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**Dental Caries Prevention:  
The Physician's Role in Child Oral Health**

**Systematic Evidence Review**

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# **Dental Caries Prevention: The Physician's Role in Child Oral Health Systematic Evidence Review**

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Technical Support for the U.S. Preventive Services Task Force

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## Preface

The Agency for Healthcare Research and Quality (AHRQ) sponsors the development of Systematic Evidence Reviews (SERs) through its Evidence-based Practice Program. With guidance from the U.S. Preventive Services Task Force\* (USPSTF) and input from Federal partners and primary care specialty societies, the Evidence-based Practice Center at Oregon Health Sciences University systematically reviews the evidence of the effectiveness of a wide range of clinical preventive services, including screening, counseling, and chemoprevention, in the primary care setting. The SERs—comprehensive reviews of the scientific evidence on the effectiveness of particular clinical preventive services—serve as the foundation for the recommendations of the USPSTF, which provide age- and risk-factor-specific recommendations for the delivery of these services in the primary care setting. Details of the process of identifying and evaluating relevant scientific evidence are described in the “Methods” section of each SER.

The SERs document the evidence regarding the benefits, limitations, and cost-effectiveness of a broad range of clinical preventive services and will help further awareness, delivery, and coverage of preventive care as an integral part of quality primary health care.

AHRQ also disseminates the SERs on the AHRQ Web site (<http://www.ahrq.gov/clinic/uspstfix.htm>) and disseminates summaries of the evidence (summaries of the SERs) and recommendations of the USPSTF in print and on the Web. These are available through the AHRQ Web site and through the National Guideline Clearinghouse (<http://www.ngc.gov>).

We welcome written comments on this SER. Comments may be sent to: Director, Center for Practice and Technology Assessment, Agency for Healthcare Research and Quality, 540 Gaither Road, Suite 3000, Rockville, MD 20850, or e-mail [uspstf@ahrq.gov](mailto:uspstf@ahrq.gov).

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\*The USPSTF is an independent panel of experts in primary care and prevention first convened by the U.S. Public Health Service in 1984. The USPSTF systematically reviews the evidence on the effectiveness of providing clinical preventive services—including screening, counseling, and chemoprevention—in the primary care setting. AHRQ convened the current USPSTF in November 1998 to update existing Task Force recommendations and to address new topics.

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## Contents

Chapter 1. Introduction.....	1
Epidemiology.....	1
Prevention.....	4
Guidelines for Prevention of Dental Caries.....	5
Access.....	7
Analytic Framework and Key Questions.....	10
Chapter 2. Methods.....	14
Studies Involving Primary Care Physicians.....	14
Studies in the Dental Literature.....	15
Chapter 3. Results.....	17
Accuracy of Screening by Primary Care Clinicians.....	17
Identifying Needed Referrals.....	17
Effectiveness of Primary Care Clinician Referral to a Dentist.....	19
Effectiveness of Fluoride Supplementation.....	20
Effectiveness of Professional Fluoride Application.....	26
Effectiveness of Counseling for Caries Prevention.....	30
Chapter 4. Discussion.....	33
Screening Accuracy.....	33
Referral Effectiveness.....	34
Effectiveness of Fluoride Supplementation.....	34
Appropriateness of Supplementation Decision.....	34
Parental Adherence.....	35
Effectiveness of Supplements.....	35
Effectiveness of Fluoride Application.....	38
Appropriateness of Application Decision.....	38
Effectiveness of Counseling.....	40
Adherence to Recommendations and Caries Prevention.....	40
Other Issues: Pediatric Medications Containing Sugar.....	41
A Research Agenda.....	42
References.....	45
Figure 1. Dental Care for Young Children from Primary Care Physicians: Analytic Framework.....	54
Table 1. Search Results on Studies of Primary Care Providers' Involvement in Child Oral Health.....	55
Table 2. Sources of Data for Collateral Evidence from the Dental Literature.....	56

Table 3. Studies Reporting Screening Accuracy for Primary Care Providers.....	57
Table 4. Risk Indicators for Dental Caries in Children Suggested for Use in Dental Practice.....	58
Table 5. Studies Reporting Referral Effectiveness.....	59
Table 6. Physicians’ Knowledge of and Behavior Regarding Fluoride Supplementation.....	60
Table 7A. Effects of Fluoride Supplements on Primary Teeth: Study Design Characteristics.....	61
Table 7B. Effects of Fluoride Supplements on Primary Teeth: Study Results.....	62
Table 8A. Clinical Studies of Fluoride Varnish Applied to Primary Teeth: Study Design.....	63
Table 8B. Clinical Studies of Fluoride Varnish Applied to Primary Teeth: Results.....	65
Table 9. Summary of Systematic Reviews of the Effectiveness of Oral Health Promotion and Education.....	67
Appendix A. Acknowledgements.....	A1
Appendix B.....	B1

## Chapter 1. Introduction

Issues of oral health in children revolve almost exclusively around dental caries. In the United States, dental caries is the most common chronic childhood disease,<sup>1</sup> and its treatment is the most prevalent unmet health need in children.<sup>2</sup> A substantial portion of caries lesions can be prevented; indeed, the incidence of this disease has declined among school-age children and adults in the past three decades. However, incidence among preschool children has not declined at a similar rate over this same time period.

### Epidemiology

Dental caries is an infectious disease that can occur when cariogenic bacteria colonize a tooth surface in the presence of dietary carbohydrates, especially refined sugars. The bacteria metabolize the carbohydrates, producing lactic acid, which over time demineralizes the tooth structure.<sup>3</sup> The earliest visible manifestation of dental caries is the appearance of a demineralized area on the tooth surface, which presents either as a small white spot on a smooth surface or a pit or fissure. At this stage, a caries lesion is usually reversible. If oral conditions do not change, demineralization will continue with the eventual result that the tooth surface loses its natural contour and a “cavity” develops. At this stage, restorative treatment is necessary to prevent the continuation of the caries process, which if left untreated will eventually result in pulpitis and ultimately tooth loss.

Progression of individual caries lesions is typically slow, but it can be extremely rapid in a small proportion of individuals and especially in primary teeth, which have thinner enamel. Because dental caries is a chronic disease of microbial origin, modified by diet, the elimination

of active caries lesions through treatment does not necessarily mean that the disease has been eradicated. An individual's risk for dental caries can change with time as etiologic factors change, leading to new caries events around already treated lesions or on previously unaffected tooth surfaces.

Dental caries can occur soon after eruption of the primary teeth, starting at 6 months of age. The most recent national survey (1988-1994) indicated that 52% of children 5 to 9 years of age have experienced dental caries;<sup>4</sup> of children 2 to 5 years of age, 18.7% have at least 1 primary tooth with untreated decay.<sup>5</sup> Referred to as early childhood caries (ECC), dental caries in preschool children can take several forms. The most severe form has a pattern of early initial attack on the maxillary incisors with the attack continuing on other teeth as they erupt.<sup>6</sup>

Dental caries incidence begins in the permanent teeth at about 6 years with the eruption of central incisors and first molars. Among children 5 to 11 years of age, 26% have experienced one or more lesions in permanent teeth; this proportion increases to 67% among adolescents 12 to 17 years of age.<sup>7</sup>

Dental caries is unequally distributed among the population. Caries incidence, prevalence, and severity is greater in minority and economically disadvantaged children.<sup>2,4,5,8</sup> Among children 1 to 2 years of age examined in the most recent national survey, all who had obvious dental caries in the maxillary incisors were in the group with incomes at or below 200% of the federal poverty line.<sup>9</sup> Among children 2 to 5 years of age, those in families at or below the poverty level are 106% more likely to have experienced dental caries than children in families with incomes above the poverty level.<sup>5</sup> At this same age, black children have 43% more untreated carious primary teeth than white children, and children at or below the federal poverty line have 138% more than children above the poverty line.<sup>10</sup>

Dental caries in primary teeth can have both short- and longer-term negative consequences. Caries lesions often cause pain because they can progress rapidly in primary teeth and involve the pulp before they are either detected or treated. About 1 in 10 children 2 to 17 years of age and 1 in 5 children from low-income families made dental visits because they were in pain or something was bothering them.<sup>11</sup> Regardless of their degree of progression, lesions cavitated into dentin require reparative treatment or tooth extraction; both are frequently traumatic experiences for young children. Young children with untreated, symptomatic carious teeth often present to emergency departments of hospitals for their first dental visit.<sup>12</sup> Also, untreated caries lesions in young children may be associated with failure to thrive,<sup>13</sup> although evidence is conflicting regarding this association.<sup>14</sup> Social outcomes of dental caries in young children are poorly documented, but children 5 to 7 years of age in the United States have been estimated to lose more than 7 million school hours annually because of dental problems and/or visits.<sup>15</sup> Untreated caries typically is cited as leading to increased infections, dysfunction, poor appearance, and low self-esteem,<sup>16</sup> but most of these associations stem from conventional wisdom rather than observational studies.

Longer-term consequences of dental caries in primary teeth include an increased probability of caries in the permanent dentition<sup>17,18</sup> and possible loss of arch space. Lack of treatment for caries in primary teeth will often result in the premature loss of the primary teeth, especially molars, which are at risk for the longest period. Premature loss of primary molars can lead to loss of arch space as the first permanent molars drift into the missing tooth spaces.<sup>19</sup> The result can be crowding of the permanent teeth, the severity of which depends on the amount of lost space. Anterior tooth crowding affects aesthetics and may necessitate orthodontic treatment for correction.

Some dentists believe that crowding increases the risk of both caries and periodontal disease in the permanent dentition because of the disruption of normal tooth-to-tooth relations that promote self-cleaning. This widely held belief is not well supported by observational studies, however.

## **Prevention**

Approaches to the prevention of dental caries involve attempts to reduce the microbiological burden, reduce the availability of refined sugars, increase the resistance of teeth, or some combination of these approaches. Reducing the microbiological burden is the focus of interventions using antimicrobial rinses and dentifrices and behavioral interventions to improve oral hygiene and thus remove the bacterial plaque coating tooth surfaces. Behavioral interventions are also used to reduce the availability of fermentable carbohydrates through changes in the composition of the diet and frequency of ingestion of refined sugar. Increasing the resistance of teeth is typically achieved through the use of sealants and fluorides. Sealants are applied to the occlusal surfaces of molars and premolars, denying bacteria access to these often hard-to-clean areas. Fluorides are used both topically (fluoride dentifrices, rinses, gels, foams, and varnishes) and systemically (fluoridated water, dietary fluoride supplements) for both prevention and management (i.e., remineralization) of dental caries. After exposure, fluoride becomes available in plaque, saliva, and the tooth's outer layer, where it increases resistance to acid dissolution, serves as a reservoir for remineralization of the initial caries lesions, or acts as a bacterial inhibitor when released through acid dissolution.<sup>3,20</sup> Another approach currently receiving attention but not yet widely endorsed attempts to eliminate transmission of cariogenic

bacteria from caregiver to child through the use of antimicrobial and behavioral interventions to reduce the reservoir of bacteria in the caregiver.<sup>21,22</sup>

## Guidelines for Prevention of Dental Caries

A growing number of guidelines provide recommendations on individual, professional, and community interventions to prevent and control dental caries.<sup>4,23-30</sup> Most recently, the Task Force on Community Preventive Services has supported the effectiveness and safety of community water fluoridation; like several of the more recent guidelines, this statement is based on systematic reviews of the evidence of effectiveness and safety.<sup>31</sup>

In 1996, the U.S. Preventive Services Task Force (USPSTF) recommended (in Chapter 61 of the *Guide to Clinical Preventive Services*) counseling patients to visit a dental care provider on a regular basis, floss daily, and brush their teeth daily with fluoride-containing toothpaste based on evidence of risk reduction from these interventions.<sup>32</sup> The USPSTF also recommended counseling caregivers to avoid putting infants and children to bed with a bottle. Dietary fluoride supplementation (hereafter referred to as fluoride supplementation) of persons 6 months to 16 years of age who drink water with inadequate fluoride was recommended based on well-designed controlled trials.

