Dental caries remains the most common chronic disease of childhood in the United States. Caries is a largely preventable condition, and fluoride has proven effectiveness in the prevention of caries. The goals of this clinical report are to clarify the use of available fluoride modalities for caries prevention in the primary care setting and to assist pediatricians in using fluoride to achieve maximum protection against dental caries while minimizing the likelihood of enamel fluorosis.

Dental caries (ie, tooth decay) is an infectious disease in which acid produced by bacteria dissolves tooth enamel. If not halted, this process will continue through the tooth and into the pulp, resulting in pain and tooth loss. This activity can further progress to local infections (ie, dental alveolar abscess or facial cellulitis), systemic infection, and, in rare cases, death. Dental caries in the United States is responsible for many of the 51 million school hours lost per year as a result of dental-related illness, which translates into lost work hours for the parent or adult caregiver. Early childhood caries is the single greatest risk factor for caries in the permanent dentition. Good oral health is a necessary part of overall health, and recent studies have demonstrated the adverse effects of poor oral health on multiple other chronic conditions, including diabetes control. Therefore, the failure to prevent caries has health, educational, and financial consequences at both the individual and societal level.

Dental caries is the most common chronic disease of childhood, with 50% of 12- to 19-year-olds having at least 1 documented cavity. Caries is the “silent epidemic” that disproportionately affects poor, young, and minority populations. The prevalence of dental caries in very young children increased during the period between the last 2 national surveys, despite improvements for older children. Because many children do not receive dental care at young ages, and risk factors for dental caries are influenced by parenting practices, pediatricians have a unique opportunity to participate in the primary prevention of dental caries. Studies show that simple home and primary care setting prevention measures would save health care dollars.

Development of dental caries requires 4 components: teeth, bacteria, carbohydrate exposure, and time. Once teeth emerge, they may become colonized with cariogenic bacteria. The bacteria metabolize carbohydrates...
and create acid as a byproduct. The acid dissolves the mineral content of enamel (demineralization) and, over time with repeated acid attacks, the enamel surface collapses and results in a cavity in the tooth. Protective factors that help to remineralize enamel include exposing the teeth to fluoride, limiting the frequency of carbohydrate consumption, choosing less cariogenic foods, practicing good oral hygiene, receiving regular dental care, and delaying bacterial colonization. If carious lesions are identified early, the process can be halted or reversed by modifying the patient’s individual risk and protective factors. Certain American Academy of Pediatrics (AAP) publications (Oral Health Risk Assessment Timing and Establishment of the Dental Home and Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents) discuss these concepts in greater depth and provide targeted preventive anticipatory guidance. The Medical Expenditure Panel Survey demonstrated that 89% of infants and 1-year-olds have office-based physician visits annually, compared with only 1.5% who have dental visits. For primary prevention to be effective, it is imperative that pediatricians be knowledgeable about the process of dental caries, prevention of the disease, and available interventions, including fluoride.

Fluoride is available from many sources and is divided into 3 major categories: tap water (and foods and beverages processed with fluoridated water), home administered, and professionally applied. There has been substantial public and professional debate about fluoride, and myriad information is available, often with confusing or conflicting messages. The widespread decline in dental caries in many developed countries, including the United States, has been largely attributable to the use of fluoride. Fluoride has 3 main mechanisms of action: (1) it promotes enamel remineralization; (2) it reduces enamel demineralization; and (3) it inhibits bacterial metabolism and acid production. The mechanisms of fluoride are both topical and systemic, but the topical effect is the most important, especially over the life span.

**RISK OF FLUOROSIS**

The only scientifically proven risk of fluoride use is the development of fluorosis, which may occur with fluoride ingestion during tooth and bone development. Fluorosis of permanent teeth occurs when fluoride of sufficient quantity for a sufficient period of time is ingested during the time that tooth enamel is being mineralized. Fluorosis is the result of subsurface hypomineralization and porosity between the developing enamel rods. This risk exists in children younger than 8 years, and the most susceptible period for permanent maxillary incisor fluorosis is between 15 and 30 months of age. The risk of fluorosis is influenced by both the dose and frequency of exposure to fluoride during tooth development.

Recent evidence also suggests that individual susceptibility or resistance to fluorosis includes a genetic component.

