PREVENTING DENTAL CARIES IN CHILDREN <5 YEARS: SYSTEMATIC REVIEW UPDATING USPSTF RECOMMENDATION

ABSTRACT

BACKGROUND AND OBJECTIVE: Screening and preventive interventions by primary care providers could improve outcomes related to early childhood caries. The objective of this study was to update the 2004 US Preventive Services Task Force systematic review on prevention of caries in children younger than 5 years of age.

METHODS: Searching Medline and the Cochrane Library (through March 2013) and reference lists, we included trials and controlled observational studies on the effectiveness and harms of screening and treatments. One author extracted study characteristics and results, which were checked for accuracy by a second author. Two authors independently assessed study quality.

RESULTS: No study evaluated effects of screening by primary care providers on clinical outcomes. One good-quality cohort study found pediatrician examination associated with a sensitivity of 0.76 for identifying a child with cavities. No new trials evaluated oral fluoride supplementation. Three new randomized trials were consistent with previous studies in finding fluoride varnish more effective than no varnish (reduction in caries increment 18% to 59%). Three trials of xylitol were inconclusive regarding effects on caries. New observational studies were consistent with previous evidence showing an association between early childhood fluoride use and enamel fluorosis. Evidence on the accuracy of risk prediction instruments in primary care settings is not available.

CONCLUSIONS: There is no direct evidence that screening by primary care clinicians reduces early childhood caries. Evidence previously reviewed by the US Preventive Services Task Force found oral fluoride supplementation effective at reducing caries incidence, and new evidence supports the effectiveness of fluoride varnish in higher-risk children. Pediatrics 2013;132:332–350

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KEY WORDS: Dental caries, children, screening, treatment, prevention, fluoride, fluorosis, xylitol, education, counseling

ABBREVIATIONS: dmfs—decayed, missing, or filled tooth surfaces OR—odds ratio USPSTF—US Preventive Services Task Force

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Dental caries is an infectious process involving breakdown of the tooth enamel. It is the most common chronic disease of children in the United States, and is increasing in prevalence among 2- to 5-year-olds. Approximately three-quarters of children with caries have not received treatment.

Early childhood caries is associated with pain and tooth loss, as well as impaired growth, decreased weight gain, and negative effects on speech, appearance, self-esteem, school performance, and quality of life. Dental caries disproportionately affects minority and economically disadvantaged children. Risk factors for dental caries include high levels of colonization by cariogenic bacteria, frequent exposure to dietary sugar and refined carbohydrates, inappropriate bottle feeding, low saliva flow rates, developmental defects of tooth enamel, previous caries, lack of access to dental care, low community water fluoride levels, inadequate tooth brushing or use of fluoride-containing toothpastes, lack of parental knowledge regarding oral health, and maternal risk factors, including caries, high levels of cariogenic bacteria, or poor maternal oral hygiene.

Screening for dental caries before school entry could lead to interventions to treat existing caries at an earlier stage and prevent future caries. Young children often see a primary care medical provider starting shortly after birth, but do not see a dentist until they are older, suggesting an important primary care role for caries prevention. Access to dental care is limited by many factors, including lack of dental coverage and shortages in dentists treating young children, particularly those who are uninsured or publicly insured. Once children enter school, there are additional opportunities for screening and treatment.

In 2004, the US Preventive Services Task Force (USPSTF) recommended that primary care clinicians prescribe dietary fluoride supplementation to children 6 months of age whose primary water source is deficient in fluoride (B recommendation). The USPSTF found insufficient evidence to recommend for or against primary care clinician risk assessment of children 5 years of age for the prevention of dental disease (I recommendation). The USPSTF found no validated risk-assessment tools or algorithms for assessing dental disease risk by primary care clinicians, and little evidence on the accuracy of primary care clinicians in performing oral examinations or assessing dental caries risk. In addition, the USPSTF found little evidence on the effectiveness of parental education or referring children at high risk to dental care providers in reducing risk of caries and related dental disease.

AIMS OF THIS REVIEW
This report was commissioned by the USPSTF to update its 2004 recommendation on dental caries prevention in children <5 years of age. With the input of members of the USPSTF, we developed an analytic framework (Fig 1) and key questions to guide our literature search and review:

1. How effective is oral screening (including risk assessment) by the primary care clinician in preventing dental caries in children <5 years of age?
2. How accurate is screening by the primary care clinician in identifying children <5 years of age who:
   a. have cavitated or noncavitated caries lesions?

![Analytic framework](image_url)
b. are at increased risk for future dental caries?

3. What are the harms of oral health screening by the primary care clinician?

4. How effective is parental or caregiver/guardian oral health education by the primary care clinician in preventing dental caries in children <5 years of age?

5. How effective is referral by a primary care clinician to a dentist in preventing dental caries in children <5 years of age?

6. How effective is preventive treatment (dietary fluoride supplementation, topical fluoride application, or xylitol) in preventing dental caries in children <5 years of age?

7. What are the harms of specific oral health interventions for prevention of dental caries in children <5 years of age (parental or caregiver/guardian oral health education, referral to a dentist, and preventive treatments)?

