Fluoride Varnish Policy Statement
Association of State and Territorial Dental Directors (ASTDD)
Adopted: April 25, 2010 Updated: October 2015

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,[1] with some individuals experiencing moderate or severe disease. Dental caries prevalence and severity vary by age, dentition and type of tooth surface.[2] Tooth decay is highly related to socio-environmental determinants, with the greatest burden on disadvantaged and socially-marginalized populations.[3,4] 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.[5]

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.[6,7,8,9,10,11,12] Fluorides are most effective when used in combination with other modalities to prevent, control and reverse early dental caries.[13,14,15,16] Fluorides are especially effective in preventing dental caries on the smooth surfaces of teeth.[17] 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.[18,19] 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.[20,21]

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.[15,22,23,24]

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.[25] 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 affects from fluoride varnish application in infants and toddlers.[26, 27] 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.[6] 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.[28]

Fluoride varnish is effective in preventing caries.[29] 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.[6,11,16,30, 31,32,33,34,35] These organizations strongly recommend fluoride varnish because of consistent, good quality, patient-oriented evidence.[6,36]

Fluoride varnish may arrest early active enamel lesions.[35] 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.[37, 38] In high-risk populations, the preventive effect is strongest when fluoride varnish applications begin before the onset of detectable dental caries.[31] 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.[32] 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.[32,39,40] 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.[4] In very high-risk populations, intensive programs of fluoride varnish application, greater than twice annually, did not provide additional benefits.[41,42,43] The goal of four or more applications over two years appears to be consistent for ongoing caries prevention.[44,45]

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.[46,47] Outside the US, there is mixed evidence that fluoride varnish can be effective in a school program. A Brazilian study of 7 to14year-old school children, demonstrating a 41% caries reduction in permanent teeth, may have been influenced by a 44.6% attrition rate.[48] A similar study of adolescents and fluoride varnish by Zimmer demonstrated 37% caries reduction in permanent teeth after two applications for four years.[49]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.[39,1] Tagliaferro et al reported demonstrable benefits from dental sealants in school programs, but not fluoride varnish in high-risk schools.[50] Exposures to fluoride (water, toothpastes, mouthrinses and other dental products) in the United States have increased significantly since the early 1960s.[51] 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.[9] Community prevention programs utilizing fluoride varnish will be more effective when initiated before age two for the primary dentition of children at highest risk.[52,53, 54]

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.[55] However, the AAP recommends pediatric medical providers conduct a risk-assessment for all children when there is no access to a dentist.[56] 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.[57] 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.[44,2] 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.[45]

Fluoride varnish is effective in preventing dental caries in both permanent and primary teeth.[8,15,58] 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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RESEARCH REPORTS
Clinical

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Fluoride Varnish Efficacy in Preventing Early Childhood Caries

ABSTRACT

To determine the efficacy of fluoride varnish (5% NaF, Duraphat®, Colgate) added to caregiver counseling to prevent early childhood caries, we conducted a two-year randomized, dental-examiner-masked clinical trial. Initially, 376 caries-free children, from low-income Chinese or Hispanic San Francisco families, were enrolled (mean age ± standard deviation, 1.8 ± 0.6 yrs). All families received counseling, and children were randomized to the following groups: no fluoride varnish, fluoride varnish once/year, or fluoride varnish twice/year. An unexpected protocol deviation resulted in some children receiving less active fluoride varnish than assigned. Intent-to-treat analyses showed a fluoride varnish protective effect in caries incidence, $p < 0.01$. Analyzing the number of actual, active fluoride varnish applications received resulted in a dose-response effect, $p < 0.01$. Caries incidence was higher for 'counseling only' *vs.* 'counseling + fluoride varnish assigned once/year' (OR = 2.20, 95% CI 1.19-4.08) and 'twice/year' (OR = 3.77, 95% CI 1.88-7.58). No related adverse events were reported. Fluoride varnish added to caregiver counseling is efficacious in reducing early childhood caries incidence.

KEY WORDS: dental caries, prevention, fluorides, preschool child, randomized controlled trial.

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INTRODUCTION

Early childhood caries is a public health problem sometimes affecting young children almost as soon as their teeth erupt. In severe cases, pediatric dental services may require anesthesia in the operating room, services often unavailable, especially for low-income, underserved groups. In California, the early childhood caries prevalence is particularly high in some low-income racial/ethnic populations. Findings from the 1993-94 statewide oral health needs assessment (Pollick *et al.*, 1999; Shiboski *et al.*, 2003) showed early childhood caries prevalence (≥ 1 decayed, extracted, or filled primary maxillary incisor) was 14% among all preschool children, but higher in children from low-income families enrolled in Head Start programs: 44% among Asians and 39% among Latinos.