After 8 years of age, there is no further risk of fluorosis (except for the third molars) because the permanent tooth enamel is fully mineralized. The vast majority of enamel fluorosis is mild or very mild and characterized by small white striations or opaque areas that are not readily noticeable to the casual observer. Although this type of fluorosis is of no clinical consequence, enamel fluorosis has been increasing in frequency over the last 2 decades to a rate of approximately 41% among adolescents because fluoride sources are more widely available in varied forms. Moderate and severe forms of enamel fluorosis are uncommon in the United States but have both an aesthetic concern and potentially a structural concern, with pitting, brittle incisal edges, and weakened groove anatomy in the permanent 6-year molars.

In 2001, the AAP endorsed the guidelines from the Centers for Disease Control and Prevention (CDC), “Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States.” Dental and governmental organizations (American Dental Association [ADA], American Academy of Pediatric Dentistry, the Department of Health and Human Services, and the CDC) have more recently published guidelines on the use of fluoride, but current AAP publications do not reflect these newer evidence-based guidelines. Table 1 provides a simple explanation of fluoride use for patients at low and high risk of caries.

The present report has 2 goals: (1) to assist pediatricians in using fluoride to achieve maximum protection against

<table>
<thead>
<tr>
<th>TABLE 1 Summary of Fluoride Modalities for Low- and High-Risk Patients</th>
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<tbody>
<tr>
<td><strong>Fluoride Modality</strong></td>
</tr>
<tr>
<td>Toothpaste</td>
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<tr>
<td>Fluoride varnish</td>
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<tr>
<td>Over-the-counter mouth rinse</td>
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<tr>
<td>Community water fluoridation</td>
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<tr>
<td>Dietary fluoride supplements</td>
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dental caries while minimizing the likelihood of enamel fluorosis; and (2) to clarify the advice that should be given by pediatricians regarding fluoride in the primary care setting.

CURRENT INFORMATION REGARDING FLUORIDE USE IN CARIES PREVENTION

The following information aims to assist pediatricians in achieving maximum protection against dental caries for their patients while minimizing the likelihood of enamel fluorosis. Sources of ingested fluoride include drinking water, infant formula, fluoride toothpaste, prescription fluoride supplements, fluoride mouth rinses, professionally applied topical fluoride, and some foods and beverages.18

Fluoride Toothpaste

Fluoride toothpaste has consistently been proven to provide a caries-preventive effect for individuals of all ages.15,19 In the United States, the fluoride concentration of over-the-counter toothpaste ranges from 1000 to 1100 ppm. In some other countries, toothpastes containing 1500 ppm of fluoride are available. A 1-inch (1-g) strip of toothpaste translates to 1 or 1.5 mg of fluoride, respectively. A pea-sized amount of toothpaste is approximately one-quarter of an inch. Therefore, a pea-sized amount of toothpaste containing 1000/1100 ppm of fluoride would have approximately 0.25 mg of fluoride, and the same amount of toothpaste containing 1500 ppm of fluoride would have approximately 0.38 mg of fluoride. Most fluoride toothpaste in the United States contains sodium fluoride, sodium monofluorophosphate, or stannous fluoride as the active ingredient. Parents should supervise children younger than 8 years to ensure the proper amount of toothpaste and effective brushing technique. Children younger than 6 years are more likely to ingest some or all of the toothpaste used. Ingestion of excessive amounts of fluoride can increase the risk of fluorosis. This excess can be minimized by limiting the amount of toothpaste used and by storing toothpaste where young children cannot access it without parental help.

Use of fluoride toothpaste should begin with the eruption of the first tooth. When fluoride toothpaste is used for children younger than 3 years, it is recommended that the amount be limited to a smear or grain of rice size (about one-half of a pea). Once the child has turned 3 years of age, a pea-sized amount of toothpaste should be used.20,21 Young children should not be given water to rinse after brushing because their instinct is to swallow. Expectorating without rinsing will both reduce the amount of fluoride swallowed and leave some fluoride in the saliva, where it is available for uptake by the dental plaque. Parents should be strongly advised to supervise their child’s use of fluoride toothpaste to avoid overuse or ingestion.