Key question 1 focuses on direct evidence on the effectiveness of oral screening (including oral examination and assessment of risk for future caries) by primary care clinicians in preventing future dental caries and associated complications, compared with no screening. Such direct evidence on the effectiveness of screening interventions is often limited. Therefore, the remainder of the analytic framework (key questions 2 through 7) evaluates the chain of indirect evidence needed to link screening with improvement in important health outcomes. Links in the chain of indirect evidence include the accuracy of screening to identify children with caries or at increased risk of developing caries, the effectiveness of interventions to reduce the incidence of dental caries and associated complications, and harms (including dental fluorosis) associated with screening and preventive treatments. Implicit in the indirect chain of evidence is that, to understand benefits and harms of screening, it is not sufficient to show that children at risk for dental caries can be identified; it is also necessary to show that there are effective treatments for those identified.

METHODS

This review was conducted at the Pacific Northwest Evidence-Based Practice Center under contract with the Agency for Healthcare Research and Quality (Contract No. HHSA-290-2007-10057-I, Task Order No. 13), by using the systematic review methods developed by the USPSTF.16,17

Search Strategies

We searched Ovid Medline (January 1999 to March 8, 2013) and the Cochrane Library Database (through the first quarter of 2013) for relevant articles, and reviewed reference lists for additional citations. Search strategies are shown in Supplemental Appendix 1.

Study Selection and Processes

Abstracts were selected for full-text review if they included children <5 years old (including those with caries at baseline), were relevant to a key question, and met the predefined inclusion criteria (Supplemental Appendix 2). We restricted inclusion to English-language articles and excluded studies published only as abstracts. Studies of nonhuman subjects were also excluded, and studies had to report original data.

We focused on studies of screening or diagnostic accuracy performed in primary care settings. For preventive treatments (key question 6), we also included studies of primary care–feasible treatments (treatments that could be administered or prescribed without requiring extensive dental training) performed in non–primary care settings. Treatment interventions were parental or caregiver education, referral to a dentist by a primary care clinician, and preventive treatments, including dietary fluoride supplementation, fluoride varnish, and xylitol. Interventions not commonly used or available in the United States (such as chlorhexidine varnish, povidone iodine rinses, and alternative methods for applying topical fluoride) are discussed in the full report,18 as are studies that compared different doses of xylitol. Outcomes included decreased incidence of dental caries and associated complications and harms, including dental fluorosis. Many studies reported a composite caries outcome of the presence of 1 or more decayed (noncavitated or cavitated), missing (due to caries), or filled tooth surfaces in preschool-age children.19

The abbreviation dmfs refers to decayed, missing, or filled primary tooth surfaces, and dmft refers to decayed, missing, or filled primary teeth (1 tooth may have more than 1 affected surface).

We included randomized controlled trials, nonrandomized controlled clinical trials, and cohort studies for all key questions. We also included an updated systematic review originally included in the 2004 USPSTF review of observational studies on risk of enamel fluorosis.20,21 Community interventions for prevention of dental caries and school-based interventions for older children are addressed elsewhere by the US Community Services Task Force.22

At least 2 reviewers independently evaluated each study to determine inclusion eligibility. One investigator abstracted details about each article’s study design, patient population, setting, screening method, treatment regimen, analysis, follow-up, and results.
A second investigator reviewed data abstraction for accuracy.

**Quality Assessment and Synthesis**

Two investigators independently applied criteria developed by the USPSTF\(^16,17\) to rate the quality of each study as good, fair, or poor (Supplemental Appendix 3). Discrepancies were resolved through a consensus process. See Table 1 for a list of quality ratings for the included randomized trials. We assessed the aggregate internal validity (quality) of the body of evidence for each key question (“good,” “fair,” “poor”) using methods developed by the USPSTF, based on the number, quality, and size of studies; consistency of results among studies; and directness of evidence.\(^16,17\) Meta-analysis was not attempted because of methodological shortcomings in the studies and differences across studies in design, interventions, populations, and other factors.

**RESULTS**

Our literature search identified a total of 1215 citations, of which we reviewed 539 full-text publications and included 20 studies (Fig 2).

**Benefits and Harms of Screening**

No randomized trial or observational study compared clinical outcomes between children <5 years of age screened and not screened by primary care clinicians.

**Accuracy of Oral Examination**

One good-quality study found primary care pediatrician examination of Medicaid-eligible children <36 months of age (n = 258) after 2 hours of oral health education associated with a sensitivity of 0.76 (19/25) for identifying a child with 1 or more cavities and 0.63 (17/27) for identifying children in need of a dental referral, compared with a pediatric dentist evaluation (Supplemental Tables 5 and 6).\(^41\) Specificity was 0.95 and 0.98, respectively. The need for referral was determined by the presence of a cavity, soft tissue pathology, or evidence of tooth or mouth trauma. A study included in the 2004 USPSTF review found pediatrician examination after 4 hours of oral health education associated with a sensitivity of 1.0 and specificity of 0.87 for identifying nursing caries in children 18 to 36 months of age.\(^42\)

