Fluoride Varnish: an Evidence-Based Approach
Research Brief
Association of State and Territorial Dental Directors
Fluorides Committee
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Background

In response to questions from state oral health program directors and staff, the ASTDD Fluorides Committee was tasked in 2005 with reviewing the evidence for fluoride varnish programs, especially in community-based settings, and developing a research brief appropriate for health professionals, including dental professionals, and health advisory committee members. Drafts were disseminated for feedback during roundtable discussions at the 2006 and 2007 National Oral Health Conferences and shared with numerous reviewers. A review of recent literature since those meetings has enabled the Committee to develop a more scientifically sound document for states to use when planning targeted population-based programs to reduce dental caries.

The American Dental Association (ADA) defines the term "evidence-based dentistry" as an approach to oral health care that requires careful integration of systematic assessments of clinically relevant scientific evidence related to the patient's oral and medical history, the dental professional's expertise, and the patient's needs and preferences. (ADA, 2003) The Institute of Medicine's (IOM) review of evidence-based health care found that, despite benefits from rapid growth in medical research and increasing expenditures for health care in the United States, far too much time is spent on health care activities that do not improve health, and not enough time is spent on healthcare activities that will. (Olson, Aisner, McGinnis, 2007)

The use of fluoride varnish to prevent and control dental caries in children and adults is expanding in both public and private dental practice settings and in non-dental settings that incorporate health risk assessments and counseling. These settings include Head Start programs and Special Supplemental Nutrition Programs for Women, Infants, and Children (WIC); medical offices; well-child clinics and home visits conducted by public health nurses; childcare programs; and other, sometimes overlapping, community programs. Outcome evaluations will be critical for developing optimal protocols and evaluating the cost-effectiveness of this new prevention strategy in various public health settings, especially when coordination of services is complex.

The following questions and responses are provided to present the best available evidence and to help professionals design and evaluate community-based programs that use fluoride varnish:

1. What is fluoride varnish?
2. How do fluorides prevent dental decay?
3. What are the advantages of fluoride varnish over other professionally applied fluorides?
4. Does fluoride varnish prevent dental caries in both primary and permanent teeth?
5. How often should fluoride varnish be applied?
6. Are fluoride varnishes Federal Drug Administration (FDA) approved?
7. Is fluoride varnish safe?
8. Does fluoride varnish contribute to fluorosis?
9. What could improve the cost-effectiveness of community-based fluoride varnish programs?

What Is Fluoride Varnish?

Most fluoride varnishes are lacquers containing 5% sodium fluoride in a colophony/resin base (see Appendix 1). Depending on the brand, there are significant differences in fluoride varnish preparations, making comparisons difficult. (Shen, Autio-Gold, 2002) Fluoride varnish provides a highly concentrated, temporary dose of fluoride to the tooth surface. The varnish holds fluoride close to the tooth surface for a longer period of time than other concentrated fluoride products. Unlike low-dose fluorides available over the counter such as fluoride toothpaste, highly concentrated fluoride products such as fluoride varnish must be applied by a healthcare professional in most states.

How Do Fluorides Prevent Dental Decay?

For all tooth surfaces, there is a continuous cycle of demineralization and remineralization of tooth enamel. Tooth decay is an infectious, transmissible disease caused by bacteria colonizing on the teeth and producing acid that dissolves enamel, resulting in greater demineralization. All fluorides act to slow demineralization and boost remineralization. If unchecked, bacteria continue destroying tooth structure, eventually infecting the soft pulp tissue and causing pain.

Fluorides work in at least four different ways to protect teeth from tooth decay. Fluoride is incorporated in tooth structure when small amounts are swallowed daily while the teeth are forming. Fluoride becomes concentrated in the outer enamel surfaces when applied after teeth erupt into the mouth. Dental plaque and saliva act as fluoride reservoirs to enhance the remineralization process. In addition, fluorides interfere with the decay-causing bacteria colonizing on teeth and reduce their acid production, thus slowing demineralization.