High-concentration toothpaste (5000 ppm) is available by prescription only. The active ingredient in this toothpaste is sodium fluoride. This agent can be recommended for children 6 years and older and adolescents who are at high risk of caries and who are able to expectorate after brushing. Dentists may also prescribe this agent for adolescents who are undergoing orthodontic treatment, as they are at increased risk of caries during this time.22

Fluoride Varnish

Fluoride varnish is a concentrated topical fluoride that is applied to the teeth by using a small brush and sets on contact with saliva. Advantages of this modality are that it is well tolerated by infants and young children, has a prolonged therapeutic effect, and can be applied by both dental and non-dental health professionals in a variety of settings.23 The concentration of fluoride varnish is 22 600 ppm (2.26%), and the active ingredient is sodium fluoride. The unit dose packaging from most manufacturers provides a specific measured amount (0.25 mg, providing 5 mg of fluoride ion). The application of fluoride varnish during an oral screening is of benefit to children, especially those who may have limited access to dental care. Current American Academy of Pediatric Dentistry recommendations for children at high risk of caries is that fluoride varnish be applied to their teeth every 3 to 6 months.24 The 2013 ADA guideline recommends application of fluoride varnish at least every 6 months to both primary and permanent teeth in those subjects at elevated caries risk.25 The US Preventive Services Task Force recently published a new recommendation that primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption (B recommendation).26

In most states, Medicaid will pay physicians for the application of fluoride varnish. Information regarding fluoride varnish application reimbursement and which states currently provide payment can be found on the AAP Web site (http://www2.aap.org/oralhealth/docs/OHRReimbursementChart.pdf) and the Pew Charitable Trusts Web site (http://www.pewstates.org/research/analysis/reimbursing-physicians-for-fluoride-varnish-8589377335). Because state regulations vary regarding whether fluoride varnish must be applied within the context of a preventive care code, this information should be determined before billing.

Indications for Use

In the primary care setting, fluoride varnish should be applied to the teeth of all infants and children at least once every 6 months and preferably every 3 months, starting when the first tooth
erupts and until establishment of a dental home.

Instructions for Use
Fluoride varnish must be applied by a dentist, dental auxiliary professional, physician, nurse, or other health care professional, depending on the practice regulations in each state. It should not be dispensed to families to apply at home. Application of fluoride varnish is most commonly performed at the time of a well-child visit. Teeth are dried with a 2-inch gauze square, and the varnish is then painted onto all surfaces of the teeth with a brush provided with the varnish. Children are instructed to eat soft foods and not to brush their teeth on the evening after the varnish application to maximize the contact time of the varnish to the tooth. The following day, they should resume brushing twice daily with fluoridated toothpaste.

Over-the-Counter Fluoride Rinse
Over-the-counter fluoride rinse provides a lower concentration of sodium fluoride than toothpaste or varnish. The concentration is most commonly 230 ppm (0.05% sodium fluoride). Expert panels on this topic have concluded that over-the-counter fluoride rinses should not be recommended for children younger than 6 years because of their limited ability to rinse and spit and the risk of swallowing higher-than-recommended levels of fluoride.27 A teaspoon (5 mL) of over-the-counter fluoride rinse contains approximately 1 mg of fluoride. For children younger than 6 years, this type of rinse provides an additional, low-dose topical fluoride application that may assist in the prevention of enamel demineralization. However, the evidence for an anticaries effect is limited. The daily use of a 0.05% sodium fluoride rinse may be of benefit for children older than 6 years who are at high risk of dental caries; however, there is no additional benefit beyond daily use of fluoridated toothpaste for children at low risk of caries.28,29

Dietary Fluoride Supplements
Dietary fluoride supplements should be considered for children living in communities in which the community water is not fluoridated or who drink well water that does not contain fluoride.26 Because there are many sources of fluoride in the water supply and in processed food, it is essential that all potential sources of fluoride be assessed before prescribing a dietary supplement, including consideration of differing environmental exposures (eg, dual homes, child care). As a general guideline, if the primary source of water is fluoridated tap or well water, the child will not require fluoride supplementation, even if he or she primarily drinks bottled water; because the teeth are exposed to fluoride through cooking and brushing. The risk of fluorosis is high if fluoride supplements are given to a child consuming fluoridated water.30 Information about the fluoridation levels in many community water systems can be found on the CDC Web site entitled My Water's Fluoride (http://apps.nccd.cdc.gov/MyWaterFluoride). Not all communities report this information to the CDC; therefore, it may be necessary to contact the local water department to determine the level of fluoride in the community water. Well water must be tested for fluoride content before prescribing supplements; such testing is available in most states through the state or county public health laboratory.

Guidelines for Use
CDC recommendations regarding fluoride supplementation are provided in Table 2. Supplements can be prescribed in liquid or tablet form. Tablets are preferable for children old enough to chew, because they gain an additional topical benefit to the teeth during the chewing process. Liquid supplements are recommended for younger children and should ideally be added to water or put directly into the child’s mouth. Addition of the fluoride supplement to milk or formula is not recommended because of the reduced absorption of fluoride in the presence of calcium.51 The risk of mild fluorosis can be minimized by health care providers verifying that there are no other sources of fluoride exposure before prescribing systemic fluoride supplements.

