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Prevention of Dental Caries in Children Younger Than 5 Years Old: Systematic Review to Update the U.S. Preventive Services Task Force Recommendation

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment.

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Structured Abstract

Background: A 2004 U.S. Preventive Services Task Force (USPSTF) review recommended that primary care clinicians prescribe oral fluoride supplementation to preschool children over the age of 6 months whose primary water source is deficient in fluoride but found insufficient evidence to recommend for or against risk assessment of preschool children by primary care clinicians for the prevention of dental caries.

Purpose: To systematically update the 2004 USPSTF review on prevention of dental caries in children younger than age 5 years by medical primary care clinicians.

Methods: We searched the Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews (through the 1st quarter of 2013) and Ovid MEDLINE® (1999 through March 8, 2013) and manually reviewed reference lists.

Results: No randomized trial or observational study compared clinical outcomes between children younger than age 5 years screened and not screened by primary care clinicians for dental caries. One good-quality cohort study found primary care pediatrician examination following 2 hours of training associated with a sensitivity of 0.76 for identifying a child with one or more cavities and 0.63 for identifying children age <36 months in need of a dental referral compared with a pediatric dentist evaluation. No study evaluated the accuracy of risk-assessment tools applied by primary care clinicians to identify children younger than age 5 years at increased risk for future dental caries. We identified no new trials on the effects of oral fluoride supplementation in children younger than 5 years on dental caries outcomes. Three randomized trials published since the prior USPSTF review were consistent with three previous trials in finding fluoride varnish more effective than no fluoride varnish in reducing caries incidence in higher risk children younger than age 5 years (percent reduction in caries increment, 18 to 59%), although in all trials fluoride varnish was applied by dental personnel. Three trials reported no clear effects of xylitol versus no xylitol on caries incidence in children younger than 5 years. Five new observational studies in an updated systematic review were consistent with previous findings of an association between early childhood exposure to systemic fluoride and enamel fluorosis. Other than diarrhea, reported in two trials of xylitol, harms were poorly reported in trials of caries prevention interventions. Evidence on the effectiveness of educational or counseling interventions and the effectiveness of primary care referral to a dentist remains sparse or unavailable

Limitations: Only English-language articles were included. Due to limited evidence from randomized trials, we included nonrandomized trials. Studies conducted in resource-poor settings may be of limited applicability to screening in the United States.

Conclusions: Evidence previously reviewed by the USPSTF found oral fluoride supplementation effective at reducing caries incidence in children younger than age 5 years but associated with risk of enamel fluorosis. New evidence supports the effectiveness of professionally applied fluoride varnish at preventing caries in higher risk children younger than age 5 years. Research is needed to understand the accuracy of primary care oral health

examination and caries risk assessment, primary care referral to dental care, and effective parental and caregiver/guardian educational and counseling interventions.

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Chapter 1. Introduction

Purpose and Previous U.S. Preventive Services Task Force Recommendation

This report was commissioned by the U.S. Preventive Services Task Force (USPSTF) in order to update its 2004 recommendation on prevention of dental caries by medical primary care clinicians in children younger than age 5 years.[1]

In 2004, the USPSTF recommended that primary care clinicians prescribe dietary fluoride supplementation to children over the age of 6 months whose primary water source is deficient in fluoride (B recommendation).[1] This recommendation was based on fair evidence that in young children with low fluoride exposure, prescription of dietary fluoride supplements by primary care clinicians is associated with reduced risk of dental caries that outweighs potential harms of enamel fluorosis, which in the United States is primarily manifested as mild cosmetic discoloration of teeth.[2]

In 2004, the USPSTF also concluded that the evidence was insufficient to recommend for or against routine risk assessment of children younger than age 5 years by primary care clinicians 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 assessing dental disease risk or in performing oral examinations.[3] In addition, the USPSTF found little evidence on the effectiveness of counseling parents or referring high-risk children to dental care providers in reducing risk of caries and related dental disease. Therefore, the USPSTF concluded that there was insufficient evidence to determine the balance between benefits and harms of routine risk assessment to prevent dental disease in children younger than age 5 years.

Condition Definitions

Dental caries, or tooth decay, is an infectious process involving breakdown of the tooth enamel. Caries form through a complex interaction between cariogenic acid-producing bacteria in combination with fermentable carbohydrates and other dietary, genetic, behavioral, social, and cultural factors.[3-5]

Children are susceptible to caries as soon as the first teeth appear, which usually occurs around age 6 months. Early childhood caries is defined as the presence of one or more decayed (noncavitated or cavitated), missing (due to caries), or filled tooth surfaces (dmf) in preschool-age children.[6] The abbreviation dmfs refers to decayed, missing, or filled primary tooth surfaces, and dmft refers to decayed, missing, or filled primary teeth (one tooth may have more than one affected surface).

Prevalence and Burden of Disease

Dental caries is the most common chronic disease of children in the United States and is increasing in prevalence among young children.[7,8] The National Health and Nutrition Examination Survey (NHANES) found that the prevalence of caries in primary teeth in 2- to 5-year-olds increased from approximately 24 to 28 percent between the periods 1988 to 1994 and 1999 to 2004.[9] Approximately three-quarters of children with caries had not received treatment for the condition.

Dental caries disproportionately affects minority and economically disadvantaged children. NHANES found that 54 percent of children age 2 to 11 years in families below the Federal poverty threshold experienced primary tooth dental caries, compared with one-third of children in families with incomes above 200 percent of the poverty threshold.[9] Mexican-American children were more likely to experience dental caries in primary teeth (55%) than were black children (43%) or white children (39%), and were more likely to have untreated dental caries (33, 28, and 20%, respectively). In addition to higher prevalence, the severity of dental caries is also greater in economically disadvantaged and minority children.[9]

Early childhood caries is associated with pain and loss of teeth, as well as impaired growth, decreased weight gain, and negative effects on quality of life.[3,10] Repairs or extractions of carious teeth can be traumatic experiences for young children and occasionally result in serious complications. Early childhood caries is also associated with failure to thrive; can affect appearance, self-esteem, speech, and school performance; and is associated with future caries in both the primary and permanent dentitions.[11] Premature loss of primary molars due to early childhood caries can result in loss of arch space, leading to crowding of the permanent teeth, affecting aesthetics and potentially requiring orthodontic correction.[3] In 2000, the U.S. Surgeon General estimated that over 50 million school hours are lost each year nationally due to dental-related concerns.[8] More recent data indicate that more than 4 million school hours are lost each year due to dental care in the State of North Carolina, with over 700,000 of these hours lost due to dental pain or infection.[12]

Etiology and Natural History

Dental caries is a disease that occurs when bacteria, predominantly *Streptococcus mutans*, colonize the tooth surface and metabolize dietary carbohydrates (especially refined sugars) to produce lactic and other acids, resulting in demineralization of teeth.[3,13] In children age 12 to 30 months, caries typically initially affects the maxillary primary incisors and first primary molars, reflecting the pattern of eruption. Dental caries first manifests as white spot lesions, which are small areas of demineralization under the enamel surface. At this stage, the caries lesion is usually reversible. If oral conditions do not improve, demineralization progresses and eventually results in irreversible cavities, with a loss of the normal tooth shape and contour. Continued progression of the caries process leads to pulpitis and tooth loss, and can be associated with complications such as facial cellulitis and systemic infections.[13,14]

Risk Factors and Indicators

Risk factors for dental caries in young children include high levels of cariogenic bacterial colonization, frequent exposure to dietary sugar and refined carbohydrates, inappropriate bottle feeding, low saliva flow rates, developmental defects of tooth enamel, low socioeconomic status, previous caries, maternal caries, high maternal levels of cariogenic bacteria, and poor maternal oral hygiene.[13,15] Other risk factors include lack of access to dental care, low community water fluoride levels, inadequate tooth brushing or inadequate use of fluoride-containing toothpastes, and lack of parental knowledge regarding oral health.[8]

Rationale for Screening and Screening Strategies

Screening for dental caries and risk for caries in young children prior to school entry could identify caries at an earlier and reversible stage, and lead to interventions to treat existing caries, prevent progression of caries, and reduce incidence of future lesions. Screening strategies typically include oral health risk assessment and visual examination to identify high-risk children, including those who already have caries. Primary care clinicians can play an important role in screening for dental caries because many young children routinely see a primary care provider starting shortly after birth but do not see a dentist until they are older.[16] Approximately three-quarters of children under age 6 years did not have at least one visit to a dentist in the previous year, although the proportion with a visit increased from 21 percent in 1996 to 25 percent in 2004.[17] Access to dental care is limited by many factors, including shortages in dentists treating young children, particularly children who are not insured or who are publicly insured.[18] Once children enter school, there are additional opportunities for screening and treatment.[19]

Interventions and Treatment

In young children at risk for dental caries, interventions focus on reducing the burden of bacteria, reducing the intake of refined sugars, and increasing the resistance of teeth to caries development.[3,15] Strategies to reduce the burden of bacteria include the use of fluoride, parental counseling to improve oral hygiene, xylitol, and topical antimicrobials such as chlorhexidine or povidone-iodine. Educational and behavioral interventions can reduce intake of refined sugars through changes in diet and feeding practices. Children with caries or at risk of caries can also be referred for needed dental care.

Fluoride increases the resistance of teeth to caries development. Fluoride exposure can be topical (fluoride dentifrices, rinses, gels, foams, varnishes) or systemic (dietary fluoride supplements).[3,15] Effects of fluoridated water are both topical and systemic. After exposure, fluoride is incorporated into dental plaque, saliva, and tooth enamel, and increases tooth resistance to acid decay, acts as a reservoir for remineralization of caries lesions, and inhibits cariogenic bacteria.[3,14] A potential harm of excessive systemic fluoride exposure is enamel fluorosis, a visible change in enamel opacity due to altered mineralization. The severity of change depends on the dose, duration and timing of fluoride intake, and is most strongly

associated with cumulative intake during enamel development. Mild fluorosis manifests as small opaque white streaks or specks in the tooth enamel.[2] Severe fluorosis results in discoloration and pitted or rough enamel.[14] The prevalence of severe enamel fluorosis in the United States was estimated at less than 1 percent in the period 1999 to 2004.[2]

Topical fluoride is typically applied as a varnish in young children. Unlike fluoride gels, which are commonly used in older school-aged children, fluoride varnish does not require specialized dental devices or equipment and can be applied quickly without the risk of the child swallowing large amounts, which can cause transient gastric irritation.[3] Compared with other topical fluoride application methods (such as acidulated phosphate fluoride or sodium fluoride gel), systemic exposure to fluoride is low following application of fluoride varnish.[20,21] The varnish results in prolonged contact time between the fluoride and the tooth surface, enhancing incorporation into the tooth surface layers and more prolonged release. Fluoride varnish is typically available in the United States as 5-percent sodium fluoride (2.26% fluoride).

Xylitol is a naturally occurring sugar with properties that reduce levels of caries-forming mutans streptococci in the plaque and saliva.[22] In young children, xylitol can be administered as a syrup or topically via wipes. In older children, xylitol can also be administered in gum, lozenges, or snack foods. Other topical antimicrobials such as chlorhexidine varnish and povidone-iodine rinses are not in common use in young children in the United States or are not available, as in the case of chlorhexidine varnish.

Current Clinical Practice

Since the publication of the Surgeon General's Report on Oral Health in 2000,[8] many organizations have emphasized the importance of preventive oral health care for young children, particularly in the primary care setting. The American Academy of Pediatrics (AAP) has developed an oral health risk-assessment tool for use in primary care settings starting at the 6-month visit, along with suggested interventions for children at risk.[23] The American Academy of Pediatric Dentistry (AAPD) developed the Caries-risk Assessment Tool (CAT), designed for use by dental and nondental personnel.[24] Although the vast majority of pediatricians agree with recommendations on oral health screening, only about half report examining the teeth of more than half of their patients age 0 to 3 years, and few (4 percent) report regularly applying fluoride varnish.[18]

Recommendations of Other Groups

In 2003, the AAP issued a policy statement that encouraged practitioners to incorporate oral-health–related services into their practice by engaging in oral health assessments, anticipatory guidance, and preventive services, including making referrals to dentists. More specifically, an oral health assessment was recommended for all children by age 6 months and a first dental visit by age 1 year.[25] These recommendations were reaffirmed in 2009 and were also endorsed by the Bright Futures program.[26,27] In a second policy statement, the AAP supported the use of dietary fluoride supplementation and the application of fluoride varnish for children at risk for dental

caries.[28] The American Dental Association (ADA) recommends the application of fluoride varnish every 6 months in preschool children at moderate risk of dental caries and every 3 to 6 months in those at high risk.[29] The American Academy of Family Physicians, the ADA, and others recommend that clinicians consider the use of dietary fluoride supplementation in children age 6 months to 16 years who lack access to adequately fluoridated drinking water.[30,31] Recommended doses of dietary fluoride supplementation range from 0.25 to 1.0 mg per day, depending on age, the level of community or household water fluoridation, and ingestion of other dietary fluoride sources.[31,32] Dietary fluoride supplementation is not recommended when water fluoridation levels are greater than 0.6 parts per million fluoride (ppm F) or when caries risk is low.[31]

The U.S. Centers for Disease Control and Prevention recommend that clinicians counsel parents about appropriate use of fluoride toothpaste, especially in children under age 2 years; prescribe dietary fluoride supplements in children at high risk of dental caries whose drinking water lacks adequate fluoride, and limit the use of products with high fluoride concentration, such as varnish and gel, to high-risk individuals.[14] It recommends that clinicians account for overall ingestion of fluoride through diet, drinking water, and other sources and consider the risk of dental fluorosis before prescribing supplements or applying products with high fluoride concentration.

The AAPD recommends use of xylitol in age-appropriate formulations for moderate- and high-risk children.[22] The ADA recommends xylitol in children age 5 years or older, recommends against use of chlorhexidine varnish, and found insufficient evidence to determine effectiveness of povidone-iodine.[33]

Chapter 2. Methods

Key Questions and Analytic Framework

Using methods developed by the USPSTF,[34,35] representatives from the USPSTF and the Agency for Healthcare Research and Quality (AHRQ) determined the scope and Key Questions for this review. Investigators created an analytic framework with the Key Questions and the patient population, interventions, and outcomes reviewed (**Figure 1**). The target population was asymptomatic children younger than age 5 years, including children with existing dental caries who need additional preventive or restorative interventions for untreated disease. Community interventions for prevention of dental caries and school-based interventions for older children are addressed elsewhere by the U.S. Community Services Task Force.[36]

We also addressed a "contextual question" requested by the USPSTF to help inform the report. Contextual questions address background areas deemed important by the USPSTF for informing its recommendations. Contextual questions are not reviewed using systematic review methodology, but rather summarize the evidence from key informative studies.

Key Questions

1. How effective is oral screening (including risk assessment) by the primary care clinician in preventing dental caries in children younger than 5 years of age?
2. How accurate is screening by the primary care clinician in identifying children younger than 5 years of age who:
   a. Have cavitated or noncavitated caries lesions?
   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 oral health education by the primary care clinician in preventing dental caries in children younger than 5 years of age?
5. How effective is referral by a primary care clinician to a dentist in preventing dental caries in children younger than 5 years of age?
6. How effective is preventive treatment (dietary fluoride supplementation, topical fluoride application, or xylitol) in preventing dental caries in children younger than 5 years of age?
7. What are the harms of specific oral health interventions for prevention of dental caries in children younger than 5 years of age (parental or caregiver oral health education, referral to a dentist, and preventive treatments)?

Contextual Question

What percentage of children younger than 5 years of age in the United States have access to dental care, and what factors are associated with access to dental care in this population? (Access to dental care is defined as the ability of a child to receive dental care services, based on availability of dental care providers and/or ability to pay for those services.)

Key Question 1 focuses on direct evidence on the effectiveness of oral screening (defined to include oral examination as well as risk assessment for future caries) by medical primary care clinicians in preventing future dental caries and associated complications compared with not screening. Such direct evidence on the effectiveness of screening interventions may be 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 by primary care clinicians in identifying children with dental caries or at increased risk of developing caries, the effectiveness of primary care interventions for reducing the incidence of dental caries and associated complications, and harms (including dental fluorosis) associated with screening and preventive treatments. It is implicit in the indirect chain of evidence that, to understand benefits and harms of screening, it is necessary but 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.

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. Search strategies are shown in **Appendix A1**. We also reviewed reference lists of relevant articles.

Study Selection

At least two reviewers independently evaluated each study to determine inclusion eligibility. We selected studies on the basis of inclusion and exclusion criteria developed for each Key Question (**Appendix A2**). Articles were selected for full review if they were about dental caries in preschool children, were relevant to a Key Question, and met the predefined inclusion criteria. 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.

For all Key Questions, we included studies of children younger than age 5 years, including those with dental caries at baseline. 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 treatments feasible in primary care (treatments not requiring extensive dental-specific training) that were performed in non–primary care settings, but noted whether the treatment was administered by people with dental training. Interventions were parental or caregiver education, referral to a dentist by a primary care clinician, and preventive treatments, including dietary fluoride supplementation, topical fluoride application, xylitol, and antimicrobial rinses and varnishes. Outcomes were decreased incidence of dental caries and associated complications, and harms, including dental fluorosis. We included randomized, controlled trials, nonrandomized, controlled clinical trials, and cohort studies for all Key Questions. We also included an updated systematic review of observational studies on risk of

enamel fluorosis that was originally included in the 2004 USPSTF review.[37,38] **Appendix A3** shows the results of our literature search and selection process, and **Appendix A4** lists excluded studies with reasons for exclusion.

Data Abstraction and Quality Rating

One investigator abstracted details about each article's study design, patient population, setting, screening method, treatment regimen, analysis, followup, and results. A second investigator reviewed data abstraction for accuracy. Two investigators independently applied criteria developed by the USPSTF[34,35] to rate the quality of each study as good, fair, or poor (**Appendix A5**). Discrepancies were resolved through a consensus process.

Data Synthesis

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.[34,35] Meta-analysis was not attempted due to methodological shortcomings in the studies and differences across studies in design, interventions, populations, and other factors.

External Review

The draft report was reviewed by content experts, USPSTF members, AHRQ Project Officers, and collaborative partners, and revised prior to finalization (**Appendix A6**).

