Professionally applied topical fluoride
Evidence-based clinical recommendations

American Dental Association Council on Scientific Affairs

Definition of evidence-based dentistry. The American Dental Association defines the term “evidence-based dentistry” as follows:

Evidence-based dentistry (EBD) is an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence relating to the patient’s oral and medical condition and history, with the dentist’s clinical expertise and the patient’s treatment needs and preferences.

In adopting this definition for EBD, the American Dental Association recognizes that treatment recommendations should be determined for each patient by his or her dentist, and that patient preferences should be considered in all decisions. Dentists’ experience and other circumstances, such as patients’ characteristics, also should be considered in treatment planning. EBD does not provide a “cookbook” that dentists must follow, nor does it establish a standard of care. Box 1 lists definitions of terms commonly used in evidence-based dentistry.

Background. With the dramatic increase in the amount of scientific information available about oral health, an evidence-based approach to oral health care and the practice of dentistry is necessary. There is a need to summarize, critique and disseminate scientific evidence and to translate the evidence into a practical format that is used easily by dentists. The evidence-based clinical recommendations in this report were developed by an expert panel established by the American Dental Association Council on Scientific Affairs 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.

Types of Studies Reviewed. MEDLINE and the Cochrane Library were searched for systematic reviews and clinical studies of professionally applied topical fluoride—including gel, foam and varnish—through October 2005.

Results. Panelists were selected on the basis of their expertise in the relevant subject matter. The recommendations are stratified by age groups and caries risk and indicate that periodic fluoride treatments should be considered for both children and adults who are at moderate or high risk of developing caries. Included in the clinical recommendations is a summary table that can be used as a chairside resource.

Clinical Implications. 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. These clinical recommendations must be balanced with the practitioner’s professional expertise and the individual patient’s preferences.

Key Words. Fluoride; caries; caries prevention; evidence-based dentistry; clinical recommendations.
EVIDENCE-BASED CLINICAL RECOMMENDATIONS

Are developed on the basis of findings from systematic reviews of randomized clinical trials or, in the absence of such evidence, nonrandomized intervention studies, follow-up (cohort) or case-control studies, or other study designs that may have a higher potential for bias compared with randomized controlled trials. The clinical recommendations are developed using the ADA evidence-based process, which requires a critical evaluation of the collective body of evidence on a particular topic to provide dentists and other professionals with practical applications of scientific information to use in their clinical decision-making process. 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 judgment and the individual patient’s preferences.

EVIDENCE-BASED DENTISTRY

An approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence relating to the patient’s oral and medical condition and history, with the dentist’s clinical expertise and the patient’s treatment needs and preferences.

RANDOMIZED CONTROLLED CLINICAL TRIAL

A study that randomly (that is, by chance alone) assigns participants of a defined population to receive one of two or more interventions. One of the interventions acts as the standard of comparison or control. The control may be the standard of practice, a placebo or no intervention. Another intervention is the treatment(s) under investigation. These groups are followed over time for predetermined outcome(s) of interest.

Definition of terms used in evidence-based dentistry.

**CASE-CONTROL STUDY**

Involves identifying subjects with a clinical condition (cases) and subjects free from the condition (controls), and investigating whether the two groups have similar or different exposures to risk indicator(s) or factor(s) associated with the disease.

**COHORT STUDY**

Involves identification of two groups (cohorts) of patients, one which did receive the exposure of interest, and one which did not, and following these cohorts forward for the outcome of interest.

**EVIDENCE-BASED DENTISTRY**

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Evidence-based dentistry.

**What are evidence-based clinical recommendations?** Evidence-based clinical recommendations are developed through evaluation of the collective body of evidence on a particular topic to provide practical applications of scientific information that can assist dentists in clinical decision-making. The best available scientific evidence is objectively assessed and used to develop clinical recommendations based on the currently available science. The clinical recommendations are graded according to the strength of the evidence that forms the basis for the recommendation. It is important to note that the grade of the recommendation is not related to the importance of the recommendation, but rather reflects the quality of scientific evidence to support the recommendation.

These recommendations are offered with the understanding that the dentist, knowing the patient’s health history and vulnerability to oral disease, is in the best position to make treatment recommendations 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 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.