Fluorides are delivered to the teeth in different dosages and in a variety of ways. They can be delivered topically or systemically. Low doses of topical fluoride are found in most over-the-counter toothpastes and optimally fluoridated water. These methods of fluoride delivery have the advantage of being inexpensive and widely accessible and, therefore, offer caries-preventive benefits at low cost. Higher doses are found in prescription-only strength rinses, in some toothpastes and in dietary fluoride supplements (pills or liquids) that are used at home. By state licensing regulations, high-dose topical fluoride gels and varnishes must be applied by health professionals, which contributes to their greater costs for benefits. Using a fluoride supplement or drinking optimally fluoridated water provides both topical and systemic effects. While swallowed fluorides are incorporated into tooth structure before eruption and are effective in strengthening tooth enamel, the topical fluoride actions of low dose fluorides appear to be responsible for the greater proportion of reductions in tooth decay. (Featherstone, 2004; Featherstone, 2006; Newbrun, 2001) One recent study suggests the strongest caries-preventive effect is produced by a high pre-eruptive fluoride exposure supplemented by a high exposure at maturation and/or post-eruption. (Singh, Spencer, Brennan, 2007)

High-dose fluorides are similar to low-dose fluorides in how they prevent tooth decay. Repeated exposure is necessary to maintain a high concentration on tooth surfaces, but exposure/reapplication is needed less often for high-dose fluorides. When an adequate balance of remineralization and demineralization is maintained with low-doses of fluoride, high-dose fluorides may not provide any additional protection. A low level of fluoride maintained in plaque and enamel can prevent or control dental caries throughout life. (Wei, 1985; IOM, 1997; Beltran-Aguilar, Goldstein, Lockwood, 2000; NIH, 2001; Marinho, Higgins, Logan, Sheiham, 2004, 2003, 2002, 2002a; Marinho, Higgins, Sheiham, Logan, 2003a, 2004a; ADA 2006)

What Are The Advantages Of Fluoride Varnish Over Other Professionally Applied Fluorides?

Fluoride varnish works by increasing the concentration of fluoride in the outer surface of teeth, thereby enhancing fluoride uptake during early stages of demineralization. The varnish hardens on the tooth as soon as it contacts saliva, allowing the high concentration of fluoride to be in contact with tooth enamel for an extended period of time (about 1 to 7 days). This is a much longer exposure compared to other high-dose topical fluorides such as gels or foams, which is typically 10 to 15 minutes. The amount of fluoride deposited in the tooth surface is considerably greater in demineralized versus sound tooth surfaces. (Skold-Larsson, Modeer, Twetman, 2000; ten Cate, Featherstone, 1991) Thus, the benefits of fluoride varnish are greatest for individuals at moderate-risk or high-risk for demineralization or tooth decay. (Marinho et al, 2004; Marinho et al, 2004a; ADA 2006)

Inadvertent ingestion of a high dose of fluoride with a varnish application is less likely than with other highly concentrated fluoride products. Fluoride varnish can be recommended in situations where the clinical setting is not adequate to support application of four-minute acidulated phosphate fluoride (APF) gels. (CDC, 2001a) Fluoride varnish is quickly and easily applied, without trays or suction. This is especially helpful for infants and toddlers, developmentally disabled individuals, or people with severe gag reflexes who otherwise could not tolerate the use of trays or the bulkiness of gels or foams. (Bawden, 1998)

By contrast, neither professionally applied rinses nor fluoride foams have been sufficiently evaluated to recommend their use over APF fluoride gel or fluoride varnish. The 2006 ADA recommendations acknowledge that while foams are commonly used in dental practice, the weight of evidence for effectiveness is not as strong as gels and varnish. See Appendix 2.

Does Fluoride Varnish Prevent Dental Caries In Both Permanent Teeth And Primary Teeth?

