The Science Of Fluoride

POLICY AND INFORMATION ON FLUORIDE FROM AMERICA'S LEADING SCIENTIFIC AND CONSUMER ADVOCATES

Introduction

This publication pulls together the official policy statements and consumer information on fluoride from the nation's leading scientific and advocacy organizations that support community water fluoridation. It is an effort to give you the whole truth about fluoride — its benefits, its risks and its history.

All the statements in this document, with the exception of the reports from the U.S. Surgeon General and the National Research Council, which at full length are each hundreds of pages long, are quoted in their entirety. Every section – including the Surgeon General's Report and NRC Report – is unedited. Phrases are not cherry picked or commandeered for political purposes, but quoted verbatim and at length. To provide context, a brief summary above each document explains the origins of the document and summarizes its contents.

Fluoridation of community water systems is not the only way to administer fluoride and reduce cavities. Some countries in Europe put fluoride in salt. Some invest heavily in school-based dental programs. Many countries rely on socialized medicine to ensure regular dental care and fluoride treatments. The American model allows individual states or communities to decide on the best ways to protect oral health. Since the 1940s, many have relied upon community water fluoridation. To date, about two-thirds of the nation adds fluoride to its water, one reason once common dental problems are now at an all-time low.

In the 1950s, before community water fluoridation became widespread, the majority of people over 65 no longer had any teeth. That number has plummeted since then to about 20%, and is expected to continue declining as more people who grew up drinking fluoridated water age into the cohort. Yet even today, millions of Americans lack access to the right amount of fluoride and many people, including children, continue to suffer from serious oral health issues, some life threatening, that might otherwise be prevented.

Use this document to learn more about fluoridation and its effect on health, relying upon the unedited testimony of some of the America's most trusted institutions.

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AMERICAN ACADEMY OF PEDIATRICS

Policy Statement: Preventive Oral Health Intervention For Pediatricians (2008)

Founded 80 years ago to set standards for pediatric health care, the 60,000-member American Academy of Pediatrics issues policy statements on a wide variety of topics, from breastfeeding to endocrinology to neurological surgery. Policy statements influence pediatric policies and practices worldwide. This policy statement, published in the AAP's peer-reviewed journal Pediatrics in 2008, compiles the scientific evidence on pediatric oral health and recommends preventive measures. The policy statement underscores the importance of oral health to children's overall health and well-being, calls on pediatricians to include oral health in their daily practices, and endorses community water fluoridation as the "cheapest and most effective way to deliver anticaries benefits to communities."

Source

American Academy of Pediatrics, Policy Statement: Preventative Oral Health Intervention for Pediatricians, 2008

ABSTRACT

This policy is a compilation of current concepts and scientific evidence required to understand and implement practice-based preventive oral health programs designed to improve oral health outcomes for all children and especially children at significant risk of dental decay. In addition, it reviews cariology and caries risk assessment and defines, through available evidence, appropriate recommendations for preventive oral health intervention by primary care pediatric practitioners. ***Pediatrics*** 2008; 122:1387–1394

PURPOSE/INTRODUCTION

Review of Circumstances Leading to Development of This Policy

Oral health is an integral part of the overall health of children. [1] Dental caries is a common and chronic disease process with significant consequences. As health care professionals responsible for the overall health of children, pediatricians frequently confront morbidity associated with dental caries. Because caries is a nonclassic infectious process (arising from shifts in subpopulation ratios of established normal flora), pediatricians have an opportunity to prevent, intervene, and, in collaboration with dental colleagues, manage this disease.

Justification of Policy

The prevalence of dental caries for the youngest of children has not decreased over the past decade, despite improvements for older children.[2] Data from the Medical Expenditure Panel Survey revealed that 89% of infants and 1-year-olds had office-based physician visits annually, compared with only 1.5% who had dental visits. Consequently, visits to physicians outnumbered visits to dentists at 250 to 1 for this age group.[3] Because the youngest of the pediatric patient population visit the pediatrician more than the dentist, it is critical that pediatricians be knowledgeable about dental caries, prevention of the disease, and interventions available to the pediatrician and the family.

Rationale for Format

This policy statement is an effort to assist the primary care pediatric practitioner in addressing issues of dental caries and general oral health. The statement begins by building a knowledge base regarding the caries process that can serve as a foundation for understanding prevention and intervention strategies. After explaining the science of cariology, assessment of caries risk is described to assist the pediatrician in deciding which preventive and interventional strategies need to be used. Specific prevention and intervention strategies are then described and explained. In addition, the concept and importance of the dental home as well as strategies for improving the connection of the medical and dental homes are presented. Last, recommendations are provided to assist the pediatrician with implementation of the provided information.

BACKGROUND CONCEPTS

Cariology

The most common oral disease encountered by children is dental caries. Dental caries is a nonclassic infectious disease[4] that results from an interaction between oral flora and dietary carbohydrates on the tooth surface. To adhere to tooth structure, oral flora utilize dietary sugars to create a sticky biofilm that is referred to as dental plaque. Dietary sugar can change the biochemical and microbiologic composition of dental plaque. In the presence of a high-carbohydrate diet, cariogenic organisms constitute a greater portion of the total bacterial population.[5,6] Acids produced by bacterial fermentation of carbohydrates reduce the pH of dental plaque to the point at which demineralization of the enamel occurs. The initial carious lesion appears as an opaque white spot on the enamel, and progressive demineralization results in cavitations of the teeth. Dental caries is a process, and loss of tooth structure (a dental cavity) is an end stage in the process.[7] Human dental flora, generally regarded as qualitatively stable once established and site specific to human dentition, is believed to consist of more than 1000 different organisms, of which only a limited number are associated with dental caries.[8] *Streptococcus mutans* is most strongly associated with dental caries and is considered to be an indicator organism of a subpopulation of cariogenic organisms. *S mutans*, like its related cariogenic cohorts, has the ability to adhere to enamel and is uniquely equipped to produce significant amounts of acid (acidogenic) and endure with in that acidic environment (aciduric). Dental flora adheres to the teeth by creating a tenacious and highly complex biofilm referred to as dental plaque. Dental plaque is capable of concentrating dietary sugars; therefore, the chronic consumption of sugary foods and liquids will continually recharge the plaque matrix, resulting in copious supplies of sugars within the plaque matrix. *S mutans* and other cariogenic flora will then ferment available sugars, resulting in high levels of lactic acid, a decreased local pH (~5.0), and demineralization of dental enamel (at an approximate pH of <5.5). Because *S mutans* and its aciduric cohorts continue to thrive at low pH, the resulting environments elects against nonaciduric flora, creating a shift in the sub-population ratio of benign to aciduric flora. As this process continues over multiple generations, aciduric organisms incur an upregulation of virulence genes that allow them to thrive at even lower pH (4.0). Diet-mediated shifts in subpopulation ratios of dental flora are instigated by significant sugar intake (environmentally selecting for carious organisms). Therefore, significant sugar intake is a driving cause of the caries process.

Preventive Strategies

An understanding of normal dental flora serves as a foundation for the development of preventive strategies, with 2 important considerations. First, dental flora exists in a symbiosis with the human species. Second, only a small number of the organisms within dental flora cause caries. Therefore, our objective is not to eliminate all dental flora but to suppress the cariogenic bacteria within the flora. Preventive strategies can be differentiated into 2 distinct categories. Primary prevention involves optimization of maternal dental flora before and during colonization of the oral flora of the infant (during eruption of the primary dentition). This invaluable mode of prevention provides an opportunity for a reduction in the mother's constitutionally virulent, aciduric flora and down regulation of virulence genes within the aciduric flora, decreasing the child's risk of dental decay, and is the basis for first dental visit recommendations at 1 year or earlier made by various medical and dental organizations. This mode of prevention and its adjuncts are reviewed in detail in a policy statement from the American Academy of Pediatrics, "Oral Health Risk Assessment Timing and Establishment of the Dental Home." [9] Secondary prevention is the continual and on going management of subpopulation ratios of benign and aciduric flora within dental plaque. This mode of prevention consists of managing the balance between causative factors and protective factors and is critical for preventing and reversing the caries process. Secondary preventive strategies are hierarchical and currently consist of dietary counseling, oral hygiene instruction, and judicious administration of fluoride modalities. Therefore, although all preventive modalities are important, modification of diet is most important, followed by oral hygiene compliance and then administration of fluorides. By controlling risk factors before disease occurs, the probability of preventing disease, both in the immediate future and the long-term, is improved. Preventive strategies for this complex, chronic disease require a comprehensive and multifocal approach that begins with caries risk assessment.

Caries Risk Assessment

Caries risk assessment, based on developmental, biological, behavioral, and environmental factors, evaluates the probability of enamel demineralization exceeding enamel remineralization over time. The goal of risk assessment is to anticipate and prevent caries initiation before the first sign of disease. During the period of 1999–2002, 41% of US children 2 to 11 years of age had caries in primary teeth. 2 An earlier study noted that 25% of children 5 to 17 years of age had 80% of carious permanent teeth. [10] Assessing each child's risk of caries and tailoring preventive strategies to specific risk factors are necessary for improving oral health in a cost-effective manner. Caries risk assessment is very much a work in progress. In a systematic review of literature regarding risk factors in primary teeth of children aged 6 years and younger, a paucity of studies of optimal (ie, longitudinal) design was noted.[11] A study that evaluated the reliability of multiple risk indicators determined that there is no consistent combination of risk variables that provide a good predictor of caries risk when applied to different populations across different age groups.12 The authors concluded that the best predictor of caries in primary teeth was previous caries experience, followed by parents' education and socioeconomic status.[12] Although previous caries experience cannot be used as a risk indicator for the predentate or very young child, white-spot lesions, as precursors to cavities, can be considered analogous to previous caries experience when assessing the risk of a very young patient. Ananalysis of National Health and Nutrition Examination Survey (NHANES) III data revealed that children from households with low income levels are more likely to experience caries and have higher levels of untreated caries than their counterparts from higher-income house holds.[13] Collectively, children enrolled in Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) programs, HeadStart, or Medicaid are at higher risk than are children in the general population. Caries risk factors unique to infants and young children include perinatal considerations, establishment of oral flora and host-defense systems, susceptibility of newly erupted teeth, dietary transitioning from breast and bottle feedings to cups and solid foods, and establishment of childhood food preferences. Although pre-term birth per se is not a risk factor, a child with low birth weight may require a special diet or have developmental enamel defects or disabilities that increase caries risk. Early acquisition of *S mutans* is a major risk factor for early childhood caries and future caries experience.[14] A reduction of the salivary level of *S mutans* in highly infected mothers can inhibitor delay colonization of their infants.[15] Although evidence suggests that children are most likely to develop caries if *S mutans* is acquired at an early age, this may be compensated in part by other factors such as good oral hygiene and a noncariogenic diet.11 High-risk dietary practices seem to be established early, probably by 12 months of age, and are maintained throughout early childhood.[16] In addition to the amount of sugar consumed, frequency of intake is important.[17] Sugar consumption likely is a more significant factor for those without regular exposure to fluorides.[18] Children experiencing caries as infants and toddlers have a much greater probability of subsequent caries in both the primary and permanent dentitions.[19] Early risk assessment targets infants and young children who traditionally have yet to establish a dental home. Unrecognized disease and delayed care can result in exacerbated problems, leading to more extensive, costly, and time-consuming care. Risk-assessment strategies most applicable for screening purposes include those that are acceptable to patients, reliable, inexpensive, and performed easily and efficiently and require limited equipment/supplies. The American Academy of Pediatric Dentistry (AAPD) has developed a caries risk-assessment tool for use by dentists and primary care practitioners familiar with the clinical presentation of caries and factors related to caries initiation and progression (seewww.aapd.org/media/PoliciesGuidelines/PCariesRiskAssess.pdf).[20] Radiographic assessment and microbiologic testing have been included in the caries risk-assessment tool but are not required. In addition, the American Academy of Pediatrics has created Oral Health Risk Assessment Training for Pediatricians and Other Child Health Professionals, which provides a concise overview of the elements of risk assessment and triage for infants and young children (seewww.aap.org/commpeds/dochs/oralhealth/screening.cfm).[21] The chronic, complex nature of caries requires that risk be reassessed periodically to detect changes in the child's behavioral, environmental, and general health conditions. All available data must be analyzed to determine the patient's caries risk profile. Periodic reassessment allows the practitioner to individualize preventive programs and optimize the frequency of recall and dental radiographic examinations.

SPECIFIC PREVENTIVE STRATEGIES

Dietary Counseling

Dietary counseling for optimal oral health in children should be an essential part of general health counseling. The recent policy statement from the American Academy of Pediatrics on prevention of pediatric overweight and obesity highlighted concerns about health problems in overweight children, including cardiovascular, endocrine, and mental health problems, and the importance of promoting healthy eating behaviors. Consumption of juice and sugar-sweetened beverages has been linked to childhood obesity and caries development.[22–25] Sugars are a critical factor in caries development. Caries risk is greatest if sugars are consumed at high frequency and are in a form that remains in the mouth for longer periods.[26] Sucrose is the most cariogenic sugar, because it can form glucan, which enables bacterial adhesion to teeth and limits diffusion and buffering of acids. Although starch-rich foods pose a low caries risk, mixtures of finely ground, heat-treated starch and sucrose (eg, cereals, potato or corn chips) are also cariogenic.[27] Human milk by itself does not promote tooth decay.[28] However, breast fed infants are at risk of caries when they receive sugary liquids or eat foods with sugars and fermentable carbohydrates.[26] Parents and caregivers should be counseled on the importance of reducing exposure to sugars in foods and drinks. To decrease the risk of dental caries and ensure the best possible health and developmental outcomes, it is recommended that parents do the following:

- Breast feed infants during the first year of life and beyond as is mutually desired.[29]
- After nursing, remove the breast from a sleeping infant's mouth and cleanse the gums and teeth after feedings and before bedtime.
- Discourage a child's sleeping with a bottle; any bottle taken to bed should contain only water.
- Limit sugary foods and drinks to meal times.
- Avoid carbonated beverages and juice drinks (juice drinks contain high-fructose corn syrup and 100% natural juice).
- Encourage children to drink only water and milk between meals.
- Encourage children to eat fruits.
- Limit the intake of 100% fruit juice to no more than 4 oz per day.
- Foster eating patterns that are consistent with My-Pyramid guidelines from the US Department of Agriculture.[30]

Optimal Use of Fluorides

Fluoride, a naturally occurring element, has been instrumental in the widespread decrease in dental caries.[31,32] The mechanisms of fluoride are both topical and systemic, with evidence pointing to a greater topical effect.[33] Fluoride reduces enamel dissolution while it encourages remineralization.[34] Antimicrobial effects of fluorides at low pH are also significant.[35] The delivery of fluoride includes community-based, professionally applied, and self-administered modalities. Water fluoridation is a community-based intervention that optimizes the level of fluoride in drinking water, resulting in preeruptive and posteruptive protection of the teeth.[36] Water fluoridation is a cost-effective means of preventing dental caries, with the lifetime cost per person equaling less than the cost of 1 dental restoration.[37,38] In short, fluoridated water is the cheapest and most effective way to deliver anticaries benefits to communities. Professionally applied topical fluorides (PATFs) have their greatest effect preventing caries and must be applied at regular intervals.[39] PATFs include gel, foam, in-office rinse, and varnish. PATFs are safe and efficacious, with varnishes having the advantage of adherence to the tooth surface, decreasing likelihood of ingestion, and increasing time of contact between the fluoride and tooth surface.[37,39] In the primary dentition, varnish effectiveness (measured by percent of caries reduction) ranges from 30% to 63.2%,[40,41] and an analysis of the number of fluoride-varnish applications received resulted in a dose-response effect that was enhanced when coupled with counseling.[42] Finally, self-administered fluorides, including dietary fluoride supplementation and fluoridated toothpaste, have proven effective, providing low but protracted elevation of fluoride concentrations.[35,43] Caries reduction associated with self-administered fluoride supplementation ranges from 32% to 72% in the primary dentition.[40] In children and adolescents, fluoride toothpastes, mouth rinses, and gels reduce dental caries to a similar extent.[44] The decision to use fluoride therapies must balance the risk of caries against the risk of enamel fluorosis (hypomineralization of the developing enamel caused by excess fluoride ingestion). Patients determined to beat increased risk of dental caries are candidates for more aggressive fluoride therapy utilization. Caries susceptibility and sources of dietary fluoride (eg, water supplies, beverages, prepared food, toothpaste) should be considered before recommending fluoride therapies.[45–48] Enamel fluorosis develops before tooth maturation and emergence, typically in children younger than 8 years.[49] The risk of enamel fluorosis is an aesthetic concern, with very mild or mild forms most commonly observed in the general population.[2,50]

ANTICIPATORY GUIDANCE

Anticipatory guidance is the process of providing practical, developmentally appropriate information about children's health to prepare parents for significant physical, emotional, and psychological milestones.51 Anticipatory guidance during well-child visits is an effective tool to educate parents about maintaining children's health. Mirroring the pediatric model, the American Academy of Pediatric Dentistry advocates oral health anticipatory guidance.[52–55] Anticipatory guidance focused on oral health disease should be an integral part of preventive pediatrics. Information concerning the impact of diet on dental health and counseling in regards to oral hygiene, nonnutritive oral habits, and dental safety should be shared with parents. Therefore, in addition to dietary counseling and optimizing fluoride exposure, anticipatory guidance for oral health includes:

1. Infant oral hygiene instruction: Teeth should be brushed at least twice daily with caregiver supervision and assistance for children. For children with elevated dental caries risk, consider using a pea-sized amount of toothpaste or an amount equivalent to the child's fifth-digit fingernail. Flossing should begin as soon as adjacent teeth are in contact and for surfaces at which 2 teeth touch and they can no longer be cleansed with a tooth brush.

2. Counseling regarding nonnutritive oral habits: Use of pacifiers in the first year of life may prevent sudden infant death syndrome.[56] Sucking habits (eg, pacifiers or digits) of sufficient frequency, duration, and intensity may be associated with dentoalveolarde formations. Some changes persist past cessation of the habit. Professional evaluation is indicated for nonnutritive sucking habits that continue beyond 3 years of age.[53]

3. Age-appropriate information regarding dental injury prevention: Parents should cover sharp corners of household furnishings at the level of walking toddlers, ensure use of car safety seats, and be aware of electrical cord risk for mouth injury. Properly fitted mouth guards are indicated for youths involved in sporting activities that carry a risk of orofacial injury.

Anticipatory guidance is valuable, because it emphasizes prevention of dental problems rather than surgical or restorative care. Anticipatory guidance and well-child visits during the first 2 years of life decrease the number of hospitalizations among poor and near-poor children irrespective of race and health status.[57] Oral health anticipatory guidance can reduce dental expenditures.[58] In light of this evidence, oral health anticipatory guidance should be integrated as a part of comprehensive counseling during well-child visits.[59]

INTERPROFESSIONAL COLLABORATION AND ESTABLISHMENT OF A DENTAL HOME

To be successful in preventing dental disease, interventions must begin within the first year of life. Pediatricians are well positioned to initiate preventive oral health care by providing early assessment of risk, anticipatory guidance, and timely referral to establish a dental home. The American Academy of Pediatric Dentistry, the American Dental Association, and the American Association of Public Health Dentistry recommend that infants be scheduled for an initial oral examination within 6 months of the eruption of the first primary tooth but by no later than 12 months of age. The pediatric community promotes the concept of a medical home to improve families' care utilization, seeking appropriate and preventive services with optimal compliance to recommendations. The concept of the dental home is based on this model and is intended to improve access to oral care. A dental home is the ongoing relationship between the dentist and the patient, inclusive of all aspects of oral healthcare delivered in a comprehensive, continuously accessible, coordinated, and family-centered way.[52,60,61] A dental home should be able to provide the following:

1. an accurate risk assessment for oral diseases and conditions;
2. an individualized preventive dental health program based on risk assessment;
3. anticipatory guidance about growth and development issues (eg, maxillofacial and dentoalveolar de-velopment);
4. a plan for emergency dental trauma management;
5. information regarding care of teeth and oral soft tissues;
6. nutrition and dietary counseling;
7. comprehensive oral health care in accordance with accepted guidelines and periodicity schedules for pediatric oral health; and
8. referrals to dental specialists such as endodontists, oral surgeons, orthodontists, and periodontists when care cannot be provided directly within the dental home.

Lack of access to dental care can be a barrier to establishment of a dental home. Because of the specialized training and expertise, the dentist provides an ideal dental home; however, when a dentist is not available, the pediatric medical provider should fulfill the dictates of preventive oral health care until a dentist can be accessed and a dental home can be established. Therefore, primary care pediatric practitioners are an integral community component in the overall effort to address oral health issues (eg, access to care, preventive intervention). With the continuing challenges of access to dentistry coupled with preschool-aged children making many more visits to medical offices than to dental offices, primary care practitioners with oral health training have reported that they have provided preventive oral health services for their pediatric patients.[51,52] North Carolina primary care practitioners were able to integrate preventive dental services into their practices, increasing preventive services for young children who receive Medicaid benefits and whose access to dentists is restricted (eg, geographically or because of nonparticipation of dentists).[62] Often, the first step of timely establishment of a dental home is a referral from the physician. Although a report from the US Preventive Services Task Force on physicians' roles in preventing dental caries in preschool-aged children found referral by a primary care practitioner only partially effective in increasing dental visits,[40] another study[63] reported that dentists were more likely to see young children referred by primary care practitioners. Primary care practitioners are able to identify children in need of a referral to a dentist.[64] After 2 hours of training in infant oral health, primary care pediatric practitioners accurately identified children with cavities with good specificity (92%–100%) and sensitivity (87%–

99%).[40,63] These results suggest that dental screening can be incorporated into a busy pediatrics practice and that primary care pediatric practitioners can contribute significantly to the overall oral health of young children by encouraging parents to enroll their children in a dental home as early as possible. In summary, the ideal setting for administration of oral health care is the dental home. When there is no access to a dentist, the pediatric medical provider should consider administering risk-based preventive oral health measures until a dental home can be made available. With preparation, primary care practitioners are routinely able to screen accurately and provide oral health anticipatory guidance for children. Furthermore, they are ideally positioned to refer children to a dental home in a timely manner. Establishing collaborative relationships between physicians and dentists at the community level is essential for increasing access to dental care for all children and improving their oral and overall health.

RECOMMENDATIONS FOR PRIMARY CARE PEDIATRIC PRACTITIONERS

1. An oral health risk assessment should be administered periodically to all children.
2. Oral health risk-assessment training should be recommended for medical practitioners who are in training programs and those who currently administer care to children.
3. Dietary counseling for optimal oral health should be an intrinsic component of general health counseling.
4. Anticipatory guidance for oral health should be an integral part of comprehensive patient counseling.
5. Administration of all fluoride modalities should be based on an individual's caries risk. Patients who have a high risk of caries are candidates for consideration of more intensive fluoride exposure after di-etary counseling and oral hygiene instruction as compared with patients with a lower risk of caries (see Figs 1 and 2).
6. Supervised use of fluoride toothpaste is recommended for all children with teeth.
7. The application of fluoride varnish by the medical practitioner is appropriate for patients with significant risk of dental caries who are unable to establish a dental home.
8. Every child should have a dental home established by 1 year of age.
9. Collaborative relationships with local dentists should be established to optimize the availability of a dental home.

CONCLUSIONS

Oral health is an integral part of the overall health and well-being of children. A pediatrician who is familiar with the science of dental caries, capable of assessing caries risk, comfortable with applying various strategies of prevention and intervention, and connected to dental resources can contribute considerably to the health of his or her patients. This policy statement, in conjunction with the oral health recommendations of the American Academy of Pediatrics Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, 3rd edition, [65] serves as a resource for pediatricians and other clinicians to be knowledgeable about addressing dental caries. With dental caries being such a common and consequential disease process in the pediatric population, it is essential that pediatricians include oral health in their daily practice of pediatrics.

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AMERICAN ASSOCIATION OF RETIRED PERSONS

Community Dental Preventive Programs

OVERVIEW

The nonprofit, non-partisan AARP is the nation's largest membership organization for people 50 and older. AARP's online Health Encyclopedia, powered by Healthline, provides numerous articles on fluoride-related topics such as water fluoridation, fluorosis, and sources of fluoride in the diet. This 2002 article from the Gale Encyclopedia of Public Health documents effective programs for preventing dental health diseases and problems in America's communities. It highlights fluoridation as a proven safe and effective measure for caries prevention, but notes 100 million Americans do not have access to fluoridated tap water. Efforts to expand fluoridation can face political barriers because "opponents often make unsubstantiated claims about averse health effects of fluoridation in attempts to influence public opinion." In addition to fluoridation, this article discusses community efforts to reduce the use of tobacco, which is a risk factor for oral cancer and periodontal diseases, and to encourage the use of mouth guards and face guards while participating in contact sports.

SOURCE

AARP website, 2010

COMMUNITY DENTAL PREVENTIVE PROGRAMS

The dental diseases and problems that pose the greatest burden to most communities are dental caries (tooth decay), periodontal (gum) diseases, oral cancer, and trauma. These can be largely prevented through a combination of community, professional, and individual strategies. Community preventive programs, particularly community water fluoridation and school-based dental sealant programs, have proven highly effective in reducing dental caries. The effectiveness of programs to prevent other oral health problems has not been demonstrated, but common sense and indirect evidence indicate that continued efforts to develop and implement such programs are warranted.

The first use of fluoride for caries prevention occurred in 1945 in the United States and Canada, when the fluoride concentration was adjusted in the drinking water supplies of four communities. This public health approach followed a long period of epidemiologic studies of the effects of naturally occurring fluoride in drinking water. Observation of dramatic declines in dental caries in the cities conducting the studies, compared to similar cities with low levels of fluoride in the water, led to fluoridation of water supplies in many other cities. The Centers for Disease Control and Prevention (CDC) has recognized water fluoridation as one of the great public health achievements of the twentieth century, since it provides an inexpensive means of substantially improving oral health that benefits all residents of a community, without regard to their interest in, or ability to receive, dental care.

In spite of its well-documented effectiveness and safety, 100 million persons in the United States remained without fluoridated water at the beginning of the twenty-first century. Adoption of water fluoridation can require political processes that make institution of this public health measure difficult, and opponents often make unsubstantiated claims about adverse health effects of fluoridation in attempts to influence public opinion. These barriers present serious challenges to expanding fluoridation in the United States.

Fluoride prevents tooth decay by making tooth surfaces more resistant to the demineralization caused by the acids produced by bacteria in dental plaque as they metabolize carbohydrates. It also remineralizes the enamel surface of teeth weakened by the decay process, reversing the cavity producing process. Through these effects on the surfaces of teeth, fluoride prevents dental caries in both children and adults. The success of fluoridation led to the development of other fluoride-containing products, most notably fluoride-containing dentifrices (toothpastes) and high strength gels for professional use. Promotion of regular use of fluoride dentifrices by their manufacturers and the dental profession through commercial advertising and health education in schools has proven to be another effective community intervention. By the year 2000, drinking of fluoridated water and the self-care habit of regular use of fluoride toothpaste by most persons had reduced dental caries markedly compared to levels that existed at the middle of the twentieth century.

Dental sealants are plastic coatings that can be professionally applied to pits and fissures, primarily on the chewing surfaces of molar (posterior) teeth, to protect them from dental caries. Without sealants, as much as 90 percent of all dental caries in schoolchildren occurs in pits and fissures. To be most effective, sealants should be placed on teeth soon after they erupt, but they can be applied across a wide age range. Community programs generally target vulnerable populations less likely to receive private dental care, such as children eligible for free or reduced-cost lunch programs (or from low-income families). These school-based programs select classes of schoolchildren at high risk and seek parental permission for referral to an off-site private practice or clinic, or for receipt of services provided in the school by dental professionals using portable equipment. School-based sealant delivery programs are strongly recommended on the basis of strong scientific evidence of their effectiveness in reducing caries on the chewing surfaces of permanent molars.

Other community dental-disease prevention and oral-health promotion efforts include those directed toward the public, practitioners, and policymakers to create a healthy environment, reduce risk factors, inform groups at risk, and improve knowledge and behaviors. There is evidence that comprehensive application of community approaches can reduce the use of tobacco, which is a risk factor for both oral cancer and periodontal diseases (gum infections and the inflammatory reaction that leads to loss of bone support for the teeth). Periodontal disease is a significant cause of tooth loss among adults, and approximately half of the cases of periodontal disease in the United States are attributable to cigarette smoking. Oral cancer is diagnosed in 30,000 Americans each year, and it causes about 8,000 deaths annually. Detection of oral cancer at an early stage is believed to improve the likelihood of successful treatment, but the success of community-based interventions for early detection of oral cancers has not been demonstrated. Nevertheless, it is prudent for all persons to seek regular oral examinations and for health practitioners to be particularly proactive in assuring that tobacco users receive annual oral examinations.

The promotion of oral hygiene by manufacturers of toothbrushes and dentifrices is likely responsible for improvements in oral hygiene practices, including the current common practice of brushing teeth at least twice per day and the regular use of dental floss by many persons. The extent to which this has reduced periodontal diseases is not clear, but many people who attend to these daily practices are able to maintain their teeth for a lifetime.

Finally, the use of mouth guards and face guards while participating in contact sports is prudent practice, and is mandatory in many amateur sports and professional boxing. Examples of community-based interventions to prevent sports-related trauma include the development of rules and regulations; efforts to alert players, parents, and officials to the potential for injury; and better product designs.

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AMERICAN CANCER SOCIETY

Water Fluoridation and Cancer Risk

OVERVIEW

The American Cancer Society, the nation's leading health organization focused specifically on cancer, explored whether there was any link between fluoridation and cancer. The resulting explanation below, posted to the ACS website, focuses in particular on osteosarcoma, a rare bone cancer. This posting, which received its latest medical review on Nov. 3, 2010, includes a brief summary of research investigating whether there is a link between cancer and water fluoridation. It notes that much of the concern stems from a 1990 study that found uncertain evidence of cancer-causing potential of fluoridated drinking water in male rats. A review of more than 50 population-based studies, ACS says, "does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans." The posting suggests research continue and concludes that "the overall consensus among these reviews, based on the studies done to date, is that there is no strong evidence of a link between water fluoridation and cancer."

SOURCE

American Cancer Society website, 2010

More than 60 years after fluoride was first added to drinking water in some parts of the United States, there is still controversy about the possible health effects of drinking water fluoridation. Many people hold strong views either for or against water fluoridation. Their concerns are based on everything from legitimate scientific research, to freedom of choice issues, to government conspiracy theories.

Here we will explore the possible link between fluoridation and cancer. We will not address in detail other possible health effects of water fluoridation (positive or negative). This is not intended as a position statement of the American Cancer Society.

WHAT IS FLUORIDE?

Fluorides are compounds that combine the element fluorine with another substance, usually a metal. Examples include sodium fluoride, stannous fluoride, and fluoride monofluorophosphate (MFP fluoride).

Once in the body, fluorides are absorbed into the blood through the digestive tract. They travel through the blood and tend to collect in areas high in calcium, such as the bones and teeth.

WHERE IS FLUORIDE FOUND?

Some fluorides occur naturally in soil, air, or water, although the levels of fluoride can vary widely. Just about all water contains some level of fluoride.

The major sources of fluoride for humans are water and other beverages, food, and fluoride-containing dental products (toothpastes, mouth rinses, etc.). Because dental products are generally not swallowed (except, perhaps, by younger children), they may be less of a concern with regard to possible health issues.

FLUORIDE IN DRINKING WATER

Water fluoridation began in some parts of the United States in 1945, after scientists noted that people living in areas with higher water fluoride levels had fewer cavities.

The United States Public Health Service (PHS) has, since 1962, recommended that public water supplies contain between 0.7 and 1.2 milligrams of fluoride per liter (mg/L) of drinking water to help prevent tooth decay. (Some natural water sources have fluoride levels within this range, or even higher.)

Fluoride is now used in the public drinking water supplied to about 2 out of 3 Americans. The types of fluoride added to different water systems include fluorosilicic acid, sodium fluorosilicate, and sodium fluoride.

The US Environmental Protection Agency (EPA) has set a maximum amount of fluoride allowable in drinking water of 4.0 mg/L. Long-term exposure to levels higher than this can cause a condition called skeletal fluorosis, in which fluoride accumulates in the bones. This can eventually result in joint stiffness and pain, and can lead to weak or brittle bones in older adults.

The EPA also set a secondary standard of no more than 2.0 mg/L to help protect children (under the age of 9) from dental fluorosis. In this condition, fluoride collects in developing teeth, preventing tooth enamel from forming normally and resulting in permanent staining or pitting of teeth.

Some states have maximum fluoride levels in drinking water that are lower than the national 4.0 mg/L standard.

DOES FLUORIDE CAUSE CANCER?

People have raised questions about the safety and effectiveness of water fluoridation since it first began. Over the years, many studies have looked at the possible link between fluoride and cancer.

Some of the controversy concerning the possible link stems from a study of lab animals reported by the US National Toxicology Program in 1990. The researchers found "equivocal" (uncertain) evidence of cancer-causing potential of fluoridated drinking water in male rats, based on a higher than expected number of cases of osteosarcoma (a type of bone cancer). There was no evidence of cancer-causing potential in female rats or in male or female mice.

Osteosarcoma seems to be the cancer about which the most concern has been raised. One theory on how fluoridation might affect the risk of osteosarcoma is based on the fact that fluoride tends to collect in parts of bones where they are growing. These areas, known as growth plates, are where osteosarcomas typically develop. The theory is that fluoride might somehow cause the cells in the growth plate to grow faster, which might make them more likely to eventually become cancerous.

WHAT HAVE STUDIES IN HUMANS FOUND?

More than 50 population-based studies looking at the potential link between water fluoride levels and cancer have been reported in the medical literature. Most of these have not found a strong link to cancer. Just about all of the studies have been retrospective (looking back in time). They have compared, for example, the rates of cancer in a community before and after water fluoridation, or compared cancer rates in communities with lower levels of fluoride in drinking water to those with higher levels (either naturally or due to fluoridation). Some factors are hard to control for in these types of studies (that is, the groups being compared may be different in ways other than just the drinking water), so the conclusions reached by any single study must be looked at with caution.

And there are other issues that make this topic hard to study. For example, if fluoridation is a risk factor, is the type of fluoride used important? Also, is there a specific level of fluoride above which the risk is increased?

Osteosarcoma is a rare cancer. Only about 400 cases are diagnosed in children and teens each year in the United States. This means it can be hard to gather enough cases to do large studies. Smaller studies can usually detect big differences in cancer rates between 2 groups, but they may not be able to detect a smaller difference. If fluoride increased the risk only slightly, it might not be picked up by these types of studies.

Small studies by themselves may not provide the answers, but taken as a whole they tend to have more weight. Several systematic reviews over the past 25 years have looked at all of the studies published on this subject.

In its review published in 1987, the International Agency for Research on Cancer (IARC), part of the World Health Organization, labeled fluorides as "non-classifiable as to their carcinogenicity [ability to cause cancer] in humans." While they noted that the studies "have shown no consistent tendency for people living in areas with high concentrations of fluoride in the water to have higher cancer rates than those living in areas with low concentrations," they also noted that the evidence was inadequate to draw conclusions one way or the other.

In 1991, the US Public Health Service issued a report on the benefits and risks of fluoride. When looking at a possible link with cancer, they first reviewed the results of studies done with lab animals. They concluded that the few studies available "fail[ed] to establish an association between fluoride and cancer." They also looked at population-based studies, including a large study conducted by the National Cancer Institute. They concluded: "Optimal fluoridation of drinking water does not pose a detectable cancer risk to humans as evidenced by extensive human epidemiological data available to date, including the new studies prepared for this report."

The National Research Council (NRC), part of the National Academies, issued a report titled "Health Effects of Ingested Fluoride" in 1993. Its conclusion was that "the available laboratory data are insufficient to demonstrate a carcinogenic effect of fluoride in animals." They also concluded that "the weight of the evidence from the epidemiological [population-based] studies completed to date does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans." The report recommended that additional well-designed studies be done to look at the possible link to cancers, especially osteosarcomas.

In the United Kingdom, the National Health Service (NHS) Centre for Reviews and Dissemination, University of York, published a systematic review of water fluoridation in the year 2000. After searching through the medical literature, they included 26 studies in their analysis, all of which were considered to be of "low" to "moderate" quality. They concluded, "Overall, no clear association between water fluoridation and incidence or mortality of bone cancers, thyroid cancer, or all cancers was found." However, they also noted, "Given the level of interest surrounding the issue of public water fluoridation, it is surprising to find that little high quality research has been undertaken."

The National Research Council issued an update of its 1993 review in early 2006. While the review included some new data, the results of this report were essentially the same: "On the basis of the committee's collective consideration of data from humans, genotoxicity assays, and studies of mechanisms of actions in cell systems, the evidence on the potential of fluoride to initiate or promote cancers, particularly of the bone, is tentative and mixed." The report also noted that an ongoing study from the Harvard School of Public Health would add important information to the current body of research.

A partial report from the Harvard study, published in 2006, found that exposure to higher levels of fluoride in drinking water was linked to a higher risk of osteosarcoma in boys but not in girls. However, researchers linked to the study noted that early results from a second part of the study did not appear to match those of the report. They therefore advised caution in interpreting the report until the full results of the study become available. The full study has not yet been published.

The US Centers for Disease Control and Prevention (CDC) has issued a statement on water fluoridation and osteosarcoma in response to the study, noting that "at this time, the weight of the scientific evidence, as assessed by independent committees of experts, comprehensive systematic reviews, and review of the findings of individual studies does not support an association between water fluoridated at levels optimal for oral health and the risk for cancer, including osteosarcoma." The statement also noted that further results from the Harvard study should "provide further information as to whether and to what extent an association may exist between osteosarcoma and exposure to fluoride."

The general consensus among the reviews done to date is that there is no strong evidence of a link between water fluoridation and cancer. However, these reviews were all done before the partial results of the Harvard study were published in 2006. Several of the reviews noted that further studies, including the full results of the Harvard study, are needed to clarify the possible link.

CAN YOU REDUCE YOUR FLUORIDE EXPOSURE?

Even without fluoridation, the natural levels of fluoride in water in some places can be even higher than 4 mg/L. Community water systems in such areas are required to lower the fluoride level below the acceptable standard. Private water sources, however, may still be higher.

For people concerned that they or their families may be exposed to too much fluoride, there are some steps that can be taken to reduce exposure.

First, people should know the level of fluoride in their drinking water. If your drinking water comes from a public source, you can find out about the levels of certain substances in your drinking water, including fluoride, by contacting your local community water system. Each system is also required to provide its customers with an annual report on water quality known as a Consumer Confidence Report. This report lists the levels of certain chemicals and other substances in the water, including fluoride. You can also contact the EPA's Safe Drinking Water Hotline at 1-800-426-4791 for more general information about drinking water safety. Those who get their drinking water from a private source such as a well can consider having fluoride levels tested by a reputable laboratory.

People who live in areas with high levels of fluoride in the water may consider using alternative sources of drinking water, such as bottled water. Most bottled water contains at least some fluoride, with natural spring waters tending to be the lowest. You may want to contact the bottler to find out about fluoride levels. (The US Food and Drug Administration (FDA) sets the standards for allowable levels of fluoride in bottled water.) There are also several methods to filter fluoride out of water, although these can be expensive.