Response to Comments Received During the Public Comment Period

This evidence report was posted for public comment from May 21 to June 20, 2013. The systematic review team reviewed and considered comments relevant to the report and referred comments relevant to the recommendation statement to the USPSTF. No comments pointed out missing studies that met inclusion criteria or errors in the evidence reviewed. Therefore, the public comment process resulted in no changes to the findings or the conclusion of the evidence report.

Chapter 3. Results

Key Question 1. How Effective Is Oral Screening (Including Risk Assessment) by the Primary Care Clinician in Preventing Dental Caries in Children Younger Than Age 5 Years?

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

Key Question 2a. How Accurate Is Screening by the Primary Care Clinician in Identifying Children Younger Than Age 5 Years Who Have Cavitated or Noncavitated Caries Lesions?

Summary

One good-quality study found primary care pediatrician examination of children younger than age 36 months following 2 hours of oral health education associated with a sensitivity of 0.76 for identifying a child with one or more cavities and 0.63 for identifying children in need of a dental referral compared with a pediatric dentist evaluation.[39] Specificity was 0.95 for identifying children with cavities and 0.98 for identifying children who needed a dental referral. A study included in the 2004 USPSTF review found pediatrician examination following 4 hours of oral health education associated with a sensitivity of 1.0 and specificity of 0.87 for identifying nursing caries (defined as caries involving one or more of the maxillary central or lateral incisors or the primary molars, but excluding the mandibular incisors) in children age 18 to 36 months.[40]

Evidence

The 2004 USPSTF review[3] included one fair-quality study that found a pediatrician oral health exam of children age 18 to 36 months following 4 hours of training associated with a sensitivity of 1.0 and specificity of 0.87 for identifying nursing caries compared with a pediatric dentist exam.[40] A second study included in the prior USPSTF review found a non–dental nurse exam associated with high sensitivity and specificity, but it enrolled children age 5 to 12 years and is therefore of limited applicability to younger children.[41]

One good-quality study not included in the prior USPSTF review evaluated the accuracy of caries screening of children younger than age 36 months (n=258) by primary care pediatricians following 2 hours of oral health education (**Appendixes B1** and **B2**).[39] The study enrolled Medicaid-eligible children (9.7 percent with a cavity at baseline; mean, 0.3 cavities/child) attending a private pediatric group practice in North Carolina. Compared with a pediatric dentist evaluation, it found a sensitivity of 0.76 (19/25) and specificity of 0.95 (222/233) for identifying

a child with one or more cavities, a sensitivity of 0.49 (39/80) and specificity of 0.99 (3,210/3,235) for identifying a tooth with a cavity, and a sensitivity of 0.63 (17/27) and specificity of 0.98 (225/231) for identifying children in need of a dental referral. The need for referral was determined by the presence of a cavity, soft tissue pathology, or evidence of tooth or mouth trauma.

No study evaluated the accuracy of primary care screening for noncavitated caries (e.g., white spot) lesions.

Key Question 2b. How Accurate Is Screening by the Primary Care Clinician in Identifying Children Younger Than Age 5 Years Who Are at Increased Risk for Future Dental Caries?

The prior USPSTF review found no study on the accuracy of assessment by primary care clinicians in identifying children at risk for future dental caries.[3] Although risk-assessment tools for use in primary care settings are available from the AAP,[24] the AAPD,[24] and the ADA,[42] we found no study on the accuracy of risk assessment by primary care clinicians using these or other instruments.

Key Question 3. What Are the Harms of Oral Health Screening by the Primary Care Clinician?

No randomized trial or observational study compared harms between children age 5 years or younger screened and not screened by primary care clinicians.

Key Question 4. How Effective Is Parental or Caregiver Oral Health Education by the Primary Care Clinician in Preventing Dental Caries in Children Younger Than Age 5 Years?

Summary

No trial specifically evaluated an educational or counseling intervention by a primary care clinician to prevent dental caries. One fair-quality and one poor-quality nonrandomized trial found multifactorial interventions that included an educational component associated with decreased caries outcomes in underserved children younger than age 5 years.[43-45]

Evidence

The 2004 USPSTF review found no studies on the effectiveness of oral health educational or counseling interventions administered by a primary care clinician.[3] We identified no trials published since the 2004 review that specifically evaluated an educational or counseling

intervention, although two nonrandomized, controlled clinical trials (reported in three publications) evaluated oral health educational interventions as a part of multicomponent interventions (**Appendixes B3** and **B4**).[43-45] One study was rated fair quality[45] and the other poor quality.[43,44] In addition to using a nonrandomized design, other methodological shortcomings in the poor-quality study were high attrition and failure to adjust for confounders.

The fair-quality trial found a multicomponent intervention including additional pediatrician training, provision of an educational brochure, and electronic medical record reminders associated with decreased incidence of cavities versus usual care after 1 year: 18 versus 32 percent; adjusted hazard ratio (HR), 0.23; 95-percent confidence interval (CI), 0.09 to 0.62.[45] Children were age 6 months to 5 years at enrollment and recruited from an urban underserved setting. Results were adjusted for age, race/ethnicity, socioeconomic status, and dietary and oral health risk. The trial used a cluster design, with one intervention and one demographically similar control clinic. Baseline caries prevalence was about 6 percent.

The poor-quality trial also found a multicomponent intervention (including provision of educational materials, counseling on oral hygiene, and provision of toothbrush and toothpaste) associated with a lower prevalence of caries compared with usual care (54 vs. 64%; p=0.03), dental extraction (3 vs. 12%; p<0.0001), and mean dmft score (2.2 vs. 3.7; p<0.001).[43,44] The intervention was administered to children between age 8 months and 32 months recruited from primary care clinics in an urban deprived setting, and outcomes were assessed at age 5 years. The intervention was administered by health visitors (registered nurses with further training in child health, health promotion, prevention, and education) at healthy-child visits.

Key Question 5. How Effective Is Referral by a Primary Care Clinician to a Dentist in Preventing Dental Caries in Children Younger Than Age 5 Years?

Summary

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 age 18 months in children with existing dental disease was associated with increased risk of subsequent dental procedures compared with having a first visit before age 18 months, but the study was not designed to determine referral source.[46]

Evidence

The 2004 USPSTF report identified no studies on the effects of referral by a primary care clinician to a dentist on dental caries outcomes.[3] We identified no study published since the 2004 USPSTF report that specifically evaluated effects of primary care referral on dental caries outcomes. However, one study may provide indirect evidence on the effects of earlier referral for untreated dental disease. It was a fair-quality retrospective cohort study that found that, among Medicaid children with existing dental disease (n=14,389), having a first dental visit after age 18

months was associated with increased risk of subsequent dental procedures between age 43 and 72 months compared with having an earlier first visit (before age 18 months) after adjusting for sex, race, number of well-child visits, and other factors (**Appendixes B5** and **B6**); the incidence density ratio ranged from 1.1 to 1.4, depending on time of first dental visit.[46] There was no difference in risk of subsequent dental procedures among children without existing dental disease at baseline. The study does not directly address the Key Question because it was not designed to determine whether a primary care referral was the source of the initial preventive visit.

Key Question 6. How Effective Is Preventive Treatment (Dietary Fluoride Supplementation, Topical Fluoride Application, or Xylitol) in Preventing Dental Caries in Children Younger Than Age 5 Years?

Summary

We identified no trials published since the 2004 USPSTF review on effects of dietary fluoride supplementation on dental caries incidence in children younger than age 5 years. One randomized trial and four other trials 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: percent reduction in caries increment ranged from 48 to 72 percent for primary teeth and from 51 to 81 percent for tooth surfaces.[3]

We identified three randomized trials published since the 2004 USPSTF review that found fluoride varnish more effective than no fluoride varnish in reducing caries incidence: percent reduction in caries increment, 18 to 59 percent.[47-49] Results were consistent with those of three randomized trials included in the prior USPSTF review: percent reduction in caries increment, 37 to 63 percent.[3] Most trials were conducted in low socioeconomic status settings with low community water fluoridation levels, but benefits were also observed in studies conducted in adequately fluoridated settings.

Three trials reported no clear effects of xylitol versus no xylitol on caries outcomes in children younger than age 5 years, and one trial found no difference between xylitol and tooth brushing, but the trials varied with respect to dosing and formulation of xylitol.[50-53] The most promising results were from a single small trial of xylitol wipes.[50] Evidence from single trials of chlorhexidine varnish or povidone-iodine solution in children younger than age 5 years was too limited to determine effectiveness.[54,55]

Evidence

Dietary Fluoride Supplementation

We identified no trials published since the 2004 USPSTF review on effects of dietary fluoride supplementation on dental caries outcomes in children younger than age 5 years. The 2004 USPSTF review[3] included six trials[56-61] of dietary fluoride supplements. Sample sizes ranged

from 140 to 815 children. Only one of the trials was clearly randomized.[60] None of the nonrandomized trials adjusted for potential confounders. Other methodological limitations were inadequate blinding and high or unreported attrition. The trials were also clinically heterogeneous and varied with respect to age at enrollment (ranging from 2–3 weeks to 18–39 months), duration of followup (range, 2 to 6 years), dose of fluoride (range, 0.25 to 1.0 mg, varying in part based on child's age), and setting, including one Chinese trial that recruited 2-year-old children from kindergarten.[59]

The single randomized trial (n=140; fluoridation <0.1 ppm F) found use of 0.25 mg fluoride drops or chews associated with decreased incidence of caries versus no fluoride supplementation in Taiwanese children 2 years of age at enrollment.[60] Percentage reduction in incidence ranged from 52 to 72 percent for dmft and from 51 to 81 percent for dmfs, depending on whether fluoride was given as tablets or drops. Across all six trials, percentage reductions in incidence with fluoride supplementation ranged from 32 to 72 percent for dmft and 38 to 81 percent for dmfs versus placebo (vitamin drops) or no supplementation. Five trials were conducted in settings with water fluoridation levels below current thresholds for supplementation (<0.6 ppm F).[32,56,58-61] Excluding the trial conducted in a setting above this fluoridation threshold, incidence reductions were from 48 to 72 percent for dmft and 51 to 81 percent for dmfs.[57] Two trials with extended followup also found dietary fluoride supplementation in early childhood associated with decreased incidence of caries at 7 to 10 years of age: reductions ranged from 33 to 80 percent.[56,62]

Topical Fluoride

The 2004 USPSTF review included six trials[63-68] on the effectiveness of professionally applied fluoride varnish in preventing dental caries in primary teeth. Two trials[63,64] were randomized and one[66] used alternate allocation. The other three were not randomized, with sample sizes ranging from 142 to 225. All of the trials enrolled children between age 3 and 5 years and followed patients for 2 years[64,66] or 9 months.[63] Community water fluoridation status met recommended thresholds in one trial[63] and was not reported in the other two. Fluoride varnish was applied as 2.26 percent fluoride (Duraphat®) for two applications separated by 4[63] or 6 months,[66] or as four applications over 2 years.[64] No trial used a placebo or control treatment, and only one[63] clearly reported blinded outcomes assessment. The percent reduction in incident caries lesions ranged from 37 to 63 percent ($p<0.01$ in all trials), with an absolute reduction in the mean number of cavities per child of 0.67 to 1.24 per year.

We identified seven trials published since the 2004 USPSTF review on professionally applied topical fluoride in children younger than age 5 years (**Table 1** and **Appendix B7**).[47-49,69-72] We rated three trials good quality,[47,48,70] three fair quality,[49,71,72] and one poor quality[69] (**Appendix B4**). Six trials were randomized; the poor-quality trial used alternate allocation. Shortcomings in the fair-quality trials included high loss to followup, failure to describe adequate blinding, and failure to describe adequate allocation concealment.

Three trials (two good quality and one fair quality) evaluated fluoride varnish (2.26% fluoride) applied every 6 months versus no fluoride varnish.[47-49] Sample sizes ranged from 280 to 1,146 children. Two trials conducted in rural aboriginal populations in Canada (no fluoridation)[47] and

Australia (<0.6 ppm F for >90% of children) had baseline dmfs scores of 3.8 and 11[48] and used a cluster design. The third trial enrolled underserved, primarily Hispanic and Chinese, children in an urban U.S. setting with adequate fluoridation (1 ppm F) who were caries free at baseline.[49] As in the trials included in the 2004 USPSTF review, fluoride varnish was applied by dental personnel in all studies.

All three trials found use of fluoride varnish associated with decreased incidence of caries after 2 years, although the difference was not statistically significant in the Canadian study.[47] Percent reductions in dmfs increment were 18 and 24 percent in the studies of rural aboriginal populations[47,48] and 59 percent in the U.S. trial.[49] Absolute mean reductions in the number of affected surfaces ranged from 1.0 to 2.4. Fluoride varnish was also associated with decreased risk of having any cavity. The poor-quality trial, which evaluated 2.26 percent fluoride varnish applied every 3 months in Chinese children (with or without removal of carious tissue), reported findings consistent with those of the fair-quality trials.[69]

Two trials evaluated effectiveness of other methods for administering topical fluoride.[69,70] Both were conducted in China. One good-quality trial found 1.23-percent acidulated phosphate fluoride foam applied every 6 months more effective (p=0.03) than placebo (mean percent reduction in dmfs increment, 24%; absolute mean reduction in affected surfaces, 1.2).[70] A poor-quality trial found 38-percent silver diamine fluoride solution every 12 months somewhat more effective than 2.26-percent fluoride varnish every 3 months.[69]

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,[71,72] and one trial found no clear difference between a once versus twice yearly schedule.[49]

Xylitol

Xylitol was not an included intervention in the 2004 USPSTF review. We identified four fair-quality[50-52,73] and two poor-quality trials[53,74] of xylitol in children age 6 months to 5 years (**Table 2** and **Appendixes B4** and **B7**). Two trials enrolled children from settings in which water was not fluoridated[73] or inadequately fluoridated,[53] and the other four did not report water fluoridation status. Five trials were randomized[50-52,73,74] and one used a nonrandomized design.[53]

Three trials compared xylitol with no xylitol.[50,52,53] They varied with respect to dosing and formulation of xylitol. A fair-quality randomized trial (n=115) 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).[52] The trial enrolled 2-year-old Swedish children, with the intervention consisting of a xylitol tablet at bedtime for 6 months, followed by two tablets daily. One small (n=37) fair-quality randomized trial found xylitol wipes used three times per day for 1 year markedly more effective than placebo wipes in reducing caries among children age 6 months to 35 months (reduction in dmfs increment, 91%; p<0.05).[50] A poor-quality nonrandomized trial found no effect of xylitol chewing gum (1.33 g) four times daily on incidence of caries in 4-year-old children in Japan.[53]

Two studies compared xylitol with topical fluoride.[51,74] A cluster randomized trial found no

difference between 65-percent xylitol gum three times per day versus tooth brushing with fluoride, but it was conducted in a supervised daycare setting and enrolled children up to age 6 years, potentially limiting its applicability to younger children.[51] A poor-quality trial found xylitol chewable tablets (1.2 g three times daily) more effective than fluoride varnish once every 6 months.[74]

One fair-quality randomized trial found xylitol syrup 8 g per day in two or three divided doses more effective than one 2.67 g dose daily in reducing incidence of caries outcomes.[73]

Other Interventions

One fair-quality cluster randomized trial (n=290) of children age 4 to 5 years in rural China found 40-percent chlorhexidine acetate varnish associated with decreased caries outcomes versus placebo varnish, with a 37-percent reduction in dmfs incidence in the molar teeth and mean absolute dmfs-molar reduction of 0.6 (**Table 3** and **Appendixes B4** and **B7**).[54]

A fair-quality randomized trial (n=83) of high-risk children age 16 months in Puerto Rico found 0.2 ml of 10-percent povidone-iodine solution applied every 2 months associated with decreased incidence of white spot lesions on maxillary teeth after 1 year (8 vs. 32%; relative risk [RR], 0.24; 95% CI, 0.1 to 0.8).[55]

Key Question 7. What Are the Harms of Specific Oral Health Interventions for Prevention of Dental Caries in Children Younger Than Age 5 Years (Parental or Caregiver Oral Health Education, Referral to a Dentist, and Preventive Treatments)?

Summary

Five new studies in an updated systematic review were consistent with previous studies in finding an association between early childhood ingestion of systemic fluoride and enamel fluorosis of the permanent dentition.[38] Studies were observational and had methodological shortcomings, including use of retrospective recall to determine exposures. Other than diarrhea, reported in two trials of xylitol,[53,73] harms were poorly reported in trials of caries prevention interventions, and no trials reported incidence or prevalence of fluorosis with fluoride varnish.

Evidence

No trial reported risk of dental fluorosis associated with early childhood ingestion of dietary fluoride supplements. The 2004 USPSTF review included a systematic review of 14 observational studies on risk of fluorosis, based on literature searches conducted through September 1997.[37] Ten of the studies relied on retrospective parental recall of early childhood fluoride ingestion to determine subsequent risk of fluorosis in the permanent dentition. In the other four, early childhood supplemental fluoride use had been recorded at the time of exposure. The dosages of fluoride supplementation in the studies generally exceeded current

recommendations. Prevalence of fluorosis ranged from 10 to 49 percent in the studies that relied on retrospective parental recall, and from 15 (on central incisors only) to 67 percent in the studies that recorded supplement use during early childhood. The odds ratios (ORs) for dental fluorosis associated with regular early childhood use ranged from 1.3 to 10.7 in the studies that relied on retrospective recall, and RRs ranged from 4.2 to 15.6 in the studies that recorded supplement use at the time of exposure.

The systematic review included in the 2004 USPSTF review has subsequently been updated with searches conducted through June 2006 (**Appendixes B8** and **B9**).[38] The update included five additional observational studies on the association between early childhood intake of fluoride supplements and risk of fluorosis.[75-79] Determinations of early childhood exposures were all based on retrospective parental recall, with fluorosis assessed at age 8 to 14 years. Results of the new studies were consistent with those from the original systematic review, with intake of fluoride supplements prior to 7 years of age (primarily before 3 years of age) associated with increased risk of fluorosis. Risk estimates ranged from an OR of 10.8 (95% CI, 1.9 to 62) with intake during the first 2 years of life[78] to a slight increase in risk (OR, 1.1 to 1.7, depending on comparison).[75] One study reported a dose-dependent association, with an OR of 1.8 (95% CI, 1.4 to 2.4) for each year of supplementation.[79] We identified no studies published since 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 following application of fluoride varnish is believed to be low.

Two trials reported diarrhea in 11 percent of children allocated to xylitol chewing gum[53] or syrup.[73] Other trials of xylitol[50-52,74] did not report rates of diarrhea.

