



# 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, in 2005 the ASTDD Fluorides Committee was tasked 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. At the 2006 and 2007 National Oral Health Conferences drafts were disseminated for feedback during roundtable discussions and shared with numerous reviewers. A review of recent literature since those meetings has enabled the Committee to develop an updated and 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 requiring 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.<sup>1</sup> 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 health care activities supporting improvement.<sup>2</sup>

The 2012 ASTDD Synopses of State Dental Programs (2010-2011 data) reports more than 70% of states and the District of Columbia have fluoride varnish programs. As of 2014, 47 states allow physicians to apply and bill Medicaid for fluoride varnish applications.<sup>3</sup> The use of fluoride varnish to prevent and control dental caries in children and adults has expanded in public and private dental practice settings and in non-dental settings along with health risk assessments and counseling. Settings include Early Head Start; Head Start/preschool programs; Special Supplemental Nutrition Programs for Women, Infants, and Children (WIC); medical offices; well-child clinics; home visits conducted by public health nurses or home visitors; childcare programs; schools; and other, sometimes overlapping, community programs. The 2006 and 2013 ADA recommendations support the use of fluoride varnish, as any other professionally applied fluoride, for children at high-risk for tooth decay.<sup>4,5</sup> Outcome evaluations continue to be critical for developing and implementing optimal protocols and evaluating the cost-effectiveness of this prevention strategy in various public health settings, especially when coordination of services is complex.

## **Purpose**

To continue to help professionals design, implement and evaluate community-based programs using fluoride varnish, ASTDD reviewed the 2007 ASTDD Research Brief. The questions, responses and evidence have been updated and expanded for 2014. They form the subsequent headings for this report:

1. Fluoride varnish
2. Mechanism of actions
3. Characteristics
4. Effectiveness
5. Patient Selection
6. Frequency of application
7. FDA Approval
8. Safety
9. Community and school programs

## **Fluoride Varnish**

Most fluoride varnishes are lacquers containing 5% sodium fluoride in a colophony/resin base. 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 time than other concentrated fluoride products. Unlike low-dose fluorides available over the counter, such as fluoride toothpaste, state-authorized personnel apply highly concentrated fluoride products, such as fluoride varnish.

Depending on the brand, there are significant differences in fluoride varnish preparations, fluoride release and uptake.<sup>6</sup> A quick search of Pub Med by product name is one measure used to identify efficacious products. Durafluor/Duraflor and Duraphat fluoride varnishes are used extensively in caries prevention studies. Newer fluoride varnishes containing calcium and inorganic phosphate may have increased fluoride release.<sup>7,8</sup> Fluoride incorporated into similar base-type materials may have different anticaries efficacy.<sup>9</sup> Fluoride varnish at the concentration of 0.1% fluoride, 1.23% fluoride (APF\*) foam, or prophylaxis pastes are not recommended for caries prevention for any age groups.<sup>5</sup>

## **Mechanism of Actions**

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 (systemic effect).
- Fluoride is concentrated in the outer enamel surfaces when applied after teeth erupt into the mouth (topical effect).

- Dental plaque and saliva act as fluoride reservoirs to enhance the remineralization process (topical and systemic effect).
- In addition, fluorides interfere with the decay-causing bacteria colonizing on teeth and reduce their acid production, thus slowing demineralization (topical effect).

Tooth decay is an infectious, transmissible disease caused by bacteria colonizing on the teeth and producing acid from carbohydrates that then demineralizes teeth. A continuous cycle of demineralization and remineralization occurs on all tooth surfaces (enamel and root surfaces). If unchecked, bacteria continue destroying tooth structure, eventually infecting the soft pulp tissue. Pain may or may not occur prior to or subsequent to pulpal infection. Fluoride, whether from water, toothpaste or professionally-applied topical fluoride products, acts to slow demineralization and boost remineralization, thus preventing infection, pain and the need for fillings or surgical treatment.<sup>10,11</sup>

