Preventing Dental Caries in Children <5 Years: Systematic Review Updating USPSTF Recommendation

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

All authors made substantial contributions to conception and design, acquisition of data, and analysis and interpretation of data, and gave final approval of the version to be published. Dr Chou drafted the article and revised it critically for important intellectual content. He is guarantor for this article. Drs Cantor, Zakher, Mitchell, and Pappas revised the article critically for important intellectual content.

www.pediatrics.org/cgi/doi/10.1542/peds.2013-1469
doi:10.1542/peds.2013-1469

Accepted for publication May 16, 2013

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275). Copyright © 2013 by the American Academy of Pediatrics

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Supported by the Agency for Healthcare Research and Quality (AHRQ) for the US Preventive Services Task Force under Contract No. 290-2007-10057-I to support the work of the USPSTF. Staff at AHRQ and members of the USPSTF developed the scope of the work and reviewed draft manuscripts. Approval from AHRQ was required before the manuscript was submitted for publication, but the authors are solely responsible for the content and the decision to submit it for publication.

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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](http://pediatrics.aappublications.org/Downloaded from)
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 not 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\textsuperscript{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.\textsuperscript{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).\textsuperscript{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 carries in children 18 to 36 months of age.\textsuperscript{42}

Accuracy of Risk Assessment for Future Dental Caries
Although risk assessment tools for use in primary care settings are available,\textsuperscript{43,44} we found no study on the accuracy of risk assessment by primary care clinicians using these or other instruments.

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\textsuperscript{27} and 1 poor quality\textsuperscript{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.\textsuperscript{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.\textsuperscript{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\textsuperscript{46} and 4 nonrandomized trials\textsuperscript{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).\textsuperscript{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.\textsuperscript{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%).\textsuperscript{47,51}

Fluoride Varnish
Two good-quality\textsuperscript{28,31} and 1 fair-quality\textsuperscript{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>
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<th>Author, Year, Title</th>
<th>Randomization Adequate?</th>
<th>Allocation Adequate?</th>
<th>Groups Similar at Baseline?</th>
<th>Eligibility Criteria Specified?</th>
<th>Outcome Assessors Masked?</th>
<th>Care Provider Masked?</th>
<th>Patient Masked?</th>
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<td>Alamoudi et al 2012&lt;sup&gt;23&lt;/sup&gt; Effects of xylitol on salivary mutans streptococci, plaque level, and caries activity in a group of Saudi mother-child pairs</td>
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<td>Yes</td>
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<td>Yes</td>
<td>Late (very high)</td>
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<td>Davies et al 2007&lt;sup&gt;24&lt;/sup&gt; Challenges associated with the evaluation of a dental health promotion program in a deprived urban area</td>
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<td>Yes</td>
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<td>Kovanen et al 2002&lt;sup&gt;26&lt;/sup&gt; Use of xylitol chewing gum in daycare centers: a follow-up study in Savonlinna, Finland</td>
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<td>Pediatrics clinicians can help reduce rates of early childhood caries effects of a practice-based intervention</td>
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<td>Lawrence et al. 2008&lt;sup&gt;28&lt;/sup&gt;</td>
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<td>Yes</td>
<td>Yes</td>
<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 05-067)</td>
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<td>A 2 y community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children</td>
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<td>Grants from Count of Vasterbotten, the Patient Revenue Fund for Dental Prophylaxis and the Swedish Dental Society</td>
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<td>Influence of a low xylitol-dose on streptococci colonization and caries development in preschool children</td>
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<td>Unclear (dfs index)</td>
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<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, some difference in fluoridation status</td>
<td>Yes</td>
<td>No</td>
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<td>Weinstein et al 200933</td>
<td>Yes</td>
<td>Unclear</td>
<td>No, mean dmfs were not balanced</td>
<td>Yes</td>
<td>Unclear</td>
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<td>Grants No R01DE14408 and U54DE14254 from NIDCR, NIH</td>
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<td>Weintraub et al 200654</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes; stated no imbalances apparent</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Yes/No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>USPHS Research Grants P01 DE13058 and US4 DE142601 from the NIDCR and the NCHMD, 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>Zhan et al 201235</td>
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<td>Yes</td>
<td>No/Yes (0.3% in 1 group)</td>
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<td>No</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 DE17385</td>
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<td>Effects of xylitol wipes on caroinogenic bacteria and caries in young children</td>
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</table>