Fluoride varnish has been found to be effective in preventing caries on permanent teeth. Fluoride varnish also has recently been shown to prevent or reduce caries in the primary teeth of young children. (ADA 2006; Weintraub, Ramos-Gomez, June, 2006; Lawrence, 2006)

The U.S. Preventive Services Task Force document, *Prevention of Dental Caries in Preschool Children: Recommendations and Rationale,* rates preventive interventions by levels of efficacy and bases recommendations on these ratings (US Preventive Services Task Force, 2004). According to the CDC (2001a) and the ADA (2006), the quality of evidence for the efficacy of fluoride varnish in preventing and controlling dental caries in the permanent teeth of moderate/high-risk children is HIGH. These organizations strongly recommend fluoride varnish because of consistent, good quality, patient-oriented evidence. Based on the results of the University of California at San Francisco (UCSF) randomized clinical trial of 376 preschool children (Weintraub, Ramos-Gomez, June, 2006), published since the CDC and NIH reports, the ADA (2006) now rates the quality of evidence for the efficacy of fluoride varnish in preventing and controlling dental caries in the primary teeth of high-risk children as HIGH and has strongly recommended its use.

Several recent studies have shown that fluoride varnish is efficacious in reducing decay in the primary teeth of high-risk children. (Autio-Gold, Courts, 2001; Autio-Gold, Tomar, 2005; Weintraub Ramos-Gomez, June; 2006; Lawrence, Binquis, Douglas et al, 2006) There is evidence that the preventive effect is strongest when fluoride varnish is applied before the onset of detectable dental caries. In a randomized clinical trial in Canada, 1,146 young aboriginal children with high caries incidence were provided caregiver counselling and fluoride varnish three times a year for two years. Reductions in

dental caries of 18% to 25% were demonstrated when preventive care was initiated before caries was observed. Infants, toddlers and preschool children who were caries free at baseline benefited most from the intervention. (Lawrence, Binquis, Douglas et al, 2006)

How Often Should Fluoride Varnish Be Applied?

The UCSF study demonstrated a dose response relationship for caries reductions when fluoride varnish was applied to all infants and children under age four in the study. The targeted population had two risk factors for high caries risk (low-income and minority status). Results demonstrated that children who received fluoride varnish in addition to counseling had more than three times fewer decayed surfaces after three or four varnish applications. The effect on children with extensive dental caries was not studied. (Weintraub, Ramos-Gomez, June, 2006)

CDC (2001a) and the ADA (2006) recommend at least biannual applications at six-month intervals as effective in controlling or reducing dental caries in primary or permanent teeth for moderate or high-risk children. While one application of fluoride varnish may provide some benefit (Weintraub Ramos-Gomez, June, 2006), the majority of professionally applied fluoride studies demonstrate that at least two applications bi-annually, for at least two years, are necessary to demonstrate effective reductions in dental caries. The 2006 ADA clinical recommendations suggest that people at highest caries risk may obtain improved caries prevention benefit from applications at three-month intervals. The optimal number of fluoride varnish applications and the optimal intervals, however, have not yet been established. (CDC 2001a; Scheifle, Studen-Pavlovich, Markovic, 2002; ADA, 2006)

Are Fluoride Varnishes Federal Drug Administration (FDA) Approved?

Fluoride varnishes are approved as Class II Medical Devices (FDA 510k compliance) for use as a cavity liner and/or tooth desensitizer. None of the fluoride varnishes are FDA approved as caries preventive agents. They are used "off-label" for preventing dental caries. Some fluoride varnish products are not listed as having FDA approval as a device.

FDA approval is not required to use fluoride varnish off-label. (USFDA, 1998, USP DI, 2006, AHFS, 2006) Many medications are currently prescribed and administered for off-label use, and many drugs used in medical practice for children have never been tested in children. The FDA regulation states: "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects." (USFDA, 1998; AAP, 2002)

Is Fluoride Varnish Safe?

Fluoride varnishes are generally considered safe and well accepted. (Beltran-Aguilar, Goldstein, Lockwood, 2000; Seppa L, 1999; Bawden, 1998) However, published data on possible adverse effects is scarce. (Marinho, Higgins, Sheiham, Logan, 2004a, Marinho, Higgins, Logan, Sheiham, 2004) Although fluoride varnish preparations contain up to 50,000 ppm sodium fluoride, only a very small amount is applied (2.3 to 5.0 mg) (Ekstrand, Koch, Petersson, 1980)

Since the resin-based varnish sticks to the teeth, fluoride is ingested over a period of time as the varnish slowly breaks away from the tooth surface. The Beltran-Aguilar, Goldstein and Lockwood

review (2000) found the risk of acute toxic reactions with varnishes to be minimal due to the rapid setting time and small dosages even with ingestion of some product during application and following application.