The 1995 Canadian Task Force on Preventive Health Care (CTFPHC) focused on dental interventions per se; they recommended water fluoridation, fluoride supplementation in low-fluoride areas, professional topical fluoride, and self-administered fluoride mouth rinses for persons with active decay or specific risk factors, and use of fluoride dentifrice.<sup>24</sup>

An expert panel convened by the Centers for Disease Control and Prevention (CDC) recently conducted a critical analysis of scientific evidence regarding the efficacy and

effectiveness of fluoride modalities in the prevention and control of dental caries.<sup>27</sup> Fluoride toothpaste, mouth-rinse, gel, and varnish were recommended based on the quality of the evidence of effectiveness. For the first time, the evidence of effectiveness for fluoride supplements was graded according to age. Prenatal supplements were not recommended based on the results of a single randomized controlled trial. Supplements were recommended for children and adults, but only for those at high risk for dental caries. The evidence for caries prevention was judged to be good for school-aged children and poor for preschool-aged children and adults; but targeting high-risk patients was based on expert opinion alone.

The American Academy of Pediatrics (AAP) has endorsed the CDC fluoride guidelines, thus supporting (a) community water fluoridation and fluoride toothpaste for use by the general population and (b) targeted use of professional fluoride products, including prescription of dietary fluoride supplements.<sup>30</sup> The American Dental Association (ADA) in one of its widely distributed publications also recommended limiting the use of dietary fluoride supplements and other professional fluoride products to patients with moderate to high caries risk (i.e., having 1 or more risk indicators for dental caries).<sup>23</sup> Guidelines on fluoride therapy published by the American Academy of Pediatric Dentistry (AAPD) are not specific on use of fluoride according to caries risk.<sup>25</sup> Other than the CDC fluoride guidelines for dietary fluoride supplements and fluoridated toothpaste, none of these guides is specific to young children. Appendix B provides a comparison of guidelines for supplements (Appendix Table B1) and professional application of fluorides (Appendix Table B2).

## Access

Several dental organizations, including the AAPD and the ADA, recommend a first dental visit when a child is about 1 year of age.<sup>33</sup> Bright Futures recommends a dental appointment beginning at 12 months of age also, a stance that is endorsed by more than two dozen health organizations.<sup>34</sup> Available information suggests that the majority of children see a dentist for the first time rather later in life, but national data on age at first dental visit are not available. Data from the Medical Expenditures Panel Survey and the National Health and Nutrition Examination Survey describe proportions of the child population 2 to 5 years of age who had a visit in the past year; estimates vary from 20%<sup>35</sup> to 30%,<sup>36,37</sup> suggesting that the mean age at first visit is more likely between 3 and 5 years. More recent data will be necessary to determine if the public and dental professions are following the newer guidelines on age at first dental visit.

Access to dental care for young children enrolled in Medicaid is a particularly severe problem. Of children 1 to 5 years of age enrolled in the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Program, 16% receive any preventive dental care even though all are eligible for these benefits.<sup>4</sup> A large percentage of young children with early childhood caries are able to get only emergency dental services, at best. A study of North Carolina's Medicaid population found that as few as 2% of 3-year-old enrolled children received comprehensive care in a 12-month period.<sup>38</sup>

Reasons for the poor access that young children have to dental services are numerous and complex. Two situations in particular contribute to the access problem. First, general dentists are reluctant to treat young children; only a limited number of dentists have specialty training in their care. About 3,600 pediatric dentists nationwide supply 1 pediatric dentist for every 6,000

children younger than 6 years of age.<sup>11</sup> Second, in most states, Medicaid reimburses dentists only a fraction of their usual, reasonable, and customary charges, making the treatment of any Medicaid patients financially unattractive.

Compounding the problems of access to care for Medicaid and uninsured children is that the dental safety net does not function well in most areas of the country. Local, state, and federal dental programs have limited resources to meet the dental needs of those populations with limited access to private dental care.<sup>4</sup> For example, 4 major federal programs target underserved populations: the Health Center program that funds community and migrant health centers, the Indian Health Service dental program, and the National Health Service Corps and Indian Health Service loan repayment programs, both of which provide incentives for dental providers to practice in medically underserved areas. The General Accounting Office assessed all of these programs as having only a limited effect on improving access to dental services for their targeted populations.<sup>36</sup>

Use of ambulatory health care in the medical office setting during the first year of life and from 1 to 4 years is 78% and 84.1%, respectively.<sup>39</sup> Use of dental care is 0% and 19.2%, respectively, for these same 2 age groups, demonstrating the large difference in utilization of medical care and dental care by young children. Problems with access to dental care underscore the role that primary care physicians and other child health care providers can play in providing access to preventive dental services, particularly for very young children and those who do not have access to dental care. Among young children who have experienced dental caries, a professional preventive intervention for dental caries presumably would have reduced or eliminated the incidence of disease. Yet, many children do not make a dental visit until well

after the disease has progressed beyond the reversible stage. Also, those least likely to make an early dental visit are those most likely to have dental caries.

Physicians and other primary care clinicians (PCCs) see child patients during this at-risk age before the first dental visit, providing an opportunity for them to take preventive action. Recommendations for physician interventions addressing dental caries include oral health screening and referral when indicated, provision of oral hygiene, dietary information, and anticipatory guidance to parents, and prescription of fluoride supplements.<sup>30,34</sup> PCCs also now apply fluoride varnish.

The USPSTF has limited its consideration of dental health to issues associated with prevention of dental caries in preschool children. Although the complete scope of prevention of dental diseases is much wider, the rationale for focusing on preschool children and dental caries is compelling. As noted, physicians have a role in providing dental preventive services to young children. Physicians are much more likely to see preschool children than are dentists, a situation that does not reoccur until late in life. The caries process can start at an age when most children have not visited a dentist, reducing the potential for preventive interventions by dentists and permitting extensive destruction before dental intervention. Well-defined preventive procedures within the scope of medical practice are available for physicians to utilize in this preschool population.

Thus, a sound theoretical basis exists for a focus on the role of physicians in the prevention of dental caries in preschool children. This review is not intended to suggest that the role of the physician should supplant the role of the dentist in maintaining the oral health of preschool children. Rather, the fundamental assumption of the review is that the responsibility for management of a child's oral health is shared among PCCs and dentists, and major

responsibility is transferred from a PCC to a dentist at a point in time arranged jointly by the PCC, parents, and dentist.

This report represents a departure from the chapter on Oral Health that appeared in the 1996 edition of the *Guide to Clinical and Preventive Services*. That chapter focused on counseling for the prevention of dental diseases in all ages. This summary of evidence focuses exclusively on the evidence of effectiveness for procedures applied by physicians and other primary care clinicians to prevent carious lesions in young children .

Because of these different emphases, many of the recommendations from the 1996 *Guide to Clinical and Preventive Services* are not reexamined in this report.

## Analytic Framework and Key Questions

The analytic framework for this review (Figure 1) represents a risk-based approach to the prevention and management of dental caries. It begins with a child's visit to a PCC, presumably a well-child visit. The PCC screens the child for both the presence of dental caries and risk indicators for dental caries. Depending on the results of the screening (either identification of suspected caries lesions or recognition of elevated risk for dental caries), the physician either refers the child to a dentist or initiates one or more preventive interventions (prescription of supplemental fluorides, application of fluoride varnish in the office, counseling the parents concerning caries preventive behaviors). The counseling intervention may include referral as well. If no disease or risk factors are identified, the PCC may also undertake counseling. This arm as well as the outcomes of treatment by dental professionals, are shown by dotted lines, indicating that we did not evaluate them in this review.

The framework is intended to outline general types of interventions that PCCs provide and that are appropriate to children between birth and 5 years of age. Although prenatal counseling is recommended by some professional health care organizations and may be appropriate, it is not a focus of this review. Similarly, application of dental sealants, another effective dental care preventive service, is outside the scope of the review because it is unlikely to be feasible for PCCs to provide this service.

We developed 5 key questions to direct the review.

1. How accurate is PCC screening in identifying children ages 0 to 5 years who:
  - (a) have dental caries requiring referral to a dentist?
  - (b) are at elevated risk of future dental caries?
2. How effective is PCC referral of children ages 0 to 5 years to dentists in terms of the proportion of referred children making a dental visit?
3. How effective is PCC prescription of supplemental fluoride in terms of:
  - (a) appropriateness of supplementation decision?
  - (b) parental adherence to the dosage regimen?
  - (c) prevention of dental caries?
4. How effective is PCC application of fluoride in terms of:
  - (a) appropriateness of application decision?
  - (b) achieving parental agreement for the application?
  - (c) prevention of dental caries?
5. How effective is PCC counseling for caries-preventive behaviors as measured by:
  - (a) adherence to the desired behavior?
  - (b) prevention of dental caries?

For Key Question No. 5, the caries-preventive behaviors of interest relate to diet (reduction in frequency and amount of sucrose, appropriate use of the bottle), oral hygiene (brushing frequency and efficacy), dental attendance (regular dental examinations and first visits for assessment of risk of disease), appropriate use of fluoride (accepting professional recommendations, use of fluoride dentifrice at home), and implications of caregiver oral health (possible transmission of cariogenic bacteria).

## Chapter 2. Methods

For each of the 5 key questions, we first searched the literature for studies that involved primary care practitioners. Because we anticipated finding only a limited number of studies addressing the performance of PCCs in these essentially dental roles, we also planned from the outset to address Key Questions 3, 4 and 5 using the dental literature. Our approach here was to base the appraisal of the evidence on existing systematic and traditional reviews of the literature whenever possible.

### Studies Involving Primary Care Clinicians

We used separate searches for 3 of the 5 key questions; we combined the 2 fluoride-related questions (Key Questions 3 and 4) into a single search. We searched the English language literature in MEDLINE from 1966 to October 2001. Appendix Tables B3-B6 detail the search terms and numbers of articles produced for each term for each of these searches. We used combinations of (a) terms defining primary care providers or primary care sites and (b) terms defining the dental topics embodied by the individual questions.

Our initial searches included terms capturing a wide range of research designs, from randomized controlled trials (RCTs) through questionnaire surveys. We then added any studies we identified in the Cochrane Controlled Trials Register and those identified through review of the references in papers found by the searches and through personal knowledge.

For each of the resulting 4 sets of papers, 2 reviewers independently reviewed each abstract to identify those studies eligible for full review. Criteria for this level of review were simply that the study addressed the key question, reported original data, and involved primary

care practitioners. Papers undergoing full review for inclusion were subjected to the same set of criteria. When we identified studies, we prepared abbreviated evidence tables summarizing their content.

## Studies in the Dental Literature

Because of the small number of studies identified that involved PCCs, we pursued our planned strategy of using a combination of existing reviews and new searches in the dental literature to provide necessarily collateral evidence of effectiveness for 3 questions: supplemental fluoride, applied fluoride, and counseling for caries preventive behaviors. We identified recent systematic reviews that addressed the effectiveness of applied fluoride and counseling.

We could not identify an appropriate review for the effectiveness of prescribed supplemental fluoride for caries reduction in primary teeth, regardless of who made the prescription. Although reviews on the topic were numerous, none included the collection of studies that we thought pertinent to the key question. Therefore, we performed a modified systematic review for this question wherein we identified all possible studies by searching and examining reviews of the topic and then searching forward from the most recent review (Appendix Table B7). We included controlled prospective studies in English in which the intervention began before 5 years of age and investigators assessed outcomes for primary teeth and/or permanent teeth. We accepted the absence of baseline prevalence data when initiation of supplementation occurred before eruption of the primary teeth. The controlled, prospective study criterion excluded more than half of the English language studies traditionally cited in support of the effects of supplementation in primary teeth, which employed retrospective or

cross-sectional designs with no assignment or baseline examination (Appendix Table B8). We used a separate recent systematic review of fluorosis associated with the dietary intake of fluorides to assess the harms associated with supplements, as most of the included studies did not address this outcome.<sup>40</sup>

## Chapter 3. Results

Table 1 summarizes the results of the searches for studies involving PCCs. It shows (a) the number of studies initially identified by the search, (b) the number of additional studies identified through other sources, (c) the number of these studies that either of 2 reviewers targeted for detailed review, and (d) the number found to address the key question irrespective of the research design employed by the study. Table 2 summarizes the sources of collateral evidence for effectiveness from the dental literature for 3 key questions.

### Accuracy of Screening by Primary Care Clinicians

#### Identifying Needed Referrals

We considered screening to consist of visual oral examination and parental interview. We searched only for reports involving accuracy of the visual examination in identifying treatment needs requiring referral to a dentist.