Parents with concerns should give small children only a pea-sized amount of toothpaste for brushing, and should do their best to ensure their children are not swallowing, as this can be a significant source of fluoride. Speak to your child's dentist before using toothpaste in children under 2 years of age. Low- and no-fluoride toothpastes and other dental products are also available.

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Last Medical Review: *11/03/2010*

Last Revised: *11/03/2010*

AMERICAN COUNCIL ON SCIENCE AND HEALTH

Fluoridation: A Triumph of Science Over Propaganda

OVERVIEW

These two articles published by the American Council on Science and Health, an independent consumer education consortium led by a board of 350 physicians, scientists and policy advisors, feature plain talk about the quackery behind anti-fluoridation arguments. Dedicated to ensuring that public policies related to health and the environment are based on sound science, the ACSH's scientific advisors include doctors, researchers and scientists from the nation's top institutions, including Harvard and Yale universities, Memorial Sloan-Kettering Cancer Center, and the American Cancer Society. The ACHS has been praised by a diverse range of supporters, including the conservative Heritage Institute and the Wall Street Journal. In the first article, dentist and ACSH advisor Marvin Schissel reviews and discredits a Time magazine article that makes negative claims about the effects of fluoridation. The second outlines anti-fluoridation arguments and shows they have no legal or scientific basis, noting that "over 50 peer-reviewed epidemiological studies have dealt with the claim that fluoridation increases cancer risk. None has substantiated the claim. A number of nationally and internationally recognized scientific organizations, including the National Cancer Institute, have reviewed all the available scientific studies on the health of populations with fluoridated water supplies and the health of fluoride-deficient populations. These reviewers have declared fluoridation safe."

SOURCES

MARVIN SCHISSEL, DDS, Dentist and advisor to the American Council on Science and Health, 2005

TIME AND THE ANTI-FLUORIDE CAUSE

By Marvin Schissel, D.D.S.

In the words of Carl Sagan: "We've arranged a global civilization in which most critical elements depend on science and technology. We have also arranged things so that almost no one understands science and technology. This is a prescription for disaster."

The combination of a scientifically unsophisticated public and the profusion of easily accessible crackpot information on the Internet is indeed a prescription for disaster. Bogus issues ignite the paranoia of some people searching for a "meaningful" cause, and the results can be medical disaster. (As an example, the groundless hysteria about mercury in vaccines may put us all at risk of epidemics: already diseases that had been long under control are beginning to resurface.)

And now another old quack cause is being recharged: the anti-fluoridation movement. An article in Time (Oct. 24) sympathetically describes this burgeoning new/old crusade and, by getting many things wrong, adds fuel to the fire.

Historically, anti-fluoride activists have claimed, with no evidence, that fluoridation causes everything from cancer to mental disease. It was even called a Communist plot to poison our wells -- until the Russians fluoridated their own water. Typical of quack tactics, when one phony claim was disproved they came up with another. Activists claim their activity is based on "research." But looking up blogs on Google is not research: the Internet is too often a source of hysteria and paranoia rather than sound science.

The facts are clear: fluoride, one of Earth's most abundant elements, is a mineral found naturally in many water supplies. Low dosages of ingested fluoride will cause developing teeth to greatly increase their resistance to decay. Fluoridation of community water supplies is the most extensively investigated public health measure in history. Entire populations have been studied, and there is not a shred of bona fide evidence that anyone has been harmed by proper fluoridation of community water supplies. Fluoridation is widely considered one of the century's great public health achievements. The American Dental Association lists 114 prominent national and international health organizations that support fluoridation.

The poorly-informed Time article suggests that fluoride in the water is not necessary because we get it in toothpaste. Toothpaste is "a more efficient way to get the decay-fighting ingredient where it is needed and nowhere else" says Time. But while fluoride in toothpaste is indeed effective, fluoride in the water supply provides a considerable additional anti-caries effect.

Time says "with the spread of fluoride toothpastes and the use of plastic sealants by dentists, decay has plummeted even in regions where there is little or no fluoride in the water." When water fluoridation was introduced in 1945, the demonstrated reduction in caries over the control population was in the area of 65%. Today, the difference between fluoridated and non-fluoridated areas is "only" around 25%. But the decay rate has "plummeted" mostly because of the ubiquity of fluoride in the country's water supply. Sealants don't protect against common between-teeth decay, and since most of the country is fluoridated, a person in a non-fluoridated area eating a canned peach or drinking a soda will likely receive some fluoride. Just a small amount of fluoride will enhance resistance to decay.

Time says, "The most recent -- and controversial -- charge links fluoridation with bone cancer." This "most recent" allegation goes back to the unauthorized release of preliminary data from a 1990 study, data that was subsequently discredited by the U.S. Public Health Service. More recent studies do not demonstrate a cancer-fluoride connection.

Time cites the Environmental Working Group (EWG) as a "watchdog organization." This lends credence to EWG's anti-fluoride stance. But EWG has been criticized as an outfit that promotes propaganda rather than science and ignores the principle that "only the dose makes the poison." The ACSH publication Good Stories, Bad Science gives two recent examples of EWG's wrong-headed conclusions: the issues of pressure-treated wood and farmed salmon; the latest example is anti-fluoridation.

Time quotes an activist: "Why would I want to put a toxic industrial chemical in my children's bodies?" The public would have been better served had the reporter noted that only the dose makes the poison and that fluoride in community water supplies is not at all toxic. Of course, in high dosage fluoride is toxic, as is most everything. But in low dosage fluoride is an essential element for the developing individual.

Time cites a thesis from a doctoral student that shows a sevenfold increase in osteosarcoma from fluoridated water. But this is a lone student-researcher's study that has never been published or subject to peer review. Indeed, the student notes in her thesis that there are several limitations to her study and recommends that the findings be confirmed using data from other studies. For example, she notes that the study may not accurately reflect the actual amount of fluoride consumed by study subjects. Time should have mentioned this.

Time talks about the cosmetic hazard of "mottled" teeth caused by fluoride and claims that 32% of American children have some form of mottling. To me, this is puzzling: New York City fluoridated its water in the 1960s and since then, as a practicing dentist with hundreds of New York children as patients, I almost never noticed any youngsters with mottled teeth. I suspect that the 32% figure mostly represents slight mottling that is not visible.

Early in my dental career I saw many children with "bombed out" mouths, mouths with heavy decay in most every tooth. But once the fluoridation program was established, I rarely saw decay at all in children.

One disturbing exception: a woman brought in a child ridden with decay. I explored the usual suspects: bottle with milk or juice at night, excess candy consumption, poor diet, poor oral hygiene, did she come from a non-fluoridated area? She answered no to all. "I can't understand it," she said. "We are very health conscious and only use bottled water!"

Time says "the risks of water fluoridation are hotly debated." I say, science is to be preferred to heat. Consumer's Union put it well some years ago: "The survival of this fake controversy represents one of the major triumphs of quackery over science in our generation."

Dr. Marvin J. Schissel is a dentist and an advisor to the American Council on Science and Health, the National Council Against Health Fraud, and the Committee for Scientific Investigation of Claims of the Paranormal

FLUORIDATION: A TRIUMPH OF SCIENCE OVER PROPAGANDA

By Dr. Michael W. Easley

Community water fluoridation (herein called simply "fluoridation") is the precise adjustment of the concentration of the essential trace element fluoride in the public water supply to protect teeth and bones. In 1945 Grand Rapids, Michigan, became the first city in the world to fluoridate its public water supply. Since then, communities throughout the United States have adopted the practice. Fluoridation is similar to food fortification and enrichment, which encompass the addition of iodine to table salt; vitamins to fruit drinks, milk, and various kinds of pasta; and vitamins and minerals to breakfast cereals and bread. Fluoridation is the perfect public health intervention. Whole towns are protected in a nondiscriminatory manner. The protection is continuous and effortless to obtain. The fluoride in the water is incorporated into the enamel of developing teeth in children below the age of 16, making their teeth more resistant to decay for a lifetime. It also promotes remineralization of early decay in adults and interferes with the life cycle of decay-causing bacteria present in the mouths of both children and adults.

Fluoridation is remarkably simple to implement and mimics nature: Virtually all sources of drinking water in North America naturally contain some fluoride. Fluoride levels in the United States are adjusted to about one part fluoride per million parts of water — a minute concentration.

The Antifluoridationists

While only a minuscule percentage of Americans opposes fluoridation, an extremist minority urges avoidance of fluoridation. These antifluoridationists or flurophobics falsely allege that it is unsafe, ineffective, or costly. They assert that exposure to fluoridated water increases the risk of contracting AIDS, cancer, Down's syndrome, heart disease, kidney disease, osteoporosis, and many other health problems. But the overwhelming weight of scientific evidence confirms fluoridation's safety and effectiveness, and hundreds of peer-reviewed studies on fluoride have discredited antifluoridation propaganda. Almost at the moment Grand Rapids became the first community to adjust the fluoride content of its water supply, small groups of ill-informed people began objecting to water fluoridation. Early opponents included chiropractors, health food advocates, and members of fringe political and religious groups. The convergence of such individuals and groups led to the formation of small but highly active regional societies whose primary mission was to fight fluoridation. Most of these organizations lacked the funds, political expertise, or scientific credibility to have an impact outside their respective communities. Eventually, however, a few better-funded national organizations appeared whose agendas included opposition to fluoridation. By exploiting scientific illiteracy, common phobias, paranoia concerning communist plots and Big Brotherism, and occasional acceptance of folk medicine, these organizations persuaded a minority of Americans. Their tactics included attracting the media; holding demonstrations at the local-government level; promoting referenda; lobbying public health agencies, state legislatures, and the United States Congress; and litigating at state and federal levels. The effects of such activities did not have lasting importance, and antifluoridation efforts have diminished significantly in recent years. Today, most fluoridation initiatives are successful; court challenges by antifluoridationists are rare; and effective antifluoridation lobbying at both state and federal levels is virtually nonexistent. A latter-day antifluoridationist highspot was the movement's extensive campaign in 1995 to prevent enactment of mandatory statewide fluoridation in California. The campaign failed.

. . . And Justice for All

Despite the decrease in antifluoridation activities, they remain a factor — albeit a minor one — in the success or failure of profluoridation efforts in most American cities. The tactics of contemporary antifluoridationists tend more to delay fluoridation than to stop it, but in some areas of the United States fluoridation remains in limbo. This lack of implementation translates into tooth decay, pain, infection, and dental-care expense (see sidebar on page XX). [Note: This sidebar can be found at the end of this article].]Moreover, antifluoridation efforts cost taxpayers money by compelling defense of fluoridation to legislators, judges, and the media. But litigation, which antifluoridationists once considered the ultimate solution to the "fluoridation menace," has failed as an antifluoridation tactic. No American court of last resort has ever ruled against community water fluoridation. And court decisions that uphold fluoridation as an acceptable public health measure within the police powers of state and local government have bolstered profluoridation efforts. Furthermore, with only two exceptions, American courts have never ruled on the scientific merits of fluoridation but have allowed the scientific method — which includes clinical research and peer review — to determine whether community water fluoridation is acceptable. In both of the exceptions, higher courts overruled lower-court judges and decreed continuance of fluoridation in the communities in question.

"Quackery" versus Science

Fluoride is harmless at the levels necessary for maximum benefits. Thousands of studies on fluorides and fluoridation have been completed in the last 50 years — more than 3,700 since 970 alone. Over 50 peer-reviewed epidemiological studies have dealt with the claim that fluoridation increases cancer risk. None has substantiated the claim. A number of nationally and internationally recognized scientific organizations, including the National Cancer Institute, have reviewed all the available scientific studies on the health of populations with fluoridated water supplies and the health of fluoride-deficient populations. These reviewers have declared fluoridation safe. Indeed, no legitimate epidemiological, laboratory, or clinical study has demonstrated that lifelong ingestion of fluoride at optimal levels in water causes disease in any form. We now have over fifty years' experience with water fluoridation. Moreover, many generations of Americans have spent their lives in areas whose water supplies had naturally occurring fluoride levels 800 to 1,300 percent higher than the levels in fluoridated water. There is no evidence that members of communities with fluoridated water supplies, or with naturally high concentrations of fluoride in their water supplies, have had a higher incidence of any disease than have their contemporaries in areas with water supplies low in fluoride. In 1978 Consumer Reports magazine summed up the situation well: "The simple truth is that there's no 'scientific controversy' over the safety of fluoridation. The practice is safe, economical, and beneficial. The survival of this fake controversy represents, in our opinion, one of the major triumphs of quackery over science in our generation." Nearly 145 million Americans can avail themselves of water whose fluoride concentration is optimal. Of the 50 largest municipalities in the United States, 43 have fluoridated water supplies, including four of the five largest cities. Eight states, the District of Columbia, and Puerto Rico have mandated fluoridation throughout their respective territories. Three states and the District of Columbia have fluoridated all of their treatable community water supplies. Viable options to community water fluoridation as a public health measure do not exist. There are other community-based methods of fluoride delivery — school-based programs that involve rinsing the mouth with a fluoride preparation, ingesting fluoride tablets, or submitting to professional dental application of fluoride, for example. But these methods cost considerably more than community water fluoridation, are much more difficult to implement, and are available only to limited numbers of people and only under special circumstances. Such methods are useful to populations without public water systems but decidedly are second-rate.

The Bottom Line

In recent years public resistance to water fluoridation has waned across the United States, partly because of a higher level of education among voters and partly because of consumers' positive experiences with fluoride (as an ingredient in fluoride toothpastes, for example). Healthcare reform movements have made all Americans aware of the importance of disease prevention. Federal, state, and local officials have acted on this awareness, and the pace of efforts to fluoridate America's remaining deficient water supplies has increased markedly. Fluoridation is the high-water mark of efficient public health intervention.

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Dollars and Sense

The dental benefits — and concomitant cost savings — from fluoridation have been documented for more than half a century. Here are a few facts:

- People who drink fluoridated water for a lifetime will develop up to 70 percent fewer cavities (occurrences of tooth decay) than they would have without fluoridation.
- Because the technology is so simple and the fluoride supplement so inexpensive, fluoridation is extremely cost-effective. Studies indicate that a $100,000 investment in water fluoridation prevents 500,000 cavities.
- Each dollar invested in fluoridation prevents over $80 of dental treatment. Few disease-prevention efforts, and even fewer government-sponsored programs, achieve that level of return on investment.
- The average per capita cost of fluoridating America's public water supplies is 54 cents per year (or $40.50 over a lifetime). The cost of an average single-surface dental restoration is $55. Thus, provision of fluoride in water for a lifetime costs less than one small dental filling.

(From Priorities Vol. 8, No. 4, 1996)

AMERICAN DENTAL ASSOCIATION

Fluoride & Fluoridation

The American Dental Association, the world's oldest and largest national dental society, strongly supports community water fluoridation as "the single most effective public health measure to prevent tooth decay." Dedicated to ethics, science and professional advancement in dentistry, the ADA is a leading authority on public oral health. The ADA website provides extensive information and resources about fluoride and the safety and effectiveness of community fluoridated water. The ADA has published numerous policies and statements in support of water fluoridation, and notes that these polices "are based on the overwhelming weight of peer-reviewed, credible scientific evidence." The ADA works at the local, state and federal level to increase the number of communities that have optimally fluoridated water. The information below includes the Fluoride & Fluoridation section of the association's website, as well as four ADA statements in support of fluoridation and its safety and effectiveness.

SOURCE

American Dental Association Website, 2010

FLUORIDE & FLUORIDATION

More than 65 years ago - on January 25,1945 - Grand Rapids, Michigan became the world's first city to adjust the level of fluoride in its water supply. Since that time, fluoridation has dramatically improved the oral health of tens of millions of Americans. Community water fluoridation is the single most effective public health measure to prevent tooth decay. The Centers for Disease Control and Prevention has proclaimed community water fluoridation as one of 10 great public health achievements of the 20th century. Approximately 72.4% of the U.S. population served by public water systems receive the benefit of optimally fluoridated water.

Fluoridation of community water supplies is simply the adjustment of the existing, naturally occurring fluoride levels in drinking water to an optimal fluoride level recommended by the U.S. Public Health Service (0.7 - 1.2 parts per million) for the prevention of tooth decay. Water that has been fortified with fluoride is similar to fortifying milk with Vitamin D, table salt with iodine, and bread and cereals with folic acid.

Studies conducted throughout the past 65 years have consistently shown that fluoridation of community water supplies is safe and effective in preventing dental decay in both children and adults. Simply by drinking water, children and adults can benefit from fluoridation's cavity protection whether they are at home, work or school.

Today, studies prove water fluoridation continues to be effective in reducing tooth decay by 20-40%, even in an era with widespread availability of fluoride from other sources, such as fluoride toothpaste.

Fluoridation is one public health program that actually saves money. An individual can have a lifetime of fluoridated water for less than the cost of one dental filling.

The American Dental Association continues to endorse fluoridation of community water supplies as safe and effective for preventing tooth decay. This support has been the Association's position since policy was first adopted in 1950. The ADA's policies regarding community water fluoridation are based on the overwhelming weight of peer-reviewed, credible scientific evidence. The ADA, along with state and local dental societies, continues to work with federal, state and local agencies to increase the number of communities benefiting from water fluoridation.

American Dental Association Supports Fluoridation

The American Dental Association unreservedly endorses the fluoridation of community water supplies as safe, effective and necessary in preventing tooth decay. This support has been the Association's position since policy was first adopted in 1950.

Fluoridation of Water Supplies (Trans.1950:224)

Resolved, that in the interest of public health, the American Dental Association recommends the fluoridation of municipal water supplies when the fluoridation procedure is approved by the local dental society and utilized in accordance with the standards established by the responsible health authority, and be it further

Resolved, that the American Dental Association recommends the continuation of controlled studies of the benefits derived from the fluoridation of water supplies.

Since the inception of water fluoridation, the American Dental Association has carefully monitored scientific research regarding safety and efficacy. Based on that review, the Association has continually reaffirmed water fluoridation as the most effective public health measure for the prevention of dental caries and strongly urges that its benefits be extended to those served by communal water systems. In 1997, the ADA House of Delegates confirmed its support for fluoridation by setting forth a comprehensive policy statement.

Operational Policies and Recommendations Regarding Community Water Fluoridation (Trans.1997:673)

1. The Association endorses community water fluoridation as a safe, beneficial and cost-effective public health measure for preventing dental caries.

2. The Association supports the position that all communal water supplies that are below the optimum fluoride level recommended by the U.S. Public Health Service (a range from 0.7–1.2 parts per million) should be adjusted to an optimum level.

3. The Association urges individual dentists and dental societies to exercise leadership in all phases of activity which lead to the initiation and continuation of community water fluoridation, including making scientific knowledge and resources available to the community and collaborating with state and local agencies.

4. The Association encourages individual dentists and dental societies to utilize Association materials on the community organization and public education aspects of fluoridation.

5. The Association encourages states to utilize the corps of experts in the area of fluorides and fluoridation that is maintained through appropriate Association agencies in order to promote the safety, benefits and cost-effectiveness of fluoridation.

6. The Association encourages governmental agencies and philanthropic organizations to make funding available to communities seeking to adjust the fluoride content of the community's water supply to the optimal level.

7. The Association supports the following actions to maintain the quality of national community water fluoridation and its infrastructure:

    - performance of a community water fluoridation infrastructure needs assessment by state health departments where such information is not currently available;

    - allocation of needed resources to appropriate state agencies to upgrade and maintain the fluoridation infrastructure; and

- observance of the Centers for Disease Control and Prevention's Engineering and Administrative Recommendations for Water Fluoridation—1995 by fluoridated water systems in all states.

Statement Commemorating the 60th Anniversary of Community Water Fluoridation

Sixty years ago, Grand Rapids, Michigan became the world's first city to adjust the level of fluoride in its water supply. Since that time, fluoridation has dramatically improved the oral health of tens of millions of Americans. Community water fluoridation is the single most effective public health measure to prevent tooth decay. Additionally, the Centers for Disease Control and Prevention proclaimed community water fluoridation as one of 10 great public health achievements of the 20th century.

Fluoridation of community water supplies is simply the precise adjustment of the existing naturally occurring fluoride levels in drinking water to an optimal fluoride level recommended by the U.S. Public Health Service (0.7–1.2 parts per million) for the prevention of dental decay. Based on data from 2002, approximately 170 million people (or over two-thirds of the population) in the United States are served by public water systems that are fluoridated.

Studies conducted throughout the past 60 years have consistently indicated that fluoridation of community water supplies is safe and effective in preventing dental decay in both children and adults. It is the most efficient way to prevent one of the most common childhood diseases—tooth decay (5 times as common as asthma and 7 times as common as hay fever in 5- to17-year-olds).

Early studies, such as those conducted in Grand Rapids, showed that water fluoridation reduced the amount of cavities children get in their baby teeth by as much as 60 percent and reduced tooth decay in permanent adult teeth nearly 35 percent. Today, studies prove water fluoridation continues to be effective in reducing tooth decay by 20–40 percent, even in an era with widespread availability of fluoride from other sources, such as fluoride toothpaste.

The average cost for a community to fluoridate its water is estimated to range from approximately $0.50 a year per person in large communities to approximately $3.00 a year per person in small communities. For most cities, every $1 invested in water fluoridation saves $38 in dental treatment costs.

The American Dental Association continues to endorse fluoridation of community water supplies as safe and effective for preventing tooth decay. This support has been the Association's position since policy was first adopted in 1950. The ADA's policies regarding community water fluoridation are based on the overwhelming weight of peer-reviewed, credible scientific evidence. The ADA, along with state and local dental societies, continues to work with federal, state, local agencies and community coalitions to increase the number of communities benefiting from water fluoridation.

Statement on the Effectiveness of Community Water Fluoridation

The effectiveness of water fluoridation has been documented in scientific literature for well over 55 years. Even before the first community fluoridation program began in 1945, data from the 1930s and 1940s revealed 50-60% lower tooth decay rates in children consuming naturally occurring, optimally fluoridated water compared to children consuming fluoride-deficient water. Since that time, numerous studies have been published making fluoridation one of the most widely studied public health measures in history. Studies prove water fluoridation continues to be effective in reducing tooth decay by 20-40%, even in an era with widespread availability of fluoride from other sources, such as fluoride toothpaste.

In April 1999, the Centers for Disease Control and Prevention (CDC) proclaimed community water fluoridation as one of 10 great public health achievements of the 20th century. The list of achievements, which also includes vaccinations and control of infectious diseases, was developed to highlight significant contributions that impact the health and well being of the public. Additionally, in 2001, the CDC restated, "Community water fluoridation is a safe, effective and inexpensive way to prevent dental caries." The

CDC not only recommended continuation of fluoridation but also called for its adoption in additional U.S. communities.

In August 2002, the U.S. Task Force on Community Preventive Services concluded that the evidence for the effectiveness of fluoridation is strong based on the number and quality of studies that have been done, the magnitude of observed benefits and the consistency of the findings. The Task Force issued a strong recommendation that water fluoridation be included as part of a comprehensive population-based strategy to prevent or control tooth decay in communities.

The American Dental Association (ADA) continues to endorse fluoridation of community water supplies as safe and effective for preventing tooth decay. This support has been the Association's position since policy was first adopted in 1950. Based on data for 2000, approximately 162 million people (two-thirds of the population) in the United States are served by public water systems that are fluoridated. The ADA, along with state and local dental societies, continues to work with federal, state, and local agencies to increase the number of communities benefiting from water fluoridation.

For more information regarding fluoride and fluoridation, visit the American Dental Association's "Fluoride and Fluoridation" Web site at http://www.ada.org/goto/fluoride.

Statement on the Safety of Community Water Fluoridation

Fluoridation of community water supplies is safe. This has been the American Dental Association's (ADA) policy since 1950. The ADA's policies regarding community water fluoridation are based on the overwhelming weight of credible scientific evidence. This body of knowledge is based on the efforts of nationally recognized scientists who have conducted research using the scientific method, have drawn appropriate balanced conclusions based on their research findings and have published their results in refereed (peer-reviewed) professional journals that are widely held or circulated such as The Journal of the American Medical Association and the American Journal of Public Health. Studies showing the safety of water fluoridation have been confirmed by independent scientific studies.

Fluoride is nature's cavity fighter occurring naturally in the earth's crust in combination with other minerals found in soil and rocks. Small amounts of fluoride occur naturally in all water sources. Water fluoridation is the process of adjusting the natural level of fluoride to a concentration sufficient to protect against tooth decay (0.7 to 1.2 parts per million). Fluoride in these low concentrations is not toxic or harmful.

Throughout more than 55 years of research and practical experience, the overwhelming weight of credible scientific evidence has consistently indicated that fluoridation of community water supplies is safe. The possibility of any adverse health effects from continuous low-level consumption of fluoride has been and continues to be extensively studied. Of the hundreds of credible scientific studies on fluoridation, none has shown health problems associated with the consumption of optimally fluoridated water.

In 2000, the U.S. Surgeon General David Satcher wrote in his report, Oral Health in America, "Community water fluoridation is safe and effective in preventing dental caries in both children and adults. Water fluoridation benefits all residents served by community water supplies regardless of their social or economic status." Additionally, the Centers for Disease Control and Prevention and the National Institute of Dental and Craniofacial Research continue to support water fluoridation as a safe method of preventing tooth decay in people of all ages.

Based on data for 2000, approximately 162 million people (two-thirds of the population) in the United States are served by public water systems that are fluoridated. The ADA, along with state and local dental societies, continues to work with federal, state, and local agencies to increase the number of communities benefiting from water fluoridation. For more information regarding fluoride and fluoridation, visit the American Dental Association's "Fluoride and Fluoridation" Web site at http://www.ada.org/goto/fluoride.

AMERICAN PUBLIC HEALTH ASSOCIATION

Policy Statement: Community Water Fluoridation in the United States

OVERVIEW

The American Public Health Association is the oldest and most diverse organization of public health professionals in the world. Founded in 1872, APHA and its state affiliates represent over 50,000 health professionals and others who work to promote health, prevent disease and ensure safety. APHA policy statements are developed through a lengthy process that includes open participation of the membership and careful review by APHA boards, committees, and other association entities. Since 1950, the APHA has adopted numerous policies around community water fluoridation. This 2008 policy statement reviews and updates the evidence and reiterates the APHA's endorsement of "this important public health practice." The statement says 70% of Americans support fluoridation but it is opposed by a vocal minority of opponents who "sow doubts about the risks and benefits of CWF, often with little scientific basis." The APHA offers a number of recommendations to improve education and advocacy to aid the expansion of community water fluoridation, which it calls "the foundation for improving a community's public health by minimizing the prevalence and severity of tooth decay."

SOURCE

American Public Health Association, 2008

COMMUNITY WATER FLUORIDATION IN THE UNITED STATES

Policy Date: *10/28/2008*
Policy Number: *20087*

This position paper provides updated evidence for the many supportive policies held by the American Public Health Association (APHA) on community water fluoridation (CWF). This position paper provides the scientific basis and justification for the importance of continuing to support CWF for our nation's public water supplies. It also emphasizes the critical role that public health practitioners, health care professionals, and policymakers can play with respect to this important public health practice. The position paper will enable APHA to continue as a policy leader for CWF and safe drinking water. The objectives of this position paper are for APHA to be well positioned to—

- Provide expert guidance to regulatory agencies on decision-making regarding CWF standards and regulations;
- Improve public health education about the safety and efficacy of CWF, specifically education for public health and other health professionals, decision makers, and the public; and
- Promote sufficient funding for federal, state, and local CWF programs.

Relationship to Existing APHA Policies

The following APHA policies are updated and replaced by this position paper and are archived with the adoption of this resolution: 5005, 5508, 5904, 6912, and 7402.

The Problem

Tooth decay (dental caries) is one of the most common diseases in our country, affecting almost the total population. Although the scientific evidence base supports CWF as the foundation for improving a community's public health by minimizing the prevalence and severity of tooth decay, many communities have not successfully initiated or continued this public health measure.1–4 Those opposed to fluoridation sow doubts about the risks and benefits of CWF, often with little scientific basis. In addition, there is often insufficient advocacy for CWF in the face of ongoing media campaigns by activists opposed to fluoridation, commonly referred to in the literature as antifluoridationists.2

Support for CWF

Since 1950,5 APHA has supported CWF as a safe and effective public health measure for the prevention of dental caries (tooth decay), reaffirming this policy in 1955,6 1956,7 1959,8 1963,9 1965,10 1969,11 1974,12 1975,13 1976,14 1977,15,16 1979,17 1980,18 1982,19,20 1992,21 1997,22 2000,23 2001,24 and 2006.25 In addition, more than 100 national and international organizations have recognized the public health benefits of community water fluoridation.26

Because of its health and economic benefits, CWF has been and is included in the 1990, 2000, and 2010 national health objectives (e.g., Healthy People 2010). Between 1992 and 2002, the proportion of the US population served by CWF increased from 62% to 67%. The Healthy People 2010 CWF objective [21–9] is to increase to 75% the proportion of the US population served by community water systems with optimally fluoridated water.27

More Americans have access to fluoridated drinking water than ever before; in 2006, it was estimated that 184 million or 69% of those served by public water supplies and 61.5% of the US population overall had access to optimally fluoridated water.28 More than 405 million people in more than 60 countries worldwide enjoy the benefits of fluoridated water.29 Community water fluoridation has been hailed as one of 10 great public health achievements of the 20th century.30

Because many communities have not yet adopted fluoridation, the US Centers for Disease Control and Prevention (CDC) has set as a priority the evaluation of the effectiveness of laws, policies, and incentives related to water fluoridation and other public health measures designed to promote and sustain health for all residents across diverse community settings.31 However, opposition to this well-supported public health program continues to frustrate efforts by communities to begin or to continue fluoridation.2

Safety of CWF

The scientific evidence base continues to support CWF as a safe and effective public health measure. Reviews of the scientific literature on the health effects of fluoride in the last 18 years have been conducted by the National Health and Medical Research Council, Australian Government (2007)32; National Research Council (NRC), USA (1993, 2006)33,34; World Health Organization (1994, 1996, 2006)35–37; US Agency for Toxic Substances and Disease Registry (2003)38; International Programme on Chemical Safety; WHO (2002)39; Forum on Fluoridation, Ireland (2002)40; Medical Research Council, UK (2002)41; University of York, UK (2000)42,43; Institute of Medicine, USA (1999)44; Health Canada (1999)45; Lewis and Banting, Canada (1994)46; US Public Health Service (1991)47; and Kaminsky et al., New York State Department of Health (1990).48 In addition, the environmental impact of CWF has been reviewed.49,50 All of these reviews have found CWF to be safe and effective. Opponents have claimed potential toxicity from fluoridated water, but none of these claims has been supported by studies of scientific merit.2,51

Water safety is defined and determined by federal, state, and local regulations. The main federal law that ensures the quality of US drinking water is the Safe Drinking Water Act (SDWA). Under SDWA, the US Environmental Protection Agency (EPA) sets standards for drinking water quality and oversees the states, localities, and water suppliers who implement those standards. The current maximum contaminant level goal (MCLG) for fluoride in water is set at 4.0 mg/L,52 well above the optimal levels (0.7 mg/L F–1.2 mg/L F) currently recommended for CWF in the United States for the prevention of tooth decay.53 It has recently been recommended by a committee of the NRC that the MCLG of 4 mg/L for naturally occurring fluoride in water should be lowered to protect against the development of severe enamel fluorosis. The majority of the NRC committee concluded that the MCLG of 4 mg/L is not likely to be protective against bone fractures. Although the NRC committee concluded that the secondary maximum contaminant level of 2 mg/L adequately protects the public from the most severe stage of enamel fluorosis (enamel pitting), there were few studies to assess bone fracture risk in populations exposed to fluoride at the same level in drinking water. However, there was evidence that none of these concerns exist at the optimal levels of fluoride for the prevention of tooth decay.34

Fluorosilicic acid (FSA) is commonly used to fluoridate water. The majority of FSA samples have no impurities, and there is no credible evidence that the use of FSA is of concern.49,54,55

Legality of CWF

During the last 60 years, the legality of fluoridation in the United States has been thoroughly tested in our court systems.56 Fluoridation is viewed by the courts as a proper means of furthering public health and welfare.57 No court of last resort has ever rendered an opinion against fluoridation. The highest courts of more than a dozen states have confirmed the constitutionality of fluoridation.58 In 1984, the Illinois Supreme Court upheld the constitutionality of the state's mandatory fluoridation law, culminating 16 years of court action at a variety of judicial levels.59 Moreover, the US Supreme Court has denied review of fluoridation cases 13 times, citing that no substantial federal or constitutional questions were involved.58

It has been the position of the US courts that a significant government interest in the health and welfare of the public generally overrides individual objections to public health regulation.1 Consequently, the courts have rejected the contention that fluoridation ordinances are a deprivation of religious or individual freedoms guaranteed under the Constitution.58,60 In reviewing the legal aspects of fluoridation, the courts have dealt with this concern by ruling that (1) fluoride is a nutrient, not a medication, and is present naturally in the environment; (2) no one is forced to drink fluoridated water because alternative sources are available; and (3) when a person believes that fluoridation interferes with religious beliefs, there is a difference between the freedom to believe, which is absolute, and the freedom to practice beliefs, which may be restricted in the public's interest.61,62 Courts have consistently ruled that water fluoridation is not a form of compulsory mass medication or socialized medicine.58,61 Recent legal decisions have upheld CWF, including the use of FSA, that there is no fundamental constitutional right to fluoride-free water, and that the use of fluoride is not forced medication.63–66

Continued Benefit and Need for Fluoridation

There is a continued need for CWF to maintain and enhance the reduced prevalence and severity of dental caries. Dental caries remains the most prevalent chronic disease of childhood, with 28% of children aged 2 to 5 years affected by tooth decay. The incidence of dental caries is experienced by 6 of 10 adolescents (12–19 years) and more than 90% of adults (20–64 years).67 The prevalence and severity of dental caries has decreased significantly in the United States as a result of CWF and the nearly ubiquitous use of fluoride toothpaste. The US Task Force on Community Preventive Services strongly recommended CWF for the prevention of dental caries.68 The review that included 21 studies, considered good to fair quality, found a median decrease in dental caries of 29.1% (before-and-after measures) and 50.7% (after measures only) for children aged 4 to 17 years, with varying levels of baseline caries and socioeconomic status. The task force found the evidence of effectiveness was strong. Overall, the prevalence of dental caries among children aged 12 to 17 years declined from 90% in 1971 to 1974 to 67% in 1988 to 1991, and the mean number of teeth that were decayed, missing, or filled (DMFT) as a result of caries declined from 6.2 to 2.8 during this period. More recent data have been aggregated into different age groups of adolescents; for 12 to 19 year olds, the mean DMFT declined from 3.1 in 1988 to 1994 to 2.55 in 1999 to 2004. For 20 to 64 year-old adults, there continues to be a decline in the number of DMFT, from a mean of 12.5 in 1988 to 1994 to 10.3 in 1999 to 2004.67

Additional Considerations

Diffusion/Halo Effect

There is a benefit from the diffusion of fluoride from fluoridated communities to surrounding nonfluoridated communities via the export of bottled beverages and processed foods.69 This diffusion effect, also referred to as the halo effect, as well as additional sources of fluoride, have reduced the absolute and proportional benefit of water fluoridation, as measured between fluoridated and nonfluoridated communities, from approximately 60% in the 1950 to 1970 era to 18% to 40% since the 1980s. Based on 1986 to 1987 data,70 in regions where 75% of public water supplies are fluoridated, the benefit may not be apparent when measuring caries experience between fluoridated and nonfluoridated communities because of the halo or diffusion effect.71 However, in the Pacific region of the United States where less than 20% of public water supplies were fluoridated, there was a 60% difference in tooth decay experience between fluoridated and non-fluoridated communities.71 Continued CWF programs are essential to maintaining this improved oral health status.

Benefit for Adults

CWF benefits everyone in the community, including adults and seniors as well as children. The combined results of 9 studies (7853 participants) examining the effectiveness of water fluoridation in preventing tooth decay in adults were found to be significant at $p < .001$.72 Adults have more tooth and root surfaces at risk for tooth decay than children. The incidence of dental caries for adults equals or exceeds that of children.73,74 Griffin et al. summarized the need for placing increased attention on the prevention of tooth decay in adults72: Although adults are as likely to experience new caries as children, certain segments of the US adult population—those with low incomes and the elderly—may have little or no access to restorative or preventive clinical care. At present, approximately 15% of state Medicaid programs provide no adult dental benefits at all, and approximately 45% cover only tooth extraction and emergency services (Oral Health America, 2003). Routine dental care is one of the few health areas not covered by Medicare. Limited access to restorative care increases the need for effective prevention; complications and pain and suffering are more likely if caries remain untreated. The proportion of the US population comprised of older adults is increasing, most of these persons are likely to be dentate and at risk for dental caries, and many lower-income adults lack access to timely restorative care. Our finding that fluoride is effective among all adults supports the development and implementation of fluoride programs to serve this population.72, p 414-5

Cost-Effectiveness

Fluoridation is a highly cost-effective means of preventing tooth decay in the United States, regardless of socioeconomic status.75–77 The cost of CWF can vary in each community depending on several factors: size of the community (population and water usage); number of fluoride injection points where fluoride will be added to the water system; amount and type of equipment used to add and monitor fluoride levels; amount and type of fluoride compound used, its price, and its costs of transportation and storage; and expertise of personnel at the water plant.78 The annual cost for a US community to fluoridate its water is estimated to range from approximately \$3.00 per person in small communities to approximately \$0.50 per person in large communities.76

Cost Savings of CWF

For communities of more than 20,000 people where it costs approximately \$0.50 per person per year to fluoridate the water, every \$1.00 (1995) invested in this preventive measure yields approximately \$38 savings in dental treatment costs.79 At least 60% of the US population on public water systems has received fluoridated water since 1990, translating to savings in dental treatment costs of more than \$25.7 billion between 1990 and 2000.80

In analyzing annual per person cost savings resulting from fluoridation, Griffin, Jones, and Tomar found a range from \$16 in very small communities to \$19 in large communities.76 These authors concluded, "On the basis of the most current data available on the effectiveness and cost of fluoridation, caries increment, and the cost and longevity of dental restorations, we find that water fluoridation offers significant cost savings."76, p78

The annual incremental mean benefit of fluoridation has been found to be 0.19 tooth surfaces (range 0.04 to 0.34). This equates to a mean of 1.9 tooth surfaces every decade, or 9.5 tooth surfaces over 50 years.[76] Preventing 10 tooth surfaces from decay translates into preventing the need for 10 fillings or perhaps two molars from needing crowns (a molar has five tooth surfaces). The tooth surface index (DMFS) does not address the severity of decay in any one surface or the need for treatment, which could vary from a small filling to a root canal treatment and crown or an extraction.