**Effectiveness of Oral Health Education**

No trial specifically evaluated an educational or counseling intervention by a primary care clinician to prevent dental caries. Two nonrandomized trials (1 fair quality\(^27\) and 1 poor quality\(^24,25\)) found multifactorial interventions that included an educational component were associated with decreased caries outcomes in underserved children <5 years of age. Other components of the interventions included additional pediatrician training, electronic medical record reminders, and provision of tooth-brushing materials. In addition to use of a nonrandomized design, other methodological shortcomings in the poor-quality study were high attrition and failure to adjust for confounders.\(^24,25\)

**Effectiveness of Dental Referral**

No study directly evaluated the effects of referral by a primary care clinician to a dentist on caries incidence. A fair-quality retrospective cohort study (n = 14,389) found that having a first dental preventive visit after 18 months of age in Medicaid children with existing dental disease was associated with increased risk of subsequent dental procedures compared with having a first visit before 18 months of age (incidence density ratio ranged from 1.1 to 1.4, depending on time of first dental visit, after adjusting for gender, race, number of well-child visits, and other factors), but was not designed to determine referral source.\(^45\)

**Effectiveness of Preventive Treatments**

**Dietary Fluoride Supplementation**

We identified no trials published since the 2004 USPSTF review on effects of dietary fluoride supplementation in children <5 years of age. One randomized trial\(^46\) and 4 nonrandomized trials\(^47–50\) included in the 2004 USPSTF review found dietary fluoride supplementation in settings with water fluoridation levels below 0.6 ppm F associated with decreased caries incidence versus no fluoridation (percentage reduction in incidence ranged from 48% to 72% for primary teeth and 51% to 81% for primary tooth surfaces).\(^2\) In the single randomized trial (n = 140, fluoridation <0.1 ppm F), percent reductions in incidence ranged from 52% to 72% for teeth and 51% to 81% for tooth surfaces, depending on whether fluoride was given as tablets or drops.\(^46\) Two of the trials with extended follow-up also found dietary fluoride supplementation associated with decreased incidence of caries at 7 to 10 years of age (reductions ranged from 33% to 80%).\(^47,51\)

**Fluoride Varnish**

Two good-quality\(^28,31\) and 1 fair-quality\(^24\) trials published since the 2004 USPSTF review evaluated fluoride varnish (2.26% F) applied every 6 months versus no fluoride varnish (Table 2). Sample sizes ranged from 280 to 1146...
<table>
<thead>
<tr>
<th>Author, Year, Title</th>
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<th>Allocation Concealment Adequate?</th>
<th>Groups Similar at Baseline?</th>
<th>Eligibility Criteria Specified?</th>
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<th>Reporting of Attrition, Crossovers, Adherence, and Contamination</th>
<th>Loss To Follow-up Differential/High</th>
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<td>No</td>
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<td>The Institute of Aboriginal Peoples' Health of the Canadian Institutes of Health Research (Grant # MOP-64215) and the Toronto Hospital for Sick Children Foundation (Grant # XG 06-067)</td>
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<td>Yes</td>
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<td>No</td>
<td>Unclear (dfs index)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>The Uemura Fund, Nihon University School of Dentistry, a grant to promote multidisciplinary research projects from the Ministry of Education, Science, Sports, Culture and Technology, Japan</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes, some difference in fluoridation status</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
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<td>No</td>
<td>No</td>
<td>Grant No. R03 DE-012158 from NIH Head Start program</td>
<td>Fair</td>
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**Effect of xylitol gum on the level of oral mutans streptococci of preschoolers: block randomized trial**

**Effect of health promotion and fluoride varnish on dental caries among Aboriginal Australian children: results from a community-randomized controlled trial**

**Equivalence between massive versus standard fluoride varnish treatments in high caries children aged 3-5 y**
### TABLE 1

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<td>No, mean dmfs were not balanced</td>
<td>Yes</td>
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<td>No</td>
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<td><strong>Weintraub et al 2006</strong>&lt;sup&gt;34&lt;/sup&gt;</td>
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<td>Yes</td>
<td>Yes, stated no imbalances apparent</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>USPHS Research Grants P01 DE13058 and US4 DE142501 from the NIDCR and the NCHD, NIH, and by the UCSF Department of Preventive and Restorative Dental Sciences</td>
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<td>Fluoride varnish efficacy in preventing early childhood caries</td>
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<td><strong>Zhan et al 2012</strong>&lt;sup&gt;35&lt;/sup&gt;</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No/Yes (0.3% in 1 group)</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>California Society of Pediatric Dentistry Foundation, a Graduate Scientific Research Award from American Academy of Pediatric Dentistry, and NIH/NIDCR grant US4 DE171935</td>
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<td>Effects of xylitol wipes on carcinogenic bacteria and caries in young children</td>
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dmfs, decayed filled surfaces; NCHD, National Center on Minority Health and Health Disparities; NIDCR, National Institute of Dental and Craniofacial Research; NIH, National Institutes of Health; UCSF, University of California San Francisco; USPHS, United States Public Health Service; VA, Veterans Affairs; NR, not reported.
children. The main methodological shortcoming in the fair-quality trial was differential loss to follow-up in the treatment groups. The 2 good-quality trials were conducted in rural aboriginal populations in Canada (no fluoridation) and Australia (0.6 ppm F for >90% of children, baseline dmfs scores of 3.8 and 11.0) and used a cluster design. The fair-quality trial enrolled underserved, primarily Hispanic and Chinese children in an urban United States setting with adequate fluoridation (1 ppm F) who were caries-free at baseline. In all studies, the fluoride varnish was applied by dental personnel.