Fluoride varnish is a concentrated topical fluoride with a resin or synthetic base. At least 19 fluoride varnish reviews (Weintraub, 2003), including a systematic review (Bader *et al.*, 2001) and three meta-analyses (Helfenstein and Steiner, 1994; Strohmenger and Brambilla, 2001; Marinho *et al.*, 2002) have been published in English. Most studies examined fluoride varnish efficacy in the permanent teeth of school-aged children. Consensus statements (NIH, 2001) regarding fluoride varnish differed for permanent and primary teeth. They stated, "The evidence for the benefit of applying fluoride varnish to permanent teeth is generally positive. In contrast, the evidence for the effectiveness of fluoride varnish applied to primary teeth is incomplete and inconsistent."

The objective of this two-year randomized controlled trial was to determine the efficacy of different fluoride varnish application frequencies with parental/caregiver oral health counseling *vs.* counseling alone in preventing early childhood caries incidence in young, initially caries-free children.

MATERIALS & METHODS

Before implementation, the University of California, San Francisco Institutional Review Board approved this study. An NIH-appointed Data and Safety Monitoring Board provided additional oversight.

Participants

This trial occurred at two public health centers, the Family Dental Center at San Francisco General Hospital (SFGH), and the San Francisco Department of Public Health's Chinatown Public Health Center (CPHC), serving primarily low-income, underserved Hispanic and Chinese populations, respectively. San Francisco has been optimally fluoridated (~ 1 ppm) since 1952.

Inclusion criteria for children at enrollment were: four erupted maxillary incisors; all primary teeth caries-free without demineralized, white spots; age 6-44 months; born in San Francisco or a fluoridated community in the San Francisco Bay Area and planning to reside in San Francisco for at least two years (eliminating water fluoridation as a potential confounder and

demonstrating geographic stability); and a parent providing informed consent in English, Spanish, or Chinese. Children were excluded from the study if they had: medical problems or medications possibly affecting oral health; cleft lip/palate; developmental disabilities; transient residence; or another household member participating.

Recruitment and Follow-up

Between October, 2000, and August, 2002, families were recruited primarily from Well Child Clinics, Women, Infants and Children Supplemental Nutrition Programs, and dental clinics. Follow-up was completed in August, 2004.

Randomization

Children with parental consent were randomly assigned to one of three arms: parental counseling plus fluoride varnish twice/year (baseline, 6, 12, and 18 months) with four intended applications (4FV); parental counseling plus fluoride varnish once/year (baseline and 12 months) with two intended applications (2FV); or counseling only, with no fluoride varnish (0FV). The study team's biostatisticians conducted the computer-generated random assignment of participants, stratified by center, using permuted blocks of various sizes unknown to the clinicians. Assignment was concealed in sealed, opaque, labeled envelopes, unopened until time for treatment by the clinician.

Intervention and Measurements

Dental Examinations

Dental examinations, without radiographs, were conducted three times: at baseline prior to the intervention, and one and two years post-intervention. Older children's examinations were conducted in a dental office; very young children had a knee to-knee examination (Ramos-Gomez *et al.,* 2002). Universal infection control procedures were followed. Children's saliva samples were collected during dental examinations, before any fluoride varnish application, for the assessment of salivary mutans streptococci (MS), lactobacilli (LB), and fluoride concentrations. Salivary assay results will be reported separately.

Parental Interview

The Project Director trained and calibrated staff in conducting interviews. Questionnaires were translated into Spanish and Cantonese, back translated into English for the assessment accuracy, and revised if necessary. The family member/caregiver was interviewed about factors associated with early childhood caries or dental caries, potential confounders, and effect modifiers, including sociodemographic, biologic, and behavioral factors, including questions about bottle use, diet, and dental utilization.

Parental Counseling

The annual counseling protocol followed the American Academy of Pediatric Dentistry's (AAPD) anticipatory guidance recommendations (Nowak and Casamassimo, 1995; Nowak, 1998). Thus, it was inappropriate for the control group to receive an examination without counseling or education having been provided. Individualized counseling visits followed these age-specific recommendations (6-12 months, 12-24 months, 2-5 years), in the parents' preferred language, by a trained team member.

Fluoride Varnish Application

Duraphat® (Colgate Oral Pharmaceuticals, New York, NY, USA) fluoride varnish was used with 0.1 mL (1 drop) applied *per* arch. Parents/caregivers were asked to refrain from brushing their children's teeth with a fluoride dentifrice the day of varnish treatment, to minimize total fluoride exposure that day. Teeth were dried with gauze, and varnish was brushed onto all surfaces of the maxillary and mandibular anterior teeth, and the proximal and occlusal surfaces of the posteriors. One dentist (BJ) who spoke English, Spanish, and Cantonese provided clinical interventions at both sites. Masking accompanying caregivers to the control group assignment was attempted. The control group's tray set-up was the same. For children in this group, fluoride varnish was placed on gauze, which was then folded. The dry area was used to wipe the child's teeth, and no fluoride varnish was applied.

