

Executive Summary of *Evidence-based Clinical Recommendations: Professionally Applied Topical Fluoride*

*The Council on Scientific Affairs, American Dental Association
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These evidence-based clinical recommendations were developed through evaluation of the collective body of scientific evidence on the effectiveness of professionally applied topical fluoride for caries prevention, and are intended to assist dentists in clinical decision-making. The dentist, knowing the patient's health history and vulnerability to oral disease, is in the best position to make treatment decisions in the interest of each patient. For this reason, *evidence-based clinical recommendations are intended to provide guidance, and are not a standard of care, requirements or regulations.* The clinical recommendations must be balanced with the practitioner's professional expertise and the individual patient's preferences.

MedLine and the Cochrane Library were searched for systematic reviews and clinical studies on professionally applied topical fluoride, including gel, foam and varnish through October 2005. An expert panel was assembled to evaluate the collective evidence and develop these clinical recommendations. Panelists were selected based on their expertise in the relevant subject matter. Panelists were required to sign a disclosure stating that neither they nor their spouse or dependent children had a significant financial interest that would reasonably appear to affect the development of these recommendations. The panel's recommendations are detailed in a document titled *Evidence-based Clinical Recommendations: Professionally Applied Topical Fluoride*, for which this is the executive summary. The document was submitted for review to scientists with expertise in fluoride and caries, ADA agencies and 46 organizations representing academia, professional organizations, industry and third party payers. The clinical recommendations are approved by the ADA Council on Scientific Affairs.

GRADING THE EVIDENCE AND CLASSIFYING THE STRENGTH OF THE RECOMMENDATIONS

The scientific evidence was classified according to the following format:

Grade	Category of evidence
Ia	Evidence from systematic reviews of randomized controlled trials
Ib	Evidence from at least one randomized controlled trial
IIa	Evidence from at least one controlled study with out randomization
IIb	Evidence from at least one other type of quasi-experimental study
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
IV	Evidence from expert committee reports or opinions or clinical experience of respected authorities

The strength of the recommendations were classified according to the following format:

Classification	Strength of recommendations
A	Directly based on category I evidence
B	Directly based on category II evidence or extrapolated recommendation from category I evidence
C	Directly based on category III evidence or extrapolated recommendation from category I or II evidence
D	Directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence

Shekelle, P.G., et al., Clinical guidelines: developing guidelines. *BMJ*, 1999. 318(7183): 593-96.

PANEL CONCLUSIONS BASED UPON THE EVIDENCE

The following evidence statements and corresponding classification of evidence represent the conclusions of the expert panel.

1. Fluoride gel is effective in preventing caries in school-aged children. **Ia**
2. Patients whose caries risk is low, as defined in this document, may not receive additional benefit from professional topical fluoride application. **Ia**
3. There are considerable data on caries reduction for professionally applied topical fluoride gel treatments of 4 minutes or more. **Ia** In contrast, there is laboratory, but no clinical equivalency data, on the effectiveness of 1-minute fluoride gel applications. **IV**
4. Fluoride varnish applied every six months is effective in preventing caries in the primary and permanent dentition of children and adolescents. **Ia**
5. Two or more applications of fluoride varnish per year are effective in preventing caries in high risk populations. **Ia**
6. Fluoride varnish applications take less time, create less patient discomfort and achieve greater patient acceptability than fluoride gel especially in preschool children. **III**
7. Four-minute fluoride foam applications, every 6 months, are effective in caries prevention in the primary dentition and newly erupted permanent first molars. **Ib**
8. There is insufficient evidence to address whether or not there is a difference in the efficacy of NaF versus APF gels. **IV**

CARIES RISK CATEGORIES

The panel encourages dentists to employ caries risk assessment strategies in their practices. Appropriate preventive dental treatment (including topical fluoride therapy) can be planned after identification of caries risk status. It is also important to consider that risk for dental caries exists on a continuum and changes over time as risk factors change. Therefore caries risk status should be periodically reevaluated.

The panel understands that there is no single system for caries risk assessment that has been shown to be valid and reliable. However, there is evidence that dentists can use simple clinical indicators to classify caries risk status that is predictive of future caries experience. The panel offers the system outlined below, which was tested in a clinical setting to classify patients with either: low, moderate or high-caries risk. This system is offered for guidance and, as stated above, *must be balanced with the practitioner's professional expertise*. The reader is referred to these other resources for further discussion of caries risk.