All 3 trials found use of fluoride varnish associated with decreased caries incidence after 2 years, although the difference was not statistically significant in the Canadian study. Absolute mean reductions in the number of affected surfaces ranged from 1.0 to 2.4. Results were consistent with findings from the 2004 USPSTF review, which reported a percent reduction in incident caries lesions that ranged from 37% to 63% (absolute reduction in the mean number of cavities per child of 0.67 to 1.24 per year), based on 6 trials, 2 of which were randomized. Two trials found multiple fluoride varnish applications within a 2-week period associated with no clear differences versus a standard application schedule of every 6 months, and 1 trial found no clear difference between a once versus twice yearly schedule (Table 2).

Xylitol
Three trials compared xylitol to no xylitol (Table 3). Water was inadequately fluoridated in 1 trial and water fluoridation status was not reported in the other 2. The trials varied with respect to dosing and formulation of xylitol. A fair-quality randomized trial (n = 115) of children 2 years of age found xylitol tablets (0.48 g) associated with reduced dmfs increment after 2 years, but the difference was not statistically significant (mean percent reduction 52%, absolute mean reduction in affected surfaces 0.42). One small (n = 37) fair-quality randomized trial found xylitol wipes used 3 times per day for 1 year markedly more effective than placebo wipes in reducing caries among children aged 6 to 35 months (reduction in dmfs increment 91%, P < .05). A poor-quality, nonrandomized trial found no effect of xylitol chewing gum (1.33 g) 4 times daily on incidence of caries in 4-year old children in Japan. Xylitol was not an included intervention in the 2004 USPSTF review.

**FIGURE 2**
Literature flow diagram. Cochrane databases include the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews. Identified from reference lists, hand searching, suggested by experts, and so forth. Studies may have provided data for more than 1 key question. Studies that provided data and contributed to the body of evidence were considered “included.” Five studies reported in the full evidence review but not reported in this article evaluated topical fluoride varnishes not commonly used in the United States, compared different dosing regimens of xylitol or evaluated povidone-iodine or chlorhexidine varnish.
<table>
<thead>
<tr>
<th>Author, Year, Quality</th>
<th>Study Design</th>
<th>Interventions</th>
<th>Country, Setting; Fluoridation Status</th>
<th>Age at Enrollment</th>
<th>Sample Size</th>
<th>F-U, y</th>
<th>Mean Caries Increment</th>
<th>Absolute Reduction in Caries Increment</th>
<th>Reduction in Caries Increment</th>
<th>Other Dental Caries Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lawrence et al 2008²³ Good</td>
<td>Cluster RCT (20 clusters)</td>
<td>A: 0.3–0.5 mL 5% sodium fluoride varnish applied to full primary dentition every 6 mo&lt;br&gt;B: No fluoride varnish</td>
<td>Canada; Rural Aboriginal communities; Water fluoridation status: No fluoridation</td>
<td>2.5 y</td>
<td>1146</td>
<td>2</td>
<td>dmfs</td>
<td>2.4 (1.8)²⁴</td>
<td>18% (29%)²⁴</td>
<td>A versus B</td>
</tr>
<tr>
<td>Slade et al 2011³¹ Good</td>
<td>Cluster RCT (30 clusters)</td>
<td>A: 0.25 mL of 5% sodium fluoride varnish to maxillary anterior teeth/molars, mandibular molars/incisors every 6 mo, education/advice to caregiver with toothbrush/paste provided, community oral health promotion program&lt;br&gt;B: No interventions</td>
<td>Australia; Rural Aboriginal communities; Water fluoridation status: 81% to 92% had &lt;0.6 ppm F</td>
<td>2.8 y</td>
<td>666</td>
<td>2</td>
<td>dmfs</td>
<td>2.3²⁵</td>
<td>24%²⁵</td>
<td></td>
</tr>
<tr>
<td>Weinstein et al 2001³² Fair</td>
<td>RCT with 3 treatment groups</td>
<td>A: One application of 5% fluoride varnish at baseline and 6 mo&lt;br&gt;B: Three applications of 5% fluoride varnish within 2 wk of baseline&lt;br&gt;C: Three applications of 5% fluoride varnish within 2 wk of baseline and 6 mo</td>
<td>United States; Head Start programs; Water fluoridation status: NR</td>
<td>3–5 y</td>
<td>111</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>Clinical dmfs A: Not calculated&lt;br&gt;B: 4.6&lt;br&gt;C: 3.2&lt;br&gt;Radiographic mean dmfs&lt;br&gt;A: 0.9&lt;br&gt;B: 0.5&lt;br&gt;C: 0.1&lt;br&gt;P = .28</td>
</tr>
</tbody>
</table>