Fluoride reaches teeth in different dosages and in several ways (Table 1). Fluoride in water and all fluoride products have both a systemic and topical effects. These effects must be balanced with a comparison of the risks and benefits. Low concentrations of fluoride are 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 fluoride concentrations are found in rinses, toothpastes, and dietary fluoride supplements (tablets, lozenges, or liquids) prescribed by a health care professional for home use. Beneficial topical and systemic effects occur when using a fluoride supplement, drinking optimally fluoridated water and eating foods prepared using fluoridated water. Systemic fluorides are incorporated in developing tooth structure before teeth erupt into the mouth. The topical fluoride actions of frequent low concentrations of fluoride appear to be responsible for the greater proportion of lifetime reductions in tooth decay.<sup>12,13,14</sup> Studies suggest the strongest caries-preventive effect is produced by a pre-eruptive fluoride exposure supplemented by exposure at maturation and/or post-eruption.<sup>15</sup>

<b>Table 1</b>			
<b>Using Topical Fluoride Agents for Caries Management and Prevention</b>			
	<b>Fluoride Concentration</b>		
<b>Recommended Topical Fluoride Agents</b>	<b>Fluoride PPM</b>	<b>Fluoride ION Percent</b>	<b>Sodium Fluoride Percent</b>
<b>Professionally-applied Agents:</b>			
2.26% fluoride varnish	22,600	2.26	5.0
Acidulated phosphate fluoride (APF) gel (with 0.1M phosphoric acid)	12,300	1.23	2.7
<b>Prescription-strength, Home-Use Agents:</b>			
<b>Gel or paste with or without acidulation (0.1M phosphoric acid)</b>	5,000	0.50	1.1
<b>Mouthrinse, RX strength</b>	900	0.09	0.2
<b>Over-the-counter Strength:</b>			
<ul style="list-style-type: none"> <li>• Toothpaste with 1150 ppm (0.12%) fluoride or less [i.e., 0.25% sodium fluoride]</li> <li>• Mouthrinse with 100 ppm (0.01%) or 225 ppm (0.02%) fluoride [i.e., 0.02/0.05% sodium fluoride]</li> </ul>			
<b>Toothpaste</b>	1150	0.12	0.25
<b>Mouthrinse</b>	100	0.01	0.02
Adapted from Weyant RJ, Tracy SL and colleagues. Topical fluoride for caries prevention. Executive summary of the updated clinical recommendations and supporting systematic review. JADA 2013;144(11).			

Highly concentrated, professionally applied fluorides are similar to low-concentration fluorides in how they prevent tooth decay. Repeated exposure is necessary to maintain fluoride at the tooth surface, yet exposure/reapplication is needed less often for highly concentrated fluorides. Unlike fluoride products with lower fluoride concentrations, fluoride varnish and fluoride gels form calcium fluoride globules within the enamel-plaque interface, very slowly releasing fluoride in acidic plaque.<sup>16</sup> Highly concentrated fluoride varnish or acidulated phosphate fluoride (APF) gels will be more effective in high-risk individuals or groups when used in addition to the lower concentration fluorides, such as toothpaste (1100ppm) and even lower community water fluoridation (0.7ppm).<sup>4,17</sup> An adequate balance of remineralization and demineralization is maintained with a daily low concentration of fluoride. Intermittent applications of highly concentrated fluorides may not provide any additional protection.<sup>18</sup> Low concentrations of fluoride maintained in plaque and enamel can prevent or control dental caries throughout life.<sup>19,20,21,22,23,24,25,26,27,28</sup>

## Characteristics of Fluoride Varnish

Fluoride varnish is quickly and easily applied without the need for bulky mouth trays or suctioning of saliva. This is especially helpful for infants and toddlers, some developmentally disabled individuals, or people with severe gag reflexes who otherwise might not tolerate the use of trays or the bulkiness of gels or foams.<sup>29</sup> Fluoride varnish is the only professionally applied topical fluoride recommended for children younger than age 6.5

Fluoride varnish is effective when applied to teeth dried with cotton gauze and without rubber cup polishing or professional cleaning.<sup>30</sup> 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 one to seven 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.<sup>15,31</sup> Benefits of fluoride varnish are greatest for individuals at moderate-risk or high-risk for demineralization or tooth decay.<sup>4,5</sup>

The 2013 ADA recommendations acknowledge that, while common in dental practice, fluoride foams are no longer recommended. The weight of evidence for effectiveness is not as strong as for gels and varnish.<sup>4</sup> See the November 2013 ADA Chairsides Guide: [Clinical Recommendations for Use of Professionally-Applied or Prescription-Strength, Home-Use Topical Fluoride Agents for Caries Prevention in Patients at Elevated Risk of Developing Caries](#).<sup>32</sup> Professionally applied fluoride rinses have not been sufficiently evaluated to recommend their use compared to APF fluoride gel or fluoride varnish.

