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Topical fluoride for caries prevention:

Executive summary of the updated clinical recommendations and supporting systematic review

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the American Dental Association Council on Scientific Affairs Expert Panel on Topical Fluoride Caries Preventive Agents

Abstract

Background—A panel of experts convened by the American Dental Association (ADA) Council on Scientific Affairs presents evidence-based clinical recommendations regarding professionally applied and prescription-strength, home-use topical fluoride agents for caries prevention. These recommendations are an update of the 2006 ADA recommendations regarding professionally applied topical fluoride and were developed by using a new process that includes conducting a systematic review of primary studies.

Types of Studies Reviewed—The authors conducted a search of MEDLINE and the Cochrane Library for clinical trials of professionally applied and prescription-strength topical fluoride agents—including mouthrinses, varnishes, gels, foams and pastes—with caries increment outcomes published in English through October 2012.

Results—The panel included 71 trials from 82 articles in its review and assessed the efficacy of various topical fluoride caries-preventive agents. The panel makes recommendations for further research.

Practical Implications—The panel recommends the following for people at risk of developing dental caries: 2.26 percent fluoride varnish or 1.23 percent fluoride (acidulated phosphate fluoride) gel, or a prescription-strength, home-use 0.5 percent fluoride gel or paste or 0.09 percent fluoride mouthrinse for patients 6 years or older. Only 2.26 percent fluoride varnish is recommended for children younger than 6 years. The strengths of the recommendations for the recommended products varied from “in favor” to “expert opinion for.” 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.

Keywords

Caries prevention; caries; evidence-based dentistry; fluoride; practice guidelines; preventive dentistry

In 2006, the Council on Scientific Affairs (CSA) of the American Dental Association (ADA) published recommendations for the use of professionally applied topical fluorides for caries prevention.¹ It is ADA policy to start updating the evidence and clinical recommendations at five-year intervals. The objective of this report is to provide an update on professionally applied topical fluorides and address additional questions related to the use of prescription-strength, home-use topical fluorides for caries prevention. The panel evaluated sodium, stannous and acidulated phosphate fluoride (APF) for professional and prescription-strength home-use, including varnishes, gels, foams, mouthrinses and prophylaxis pastes. The panel did not include over-the-counter products, slow-release delivery devices, dental materials that release fluorides and products that contain sodium monofluorophosphate, silver diamine fluoride and titanium tetrafluoride in this report. Sodium monofluorophosphate is primarily a nonprescription, daily-use fluoride product. Silver diamine fluoride and titanium fluoride are not available in any products in the United States. For the remainder of this article, the term “topical fluoride agents” will be used to include professionally applied, as well as prescriptionstrength, home-use products.

The grading system² used in this report was adapted from the U.S. Preventive Services Task Force (USPSTF) system,³ and it differs markedly from the system the previous panel used for the 2006 clinical recommendations.¹ One difference is that the current clinical recommendations are based on a synthesis of primary evidence collected by means of a de novo systematic review, whereas the previous clinical recommendations were based primarily on published systematic reviews. Another difference is that the current recommendations are based on the net benefit of the intervention (that is, a balance of benefits with potential harm) in conjunction with the level of certainty in the evidence, whereas the 2006 clinical recommendations were based solely on the study design.⁴ These changes have resulted in some modifications to the strengths assigned to the individual recommendations for products reviewed in this report compared with recommendations for the products reviewed in the 2006 clinical recommendations report.

The current grading system includes the use of expert opinion as a means of determining whether to make clinical recommendations when evidence is lacking, contradictory or judged to have a high risk of bias (that is, a reliable estimate of the net benefit of the intervention is not possible). Practitioners should note the strength of the recommendations and endeavor to understand the underlying evidence in terms of the level of certainty and the balance of benefits with potential harm. They should discuss uncertainties in evidence with their patients, providing awareness that there usually is some level of uncertainty in the evidence used for making clinical decisions, in part arising from lack of clinical data, changes in product formulations across time and the availability of a wide variety of products.

The panel prepared this report to help practitioners make decisions about the use of topical fluoride caries preventive agents. (The full report, which includes more details, is available at <http://ebd.ada.org/ClinicalRecommendations.aspx>.) The recommendations in this report are not intended to define a standard of care but rather should be integrated with each practitioner's professional judgment and each patient's needs and preferences.

METHODS

The ADA CSA convened the panel, which was multidisciplinary and comprised subject matter and methodology experts, as well as representatives from various stakeholder groups. They addressed two clinical questions:

- In primary and permanent teeth, does the use of a topical fluoride agent reduce the incidence of new lesions in coronal caries, root caries or both compared with no topical fluoride use?
- Does the use of prophylaxis before application of topical fluoride reduce the incidence of caries to a greater extent than the application of topical fluoride without prophylaxis?

In the first part of the process, the authors conducted a systematic review of the literature. They then developed evidence statements based on a statistical evaluation of the evidence, as well as an assessment of their level of certainty in the statement (high, moderate, low), according to a standardized grading system (Table 1^{2,3}).

In the second part of the process, the panel developed clinical recommendations and graded the strength of the recommendations, according to a standardized process. The panel ascertained the net benefit rating by judging the balance of benefits with potential harm. For example, if a topical fluoride agent was found to be effective, and the benefit was judged to outweigh the potential harm, the net benefit was “benefit outweighs potential harm.” The panel used the information in Table 2³ to combine the level of certainty with the net benefit rating to arrive at the strength of the recommendation (strong, in favor, weak, expert opinion for, expert opinion against or against) to determine the strength of the clinical recommendation as defined in Table 1.^{2,3} Table 3³ shows the definitions of these recommendation strengths.

The panel approved the clinical recommendations by a simple majority vote. The panel sought comments on this report from other subject matter experts, methodologists, epidemiologists and end-users before finalizing the recommendations. The ADA CSA approved the final report for publication.

CLINICAL RECOMMENDATIONS: SUMMARY

For people who are at an elevated risk of developing dental caries, the panel makes clinical recommendations for the use of specific topical fluoride agents (Table 4); these recommendations are based on the evidence statements and the balance of benefits with potential harm (Table 5,^{5,6} pages 1284-1285). The panel recommends topical fluoride agents only for people what are at elevated risk of developing dental caries.

The panel recommends the following for people at risk of developing dental caries: 2.26 percent fluoride varnish or 1.23 percent fluoride (APF) gel, or a prescription-strength, home-use 0.5 percent fluoride gel or paste or 0.09 percent fluoride mouthrinse for patients 6 years or older. Only 2.26 percent fluoride varnish is recommended for children younger than 6 years. The strengths of the recommendations for the recommended products varied from “in favor” to “expert opinion for.”

The panel judged that the benefits outweighed the potential for harm for all professionally applied and prescription-strength, home-use topical fluoride agents and age groups except for children younger than 6 years. In these children, the risk of experiencing adverse events (particularly nausea and vomiting) associated with swallowing professionally applied topical fluoride agents outweighed the potential benefits of using all of the topical fluoride agents except for 2.26 percent fluoride varnish.