Contextual Question. What Percentage of Children Younger Than Age 5 Years in the United States Have Access to Dental Care, and What Factors Are Associated With Access to Dental Care in This Population?

Based on a national telephone survey (n=89,071) of parents performed in 2003 to 2004, 23 percent of children age 1 to 5 years lacked dental insurance coverage in the previous year, 51 percent did not receive dental care, and 3.5 percent had a perceived unmet dental need.[80] Children who lacked dental insurance were also less likely to receive preventive care and more likely to have a perceived unmet need for care. In multivariate analyses, factors associated with lack of dental insurance coverage among all children age 1 to 17 years were being a foreign-born Hispanic, having a non-English primary language spoken at home, having three or more children in the family, lower socioeconomic status, rural residence, living in the South, and lower household education level. An analysis based on 2004 Medical Expenditure Panel Survey (MEPS) data also found that a primary care provider's recommendation for dental care was associated with a threefold increased likelihood (OR, 2.9; 95% CI, 2.2 to 3.9) of having a subsequent dental visit.[81] In 2009, based on MEPS data, the proportion of children age 1 to 5

years with a dental visit in the prior year was 31 percent (95% CI, 28 to 34%).[82]

Several studies have shown that expanding access to dental coverage for low-income families through the State Children's Health Insurance Program (SCHIP) and Medicaid programs was associated with an increase in preventive dental visits in eligible children.[83-85] Higher Medicaid payment levels were associated with higher rates of receipt of care.[86]

Chapter 4. Discussion

Summary of Review Findings

Dental caries is highly prevalent in children younger than age 5 years. A high proportion of children in this age group do not receive recommended dental care,[80] suggesting a potential role for primary care providers in dental caries prevention. However, as in the 2004 USPSTF review,[3] we found no direct evidence on the effects of screening for dental caries by primary care clinicians in children younger than age 5 years versus no screening on caries incidence and related outcomes. Other evidence reviewed for this update is summarized in **Table 4**.
Newer evidence identified for this update was consistent with findings from the 2004 USPSTF review in showing that fluoride varnish in children younger than age 5 years is effective at reducing caries incidence.[47-49] 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 believed to be easily applied with minimal training.[87,88]

We identified no new trials on the effectiveness of dietary fluoride supplementation in children younger than age 5 years. Although the 2004 USPSTF review found dietary fluoride supplementation to be effective at reducing caries incidence in children younger than age 5 years primarily in settings with water fluoridation levels less than 0.6 ppm F, conclusions were mostly based on nonrandomized trials.[3] 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.[38] Risk of enamel fluorosis appears to be impacted by total intake of fluoride (from supplements, drinking water, other dietary sources, and dentifrices), as well as age at intake, with intake before age 2 to 3 years appearing to confer the highest risk.[89] Although the prevalence of enamel fluorosis has increased in the United States, severe fluorosis is uncommon, with a prevalence of less than 1 percent.[2,90,91]

Trials of xylitol in children younger than age 5 years found no clear effects on caries incidence, although studies differed in the doses and formulations evaluated.[50,52,53] The most promising results were from a small trial of xylitol wipes that reported a marked decrease in caries incidence, but they require confirmation.[50] Evidence on the effectiveness of other interventions not in common use in the United States in young children, such as chlorhexidine varnish and povidone-iodine solution, is limited to single trials, precluding reliable conclusions.[54,55]

Evidence remains limited on the accuracy of primary care clinicians in identifying caries lesions in children younger than age 5 years or in predicting caries incidence. One study not included in the prior USPSTF review found that primary care pediatricians missed 37 percent of children in need of a dental referral and 24 percent of children with a cavity compared with a pediatric dentist exam, although specificity was high.[39] 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.[24] Some studies have

assessed caries risk-assessment instruments in children younger than age 5 years, but the instruments were not administered by primary care providers or in primary care settings. In addition, 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),[92,93] potentially limiting applicability of findings to primary care settings.[94,95]

No trial specifically evaluated the effectiveness of parental or caregiver/guardian education on caries outcomes, although limited evidence from two trials suggests that multifactorial interventions in which education is a component could be effective.[43-45] Although some evidence indicates that health care providers' recommendation for dental care increases the likelihood of subsequent dental visits in young children,[81] no trial evaluated the effectiveness of primary care referral to a dentist on caries outcomes. One retrospective cohort study found an association between an early (prior to age 18 months) dental visit and fewer subsequent dental procedures in children with dental disease at baseline.[46]

Limitations

We excluded non–English-language articles, which could result in language bias, although we identified no non–English-language studies that would have met inclusion criteria. We did not search for studies published only as abstracts, and we 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 the 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 studies (for harms), which are more susceptible to bias and confounding than are well-conducted randomized trials.

Emerging Issues

The increasing prevalence of dental caries in young children is an important emerging issue.[9] The reasons for this trend are not completely understood but could include changes in dietary patterns, access to dental care, demographics, or socioeconomic status.

Future Research

Research is needed to identify effective oral health educational and counseling interventions for parents and caregivers and guardians 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 clinicians of young children for dental care affects caries outcomes. Additional trials would strengthen conclusions regarding the effectiveness of dietary fluoride supplementation in young children, especially in the current U.S. context of exposure to multiple sources of fluoride, and trials are needed to demonstrate that results from trials of fluoride varnish applied by dental personnel can be reproduced in primary care settings.

Conclusions

Dietary fluoride supplementation and fluoride varnish appear to be effective at preventing caries outcomes in higher risk children younger than age 5 years. Dietary fluoride supplementation in early childhood is associated with risk of enamel fluorosis, which is usually mild. More research is needed to understand the accuracy of oral health examination and caries risk assessment by primary care clinicians, primary care referral for dental care, and effective parental or caregiver educational and counseling interventions.

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Figure 1. Analytic Framework

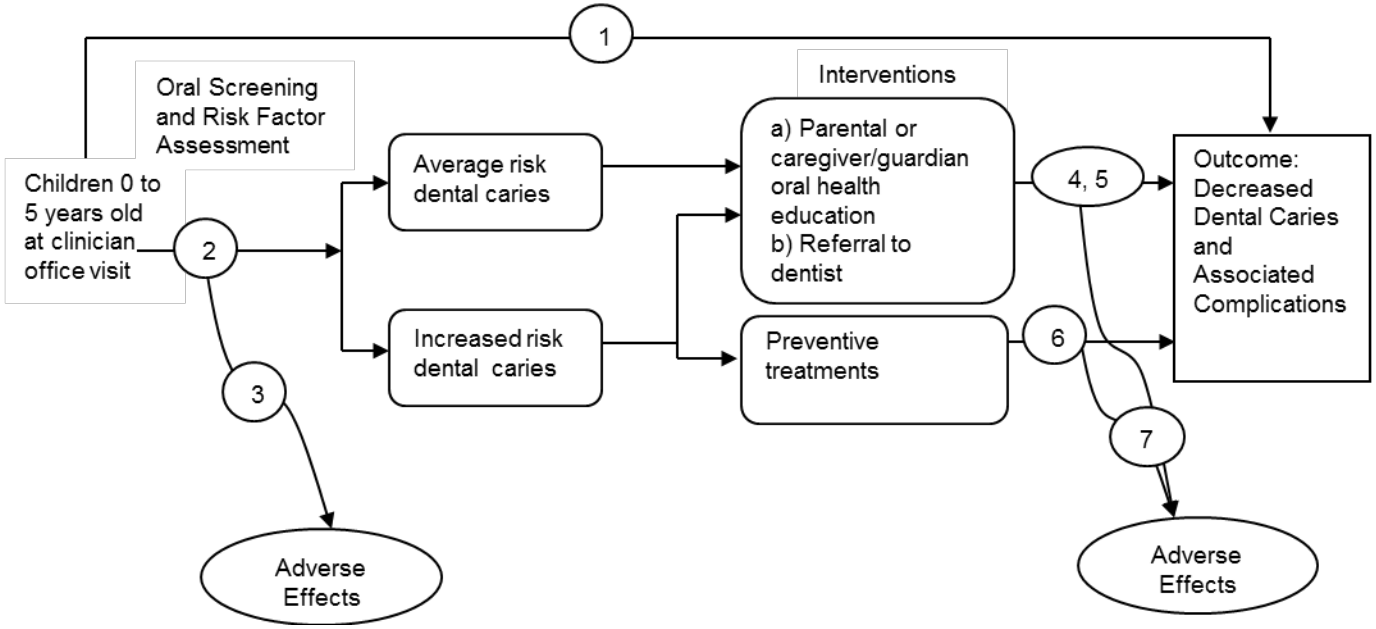

Table 1. Summary of Topical Fluoride Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Chu et al., 2002[69] Poor	Controlled clinical trial	A: Removal of carious tissue plus 38% silver diamine fluoride solution every 12 months B: 38% silver diamine fluoride solution every 12 months C: Removal of carious tissue plus 5% sodium fluoride varnish every 3 months D: 5% sodium fluoride varnish every 3 months E: Placebo (water)	China; Kindergarten; Water fluoridation status: <0.2 ppm	4 years	308	2.5	New caries surfaces: A: 0.26 B: 0.47 C: 0.89 D: 0.70 E: 1.58 p for ANOVA <0.001, E vs. others	A: 1.32 B: 1.11 C: 0.69 D: 0.88 E vs. others	A: 84% B: 70% C: 44% D: 56% E vs. others	Arrested caries surfaces: A: 2.49 B: 2.82 C: 1.45 D: 1.54 E: 1.27 p for ANOVA <0.001, E vs. others

Table 1. Summary of Topical Fluoride Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Jiang et al., 2005[70] Good	Cluster RCT (15 clusters)	A: 0.6-0.8 g of 1.23% acidulated phosphate fluoride foam applied every 6 months, max 4 applications B: Placebo foam	China; Kindergarten; Water fluoridation status: 0.1-0.3 ppm	3.5-3.6 years	318	2	dmfs A: 3.8 B: 5.0 p=0.03	1.2	24%	A vs. B No increase in dmfs: 38% (64/167) vs. 26% (40/151) dmfs Increase of 1 to 5: 34% (56/167) vs. 38% (58/151) dmfs Increase of 6 to 10: 17% (28/167) vs. 18% (27/151) dmfs Increase of >10: 11% (19/167) vs. 17% (26/151)

Table 1. Summary of Topical Fluoride Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Lawrence et al., 2008[47] Good	Cluster RCT (20 clusters)	A: 0.3-0.5 ml 5% sodium fluoride varnish applied to full primary dentition every 6 months B: No fluoride varnish	Canada; Rural Aboriginal communities; Water fluoridation status: No fluoridation	2.5 years	1146	2	dmfs A: 11.0 (4.3)* B: 13.4 (6.1)* p=0.24 (p=0.18)*	2.4 (1.8)*	18% (29%)*	A vs. B Dental caries in aboriginal cohort: 72% (595/832) vs. 75% (247/328), adjusted OR 0.72 (95% CI 0.42 to 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 to 1.1); NNT 7.4
Slade et al., 2011[48] Good	Cluster RCT (30 clusters)	A: 0.25 ml of 5% sodium fluoride varnish to maxillary anterior teeth/molars, mandibular molars/incisors every 6 months, education/advice to caregiver with toothbrush/paste provided, community oral health promotion program B: No interventions	Australia; Rural Aboriginal communities; Water fluoridation status: 81-92% had <0.6 ppm F	2.8 years	666	2	dmfs A: 7.3 B: 9.6[†] p<0.05	2.3	24%	

Table 1. Summary of Topical Fluoride Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Weinstein et al., 2001[71] Fair	RCT with 3 treatment groups	A: One application of 5% fluoride varnish at baseline and 6 months B: Three applications of 5% fluoride varnish within 2 weeks of baseline C: Three applications of 5% fluoride varnish within 2 weeks of baseline and 6 months	United States; Head Start programs; Water fluoridation status: NR	3-5 years	111	1	Clinical dmfs: A: 4.6 B: 3.2 C: 4.7 p=0.65 Radiographic mean dmfs: A: 0.9 B: 0.5 C: 0.1 p=0.28	Not calculated	Not calculated	
Weinstein et al., 2009[72] Fair	RCT with 2 treatment groups	A: One 5% fluoride varnish treatment and 2 placebo treatments every 6 months B: One set of three 5% fluoride varnish treatments over 2 weeks once per year and 3 placebo treatments over 2 weeks 6 months later	United States Recruitment setting: Head Start programs Water fluoridation status: NR (Yakima voters approved fluoridation in 1999)	55-56 months	515	3	dmfs A: 7.4 B: 9.8 p=0.001	2.4	24%	Adjusted rate ratio of new tooth decay in primary surfaces 1.13 (95% CI 0.94 to 1.37)

Table 1. Summary of Topical Fluoride Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Weintraub et al., 2006[49,] ‡ Fair	RCT	A: 0.1 mL of 5% sodium fluoride varnish per arch applied twice per year with 4 intended applications B: 0.1 mL of 5% sodium fluoride varnish per arch applied once per year with 2 intended applications C: No fluoride varnish	United States; Family dental center and public health center serving primarily low-income, underserved Hispanic and Chinese populations; Water fluoridation status: ~1 ppm	1.8 years	280	2	$d_{2+}fs$[§] A: 0.7 B: 0.7 C: 1.7 p<0.01 for A or B vs. C	1.0	59% (A + B vs. C)	A vs. B vs. C Caries lesions at 12 months: 13% (11/83) vs. 15% (13/86) vs. 29% (27/92); RR 0.45 (95% CI 0.24 to 0.85); NNT 7 for A vs. C and 0.52 (95% CI 0.28 to 0.93); NNT 8 for B vs. C Caries lesions at 24 months: 4.3% (3/70) vs. 14% (10/69) vs. 24% (15/63); RR 0.18 (95% CI 0.06 to 0.59); NNT 6 for A vs. C and 0.61 (95% CI 0.30 to 1.26); NNT 11 for B vs. C

*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 caries free at baseline.

Abbreviations: ANOVA = Analysis of Variance; CI = confidence interval; $d_{2+}fs$ = number of decayed or filled surfaces; dmfs = number of decayed, missing and filled surfaces; F = fluoride; g = gram; mL = milliliter; NNT = number needed to treat; NR = not reported; OR = odds ratio; ppm = parts per million; RCT = randomized controlled trial; RR = relative risk.

Table 2. Summary of Xylitol Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Alamoudi et al., 2012[74] Poor	RCT	A: Xylitol chewable tablets (1.2 g, 84% xylitol) chewed for 5 minutes 3 times daily B: Fluoride varnish every 6 months throughout study	Saudi Arabia Recruitment setting: Well baby clinics and dental clinics Water fluoridation status: NR	2 to 5 years	34	1.5	dmft A: 0.8 B: 4.4 p=not reported	3.6	82%	A vs. B dmft at baseline: 8.4 vs. 10.3 (p=0.19) dmft at 18 months: 9.2 vs. 14.7 (p=0.001)
Kovari et al., 2003[51,*] Fair	Cluster RCT (11 clusters)	A: 65% Xylitol gum 3 times per day, chewed for 3-5 minutes, for total of 2.5 g/day B: Tooth brushing with 0.05% NaF toothpaste after lunch	Finland Recruitment setting: Daycare centers Water fluoridation status: NR	3 to 6 years	786	3-6	NR	NR	NR	A vs. B Caries at 7 years old: 31% (98/316) vs. 35% (149/427), RR 0.88 (95% CI 0.72 to 1.10) Caries at 9 years old: 43% (133/310) vs. 51% (221/434), RR 0.84 (95% CI 0.72 to 0.99) dmft: 1.1 vs. 1.0 at 7 years, 1.2 vs. 1.6 at 9 years

Table 2. Summary of Xylitol Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Milgrom et al., 2009[73, *] Fair	RCT	A: Xylitol 8 g per day syrup, divided into 2 doses (4 g per dose) B: Xylitol 8 g per day syrup, divided into 3 doses (2.67 g per dose) C: Xylitol 2.67 g dose syrup, 1 dose per day	Marshall Islands Recruitment setting: Community based Water fluoridation status: Drinking water not fluoridated (supplemental and topical fluoride not available)	14 to 16 months	94	1	Number of decayed teeth A: 0.6 B: 1.0 C: 1.9 p<0.05 for A or B vs. C	A: 1.3 B: 0.9 vs. C	A: 68% B: 47% vs. C	A vs. B vs. C Tooth decay: 24.2% (8/33) vs. 40.6% (13/32) vs. 51.7% (15/29), RR 0.47 (95% CI 0.23 to 0.94) for A vs. C and 0.79 (95% CI 0.45 to 0.1.4) for B vs. C Incidence rates for decayed primary teeth per year: 0.66 vs. 1.10 vs. 2.20
Oscarson et al., 2006[52] Fair	RCT	A: One 0.48 g xylitol tablet at bedtime after brushing for 6 months; then 1 tablet twice daily to age 3 years and 6 months B: No tablets	Sweden Recruitment setting: Public dental clinic;] Water fluoridation status: Not reported	25 months	115	2	dmfs A: 0.38 B: 0.80 p>0.05	0.42	52%	A vs. B Dental caries: 18% (10/55) vs. 25% (16/63), OR 0.65 (95% CI 0.27 to 1.59)

Table 2. Summary of Xylitol Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Seki et al., 2011[53] Poor	Cluster, nonrandomized controlled clinical trial (3 clusters)	A: Xylitol chewing gum (100% xylitol, 1.33 g); 1 pellet chewed 5 minutes 4 times daily B: No intervention	Japan Recruitment setting: Preschool Water fluoridation status: NR (states fluoridation "limited" in Japan)	66-72% 4 years old	161	1	dfs A: 3.3 B: 3.4 p>0.05	0.1	3%	A vs. B Development of caries from baseline to 6 months: 1.7 vs. 1.6 (p>0.05) Development of caries from 6 months to 1 year: 1.6 vs. 1.8 (p>0.05)
Zhan et al., 2012[50] Fair	RCT	A: Xylitol wipes, 2 at a time, 3 times per day (estimated daily dosage 4.2 g) every 3 months B: Placebo wipes	United States. Recruitment setting: University pediatric clinic Water fluoridation status: Not reported	6-35 months	37	1	dmfs[†] A: 0.05 B: 0.53 p=0.01	0.48	91%	A vs. B New caries lesions at 1 year:[†] 5% vs. 40% (p=0.03); NNT 3 ITT analysis of new caries lesions at 1 year: 5% vs. 32%; RR 0.14 (95% CI 0.02 to 1.07); NNT 4

*****Baseline caries status not defined.
[†]Numbers based on per protocol analysis.

Abbreviations: CI = confidence interval; dfs = decayed and filled surfaces; dmfs = decayed, missing, and filled surfaces; dmft = decayed, missing, and filled teeth; g = grams; ITT = intention-to-treat; NaF = sodium fluoride; NNT = number needed to treat; NR = not reported; OR = odds ratio; RCT = randomized, controlled trial; RR = relative risk.