dmfs, decayed filled surfaces; NCHMD, National Center for 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 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 and used a cluster design. 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. Percent reductions in dmfs increment were 18% and 24% in the 2 good-quality trials and 59% in the fair-quality trial. 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. Two studies compared xylitol to topical fluoride (Table 3).
<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 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)³</td>
<td>18% (29%)³</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 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>2.3</td>
<td>24%</td>
<td>Dental caries in aboriginal cohort: 72% (595/832) vs 75% (247/328), adjusted OR 0.72 (95% CI 0.42–1.25); NNT 26 Dental caries in those caries-free at baseline: 44% (157/354) vs 58% (73/126); adjusted OR 0.63 (95% CI 0.33–1.1); NNT 7.4</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 B: Three applications of 5% fluoride varnish within 2 wk of baseline 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>dmfs</td>
<td>Not calculated</td>
<td>Not calculated</td>
<td>Clinical dmfs A: Not calculated B: 0.5 C: 4.7 P = .05 Radiographic mean dmfs A: 0.9 B: 0.5 C: 0.1 P = .28</td>
</tr>
<tr>
<td>Author, Year, Quality</td>
<td>Study Design</td>
<td>Interventions</td>
<td>Country, Setting, Fluoridation Status</td>
<td>Age at Enrollment</td>
<td>Sample Size</td>
<td>F-U, y</td>
<td>Mean Caries Increment</td>
<td>Absolute Reduction in Caries Increment</td>
<td>Reduction in Caries Increment</td>
<td>Other Dental Caries Outcomes</td>
</tr>
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</tr>
<tr>
<td>Weinstein et al 200933 Fair</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>
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<tr>
<td></td>
<td></td>
<td>Water fluoridation status: NR (Yakima voters approved fluoridation in 1999)</td>
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<tr>
<td>Weintraub et al 200634 Fair</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>d2+fs</td>
<td>1.0</td>
<td>58% (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>
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<td></td>
<td></td>
<td>C: No fluoride varnish</td>
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</tbody>
</table>

ANOVA, analysis of variance; CI, confidence interval; d2+fs, 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.

a Children caries-free at baseline.
b Adjusted.
c In the fluoride varnish treatment group, some children received a placebo varnish instead of fluoride varnish due to protocol errors.
d 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>
<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>Alamoudi et al 2012</td>
<td>RCT</td>
<td>A: Xylitol chewable tablets (1.2 g, 84% xylitol) chewed for 5 min 3 times daily &lt;br&gt; B: Fluoride varnish, every 6 mo throughout study</td>
<td>Saudi Arabia; Recruitment setting: Well-infant clinics and dental clinics; Water fluoridation status: Not reported</td>
<td>2–5 y</td>
<td>34</td>
<td>1.5</td>
<td>dmft</td>
<td>3.6</td>
<td>82%</td>
<td>A vs B</td>
</tr>
<tr>
<td>Kovari et al 2003</td>
<td>Cluster RCT (11 clusters)</td>
<td>A: 65% Xylitol gum 3 times per day, chewed for 3–5 min, for total of 2.5 g/d &lt;br&gt; B: Tooth brushing with 0.05% NaF toothpaste after lunch</td>
<td>Finland; Recruitment setting: day care centers; Water fluoridation status: Not reported</td>
<td>3–6 y</td>
<td>786</td>
<td>3-6</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>A vs B</td>
</tr>
<tr>
<td>Oscarson et al 2006</td>
<td>RCT</td>
<td>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 &lt;br&gt; B: No tablets</td>
<td>Sweden; Recruitment setting: Public dental clinic; Water fluoridation status: Not reported</td>
<td>25 mo</td>
<td>115</td>
<td>2</td>
<td>dmfs</td>
<td>0.42</td>
<td>52%</td>
<td>A vs B</td>
</tr>
<tr>
<td>Seki et al 2011</td>
<td>Cluster, non-randomized controlled clinical trial (5 clusters)</td>
<td>A: Xylitol chewing gum (100% xylitol, 1.33 g); 1 pellet chewed 5 min 4 times daily &lt;br&gt; B: No intervention</td>
<td>Japan; Recruitment setting: Preschool; Water fluoridation status: Not reported (states fluoridation “limited” in Japan)</td>
<td>68%–72% 4 y old</td>
<td>161</td>
<td>1</td>
<td>dfs</td>
<td>0.1</td>
<td>3%</td>
<td>A vs B</td>
</tr>
</tbody>
</table>
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.26 A poor-quality trial found xylitol chewable tablets (1.2 g 3 times daily) more effective than fluoride varnish once every 6 months.23