DISCUSSION OF EVIDENCE AND CLINICAL RECOMMENDATIONS

The panel included 71 trials in 82 published articles (some clinical studies were published in multiple articles) in its review and assessed the efficacy of various topical fluoride agents for preventing caries. Table 5^{5,6} (pages 1284-1285) summarizes the expert panel's assessment of the evidence. There were some general considerations to take into account when reviewing the evidence. First, some of the studies were conducted before the 1970s, when dental caries rates among children were higher,⁷ the percentage of the population receiving fluoridated water was substantially lower,⁸ and the percentage of people using fluoridated dentifrice was

much lower.⁹ Second, some studies were conducted in countries with different caries prevalence and different levels of background fluoride exposure and other caries prevention efforts. Third, the study populations often could not be categorized in terms of caries risk, and the panel could not assign risk categories to the populations as they are defined today. Therefore, caution is advised when extrapolating the results to today's high-risk populations, such as children at high risk of developing early childhood caries.

Table 6 (page 1286) presents the fluoride concentrations of each of topical fluoride agent evaluated, both as a concentration of fluoride ion and a concentration of sodium fluoride.

Varnish

There are more than 30 fluoride-containing varnish products on the market today, and they have varying compositions and delivery systems. These compositional differences lead to widely variable pharmacokinetics, the effects of which remain largely untested clinically. Through the literature search, the panel found clinical trials¹⁰⁻³⁸ regarding four brand-name products and decided to summarize the results of these trials on the basis of the percentage of fluoride, which was either 2.26 percent or 0.1 percent. Further research revealed that products identified with an identical brand name (Fluor Protector, Ivoclar Vivadent, Amherst, N.J.) underwent a compositional change in 1987 from 0.7 percent fluoride to 0.1 percent fluoride.³⁹ Because the 0.7 percent fluoride product no longer is available commercially, these trials¹⁰⁻¹⁴ were not eligible for inclusion in this review. Therefore, the data are subdivided into 2.26 percent fluoride and 0.1 percent fluoride varnish categories.

2.26 percent fluoride varnish—The panel identified 17 randomized and five nonrandomized clinical trials that evaluated 2.26 percent fluoride varnish. There were six randomized^{11-13,15-19} and two nonrandomized^{20,21} clinical trials concerning the primary dentition, 11 randomized^{11-13,22-32} and two nonrandomized^{33,34} clinical trials concerning the permanent dentition and one controlled³⁵ clinical trial that combined results for both dentitions. The interventions for the control groups were no treatment, oral health counseling or placebo varnish. The studies were carried out in populations with various levels of dental caries. The studies were conducted in many countries (Brazil, Canada, Hong Kong, India, Kuwait, Netherlands, Poland, Spain, Sweden, United Kingdom and United States) in participants with and without additional fluoride use or other fluoride exposures (although most studies were conducted in low-fluoride areas) and with and without prior prophylaxis. The ages of the children at baseline varied from 6 months to 8 years for studies of the primary teeth; and from 5 to 15 years for studies of the permanent teeth. The panel identified two studies^{30,31} of root caries. The age range in these two studies was 44 to 79 years. The varnish was applied professionally every three to 12 months; in most of studies, the varnish was applied every six months.

Because of the low risk of experiencing harm in children younger than 6 years, unit doses of 2.26 percent fluoride varnish are the only topical fluoride agents that are recommended for this age group, even though other topical fluorides may have some evidence of a benefit. The panel had a moderate level of certainty that there is a benefit of 2.26 percent fluoride varnish in the permanent teeth of children aged 6 through 18 years. Although there were no

studies of coronal caries prevention in adults older than 18 years, the panel extrapolated the data from 6- through 18-year-olds to recommend using 2.26 percent varnish for this age group for both coronal and root caries. The benefits were judged to outweigh the potential for harm for all age groups.

0.1 percent fluoride varnish—The panel identified two nonrandomized clinical trials^{36,37} in which investigators evaluated 0.1 percent fluoride varnish on the primary dentition and one randomized clinical trial³⁸ in which investigators evaluated 0.1 percent fluoride varnish in the permanent dentition. The control groups received oral hygiene instruction or no treatment. The studies were carried out in Germany and Sweden in populations with various baseline levels of dental caries. The ages of the children at baseline varied from 4 through 5 years for primary dentition and 9 through 12 years for permanent dentition. The varnish was applied professionally every six months in the primary dentition and every four months in the permanent dentition. Additional fluoride use or other fluoride exposure was variable, and all studies included prior prophylaxis.

The panel found evidence of no benefit from use of 0.1 percent fluoride varnish in children. Although there were no studies regarding coronal caries prevention in adults older than 18 years, the panel extrapolated the data from 6- through 18-year-olds that showed no benefit of 0.1 percent varnish for this age group. The panel was not comfortable extrapolating these results to root caries and gives no clinical recommendation for this form of the disease.

1.23 percent fluoride (APF) gel

The panel identified 11 randomized^{5,40-50} and four nonrandomized^{35,51-55} clinical trials that evaluated 1.23 percent fluoride (APF) gel quarterly, semiannually, annually or biannually (one application was observed after two years). The comparison groups received no treatment, a placebo, prophylaxis or a nonfluoride placebo gel. All studies except one⁵¹ involved permanent teeth. In all of the studies, investigators applied fluoride gel for four minutes. All of the studies involved school-aged children (from 3 through 16 years) except for one.⁴⁹ This study involved noninstitutionalized adults who were at least 60 years of age, and investigators reported on root caries. Ten studies^{40-45,48,49,51-55} were conducted in the United States and five elsewhere (India,^{35,50} United Kingdom,⁴⁶ China⁵ and Canada⁴⁷).

Although the panel had a low level of certainty that there was a benefit in using 1.23 percent fluoride (APF) gel in the primary dentition of children younger than 6 years, they judged that the potential for harm associated with swallowing APF gel could outweigh these benefits. The panel had a moderate level of certainty that there was a benefit of using 1.23 percent fluoride (APF) gel in the permanent teeth of children aged 6 through 18 years. The panel found no studies regarding the effect of 1.23 percent fluoride (APF) gel on coronal caries of adults older than 18 years, but they extrapolated the evidence from permanent teeth of children 6 through 18 years of age to recommend (at the strength of expert opinion) for this age group.

Prophylaxis before APF gel application

Although the panel searched the literature for prophylaxis before any topical fluoride application (per the second clinical question), it only found studies regarding prophylaxis before application of 1.23 percent fluoride (APF) gel. The panel identified two randomized⁵⁶⁻⁵⁸ and one nonrandomized⁵⁹ clinical trials in which investigators assessed whether prophylaxis before professional application of APF gel affects its efficacy. Two studies were conducted in the United States,⁵⁷⁻⁵⁹ and one was conducted in Canada.⁵⁶ All of the studies involved children aged 6 through 14 years at baseline. Investigators for both studies reported data regarding permanent teeth, and investigators for one⁵⁶ also reported data regarding primary teeth.

The panel found no benefit for performing prophylaxis before the application of 1.23 percent fluoride (APF) gel for the primary and permanent dentition of children. Although no studies were found in this category regarding adult populations, the panel extrapolated the evidence from the permanent teeth of children aged 6 through 18 years to coronal caries in adults, but it was not comfortable doing so for root caries and gives no clinical recommendation for this form of the disease.