Through the development of clinical recommendations, areas for which there is little evidence were identified. To address these gaps in the evidence, topics for future research are included in this document.

**Rationale for evidence-based clinical recommendations on professionally applied topical fluoride.** The dental profession is committed to delivering the highest quality of care to individual patients and applying advancements in technology and science to continually improve the oral health status of the U.S. population. Toward this end, the ADA convened the expert panel on professionally applied topical fluoride to review the scientific evidence and develop clinical recommendations. These clinical recommendations are intended to serve as an adjunct to the dentist’s professional judgment of how to best utilize professionally applied topical fluoride for each individual patient.

Several systematic reviews of the effectiveness of topical fluorides were published between 1994 and 2004. In addition, a number of clinical studies have been published since these systematic reviews were conducted. The evidence-based clinical recommendations on professionally applied topical fluoride were developed by a panel formed by the ADA’s Council on Scientific Affairs after assessing this body of evidence, and are intended to provide recommendations that are widely used by dental health care professionals.

**Definition of the clinical problem.** While den-
tistry has been successful in preventing dental caries through community, professional and individual preventive measures, this review was initiated to assess the current state of the evidence on professionally applied topical fluoride and develop recommendations for use by the profession in promoting oral health. The guiding issues for the review panel were whether or not the existing practices for professional fluoride applications in dental offices are supported by current scientific evidence, and whether or not existing recommendations need to be strengthened. As practiced today, dentists apply fluoride products in their offices for the primary prevention of dental caries. They also may apply fluoride products to prevent early carious lesions from progressing; this mode of application, however, usually is not well-defined in payment systems and in research reports. Hence, the panel focused on developing recommendations for the application of topical fluorides for the primary prevention of dental caries.

**Treatment options available.** Forms of professionally applied topical fluoride include gel, foam and varnish. Commonly used fluoride gels include acidulated phosphate fluoride (APF), which contain 1.23 percent or 12,300 parts per million (ppm) fluoride ion, and 2 percent sodium fluoride (NaF), which contain 0.90 percent or 9,050 ppm fluoride ion. Fluoride-containing varnishes typically contain 5 percent NaF, which is equivalent to 2.26 percent or 22,600 ppm fluoride ion. In the 1990s, fluoride foam was introduced into dental practice. However, there are few clinical studies of the effectiveness of these foams. Fluoride varnish is cleared for marketing by the U.S. Food and Drug Administration (FDA) for the treatment of dentin hypersensitivity associated with the exposure of root surfaces or as a cavity varnish, but not for reducing caries. There is, however, an increasing body of evidence indicating that fluoride varnish is effective in caries prevention. Use of fluoride varnish for caries prevention has been endorsed by the ADA, but remains an “off-label” use of the product, because it is not cleared for marketing by FDA for this purpose.

**ADA process for clinical recommendations.** MEDLINE and the Cochrane Database of Systematic Reviews were searched for systematic reviews published in English regarding professionally applied topical fluoride—including gel, foam and varnish forms—through October 2005. The “Find Systematic Reviews” tool of the PubMed Clinical Queries search engine (“www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml#reviews”) was used. Search terms were fluoride OR APF OR “acidulated phosphate fluoride” OR “sodium fluoride” OR “fluoride gel” OR “fluoride foam.” Seventeen systematic reviews were identified.1-17 The Cochrane Oral Health Group list of systematic reviews (“www.update-software.com/abstracts/ORALAbstractIndex.htm”) was searched manually for additional systematic reviews. Clinical studies published after January 200418-25 and, thus, not included in the systematic reviews also were identified through MEDLINE using the same search terms. The American Dental Association Council on Scientific Affairs formed a panel of experts to evaluate the identified systematic reviews and clinical trials. The expert panelists, listed in the acknowledgments at the end of this article, were provided with the identified publications and asked to identify any additional systematic reviews or other relevant published trials. One publication—Weintrab and colleagues,26 for which one of the panelists (J.D.B.F.) was a co-author—had been accepted for publication by the Journal of Dental Research and was included for consideration by the panelists.