Other Sources of Fluoride
Fluoride is present in processed foods and beverages and may be naturally occurring in some areas of the country. The presence of fluoride in juices and carbonated beverages does not counteract the cariogenic nature of these beverages.

Reconstitution of Infant Formula
In a study of infant feeding practices, 70% to 75% of mothers who fed their infants formula used tap water to reconstitute the powdered formula.52 According to CDC data from 2012, approximately 67% of US households using public water supplies received

<p>| TABLE 2 Fluoride Supplementation Schedule for Children |</p>
<table>
<thead>
<tr>
<th>Age</th>
<th>Fluoride Ion Level in Drinking Watera</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth–6 mo</td>
<td>None</td>
</tr>
<tr>
<td>6 mo–3 y</td>
<td>0.25 mg/db</td>
</tr>
<tr>
<td>3–6 y</td>
<td>0.50 mg/d</td>
</tr>
<tr>
<td>6–16 y</td>
<td>1.0 mg/d</td>
</tr>
<tr>
<td>Source: Centers for Disease Control and Prevention.46</td>
<td></td>
</tr>
<tr>
<td>a 1.0 ppm = 1 mg/L</td>
<td></td>
</tr>
<tr>
<td>b 2.2 mg of sodium fluoride contains 1 mg of fluoride ion</td>
<td></td>
</tr>
</tbody>
</table>
optimally fluoridated water (between 0.7 and 1.2 ppm).35

ADA Evidenced-Based Clinical Recommendations
In 2011, the ADA Council on Scientific Affairs examined the existing evidence and made 2 recommendations. The first recommendation supported the continued use of optimally fluoridated water to reconstitute powdered and liquid infant formula, being cognizant of the small risk of fluorosis in permanent teeth. The second recommendation stated that if there was concern about the risk of mild fluorosis, the formula could be reconstituted with bottled (nonfluoridated) water.18 It should be noted that most bottled water has suboptimal levels of fluoride and that fluoride content is not listed unless it is added.

Community Water Fluoridation
Community water fluoridation is the practice of adding a small amount of fluoride to the water supply. It has been heralded as 1 of the top 10 public health achievements of the 20th century by the CDC.34 Community water fluoridation is a safe, efficient, and cost-effective way to prevent tooth decay and has been shown to reduce tooth decay by 29%.35 It prevents tooth decay through the provision of low levels of fluoride exposure to the teeth over time and provides both topical and systemic exposure. It is estimated that every dollar invested in water fluoridation saves $38 in dental treatment costs (http://www.cdc.gov/fluoridation/benefits/). Currently, although more than 210 million Americans live in communities with optimally fluoridated water, there are more than 70 million others with public water systems who do not have access to fluoridated water.33 The fluoridation status of a community water supply can be determined by contacting the local water department or accessing the Web site My Water’s Fluoride (http://apps.nccd.cdc.gov/MWF/Index.asp).

Recommended Concentration
Water fluoridation was initiated in the United States in the 1940s. In January 2011, the US Department of Health and Human Services proposed a change to lower the optimal fluoride level in drinking water. The proposed new recommendation is 0.7 mg of fluoride per liter of water to replace the previous recommendation, which was based on climate and ranged from 0.7 mg/L in the warmest climates to 1.2 mg/L in the coldest climates.36 The change was recommended because recent studies showed no variation in water consumption by young children based on climate and to adjust for an overall increase in sources of fluoride (foods and beverages processed with fluoridated water and fluoridated mouth rinses and toothpastes) in the American diet.