Table 3. Summary of Other Preventive Treatments

Author, Year, Quality	Study Design	Interventions	Country; Setting; Fluoridation Status	Age at Enrollment	Sample Size	Followup (Years)	Mean Caries Increment	Absolute Reduction in Caries Increment	Reduction in Caries Increment	Other Dental Caries Outcomes
Du et al., 2006[54] Fair	Cluster RCT (14 clusters)	A: 40% w/w chlorhexidine acetate varnish every 6 months B: Placebo varnish	China Kindergartens in rural communities; Water fluoridation status: 0.1-0.3 ppm	4-5 years	290	2	dmfs-molar: A: 1.0 B: 1.6 p=0.036	0.6	37%	
Lopez et al., 2002[55] Fair	RCT	A: 0.2 ml of 10% povidone-iodine solution every 2 months B: Placebo solution	United States Women, infants, and children clinic in Puerto Rico; Water fluoridation status: NR	16 months	83	1	NR	NR	NR	A vs. B* White spot lesions - maxillary primary incisors: 8% (3/39) vs. 32% (14/44); RR 0.24 (95% CI 0.1 to 0.8)

*Participants were caries free at baseline.

Abbreviations: CI = confidence interval; dmfs = decayed, missing, filled surfaces; mL = milliliter; NR = not reported; ppm = parts per million; RCT = randomized, controlled trial; RR = relative risk; w/w = weight/weight.

Table 4. Summary of Evidence

Main Findings From 2004 USPSTF Review	Number and Type of Studies Identified for Update *Overall Quality**	Limitations	Consistency	Applicability	Summary of Findings
Key Question 1. How effective is oral screening (including risk assessment) by the primary care clinician in preventing dental caries in children younger than age 5 years?					
No evidence	No studies	No studies	No studies	No studies	No randomized trial or observational study compared clinical outcomes between children younger than 5 years of age screened and not screened by primary care clinicians.
Key Question 2a. How accurate is screening by the primary care clinician in identifying children younger than age 5 years who have cavitated or noncavitated caries lesions?					
One study found pediatrician examination following 4 hours of oral health education associated with a sensitivity of 1.0 and specificity of 0.87 for identifying nursing caries in children 18-36 months of age.	1 cohort study *Overall quality: Fair*	Evidence limited to 1 study	N/A	Study conducted in a primary care setting	One study found primary care pediatrician examination following 2 hours of oral health education associated with a sensitivity of 0.76 for identifying a child with 1 or more cavities and 0.63 for identifying children <36 months of age in need of a dental referral, compared with a pediatric dentist evaluation.
Key Question 2b. How accurate is screening by the primary care clinician in identifying children younger than age 5 years who are at increased risk for future dental caries?					
No evidence	No studies	No studies	No studies	No studies	No study evaluated the accuracy of risk-assessment tools applied by primary care clinicians to identify children at increased risk for future dental caries.
Key Question 3. What are the harms of oral health screening by the primary care clinician?					
No evidence	No studies	No studies	No studies	No studies	No randomized trial or observational study compared harms between children younger than 5 years of age screened and not screened by primary care clinicians.

Table 4. Summary of Evidence

Main Findings From 2004 USPSTF Review	Number and Type of Studies Identified for Update *Overall Quality**	Limitations	Consistency	Applicability	Summary of Findings
Key Question 4. How effective is parental or caregiver oral health education by the primary care clinician in preventing dental caries in children younger than age 5 years?					
No evidence	1 randomized trial, 1 nonrandomized trial *Overall quality: Poor*	Nonrandomized design, high attrition, failure to adjust for confounders	Moderate inconsistency	Education evaluated as part of a multifactorial intervention	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 younger than 5 years of age.
Key Question 5. How effective is referral by a primary care clinician to a dentist in preventing dental caries in children younger than age 5 years?					
No evidence	1 cohort study *Overall quality: Poor*	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 months of age in children with existing dental disease associated with increased risk of subsequent dental procedures compared with a first visit before 18 months 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 younger than age 5 years?					
Six trials of dietary fluoride supplements. One randomized trial and 4 other trials found oral fluoride supplementation in settings with water fluoridation levels below 0.6 ppm F associated with decreased caries incidence vs. no fluoridation (ranges of 48-72% for primary teeth and 51- 81% for primary tooth surface).	No studies *Overall quality: Fair*	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 younger than 5 years of age on dental caries incidence.

Table 4. Summary of Evidence

Main Findings From 2004 USPSTF Review	Number and Type of Studies Identified for Update *Overall Quality**	Limitations	Consistency	Applicability	Summary of Findings
Key Question 6. How effective is preventive treatment with *topical fluoride* application (fluoride varnish) in preventing dental caries in children younger than age 5 years?					
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).	6 randomized trials, 1 trial using alternate allocation *Overall quality: Fair*	High loss to followup, 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 prior 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.
Key Question 6. How effective is preventive treatment with *xylitol* in preventing dental caries in children younger than 5 years of age?					
No studies (not included in the prior review).	5 randomized trials; 1 nonrandomized *Overall quality: Fair*	Variability in xylitol formulation and dosing	Some inconsistency	Children from settings in which water was not fluoridated or fluoridation limited	Three trials reported no clear effects of xylitol vs. no xylitol on caries incidence in children younger than 5 years, with the most promising results from a small (n=37) trial of xylitol wipes. One trial found no difference between xylitol and toothbrushing.
Key Question 7. What are the harms of specific oral health interventions for prevention of dental caries in children younger than 5 years of age (parental or caregiver oral health education, referral to a dentist, and preventive treatments)?					
One systematic review of 14 observational studies found dietary fluoride supplementation in early childhood associated with increased risk of fluorosis; odd ratios ranged from 1.3-15.6 and prevalence ranged from 10-67%.	5 observational studies in an updated systematic review *Overall quality: Fair*	Use of retrospective parental recall to determine exposures	Consistent	Doses of fluoride generally higher than currently recommended	Five observational studies in an updated systemic 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 trials of caries prevention interventions in children younger than 5 years of age.

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

Abbreviations: USPSTF = U.S. Preventive Services Task Force.

Appendix A1. Search Strategies

Database: Ovid MEDLINE® without Revisions <1999 to March 8, 2013>
Search Strategy:
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1 exp physicians/
2 exp pediatrics/ or pediatrician$.mp.
3 exp nurse practitioners/
4 exp nurse's aides/
5 exp physician assistants/
6 exp nurse clinicians/
7 nurses/
8 Primary care physician$.mp.
9 General practitioner$.mp.
10 Primary care clinician$.mp.
11 exp ambulatory care facilities/
12 exp primary health care/
13 exp physician's role/
14 exp physician's practice patterns/
15 exp mass screening/
16 exp health behavior/
17 exp health promotion/
18 exp infant welfare/
19 exp health services accessibility/
20 exp child health services/
21 exp "referral and consultation"/
22 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23 limit 22 to (english language and humans)
24 limit 23 to (clinical trial or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or evaluation studies or meta analysis or multicenter study or randomized controlled trial or technical report or validation studies)
25 exp epidemiologic study characteristics/
26 exp epidemiologic research design/
27 exp questionnaires/
28 (25 or 26 or 27) and 23
29 24 or 28
30 exp dental caries/
31 Dental screening.mp. or exp dental care for children/
32 dental care/ or dental examination.mp. or exp diagnosis, oral/
33 30 or 31 or 32
34 29 and 33
35 limit 34 to (infant <1 to 23 months> or preschool child <2 to 5 years>)

Appendix A1. Search Strategies

Database: Ovid MEDLINE® without Revisions <1999 to March 8, 2013>
Search Strategy:
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1 exp physicians/
2 exp pediatrics/ or pediatrician$.mp.
3 exp nurse practitioners/
4 exp nurse's aides/
5 exp physician assistants/
6 exp nurse clinicians/
7 nurses/
8 Primary care physician$.mp.
9 General practitioner$.mp.
10 Primary care clinician$.mp.
11 exp ambulatory care facilities/
12 exp primary health care/
13 exp physician's role/
14 exp physician's practice patterns/
15 exp mass screening/
16 exp health behavior/
17 exp health promotion/
18 exp infant welfare/
19 exp health services accessibility/
20 exp child health services/
21 exp "referral and consultation"/
22 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23 limit 22 to (english language and humans)
24 limit 23 to (clinical trial or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or evaluation studies or meta analysis or multicenter study or randomized controlled trial or technical report or validation studies)
25 exp epidemiologic study characteristics/
26 exp epidemiologic research design/
27 exp questionnaires/
28 (25 or 26 or 27) and 23
29 24 or 28
30 exp MOTHERS/
31 exp PARENTS/
32 30 or 31
33 exp dental health services/ or dental utilization.mp. or exp dental care/
34 29 and 33
35 limit 34 to (infant <1 to 23 months> or preschool child <2 to 5 years>)

Appendix A1. Search Strategies

Database: Ovid MEDLINE® without Revisions <1999 to March 8, 2013>
Search Strategy:
---

1 exp physicians/
2 exp pediatrics/ or pediatrician$.mp.
3 exp nurse practitioners/
4 exp nurse's aides/
5 exp physician assistants/
6 exp nurse clinicians/
7 nurses/
8 Primary care physician$.mp.
9 General practitioner$.mp.
10 Primary care clinician$.mp.
11 exp ambulatory care facilities/
12 exp primary health care/
13 exp physician's role/
14 exp physician's practice patterns/
15 exp mass screening/
16 exp health behavior/
17 exp health promotion/
18 exp infant welfare/
19 exp health services accessibility/
20 exp child health services/
21 exp "referral and consultation"/
22 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23 limit 22 to (english language and humans)
24 limit 23 to (clinical trial or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or evaluation studies or meta analysis or multicenter study or randomized controlled trial or technical report or validation studies)
25 exp epidemiologic study characteristics/
26 exp epidemiologic research design/
27 exp questionnaires/
28 (25 or 26 or 27) and 23
29 24 or 28
30 exp mothers/
31 exp parents/
32 30 or 31
33 exp fluorides, topical/
34 exp fluorides/
35 exp cariostatic agents/
36 Supplemental fluoride$.mp.
37 Fluoride tab$.mp.
38 Fluoride drop$.mp.

39 Fluoride varnish$.mp.
40 33 or 34 or 35 or 36 or 37 or 38 or 39
41 29 and 40
42 limit 41 to (newborn infant <birth to 1 month> or infant <1 to 23 months> or preschool child <2 to 5 years>)

Database: Ovid MEDLINE® without Revisions <1999 to March 8, 2013>
Search Strategy:
---
1 exp physicians/
2 exp pediatrics/ or pediatrician$.mp.
3 exp nurse practitioners/
4 exp nurse's aides/
5 exp physician assistants/
6 exp nurse clinicians/
7 nurses/
8 Primary care physician$.mp.
9 General practitioner$.mp.
10 Primary care clinician$.mp.
11 exp ambulatory care facilities/
12 exp primary health care/
13 exp physician's role/
14 exp physician's practice patterns/
15 exp mass screening/
16 exp health behavior/
17 exp health promotion/
18 exp infant welfare/
19 exp health services accessibility/
20 exp child health services/
21 exp "referral and consultation"/
22 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23 limit 22 to (english language and humans)
24 limit 23 to (clinical trial or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or evaluation studies or meta analysis or multicenter study or randomized controlled trial or technical report or validation studies)
25 exp epidemiologic study characteristics/
26 exp epidemiologic research design/
27 exp questionnaires/
28 (25 or 26 or 27) and 23
29 24 or 28
30 exp MOTHERS/
31 exp PARENTS/
32 30 or 31
33 exp dental care for children/

34 exp dental caries/
35 exp oral hygiene/
36 exp oral health/
37 exp health education, dental/
38 exp diet, cariogenic/
39 exp dental care/
40 33 or 34 or 35 or 36 or 37 or 38 or 39
41 29 and 40
42 limit 41 to (infant <1 to 23 months> or preschool child <2 to 5 years>)

Database: Ovid MEDLINE® and Ovid OLDMEDLINE® <1946 to March 8, 2013>
Search Strategy:
---
1 exp "Pit and Fissure Sealants"/
2 exp Dental Caries/
3 exp fluorosis, dental/
4 2 or 3
5 1 and 2
6 limit 5 to "all child (0 to 18 years)"
7 ((tooth or teeth or pit or pits or fissur$) adj5 seal$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
8 2 and 7
9 limit 8 to "all child (0 to 18 years)"
10 ((tooth or teeth or enamel$ or crown or root or dental$ or molar$ or incisor$ or bicuspid$ or canine$ or premolar$) adj5 (decay$ or carie$ or fluorosis)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
11 1 and 10
12 limit 11 to "all child (0 to 18 years)"
13 6 or 9 or 12
14 (201206$ or 201207$ or 201208$ or 201209$ or 20121$).ed.
15 13 and 14
16 exp Tooth Demineralization/
17 ((tooth or teeth or root$ or crown$ or dental$ or dentist$) adj5 (caries or cario$ or decay$ or cavit$ or fluorosis)).mp.
18 16 or 17
19 xylitol.mp.
20 18 and 19
21 limit 20 to "all child (0 to 18 years)"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2013>
Search Strategy:
---
1 (physician$ or pediatrician$ or general practi$ or primary care or primary health care or nurse or nurses or (nurs$ adj3 (care or caring or cared or cares)) or screen$ or (health$ adj3

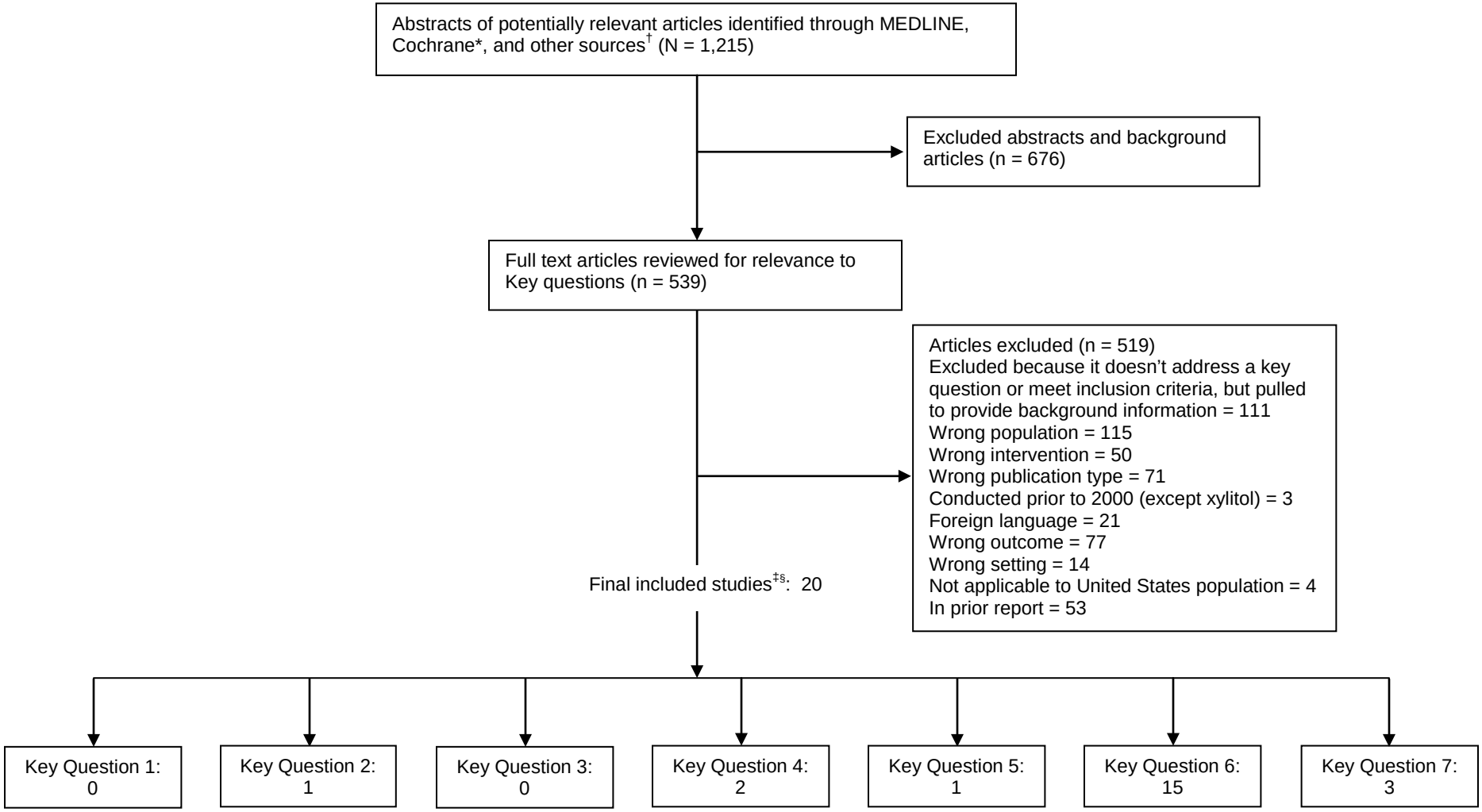
(behav$ or promot$ or access$)) or referral$ or consult$ or counsel$ or parent$ or mother$ or father$ or guardian$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (62097)
2 ((dental$ or tooth or teeth$) adj7 (caries or decay$ or fluorid$ or xylitol or sealant$ or sealing or cariostat$ or fluorosis) adj10 (child$ or pediatric$ or infant$ or infancy or toddler$)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (968)
3 ((dental or dentist$ or oral) adj7 (screen$ or fluorid$ or checkup$ or (check$ adj up) or exam or exams or examine$ or examination$) adj10 (child$ or pediatric$ or infant$ or infancy or toddler$)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (343)
4 ((dental or dentist$ or oral) adj3 (hygien$ or health$ or prophyla$) adj10 (child$ or pediatric$ or infant$ or infancy or toddler$)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (384)
5 2 or 3 or 4 (1263)
6 1 and 5 (239)