The expert panel assessed the data from the individual studies that were summarized in the systematic reviews and from the identified clinical studies and convened at a workshop held at the ADA Headquarters in Chicago Oct. 17-18, 2005, to evaluate the collective evidence and develop evidence-based clinical recommendations on professionally applied topical fluoride. The product of this workshop was this document, which was submitted for review to scientists with expertise in fluoride and caries, relevant ADA agencies and the external reviewers listed in the acknowledgments. The comments received were considered by the expert panel. The clinical recommendations were approved by the ADA Council on Scientific Affairs.

**Expert panel on professionally applied topical fluoride.** 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.
Table 1

System used for grading the evidence.

<table>
<thead>
<tr>
<th>GRADE</th>
<th>CATEGORY OF EVIDENCE</th>
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<tbody>
<tr>
<td>Ia</td>
<td>Evidence from systematic reviews of randomized controlled trials</td>
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<tr>
<td>Ib</td>
<td>Evidence from at least one randomized controlled trial</td>
</tr>
<tr>
<td>Iia</td>
<td>Evidence from at least one controlled study without randomization</td>
</tr>
<tr>
<td>Iib</td>
<td>Evidence from at least one other type of quasi-experimental study</td>
</tr>
<tr>
<td>III</td>
<td>Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case-control studies</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence from expert committee reports or opinions or clinical experience of respected authorities</td>
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* Amended with permission of the BMJ Publishing Group from Shekelle and colleagues.27

Table 2

System used for classifying the strength of recommendations.

<table>
<thead>
<tr>
<th>CLASSIFICATION</th>
<th>STRENGTH OF RECOMMENDATIONS</th>
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<tbody>
<tr>
<td>A</td>
<td>Directly based on category I evidence</td>
</tr>
<tr>
<td>B</td>
<td>Directly based on category II evidence or extrapolated recommendation from category I evidence</td>
</tr>
<tr>
<td>C</td>
<td>Directly based on category III evidence or extrapolated recommendation from category I or II evidence</td>
</tr>
<tr>
<td>D</td>
<td>Directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence</td>
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</tbody>
</table>

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Grading the Evidence and Classifying the Strength of the Recommendations

System used for grading the evidence. The panel graded the evidence on the effectiveness of professionally applied topical fluoride for the prevention of caries on the basis of the system of Shekelle and colleagues27 (Table 1).

Strength of the recommendations. The panel classified the strength of the recommendations on professionally applied topical fluoride on the basis of the system of Shekelle and colleagues27 (Table 2).

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 children14,17 (Ia).
2. Patients whose caries risk is low, as defined in this document, may not receive additional benefit from professional topical fluoride application14,17,22-25 (Ia).
3. There are considerable data on caries reduction for professionally applied topical fluoride gel treatments of four minutes or more8 (Ia). In contrast, there is laboratory, but no clinical equivalency, data on the effectiveness of one-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 adolescents12,14,22,26 (Ia).
5. Two or more applications of fluoride varnish per year are effective in preventing caries in high-risk populations9,22 (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 children8 (III).
7. Four-minute fluoride foam applications, every six months, are effective in caries prevention in the primary dentition and newly erupted permanent first molars20,28 (Ib).
8. There is insufficient evidence to address whether or not there is a difference in the efficacy of NaF versus APF gels (IV).

Clinical Recommendations

Discussion of caries risk. 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.29 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 in Box 2, 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. The reader is referred to these other resources for further discussion of caries risk (including the role of low socioeconomic status).

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

**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.

**Younger than 6 years**
- Patients whose caries risk is lower, as defined in this document, may not receive additional benefit from professional topical fluoride application (Ia, B). (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.)
- Moderate-risk patients should receive fluoride varnish applications at six-month intervals (Ia, A). Fluoride varnish contains a smaller quantity of fluoride compared to fluoride gels; and, therefore, its use reduces the risk of inadvertent ingestion in children younger than 6 years.
- Higher-risk patients should receive fluoride varnish applications at 3 (Ia, D) to six-month (Ia, A) intervals.

**6 to 18 years of age**
- Patients whose caries risk is lower, as defined in this document, may not receive additional benefit from professional topical fluoride application (Ia, B). (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.)
- Moderate-risk patients should receive fluoride
Laboratory data demonstrate foam’s equivalence to gels in terms of fluoride release; however, only two clinical trials have been published evaluating its effectiveness.20,28 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 four minutes. A one-minute fluoride application is not endorsed.