Disparities

Because of the multifactorial nature of tooth decay, oral health disparities within and between countries are related to sugar consumption, fluoride use, dental care, and social determinants of health.[80] However, it has been shown that children with the greatest dental need and who are at highest risk for tooth decay benefit the most from water fluoridation.[82–87] Therefore, CWF helps reduce disparities in tooth decay prevalence. This has been most eloquently and succinctly articulated by Burt: "There is no practical alternative to water fluoridation for reducing these disparities in the United States."[88, p195]

Pre- and Post-Eruptive Benefits

Fluoridation protects teeth in two ways: systemically, when delivered through the water supply to children during the tooth forming years, and topically, through direct contact with teeth throughout life.[89] Animal and human studies have demonstrated the topical and systemic benefits of fluoride.[90,91] Epidemiological studies using data collected between 1991 and 1995 on children in Australia have confirmed earlier findings that higher pre- than posteruptive fluoride exposure is more beneficial for overall caries experience and for pit and fissure surfaces caries reduction. In those studies, children with optimum exposure to fluoridated water both pre- and posteruption had the lowest caries levels in all surface types and there was an exposure–response relationship between preeruptive exposure and caries.[92–94]

Total Fluoride Intake and Enamel Fluorosis

Enamel fluorosis is a biomarker of fluoride intake during tooth developing years. In a minority of children, fluoride exposure from birth through age 8, when teeth are forming, may result in changes within the outer surface of the tooth called enamel fluorosis. Fluorosis occurs only on primary and permanent teeth while they are forming under the gums; once the teeth come into the mouth, they are no longer able to develop this condition. Clinically, the appearance of enamel fluorosis may vary and is usually bilateral. In its mildest form, it appears as faint white lines or streaks visible only to trained examiners under controlled examination conditions. In its pronounced moderate form, fluorosis manifests as white mottling of the teeth in which noticeable white lines or streaks often have coalesced into larger opaque areas; brown staining of the enamel also may be present. In its most severe form, pitting and actual breakdown of the enamel may occur. The prevalence of severe enamel fluorosis is very low (near zero) at fluoride concentrations in drinking water less than 2 mg/L.[95] In recent years, there has been an increase in the prevalence of children seen with nonsevere enamel fluorosis in both optimally fluoridated and nonfluoridated areas of the United States. The greatest relative increase in enamel fluorosis prevalence has occurred in nonfluoridated areas.[96] Although US NHANES data from 1999–2002 have shown that 32% of US children aged 6 to 19 years have some enamel fluorosis,[97] few survey participants had severe enamel fluorosis and less than 4% had moderate or severe enamel fluorosis. Although professional interest in limiting the amount of fluoride toothpaste delivered to young children and supervising their toothbrushing was expressed in the 1980s as a means of reducing the risk for enamel fluorosis, only during the early 1990s was this approach adopted broadly as a public health measure, which was too late to alter the risk for fluorosis among the 12 to 19 year age cohort in NHANES 1999–2002.[97] Although it has been estimated that only approximately 2% of US schoolchildren may experience perceived esthetic problems related to enamel fluorosis that could be attributed to the currently recommended levels of fluoride in drinking water,[98] in more recent studies, it has been found that mild fluorosis does not have a negative association on the perception of dental appearance.[99] Children and their parents who had mild fluorosis were even better off in perception of oral health when other factors were controlled for in multivariate models. This rather unexpected finding, the authors suggest, might be explained by the fact that better oral health was often perceived as being without caries.[99]

Various studies in Canada, Australia, and the United States have shown a relationship between young children swallowing too much fluoride from fluoride toothpaste and subsequent enamel fluorosis development.96,100,101 In a study of 10- to 14-year-old children in Massachusetts and Connecticut, Pendrys found that enamel fluorosis in the optimally fluoridated study sample was attributed to early toothbrushing behaviors, inappropriate fluoride supplementation, and the use of infant formula in the form of a powdered concentrate.96 Enamel fluorosis in the nonfluoridated study sample was attributed to fluoride supplementation under the pre-1994 protocol and early toothbrushing behaviors. In the nonfluoridated study sample, 65% of the enamel fluorosis cases were attributed to fluoride supplementation under the pre-1994 protocol. An additional 34% was explained by the children swallowing fluoride toothpaste when they brushed more than once per day during the first 2 years of life. In the optimally fluoridated study sample, 68% of the enamel fluorosis cases were explained by the children using more than a pea-sized amount of toothpaste during the first year of life, 13% by having been inappropriately given a fluoride supplement, and 9% by the use of infant formula in the form of a powdered concentrate. Recommendations have been made to reduce the occurrence of enamel fluorosis by controlling identified risk factors.78

Fluoride Intake From Foods and Beverages

Water and water-based beverages are the chief source of dietary fluoride intake. Conventional estimates are that approximately 65% to 75% of dietary fluoride comes from water and water-based beverages.102 In 1997, the Food and Nutrition Board of the Institute of Medicine developed a comprehensive set of reference values for dietary nutrient intakes.44 The adequate intake (AI) establishes a goal for intake to sustain a desired indicator of health without causing side effects. In the case of fluoride, the AI is the daily intake level required to reduce dental decay without causing moderate enamel fluorosis. The AI for fluoride from all sources (fluoridated water, food, beverages, fluoride-containing dental products and dietary fluoride supplements) is set at 0.05 mg/kg/day.44 Using the established AI of 0.05 mg/kg, the amount of fluoride for optimal health to be consumed each day has been calculated by gender and age group (expressed as average weight).103 The tolerable upper intake levels (UL) are higher than the AI and are not the recommended level of intake. The UL is the estimated maximum intake level that should not produce unwanted effects on health. The UL for fluoride from all sources (fluoridated water, food, beverages, fluoride-containing dental products and dietary fluoride supplements) is set at 0.10 mg/kg/day for infants, toddlers, and children through 8 years of age. For older children and adults, who are no longer at risk for enamel fluorosis, the UL for fluoride is set at 10 mg/day, regardless of weight.44

Dietary fluoride intakes by adults from food, water, and beverages, where the concentration is 1.0 parts per million (ppm) fluoride in water, range from 1.4 to 3.4 mg/day; where the concentration is less than 0.3 ppm fluoride, the range is from 0.3 to 1.0 mg/day.44 USEPA has set the MCLG for fluoride in drinking water at 4 mg/L; by converting the MCLG of 4.0 mg/L to a mg/kg/day basis using standard water consumption estimates and body weight data from the NHANES III survey, EPA has concluded that dietary exposure to fluoride, including food exposure to sulfuryl fluoride used as an insecticide, uses 35% of the MCLG (expressed as mg/kg/day) for the US population; 23% of the MCLG (expressed as mg/kg/day) for youth 13 to 19 years, 37% of the MCLG (expressed as mg/kg/day) for children 3 to 5 years, 28% of the MCLG (as mg/kg/day) for children 1 to 2 years, and 35% of the MCLG (expressed as mg/kg/day) for all infants younger than 1 year old. These risk estimates are below the USEPA's level of concern.104

Infant Formula and the Risk for Enamel Fluorosis

Although only a small factor in the risk for enamel fluorosis, the American Dental Association (ADA) (and the CDC) has issued guidance for parents and caregivers of infants younger than 12 months of age to consult with their pediatrician, family physician, or dentist on the most appropriate type of water to use to reconstitute infant formula.105 Recent evidence suggests that mixing powdered or liquid infant formula concentrate with fluoridated water on a regular basis for infants primarily fed in this way may increase the chance of a child's developing the faint white markings of very mild or mild enamel fluorosis. Occasional use of water containing optimal levels of fluoride should not appreciably increase a child's risk for fluorosis. Studies have not shown that teeth are likely to develop more esthetically noticeable forms of fluorosis, even with regular mixing of formula with fluoridated water.106

CWF and Fluoride Toothpaste

Because frequent exposure to small amounts of fluoride each day will best reduce the risk for dental caries in all age groups, all people are recommended to drink water with an optimal fluoride concentration and to brush their teeth twice daily with fluoride toothpaste.78 Fluoride is the only nonprescription toothpaste additive proven to prevent dental caries.78 Because water fluoridation is not available in many countries, toothpaste might be the most important source of fluoride globally.78 There is an additive benefit of fluoride toothpaste. Combined use of fluoride toothpaste and fluoridated water offers protection greater than either used alone.78 In the United States, the standard concentration of fluoride in fluoride toothpaste is 1,000 to 1,100 ppm. Fluoride toothpaste is helpful to all age groups and should be used at least twice a day. Since 1991, manufacturers of fluoride toothpaste marketed in the United States have, as a requirement for obtaining the ADA Seal of Acceptance, placed instructions on the package label stating that children aged younger than 6 years should use only a pea-sized amount of fluoride toothpaste. This is reported to sharply reduce the role of fluoride toothpaste as a risk factor for enamel fluorosis.107 Toothpaste labeling requirements mandated by FDA in 1996 also direct parents of children aged younger than 2 years to seek advice from a dentist or physician before introducing their child to fluoride toothpaste.108 Children younger than 6 years of age should have parents supervise and apply the toothpaste so as to limit the amount that may be swallowed; fluoride toothpaste should be spit out rather than swallowed.

The propensity of young children to swallow toothpaste has led to development of "child-strength" toothpaste with lower fluoride concentrations. Such a product, not currently available in the United States, would be a desirable alternative to currently available products for many young children. Toothpaste containing 500 to 550 ppm fluoride might be almost as efficacious as that containing 1,000 ppm fluoride.109 A British study reported that the prevalence of diffuse enamel opacities (an indicator of mild enamel fluorosis) in the upper incisors was substantially lower among children who used toothpaste containing 550 ppm fluoride than among those who used toothpaste containing 1,050 ppm fluoride.110 An Australian study reported a decrease in the prevalence of enamel fluorosis and no increase in caries after steps were taken to promote use of toothpaste for children containing 400 ppm fluoride and reduce dosages for dietary supplements.111

Adults benefit considerably from CWF and fluoride toothpaste. A review of adult studies after 1980 found that any fluoride, whether self-applied, professionally applied, via water fluoridation, or in combination, averted 0.51 carious coronal and root surfaces per year.72

Fluoridation and Dental Sealants

The effectiveness of dental sealants in community-based programs may be further improved when coupled with lifetime exposure to optimally fluoridated water.112

Bottled Water

In 2006, the FDA's Center for Food Safety and Applied Nutrition issued a Health Claim Notification for Fluoridated Water and Reduced Risk of Dental Caries.113 Labels on bottled water with 0.6 to 1.0 mg/L fluoride may claim "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]." In addition, the health claim is not intended for use on bottled water products specifically marketed for use by infants.

Because the use of bottled water has increased and because the majority of commercial bottled water is low in fluoride, there is the potential for an increase in dental caries.114,115 To encourage bottled water manufacturers to provide optimally fluoridated water, the ADA has introduced a certification program for foods and beverages that are beneficial to oral health, including fluoridated bottled water.116

Per capita consumption of bottled water has increased from approximately 190 mL/person/day in 2001 to approximately 285 mL/person/day in 2006.117 Considering water from all sources, EPA surveys in 1994 to 1998 found the mean per capita daily average total water ingestion was 1.233 L.118 In the EPA surveys, 75% was from community water, 13% from bottled water, 10% from other sources (e.g., well, spring, and cistern), and 2% from unidentified sources. Assuming no general increase in overall water consumption, bottled water use has increased from 15% in 2001 to 23% in 2006 as a proportion of total water consumption. ADA recommends that dentists ask their patients about bottled water use and advise them about the possible removal of fluoride by some home water treatment systems.118 Further, ADA and CDC recommend labeling of bottled water with the fluoride concentration of the product.78,119

Salt Fluoridation

Salt fluoridation is practiced as a community-based alternative to water fluoridation in many countries where there are few central water systems, water infrastructure is otherwise not appropriate, or where other factors preclude the use of water fluoridation. It has been estimated that 40 million people use salt fluoridation, mainly in European, South American, and Central American countries.120 A concentration of 200 to 250 mg fluoride per kg salt is typically used in fluoridated salt. It is recommended that a national fluoride program use only one of these approaches.121

Fluoride Supplements

Where community water fluoridation is not feasible because there is no central water supply or because there are a large number of wells and a small population, school-based fluoride supplement programs are an alternative for communities with suboptimal fluoride in drinking water.122 Prescription fluoride supplements (of 0.25 mg/day, 0.5 mg/day, or 1 mg/day, depending on the age of the child and the concentration of fluoride in the water supply—whether less than 0.3 mg/L or between 0.3 and 0.6 mg/L, and all sources of fluoride) are currently recommended daily for children between 6 months of age and 16 years where the fluoride concentration of the water supply is less than 0.6 mg/L (ppm).78 Currently, in addition to age and fluoride concentration of drinking water, all sources of fluoride should be evaluated with a thorough fluoride history when physicians or dentists prescribe fluoride supplements. Patient exposure to multiple water sources can make proper prescribing complex.123

Home compliance with use of fluoride supplements can be challenging. Health care providers must educate parents, or school personnel in the case of school-based programs, about the appropriate use of the fluoride supplements; moreover, parents and recipients must understand the importance of fluoride supplements, the recommended dose, and the need for compliance on a daily basis for many years. Concomitantly, fluoride supplements are not always prescribed as recommended; studies have found more than one third of children receive prescriptions with incorrect dosage or do not receive prescriptions.124,125 Long-term compliance with daily fluoride supplements has been reported as poor.126,127 As a public health measure, because of poor compliance by individual providers and patients in the private sector, fluoride supplements are less effective than water fluoridation for providing caries prevention. Because inappropriate prescribing of fluoride supplements in fluoridated communities and high doses of fluoride supplements have been found to contribute to enamel fluorosis, alternative doses and schedules have been proposed and are being used in other countries.128

Comparative Costs of Community-Based Tooth Decay Prevention Programs

The costs of school-based fluoride supplement programs have been compared with the cost of CWF, noting that school-based programs affect children only, whereas CWF benefits all age groups of children and adults. The cost to achieve the same level of benefit of prevention of tooth decay was three times higher for fluoride supplements provided in a school-based program compared with water fluoridation for all residents.129 The largest US study conducted to determine the cost and effectiveness of various tooth decay prevention strategies for schoolchildren was conducted between 1977 and 1982. The National Preventive Dentistry Demonstration Program found that dental health lessons, brushing and flossing, fluoride tablets and mouthrinsing, and professionally applied topical fluorides were not effective in reducing a substantial amount of dental decay, even when all of these procedures were used together. Occlusal sealants prevented 1 to 2 carious surfaces in 4 years. Children who were especially susceptible to decay did not benefit appreciably more from any of the preventive measures than did children in general. However, CWF was reaffirmed as the most cost-effective means of reducing tooth decay in children. By contrast to the $23 per year cost of maintaining a child in a sealant program, the annual per capita cost (in 1981 dollars) of water fluoridation in 5 US communities ranged from $0.06 in Denver, Colorado, to $0.80 in rural West Virginia.73

Topical Fluorides

Because of the adoption of water fluoridation and widespread use of fluoride toothpaste, approximately

75% of the US public is at low risk for dental caries. Therefore, the use of any professionally applied fluoride, including fluoride varnish, should be limited to those individuals and communities deemed to be at moderate to high risk for developing dental caries.130 A targeted approach offers additional opportunities toward improving the prevention and control of dental caries.130 The use of fluoride varnish to prevent and control dental caries in young children and seniors is expanding in both public and private dental practice settings and in nondental settings that incorporate health risk assessments and counseling. These settings include Head Start programs and Special Supplemental Nutrition Programs for Women, Infants, and Children; medical offices; well-child clinics and home visits conducted by public health nurses; child care programs; and other, sometimes overlapping, community programs.

Public Information on CWF

Public opinion polls have consistently shown 70% or more of the adult US population supports fluoridation.131 Several organizations provide detailed information on CWF on Web sites, including the CDC132 and ADA.133 The ADA periodically updates Fluoridation Facts, a review of fluoridation literature in question and answer format.134 In addition, ADA has a resource list of materials.135 However, a review of Web sites providing information on CWF revealed that, of 59 sites meeting specific criteria from a list of the first 100 Web sites found when searching "water fluoridation" using the Google search engine (www.google.com) on February 15, 2003, 54% recommend water fluoridation compared with 31% that oppose it.136 Armfield analyzed Web information on fluoridation from Australia in 2006 using 5 search engines—Google, Yahoo, MSN, AOL, and Ask—and found that of the first 20 results from each Web site, searching for "water fluoridation," 29 of the sites were for fluoridation, 55 were against it, with 9 reviews and 7 others.2 Armfield stated, "Although the overwhelming majority of scientific enquiry supports the benefits of water fluoridation, members of the public who type the term 'water fluoridation' into any of the major search engines would immediately be presented with a disproportionate percentage of anti-fluoridation websites."2, p3 Thus, there may be an increasing number of Web sites providing information that is in opposition to established public health policy on water fluoridation.

Water fluoridation opponents are said to use multiple techniques to undermine the scientifically established effectiveness and safety of water fluoridation. The materials they use are often based on Internet resources or published books that present a highly misleading picture of water fluoridation. Despite an extensive body of literature, both studies and results within studies are often selectively reported, giving a biased portrayal of water fluoridation effectiveness. Positive findings are downplayed or trivialized, and the population implications of these findings misinterpreted. Ecological comparisons are sometimes used to support spurious conclusions. Opponents of water fluoridation frequently repeat that water fluoridation is associated with adverse health effects and studies are selectively picked from the extensive literature to convey only claimed adverse findings related to water fluoridation.2

Ethics of CWF

Several reviews have considered the ethics of CWF.137–140 The reviews rely on the preponderance of scientific evidence of benefit and lack of harm and have concluded that CWF is ethical, in part, because it leads to the reduction of health inequalities and the reduction of ill health, particularly among vulnerable groups, and provides an economic benefit to both society and to individuals. With water fluoridation, a whole area either receives fluoridated water or does not. Populations do not remain static, as people move to and from an area. In practical terms, it would therefore not be feasible to seek individual consent. The most appropriate way of deciding whether fluoride should be added to water supplies is to rely on democratic decisionmaking procedures, with public input informing those empowered by the public to make such public health decisions (e.g., local health board, city council, water board, or state legislature). These procedures should be implemented at the local and regional, rather than national, levels because the need for and perception of water fluoridation varies in different areas.138 Account should be taken of relevant evidence and of alternative ways of achieving the intended benefit in the area concerned. Whatever policy is adopted, dental health and any adverse effects of fluoridation should be monitored. The Nuffield Council found there is a need for better and more balanced information for the public and policymakers.138

From an ethical perspective, fluoridating water supplies can be seen as replicating the benefits already conferred on those communities receiving water naturally containing 1 part per million of fluoride. Moreover, the greatest benefit of all goes to that section of the population least able to help themselves—children. Drinking fluoride-free water is not a basic human right but a question of individual preference. In a society where people come together for mutual benefit, it is a question of balancing such personal preferences against the common good arising from less disease, less pain, less suffering, and better health that fluoridation brings.139

Summary

Dental caries (tooth decay) continues to be the most common chronic disease of childhood, and dental caries incidence for adults exceeds that of children. Although there are gross oral health disparities for minorities, eliminating health disparities is an overarching priority area for APHA. Community water fluoridation has been shown to be the most cost-effective public health measure for the primary prevention of dental caries and has been shown to be the most effective public health strategy to reduce disparities in dental caries between ethnic and racial groups. Yet, the US public is generally uninformed about the appropriate use of fluoride and community water fluoridation, and information available to the public on community water fluoridation is not always evidence based.

Therefore be it resolved that APHA—

- Reiterates its strong endorsement and recommendation for the fluoridation of all community water systems as a safe and effective public health measure for the prevention of tooth decay;
- Recommends that federal, state, and local agencies and organizations in the United States promote water fluoridation as the foundation for better oral health;
- Recommends promotion and increased support by federal, state, and local entities for adequate public health infrastructure to ensure safe and effective water fluoridation practices, including monitoring, training, technical and financial assistance, and promotion to expand and maintain water fluoridation programs;
- Recommends increased support by federal agencies for continued research on the safety and effectiveness of water fluoridation and other measures to deliver fluoride to communities and individuals, including effective programs and long-term outcomes;
- Supports efforts to educate public health and other health professionals, decisionmakers, and the public on community water fluoridation and other appropriate uses of fluoride in the prevention of tooth decay;
- Recommends that bottled water manufacturers offer an option of bottled water with an optimal level of fluoride, all bottled water be labeled with its fluoride concentration, and APHA collaborate with other professional groups to promote this recommendation;
- Recommends that the FDA consider all US and non-US evidence-based studies concerning low-concentration fluoride toothpaste for children under age 6 during tooth developing years to reduce the risk of enamel fluorosis and tooth decay; and
- Should collaborate with other professional groups to encourage the National Institutes of Health to study the efficacy and safety of low fluoride toothpastes.

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AMERICAN WATER WORKS ASSOCIATION

Fluoridation Policy

Founded in 1881 as the American Water Works Association, the AWWA is the nation's largest organization of water utilities. The AWWA's more than 4,600 member utilities supply water, much of it fluoridated, to roughly 180 million people in North America. Below is the organization's Fluoridation Policy, first passed in 1976 and subsequently updated in 2007. The policy supports fluoridation as a pubic health benefit and states the organization's continued commitment to regularly review of the most current fluoride research.

SOURCE

AWWA Board of Directors, Fluoride Policy, 2007

AWWA supports the recommendations of the World Health Organization (WHO), American Medical Association (AMA), Canadian Medical Association (CMA), Centers for Disease Control (CDC), American Dental Association (ADA), Canadian Dental Association (CDA) and other professional organizations in the medical community, for the fluoridation of public water supplies as a public health benefit. AWWA supports the application of fluoride in a responsible, effective and reliable manner that includes monitoring and control of fluoride levels mandated by provincial, state and/or federal laws and that is subject to community acceptance through applicable local decision-making processes. AWWA is committed to regular reviews of the most current research on fluoride and the positions of the medical and dental communities.

THE NATIONAL ACADEMY OF SCIENCES

Fluoride In Drinking Water: A Scientific Review of EPA's Standards

OVERVIEW

Founded in 1863 to provide independent scientific advice to the government and the public, the nonprofit National Academies is a membership organization for thousands of the nation's top scientists, engineers, and health professionals, including several hundred Nobel laureates. National Academies studies are undertaken by committees of experts and undergo a rigorous peer review; funders, whether public or private, have no control over the way studies are conducted or their conclusions. The National Academies, which produces reports on everything from the Hubble Telescope to the safety of vaccines, has considered the health effects of fluoride in drinking water on several occasions. This 2006 study looked the effects of ingesting fluoride at the Environmental Protection Agency's maximum allowable concentration of 4 parts per million. The report did not examine community fluoridated water, which contains much less fluoride, but instead looked at a few areas of the United States where fluoride concentrations in water are much higher than normal, mostly from natural sources. The report concluded that ingesting fluoride at such elevated levels increases the risks of severe fluorosis in children as well as bone fractures and severe forms of skeletal fluorosis (a rare condition in the United States).

A National Academies Report in Brief on the report appears below. The full report can be viewed online at *http://www.nap.edu/openbook.php?record_id=11571&page=1.*

SOURCE

Fluoride in Drinking Water: A Scientific Review of EPA's Standards

Report in Brief

FLUORIDE IN DRINKING WATER: A SCIENTIFIC REVIEW OF EPA'S STANDARDS

March 2006

After reviewing research on various health effects from exposure to fluoride, including studies conducted in the last 10 years, this report concludes that EPA's drinking water standard for fluoride—a maximum of 4 milligrams of fluoride per liter of water (4 mg/L)—does not protect against adverse health effects. Just over 200,000 Americans live in communities where fluoride levels in drinking water are 4 mg/L or higher. Children in those communities are at risk of developing severe tooth enamel fluorosis, a condition that can cause tooth enamel loss and pitting. A majority of the report's authoring committee also concluded that people who drink water containing 4 mg/L or more of fluoride over a lifetime are likely at increased risk for bone fractures.

Most people associate fluoride with the practice of intentionally adding fluoride to public drinking-water supplies for the prevention of tooth decay. However, fluoride can also enter public water systems from natural sources, including runoff from weathering of fluoridecontaining rocks and soils and leaching from soil into groundwater. Fluoride pollution from various industrial discharges and emissions can also contaminate water supplies. In a few areas of the United States, fluoride concentrations in water are much higher than normal, mostly from natural sources. Because it can occur at toxic levels, fluoride is one of the drinking water contaminants regulated by the U.S. Environmental Protection Agency (EPA). In 1986, EPA established a maximum allowable concentration for fluoride in drinking water of 4 milligrams per liter (mg/L), a guideline designed to prevent the public from being exposed to harmful levels of fluoride. A concentration of 2 mg/L was set to manage the severity and occurrence of a cosmetic consequence of exposure to fluoride (mottling of tooth enamel).

Estimates from 1992 indicate that approximately 1.4 million people in the United States had fluoride concentrations of 2.0 to 3.9 mg/L in the sources of their drinking water, and just over 200,000 people had concentrations equal to or exceeding 4 mg/L. For the vast majority of people in the United States, fluoride concentrations in drinking water without any treatment to remove fluoride are below the EPA standards. Information on the fluoride content of public water supplies is available from local water suppliers and local, county, or state health departments. Many public health agencies and experts endorse adding fluoride to the water as an effective method of preventing tooth decay in communities where natural fluoride levels are low. The "optimal" concentration range of fluoride in drinking-water for

EPA Drinking Water Standards

EPA sets 3 types of standards for environmental contaminants. The maximum contaminant level goal (MCLG) is a health goal set at a concentration at which no adverse health effects are expected to occur and the margins of safety are judged "adequate." The maximum contaminant level (MCL) is the enforceable standard that is set as close to the MCLG as possible, taking into consideration other factors such as treatment technology and costs. For fluoride, the MCLG and the MCL are both 4 milligrams per liter (mg/L). For some contaminants, EPA also establishes a secondary maximum contaminant level (SMCL) to manage drinking water for aesthetic or cosmetic effects. The SMCL for fluoride is 2 mg/L.

FLUORIDE IN DRINKING WATER: A SCIENTIFIC REVIEW OF EPA'S STANDARDS

Severe enamel fluorosis occurs in approximately 10%, on average, of children in U.S. communities with water fluoride concentrations at or near 4 mg/L. The condition develops as teeth are forming. preventing tooth decay was set at a range of 0.7 to 1.2 mg/L more than 40 years ago by the U.S. Public Health Service. In 2000, it was estimated that approximately 162 million people had artificially fluoridated water. The recommended range for artificial fluoridation is below the EPA standards and was designed for a different purpose, so it is important to note that the safety and effectiveness of the practice of water fluoridation was outside the scope of this report and is not evaluated. This report only evaluates EPA's standards. A 1993 report from the National Research Council had concluded that the EPA standard of 4 mg/L was an appropriate interim standard until more research could be conducted. However, following a comprehensive review of the research conducted since 1993, this report concludes the EPA standard is not protective of health because fluoride exposure at 4 mg/L puts children at risk of developing severe enamel fluorosis that can compromise tooth enamel function and appearance. Fluoride exposure at 4 mg/L could also weaken bone and increase the risk of fractures.

Exposure to Fluoride

Water and water-based beverages are the largest contributors to an individual's total exposure to fluoride, although there are other sources of exposure. For the average person, depending on age, drinking water accounts for 57% to 90% of total fluoride exposure at concentrations of 2 mg/L and accounts for 72% to 94% of total fluoride exposure at concentrations of 4 mg/L. Non-beverage food sources containing various concentrations of fluoride are the second largest contributor to fluoride exposure. The greatest source of nondietary fluoride is dental products, primarily toothpastes. The public is also exposed to fluoride from background air concentrations and from some pesticide residues. Other sources include some pharmaceuticals and consumer products. EPA based its standards on the assumption that adults consume 2 liters of water-based beverages per day. People who are exposed to higher concentrations include those who live where there are high concentrations of fluoride in drinking water; those who drink unusually large volumes of water, such as athletes or people with certain medical conditions; and those who are exposed to other important sources of fluoride such as from occupational exposures. On a per-bodyweight basis, infants and young children have approximately three to four times greater exposure than do adults. Dental-care products are also a special consideration for children, because many tend to use more toothpaste than is advised and may swallow some.

Dental Effects

Exposure to fluoride can cause a condition known as enamel fluorosis. Depending on the amount of fluoride exposure (the dose) and the period of tooth development at which the exposure occurs, the effects of enamel fluorosis can range from mild discoloration of the tooth surface to severe staining, enamel loss, and pitting. The condition is permanent after it develops in children during tooth formation (from birth until about the age of 8). Severe enamel fluorosis occurs at an appreciable frequency, approximately 10% on average, among children in U.S. communities with water fluoride concentrations at or near the current allowable concentration of 4 mg/L. The prevalence of severe enamel fluorosis is very low below about 2 mg/L of fluoride in drinking water. The biggest debate concerning enamel fluorosis, particularly the moderate to severe forms, is whether to consider it an adverse health effect or a cosmetic effect. Previous assessments considered all forms of enamel fluorosis to be aesthetically displeasing, but not adverse to health. This view has been based largely on the lack of direct evidence that severe enamel fluorosis results in tooth loss, loss of tooth function, or psychological, behavioral, or social problems. There was suggestive but inconclusive evidence that severe enamel fluorosis increased the risk of cavities. It is known that restorative dental treatment is often considered for children with the enamel pitting that characterizes this condition. The committee concludes that the current EPA standard does not protect against severe enamel fluorosis. All members of the committee agreed that the condition damages the tooth and that the EPA standard should prevent the occurrence of this unwanted condition. The majority of the members judged the condition to be an adverse health effect because enamel loss and pitting can compromise the ability of the tooth enamel to protect the dentin and, ultimately, the pulp from decay and infection. Two of the 12 members of the committee did not agree that enamel defects alone are sufficient to consider severe enamel fluorosis an adverse health effect, as opposed to a cosmetic one. Studies relied upon by EPA indicated that the prevalence of moderate enamel fluorosis, which causes staining but not pitting of teeth, at 2 mg/L could be as high as 15%. A 1997 report from the Institute of Medicine recommended tolerable upper intake levels for children of different ages intended to protect against moderate enamel fluorosis. At EPA's current secondary maximum contaminant level of 2 mg/L, between 25% and 50% of infants up to one year of age in EPA's 2004 water intake survey consumed enough water to exceed the tolerable upper intakes for their age groups.

Skeletal Effects of Fluoride

Fluoride is readily incorporated into the crystalline structure of bone, and will accumulate over time. Concerns about fluoride's effects on the musculoskeletal system are focused on a condition called skeletal fluorosis and also on increased risks of bone fracture. Models that estimate the accumulation of fluoride into bone (pharmacokinetic models) have been developed that are useful in understanding fluoride's effect on bone. Skeletal fluorosis is a bone and joint condition associated with prolonged exposure to high concentrations of fluoride. Fluoride increases bone density and causes changes in the bone that lead to joint stiffness and pain. The condition is categorized into a preclinical stage and stage I, II, and III, the last of which is sometimes referred to as the "crippling" stage because mobility is affected. At stage II, mobility is not significantly affected, but it is characterized by sporadic pain, stiffness of joints, and osteosclerosis (bone thickening) of the pelvis and spine. The committee concluded that both stage II and stage III skeletal fluorosis should be considered adverse. There are very few known clinical cases of skeletal fluorosis in the United States. Pharmacokinetic models show that bone fluoride concentrations resulting from lifetime exposure to fluoride in drinking water at 2 mg/L or 4 mg/L fall within or exceed the ranges historically associated with stage II and stage III skeletal fluorosis. However, this evidence is not conclusive because the levels at which skeletal fluorosis occurs vary widely, and because it appears to be rare in the United States. The effects of fluoride exposure on bone strength and risk of bone fracture have been studied in animals. The weight of evidence indicates that, although fluoride might increase bone volume, fluoride affects the quality of the bone such that there is less strength per unit volume. Evidence for this effect in humans was found in several new studies of populations exposed to fluoride in their drinking water at 4 mg/L, as well as studies of fluoride as a therapeutic agent, which collectively showed an increased risk of bone fracture. Overall, there was consensus among the committee that there is scientific evidence that under certain conditions fluoride can weaken bone and increase the risk of fractures. The majority of the committee concluded that lifetime exposure to fluoride at drinking water concentrations of 4 mg/L or higher is likely to increase fracture rates in the population, particularly in some demographic subgroups that are prone to accumulate fluoride into their bones (e.g., people with renal disease). However, three of the 12 members judged that the evidence only supported a conclusion that the EPA standard (MCLG) might not be protective against bone fracture, and that more evidence is needed that bone fractures occur at an increased frequency in human populations exposed to fluoride at 4 mg/L before drawing a conclusion that the EPA standard likely poses a risk of increased bone fracture. There were few studies to assess risks of bone fracture in populations exposed to fluoride at 2 mg/L in drinking water. The best available study suggested an increased rate of hip fracture in populations exposed to fluoride at concentrations above 1.5 mg/L. However, this study alone is not sufficient to judge fracture risk for people exposed to fluoride at 2 mg/L. Thus, no conclusions could be drawn about fracture risks at 2 mg/L.

Studies of Fluoride and Cancer

Whether fluoride might be associated with bone cancer has been a subject of debate. Animal studies have suggested the possibility of increased risk of osteosarcoma (a bone cancer) in male rats, but no new animal bioassays have been performed to evaluate this further. Several new population studies investigating cancer in relation to fluoride exposure are now available. Some of those studies had significant methodological limitations that make it difficult to draw conclusions. Overall, the results were mixed, with some studies reporting a positive association and others no association. The committee concluded that the evidence to date is tentative and mixed as to whether fluoride has the potential to initiate or promote cancers, particularly of the bone. A relatively large hospital-based case-control study of osteosarcoma and fluoride exposure is under way at the Harvard School of Dental Medicine and is expected to be published in the summer of 2006. The results of that study might help to identify what future research will be most useful in elucidating fluoride's carcinogenic potential.

Implications for EPA's Drinking Water Standards

In light of the collective evidence on adverse health effects and total exposure to fluoride, the committee concludes that EPA's drinking water standard of 4 mg/L is not adequately protective of health. Lowering it will prevent children from developing severe enamel fluorosis and will reduce the lifetime accumulation of fluoride into bone that the majority of the committee concludes is likely to put individuals at increased risk of bone fracture and possibly skeletal fluorosis, which are particular concerns for those of the public who are prone to accumulating fluoride in their bones. To develop a standard that is protective against severe enamel fluorosis, clinical stage II skeletal fluorosis, and bone fractures, EPA should update its risk assessment of fluoride to include new data on health risks and better estimates of total exposure (relative source contribution) for individuals. EPA should use current approaches for quantifying risk, considering susceptible subpopulations, and characterizing uncertainties and variability.

From a cosmetic standpoint, EPA's standard for cosmetic effects of 2 mg/L does not completely prevent the occurrence of moderate enamel fluorosis. EPA has indicated that the standard was intended to reduce the severity and occurrence of the condition to 15% or less of the exposed population. Recent EPA water intake survey data indicate that substantial proportions of children in communities with fluoride at 2 mg/L consume enough water to exceed the age-specific tolerable upper intake levels recommended by the Institute of Medicine. The degree to which moderate enamel fluorosis might go beyond a cosmetic effect to create an adverse psychological effect or an adverse effect on social functioning on children or their parents is not known.

The committee did not evaluate the risks or benefits of the lower fluoride concentrations (0.7 to 1.2 mg/L) used in water fluoridation. Therefore, the committee's conclusions regarding the potential for adverse effects from fluoride at 2 to 4 mg/L in drinking water do not apply at the lower water fluoride levels commonly experienced by most U.S. citizens.

Recommended Research

As noted above, gaps in the information on fluoride prevented the committee from making some judgments about the safety or the risks of fluoride at concentrations between 2 and 4 mg/L and below. The report makes several recommendations for future research to fill those gaps, as well as recommendations to pursue lines of evidence on other potential health risk (e.g., endocrine effects and brain function). Recommendations include exposure assessment at the individual level rather than the community level; population studies of moderate and severe enamel fluorosis in relation to tooth decay and to psychological, behavioral, or social effects; studies designed to clarify the relationship between fluoride ingestion, fluoride concentration in bone, and clinical symptoms of skeletal fluorosis; and more studies of bone fracture rates in people exposed to high concentrations of fluoride in drinking water.

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This report brief was prepared by the National Research Council based on the committee's report. For more information, contact the Board on Environmental Studies and Toxicology at (202) 334-3060 or visit http://dels.nas.edu/best. *Fluoride in Drinking Water* is available from the National Academies Press, 500 Fifth Street, NW, Washington, D.C. 20001; (800) 624-6242; www. nap.edu.

The Story Of Fluoridation

OVERVIEW

The National Institute of Dental and Craniofacial Research (NIDCR) is the nation's primary sponsor of oral health research. The third oldest of the 27 institutes and centers that make up the National Institutes of Health, the NIDCR was founded in 1948 to address how tooth decay was impeding the nation's military readiness. During the World War II, close to 10% of Army recruits were rejected because they had too many missing teeth. The NIDCR initially focused on promising new research into the role of fluoride in preventing cavities. This detailed history of fluoridation, posted on the NIDCR's website, explains how dental researchers in the early 1900s discovered the link between naturally fluoridated water and the prevention of tooth decay, determined the optimal level of 1.0 parts per million (ppm) at which fluoride protects teeth without causing the brown stains known as fluorosis, and began a water fluoridation program in Grand Rapids, Michigan, that reduced cavity rates among children by 60%. The history concludes by noting that more than a half century later, "fluoride continues to be dental science's main weapon in the battle against tooth decay."

SOURCE

National Institute of Dental and Craniofacial Research website, 2010 [http://www.nidcr.nih.gov/oralhealth/topics/fluoride/thestoryoffluoridation.htm]

THE STORY OF FLUORIDATION

It started as an observation, that soon took the shape of an idea. It ended, five decades later, as a scientific revolution that shot dentistry into the forefront of preventive medicine. This is the story of how dental science discovered-and ultimately proved to the world-that fluoride, a mineral found in rocks and soil, prevents tooth decay. Although dental caries remains a public health worry, it is no longer the unbridled problem it once was, thanks to fluoride.

A Mysterious Disorder

In 1909 Dr. McKay (r) persuaded the Colorado State Dental Association to invite Dr. Green Vardiman Black (l), one of the nation's most eminent dental researchers, to attend 1909 convention where McKay's findings were to be presented. The two men began joint research and discovered other areas of the country where brown staining of teeth occurred.

Fluoride research had its beginnings in 1901, when a young dental school graduate named Frederick McKay left the East Coast to open a dental practice in Colorado Springs, Colorado. When he arrived, McKay was astounded to find scores of Colorado Springs natives with grotesque brown stains on their teeth. So severe could these permanent stains be, in fact, sometimes entire teeth were splotched the color of chocolate candy. McKay searched in vain for information on this bizarre disorder. He found no mention of the brown-stained teeth in any of the dental literature of the day. Local residents blamed the problem on any number of strange factors, such as eating too much pork, consuming inferior milk, and drinking calcium-rich water. Thus, McKay took up the gauntlet and initiated research into the disorder himself. His first epidemiological investigations were scuttled by a lack of interest among most area dentists. But McKay persevered and ultimately interested local practitioners in the problem, which was known as Colorado Brown Stain.