1.23 percent fluoride (APF) foam

The panel identified two randomized clinical trials^{5,6} that evaluated 1.23 percent fluoride (APF) foam in children aged 3 through 7 years at baseline. One study involved the primary dentition⁶ and the other the permanent dentition.⁵ The comparison groups received either no treatment or placebo. Both studies were conducted in China.

Although a benefit was found with using 1.23 percent fluoride (APF) foam in children younger than 6 years, the panel judged that the potential for harm—including swallowing APF foam—outweighed this benefit. The panel found no benefit regarding caries prevention in the permanent dentition of children. The panel extrapolated this finding to permanent teeth in adults and does not recommend foam use in adults older than 18 years. The panel was not comfortable extrapolating these results to root caries and gives no clinical recommendation for this form of the disease.

Prophylaxis pastes containing fluoride

The panel identified three randomized⁶⁰⁻⁶² and three nonrandomized⁶³⁻⁶⁵ clinical trials in which investigators evaluated the annual or semiannual application of prophylaxis pastes, most of which contained 1.23 percent fluoride (APF), for caries prevention. These studies were conducted between 1966 and 1980. The comparison groups received placebo prophylaxis pastes. All studies except one⁶⁵ (regarding children aged 3-5 years at baseline) involved the permanent teeth of children aged 8 through 16 years at baseline.

The panel found no benefit of using prophylaxis pastes containing fluoride on the primary or permanent teeth of children. Although no studies were found regarding adult populations, the panel extrapolated the evidence of no benefit to coronal caries in adults but was not comfortable doing so for root caries and gives no clinical recommendation for this form of the disease.

Prescription-strength, home-use (0.5 percent fluoride) gels or pastes

The panel reviewed the data for prescription-strength, home-use gels and pastes together. The primary difference between gels and pastes is that pastes contain a small amount of an abrasive component. The panel noted that investigators in only one study⁶⁶ evaluated prescription-strength fluoride paste or gel (in this case, it was paste) in an unsupervised home environment, rather than by professional application in trays or with floss or in a supervised school setting. These products are often used at home and applied with a toothbrush.

The panel identified eight randomized⁶⁶⁻⁷⁵ and one nonrandomized⁷⁶ clinical trials that met the inclusion criteria regarding prescription-strength (0.5 percent fluoride) paste or gel for home use. Six of the studies^{66,69-73,75,76} involved permanent teeth, one⁶⁷ involved root caries, and two^{71,72,74} involved primary teeth. The comparison group for all studies was either placebo, 0.125-0.145 percent fluoride paste or no treatment. The baseline age range of children was 2 through 15 years for most of the studies, and one study included participants older than 75 years.⁶⁷ The studies were performed in Denmark, French Polynesia, Netherlands, Sweden and the United States.

Although the panel found a benefit with 0.5 percent fluoride paste or gel treatment in children younger than 6 years, it judged that the potential for harm—including swallowing gels or pastes—outweighed this benefit. The panel had a low level of certainty regarding the benefit of 0.5 percent fluoride paste or gel on the permanent teeth of children and on root caries because there were few data on the home use of these products. However, the panel judged that the benefits outweighed potential harm. Although the panel found no studies in this category regarding permanent teeth in adults, the panel extrapolated the available evidence and judged that the benefits outweighed the potential for harm in this age group.

Prescription-strength, home-use (0.09 percent fluoride) mouthrinse

The panel identified 10 randomized⁷⁷⁻⁸⁸ and two nonrandomized^{89,90} clinical trials in which investigators evaluated 0.09 percent fluoride mouthrinse applications with daily, weekly or biweekly applications. Investigators in most of the studies compared the intervention with placebo mouthrinses, although some compared the intervention with no treatment^{85,89} or oral hygiene instruction and prophylaxis.⁷⁹ All studies were conducted on permanent teeth. All of the studies but one⁸⁷ were conducted in school-aged children (5 through 12 years). No adult populations were studied except elderly people living in long-term care facilities (mean age, 83 years) in one study.⁸⁷ In most studies, the children's teachers supervised the use of the fluoride rinse. In only one study⁸⁸ were children enrolled on the basis of their caries risk status. Four of the studies^{77,78,80-82,84} were conducted in the United States. The other studies were conducted in Canada,⁸⁷ Denmark,⁸³ New Zealand,⁷⁹⁻⁸⁸ Philippines,⁹⁰ South Africa^{86,89} and Sweden.⁸⁵

The panel judged that the benefits outweighed the potential for harm in children 6 years or older and adults. Although there were no studies regarding the effect of 0.09 percent fluoride mouthrinse on caries in children younger than 6 years, the panel judged that the risk of swallowing mouthrinse outweighed the potential for unknown benefits. Although there were

no studies regarding coronal caries in adults older than 18 years, the panel extrapolated the results from children aged 6 through 18 years to arrive at a clinical recommendation based on expert opinion.

GENERAL REMARKS ON CLINICAL RECOMMENDATIONS

A practitioner should consider a patient's risk of experiencing disease when developing an optimal caries-prevention plan. Part of a patient's risk status includes whether the patient lives in an optimally fluoridated community and uses fluoridated toothpaste. Patients at low risk of developing caries may not need additional fluoride interventions, whereas caries in people at high risk of developing caries appears at times to be refractory to additional intensive preventive interventions.^{91,92}

Professional judgment is required to interpret the clinical relevance of preventive measures for individual patients. The combination of evidence from clinical studies, the patient's caries risk status, the practitioner's professional judgment and the patient's needs and preferences should guide decision making. Patient education, assessment of readiness for change, dietary advice, other preventive modalities and periodic clinical examinations should be considered as a part of the caries-prevention plan. In public health care settings, additional considerations include the feasibility and cost of the proposed intervention. The panel did not consider these issues when providing its clinical recommendations.

The panel noted that clinical trials generally test the efficacy of an intervention, which results in the best possible outcome for the intervention because of the controlled nature of the trial and strict inclusion and exclusion criteria for participants. These results do not necessarily reflect the effectiveness of an intervention (that is, how the intervention works in routine practice), which typically includes patients with comorbidities who may be taking multiple medications. Under controlled study conditions, the efficacy is almost always higher than the effectiveness because of the presence of idealized conditions.

The panel has reported on several different topical fluoride agents, including those planned for home use. Practitioners can expect different compliance with treatment plans incorporating home-use products than with professionally applied products. Cost, efficacy or effectiveness related to the intended usage environment also may vary.

