrys DG, Haugejorden O, Bardsen A, Wang NJ, Gustavsen F. The risk of enamel fluorosis and caries among Norwegian children: implications for Norway and the United States. *JADA* 2010;141(4):401-414.
48. Shekelle PG, Woolf SH, Eccles M, Grimshaw J. *Clinical guidelines: developing guidelines*. *BMJ* 1999;318(7183):593-596.
49. Hennon DK, Stookey GK, Beiswanger BB. Fluoride-vitamin supplements: effects on dental caries and fluorosis when used in areas with suboptimum fluoride in the water supply. *JADA* 1977;95(5):965-971.
50. Hennon DK, Stookey GK, Muhler JC. The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations: results at the end of three years. *J Dent Child* 1966;33(1):3-12.
51. Hennon DK, Stookey GK, Muhler JC. The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations: results at the end of four years. *J Dent Child* 1967;34(6):439-443.
52. Driscoll WS, Heifetz SB, Brunelle JA. Caries-preventive effects of fluoride tablets in schoolchildren four years after discontinuation of treatments. *JADA* 1981;103(6):878-881.
53. Driscoll WS, Heifetz SB, Brunelle JA. Treatment and posttreatment effects of chewable fluoride tablets on dental caries: findings after 7 1/2 years. *JADA* 1979;99(5):817-821.
54. Pendrys DG, Katz RV. Risk factors for enamel fluorosis in optimally fluoridated children born after the US manufacturers' decision to reduce the fluoride concentration of infant formula. *Am J Epidemiol* 1998;148(10):967-974.
55. Hamberg L. Controlled trial of fluoride in vitamin drops for prevention of caries in children. *Lancet* 1971;1(7696):441-442.
56. Hu D, Wan H, Li S. The caries-inhibiting effect of a fluoride drop program: a 3-year study on Chinese kindergarten children. *Chin J Dent Res* 1998;1(3):17-20.
57. Lin YT, Tsai CL. Comparative anti-caries effects of tablet and liquid fluorides in cleft children. *J Clin Dent* 2000;11(4):104-106.
58. Hennon DK, Stookey GK, Muhler JC. Prophylaxis of dental caries: relative effectiveness of chewable fluoride preparations with and without added vitamins. *J Pediatr* 1972;80(6):1018-1021.
59. Margolis FJ. Editorial: value of fluoride supplements in prevention of dental caries. *JAMA* 1975;234(3):312-313.
60. Allmark C, Green HP, Linney AD, Wills DJ, Picton DC. A community study of fluoride tablets for school children in Portsmouth: results after six years. *Br Dent J* 1982;153(12):426-430.

61. Driscoll WS, Heifetz SB, Korts DC. Effect of acidulated phosphate-fluoride chewable tablets on dental caries in schoolchildren: results after 30 months. *JADA* 1974;89(1):115-120.
62. Driscoll WS, Heifetz SB, Korts DC, Meyers RJ, Horowitz HS. Effect of acidulated phosphate-fluoride chewable tablets in schoolchildren: results after 55 months. *JADA* 1977;94(3):537-543.
63. Evans RW, Darvell BW. Refining the estimate of the critical period for susceptibility to enamel fluorosis in human maxillary central incisors. *J Public Health Dent* 1995;55(4):238-249.
64. Evans RW, Stamm JW. An epidemiologic estimate of the critical period during which human maxillary central incisors are most susceptible to fluorosis. *J Public Health Dent* 1991;51(4):251-259.
65. American Dental Association. Fluoride Supplement Dosage Schedule: 1994. "www.ada.org/3088.aspx#dosschedule". Accessed Sept. 21, 2010.
66. Pendrys DG. Risk of enamel fluorosis in nonfluoridated and optimally fluoridated populations: considerations for the dental professional. *JADA* 2000;131(6):746-755.
67. American Dental Association. Caries Risk Assessment Form (Ages 0-6). "www.ada.org/sections/professionalResources/docs/topics\_caries\_under6.doc". Accessed Sept. 21, 2010.
68. American Dental Association. Caries Risk Assessment Form (Age > 6). "www.ada.org/sections/professionalResources/docs/topics\_caries\_over6.doc". Accessed Sept. 21, 2010.
69. American Academy of Pediatric Dentistry. Policy on Use of a Caries-risk Assessment Tool (CAT) for Infants, Children and Adolescents. In: Oral Health Policies Reference Manual; 2006. "www.aapd.org/media/Policies\_Guidelines/P\_CariesRiskAssess.pdf". Accessed Sept. 21, 2010.
70. Featherstone JD, Domejean-Orliaguet S, Jensen L, Wolff M, Young DA. Caries risk assessment in practice for age 6 through adult. *J Calif Dent Assoc* 2007;35(10):703-707, 710-713.
71. Ramos-Gomez FJ, Crall J, Gansky SA, Slayton RL, Featherstone JD. Caries risk assessment appropriate for the age 1 visit (infants and toddlers). *J Calif Dent Assoc* 2007;35(10):687-702.
72. National Maternal and Child Oral Health Resource Center. Bright Futures in Practice: Oral Health Pocket Guide. "www.mchoralhealth.org/PocketGuide/tables1.html". Accessed Sept. 21, 2010.
73. Adair SM. Evidence-based use of fluoride in contemporary pediatric dental practice. *Pediatr Dent* 2006;28(2):133-142.