Primary Outcome Measures

The primary outcome was any caries incidence. We used the NIDCR diagnostic criteria for dental caries (USDHHS, 1991) for assessing cavitated, decayed (d_{2+}), and filled surfaces on primary teeth (d_{2+}fs). We used supplemental criteria (Drury *et al.*, 1999) to diagnosis pre-cavitated lesions (d_1). One pediatric dentist (FRG), masked to treatment group, conducted all dental examinations. Intra-examiner reliability, from repeat examinations of 21 children, yielded a kappa statistic of 0.96, indicating excellent agreement. Two years of follow-up were planned unless caries was detected at the one-year follow-up examination, in which case children were considered treatment failures and were referred for dental care.

Sample Size

We planned a sample size of 384 participants (128/study arm) (alpha = 0.05, power = 90%, 50% attrition, χ^2 test) to detect caries incidence differences, based on caries incidence in the literature (20% to 50% over two years). A similar study (Weinstein *et al.*, 1994) reported 53% attrition in six months.

Data Analysis

For primary analysis, we used the intention-to-treat (ITT) approach (Fisher *et al.*, 1990). Protocol-compatible analyses used number of actual active fluoride varnish applications. Analyses used data from all children with a follow-up dental examination. Primary analysis tested two-year caries incidence among treatment groups, with a two-degree-of-freedom (d.f.) non-parametric extended Mantel-Haenszel (EMH) test stratifying on center (Koch and Edwards, 1988). *A priori* step-down comparisons (Koch and Gansky, 1996) of each varnish group *vs.* control were performed, each at $p \leq 0.05$: (1) 4FV *vs.* 0FV and (2) 2FV *vs.* 0FV; step (2) was performed only if step (1) was significant. A 1 d.f. EMH test, stratifying on center, tested trends across intended and actual number of applications. Logistic regression tested treatment group differences in incidence, with adjustment for covariates and treatment x center homogeneity. Supplemental analyses used linear regression to compare log (d_{2+}fs +1) and log (d_{1+}fs +1) among groups, adjusted for covariates (since d_{n+}fs is skewed). Confounders were defined as changing model treatment coefficients by ≥ 20%. Since 96 children had no follow-up examination, multiple imputation (Schafer, 1997) with the Markov Chain Monte Carlo estimation (20 imputations) used center, assigned group, number of actual fluoride varnish applications, factors related to loss-to-follow-up (mother's age, dental pain barrier, dental fear barrier, and fluoride toothpaste use), and salivary measures ($\log_{10}$MS and $\log_{10}$LB) to impute log (d_{2+}fs +1) scores.

RESULTS

Enrollment and Retention

There were 376 children enrolled and randomized, with a mean

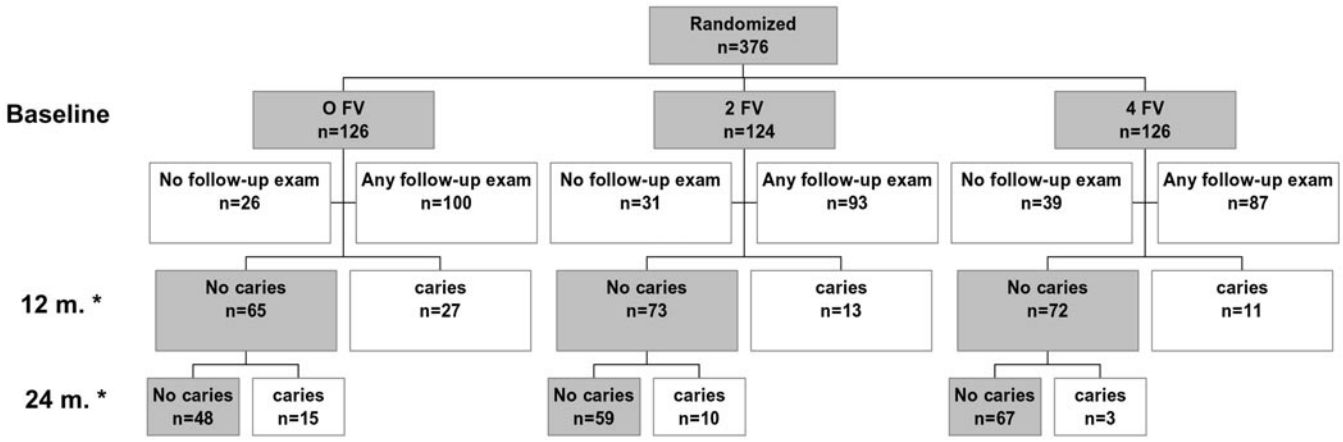

Figure 1. Flow of study participants. Children with and without dental caries at each examination by intended (randomized) fluoride varnish (FV) treatment group. * 27 children with no caries at 12 months were not seen at 24 months; 19 children with a 24-month examination missed the 12-month examination.