When considering any intervention, the practitioner and patient must balance the potential benefits with the potential harm. The panel considered harm reported by investigators of the included articles as well as known potential harm of fluoride use. Potential harm of topical fluorides includes, but may not be limited to, nausea and vomiting associated with the ingestion of topical fluorides⁹³ and dental fluorosis (an esthetic concern) while tooth enamel is developing (until about age 6 years) due to daily ingestion of topical fluoride, such as from toothpaste or from prescription-strength, home-use gels. There is less of a concern about professionally applied topical fluorides for which there are longer intervals between applications.⁹⁴ Fluoride varnish dispensed in unit doses has lower potential for harm than do other forms of high-concentration topical fluoride agents, because the amount of fluoride that is placed in the mouth by means of fluoride varnish is approximately one-tenth that of other professionally applied products.⁹⁵

FUTURE RESEARCH

The panel recommends that multiple well-designed, appropriately powered, placebo-controlled randomized trials that follow the Consolidated Standards of Reporting Trials guidelines⁹⁶ with standardized reporting according to age, dentition and caries risk status be conducted in the United States. Standard methodologies for caries and fluoride randomized controlled trials should be developed. The panel recommends that future trials be registered with ClinicalTrials.gov or equivalent registries. Specific areas of research recommendations are as follows:

- **Mechanisms of fluoride action and effects.** Research is needed regarding various topical fluorides to determine their mechanism of action and caries-preventive effects when in use at the current level of background fluoride exposure (that is, fluoridated water and fluoride toothpaste) in the United States. Studies regarding strategies for using fluoride to induce arrest or reversal of caries progression, as well as topical fluoride's specific effect on erupting teeth, also are needed.
- **Populations.** Research is needed concerning the following subpopulations: adults aged 18 through 65 years, high-risk adults older than 65 (including those living in long-term care facilities) who are at high risk of developing caries, children and adults who are at extremely high risk of developing caries, U.S.-specific populations, special needs populations (for example, those with cognitive disabilities, compromised self-care abilities or physical disabilities) and populations with chronic diseases (such as Sjögren syndrome). Comparative effectiveness studies of different fluoride strategies in these populations, as well as studies regarding strategies to manage xerostomia-induced coronal and root caries also are needed.
- **Products and usage.** Research is needed concerning the effectiveness and risks of specific products in the following areas: self-applied, prescription-strength, home-use fluoride gels, toothpastes or drops; 2 percent professionally applied sodium fluoride gel; alternative delivery systems, such as foam; optimal application frequencies for fluoride varnish and gels; one-minute applications of APF gel; and combinations of products (home-use and professionally applied).
- **Measurement and outcomes.** Development of measurements to evaluate caries arrest and reversal are needed.
- **Economics.** Studies regarding caries prevention and the economic benefit of topical fluoride in different caries risk populations are needed.
- **Dissemination and implementation.** Research on the best ways to help practitioners incorporate clinical recommendations into practice are needed.

CONCLUSIONS

The panel recommends the following for people at risk of developing dental caries: 2.26 percent fluoride varnish or 1.23 percent fluoride (APF) gel; or prescription-strength, home-use 0.5 percent fluoride gel or paste or 0.09 percent fluoride mouthrinse for patients 6 years or older. Only 2.26 percent fluoride varnish is recommended for children younger than 6

years. The strengths of the recommendations for the recommended products varied from “in favor” to “expert opinion for.” 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.

ABBREVIATION KEY

ADA	American Dental Association
APF	Acidulated phosphate fluoride
CSA	Council on Scientific Affairs
USPSTF	U.S. Preventive Services Task Force

References

1. American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: evidence-based clinical recommendations. *JADA*. 2006; 137(8):1151–1159. [PubMed: 16873333]
2. American Dental Association Center for Evidence-Based Dentistry. 2011 ADA Clinical Recommendations Handbook. American Dental Association; Chicago: 2011.
3. U.S. Preventive Services Task Force. [Sept. 10, 2013] Methods and processes. www.uspreventiveservicestaskforce.org/methods.htm.
4. Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Clinical guidelines: developing guidelines. *BMJ*. 1999; 318(7183):593–596. [PubMed: 10037645]
5. Jiang H, Tai B, Du M, Peng B. Effect of professional application of APF foam on caries reduction in permanent first molars in 6-7-year-old children: 24-month clinical trial. *J Dent*. 2005; 33(6):469–473. [PubMed: 15935266]
6. Jiang H, Bian Z, Tai BJ, Du MQ, Peng B. The effect of a bi-annual professional application of APF foam on dental caries increment in primary teeth: 24-month clinical trial. *J Dent Res*. 2005; 84(3): 265–268. [PubMed: 15723868]
7. Burt, BA.; Eklund, SA. Dental caries.. In: Burt, BA.; Eklund, SA., editors. *Dentistry, Dental Practice, and the Community*. 6th ed.. Elsevier/Saunders; St. Louis: 2005. p. 236-237.
8. Centers for Disease Control and Prevention. [Sept. 10, 2013] Community water fluoridation: 2010 water fluoridation statistics. www.cdc.gov/fluoridation/statistics/2010stats.htm.
9. Miskell, P. [Sept. 10, 2013] How Crest made business history.. Harvard Business School, Working Knowledge for Business Leaders Archive. 2005. <http://hbswk.hbs.edu/archive/4574.html>.
10. Axelsson P, Paulander J, Nordkvist K, Karlsson R. Effect of fluoride containing dentifrice, mouthrinsing, and varnish on approximal dental caries in a 3-year clinical trial. *Community Dent Oral Epidemiol*. 1987; 15(4):177–180. [PubMed: 3476237]
11. Clark DC, Stamm JW, Quee TC, Robert G. Results of the Sherbrooke-Lac Megantic fluoride varnish study after 20 months. *Community Dent Oral Epidemiol*. 1985; 13(2):61–64. [PubMed: 3857148]
12. Clark DC, Stamm JW, Robert G, Tessier C. Results of a 32-month fluoride varnish study in Sherbrooke and Lac-Megantic, Canada. *JADA*. 1985; 111(6):949–953. [PubMed: 3905917]
13. Clark DC, Stamm JW, Tessier C, Robert G. The final results of the Sherbrooke-Lac Megantic fluoride varnish study. *J Can Dent Assoc*. 1987; 53(12):919–922. [PubMed: 3319099]
14. van Eck AA, Theuns HM, Groeneveld A. Effect of annual application of polyurethane lacquer containing silane-fluoride. *Community Dent Oral Epidemiol*. 1984; 12(4):230–232. [PubMed: 6590174]
15. Autio-Gold JT, Courts F. Assessing the effect of fluoride varnish on early enamel carious lesions in the primary dentition. *JADA*. 2001; 132(9):1247–1253. [PubMed: 11665349]

