

Professionally Applied Topical Fluoride Executive Summary of Evidence-Based Clinical Recommendations

The ADA Council on Scientific Affairs
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These evidence-based clinical recommendations were developed by an expert panel established by the American Dental Association Council on Scientific Affairs (CSA) that evaluated the collective body of scientific evidence on the effectiveness of professionally applied topical fluoride for caries prevention. The recommendations 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. These clinical recommendations must be balanced with the practitioner's professional expertise and the individual patient's preferences.

MedLine and the Cochrane Database of Systematic Reviews were searched for systematic reviews and clinical studies of professionally applied topical fluoride—including

gel, foam and varnish forms—through October 2005. The American Dental Association Council on Scientific Affairs formed a panel of experts to evaluate the collective evidence and develop these clinical recommendations. Panelists were selected on the basis of their expertise in the relevant subject matter. They 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 "Professionally Applied Topical Fluoride: Evidence-Based Clinical Recommendations," 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

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PANEL CONCLUSIONS BASED ON THE EVIDENCE

The following evidence statements and corresponding classification of evidence (in parentheses) 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 does fluoride gel, especially in preschool-aged 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 also is important to consider that risk of developing dental caries exists on a continuum and changes over time as risk factors change. Therefore, caries risk status should be re-evaluated periodically.

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 is modified from systems that were 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. Other resources for assessing caries risk exist and are referenced in the full document.

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

Younger than 6 years

No incipient or cavitated primary or secondary carious lesions during the last three years but presence of at least one factor that may increase caries risk*

Older than 6 years (any of the following)

One or two incipient or cavitated primary or secondary carious lesions in the last three years

No incipient or cavitated primary or secondary carious lesions in the last three years but presence of at least one factor that may increase caries risk*

High caries risk

Younger than 6 years (any of the following)

Any incipient or cavitated primary or secondary carious lesion during the last three years

Presence of multiple factors that may increase caries risk*

Low socioeconomic status†

Suboptimal fluoride exposure

Xerostomia‡

Older than 6 years (any of the following)

Three or more incipient or cavitated primary or secondary carious lesions in the last three years

Presence of multiple factors that may increase caries risk*

Suboptimal fluoride exposure

Xerostomia‡

*Factors increasing risk of developing caries also may include, but are not limited to

- high titers of cariogenic bacteria;
- poor oral hygiene;
- prolonged nursing (bottle or breast);
- poor family dental health;
- developmental or acquired enamel defects;
- genetic abnormality of teeth;
- many multisurface restorations;
- chemotherapy or radiation therapy;
- eating disorders;
- drug or alcohol abuse;
- irregular dental care;
- cariogenic diet;
- active orthodontic treatment;
- presence of exposed root surfaces;
- restoration overhangs and open margins;
- physical or mental disability with inability or unavailability of performing proper oral health care.

† On the basis of findings from population studies, groups with low socioeconomic status have been found to have an increased risk of developing caries. In children too young for their risk to be based 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 To 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*	Ia	B	May not receive additional benefit from professional topical fluoride application*	Ia	B	May not receive additional benefit from professional topical fluoride application*	IV	D
Moderate	Varnish application at 6-month intervals	Ia	A	Varnish application at 6-month intervals OR Fluoride gel application at 6-month intervals	Ia Ia	A A	Varnish application at 6-month intervals OR Fluoride gel application at 6-month intervals	IV IV	D§ D‡
High	Varnish application at 6-month intervals OR Varnish application at 3-month intervals	Ia Ia	A D†	Varnish application at 6-month intervals OR Varnish application at 3-month intervals OR Fluoride gel application at 6-month intervals OR Fluoride gel application at 3-month intervals	Ia Ia Ia IV	A A† A D‡	Varnish application at 6-month intervals OR Varnish application at 3-month intervals OR Fluoride gel application at 6-month intervals OR Fluoride gel application at 3-month intervals	IV IV IV IV	D§ D§ D‡ 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 per year may be more effective in preventing caries.

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

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

Laboratory data demonstrate foam's equivalence to gels in terms of fluoride release; however, only two 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.

ACKNOWLEDGMENTS

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The complete document, "Professionally Applied Topical Fluoride: Evidence-Based Clinical Recommendations," is available online at "www.ada.org/goto/ebd" or by calling the ADA's toll-free number, Ext. 2878.