A few articles on fluoride varnish for the prevention, management, and treatment of dental caries reported no acute toxic effects in children or adolescents as a result of the therapeutic application of fluoride varnish. (Seppa, 1999 ; Moberg, Petersson, Lith, Birkhed, 2005)

Two studies looked at differences in plasma fluoride levels after fluoride varnish application in preschool children specifically. Ekstrand and colleagues (1980) reported a low plasma fluoride level following placement of a 5% fluoride varnish on two preschool children, which was comparable to plasma fluoride levels experienced after toothbrushing with a fluoridated dentifrice or after ingesting a 1 mg fluoride tablet. (Roberts, Longhurst, 1987; Ekstrand J, Koch G, Petersson, 1983)

The level was also significantly lower than plasma fluoride levels seen after a professionally applied 1.23 percent APF gel. (Ekstrand J, Koch G, Lindgren LE, Petersson, 1981)

Pessan and co-authors (2005) found that the low rise in urinary fluoride excretion (n=20) returned to normal within 24 hours in preschool children who brushed daily with fluoride toothpaste and drank fluoridated water. Peak plaque/salivary fluoride levels are generally observed within 24 to 72 hours, with higher fluoride levels found for up to a week following application. (Skold-Larson, Modeer, Twetman, 2000)

Infants and toddlers

The two Cochrane reviews by Marinho and colleagues (2004, 2004a) recommended that future fluoride varnish studies include reports of adverse events or safety concerns. The UCSF study was the first one to intentionally collect data on adverse effects and report the lack of such effects for infants and toddlers. (Weintraub, Ramos-Gomez, June, 2006) No adverse effects were reported from 250 children following application of fluoride varnishes. Infants and toddlers absorb fluoride differently from older children, due to the substantial growth rate between birth and age two. (Whitford, 1999) Hence, care must be exercised by applying fluoride sparingly and preventing children from swallowing the excess product during applications.

Allergy

According to the ADA (2006), there are no confirmed allergic reactions to fluoride. Though uncommon, allergic reactions can occur in individuals with a known sensitivity to colophony/rosin. (Sharma, 2006) Colophony is a contact sensitizer present in fluoride varnish and in many household products such as cosmetics, nail varnish, sticking plasters and chewing gum, as well as in some dental materials. Direct skin/mucosa exposure to colophony from varnish in a hypersensitive person may initiate an allergic contact dermatitis/stomatitis. Two cases of contact allergy to Duraphat varnish have been reported in the literature: one is a case of dermatitis on a dental assistant's hand, and the other is a case of stomatitis in a patient. (Isaksson, Bruze, Bjorkner, Kiklasson, 1993) These allergies were likely related to the colophony component of the varnish. A thorough health history to determine known allergies, similar to that obtained prior to the administration of any therapeutic agent, is recommended prior to fluoride varnish use. Fluoride varnish is contraindicated when ulcerative gingivitis and stomatitis is present and should not be applied on large open lesions.

Does Fluoride Varnish Contribute To Fluorosis?

Fluoride varnish (with peak plasma fluoride levels less than a daily fluoride tablet or brushing with fluoride toothpaste) applied infrequently (two to four times a year at three-to- six-month intervals) is unlikely to contribute to fluorosis in children under age six. (Ekstrand, Koch, Petersson, 1980) Any risk for very young children following multiple applications (three or more times in one week or greater than four times a year) has not been determined.

What Could Improve The Cost-Effectiveness Of Community-Based Fluoride Varnish Programs?