A Fruitful Collaboration

McKay's first big break came in 1909, when renowned dental researcher Dr. G.V. Black agreed to come to Colorado Springs and collaborate with him on the mysterious ailment. Black, who had previously scoffed that it was impossible such a disorder could go unreported in the dental literature, was lured West shortly after the Colorado Springs Dental Society conducted a study showing that almost 90 percent of the city's locally born children had signs of the brown stains. When Black arrived in the city, he too was shocked by the prevalence of Colorado Brown Stain in the mouths of native-born residents. He would write later:

"I spent considerable time walking on the streets, noticing the children in their play, attracting their attention and talking with them about their games, etc., for the purpose of studying the general effect of the deformity. I found it prominent in every group of children. One does not have to search for it, for it is continually forcing itself on the attention of the stranger by its persistent prominence. This is much more than a deformity of childhood. If it were only that, it would be of less consequence, but it is a deformity for life."

Black investigated fluorosis for six years, until his death in 1915. During that period, he and McKay made two crucial discoveries. First, they showed that mottled enamel (as Black referred to the condition) resulted from developmental imperfections in children's teeth. This finding meant that city residents whose permanent teeth had calcified without developing the stains did not risk having their teeth turn brown; young children waiting for their secondary set of teeth to erupt, however, were at high risk. Second, they found that teeth afflicted by Colorado Brown Stain were surprisingly and inexplicably resistant to decay. The two researchers were still a long way from determining the cause of Colorado Brown Stain, but McKay had a theory tucked away in the back of his head. Maybe there was, as some local residents suggested, an ingredient in the water supply that mottled the teeth? Black was skeptical; McKay, though, was intrigued by this theory's prospects.

The water-causation theory got a gigantic boost in 1923. That year, McKay trekked across the Rocky Mountains to Oakley, Idaho to meet with parents who had noticed peculiar brown stains on their children's teeth. The parents told McKay that the stains began appearing shortly after Oakley constructed a communal water pipeline to a warm spring five miles away. McKay analyzed the water, but found nothing suspicious in it. Nonetheless, he advised town leaders to abandon the pipeline altogether and use another nearby spring as a water source.

McKay's advice did the trick. Within a few years, the younger children of Oakley were sprouting healthy secondary teeth without any mottling. McKay now had his confirmation, but he still had no idea what could be wrong with the water in Oakley, Colorado Springs, and other afflicted areas. The answer came when McKay and Dr. Grover Kempf of the United States Public Health Service (PHS) traveled to Bauxite, Arkansas-a company town owned by the Aluminum Company of America-to investigate reports of the familiar brown stains. The two discovered something very interesting: namely, the mottled enamel disorder was prevalent among the children of Bauxite, but nonexistent in another town only five miles away. Again, McKay analyzed the Bauxite water supply. Again, the analysis provided no clues. But the researchers' work was not done in vain.

McKay and Kempf published a report on their findings that reached the desk of ALCOA's chief chemist, H. V. Churchill, at company headquarters in Pennsylvania. Churchill, who had spent the past few years refuting claims that aluminum cookware was poisonous, worried that this report might provide fresh fodder for ALCOA's detractors. Thus, he decided to conduct his own test of the water in Bauxite-but this time using photospectrographic analysis, a more sophisticated technology than that used by McKay. Churchill asked an assistant to assay the Bauxite water sample. After several days, the assistant reported a surprising piece of news: the town's water had high levels of fluoride. Churchill was incredulous. "Whoever heard of fluorides in water," he bellowed at his assistant. "You have contaminated the sample. Rush another specimen."

Shortly thereafter, a new specimen arrived in the laboratory. Churchill's assistant conducted another assay on the Bauxite water. The result? Photospectrographic analysis, again, showed that the town's water had high levels of fluoride tainting it. This second and selfsame finding prompted Churchill to sit down at his typewriter in January, 1931, and compose a five-page letter to McKay on this new revelation. In the letter, he advised McKay to collect water samples from other towns "where the peculiar dental trouble has been experienced... We trust that we have awakened your interest in this subject and that we may cooperate in an attempt to discover what part 'fluorine' may play in the matter." McKay collected the samples. And, within months, he had the answer and denouement to his 30-year quest: high levels of water-borne fluoride indeed caused the discoloration of tooth enamel.

New Questions Emerge

Hence, from the curious findings of Churchill's lab assistant, the mystery of the brown stained teeth was cracked. But one mystery often ripples into many others. And shortly after this discovery, PHS scientists started investigating a slew of new and provocative questions about water-borne fluoride. With these PHS investigations, research on fluoride and its effects on tooth enamel began in earnest. The architect of these first fluoride studies was Dr. H. Trendley Dean, head of the Dental Hygiene Unit at the National Institute of Health (NIH). Dean began investigating the epidemiology of fluorosis in 1931. One of his primary research concerns was determining how high fluoride levels could be in drinking water before fluorosis occurred. To determine this, Dean enlisted the help of Dr. Elias Elvove, a senior chemist at the NIH. Dean gave Elvove the hardscrabble task of developing a more accurate method to measure fluoride levels in drinking water. Elvove labored long and hard in his laboratory, and within two years he reported back to Dean with success. He had developed a state-of-the-art method to measure fluoride levels in water with an accuracy of 0.1 parts per million (ppm). With this new method in tow, Dean and his staff set out across the country to compare fluoride levels in drinking water. By the late 1930s, he and his staff had made a critical discovery. Namely, fluoride levels of up to 1.0 ppm in drinking water did not cause enamel fluorosis in most people and only mild enamel fluorosis in a small percentage of people.

Proof That Fluoride Prevents Caries

This finding sent Dean's thoughts spiraling in a new direction. He recalled from reading McKay's and Black's studies on fluorosis that mottled tooth enamel is unusually resistant to decay. Dean wondered whether adding fluoride to drinking water at physically and cosmetically safe levels would help fight tooth decay. This hypothesis, Dean told his colleagues, would need to be tested.In 1944, Dean got his wish. That year, the City Commission of Grand Rapids, Michigan-after numerous discussions with researchers from the PHS, the Michigan Department of Health, and other public health organizations-voted to add fluoride to its public water supply the following year. In 1945, Grand Rapids became the first city in the world to fluoridate its drinking water.The Grand Rapids water fluoridation study was originally sponsored by the U.S. Surgeon General, but was taken over by the NIDR shortly after the Institute's inception in 1948. During the 15-year project, researchers monitored the rate of tooth decay among Grand Rapids' almost 30,000 schoolchildren. After just 11 years, Dean- who was now director of the NIDR-announced an amazing finding. The caries rate among Grand Rapids children born after fluoride was added to the water supply dropped more than 60 percent. This finding, considering the thousands of participants in the study, amounted to a giant scientific breakthrough that promised to revolutionize dental care, making tooth decay for the first time in history a preventable disease for most people.

A Lasting Achievement

Almost 30 years after the conclusion of the Grand Rapids fluoridation study, fluoride continues to be dental science's main weapon in the battle against tooth decay. Today, just about every toothpaste on the market contains fluoride as its active ingredient; water fluoridation projects currently benefit over 200 million Americans, and 13 million schoolchildren now participate in school-based fluoride mouth rinse programs. As the figures indicate, McKay, Dean, and the others helped to transform dentistry into a prevention-oriented profession. Their drive, in the face of overwhelming adversity, is no less than a remarkable feat of science-an achievement ranking with the other great preventive health measures of our century.

TASK FORCE ON COMMUNITY PREVENTION SERVICES

Preventing Dental Caries: Community Water Fluoridation

OVERVIEW

The Task Force on Community Preventive Services is an independent, non-federal, volunteer body of public health and prevention experts, whose members are appointed by the Director of CDC. The task force weighs in on systematic reviews of public health interventions, participates in the development and refinement of review methods, and makes recommendations about policy, practice, research, and research funding across the country. In 2002, the Task Force evaluated the evidence around the effectiveness of community water fluoridation and four other interventions as strategies to prevent or control dental caries. Below is how the task force described its findings on its website.

Preventing Dental Caries: Community Water Fluoridation

Community water fluoridation involves adding fluoride (which prevents tooth decay) to community water sources, then adjusting and monitoring the amount of fluoride to ensure that it stays at the desired level.

Task Force Recommendations & Findings

The Task Force on Community Prevention Services recommends community water fluoridation based on strong evidence of effectiveness in reducing tooth decay.

Community water fluoridation (CWF) is the controlled addition of a fluoride compound to a public water supply to achieve an optimal fluoride concentration. Since 1962, the U.S. Public Health Service has recommended that community drinking waters contain 0.7 to 1.2 ppm of fluoride. In 1992, more than 144 million people in the United States (56% of the population and 62% of those receiving municipal water supplies) were being supplied with water containing enough fluoride to protect teeth from caries. In 2000, a total of 38 states and the District of Columbia provided access to fluoridated public water supplies to ≥50% of their populations. A national objective aims to ensure that at least 75% of the population will be served by community water systems providing optimal levels of fluoride by the year 2010.

CWF is strongly recommended based on its effectiveness in reducing the occurrence of dental caries within communities. Other positive effects mentioned, but not systematically evaluated, include (1) reducing disparities in caries risk and experience across subgroups defined by socioeconomic status, race or ethnicity, and other predictors of caries risk; and (2) the “halo” or “diffusion” benefits to residents of nonfluoridated communities by means of exposure to processed food and beverages made from fluoridated water.

The safety of fluoride is well documented and has been reviewed comprehensively. Enamel fluorosis (visible discoloration of tooth enamel) is one of the potential adverse effects seen in children who ingest too much fluoride from any and all sources while tooth enamel is forming. Most cases of enamel fluorosis seen today are of the mildest form, which does not affect aesthetics or function. The most recent review of potential adverse effects of CWF showed no clear association between water fluoridation and incidence of mortality from bone cancers, thyroid cancer, or all cancers. Program costs of CWF are affordable. Median cost per person per year ranges from $2.70 among 19 public water systems serving ≤5000 people to $0.40

among 35 systems serving populations ≥20,000. Estimated cost-effectiveness ratios (i.e., net cost per tooth surface spared from decay) indicate that CWF is cost saving (i.e., saves money from a societal perspective and also reduces caries).

Results from the Systematic Reviews

Twenty-one studies qualified for review.

- Decay rates measured before and after water fluoridation: median decrease of 29.1% among children ages 4 to 17 years when compared with control groups (21 study arms).
- Decay rates measured after water fluoridation only: median decrease of 50.7% among children ages 4 to 17 years when compared with control groups (20 study arms).
- Fluoridation was found to help decrease tooth decay both in communities with varying decay rates and among children of varying socioeconomic status.

Nine studies qualified for review of the economic efficiency of community water fluoridation programs.

- Median cost per person per year for 75 water systems receiving fluoridated water: $2.70 among 19 systems serving < =5000 people to $0.40 among 35 systems serving >=20,000 people (7 studies).
- Community water fluoridation was cost saving (5 studies).
- In smaller communities (5000 to 20,000 residents), fluoridation was estimated to be cost-saving where decay incidence in the community exceeds 0.06 tooth surfaces per person annually.

These results were based on a systematic review of all available studies, conducted on behalf of the Task Force by a team of specialists in systematic review methods, and in research, practice and policy related to oral health.

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Recommendations For Using Fluoride To Prevent And Control Dental Caries In The United States

OVERVIEW

The Centers for Disease Control and Prevention is the nation's public health agency. In the late 1990s, the CDC convened a work group of dental experts to develop recommendations for how best to use fluoride to prevent cavities. This work group, which labored several years and reviewed 270 studies, looked at different methods for delivering fluoride and ranked them according to cost and effectiveness. The report concludes that protection against cavities increases when more than one source of fluoride is used, and recommends that "all persons drink water with an optimal fluoride concentration and brush their teeth twice daily with fluoride toothpaste." Additional treatments such as fluoride supplements or topical gels, foams or varnishes are recommended only for those people at a high risk for cavities. The report also examines the risks that children will develop fluorosis, which usually appears as white flecks in the teeth. To avoid fluorosis, the report recommends that children under the age of 6 avoid high-fluoride toothpaste and use only a pea-sized amount at each brushing.

SOURCE

Centers for Disease Control and Prevention, 2001

RECOMMENDATIONS FOR USING FLUORIDE TO PREVENT AND CONTROL DENTAL CARIES IN THE UNITED STATES

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SUMMARY

Widespread use of fluoride has been a major factor in the decline in the prevalence and severity of dental caries (i.e., tooth decay) in the United States and other economically developed countries. When used appropriately, fluoride is both safe and effective in preventing and controlling dental caries. All U.S. residents are likely exposed to some degree to fluoride, which is available from multiple sources. Both health-care professionals and the public have sought guidance on selecting the best way to provide and receive fluoride. During the late 1990s, CDC convened a work group to develop recommendations for using fluoride to prevent and control dental caries in the United States. This report includes these recommendations, as well as a) critical analysis of the scientific evidence regarding the efficacy and effectiveness of fluoride modalities in preventing and controlling dental caries, b) ordinal grading of the quality of the evidence, and c) assessment of the strength of each recommendation.

Because frequent exposure to small amounts of fluoride each day will best reduce the risk for dental caries in all age groups, the work group recommends that all persons drink water with an optimal fluoride concentration and brush their teeth twice daily with fluoride toothpaste. For persons at high risk for dental caries, additional fluoride measures might be needed. Measured use of fluoride modalities is particularly appropriate during the time of anterior tooth enamel development (i.e., age <6 years).

The recommendations in this report guide dental and other health-care providers, public health officials, policy makers, and the public in the use of fluoride to achieve maximum protection against dental caries while using resources efficiently and reducing the likelihood of enamel fluorosis. The recommendations address public health and professional practice, self-care, consumer product industries and health

agencies, and further research. Adoption of these recommendations could further reduce dental caries in the United States and save public and private resources.

INTRODUCTION

Dental caries (i.e., tooth decay) is an infectious, multifactorial disease afflicting most persons in industrialized countries and some developing countries (1). Fluoride reduces the incidence of dental caries and slows or reverses the progression of existing lesions (i.e., prevents cavities). Although pit and fissure sealants, meticulous oral hygiene, and appropriate dietary practices contribute to caries prevention and control, the most effective and widely used approaches have included fluoride use. Today, all U.S. residents are exposed to fluoride to some degree, and widespread use of fluoride has been a major factor in the decline in the prevalence and severity of dental caries in the United States and other economically developed countries (1). Although this decline is a major public health achievement, the burden of disease is still considerable in all age groups. Because many fluoride modalities are effective, inexpensive, readily available, and can be used in both private and public health settings, their use is likely to continue.

Fluoride is the ionic form of the element fluorine, the 13th most abundant element in the earth's crust. Fluoride is negatively charged and combines with positive ions (e.g., calcium or sodium) to form stable compounds (e.g., calcium fluoride or sodium fluoride). Such fluorides are released into the environment naturally in both water and air. Fluoride compounds also are produced by some industrial processes that use the mineral apatite, a mixture of calcium phosphate compounds. In humans, fluoride is mainly associated with calcified tissues (i.e., bones and teeth) because of its high affinity for calcium.

Fluoride's ability to inhibit or even reverse the initiation and progression of dental caries is well documented. The first use of adjusted fluoride in water for caries control began in 1945 and 1946 in the United States and Canada, when the fluoride concentration was adjusted in the drinking water supplying four communities (2--5). The U.S. Public Health Service (PHS) developed recommendations in the 1940s and 1950s regarding fluoride concentrations in public water supplies. At that time, public health officials assumed that drinking water would be the major source of fluoride for most U.S. residents. The success of water fluoridation in preventing and controlling dental caries led to the development of fluoride-containing products, including toothpaste (i.e., dentifrice), mouthrinse, dietary supplements, and professionally applied or prescribed gel, foam, or varnish. In addition, processed beverages, which constitute an increasing proportion of the diets of many U.S. residents (6,7), and food can contain small amounts of fluoride, especially if they are processed with fluoridated water. Thus, U.S. residents have more sources of fluoride available now than 50 years ago.

Much of the research on the efficacy and effectiveness of individual fluoride modalities in preventing and controlling dental caries was conducted before 1980, when dental caries was more common and more severe. Modalities were usually tested separately and with the assumption that the method would provide the main source of fluoride. Thus, various modes of fluoride use have evolved, each with its own recommended concentration, frequency of use, and dosage schedule. Health-care professionals and the public have sought guidance regarding selection of preventive modalities from among the available options. The United States does not have comprehensive recommendations for caries prevention and control through various combinations of fluoride modalities. Adoption of such recommendations could further reduce dental caries while saving public and private resources and reducing the prevalence of enamel fluorosis, a generally cosmetic developmental condition of tooth enamel.

This report presents comprehensive recommendations on the use of fluoride to prevent and control dental caries in the United States. These recommendations were developed by a work group of 11 specialists in fluoride research or policy convened by CDC during the late 1990s and reviewed by an additional 23 specialists. Although the recommendations were developed specifically for the United States, aspects of this report could be relevant to other countries. The recommendations guide health-care providers and the public on efficient and appropriate use of fluoride modalities, direct attention to fluoride intake among children aged <6 years to decrease the risk for enamel fluorosis, and suggest areas for further research. This report focuses on critical analysis of the scientific evidence regarding the efficacy and effectiveness of each fluoride modality in preventing and controlling dental caries and on the use of multiple sources of fluoride. The safety of fluoride, which has been documented comprehensively by other scientific and public health organizations (e.g., PHS [8], National Research Council [9], World Health Organization [10], and Institute of Medicine [11]) is not addressed.

HOW FLUORIDE PREVENTS AND CONTROLS DENTAL CARIES

Dental caries is an infectious, transmissible disease in which bacterial by-products (i.e., acids) dissolve the hard surfaces of teeth. Unchecked, the bacteria can penetrate the dissolved surface, attack the underlying dentin, and reach the soft pulp tissue. Dental caries can result in loss of tooth structure, pain, and tooth loss and can progress to acute systemic infection.

Cariogenic bacteria (i.e., bacteria that cause dental caries) reside in dental plaque, a sticky organic matrix of bacteria, food debris, dead mucosal cells, and salivary components that adheres to tooth enamel. Plaque also contains minerals, primarily calcium and phosphorus, as well as proteins, polysaccharides, carbohydrates, and lipids. Cariogenic bacteria colonize on tooth surfaces and produce polysaccharides that enhance adherence of the plaque to enamel. Left undisturbed, plaque will grow and harbor increasing numbers of cariogenic bacteria. An initial step in the formation of a carious lesion takes place when cariogenic bacteria in dental plaque metabolize a substrate from the diet (e.g., sugars and other fermentable carbohydrates) and the acid produced as a metabolic by-product demineralizes (i.e., begins to dissolve) the adjacent enamel crystal surface (Figure 1). Demineralization involves the loss of calcium, phosphate, and carbonate. These minerals can be captured by surrounding plaque and be available for reuptake by the enamel surface. Fluoride, when present in the mouth, is also retained and concentrated in plaque.

Fluoride works to control early dental caries in several ways. Fluoride concentrated in plaque and saliva inhibits the demineralization of sound enamel and enhances the remineralization (i.e., recovery) of demineralized enamel (12,13). As cariogenic bacteria metabolize carbohydrates and produce acid, fluoride is released from dental plaque in response to lowered pH at the tooth-plaque interface (14). The released fluoride and the fluoride present in saliva are then taken up, along with calcium and phosphate, by de-mineralized enamel to establish an improved enamel crystal structure. This improved structure is more acid resistant and contains more fluoride and less carbonate (12,15--19) (Figure 1). Fluoride is more readily taken up by demineralized enamel than by sound enamel (20). Cycles of demineralization and remineralization continue throughout the lifetime of the tooth.

Fluoride also inhibits dental caries by affecting the activity of cariogenic bacteria. As fluoride concentrates in dental plaque, it inhibits the process by which cariogenic bacteria metabolize carbohydrates to produce acid and affects bacterial production of adhesive polysaccharides (21). In laboratory studies, when a low concentration of fluoride is constantly present, one type of cariogenic bacteria, Streptococcus mutans, produces less acid (22--25). Whether this reduced acid production reduces the cariogenicity of these bacteria in humans is unclear (26).

Saliva is a major carrier of topical fluoride. The concentration of fluoride in ductal saliva, as it is secreted from salivary glands, is low --- approximately 0.016 parts per million (ppm) in areas where drinking water is fluoridated and 0.006 ppm in nonfluoridated areas (27). This concentration of fluoride is not likely to affect cariogenic activity. However, drinking fluoridated water, brushing with fluoride toothpaste, or using other fluoride dental products can raise the concentration of fluoride in saliva present in the mouth 100- to 1,000-fold. The concentration returns to previous levels within 1--2 hours but, during this time, saliva serves as an important source of fluoride for concentration in plaque and for tooth remineralization (28).

Applying fluoride gel or other products containing a high concentration of fluoride to the teeth leaves a temporary layer of calcium fluoride-like material on the enamel surface. The fluoride in this material is released when the pH drops in the mouth in response to acid production and is available to remineralize enamel (29).

In the earliest days of fluoride research, investigators hypothesized that fluoride affects enamel and inhibits dental caries only when incorporated into developing dental enamel (i.e., preeruptively, before the tooth erupts into the mouth) (30,31). Evidence supports this hypothesis (32--34), but distinguishing a true preeruptive effect after teeth erupt into a mouth where topical fluoride exposure occurs regularly is difficult. However, a high fluoride concentration in sound enamel cannot alone explain the marked reduction in dental caries that fluoride produces (35,36). The prevalence of dental caries in a population is not inversely related to the concentration of fluoride in enamel (37), and a higher concentration of enamel fluoride is not necessarily more efficacious in preventing dental caries (38).

The laboratory and epidemiologic research that has led to the better understanding of how fluoride prevents dental caries indicates that fluoride's predominant effect is posteruptive and topical and that the effect depends on fluoride being in the right amount in the right place at the right time. Fluoride works primarily after teeth have erupted, especially when small amounts are maintained constantly in the mouth, specifically in dental plaque and saliva (37). Thus, adults also benefit from fluoride, rather than only children, as was previously assumed.

RISK FOR DENTAL CARIES

The prevalence and severity of dental caries in the United States have decreased substantially during the preceding 3 decades (39). National surveys have reported that the prevalence of any dental caries among children aged 12--17 years declined from 90.4% in 1971--1974 to 67% in 1988--1991; severity (measured as the mean number of decayed, missing, or filled teeth) declined from 6.2 to 2.8 during this period (40--43).

These decreases in caries prevalence and severity have been uneven across the general population; the burden of disease now is concentrated among certain groups and persons. For example, 80% of the dental caries in permanent teeth of U.S. children aged 5--17 years occurs among 25% of those children (43). To develop and apply appropriate and effective caries prevention and control strategies, identification and assessment of groups and persons at high risk for developing new carious lesions is essential (44). Caries risk assessment is difficult because it attempts to account for the complex interaction of multiple factors. Although various methods for assessing risk exist, no single model predominates in this emerging science. Models that take multiple factors into account predict the risk more accurately, especially for groups rather than persons. However, for persons in a clinical setting, models do not improve on a dentist's perception of risk after examining a patient and considering the personal circumstances (45).

Populations believed to be at increased risk for dental caries are those with low socioeconomic status (SES) or low levels of parental education, those who do not seek regular dental care, and those without dental insurance or access to dental services (45--47). Persons can be at high risk for dental caries even if they do not have these recognized factors. Individual factors that possibly increase risk include active dental caries; a history of high caries in older siblings or caregivers; root surfaces exposed by gingival recession; high levels of infection with cariogenic bacteria; impaired ability to maintain oral hygiene; malformed enamel or dentin; reduced salivary flow because of medications, radiation treatment, or disease; low salivary buffering capacity (i.e., decreased ability of saliva to neutralize acids); and the wearing of space maintainers, orthodontic appliances, or dental prostheses. Risk can increase if any of these factors are combined with dietary practices conducive to dental caries (i.e., frequent consumption of refined carbohydrates). Risk decreases with adequate exposure to fluoride (44,45).

Risk for dental caries and caries experience* exists on a continuum, with each person at risk to some extent; 85% of U.S. adults have experienced tooth decay (48). Caries risk can vary over time --- perhaps numerous times during a person's lifetime --- as risk factors change. Because caries prediction is an inexact, developing science, risk is dichotomized as low and high in this report. If these two categories of risk were applied to the U.S. population, most persons would be classified as low risk at any given time.

Children and adults who are at low risk for dental caries can maintain that status through frequent exposure to small amounts of fluoride (e.g., drinking fluoridated water and using fluoride toothpaste). Children and adults at high risk for dental caries might benefit from additional exposure to fluoride (e.g., mouthrinse, dietary supplements, and professionally applied products). All available information on risk factors should be considered before a group or person is identified as being at low or high risk for dental caries. However, when classification is uncertain, treating a person as high risk is prudent until further information or experience allows a more accurate assessment. This assumption increases the immediate cost of caries prevention or treatment and might increase the risk for enamel fluorosis for children aged <6 years, but reduces the risk for dental caries for groups or persons misclassified as low risk.

RISK FOR ENAMEL FLUOROSIS

The proper amount of fluoride helps prevent and control dental caries. Fluoride ingested during tooth development can also result in a range of visually detectable changes in enamel opacity (i.e., light refraction at or below the surface) because of hypomineralization. These changes have been broadly termed enamel fluorosis, certain extremes of which are cosmetically objectionable (49). (Many other developmental changes that affect the appearance of enamel are not related to fluoride [50].) Severe forms of this condition can occur only when young children ingest excess fluoride, from any source, during critical periods of tooth development. The occurrence of enamel fluorosis is reported to be most strongly associated with cumulative fluoride intake during enamel development, but the severity of the condition depends on the dose, duration, and timing of fluoride intake. The transition and early maturation stages of enamel development appear to be most susceptible to the effects of fluoride (51); these stages occur at varying times for different tooth types. For central incisors of the upper jaw, for example, the most sensitive period is estimated at age 15--24 months for boys and age 21--30 months for girls (51,52).

Concerns regarding the risk for enamel fluorosis are limited to children aged <8 years; enamel is no longer susceptible once its preeruptive maturation is complete (11). Fluoride sources for children aged <8 years are drinking water, processed beverages and food, toothpaste, dietary supplements that include fluoride (tablets or drops), and other dental products. This report discusses the risk for enamel fluorosis among children aged <6 years. Children aged >6 years are considered past the age that fluoride ingestion can cause cosmetically objectionable fluorosis because only certain posterior teeth are still at a susceptible stage of enamel development, and these will not be readily visible. In addition, the swallowing reflex has developed sufficiently by age 6 years for most children to be able to control inadvertent swallowing of fluoride toothpaste and mouthrinse.

The very mild and mild forms of enamel fluorosis appear as chalklike, lacy markings across a tooth's enamel surface that are not readily apparent to the affected person or casual observer (53). In the moderate form, >50% of the enamel surface is opaque white. The rare, severe form manifests as pitted and brittle enamel. After eruption, teeth with moderate or severe fluorosis might develop areas of brown stain (54). In the severe form, the compromised enamel might break away, resulting in excessive wear of the teeth. Even in its severe form, enamel fluorosis is considered a cosmetic effect, not an adverse functional effect (8,11,55,56). Some persons choose to modify this condition with elective cosmetic treatment.

The benefits of reduced dental caries and the risk for enamel fluorosis are linked. Early studies that examined the cause of "mottled enamel" (now called moderate to severe enamel fluorosis) led to the unexpected discovery that fluoride in community drinking water inhibits dental caries (57). Historically, a low prevalence of the milder forms of enamel fluorosis has been accepted as a reasonable and minor consequence balanced against the substantial protection from dental caries from drinking water containing an optimal concentration of fluoride, either naturally occurring or through adjustment (11,53). When enamel fluorosis was first systematically investigated during the 1930s and 1940s, its prevalence was 12%--15% for very mild and mild forms and zero for moderate and severe forms among children who lived in communities with drinking water that naturally contained 0.9--1.2 ppm fluoride (53). Although the prevalence of this condition in the United States has since increased (8,58,59), most fluorosis today is of the mildest form, which affects neither cosmetic appearance nor dental function. The increased prevalence in areas both with and without fluoridated community drinking water (8) indicates that, during the first 8 years of life (i.e., the window of time when this condition can develop), the total intake of fluoride from all sources has increased for some children.

The 1986--1987 National Survey of Dental Caries in U.S. School Children (the most recent national estimates of enamel fluorosis prevalence) indicated that the prevalence of any enamel fluorosis among children was 22%--23% (range: 26% of children aged 9 years to 19% of those aged 17 years) (60,61). Almost all cases reported in the survey were of the very mild or mild form, but some cases of the moderate (1.1%)

and severe (0.3%) forms were observed. Cases of moderate and severe forms occurred even among children living in areas with low fluoride concentrations in the drinking water (61). Although this level of enamel fluorosis is not considered a public health problem (53), prudent public health practice should seek to minimize this condition, especially moderate to severe forms. In addition, changes in public perceptions of what is cosmetically acceptable could influence support for effective caries-prevention measures. Research into the causes of enamel fluorosis has focused on identifying risk factors (62--65). Adherence to the recommendations in this report regarding appropriate use of fluoride for children aged <6 years will reduce the prevalence and severity of enamel fluorosis.

NATIONAL GUIDELINES FOR FLUORIDE USE

PHS recommendations for fluoride use include an optimally adjusted concentration of fluoride in community drinking water to maximize caries prevention and limit enamel fluorosis. This concentration ranges from 0.7 ppm to 1.2 ppm depending on the average maximum daily air temperature of the area (66--68). In 1991, PHS also issued policy and research recommendations for fluoride use (8). The U.S. Environmental Protection Agency (EPA), which is responsible for the safety and quality of drinking water in the United States, sets a maximum allowable limit for fluoride in community drinking water at 4 ppm and a secondary limit (i.e., nonenforceable guideline) at 2 ppm (69,70). The U.S. Food and Drug Administration (FDA) is responsible for approving prescription and over-the-counter fluoride products marketed in the United States and for setting standards for labeling bottled water (71) and over-the-counter fluoride products (e.g., toothpaste and mouthrinse) (72).

Nonfederal agencies also have published guidelines on fluoride use. The American Dental Association (ADA) reviews fluoride products for caries prevention through its voluntary Seal of Acceptance program; accepted products are listed in the ADA Guide to Dental Therapeutics (73). A dosage schedule for fluoride supplements for infants and children aged <16 years, which is scaled to the fluoride concentration in the community drinking water, has been jointly recommended by ADA, the American Academy of Pediatric Dentistry (AAPD), and the American Academy of Pediatrics (AAP) (Table 1) (44,74,75). In 1997, the Institute of Medicine published age-specific recommendations for total dietary intake of fluoride (Table 2). These recommendations list adequate intake to prevent dental caries and tolerable upper intake, defined as a level unlikely to pose risk for adverse effects in almost all persons.

FLUORIDE SOURCES AND THEIR EFFECTS

Fluoridated community drinking water and fluoride toothpaste are the most common sources of fluoride in the United States and are largely responsible for the low risk for dental caries for most persons in this country. Persons at high risk for dental caries might require more frequent or more concentrated exposure to fluoride and might benefit from use of other fluoride modalities (e.g., mouthrinse, dietary supplements, and topical gel, foam, or varnish). The effects of each of these fluoride sources on dental caries and enamel fluorosis are described.

Fluoridated Drinking Water and Processed Beverages and Food

Fluoridated drinking water contains a fluoride concentration effective for preventing dental caries; this concentration can occur naturally or be reached through water fluoridation, which is the controlled addition of fluoride to a public water supply. When fluoridated water is the main source of drinking water, a low concentration of fluoride is routinely introduced into the mouth. Some of this fluoride is taken up by dental plaque; some is transiently present in saliva, which serves as a reservoir for plaque fluoride; and some is loosely held on the enamel surfaces (76). Frequent consumption of fluoridated drinking water and beverages and food processed in fluoridated areas maintains the concentration of fluoride in the mouth.

Estimates of fluoride intake among U.S. and Canadian adults have ranged from <1.0 mg fluoride per day in nonfluoridated areas to 1--3 mg fluoride per day in fluoridated areas (77--80). The average daily dietary fluoride intake for both children and adults in fluoridated areas has remained relatively constant for several years (11). For children who live in optimally fluoridated areas, this average is approximately 0.05 mg/kg/day (range: 0.02--0.10); for children who live in nonfluoridated areas, the average is approximately half (11). In a survey of four U.S. cities with different fluoride concentrations in the drinking water (range: 0.37--1.04 ppm), children aged 2 years ingested 0.41--0.61 mg fluoride per day and infants aged 6 months ingested 0.21--0.54 mg fluoride per day (81,82).

In the United States, water and processed beverages (e.g., soft drinks and fruit juices) can provide approximately 75% of a person's fluoride intake (83). Many processed beverages are prepared in locations where the drinking water is fluoridated. Foods and ingredients used in food processing vary in their fluoride content (11). As consumption of processed beverages by children increases, fluoride intake in communities without fluoridated water will increase whenever the water source for the processed beverage is fluoridated (84). In fluoridated areas, dietary fluoride intake has been stable because processed beverages have been substituted for tap water and for beverages prepared in the home using tap water (11).

A study of Iowa infants estimated that the mean fluoride intake from water during different periods during the first 9 months of life, either consumed directly or added to infant formula or juice, was 0.29--0.38 mg per day, although estimated intake for some infants was as high as 1.73 mg per day (85). As foods are added to an infant's diet, replacing some of the formula prepared with fluoridated water, the amount of fluoride the infant receives typically decreases (86). The Iowa study also reported that infant formula and processed baby food contained variable amounts of fluoride. Since 1979, U.S. manufacturers of infant formula have voluntarily lowered the fluoride concentration of their products, both ready-to-feed and concentrates, to <0.3 ppm fluoride (87).

Drinking Water

Community Water.

During the 1940s, researchers determined that 1 ppm fluoride was the optimal concentration in community drinking water for climates similar to the Chicago area (88,89). This concentration would substantially reduce the prevalence of dental caries, while allowing an acceptably low prevalence (i.e., 10%--12%) of very mild and mild enamel fluorosis and no moderate or severe enamel fluorosis. Water fluoridation for caries control began in 1945 and 1946, when the fluoride concentration was adjusted in the drinking water supplying four communities in the United States and Canada (2--5). This public health approach followed a long period of epidemiologic research into the effects of naturally occurring fluoride in drinking water (53,57,88,89).

Current federal fluoridation guidelines, maintained by the PHS since 1962, state that community drinking water should contain 0.7--1.2 ppm fluoride, depending on the average maximum daily air temperature of the area. These temperature-related guidelines are based on epidemiologic studies conducted during the 1950s that led to the development of an algebraic formula for determining optimal fluoride concentrations (67,90--92). This formula determined that a lower fluoride concentration was appropriate for communities in warmer climates because persons living in warmer climates drank more tap water. However, social and environmental changes since 1962 (e.g., increased use of air conditioning and more sedentary lifestyles) have reduced the likelihood that persons in warmer regions drink more tap water than persons in cooler regions (7).

By 1992, fluoridated water was reaching 144 million persons in the United States (56% of the total population and 62% of those receiving municipal water supplies) (93). Approximately 10 million of these persons were receiving water containing naturally occurring fluoride at a concentration of >0.7 ppm. In 11 states and the District of Columbia, >90% of the population had such access, whereas <5% received this benefit in two states. In 2000, a total of 38 states and the District of Columbia provided access to fluoridated public water supplies to >50% of their population (CDC, unpublished data, 2000) (Figure 2).

Initial studies of community water fluoridation demonstrated that reductions in childhood dental caries attributable to fluoridation were approximately 50%--60% (94--97). More recent estimates are lower --- 18%--40% (98,99). This decrease in attributable benefit is likely caused by the increasing use of fluoride from other sources, with the widespread use of fluoride toothpaste probably the most important.
The diffusion or "halo" effect of beverages and food processed in fluoridated areas but consumed

in nonfluoridated areas also indirectly spreads some benefit of fluoridated water to nonfluoridated communities. This effect lessens the differences in caries experience among communities (100).

Quantifying the benefits of water fluoridation among adults is more complicated because adults are rarely surveyed, their fluoride histories are potentially more varied, and their tooth loss or restorations might be caused by dental problems other than caries (e.g., trauma or periodontal diseases). Nevertheless, adults are reported to receive caries-preventive benefits from community water fluoridation (99,101--103). These benefits might be particularly advantageous for adults aged >50 years, many of whom are at increased risk for dental caries. Besides coronal caries, older adults typically experience gingival recession, which results in teeth with exposed root surfaces. Unlike the crowns of teeth, these root surfaces are not covered by enamel and are more susceptible to caries. Because tooth retention among older age groups has increased in recent decades in the United States (39), these groups' risk for caries will increase as the country's population ages. Older adults also frequently require multiple medications for chronic conditions, and many of these medications can reduce salivary output (104). Drinking water containing an optimal concentration of fluoride can mitigate the risk factors for caries among older adults. Studies have reported that the prevalence of root caries among adults is inversely related to fluoride concentration in the community drinking water (105--107).

Water fluoridation also reduces the disparities in caries experience among poor and nonpoor children (108--111). Caries experience is considerably higher among persons in low SES strata than among those in high SES strata (39,46,112). The reasons for this discrepancy are not well understood; perhaps persons in low SES strata have less knowledge of oral diseases, have less access to dental care, are less likely to follow recommended self-care practices, or are harder to reach through traditional approaches, including public health programs and private dental care (48). Thus, these persons might receive more benefit from fluoridated community water than persons from high SES strata. Regardless of SES, water fluoridation is the most effective and efficient strategy to reduce dental caries (112).

Enamel fluorosis occurs among some persons in all communities, even in communities with a low natural concentration of fluoride. During 1930--1960, U.S. studies documented that, in areas with a natural or adjusted concentration of fluoride of approximately 1.0 ppm in the community drinking water, the permanent teeth of 7%-- 16% of children with lifetime residence in those areas exhibited very mild or mild forms of enamel fluorosis (53,113,114). Before 1945, when naturally fluoridated drinking water was virtually the only source of fluoride, the moderate and severe forms of this condition were not observed unless the natural fluoride concentration was >2 ppm (53). The likelihood of a child developing the mild forms of enamel fluorosis might be higher in a fluoridated area than in a nonfluoridated area, but prevalence might not change in every community (115,116). The most recent national study of this condition indicated that its prevalence had increased in both fluoridated and nonfluoridated areas since the 1940s, with the relative increase higher in nonfluoridated areas. In communities with drinking water containing 0.7--1.2 ppm fluoride, the prevalence was 1.3% for the moderate form of enamel fluorosis and zero for the severe form; thus, few cases of enamel fluorosis were likely to be of cosmetic consequence (8,61). Because combined fluoride intake from drinking water and processed beverages and food by children in fluoridated areas has reportedly remained stable since the 1940s, the increase in fluoride intake resulting in increased enamel fluorosis almost certainly stems from use of fluoride-containing dental products by children aged <6 years (11).

Two studies reported that extended consumption of infant formula beyond age 10--12 months was a risk factor for enamel fluorosis, especially when formula concentrate was mixed with fluoridated water (62,63). These studies examined children who used pre-1979 formula (with higher fluoride concentrations). Whether fluoride intake from formula that exceeds the recommended amount during only the first 10--12 months of life contributes to the prevalence or severity of enamel fluorosis is unknown.

Fluoride concentrations in drinking water should be maintained at optimal levels, both to achieve effective caries prevention and because changes in fluoride concentration as low as 0.2 ppm can result in a measurable change in the prevalence and severity of enamel fluorosis (52,117). Since the late 1970s, CDC has provided guidelines and recommendations for managers of fluoridated water supply systems at state and local levels to help them establish and maintain appropriate fluoride concentrations. CDC periodically updates these guidelines; the most recent revision was published in 1995 (68).