We found 2 studies germane to the visual oral examination component of PCC screening accuracy among children; both reported the performance of a single PCC visual screener, a nurse and a pediatrician (Table 3).<sup>41,42</sup> The pediatrician identified presence or absence of “nursing caries,” i.e., a caries lesion on any teeth other than mandibular incisors through examination with a mirror among children 18 to 36 months of age. No criteria for visual recognition of caries were reported, and 4 hours of training were provided. The comparison standard was a similar screening by a pediatric dentist. The nurse identified presence or absence of caries lesions, restorations, fluorosis, intraoral injuries, sealants, and urgent and nonurgent treatment needs

among children 5 to 12 years of age using a flashlight and tongue blade. Caries lesions were to be noted only if cavitation (loss of surface continuity) was present. Five hours of training preceded the assessment. The comparison standard was a visual-tactile screening examination by a dentist.

In both studies, the clinicians achieved high levels of screening accuracy (sensitivity and specificity) for dental caries following training. Sensitivities were 100% and 92% and specificities were 87% and 99% for the pediatrician (20% prevalence) and nurse (35% prevalence), respectively.<sup>41,42</sup> The nurse performed similarly in identifying children with restorations but was less accurate in identifying fluorosis, injuries, sealants, and nonurgent treatment. Many of the children in this study were older than 5 years, which may have reduced behavioral problems, thereby improving examination conditions.

### Identifying Elevated Risk for Caries

Although formal risk categorization is infrequent in current dental practice, its use has been encouraged.<sup>43,44</sup> The number of risk indicators for dental caries is large,<sup>18,28</sup> and subsets of these indicators are frequently suggested for use in dental practice. Table 4 lists risk indicators identified in 2 widely distributed sources, the Bright Futures project from the Health Resources and Services Administration (HRSA)<sup>34</sup> and the *Journal of the American Dental Association's* special supplement on caries diagnosis and risk assessment.<sup>23</sup>

The clinical risk indicators most accessible for PCC to use in screening preschool children are the presence of caries lesions, plaque retention, and the presence of white spots or other evidence of demineralization, such as discolored pits and fissures of teeth. PCCs might ascertain several of the socio-environmental and behavior indicators by interview or questionnaire, and they may already be available through health history and behavioral data that

are routinely collected. Nevertheless, we found no studies that examined PCC accuracy in identifying children who displayed one or more risk indicators using these or other risk indicators, with the exception of the studies summarized under key question 3a, which examine the appropriateness of PCC's decisions regarding fluoride supplements.

### **Effectiveness of Primary Care Clinician Referral to a Dentist**

A single case study reported on the effectiveness of PCC referral (Key Question No. 2).<sup>45</sup> The study (Table 5) examined the effectiveness of referrals to dentists made by health professional assistants for the Women, Infants and Children (WIC) Supplemental Food Program for eligible children ages 6 months to 5 years. Children who were referred on the basis of non-normal findings during intraoral screening examinations were almost twice as likely to have made a dental visit in their lifetime than children who were not referred, 37% compared to 19%. The study did not control for time elapsed since the referral had been made, and the difference in the visit rates was not significant when controlled in a multivariate analysis for child age, maternal age, household size, presence of dental insurance, and mother's perception of the child's dental needs. We did not examine collateral evidence in the dental literature for this question because no parallel situation exists.

A study that did not meet the inclusion requirement of patient contact in an office or clinic environment reported still less effective results.<sup>46</sup> When health visitors in England referred children ages birth to 2 years to dentists for dental examinations, 21% of those referred actually visited a dentist.

## Effectiveness of Fluoride Supplementation

### Appropriateness of Supplementation Decision

We identified 12 studies that addressed the appropriateness of PCCs' prescription of supplemental fluorides; of these, 10 were surveys of physicians' knowledge and behavior concerning fluoride supplementation (Table 6).<sup>47-56</sup> These studies offer only indirect evidence concerning the appropriateness of fluoride supplementation in young children because they constitute self-reported physician data and do not assess prescribing behaviors for individual children. The survey items are too dissimilar and the results too heterogeneous to permit quantitative synthesis.

Although survey results vary considerably, in general a large proportion (more than 75%) of pediatricians and a lesser proportion of family practitioners have reported providing supplemental fluoride to at least some of their child patients. Individual questions in some of the surveys indicated, however, that at the community and individual levels, physicians were not perfectly informed about local fluoridation status, which may lead to inappropriate supplementation decisions. In 2 studies,<sup>48,50</sup> only 69% and 74% of pediatricians and 26% and 58% of family practitioners reported knowing the fluoridation status of their practice areas. Only small proportions of physicians ever reported using water sample analyses to determine fluoride levels for individual water supplies.<sup>51,52,54,55</sup> In another study, 56% and 71% of physicians practicing in large and smaller fluoridated cities, respectively, reported prescribing supplements, signaling possible inappropriate supplementation.<sup>53</sup> Finally, in 1 study, 15% of family physicians and 9% of pediatricians indicated making no inquiries about fluoridation status before prescribing fluoride supplements.<sup>52</sup>

Further, physicians' age-specific dosage recommendations were often different from recommendations from the AAPD or the ADA. The right-most column in Table 6 summarizes the percentage of appropriate responses to survey items regarding age-specific dosage and recommended prescribing procedures. Pediatricians tended to answer appropriately more often than other physicians. Apart from the differences evident in the 2 surveys by Margolis and colleagues (in 1980 and 1987),<sup>47,53</sup> we could see no indications that physician knowledge has improved in the past two decades. Similarly, no obvious change has occurred in the proportion of physicians who prescribe fluoride supplements to at least some of their patients.

Two patient-based assessments of appropriate management of fluoride supplementation have been reported.<sup>57,58</sup> Twenty family medicine residents improved their knowledge of systemic fluoride therapy following a videotape presentation, but the percentage of patients appropriately managed did not change, remaining around 60%. In contrast, 88% of children visiting a single family health center were managed appropriately immediately following the institution of a new protocol. The pre-protocol level of appropriate management was estimated to have been no more than 25%. Primary care providers in the study were 2 family physicians, 1 physician assistant, and an unknown number of medical students. This study did not follow up to determine whether appropriate management was maintained at the higher post-protocol level over the longer term.

## **Parental Adherence**

We found no eligible studies of PCC effectiveness in terms of the level of parental adherence achieved with the daily dosage regimen. Our review of the dental literature similarly found no studies of effectiveness of dentists with respect to gaining parental adherence.

Indirect evidence is available for this question from adherence information collected during some supplement trials and from studies of population cohorts. Based on recent parental estimates, among Iowa infants receiving supplements at any time in the first 12 months, the mean daily dose over the full year was 0.07 mg, far less than the recommended 0.25 mg.<sup>59</sup> Parental adherence in providing supplements for Swedish preschool children had been no better two decades earlier.<sup>60</sup> Parental reports indicated that 51% of children had received supplements at some time during ages 6 months to 7 years; 12% had taken supplements regularly for a minimum of 5.5 years. Similarly, among Australian children who began receiving supplements early in life, only 18% received them regularly by age 5 to 6 years.<sup>61</sup> In a group of Canadian children 3 to 9 years old, of 35% reported to be using supplements at a certain point, 58% had discontinued their use within 1 year.<sup>62</sup>

### **Prevention of Dental Caries**

Tables 7A and 7B summarize 6 trials of the effectiveness of fluoride supplements in preventing dental caries in primary teeth when the supplementation was initiated before the age of 5 years.<sup>63-68</sup> These studies represent a variety of designs in terms of age at first use of fluoride, dosage, background fluoride level, duration of the trial, and assignment method (Table 7A).

Across these differences, reductions in the number of both teeth and tooth surfaces with caries lesions were consistently associated with use of supplements (Table 7B). The ranges of percentage reductions were 32% to 72% for primary teeth and 38% to 81% for primary tooth surfaces. The smallest proportional reductions occurred in the study with the highest background fluoride level, a level that is not considered appropriate for supplementation under current guidelines.<sup>25</sup> All reported statistical tests were significant.

These studies indicate that fluoride supplementation is effective in preventing dental caries; numbers needed to treat (NNTs) to prevent 1 additional carious tooth surface over 1 year ranged from 0.3 to 1.5. Nonetheless, generalization of these results must be done cautiously. Dropout rates in 2 studies were high (approximately two-thirds of the original samples); the dropout rate could not be determined in 2 studies. Two other studies with lower dropout rates involved a school-based program and a Taiwanese study of cleft palate children, where parental motivation may have been high because of both societal norms and other childcare requirements. No study used an intent-to-treat analysis. Equally as problematic, assignment method could not be determined in 4 studies.

Not shown in Table 7 are data about caries reductions for permanent teeth associated with use of fluoride supplements initiated before age five. Two such studies met our inclusion criteria; both are extensions of studies described in Table 7. Margolis et al reported total permanent tooth caries increments at ages 7 to 10 years for children taking fluoride supplements since age 1 to 4 months.<sup>65</sup> Compared to controls, the total number of permanent teeth experiencing caries was reduced 58% and 33% in 2 communities. The latter reduction was not statistically significant; only 28 intervention group children were available for examination in this community. Hamberg reported a 70% to 80% reduction in caries increments at age 7 to 8 years among first molars in the supplement group compared to controls but gave no statistical testing information.<sup>63</sup> These reductions mirror the wide range of statistically significant reductions in caries experienced in permanent teeth when supplementation has been started later, as a part of a school-based program.<sup>69</sup>

## Enamel Fluorosis

Enamel fluorosis is the only harm that can result from the use of dietary fluoride supplements and that is only of aesthetic importance.<sup>70,71</sup> This condition is characterized by a continuum of changes in the enamel that result from increasing degrees of hypomineralization. The very mild forms of fluorosis appear as chalklike, lacy markings across a tooth's enamel surface. Most often these slight changes are visible only when the enamel is dried and viewed under direct and careful observation. As the severity of fluorosis increases, larger areas of the enamel surface are affected and it can be observed during normal day-to-day personal interactions. The threshold at which fluorosis generally is thought to be noticeable by the public is when more than one-fourth of the enamel surface of a visible tooth is affected with a change in color from its normal, glossy creamy white appearance to an opaque-white appearance (mild or greater according to Dean's criteria).<sup>71</sup>

The prevalence of fluorosis has increased during the last 50 years.<sup>72-75</sup> The only national survey of fluorosis in the United States found a prevalence of 23.5% for permanent teeth in children 5 to 17 years of age (13.5% in children attending schools with < 0.3 ppm F; 21.7% with 0.3 to 0.7 ppm F; 29.9% with 0.7 to 1.2 ppm F).<sup>74</sup> Almost all cases were of the very mild form. About 13.1% of children who were continuous residents of nonfluoridated communities had very mild fluorosis; the figure was 28.3% in fluoridated communities. The prevalence of cases in children considered to be of some aesthetic consequence by dental professionals or the public is between 3% and 7%.

Dietary fluoride supplements are a primary risk factor for fluorosis.<sup>40</sup> A recent systematic review examined individuals' risk of enamel fluorosis resulting from the regular use of fluoride supplements in nonfluoridated communities among children birth to 6 years of age.<sup>40</sup> The review included 10 cross-sectional studies that depended on parental recall to identify extent

of exposure to supplements and 4 follow-up studies in which supplement use had been recorded earlier and outcomes were determined via subsequent clinical examinations.

In general, the dosage(s) used in these studies exceeded current recommendations. Prevalence of fluorosis associated with regular use ranged from 10% to 49% in the cross-sectional studies; incidence ranged from 15% (on central incisors only) to 67% in the follow-up studies. The cross-sectional studies identified odds ratios of dental fluorosis associated with regular use during the early years of life ranging from 1.3 to 10.7. Meta-analyses using 3 different approaches (Mantel-Haenszel, generalized variance, DerSimonian-Laird) gave summary odds ratios of 2.6, 2.6, and 2.4; the widest 95% confidence interval (CI) was 1.7 to 4.1. For the follow-up studies, individual relative risks ranged from 4.2 to 15.6; summary relative risks derived using the three meta-analytic approaches were 12.2 (95% CI, 4.9-30.4), 5.6 (95% CI, 3.4-9.4), and 5.5 (95% CI, 2.7-11.4).

The review concluded that use of fluoride supplements increases the risk of developing dental fluorosis, even though the condition is very mild in the large majority of children. No analysis of the proportion of all children experiencing fluorosis who will experience more severe forms was presented, largely because the original studies did not report these data.