(standard deviation) age of 1.8 (0.6) yrs: 200 at SFGH and 176 at CPHC. Overall, 53% were girls, 47% were Hispanic, 46% were Asian, and 7% were other race/ethnicity. No randomization imbalances were apparent. About 60% of those screened and found to be ineligible had existing dental caries. At the 12-month follow-up examination, 70% of enrolled children (n = 261) were seen; 51 of them were discontinued from the study due to caries, and were referred for care (Fig. 1). Twenty-seven caries-free children seen at 12 months were not seen at 24 months. Thus, 78 children had their last follow-up examination at 12 months. At the final, 24-month follow-up, 202 children were seen (67% retention, including the 51 children with caries at 12 months). There were 280 (74%) children with a 12- or 24-month follow-up visit.

Protocol Deviation

Due to an unexpected protocol violation (see APPENDIX), children unintentionally received a placebo varnish instead of active product during a 10-month period, even though this study had no planned placebo varnish. Among children with follow-up examinations, most (75%) who were intended to receive two applications received only one with active product; 15% received two. About half (49%) who were intended to receive four applications received only two, and 29% received three. Only one child received four active applications. For five weeks, a total of 21 varnish applications could not be confirmed as active. We conservatively assumed, for analytical purposes, that they were placebo applications.

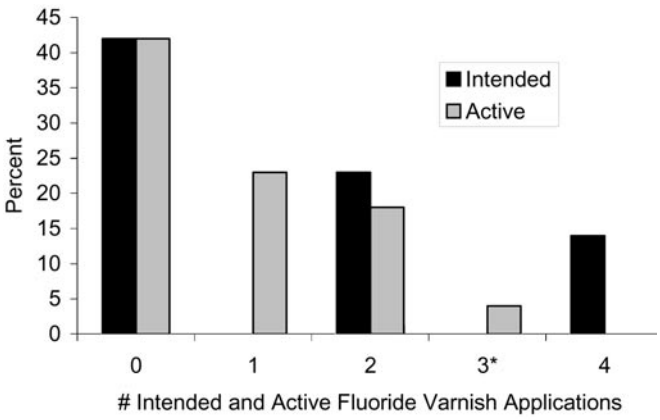

Figure 2. Caries incidence at last follow-up examination by intended treatment group and number of active fluoride varnish applications (n = 280). * 3 active applications + one child with 4 active applications. Intended groups are the groups randomized to receive 0, 2, or 4 fluoride varnish applications. Active groups are the children stratified by number of actual fluoride-containing varnish applications received (see text and APPENDIX).

Clinical Outcomes

Primary analysis showed a statistically significant reduced percentage of children with any caries incidence (any decayed or filled surfaces at the last follow-up examination), when children in groups with any intended fluoride (2 or 4 treatments) were compared with the control group (Fig. 2) (2 d.f. EMH $p < 0.001$; 1 d.f. step-down 4FV *vs.* 0FV and 2FV *vs.* 0FV both $p < 0.003$; multiple imputation 2 d.f. $p < 0.034$), or actual active applications *vs.* none (3 d.f. EMH $p < 0.001$; multiple imputation 3.d.f. $p < 0.001$). The percentage of children with caries decreased with increasing numbers of intended or actual active applications linearly (both $p < 0.001$).

Supplemental analyses showed that the child who received four fluoride varnish applications had no caries, but did have a pre-cavitated lesion at the final visit. The magnitude of caries experience at the last examination, by intended treatment group and number of active fluoride varnish applications, was analyzed two ways, with and without pre-cavitated lesions ($d_{1+}fs$ and $d_{2+}fs$). For both, results showed significant inverse dose-response effects (Table 1). Linear regression of log ($d_{2+}fs$ +1) and log ($d_{1+}fs$ +1), adjusted for center, showed statistically significant decreases in caries experience with increasing number of intended or actual active fluoride varnish treatments (both $p < 0.001$; both multiple imputation $p < 0.002$). Of the 79 children with d2+fs, only 12 had any restorations. The magnitude of caries experience was also reduced for a single dose of fluoride against none ($p = 0.004$). However, this comparison is not significant when the proportion of children with caries is compared ($p = 0.121$). Significant odds ratios

were obtained when the caries incidence in the counseling only group was compared with the intended and actual number of fluoride varnish applications (Table 2). Center was never a significant predictor or effect modifier of caries incidence or magnitude ($p > 0.540$). No adverse events or safety issues resulting from the fluoride varnish use were reported by accompanying adults.