Database: EBM Reviews - Cochrane Database of Systematic Reviews <1999 to February 2013>
Search Strategy:
---
1 (physician$ or pediatrician$ or general practi$ or primary care or primary health care or nurse or nurses or (nurs$ adj3 (care or caring or cared or cares)) or screen$ or (health$ adj3 (behav$ or promot$ or access$)) or referral$ or consult$ or counsel$ or parent$ or mother$ or father$ or guardian$).mp. [mp=title, abstract, full text, keywords, caption text] (6578)
2 ((dental$ or tooth or teeth$) adj7 (caries or decay$ or fluorid$ or xylitol or sealant$ or sealing or cariostat$ or fluorosis) adj10 (child$ or pediatric$ or infant$ or infancy or toddler$)).mp. [mp=title, abstract, full text, keywords, caption text] (43)
3 ((dental or dentist$ or oral) adj7 (screen$ or fluorid$ or checkup$ or (check$ adj up) or exam or exams or examine$ or examination$) adj10 (child$ or pediatric$ or infant$ or infancy or toddler$)).mp. [mp=title, abstract, full text, keywords, caption text] (39)
4 ((dental or dentist$ or oral) adj3 (hygien$ or health$ or prophyla$) adj10 (child$ or pediatric$ or infant$ or infancy or toddler$)).mp. [mp=title, abstract, full text, keywords, caption text] (47)
5 2 or 3 or 4 (78)
6 1 and 5 (75)

Appendix A2. Inclusion and Exclusion Criteria

	Include	Exclude
Population	All key questions: Asymptomatic children less than 5 years of age	All key questions Animal studies, adults, children older than preschool age (>5 years), symptomatic
Interventions	Key questions 1-3: Oral screening and risk factor assessment performed by primary care clinicians Key questions 4 and 5: Parent/caregiver oral health education and/or referral to dentist Key questions 6 and 7: Preventive treatments: including oral fluoride supplementation, topical fluoride application, or xylitol	Key questions 1-3: Community or school-based interventions Key questions 4 and 5: Interventions not performed in primary care settings Key questions 6 and 7: Treatments not available for preschool children or not available in the United States
Outcomes	All key questions: Reduced dental caries and associated outcomes Key questions 2 and 3: Diagnostic accuracy and measures of risk prediction Key question 7: Dental fluorosis, emotional stress, acute toxicity, and other associated complications	All key questions Cost-effectiveness
Study types and designs	Key questions 1, 4, 5, and 6: Randomized controlled trials, non-randomized controlled clinical trials, and cohort studies Key question 2: Studies of diagnostic accuracy or risk prediction Key questions 3 and 7: Randomized controlled trials, cohort studies, case-control studies, and systematic reviews	Key questions 1, 2, 4, 5, and 6: Case-control studies, uncontrolled intervention studies All key questions: Opinion, editorials, or case reports

Appendix A3. 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, etc.
‡Studies that provided data and contributed to the body of evidence were considered "included."
§Studies may have provided data for more than one key question.

Appendix A4. Excluded Studies List

Key to exclusion codes

2	Excluded because it doesn't address a key question or meet inclusion criteria, but pulled to provide background information
3	Wrong population
4	Wrong intervention
5	Wrong publication type
6	Conducted prior to 2000 (except xylitol)
7	Foreign language, otherwise included
8	Wrong outcome
9	Wrong setting
10	Not applicable to United States population
11	In prior report

List of excluded studies

Diet, nutrition, and oral health: a rational approach for the dental practice. *J Am Dent Assoc.* 1984;109(1):20-32, [PMID: 6589288]
Exclusion code: 5

NIH Consensus Development Conference on Diagnosis and Management of Dental Caries Throughout Life. Bethesda, MD, March 26-28, 2001. Conference Papers. *J Dent Educ.* 2001;65(10):935-1179., [PMID: 11706839]
Exclusion code: 11

The endless learning curve: 2005 Table Clinic winners. *Northwest Dent.* 2005;84(3):23-27, [PMID: 16044850]
Exclusion code: 2

Xylitol-containing oral syrup may prevent caries in children. *J Am Dent Assoc.* 2009;140(8):972, [PMID: 19654247]
Exclusion code: 5

Aaltonen AS, Suhonen JT, Tenovuo J, Inkila-Saari I. Efficacy of a slow-release device containing fluoride, xylitol and sorbitol in preventing infant caries. *Acta Odontol Scand.* 2000;58(6):285-292, [PMID: 11196405]
Exclusion code: 4

Aasenden R, DePaola PF, Brudevold F. Effects of daily rinsing and ingestion of fluoride solutions upon dental caries and enamel fluoride. *Archives of Oral Biology.* 1972;17(12):1705-1714, [PMID: 4405216]
Exclusion code: 3

Ad Hoc Committee on Fluoride, Committee to Coordinate Environmental Health and Related Programs. Review of Fluoride: Benefits and Risks. Washington, DC: US Department of Health and Human Services; 1991: http://health.gov/environment/ReviewofFluoride/. Exclusion code: 11

Appendix A4. Excluded Studies List

Adair PM, Pine CM, Burnside G, et al. Familial and cultural perceptions and beliefs of oral hygiene and dietary practices among ethnically and socio-economically diverse groups. *Community Dent Health.* 2004;21(1 Suppl):102-111, [PMID: 15072479]
Exclusion code: 4

Adams SH, Hyde S, Gansky SA. Caregiver acceptability and preferences for early childhood caries preventive treatments for Hispanic children. *J Public Health Dent.* 2009;69(4):217-224, [PMID: 19486461]
Exclusion code: 8

Agency for Healthcare Research and Quality. Medical Expenditure Panel Survey. 2011; http://meps.ahrq.gov/data_stats/download_data_files_detail.jsp?cboPufNumber=HC-126B. Accessed 27 March, 2013
Exclusion code: 2

Akerblom HK, Koivukangas T, Puukka R, Mononen M. The tolerance of increasing amounts of dietary xylitol in children. *International journal for vitamin and nutrition research. Supplement.* 1982;22:53-66, [PMID: 6802776]
Exclusion code: 3

Al Ghanim NA, Adenubi JO, Wyne AA, Khan NB. Caries prediction model in pre-school children in Riyadh, Saudi Arabia. *Int J Paediatr Dent.* 1998;8(2):115-122, [PMID: 9728096]
Exclusion code: 8

Alaluusua S, Malmivirta R. Early plaque accumulation – a sign for caries risk in young children. *Comm Dent Oral Epidemiol* 1994;22:273-276, [PMID: 7813174]
Exclusion code: 8

Alanen P, Holsti ML, Pienihakkinen K. Sealants and xylitol chewing gum are equal in caries prevention. *Acta Odontol Scand.* 2000;58(6):279-284, [PMID: 11196404]
Exclusion code: 3

Alanen P, Isokangas P, Gutmann K. Xylitol candies in caries prevention: results of a field study in Estonian children. *Community Dent Oral Epidemiol.* 2000;28(3):218-224, [PMID: 10830649]
Exclusion code: 3

Alonge OK, Williamson DD, Narendran S. Dental fluorosis among third graders in Harris County, Texas--1998 study findings. *Texas dental journal.* 2000;117(9):22-29, [PMID: 11857845]
Exclusion code: 3

American Academy of Family Physicians. Fluoridation of public water supplies. *Policies* 2008; http://www.aafp.org/online/en/home/policy/policies/f/fluoridationofpublicwatersupplies.html. Accessed 12 January, 2013
Exclusion code: 2

American Academy of Pediatric Dentistry. Caries risk assessment for infants, children, and adolescents. *Pediatr Dent.* 2011;33:110-117.
Exclusion code: 2

American Academy of Pediatric Dentistry. Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents. *American Academy of Pediatric Dentistry Reference Manual.* 2011;32(6):101-108.
Exclusion code: 2

Appendix A4. Excluded Studies List

American Academy of Pediatric Dentistry. Guideline on fluoride therapy. *AAPD 2012-2013 Clinical Guidelines.* 2012;34(6). http://www.aapd.org/media/Policies_Guidelines/G_FluorideTherapy.pdf.
Exclusion code: 11

American Academy of Pediatric Dentistry. Guideline on Xylitol Use in Caries Prevention. *American Academy of Pediatric Dentistry Reference Manual.* 2012/2013;34(6):166-169.
Exclusion code: 2

American Academy of Pediatric Dentistry. *Guideline on Fluoride Therapy.* 2012/2013.
Exclusion code: 2

American Academy of Pediatric Dentistry. Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents. *American Academy of Pediatric Dentistry Reference Manual.* 2012/2013;34(6):118-125.
Exclusion code: 2

American Academy of Pediatrics. Policy Statement - AAP Publications Retired and Reaffirmed. *Policy Statement* http://pediatrics.aappublications.org/content/124/2/845.full. Accessed 12 January, 2013
Exclusion code: 2

American Academy of Pediatrics. *Oral health risk assessment timing and establishment of the dental home.* 2003
Exclusion code: 2

American Academy of Pediatrics. *Profile of pediatric visits: Annualized estimates 2000-2004.* Elk Grove Village, Illinois 2007
Exclusion code: 2

American Academy of Pediatrics. *Recommendations for Preventive Pediatric Health Care.* 2008.
Exclusion code: 2

American Academy of Pediatrics. Preventive oral health intervention for pediatricians: Section on pediatric dentistry and oral health. *Pediatrics.* 2008;122(6):1387-1394, [PMID: 19015205]
Exclusion code: 2

American Academy of Pediatrics. Oral Health Risk Assessment Tool. 2011. http://www2.aap.org/oralhealth/docs/RiskAssessmentTool.pdf. Accessed 13 Dec 2012
Exclusion code: 2

American Academy on Pediatric Dentistry Council on Clinical Affairs. Policy on use of a caries-risk assessment tool (CAT) in infants, children, and adolescents. *Pediatr Dent.* 2002;24(Suppl):15-17.
Exclusion code: 5

American Academy on Pediatric Dentistry Council on Clinical Affairs. Policy on Use of a Caries-risk Assessment Tool (CAT) for Infants, Children and Adolescents. *Pediatr Dent.* 2006;31(6).
Exclusion code: 2

American Academy on Pediatric Dentistry Council on Clinical Affairs. Policy on the use of xylitol in caries prevention. *Pediatr Dent.* 2008;30(7 Suppl):36-37, [PMID: 19216379]
Exclusion code: 2

American Academy on Pediatric Dentistry Council on Clinical Affairs. Policy on use of a caries-risk assessment tool (CAT) for infants, children, and adolescents. *Pediatr Dent.* 2008;30(7 Suppl):29-33, [PMID: 19216377]
Exclusion code: 2

Appendix A4. Excluded Studies List

American Dental Association. Statement on Early Childhood Caries. 2000; http://www.ada.org/2057.aspx. Accessed 13 Dec, 2012
Exclusion code: 2

American Dental Association. ADA Caries Risk Assessment Forms. 2009; http://www.ada.org/5157.aspx?currentTab=2. Accessed 23 Oct 2012.
Exclusion code: 2

American Dental Association. Caries Risk Assessment Form (Age 0-6). 2011; http://www.ada.org/sections/professionalResources/pdfs/topics_caries_under6.pdf. Accessed 27 March, 2013
Exclusion code: 2

American Dental Association Council on Scientific Affairs. Professionally applied topical flouride: Evidence-based clinical recommendations. *J Dent Educ.* 2007;71(3):393-402, [PMID: 17389574]
Exclusion code: 2

Ammari AB, Bloch-Zupan A, Ashley PF. Systematic review of studies comparing the anti-caries efficacy of children's toothpaste containing 600 ppm of fluoride or less with high fluoride toothpastes of 1,000 ppm or above. *Caries Res.* 2003;37(2):85-92, [PMID: 12652045]
Exclusion code: 3

Ananaba N, Malcheff S, Briskie D, Inglehart MR. Infant oral health examinations: attitudes and professional behavior of general and pediatric dentists in Michigan and pediatric dentists in the U.S. *J Mich Dent Assoc.* 2010;92(12):38-43, [PMID: 21291093]
Exclusion code: 2

Andruskeviciene V, Milciuviene S, Bendoraitiene E, et al. Oral health status and effectiveness of caries prevention programme in kindergartens in Kaunas city (Lithuania). *Oral health prev.* 2008;6(4):343-348, [PMID: 19178101]
Exclusion code: 4

Ansai T, Yamashita Y, Shibata Y, et al. Relationship between dental caries experience of a group of Japanese kindergarten children and the results of two caries activity tests conducted on their saliva and dental plaque. *International journal of paediatric dentistry / the British Paedodontic Society [and] the International Association of Dentistry for Children.* 1994;4(1):13-17, [PMID: 7748842]
Exclusion code: 8

Anttonen V, Larmas M, Raitio M. Children were guaranteed regular check ups in dental study. *BMJ.* 1999;319(7222):1432, [PMID: 10574873]
Exclusion code: 5

Armfield JM. Community effectiveness of public water fluoridation in reducing children's dental disease. *Public Health Rep.* 2010;125(5):655-664, [PMID: 20873281]
Exclusion code: 4

Arora A, Scott JA, Bhole S, Do L, Schwarz E, Blinkhorn AS. Early childhood feeding practices and dental caries in preschool children: a multi-centre birth cohort study. *BMC Public Health.* 2011;11:28, [PMID: 21223601]
Exclusion code: 5

Appendix A4. Excluded Studies List

Arruda AO, Senthamarai Kannan R, Inglehart MR, Rezende CT, Sohn W. Effect of 5% fluoride varnish application on caries among school children in rural Brazil: A randomized controlled trial. *Community Dentistry and Oral Epidemiology.* 2012;40(3):267-276, [PMID: 22150341]
Exclusion code: 3

Assael LA. Should dentists become 'oral physicians'? No, dentistry must remain dentistry. *J Am Dent Assoc.* 2004;135(4):439+441+443+445+447-449, [PMID: 15127866]
Exclusion code: 5

Autio JT. Effect of xylitol chewing gum on salivary Streptococcus mutans in preschool children. *J Dent Child.* 2002;69(1):81-86, 13, [PMID: 12119821]
Exclusion code: 8

Autio JT, Courts FJ. Acceptance of the xylitol chewing gum regimen by preschool children and teachers in a Head Start program: a pilot study. *Pediatr Dent.* 2001;23(1):71-74, [PMID: 11242737]
Exclusion code: 8

Autio-Gold J. Recommendations for fluoride varnish use in caries management. *Dent Today.* 2008;27(1):64-67; quiz 67, 58, [PMID: 18240633]
Exclusion code: 2

Autio-Gold JT, Courts F. Assessing the effect of fluoride varnish on early enamel carious lesions in the primary dentition. *J Am Dent Assoc.* 2001;132(9):1247-1253, [PMID: 1665349]
Exclusion code: 11

Azarpazhooh A, Limeback H, Lawrence HP, Shah PS. Xylitol for preventing acute otitis media in children up to 12 years of age. *Cochrane Database Syst Rev.* 2011(11):CD007095, [PMID: 22071833]
Exclusion code: 8

Baca P, Muñoz MJ, Bravo M, Junco P, Baca AP. Effectiveness of chlorhexidine-thymol varnish in preventing caries lesions in primary molars. *J Dent Child.* 2004;71(1):61-65, [PMID: 15272659]
Exclusion code: 3

Bader JD, Rozier RG, Lohr KN, Frame PS. Physicians' roles in preventing dental caries in preschool children: a summary of the evidence for the U.S. Preventive Services Task Force. *Am J Prev Med.* 2004;26(4):315-325, [PMID: 15110059]
Exclusion code: 2

Bader JD, Shugars DA, Bonito AJ. Systematic reviews of selected dental caries diagnostic and management methods. *J Dent Educ.* 2001;65(10):960-968, [PMID: 11699997]
Exclusion code: 5

Badet MC, Richard B, Dorignac G. An in vitro study of the pH-lowering potential of salivary lactobacilli associated with dental caries. *J Appl Microbiol.* 2001;90(6):1015-1018, [PMID: 11412333]
Exclusion code: 8

Balaban R, Aguiar CM, Da Silva Araújo AC, Dias Filho EBR. Knowledge of paediatricians regarding child oral health. *Int J Paediatr Dent.* 2012;22(4):286-291, [PMID: 22092596]
Exclusion code: 3

Appendix A4. Excluded Studies List

Baldani MH, Antunes JLF. Inequalities in access and utilization of dental services: a cross-sectional study in an area covered by the Family Health Strategy. *Cad Saude Publica.* 2011;27 Suppl 2:S272-283, [PMID: 21789419]
Exclusion code: 2

Baldani MH, Mendes YBE, Lawder JAdC, de Lara API, Rodrigues MMAdS, Antunes JLF. Inequalities in dental services utilization among Brazilian low-income children: the role of individual determinants. *J Public Health Dent.* 2011;71(1):46-53, [PMID: 21667543]
Exclusion code: 2

Banoczy J, Scheinin A, Esztari I, Szoke J, Hadas E, Zimmermann P. [Caries-preventing action of xylitol-containing sweets, studied in children's institutions]. *Orv Hetil.* 1985;126(40):2447-2451, [PMID: 4047645]
Exclusion code: 7

Banoczy J, Scheinin A, Esztari I, et al. [3-year results of a WHO-supported caries-prevention program, using xylitol, in Hungarian children's homes. I. Clinical caries studies]. *Fogorv Sz.* 1985;78(11):329-338, [PMID: 3914420]
Exclusion code: 7

Bär A. Caries prevention with xylitol. A review of the scientific evidence. *World review of nutrition and dietetics.* 1988;55:183-209, [PMID: 3287773]
Exclusion code: 5

Barber LR, Wilkins EM. Evidence-based prevention, management, and monitoring of dental caries. *J Dent Hyg.* 2002;76(4):270-275, [PMID: 12592918]
Exclusion code: 2

Barmes D, Barnaud J, Khambonanda S, Infirri JS. Field trials of preventive regimens in Thailand and French Polynesia. *Int Dent J.* 1985;35(1):66-72, [PMID: 3888852]
Exclusion code: 3

Bawden JW. Fluoride varnish: a useful new tool for public health dentistry. *J Public Health Dent.* 1998;58(4):266-269, [PMID: 10390707]
Exclusion code: 2

Beil H, Mayer M, Rozier RG. Dental care utilization and expenditures in children with special health care needs. *J Am Dent Assoc.* 2009;140(9):1147-1155, [PMID: 19723949]
Exclusion code: 3