Harms of Preventive Interventions

A systematic review included in the 2004 USPSTF review (searches conducted through September 1997) has subsequently been updated (searches conducted through June 2006).21 The update included 5 new observational studies on the association between early childhood intake of fluoride supplements and risk of fluorosis.58–62 Determinations of early childhood exposures were all based on retrospective parental recall with fluorosis assessed at 8 to 14 years of age (primarily before 3 years of age, depending on comparison).38 One study reported a dose-dependent association, with an odds ratio (OR) of 0.8 (95% confidence interval 1.8–6.2) for each year of supplementation.62 In the prior systematic review of the ORs for dental fluorosis associated with early childhood use of fluoride supplements ranged from 1.3 to 10.7 in 10 studies that recorded supplementation use at the time of exposure. We identified no studies published since this prior systematic review.43

### TABLE 3

<table>
<thead>
<tr>
<th>Author, Year, Quality</th>
<th>Study Design</th>
<th>Interventions</th>
<th>Country, Setting</th>
<th>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>Zhan et al 201225 Fair</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>dmfs&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.48</td>
<td>91%</td>
<td>A vs B</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B: Placebo wipes</td>
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</tbody>
</table>

<sup>a</sup> Baseline caries status not defined.

<sup>b</sup> Numbers based on per protocol analysis.

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the updated systematic review on the association between early childhood intake of dietary fluoride supplements and risk of enamel fluorosis. No study reported the risk of fluorosis 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 xylitol23,26,29 did not report rates of diarrhea.

**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. Evidence 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 children <5 years of age is effective at reducing caries incidence.28,31,34 Because trials were primarily conducted in higher-risk children (based on community water fluoride levels or socioeconomic status), the applicability of these findings to children not at increased risk may be limited, particularly for studies conducted in countries and settings in which sources of fluoride and health behaviors differ markedly from the United States. In all trials, the varnish was applied by dental personnel, although fluoride varnish is considered easy to apply with minimal training.32,64 We identified no new trials on the effectiveness of dietary fluoride supplementation 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 trials.2 Newer observational studies were consistent with the 2004 USPSTF review in finding an association between early childhood intake of dietary fluoride supplementation and risk of enamel fluorosis.21 Risk of enamel fluorosis appears to be affected by total intake of fluoride (from supplements, 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.65 Although the prevalence of enamel fluorosis has increased in the United States, severe fluorosis is uncommon, with a prevalence of <1%.66

Trials of xylitol in children <5 years of age found no clear effects on caries incidence, although studies differed in the doses and formulations evaluated.29,30,35 The most promising results were from a small trial of xylitol wipes that reported a marked decrease in caries incidence, but require confirmation.35 Evidence remains limited on the accuracy 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 specificity was high.41 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.43 Some studies have assessed caries risk assessment 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 examination by dental personnel, and include tests not commonly obtained in primary care (such as mutans streptococci levels, saliva secretion level, or saliva buffer capacity).68,70 likely limiting their applicability to primary care settings.71,72

No trial specifically evaluated the effectiveness of parental or caregiver education on caries outcomes, although limited evidence from 2 trials suggests that multifactorial interventions that included an educational component could be effective.13,24,25,27 Although some evidence indicates that health care providers' recommendation for dental care increases the likelihood of subsequent dental visits in young children,72 no trial directly evaluated the effectiveness of primary care referral to a dentist on caries outcomes, although 1 retrospective cohort study suggests that earlier dental care (before 18 months of age) is associated with fewer subsequent dental procedures in children with dental disease at baseline.45