Table 1. Mean dfs and dfs + Pre-cavitated Lesions at Last Follow-up Visit by Intended Treatment Group and Number of Active Fluoride Varnish Applications (n = 280)

	n	Mean $d_{2+}fs$*	SD	Mean $d_{1+}fs$	SD	PF% $d_{2+}fs$
Intended Treatment Group						
0	100	1.7 **	3.1	2.7 **	3.4	-
2	93	0.7 **	1.8	1.3 **	2.3	58
4	87	0.7	2.1	1.4	3.1	61
# Active Fluoride Varnish Applications						
0	118	1.6 **	3.0	2.8 **	3.7	-
1	79	0.8	2.1	1.2	2.3	53
2	57	0.7	2.1	1.2	2.4	58
3-4	26	0.1	0.6	0.6	1.6	93

* $d_{2+}fs$ = number of cavitated decayed or filled surfaces.
$d_{1+}fs$ = number of pre-cavitated or cavitated decayed or filled surfaces.
SD = standard deviation.
PF% = prevented fraction: [(control mean - intervention mean)/control mean] x 100.
Intended Group = as randomized, intention-to-treat analysis.
Active Applications = number of varnish applications containing fluoride actually received (see text and APPENDIX).
3-4 includes one child with 4 applications.
** p-values ≤ 0.01 for comparisons with group receiving no fluoride varnish applications.

DISCUSSION

Study findings support the use of fluoride varnish to prevent early childhood caries and reduce caries increment in very young children. AAPD (www.aapd.org, 2004) and AAPHD (www.aaphd.org, 2004) guidelines support a dental assessment by a child's first birthday or first tooth eruption. Fluoride varnish efficacy in this age group provides additional rationale for an early dental visit, especially for high-caries-risk children, since the application of fluoride varnish at this first visit will help reduce future disease. Some children were even younger than age 1 at the first visit. We had little difficulty with cooperation of the young infants with the fluoride varnish. Collecting saliva was more problematic, but was possible with parental help. Public facilities sometimes find it difficult to see children at regular six-month intervals. Thus, determining the efficacy of only one application of varnish a year was important. Although more frequent varnish applications were more beneficial, one application was preferable to none.

The Cochrane collaboration meta-analysis (Marinho *et al.*, 2002) obtained a pooled d(e/m)fs prevented fraction of 33% (95% CI, 19-48%) based on three clinical trials. In our study, it ranged from 52 to 92%, by treatment group. The systematic review (Rozier, 2001) for the NIH Consensus Conference compared seven studies of fluoride varnish showing mixed effectiveness on primary teeth. Some were not randomized clinical trials, and none included children as young as those in our study (see APPENDIX).

The Cochrane reviewers (Marinho *et al.*, 2002) recommended that fluoride varnish studies include reports of adverse events or safety concerns. At each visit, families were asked about adverse events; only 1 adverse event was noted for a child in the four-fluoride-varnish group, with "ulcer on the cheek" at the 18-month visit having onset 2 months after the last fluoride varnish application, which was "fluoride-free". The ulcer was gone at the 24-month visit. Some concerns about applying fluoride varnish to asthmatic children have been noted (Blinkhorn and Davies, 1998). However, from parental report, of the 21 children with asthma, none of the fluoride varnish recipients had adverse events. A 95% upper bound on adverse event incidence in asthmatic children was 0.14 (Hanley and Lippman-Hand, 1983).

Many children with caries at the screening examination were ineligible. This study was intended to determine the success of preventing caries incidence, not increment. It did not address fluoride varnish efficacy for children with extant caries.

An important lesson in efficacy trials is always to test the presence and quantity of the product's active ingredient prior to and during study implementation, and to implement quality control measures to identify and correct protocol deviations as soon as possible. Most studies' non-compliance/non-adherence is participant-generated. In this study, only the entry time was related to number of active treatments, making results more generalizable. This study provides support for the conduct of future caries-prevention clinical research in community health centers serving vulnerable and minority populations. Because the study occurred at these sites, findings are more generalizable to settings serving many high-caries-risk children than other potential locations. Similar results from the two

Table 2. Caries Incidence Comparisons, Adjusted for Center, by Intended Treatment Group and Actual # Active Fluoride Varnish Applications (n = 280)

Comparison by Intended Treatment Group	Odds Ratio	95% Confidence Interval
0 *vs.* 4	3.8	1.9, 7.6
0 *vs.* 2	2.2	1.2, 4.1
Comparison by # Active Fluoride Varnish Applications		
0 *vs.* 3-4*	18.3	2.4, 138.5
0 *vs.* 2	3.4	1.6, 7.5
0 *vs.* 1	2.5	1.3, 4.7

* Includes one child with 4 active fluoride applications.

clinical sites with different populations increase generalizability of the findings. Fluoride varnish and parental counseling should be recommended as part of caries prevention programs targeting infants and toddlers.