²¹REVIEW ARTICLE
### TABLE 2 Continued

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design</th>
<th>Interventions</th>
<th>Country, Setting, Fluoridation Status</th>
<th>Age at Enrollment</th>
<th>Sample Size</th>
<th>F-U, y</th>
<th>Mean Caries Increment</th>
<th>Absolute Reduction in Caries Increment</th>
<th>Reduction in Caries Increment</th>
<th>Other Dental Caries Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weinstein et al 2009</td>
<td>RCT with 2 treatment groups</td>
<td>A: One 5% fluoride varnish treatment and 2 placebo treatments every 6 mo</td>
<td>United States</td>
<td>55–56 mo</td>
<td>515</td>
<td>3</td>
<td>dmfs</td>
<td>2.4</td>
<td>24%</td>
<td>Adjusted rate ratio of new tooth decay in primary surfaces 1.13 (95% CI 0.94–1.37)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B: One set of 3, 5% fluoride varnish treatments over 2 wk once per year and 3 placebo treatments over 2 wk, 6 mo later</td>
<td>Recruitment setting: Head Start programs</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Water fluoridation status: NR (Yakima voters approved fluoridation in 1999)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weintraub et al 2006</td>
<td>RCT</td>
<td>A: 0.1 mL of 5% sodium fluoride varnish per arch applied twice per year with 4 intended applications</td>
<td>United States; Family dental center and public health center serving primarily low-income, underserved Hispanic and Chinese populations</td>
<td>1.8 y</td>
<td>280</td>
<td>2</td>
<td>dsf,ts</td>
<td>1.0</td>
<td>59% (A + B vs C)</td>
<td>A vs B vs C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B: 0.1 mL of 5% sodium fluoride varnish per arch applied once per year with 2 intended applications</td>
<td>Water fluoridation status: Approximately 1 ppm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Recruitment setting:</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>C: No fluoride varnish</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

ANOVA, analysis of variance; CI, confidence interval; dsf,ts, number of decayed or filled surfaces; F-U, follow-up; NNT, number needed to treat; NR, not reported; RCT, randomized controlled trial; RR, relative risk.

* Children caries-free at baseline.

* Adjusted.

* In the fluoride varnish treatment group, some children received a placebo varnish instead of fluoride varnish due to protocol errors.

* Participants were caries-free at baseline.
<table>
<thead>
<tr>
<th>Author, Year, Quality</th>
<th>Study Design</th>
<th>Interventions</th>
<th>Country, Setting, Fluoridation Status</th>
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<th>Absolute Reduction in Caries Increment</th>
<th>Reduction in Caries Increment</th>
<th>Other Dental Caries Outcomes</th>
</tr>
</thead>
</table>
| Alamoudi et al 2012, Poor | RCT          | A: Xylitol chewable tablets (1.2 g, 84% xylitol) chewed for 5 min 3 times daily  
B: Fluoride varnish, every 6 mo throughout study | Saudi Arabia; Recruitment setting: Well-infant clinics and dental clinics; Water fluoridation status: Not reported | 2–5 y | 34 | 1.5 | 3.6 | 82% | A vs B | dmft at baseline: 8.4 vs 10.3 (P = .19)  
dmft at 18 mo: 9.2 vs 14.7 (P = .001) |
| Kovari et al 2003, Fair | Cluster RCT (11 clusters) | A: 65% Xylitol gum 3 times per day, chewed for 3–5 min, for total of 2.5 g/d  
B: Tooth brushing with 0.05% NaF toothpaste after lunch | Finland; Recruitment setting: day care centers; Water fluoridation status: Not reported | 3–6 y | 786 | 3–6 | Not reported | Not reported | Not reported | A vs B | Caries at 7 y old: 31% (98/316) vs 35% (149/427), RR 0.88 (95% CI 0.72–1.10)  
Caries at 9 y old: 43% (133/310) vs 51% (221/434), RR 0.84 (95% CI 0.72–0.99)  
dmft: 1.1 vs 1.0 at 7 y, 1.2 vs 1.6 at 9 y |
| Oscarson et al 2006, Fair | RCT          | A: One 0.48-g xylitol tablet at bedtime after brushing for 6 mo; then 1 tablet twice daily to age 3 y and 6 mo  
B: No tablets | Sweden; Recruitment setting: Public dental clinic; Water fluoridation status: Not reported | 25 mo | 115 | 2 | 0.42 | 52% | A vs B | Dental caries: 18% (10/55) vs 25% (16/63), OR 0.65 (95% CI 0.27–1.59) |
| Seki et al 2011, Poor | Cluster, non-randomized controlled clinical trial (5 clusters) | A: Xylitol chewing gum (100% xylitol, 1.33 g); 1 pellet chewed 5 min 4 times daily  
B: No intervention | Japan; Recruitment setting: Preschool; Water fluoridation status: Not reported (states fluoridation “limited” in Japan) | 68%–72% 4 y old | 161 | 1 | 0.1 | 3% | A vs B | Development of caries from baseline–6 mo: 1.7 vs 1.6 (P > .05)  
Development of caries from 6 mo–1 y: 1.6 vs 1.8 (P > .05) |
A systematic review included in the 2004 USPSTF review (searches conducted through September 1997) has subsequently been updated (searches conducted through June 2006). The update included 5 new observational studies on the association between early childhood intake of fluoride supplements and risk of fluorosis.