Our review has some limitations. We excluded non–English language articles, 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 assess for publication bias with graphical or statistical methods because of small numbers of studies for each key question and differences in study design, populations, and outcomes assessed. We found few or no randomized trials for a number of key questions. Therefore, we included nonrandomized trials, as well as observational
<table>
<thead>
<tr>
<th>Key Question</th>
<th>How effective is oral screening (including risk assessment) by the primary care clinician in preventing dental caries in children &lt;5 y of age?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No evidence</td>
<td>No studies</td>
</tr>
</tbody>
</table>

| Key Question 2a. How accurate is screening by the primary care clinician in identifying children <5 y of age who have cavitated or noncavitated caries lesions? |
| 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. |
| One cohort study | Evidence limited to two studies, one good-quality | N/A | Study conducted in a primary care setting |

| Key Question 2b. How accurate is screening by the primary care clinician in identifying children <5 y of age who are at increased risk for future dental caries? |
| No evidence | No studies | No studies | No studies | No randomized trial or observational study compared clinical outcomes between children <5 y of age screened and not screened by primary care clinicians. |

| Key Question 3. What are the harms of oral health screening by the primary care clinician? |
| No evidence | No studies | No studies | No randomized trial or observational study compared harms between children <5 y of age screened and not screened by primary care clinicians. |

| Key Question 4. How effective is parental or caregiver/guardian oral health education by the primary care clinician in preventing dental caries in children <5 y of age? |
| No evidence | 1 randomized trial, 1 nonrandomized trial | Nonrandomized design, high attrition, failure to adjust for confounders. | Moderate inconsistency | Education evaluated as part of a multifactorial intervention |

| Overall quality: Poor | Overall quality: Fair | 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 Summary of Evidence**

<table>
<thead>
<tr>
<th>Main Findings From 2005 USPSTF Review</th>
<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 1. 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;5 y of age screened and not screened by primary care clinicians.</td>
</tr>
<tr>
<td>Key Question 2a. 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>Key Question 2b. 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 randomized trial or observational study compared clinical outcomes between children &lt;5 y of age screened and not screened by primary care clinicians.</td>
</tr>
<tr>
<td>Key Question 3. 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>Key Question 4. 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>

**Overall quality:** Fair

**Overall quality:** Poor
| Key Question 5. How effective is referral by a primary care clinician to a dentist in preventing dental caries in children <5 y of age? | No evidence | 1 cohort study | Study not designed to determine whether a primary care referral was the source of the initial preventive visit | N/A | Medicaid population, higher-risk children | No study directly evaluated the effects of referral by a primary care clinician to a dentist on caries incidence. One study found a first dental preventive visit after 18 mo of age in children with existing dental disease associated with increased risk of subsequent dental procedures compared with a first visit before 18 mo of age, but was not designed to determine referral source. |
| Key Question 6. How effective is preventive treatment with dietary fluoride supplementation in preventing dental caries in children <5 y of age? | Six trials of dietary fluoride supplements. One randomized trial and 4 other trials found oral fluoride supplementation in settings with water fluoridation levels < 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). | No studies | Limitations in previously reviewed studies include use of nonrandomized design, not controlling for confounders, inadequate blinding and high or unreported attrition | N/A | No studies | We identified no new trials on the effects of dietary fluoride supplementation in children <5 y of age on dental caries incidence. |
| Key Question 6. How effective is preventive treatment with topical fluoride application (fluoride varnish) in preventing dental caries in children <5 y of age? | 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.) | 3 randomized trials | High loss to follow-up, failure to describe adequate blinding, and failure to describe adequate allocation concealment | Consistent | Rural settings with inadequate fluoridation or low socioeconomic status settings | Three randomized trials published since the previous review found fluoride varnish more effective than no fluoride varnish in reducing caries incidence (percent reduction in caries increment 18%–59%). Other trials evaluated methods of topical fluoride application not used in the United States or compared different doses or frequencies of topical fluoride. |
studies, which are more susceptible to bias and confounding 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 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, and Virginia Moyer, MD, MPH. We also thank Andrew Hamilton, MLS, MS, for assistance with literature searches and Amanda Brunton, BS, for assistance with preparing this article.
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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* 2013;132;332
DOI: 10.1542/peds.2013-1469 originally published online July 15, 2013;

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Supplementary material can be found at:
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Roger Chou, Amy Cantor, Bernadette Zakher, Jennifer Priest Mitchell and Miranda Pappas

*Pediatrics* 2013;132;332

DOI: 10.1542/peds.2013-1469 originally published online July 15, 2013;

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