Beil HA, Rozier RG. Primary health care providers' advice for a dental checkup and dental use in children. *Pediatrics.* 2010;126(2):e435-441, [PMID: 20660547]
Exclusion code: 8

Bell JF, Huebner CE, Reed SC. Oral health need and access to dental services: evidence from the National Survey of Children's Health, 2007. *Maternal and Child Health Journal.* 2012;16 Suppl 1:S27-34, [PMID: 22456986]
Exclusion code: 2

Beltrán ED, Malvitz DM, Eklund SA. Validity of two methods for assessing oral health status of populations. *J Public Health Dent.* 1997;57(4):206-214, [PMID: 9558624]
Exclusion code: 6

Appendix A4. Excluded Studies List

Beltran-Aguilar D, Barker LK, Dye BA. *Prevalence and severity of dental fluorosis in the United States, 1999-2004. National Center for Health Statistics Data Brief.* Hyattsville, MD. 2010.
Exclusion code: 2

Beltran-Aguilar ED, Barker LK, Canto MT, et al. Surveillance for dental caries, dental sealants, tooth retention, edentulism, and enamel fluorosis--United States, 1988-1994 and 1999-2002. *MMWR Surveill Summ.* 2005;54(3):1-43, [PMID: 16121123]
Exclusion code: 4

Beltran-Aguilar ED, Goldstein JW, Lockwood SA. Fluoride varnishes. A review of their clinical use, cariostatic mechanism, efficacy and safety. *J Am Dent Assoc.* 2000;131(5):589-596, [PMID: 10832252]
Exclusion code: 11

Beltran-Aguilar ED, Griffin SO, Lockwood SA. Prevalence and trends in enamel fluorosis in the United States from the 1930s to the 1980s. *J Am Dent Assoc.* 2002;133(2):157-165, [PMID: 11868834]
Exclusion code: 11

Beltrán-Valladares PR, Cocom-Tun H, Casanova-Rosado JF, Vallejos-Sánchez AA, Medina-Solís CE, Maupomé G. Prevalence of dental fluorosis and additional sources of exposure to fluoride as risk factors to dental fluorosis in schoolchildren of Campeche, Mexico. *Rev Invest Clin.* 2005;57(4):532-539, [PMID: 16315637]
Exclusion code: 7

Bentley EM, Holloway PJ. An evaluation of the role of health visitors in encouraging dental attendance of infants. *Community Dent Health.* 1993;10(3):243-249., [PMID: 8269339]
Exclusion code: 11

Berg JH. Early dental caries detection as a part of oral health maintenance in young children. *Compend Contin Educ Dent.* 2005;26(5 Suppl 1):24-29, [PMID: 17036541]
Exclusion code: 5

Binkley CJ, Garrett B, Johnson KW. Increasing dental care utilization by Medicaid-eligible children: A dental care coordinator intervention. *J Public Health Dent.* 2010;70(1):76-84, [PMID: 19765202]
Exclusion code: 2

Blackwell DL, Tonthat L. Summary health statistics for U.S. children: National Health Interview Survey, 1999. *Vital Health Stat [10].* 2003(210):1-50, [PMID: 15789511]
Exclusion code: 2

Blair Y, Macpherson L, McCall D, McMahon A. Dental health of 5-year-olds following community-based oral health promotion in Glasgow, UK. *Int J Paediatr Dent.* 2006;16(6):388-398, [PMID: 17014536]
Exclusion code: 9

Blair Y, Macpherson LMD, McCall DR, McMahon AD, Stephen KW. Glasgow nursery-based caries experience, before and after a community development-based oral health programme's implementation. *Community Dent Health.* 2004;21(4):291-298, [PMID: 15617414]
Exclusion code: 9

Bloom B, Cohen RA, Freeman G. Summary health statistics for U.S. children: National Health Interview Survey, 2010. *Vital and health statistics. Series 10, Data from the National Health Survey.* 2011(250):1-80, [PMID: 22338334]
Exclusion code: 2

Appendix A4. Excluded Studies List

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Exclusion code: 2

Randomized, controlled trials (RCTs)

Criteria:

- Initial assembly of comparable groups**:** RCTs—adequate randomization, including concealment and whether potential confounders were distributed equally among groups; cohort studies—consideration of potential confounders with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts
- Maintenance of comparable groups (includes attrition, cross-overs, adherence, contamination)
- Important differential loss to follow-up or overall high loss to follow-up
- Measurements: equal, reliable, and valid (includes masking of outcome assessment)
- Clear definition of interventions
- Important outcomes considered
- Analysis: adjustment for potential confounders for cohort studies, or intention-to-treat analysis for RCTs; for cluster RCTs, correction for correlation coefficient

Definition of ratings based on above criteria:

Good: Meets all criteria: Comparable groups are assembled initially and maintained throughout the study (followup at least 80 percent); reliable and valid measurement instruments are used and applied equally to the groups; interventions are spelled out clearly; important outcomes are considered; and appropriate attention to confounders in analysis.

Fair: Studies will be graded "fair" if any or all of the following problems occur, without the important limitations noted in the "poor" category below: Generally comparable groups are assembled initially but some question remains whether some (although not major) differences occurred in follow-up; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for.

Poor: Studies will be graded "poor" if any of the following major limitations exists: Groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied at all equally among groups (including not masking outcome assessment); and key confounders are given little or no attention.

Diagnostic accuracy studies

Criteria:

- Screening test relevant, available for primary care, adequately described
- Study uses a credible reference standard, performed regardless of test results
- Reference standard interpreted independently of screening test
- Handles indeterminate results in a reasonable manner
- Spectrum of patients included in study
- Sample size
- Administration of reliable screening test
- Random or consecutive selection of patients
- Screening cutoff pre-determined
- All patients undergo the reference standard

Definition of ratings based on above criteria:

Good: Evaluates relevant available screening test; uses a credible reference standard; interprets reference standard independently of screening test; reliability of test assessed; has few or handles indeterminate results in a reasonable manner; includes large number (more than 100) broad-spectrum patients with and without disease; study attempts to enroll a random or consecutive sample of patients who meet inclusion criteria screening cutoffs pre-stated.

Fair: Evaluates relevant available screening test; uses reasonable although not best standard; interprets reference standard independent of screening test; moderate sample size (50 to 100 subjects) and a "medium" spectrum of patients (i.e. applicable to most screening settings).

Poor: Has important limitation such as: uses inappropriate reference standard; screening test improperly administered; biased ascertainment of reference standard; very small sample size of very narrow selected spectrum of patients.

Sources: Harris et al, 2001[34] and USPSTF Procedure Manual[35]

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Appendix B1. Diagnostic Accuracy Studies for the Prevention of Dental Caries

Author, Year, Title	Screening Test	Reference Standard	Country Setting Screener	Population	Sample Size Proportion With Condition	Positive Screening Exam Definition	Proportion Un-examinable by Screening Test
Beltran et al., 1997[41] *Validity of two methods for assessing oral health status of populations*	Nurse exam (no previous dental experience; received written material on procedures and diagnostic criteria for conditions to be evaluated)	Pediatric dentist exam	U.S. rural school nurse	Children 5-12 years old attending school	n=258 children Cavitated lesions: 9.7% (mean 0.3/child)	ID of untreated decay ID of need for treatment (urgent or nonurgent)	Appears to be none
Pierce et al., 2002[39] *Accuracy of pediatric primary care providers' screening and referral for early childhood caries*	Primary care pediatrician exam following 2 hours of training	Pediatric dentist exam	U.S. pediatric group practice primary care pediatrician	Children <36 months of age with erupted teeth participating in the "Into the Mouths of Babes" program. Excluded if received fluoride varnish and oral screening within 3 months or were very ill	n=258 children Cavitated lesions: 9.7% (mean 0.3/child)	ID of a cavitated lesion ID of need for referral	Appears to be none
Serwint et al., 1993[40] *Child-rearing practices and nursing caries*	Pediatrician exam (not primary care provider) following 4 hours of training	Pediatric dentist exam	U.S. general pediatric clinic pediatrician	Children 18-36 months of age, mother primary caretaker Excluded for developmental delay or facial abnormalities	n=110 children Nursing caries (caries involving one or more teeth including the maxillary central or lateral incisors or the primary molars but sparing the mandibular incisors): 20% (22/110)	ID of nursing caries	NR

Appendix B1. Diagnostic Accuracy Studies for the Prevention of Dental Caries, Continued

Author, Year, Title	Analysis of Screening Failures	Proportion Who Underwent Reference Standard and Included in Analysis	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Quality Rating
Beltran et al., 1997[41] *Validity of two methods for assessing oral health status of populations*	NA	Appears to be all	Untreated decay: 0.92 (71/77) Any treatment needed: 0.80 (70/88)	Untreated decay: 0.99 (141/142) Any treatment needed: 0.99 (233/235)	Untreated decay: 0.99 (71/72) Any treatment needed: 0.97 (70/72)	Untreated decay: 0.96 (141/147) Any treatment needed: 0.93 (233/251)	Fair
Pierce et al., 2002[39] *Accuracy of pediatric primary care providers' screening and referral for early childhood caries*	NA	Appears to be all	Patient-level analysis: 0.76 (19/25) Tooth-level analysis: 0.49 (39/80) Need for referral: 0.63 (17/27)	Patient-level analysis: 0.95 (222/233) Tooth-level analysis: 0.99 (3210/ 3235) Need for referral: 0.98 (225/231)	Patient-level analysis: 0.63 (19/30); 0.83 (25/30) if precavitated lesions reclassified as true-positives Tooth-level analysis: 0.61 (39/64) Need for referral: 0.74 (17/23)	Patient-level analysis: 0.97 (222/228) Tooth-level analysis: 0.99 (3210/ 3251) Need for referral: 0.96 (225/235)	Good
Serwint et al., 1993[40] *Child-rearing practices and nursing caries*	NR	55% (61/110)	1.0 (n/N not calculable)	0.87 (n/N not calculable)	Not calculable	Not calculable	Fair

Abbreviations: ID = identification; NA = not applicable; NR = not reported; U.S. = United States.

Appendix B2. Quality Ratings for Diagnostic Accuracy Studies

Author, Year, Title	Representative Spectrum	Random or Consecutive Sample	Screening Test Adequately Described	Screening Cutoffs Predefined	Credible Reference Standard	Reference Standard Applied to All Screened Patients	Same Reference Standard Applied to All Patients	Reference Standard and Screening Examination Interpreted Independently	High Rate of Uninterpretable Results or Noncompliance With Screening Test	Analysis Includes Patients With Uninterpretable Results or Noncompliance	Quality Rating
Beltran et al., 1997[41] *Validity of two methods for assessing oral health status of populations*	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	Not applicable	Fair
Pierce et al., 2002[39] *Accuracy of pediatric primary care providers' screening and referral for early childhood caries*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Not applicable	Good
Serwint et al., 1993[40] *Child-rearing practices and nursing caries*	Yes	Unclear	Yes	Yes	Yes	No	Yes	Yes	No	Not applicable	Fair

Appendix B3. Trials of Educational Interventions for the Prevention of Dental Caries

Author, Year, Title	Study Design	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country
Davies et al., 2007[44] *Challenges associated with the evaluation of a dental health promotion programme in a deprived urban area* Davies et al., 2005[43] *A staged intervention dental health promotion programme to reduce early childhood caries*	Cluster, nonrandomized controlled clinical trial (2 clusters)	A: Series of interventions from age 8-32 months by health visitor including provision of educational materials, counseling on oral hygiene, and provision of toothbrush and toothpaste B: No intervention	Age at time of initial followup evaluation (mean, years): 4 vs. 4 Female: 48% vs. 49% Non-white: 51% vs. 37% Proportion of adults unemployed: 24% vs. 22% Jarman index (under-privileged area score): 39 vs. 40	Children 8 months of age attending a primary care clinic	Number approached: 1545 (839 vs. 706) Number eligible: 1545 (839 vs. 706) Number enrolled: 1545 (839 vs. 706) Number analyzed: 1545 (839 vs. 706)	UK Primary care clinics
Kressin et al., 2009[45] *Pediatric clinicians can help reduce rates of early childhood caries: effects of a practice based intervention*	Cluster, nonrandomized, controlled clinical trial (2 clusters)	A: Multi-component intervention including training of pediatricians in patient- centered counseling, providing parents/caregivers with educational brochure, and editing the electronic medical record to prompt counseling B: Usual care	Age <1 year: 1% vs. 3% Age 1 to <2 year: 55% vs. 55% Age 2 to <3 year: 25% vs. 26% Caregiver employed: 57% vs. 69% (p<0.0001) White: 17% vs. 45% (p<0.0001 for differences in race) Black: 76% vs. 35% Asian: 6% vs. 19% Hispanic: 13% vs. 15% Diet summary score (0-6 scale): 3.2 vs. 3.5 (p<0.0001) Hygiene summary score (0 to 6 scale, higher= better): 4.9 vs. 4.5 (p<0.0001) Tooth-monitoring summary score (0-3 scale): 0.7 vs. 0.9 (p=0.02) Baseline caries: 5.8% vs. 6.4% (p=0.66)	Parents/ caregivers of children 6 months-5 years of age attending well-child visits Excluded for congenital oral anomalies, ectodermal dysplasias, or other disease other than caries	Number approached: NR Number eligible: NR Number enrolled: 1087 (635 vs. 452) Number analyzed: 1045	U.S.

Appendix B3. Trials of Educational Interventions for the Prevention of Dental Caries, Continued

Author, Year, Title	Sponsor	Followup Duration	Confounders Adjusted for in Analysis	Outcomes	Adverse Events/Harms	Attrition	Quality Rating
Davies et al., 2007[44] *Challenges associated with the evaluation of a dental health promotion programme in a deprived urban area* Davies et al., 2005[43] *A staged intervention dental health promotion programme to reduce early childhood caries*	National Health Service Research and Development Programme for Primary Dental Care	Evaluated at ages 3-4 years and age 5 years	None	A vs. B at 3-4 year old followup; all children and restricted to children who attended developmental check and MMR vaccination (n=1207, 649 vs. 558) Caries experience: 34% vs. 40%, p=0.01; 29% vs. 39%, p=0.001 Nursing caries: 21% vs. 23%, p=0.49; 17% vs. 24%, p=0.003 dmft (mean): 1.5 vs. 1 .7, p=0.09; 1.2 vs. 1.7, p=0.001 dmfs (mean): 3.3 vs. 3.7, p=0.35; 2.6 vs. 3.8, p=0.008 A vs. B at 5 year old followup; restricted to children who attended developmental check and MMR vaccination (n=539, 253 vs. 286) Caries experience: 54% vs. 64%, p=0.03 Nursing caries: 20% vs. 32%, p=0.002 Extraction: 3% vs. 12%, p<0.0001 dmft (mean): 2.2 vs. 3.7, p<0.001	Not reported	At age 3-4 years, 22% (338/1545) of potentially eligible cohort did not attend developmental check or MMR vaccination and would not have received all interventions; at 5 years 65% (1006/1545) excluded	Poor
Kressin et al., 2009[45] *Pediatric clinicians can help reduce rates of early childhood caries: effects of a practice based intervention*	NIH/NIDCR and VA	1 year	Length of enrollment, sex, race, treatment before 42 months, continuously enrolled in Medicaid number of well-child visits	A vs. B Caries (irreversible cavitated lesions): 18% vs. 32%, adjusted HR 0.23 (95% CI 0.09 to 0.62)	NR	42/1087 enrolled were not analyzed	Fair

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; CI = confidence interval; dmfs = decayed missing filled surfaces; dmft = decayed missing filled teeth; HR = hazard ratio; MMR = measles, mumps, and rubella; NIDCR = National Institute of Dental and Craniofacial Research; NIH = National Institutes of Health; NR = not reported; UK = United Kingdom; U.S. = United States; VA = Veterans Affairs.