Some fluoride varnish products leave a temporary yellow-brown tinge where they are applied. New fluoride varnish products have improved color, texture and tastes.<sup>33</sup>

Application of fluoride varnish is no more costly than other professionally applied topical fluoride products. In a number of states, fluoride varnish is applied by lay people. The American Academy of Pediatrics created a table of all state policies describing oral health services including: non-dental clinicians who may apply it, age limits of children who can receive fluoride varnish, the number of applications allowed, any training

required prior to implementation, allowable delegation and the codes used to submit for Medicaid payment.<sup>34</sup>

## Effectiveness

Fluoride varnish is effective in preventing caries on permanent teeth.<sup>35</sup> According to the Centers for Disease Control and Prevention (CDC) and the ADA, 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.<sup>36</sup> These organizations strongly recommend fluoride varnish because of consistent, good quality, patient-oriented evidence.<sup>37</sup> The ADA (2013) 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 strongly recommends fluoride varnish as the professional application of choice for children younger than six years of age.

Fluoride varnish prevents or reduces caries in the primary teeth of young children.<sup>38,39</sup> Studies continue to show fluoride varnish is efficacious in reducing decay in the primary teeth of high-risk children.<sup>40,41, 42,43</sup> Fluoride varnish may arrest early active enamel lesions in the primary dentition.<sup>40</sup> The preventive effect is strongest when fluoride varnish applications begin before the onset of detectable dental caries in high-risk populations. 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.<sup>39</sup> Infants, toddlers and preschool children who were caries free at baseline benefited most from the intervention.

## Patient Selection

In 2013, the ADA summarized recommendations for use of fluoride varnish or other professionally applied fluoride agents.

<b>Table 2</b>					
Clinical recommendations for use of professionally applied or prescription-strength, home-use topical fluorides for caries prevention in patients at elevated risk of developing caries.					
<b>Strength of recommendations:</b> Each recommendation is based on the best available evidence. The level of evidence available to support each recommendation may differ.					
<b>Strong</b>	<b>In favor</b>	<b>Weak</b>	<b>Expert Opinion For</b>	<b>Expert Opinion Against</b>	<b>Against</b>
Evidence strongly supports providing this intervention	Evidence favors providing this intervention	Evidence suggests implementing this intervention only after alternatives have been considered	Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation	Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention	Evidence suggests not implementing this intervention or discontinuing ineffective procedures

