California Program on Access to Care **Findings**

Fluoride Varnish Can Prevent Caries in California's Low-Income Preschool Children

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Dental caries (tooth decay) among children is a significant health problem. As the Surgeon General has noted, caries is the most prevalent chronic disease among children—five times more prevalent than asthma. In April 2007, the National Center for Health Statistics announced that tooth decay prevalence has decreased in older children and adults, but *increased* in children age two to five. Caries prevalence in this age group (known as early childhood caries, or ECC) increased from 24% in 1988–1994 to 28% in 1999–2004. Caries in general, and in preschool-age children in particular, disproportionately affects children from lower socioeconomic strata, certain racial/ethnic groups, rural areas, and inner cities.

This issue is particularly a problem in California. The 2005 California Smile Survey (Oral Health Needs Assessment) ranked California as having the second worst children's oral health of the 25 states reporting data. Moreover, California lags behind US DHHS *Healthy People 2010* oral health objectives.

Low-cost, efficacious preventive interventions for preschoolers are greatly needed. The recent University of California, San Francisco (UCSF) fluoride varnish randomized clinical trial demonstrated the efficacy of fluoride varnish in reducing the incidence and severity of tooth decay with no related adverse experiences for preschool-age children in two San Francisco community clinics. Fluoride varnish is concentrated fluoride in a resin or synthetic base. It is painted on the teeth with a small brush after the teeth are dried with gauze, and sets almost immediately. The fluoride remains detectable in saliva for about a day.

Several independent evaluations consider that the UCSF fluoride varnish randomized clinical trial provides the strongest evidence possible from a single study of the varnish's effect. Using data from the UCSF fluoride varnish clinical trial, our goal was to answer four new questions:

- Is a single fluoride varnish treatment sufficient to impart a significant preventive benefit?
- Does the varnish itself impart some of the preventive effect apart from fluoride?
- Can an optimal number of fluoride varnish applications be extrapolated?
- Is the preventive benefit limited to teeth that have already erupted at the time of fluoride varnish application?

Methods

The UCSF fluoride varnish trial was a randomized, controlled, blinded clinical trial with up to two years of follow-up. Participants were 376 preschool children, recruited from two San Francisco community clinics—Chinatown Public Health Center and San Francisco General Hospital—serving predominantly low-income Chinese and Latino clients, respectively. Children were 6–44 months old (mean = 22) and caries-free at enrollment. The study was approved by the UCSF Committee on Human Research. All parents provided informed consent and received educational counseling about oral health. Children were randomly assigned to one of three groups: control (no treatment) or fluoride varnish application (5% sodium fluoride, Duraphat®, Colgate Oral Pharmaceuticals, New York, NY) every 12 months or every six months. A shipping issue resulted in 18 children receiving placebo varnish. As a result, we compared active fluoride varnish to placebo varnish to assess the effect of varnish by itself. Follow-up full-mouth dental examinations were performed blinded to treatment group one year and two years after enrollment.

We assessed two outcomes: early childhood caries incidence and early childhood caries severity (number of tooth surfaces with cavitated decay or fillings). These outcomes were examined in relation to the number of active fluoride varnish applications received, the type of teeth, and the type of tooth surfaces, adjusting for the child's age in months. Logistic, linear, and nonparametric regression were used to model the outcomes. The study included one- or two- year follow-up data on 280 preschool-age children (75% retention, compared to the expected 50% retention based on other studies of similar children).