Pendrys has calculated attributable risk estimates for dietary fluoride supplements for middle school children living in several communities in Massachusetts and Connecticut.<sup>76</sup> After adjusting for a several other fluoride sources, nearly two-thirds of the cases of mild-to-moderate enamel fluorosis (i.e., greater than 50% of at least 2 tooth surfaces as defined by the Fluorosis Risk Index having paper-white streaking, coalescences to opacities, or both) observed in nonfluoridated areas (prevalence of 39%) could be attributed to the use of supplements with the pre-1994 dosage schedule. The other one-third of cases could be attributed to the early use of

fluoride toothpaste. As many as 13% of cases in fluoridated communities (prevalence of 34%) could be explained by the inappropriate use of supplements.

## **Effectiveness of Professional Fluoride Application**

Fluoride products have been applied topically to the teeth of dental patients in the form of solutions, gels, and foams for many years. The fluoride product and protocol with the most data on clinical effectiveness is a 4-minute application of 1.23% sodium fluoride gel applied in a disposable tray that conforms to the dental arch. The effectiveness of this fluoride regimen in the prevention of dental caries in permanent teeth of school-aged children is well established.<sup>77</sup> However, adherence to this protocol is very difficult in the treatment of most preschool-aged children because the trays are cumbersome and sometimes uncomfortable for young children, particularly for the required application time, and children can swallow enough of the gel to cause them transient gastric irritation. Because of this latter reason, professional opinion is that gel should not be used in most children under 6 years of age. No clinical trial has tested this standard professional topical fluoride application for caries preventive effectiveness in preschool-aged children.

Fluoride varnish, which was first marketed in the United States in 1994 after the Food and Drug Administration (FDA) approved it as a medical device (as a cavity liner), has overcome these difficulties in the professional application of topical fluorides to the teeth of very young children. Because of the infrequent use of topical fluorides other than fluoride varnish in young children and the absence of clinical trials of the caries preventive effectiveness of other products, the focus of this review is on fluoride varnish alone.

Fluoride varnish was developed in Europe during the 1960s with the aim of prolonging the contact time between fluoride and the tooth surface after professional topical fluoride applications, thereby improving fluoride incorporation into the surface layers of the tooth and prolonging its release into the oral environment. Unlike some other commonly used topical fluoride agents such as gels, varnish can be applied quickly to the teeth without the need of dental devices or equipment. Its use is commonplace in Europe. Four commercial products with 2 fluoride compounds are available—5% sodium fluoride in a natural resin carrier (2.26% F, 22.6 mg/mL F, 22,600 ppm) and 1% difluorsilane in a polyurethane-based resin (0.1% F, 1.0 mg/mL F, 1,000 ppm F).

### **Appropriateness**

We identified no study addressing the appropriateness of PCC use of topical fluoride agents. The principal issues related to appropriateness are PCC familiarity with the procedure, patient selection, and adherence to clinical protocol.

Only indirect evidence is available from a single study that partially addresses these issues.<sup>78</sup> Of respondents to a national survey of pediatricians, 22% reported that they were familiar with fluoride varnish. Seventy-four percent were willing to consider the use of fluoride varnish once its purpose, clinical procedure, and costs were described briefly, but only 21% agreed that application of fluoride varnish should be part of a well-child care provided by the pediatrician.

## Parental Agreement

We identified no studies describing PCC effectiveness in obtaining parental agreement for in-office application of topical fluoride. We also were unable to locate any study describing the effectiveness of dentists in obtaining such permission.

Again, only indirect evidence of the effectiveness of providers in gaining patient acceptance is available.<sup>79</sup> Twenty-five dental hygienists practicing in Houston, Texas, recruited their patients into a study in which respondents compared fluoride varnish applications in their most recent dental hygiene visit with a previous visit in which fluoride gel was applied. The majority of the 144 patients of unspecified age rated fluoride varnish better than gel on comfort (56.5%) and taste (71.4%). A large percentage of the remaining respondents rated the two items the same. Even though the patients were divided on their assessment of the temporary discoloration resulting from the treatment (51% objecting; 49% not objecting), 64.3% reported that they would choose to have fluoride varnish over gel treatments in subsequent visits. Although this study provides only indirect evidence for effectiveness of PCCs or even dental professionals in obtaining caregivers' agreement for fluoride applications for their children, the results do suggest a higher level of patient acceptance compared to the standard topical fluoride treatment, which should make recommendations for treatment more likely to be followed.

## Prevention of Dental Caries

Table 8 summarizes 6 clinical trials of the effectiveness of fluoride varnish in preventing dental caries in primary teeth. The table updates a systematic review on the topic completed for the National Institutes of Health (NIH) Caries Consensus Development Conference.<sup>77</sup> The original review included 7 papers retrieved from MEDLINE for 1966 through 2000 having primary tooth caries increments in both experimental and control groups. In the updated review,

we deleted 2 studies in which treatment began after age 5, and added a 9-month RCT.<sup>80</sup> Three of the trials randomized assignment of treatment to groups. The 6 trials tested 2 fluoride products, 2.26% F (Duraphat®) and 0.1% F (Fluor Protector®), compared to negative (untreated) controls.

Four trials, including all 3 RCTs, found statistically significant reductions in the number of tooth surfaces with cavitated lesions in the treatment groups. Percentage reductions ranged from 30% to 63.2% in these 4 studies; the actual reduction in affected surfaces ranged from 0.23 to 1.24 per year. Results related to the increments of non-cavitated lesions (incipient lesions) were mixed, with large reductions in one trial, and non-significant increases in two experimental arms of another trial where participants consumed special diets.

### **Risks for Fluorosis**

No studies have been published on the risk of enamel fluorosis from the use of fluoride varnish.<sup>27</sup> The amount of fluoride in a typical varnish application (0.3 to 0.5 milliliters) varies from 0.3 mg to 11.3 mg.<sup>81</sup> Because only a small amount of varnish is applied, the total amount of active agent administered to the patient is markedly reduced compared to other topical fluoride application methods. The plasma fluoride peak after Duraphat® application is only about one-seventh of the peak after application of 1.23% acidulated phosphate fluoride (APF) gel.<sup>82,83</sup> In addition to the small dose, its rapid setting time when it comes in contact with saliva and its dissolution over an extended period of time minimize the risk of acute toxic reactions.

## Effectiveness of Counseling for Caries Prevention

### Adherence to Recommendations

We found a single study examining PCC effectiveness of early counseling (6 to 12 months) for caries preventive behaviors.<sup>84</sup> A quasi-experimental design involved a brief oral health promotional message provided individually by nurses in mother and child health centers compared to negative controls. Pre-post behavioral data were self-report. The intervention was essentially ineffective with respect to bottle use and minimally effective with respect to tooth brushing.

### Prevention of Dental Caries

We found no study assessing the effectiveness of a PCC-supplied counseling intervention in preventing dental caries.

We examined 4 published systematic reviews of the effectiveness of oral health promotion and dental health education from the dental literature. One of these reviews included a meta-analysis for an intermediate outcome measure, plaque score. The interventions included in these reviews were conducted by either dental personnel or public health education specialists in institutional settings and mostly for participants older than included in this review.<sup>85-88</sup>

Table 9 summarizes the findings of these reviews for knowledge level, oral hygiene behaviors, and caries prevention. Search strategies and inclusion criteria differed across the reviews, but the results were generally similar.

Interventions aimed at increasing knowledge of oral health topics were effective in the short term, but they needed reinforcement over time. However, improvement in knowledge of oral health topics was not related to changes in oral health behavior. Changing oral health

behaviors, principally oral hygiene behaviors, could be accomplished by a variety of interventions, but personal one-on-one attention with active involvement was generally the most effective strategy. The effects of interventions designed to alter oral hygiene behaviors are seen only in short-term studies; the effects are lost over periods longer than three to six months without additional intervention. The evidence for effectiveness of oral health education and promotion interventions on dental caries is extremely limited; it is associated almost entirely with adoption of the use of fluoride products. There is no conclusive evidence that interventions designed to improve oral hygiene result in caries reduction.

These reviews examined all available literature concerning oral health education and promotion. Many interventions reviewed were school-based or offered at work. The number of studies identified in the reviews that examined specific effects of dentist or dental hygienist counseling is limited, and the number that focus on dentist or dental hygienist counseling of parents for improving oral hygiene and caries outcomes among preschool children is very small.

Three studies identified by the reviews are relevant. In one, home visits by a dental health educator were more effective in initiation of fluoride supplementation and subsequent reduction of caries than in a no-contact control group and a control group offered fluoride supplementation through visits to the health department.<sup>89</sup> However, long-term outcomes were questionable because of 90% attrition. In another study, oral hygiene instructions delivered in mothers' native language at infant ages of 6, 18, and 36 months were not significantly more effective in reducing primary tooth caries than instruction delivered in mothers' adopted language when the mothers were fluent in the adopted language.<sup>90</sup> In this study, 3 clinic visits where instructions were reviewed did result in significantly less caries than 2 visits (at 6 and 18 months). The reduction may be attributable to reported adherence with fluoride supplementation

as well as more frequent attention to brushing and reduction in soft drinks. In the third study, 3- and 4-year-old children whose parents had received brushing instructions via a home visit from a dental hygienist exhibited plaque index scores comparable to those of children who brushed in small groups under supervision in preschool. Plaque index scores were significantly lower than for a control group with no group brushing or home visits. The combination of home visits and supervised group brushing did not lead to further improvement.<sup>91</sup>

## Chapter 4. Discussion

This section summarizes the strength of the evidence as well as the general findings for each of the key questions. Our approach to rating the strength of the evidence follows the current Task Force methods, in that we indicate the explicit reason(s) for each strength rating rather than rely on a fixed set of criteria.<sup>21</sup> The ratings used are “good,” “fair,” and “poor,” and they take into account the aggregate internal validity, the aggregate external validity, and the coherence and consistency of the evidence.

### Screening Accuracy

The strength of the evidence addressing the accuracy of visual oral screening examinations by primary care clinicians is poor. It consists of 2 case studies in which single PCCs identified caries lesions with an accuracy approaching that of dentists. The studies were consistent, but their formats raise substantial external validity issues.

No evidence is available for the accuracy with which PCCs can identify children at elevated risk of dental caries. Among preschool children, the strongest clinical predictor of future caries is the presence of caries lesions, so risk identification and screening accuracy may focus on the same indicator. Other risk indicators for early childhood caries are available from observational, demographic and health history data, but they remain untested. Of course, if the object of risk assessment is to prevent any incidence of caries, these risk indicators assume additional importance, as the presence of 1 or more lesions represents both an indication of elevated risk and a failure of prevention. Not only are there no studies examining the predictive

validity of PCC classifications of children based on these risk indicators, there are also no studies of how accurately PCCs can identify the presence of these indicators in preschool children.

## **Referral Effectiveness**

The evidence assessing the effectiveness of PCC referral for dental care is poor. We identified only 1 study pertinent to the key question, and it had internal validity problems. This study, as well as a study excluded because a home visitor made the referral, suggests that PCC referral may be only partially effective.

## **Effectiveness of Fluoride Supplementation**

### **Appropriateness of Supplementation Decision**

The strength of the evidence assessing the appropriateness of PCC's prescription of supplemental fluoride is fair principally because of its consistency. The studies in this evidence base are primarily self-report, have relatively low response rates, were conducted chiefly in the 1980s when dosing recommendations were different, and address general behaviors and knowledge more than specific patient-based decisions. Thus, most studies have both internal and external validity problems.

The studies indicate that the majority of physicians and the large majority of pediatricians do prescribe fluoride supplements to at least some of their patients. However, not all physicians report that they know the fluoride status or the specific fluoridation level of their patients' water supplies. This finding suggests that inappropriate prescribing is possible because fluoride availability is a key component in the decision to prescribe supplements.

Further, respondents' performance on tests of knowledge of appropriate prescribing behaviors ranged from 42% to 91%, generally indicating a knowledge deficit that tended to be smaller among pediatricians than among family and other physicians. The 2 patient-based assessments of appropriateness support the self-report findings. Physicians, residents, and medical students made imperfect supplementation decisions after educational interventions designed to improve those decisions.

Although they must be considered as indirect evidence, the results concerning physicians' knowledge of fluoridation status of their patients do represent the only information available describing physicians' accuracy in assessing risk for dental caries. The results suggest that, at least for this risk factor, physicians do not achieve high levels of accuracy, principally because the information necessary for risk assessment is not collected.

## **Parental Adherence**

The strength of the evidence for PCC effectiveness in securing parental adherence to daily supplementation regimens is poor. We found no studies examining this question. Available formal studies of parental adherence suggest that it is poor, with the dropout rate largest early in the course of supplementation.

