Evidence-based Clinical Recommendations: Professionally Applied Topical Fluoride

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1 Introduction

1.1 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. Dentist experience and other circumstances, such as patients' characteristics, should also be considered in treatment planning. EBD does not provide a "cookbook" that dentists must follow, nor does it establish a standard of care.

1.2 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. In order to address these gaps in the evidence, topics for future research are included in this document.

1.3 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 on the effectiveness of topical fluorides have been 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.

1.3.1 Definition of the clinical problem

While dentistry 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 may also apply fluoride products to prevent early carious lesions from progressing; this mode of application, however, is not usually 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.

1.3.2 Treatment options available

Methods for professionally applied topical fluoride include gel, foam and varnish. Commonly used fluoride gels include acidulated phosphate fluoride (APF), which contain 1.23% or 12,300 parts per million fluoride ion, and 2% sodium fluoride (NaF), which contain 0.90% or 9,050 parts per million fluoride ion. Fluoride-containing varnishes typically contain 5% sodium fluoride, which is equivalent to 2.26% or 22,600 parts per million fluoride ion. More recently, fluoride foam has been introduced into dental practice. However, there are few clinical studies on the effectiveness of fluoride foams. Fluoride varnish is cleared for market 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.

1.4 ADA process for clinical recommendations

MedLine and the Cochrane Database of Systematic Reviews were searched for systematic reviews published in English on professionally applied topical fluoride, including gel, foam and varnish through October, 2005. The "Find Systematic Reviews" tool of the PubMed Clinical Queries search engine was used (http://www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml#reviews). 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 (http://www.update-software.com/abstracts/ORALAbstractIndex.htm) was manually searched for additional systematic reviews. Clinical studies published after January 2004,[18-25] and, thus not included in the systematic reviews, were also identified through MedLine using the same search terms. The expert panelists (described below) were provided with the identified publications and asked to identify any additional Systematic Reviews or other relevant published trials. One publication, Weintraub et al, 2006,[26] for which one of the panelists was a co-author (JF), had been accepted for publication by the Journal of Dental Research and was included for consideration by the panelists.

A panel of experts was formed to evaluate the identified systematic reviews and clinical trials. 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, IL on October 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 as been submitted for review to scientists with expertise in fluoride and caries, relevant ADA agencies and the external reviewers listed below. The comments received were considered by the expert panel. The clinical recommendations are approved by the ADA Council on Scientific Affairs.

1.4.1 Expert panel on professionally applied topical fluoride

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.

1.4.2 External reviewers

This document was reviewed by the following scientific experts:

Dr. Nigel Pitts, University of Dundee, Scotland

Dr. Gail Topping, University of Dundee, Scotland

Dr. James Leake, University of Toronto

Dr. Brian Clarkson, University of Michigan

Dr. Steve Levy, University of Iowa

Dr. George K. Stookey, Indiana University

Dr. Helen Whelton, University Dental School, Wilton, Cork, Ireland

Dr. Alexia Antczak-Bouckoms, Tufts-New England Medical Center

Dr. Janet Clarkson, University of Dundee; Cochrane Oral Health Group

Dr. James Bader, University of North Carolina

The following organizations were given the opportunity to review this document:

American Academy of Pediatric Dentistry

American Association of Public Health Dentistry

Centers for Disease Control and Prevention

Special Care Dentistry

National Institute of Dental and Craniofacial Research

American Academy of Oral and Maxillofacial Pathology

American Academy of Periodontology

American Association of Endodontists

American Association of Oral and Maxillofacial Surgeons

Academy of General Dentistry

American College of Prosthodontists

American Academy of Oral and Maxillofacial Radiology

American Association of Dental Editors

Evidence-Based Dentistry

Agency for Healthcare Research and Quality

Centers for Medicare & Medicaid Services

American Association for Dental Research

American Dental Assistants Association

American Dental Education Association

American Dental Hygienists Association

American Student Dental Association

National Association of Dental Laboratories

American Dental Association Foundation

ADA Committee on the New Dentist

Dental Select

America‘s Health Insurance Plans

National Association of Dental Plans

Delta Dental Plans Association

Blue Cross & Blue Shield Association

Dental Trade Alliance

American Dental Trade Association

Journal of the American Dental Association

The University of Birmingham, United Kingdom

Hispanic Dental Association

American Medical Association

National Dental Association

American Association of Women Dentists

Canadian Dental Association

Doral Dental USA

Aetna Inc.