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STATE HEALTH POLICY MONITOR

In This Monitor: Preventive Oral Health, Primary Care, Children's Coverage

December 2008

A PUBLICATION OF THE NATIONAL ACADEMY FOR STATE HEALTH POLICY

The Role of Physicians in Children's Oral Health

Chris Cantrell

Introduction

Twenty-five state Medicaid programs reimburse primary care physicians for performing basic preventive oral health care on young children during regular office visits, an approach that began in North Carolina nearly 10 years ago. Two recent surveys by The National Academy for State Health Policy (NASHP), the Medicaid/SCHIP Dental Association, and the American Academy of Pediatrics detail the extent and characteristics of these programs. States most often reimburse for application of fluoride varnish, which helps prevent cavities; some states also reimburse separately for additional services such as risk assessments, oral exams, and anticipatory guidance.[1*]

Although Medicaid entitles children to medically necessary dental care under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit, many children do not see a dentist until age 3 or later – even though cavity risk factors can be well established before a child's first birthday and before the first tooth erupts. More than 40 percent of children experience some form of tooth decay before reaching kindergarten.[1] Through fluoride varnish programs, policy makers seek to take advantage of children's early and frequent visits to physicians. By encouraging the dental and medical communities to share responsibility for children's oral health, policy makers hope to decrease the startling rate of caries in low-income children, who disproportionately bear the burden of dental disease.

1* Anticipatory guidance refers to face-to-face parent/caregiver education about proper oral health practices, including counseling for important developmental milestones.

Oral Health Care Must Begin in Childhood

Dental disease is the most common chronic disease among children in the United States.[2] It is the result of a bacterial infection that is most often passed from mother to child by the time the first tooth erupts (between 9 months and 1 year). Despite Medicaid's inclusion of dental coverage for young children under EPSDT and recommendations by the American Academy of Pediatric Dentistry that a child see a dentist no later than age 1, only 25.1 percent of children younger than 6 see a dentist.[3,4] The burden of dental disease falls disproportionately on low-income children, who are five times more likely to have cavities than children in higher-income families.[5]

Because dental disease is largely preventable, the consequences of a lack of oral health care are often unnecessary.[6] Untreated dental disease can lead to

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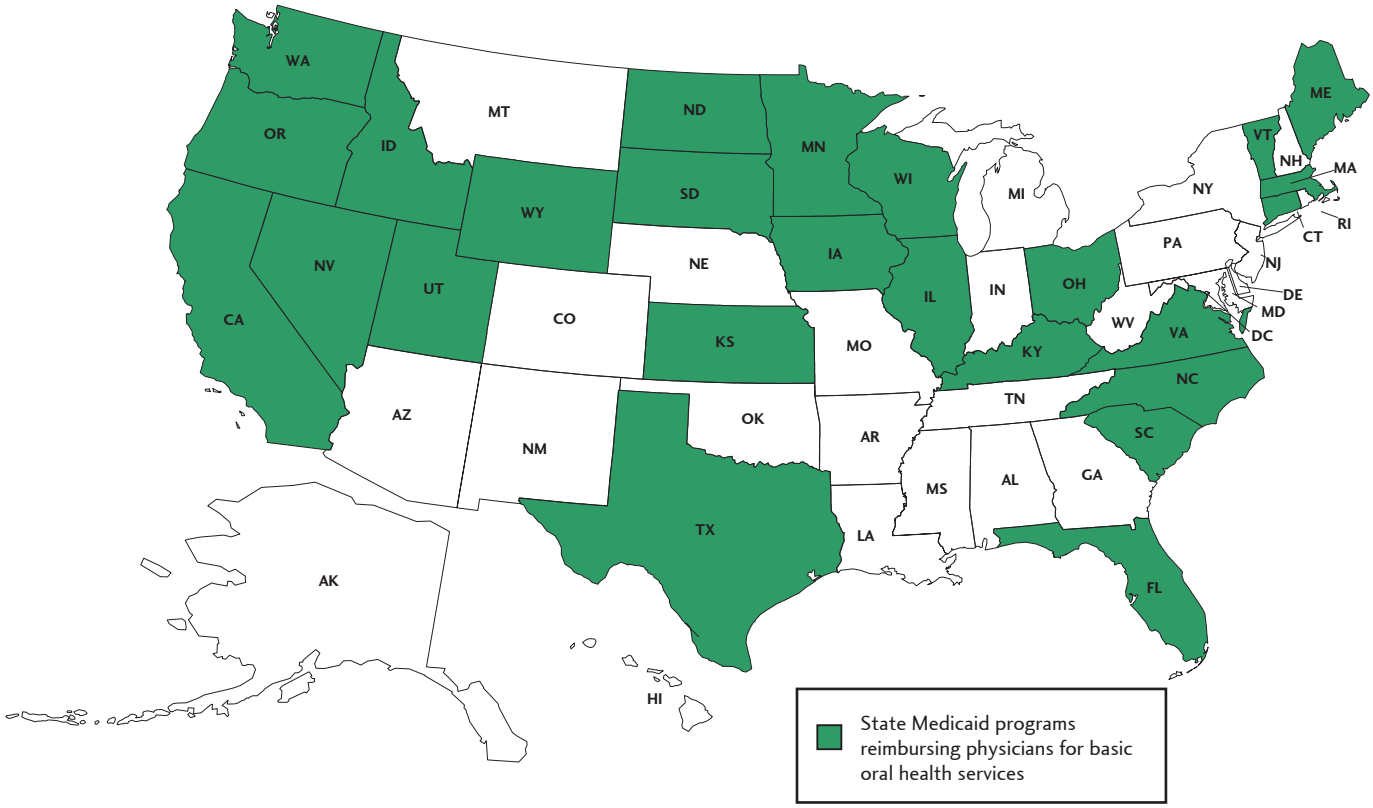
State Health Policy Monitor tracks how health policy issues, policies, and practices are being implemented in states and across the country.