<b>Age Group or Dentition Affected</b>	<b>Professionally Applied Topical Fluoride Agent</b>	<b>Prescription-Strength, Home-Use Topical Fluoride Agent</b>
<b>Younger Than 6 Years</b>	2.26 percent fluoride varnish at least every three to six months • In Favor	
<b>6-18 Years</b>	2.26 percent fluoride varnish at least every three to six months • In Favor <b>OR</b> 1.23 percent fluoride (APF*) gel for four minutes at least every three to six months • In Favor	0.09 percent fluoride mouthrinse at least weekly • In Favor <b>OR</b> 0.5 percent fluoride gel or paste twice daily • Expert Opinion For
<b>Older Than 18 Years</b>	2.26 percent fluoride varnish at least every three to six months • Expert Opinion For <b>OR</b> 1.23 percent fluoride (APF) gel for four minutes at least every three to six months • Expert Opinion For	0.09 percent fluoride mouthrinse at least weekly • Expert Opinion For <b>OR</b> 0.5 percent fluoride gel or paste twice daily • Expert Opinion For
<b>Adult Root Caries</b>	2.26 percent fluoride varnish at least every three to six months • Expert Opinion For <b>OR</b> 1.23 percent fluoride (APF) gel for four minutes at least every three to six months • Expert Opinion For	0.09 percent fluoride mouthrinse daily • Expert Opinion For <b>OR</b> 0.5 percent fluoride gel or paste twice daily • Expert Opinion For
<b>Additional Information:</b>		
<ul style="list-style-type: none"> <li>• 0.1 percent fluoride varnish, 1.23 percent fluoride (APF) foam or prophylaxis pastes are not recommended for preventing coronal caries in all age groups (• Expert Opinion Against or • Against). The full report, which includes more details, is available at <a href="http://ebd.ada.org/ClinicalRecommendations.aspx">http://ebd.ada.org/ClinicalRecommendations.aspx</a>.</li> <li>• No prescription-strength or professionally applied topical fluoride agents except 2.26 percent fluoride varnish are recommended for children younger than 6 years (• Expert Opinion Against or • Against), but practitioners may consider the use of these other agents on the basis of their assessment of individual patient factors that alter the benefit-to-harm relationship.</li> <li>• Prophylaxis before to 1.23 percent fluoride (APF) gel application is not necessary for coronal caries prevention in all age groups (• Expert Opinion Against or • Against). The full report, which includes more details, is available at <a href="http://ebd.ada.org/ClinicalRecommendations.aspx">http://ebd.ada.org/ClinicalRecommendations.aspx</a>. No recommendation can be made for prophylaxis before application of other topical fluoride agents.</li> </ul>		
<b>Patients at low risk of developing caries may not need additional topical fluorides other than over-the-counter fluoridated toothpaste and fluoridated water.</b>		
* APF: Acidulated phosphate fluoride.		
Weyant RJ, Tracy SL and colleagues. Topical fluoride for caries prevention. Executive summary of the updated clinical recommendations and supporting systematic review. JADA 2013;144(11):Table 4, page 1282.		

## Frequency of Application

The frequency of fluoride varnish applications depends on the professional's determination of the individual's risk for dental caries and concomitant use of other fluoride modalities.<sup>33,44</sup>

## Dental Professionals

The optimal number of fluoride varnish applications and optimal intervals for application have not been firmly established.<sup>45,46,47</sup> Where there is agreement from CDC and the ADA is that *at least* biannual applications at six-month intervals for at least two years are necessary to control or reduce dental caries in primary or permanent teeth for moderate or high-risk children.<sup>4</sup> There have been a variety of findings from

different studies and different organizations. In very high-risk populations, intensive programs of fluoride varnish application, greater than twice annually, did not provide additional benefits.<sup>48,49,50</sup> However, the Indian Health Service (IHS) recommends four or more topical applications of fluoride varnish between 9 and 24 months of age to be the best practice for children participating in tribal Head Start programs in the United States.<sup>51</sup> The 2006 ADA clinical recommendations suggest people at highest caries risk may obtain improved caries prevention benefit from applications at three-month intervals.<sup>4,52</sup>

There is also agreement, as indicated in the ADA guidance on professionally applied topical fluorides, that low risk children or adults (i.e., adults or children who have not had incipient or cavitated lesions for at least three years and no other risk factors for increased caries risk) may not benefit from any professionally applied fluoride treatments.<sup>5</sup> For individuals at moderate or high-risk for dental caries, fluoride varnish or 2.26% fluoride gel applied more often, i.e., three-month intervals is recommended.<sup>53,54,55,56</sup> A single application is not sufficient for ongoing caries prevention. The Weintraub, et al. UCSF study demonstrated a dose response relationship for caries reductions accrued to caries-free infants and children younger than age four. The targeted population had two risk factors for high caries risk (low-income and minority status); however, children with white spots or frank caries were dropped from the study.<sup>38</sup> In this case, increased frequency of fluoride varnish applications was effective when initiated in a high-risk population before cavitation was observable. "Two is too late" is a mantra indicating higher frequency may be more effective when initiated at earlier ages for highest risk populations.<sup>57</sup>