Results of the new studies were consistent with the original systematic review, with intake of fluoride supplements before 7 years of age (primarily before 3 years of age) associated with increased risk of fluorosis. Risk estimates ranged from an odds ratio (OR) of 1.8 (95% CI 1.1–2.4) for each year of supplementation.

In the prior systematic review, the ORs for dental fluorosis associated with regular early childhood use ranged from 1.3 to 10.7 in 10 studies that relied on retrospective recall, and relative risks ranged from 4.2 to 15.6 in 4 studies that recorded supplement use at the time of exposure. We identified no studies published since 2004.

### Harms of Preventive Interventions

**Conclusion:**

Apoor-quality trial found xylitol chewable tablets (1.2 g 3 times daily) more effective than fluoride varnish once every 6 months. A randomized trial found no difference between 65% xylitol gum 3 times per day versus tooth brushing with fluoride, but was conducted in a supervised day care setting, and enrolled children up to 6 years of age, potentially limiting its applicability to younger children.

### TABLE 3 Continued

<table>
<thead>
<tr>
<th>Author, Year, Quality</th>
<th>Study Design</th>
<th>Interventions</th>
<th>Country; Setting; Fluoridation Status</th>
<th>Age at Enrollment</th>
<th>Sample Size</th>
<th>F-U, y</th>
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<th>Absolute Reduction in Caries Increment</th>
<th>Reduction in Caries Increment</th>
<th>Other Dental Caries Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zhan et al 2012</td>
<td>RCT</td>
<td>A: Xylitol wipes, 2 at a time, 5 times per day (estimated daily dosage 4.2 g) every 3 mo</td>
<td>United States; Recruitment setting: University pediatric clinic; Water fluoridation status: Not reported</td>
<td>6–35 mo</td>
<td>37</td>
<td>1</td>
<td>dmf$s^{1}$</td>
<td>0.48</td>
<td>91%</td>
<td>A vs B</td>
</tr>
<tr>
<td>B: Placebo wipes</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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CI, confidence interval; dfs, decayed and filled surfaces; dmft, decayed, missing, and filled teeth; F-U, follow-up; NNT = number needed to treat; OR, odds ratio; RCT, randomized controlled trial; RR, relative risk.

---

$^{a}$Baseline caries status not defined.

$^{b}$Numbers based on per protocol analysis.
the updated systematic review on the
association between early childhood
intake of dietary fluoride supple-
ments and risk of enamel fluorosis.
No study reported the risk of flu-
rosis associated with use of fluoride
varnish. However, the degree of
systemic exposure after application
of fluoride varnish is believed to be
low.
Two trials reported diarrhea in 11%
of children allocated to xylitol chewing
gum or syrup. Other trials of xylitol
chewing gum did not report rates of di-
arrhea.

DISCUSSION
As in the 2004 USPSTF review, we
found no direct evidence on the effects of
screening for dental caries by primary
care clinicians in children <5 years
of age versus no screening on caries
incidence and related outcomes. Evi-
dence reviewed for this update is
summarized in Table 4.
New evidence was consistent with
findings from the 2004 USPSTF review in
showing that fluoride varnish in chil-
ren <5 years of age is effective at
reducing caries incidence. Because trials were primarily conducted
in higher-risk children (based on com-
munity water fluoride levels or socio-
economic status), the applicability of
these findings to children not at in-
creased risk may be limited, particu-
larly for studies conducted in countries
and settings in which sources of fluo-
rise and health behaviors differ mark-
edly from the United States. In all trials,
the varnish was applied by dental per-
sonnel, although fluoride varnish is
considered easy to apply with minimal
training.
We identified no new trials on the ef-
effectiveness of dietary fluoride supple-
mentation in children <5 years of age.
Although the 2004 USPSTF review found
dietary fluoride supplementation to be
effective at reducing caries incidence
in children <5 years of age primarily
in settings with water fluoridation
levels <0.6 ppm F, conclusions were
mostly based on nonrandomized tri-
als. Newer observational studies were
consistent with the 2004 USPSTF re-
view in finding an association between
early childhood intake of dietary
fluoride supplementation and risk of
enamel fluorosis. Risk of enamel
fluorosis appears to be affected by
total intake of fluoride (from supple-
ments, drinking water, other dietary
sources, and dentifrices), as well as
age at intake, with intake before 2 to 3
years of age appearing to confer
highest risk. Although the prev-
ance of enamel fluorosis has in-
creased in the United States, severe
fluorosis is uncommon, with a prev-
ance of <1%. Trials of xylitol in children <5 years of age found no clear effects on caries
incidence, although studies differed
in the doses and formulations eval-
uated. The most promising re-
sults were from a small trial of xylitol
wipes that reported a marked de-
crease in caries incidence, but require
confirmation.
Evidence remains limited on the ac-
curacy of primary care clinicians in
identifying caries lesions in children
<5 years of age or predicting caries
incidence. One study not included in the
previous USPSTF review found that
primary care pediatricians missed
37% of children in need of a dental
referral and 24% of children with
a cavity, compared with a pediatric
dentist examination, although speci-
nicity was high. No study evaluated the
diagnostic accuracy of caries risk
assessment instruments administered
by primary care clinicians, despite
the availability of instruments designed for
use in primary care settings. Some
studies have assessed caries risk as-
essment instruments in children
younger than 5 years of age, but the
instruments were not administered by
primary care providers or in primary
care settings. These instruments often
incorporate findings from an oral ex-
amination by dental personnel, and
include tests not commonly obtained in
primary care (such as mutans strep-
tococci levels, saliva secretion level, or
saliva buffer capacity), likely limiting
their applicability to primary care
settings.
No trial specifically evaluated the
effectiveness of parental or caregiver
education on caries outcomes, al-
though limited evidence from 2 trials
suggests that multifactorial inter-
ventions that included an educational
component could be effective. Although some evidence indicates
that health care providers’ recom-
men dation for dental care increases
the likelihood of subsequent dental
visits in young children, no trial di-
rectly evaluated the effectiveness
of primary care referral to a dentist
on caries outcomes, although 1 ret-
spective cohort study suggests that
erial care (before 18 months of age) is associated with
fewer subsequent dental procedures
in children with dental disease at
baseline.
Our review has some limitations. We
excluded non–English language arti-
cles, which could result in language
bias, although we did not identify non–
English language studies otherwise
meeting inclusion criteria. We did not
search for studies published only as
abstracts and could not formally as-
 sess for publication bias with graphical
or statistical methods because of small
numbers of studies for each key
question and differences in study de-
sign, populations, and outcomes as-
sessed. We found few or no randomized
trials for a number of key questions.
Therefore, we included nonrandomized
trials, as well as observational