FIGURE 1: 25 STATE MEDICAID PROGRAMS REIMBURSE PHYSICIANS FOR BASIC ORAL HEALTH SERVICES



dietary problems, infection, missed school days, and a lower quality of life. The high cost of hospitalization makes the consequences of untreated dental decay burdensome on low-income families. Since cavities can form soon after the eruption of the first tooth, early preventive oral health care is essential to mitigating the infectious and rapidly progressive dental decay that occurs in high-risk children.[7,8] Introducing the parents of young children to proper dental care not only helps ensure proper family oral hygiene practices, but can also reduce the need for expensive restorative dental procedures in the future.[9]

Physicians Can Play a Key Role in Combating Dental Disease

The early and frequent contact that most young children typically have with physicians presents a unique opportunity to evaluate their oral condition and perform basic preventive services. The American Academy of Pediatrics' Bright Futures guidelines recommend that children see a physician 11 times by age 2.[10] Since many children have not seen a dentist by this age, the timing and frequency of physician's checkups provide great opportunities to assess the health of a child's mouth, provide appropriate preventive dental services, such as oral examinations and fluoride varnish, and screen children for referrals to dentists when disease is identified. One study found that physicians trained to identify the signs of dental disease were 93 percent accurate in identifying young children with dental disease and referring them to a dental care provider.[11] Some states also reimburse nurse practitioners and physician's assistants for performing these services, further expanding the pool of providers available to deliver preventive dental services to young children.

Fluoride Varnish Can Reduce Cavities

Applying fluoride varnish to the teeth at an early age has been shown to reduce significantly caries in young

children.[12] It can be applied safely as soon as teeth have erupted – much earlier than other preventive measures. Sealants, for example, are usually applied to permanent molars around age 6 or 7. The varnish can be painted on the teeth quickly, making it easy to incorporate into a routine well-child visit in a medical office. Although widely used in Europe for quite some time, fluoride varnish was first approved for use in the United States in the 1990s.[13]

Fluoride varnish works by re-mineralizing teeth that have been weakened by the acid produced by bacteria in the mouth. Reports have stated that fluoride varnish is most effective in preventing caries when applied three or four times annually during the first few years of a child's life.[14,15] Through a periodic schedule of fluoride varnish application, coupled with greater provider participation in Medicaid, policy makers hope to reduce both the prevalence of caries in young children and the cost of future restorative procedures.

Results from Recent State Survey

Table 1 provides more detail about the 25 state Medicaid programs that reimburse primary care providers for performing preventive oral health care. Twenty-four state Medicaid programs reimburse for the application of fluoride varnish, with five states also reimbursing for other services, such as oral examinations and risk assessments. Although oral examinations and anticipatory guidance are advised to be part of every well-child visit, some states aim to provide additional incentives by reimbursing for those services separately.

The reimbursement for fluoride varnish applications ranges from $12 to $53[16] per application, and states generally limit the number of applications to two or three per year. Most of these states reimburse physicians for providing the service to young children, but some states pay for all children up to age 21. In addition, 20 of the states require that primary care providers undergo some form of training before becoming eligible for oral-services reimbursement.