MetLife

2 Grading the evidence and classifying the strength of the recommendations

2.1 *System used for grading the evidence*

The panel graded the evidence on the effectiveness of professionally applied topical fluoride for the prevention of caries based on the system of Shekelle, Woolf, Eccles, and Grimshaw.[27]

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 without 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, cohort studies and case-control studies
IV	Evidence from expert committee reports or opinions or clinical experience of respected authorities

2.2 *Strength of the recommendations*

The panel classified the strength of the recommendations on professionally applied topical fluoride based on the system of Shekelle, Woolf, Eccles, and Grimshaw.[27]

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

3 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.[8, 14, 17] **Ia**

2. Patients whose caries risk is low, as defined in this document, may not receive additional benefit from professional topical fluoride application.[8, 14, 17, 22-25] **Ia**

3. There are considerable data on caries reduction for professionally applied topical fluoride gel treatments of 4 minutes or more.[8] **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.[9, 12, 14, 22, 26] **Ia**

5. Two or more applications of fluoride varnish per year are effective in preventing caries in high risk populations. [9, 22] **Ia**

6. Fluoride varnish applications take less time, create less patient discomfort and achieve greater patient acceptability than fluoride gel especially in preschool children.[19] **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.[20, 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**

4 Clinical Recommendations

4.1 *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 is also important to consider that risk for dental caries exists on a continuum and changes over time as risk factors change.[29] 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.[30] 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.[30, 31] 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.[30, 32-37]

Patients should be evaluated using caries risk criteria such as:

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.

4.2 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.

Under 6 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**). [8, 14, 17, 22-25]

- Moderate-risk patients should receive fluoride varnish applications at 6 month intervals (**Ia, A**). [9, 12, 14, 22, 26] Fluoride varnish contains a smaller quantity of fluoride compared to fluoride gels; and, therefore, its use reduces the risk of inadvertent ingestion in children under 6 years of age.

- Higher-risk patients should receive fluoride varnish applications at 3 (**Ia, D**) to 6 month (**Ia, A**) intervals. [9, 26]

6-18 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**). [8, 14, 17, 22-25]

- Moderate-risk patients should receive fluoride varnish or gel applications at 6 month intervals (**Ia, A**). [8, 9, 12, 14, 17]

- Higher-risk patients should receive fluoride varnish or gel application at 6 months intervals (**Ia, A**).[8, 9, 12, 14, 17, 22] Fluoride varnish applications at 3 months intervals (**Ia, A**), or fluoride gels at 3 month intervals (**IV, D**) may provide additional caries prevention benefit. [9, 22]

Over 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* (**IV, D**). [8, 14, 17, 22-25]

- Moderate-risk patients should receive fluoride varnish or gel applications at 6 month intervals (**IV, D**). [8, 9, 12, 14, 17]

- Higher-risk patients should receive fluoride varnish or gel applications at 3 to 6 month intervals (**IV, D**). [8, 9, 12, 14, 17, 22, 26]

All ages

- Application time for fluoride gel and foam should be 4-minutes. [8] A 1-minute fluoride application is not endorsed (**IV, D**).

Other Considerations

Foam is commonly used in dental practice, however, the weight of the clinical evidence for its effectiveness is not as strong as that for fluoride gel and varnish. There is clinical and laboratory data that demonstrates foam's equivalence to gels in terms of fluoride release,[40-45] however only a couple of clinical trials have been published evaluating its effectiveness in caries prevention.[20, 28] Because of this, the panel was reluctant to extrapolate their recommendations for use of fluoride varnish and gel to foams. It is important to note, however, that this does not mean that fluoride foam is not effective in caries prevention. Foam does provide the benefit of requiring a smaller amount for application resulting in a lower fluoride dose, thereby, reducing the risk associated with inadvertent ingestion.

*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.

4.3 Summary Chart of Evidence-based Clinical Recommendations

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.

Evidence-based Clinical Recommendations for Professionally Applied Topical Fluoride

	Age Category for Recall Patients								
Risk Category	**<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 OR Fluoride gel at 6 month interval	1a 1a	A A	Varnish application at 6 month interval OR Fluoride gel at 6 month interval	IV IV	D*** D****
High	Varnish application at 6 month interval OR Varnish application at 3 month interval	1a 1a	A D**	Varnish application at 6 month interval OR Varnish application at 3 month interval OR Fluoride gel at 6 month interval OR Fluoride gel at 3 month interval	1a 1a 1a IV	A A** A D****	Varnish application at 6 month interval OR Varnish application at 3 month interval OR Fluoride gel at 6 month interval OR Fluoride gel at 3 month interval	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 a year may be more effective in preventing caries.[9, 22]
*** 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,[40-45] however only a couple of 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 4-minutes. A 1-minute fluoride application is not endorsed.

5 Recommendations for Research

The following topics were identified as areas for additional research in order 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 individuals 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 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 1 minute versus 4 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 for 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.

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7 *Appendix*

Definition of terms

Case-control study involves identifying subjects with a clinical condition (cases) and subjects free from the condition (controls), and investigating if 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 clinical recommendations are developed based upon findings from systematic reviews of randomized clinical trials or in the absence of such evidence, non-randomized 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 that 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 opinion and the individual patient's preferences.

Evidence-based dentistry 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.

Randomized controlled clinical trial is a study that randomly (i.e., 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/are the treatment(s) under investigation. These groups are followed over time for predetermined outcome(s) of interest.