Consideration of the cost-effectiveness of programs has been a hallmark of optimal public health interventions. Reviews by the Cochrane Collaborative, CDC, and the ADA recognize that universal application (versus a targeted approach) of professionally applied fluoride, including fluoride varnish, is unlikely to be cost-effective. (ASTDD, 2005) Programs that increase the frequency of fluoride applications for low-income groups alone, without considering the incidence of dental caries or other risk indicators, may not result in optimal outcomes. (Quinonez, Stearns, Talehar et al, 2006; Psoter, Pendrys, Morse et al, 2006) Programs utilizing fluoride varnish will need to consider age relative to the dentition to be protected and the tooth surfaces affected for planning the most cost-effective programs. (Macek, Heller, Selwitz, Manz, 2004; Warren, Levy, Broffitt, Kanellis, 2006; Brown, Lowe, Simmermann et al, 2006) For example, fluorides are generally accepted to be more effective in preventing dental caries on the smooth surfaces of teeth, rather than the pits and fissures. Delegation of fluoride varnish application to healthcare providers in existing programs that serve children may be more cost-effective than the addition of oral health professionals to those settings. (Rozier, Sutton, Bawden et al, 2003; Rozier, Slade, Zelder, Wang, 2005) Community level caries assessment before implementation of population-based programs is highly recommended to adequately describe health outcomes after the intervention.

Clear definitions will help programs target populations and select the appropriate outcome measures for program evaluation. The definition of early childhood caries has changed many times in the last decade for research purposes. One current definition includes any tooth decay that begins before age two and/or affects a significant number of smooth surfaces of primary teeth before age 6. (AAPD, 2003) Others define tooth decay by the surfaces affected, such as smooth surface decay in anterior teeth alone. (Ismail, Sohn, 1999) Psoter, Pendrys, Morse et al (2006) found dental caries to progress more rapidly in the pits and fissures of primary teeth rather than on the smooth surfaces.

There is general agreement that caries risk assessment tools, while imperfect, provide a cost-effective approach for community programs to model. Due to the adoption of water fluoridation and widespread use of fluoride toothpaste, about 75% of the American public is at low risk for dental caries. Therefore, the use of fluoride varnish, like any professionally applied fluoride, should be limited to those individuals and communities deemed moderate to high-risk for developing dental caries. (ADA, 1995; ADA, 2006; AAPD, 2002)

For Individuals

The single greatest individual risk factor for predicting dental caries is dental caries experience in the previous two or three years. (ADA, 1995; ADA, 2006) In infants, risk is often determined by caregiver or sibling dental status. Risk rises with multiple individual factors that may include: high levels of

cariogenic bacteria, poor oral hygiene, family oral health status, enamel defects, radiation therapy, eating disorders, irregular dental care, cariogenic diet, ortho treatment, etc. (Selwitz, Ismail, Pitts, 2007) For children under age three, SES and family risk factors may be the best predictors that we have today. Low-risk individuals may not receive additional benefits from professional topical fluoride application, especially if they are using fluoride toothpaste and/or drink water that is optimally fluoridated. (Marinho,Higgins, Logan, Sheiham, 2004; Marinho, Higgins, Sheiham, Logan, 2004a) The frequency of varnish application, as with any professionally applied fluoride, will depend upon the individual's risk for dental caries. (CDC, 2001a; AAPD, 2002; Featherstone, Adair, Anderson et al, 2003; Featherstone, 2004; Featherstone, 2006; Crall, 2005; Crall, 2006; ADA, 2006)

For Communities

The single greatest risk factor predicting dental caries in populations is low socio-economic status, especially for children under the age of three who are too young to base risk on individual caries history. (NIH, 2001; ADA, 2006; CDC, 2001a) However, programs based on populations selected for socio-economic status alone, without considering dental caries incidence, may result in increased costs compared to the benefits. (Macek, Heller, Selwitz, Manz, 2004; Quinonez, Stearns, Talehar et al, 2006; Psoter, Pendrys, Morse et al, 2006) Community programs can demonstrate improved outcomes when fluoride varnish applications are incorporated into programs of ongoing health assessment and counseling, rather than as stand alone events. (Crall, 2006) Programs that offer a single application of fluoride varnish are generally less efficacious than those that incorporate multiple visits and applications. Most studies recommend that fluoride varnish programs include applications at least at six-month intervals for at least two years for the high-risk individual, although applications at 3-month intervals may yield greater benefits for some. (Gartlehner et al, 2006; ADA, 2006; CDC, 2001a) Similar effectiveness may be achieved from universal application of fluoride varnish versus a more targeted approach when communities exhibit two or more community risk factors for high caries experience. (Weintraub, Ramos-Gomez, June, 2006; Lawrence, Binquis, Douglas et al, 2006) Other population risk or protective factors to consider in program planning include availability of dental care; proportion of the population who 1) are low SES, 2) are an ethnic minority, 3) speak English as a second language, 4) are homeless, 5) have limited education, 6) have special health care needs, 7) have high caries incidence and prevalence rates or advanced disease, and 8) lack access to fluoridated water.