## **Effectiveness of Supplements**

The strength of the evidence concerning the effectiveness of fluoride supplementation is fair, chiefly owing to its consistency. The available clinical trials are generally of fair to poor quality, typically using convenience samples without random assignment. None of the studies used an intent-to-treat analysis; in most studies, subjects were excluded from the analyses for

nonadherence. Dropout rates, when noted, were high, and measurement reliability generally was not assessed. External validity is also an issue, with 4 studies completed in the 1970s and the more recent trials performed in China and Taiwan. The studies were consistent, indicating that among those who comply with supplementation schedules, supplementation is effective in preventing 30% to 80% of caries lesions in primary teeth, with NNTs ranging from 0.6 to 2.6.

A smaller body of evidence points to effectiveness with respect to permanent teeth when supplements are initiated in preschool children. These 2 studies are supported by a larger body of evidence (not reviewed here) examining the effectiveness of supplementation on permanent teeth when initiated in school-aged children.<sup>69</sup>

A recommendation on the use of fluoride supplements during the first 5 years of life must consider the risks of dental caries, the effectiveness of supplements in preventing dental caries, and the potential for harms. Dental caries does not affect the majority of preschool children. By 5 years of age, about 40% of children are affected, and its presence is highly dependent on the socioeconomic circumstances of the family.

Moreover, the prevalence and severity of fluorosis has increased since baseline measures for water fluoridation were assessed in the 1940s. Limited evidence suggests that the public can discern changes in tooth color due to fluorosis. Cases of objectionable fluorosis can be attributed primarily to inappropriate use of fluoride, such as early use of too much fluoridated dentifrice, preparing infant formula with fluoridated water, or inappropriate use of supplements in fluoridated communities. The evidence regarding a cause-and-effect association between use of supplements in communities with fluoride-deficient drinking water and elevated risk for fluorosis is strong. One study suggests that two-thirds of moderate fluorosis in nonfluoridated areas is attributable to supplement use, albeit based on dosages no longer recommended.<sup>76</sup>

Dental caries remains a major public health problem for the poor and those without adequate access to dental care. Fluoride therapy is important in the prevention and control of this disease for this segment of the population as well as the population in general. However, a number of uncertainties exist concerning the importance of dietary fluoride supplements in caries prevention for US populations. The USPSTF has rated the evidence for effectiveness of supplements in preventing caries in the primary dentition as fair, and only 2 studies have been conducted of caries in permanent teeth when supplementation was started before 5 years of age. Limited research has been done on the public's perceptions of enamel fluorosis in the United States, and no studies have been conducted with the general population according to socio-economic status, which has a major effect on caries experience. Likewise, there are no studies of the caries preventive effects of supplements using the 1994 dosage schedule or the amount of fluorosis that might occur.

Expert panels have twice considered the tradeoff between caries prevention and fluorosis since the dosage schedule for dietary fluoride supplements was first developed. Each time the deliberations resulted in a reduction in the dosage schedule. The most recent change occurred in 1994: initial supplementation was delayed to 6 months of age, and the dosage was reduced for children younger than 6 years, the ages when enamel of most permanent teeth is at risk for fluorosis. No studies have assessed the effect of these changes on dental caries or fluorosis prevalence.

CDC guidelines on fluoride use concluded that children and adults who have low risk for caries are able to maintain their oral health through frequent exposures to small amounts of fluoride, notably drinking fluoridated water and use of fluoridated toothpaste. About one-third of the US population does not have access to drinking water that is fluoridated, a fundamental

intervention for the prevention and control of dental caries. Thus, a large percentage of US children still can be considered for fluoride supplementation, which is intended to mimic the caries-inhibiting effects of water fluoridation. Residence in a nonfluoridated community should be one of the considerations for risk determinations. However, large numbers of children in nonfluoridated communities are caries free or have small numbers of affected teeth, which suggests that fluoridation alone is not the only risk factor to be considered in this complex disease.

Both ADA and CDC guidelines suggest that supplements be used judiciously and be reserved for children who are at elevated risk for caries regardless of the fluoridation status of their drinking water; AAP has endorsed the CDC guidelines on fluoride use. This approach to fluoride supplementation acknowledges that the risk of fluorosis might outweigh the benefits of caries reductions in those children who have low risk for disease.

## **Effectiveness of Fluoride Application**

### **Appropriateness of Application Decision**

Adoption of fluoride varnish by primary care providers is in its early stages in the United States. Its use in dentistry is common practice in Europe. Information on the extent to which fluoride varnish is used in dental practice in the United States is limited, but anecdotal information suggests that it might be increasing. Some dental schools are teaching its use, the number of products available on the market has increased from one when it was first approved by the FDA to four, and insurance companies are promoting its use. Use of fluoride varnish by general dentists increased from 32% to 44% in Washington State after it was promoted as a

dental benefit.<sup>92</sup> The primary incentives for its use over other topical fluoride agents are its ease of use, patient acceptance, and reduced potential for toxicity.

Information on use of fluoride varnish by physicians or other primary health care providers is even more limited than for the dental profession. A few states provide reimbursement to physicians through their Medicaid programs, but service statistics are generally unavailable.<sup>93</sup> A national study supports the early stages of exposure of physicians to this intervention. Only 22% of pediatricians reported that they were familiar with fluoride varnish.<sup>78</sup>

### **Parental Agreement**

No information is available on parental acceptance of a PCC's recommendation to have a topical fluoride application for their child. Likewise, no evidence of concern or refusals has been reported in the literature.

### **Effectiveness of Fluoride Application**

The evidence supporting the effectiveness of fluoride varnish in the prevention of dental caries in preschool-aged children is fair. No studies are available beginning at 1 or 2 years of age (i.e., the time that children at high risk for dental caries need to begin treatment), but results of clinical trials of older children are consistent.

Six trials have tested the caries-inhibiting effects of fluoride varnish when applied to primary teeth of children younger than 6 years of age. The quality of these studies is generally good. Four studies, including all 3 RCTs, showed caries-inhibiting effects. In 1 of the 2 studies with nonsignificant differences, Grodzka et al. used group assignment of children attending education centers and were unable to control adequately for potential group differences.<sup>94</sup>

Petersson et al. studied Swedish clinic patients with low caries rates.<sup>95</sup> Fluor Protector® had no

effect overall but did have statistically significant caries-inhibiting effects for children with high rates of decay on interproximal tooth surfaces, which presumably places these children in a high-risk category.

The RCT by Holm provides the strongest evidence of a caries-preventive effect.<sup>96</sup> Children were followed for 2 years, with a caries reduction of 43.8% and an NNT of 1.2. The other 2 RCTs with positive effects are either of short duration<sup>80</sup> or embed the evaluation of Duraphat® in a selected population derived from an intervention study of invert sugar.<sup>97</sup> The Duraphat®-only group resulted from random assignment of those who did not want to participate in the sugar trial to the treatment and control groups. These studies of fluoride varnish use in young children are supported by a larger body of evidence that provides good evidence of effectiveness in permanent teeth for topical applications of both fluoride varnish<sup>98,99</sup> and other fluoride compounds.<sup>100,101</sup>

## **Effectiveness of Counseling**

### **Adherence to Recommendations and Caries Prevention**

The USPSTF found insufficient evidence for the effectiveness of counseling provided by PCCs for caries-preventive behaviors. The single available study describes an ineffective intervention.

The systematic reviews of the oral health promotion and dental health education literature suggest that knowledge improvement is easily achieved but that behavioral change is more difficult. They also suggest that caries reduction is likely only if the behavioral change involves use of fluoride. The 3 studies of counseling parents of infants describe oral hygiene behavior and caries reduction results that are more promising than what the entire literature would

suggest, as noted in Table 9. These three interventions all featured individual, personalized contact, which the reviews suggested is more effective in achieving behavioral change than more impersonal methods. Also, the personnel involved in the interventions were either dental auxiliary personnel (dental hygienists, dental assistants) or dental health educators.

### **Other Issues: Pediatric Medications Containing Sugar**

In the course of completing the reviews required to address the key questions, we encountered an additional aspect of dental health among children that may involve primary care providers. Many pediatric medicines contain sugar, presumably to make them more palatable. The extent to which long-term use of these medicines affects oral health is at issue. The strongest evidence available comes from 2 cross-sectional comparisons of children with histories of long-term (6 or more months) use of sugar-sweetened liquid medication with controls matched on age and, in 1 study, race, sex, number of teeth, fluoridation history, and dentist.<sup>102,103</sup> One study, which was conducted in a nonfluoridated area using visual examination techniques only, included 44 children in the exposure group and 47 controls. Mean primary tooth caries experience was 4.4 times as great in the exposure group (defs = 5.55) as in the controls (defs = 1.26). The other study was conducted in a fluoridated area, used radiographs as a part of the examination, and included 40 children in both the exposure and control groups. Mean caries experience was 2.9 times as great in the exposure group (defs = 4.57) as in the controls (defs = 1.55). Although these studies were unable to control for all possible risk factors, their results should be considered at least suggestive of the oral health risk associated with the long-term use of sucrose-sweetened medications among preschool children.

## A Research Agenda

The evidence base for recommendations to physicians concerning dental caries prevention in young children needs to be strengthened. A key issue that underlies many of the possible preventive initiatives available to physicians and other primary care clinicians is whether they can accurately assess risk of dental caries. Elements of this issue include the predictive validity of current risk indicators and physicians' application of these indicators. Not all of the risk indicators currently advocated for use (Table 4) have been validated individually in prospective studies, and the relative strength of combinations of these indicators is entirely untested. Thus, echoing the recommendation of the recent NIH Consensus Development Conference on Diagnosis and Management of Dental Caries Throughout Life,<sup>104</sup> "more and higher-quality comprehensive, longitudinal, multifactor studies of implicated risk indicators are needed to obtain firm support for their associations with caries incidence, to clarify the strengths of these associations in differing populations, and to reveal the extent to which the indicators provide independent as opposed to redundant information." In addition, assessments of the accuracy of physicians' use of these risk indicators in identifying young children at elevated risk for dental caries are needed.

Several other issues also merit additional examination. One is the effectiveness of PCC application of fluoride varnish for delaying the initial onset and reducing the incidence and increment of dental caries in young children. The existing studies constitute only fair evidence, represent efficacy studies, and were all performed by dental personnel. One or more effectiveness studies performed under field conditions by PCCs would strengthen the evidence base for this incompletely evaluated approach to prevention.

A second issue that could benefit from additional studies is the effectiveness and adverse outcomes of the current dosing schedule for supplemental fluoride. As noted, the recommended dose has been reduced twice in little more than a decade, and no studies of the effects of the most recently recommended regimen have been reported. Studies should examine preventive effectiveness and also quantify risk of fluorosis by severity.

Another issue for which further study is recommended is already the focus of increasing interest, and the results of ongoing studies may have substantial implications for counseling pregnant women and new mothers in the future. Efforts to block or delay the transmission of cariogenic bacteria from caregiver to child should be evaluated for their long-term effectiveness as well as their effectiveness in the short term. Even if the outcome of such efforts is simply to delay the appearance of lesions among the most susceptible, such a delay would increase the likelihood of exposure to other preventive interventions before the time that the development of a child's first lesion could be expected, which presumably could have an effect on caries incidence. The investigations into this potential approach to prevention should be broadened to include additional populations and investigators.

Obviously, the effectiveness of PCC counseling for behaviors to promote oral health needs to be examined. Given the little that is known about effectiveness, the greater amount of effort should be placed on developing approaches to increase current levels of effectiveness, rather than simply documenting these levels. Much of the arsenal of preventive interventions available to PCCs depends on parental compliance with counseled behaviors, and methods to increase compliance need to be explored.