Programs that offer a single application of fluoride varnish are generally less effective than those that incorporate multiple visits and applications. Multiple fluoride varnish applications incorporated into school or community programs of ongoing health assessment and counseling rather than as stand-alone events demonstrate improved outcomes.<sup>58</sup> A study of American Indian preschoolers who received fluoride application at 9-, 12-, 15-, 18-, 24-, and 30-month well-child visits concluded children who received four or more fluoride varnish treatments during the study period had significant reductions in dental caries. Children who received less than four treatments during the study period showed no significant difference in decayed, missing or filled surfaces (dmfs) from the children in a control group who received no varnish treatments.<sup>59</sup>

## **Medical Professionals**

In North Carolina's 2011 evaluation of their medical office-based preventive dentistry program for Medicaid-enrolled children, children who had four or more fluoride varnish applications had fewer carious lesions compared to children who had fewer than four visits.<sup>60</sup>

The 2014 U.S. Preventive Services Task Force document, [Prevention of Dental Caries in Preschool Children: Recommendations and Rationale](#), recommends that all primary care clinicians apply fluoride varnish to primary teeth of all infants and children starting at the age of primary tooth eruption to age five. (Grade: B) They conclude that current evidence is insufficient for making a recommendation for or against risk assessment performed by primary care clinicians in children younger than age six.<sup>61</sup> However, the American Academy of Pediatrics recommends pediatric medical providers administer risk-assessment for all children when there is no access to a dentist.<sup>62</sup> Primary care practitioners are able to screen accurately and provide fluoride varnish and oral health anticipatory guidance for children *until a dental home is established*.<sup>63</sup>

## FDA Approval

Fluoride varnishes are approved as Class II Medical Devices (FDA 510k compliance), as a cavity liner and/or tooth desensitizer and used “off-label” for preventing dental caries.<sup>64</sup> Many medications are prescribed and/or administered for off-label use. The FDA regulation states: “Good medical practice and the best interests of the patient require physicians to use legally available drugs, biologics and devices according to their best knowledge and judgment. When physicians use a product for an indication not in the approved labeling, they have the responsibility to be well-informed about the product. They must base the product’s use on firm scientific rationale, on sound medical evidence, and to maintain records of the product’s use and effects.”<sup>65,66</sup> Search the [FDA Medical Devices database](#) by putting ‘varnish’ in the device name search box to find the list of current Medical Devices.<sup>67</sup>

## Safety

Fluoride varnishes are generally considered safe and well accepted.<sup>68,69,70,71</sup> Recent randomized clinical trials (2012) did not report any adverse events, safety concerns or serious short-term effects with the application of fluoride varnish for infants or children.<sup>72,73,74</sup> The risk of acute toxic reactions with varnishes is considered to be minimal due to the rapid setting time and small dosages even with ingestion of some product during application and following application.<sup>75,76,32</sup>

Application of fluoride varnish does result in a transitory rise in urinary fluoride output in five-year-old children.<sup>77</sup> The low rise in urinary fluoride excretion in preschool children with a fluoride varnish application who also brush daily with fluoride toothpaste and drink fluoridated water will return to baseline within 2-24 hours.<sup>78,79</sup>

Peak plaque/salivary fluoride levels (3.2 to 6.3 Umol/L) are generally observed within 24 to 72 hours, with higher fluoride levels found for up to a week following application.<sup>80</sup> There are differences in plasma fluoride levels after fluoride varnish application in preschool children.<sup>81,82</sup> Ekstrand and colleagues reported a low plasma fluoride level following placement of a 5% fluoride varnish on two preschool children, comparable to plasma fluoride levels experienced after tooth brushing with a fluoridated dentifrice (3.63Umol/L) or after ingesting a 1 mg fluoride tablet (4.47 Umol/L).<sup>83,84</sup> The level was also significantly lower than plasma fluoride levels seen after a professionally applied 1.23% APF gel (16-76 Umol/L).<sup>73</sup>

## Infants/toddlers

Infants and toddlers absorb fluoride differently from older children due to the substantial rate of growth between birth and age two years.<sup>85</sup> Renal clearance is less, and skeletal deposition of fluoride is greater. Whitford and Ekstrand found a dose-dependent mechanism for fluoride uptake by calcified tissues in children, a phenomenon not known to occur in adults. Overall, the infants retained an average of 86.8% of the fluoride dose, which is about 50% higher than expected for adults.<sup>86,87</sup> Exercise care by applying fluoride sparingly and preventing children from swallowing the excess product during applications.