16. Hardman MC, Davies GM, Duxbury JT, Davies RM. A cluster randomised controlled trial to evaluate the effectiveness of fluoride varnish as a public health measure to reduce caries in children. *Caries Res.* 2007; 41(5):371–376. [PubMed: 17713337]
17. Lawrence HP, Binguis D, Douglas J, et al. A 2-year community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children. *Community Dent Oral Epidemiol.* 2008; 36(6):503–516. [PubMed: 18422711]
18. Weintraub JA, Ramos-Gomez F, Jue B, et al. Fluoride varnish efficacy in preventing early childhood caries. *J Dent Res.* 2006; 85(2):172–176. [PubMed: 16434737]
19. Gugwad SC, Shah P, Lodaya R, et al. Caries prevention effect of intensive application of sodium fluoride varnish in molars in children between age 6 and 7 years. *J Contemp Dent Pract.* 2011; 12(6):408–413. [PubMed: 22269229]
20. Grodzka K, Augustyniak L, Budny J, et al. Caries increment in primary teeth after application of Duraphat fluoride varnish. *Community Dent Oral Epidemiol.* 1982; 10(2):55–59. [PubMed: 6952970]
21. Holm AK. Effect of fluoride varnish (Duraphat) in preschool children. *Community Dent Oral Epidemiol.* 1979; 7(5):241–245. [PubMed: 295702]
22. Arruda AO, Senthamarai Kannan R, Inglehart MR, Rezende CT, Sohn W. Effect of 5 percent fluoride varnish application on caries among school children in rural Brazil: a randomized controlled trial. *Community Dent Oral Epidemiol.* 2012; 40(3):267–276. [PubMed: 22150341]
23. Bravo M, Baca P, Llodra JC, Osorio E. A 24-month study comparing sealant and fluoride varnish in caries reduction on different permanent first molar surfaces. *J Public Health Dent.* 1997; 57(3): 184–186. [PubMed: 9383759]
24. Bravo M, Garcia-Anllo I, Baca P, Llodra JC. A 48-month survival analysis comparing sealant (Deltol) with fluoride varnish (Duraphat) in 6- to 8-year-old children. *Community Dent Oral Epidemiol.* 1997; 25(3):247–250. [PubMed: 9192156]
25. Holm GB, Holst K, Mejare I. The caries-preventive effect of a fluoride varnish in the fissures of the first permanent molar. *Acta Odontol Scand.* 1984; 42(4):193–197. [PubMed: 6594021]
26. Koch G, Petersson LG. Caries preventive effect of a fluoride-containing varnish (Duraphat) after 1 year's study. *Community Dent Oral Epidemiol.* 1975; 3(6):262–266. [PubMed: 1059514]
27. Milsom KM, Blinkhorn AS, Walsh T, et al. A cluster-randomized controlled trial: fluoride varnish in school children. *J Dent Res.* 2011; 90(11):1306–1311. [PubMed: 21921250]
28. Modeer T, Twetman S, Bergstrand F. Three-year study of the effect of fluoride varnish (Duraphat) on proximal caries progression in teenagers. *Scand J Dent Res.* 1984; 92(5):400–407. [PubMed: 6593805]
29. Moberg Skold U, Petersson LG, Lith A, Birkhed D. Effect of school-based fluoride varnish programmes on approximal caries in adolescents from different caries risk areas. *Caries Res.* 2005; 39(4):273–279. [PubMed: 15942186]
30. Schaeken MJ, Keltjens HM, Van Der Hoeven JS. Effects of fluo-ride and chlorhexidine on the microflora of dental root surfaces and progression of root-surface caries. *J Dent Res.* 1991; 70(2): 150–153. [PubMed: 1991872]
31. Tan HP, Lo EC, Dyson JE, Luo Y, Corbet EF. A randomized trial on root caries prevention in elders. *J Dent Res.* 2010; 89(10):1086–1090. [PubMed: 20671206]
32. Tewari A, Chawla HS, Utreja A. Comparative evaluation of the role of NaF, APF and Duraphat topical fluoride applications in the prevention of dental caries: a 2 1/2 years study. *J Indian Soc Pedod Prev Dent.* 1991; 8(1):28–35. [PubMed: 2056344]
33. Ibricevic H, Honkala S, Honkala E, Al-Quraini W. A field trial on semi-annual fluoride varnish applications among the special needs schoolchildren. *J Clin Pediatr Dent.* 2005; 30(2):135–138. [PubMed: 16491968]
34. Tagliaferro EP, Pardi V, Ambrosano GM, et al. Occlusal caries prevention in high and low risk schoolchildren: a clinical trial. *Am J Dent.* 2011; 24(2):109–114. [PubMed: 21698991]
35. Shobha T, Nandlal B, Prabhakar AR, Sudha P. Fluoride varnish versus acidulated phosphate fluoride for schoolchildren in Manipal. *J Indian Dent Assoc.* 1987; 59(6,7,8,9):157–160. [PubMed: 3509563]

36. Petersson LG, Twetman S, Pakhomov GN. The efficiency of semiannual silane fluoride varnish applications: a two-year clinical study in preschool children. *J Public Health Dent.* 1998; 58(1): 57–60. [PubMed: 9608447]
37. Twetman S, Petersson LG, Pakhomov GN. Caries incidence in relation to salivary mutans streptococci and fluoride varnish applications in preschool children from low- and optimal-fluoride areas. *Caries Res.* 1996; 30(5):347–353. [PubMed: 8877088]
38. Zimmer S, Bizhang M, Seemann R, Witzke S, Roulet JF. The effect of a preventive program, including the application of low- concentration fluoride varnish, on caries control in high-risk children. *Clin Oral Investig.* 2001; 5(1):40–44.
39. Protector, Fluor. [Sept. 10, 2010] Ivoclar Vivadent. 2010. www.ivoclarvivadent.com/en/products/prevention-care/fluoridation/fluor-protector
40. Bryan ET, Williams JE. The cariostatic effectiveness of a phosphate-fluoride gel administered annually to school children, part I: the results of the first year. *J Public Health Dent.* 1968; 28(3): 182–185. [PubMed: 4386807]
41. Bryan ET, Williams JE. The cariostatic effectiveness of a phosphate-fluoride gel administered annually to school children: final results. *J Public Health Dent.* 1970; 30(1):13–16. [PubMed: 4149070]
42. Cobb HB, Rozier RG, Bawden JW. A clinical study of the caries preventive effects of an APF solution and APF thixotropic gel. *Pediatr Dent.* 1980; 2(4):263–266. [PubMed: 6941001]
43. Cons NC, Janerich DT, Senning RS. Albany topical fluoride study. *JADA.* 1970; 80(4):777–781. [PubMed: 4392097]
44. Hagan PP, Rozier RG, Bawden JW. The caries-preventive effects of full- and half-strength topical acidulated phosphate fluoride. *Pediatr Dent.* 1985; 7(3):185–191. [PubMed: 3865156]
45. Ingraham RQ, Williams JE. An evaluation of the utility of application and cariostatic effectiveness of phosphate-fluorides in solution and gel states. *J Tenn State Dent Assoc.* 1970; 50(1):5–12. [PubMed: 4391820]
46. Mainwaring PJ, Naylor MN. A three-year clinical study to determine the separate and combined caries-inhibiting effects of sodium monofluorophosphate toothpaste and an acidulated phosphate-fluoride gel. *Caries Res.* 1978; 12(4):202–212. [PubMed: 356989]
47. Olivier M, Brodeur JM, Simard PL. Efficacy of APF treatments without prior toothcleaning targeted to high-risk children. *Community Dent Oral Epidemiol.* 1992; 20(1):38–42. [PubMed: 1547611]
48. Trubman A, Crellin JA. Effect on dental caries of self-application of acidulated phosphate fluoride paste and gel. *JADA.* 1973; 86(1):153–157. [PubMed: 4404788]
49. Wallace MC, Retief DH, Bradley EL. The 48-month increment of root caries in an urban population of older adults participating in a preventive dental program. *J Public Health Dent.* 1993; 53(3):133–137. [PubMed: 8371190]
50. Agrawal N, Pushpanjali K. Feasibility of including APF gel application in a school oral health promotion program as a caries-preventive agent: a community intervention trial. *J Oral Sci.* 2011; 53(2):185–191. [PubMed: 21712623]
51. Andruskeviciene V, Milciuviene S, Bendoraitiene E, et al. Oral health status and effectiveness of caries prevention programme in kindergartens in Kaunas city (Lithuania). *Oral Health Prev Dent.* 2008; 6(4):343–348. [PubMed: 19178101]
52. Horowitz HS. The effect on dental caries of topically applied acidulated phosphate-fluoride: results after one year. *J Oral Ther Pharmacol.* 1968; 4(4):286–291. [PubMed: 4384484]
53. Horowitz HS. Effect on dental caries of topically applied acidulated phosphate-fluoride: results after two years. *JADA.* 1969; 78(3):568–572. [PubMed: 4387801]
54. Horowitz HS, Doyle J. The effect on dental caries of topically applied acidulated phosphate-fluoride: results after three years. *JADA.* 1971; 82(2):359–365. [PubMed: 4395304]
55. Szwejda LF. Fluorides in community programs: results after two years from a fluoride gel applied topically. *J Public Health Dent.* 1971; 31(4):241–242. [PubMed: 4398972]
56. Johnston DW, Lewis DW. Three-year randomized trial of professionally applied topical fluoride gel comparing annual and biannual applications with/without prior prophylaxis. *Caries Res.* 1995; 29(5):331–336. [PubMed: 8521432]