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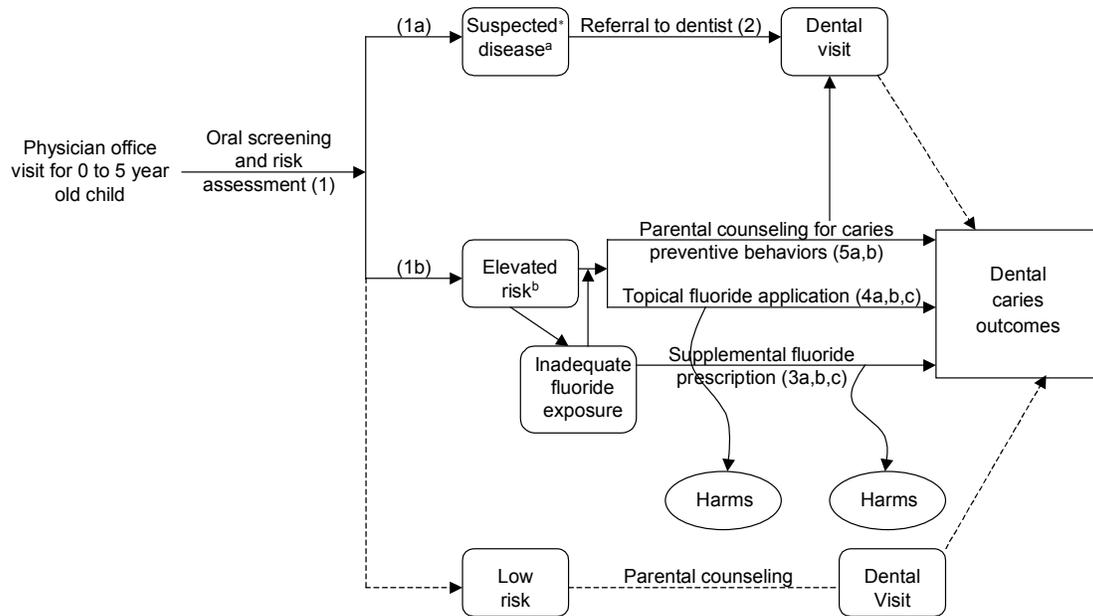
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Figure 1. Dental Care for Young Children from Primary Care Physicians: Analytic Framework



<sup>a</sup> Suspected disease: The PCC either visually identifies one or more cavitated lesions, or suspects that such a condition is present.

<sup>b</sup> Elevated risk: The PCC identifies one or more risk indicators such as:

- inadequate fluoride exposure
- caries in siblings or parents
- irregular brushing/plaque retention
- white spots on smooth tooth surfaces
- frequent/prolonged carbohydrate exposure
- special needs/medical conditions that increase risk
- lower socioeconomic status

## **Appendix A**

### **Acknowledgments**

## Appendix A Acknowledgments

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## **APPENDIX B**

**Appendix Table B1. Recommendations on Use of Daily Dietary Fluoride Supplementation**

<b>Organization</b>	<b>Dosage Schedule</b>	<b>Risks</b>	<b>Level of Evidence</b>	<b>Recommendation</b>
USPSTF, 1996 <sup>32</sup>	ADA and AAP 1995 guidelines.	Increase in the prevalence of dental fluorosis has been attributed to inappropriate use of fluoride supplements by health professionals and parents, which is particularly common among infants.	Nonrandomized controlled trials (II-1).	For children <16 years living in an area with inadequate water fluoridation (<0.6 ppm), the prescription of daily fluoride drops or tablets is recommended (A).
CTFPHC, 1995 <sup>24</sup>	CDA guidelines.	Inappropriate prescribing of excess fluoride supplements is the main factor in recent increases in the incidence of fluorosis.	Nonrandomized controlled trials (II-1). The new lower dosage schedule approved by the Canadian Dental Association has not been subjected to clinical trials.	Good evidence of reductions in the incidence of decay if the proper dosage schedule is carefully followed (A).
CDC, 2001 <sup>27</sup>	ADA, AAPD, and AAP 1995 guidelines.	For children aged <6 years, the dentist, physician, or other health-care provider should weigh the risk for caries without fluoride supplements, the caries prevention offered by supplements, and the potential for enamel fluorosis.	The evidence for using fluoride supplements to mitigate dental caries is mixed. Use of fluoride supplements by pregnant women does not benefit their offspring (I). Many studies of the effectiveness of fluoride supplements in preventing dental caries among children aged <6 years have been flawed in design and conduct. Because of these flaws, the quality of evidence to support use of fluoride supplements by children aged <6 years is Grade II-3. Among children aged 6-16 years, fluoride supplements taken after teeth erupt reduce caries experience (I). Fluoride supplements might be beneficial among adults who have limitations with toothbrushing, but this use requires further study.	Fluoride supplements can be prescribed for children at high risk for dental caries and whose primary drinking water has a low fluoride concentration (C high-risk children <6 yrs; A high risk children 6-16 yrs; C high risk >16 yrs; E pregnant women).

**Appendix Table B1. Recommendations on Use of Daily Dietary Fluoride Supplementation (continued)**

<b>Organization</b>	<b>Dosage Schedule</b>	<b>Risks</b>	<b>Level of Evidence</b>	<b>Recommendation</b>
AAP, 2001 <sup>30</sup>	Endorses CDC fluoride recommendations			
AAPD, 2000 <sup>25</sup>	ADA, AAPD, and AAP 1995 guidelines.			Should be considered for all children drinking fluoride deficient water.

Note: USPSTF, U.S. Preventive Services Task Force; CTFPHC, Canadian Task Force on the Preventive Health Care; CDC, Centers for Disease Control and Prevention; AAP, American Academy of Pediatrics; AAPD, American Academy of Pediatric Dentistry; ADA, American Dental Association

**Appendix Table B2. Recommendations on the Use of Professional Topical Fluoride Applications**

Organization	Agent	Risks	Evidence	Recommendation
USPSTF, 1996 <sup>32</sup>	Topical fluorides	Not evaluated		
CTFPHC, 1995 <sup>24</sup>	Topical fluorides, e.g., APF gel 1-2 time per yr		RCTs (I) involving mainly children & adolescents conducted before incidence of caries declined.	For use in those with very active decay or a high risk of caries, since their ds. mimics that in general population before decline.
NIH Consensus Statement, 2001 <sup>104</sup>	APF gel 1-2 times per yr		Consistently positive.	
	Fluoride varnish		<i>Permanent teeth</i> —generally positive <i>Primary teeth</i> —Incomplete and inconsistent	
CDC Fluoride Recommendations, 2001 <sup>27</sup>	Fluoride gel	Because application is infrequent, poses little risk for fluorosis.	RCTs (Grade I)	Important in the prevention and control of caries in high-risk persons. Likely to have little benefit in person not at high risk (A).
	Fluoride varnish	No evidence that it is a risk factor for fluorosis.	RCTs (Grade I)	If approved by the FDA for prevention of caries, indications for use will be similar to gel (i.e., high risk). Has practical advantages for <6.
Scottish Intercollegiate Guidelines Network, 2000 <sup>*26</sup>	Fluoride varnish		At least one RCT (Level Ib)	May be applied every 4-6 mo to teeth of high-caries-risk children (B)

Note: USPSTF, U.S. Preventive Services Task Force; CTFPHC, Canadian Task Force on the Preventive Health Care, National Institutes of Health; CDC, Centers for Disease Control and Prevention; FDA, Food and Drug Administration; RCT, randomized controlled trials

\* Review limited to permanent teeth of children 6 to 16 years of age. Topical fluorides other than varnish were not addressed.

Appendix Table B3. Search Strategy: Screening for Dental Caries (Key Question No. 1)

Step	Search History	Number of Articles
1	Explode physicians	42,299
2	Explode pediatrics/ or pediatrician\$.mp	20,495
3	Explode nurse practitioners	8,419
4	Explode nurse's aides	2,512
5	Explode physician assistants	3,087
6	Explode nurse clinicians	3,874
7	Nurses	17,410
8	Primary care physician\$.mp.	5,771
9	General practitioner\$.mp.	15,510
10	Primary care clinician\$.mp.	215
11	Explode ambulatory care facilities	26,003
12	Explode primary health care	30,950
13	Explode physician's role	14,507
14	Explode physician's practice patterns	11,285
15	Explode mass screening	51,371
16	Explode health behavior	32,461
17	Explode health promotion	19,365
18	Explode infant welfare	424
19	Explode health services accessibility	40,624
20	Explode child health services	11,926
21	Explode child health services	11,926
22	Explode "referral and consultation"	31,229
23	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 or 22	334,557
24	Limit 23 to (human and english language)	227,440
25	Limit 24 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)	10,765
26	Explode epidemiologic study characteristics	770,784
27	Explode epidemiologic research design	277,013
28	Explode questionnaires	86,495
29	(26 or 27 or 28) and 24	47,943
30	25 or 29	51,804
31	Explode dental caries	23,407
32	Dental screening.mp. Or explode dental care for children	842
33	Explode dental care/ or dental examination.mp. Or explode diagnosis, oral	27,796
34	31 or 32 or 33	48,933
35	34 and 30	497
36	Limit 35 to (infant <1 to 23 months> or preschool child <2 to 5 years>)	117
37	From 36 keep 1-117	117

Appendix Table B4. Search Strategy: Referral for Dental Care (Key Question No. 2)

Step	Search History	Number of Articles
1	Explode physicians	42,299
2	Explode pediatrics/ or pediatrician\$.mp.	20,495
3	Explode nurse practitioners	8,419
4	Explode nurse's aides	2,512
5	Explode physician assistants	3,087
6	Explode nurse clinicians	3,874
7	Nurses	17,410
8	Primary care physician\$.mp.	5,771
9	General practitioner\$.mp.	15,510
10	Primary care clinician\$.mp.	215
11	Explode ambulatory care facilities	26,003
12	Explode primary health care	30,950
13	Explode physician's role	14,507
14	Explode physician's practice patterns	11,285
15	Explode mass screening	51,371
16	Explode health behavior	32,461
17	Explode health promotion	19,365
18	Explode infant welfare	424
19	Explode health services accessibility	40,624
20	Explode child health services	11,926
21	Explode child health services	11,926
22	Explode "referral and consultation"	31,229
23	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 24 limit 23 to (human and english language)	227,440
25	Limit 24 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)	10,765
26	Explode epidemiologic study characteristics	770,784
27	Explode epidemiologic research design	277,013
28	Explode questionnaires	86,495
29	(26 or 27 or 28) and 24	47,943
30	25 or 29	51,804
31	Explode MOTHERS	8,839
32	Explode PARENTS	27,870
33	31 or 32	27,870
34	Explode dental health services/ or dental utilization.mp. Or explode dental care	19,128
35	30 and 34	438
36	Limit 35 to (infant <1 to 23 months> or preschool child <2 to 5 years>)	92
37	33 and 35	22
38	36 or 37	102

**Appendix Table B5. Search Strategy: Fluoride Prescription and Application (Key Question Nos. 3 and 4)**

Step	Search History	Number of Articles
1	Explode physicians	48,669
2	Explode pediatrics/ or pediatrician\$.mp.	24,373
3	Explode nurse practitioners	8,436
4	Explode nurse's aides	2,521
5	Explode physician assistants	3,113
6	Explode nurse clinicians	3,891
7	Nurses	17,980
8	Primary care physician\$.mp.	5,864
9	General practitioner\$.mp.	15,688
10	Explode physicians, family	8,489
11	Primary care clinician\$.mp.	217
12	Explode ambulatory care facilities	26,115
13	Explode primary health care	31,703
14	Explode physician's role	16,055
15	Explode physician's practice patterns	11,495
16	Explode mass screening	53,682
17	Explode health behavior	35,622
18	Explode health promotion	19,558
19	Explode infant welfare	444
20	Explode health services accessibility	43,806
21	Explode child health services	11,981
22	Explode "referral and consultation"	32,015
23	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 or 22	353,428
24	Limit 23 to (human and english language)	234,983
25	Limit 24 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)	10,995
26	Explode epidemiologic study characteristics	775,270
27	Explode epidemiologic research design	279,029
28	Explode questionnaires	87,784
29	(26 or 27 or 28) and 24	49,240
30	25 or 29	53,190
31	Explode mothers	9,310
32	Explode parents	30,640
33	31 or 32	30,640
34	Explode fluorides, topical	3,044
35	Explode fluorides	18,617
36	Explode cariostatic agents	20,675
37	Supplemental fluoride\$.mp.	25
38	Fluoride tab\$.mp.	263
39	Fluoride drop\$.mp.	10
40	Fluoride varnish\$.mp.	197
41	34 or 35 or 36 or 37 or 38 or 39 or 40	21,167
42	30 and 41	71
43	Limit 42 to (newborn infant <birth to 1 month> or infant <1 to 23 months> or preschool child <2 to 5 years>)	31
44	42 and 33	5
45	43 or 44	31