SPOTLIGHT: NORTH CAROLINA'S INTO THE MOUTHS OF BABES PROGRAM

In 2000, North Carolina's Smart Smiles pilot program was expanded statewide and renamed Into the Mouths of Babes (IMB). The program uses Medicaid funding to encourage primary care physicians to perform basic preventive oral health procedures. The IMB procedure consists of three components:

1) Risk assessment and oral health evaluation, including referral to a dentist when needed.
2) Oral health education and anticipatory guidance for primary caregivers.
3) Application of fluoride varnish.

Reimbursement of approximately $54 is paid only if all three components of the package are provided. Providers must bill two reimbursement codes together on the same date of service to receive reimbursement. This package of services can be reimbursed six times from the first tooth eruption until the child is 3.

IMB has expanded access to preventive dental services for children younger than 3, with more than 100,000 annual visits. A 2007 evaluation of the IMB program found a 39 percent reduction in restorative-treatment needs for anterior (front) teeth in IMB patients who received at least four preventive procedures before age 3. The study also found that the state did not experience a reduction in dental visits for preventative care, indicating that the program was supplementing, rather than replacing, the services of dentists. The impact of the program continues to be monitored to determine whether it produces long-term savings for the state.

Conclusion

State Medicaid programs that reimburse primary care physicians for providing basic preventive oral health care aim to reduce dental disease by creating a shared responsibility for children's oral health. By providing care that focuses on prevention, states hope to prevent dental decay in young children and decrease their risk of developing oral health problems. Some states, such as North Carolina, are seeing fewer dental caries in their young populations and an increase in the utilization of oral health care services. As many states already have found, battling early childhood dental decay requires the cooperation of both the dental and medical communities.

TABLE 1: REIMBURSEMENTS FOR PHYSICIAN-RENDERED BASIC ORAL HEALTH SERVICES

State	Fluoride Varnish	Oral Exam	Anticipatory Guidance	Risk Assessment	Fluoride Varnish Rate	Age Limit	Is training required?	Max. # of Varnishes Reimbursed Per Year
California	✓				$18	≤ 6 yrs	No	3
Connecticut	✓	✓		✓	TBD	≤ 40 months	Yes	At each well-child exam
Florida	✓				$27	6 to 42 months	No	4
Idaho	✓				$13.58	21 yrs	Yes	2
Illinois	✓				$26	< 3 yrs	Yes	3
Iowa	✓				$14.41	≤ 3 yrs	Yes	3
Kansas	✓				$17	None	Yes*	3 (MD) + 3 (DDS) = 6/yr
Kentucky	✓				$15	1 to 5 yrs	Yes	2
Maine	✓				$12	≤ 21 yrs	No	3
Massachusetts	✓				TBD	≤ 20 yrs	Yes	2
Minnesota	✓				$14	None	Yes	No limit
Nevada	✓	✓			$53.30	≤ 20 yrs	Yes	2
North Carolina	✓	✓	✓	✓	$16.80	≤ 42 months	Yes	6 total over age range
North Dakota	✓				$18.68	0 to 21 yrs	Yes	2
Ohio	✓				$14.70	≤ 3 yrs	Yes	2
Oregon	✓				$13.19	≤ 6 yrs	No	4
South Carolina	✓				$17.06	≤ 3 yrs	Yes	2 (MD) + 2 (DDS) = 4/yr
South Dakota	✓				$18	≤ 5 yrs	No	3
Texas	✓				$34.16	6 to 35 months	Yes%	6 total over age range
Utah	✓				$15	≤ 4 yrs	Yes	At each well-child exam
Vermont		✓	✓	✓	TBD	≤ 2 yrs	Yes	n/a
Virginia	✓				$20.79	≤ 3 yrs	Yes	2
Washington	✓	✓	✓		$13.46	≤ 20 yrs	Yes	3
Wisconsin	✓				$12.76	≤ 12 yrs	Yes	n/a
Wyoming	✓				$35	≤ 3 yrs	Yes	3
TOTAL:	24	5	3	3				

This summary reflects results obtained from a survey of the 50 states and D.C. performed by Amos Deinard, MD, MPH, on behalf of the Oral Health Initiative, American Academy of Pediatrics, Medicaid/SCHIP Dental Association and Chris Cantrell, et al. of the National Academy for State Health Policy.

Unchecked services may be reimbursed as part of a well-child visit.
TBD: To be decided.
*Depends on state licensing boards.
%Training is required for CMAs, LPNs and RNs.

Notes

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13 Kevin Donly, "Fluoride Varnishes," Journal of the California Dental Association, (March 2003).

14 Weintraub, J.A., et al., IBID.

15 Some studies have stated that even more frequent applications increase the level of caries prevention.

16 Some states do not separately reimburse for the application of fluoride varnish, but instead require that other services be performed in conjunction with the varnish in order to be reimbursed.

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