## Allergy

There are no confirmed allergic reactions to fluoride.<sup>88</sup> Though uncommon, allergic reactions can occur in individuals with a known sensitivity to colophony/rosin. 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. Contact allergy to Duraphat varnish has been reported in the literature: dermatitis on a dental assistant's hand and stomatitis in patients.<sup>89</sup> These allergies are related to the colophony component of the varnish. Fluoride varnish is contraindicated when ulcerative gingivitis and stomatitis is present and should not be applied next to large open soft tissue lesions.<sup>90</sup> A health history to determine known allergies, as with the administration of any therapeutic agent, is recommended prior to fluoride varnish use.

## **Fluorosis**

Ingestion of fluoride varnish seems implausible as a contributor to fluorosis in children.<sup>86,91,92</sup> Fluoride varnish applied infrequently (two to four times a year at three-to six-month intervals) is unlikely to contribute to fluorosis in children younger than age six.<sup>93</sup> Pre-eruptive effects of ingested fluoride decline significantly after enamel maturation of the permanent anterior teeth around the age of six to eight years. Fluoride varnish preparations contain up to 22,500 ppm fluoride, but only a very small amount is applied (2.3 to 5.0 mg). The resin-based varnish initially sticks to the teeth; then, as the varnish slowly breaks away from the tooth surface, it is ingested over time.

## **Community and School Dental Caries Prevention Programs**

### **Program Selection**

In 2007, the United State Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB) convened an expert panel to provide guidance for topical fluoride use for populations of high-risk children younger than age six. The MCHB panel concluded that preschool children enrolled in programs where they meet income eligibility requirements or who require health and related services of a type or amount beyond those required by children generally will benefit from fluoride varnish applied every three to six months.<sup>94</sup>

As of 2014, while the efficiency and efficacy of fluoride varnish for individuals is established, the benefits of fluoride varnish in population-based programs, such as schools, have not been established. Outside the US, mixed evidence supports fluoride varnish effectiveness in school programs. In a Brazilian study of 7-14 year-old school children, a 41% caries reduction in permanent teeth occurred with biannual applications of fluoride varnish. However, the result may have been influenced by a 44.6% attrition rate.<sup>95</sup> In a similar study by Zimmer of German adolescents, fluoride varnish demonstrated a 37% caries reduction in permanent teeth after two applications for four years.<sup>96</sup>

Two 2011 studies were not able to demonstrate a preventive benefit when fluoride varnish was applied in low-income and high-caries prevalence schools. In a randomized clinical trial by Milsom, et al., the authors suspect exposure to fluoride toothpaste was responsible for the lack of demonstrable benefits.<sup>97</sup> Tagliaferro et al. reported that dental sealants, but not fluoride varnish, demonstrated caries reductions in permanent

dentition in high-caries prevalence schools.<sup>98</sup> Exposures to fluoride (water, toothpastes, mouthrinses and other dental products) in the United States have increased significantly since the early 1960s.<sup>99</sup>

## Cost-Effective Programs

Consideration of the cost-effectiveness of community programs has been a hallmark of optimal public health interventions.<sup>12,83</sup> 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.<sup>20,21,22,23,24,25,26,27,28</sup> Programs increasing the frequency of fluoride applications for populations based upon low income (or the United States Department of Agriculture (USDA) eligibility for free and reduced price meals) without considering the incidence of dental caries or other risk indicators may not result in optimal outcomes.<sup>100,101</sup> 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.<sup>102,103,104,105</sup> For example, fluorides are generally accepted to be more effective in preventing dental caries on the smooth surfaces of teeth rather than in the pits and fissures. Delegation of fluoride varnish application to non-dental health care providers in existing programs serving children may be more cost-effective than the addition of oral health professionals to those settings.<sup>106</sup> Program efforts may be more likely to generate improved outcomes if efforts increase the number of years fluoride varnish is applied. Fluoride varnish, when applied before age three and prior to caries development, appears to be an effective primary prevention strategy.<sup>107</sup> In contrast, fluoride varnish programs in community populations where caries is established have not demonstrated comparable benefits. New evidence from North Carolina demonstrated a 0.32 decrease in dmft prevalence of Kindergarten children at the highest risk schools. The widespread adoption of fluoride varnish in medical offices in North Carolina is reducing oral health disparities.<sup>108</sup>