RECOMMENDATIONS FOR RESEARCH
The following topics were identified as areas for additional research to provide a stronger evidence base for the use of professionally applied topical fluoride:

- systematic review on the effectiveness of fluoride varnish and gel in high-risk people and/or groups and the effects of varied frequency of application;
- research on the effects of frequency and mode of application (varnish, gel and foam) of fluoride products in adults and especially in populations with special needs;
- research on the use of fluoride varnish and gel for the prevention of root caries and recurrent caries;
- research on application strategies, especially for appropriate intervals of fluoride varnish and gel application in high-risk groups, including consideration of multiple applications over short time intervals;
- research on the best fluoride regimen to assist in the remineralization of early carious lesions;
- clinical trial on the effects of fluoride foam versus gel in various target populations;
- clinical trial on the effectiveness of one-minute versus four-minute gel applications in various target populations;
- development of slow-release fluoride systems that are responsive to changing pH levels in plaque fluid and/or saliva;
- research on methods of assessing caries risk;
- research on the safety and effectiveness of chewable topical fluoride supplements or troches for adults;
- research to evaluate whether the caries prevention effect of topical fluoride treatments is influenced by fluoridated water and toothpastes.

SUMMARY OF EVIDENCE-BASED CLINICAL RECOMMENDATIONS
Table 3 summarizes the evidence-based clinical recommendations for the use of professionally applied topical fluoride.

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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.

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 sodium fluoride versus acidulated phosphate fluoride gels, the clinical recommendations do not specify between these two formulations of fluoride gels. Application time for fluoride gel and foam should be four minutes. A one-minute fluoride application is not endorsed.

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**TABLE 3**

**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 younger than 6 years not exceed the size of a pea. For patients at moderate and high risk of caries, additional preventive interventions should be considered, including use of additional fluoride products at home, pit-and-fissure sealants and antibacterial therapy.

<table>
<thead>
<tr>
<th>RISK CATEGORY</th>
<th>AGE CATEGORY FOR RECALL PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 6 Years</td>
</tr>
<tr>
<td></td>
<td>Recommendation</td>
</tr>
<tr>
<td>Low</td>
<td>May not receive additional benefit from professional topical fluoride application*</td>
</tr>
<tr>
<td>Moderate</td>
<td>Varnish application at 6-month intervals</td>
</tr>
<tr>
<td>High</td>
<td>Varnish application at 6-month intervals OR Varnish application at 3-month intervals</td>
</tr>
</tbody>
</table>

* 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.

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The American Dental Association Council on Scientific Affairs thanks the members of the Expert Panel on Professionally Applied Topical Fluoride: Jeffrey W. Hatter, DMD, Med (Chairman), Goldman School of Dental Medicine, Boston University; Boston; Jarvis T. Chan, PhD, DDS, The University of Texas Health Science Center—Houston, Medical School; John D.B. Featherstone, MSc, PhD, University of California, San Francisco; Amid Isg loin, BDS, MPH, MBA, DrPH, University of Michigan, School of Dentistry, Ann Arbor; Albert Kingman, PhD, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, Md.; John Stamm, MScD, DDPH, DDS, School of Public Health, The University of North Carolina at Chapel Hill; Norman Tinanoff, DDS, MS, University of Maryland, Baltimore College of Dental Surgery; James S. Wefel, PhD, The University of Iowa College of Dentistry, Iowa City; Domenick T. Zero, DDS, MS, Indiana University School of Dentistry, Indianapolis. The Council also thanks members of the ADA Division of Science: Daniel M. Meyer, DDS, associate executive director; Kathleen Todd, senior director, administration, and assistant to the associate executive director; P.L. Fan, PhD, director, international science and standards; Helen Rustie, PhD, director, scientific information; Julie Frantsve-Hawley, RDH, PhD, assistant director, scientific information; Roger Connolly, scientific writer, scientific information.

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33. American Academy of Pediatric Dentistry, Council on Clinical Affairs. Policy on use of a caries-risk assessment tool (cat) for infants,