Appendix B4. Quality Ratings of Randomized, Controlled Trials

Author, Year, Title	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Care Provider Masked?	Patient Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination
Alamoudi et al., 2012[74] *Effects of xylitol on salivary mutans streptococcus, plaque level, and caries activity in a group of Saudi mother-child pairs*	Unclear	Yes	Unclear	Yes	Unclear	No	No	Yes
Chu et al., 2002[69] *Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin carries in Chinese pre-school children*	No	No	Unclear	Yes	Yes	No	Unclear	Yes
Davies et al., 2007[44] *Challenges associated with the evaluation of a dental health promotion programme in a deprived urban area* Davies et al., 2005[43] *A staged intervention dental health promotion programme to reduce early childhood caries*	Not randomized	Unclear	Yes	Yes	Unclear	Unclear	Unclear	No
Du et al., 2006[54] *A two-year randomized clinical trial of chlorhexidine varnish on dental caries in Chinese preschool children*	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes
Jiang et al., 2005[70] *The effect of a bi-annual professional application of APF foam on dental caries increment in primary teeth: 24-month clinical trial*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Appendix B4. Quality Ratings of Randomized, Controlled Trials

Author, Year, Title	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Care Provider Masked?	Patient Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination
Kovari et al., 2003[51] *Use of xylitol chewing gum in daycare centers: a follow-up study in Savonlinna, Finland*	NR	NR	Unclear	Yes	Unclear	No	No	Yes
Kressin et al., 2009[45] *Pediatric clinicians can help reduce rates of early childhood caries: Effects of a practice based intervention*	Not randomized	Yes	Yes	Yes	No	No	Yes	Yes
Lawrence et al., 2008[47] *A 2-year community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children*	Yes	Unclear	Yes	Yes	Yes	No	No	Yes
Milgrom et al., 2009[73] *Xylitol pediatric topical oral syrup to prevent dental caries*	Yes	Unclear	No (age)	Yes	Yes	Yes	Yes	Yes
Oscarson et al., 2006[52] *Influence of a low xylitol-dose on mutans streptococci colonisation and caries development in preschool children*	NR	NR	Yes	Yes	Yes	No	No	Yes
Seki et al., 2011[53] *Effect of xylitol gum on the level of oral mutans streptococci of preschoolers: block-randomized trial*	No	No	Unclear (dfs index)	Yes	Yes	No	No	Yes

Appendix B4. Quality Ratings of Randomized, Controlled Trials

Author, Year, Title	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Care Provider Masked?	Patient Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination
Slade et al., 2011[48] *Effect of health promotion and fluoride varnish on dental caries among Australian Aboriginal children: results from a community-randomized controlled trial*	Yes	Yes	Yes; some difference in fluoridation status	Yes	No	No	No	Yes
Weinstein et al., 2001[71] *Equivalence between massive versus standard fluoride varnish treatments in high caries children aged 3-5 years*	Yes	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	Yes
Weinstein et al., 2009[72] *Randomized equivalence trial of intensive and semiannual applications of fluoride varnish in the primary dentition*	Yes	Unclear	No; mean dmfs were not balanced	Yes	Yes	Unclear	Unclear	Yes
Weintraub et al., 2006[49] *Fluoride varnish efficacy in preventing early childhood caries*	Yes	Yes	Yes; stated no imbalances apparent	Yes	Yes	No	Yes	Yes
Zhan et al., 2012[50] *Effects of xylitol wipes on carcinogenic bacteria and caries in young children*	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes

Appendix B4. Quality Ratings of Randomized, Controlled Trials, Continued

Author, Year, Title	Loss to Followup: Differential/High	Intention-To-Treat (ITT) Analysis	Post-Randomization Exclusions	Outcomes Pre-Specified	Funding Source	External Validity	Quality Rating
Alamoudi et al., 2012[74] *Effects of xylitol on salivary mutans streptococcus, plaque level, and caries activity in a group of Saudi mother-child pairs*	Yes (very high)	Yes	Yes	Yes	The Deanship of Scientific Research, King Abdulaziz University, Jeddah, Saudi Arabia (Project No. 429/011-9)	Fair	Poor
Chu et al., 2002[69] *Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin carries in Chinese pre-school children*	No//No	Yes	No	Yes	A research grant from The University of Hong Kong (CRCG)	Limited: Chinese fluoridated water, 73% used fluoridated toothpaste	Poor
Davies et al., 2007[44] *Challenges associated with the evaluation of a dental health promotion programme in a deprived urban area* Davies et al., 2005[43] *A staged intervention dental health promotion programme to reduce early childhood caries*	Yes	No	No	Yes	National Health Service Research and Development Programme for Primary Dental Care	Fair	Poor
Du et al., 2006[54] *A two-year randomized clinical trial of chlorhexidine varnish on dental caries in Chinese preschool children*	No/Unclear	Yes	No	Yes	The National Key Technologies R & D Program of the tenth Five-Year Plan, the Ministry of Science and Technology, and the National Committee for Oral Health, China	Limited: Chinese children in China, no organized oral health care programs, but access to fluoridated water	Fair
Jiang et al., 2005[70] *The effect of a bi-annual professional application of APF foam on dental caries increment in primary teeth: 24-month clinical trial*	No/No	Yes	No	Yes	National Key Technologies R & D Program of the Tenth-five Year Plan, the Ministry of Science and Technology, China (2004BA720A24)	Limited: Chinese children, fluoridated water, no organized health care programs, limited use of fluoride toothpaste	Good

Appendix B4. Quality Ratings of Randomized, Controlled Trials, Continued

Author, Year, Title	Loss to Followup: Differential/High	Intention-To-Treat (ITT) Analysis	Post-Randomization Exclusions	Outcomes Pre-Specified	Funding Source	External Validity	Quality Rating
Kovari et al., 2003[51] *Use of xylitol chewing gum in daycare centers: a follow-up study in Savonlinna, Finland*	No	Yes	No	Yes	NR	Limited	Fair
Kressin et al., 2009[45] *Pediatric clinicians can help reduce rates of early childhood caries: Effects of a practice based intervention*	No	Yes	No	Yes	NIDCR, NIH, and VA	Fair	Fair
Lawrence et al., 2008[47] *A 2-year community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children*	No/No	Yes	No	Yes	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 03-067)	Limited: Aboriginal communities in rural Canada	Good
Milgrom et al., 2009[73] *Xylitol pediatric topical oral syrup to prevent dental caries*	No	Yes	No	Yes	The Maternal and Child Health Bureau (HRSA) and NIDCR	Fair	Fair
Oscarson et al., 2006[52] *Influence of a low xylitol-dose on mutans streptococci colonisation and caries development in preschool children*	No	Yes	No	Yes	Grants from Count of Vasterbotten, the Patient Revenue Fund for Dental Prophylaxis and the Swedish Dental Society	Fair	Fair
Seki et al., 2011[53] *Effect of xylitol gum on the level of oral mutans streptococci of preschoolers: block-randomized trial*	Yes	Yes	Yes	Yes	The Uemura Fund, Nihon University School of Dentistry	Fair	Poor
Slade et al., 2011[48] *Effect of health promotion and fluoride varnish on dental caries among Australian Aboriginal children: results from a community-randomized controlled trial*	No/No	Yes	No	Yes	Project grant 320858 from the Australian National Health and Medical Research Council	Limited: Aboriginal communities in rural Australia	Good

Appendix B4. Quality Ratings of Randomized, Controlled Trials, Continued

Author, Year, Title	Loss to Followup: Differential/High	Intention-To-Treat (ITT) Analysis	Post-Randomization Exclusions	Outcomes Pre-Specified	Funding Source	External Validity	Quality Rating
Weinstein et al., 2001[71] *Equivalence between massive versus standard fluoride varnish treatments in high caries children aged 3-5 years*	Yes/Yes	Yes	No	Yes	Grant R03 DE012138 from NIDCR, NIH	Head Start program	Fair
Weinstein et al., 2009[72] *Randomized equivalence trial of intensive and semiannual applications of fluoride varnish in the primary dentition*	No/No	Yes	No	Yes	Grants R01DE14403 and U54DE14254 from NIDCR, NIH	Head Start program	Fair
Weintraub et al., 2006[49] *Fluoride varnish efficacy in preventing early childhood caries*	Yes/No	Yes	No	Yes	USPHS research grants P60DE13058 and U54DE142501 from NIDCR and NCMHD, NIH; and by UCSF's Department of Preventive and Restorative Dental Sciences	Limited: "Under-serviced" community in U.S.; all non-white	Fair
Zhan et al., 2012[50] *Effects of xylitol wipes on carcinogenic bacteria and caries in young children*	No/Yes 23% in one group	Yes	No	Yes	California Society of Pediatric Dentistry Foundation (a Graduate Scientific Research Award from AAPD) and NIH/NIDCR grant U54 DEO19285	Single center	Fair

Abbreviations: AAPD = American Academy of Pediatric Dentistry; dfs = decayed filled surfaces; dmfs = decayed missing filled surfaces; HRSA = Health Resources and Services Administration; NCMHD = National Center on Minority Health and Health Disparities; NIDCR = National Institute of Dental and Craniofacial Research; NIH = National Institutes of Health; NR = not reported; UCSF = University of California San Francisco; U.S. = United States; USPHS = U.S. Public Health Service; VA = U.S. Department of Veterans Affairs.

Appendix B5. Cohort Study of Dental Referral From a Primary Care Clinician for the Prevention of Dental Caries

Author, Year, Title	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country	Sponsor	Followup Duration	Adjusted Confounders in Analysis	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Beil et al., 2012[46] *Effect of early preventive dental visits on subsequent dental treatment and expenditures*	A: First preventive dental visit by age 18 months B: First preventive dental visit after age 18 months	Primary or secondary dental preventive visit before age18 months vs. between age18-42 months Female: 46% vs. 48-51% Non-white race: 67% vs. 66-67% Number of well-child visits: 1.8 vs. 1.4-1.7 Percent of population in county under 18 months of age enrolled in Medicaid: 30% vs. 31-33% Dentists per capita in county: 5.1 vs. 4.5-4.9	Children enrolled in North Carolina Medicaid prior to first birthday, enrolled for at least 12 months, with a paid claim for dental care Excluded if received dental services in medical office as part of the Into the Mouths of Babes fluoride varnish program	Approached: 165,383 Eligible: 19,888 Enrolled: 19,888 Analyzed: 19,888	U.S.	AHRQ and NIDCR	Through age 72 months	Age, race/ ethnicity, caregiver employment, caregiver education, language spoken at home, diet score, hygiene score, tooth monitoring score	First preventive visit at age 18-24, 25-30, 31-36, or 37-42 months vs. <18 months (reference) Primary or secondary preventive visit: Incidence density ratio: 0.98 (0.87-1.1), 1.1 (0.94-1.2), 1.1 (0.96-1.2), and 1.1 (0.95-1.2) Tertiary preventive visit: Incidence density ratio: 1.2 (1.0-1.4), 1.2 (1.1-1.4), 1.1 (0.99-1.3), and 1.4 (1.2-1.6)	NR	None	Fair

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; NIDCR = National Institute of Dental and Craniofacial Research; NR = not reported; U.S. = United States.

Appendix B6. Quality Rating of Included Cohort Study

Author, Year, Title	Did Study Attempt to Enroll a Random Sample or Consecutive Patients Meeting Inclusion Criteria (Inception Cohort)?	Were Groups Comparable at Baseline?	Did Study Use Accurate Methods for Ascertaining Exposures, Potential Confounders, and Outcomes?	Were Outcome Assessors and/or Data Analysts Blinded to Treatment?	Did the Article Report Attrition?	Did Study Perform Appropriate Statistical Analyses on Potential Confounders?	Is There Important Differential Loss to Followup or Overall High Loss to Followup?	Were Outcomes Pre-Specified and Defined, and Ascertained Using Accurate Methods?	Quality
Beil et al., 2012[46] *Effect of early preventive dental visits on subsequent dental treatment and expenditures*	Yes	Yes	Unclear	Unclear	Yes	Yes	No	Yes	Fair

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Topical Fluoride												
Chu et al., 2002[69] *Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children*	Controlled clinical trial	A: Removal of carious tissue plus 38% silver diamine fluoride solution every 12 months B: 38% silver diamine fluoride solution every 12 months C: Removal of carious tissue plus 5% sodium fluoride every 3 months D: 5% sodium fluoride varnish every 3 months E: Placebo (water)	Age, mean: 4 years Female: 44% Race: NR (study conducted in China) dmfs score: 3.92 Used fluoridated toothpaste: 73%	Children from 8 kindergartens with caries in upper primary anterior teeth	Number approached: NR Number eligible: NR Number enrolled: 375 (76 vs. 77 vs. 76 vs. 73 vs. 73) Number analyzed: 308 (61 vs. 62 vs. 62 vs. 61 vs. 62)	China recruitment setting: Kindergarten Water fluoridation status: <0.2 ppm	University of Hong Kong	2.5 years	A vs. B vs. C vs. D vs. E New caries surfaces: 0.26 vs. 0.47 vs. 0.89 vs. 0.70 vs. 1.58, p for ANOVA <0.001 (E vs. others) Arrested caries surfaces: 2.49 vs. 2.82 vs. 1.45 vs. 1.54 vs. 1.27; p for ANOVA <0.001 (E vs. others) Absolute reduction in caries increment: 1.32 vs. 1.11 vs. 0.69 vs. 0.88 vs. E as comparator (vs. others) Reduction in caries increment: 84% vs. 70% vs. 44% vs. 56% vs. E as comparator (vs. others)	No adverse events detected	Overall 18%; 20% vs. 19% vs. 18% vs. 16% vs. 15%	Poor

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Jiang et al., 2005[70] *The effect of a bi-annual professional application of APF foam on dental caries increment in primary teeth: 24-month clinical trial*	Cluster RCT (15 clusters)	A: 0.6-0.8 g of 1.23% acidulated phosphate fluoride foam applied every 6 months, max 4 applications B: Placebo foam	Age, mean: 3.5 vs. 3.6 years Female: 46% vs. 46% Non-white: 100% Chinese dmft, mean: 1.6 vs. 1.7 dmfs, mean: 2.4 vs. 2.8 Use of fluoride toothpaste: 23% vs. 20% Tooth-brushing at least once a day: 42% vs. 50%	Children from 4 kindergartens	Number approached: NR Number eligible: NR Number enrolled: 392 (209 vs. 183) Number analyzed: 318 (167 vs. 151)	China recruitment setting: Kindergarten Water fluoridation status: 0.1-0.3 ppm	National Key Technologies R&D Program of the Tenth-five Year Plan, Ministry of Science and Technology, China	2 years	A vs. B No increase in dmfs: 38% (64/167) vs. 26% (40/151) dmfs increase of 1 to 5: 34% (56/167) vs. 38% (58/151) dmfs increase of 6 to 10: 17% (28/167) vs. 18% (27/151) dmfs increase of >10: 11% (19/167) vs. 17% (26/151) Net dmfs increment (all surfaces): 3.8 vs. 5.0; p=0.03 Absolute reduction in caries increment: 1.2 Reduction in caries increment: 24%	No adverse events detected	A vs. B: 20% (42/209) vs. 17% (32/183)	Good
Lawrence et al., 2008[47] *A 2-year community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children*	Cluster RCT (20 clusters)	A: 0.3-0.5 ml 5% sodium fluoride varnish applied to full primary dentition every 6 months B: No fluoride varnish	A vs. B Age, mean: 2.5 years overall Female: 50% vs. 52% Race: 100% aboriginal dmft, mean: 7.2 vs. 6.5 (p=0.80)	Children ages 6 months-5 years, with at least 1 primary tooth, residing in First Nations community in study region, with signed consent from primary caregiver Excluded children with	Number approached: 1,793 Number eligible: 1,275 Number enrolled: 1,275 Number analyzed: 1,146 (818 vs. 328)	Canada recruitment setting: Rural Aboriginal communities Water fluoridation status: No fluoridation	Institute of Aboriginal Peoples' Health/ Canadian Institutes of Health Research; Toronto Hospital for Sick Children Foundation	2 years	A vs. B Dental caries in aboriginal cohort: 72% (595/832) vs. 75% (247/328), adjusted OR 0.72 (95% CI 0.42 to 1.25); NNT 26 Dental caries in those caries free at baseline: 44% (157/354) vs. 58% (73/126); adjusted	One child allergic to lanolin experienced an adverse event	11% (96/915) vs. 9% (32/360)	Good

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
			Caries experience: 73% vs. 69% (p=0.50)	no teeth, stainless steel crowns only, ulcerative gingivitis, stomatitis or allergy to colophony component					OR 0.63 (95% CI 0.33 to 1.1); NNT 7.4 Net dmfs increment in aboriginal cohort, mean: 11 vs. 13.4; adjusted difference, mean (SE) 2.4 (2.0), p=0.24; prevented fraction 18% Net dmfs increment in those caries free at baseline, mean (SE): 4.3 (0.5) vs. 6.1 (0.8); adjusted difference, mean (SE): 1.8 (1.3); p=0.18; prevented fraction 29% Absolute reduction in caries increment: 2.4 (1.8) Reduction in caries increment: 18% (29%)			

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Slade et al., 2011[48] *Effect of health promotion and fluoride varnish on dental caries among Australian Aboriginal children: results from a community-randomized controlled trial*	Cluster RCT (30 clusters)	A: 0.25 ml of 5% sodium fluoride varnish to maxillary anterior teeth/ molars, mandibular molars/incisors every 6 months, education/ advice to caregiver with toothbrush/ paste provided, community oral health promotion program B: No intervention	A vs. B Age, mean: 34 vs. 33 months Female: 50% vs. 48% Race: All aboriginal dmfs >0: 64% vs. 65% d3mfs (mean): 4.9 vs. 4.6 Fluoride concentration in drinking water <0.6 ppm F: 92% vs. 81%	Aboriginal identity, permanent residency in community, 18-48 months old, no history of asthma, signed informed consent of caregivers	Number approached: 685 Number eligible: 666 Number enrolled: 666 Number analyzed: 666 (344 vs. 322)	Australia recruitment setting: Rural Aboriginal communities Water fluoridation status: See population characteristics	Australian National Health and Medical Research Council	2 years	A vs. B Net dmfs increment per child, (mean) Adjusted for cluster effects: 6.9 vs. 9.9, difference 3.0 (95% CI 1.2 to 4.9), prevented fraction 31% Adjusted for cluster effects plus fluoride concentration in water: 6.2 vs. 9.7, difference 3.5 (95% CI 1.9 to 5.1), prevented fraction 36% Adjusted for cluster effects plus child's age and baseline d3mfs: 7.0 vs. 9.4, 2.4 (0.6 to 4.3), prevented fraction 26% Adjusted for cluster effects plus loss to followup: 7.3 vs. 9.6, difference 2.3 (0.8 to 3.7), prevented fraction 24% Absolute reduction in caries increment: 2.3 Reduction in caries increment: 24%	No adverse events detected	A vs. B: 19% (60/322) vs. 18% (63/344)	Good

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Weinstein et al., 2001[71] *Equivalence between massive versus standard fluoride varnish treatments in high caries children aged 3-5 years*	RCT with 3 treatment groups	A: One application of 5% fluoride varnish at baseline and 6 months B: Three applications of 5% fluoride varnish within 2 weeks of baseline C: Three applications of 5% fluoride varnish within 2 weeks of baseline and 6 months	Age: NR Female: 46% Race: 90% Hispanic, 10% Caucasian or Native American Clinical dmfs, mean: 11 vs. 13 vs. 10 Radiographic dmfs, mean: 3.5 vs. 3.1 vs. 3.4 Mean dmft for entire population: 6.0	Children ages 3-5 years, with ≥1 carious lesion in primary molars and no fluoride treatment in the previous 6 months	Number approached: NR Number eligible: 156 Number enrolled: 156 (51 vs. 52 vs. 53) Number analyzed: 111 (32 vs. 36 vs. 43)	U.S. recruitment setting: Head Start programs Water fluoridation status: NR (Yakima voters approved fluoridation in 1999)	NIDCR, NIH grants	1 year	A vs. B vs. C Radiographic dmfs increment, mean: 0.9 vs. 0.5 vs. 0.1, p=0.28 Clinical dmfs increment, mean: 4.6 vs. 3.2 vs. 4.7, p=0.65 Absolute reduction in caries increment: Not calculated Reduction in caries increment: Not calculated	Study states no loss to followup from adverse events	A vs. B vs. C: 33% (17/51) vs. 27% (14/52) vs. 13% (7/53) Note: Study states 119 subjects examined at 1- year visit, but analysis shows 111	Fair