School Water Systems.

In some areas of the United States where fluoridating a community's drinking water was not feasible (e.g., rural areas), the alternative of fluoridating a school's public water supply system was promoted for many years. This method was used when a school had its own source of water and was not connected to a community water supply system (i.e., stand-alone systems). Because children are at school only part of each weekday, a fluoride concentration of 4.5 times the optimal concentration for a community in the same geographic area was recommended (118) to compensate for the more limited consumption of fluoridated water. At the peak of this practice in the early 1980s, a total of 13 states had initiated school water fluoridation in 470 schools serving 170,000 children (39). Since then, school water fluoridation has been phased out in several states; the current extent of this practice is not known.

Studies of the effects of school water fluoridation in the United States reported that this practice reduced caries among schoolchildren by approximately 40% (118--122). A more recent study indicated that this effect might no longer be as pronounced (123).

Several concerns regarding school water fluoridation exist. Operating and maintaining small fluoridation systems (i.e., those serving <500 persons) create practical and logistical difficulties (68). These difficulties have occasionally caused higher than recommended fluoride concentrations in the school drinking water, but no lasting effects among children have been observed (124--126). In schools that enroll preschoolers in day care programs, children aged <6 years might receive more than adequate fluoride.

Bottled Water.

Many persons drink bottled water, replacing tap water partially or completely as a source of drinking water. Water is classified as "bottled water" if it meets all applicable federal and state standards, is sealed in a sanitary container, and is sold for human consumption. Although some bottled waters marketed in the United States contain an optimal concentration of fluoride (approximately 1.0 ppm), most contain <0.3 ppm fluoride (127--129). Thus, a person substituting bottled water with a low fluoride concentration for fluoridated community water might not receive the full benefits of community water fluoridation (130). For water bottled in the United States, current FDA regulations require that fluoride be listed on the label only if the bottler adds fluoride during processing; the concentration of fluoride is regulated but does not have to be stated on the label (Table 3). Few bottled water brands have labels listing the fluoride concentration.

Determining Fluoride Concentration. Uneven geographic coverage of community water fluoridation throughout the United States, wide variations in natural fluoride concentrations found in drinking water, and almost nonexistent labeling of fluoride concentration in bottled water make knowing the concentration of fluoride in drinking water difficult for many persons. Persons in nonfluoridated areas can mistakenly believe their water contains an optimal concentration of fluoride. To obtain the fluoride concentration of community drinking water, a resident can contact the water supplier or a local public health authority, dentist, dental hygienist, physician, or other knowledgeable source. EPA requires that all community water supply systems provide each customer an annual report on the quality of water, including the fluoride concentration (131). Testing for private wells is available through local and state public health departments as well as some private laboratories. If the fluoride concentration is not listed on the label of bottled water, the bottler can be contacted directly to obtain this information.

Fluoride Toothpaste

Fluoride is the only nonprescription toothpaste additive proven to prevent dental caries. When introduced into the mouth, fluoride in toothpaste is taken up directly by dental plaque (132--134) and demineralized enamel (135,136). Brushing with fluoride toothpaste also increases the fluoride concentration in saliva 100- to 1,000-fold; this concentration returns to baseline levels within 1--2 hours (137). Some of this salivary fluoride is taken up by dental plaque. The ambient fluoride concentration in saliva and plaque can increase during regular use of fluoride toothpaste (132,133).

By the 1990s, fluoride toothpaste accounted for >90% of the toothpaste market in the United States, Canada, and other developed countries (138). Because water fluoridation is not available in many countries, toothpaste might be the most important source of fluoride globally (1).

Studies of 2--3 years duration have reported that fluoride toothpaste reduces caries experience among children by a median of 15%--30% (139--148). This reduction is modest compared with the effect of water fluoridation, but water fluoridation studies usually measured lifetime --- rather than a few years' --- exposure. Regular lifetime use of fluoride toothpaste likely provides ongoing benefits that might approach those of fluoridated water. Combined use of fluoride toothpaste and fluoridated water offers protection above either used alone (99,149,150).

Few studies evaluating the effectiveness of fluoride toothpaste, gel, rinse, and varnish among adult populations are available. Child populations have typically been used for studies on caries prevention because of perceived increased caries susceptibility and logistical reasons. However, teeth generally remain susceptible to caries throughout life, and topically applied fluorides could be effective in preventing caries in susceptible patients of any age (151,152).

Most persons report brushing their teeth at least once per day (153,154), but more frequent use can offer additional protection (139,141,155--158). Brushing twice a day is a reasonable social norm that is both effective and convenient for most persons' daily routines, and this practice has become a basic recommendation for caries prevention. Whether increasing the number of daily brushings from two to three times a day results in lower dental caries experience is unclear. Because the amount and vigor of rinsing after toothbrushing affects fluoride concentration in the mouth and reportedly affects caries experience (157--160), persons aged >6 years can retain more fluoride in the mouth by either rinsing briefly with a small amount of water or not at all.

In the United States, the standard concentration of fluoride in fluoride toothpaste is 1,000--1,100 ppm. Toothpaste containing 1,500 ppm fluoride has been reported to be slightly more efficacious in reducing dental caries in U.S. and European studies (161--164). Products with this fluoride concentration have been marketed in the United States, but are not available in all areas. These products might benefit persons aged >6 years at high risk for dental caries.

Children who begin using fluoride toothpaste at age <2 years are at higher risk for enamel fluorosis than children who begin later or who do not use fluoride toothpaste at all (62,63,165--170). Because studies have not used the same criteria for age of initiation, amount of toothpaste used, or frequency of toothpaste use, the specific contribution of each factor to enamel fluorosis among this age group has not been established.

Fluoride toothpaste contributes to the risk for enamel fluorosis because the swallowing reflex of children aged <6 years is not always well controlled, particularly among children aged <3 years (171,172). Children are also known to swallow toothpaste deliberately when they like its taste. A child-sized toothbrush covered with a full strip of toothpaste holds approximately 0.75--1.0 g of toothpaste, and each gram of fluoride toothpaste, as formulated in the United States, contains approximately 1.0 mg of fluoride. Children aged <6 years swallow a mean of 0.3 g of toothpaste per brushing (11) and can inadvertently swallow as much as 0.8 g (138,173--176). As a result, multiple brushings with fluoride toothpaste each day can result in ingestion of excess fluoride (177). For this reason, high-fluoride toothpaste (i.e., containing 1,500 ppm fluoride) is generally contraindicated for children aged <6 years.

Use of a pea-sized amount (approximately 0.25 g) of fluoride toothpaste <2 times per day by children aged <6 years is reported to sharply reduce the importance of fluoride toothpaste as a risk factor for enamel fluorosis (65). Since 1991, manufacturers of fluoride toothpaste marketed in the United States have, as a requirement for obtaining the ADA Seal of Acceptance, placed instructions on the package label stating that children aged <6 years should use only this amount of toothpaste. Toothpaste labeling requirements mandated by FDA in 1996 (72) also direct parents of children aged <2 years to seek advice from a dentist or physician before introducing their child to fluoride toothpaste.

The propensity of young children to swallow toothpaste has led to development of "child-strength" toothpaste with lower fluoride concentrations (176). Such a product would be a desirable alternative to currently available products for many young children. Clinical trials outside the United States have reported that toothpaste containing 250 ppm fluoride is less effective than toothpaste containing 1,000 ppm fluoride in preventing dental caries (178,179). However, toothpaste containing 500--550 ppm fluoride might be almost as efficacious as that containing 1,000 ppm fluoride (180). A British study reported that the prevalence of diffuse enamel opacities (an indicator of mild enamel fluorosis) in the upper anterior incisors was substantially lower among children who used toothpaste containing 550 ppm fluoride than among those who used toothpaste containing 1,050 ppm fluoride (181). Toothpaste containing 400 ppm fluoride has been available in Australia and New Zealand for approximately 20 years, but has not been tested in clinical trials, and no data are available to assess whether toothpaste at this concentration has reduced the prevalence of enamel fluorosis in those countries. A U.S. clinical trial of the efficacy of toothpaste with lower fluoride concentrations, required by FDA before approval for marketing and distribution, has not been conducted (182).

Fluoride Mouthrinse

Fluoride mouthrinse is a concentrated solution intended for daily or weekly use. The fluoride from mouthrinse, like that from toothpaste, is retained in dental plaque and saliva to help prevent dental caries (183). The most common fluoride compound used in mouthrinse is sodium fluoride. Over-the-counter solutions of 0.05% sodium fluoride (230 ppm fluoride) for daily rinsing are available for use by persons aged >6 years. Solutions of 0.20% sodium fluoride (920 ppm fluoride) are used in supervised, school-based weekly rinsing programs. Throughout the 1980s, approximately 3 million children in the United States participated in school-based fluoride mouthrinsing programs (39). The current extent of such programs is not known.

Studies indicating that fluoride mouthrinse reduces caries experience among schoolchildren date mostly from the 1970s and early 1980s (184--191). In one review, the average caries reduction in nonfluoridated communities attributable to fluoride mouthrinse was 31% (191). Two studies reported benefits of fluoride mouthrinse approximately 2.5 and 7 years after completion of school-based mouthrinsing programs (192,193), but a more recent study did not find such benefits 4 years after completion of a mouthrinsing program (194). The National Preventive Dentistry Demonstration Program (NPDDP), a large project conducted in 10 U.S. cities during 1976--1981 to compare the cost and effectiveness of combinations of caries-prevention procedures, reported that fluoride mouthrinse had little effect among schoolchildren, either among first-grade students with high and low caries experience (195) or among all second- and fifth-grade students (196). NPDDP documented only a limited reduction in dental caries attributable to fluoride mouthrinse, especially when children were also exposed to fluoridated water.

Although no studies of enamel fluorosis associated with use of fluoride mouthrinse have been conducted, studies of the amount of fluoride swallowed by children aged 3--5 years using such rinses indicated that some young children might swallow substantial amounts (191). Use of fluoride mouthrinse by children aged >6 years does not place them at risk for cosmetically objectionable enamel fluorosis because they are generally past the age that fluoride ingestion might affect their teeth.

Dietary Fluoride Supplements

Dietary fluoride supplements in the form of tablets, lozenges, or liquids (including fluoride-vitamin preparations) have been used throughout the world since the 1940s. Most supplements contain sodium fluoride as the active ingredient. Tablets and lozenges are manufactured with 1.0, 0.5, or 0.25 mg fluoride. To maximize the topical effect of fluoride, tablets and lozenges are intended to be chewed or sucked for 1--2 minutes before being swallowed. For infants, supplements are available as a liquid and used with a dropper.

In 1986, an estimated 16% of U.S. children aged <2 years used fluoride supplements (197). All fluoride supplements must be prescribed by a dentist or physician. The prescription should be consistent with the 1994 dosage schedule developed by ADA, AAPD, and AAP (Table 1). Because fluoride supplements are intended to compensate for fluoride-deficient drinking water, the dosage schedule requires knowledge of the fluoride content of the child's primary drinking water; consideration should also be given to other sources of water (e.g., home, child care settings, school, or bottled water) and to other sources of fluoride (e.g., toothpaste or mouthrinse), which can complicate the prescribing decision.

The evidence for using fluoride supplements to mitigate dental caries is mixed. Use of fluoride supplements by pregnant women does not benefit their offspring (198). Several studies have reported that fluoride supplements taken by infants and children before their teeth erupt reduce the prevalence and severity of caries in teeth (98,199--207), but several other studies have not (19,208--212). Among children aged 6--16 years, fluoride supplements taken after teeth erupt reduce caries experience (213--215). Fluoride supplements might be beneficial among adults who have limitations with toothbrushing, but this use requires further study.

A few studies have reported no association between supplement use by children aged <6 years and enamel fluorosis (208,216), but most have reported a clear association (19,62,64,165,170,199--201,209,210,212,217--222). In one study, the risk for this condition was high when supplements were used in fluoridated areas (odds ratio = 23.74; 95% confidence interval = 3.43--164.30) (62), a use inconsistent with the supplement schedule. Reports of the frequency of supplement use in fluoridated areas have ranged from 7% to 35% (223--228). In response to the accumulated data on fluoride intake and the prevalence of enamel fluorosis, the supplement dosage schedule for children aged <6 years was markedly reduced in 1994 when ADA, AAPD, and AAP jointly established the current schedule (Table 1) (73). The risk for enamel fluorosis among children this age attributable to fluoride supplements could be lower, but not enough information is available yet to evaluate the effects of this change.

When prescribing any pharmaceutical agent, dentists and physicians should attempt to maximize benefit and minimize harm (229). For infants and children aged <6 years, both a benefit of dental caries prevention and a risk for enamel fluorosis are possible. Although the primary (i.e., "baby") teeth of children aged 1--6 years would benefit from fluoride's posteruptive action, and some preeruptive benefit for developing permanent teeth could exist, fluoride supplements also could increase the risk for enamel fluorosis at this age (138,223).

Professionally Applied Fluoride Compounds

In the United States, dentists and dental hygienists have been applying high-concentration fluoride compounds directly to patients' teeth for approximately 50 years. Application procedures were developed on the assumption that the fluoride would be incorporated into the crystalline structure of the dental enamel and develop a more acid-resistant enamel. To maximize this reaction, a professional tooth cleaning was considered mandatory before the application. However, subsequent research has demonstrated that high-concentration fluoride compounds (e.g., those in gel or varnish) do not directly enter the enamel's crystalline structure (230). The compound forms a calcium fluoride-like material on the enamel's surface that releases fluoride for remineralization when the pH in the mouth drops. Thus, professional tooth cleaning solely to prepare the teeth for application of a fluoride compound is unnecessary; toothbrushing and flossing appear equally effective in improving the efficacy of high-concentration fluoride compounds (231).

Fluoride Gel and Foam

Because an early study reported that fluoride uptake by dental enamel increased in an acidic environment (232), fluoride gel is often formulated to be highly acidic (pH of approximately 3.0). Products available in the United States include gel of acidulated phosphate fluoride (1.23% [12,300 ppm] fluoride), gel or foam of sodium fluoride (0.9% [9,040 ppm] fluoride), and self-applied (i.e., home use) gel of sodium fluoride (0.5% [5,000 ppm] fluoride) or stannous fluoride (0.15% [1,000 ppm] fluoride) (73).

Clinical trials conducted during 1940--1970 demonstrated that professionally applied fluorides effectively reduce caries experience in children (233). In more recent studies, semiannual treatments reportedly caused an average decrease of 26% in caries experience in the permanent teeth of children residing in nonfluoridated areas (191,234--236). The application time for the treatments was 4 minutes. In clinical practice, applying fluoride gel for 1 minute rather than 4 minutes is common, but the efficacy of this shorter application time has not been tested in human clinical trials. In addition, the optimal schedule for repeated application of fluoride gel has not been adequately studied to support definitive guidelines, and studies that have examined the efficacy of various gel application schedules in preventing and controlling dental caries have reported mixed results. On the basis of the available evidence, the usual recommended frequency is semiannual (151,237,238).

Because these applications are relatively infrequent, generally at 3- to 12-month intervals, fluoride gel poses little risk for enamel fluorosis, even among patients aged <6 years. Proper application technique reduces the possibility that a patient will swallow the gel during application.

Fluoride Varnish

High-concentration fluoride varnish is painted directly onto the teeth. Fluoride varnish is not intended to adhere permanently; this method holds a high concentration of fluoride in a small amount of material in close contact with the teeth for many hours. Fluoride varnish has practical advantages (e.g., ease of application, a nonoffensive taste, and use of smaller amounts of fluoride than required for gel applications). Such varnishes are available as sodium fluoride (2.26% [2,600 ppm] fluoride) or difluorsilane (0.1% [1,000 ppm] fluoride) preparations.

Fluoride varnish has been widely used in Canada and Europe since the 1970s to prevent dental caries (152,239). FDA's Center for Devices and Radiological Health has cleared fluoride varnish as a medical device to be used as a cavity liner (i.e., to provide fluoride at the junction of filling material and tooth) and root desensitizer (i.e., to reduce sensitivity to temperature and touch that sometimes occurs on root surfaces exposed by receding gingiva) (240); FDA has not yet approved this product as an anticaries agent. Caries prevention is regarded as a drug claim, and companies would be required to submit appropriate clinical trial evidence for review before this product could be marketed as an anticaries agent. However, a prescribing practitioner can use fluoride varnish for caries prevention as an "off-label" use, based on professional judgement (241).

Studies conducted in Canada (242) and Europe (243--246) have reported that fluoride varnish is efficacious in preventing dental caries in children. Applied semiannually, this modality is as effective as professionally applied fluoride gel (247). Some researchers advocate application of fluoride varnish as many as four times per year to achieve maximum effect, but the evidence of benefits from more than two applications per year remains inconclusive (240,246,248). Other studies have reported that three applications in 1 week, once per year, might be more effective than the more conventional semiannual regimen (249,250).

European studies have reported that fluoride varnish prevents decalcification (i.e., an early stage of dental caries) beneath orthodontic bands (251) and slows the progression of existing enamel lesions (252). Studies examining the effectiveness of varnish in controlling early childhood caries are being conducted in the United States. Research on fluoride varnish (e.g., optimal fluoride concentration, the most effective application protocols, and its efficacy relative to other fluoride modalities) is likely to continue in both Europe and North America.

No published evidence indicates that professionally applied fluoride varnish is a risk factor for enamel fluorosis, even among children aged <6 years. Proper application technique reduces the possibility that a patient will swallow varnish during its application and limits the total amount of fluoride swallowed as the varnish wears off the teeth over several hours.

Fluoride Paste

Fluoride-containing paste is routinely used during dental prophylaxis (i.e., cleaning). The abrasive paste, which contains 4,000--20,000 ppm fluoride, might restore the concentration of fluoride in the surface layer of enamel removed by polishing, but it is not an adequate substitute for fluoride gel or varnish in treating persons at high risk for dental caries (151). Fluoride paste is not accepted by FDA or ADA as an efficacious way to prevent dental caries.

Combinations of Fluoride Modalities

Studies comparing various combinations of fluoride modalities have generally reported that their effectiveness in preventing dental caries is partially additive. That is, the percent reduction in the prevalence or severity of dental caries from a combination of modalities is higher than the percent reduction from each modality, but less than the sum of the percent reduction of the modalities combined. Attempts to use a formula to apply sequentially the percent reduction of an additional modality to the estimated remaining caries increment have overestimated the effect (151,253). For example, if the first modality reduces caries by 40% and the second modality reduces caries by 30%, then the calculation that caries will be reduced by a total of 58% (i.e., 40% plus 18% [30% of the 60% decay remaining after the first modality]) will likely be an overestimate.

QUALITY OF EVIDENCE FOR DENTAL CARIES PREVENTION AND CONTROL

Members of the work group convened by CDC identified the published research in their areas of expertise and evaluated the quality of scientific evidence for each fluoride modality in preventing and controlling dental caries. Evidence was drawn from the most relevant English-language, peer-reviewed scientific publications regarding the current effectiveness of fluoride modalities. Additional references were suggested by reviewers. Members used their own methods for critically analyzing articles. A formal protocol for duplicate review was not followed, but members collectively agreed on the grade reflecting the quality of evidence regarding each fluoride modality. Criteria used to grade the quality of scientific evidence (i.e., ordinal grading) was adapted from the U.S. Preventive Services Task Force (Box 1) (254). Grades range from I to III.

Community Water Fluoridation

Studies on the effectiveness of adjusting fluoride in community water to the optimal concentration cannot be designed as randomized clinical trials. Random allocation of study subjects is not possible when a community begins to fluoridate the water because all residents in a community have access to and are exposed to this source of fluoride. In addition, clinical studies cannot be conducted double-blind because both study subjects and researchers usually know whether a community's water has been fluoridated. Efforts to blind the examiners by moving study subjects to a neutral third site for clinical examinations, using radiographs of teeth without revealing where the subjects live, or including transient residents as study subjects have not fully resolved these inherent limitations. Early studies that led to the unexpected discovery that dental caries was less prevalent and severe among persons with mottled enamel (subsequently identified as a form of enamel fluorosis) were conducted before the caries-preventive effects of fluoride were known (255). In those studies, researchers did not have an a priori reason to suspect they would find either reduced or higher levels of dental caries experience in communities with low levels of mottled enamel. Researchers also had no reason to believe that patients selected where they lived according to their risk for dental caries. In that regard, these studies were randomized, and examiners were blinded.

Despite the strengths of early studies of the efficacy of naturally occurring fluoride in community drinking water, the limitations of these studies make summarizing the quality of evidence on community water fluoridation as Grade I inappropriate (Table 1). The quality of evidence from studies on the effectiveness of adjusting fluoride concentration in community water to optimal levels is Grade II-1. Research limitations are counterbalanced by broadly similar results from numerous well-conducted field studies by other investigators that included thousands of persons throughout the world (256,257).

School Water Fluoridation

Field trials on the effect of school water fluoridation were not blindly conducted and had no concurrent controls (118). Thus, the quality of evidence for this modality is Grade II-3.

Fluoride Toothpaste

Studies that have demonstrated the efficacy of fluoride toothpaste in preventing and controlling dental caries include all of the essential features of well-conducted clinical trials. These include randomized groups, double-blind designs, placebo controls, and meticulous procedural protocols. Taken together, the trials on fluoride toothpaste provide solid evidence that fluoride is efficacious in controlling caries (144). The quality of evidence for toothpaste is Grade I.

Fluoride Mouthrinse

Early studies of the efficacy of fluoride mouthrinse in reducing dental caries experience were randomized clinical trials (184,185) or studies that used historical control groups rather than concurrent control groups (186--189). The quality of evidence for fluoride mouthrinse is Grade I.

Dietary Fluoride Supplements

The only randomized controlled trial to assess fluoride supplements taken by pregnant women provides Grade I evidence of no benefit for their children. Many studies of the effectiveness of fluoride supplements in preventing dental caries among children aged <6 years have been flawed in design and conduct. Problems included self-selection into test and control groups, absence of concurrent controls, high attrition rates, and nonblinded examiners. Because of these flaws, the quality of evidence to support use of fluoride supplements by children aged <6 years is Grade II-3. The well-conducted randomized clinical trials on the effects of fluoride supplements on dental caries among children aged 6--16 years in programs conducted in schools provide Grade I evidence.

Fluoride Gel

The quality of evidence for using fluoride gel to prevent and control dental caries in children is Grade I. However, data were gathered when dental caries was more prevalent and severe than today. Subjects in earlier studies were probably more representative of persons who now would be characterized as being at high risk for caries.

Fluoride Varnish

The quality of evidence for the efficacy of high-concentration fluoride varnish in preventing and controlling dental caries in children is Grade I. Although the randomized controlled clinical studies that established Grade I evidence were conducted in Europe, U.S. results should be the same.

COST-EFFECTIVENESS OF FLUORIDE MODALITIES

Documented effectiveness is the most basic requirement for providing a health-care service and an important prerequisite for preventive services (e.g., caries-preventive modalities). However, effectiveness alone is not a sufficient reason to initiate a service. Other factors, including cost, must be considered (254). A modality is more cost-effective when deemed a less expensive way, from among competing alternatives, of meeting a stated objective (258). In public health planning, determination of the most cost-effective alternative for prevention is essential to using scarce resources efficiently. Dental-insurance carriers are also interested in cost-effectiveness so they can help purchasers use funds efficiently. Because half of dental expenditures are out of pocket (259), this topic interests patients and their dentists as well. Potential improvement to quality of life is also a consideration. The contribution of a healthy dentition to quality of life at any age has not been quantified, but is probably valued by most persons.

Although solid data on the cost-effectiveness of fluoride modalities alone and in combination are needed, this information is scarce. In 1989, the Cost Effectiveness of Caries Prevention in Dental Public Health workshop, which was attended by health economists, epidemiologists, and dental public health professionals, attempted to assess the cost-effectiveness of caries-preventive approaches available in the United States (260).

All other things being equal, fluoride modalities are most cost-effective for persons at high risk for dental caries. Because persons at low risk develop little dental caries, limited benefit is gained by adding caries-preventive modalities to water fluoridation and fluoride toothpaste, even those demonstrated to be effective among populations at high risk. Members of the CDC work group reached consensus regarding the populations for which each modality would be expected to have the necessary level of cost-effectiveness to warrant its use.

Community Water Fluoridation

Health economists at the 1989 workshop on cost-effectiveness of caries prevention calculated that the average annual cost of water fluoridation in the United States was $0.51 per person (range: $0.12--$5.41) (260). In 1999 dollars,** this cost would be $0.72 per person (range: $0.17--$7.62). Factors reported to influence the per capita cost included

- size of the community (the larger the population reached, the lower the per capita cost);
- number of fluoride injection points in the water supply system;
- amount and type of system feeder and monitoring equipment used;
- amount and type of fluoride chemical used, its price, and its costs of transportation and storage; and
- expertise of personnel at the water plant.

When the effects of caries are repaired, the price of the restoration is based on the number of tooth surfaces affected. A tooth can have caries at >1 location (i.e., surface), so the number of surfaces saved is a more appropriate measure in calculating cost-effectiveness than the number of teeth with caries. The 1989 workshop participants concluded that water fluoridation is one of the few public health measures that results in true cost savings (i.e., the measure saves more money than it costs to operate); in the United States, water fluoridation cost an estimated average of $3.35 per carious surface saved ($4.71 in 1999 dollars**) (260). Even under the least favorable assumptions in 1989 (i.e., cities with populations <10,000, higher operating costs, and effectiveness projected at the low end of the range), the cost of a carious surface saved because of community water fluoridation ranged from $8 to $12 ($11--$17 in 1999 dollars**) (260), which is still lower than the fee for a one-surface restoration ($54 in 1995 or $65 in 1999 dollars***) (261).

A Scottish study conducted in 1980 reported that community water fluoridation resulted in a 49% saving in dental treatment costs for children aged 4--5 years and a 54% saving for children aged 11--12 years (262). These savings were maintained even after the secular decline in the prevalence of dental caries was recognized (263). The effect of community water fluoridation on the costs of dental care for adults is less clear. This topic cannot be fully explored until the generations who grew up drinking optimally fluoridated water are older.

School Water Fluoridation

Costs for school water fluoridation are similar to those of any public water supply system serving a small population (i.e., <1,000 persons). In 1988, the average annual cost of school water fluoridation was $4.52 per student per year (range: $0.81--$9.72) (264). In 1999 dollars,**** this cost would be $6.37 per person (range: $1.14--$13.69). Use of this modality must be carefully weighed in the current environment of low caries prevalence, widespread use of fluoride toothpaste, and availability of other fluoride modalities that can be delivered in the school setting.

Fluoride Toothpaste

Fluoride toothpaste is widely available, no more expensive than nonfluoride toothpaste, and periodically improved. Use of a pea-sized amount (0.25 g) twice per day requires approximately two tubes of toothpaste per year, for an estimated annual cost of $6--$12, depending on brand, tube size, and retail source (265). Persons who brush and use toothpaste regularly to maintain periodontal health and prevent stained teeth and halitosis (i.e., bad breath) incur no additional cost for the caries-preventive benefit of fluoride in toothpaste. Because of its multiple benefits, most persons consider fluoride toothpaste a highly cost-effective caries-preventive modality.

Fluoride Mouthrinse

Public health programs of fluoride mouthrinsing have long been presumed to be cost-effective, especially when teachers can supervise weekly rinsing in classrooms at no direct cost to the program. In other programs, volunteers or hourly workers provide supervision. Under these circumstances, administrators of fluoride mouthrinsing programs have claimed annual program costs of approximately $1 per child ($1.41 in 1999 dollars****) (264). This figure likely is an underestimate because indirect costs are not included (196,266). Fluoride mouthrinsing is a reasonable procedure for groups and persons at high risk for dental caries, but its cost-effectiveness as a universal, population-wide strategy in the modern era of widespread fluoride exposure is questionable (267).

Dietary Fluoride Supplements

Dietary fluoride supplements prescribed to persons cost an estimated $37 per year. Fluoride supplements in school programs have direct costs of approximately $2.50 per child ($3.52 in 1999 dollars****) for the tablet or lozenge (264); program administrative costs and considerations are similar to those in school mouthrinsing programs.

Professionally Applied Fluoride Compounds

High-concentration fluoride gel and varnish are effective in preventing dental caries, but because application requires professional expertise, they are inherently more expensive than self-applied methods (e.g., drinking fluoridated water or brushing with fluoride toothpaste). For groups and persons at low risk for dental caries, professionally applied methods are unlikely to be cost-effective (268,269). In the NPDDP study, prophylactic cleaning and gel application costs were $23 per year ($66 in 1999 dollars*****) for semiannual applications, which prevented 0.03--0.26 decayed surfaces per year (196). A Swedish study claimed that fluoride varnish was cost-effective, but few supporting data were presented (270). Varnish might be cost-effective in Scandinavian school dental services, in which dental professionals regularly examine and treat each student, but the cost-effectiveness of fluoride varnish in public health programs in the United States remains undocumented. Whether fluoride varnish or gel would be most efficiently used in clinical programs targeting groups at high risk for dental caries or should be reserved for individual patients at high risk is unclear.

Combinations of Fluoride Modalities

Because the caries-preventive effects of a combination of fluoride modalities are only partially additive, estimates of the cost-effectiveness when adding a modality (e.g., fluoride mouthrinse for a group already drinking fluoridated water and using fluoride toothpaste) should take into account these smaller, incremental reductions in caries. This consideration is particularly relevant for groups and persons at low risk for caries (253). The scarcity of research on the costeffectiveness of combinations limits the ability to draw more detailed conclusions.

RECOMMENDATIONS

In developing the recommendations for specific fluoride modalities that address public health and clinical practice and self-care, the CDC work group considered the quality of evidence of each modality's effect on dental caries, its association with enamel fluorosis, and its cost-effectiveness. The strength of the recommendation for each fluoride modality was determined by the work group, which adapted a coding system used by the U.S. Preventive Services Task Force (Box 2). The work group considered these factors when determining the population for which each recommendation applies (Table 4). The work group recognized that some recommendations can only be addressed by health-care industries or agencies and that additional research is required to resolve some questions regarding fluoride modalities.

Before promoting a fluoride modality or combination of modalities, the dental-care or other health-care provider must consider a person's or group's risk for dental caries, current use of other fluoride sources, and potential for enamel fluorosis. Although these recommendations are based on assessments of caries risk as low or high, the health-care provider might also differentiate among patients at high risk and provide more intensive interventions as needed. Also, a risk category can change over time; the type and frequency of preventive interventions should be adjusted accordingly.

Public Health and Clinical Practice

Continue and Extend Fluoridation of Community Drinking Water

Community water fluoridation is a safe, effective, and inexpensive way to prevent dental caries. This modality benefits persons in all age groups and of all SES, including those difficult to reach through other public health programs and private dental care. Community water fluoridation also is the most cost-effective way to prevent tooth decay among populations living in areas with adequate community water supply systems. Continuation of community water fluoridation for these populations and its adoption in additional U.S. communities are the foundation for sound caries-prevention programs.

In contrast, the appropriateness of fluoridating stand-alone water systems that supply individual schools is limited. Widespread use of fluoride toothpaste, availability of other fluoride modalities that can be delivered in the school setting, and the current environment of low caries prevalence limit the appropriateness of fluoridating school drinking water at 4.5 times the optimal concentration for community drinking water. Decisions to initiate or continue school fluoridation programs should be based on an assessment of present caries risk in the target school(s), alternative preventive modalities that might be available, and periodic evaluation of program effectiveness.

Counsel Parents and Caregivers Regarding Use of Fluoride Toothpaste by Young Children, Especially Those Aged <2 Years

Fluoride toothpaste is a cost-effective way to reduce the prevalence of dental caries. However, for children aged <6 years, especially those aged <2 years, an increased risk for enamel fluorosis exists because of inadequately developed control of the swallowing reflex. Parents or caregivers should be counseled regarding selfcare recommendations for toothpaste use for young children (i.e., limit the child's toothbrushing to <2 times a day, apply a peasized amount to the toothbrush, supervise toothbrushing, and encourage the child to spit out excess toothpaste).

For children aged <2 years, the dentist or other healthcare provider should consider the fluoride level in the community drinking water, other sources of fluoride, and factors likely to affect susceptibility to dental caries when weighing the risk and benefits of using fluoride toothpaste.

Target Mouthrinsing to Persons at High Risk

Because fluoride mouthrinse has resulted in only limited reductions in caries experience among schoolchildren, especially as their exposure to other sources of fluoride has increased, its use should be targeted to groups and persons at high risk for caries (see Risk for Dental Caries). Children aged <6 years should not use fluoride mouthrinse without consultation with a dentist or other health-care provider because enamel fluorosis could occur if such mouthrinses are repeatedly swallowed.

Judiciously Prescribe Fluoride Supplements

Fluoride supplements can be prescribed for children at high risk for dental caries and whose primary drinking water has a low fluoride concentration. 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. Consideration of the child's other sources of fluoride, especially drinking water, is essential in determining this balance. Parents and caregivers should be informed of both the benefit of protection against dental caries and the possibility of enamel fluorosis. The prescription dosage of fluoride supplements should be consistent with the schedule established by ADA, AAPD, and AAP. Supplements can be prescribed for persons as appropriate or used in school-based programs. When practical, supplements should be prescribed as chewable tablets or lozenges to maximize the topical effects of fluoride.

Apply High-Concentration Fluoride Products to Persons at High Risk for Dental Caries

High-concentration fluoride products can play an important role in preventing and controlling dental caries among groups and persons at high risk. Dentists and other health-care providers must consider the risk status and age of the patient to determine the appropriate intensity of treatment. Routine use of professionally applied fluoride gel or foam likely provides little benefit to persons not at high risk for dental caries, especially those who drink fluoridated water and brush daily with fluoride toothpaste.

If FDA approves use of fluoride varnish to prevent and control dental caries, its indications for use will be similar to those of fluoride gel. Such varnishes have practical advantages for children aged <6 years at high risk.

Self-Care

Know the Fluoride Concentration in the Primary Source of Drinking Water

All persons should know whether the fluoride concentration in their primary source of drinking water is below optimal, optimal, or above optimal. This knowledge is the basis for all individual and professional decisions regarding use of other fluoride modalities (e.g., mouthrinse or supplements). Parents and caregivers of children, especially children aged <6 years, must know the fluoride concentration in their child's drinking water when considering whether to alter the child's fluoride intake. For example, in nonfluoridated areas where the natural fluoride concentration is below optimal, fluoride supplements might be considered, whereas in areas where the natural fluoride concentration is >2 ppm, children should use alternative sources of drinking water. Knowledge of the water's fluoride concentration is also key in public policy discussions regarding community water fluoridation.

Frequently Use Small Amounts of Fluoride

All persons should receive frequent exposure to small amounts of fluoride, which minimizes dental caries by inhibiting demineralization of tooth enamel and facilitating tooth remineralization. This exposure can be readily accomplished by drinking water with an optimal fluoride concentration and brushing with a fluoride toothpaste twice daily.

Supervise Use of Fluoride Toothpaste Among Children Aged <6 Years

Children's teeth should be cleaned daily from the time the teeth erupt in the mouth. Parents and caregivers should consult a dentist or other health-care provider before introducing a child aged <2 years to fluoride toothpaste. Parents and caregivers of children aged <6 years who use fluoride toothpaste should follow the directions on the label, place no more than a pea-sized amount (0.25 g) of toothpaste on the toothbrush, brush the child's teeth (recommended particularly for preschool-aged children) or supervise the toothbrushing, and encourage the child to spit excess toothpaste into the sink to minimize the amount swallowed. Indiscriminate use can result in inadvertent swallowing of more fluoride than is recommended.

Consider Additional Measures for Persons at High Risk for Dental Caries

Persons at high risk for dental caries might require additional fluoride or other preventive measures to reduce development of caries. This additional fluoride can come from daily use of another fluoride product at home or from professionally applied, topical fluoride products. Other preventive measures might include dental sealants and targeted antimicrobial therapies. Parents and caregivers should not provide additional fluoride to children aged <6 years without consulting a dentist or other health-care provider regarding the associated benefits and potential for enamel fluorosis. Persons should seek professional advice regarding their risk status or that of their children.

Use an Alternative Source of Water for Children Aged <8 Years Whose Primary Drinking Water Contains >2 ppm Fluoride

In some regions in the United States, community water supply systems and home wells contain a natural concentration of fluoride >2 ppm. At this concentration, children aged <8 years are at increased risk for developing enamel fluorosis, including the moderate and severe forms, and should have an alternative source of drinking water, preferably one containing fluoride at an optimal concentration.

In areas where community water supply systems contain >2 ppm but <4 ppm fluoride, EPA requires that each household be notified annually of the desirability of using an alternative source of water for children aged <8 years. For families receiving water from home wells, testing is necessary to determine the natural fluoride concentration.

Consumer Product Industries and Health Agencies

Label the Fluoride Concentration of Bottled Water

Producers of bottled water should label the fluoride concentration of their products. Such labeling will allow consumers to make informed decisions and dentists, dental hygienists, and other health-care professionals to appropriately advise patients regarding fluoride intake and use of fluoride products.

Promote Use of Small Amounts of Fluoride Toothpaste Among Children Aged <6 Years
Labels and advertisements for fluoride toothpaste should promote use of a pea-sized amount (0.25 g) of toothpaste on a child-sized toothbrush for children aged <6 years. Efforts to educate parents and caregivers and to encourage supervised use of fluoride toothpaste among young children can reduce inadvertent swallowing of excess toothpaste.

Develop a Low-Fluoride Toothpaste for Children Aged <6 Years
Manufacturers are encouraged to develop a dentifrice for children aged <6 years that is effective in preventing dental caries but alleviates the risk for enamel fluorosis. A “child-strength” toothpaste with a fluoride concentration lower than current products could reduce the risk for cosmetic concerns associated with inadvertent swallowing of toothpaste.

Collaborate to Educate Health-Care Professionals and the Public
Professional health-care organizations, public health agencies, and suppliers of oral-care products should collaborate to educate health-care professionals and trainees and the public regarding the recommendations in this report. Broad collaborative efforts to educate health-care professionals and the public and to encourage behavior change can promote improved, coordinated use of fluoride modalities.

Further Research

Continue Metabolic Studies of Fluoride
Metabolic studies with animals and humans to determine the influence of environmental, physiological, and pathological conditions on the pharmacokinetics and effects of fluoride should continue. Research in these areas will enhance the knowledge base concerning fluoride use, thereby resulting in more effective and efficient use of fluoride.

Identify Biomarkers of Fluoride
As an alternative to direct fluoride intake measurement, biomarkers (i.e., distinct biological indicators) should be identified to estimate a person’s fluoride intake and the amount of fluoride in the body. Identification of such biomarkers could allow more efficient research.

Reevaluate the Method of Determining Optimal Fluoride Concentration of Community Drinking Water
The current method of determining the optimal concentration of fluoride in community drinking water, which depends on the average maximum annual ambient air temperature, should be reevaluated because of the social and environmental changes that have occurred since it was adopted in 1962. Research into current consumption patterns of water, processed beverages, and processed foods is also needed. Such research will either validate the current method for determining optimal fluoride concentration in community drinking water or indicate improved methods.