Low-caries risk

All age groups

- No incipient or cavitated primary or secondary carious lesions during the last three years and no factors that may increase caries risk*

Moderate-caries risk

<6 years of age

- No incipient or cavitated primary or secondary carious lesions during the last 3 years but have at least one factor that may increase caries risk*

>6 years of age (any of the following)

- 1 or 2 incipient or cavitated primary or secondary carious lesions in the last 3 years
- No incipient or cavitated primary or secondary carious lesions in the last 3 years but have at least one factor that may increase caries risk*

High-caries risk

<6 years of age (any of the following)

- Any incipient or cavitated primary or secondary carious lesion during the last 3 years
- Have multiple factors that may increase caries risk*
- Low socioeconomic status**
- Suboptimal fluoride exposure

- Xerostomia***
- >6 years of age (any of the following)
- 3 or more incipient or cavitated primary or secondary carious lesions in the last 3 years
 - Have multiple factors that may increase caries risk*
 - Suboptimal fluoride exposure
 - Xerostomia***

*Factors increasing risk for caries may also include, but are not limited to:

1. High titers of cariogenic bacteria
2. Poor oral hygiene
3. Prolonged nursing (bottle or breast)
4. Poor family dental health
5. Developmental or acquired enamel defects
6. Genetic abnormality of teeth
7. Many multisurface restorations
8. Chemo/radiation therapy
9. Eating disorders
10. Drug/alcohol abuse
11. Irregular dental care
12. Cariogenic diet
13. Active orthodontic treatment
14. Presence of exposed root surfaces
15. Restoration overhangs and open margins
16. Physical or mental disability with inability or unavailability of performing proper oral health care

**Based on findings from population studies, groups with low socioeconomic status have been found to have an increased risk for caries.^{38, 39} In children too young to base risk on caries history, low socioeconomic status should be considered as a caries risk factor.

***Medication, radiation or disease induced xerostomia.

When reviewing the systematic reviews and clinical trials, the panel considered the caries risk status of the individuals who participated in the studies.

EVIDENCE-BASED CLINICAL RECOMMENDATIONS FOR PROFESSIONALLY APPLIED TOPICAL FLUORIDE

The following table summarizes the evidence-based clinical recommendations for the use of professionally applied topical fluoride. The clinical recommendations are a resource for dentists to use. These clinical recommendations must be balanced with the practitioner's professional judgment and the individual patient's preferences.

It is recommended that all age and risk groups use an appropriate amount of fluoride toothpaste when brushing twice a day, and that the amount of toothpaste used for children under 6 years of age not exceed the size of a pea. For patients at moderate and high risk of caries, additional preventative interventions should be considered, including use of additional fluoride products at home, pit-and-fissure sealants and antibacterial therapy.

Risk Category	Age Category for Recall Patients											
	<6 years			6-18 years			18+ years					
	Recommendation	Grade of Evidence	Strength of Recommendation	Recommendation	Grade of Evidence	Strength of Recommendation	Recommendation	Grade of Evidence	Strength of Recommendation			
Low	May not receive additional benefit from professional topical fluoride application*	1a	B	May not receive additional benefit from professional topical fluoride application *	1a	B	May not receive additional benefit from professional topical fluoride application *	IV	D			
Moderate	Varnish application at 6 month interval	1a	A	Varnish application at 6 month interval	1a	A	Varnish application at 6 month interval	IV	D***			
				OR Fluoride gel at 6 month interval			OR Fluoride gel at 6 month interval			D****		
High	Varnish application at 6 month interval	1a	A	Varnish application at 6 month interval	1a	A	Varnish application at 6 month interval	IV	D***			
	OR			OR								
	Varnish application at 3 month interval			Varnish application at 3 month interval			A**			Varnish application at 3 month interval	IV	D***
	OR			OR			A			OR	IV	D****
	Fluoride gel at 6 month interval	1a		Fluoride gel at 6 month interval	1a		Fluoride gel at 6 month interval	IV	D****			
	OR			OR			OR					
	Fluoride gel at 3 month interval			Fluoride gel at 3 month interval	IV	D****	Fluoride gel at 3 month interval	IV	D****			

*Fluoridated water and fluoride toothpastes may provide adequate caries prevention in this risk category. Whether or not to apply topical fluoride in such cases is a decision that should balance this consideration with the practitioner's professional judgment and the individual patient's preferences.

** Emerging evidence indicates that applications more frequent than twice a year may be more effective in preventing caries.

*** Although there are no clinical trials, there is reason to believe that fluoride varnish would work similarly in this age group.

**** Although there are no clinical trials, there is reason to believe that fluoride gels would work similarly in this age group.

There is laboratory data that demonstrates foam's equivalence to gels in terms of fluoride release, however only a couple of clinical trials have been published evaluating its effectiveness. Because of this, the recommendations for use of fluoride varnish and gel have not been extrapolated to foams.

Because there is insufficient evidence to address whether or not there is a difference in the efficacy of NaF versus APF gels, the clinical recommendations do not specify between these two formulations of fluoride gels. Application time for fluoride gel and foam should be 4-minutes. A 1-minute fluoride application is not endorsed.

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The complete document, *Evidence-Based Clinical Recommendations: Professionally Applied Topical Fluoride*, is available online at <http://www.ada.org/goto/ebd> or by calling the ADA at 800-621-8099 X 2878.