

## **Problem**

Dental caries is a chronic, progressive, multi-factorial, infectious disease that can begin in early infancy. By adulthood, dental caries will affect the majority of the US adult population,<sup>1</sup> with some individuals experiencing moderate or severe disease. Dental caries prevalence and severity vary by age, dentition and type of tooth surface.<sup>2</sup> Tooth decay is highly related to socio-environmental determinants, with the greatest burden on disadvantaged and socially-marginalized populations.<sup>3,4</sup> Historically, efforts to prevent and control dental caries have primarily focused on promoting daily brushing, modifying dietary practices, and improving the resistance of tooth enamel to acid attack. Scientific evidence supports the effectiveness of fluoride and dental sealants at reducing dental caries in populations. Benefiting from fluoridated water and toothpastes, baby boomers will be the first generation to routinely maintain natural teeth throughout their lives.<sup>5</sup>

## **Methods**

Fluoride modalities, systemic and topical, include: drinking water (natural and adjusted levels), milk, salt, toothpaste, mouthrinse, and professionally applied fluoride in gels or varnishes. Caries protection, lifetime cost and appropriateness for use in populations will vary by the fluoride method or combination of fluoride methods selected.<sup>6,7,8,9,10,11,12</sup> Fluorides are most effective when used in combination with other modalities to prevent, control and reverse early dental caries.<sup>13,14,15,16</sup> Fluorides are especially effective in preventing dental caries on the smooth surfaces of teeth.<sup>17</sup> For the prevention of carious lesions in the pits and fissures of teeth, dental sealants, alone or combined with fluoride, are more effective than fluoride alone.<sup>18,19</sup> Daily, multiple, low-dose topical exposures to fluorides facilitate the balance between remineralization and demineralization of tooth enamel, thus reducing the prevalence and incidence of dental caries throughout life.<sup>20,21</sup>

Fluoride varnish, like other highly concentrated fluoride products, is available only by prescription from authorized health professionals. 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. This layer slowly disappears over the following months and repeated application of the varnish is needed to maintain effectiveness.<sup>15,22,23,24</sup>

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.<sup>25</sup> There have been a few reports of contact dermatitis to the resin base used in fluoride varnish; however, there have been no reports of acute effects from fluoride varnish application in infants and toddlers.<sup>26,27</sup> Although the fluoride concentration in varnish is relatively high, since applications occur infrequently, generally at 3 to 12 month intervals, fluoride varnishes pose little risk for enamel fluorosis.

A panel of experts convened by the American Dental Association (ADA) Council on Scientific Affairs recommends fluoride varnish as an alternative to acidulated phosphate gels (APF) for people six years or

older at risk of developing dental caries and as the only professionally applied fluoride for children under age six.<sup>6</sup> Fluoride varnish has an advantage over APF gels, particularly for use in settings outside the dental office since no special equipment or prophylaxis is needed. 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 individuals who are not oral health professionals. The American Academy of Pediatrics (AAP) created and maintains a table of all state policies ([Caries Prevention Services Reimbursement Table](#)) describing oral health services including dental and 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>28</sup>

Fluoride varnish is effective in preventing caries.<sup>29</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 primary and permanent teeth of moderate/high-risk children is high.<sup>6,11,16,30,31,32,33,34,35</sup> These organizations strongly recommend fluoride varnish because of consistent, good quality, patient-oriented evidence.<sup>6,36</sup>

Fluoride varnish may arrest early active enamel lesions.<sup>35</sup> Fluoride varnish enhances enamel remineralization with the initial fluoride uptake in early carious lesions (white spots) until it is brushed off or it flakes off. Calcium fluoride formed in carious lesions makes them more resistant to future demineralization. Fluoride varnish used as a secondary prevention strategy may be especially cost-effective when active, non-cavitated, smooth surface caries are detectable in low-risk populations.<sup>37,38</sup> In high-risk populations, the preventive effect is strongest when fluoride varnish applications begin before the onset of detectable dental caries.<sup>31</sup> 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>32</sup> Infants, toddlers and preschool children who were caries free at baseline benefited most from the intervention.

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>32,39,40</sup> The CDC and the ADA agree that *at least* biannual applications for two years reduces dental caries in primary or permanent teeth for moderate or high-risk children.<sup>4</sup> In very high-risk populations, intensive programs of fluoride varnish application, greater than twice annually, did not provide additional benefits.<sup>41,42,43</sup> The goal of four or more applications over two years appears to be consistent for ongoing caries prevention.<sup>44,45</sup>

As of 2015, while the efficiency and efficacy of fluoride varnish for individuals has been established, the benefits of fluoride varnish in population-based programs, such as schools, have not. Approximately 46% of children have had a dental visit in the last 12 months, ranging by income from 36% of children from families at less than 100% of the federal poverty level and 58% for children in higher income brackets.<sup>46,47</sup> Outside the US, there is mixed evidence that fluoride varnish can be effective in a school program. A Brazilian study of 7 to 14-year-old school children, demonstrating a 41% caries reduction in permanent teeth, may have been influenced by a 44.6% attrition rate.<sup>48</sup> A similar study of adolescents and fluoride varnish by Zimmer demonstrated 37% caries reduction in permanent teeth after two applications for four years.<sup>49</sup> Yet two 2011 studies were not able to conclude that fluoride varnish applied in low-income and high-caries prevalence schools provided a preventive benefit. It is theorized that exposure to

fluoride toothpastes may have been responsible for the lack of demonstrable benefits.<sup>39,1</sup> Tagliaferro et al reported demonstrable benefits from dental sealants in school programs, but not fluoride varnish in high-risk schools.<sup>50</sup> Exposures to fluoride (water, toothpastes, mouthrinses and other dental products) in the United States have increased significantly since the early 1960s.<sup>51</sup> The addition of fluoride varnish in caries prevention programs for low-risk individuals and populations, especially those that use fluoridated water and fluoride toothpastes, is unlikely to be cost-effective.<sup>9</sup> Community prevention programs utilizing fluoride varnish will be more effective when initiated before age two for the primary dentition of children at highest risk.<sup>52,53, 54</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. They concluded 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>55</sup> However, the AAP recommends pediatric medical providers conduct a risk-assessment for all children when there is no access to a dentist.<sup>56</sup> Until a dental home is established, primary care practitioners are able to screen accurately and provide fluoride varnish and oral health anticipatory guidance for children.<sup>57</sup> In North Carolina's 2011 evaluation of their medical office-based preventive dentistry program for Medicaid-enrolled children, children who had at least four or more fluoride varnish applications at office visits in three years had fewer carious lesions by age six compared to children who had no visits.<sup>44,2</sup> In addition, North Carolina demonstrated a significant population effect in reducing dental caries in school children from at risk schools when children had had at least four fluoride varnish applications before four years of age.<sup>45</sup>

Fluoride varnish is effective in preventing dental caries in both permanent and primary teeth.<sup>8,15,58</sup> School and community program outcome evaluations are strongly recommended.

### **Policy Statement**

The Association of State and Territorial Dental Directors (ASTDD) supports the judicious use of fluoride varnish beginning with primary tooth eruption as an effective adjunct in programs designed to reduce lifetime dental caries experience.

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