PEDIATRICS Volume 132, Number 2, August 2013
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### TABLE 4 Summary of Evidence

<table>
<thead>
<tr>
<th>Main Findings From 2005 USPSTF Review</th>
<th>Number and Type of Studies Identified for Update Overall Quality</th>
<th>Limitations</th>
<th>Consistency</th>
<th>Applicability</th>
<th>Summary of Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key Question 1.</strong> How effective is oral screening (including risk assessment) by the primary care clinician in preventing dental caries in children &lt;5 y of age?</td>
<td>No evidence</td>
<td>No studies</td>
<td>No studies</td>
<td>No studies</td>
<td>No randomized trial or observational study compared clinical outcomes between children &lt;3 y of age screened and not screened by primary care clinicians.</td>
</tr>
<tr>
<td><strong>Key Question 2a.</strong> How accurate is screening by the primary care clinician in identifying children &lt;5 y of age who have cavitated or noncavitated caries lesions?</td>
<td>One study found pediatrician examination after 4 h of oral health education associated with a sensitivity of 1.0 and specificity of 0.87 for identifying nursing caries in children 18 to 36 mo of age.</td>
<td>One cohort study</td>
<td>Evidence limited to two studies, one good-quality</td>
<td>N/A</td>
<td>Study conducted in a primary care setting</td>
</tr>
<tr>
<td><strong>Key Question 2b.</strong> How accurate is screening by the primary care clinician in identifying children &lt;5 y of age who are at increased risk for future dental caries?</td>
<td>No evidence</td>
<td>No studies</td>
<td>No studies</td>
<td>No studies</td>
<td>No study evaluated the accuracy of general assessment or use of risk assessment tools by primary care clinicians to identify children at increased risk for future dental caries.</td>
</tr>
<tr>
<td><strong>Key Question 3.</strong> What are the harms of oral health screening by the primary care clinician?</td>
<td>No evidence</td>
<td>No studies</td>
<td>No studies</td>
<td>No studies</td>
<td>No randomized trial or observational study compared harms between children &lt;5 y of age screened and not screened by primary care clinicians.</td>
</tr>
<tr>
<td><strong>Key Question 4.</strong> How effective is parental or caregiver/guardian oral health education by the primary care clinician in preventing dental caries in children &lt;5 y of age?</td>
<td>No evidence</td>
<td>1 randomized trial, 1 nonrandomized trial</td>
<td>Nonrandomized design, high attrition, failure to adjust for confounders</td>
<td>Moderate inconsistency</td>
<td>Education evaluated as part of a multifactorial intervention</td>
</tr>
</tbody>
</table>

No trial specifically evaluated an educational or counseling intervention to prevent dental caries. Two studies found multifactorial interventions that included an educational component associated with decreased incidence or prevalence of cavities in underserved children <5 y of age.
### TABLE 4 Continued