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Weinstein et al., 2009[72] *Randomized equivalence trial of intensive and semiannual applications of fluoride varnish in the primary dentition*	RCT with 2 treatment groups	A: One 5% fluoride varnish treatment and 2 placebo treatments every 6 months B: One set of three 5% fluoride varnish treatments over 2 weeks once per year and 3 placebo treatments over 2 weeks 6 months later	A vs. B Age, mean: 55 vs. 56 months Female: 48% vs. 51% Race: All Hispanic >7 dmfs at baseline: 22% vs. 33% dmfs, mean (SD): 5.3 (9.8) vs. 7.2 (9.3)	Hispanic children ages 36-71 months, living in study county, with at least one sound primary tooth surface present Children were excluded if they were developmentally unable to participate in the study	Number approached: 787 Number eligible: 600 Number enrolled: 600 (306 vs. 294) Number analyzed: 515 (264 vs. 251)	U.S. recruitment setting: Head Start programs Water fluoridation status: NR (Yakima voters approved fluoridation in 1999)	NIDCR, NIH grants	3 years	A vs. B New tooth decay in primary surfaces (number of surfaces per child): 7.4 vs. 9.8, p=0.001; adjusted rate ratio 1.13 (95% CI 0.94 to 1.37) Absolute reduction in caries increment: 2.4 Reduction in caries increment: 24%	No adverse events detected	A vs. B: 27% (84/306) vs. 29% (86/294); 38% (230/600) not followed entire 3 years	Fair

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Weintraub et al., 2006[49] *Fluoride varnish efficacy in preventing early childhood caries*	RCT	A: 0.1 mL of 5% sodium fluoride varnish per arch applied twice per year with 4 intended applications B: 0.1 mL of 5% sodium fluoride varnish per arch applied once per year with 2 intended applications C: No fluoride varnish	Age, mean: 1.8 years Female: 53% Race: 47% Hispanic, 46% Asian, 7% other race/ethnicity All caries free at baseline, see eligibility criteria	Children ages 6-44 months with 4 erupted maxillary incisors, all primary teeth caries-free without demineralized, white spots, born in San Francisco or fluoridated community in the San Francisco Bay Area, planning to reside in San Francisco for at least 2 years, parent providing informed consent Excluded children with medical problems or medications affecting oral health (e.g., cleft lip or palate)	Number approached: NR Number eligible: NR Number enrolled: 376 Number analyzed: 280 (87 vs. 93 vs. 100)	U.S. recruitment setting: Family dental center and public health center serving primarily low-income, underserved Hispanic and Chinese populations Water fluoridation status: ~1 ppm	NIDCR; National Center for Minority Health and Health Disparities; UCSF Department of Preventive and Restorative Dental Sciences	2 years	A vs. B vs. C Caries lesions at 12 months: 11/83 vs. 13/86 vs. 27/92; RR 0.45 (95% CI 0.24 to 0.83) NNT 7 for A vs. C and 0.52 (95% CI 0.28 to 0.93) NNT 8 for B vs. C Caries lesions at 24 months: 3/70 vs. 10/69 vs. 15/63; RR 0.18 (95% CI 0.06 to 0.59) NNT 6 for A vs. C and 0.61 (95% CI 0.30 to 1.26) NNT 11 for B vs. C dmfs, mean: 0.7 vs. 0.7 vs. 1.7; p<0.01 for A vs. C and B vs. C dmfs + precavitated lesions, mean: 1.4 vs. 1.3 vs. 2.7; p<0.01 for A vs. C and B vs. C Absolute reduction in caries increment: 1.0 Reduction in caries increment: 59% (A + B vs. C)	No adverse events detected	A vs. B vs. C: 31% (39/126) vs. 25% (31/124) vs. 21% (26/126)	Fair

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Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Xylitol												
Alamoudi et al., 2012[74] *Effects of xylitol on salivary mutans streptococcus, plaque level, and caries activity in a group of Saudi mother-child pairs*	RCT	A: Xylitol chewable tablets (1.2 g, 84% xylitol) chewed for 5 minutes 3 times daily B: Fluoride varnish, every 6 months throughout study	Age: 2- 5 years Female: NR Race: NR (conducted in Saudi Arabia) High mutans streptococci (>=10^5 CFU): 100% vs. 100% Baseline dmft score: 8.37 vs. 10.27 (p=0.191)	Mothers and children with high count of salivary MS ($\geq$ 105), presence of one or more decayed or filled primary teeth in mothers Excluded children with systemic disorders such as diabetes, hyperglycemia or sleeping disorders; irregular medications; removable dental prosthesis, or prone to TMJ complaints; and children attending clinics without mothers, or reared by a nanny	Number approached: 62 Number eligible: 60 Number enrolled: 60 (30 vs. 30) Number analyzed: 34 (21 vs. 13)	Saudi Arabia recruitment setting: Well baby clinics and dental clinics Water fluoridation status: NR	Deanship of Scientific Research, King Abdulaziz University, Jeddah, Saudi Arabia	18 months	A vs. B dmft score at 6 months (mean): 8.95 vs. 13.00, p=0.024 dmft score at 12 months (mean): 9.64 vs. 13.12, p=0.041 dmft score at 18 months (mean): 9.19 vs. 14.69, p=0.001 dmft, mean: 0.8 vs. 4.4; p=NR Absolute reduction in caries increment: 3.6 Reduction in caries increment: 82%	NR	A vs. B 30% (9/30) vs. 57% (17/30)	Poor

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Kovari et al., 2003[51] *Use of xylitol chewing gum in daycare centers: a follow-up study in Savonlinna, Finland*	Cluster RCT (11 clusters)	A: 65% Xylitol gum 3 times per day, chewed for 3-5 minutes, for total of 2.5 g/day B: Toothbrushing with Aquafresh with 0.05% NaF after lunch	Age: 3-6 years Female: 46.9% (184/392) vs. 46.7% (247/529) Non-white: NR Risk level: NR	Children in the town of Savolinna, Finland, ages 3-6 years attending daycare centers	Number approached: NR Number eligible: NR Number enrolled: 921 Number analyzed: 786 (392 vs. 529)	Finland recruitment setting: Daycare centers Water fluoridation status: NR	NR	3-6 years (up to age 9 years)	A vs. B Caries-free at 7 years old: 69% (218/316) vs. 65% (278/427), RR 1.06 (95% CI 0.96 to 1.17) Caries-free at 9 years old: 57% (177/310) vs. 49% (213/434), RR 1.16 (95% CI 1.02 to 1.33) Decayed/missing/ filled teeth: 1.1 vs. 1.0 at 7 years, 1.2 vs. 1.6 at 9 years dmft, mean: NR Absolute reduction in caries increment: NR Reduction in caries increment: NR	NR	A vs. B: 16.3% (64/392) vs. 13.4% (71/529) at age 9 years followup	Fair

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Milgrom et al., 2009[73] *Xylitol pediatric topical oral syrup to prevent dental caries*	RCT	A: Xylitol 8 g/day syrup, divided into 2 doses (4 g per dose) B: Xylitol 8 g/day syrup, divided into 3 doses (2.67 g per dose) C: Xylitol 2.67 g dose syrup, 1 dose per day	Age: 15.9 vs. 13.7 vs. 15.6 months Female: 58% vs. 56% vs. 48% Non-white: NR Risk level: NR	Children ages 9-15 months Excluded for history of esophageal or digestive disease, congenital craniofacial malformations or history of adenoidectomy, or lower than 10th percentile of U.S. standard weight and height	Number approached: 110 Number eligible: 108 Number enrolled: 100 Number analyzed: 94 (33 vs. 32 vs. 29)	Marshall Islands Recruitment setting: Community-based Water fluoridation status: Drinking water not fluoridated (supple-mental and topical fluoride not available)	HRSA's Maternal and Child Health Bureau and NIDCR	1 year	A vs. B vs. C Tooth decay: 24.2% (8/33) vs. 40.6% (13/32) vs. 51.7% (15/29), RR 0.47 (95% CI 0.23 to 0.94) for A vs. C and 0.79 (95% CI 0.45 to 0.1.4) for B vs. C Mean decayed teeth: 0.6 vs. 1.0 vs. 1.9; p<0.05 for A or B vs. C; incidence rate ratio 0.30 (95% CI 0.13 to 0.66) for A vs. C and 0.50 (95% CI 0.26 to 0.96)for B vs. C Decayed primary teeth per year: 0.66 vs. 1.10 vs. 2.20 Absolute reduction in caries increment: 1.3 vs. 0.9 vs. C as comparator (vs. others) Reduction in caries increment: 68% vs. 47% vs. C as comparator (vs. others)	A vs. B vs. C Withdrawals due to adverse events: NR Loose stool or diarrhea: 11.7% vs. 10.6% vs. 11.4% (p>0.05)	A vs. B vs. C: 17.1% (6/35) vs. 15.2% (5/33) vs. 15.6% (5/32)	Fair

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Oscarson et al., 2006[52] *Influence of a low xylitol-dose on mutans streptococci colonisation and caries development in preschool children*	RCT	A: One 0.48 g xylitol tablet at bedtime after brushing for 6 months; then 1 tablet twice daily to age 3 years and 6 months B: No tablets	Age: 25 vs. 25 months Female: 49% vs. 46% (p>0.05) Non-white: NR Seldom/ Irregular tooth-brushing: 7% vs. 3% (p>0.05) High (>100 CFU) mutans streptococci counts: 11% vs. 6% (p>0.05) Daily sugary soft drinks: 17% vs. 27% (p>0.05) Daily sugars sweets: 0% vs. 2% (p>0.05)	Healthy children age 2 years Excluded children with severe disabilities or uncooperative for oral exam	Number approached: NR Number eligible: NR Number enrolled: 132 (66 vs. 66) Number analyzed: 115 (55 vs. 63)	Sweden recruitment setting: Public dental clinic Water fluoridation status: NR	County of Vasterbotten, The Patent Revenue Fund for Dental Prophylaxis and Swedish Dental Society	2 years	A vs. B Dental caries: 18% (10/55) vs. 25% (16/63), OR 0.65 (95% CI 0.27 to 1.59) dmfs, mean: 0.38 vs. 0.80 (p>0.05) Absolute reduction in caries increment: 0.42 Reduction in caries increment: 52%	A vs. B Withdrawals due to adverse events: NR	A vs. B: 16.7% (11/66) vs. 4.5% (3/66)	Fair

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
Seki et al., 2011[53] *Effect of xylitol gum on the level of oral mutans streptococci of preschoolers: block-randomized trial*	Cluster, non-randomized controlled clinical trial (3 clusters)	A: Xylitol chewing gum (100% xylitol); 1 pellet chewed 5 minutes 4 times daily B: No intervention	Baseline data only reported by group for children who completed followup Age 4 years old: 66% vs. 72% Female: 46% vs. 48% Race: NR (conducted in Japan) dfs index (mean): 2.5 vs. 4.2 (p=0.07) Individual plaque mutans streptococci score: 0.5 vs. 0.7 Salivary mutans streptococci score >0: 25% vs. 42%	Attending preschool in one region in Tokyo	Number approached: NR Number eligible:432 Number enrolled: 248 (142 vs. 106) Number analyzed: 161(76 vs. 85)	Japan recruitment setting: Preschool Water fluoridation status: Not reported (states fluoridation "limited" in Japan)	Uemura Fund, Nihon University School of Dentistry from the Ministry of Education, Science, Sports, Culture and Technology, Japan	1 year	A vs. B Development of caries from baseline to 6 months: 1.7 vs. 1.6 (p>0.05) Development of caries from 6 months to 1 year: 1.6 vs. 1.8 (p>0.05) Mean development of caries: 3.3 vs. 3.4; p>0.05 Absolute reduction in caries increment: 0.1 Reduction in caries increment: 3%	Diarrhea in 11% (8/76) in xylitol group	A vs. B 46% (66/142) vs. 20% (21/106)	Poor
Zhan et al., 2012[50] *Effects of xylitol wipes on cariogenic bacteria and caries in young children*	RCT	A: Xylitol wipes, 2 at a time, 3 times per day (estimated daily dosage 4.2 g) every 3 months B: Placebo wipes	Age: 6-35 months vs. 6-35 months Female: 36% vs. 40%	Mothers with healthy children aged 6-35 months; mothers were primary care givers (>8 hours daily) and with	Number approached: 82 Number eligible: 57 Number	Water	California Society of Pediatric Dentistry Foundation, a Graduate Scientific Research	1 year	A vs. B Mean new decayed surfaces: 0.05 vs. 0.53 (p=0.01) New caries lesions at 1 year: 5% vs. 40%	None	A vs. B 9% (2/22) vs. 23% (5/22)	Fair

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
			Non-white: 90% vs. 95% Brush teeth daily: 68% vs. 68% Use fluoride toothpaste: 36% vs. 27%	minimum of 1 active caries lesion within a year No children with oral or systemic diseases; no mothers or children who took antibiotics or other medication affecting oral flora in previous 3 months	enrolled: 44 (22 vs. 22) Number analyzed: 37 (20 vs. 17)	fluoridation status: NR	Award from AAPD, and NIH NIDCR grant U54-DEO19285		(p=0.03); NNT 3 ITT analysis of new caries lesions at 1 year: 5% vs. 32%; RR 0.14 (95% CI 0.02 to 1.07); NNT 4 Absolute reduction in caries increment: 0.48 Reduction in caries increment: 91%			
Other Interventions												
Du et al., 2006[54] *A two-year randomized clinical trial of chlorhexidine varnish on dental caries in Chinese preschool children*	Cluster RCT (14 clusters)	A: 40% w/w chlorhexidine acetate varnish every 6 months B: Placebo varnish	Age: NR Female: NR Race: NR (study conducted in China) dmfs-molar, mean: 2.8 vs. 2.6, p=0.39	All children ages 4-5 years, attending 1 of 4 kindergartens in study district	Number approached: NR Number eligible: NR Number enrolled: 334 Number analyzed: 290 (155 vs. 135)	China recruitment setting: Kindergartens in rural communities Water fluoridation status: 0.1-0.3 ppm	National Key Technologies R&D Program of the tenth Five-Year Plan; Ministry of Science and Technology; National Committee for Oral Health; China	2 years	A vs. B dmfs-molar increment, mean: 1.0 vs. 1.6, mean difference 0.6, 37% reduction in caries molar increment, p = 0.036 Absolute reduction in caries increment: 0.6 Reduction in caries increment: 37%	No adverse events detected	13% (44/334) overall	Fair
Lopez et al., 2002[55] *Topical antimicrobial therapy in the prevention of early childhood caries: a followup*	RCT	A: 0.2 ml of 10% povidone iodine solution applied every 2 months B: Placebo solution	Age, mean (range): 16 (12-19) months Female: 48% Non-white:	Infants attending 1 clinic with unremarkable medical history, 4 maxillary primary incisors with no visible defects and	Number approached: NR Number eligible: NR Number	U.S. recruitment setting: Women, infants, and children clinic in Puerto Rico	National Institute of Health Grants; University of Puerto Rico	1 year	A vs. B White spot lesions on maxillary primary incisors at 1 year: 8% (3/39) vs. 32% (14/44); RR 0.24 (95% CI 0.1 to 0.8)	NR	A vs. B: 44% (17/39) vs. 34% (15/44)	Fair

Appendix B7. Trials of Treatments for the Prevention of Dental Caries

Author, Year, Title	Study Type	Interventions	Population Characteristics	Eligibility Criteria	Number Approached, Eligible, Enrolled, Analyzed	Country Setting	Sponsor	Followup Duration	Outcomes	Adverse Events/ Harms	Attrition	Quality Rating
report			NR All children high risk (used bottle at bedtime containing cariogenic liquid, 2 consecutive positive *streptococcus mutans* cultures)	were caries free, who used a bottle at naptime/ bedtime containing cariogenic liquid, and had 2 consecutive positive *streptococcus mutans* cultures from pooled maxillary incisor plaque	enrolled: 83 (39 vs. 44) Number analyzed: 83 (39 vs. 44)	Water fluoridation status: NR			Mean white spot lesions: NR Absolute reduction in caries increment: NR Reduction in caries increment: NR			

Abbreviations: AAPD = American Academy of Pediatric Dentistry; ANOVA = Analysis of Variance; CI = confidence interval; CFU = colony forming unit; dmfs = decayed, missing, filled surfaces; dmft = decayed, missing, filled teeth; g = gram; HRSA = Health Resources and Services Administration; ITT = intention to treat; mL = milliliter; MS = mutans streptococcus; NaF = sodium fluoride; NIDCR = National Institute of Dental and Craniofacial Research; NIH = National Institutes of Health; NNT = number needed to treat; NR = not reported; OR = odds ratio; ppm = parts per million; RCT = randomized controlled trial; RR = relative risk; SE = standard error; TMJ = temporomandibular joint disorder; UCSF = University of California San Francisco; U.S. = United States.

Appendix B8. Systematic Review of Fluorosis Due to Fluoride Supplements

Author, Year, Title	Databases Searched, Date of Last Search	Number and Type of Studies	Methods For Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies	Number of Patients (Treatment and Control)	Adverse Events	Quality Rating
Ismail and Hasson, 2008[38] *Fluoride supplements, dental caries, and fluorosis: A systematic review*	MEDLINE: 1966-June 2006 Cochrane: up to 2nd quarter 2006 EMBASE: 1974-2006	5 observational studies	Cochrane Handbook of Systematic Reviews	Qualitative analyses only, due to high heterogeneity of subjects, outcomes, and duration of followup	Not reported	5 observational studies reported fluorosis outcomes associated with early childhood use of fluoride supplementation All studies found an association between fluoride G2 supplementation in early childhood and risk of fluorosis One study (n=383) found OR increased by 84% per year of use of fluoride supplements (95% CI 1.4 to 2.5) One study (n=188) OR 10.8 in children started on fluoride supplements within the first 2 years of life (95% CI 1.9 to 61.6) Largest study (n=3978) found slightly increased risk that ranged from OR 1.1 to 1.7	Good

Abbreviations: CI = confidence interval; OR = odds ratio.

Appendix B9. Quality Rating of Systematic Review

Author, Year, Title	Ismail and Hasson, 2008[38] *Fluoride supplements, dental caries, and fluorosis: a systematic review*
Study Design Pre-Determined?	Yes
Dual Review of Studies and Data Abstraction?	Not reported
Comprehensive Literature Search?	Yes
Publication Status Used as Inclusion Criteria?	No
List of Included and Excluded Studies Provided?	No
Characteristics of Included Studies Provided?	Yes
Included Studies Quality Assessed?	Yes
Quality of Included Studies Considered in Formulating Conclusions?	No
Appropriate Methods Used to Combine Studies?	Yes
Publication Bias Assessed?	No
Conflict of Interest Stated?	Yes
Quality Rating	Good