57. Ripa LW, Leske GS, Sposato A, Varma A. Effect of prior tooth-cleaning on biannual professional APF topical fluoride gel-tray treatments: results after two years. *Clin Prev Dent*. 1983; 5(4):3–7. [PubMed: 6607812]
58. Ripa LW, Leske GS, Sposato A, Varma A. Effect of prior tooth-cleaning on bi-annual professional acidulated phosphate fluoride topical fluoride gel-tray treatments: results after three years. *Caries Res*. 1984; 18(5):457–464. [PubMed: 6592048]
59. Houpt M, Koenigsberg S, Shey Z. The effect of prior toothcleaning on the efficacy of topical fluoride treatment: two-year results. *Clin Prev Dent*. 1983; 5(4):8–10. [PubMed: 6607813]
60. Beiswanger BB, Mercer VH, Billings RJ, Stookey GK. A clinical caries evaluation of a stannous fluoride prophylactic paste and topical solution. *J Dent Res*. 1980; 59(8):1386–1391. [PubMed: 6995506]
61. DePaola PF, Mellberg JR. Caries experience and fluoride uptake in children receiving semiannual prophylaxes with an acidulated phosphate fluoride paste. *JADA*. 1973; 87(1):155–159. [PubMed: 4513365]
62. Peterson JK, Horowitz HS, Jordan WA, Pugnier V. Effectiveness of an acidulated phosphate fluoride-pumice prophylactic paste: a two-year report. *J Dent Res*. 1969; 48(3):346–350. [PubMed: 4389149]
63. Barenie JT, Ripa LW, Trummel C, Mellberg JR, Nicholson CR. Effect of professionally applied biannual applications of phosphate-fluoride prophylaxis paste on dental caries and fluoride uptake: results after two years. *ASDC J Dent Child*. 1976; 43(5):340–344. [PubMed: 787024]
64. Horowitz HS, Lucye HS. A clinical study of stannous fluoride in a prophylaxis paste and as a solution. *J Oral Ther Pharmacol*. 1966; 3(1):17–25. [PubMed: 5334852]
65. Schutze HJ, Forrester DJ, Balis SB. Evaluation of a fluoride prophylaxis paste in a fluoridated community. *Dent J*. 1974; 40(10):675–683. [PubMed: 4154056]
66. Nordstrom A, Birkhed D. Preventive effect of high-fluoride dentifrice (5,000 ppm) in caries-active adolescents: a 2-year clinical trial. *Caries Res*. 2010; 44(3):323–331. [PubMed: 20606431]
67. Ekstrand K, Martignon S, Holm-Pedersen P. Development and evaluation of two root caries controlling programmes for home-based frail people older than 75 years. *Gerodontology*. 2008; 25(2):67–75. [PubMed: 18194330]
68. Gisselsson H, Birkhed D, Emilson CG. Effect of professional flossing with NaF or SnF₂ gel on approximal caries in 13-16-year-old schoolchildren. *Acta Odontol Scand*. 1999; 57(2):121–125. [PubMed: 10445367]
69. Truin GJ, van 't Hof MA. Professionally applied fluoride gel in low-caries 10.5-year-olds. *J Dent Res*. 2005; 84(5):418–421. [PubMed: 15840776]
70. Truin GJ, van't Hof M. The effect of fluoride gel on incipient carious lesions in a low-caries child population. *Community Dent Oral Epidemiol*. 2007; 35(4):250–254. [PubMed: 17615011]
71. Truin GJ, van't Hof MA. Caries prevention by professional fluoride gel application on enamel and dentinal lesions in low-caries children. *Caries Res*. 2005; 39(3):236–240. [PubMed: 15914987]
72. van Rijkom HM, Truin GJ, van 't Hof MA. Caries-inhibiting effect of professional fluoride gel application in low-caries children initially aged 4.5-6.5 years. *Caries Res*. 2004; 38(2):115–123. [PubMed: 14767168]
73. Englander HR, Keyes PH, Gestwicki M, Sultz HA. Clinical anticaries effect of repeated topical sodium fluoride applications by mouthpieces. *JADA*. 1967; 75(3):638–644. [PubMed: 4382492]
74. Englander HR, Mellberg JR, Engler WO. Observations on dental caries in primary teeth after frequent fluoride toplications in a program involving other preventives. *J Dent Res*. 1978; 57(9-10):855–860. [PubMed: 281356]
75. Englander HR, Sherrill LT, Miller BG, Carlos JP, Mellberg JR, Senning RS. Incremental rates of dental caries after repeated topical sodium fluoride applications in children with lifelong consumption of fluoridated water. *JADA*. 1971; 82(2):354–358. [PubMed: 4395303]
76. Cutress T, Howell PT, Finidori C, Abdullah F. Caries preventive effect of high fluoride and xylitol containing dentifrices. *ASDC J Dent Child*. 1992; 59(4):313–318. [PubMed: 1430505]
77. Driscoll WS, Swango PA, Horowitz AM, Kingman A. Caries-preventive effects of daily and weekly fluoride mouthrinsing in an optimally fluoridated community: findings after eighteen months. *Pediatr Dent*. 1981; 3(4):316–320. [PubMed: 6952165]