<table>
<thead>
<tr>
<th>Main Findings From 2005 USPSTF Review</th>
<th>Number and Type of Studies Identified for Update Overall Quality&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Limitations</th>
<th>Consistency</th>
<th>Applicability</th>
<th>Summary of Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key Question 5. How effective is referral by a primary care clinician to a dentist in preventing dental caries in children &lt;5 y of age?</strong></td>
<td>No evidence</td>
<td>1 cohort study</td>
<td>Study not designed to determine whether a primary care referral was the source of the initial preventive visit</td>
<td>N/A</td>
<td>Medicaid population, higher-risk children</td>
</tr>
<tr>
<td><strong>Key Question 6. How effective is preventive treatment with dietary fluoride supplementation in preventing dental caries in children &lt;5 y of age?</strong></td>
<td>Six trials of dietary fluoride supplements. One randomized trial and 4 other trials found oral fluoride supplementation in settings with water fluoridation levels &lt; 0.6 ppm F associated with decreased caries incidence versus no fluoridation (ranges of 48%-72% for primary teeth and 51%-81% for primary tooth surface).</td>
<td>No studies</td>
<td>Limitations in previously reviewed studies include use of nonrandomized design, not controlling for confounders, inadequate blinding and high or unreported attrition</td>
<td>N/A</td>
<td>No studies</td>
</tr>
<tr>
<td><strong>Key Question 6. How effective is preventive treatment with topical fluoride application (fluoride varnish) in preventing dental caries in children &lt;5 y of age?</strong></td>
<td>Three randomized trials found fluoride varnish more effective than no fluoride varnish in reducing caries incidence (percent reduction 37%-63%, with an absolute reduction in the mean number of cavities per child of 0.67–1.24 per year.)</td>
<td>3 randomized trials&lt;sup&gt;b&lt;/sup&gt;</td>
<td>High loss to follow-up, failure to describe adequate blinding, and failure to describe adequate allocation concealment</td>
<td>Consistent</td>
<td>Rural settings with inadequate fluoridation or low socioeconomic status settings</td>
</tr>
</tbody>
</table>
studies (for harms), which are more susceptible to bias than are well-conducted randomized trials. Research is needed to identify effective oral health educational and counseling interventions for parents and caregivers of young children. Research is also needed to validate the accuracy and utility of caries risk assessment instruments for use in primary care settings, and to determine how referral by primary care physicians of young children for dental care affects caries outcomes.

CONCLUSIONS

Dental caries is common in young children, many of whom do not receive primary care referral for dental care. Dietary fluoride supplementation and fluoride varnish are primary care feasible interventions for preventing caries outcomes in higher-risk children. Dietary fluoride supplementation in early childhood is associated with increased risk of fluorosis; ORs ranged from 1.3–15.6 and prevalence ranged from 10%–67%. We identified no studies published since the updated systematic review on the association between early childhood ingestion of dietary fluoride supplements and risk of enamel fluorosis. Five new studies in an updated systematic review were consistent with previously reported findings in showing an association between early childhood ingestion of systemic fluoride and enamel fluorosis. Other than diarrhea reported in 2 trials of xylitol, harms were poorly reported in other trials of caries prevention interventions in children <5 y of age.

ACKNOWLEDGMENTS

The authors thank the responsible medical officer at the Agency of Healthcare Research and Quality, Aileen Buckler, MD, MPH; and US Preventive Services Task Force members Linda Baumann, PhD, RN, Adelita Cantu, PhD, RN, David Grossman, MD, MPH, Glenn Flores, MD, MPH, and Virginia Moyar, MD, MPH, for assistance with literature searches and review. We also thank Andrew Hamilton, MLS, MS, and Amanda Brunton, BS, for assistance with preparing this article.

TABLE 4

Main Findings From 2005 USPSTF Review

<table>
<thead>
<tr>
<th>Number and Type of Studies Identified for Update Overall Qualitya</th>
<th>Limitations</th>
<th>Consistency</th>
<th>Applicability</th>
<th>Summary of Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Question 6. How effective is preventive treatment with xylitol in preventing dental caries in children &lt;5 y of age?</td>
<td>No studies (not included in the prior review)</td>
<td>Variability in xylitol formulation and dosing</td>
<td>Some inconsistency</td>
<td>Children from settings in which water was not fluoridated or fluoridation limited</td>
</tr>
<tr>
<td>Key Question 7. What are the harms of specific oral health interventions for prevention of dental caries in children &lt;5 y of age (parental or caregiver/guardian oral health education, referral to a dentist, and preventive treatments)?</td>
<td>One systematic review of 14 observational studies found dietary fluoride supplementation in early childhood associated with increased risk of fluorosis; ORs ranged from 1.3–15.6 and prevalence ranged from 10%–67%.</td>
<td>Use of retrospective parental recall to determine exposures</td>
<td>Consistent</td>
<td>Doses of fluoride generally higher than currently recommended</td>
</tr>
</tbody>
</table>

a Overall quality is based on new evidence identified for this update plus previously reviewed evidence.

b Five studies reported in the full evidence review18 but not reported in this article evaluated topical fluoride varnishes not commonly used in the United States, compared different dosing regimens of xylitol, or evaluated povidone-iodine or chlorhexidine varnish. N/A, not applicable.
REFERENCES


Preventing Dental Caries in Children <5 Years: Systematic Review Updating USPSTF Recommendation
Roger Chou, Amy Cantor, Bernadette Zakher, Jennifer Priest Mitchell and Miranda Pappas
*Pediatrics,* originally published online July 15, 2013;
DOI: 10.1542/peds.2013-1469

<table>
<thead>
<tr>
<th>Updated Information &amp; Services</th>
<th>including high resolution figures, can be found at: /content/early/2013/07/10/peds.2013-1469</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplementary Material</td>
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