Evaluate the Effect of Fluoride Mouthrinse, Fluoride Supplements, and Other Fluoride Modalities on Dental Caries
Additional clinical trials are needed to evaluate the current effect of fluoride mouthrinse, supplements, and other modalities on dental caries both individually and in combination. Cohorts of particular interest are groups and persons at high risk for dental caries, including older adults (i.e., those aged >50 years). Such research, as well as studies to determine the effects of new fluoride modalities and various combinations among groups and persons at high risk, could lead to more effective and efficient use of these interventions.

Study the Current Cost-Effectiveness of Fluoride Modalities
The increasing availability of multiple fluoride modalities and the lower caries prevalence in the United States indicate a need for current cost-effectiveness studies of fluoride modalities, especially logical combinations of regimens in populations with different caries risks. Such research will allow both more efficient use of resources and a better understanding of the additive effects of combined modalities.

Conduct Descriptive and Analytic Epidemiologic Studies

Descriptive and analytic epidemiologic studies should be conducted to determine the association between dental caries and fluoride exposure from several sources, as well as the current role of community water fluoridation in preventing coronal and root caries among adults. Studies should assess the effect of interruption or discontinuation of water fluoridation; the prevalence of fluorosis associated with different patterns of fluoride use and intake among various populations; and the relationship between objectively measured fluorosis and the aesthetic perceptions of persons, parents, and dentists and other health-care professionals. Studies are needed to refine methods of caries risk assessment. As appropriate, studies should use national, state, and local data. Research addressing these questions will improve understanding of the relationships between fluoride modalities and the benefits and unintended effects of their use.

Identify Effective Strategies to Promote Adoption of Recommendations for Using Fluoride

Effective strategies should be identified to promote adherence by parents, caregivers, children, adults, and health-care providers to recommendations regarding fluoride use. Such research could result in more effective behavior change, more efficient use of resources, improved caries prevention, and less enamel fluorosis.

CONCLUSION

When used appropriately, fluoride is a safe and effective agent that can be used to prevent and control dental caries. Fluoride has contributed profoundly to the improved dental health of persons in the United States and other countries. Fluoride is needed regularly throughout life to protect teeth against tooth decay. To ensure additional gains in oral health, water fluoridation should be extended to additional communities, and fluoride toothpaste should be used widely. Adoption of these and other recommendations in this report could lead to considerable savings in public and private resources without compromising fluoride's substantial benefit of improved dental health.

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*For this report, the term "caries experience" is used to mean the sum of filled and unfilled cavities, along with any missing teeth resulting from tooth decay.

**US$ 1988 converted to US$ 1999 using the Consumer Price Index for All Urban Customers (CPI-Urban) (all items). More information is available at the U.S. Department of Labor, Bureau of Labor Statistics website at <http://stats.bls.gov/cpihome.htm>. Accessed June 25, 2001.

***US$ 1995 converted to US$ 1999 using CPI-Urban (dental services). More information is available at the U.S. Department of Labor, Bureau of Labor Statistics website at <http://stats.bls.gov/cpihome.htm>. Accessed June 25, 2001.

****US$ 1988 converted to US$ 1999 using CPI-Urban (all items). More information is available at the U.S. Department of Labor, Bureau of Labor Statistics website at <http://stats.bls.gov/cpihome.htm>. Accessed June 25, 2001.

*****US$ 1981 converted to US$ 1999 using CPI-Urban (dental services). More information is available at the U.S. Department of Labor, Bureau of Labor Statistics website at <http://stats.bls.gov/cpihome.htm>. Accessed June 25, 2001.

FIGURES, TABLES AND BOXES

TABLE 1. Recommended dietary fluoride supplement* schedule

	Fluoride concentration in community drinking water†		
Age	**<0.3 ppm**	**0.3–0.6 ppm**	**>0.6 ppm**
0–6 months	None	None	None
6 months–3 years	0.25 mg/day	None	None
3–6 years	0.50 mg/day	0.25 mg/day	None
6–16 years	1.0 mg/day	0.50 mg/day	None

* Sodium fluoride (2.2 mg sodium fluoride contains 1 mg fluoride ion).

† 1.0 parts per million (ppm) = 1 mg/L.

Sources:

Meskin LH, ed. Caries diagnosis and risk assessment: a review of preventive strategies and management. J Am Dent Assoc 1995;126(suppl):1S–24S.

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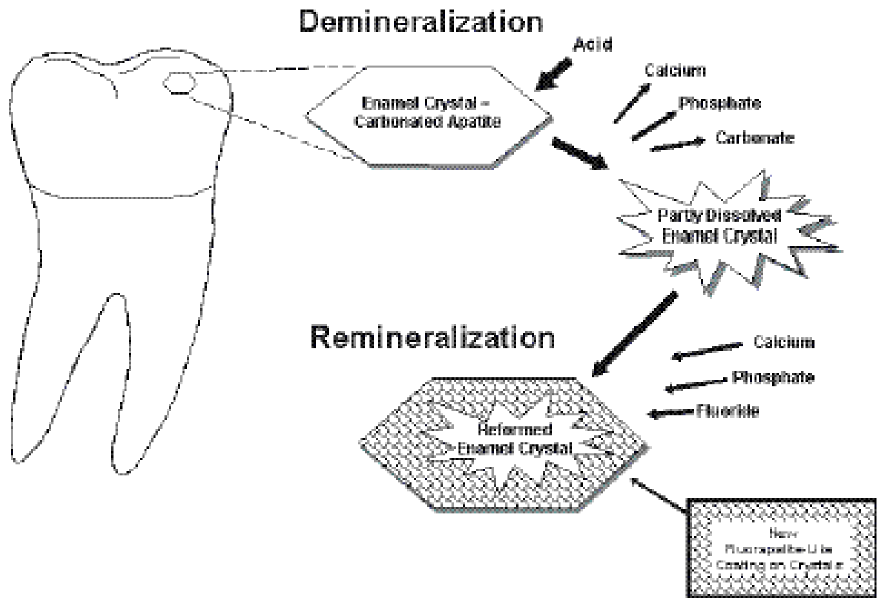
FIGURE 1. The demineralization and remineralization processes lead to remineralized enamel crystals with surfaces rich in fluoride and lower in solubility



Source: Adapted from Featherstone JDB. Prevention and reversal of dental caries: role of low level fluoride. Community Dent Oral Epidemiol 1999;27:31–40. Reprinted with permission from Munksgaard International Publishers Ltd., Copenhagen, Denmark.

TABLE 2. Recommended total dietary fluoride intake

Age	Reference weight*		Adequate intake†	Tolerable upper intake§
	kg	lb	mg/day	mg/day
0–6 months	7	16	0.01	0.7
6–12 months	9	20	0.5	0.9
1–3 years	13	29	0.7	1.3
4–8 years	22	48	1.1	2.2
≥9 years	40–76	88–166	2.0–3.8	10.0

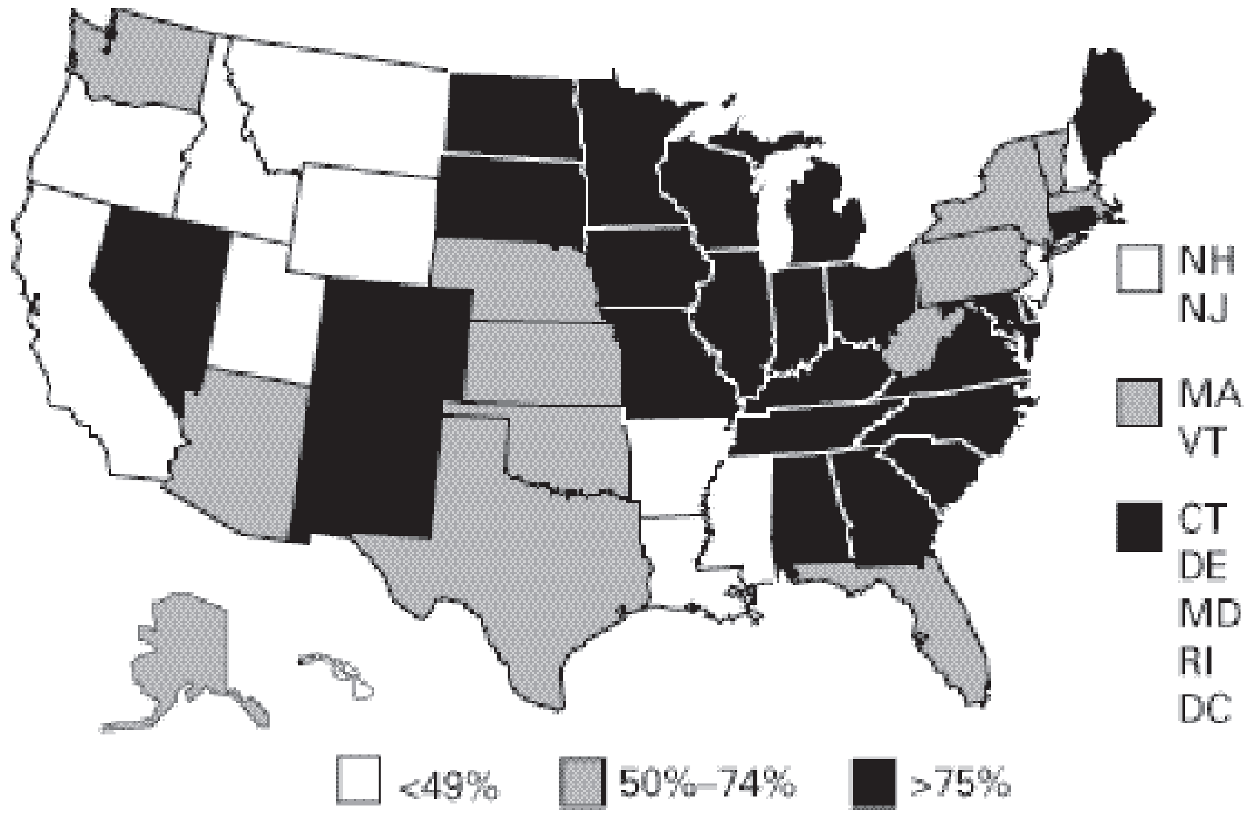
* Values based on data collected during 1988–1994 as part of the third National Health and Nutrition Examination Survey.

† Intake that maximally reduces occurrence of dental caries without causing unwanted side effects, including moderate enamel fluorosis.

§ Highest level of nutrient intake that is likely to pose no risks for adverse health effects in almost all persons.

Source: Adapted from Institute of Medicine. Fluoride. In: Dietary reference intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. Washington, DC: National Academy Press, 1997:288–313.

FIGURE 2. Percentage of state populations with access to fluoridated water through public water systems



Source: CDC, unpublished data, 2000.

TABLE 3. U.S. Food and Drug Administration (FDA) fluoride requirements for bottled water packaged in the United States

	Maximum fluoride concentration (mg/L) allowed in bottled water	
Annual average of maximum daily air temperature (F) where the bottled water is sold at retail	**No fluoride added to bottled water**	**Fluoride added to bottled water**
≤53.7	2.4	1.7
53.8–58.3	2.2	1.5
58.4–63.8	2	1.3
63.9–70.6	1.8	1.2
70.7–79.2	1.6	1
79.3–90.5	1.4	0.8

Note: FDA regulations require that fluoride be listed on the label only if the bottler adds fluoride during processing; the bottler is not required to list the fluoride concentration, which might or might not be optimal. FDA does not allow imported bottled water with no added fluoride to contain >1.4 mg fluoride/L or imported bottled water with added fluoride to contain >0.8 mg fluoride/L.

Source: US Department of Health and Human Services, Food and Drug Administration. 21 CFR Part 165.110. Bottled water. Federal Register 1995;60:57124–30.

TABLE 4. Quality of evidence, strength of recommendation, and target population of recommendation for each fluoride modality to prevent and control dental caries

Modality*	Quality of evidence (grade)	Strength of recommendation (code)	Target population†
Community water fluoridation	II-1	A	All areas
School water fluoridation	II-3	C	Rural, nonfluoridated areas
Fluoride toothpaste	I	A	All persons
Fluoride mouthrinse	I	A	High risk§
Fluoride supplements			
Pregnant women	I	E	None
Children aged <6 years	II-3	C	High risk
Children aged 6–16 years	I	A	High risk
Persons aged >16 years	¶	C	High risk
Fluoride gel	I	A	High risk
Fluoride varnish	I	A	High risk

* Modalities are assumed to be used as directed in terms of dosage and age of user.

† Quality of evidence for targeting some modalities to persons at high risk is grade III (i.e., representing the opinion of respected authorities) and is based on considerations of cost-effectiveness that were not included in the studies establishing efficacy or effectiveness.

§ Populations believed to be at increased risk for dental caries are those with low socioeconomic status or low levels of parental education, those who do not seek regular dental care, and those without dental insurance or access to dental services. Individual factors that possibly increase risk include active dental caries; a history of high caries experience in older siblings or caregivers; root surfaces exposed by gingival recession; high levels of infection with cariogenic bacteria; impaired ability to maintain oral hygiene; malformed enamel or dentin; reduced salivary flow because of medications, radiation treatment, or disease; low salivary buffering capacity (i.e., decreased ability of saliva to neutralize acids); and the wearing of space maintainers, orthodontic appliances, or dental prostheses. Risk can increase if any of these factors are combined with dietary practices conducive to dental caries (i.e., frequent consumption of refined carbohydrates). Risk decreases with adequate exposure to fluoride.

¶ No published studies confirm the effectiveness of fluoride supplements in controlling dental caries among persons aged >16 years.

BOX 1. Grading system used for determining the quality of evidence for a fluoride modality

Grade	Criteria
I	Evidence obtained from one or more properly conducted randomized clinical trials (i.e., one using concurrent controls, double-blind design, placebos, valid and reliable measurements, and well-controlled study protocols).
II-1	Evidence obtained from one or more controlled clinical trials without randomization (i.e., one using systematic subject selection, some type of concurrent controls, valid and reliable measurements, and well-controlled study protocols).
II-2	Evidence obtained from one or more well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3	Evidence obtained from cross-sectional comparisons between times and places; studies with historical controls; or dramatic results in uncontrolled experiments (e.g., the results of the introduction of penicillin treatment in the 1940s).
III	Opinions of respected authorities on the basis of clinical experience, descriptive studies or case reports, or reports of expert committees.

Source: US Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Alexandria, VA: International Medical Publishing, 1996.

BOX 2. Coding system used to classify recommendations for use of specific fluoride modalities to control dental caries

Code	Criteria
A	Good evidence to support the use of the modality.
B	Fair evidence to support the use of the modality.
C	Lack of evidence to develop a specific recommendation (i.e., the modality has not been adequately tested) or mixed evidence (i.e., some studies support the use of the modality and some oppose it).
D	Fair evidence to reject the use of the modality.
E	Good evidence to reject the use of the modality.

Source: US Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Alexandria, VA: International Medical Publishing, 1996.

*US$ 1981 converted to US$ 1999 using CPI-Urban (dental services). More information is available at the U.S. Department of Labor, Bureau of Labor Statistics website at <http://stats.bls.gov/cpihome.htm>. Accessed June 25, 2001.

U.S. FOOD AND DRUG ADMINISTRATION

Regulating Fluoride in Bottle Water

The U.S. Food and Drug Administration is charged with protecting the nation's food supply. In that role, the agency dictates how much fluoride is allowed in bottled water and what health claims can be made on food labels. The agency does not have jurisdiction over tap water. That is regulated by the U.S. Environmental Protection Agency. The two documents below describe the FDA's position on adding fluoride to bottled water. The first is the 2006 FDA notification that gave bottle water manufacturers permission to advertise the health benefits of fluoridated water. The second document is the section of the Code of Federal Regulations (CFR) that regulates bottled water and allows the fluoridation of bottled water for human consumption.

HEALTH CLAIM NOTIFICATION FOR FLUORIDATED WATER AND REDUCED RISK OF DENTAL CARIES

Under section 403(r)(3)(C) (21 U.S.C. §343(r)(3)(C)) of the Federal Food, Drug, and Cosmetic Act (Act), a manufacturer may submit to the Food and Drug Administration (FDA) a notification of a health claim based on an authoritative statement from an appropriate scientific body of the United States Government or the National Academy of Sciences (NAS) or any of its subdivisions. The notification must be submitted to FDA at least 120 days before the food is introduced into interstate commerce. The claim may be made after 120 days from the date of submission of the notification until such time as 1) FDA issues a regulation prohibiting or modifying the claim or finding that the requirements for making the claim have not been met, or 2) a district court in an enforcement proceeding has determined that the requirements for making the claim have not been met.

On June 16, 2006, the FDA received a notification (the June 16 notification) from the law firm of Covington and Burling regarding a health claim for the relationship between fluoridated water and a reduced risk of dental caries. The 120-day period from the date of submission of the June 16 notification was October 14, 2006. Therefore, after October 14, 2006, manufacturers may use the claim specified in the notification, as modified by the notifier in a letter to FDA dated October 13, on the label and in labeling of any food product that meets the eligibility criteria described below, unless or until FDA or a court acts to prohibit the claim.

The June 16 notification cites statements from several sources as authoritative statements for the claim. FDA reviewed the sources and cited statements in their context and in light of existing authorized health claims and current science. The following three statements are considered authoritative for purposes of this notification.

- Recommendation for Using Fluoride to Prevent and Control Dental Caries in the U.S. (Centers for Disease Control, 2001): "Widespread use of fluoride has been a major factor in the decline in the prevalence and severity of dental caries (i.e., tooth decay) in the United States and other economically developed countries. When used appropriately, fluoride is both safe and effective in preventing and controlling dental caries. All U.S. residents are likely exposed to some degree of fluoride, which is available from multiple sources." (Summary section, page 1)

"Continue and extend fluoridation of community drinking water: Community water fluoridation is a safe, effective, and inexpensive way to prevent dental caries. This modality benefits persons in all age groups and of all SES, ..." (Recommendation section, page 24)

- Oral Health in America: A Report of the Surgeon General (2000): "Community water fluoridation is safe and effective in preventing dental caries in both children and adults. Water fluoridation benefits all residents served by community water supplies regardless of their social or economic status. Professional and individual measures, including the use of fluoride mouth rinses, gels, dentifrices, and dietary supplements and the application of dental sealants, are additional means of preventing dental caries." (Executive summary)

- Review of Fluoride: Benefits and Risks (Public Health Service, 1991): "Extensive studies over the past 50 years have established that individuals whose drinking water is fluoridated show a reduction in dental caries. Although the comparative degree of measurable benefit has been reduced recently as other fluoride sources have become available in non-fluoride areas, the benefits of water fluoridation are still clearly evident." (Conclusions section, page 87)

According to the June 16 notification and the letter to FDA dated October 13, the food eligible to bear the claim is bottled water meeting the standards of identity and quality set forth in 21 CFR 165.110, containing greater than 0.6 and up to 1.0 mg/L total fluoride, and meeting all general requirements for health claims (21 CFR 101.14) with the exception of minimum nutrient contribution (21 CFR 101.14 (e)(6)). The claim language is: "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]." In addition, the health claim is not intended for use on bottled water products specifically marketed for use by infants.

The notification and materials regarding the claim are publicly available from the FDA Division of Dockets Management (Docket No.2006Q-0418). Persons interested in these documents may view them at the Division of Dockets Management from 9am to 4pm, Monday through Friday at 5630 Fishers Lane, room 1061, Rockville, MD 20852. The Division of Dockets Management may be contacted at 301-827-6860. FDA also intends to make the documents available on the Dockets web site, under Docket No. 2006Q-0418.

CFR TITLE 21, SECTION 165.110 - BOTTLED WATER

(a) Identity–(1) Description. Bottled water is water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Fluoride may be optionally added within the limitations established in Sec. 165.110(b)(4)(ii). Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labelingas ``water,'' ``carbonated water,'' ``disinfected water,'' ``filtered water,'' ``seltzer water,'' ``soda water,'' ``sparkling water,'' and ``tonic water.'' The processing and bottling of bottled water shall comply with applicable regulations in part 129 of this chapter.

(2) Nomenclature. The name of the food is ``bottled water,'' ``drinking water,'' or alternatively one or more of the following terms as appropriate:

(i) The name of water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer is ``artesian water" or ``artesian well water." Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer.

(ii) The name of water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure is ``ground water." Ground water must not be under the direct influence of surface water as defined in 40 CFR 141.2.

(iii) The name of water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be ``mineral water.” Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.

(iv) The name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of ``purified water” in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. (Copies may be obtained from the United States Pharmacopial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http:// www.archives.gov/federal--register/code--of--federal--regulations/ibr-- locations.html.), may be ``purified water” or ``demineralized water.” Alternatively, the water may be called ``deionized water” if the water has been processed by deionization, ``distilled water” if it is produced by distillation, ``reverse osmosis water” if the water has been processed by reverse osmosis, and ``------ drinking water” with the blank being filled in with one of the defined terms describing the water in this paragraph (e.g., ``purified drinking water” or ``deionized drinking water”).

(v) The name of water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide from the source that it had at emergence from the source may be ``sparkling bottled water.”

(vi) The name of water derived from an underground formation from which water flows naturally to the surface of the earth may be ``spring water.” Spring water shall be collected only at the spring or through a bore hole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring’s natural orifice. Plants shall demonstrate, on request, to appropriate regulatory officials, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the bore hole.

(vii) The name of water that meets the requirements under ``Sterility Tests” <71<ls-thn-eq> in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51. (Copies may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/ code--of--federal--regulations/ibr--locations.html.), may be ``sterile water.” Alternatively, the water may be called ``sterilized water.”

(viii) The name of water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer may be ``well water.”

(3) Other label statements. (i) If the TDS content of mineral water is below 500 ppm, or if it is greater than 1,500 ppm, the statement ``low mineral content” or the statement ``high mineral content”, respectively, shall appear on the principal display panel following the statement of identity in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch. If the TDS of mineral water is between 500 and 1,500 ppm, no additional statement need appear.

(ii) When bottled water comes from a community water system, as defined in 40 CFR 141.2, except when it has been treated to meet the definitions in paragraphs (a)(2)(iv) and (a)(2)(vii) of this section and is labeled as such, the label shall state ``from a community water system” or, alternatively, ``from a municipal source” as appropriate, on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by paragraph (c) of this section, in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.

(iii) When the label or labeling of a bottled water product states or implies (e.g., through label statements or vignettes with references to infants) that the bottled water is for use in feeding infants, and the product is not commercially sterile under Sec. 113.3(e)(3)(i) of this chapter, the product's label shall bear conspicuously and on the principal display panel the statement ``Not sterile. Use as directed by physician or by labeling directions for use of infant formula.”

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) Quality. The standard of quality for bottled water, including water for use as an ingredient in beverages (except those described in the labeling as ``water,” ``carbonated water,” ``disinfected water,” ``filtered water,” ``seltzer water,” ``soda water,” ``sparkling water,” and ``tonic water”), is as follows:

(1) Definitions.

(i) Trihalomethane (THM) means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

(ii) Total trihalomethanes (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane, bromodichloromethane, and tribromomethane), rounded to two significant figures.

(iii) Haloacetic acids (five) (HAA5) means the sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid), rounded to two significant figures after addition.

(2) Microbiological quality.

(i) Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in paragraph (b)(2)(ii) of this section, meet the following standards of microbiological quality:

(A) Total coliform–(1) Multiple-tube fermentation (MTF) method. Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or

(2) Membrane filter (MF) method. Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(B) E. coli. If E. coli is present, then the bottled water will be deemed adulterated under paragraph (d) of this section.

(ii) Analyses conducted to determine compliance with paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section and Sec. 129.35(a)(3)(i) of this chapter shall be made in accordance with the multiple-tube fermentation (MTF) or the membrane filter (MF) methods described in the applicable sections of ``Standard Methods for the Examination of Water and Wastewater,'' 21st Ed. (2005), American Public Health Association. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the American Public Health Association, 800 I St. NW., Washington, DC 20001, 202-777-2742 (APHA). You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/ code--of--federal--regulations/ibr--locations.html.

(3) Physical quality. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of ``Standard Methods for the Examination of Water and Wastewater,'' 15th Ed. (1980), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies may be obtained from the American Public Health Association, 800 I St. NW., Washington, DC 20001, 202-777-2742 (APHA), or a copy may be examined at the National Archives and Records Administration (NARA), or at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163, for information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/ federal--register/code--of--federal--regulations/ibr--locations.html), meet the following standards of physical quality:

(i) The turbidity shall not exceed 5 units.

(ii) The color shall not exceed 15 units. \1\

\1\ Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(iii) The odor shall not exceed threshold odor No. 3. \1\

(4) Chemical quality. (i)(A) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(4)(i)(B) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

Substance	Concentration in miligrams per litre
Chloride \1\	250.0
Iron \1\	0.3
Manganese \1\	0.05
Phenols	0.001
Total dissolved solids \1\	500.0
Zinc \1\	5.0

\1\ Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(B) Analyses conducted to determine compliance with paragraph (b)(4)(i)(A) of this section shall be made in accordance with the methods described in the applicable sections of ``Standard Methods for the Examination of Water and Wastewater,'' 15th Ed. (1980), or ``Methods for Chemical Analysis of Water and Wastes,'' Environmental Monitoring and Support Laboratory (EMSL), EPA-600/4-79-020, March 1983, U.S. Environmental Protection Agency (EPA), both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(C) Analyses for organic substances shall be determined by the appropriate methods set forth below. The methods in paragraphs (b)(4)(i) (C)(1) and (C)(2) of this section are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and are described in ``Standard Methods for Examination of Water and Wastewater," 15th Ed. (1980). Copies may be obtained from the American Public Health Association, 800 I St. NW., Washington DC 20001, and examined at the National Archives and Records Administration (NARA) , or the Center for Food Safety and Applied Nutrition's Library, 200 C St. NW., Washington DC. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/code-- of--federal--regulations/ibr--locations.html. The methods in paragraphs (b)(4)(i)(C)(3) and (C)(4) are cross-referenced in 40 CFR part 141, subpart C, appendix C.

(1) ``Methods for Organochlorine Pesticides in Industrial Effluents;"

(2) ``Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents," November 28, 1973;

(3) ``Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method;" which is cross-referenced in 40 CFR part 141, subpart C, appendix C;

(4) ``Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction," which is cross-referenced in 40 CFR part 141, subpart C, appendix C; (ii)(A) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

Table 1

Annual average of maximum daily air temperatures ([deg] F)	Fluoride (Concentration in Miligrams per litre)
53.7 and below	2.4
53.8 - 58.3	2.2
58.4 - 63.8	2.0
63.9 - 70.6	1.8
70.7 - 79.2	1.6
79.3 - 90.5	1.4

(B) Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(C) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

Table 2

Annual average of maximum daily air temperatures ([deg] F)	Fluoride (Concentration in Miligrams per litre)
53.7 and below	1.7
53.8 - 58.3	1.5
58.4 - 63.8	1.3
63.9 - 70.6	1.2
70.7 - 79.2	1.0
79.3 - 90.5	0.8

(D) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

(iii) Having consulted with EPA as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(iii)(E) through (b)(4)(iii)(F), and (b)(4)(iii)(G) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs (b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(A) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per litre (or as specified)
Arsenic	0.010
Antimony	0.006
Barium	2.0
Beryllium	0.004
Cadmium	0.005
Chromium	0.1
Copper	1.0
Cyanide	0.2
Lead	0.005
Mercury	0.002
Nickle	0.1
Nitrate	10 (as nitrogen)
Nitrite	1 (as nitrogen)
Total Nitrate and Nitrite	10 (as nitrogen)
Selenium	0.05
Thallium	0.002

(B) The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per litre
Benzene (71-43-2)	0.005
Carbon tetrachloride (56-23-5)	0.005
o- Dichlorobenzene (95-50-1)	0.6
p- Dichlorobenzene (106-46-7)	0.075
1,2-Dichloroethane (107-06-2)	0.005
1,1-Dichloroethylene (75-35-4)	0.007
cis-1,2-Dichloroethylene (156-59-2)	0.07
trans-1,2-Dichloroethylene (156-60-5)	0.1
Dichloromethane (75-09-2)	0.005
1,2-Dichloropropane (78-87-5)	0.005
Ethylbenzene (100-41-4)	0.7
Monochlorobenzene (108-90-7)	0.1
Styrene (100-42-5)	0.1
Tetrachloroethylene (127-18-4)	0.005
Toluene (108-88-3)	1.0
1,2,4-Trichlorobenzene (120-82-1)	0.07
1,1,1-Trichloroethane (71-55-6)	0.2
1,1,2-Trichloroethane (79-00-5)	0.005
Trichloroethylene (79-01-6)	0.005

Vinyl chloride (75-01-4)	0.002
Xylenes (1330-20-7)	10.0

(C) The allowable levels for pesticides and other synthetic organic chemicals (SOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in Milligrams per litre
Alachlor (15972-60-8)	0.002
Atrazine (1912-24-9)	0.003
Benzo(a)pyrene (50-32-8)	0.0002
Carbofuran (1563-66-2)	0.04
Chlordane (57-74-9)	0.002
Dalapon (75-99-0)	0.2
1,2-Dibromo-3-chloropropane (96-12-8)	0.0002
2,4-D (94-75-7)	0.07
Di(2-ethylhexyl)adipate (103-23-1)	0.4
Dinoseb (88-85-7)	0.007
Diquat (85-00-7)	0.02
Endothall (145-73-3)	0.1
Endrin (72-20-8)	0.002
Ethylene dibromide (106-93-4)	0.00005
Glyphosate (1071-53-6)	0.7
Heptachlor (76-44-8)	0.0004
Heptachlor epoxide (1024-57-3)	0.0002
Hexachlorobenzene (118-74-4)	0.001
Hexachlorocyclopentadiene (77-47-4)	0.05
Lindane (58-89-9)	0.0002
Methoxychlor (72-43-5)	0.04
Oxamyl (23135-22-0)	0.2
Pentachlorophenol (87-86-5)	0.001
PCB's (as decachlorobiphenyl) (1336-36-3)	0.0005
Picloram (1918-02-1)	0.5
Simazine (122-34-9)	0.004
2,3,7,8-TCDD (Dioxin) (1746-01-6)	3x10-8
Toxaphene (8001-35-2)	0.003
2,4,5-TP (Silvex) (93-72-1)	0.05

(D) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations (40 CFR part 143) are as follows:

Contaminant	Concentration in milligrams per litre
Aluminum	0.2
Silver	0.1
Sulfate \1\	250.0

\1\ Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels

and do not relate to a health concern.

(E) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(A) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(E)(1) through (b)(4)(iii)(E)(14) of this section and described, unless otherwise noted, in ``Methods for Chemical Analysis of Water and Wastes,'' U.S. EPA Environmental Monitoring and Support Laboratory (EMSL), Cincinnati, OH 45258 (EPA-600/4-79-020), March 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/code--of--federal--regulations/ibr--locations.html.

(1) Antimony shall be measured using the following methods:

(i) Method 204.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(ii) Method 200.8--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/code--of--federal-- regulations/ibr--locations.html.

(iii) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iv) Method D-3697-92--``Standard Test Method for Antimony in Water,'' contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202- 741-6030, or go to: http://www.archives.gov/federal--register/code--of-- federal--regulations/ibr--locations.html.

(2) Barium shall be measured using the following methods:

(i) Method 208.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 208.1--``Atomic Absorption; direct aspiration,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(iii) Method 200.7--``Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(3) Beryllium shall be measured using the following methods:

(i) Method 210.2--``Atomic Absorption; Furnace Technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(ii) Method 200.7--``Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iii) Method 200.8--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iv) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(4) Cadmium shall be measured using the following methods:

(i) Method 213.2--``Atomic Absorption; Furnace Technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(ii) Method 200.7--``Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(5) Chromium shall be measured using the following methods:

(i) Method 218.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(ii) Method 200.7--``Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(6) Copper shall be measured as total recoverable metal without filtration using the following methods:

(i) Method 220.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 220.1--``Atomic Absorption; direct aspiration,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(iii) Method 200.7--``Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iv) Method 200.8--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(v) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(7) Cyanide shall be measured using the following methods:

(i) Method 335.1--``Titrimetric; Spectrophotometric'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 335.2--``Titrimetric; Spectrophotometric'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(iii) Method 335.3--``Colorimetric, Automated UV,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section. (iv) Method D-2036-91--``Standard Test Methods for Cyanides in Water,'' contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/code--of--federal-- regulations/ibr--locations.html.

(8) Lead shall be measured as total recoverable metal without filtration using the following methods:

(i) Method 239.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(ii) Method 200.8--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iii) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(9) Mercury shall be measured using the following methods:

(i) Method 245.1--``Manual cold vapor technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 245.2--``Automated cold vapor technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(10) Nickel shall be measured using the following methods:

(i) Method 249.1--``Atomic Absorption; direct aspiration,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 249.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(iii) Method 200.7--``Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iv) Method 200.8--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(v) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(11) Nitrate and/or nitrite shall be measured using the following methods:

(i) Method 300.0--``The Determination of Inorganic Anions in Water by Ion Chromatography--Method 300.0,'' EPA, EMSL (EPA-600/4-84-017), March 1984, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http:// www.archives.gov/federal--register/code--of--federal--regulations/ibr--locations.html.

(ii) Method 353.1--``Colorimetric, automated, hydrazine reduction,'' for nitrate only, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(iii) Method 353.2--``Colorimetric, automated, cadmium reduction,'' for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or (iv) Method 353.3--``Spectro photo metric, cadmium reduction,'' for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(12) Selenium shall be measured using the following methods:

(i) Method 270.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 270.3--``Atomic Absorption; gaseous hydride,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(13) Thallium shall be measured using the following methods:

(i) Method 279.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(ii) Method 200.8--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iii) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(14) Arsenic shall be measured using the following methods:

(i) Method 200.8--``Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Revision 5.4, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Method 200.8 is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples-- Supplement 1,'' EPA/600/R-94/111, May 1994. Copies of this publication are available from the National Technical Information Service (NTIS), PB95-125472, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and

Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http:// www.archives.gov/federal--register/code--of--federal--regulations/ibr--locations.html.

(ii) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption,'' Revision 2.2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Method 200.9 is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples--Supplement 1,'' EPA/600/R-94/111, May 1994. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(14)(i) of this section.

(F) Analyses to determine compliance with the requirements of paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be conducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (b)(4)(iii)(F)(1) through (b)(4)(iii)(F)(20) of this section and described, unless otherwise noted, in ``Methods for the Determination of Organic Compounds in Drinking Water,'' Office of Research and Development, EMSL, EPA/600/4- 88/039, December 1988, or in ``Methods for the Determination of Organic Compounds in Drinking Water, Supplement 1,'' Office of Research and Development, EMSL, EPA/600/4-90/020, July 1990, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of these publications are available from NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/ code--of--federal--regulations/ibr--locations.html.

(1) Method 502.1--``Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography,'' Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(2) Method 502.2--``Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series,'' Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(3) Method 503.1--``Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography,'' Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(4) Method 524.1--``Measurement of Purgeable Organic Compounds in Water by Packed Column Gas Chromatography/Mass Spectrometry,'' Rev. 3.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(5) Method 524.2--``Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry,'' Rev. 3.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(6) Method 504--``1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-Chloro pro pane (DBCP) in Water by Microextraction and Gas Chromatography,'' Rev. 2.0, 1989, (applicable to dibromochloropropane (DBCP) and ethylene dibromide (EDB)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(7) Method 505--``Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl (PCB) Products in Water by Microextraction and Gas Chromatography,'' Rev. 2.0, 1989, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, hexachlorocyclopentadiene, simazine, and as a screen for PCB's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(8) Method 506--``Determination of Phthalate and Adipate Esters in Drinking Water by Liquid-Liquid Extraction or Liquid-Solid Extraction and Gas Chromatography with Photoionization Detection," applicable to di(2-ethyl hexyl) adipate which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(9) Method 507--``Determination of Nitrogen- and Phosphorus- Containing Pesticides in Water by Gas Chromatography with a Nitrogen- Phosphorus Detector," Rev. 2.0, 1989, (applicable to alachlor, atrazine, and simazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(10) Method 508--``Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector," Rev. 3.0, 1989, (applicable to chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, and as a screen for PCB's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(11) Method 508A--``Screening for Polychlorinated Biphenyls by Per chlori nation and Gas Chromatography," Rev. 1.0, 1989, (used to quantitate PCB's as decachlorobiphenyl if detected in methods 505 or 508 in paragraph (b)(4)(iii)(F)(7) or (b)(4)(iii)(F)(9) of this section, respectively, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(12) Method 515.1--``Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector," Rev. 5.0, 1991, (applicable to 2,4-D, 2,4,5-TP (Silvex), pentachlorophenol, dalapon, dinoseb, and picloram), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(13) Method 525.1--``Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 2.2, May 1991, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, pentachlorophenol, benzo(a)pyrene, di(2-ethylhexyl) adipate, endrin, hexachlorobenzene, hexa chloro cyclo penta diene, and simazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(14) Method 531.1--``Measurement of N-Methylcarbamoyloximes and N- Methylcarbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization," Rev. 3.0, 1989, (applicable to carbofuran and oxamyl (vydate)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(15) Method 547--``Determination of Glyphosate in Drinking Water by Direct-Aqueous-Injection HPLC, Post-Column Derivatization, and Fluorescence Detection," (applicable to glyphosate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(16) Method 548--``Determination of Endothall in Drinking Water by Aqueous Derivatization, Liquid-Solid Extraction, and Gas Chromatography with Electron-Capture Detection," (applicable to endothall), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(17) Method 549--``Determination of Diquat and Paraquat in Drinking Water by Liquid-Solid Extraction and HPLC with Ultraviolet Detection," (applicable to diquat), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or (18) Method 550--``Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Liquid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection," (applicable to benzo(a) pyrene and other polynuclear aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(19) Method 550.1--``Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Solid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection," (applicable to benzo(a)pyrene and other polynuclear aromatic hydrocarbons), which is incorporated

by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(F) of this section.

(20) Method 1613--``Tetra- through Octa- Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS,'' Rev. A, 1990, EPA, Office of Water Regulations and Standards, Industrial Technology Division, (applicable to 2,3,7,8-TCDD (Dioxin)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from USEPA-OST, Sample Control Center, P.O. Box 1407, Alexandria, VA 22313, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/code--of--federal-- regulations/ibr--locations.html.

(G) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(D) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(G)(1) through (b)(4)(iii)(G)(3) of this section and described, unless otherwise noted, in ``Methods of Chemical Analysis of Water and Wastes,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(1) Aluminum shall be measured using the following methods:

(i) Method 202.1--``Atomic Absorption; direct aspiration technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 202.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E).

(iii) Method 200.7--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iv) Method 200.8--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(v) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(2) Silver shall be measured using the following methods:

(i) Method 272.1--``Atomic Absorption; direct aspiration technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 272.2--``Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(iii) Method 200.7--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(iv) Method 200.8--``Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(v) Method 200.9--``Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled ``Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/ 010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(3) Sulfate shall be measured using the following methods:

(i) Method 300.0--``The Determination of Inorganic Anions in Water by Ion Chromatography-- Method 300.0," EPA, EMSL (EPA-600/4-84-017), March 1984, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(11)(i) of this section.