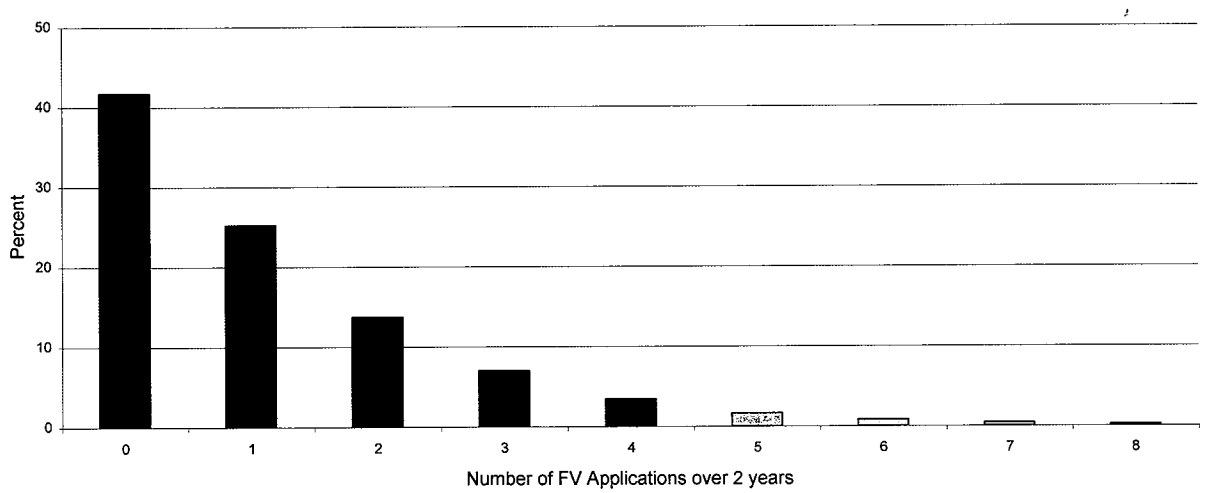
Findings

Our analyses of the UCSF fluoride varnish randomized clinical trial indicated that fluoride varnish, in addition to parent counseling, is safe and efficacious in preventing tooth decay in preschool-age children (i.e., reducing the incidence and severity of decay compared to those found in controls).

- Fluoride varnish reduced two-year tooth decay incidence and severity in preschoolers.
  - Even just one application reduced the incidence by 2.5 times compared to controls.
  - Each extra application reduced the incidence even further compared to controls: by over three times for two applications and by over 18 times for three or four applications.
  - Active fluoride varnish significantly reduced the incidence compared to placebo varnish, indicating that varnish without fluoride is insufficient to protect teeth.

Various models consistently projected the optimal number of fluoride varnish applications to be three to six over two years to adequately reduce decay incidence (see figure); studies on using more than two applications per year are needed to definitively determine optimal dosing.

Fluoride Varnish Prevents ECC Incidence
Modeled Dose-Response Effect



- Fluoride varnish protection varied by tooth surface and extended beyond the teeth receiving varnish.
  - Upper front teeth were the most protected.
  - Biting surfaces of second molars were also protected, almost as well as upper front teeth.
  - Biting surfaces of first molar teeth and smooth surfaces (other than upper front teeth) did not show protective benefits, but little decay occurred there, even among controls.
  - Tooth surfaces that were unerupted at the time of one to four applications had more than two times less risk of decay than similar tooth surfaces in children receiving no applications.

Policy Environment

The State's Dental Practice Act allows dental assistants to apply fluoride varnish under direct dentist supervision and hygienists to apply fluoride varnish under general dentist supervision. Registered dental hygienists in alternative practice can apply fluoride varnish in homebound residences, schools, institutional facilities, and dental health professional shortage areas, or in any setting if a dentist or physician writes a prescription. Some researchers and policy specialists have advocated four annual fluoride varnish applications for high-risk preschoolers and two applications annually for low-risk preschoolers.

In June 2006, the California Department of Health Services began reimbursing dental and non-dental health professionals for fluoride varnish applications. DHS instituted HCPCS code D1203 ("topical application of fluoride [prophylaxis not included], child") as a Medi-Cal benefit for children less than six years old, up to three times per year. The reimbursement level is $18.00 including supplies. Physicians, nurses, and other nonspecified medical personnel can legally apply varnish if they have an attending physician's prescription and an established

protocol. If no other medical services are provided, the billing office may also be reimbursed for an office visit ($24.98 for a new child patient or $13.09 for an established child patient).

While a regimen of four fluoride varnish applications per year may be ideal, we have demonstrated that even one fluoride varnish application significantly reduced early childhood caries incidence. Therefore, even children who do not have a regular source of dental care, who move frequently, or who may not return for follow-up visits would benefit from the protection fluoride varnish provides.

Fluoride varnish is a low-cost, low-technology prevention tool. The supplies cost as little as $1 per application, and treatment can take as little as four minutes. The price is similar to that of providing fluoridated drinking water to one person in communities of 50,000 or more. Thus, the policy recommendations that follow fit within the current scope of practice and insurance coverage specifications.

Policy Implications and Recommendations

Many dental providers are uncomfortable treating preschool-age children, while many pediatricians are unfamiliar with oral health.

- Hands-on provider trainings to apply fluoride varnish to the teeth of preschool children should be offered in dental schools, medical schools, and continuing education courses for dental and non-dental health professionals.

- Dental and non-dental health professionals should be made aware of the extent of the problem of preschoolers' tooth decay and informed that fluoride varnish in conjunction with counseling can provide low-cost, low-technology, safe, quick, and efficacious caries prevention.

Findings from this project demonstrate the need to maintain or expand programs for early childhood caries prevention in preschool-age children; fluoride varnish could help prevent tooth decay in a potentially cost-effective way.

- Policymakers should encourage insurance plans, clinic administrators, health providers, and parents to ensure that all preschool children have the opportunity for at least two fluoride varnish applications per year, regardless of family resources.
- Policymakers should also ensure that fluoride varnish reimbursement amounts are adequate incentives to providers.

- Policymakers should help publicize the benefits of fluoride varnish to pediatricians and family practice physicians, community health centers and other clinics, and parents of preschoolers.

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