Before implementation of population-based programs, community level assessment of dental caries and access to dental care is highly recommended to be able to describe health outcomes after the intervention. Current terminology, definitions and classification of caries in the primary dentition are deficient for measuring disease burden and improvement and, therefore, as a decision matrix.<sup>109</sup> A new metric may include a composite of parameters such as number of lesions, age of onset and rate of progression. For example, for many years smooth surface decay in either four or six anterior primary teeth alone was the definition of baby bottle tooth decay.<sup>110</sup> Smooth surface caries in primary molars is particularly predictive of caries in permanent teeth.<sup>111</sup> In 2011 the American Academy of Pediatric Dentistry broadened the definition of early childhood caries to include the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces in any primary tooth in a child younger than age six. Clear definitions will help programs target populations and select the appropriate outcome measures for program evaluation.<sup>112</sup>

There is general agreement that caries risk assessment tools, while imperfect, provide a cost-effective approach for community and school programs to use. Therefore, the use of fluoride varnish, as any

professionally applied fluoride, should be limited to those individuals deemed to be at moderate to high-risk for developing dental caries.<sup>4,113,114</sup> The single greatest individual risk factor for predicting dental caries is dental caries experience in the previous two or three years.<sup>4,113,114</sup> The single greatest risk factor predicting dental caries in populations is low socio-economic status, especially for children younger than the age of three who are too young to base risk on individual caries history.<sup>15,33</sup> Caries risk assessment limited to the prevalence of decayed, missing or filled surfaces (DMFS/dmfs), or type of tooth surface (pit and fissure or smooth) does not explain 63% of the variability in caries experience.<sup>115</sup> 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 or orthodontic treatment.<sup>116</sup> In infants, caregiver or sibling dental status determines risk. Low-risk individuals may not receive additional benefits from fluoride varnish, especially if they are using fluoride toothpaste and/or drink water that is optimally fluoridated.

Other population risk factors to consider in program planning include the proportion of the population who 1) are an ethnic minority, 2) speak English as a second language, 3) are homeless, 4) have limited education, 5) have special health care needs, 6) lack access to fluoridated water or fluoride toothpaste or 7) do not have available dental care.

## **Conclusion**

Fluoride varnish is applied in dental or medical offices/clinics, community-based programs or schools. Fluoride varnish programs are more likely to be effective where caries risk is high yet where carious lesions have not yet occurred. Programs should be consistent with evidence-based practice guidelines derived from current research to minimize possible risks and optimize benefits.<sup>4,37,117</sup> Caries risk assessment models are a cost-effective approach for community-based programs to follow.<sup>118,119</sup> Programs using fluoride varnish will be more likely to demonstrate benefits and reduce dental caries in at-risk populations when applications are offered at a minimum of six-month intervals over at least two years in duration in combination with counseling. For the prevention of early childhood caries for highest risk children, four applications of fluoride varnish should begin no later than age one and before age three.<sup>45,60</sup> Fluoride varnish should be the only professionally applied fluoride for children younger than age six.<sup>4</sup>

Dental sealants, fluoride toothpastes and water fluoridation are the cornerstones of individual and community practice to prevent and control dental caries.<sup>120,121,122</sup> Fluoride varnish offers an additional opportunity 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 younger than age three. Applied research is needed to: 1) develop a meaningful fluoride history that considers the relative contributions of all fluoride sources; 2) analyze multiple factors that influence cost-effectiveness of programs, specifically in school settings; and 3) determine the cost-effectiveness of community models of fluoride application programs.

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