(ii) Method 375.1--``Colorimetric, Automated, Chloranilate," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(iii) Method 375.3--``Gravimetric," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or  (iv) Method 375.4--``Turbidimetric," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(H) The allowable levels for residual disinfectants and disinfection byproducts are as follows:

Substance	Concentration in milligrams per litre
Disinfection byproducts	
Bromate	0.01
Chlorite	1.0
Haloacetic acits (five) (HAA5)	0.06
Total Trihalomethanes (TTHM)	0.08
Residual disinfectants	
Chloramine	4.0 (as Cl2)
Chlorine	4.0 (as Cl2)
Chlorine dioxide	0.8 (as ClO2)

(I) Analysis to determine compliance with the requirements of paragraph (b)(4)(iii)(H) of this section shall be conducted in accordance with an applicable method listed in paragraphs (b)(4)(iii)(I)(1) through (b)(4)(iii)(I)(7) of this section and described in ``Method 300.1, Determination of Inorganic Anions in Drinking Water by Ion Chromatography," Rev. 1.0, U.S. EPA, 1997, EPA/ 600/R-98/118; ``Methods for the Determination of Inorganic Substances in Environmental Samples,'' U.S. EPA, August 1993, EPA/600/R-93/100; ``Methods for the Determination of Organic Compounds in Drinking Water- Supplement II,'' U.S. EPA, August 1992, EPA/600/R-92/129; ``Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1995, EPA/600/R-95/131; ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., American Public Health Association, 1995; and ``Annual Book of ASTM Standards,'' vol. 11.01, American Society for Testing and Materials, 1996, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the following publications are available from the National Technical Information Service (NTIS): EPA/600/R-95/131 (NTIS number PB95-261616), EPA/600/R-92/129 (NTIS number PB92-207703), EPA/ 600/R-93/100 (NTIS number PB94-121811), and EPA/600/R-98/118 (NTIS number PB98-169196). NTIS can be contacted at NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, 1-800-553-6847 or 703-605-6000, www.ntis.gov. Copies of the publication EPA/600/R-98/118 are also available from the Chemical Exposure Research Branch, Microbiological and Chemical Exposure Assessment Research Division, National Exposure Research Laboratory, U.S. EPA, Cincinnati, OH 45268, 513-569-7757, (FAX) 513-569-7757. Copies of ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., are available from the American Public Health Association, 1015 15th Street, NW., Washington, DC 20005. All of the publications cited in paragraph (b)(4)(iii)(I) of this section may be examined at the National Archives and Records Administration (NARA), or at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740. . For information on the availability of this material at NARA, call 202- 741-6030, or go to: http://www.archives.gov/federal--register/code--of-- federal--regulations/ibr--locations.html. Copies of ``Annual Book of ASTM Standards,'' 1996, vol. 11.01, are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohoken, PA 19428, or may be examined at the Office of the Federal Register. Copies of the methods incorporated by reference in paragraph (b)(4)(iii)(I) of this section may also be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740.

(1) Bromate shall be measured using the following method: Method 300.1--``Determination of Inorganic Anions in Drinking Water by Ion Chromatography,'' Rev. 1.0, U.S. EPA, 1997, EPA/600/R-98/118, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(2) Chlorite shall be measured using the following methods:

(i) Method 300.0--``Determination of Inorganic Anions by Ion Chromatography,'' Rev. 2.1. The revision is contained in the manual entitled ``Methods for the Determination of Inorganic Substances in Environmental Samples,'' U.S. EPA, August 1993, EPA/600/R-93/100, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(ii) Method 300.1--``Determination of Inorganic Anions in Drinking Water by Ion Chromatography,'' Rev. 1.0, U.S. EPA, 1997, EPA/600/R-98/ 118, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(3) HAA5 shall be measured using the following methods:

(i) Method 552.1--``Determination of Haloacetic Acids and Dalapon in Drinking Water by Ion Exchange Liquid-Solid Extraction and Gas Chromatography with Electron Capture Detection,'' Rev. 1.0. The revision is contained in the manual entitled ``Methods for the Determination of Organic Compounds in Drinking Water-Supplement II,'' U.S. EPA, August 1992, EPA/600/R-92/129, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(ii) Method 552.2--``Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-Liquid Extraction, Derivatization and Gas Chromatography with Electron Capture Detection,'' Rev. 1.0. The revision is contained in the manual entitled ``Methods for the Determination of Organic

Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(iii) Method 6251 B--``Disinfection By-Products: Haloacetic Acids and Trichlorophenol,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(4) TTHM shall be measured using the following methods:

(i) Method 502.2--``Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series,'' Rev. 2.1. The revision is contained in the manual entitled ``Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(ii) Method 524.2--``Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry,'' Rev. 1.0. The revision is contained in the manual entitled ``Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1993, EPA/600/R-95/ 131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(iii) Method 551.1--``Determination of Chlorination Disinfection Byproducts, Chlorinated Solvents, and Halogenated Pesticides/Herbicides in Drinking Water by Liquid-Liquid Extraction and Gas Chromatography with Electron-Capture Detection,'' Rev. 1.0. The revision is contained in the manual entitled ``Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,'' U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(5) Compliance with the chloramine standard can be determined by measuring combined or total chlorine. The following methods shall be used to measure chloramine:

(i) ASTM Method D1253-86--`` Standard Test Method for Residual Chlorine in Water,'' which is contained in the book entitled ``Annual Book of ASTM Standards,'' 1996, vol. 11.01, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(ii) Method 4500-Cl D--``Amperometric Titration Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(iii) Method 4500-Cl F--``DPD Ferrous Titrimetric Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(iv) Method 4500-Cl G--``DPD Colorimetric Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(v) Method 4500-Cl E--``Low-Level Amperometric Titration Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(vi) Method 4500-Cl I--``Iodometric Electrode Technique,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(6) Compliance with the chlorine standard can be determined by measuring free or total chlorine. The following methods shall be used to measure chlorine:

(i) ASTM Method D1253-86--``Standard Test Method for Residual Chlorine in Water,'' which is contained in the book entitled ``Annual Book of ASTM Standards,'' 1996, vol. 11.01, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(ii) Method 4500-Cl D--``Amperometric Titration Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(iii) Method 4500-Cl F--``DPD Ferrous Titrimetric Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(iv) Method 4500-Cl G--``DPD Colorimetric Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(v) Method 4500-Cl E--``Low-Level Amperometric Titration Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(vi) Method 4500-Cl I--``Iodometric Electrode Technique,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(vii) Method 4500-Cl H--``Syringaldazine (FACTS) Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(7) Chlorine dioxide shall be measured using the following methods:

(i) Method 4500-ClO<INF>2</INF> D--``DPD Method,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(ii) Method 4500-ClO<INF>2</INF>E--``Amperometric Method II,'' which is contained in the book entitled ``Standard Methods for the Examination of Water and Wastewater,'' 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(5) Radiological quality. (i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(5)(ii) of this section, meet standards of radiological quality as follows:

(A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

(B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

(C) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

(D) The bottled water shall not contain uranium in excess of 30 micrograms per liter of water.

(ii) Analyses conducted to determine compliance with the requirements of paragraph (b)(5)(i) of this section shall be made in accordance with the methods described in the applicable sections of ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., may be obtained from the American Public Health Association, 1015 15th St. NW., Washington, DC 20005. Copies of the methods incorporated by reference in this paragraph (b)(5)(ii) may also be examined at the National Archives and Records Administration (NARA), or at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD. For information on the availability of this material at NARA, call 202- 741-6030, or go to: http://www.archives.gov/federal--register/code--of-- federal--regulations/ibr--locations.html.

(A) Combined radium-226/-228 shall be measured using the following methods:

(1) Method 7500-Ra B--``Precipitation Method,'' which is contained in ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(2) Method 7500-Ra D--``Sequential Precipitation Method,'' which is contained in ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(B) Gross alpha particle radioactivity shall be measured using the following method: Method 7110 C--``Coprecipitation Method for Gross Alpha Radioactivity in Drinking Water,'' which is contained in ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(C) Beta particle and photon radioactivity shall be measured using the following methods:

(1) Method 7500-Sr B--``Precipitation Method,'' which is contained in ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(2) Method 7500-\3\H B--``Liquid Scintillation Spectrometric Method,'' which is contained in

``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(3) Method 7120 B--``Gamma Spectroscopic Method,'' which is contained in ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(D) Uranium shall be measured using the following methods:

(1) Method 7500-U B--``Radiochemical Method'' which is contained in ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(2) Method 7500-U C--``Isotopic Method'' which is contained in ``Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(c) Label statements. When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(2) through (b)(5), of this section, the label shall bear the statement of substandard quality specified in Sec. 130.14(a) of this chapter except that, as appropriate, instead of or in addition to the statement specified in Sec. 130.14(a) the following statement(s) shall be used:

(1) ``Contains Excessive Bacteria'' if the bottled water fails to meet the requirements of paragraph (b)(2)(i)(A) of this section. (2) ``Excessively Turbid'', ``Abnormal Color'', and/or ``Abnormal Odor'' if the bottled water fails to meet the requirements of paragraph (b)(3) (i), (ii), or (iii), respectively, of this section.

(3) ``Contains Excessive ------,'' with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., ``Contains Excessive Arsenic,'' ``Contains Excessive Trihalomethanes'') except that ``Contains Excessive Chemical Substances'' may be used if the bottled water is not mineral water.

(4) ``Excessively Radioactive'' if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) Adulteration. Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act), or that consists in whole or in part of any filthy, putrid, or decomposed substance, or that is otherwise unfit for food under section 402(a)(3) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section. If E. coli is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act.

THE SURGEON GENERAL OF THE UNITED STATES

Oral Health In America: A Report Of The Surgeon General (2000)

Since the mid-1960s, the Surgeon General of the United States has been issuing comprehensive reviews of health topics – from smoking to metal health to physical activity. These are massive documents assembled over several years that involve the participation of hundreds of experts inside and outside government. Just 53 such reports have been issued in the past half century. The Surgeon General's Report on Oral Health in America came out in the year 2000. The 308-page report described oral health as integral to general health and found a "silent epidemic" of poor oral health that falls disproportionately on the poor. One major recommendation was to expand community water fluoridation, which the report found to be "an ideal public health measure, which benefits individuals of all ages and all socioeconomic strata."

Below, in their entirety, are the preface by Surgeon General David Satcher and the chapter of the report that focuses on fluoridation. The full report is available for download at *http://silk.nih.gov/public/hck1ocv.@www.surgeon.fullrpt.pdf*.

Source
U.S. Department of Health and Human Services. Oral Health in America: A Report of the Surgeon General. Rockville, MD: U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000.

PREFACE

From the Surgeon General, U.S. Public Health Service

As we begin the twenty-first century, we can be proud of the strides we have made in improving the oral health of the American people. At the turn of the last century, most Americans could expect to lose their teeth by middle age. That situation began to change with the discovery of the properties of fluoride, and the observation that people who lived in communities with naturally fluoridated drinking water had far less dental caries (tooth decay) than people in comparable communities without fluoride in their water supply. Community water fluoridation remains one of the great achievements of public health in the twentieth century — an inexpensive means of improving oral health that benefits all residents of a community, young and old, rich and poor alike. We are fortunate that additional disease prevention and health promotion measures exist for dental caries and for many other oral diseases and disorders — measures that can be used by individuals, health care providers, and communities.

Yet as we take stock of how far we have come in enhancing oral health, this report makes it abundantly clear that there are profound and consequential disparities in the oral health of our citizens. Indeed, what amounts to a "silent epidemic" of dental and oral diseases is affecting some population groups. This burden of disease restricts activities in school, work, and home, and often significantly diminishes the quality of life. Those who suffer the worst oral health are found among the poor of all ages, with poor children and poor older Americans particularly vulnerable. Members of racial and ethnic minority groups also experience a disproportionate level of oral health problems Individuals who are medically compromised or who have disabilities are at greater risk for oral diseases, and, in turn, oral diseases further jeopardize their health.

The reasons for disparities in oral health are complex. In many instances, socioeconomic factors are the explanation. In other cases, disparities are exacerbated by the lack of community programs such as fluoridated water supplies. People may lack transportation to a clinic and flexibility in getting time off from work to attend to health needs. Physical disability or other illness may also limit access to services. Lack of resources to pay for care, either out-of-pocket or through private or public dental insurance, is clearly another barrier. Fewer people have dental insurance than have medical insurance, and it is often lost when individuals retire. Public dental insurance programs are often inadequate. Another major barrier to seeking and obtaining professional oral health care relates to a lack of public understanding and awareness of the importance of oral health.

We know that the mouth reflects general health and well-being. This report reiterates that general health risk factors common to many diseases, such as tobacco use and poor dietary practices, also affect oral and craniofacial health. The evidence for an association between tobacco use and oral diseases has been clearly delineated in every Surgeon General's report on tobacco since 1964, and the oral effects of nutrition and diet are presented in the Surgeon General's report on nutrition (1988). Recently, research findings have pointed to possible associations between chronic oral infections and diabetes, heart and lung diseases, stroke, and low-birth-weight, premature births. This report assesses these emerging associations and explores factors that may underlie these oral-systemic disease connections.

To improve quality of life and eliminate health disparities demands the understanding, compassion, and will of the American people. There are opportunities for all health professions, individuals, and communities to work together to improve health. But more needs to be done if we are to make further improvements in America's oral health. We hope that this Surgeon General's report will inform the American people about the opportunities to improve oral health and provide a platform from which the science base for craniofacial research can be expanded. The report should also serve to strengthen the translation of proven health promotion and disease prevention approaches into policy development, health care practice, and personal lifestyle behaviors. A framework for action that integrates oral health into overall health is critical if we are to see further gains.

— David Satcher MD, PhD, Surgeon General

CHAPTER 7

Community and Other Approaches to Promote Oral Health and Prevent Oral Disease

The remarkable improvements in oral health over the past half century reflect the strong science base for prevention of oral diseases that has been developed and applied in the community, in clinical practice, and in the home. This chapter presents the evidence for key preventive measures for those oral conditions that pose the greatest burden to U.S. society. Because the emphasis given to each condition discussed here reflects the extent of the evidence for the associated preventive measures, the chapter is heavily weighted toward the prevention and control of dental caries, for which multiple effective preventive modalities have been developed. The dental profession has long championed disease prevention and health promotion approaches to oral health. The initial observations in the 1930s that people living in communities served by naturally fluoridated water had lower dental caries inspired the trailblazing clinical prevention studies of the 1940s and 1950s. Researchers compared whole cities agreeing to fluoridate their water supplies to control cities whose drinking water contained only trace amounts of fluoride. Five years into the studies, follow-up with schoolchildren who had been examined at baseline revealed dramatic reductions in dental caries in the children drinking fluoridated water, as compared to controls. The overwhelming success of the studies led to a widespread adoption of community water fluoridation in the United States as a high-benefit, low-cost preventive method that benefited old and young, rich and poor alike. It also provided momentum for health practitioners, researchers, industry, and public health directors to consider other kinds of community-wide, provider-based, and individual strategies aimed at improving oral and general health.

Most common oral diseases can be prevented through a combination of community, professional, and individual strategies. The strategies selected here include disease prevention and health promotion interventions directed toward the public, practitioners, and policymakers to create a healthy environment, reduce risk factors, inform target groups, and improve knowledge and behaviors. They were selected on the basis of the significance of the health problem they were designed to prevent, whether in terms of prevalence, incidence, severity, cost, or impact on quality of life (see Chapters 4 and 6). Table 7.1 summarizes the strategies for the primary prevention of caries, periodontal diseases, oral and pharyngeal cancers, inherited disorders, and trauma, distinguishing among those that can be implemented community-wide, through health professionals, or through the exercise of individual responsibility. Some strategies can be applied at multiple levels. Box 7.1 provides a glossary of terms related to community health programs.

BOX 7.1

Glossary: The Nature of Community Health Programs

Community health programs are defined as health promotion and disease prevention activities that address health problems in populations. Community health programs often provide a level of organization and resources beyond those available to an individual.The programs thus complement personal care and professional services. Many programs target populations with limited access to professional services or limited resources to pay for services. Government agencies,religious organizations,charities,scho ols,foundations,and other private and public groups may spearhead such programs,tapping into the expertise,enthusiasm,and knowledge of community values of staff and volunteers. Some programs are sponsored by national,state,and local dental societies and their members.

Five terms related to community health programs—community,health promotion,health literacy,health education,and disease prevention—have been further articulated by experts in the field.

Community.

According to Last (1995),a community is “a group of individuals organized into a unit,or manifesting some unifying trait or common interest.” The unit can be a town,a geographic area,the state,nation,or body politic (Last 1995). The unit may also be a selected subgroup,such as disadvantaged children living in a large city or women urged to have mammograms according to specified schedules.

In designing and implementing community programs,planners must take into consideration that no two communities are identical. In a classic expression of this concept, McGavran (1979) wrote that a community is “an entity different from every other community as an individual is different from his neighbor: different in its physical makeup,its geographic and demographic limitation,different in its social structure,its power structure,its governmental and legal structure,different in mental and emotional patterns,in its ethnic groups,its mores,its religious and nutritional patterns,and different in its educational procedure,its institutions,and its community organization.”On the other hand,communities may have similar risk factors for poor oral health,allowing common solutions to similar problems. Lessons learned in one community may be applicable to those with similar characteristics. In recent years,investigators have begun to examine characteristics of communities,noting that some communities provide an environment that contributes to the overall health and well-being of the members,whereas others appear to be detrimental. All communities,however,have both positive and negative influences on health and well-being—the challenge is to minimize the negative factors and maximize the positive in each community. Healthy communities have been characterized as having a degree of openness and cooperation—neighbors helping neighbors. Healthy communities also are ones in which there are less extreme separations of individuals by social class (Wilkinson 1996).

Health Promotion.

Health promotion is “any planned combination of education,political,regulatory,and organizational supports for action and conditions of living conducive to the health of individuals,groups,or communities”(Green and Kreuter 1999).Examples of broad-based health pro-motion activities include programs encouraging people of all ages to stop using tobacco,regulations requiring the use of mouth guards in contact sports,laws to prohibit tobacco sales to minors,and labels that indicate the amount of sugar in a product.

Health Literacy.

Health literacy is "the capacity of individuals to obtain,interpret,and understand basic health information and services and the competence to use such information and services in ways which enhance health"(Joint Commission on National Health Education Standards 1995).Health literacy is correlated with general literacy,and both vary by educational achievement,socioeconomic status,race,and ethnicity. This is an important concern in a society that is becoming more diverse in terms of language,religion,cultur e,race,and ethnicity. Programs intending to serve,immigrants,for example,must attend to ensuring that information,programs,and systems are accessible,understandable,and culturally sensitive,particularly if the target audience for health information and services does not speak English,if there are unique cultural and religious beliefs at variance with those of the dominant culture,or if living arrangements are such that individuals lack access to sources of health information and care.

Health Education.

Health education is an important part of health promotion. It is defined as "any planned combination of learning experiences designed to predispose,enable,and reinforce voluntary behavior conducive to health in individuals,groups,or communities"(Green and Kreuter1999).Examples include the multiple campaigns to prevent tobacco use among youth. An example at the statewide level is Arizona's promotion of the use of dental sealants with an educational campaign that says "Sealants Are in the Groove."

Disease Prevention.

The term prevention embodies the goal of promoting and preserving health and minimizing suffering and distress. Community health programs generally focus on either primary prevention—removing or reducing risks or providing protection from disease before it occurs—or secondary prevention—screening and early detection and intervention to arrest the progress of disease after it occurs. Tertiary prevention—rehabilitating and restoring structure and function—is provided in some community-based programs,such as clinical dental care organized and delivered under conditions determined by the community.

TABLE 7.1

Community, provider, and individual strategies for primary prevention of key oral diseases and conditions

Community Strategies	Professional Strategies	Individual Strategies
Dental Caries		
Community-wide health promotion interventions[a]	Counseling to follow measures to reduce risk of disease	Being informed about strategies to prevent disease
Fluoride use: Community water fluoridation School-based dietary fluoride tablets School-based fluoride mouthrinse	Fluoride use: Prescriptions for fluorides (supplements or rinses) Gels and other high-fluoride topicals Topical remineralization solutions Fluoride-containing restorative materials	Fluoride use: Dentrifrice Mouthrinse, over the counter
School-based and school-linked sealant programs	Provision of sealants Prescriptions for antimicrobial agents	Asking about sealants Use of antimicrobial agents
School-linked screening and referral	Individualized recall schedule	Self-initiated use of dental services

Periodontal diseases		
Community-wide health promotion interventions[a]	Counseling to follow measures to reduce risk of disease	Being informed about strategies to prevent disease
School-based personal hygiene, reinforcement of personal oral hygiene habits in Headstart or primary school classrooms	Control of plaque bacteria by mechanical means (prophylaxis or scaling) Chemical plaque control Chemotheraputic agents	Oral hygiene measures Toothbrushing and flossing Toothbrushing with dentrifrices Plaque control
School-linked screening and referral	Monitoring and early detection of disease	Self-initiated use of dental services
Oral and pharyngeal cancers		
Community-wide health promotion interventions[a]	Professional education and patient counseling on risk factors	Being informed about strategies to prevent disease Avoidance of tobacco use Reduction of alcohol use Use of sunscreen and lip protector
Cancery screening programs (such as health fairs)	Routine soft-tissue oral examination for early detection of precancerous lesions	Self initiated use of dental services Request for cancer screening
Inherited disorders		
Early detection programs	Interdisciplinary early detection programs	
Trauma		
Community-wide health promotion interventions[a]	Professional education and patient counseling on risk factors	Being informed about stategies to prevent trauma
Mouth protector fittings for entire team	Fabrication of mouth protectors	Use of mouth protectors and helmets

[a]Community-wide health promotion interventions (education,political,regulatory,and organizational) are directed toward the public,practitioners,and policymakersto create a healthy environment,reduce risk factors,inform target groups,and improve knowledge and behaviors.

This chapter also includes a discussion of knowledge and practices of the public and health care providers regarding the three oral conditions about which we have the most knowledge. The purpose of this discussion is not to outline specific health pro-motion strategies to enhance knowledge and practices but to indicate the opportunities and needs for both broad-based and targeted health promotion programs and activities.

Weighing The Evidence That Interventions Work

Researchers, policymakers, and practitioners make judgments about whether a health intervention works based on estimates of its efficacy or effectiveness. Estimates of an intervention's efficacy are best based on randomized controlled trials, which may be conducted under ideal circumstances. Evidence for whether an intervention works when applied in the community at large is referred to as its effectiveness (O'Mullane 1976). The distinction between efficacy and effectiveness is often blurred in dental public health programs because the studies and their settings can be very similar. Nevertheless, the major difference between the two lies in the degree of control exerted over factors that can affect results. Effectiveness studies more accurately reflect results that may be expected from the implementation of interventions.

The current trend in health care and public health is to base recommendations on evidence derived from systematic reviews of the literature and an assessment of the quality of evidence. The U.S. Preventive Services Task Force (1996) and the Canadian Task Force on the Periodic Health Examination (Ismail and Lewis 1993, Lewis and Ismail 1995) are examples of groups that have used systematic reviews to establish the evidence of efficacy or effectiveness of clinical preventive services for the purpose of making recommendations. Simila reviews of the evidence of effectiveness for community preventive services are currently under way by the Task Force on Community Preventive Services (2000). These reports provide clear statements about the evidence and recommendations for or against a given strategy.

The discussion in this chapter is more illustrative than comprehensive. Readers are encouraged to seek specific guidance from the reports of the U.S. Preventive Services Task Force where available. Furthermore, because of the interest in community preventive services, "expert opinion" about the merits of community interventions is included, even though the work of the Task Force on Community Preventive Services has not been completed. Expert opinion is formed by less systematic reviews of the literature or addresses interventions to be applied in settings other than those previously studied.

In particular, suggestions are offered for several interventions intended to reduce oral disease and promote oral health that reflect the opinion of experts who contributed to this report. Until findings from additional research are available, expert opinion remains the best guidance for community interventions where only efficacy studies have been done or where they were applied to populations with different attributes or risk factors than those of current interest. Also, expert opinion has been used where there is an interest in criteria that were not considered in previous efficacy studies, such as cost-effectiveness and practicality.

Readers interested in more detailed information about interventions in areas such as control of tobacco use or motor vehicle safety are directed to the upcoming report of the Task Force on Community Preventive Services (2000). Interventions included in this chapter (and highlighted in Table 7.1) are those that have been shown to be effective in certain settings, but which can be applied in other settings. The anticipated benefits may be difficult to determine. In general, the per capita cost of an intervention is lower for community interventions and is usually a function of the number of people reached for a given level of professional effort. Effectiveness, however, is often a function of the risk characteristics of a given individual in the group receiving the intervention. Such risk factors are often easier to target by individual practitioners than by community programs. In the absence of contemporary data, the promotion of strategies deemed to be more cost-effective than others relies on the opinion of experts. Individual decision making regarding self- or provider care further reflects the subjective value placed on the outcome of care. Therefore, it is not possible to make general statements about the superiority of any given approach.

Prevention And Control Of Dental Caries

Although many caries prevention strategies, notably community water fluoridation and use of a fluoride-containing dentifrice, benefit adults and children alike, most of our understanding of the effectiveness of these strategies comes from the study of children, during a life stage when caries incidence is high.

Caries prevention programs have been designed and evaluated for children and have used a variety of fluoride and dental sealant strategies applied separately and together. Because these strategies are complementary, their use in combination has the potential of virtually eliminating dental caries in all children. However, dental caries is a problem for all ages. Although direct evidence of caries preventive strategies in adults is limited, the evidence that does exist is consistent with expected effects based on experience with children. The Centers for Disease Control and Prevention (CDC) recently convened an expert work group to develop recommendations for modalities to prevent and control dental caries based on a review of publications selected by the work group and other experts. The resulting recommendations are summarized in Table 7.2, where they are organized according to quality of evidence, strength of recommendation, and target population in accordance with criteria adapted from the U.S. Preventive Services Task Force (CDC in press).

Fluoride

Fluoride reduces the incidence of dental caries and slows or reverses the progression of existing lesions (i.e., helps prevent cavities). Today, all Americans are exposed to fluoride to some degree, and there is little doubt that widespread use of fluoride has been a major factor in the overall decline in recent decades in the prevalence and severity of dental caries in the United States and other economically developed countries (Bratthall et al. 1996).

Fluoride is the ionic form of the element fluorine, the thirteenth most abundant element in the crust of the Earth. Because of its high affinity for calcium, fluoride is mainly associated with calcified tissues (i.e., bones and teeth). The ability of fluoride to inhibit, and even reverse, the initiation and progression of dental caries is well known. Fluoride's mechanisms of action include incorporation of fluoride into enamel preeruptively, inhibition of demineralization, enhancement of remineralization, and inhibition of bacterial activity in dental plaque.

A variety of theories regarding fluoride's mechanisms of action account for the range of fluoride products available (Burt and Eklund 1999, Stookey and Beiswanger 1995). The initial theory of action was based on the belief that incorporation of fluoride into the hydroxyapatite of developing tooth enamel in the preeruptive phase reduced the mineral's solubility, thereby increasing enamel resistance. Because of the length of time the tooth is at risk of caries during the posteruptive phase, however, the topical effects of fluoride are considered to predominate (Clarkson et al. 1996). These effects are based on fluoride's role in the aqueous phase around the tooth, both in saliva and in dental biofilm (plaque). Fluoride in plaque contributes to the remineralization of demineralized enamel when bound fluoride is released during an acid challenge, resulting in a more acid-resistant enamel surface structure. Fluoride also has been shown to inhibit the process of glycolysis by which fermentable carbohydrates are metabolized by cariogenic bacteria to produce acid. All these effects occur after the tooth erupts, while it is functioning in the mouth, enabling fluoride to prevent caries over a lifetime in both children and adults.

The first use of fluoride for caries prevention was in 1945 in the United States and Canada, when the fluoride concentration was adjusted in the drinking water supplying four communities (Arnold et al. 1962, Ast and Fitzgerald 1962, Blayney and Hill 1967, Hutton et al. 1956). This public health approach followed a long period of epidemiologic studies of the effects of naturally occurring fluoride in drinking water (Burt and Eklund 1999).

The success of the community water fluoridation trials in reducing dental caries led to the development of other important fluoride-containing products, such as dietary supplements and, most notably, fluoride-containing dentifrices, in the early 1960s. Fluoride-containing gels, solutions, pastes, and varnishes were also developed for topical use, either applied by professionals or self-applied at home or in other settings. All of these products were tested for safety and effectiveness in reducing caries. Products designed for professional use generally have higher concentrations and are used at less frequent intervals than those designed for self-application.

Controlled clinical trials from the 1940s through the 1970s documented the benefits of professionally applied fluoride in reducing dental caries, and several excellent reviews are available (Horowitz and Ismail 1996, Johnston 1994, Ripa 1990, Stookey and Beiswanger 1995). Professional application of fluoride is inherently more expensive than self-applied methods, so the use of such an approach for groups and individuals at low risk of dental caries is unlikely to be cost-effective. For patients at high risk of dental caries, however, professionally applied fluoride is still considered cost-effective. It is not clear whether fluoride varnishes and gels would be most efficiently used in clinical programs targeting groups at high risk of dental caries or whether they should be reserved for individual high-risk patients.

The U.S. Preventive Services Task Force (Greene et al. 1989, USPSTF 1996) and the Canadian Task Force on Periodic Health Examination (Lewis and Ismail 1995) affirm that there is strong evidence to support the major methods for providing fluoride to prevent dental caries.

The safety of fluoride is well documented and has been reviewed comprehensively by several scientific and public health organizations (Institute of Medicine (IOM) 1997, National Research Council (NRC) 1993, Newbrun 1996, U.S. Department of Health and Human Services (USDHHS) 1991, World Health Organization (WHO) 1984). When used appropriately, fluoride has been demonstrated to be both safe and effective in preventing and controlling dental caries. The IOM (1997) classified fluoride as a micronutrient, citing it, along with calcium, phosphorus, magnesium, and vitamin D, as an important constituent in maintaining health.

Appropriate use of fluoride products can minimize the potential for enamel fluorosis, a broad term applied to certain visually detectable changes in the opacity of tooth enamel associated with areas of fluoride-related developmental hypomineralization. There are also many developmental changes in enamel that are not fluoride-related (Fejerskov et al. 1990). Most enamel fluorosis seen today is of the mildest form, which affects neither aesthetics nor dental function. Cosmetically objectionable enamel fluorosis can occur when young children ingest higher than optimal amounts of fluoride, from any source, while tooth enamel is forming (up to age 6). Its occurrence appears to be most strongly associated with the total cumulative fluoride intake during the period of enamel development, but the condition's severity depends on the dose, duration, and timing of fluoride intake. Specific recommendations have been made to control fluoride intake by children during the years of tooth development (USDHHS 1991).

Fluoridation of Drinking Water

For more than half a century, community water fluoridation has been the cornerstone of caries prevention in the United States; indeed, CDC has recognized water fluoridation as one of the great public health achievements of the twentieth century (CDC 1999). All water contains at least trace amounts of fluoride. Water fluoridation is the controlled addition of a fluoride compound to a public water supply to achieve a concentration optimal for dental caries prevention. In the 1940s, Dean et al. (1941) concluded that 1 ppm (part per million) fluoride was the optimal concentration for climates similar to that of the Chicago area; this concentration would significantly reduce the prevalence of dental caries with an acceptably low prevalence of enamel fluorosis. Current U.S. Public Health Service (USPHS) recommendations for fluoride use include an optimally adjusted concentration of fluoride in drinking water ranging from 0.7 to 1.2 ppm, depending on the mean maximum daily air temperature of the area (Galagan and Vermillion 1957, USDHEW 1962). A lower fluoride concentration is recommended for communities in warmer climates than cooler climates, because it is assumed that persons living in warmer climates drink more tap water.

Effectiveness

Numerous studies in naturally fluoridated areas preceded the field trials. There are no randomized, double-blind, controlled trials of water fluoridation because its community-wide nature does not permit randomization of people to study and control groups. Similar results have been derived from numerous well-conducted field studies by various investigators on thousands of subjects in different parts of the world. Conducting a study in which individuals are randomized to receive or not receive fluoridated water is unnecessary and is not feasible.

In 1945, Grand Rapids, Michigan, became the first city in the United States to fluoridate its water supply; the oral health of its schoolchildren was periodically compared with that of schoolchildren in the control city, Muskegon, Michigan. Dramatic declines in dental caries among children in Grand Rapids and three other cities conducting studies shortly thereafter led to fluoridation in many other cities. In an extensive review of 95 studies conducted between 1945 and 1978, Murray et al. (1991) reported the modal caries reduction following water fluoridation to be between 40 and 50 percent for primary teeth and 50 and 60 percent for permanent teeth. Newbrun (1989) reported on more than 60 studies conducted during the 1970s and early 1980s, limiting his review to those with concurrent control groups because of the continuing decline in dental caries in both fluoridated and nonfluoridated areas. Comparisons of fluoride-deficient and fluoridated communities in the United States, Australia, Britain, Canada, Ireland, and New Zealand have consistently demonstrated the continued effectiveness of water fluoridation. Caries reductions ranged between 15 and 40 percent in fluoridated, as compared with fluoride-deficient, communities (USDHHS 1991).

Fluoridation also benefits middle-aged and older adults. Benefits to adults include reductions in both coronal and root caries. These benefits are important because older people typically experience gingival recession, which results in exposed root surfaces, which are susceptible to caries. In addition, tooth retention in older U.S. cohorts has increased in recent decades, so that the number of teeth at risk for caries in older age groups is also increasing. Finally, many medications used to treat chronic diseases common in aging have the side effect of diminished salivary flow, depriving teeth of the many protective factors in saliva.

Other evidence of the benefits of fluoridation comes from studies of populations where fluoridation has ceased. Examples in the United States, Germany, and Scotland have shown that when fluoridation is withdrawn and there are few other fluoride exposures, the prevalence of caries increases. In Wick, Scotland, which began water fluoridation in 1969 but stopped it in 1979, the caries prevalence in 5- to 6-year-olds with limited exposure to other sources of fluoride increased by 27 percent between 1979 and 1984. This was despite a national decline in caries and increased availability of fluoride-containing dentifrices (Kugel and Fischer 1997, Seppä et al. 1998, Stephen et al. 1987).

Costs and Cost-effectiveness

The increase in other fluoride exposures since water fluoridation was first introduced in 1945 — particularly from fluoride-containing dentifrices, mouth-rinses, and foods and beverages processed using fluoridated water — has led to smaller differences in the prevalence of dental caries between people in fluoridated and those in nonfluoridated communities than in the past. Most public health experts believe that water fluoridation continues to be a highly cost-effective strategy, even in areas where the overall caries level has declined and the cost of implementing water fluoridation has increased (Burt 1989, CDC 1999).

Compared to the cost of restorative treatment, water fluoridation actually provides cost savings, a rare characteristic for community-based disease prevention strategies (Garcia 1989). The mean annual per capita cost of fluoridation ranges from $0.68 for systems serving populations greater than 50,000 (large systems) and $0.98 for systems serving between 10,000 and 50,000 (medium systems), to $3.00 for systems serving less than 10,000 (small systems) (reported in 1999 dollars) (Ringelberg et al. 1992). In 1992, approximately 60 percent of the U.S. population receiving fluoridated water was served by large systems, 31 percent by medium systems, and 9 percent by small systems (USDHHS 1993).

Access to Optimally Fluoridated Water in the United States

The most recent national data on the extent of community water fluoridation reflect the status of fluoridation in 1992 (see Figure 7.1 and Table 7.3). About 145 million people, or 62 percent of the population served by public water supplies, consume water with optimal fluoride levels. Of the 50 largest cities in the United States, 43 are fluoridated (Table 7.4). Residents of the seven unfluoridated cities in the group are among the almost 100 million persons in the United States who lack this method of caries prevention.

Although many states and large cities had been quick to implement fluoridation programs in the 1950s and 1960s, the trend then began to level off. In the absence of legislative mandates in most states and categorical federal funding, fluoridation decisions are left to the states, and frequently to local governments and city councils. Thus expansion of fluoridation in the United States is not simple and requires decisions at many levels. The national health promotion and disease prevention objectives in Healthy People 2010 (USDHHS 2000) call for increasing the percentage of Americans on public water supplies drinking fluoridated water from 62 to 75 percent — a 21 percent improvement (see Figure 7.1). This would mean adding 30 million people served by well over 1,000 community water systems to those who currently have access to fluoridated public water systems (USDHHS 1993).

Summary: Community Water Fluoridation

Epidemiological studies carried out during the last five decades provide strong evidence supporting the effectiveness of water fluoridation in preventing coronal and root caries in children and adults. Further support of effectiveness comes from studies that indicate that caries experience increases in communities that no longer fluoridate the water supply (and where there are few other exposures to fluorides). Given the modest cost of less than 1 dollar per person per year to fluoridate water systems serving most people, community water fluoridation is recommended as a very effective and cost-effective method of preventing coronal and root caries in children and adults. Moreover, water fluoridation benefits all residents served by community water supplies regardless of socioeconomic status. Few barriers to its implementation exist, with the important exception of the political opposition that the measure often engenders and certain technical difficulties and costs involved in fluoridating very small water systems.

School Water Fluoridation

During the 1960s, 1970s, and 1980s, programs were initiated to bring the benefits of fluoride in drinking water to children living in homes supplied by well water and whose schools had independent water supplies. The idea was to adjust the fluoride content of the water supplies of the schools these children attended, especially consolidated rural schools, to levels higher than those that would be used for community water fluoridation, taking into account that the children were present for only portions of the day and year.

Although the strategy shares some of the advantages of community water fluoridation—serving rich and poor alike and requiring no action on the part of the children (other than drinking the water)—a number of disadvantages were evident from the outset. These included the limitations inherent in beginning exposure to fluoride only when children were of school age and then providing only intermittent exposure. Also, the possibility that the exposure would not confer benefits after the children left school was a concern. Practical considerations included the cost of operations, personnel, logistical difficulties, and mandatory water testing (CDC 1995). Moreover, the intervening decades have seen increased school consolidations, increased coverage of schools by community-wide water systems, declining numbers of children who could benefit from such programs, and a continuing general decline in dental caries in children. Another concern is that schools increasingly enroll preschoolers into daycare programs for which school water fluoridation at higher levels than for community water systems is not appropriate. Only four intervention studies evaluating the effectiveness of school water fluoridation have been published.

Summary: School Water Fluoridation

Given the limitations of the evidence for effectiveness, as well as the difficulties of implementation and operation, school water fluoridation has limited application. Decisions to initiate or continue school fluoridation programs should be based on an assessment of present caries risk in the target school(s), alternative preventive modalities that may be available, and periodic evaluation of program effectiveness.

Dietary Fluoride Supplements

Dietary fluoride supplements are available as tablets that are swallowed or chewed, drops that are swallowed, and lozenges that dissolve slowly in the mouth. They can provide topical and systemic fluoride for children in the absence of optimally fluoridated drinking water. In the United States, supplements are available by prescription only, to be used once a day beginning at 6 months and ending at age 16. According to a 1986 National Health Interview Survey (NHIS), slightly more than 16 percent of children younger than 2 years used fluoride dietary supplements (Nourjah et al. 1994).