**Appendix Table B6. Search Strategy: Conseling for Caries Preventive Procedures (Key Question No. 5)**

Step	Search History	Number of Articles
1	Explode physicians	48,669
2	Explode pediatrics/ or pediatrician\$.mp. [mp=title, abstract, registry number word, mesh subject heading]	24,373
3	Explode nurse practitioners	8,436
4	Explode nurse's aides	2,521
5	Explode physician assistants	3,113
6	Explode nurse clinicians	3,891
7	Explode nurses	42,028
8	Primary care physician\$.mp.	5,864
9	General practitioner\$.mp.	15,688
10	Primary care clinician\$.mp.	217
11	Explode ambulatory care facilities	26,115
12	Explode primary health care	31,703
13	Explode physician's role	16,055
14	Explode physician's practice patterns	11,495
15	Explode mass screening	53,682
16	Explode health behavior	35,622
17	Explode health promotion	19,558
18	Explode infant welfare	444
19	Explode health services accessibility	43,806
20	Explode child health services	11,981
21	Explode "referral and consultation"	32,015
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	364,755
23	22	364,755
24	Limit 23 to (human and english language)	243,800
25	Limit 24 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)	11,058
26	Explode epidemiologic study characteristics	775,270
27	Explode epidemiologic research design	279,029
28	Explode questionnaires	87,784
29	(26 or 27 or 28) and 24	50,034
30	25 or 29	54,008
31	Explode mothers	9,310
32	Explode parents	30,640
33	31 or 32	30,640
34	Explode dental care for children	805
35	Explode dental caries	23,439
36	Explode oral hygiene	9,346
37	Explode oral health	4,812
38	Explode health education, dental	4,518
39	Explode diet, cariogenic/	973
40	Explode dental care	15,676
41	34 or 35 or 36 or 37 or 38 or 39 or 40	49,286
42	30 and 41	630
43	Limit 42 to (infant <1 to 23 months> or preschool child <2 to 5 years>)	121
44	33 and 42	41
45	43 or 44	137

**Appendix Table B7. Reviews of Fluoride Supplements for Caries Reduction\***

Step	Search History	Number of Articles
1	Fluoride supplementation.mp	147
2	Fluoride supplement\$.mp	402
3	Fluoride tab\$.mp	263
4	Explode Fluorides/ and Explode Dietary Supplements	649
5	1 or 2 or 3	56
6	4 or 5	670
7	Limit 6 to (human and English language and review articles)	
8	Limit 6 to evidence-based medicine reviews or all embd articles reviews or topic reviews <cochrane> or article reviews <acp journal club> or article reviews <dare>	1
9	7 or 8	64

\*The search was repeated from 1995 to January 2002 seeking all publication types limited to human and English language.

**Appendix Table B8. Fluoride Supplement Review, Excluded English Language Studies\***

Study	Reason
Awad et al., 1994 <sup>107</sup>	No negative control
Kalsbeek H et al., 1992 <sup>108</sup>	Cross-sectional, poor exposure history
Widenheim & Birkhed 1991 <sup>109</sup>	Cross-sectional data
D'Hoore & Van Nieuwenhuysen 1992 <sup>110</sup>	Cross-sectional, no primary teeth data, mixed exposure analysis
Mann et al., 1989 <sup>111</sup>	Subjects <5 and >5 at baseline combined
de Liefde & Herbison 1989 <sup>112</sup>	Cross-sectional, no primary tooth data, poor exposure data
Bagramian et al., 1989 <sup>113</sup>	Cross-sectional, no primary tooth data, initiation age not specified
O'Rourke et al., 1988 <sup>114</sup>	Mean child age >5 years at baseline
Widenheim et al., 1986 <sup>115</sup>	Cross-sectional, no primary tooth data
Petersson et al., 1985 <sup>116</sup>	No negative control
Friis-Hasché et al., 1984 <sup>117</sup>	Cross-sectional, poor exposure data, inadequate exposure
Holm & Andersson, 1982 <sup>118</sup>	Cross-sectional, no primary tooth data
Fanning et al., 1980 <sup>119</sup>	Cross-sectional
Thylstrup et al., 1979 <sup>120</sup>	Cross-sectional, poor exposure data
Granath et al., 1978 <sup>121</sup>	Cross-sectional
Andsenden & Grahne, 1976 <sup>122</sup>	Cross-sectional
Fanning et al., 1975 <sup>61</sup>	Cross-sectional
Aasenden & Peebles, 1974 <sup>123</sup>	Cross-sectional
Pritchard, 1969 <sup>124</sup>	Cross-sectional, exposure determination method not described
Kailis et al., 1968 <sup>125</sup>	Cross-sectional, fluoride exposure data inadequate
Hennon et al., 1967 <sup>126</sup>	Cross-sectional
Minoguchi et al., 1963 <sup>127</sup>	Cross-sectional, no primary tooth data, initiation age not specified
Arnold et al., 1960 <sup>128</sup>	No concurrent control

\* From those included in previous reviews and those identified post 1985.

**Table 1. Search Results on Studies of Primary Care Providers' Involvement in Child Oral Health**

	<b>Key Question</b>	<b>Identified in MEDLINE Search</b>	<b>Added from Other Sources</b>	<b>Reviewed in Detail</b>	<b>Included</b>
1	Screening accuracy	117	1	12	2
2	Referral effectiveness	102	0	12	1
3-4	Fluoride supplementation and fluoride application	31	7	17	12
5	Counseling for caries preventive behaviors	137	3	20	1

**Table 2. Sources of Data for Collateral Evidence from the Dental Literature**

	Key Question	Published Reviews		New Review	Updated Review
		Systematic	Narrative		
3	Fluoride supplementation	1	4	1	0
4	Fluoride application	1	0	0	1
5	Counseling for caries preventive behaviors	4	0	0	0

**Table 3. Studies Reporting Screening Accuracy for Primary Care Providers**

Citation	Condition To Be Detected	Population Screened	Population Prevalence	PCC Screener	Training	Comparison Standard	Sensitivity/ Specificity
Serwint et al, 1993 <sup>41</sup>	Untreated decay anywhere but lower primary incisors	Children 18 to 36 months, n = 61	20%	Pediatrician, n = 1 No prior dental experience	4 hours	Pediatric dentist	Sens = 100% Spec = 87%
Beltran et al, 1997 <sup>42</sup>	Untreated decay in primary and permanent teeth	Children 5 to 12 years, n = 219	35.2%	Nurse, n = 1 No prior dental experience	5 hours	Dentist	Sens = 92.2% Spec = 99.3%
	Restorations	n = 233	39.9%				Sens = 96.7% Spec = 99.3%
	Fluorosis	n = 323	40.3%				Sens = 72.3% Spec = 96.4%
	Injuries	n = 323	12.1%				Sens = 79.5% Spec = 97.5%
	Sealants	n = 323	6.8%				Sens = 59.1% Spec = 99.7%
	Nonurgent treatment	n = 288	18.4%				Sens = 66.0% Spec = 99.2%
	Urgent treatment	n = 261	10.7%				Sens = 100% Spec = 100%

Note: PCC, primary care clinician; sens, sensitivity; spec, specificity.

**Table 4. Risk Indicators for Dental Caries in Children Suggested for Use in Dental Practice\***

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<b>Clinical Indicators</b>
One or more caries lesions
Caries lesion restored within the past year
Deep pits and/or grooves on tooth surfaces
Plaque retention
White spots on smooth surfaces
Elevated <i>S mutans</i> level
Low salivary flow

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<b>Behavioral Indicators</b>
Frequent between-meal sugar intake
Special carbohydrate diet
Inappropriate baby bottle use
Irregular brushing
Eating disorders
Long-term use of sugared medications

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<b>Socio-environmental Indicators</b>
Inadequate fluoride (nonfluoridated water supply or use of bottled or filtered water)
Caries in siblings, parents, or both
Lower socioeconomic status

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\* Adapted from Bright Futures in Practice: Oral Health<sup>34</sup> and the American Dental Association.<sup>23</sup>

**Table 5. Studies Reporting Referral Effectiveness**

Citation	Population	Percent Referred	Reason For Referral	Referrer	Percent With Dental Visit
McCuniff et al., 1998 <sup>45</sup>	WIC participants, 6 months to 5 years n = 269	33%	Any abnormality found at screening	Health professional assistant	Referred = 37% Not referred = 19% <i>P</i> = < 0.05*

Note: WIC, Women, Infant and Children program.

\* Statistically significant in bivariate analysis; not significant in multivariate analysis controlling for age, maternal age, household size, dental insurance, mother's perceptions of child's dental needs.

**Table 6. Physicians' Knowledge of and Behavior Regarding Fluoride Supplementation**

Citation	Response Rate, Number of Subjects	Venue, Percent with Optimal Fluoride	Type of Physician	Prescribe Fluoride to Any Patients	Know Fluoride Level Status	Mean of Appropriate Responses, N Items
Margolis et al., 1980 <sup>47</sup>	49% 1,286	National, Varies	Pediatr	81%	96%*	79%, 3
			Fam	63%	74%*	68%, 3
Siegel and Gutgesell, 1982 <sup>48</sup>	56% 238	Houston Suboptimal	Pediatr	48% <sup>r†</sup>	69% <sup>‡</sup>	75%, 1
			Fam	18% <sup>r†</sup>	26% <sup>‡</sup>	42%, 1
Gift et al., 1984 <sup>49</sup>	50% 933	National, Varies	All Active in Child Care	80%	NR	78%, 6
Rigilano et al., 1985 <sup>50</sup>	47% 237	Air Force, Varies	Pediatr	NR	74% <sup>‡</sup>	87%, 4
			Fam and OB	NR	58% <sup>‡</sup>	64%, 4
Levy, 1987 <sup>51</sup>	77% 37	Acad. HC, Unknown	Fam (fac, res, affil)	~80%	67% <sup>§</sup>	NR
Kuthy and McTigue, 1987 <sup>52</sup>	60% 1,332	Ohio, Varies	Pediatr	86%	91%	NR
			Fam	73%	83%	NR
Margolis et al., 1987 <sup>53</sup>	45% 1,269	National, Varies	Pediatr	90%	97%*	91%, 3
			Fam	76%	86%*	91%, 3
Dillenberg et al., 1992 <sup>54</sup>	31% 280	Arizona, Suboptimal	Pediatr	70%	NR	53%, 4
			Other	47%	NR	32%, 4
Jones and Berg, 1992 <sup>55</sup>	62% 95	Houston, Suboptimal	Pediatr	97%	NR	49%, 1
Roberts et al., 1998 <sup>56</sup>	95% 40	Acad HC, Unknown	Pediatr	93% <sup>¶</sup>	NR	79%, 2

Note: subopt, suboptimal; acad HC, academic health center; pediatr, pediatrician; fam, family physician; OB, obstetrician, fac, faculty; res, resident; affil, affiliated; NR, not reported.

- \* Percentage of patients with municipally fluoridated water
- † Prescribe routinely ( r )
- ‡ Fluoride concentration of water in practice area
- § Approximate percentage of patients with fluoridated water
- ¶ Routinely addressed needs

**Table 7A. Effects of Fluoride Supplements on Primary Teeth: Study Design Characteristics**

Citation	Site and Background Fluoride Level	Base-line Number of Subjects and Age	Experimental Intervention	Control Intervention	Assignment Method	Population Description	Blinding	Number of Examiners	Examiner Agreement	Exam Criteria
Hamberg, 1971 <sup>63</sup>	Sweden ~0.2 ppm	705 2-3 weeks	0.5 mg F and V drops	V drops	Unclear: possibly random	Visitors to well-baby clinics	Parents and examiners	1	NR	NR
Hennon et al, 1972 <sup>64</sup>	Indiana <0.4 ppm, some with >exposure	815 18-39 months	E <sub>1</sub> : 1.0 mg F chews E <sub>2</sub> : 1.0 mg F and V chews	V chews	Unclear: stratified by age, caries	Unknown source	Parents; presumably examiners	NR	NR	ADA 1966 and bitewings
Margolis et al, 1967, <sup>105</sup> 1975* <sup>65</sup>	Michigan and New York nonfluoridated	297 1-4 months	0-3 yr: 0.5mg F and V drops 3+ yr: 1.0 mg F and V chews	0-3 yr: V drops 3+ yr: V chews	Unclear: may not be from same population	Infants in pediatric offices	Parents and examiners	Multiple, number not reported	NR	NR
Hennon et al, 1977 <sup>66</sup>	Indiana 0.6-0.8 ppm	456 1-14 months	0-3 yr: 0.5 mg F and V drops E <sub>1</sub> 3+ yr: 1.0 mg F and V chews E <sub>2</sub> 3+ yr: 0.5 mg F and V chews	0-3 yr: V drops 3+ yr: V chews	Systematic: stratified by age, sex	Infants in 8 towns with in-range F levels	Parents and examiner	1	NR	NR, bitewings used
Hu et al, 1998 <sup>67</sup>	China <0.3 ppm	324 24 months	2 yr: 0.25 mg F drops 3+ yr: 0.5 mg F drops	None	Unclear, all similar SES: assigned by school	Kindergarten students	NR	2	r = 0.90	Radike
Lin and Tsai, 2000 <sup>68</sup>	Taiwan <0.1 ppm	140 <sup>†</sup> 22-26 months	E <sub>1</sub> : 0.25 mg F chews E <sub>2</sub> : 0.25 mg F drops	None	Random	Patients at cleft clinic	Examiners	2	k = 0.85	WHO

Note: ppm, parts per million; wk, weeks; mo, months; yr, year; E<sub>1</sub>, experimental group 1; E<sub>2</sub>, experimental group 2; F, fluoride; V, vitamins; chews, chewable tablets; SES, socioeconomic status; NR, not reported; ADA, American Dental Association; WHO, World Health Organization.