Conclusion

Fluoride varnish is a type of fluoride that can be professionally applied outside the dental office in medical offices or in community-based programs. Programs should be consistent with evidence-based practice guidelines derived from current research to minimize possible risks and optimize benefits. (Weintraub, Ramos-Gomez, June, 2006; Lawrence, Binquis, Douglas et al, 2006; ADA, 2006) Caries risk assessment models are a cost-effective approach for community-based programs to follow (Young, Buchanan, Lubman, Badway, 2007; ADA, 2006; Bratthall, Hansel Petersson, 2005; AAPD, 2002) Programs using fluoride varnish will be more likely to demonstrate benefits and reduce dental caries in at-risk populations when applications are offered at least at six-month intervals over at least two years in duration in combination with counseling. For the prevention of early childhood caries, initiation of fluoride varnish should begin no later than age one for highest risk children. (Weintraub, Ramos-Gomez, June, 2006; Lawrence, Binquis, Douglas et al, 2006)

Dental sealants and water fluoridation are the cornerstones of individual and community practice to prevent and control dental caries. (CDC, 2001a; Truman, Gooch, Sulemana, Gift et al et al, 2002;

Reggiardo, Feigal, Casamassimo, 2006) Fluoride varnish offers additional opportunities toward improving the prevention and control of dental caries.

Future Research

Recommendations for research include implementation of longitudinal studies and larger randomized clinical trials that target specific tooth surfaces in primary teeth in children under age three. Applied research is also needed to: 1) consider training non-health care providers, including parents, to apply fluoride varnish (this would require a change in dental regulations to implement); 2) to analyze the factors that influence cost-effectiveness of programs; 3) to determine the cost-effectiveness of community models of fluoride application programs; and 4) to develop cost-effective fluoride application protocols for high-risk populations.

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Appendix I. Fluoride Varnish Products

FDA approved (510k) as a medical device/desensitizing agent	Fluoride Agent	Primary Base	Manufacturer	Packaging	Pub Med Reference Count*
Duraphat	5% sodium fluoride	resin	Colgate Oral Pharmaceutical, Inc.	10 mL tube 20 + dose per tube	131
DuraFluor/Duraflor	5% sodium fluoride	resin	Pharmascience Inc,	10mL tube-20+ dose per tube	108
Fluor Protector	1% difluorsilane	polyurethane	Vivadent, Ivoclar North America	.4 mL 1.0 mL bottles	60
CavityShield	5% sodium fluoride	resin	Omni Oral Pharmaceuticals	.5 mL unit dose	3
AllSolutions Fluoride Varnish	5% sodium fluoride	resin	Dentsply intl.	.5 mL unit dose	1
DuraShield	5% sodium fluoride	resin	Sultan Dental Products	.4 mL unit dos	0
Fluoridex	5% sodium fluoride	resin	Discus Dental inc.	.5 mL unit dose	0
Fluorilaq	5% sodium fluoride	resin	Pascal Company, Inc.	10 mL tube 20+ dose per tube	0
Flor-Opal	5% sodium fluoride	resin	Ultradent Products, Inc	.5 mL unit dose	0
Enamel Pro Varnish	5% sodium fluoride	resin	Premier Dental Products	.25 mL and .4 mL unit dose	0

*PubMed search terms April 2007 = "product name" plus "dental caries." The listed products are found in the FDA Medical Devices database: http://www.fda.gov/cdrh/databases.html. Some products available in the U.S. may not be on the list because they are not approved by the FDA as a medical device. Inclusion on this list does not constitute an endorsement by the Association of State and Territorial Dental Directors.

Appendix 2

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.

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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.