78. Driscoll WS, Swango PA, Horowitz AM, Kingman A. Caries-preventive effects of daily and weekly fluoride mouthrinsing in a fluoridated community: final results after 30 months. *JADA*. 1982; 105(6):1010–1013. [PubMed: 6961143]
79. Craig EW, Suckling GW, Pearce EI. The effect of a preventive programme on dental plaque and caries in school children. *N Z Dent J*. 1981; 77(349):89–93. [PubMed: 6944630]
80. Heifetz SB, Meyers R, Kingman A. A comparison of the anticaries effectiveness of daily and weekly rinsing with sodium fluoride solutions: findings after two years. *Pediatr Dent*. 1981; 3(1): 17–20. [PubMed: 6951146]
81. Heifetz SB, Meyers RJ, Kingman A. A comparison of the anti-caries effectiveness of daily and weekly rinsing with sodium fluoride solutions: final results after three years. *Pediatr Dent*. 1982; 4(4):300–303.
82. Horowitz HS, Creighton WE, McClendon BJ. The effect on human dental caries of weekly oral rinsing with a sodium fluoride mouthwash: a final report. *Arch Oral Biol*. 1971; 16(6):609–616. [PubMed: 4397601]
83. Poulsen S, Kirkegaard E, Bangsbo G, Bro K. Caries clinical trial of fluoride rinses in a Danish Public Child Dental Service. *Community Dent Oral Epidemiol*. 1984; 12(5):283–287. [PubMed: 6593146]
84. Ringelberg ML, Conti AJ, Ward CB, Clark B, Lotzkar S. Effectiveness of different concentrations and frequencies of sodium fluoride mouthrinse. *Pediatr Dent*. 1982; 4:305–308.
85. Torell P. Two-year clinical tests with different methods of local caries-preventive fluorine application in Swedish school-children. *Acta Odontol Scand*. 1965; 23:287–322. [PubMed: 14321743]
86. van Wyk I, van Wyk CW. The effectiveness of a 0.2 percent and a 0.05 percent neutral NaF mouthrinsing programme. *J Dent Assoc S Afr*. 1986; 41(2):35–40. [PubMed: 3462964]
87. Wyatt CC, MacEntee MI. Caries management for institutionalized elders using fluoride and chlorhexidine mouthrinses. *Community Dent Oral Epidemiol*. 2004; 32(5):322–328.
88. de Liefde B. Identification and preventive care of high caries-risk children: a longitudinal study. *N Z Dent J*. 1989; 85(382):112–116. [PubMed: 2797545]
89. Chikte UM, Lewis HA, Rudolph MJ. The effectiveness of a school-based fluoride mouth rinse programme. *J Dent Assoc S Afr*. 1996; 51(11):697–700. [PubMed: 9461935]
90. Corpus BT. The effect of 0.2 percent sodium fluoride mouth-rinse in the prevention of dental caries in school children born and reared in a non-fluoridated community. *J Philipp Dent Assoc*. 1973; 25(1):5–12. [PubMed: 4148716]
91. Seppa L, Hausen H, Pollanen S, Karkkainen S, Helasharju K. Effect of intensified caries prevention on approximal caries in adolescents with high caries risk. *Caries Res*. 1991; 25(5):392–395. [PubMed: 1747891]
92. Hausen H, Karkkainen S, Seppa L. Application of the high-risk strategy to control dental caries. *Community Dent Oral Epidemiol*. 2000; 28(1):26–34. [PubMed: 10634681]
93. Augenstein WL, Spoerke DG, Kulig KW, et al. Fluoride ingestion in children: a review of 87 cases. *Pediatrics*. 1991; 88(5):907–912. [PubMed: 1945630]
94. Wong MC, Glenny AM, Tsang BW, Lo EC, Worthington HV, Marinho VC. Topical fluoride as a cause of dental fluorosis in children. *Cochrane Database Syst Rev*. 2010; (1):CD007693. [PubMed: 20091645]
95. Beltran-Aguilar ED, Goldstein JW, Lockwood SA. Fluoride varnishes: a review of their clinical use, cariostatic mechanism, efficacy and safety. *JADA*. 2000; 131(5):589–596. [PubMed: 10832252]
96. Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Ann Intern Med*. 2010; 152(11):726–732. [PubMed: 20335313]

TABLE 1

Definitions for levels of certainty.*

LEVEL OF CERTAINTY	DEFINITION
High	This statement is strongly established by the best available evidence; the conclusion is unlikely to be affected strongly by the results of future studies.
Moderate	This statement is based on preliminary determination from the current best available evidence; as more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion.
Low	The available evidence is insufficient to support the statement, or the statement is based on extrapolation from the best available evidence; more information could allow a reliable estimation of effects on health outcomes.

* For more details, see American Dental Association Center for Evidence-Based Dentistry.² Adapted from the U.S. Preventive Services Task Force system.³

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TABLE 2

Balancing level of certainty and net benefit rating to arrive at recommendation strength. *

LEVEL OF CERTAINTY	NET BENEFIT RATING		
	Benefit Outweighs Potential Harm	Benefit Balanced With Potential Harm	No Benefit, Potential Harm Outweighs Benefit
High	Strong	In favor	Against
Moderate	In favor	Weak	Against
Low	Expert opinion for [†] or expert opinion against [†]		

* Adapted from the U.S. Preventive Services Task Force (USPSTF) system.³

[†]The USPSTF system defines this category of evidence as “insufficient”; “grade I indicates that the evidence is insufficient to determine the relationship between benefits and harms (i.e., net benefit).” The corresponding recommendation grade “I” is defined as follows: “The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.”

TABLE 3Definitions for the strength of clinical^{*}

RECOMMENDATION STRENGTH	DEFINITION
Strong	Evidence strongly supports providing this intervention.
In Favor	Evidence favors providing this intervention.
Weak	Evidence suggests implementing this intervention after alternatives have been considered.
Expert Opinion For [†]	Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation
Expert Opinion Against [†]	Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention.
Against	Evidence suggests not implementing this intervention or discontinuing ineffective procedures.

* Adapted from the U.S. Preventive Services Task Force (USPSTF) system.³

[†]The USPSTF system defines this category of evidence as “insufficient”; “grade I indicates that the evidence is insufficient to determine the relationship between benefits and harms (i.e., net benefit).” The corresponding recommendation grade “I” is defined as follows: “The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.”

TABLE 4

Clinical recommendations for use of professionally applied or prescription-strength, home-use topical fluorides for caries prevention in patients at elevated risk of developing caries.