**Table 7B. Effects of Fluoride Supplements on Primary Teeth: Study Results**

	Baseline (SD)		Exp Time	Increment (SD)		Percentage Reduction		NNT		Drop-out (%)	Compliance Addressed
	deft	defs		deft	defs	deft	defs	deft	defs		
Hamberg, 1971 <sup>63</sup>	C 0	C 0	6 yr	C 5.2 (NR)	NR			NR	NR	NR	No
	E 0	E 0		E <sup>†</sup> 2.7 (NR)		48%		2.4			
Hennon et al, 1972 <sup>64</sup>	C 0.5(0.1)	C 0.5(0.1)	2 yr	C 4.5 (0.4)	C 6.9 (0.9)					65%	No
	E <sub>1</sub> 1.2(0.3)	E <sub>1</sub> 2.0(0.7)		E <sub>1</sub> <sup>‡</sup> 1.4 (0.3)	E <sub>1</sub> <sup>‡</sup> 2.4 (0.5)	69%	65%	0.6	0.4		
	E <sub>2</sub> 0.8(0.2)	E <sub>2</sub> 1.0(0.2)		E <sub>2</sub> <sup>‡</sup> 2.0 (0.3)	E <sub>2</sub> <sup>‡</sup> 2.6 (0.4)	56%	62%	0.8	0.5		
Margolis et al, 1967, <sup>105</sup> 1975 <sup>65</sup>	C assumed 0	NR	6 yrs	C <sup>*  </sup> 2.2 (0.2)	NR			NR	NR	NR	No
	E assumed 0			E <sup>§  </sup> 0.7 (0.1)		68%		1.3			
Hennon et al, 1977 <sup>66</sup>	C assumed 0	C assumed 0	5 yrs	C 6.0 (0.6)	C 8.7 (1.1)					71%	No
	E <sub>1</sub> assumed 0	E <sub>1</sub> assumed 0		E <sub>1</sub> <sup>#</sup> 3.5 (0.5)	E <sub>1</sub> <sup>#</sup> 4.6 (0.7)	42%	47%	2.0	1.2		
	E <sub>2</sub> assumed 0	E <sub>2</sub> assumed 0		E <sub>2</sub> <sup>#</sup> 4.1 (0.4)	E <sub>2</sub> <sup>#</sup> 5.4 (0.8)	32%	38%	2.6	1.5		
Hu et al, 1998 <sup>67</sup>	C 0.4 (0.1)	C 0.6 (0.10)	3 yrs.	C 3.9 (NR)	C 6.9 (NR)					26%	School based, exclude if <180 days of receipt
	E 0.5 (0.1)	E 0.6 (0.1)		E <sup>#</sup> 1.8 (NR)	E <sup>#</sup> 3.4 (NR)	54%	51%	1.4	0.9		
Lin and Tsai, 2000 <sup>68</sup>	C 0.3 (0.1)	C 0.3 (0.1)	2 yrs	C 4.2 (0.8)	C 8.4 (2.1)					18%	Interview and check of use. Exclusion if >11% of materials not used.
	E <sub>1</sub> 0.4 (0.1)	E <sub>1</sub> 0.4 (0.1)		E <sub>1</sub> 2.0 (0.4)	E <sub>1</sub> 4.1 (1.0)	52%	51%	0.9	0.5		
	E <sub>2</sub> 0.2 (0.1)	E <sub>2</sub> 0.2 (0.1)		E <sub>2</sub> <sup>§</sup> 1.2 (0.3)	E <sub>2</sub> <sup>  </sup> 1.6 (0.5)	72%	81%	0.7	0.3		

Note: deft/s, decayed, identified for extraction, filled primary teeth/surfaces; C, control group; E, experimental group; E<sub>1</sub>, experimental group 1; E<sub>2</sub>, experimental group 2; SD, standard deviation; NNT, number needed to treat; NR, not reported; F, fluoride

\* Data from 2 parallel studies combined in this table.  
 † Children with cleft lip and/or palate.  
 ‡ No statistical testing reported.  
 § Different from control at  $P < 0.001$ .

|| Increment from age 4-6 only (2 year increment).  
 ¶ Different from control at  $P < 0.005$ .  
 # Different from control at  $P < 0.05$ .  
 \*\* Different from control at  $P < 0.01$ .

**Table 8A. Clinical Studies of Fluoride Varnish Applied to Primary Teeth: Study Design**

Study	Country	Design	Fluoride Groups	Application Frequency (times/year)	Other Fluoride Exposures
Holm, 1979 <sup>96</sup>	Sweden	RCT, alternate assignment	2.2% F Duraphat	2	71% F dentifrice 27% F tabs
Grodzka et al, 1982 <sup>94</sup>	Poland	Comparison schools, assignment method not specified	2.2% F Duraphat	2	No other professional topical F 'low' F exposure
Frostell et al, 1991 <sup>97</sup>	Sweden	RCT	2.2% F Duraphat with and without invert sugar	2	'Most' use F dentifrice 'Occasional' use of F tabs and mouth rinse
Twetman et al, 1996 <sup>106*</sup>	Sweden	Comm. trial: public clinics matched on SES	0.1% F Fluor Protector	2	0.1 ppm F in drinking water A 'few' given F tablets (0.25 mg F) 95% using F dentifrice. All regular dental visit with counseling
Petersson et al, 1998 <sup>95</sup>	Sweden	Comm. trial: public clinics matched on specified criteria	0.1% F Fluor Protector	2	10% with 1.2 ppm F in water. >90% using F dentifrice All regular dental visit with counseling
Autio-Gold and Courts, 2001 <sup>80†</sup>	United States	RCT	2.2% F Duraphat	Baseline and 4 months	0.8 ppm F in water

**Table 8A. Clinical Studies of Fluoride Varnish Applied to Primary Teeth: Study Design (continued)**

Number of Examiners	Examiner Reliability	Age at Start of Trial (yrs)	Attrition (%)	Study Length (yrs)	Equality of Groups at Baseline	Blinding	Caries Index <sup>‡</sup>
1	NR	3.0	10	2	Yes	Single	defs, x-ray
2	NR	3.5	20	2	Yes	None	dmfs <sub>1</sub>
							dmfs <sub>2</sub> partial x-ray
2	NR	4.0	NR	2	Yes	Examiners	dmfs <sub>2</sub> interprox x-ray (suicide, invert, neither)
							dmfs <sub>1</sub> (other)
NR	NR	4.5	2	2	Yes	None	dfs excluding maxillary incisors
24	NR	4.5	19	2	Yes	None	dfs excluding incisors
2	baseline: 79%, k=0.71 follow-up: 99%, k=0.91	3-5	22	.75	Yes	Single	dmfs x-ray
							dmfs <sub>2</sub> x-ray

Note: F, fluoride; comm., community; interprox, interproximal; k, kappa; NR, not reported; ppm, parts per million; RCT, randomized controlled trial; SES, socioeconomic status; defs, decayed, identified for extraction, filled surfaces; dmfs<sub>1</sub>, incipient lesions excluded from count; dmfs<sub>2</sub>, incipient lesions included in count.

\*Tvetman et al. (1996) also included children from fluoridated community, but their design does not allow determination of fluoride varnish effects.

†Auto-Gold and Courts (2001) is a 9-month study; prevented fraction is adjusted to 12 months.

Table 8B. Clinical Studies of Fluoride Varnish Applied to Primary Teeth: Results

Study	Baseline Prevalence	Sample Size		Caries Increment		Actual Reduction (per year)	% Reduction	Number Needed to Treat <sup>  </sup>
		Control Group	Exp Group	Control Group (SD)	Exp Group (SD)			
Holm, 1979 <sup>96</sup>	0.71 (C) 1.05 (E)	113	112	3.74 (4.62)	2.10 (2.75)	0.82	43.8 P<0.01	1.2
Grodzka et al, 1982 <sup>94</sup>	9.96 (C) 9.32 (E)	100	148	6.71 (5.22)	6.35 (4.98)	0.18	5.3 NS <sup>§</sup>	NC
	10.35 (C) 9.99 (E)	100	148	6.89 (5.08)	6.24 (4.75)	0.32		NC
Frostell et al, 1991 <sup>97</sup>	Sucrose 8.76 (C) 11.60 (E)	26	37	3.27	4.27	+0.50	+30.5 NS	NC
	Invert 8.83 (C) 10.18 (E)	18	33	1.89	3.78	+0.94	+50.0 NS	NC
	Neither 8.76 (C) 11.60 (E)	113	93	4.10	2.86	0.62	30.2 NS	NC
	5.14 (C) 4.36 (E)	113	93	3.60	2.26	0.67	37.2 P < 0.01	1.5
Twetman et al, 1996 <sup>106*</sup>	1.00 (C) 0.95 (E)	374	442	1.53 (2.55)	1.07 (1.96)	0.23	30.0 P < 0.05	4.3
Petersson et al, 1998 <sup>95</sup>	1.18 (C) 1.13 (E)	1916	2245	1.39 (2.66)	1.30 (2.46)	0.04	6.4 NS	NC
Autio-Gold and Courts, 2001 <sup>80</sup>	2.58 (C) 2.51 (E)	83	59	1.47	0.54	1.24	63.2% P < 0.05	0.8
	5.33 (C) 8.22 (E)	83	59	0.38	-3.59 <sup>¶</sup>	-4.78	67.3% P < 0.01	NC

Note: C, control group; e, experimental group

<sup>§</sup>NS, Not statistically significant.

<sup>||</sup>NC, number needed to treat is not calculated for studies with nonsignificant results.

<sup>¶</sup>Negative increment in experimental group because of reversal of early caries lesions.

**Table 9. Summary of Systematic Reviews of the Effectiveness of Oral Health Promotion and Education**

Review	Knowledge Level	Oral Hygiene Behaviors	Caries Prevention
Brown, 1994 <sup>85</sup> OHP and OHE, 57 studies	Most interventions effective in increasing knowledge in the short-term, little evidence for longer-term effects. (3 studies)	One-on-one instruction, repeated contact, participant involvement lead to short-term improvement, but no longer-term effects. (13 studies)	Reduction in caries if target was use of fluoride-containing product. (3 studies)
Kay and Locker, 1996 <sup>87</sup> OHE, 37 studies	Knowledge levels consistently raised by interventions; more effective interventions tended to be more expensive. (14 studies)	Plaque removal programs generally effective in short-term, but no long-term benefits. (15 studies)	No evidence that dental health education interventions affect caries levels. (4 studies)
Sprod, et al., 1996 <sup>86</sup> OHP, 70 studies	Knowledge can be easily improved using many approaches, but may fade, may need reinforcement. Has limited effect on behavior change when used alone. (NR)	Behavior change effected by active involvement, repetition, continued support. Most effective methods address social, personal environmental, and technical factors. (NR)	Very few studies, little evidence of long-term gain. (NR)
Kay and Locker, 1998 <sup>88</sup> OHP, 164 studies	Knowledge levels are invariably altered by interventions, but alterations not related to changes in behavior or health. (NR)	Simple instruction alters behavior in short-term, reducing plaque levels; no lasting effect. (20 RCTs)	Meta analysis indicates 1.8 surface reduction associated interventions increasing use of fluorides. (7 RCTs)

Note: OHP, oral health promotion; OHE, oral health education; NR, number of studies not reported; RCT, randomized controlled trials.