Evidence Supporting Community Water Fluoridation
Despite overwhelming evidence supporting the safety and preventive benefits of fluoridated water, community water fluoridation continues to be a controversial and highly emotional issue. Opponents express a number of concerns, all of which have been addressed or disproven by validated research. The only scientifically documented adverse effect of excess (nontoxic) exposure to fluoride is fluorosis. An increase in the incidence of mild enamel fluorosis among teenagers has been cited as a reason to discontinue fluoridation, even though this condition is cosmetic with no detrimental health outcomes. Recent opposition has sometimes centered on the question of who decides whether to fluoridate (elected/public officials or the voters), possibly reflecting a recent trend of distrust of the US government. Many opponents believe fluoridation to be mass medication and call the ethics of community water fluoridation into question, but courts have consistently held that it is legal and appropriate for a community to adopt a fluoridation program.37 Opponents also express concern about the quality and source of fluoride, claiming that the additives (fluorosilicic acid, sodium fluoride, or sodium fluorosilicate), in their concentrated form, are highly toxic and are byproducts of the production of phosphate fertilizer and may include other contaminants, such as arsenic. The quality and safety of fluoride additives are ensured by Standard 60 of the National Sanitation Foundation/American National Standards Institute, a program commissioned by the Environmental Protection Agency (EPA), and testing has been conducted to confirm that arsenic or other substances are below the levels allowed by the EPA.38 Finally, there have been many unsubstantiated or disproven claims that fluoride leads to kidney disease, bone cancer, and compromised IQ. More than 3000 studies or research papers have been published on the subject of fluoride or fluoridation.39 Few topics have been as thoroughly researched, and the overwhelming weight of the evidence—in addition to 68 years of experience—supports the safety and effectiveness of this public health practice.

Naturally Occurring Fluoride in Drinking Water
The optimal fluoride level in drinking water is 0.7 to 1.2 ppm, an amount that has been proven beneficial in reducing tooth decay. Naturally occurring fluoride may be below or above these levels in some areas. Under the Safe Drinking Water Act (Pub L No. 93-523 [1974]), the EPA requires notification by the water supplier if the fluoride level exceeds 2 ppm. In areas where naturally occurring fluoride levels in drinking water exceed 2 ppm, people should consider an alternative water source or home water treatments to reduce the risk of
fluorosis in young children.40 Well water should be tested for the level of fluoride; this testing is most commonly performed through the health department.

**Fluoride Toxicity**

Toxic levels of fluoride are possible, particularly in children, as a result of ingesting large quantities of fluoride supplements. The toxic dose of elemental fluoride is 5 to 10 mg of fluoride per kilogram of body weight.41 Lethal doses in children have been calculated to be between 8 and 16 mg/kg. When prescribing sodium fluoride supplements, it is recommended to limit the quantity prescribed at one time to no more than a 4-month supply. Parents should be advised to keep fluoride products out of the reach of young children and to supervise their use.

**Fluoride Removal Systems**

There are a number of water treatment systems that are effective in the removal of fluoride from water,42 including reverse osmosis and distillation. Parents should be counseled on the use of these and activated alumina filters in the home and, should they choose to use one that removes fluoride, the potential effect on their family’s oral health. Commonly used home carbon filters (eg, Brita [Brita LP, Oakland, California], PUR [Kaz USA, Incorporated, Southborough, MA]) do not remove fluoride. These can be recommended for families who are concerned about heavy metals or other impurities in their home water supply but who wish to retain the benefits of fluoridated water.

**SUGGESTIONS FOR PEDIATRICIANS**

1. Know how to assess caries risk. As recommended by the AAP’s Oral Health Risk Assessment Timing and Establishment of the Dental Home and Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents,7 pediatricians should perform oral health risk assessments on all children at preventive visits beginning at 6 months of age. An oral health risk assessment tool has been developed by the AAP/Bright Futures and endorsed by the National Interprofessional Initiative on Oral Health. This tool can be accessed at http://www2.aap.org/oralhealth/RiskAssessmentTool.html. There are currently no validated early childhood caries risk assessment tools. The aforementioned tool is a guide to help clinicians counsel patients about oral health and best identify risk.

2. Know how to assess a child’s exposure to fluoride and determine the need for topical or systemic supplements.43

3. Understand indications for fluoride varnish and how to provide it. Fluoride varnish can be a useful tool in the prevention of early childhood caries. Additional training on oral screenings, fluoride varnish indications and application, and office implementation can be found in the Smiles for Life Curriculum Course 6: Caries Risk Assessment, Fluoride Varnish and Counseling44 at www.smilesforlifeoralhealth.org. In addition, the AAP Children’s Oral Health Web site is a resource for oral health practice tools (http://www2.aap.org/oralhealth/PracticeTools.html).

4. Advocate for water fluoridation in the local community. Public water fluoridation is an effective and safe method of protecting the most vulnerable members of our population from dental caries. Pediatricians are encouraged to advocate on behalf of public water fluoridation in their communities and states. For additional information and water fluoridation facts and detailed questions and answers, see http://www.ada.org/sections/newsAndEvents/pdfs/flouridation_facts.pdf, http://www.cdc.gov/flouridation/, and http://www.ilikemyteeth.org.

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