Strength of recommendations: Each recommendation is based on the best available evidence. The level of evidence available to support each recommendation may differ.					
 Strong Evidence strongly supports providing this intervention	 In favor Evidence favors providing this intervention	 Weak Evidence suggests implementing this intervention only after alternatives have been considered	 Expert Opinion For Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation	 Expert Opinion Against Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention	 Against Evidence suggests not implementing this intervention or discontinuing ineffective procedures
Age Group or Dentition Affected	Professionally Applied Topical Fluoride Agent	Prescription-Strength, Home-Use Topical Fluoride Agent			
Younger Than 6 Years	2.26 percent fluoride varnish at least every three to six months ● In Favor				
6-18 Years	2.26 percent fluoride varnish at least every three to six months ● In Favor OR 1.23 percent fluoride (APF*) gel for four minutes at least every three to six months ● In Favor	0.09 percent fluoride mouthrinse at least weekly ● In Favor OR 0.5 percent fluoride gel or paste twice daily ● Expert Opinion For			
Older Than 18 Years	2.26 percent fluoride varnish at least every three to six months ● Expert Opinion For OR 1.23 percent fluoride (APF) gel for four minutes at least every three to six months ● Expert Opinion For	0.09 percent fluoride mouthrinse at least weekly ● Expert Opinion For OR 0.5 percent fluoride gel or paste twice daily ● Expert Opinion For			
Adult Root Caries	2.26 percent fluoride varnish at least every three to six months ● Expert Opinion For OR 1.23 percent fluoride (APF) gel for four minutes at least every three to six months ● Expert Opinion For	0.09 percent fluoride mouthrinse daily ● Expert Opinion For OR 0.5 percent fluoride gel or paste twice daily ● Expert Opinion For			
Additional Information: <ul style="list-style-type: none"> • 0.1 percent fluoride varnish, 1.23 percent fluoride (APF) foam or prophylaxis pastes are not recommended for preventing coronal caries in all age groups (● Expert Opinion Against or ● Against). The full report, which includes more details, is available at http://ebd.ada.org/ClinicalRecommendations.aspx. • No prescription-strength or professionally applied topical fluoride agents except 2.26 percent fluoride varnish are recommended for children younger than 6 years (● Expert Opinion Against or ● Against), but practitioners may consider the use of these other agents on the basis of their assessment of individual patient factors that alter the benefit-to-harm relationship. • Prophylaxis before to 1.23 percent fluoride (APF) gel application is not necessary for coronal caries prevention in all age groups (● Expert Opinion Against or ● Against). The full report, which includes more details, is available at http://ebd.ada.org/ClinicalRecommendations.aspx. No recommendation can be made for prophylaxis before application of other topical fluoride agents. 					
Patients at low risk of developing caries may not need additional topical fluorides other than over-the-counter fluoridated toothpaste and fluoridated water.					
* APF: Acidulated phosphate fluoride.					

TABLE 5

Evidence statements for professionally applied and prescription-strength, home-use topical fluorides used for caries prevention.

AGENT	AGE GROUP (YEARS) OR DENTITION AFFECTED	EVIDENCE STATEMENT	LEVEL OF CERTAINTY	NET BENEFIT RATING
Varnish (2.26 Percent Fluoride)	Younger than 6	There is a benefit of 2.26 percent fluoride varnish application at least twice per year for caries prevention.	Moderate	Benefit outweighs potential harm
	6-18	There is a benefit of 2.26 percent fluoride varnish application at least twice per year for caries prevention.	Moderate	Benefit outweighs potential harm
	Adult root caries	There is a benefit of 2.26 percent fluoride varnish application at least twice per year for root caries prevention in adults.	Low	Benefit outweighs potential harm
Varnish (0.1 Percent Fluoride)	Younger than 6	There is no benefit of 0.1 percent fluoride varnish application twice per year for caries prevention.	Moderate	No benefit
	6-18	There is no benefit of applying 0.1 percent fluoride varnish three times per year for caries prevention.	Low	No benefit
APF* Gel (1.23 Percent Fluoride)	Younger than 6	There is a benefit of APF gel (1.23 percent fluoride) application up to every three months for four ⁷ minutes for caries prevention.	Low	Potential harm outweighs benefit
	6-18	There is a benefit of APF gel (1.23 percent fluoride) application up to every three months for four ⁷ minutes for caries.	Moderate	Benefit outweighs potential harm
	Adult root caries	There is a benefit of APF gel (1.23 percent fluoride) application twice per year for four ⁷ minutes to prevent root caries.	Low	Benefit outweighs potential harm
Prophylaxis Before APF Gel (1.23 Percent Fluoride) Application	Younger than 6	There is no benefit from conducting a prophylaxis prior to APF gel (1.23 percent fluoride) application for caries prevention.	Low	No benefit
	6-18	There is no benefit from conducting a prophylaxis prior to APF gel (1.23 percent fluoride) application for caries prevention.	Moderate	No benefit
APF Foam (1.23 Percent Fluoride)	Younger than 6	There is a benefit of APF foam (1.23 percent fluoride) application twice per year for four ⁷ minutes for caries prevention.	Low	Potential harm outweighs benefit
	6-18	There is no benefit of 1.23 percent APF foam application twice per year for four ⁷ minutes for caries prevention.	Low	No benefit
Prophylaxis Pastes Containing Fluoride	Younger than 6	There is no benefit of prophylaxis paste containing fluoride application for four minutes twice per year for caries prevention.	Low	No benefit
	6-18	There is no benefit of prophylaxis paste containing fluoride application for four minutes twice per year for caries prevention.	Moderate	No benefit
Prescription-Strength, Home-Use (0.5 Percent Fluoride) Gel or Paste	Younger than 6	There is a benefit of prescription-strength, home-use (0.5 percent fluoride) gel or paste application twice daily for caries prevention.	Low	Potential harm outweighs benefit

AGENT	AGE GROUP (YEARS) OR DENTITION AFFECTED	EVIDENCE STATEMENT	LEVEL OF CERTAINTY	NET BENEFIT RATING
Prescription-Strength, Home-Use (0.09 Percent Fluoride) Mouthrinse	6-18	There is a benefit of prescription-strength, home-use (0.5 percent fluoride) gel or paste application twice daily for caries prevention.	Low	Benefit outweighs potential harm
	Adult root caries	There is a benefit of prescription-strength, home-use (0.5 percent fluoride) gel or paste application twice daily in preventing root caries.	Low	Benefit outweighs potential harm
	6-18	There is a benefit of using prescription-strength, home-use (0.09 percent fluoride) mouthrinse daily or weekly for caries prevention.	Moderate	Benefit outweighs potential harm
	Adult root caries	There is a benefit of using prescription-strength, home-use (0.09 percent fluoride) mouthrinse for root caries prevention among elderly people living in long-term care facilities.	Low	Benefit outweighs potential harm

* APF: Acidulated phosphate fluoride.

[†]No studies were found regarding professionally applied fluoride APF gels with an application time of less than three minutes.

[‡]Two studies^{5,6} regarding professionally applied fluoride (APF) foams used an application time of four minutes.

TABLE 6

Fluoride ion and sodium fluoride concentrations in topical fluoride agents.

TOPICAL FLUORIDE AGENT	FLUORIDE ION, %	SODIUM FLUORIDE, %
Professionally Applied		
2.26 Percent fluoride varnish	2.26	5.0
APF* gel (with 0.1 molar phosphoric acid)	1.23	2.7
APF foam (with 0.1 M phosphoric acid)	1.23 [†]	2.7 [†]
Prophylaxis paste containing fluoride (most as APF)	1.23	2.7
0.1 Percent fluoride varnish	0.1 [‡]	Not applicable
Prescription Strength, Home Use		
Prescription-strength gels or pastes with or without acidulation (0.1 M phosphoric acid)	0.5	1.1
Prescription-strength mouthrinses	0.09	0.2

* APF: Acidulated phosphate fluoride.

[†] Concentration of fluoride before being dispensed. When delivered as a foam by combining gel with air, the total amount of fluoride in the foam product is reduced.

[‡] The fluoride ion form was 0.09 percent difluorsilane.