The fluoride supplement dosage schedule in use in the United States was last revised by the American Dental Association (ADA) in 1994 (Table 7.5) (ADA 1995). This schedule, based on the level of fluoride in the community water supply and on the age of the child, has also been endorsed by the American Academy of Pediatric Dentistry and the American Academy of Pediatrics. Fluoride supplements should not be prescribed for individuals living in optimally fluoridated communities.

Effectiveness of Home Use

The current fluoride supplement dosage schedule does not recommend prescribing fluoride for infants younger than 6 months. A double-blind study of fluoride supplements conducted to ascertain the effects of fluoride administered to the mother during the last 6 months of pregnancy followed by 5 years of supplements to the child after birth found no additional benefits from prenatal fluoride use (Leverett et al. 1997). In a randomized, double-blind, controlled trial in which supplements were administered from birth, Henno et al. (1967) had found statistically significant 4-year reductions in caries in primary and permanent teeth of 65 and 41 percent, respectively. Beyond this study, which was conducted when other sources of fluoride were not as widespread as today, there are no well-designed clinical trials of home-based administration of postnatal supplements. As Murray and Naylor (1996) noted, many studies are difficult to interpret, either because of small size, short experimental period, or inadequate reporting. The studies are further complicated by problems in self-selection bias, in choosing comparable control groups, and in compliance to the daily regimen. Notwithstanding the paucity of true randomized controlled clinical trials to demonstrate efficacy of supplement use in children, at least 60 studies have reported on the effectiveness of fluoride tablets or drops in home- or school-based programs (Driscoll 1974, Murray and Naylor 1996, Stephen 1993). However, none used the current prescribing schedule. Altogether, the evidence for using fluoride supplements to prevent and control dental caries is mixed. Although many studies have reported that the use of fluoride supplements by infants and children before their permanent teeth erupt reduces caries in permanent teeth, many other studies have reported that it does not (CDC in press). For children aged 6 to 16 who take supplements after most teeth have erupted, the evidence is much clearer that fluoride reduces caries experience (DePaola and Lax 1968, Driscoll et al. 1978, Stephen and Campbell 1978). Most of the supplements taken at home are prescribed by physicians and dentists in private practice, with physicians prescribing the larger share. Two difficulties are associated with home use. First, the provider may prescribe incorrectly; second, compliance with home-based tablet programs can be very poor. More public and professional education is needed to overcome the difficulties inherent in following recommended regimens for home use of fluoride supplements, which require motivation and adherence on the part of children, parents, and prescribers.

Effectiveness of School-based Programs

Most community fluoride supplement programs are school-based. Each school day, participating students receive a tablet, which they chew under supervision, swishing the resultant solution between the teeth for 30 seconds before swallowing. Supplement programs in schools have been shown to be effective in preventing caries in permanent teeth when administration is tightly controlled and children are instructed to let the tablet dissolve slowly, to ensure as much topical fluoride exposure as possible. Under these conditions, randomized controlled trials in the United States reported caries reductions of 20 to 28 percent over periods of 3 to 6 years (DePaola and Lax 1968, Driscoll et al. 1978). In a randomized, double-blind, 3-year study of Scottish schoolchildren who were 5.5 years of age at the start of the study, a much higher percentage reduction in caries in permanent teeth was observed (Stephen and Campbell 1978). In this study, teachers were specifically requested to encourage children each school day to let the sodium fluoride tablet dissolve slowly. These children were from lower socioeconomic groups and may not have had access to fluoride-containing dentifrices and other sources of fluoride, factors that most likely put them at high risk for caries.

Costs of School-based Programs

The costs of a school-based tablet program are low because equipment is not necessary, the procedure does not take long, and an entire classroom of children can participate at once. A 1988 survey of five programs ranging from 7 to 49 schools and 657 to 10,751 children found an average direct cost of approximately $2.53 per child per school year (Garcia 1989). The costs ranged from $0.81 to $5.40, depending on whether paid personnel or volunteers supervised the procedure. The economic benefits of a fluoride supplement program were assessed in randomized controlled clinical trials in Manchester, England, and results showed overall health and cost benefits for the experimental group (O'Rourke et al.1988).

Summary: Dietary Fluoride Supplements

For children not exposed to optimal fluoride concentration in their water supply, the evidence from studies conducted prior to the 1980s supporting the effectiveness of home use of daily dietary fluoride supplements in preventing dental caries in school-aged children is weak. However, the evidence of the effectiveness of school-based fluoride supplement programs is strong. Such programs require highly motivated teachers and students, a requirement that likely has limited their widespread adoption. Experts recommend that school-based dietary fluoride supplement programs are likely to be effective in providing topical fluoride protection for children at high risk for dental caries in settings where supervising personnel are highly motivated (CDC in press, Clarkson 1992, Ismail 1994, WHO 1994). Under these conditions, such programs may also be cost-effective.

Fluoride Mouthrinses

Several different formulations of fluoride mouthrinses are available, differing in the amount of fluoride and suggested frequency of use. Rinses with low fluoride concentrations (0.05 percent neutral sodium fluoride or 0.1 percent stannous fluoride) are designed for daily use and are available over-the-counter. Higher-concentration rinses (0.2 percent sodium fluoride) are designed for weekly use and are available only by prescription or in public programs.

School-based Programs

Fluoride mouthrinses were developed in the 1960s as a public health measure for use primarily in schools. They were conceived as a way of avoiding the high costs associated with professional applications of gels and other topical fluoride products in school settings and the poor acceptance by children of brush-on fluoride pastes. For children in the first grade and up, the procedure consists of vigorously rinsing with 10 milliliters (ml) of solution for 60 seconds. After the rinsing, the fluoride solution is expectorated into a cup, a napkin is inserted to absorb the solution, and both are disposed. Kindergarten children rinse with only 5 ml of solution.

Effectiveness

School-based fluoride mouthrinse programs have been evaluated extensively during the past three decades and have been the subject of numerous reviews (Adair 1998, Birkland and Torell 1978, Bohannan et al. 1985, Petersson 1993, Ripa 1991, Stamm et al. 1984, Torell and Ericsson 1974). Of the many studies during the 1970s and 1980s, 13 satisfied the strict criteria of randomized controlled clinical trials. Caries reductions ranging from 20 to 50 percent were observed, firmly establishing their efficacy. No recent controlled trials have been done. After the efficacy of fluoride mouthrinses was established, a 17-site national school-based demonstration program showed that a protocol involving weekly rinsing with 0.2 percent sodium fluoride was eminently practical. Most studies done after efficacy was established used a before-and-after design with no concurrent comparison group. This design might overestimate the caries reduction effects. On the whole, however, the programs appear to have been effective. A survey conducted in 1984 found fluoride mouthrinsing programs in 48 states, with 3.2 million children participating (Bednarsh and Connolly 1984). A later study by CDC reported that 3.25 million schoolchildren were participating in mouthrinsing programs at 11,683 sites in 1988 (Burt 1989), although there are reports that some states have recently curtailed use of these programs (R. Kuthy, personal communication, 2000).

Cost-effectiveness

The cost of the procedure in 1988 ranged between $0.52 and $1.78 per child per school year, depending on whether paid or volunteer adult supervisors were used (Garcia 1989). An extensive study during the late 1970s, when downward trends of caries rates were noted, questioned the cost-effectiveness of rinse programs (Klein et al. 1985). Fluoride mouthrinses may be more cost-effective when targeted to schoolchildren with high caries activity (Bawden et al. 1980, Leverett 1989, Torell and Ericsson 1965).

Summary: School-based Fluoride Mouthrinse Programs

Sufficient evidence exists from studies conducted before 1985 to support the effectiveness of 0.2 percent sodium fluoride mouthrinses in preventing coronal caries in school populations. There is evidence that with a declining prevalence of dental caries, the cost-effectiveness of these procedures is reduced. Experts recommend that school-based rinsing once a week with 0.2 percent sodium fluoride is likely to be effective if used in schools and classrooms where students are at high risk for caries and if applied consistently over time (CDC in press). Fluoride mouthrinse programs are not recommended for preschool children in the United States, and programs for kindergarten children should use only 5 ml of solution.

Fluoride Varnishes

Fluoride varnishes have not been approved for use in the United States with an anticaries indication. However, the U.S. public health community has begun to investigate the use of fluoride varnishes, which became available in this country in 1994. The varnishes are viscous, resinous lacquers painted onto teeth. Because the varnish adheres to enamel surfaces for up to 12 hours or more, fluoride retention in the mouth is greater than with solutions or gels. Varnishes have been used in Europe for 30 years. No data are available on the use of varnishes in children under 3 years, and, although the results were positive, only two randomized clinical trials have been conducted abroad using preschoolers (Holm 1979, Peyron et al. 1992). Many fluoride rinsing programs in Finland have been replaced with fluoride varnish application programs (Seppä 1991, Sundberg et al. 1996). Studies conducted in Canada (Clark et al. 1987) and Europe (de Bruyn and Arends 1987, Helfenstein and Steiner 1994, Twetman et al.1996) have found that fluoride varnish is efficacious in preventing dental caries. Applied semiannually, this modality is as effective as professionally applied fluoride gel (Seppä et al. 1995). Some researchers advocate application of fluoride varnish up to 4 times per year to achieve maximum effect, but the evidence of benefits from more than two applications per year remains inconclusive (Mandel 1994, Seppä 1991, Seppä and Tolonen 1990). Other studies have shown that three applications in 1 week, once a year, may be more effective than the more conventional biannual regimen (Petersson et al. 1991, Skold et al. 1994). European studies have shown that fluoride varnishes prevent decalcification (a very early stage of dental caries) beneath orthodontic bands (Adriaens et al. 1990) and slow the progression of existing enamel lesions (Peyron et al. 1992). Findings on cost-effectiveness are mixed (Kirkegaard et al. 1986, Koch et al. 1979, Seppä and Pollanen 1987, Vehmanen 1993).

Dental Sealants

The pits and fissures that characterize the biting surfaces of posterior teeth provide a haven for food debris and decay-causing bacteria. Not surprisingly, these sites are often the first and most frequent to be affected by decay in children and adolescents. The width of most pits and fissures is narrower than a single toothbrush bristle, making cleaning of their deepest recesses almost impossible. According to national estimates, as much as 90 percent of all dental caries in schoolchildren occurs in pits and fissures (Kaste et al. 1996). The teeth at highest risk by far are permanent first and second molars.

Enamel bonding, a technology introduced in the mid-1950s, led to the development of sealants. These are clear or opaque plastic resinous materials designed for professional application to the pit-and-fissure surfaces of teeth. The material hardens within 60 seconds or so into a thin, hard, protective coating. Sealants were introduced in the late 1960s and received the American Dental Association Seal of Approval in 1976 (ADA 1976). Most of the dozen products approved by the ADA do not contain a therapeutic agent, but work by providing a physical barrier that prevents microorganisms and food particles from collecting in the pits and fissures (ADA 1997). First-generation sealants used ultraviolet light to harden or "cure" the material; improved second- and third-generation sealants cure by chemical or visible light activation, respectively.

Sealant placement requires meticulous attention to technique, but they can be successfully provided in "field" settings using portable dental equipment. To be most effective, sealants should be placed on teeth soon after they erupt, but they can be applied across a wide age range. Not only does the risk for caries continue across the life span, but an individual's risk can increase for any number of reasons.

Sealants are particularly helpful for persons with medical conditions associated with higher caries rates, children who have experienced extensive caries in their primary teeth, and children who already have incipient caries in a permanent molar tooth.

Efficacy

Initial clinical trials using a random half-mouth design and first- or second-generation sealant materials established their efficacy. Several comprehensive reviews and a meta-analysis of the amount of caries prevented testify to the utility of these materials (Llodra et al. 1993, Ripa 1993, Weintraub 1989). Llodra et al. (1993) used a systematic process to select and review studies of one-time sealant placement on permanent teeth in subjects unexposed to other preventive measures. Pooled results from 17 studies meeting their selection criteria found that second-generation sealants reduced caries over 70 percent. These early trials firmly established retention as essential to preventing caries; a sealant is virtually 100 percent effective if it is fully retained on the tooth (NIH 1984). Mertz-Fairhurst (1984) reported 92 to 96 percent retention rates in second-generation sealants after 1 year, with 67 to 82 percent retention after 5 years. A review of studies of long-term retention of second-generation sealants showed 41 to 57 percent intact after 10 years (Ripa 1993). The longest-running study of a one-time application of a first-generation sealant indicated a reduction in pit-and-fissure caries by 52 percent after 15 years (Simonsen 1991). Retention results for third-generation sealants are similar to those for second-generation systems (Ripa 1993).

Effectiveness

Administrators of school-linked sealant programs (Collins et al. 1985, Sterritt and Frew 1988) and of school-based programs with either fixed clinics (Ismail et al. 1989, Messer et al. 1997, Whyte et al. 1987) or portable equipment (Bravo et al. 1996, Calderone and Davis 1987, Calderone and Mueller 1983, Hardison 1983, Kumar et al. 1997, Morgan et al. 1998) have reported on their experiences with these programs. These studies, using second-generation sealants, have shown effectiveness results comparable to those of clinical trials, regardless of the physical delivery site or personnel used for sealant application. Complete retention after approximately 1 year varied from 83 to 94 percent (Calderone and Mueller 1983, Hardison 1983, Ismail et al. 1989, Sterritt and Frew 1988, Whyte et al. 1987).

A Consensus Development Conference sponsored by the National Institutes of Health concluded that "an extensive body of knowledge has firmly established the scientific basis for the use of sealants" (NIH 1984). The panel urged the development of educational materials to enhance public and professional acceptance as well as third-party reimbursement. Consensus on the value of sealants is reflected by the inclusion of sealant objectives in Healthy People 2000 and Healthy People 2010 (see Table 7.6). In addition, sealant placement is supported in federally funded programs for women and children, and sealants are covered services in all state Medicaid programs. A Workshop on Guidelines for Sealant Use has made recommendations for sealant use in both community and individual care programs (ASTDD 1995).

Community Dental Sealant Programs

Several community-based public health initiatives have arisen to promote sealant use among private practitioners and through community-based programs. These activities include reaching dentists through continuing education courses (Bader et al.1987, Callanen et al. 1986, Siegal et al. 1996); directing large-scale promotional activities to consumers, community leaders, and third-party payers (Siegal et al. 1997a); and providing sealants directly to children in school programs.

Community programs that provide sealants directly to schoolchildren generally target vulnerable populations less likely to receive private dental care, such as children eligible for free or reduced-cost lunch programs. School-based programs are usually conducted entirely on site. School-linked programs conduct some portion of the program in schools, such as patient selection and parental permission, but generally provide the sealants at an off-site private practice or clinic. Nationally, 88 community-based sealant placement programs were in operation in the 1992-93 school year. These programs served children in 1,636 schools (Siegal et al. 1997b).

Combining Sealants with a Fluoride Program

Dramatic evidence of the impact of a combined fluoride and sealant program is provided by a program in Guam (Sterritt et al. 1990). For many years the children on this island had experienced dental caries rates more than double those of their U.S. mainland counterparts. In 1984 a school-linked pit-and-fissure sealant program was added to an existing school-based fluoride mouthrinse program. More than 15,000 children participated annually in the sealant program. After 8 years of fluoride mouthrinsing (from 1976 to 1984), mean decayed, missing, and filled surface (DMFS) scores declined by 1.79 surfaces per child. Only 7 percent of that decline was due to prevention of caries on surfaces that can benefit from sealants. With the addition of the sealant program to mouthrinsing, overall DMFS scores decreased an additional 2.34 surfaces per child in only 2 years. Most of this decline took place on pit-and-fissure surfaces. For the 10-year period a reduction of 4.13 DMFS per child was seen—a decline from 7.06 DMFS per child at baseline to 2.93 DMFS in 1986. At the end of the 10 years, participating children on Guam had caries rates close to those of mainland schoolchildren.

The National Preventive Dentistry Demonstration Program, a large project conducted in 10 U.S. cities between 1976 and 1981 to compare the costs and effectiveness of combinations of caries prevention procedures, found that the inclusion of sealants was critical to the cost-effectiveness of prevention strategies (Disney et al. 1989, Klein et al. 1985). In another combined program, Morgan et al. (1998) found that a 3-year sealant program and a fluoride mouthrinse program for secondary schoolchildren incurred a low cost for each tooth surface saved from caries. The incremental cost-effectiveness ratios comparing the intervention to the control group varied from a cost of $35.60 per tooth surface spared to a net savings of $7.00, depending on the assumptions used in the analysis.

Sealing Incipient Caries

Heller et al. (1995) evaluated the effect of sealants placed as part of a school-based program on permanent first molar teeth after 5 years. Sealants were applied to both sound teeth and those with incipient carious lesions (where the fissure is stained but not yet cavitated). For the initially incipient carious surfaces, the

5-year decay rate was 10.8 percent for sealed surfaces and 51.8 percent for unsealed surfaces. Initially sound surfaces had a decay rate of 8.1 percent for sealed surfaces and 12.5 percent for unsealed surfaces. Initially sound tooth surfaces were unlikely to become decayed in 5 years and did not benefit greatly from the application of sealants. The study showed potential efficiencies in targeting teeth with incipient caries for sealants.

Cost-effectiveness of Sealant Programs

Studies suggest that sealants are an efficient use of resources when used in populations with higher-than-average disease incidence rates and when selection methods limit sealants to teeth at highest risk of disease. Weintraub et al. (1993) demonstrated cost savings or improving cost-effectiveness with time in a sealant study at a children's dental clinic for low-income families. A strategy of identifying children with prior molar restorations (an indicator of high risk) and sealing the remaining molars showed cost savings within 4 to 6 years.

Summary: Dental Sealant Programs

Studies carried out during the last 20 years provide strong evidence to support the effectiveness of sealants in preventing the development of caries in tooth pits and fissures. Economic analyses suggest that community sealant programs are cost-effective and may even provide cost savings when used in high-risk populations. Experts recommend that programs should be limited to high-risk children and high-risk teeth.

Prevention And Control Of Periodontal Diseases

Periodontal diseases, caused by specific bacteria in dental plaque, affect most adults at some point in their lives. The mildest and most common form of periodontal disease is gingivitis. Over time, periodontitis, the more severe form of periodontal disease, can lead to the destruction of the soft tissue and bone that anchor the teeth into the jaw. Lacking support, teeth can loosen and be lost.

Periodontal diseases can be prevented and controlled through an array of mechanical and chemical means (Ismail and Lewis 1993, AAP 1996). Conscientious oral hygiene and professional oral cleanings to reduce plaque can reverse gingivitis (Löe et al. 1965). Methods for personal oral hygiene include toothbrushing and flossing, which may be augmented by over-the-counter and prescription mouthrinses with antimicrobial action.

Community Programs to Prevent Gingivitis

With the confirmation of specific bacteria in dental plaque as the cause of gingivitis, public health officials began to seek ways to educate the public about plaque control in community settings, primarily in schools. These efforts have had equivocal results. Although knowledge and attitudes were enhanced in demonstration programs, improvements in plaque levels and gingivitis were short-lived in clinical trials (Horowitz et al. 1980).

Prevention of Periodontitis

Tobacco use is a major risk factor for the development and progression of periodontal diseases, and proven strategies aimed at reducing tobacco use should aid in the prevention of periodontitis. The following section on oral and pharyngeal cancers includes a discussion of such intervention strategies.

Until recently, most interest in controlling tobacco use reflected concerns about oral cancers. As appreciation of the role of tobacco in the progression of periodontal diseases and tooth loss increases, attention to these oral health effects may increase attention to tobacco cessation in primary oral health care. Periodontitis can also be a complication of poorly controlled diabetes. (See Chapters 3 and 5 for a discussion of other periodontal risk factors; Chapter 5 discusses the connection between periodontal disease and diabetes.)

Some efforts have been directed at alerting dental practitioners to the need to educate patients about diseases affecting the periodontal tissues (Bader et al. 1990, Brown and Spencer 1989). These efforts have met with some success, but they tend to reach only those people who already use dental services. Currently, there are no broad community-based intervention programs that address periodontal diseases.

Summary

Gingivitis can be controlled with available methods, and its control is the principal way to prevent periodontitis. However, the currently available methods are individually or professionally based and require conscientious oral hygiene practices and regular dental visits. Although some schools instruct children in proper methods of oral hygiene, no community methods, other than programs designed to discourage tobacco use, are available for preventing gingivitis or periodontitis in the general population.

Prevention And Control Of Oral And Pharyngeal Cancers

The term oral and pharyngeal cancers refers to a diverse group of tumors affecting the oral cavity and pharynx, the majority of which are squamous cell carcinomas. Usually included are cancers of the lips, tongue, pharynx, and oral cavity. These malignancies are among the most debilitating and disfiguring of all cancers. More than 30,000 new cases of oral and pharyngeal cancers are diagnosed each year, and more than 8,000 people die annually from these diseases. The overall 5-year survival rate (52 percent) has not changed in the past four decades (Murphy et al. 1995, Silverman 1998).

Primary risk factors for oral cancers in the United States are the use of tobacco and alcohol products and, for lip cancer, exposure to sun. Tobacco and alcohol independently increase the risk of oral and pharyngeal cancers and also act synergistically, so that persons who use both are at much higher risk than those who use only one. Other risk factors include insufficient fruits and vegetables in the diet, failure to use ultraviolet protection, and infection with certain viruses (Winn et al. 1998).

In 1996 CDC convened the National Oral Cancer Strategic Planning Conference to develop strategies for preventing and controlling oral and pharyngeal cancers in the United States. The conference, which was co-sponsored by the National Institute of Dental and Craniofacial Research and the ADA, included over 125 experts in oral and pharyngeal cancer prevention and control, treatment, and research (CDC 1998). These experts developed recommendations concerning public advocacy, collaboration, and coalition building; public education; professional education and practice; and data collection, evaluation, and research. An ongoing multidisciplinary subgroup from that conference, the Oral Cancer Working Group, met in 1997 and again in 1999 to share information on progress made and to discuss steps to implement a national plan. This group's work will augment existing interventions directed at the reduction of tobacco use, for which several community- based interventions have already been shown to be effective. The group is also developing several statewide models for the prevention and early detection of oral and pharyngeal cancers.

Many recommendations from the 1996 Strategic Planning Conference relate to the inclusion of primary prevention (i.e., reducing risk factors) and early detection. These include a recommendation that because people at high risk for oral cancers are more likely to visit a physician than a dentist, and because physicians may be less likely than dentists to perform an oral cancer examination on such patients, all primary care providers should assume more responsibility for counseling patients about behaviors that put them at risk for developing these cancers; should perform oral cancer examinations on all patients who are at high risk for developing the disease because of tobacco use or excessive alcohol consumption; and should refer patients to the appropriate specialist for management of suspicious oral lesions (CDC 1994c, Elwood and Gallagher 1985, Lynch and Prout 1986, Prout et al. 1990, Yellowitz and Goodman 1995). Further research is needed to better define screening parameters. Comprehensive education of medical and dental practitioners in diagnosing and promptly managing early lesions was recommended to facilitate the multidisciplinary collaboration needed to detect oral cancers in their earliest stages. Furthermore, because of the public's lack of knowledge about the risk factors for oral cancers and because these diseases can often be detected in the early stages, it is also recommended that programs to raise the public's awareness of oral cancers (including their risk factors, signs, and symptoms) be increased.

Community-based Interventions

Community-based interventions for oral and pharyngeal cancer prevention have depended on tobacco control programs.

School-based Prevention Programs

On average, more than 3,000 children and teenagers become regular smokers each day (USDHHS 1994). Prevention efforts aimed at young people are extremely important because nearly all initiation of tobacco use in the United States occurs by age 18. Moreover, the finding that the earlier that smoking begins the more likely it is to lead to heavy use in adulthood makes preventing tobacco use among school-age youth all the more critical (CDC 1994a).

Programs identifying the social influences that foster tobacco use in schoolchildren and teaching skills to resist such influences have yielded consistent and significant results. Reductions or delays in adolescent smoking have been documented, ranging from 25 to 60 percent and persisting from 1 to 4 years (CDC 1994b). The interventions were based on a CDC review of published research, including the conclusions of the National Cancer Institute's (NCI) Expert Advisory Panel on School-based Smoking Prevention Programs and findings from the 1994 Surgeon General's report, Preventing Tobacco Use Among Young People (CDC 1994b). The Guidelines for School Health Programs to Prevent Tobacco Use and Addiction cites seven recommendations (CDC 1994a,b):

1. Develop and enforce a school policy on tobacco use.
2. Provide instruction about the short- and long-term negative physiologic and social consequences of tobacco use, social influences on tobacco use, peer norms regarding tobacco use, and refusal skills.
3. Provide tobacco-use-prevention education in kindergarten through 12th grade; this instruction should be especially intensive in junior high or middle school and reinforced in high school.
4. Provide program-specific training for teachers.
5. Involve parents or families in support of school-based programs to prevent tobacco use.
6. Support cessation efforts among students and all school staff who use tobacco.
7. Assess the tobacco-use-prevention program at regular intervals.

A major part of most successful interventions has been the decrease of illegal sales to minors. This strategy has been accomplished by increasing merchant education and enforcement of laws prohibiting tobacco sales to minors under 18 and increasing the cost of cigarettes (CDC 1994a,b, Lewit et al. 1997, Lynch and Bonnie 1994). All 50 states and the District of Columbia have laws prohibiting the sale of tobacco, including smokeless (spit) tobacco, to minors.

In recent years, attempts to prevent and reduce the use of spit tobacco have increased. These informational and educational efforts have largely targeted baseball clubs, Little League baseball teams, and 4-H Club members. A major new initiative, the National Spit Tobacco Education Program, has been launched by Oral Health America, with support from NIH and CDC and funding largely from the Robert Wood Johnson Foundation in collaboration with the Major League Baseball Players Association, to help break the link between spit tobacco and Major League Baseball.

Other Program Models

The majority of community programs designed to prevent or reduce the use of tobacco products have focused on cigarette smoking. Initially, NCI funded randomized trials of interventions to prevent smoking in adolescents and promote cessation in adults. The value of multiple interventions delivered through multiple channels was confirmed in NCI's Community Intervention Trial for Smoking Cessation (COMMIT 1995a,b).

Findings from more than 100 intervention trials continue to provide important information abouthow to reach smokers and potential smokers. A major conclusion from these studies is that largescale reductions in smoking prevalence are unlikely when interventions focus on the individual, but that interventions can be effective when community-based. Further, researchers found a statistically significant difference in the proportion of light-to-moderate (but not heavy) smokers who quit in the intervention communities compared with control communities (COMMIT 1995a,b, Klausner 1997, NCI 1995). Findings from COMMIT and other studies in the United States and abroad led to planning for ASSIST (American Stop Smoking Intervention Study for Cancer Prevention). In 1990, California adopted the ASSIST model, and early success in the California Statewide Tobacco Control Program clearly showed an impact on per capita cigarette consumption in that state compared with consumption in the United States as a whole (Manley et al. 1997a,b, Shopland 1993). The ASSIST model uses surveillance systems that allow for time-series analysis designs comparing intervention and control communities. Media-led tobacco control campaigns, as well as efforts to increase state excise taxes on cigarettes and thereby discourage teenagers from smoking, are included in the model.

There are now dedicated tobacco-control coalitions in all 50 states, and the Agency for Healthcare Research and Quality (formerly Agency for Healthcare Policy and Research) has developed clinical practice guidelines on smoking cessation to aid health professionals in interventions with patients (Fiore 1997). Although the major focus in reducing the risk for oral and pharyngeal cancers has been on tobacco cessation programs, reduction in alcohol use is clearly indicated. Currently, alcoholic beverages carry the Surgeon General's warning label stating that pregnant women should not drink because of the risk of birth defects and admonishing that alcohol impairs the ability to drive and operate machinery and may cause other health problems. Many communities have programs that stress responsible drinking by adults related to the use of motor vehicles and completely discourage drinking among young drivers. Community approaches have also been developed to discourage drinking among young people. Targets are youth and adults who are at risk for alcohol-related problems, such as college students who may need to develop skills to avoid binge drinking, or women attending women's clinics who might not know the risk of fetal alcohol syndrome. Because alcohol use, like tobacco use, usually begins in adolescence, development and testing of community- and school-based programs that provide youth with the skills to avoid alcohol use are warranted.

Early Diagnosis of Oral and Pharyngeal Cancers

Primary care providers can counsel patients about lifestyle behaviors that increase the risk for oral cancers. Dental as well as medical personnel have provided successful tobacco control programs in their offices (see Chapter 8). Generally, Americans are ill-informed about the risk factors as well as the signs and symptoms of oral cancers (Horowitz and Nourjah 1996, Horowitz et al. 1995). The mass media have paid little attention to the topic, and health education textbooks are nearly devoid of discussion (Canto et al. 1998b, Chung et al. 2000, Gold and Horowitz 1993, Horowitz et al. 1998). The scant attention that has been paid to oral cancers has focused on the role of spit tobacco.

At present, the principal test for oral and pharyngeal cancers is a comprehensive clinical examination that includes a visual/tactile examination of the mouth, full protrusion of the tongue with the aid of a gauze wipe, and palpation of the tongue, floor of the mouth, and lymph nodes in the neck. The U.S. Preventive Services Task Force concluded that there was insufficient evidence to recommend for or against routine screening for oral cancers, but noted that clinicians should remain vigilant for signs and symptoms of oral cancers and premalignancy in people who use tobacco or regularly use alcohol (USPSTF 1996). The Canadian Task Force on Periodic Health Examination (1997) states that although there is insufficient evidence to include or exclude screening for oral cancers from the periodic health examination for the general public, those at high risk (smokers and heavy drinkers) over 60 warrant an annual oral cancer exam by a physician or dentist (Lewis and Ismail 1995). The American Cancer Society recommends annual examinations for individuals 40 and older and for individuals who are exposed to known risks. Nevertheless, a 1992 national survey showed that only 15 percent of U.S. adults reported ever having had an oral cancer examination (Horowitz and Nourjah 1996).

There are large gaps in knowledge of the efficacy of oral cancer examinations and the effectiveness and cost-effectiveness of community approaches to early detection of oral cancers. Methodologies and settings differ across studies. Moreover, these studies do not provide definitive evidence supporting the oral cancer exam, and there have been no controlled clinical trials for defining the effectiveness of screening programs. Further research is thus needed.

Summary

Although no school- or community-based interventions specifically designed for the prevention or early detection of oral and pharyngeal cancers are now in place, scientists representing the agencies in the newly formed oral cancer consortium have begun to develop statewide model protocols, beginning with the state of Maryland. In the meantime, any program that aims at eliminating tobacco use will reduce the primary risk factor for oral and pharyngeal cancers, along with other tobacco-related diseases. The evidence on the effectiveness of school-based programs to prevent tobacco use and addiction among children and adolescents provides strong support for their use as part of the school health education curriculum. Further, other community-based interventions such as COMMIT and ASSIST are recommended because they have demonstrated effectiveness in getting light-to-moderate smokers to quit. After reviewing the evidence, an expert panel convened by AHCPR (now the Agency for Healthcare Research and Quality) recommended that all primary care clinicians be trained to provide smoking cessation activities (see Chapter 8). In addition, providers should perform oral cancer examinations on high-risk persons regularly. The recommendation to use all of these interventions to prevent or cease tobacco use in communities is based on expert opinion.

Oral cancers occur in sites that lend themselves to early detection by most primary health care providers and, to a lesser extent, by self-examination. Heightened awareness in the general population could help with early detection and could stimulate dialogue between patients and their primary health care providers about behaviors that may increase their risk. Recent advances in understanding the molecular events involved in developing cancer might provide the tools needed to design novel preventive, diagnostic, prognostic, and therapeutic regimens to combat oral cancers. Acquiring greater knowledge of the biology, immunology, and pathology of the oral mucosa may also help reduce the morbidity and mortality from these cancers.

Prevention And Control Of Craniofacial Birth Defects

The causes of craniofacial birth defects are often complex and multifactorial—the result of gene-environment interactions occurring from the time of conception to birth. Even when a mutation in a single gene has been discovered as the cause of a particular syndrome, there can be considerable variation in susceptibility, with some infants showing little or no sign of a problem and others experiencing multiple organ defects.

The work to complete the mapping and sequencing of the human genome will undoubtedly shed light on the hundreds of genes involved in craniofacial development and provide details on when and how they function in development. This knowledge may in turn lead to gene therapies that restore or "rescue" the function of a defective gene and thus prevent the anomaly.

Craniofacial defects also may occur because the susceptible embryo or fetus was exposed to an environmental teratogen, a diminished oxygen supply, or a deficit in an essential nutrient. Chapter 5 reports an association between low-birth-weight, premature babies who may show other subtle craniofacial anomalies and mothers with chronic oral infectious disease. In addition, diets poor in folic acid increase the risk of spina bifida and possibly clefting syndromes. Clinical trials using vitamin supplementation with varying levels of folic acid are under development to determine if they can lower the risk of clefts in high-risk pregnancies. Outcomes of clinical trials of nutrient supplementation in pregnancy may lead to new nutritional guidelines and the development of enriched food products, which can form the basis for community-wide health promotion and disease prevention programs.

Given the array of variables affecting prenatal growth and development, the key to public health programs aimed at preventing birth defects lies primarily in health promotion and education campaigns. Individuals need to be made aware of known risk and protective factors in pregnancy. Such programs should emphasize the importance of good nutrition, avoidance of tobacco and alcohol use, and prenatal care. Education includes knowledge about the teratogenic effects of prescription drugs, such as the antiepileptic drug phenytoin and the retinoic acid drugs used to treat cystic acne.

Summary

As information from developmental biology, genetics, and epidemiologic and clinical studies accrues, dental care providers are better positioned to provide counseling. The public is best served by health promotion and disease prevention campaigns that communicate findings about risk and protective factors in pregnancy.

Prevention And Control Of Intentional And Unintentional Injury

Intentional and unintentional injuries are related to behaviors and are thus amenable to prevention. As studies of motor vehicle and sports injuries have demonstrated, injuries are frequently due to a sequence of predictable events, and a public health approach can be successful in injury prevention and control.

The interventions that have proved to be most effective in controlling injuries have been passive; that is, they do not require the individual to participate. Examples include the use of environmental controls such as vehicle and roadway design, speed limits, passenger restraints, and airbags to prevent injuries from motor vehicle collisions (Karlson 1992, Smith and Falk 1987). Passive measures such as these are more easily implemented at the state or federal level. However, many preventive measures for oral-facial injuries have been directed at the individual and professional health service levels, rather than at the population at large (see Table 7.7).

Craniofacial Injuries

The principal causes of craniofacial injuries are motor vehicle collisions, falls, assaults, and sporting activities. Except in relation to sports, injuries to the craniofacial region have received little attention.

These injuries are hardly insignificant, however, and efforts to prevent them are gaining acceptance. For example, to increase public awareness of the importance of facial protection, the inaugural National Facial Protection Month was celebrated in April 2000. This national campaign, providing information to the media and the public, was sponsored by the American Association of Oral and Maxillofacial Surgeons (AAOMS 2000).

Motor vehicle collisions are the leading cause of death during the first three decades of life in the United States and the leading cause of death from injury over most of the life span (Baker et al. 1992). Data from multiple sources indicate that craniofacial injuries account for a substantial subset of these injuries annually (USDOT 1998). Even though it is likely that passive measures enacted to reduce fatalities have reduced nonfatal craniofacial injuries, no supporting data exist.

Various sources report the number of motorcycle-and pedal-cycle-related craniofacial injuries. Data from the National Electronic Injury Surveillance System indicate that head injuries account for 50 percent of all pedal-cycle-related injuries; of those, bicycle-related events accounted for 19 percent of all facial injuries within the study period (McDonald 1994). In similar studies, tricycle-related incidents were found to be responsible for up to 61 percent of injuries to the head, face, or mouth (CDC 1987, USCPSC 1986). Motorcycle injuries are a major source of fatal and nonfatal head trauma in the United States (Rivara et al. 1988).

Helmet use reduces head and facial injuries among bicyclists (Acton et al. 1995, Grimard et al. 1995, Rivara et al. 1997) and motorcyclists (Bachulis et al. 1988, Johnson et al. 1995, Lee et al. 1995) by up to 50 percent. Health promotion efforts have increased acceptance at the community level for helmet use by bicyclists; however, helmet use regulations vary by state (Sacks et al. 1996) and with the public whim (Sosin et al. 1990). Over a dozen states currently have bicycle helmet laws, and half of the states have motorcycle helmet laws (NCHS 1992).

Many authors have described craniofacial injuries related to sports. Information is usually obtained from community or regional surveys of injuries or mouthguard use and effectiveness. Craniofacial injuries sustained during sporting activities are a major source of nonfatal injury and disability (Baker et al. 1992), possibly accounting for up to one third of all sports injuries (Cathcart 1982, Meadow et al. 1984). The increasing participation of women in competitive sports means that young women should be alerted to the risks and advised of the need for additional protective gear as appropriate.

The most comprehensive data on the effectiveness of protective equipment have been collected by agencies such as the National Alliance of Football Rules Committee, the National Collegiate Athletic Association, and the U.S. Consumer Product Safety Commission. Data on craniofacial injuries from participation in football before and after the enactment of mandatory mouthguard regulations indicate a significant decline in craniofacial injuries (Sane 1988). Further, the U.S. Consumer Product Safety

Commission's review of National Electronic Injury Surveillance System data showed that mouth injuries were more frequent in baseball than in any other sport monitored (USCPSC 1981). These combined reports were instrumental in implementing policies for protective equipment use in these two sports. (See Box 7.2, Sports Injuries and Oral-Facial Trauma.)

Research on elderly and disabled individuals has led to the development of safety measures to prevent unintentional injuries from falls in the home. These include installing adequate lighting and handrails, using nonskid materials on floors and in bathrooms, and positioning furniture to reduce the risk of tripping. Wider distribution and adoption of such safety measures should lower the risk of oral and craniofacial injuries due to falls for the general population as well, not only in the home but also in the workplace and other settings.

Summary: Prevention of Craniofacial Injuries

Health education and injury prevention campaigns addressing the need for protective gear in sports and cycling activities can increase awareness and use. More rapid adoption can occur through legislation or regulation. Greater dissemination of safety measures for home and workplace can similarly lower the risk of falls and other unintentional injuries. With regard to reducing intentional injuries in the United States, current and ongoing policy discussions, legislative proposals, and research efforts are necessary first steps toward appropriate programs.

Oral Health Promotionand Disease Preventionknowledge Andpractices

To take full advantage of emerging science-based health and health care practices,individuals, health care providers, and policymakers need to be sufficiently informed that they can take appropriate actions for themselves, for those for whom they have responsibility, and for the community at large. For the individual, these actions include brushing with a fluoride-containing dentifrice for caries prevention, brushing and flossing to prevent gingivitis and periodontal diseases, and avoiding tobacco and other substances that are detrimental to health.

Lack of knowledge can affect care. If parents are not familiar with the importance and care of their child's primary teeth or if they do not know that dental sealants exist, they are unlikely to take appropriate action or seek professional services. If the public is not aware of the benefits of community water fluoridation, public referenda and funding for such interventions are not likely to be supported. Similarly, if individuals do not know that an oral cancer examination exists, they may not ask about the need for one. However, it is well established that knowledge alone will not necessarily lead to appropriate practices. For example, even if individuals know that tobacco use is unhealthful and that it contributes to multiple life-threatening illnesses, some continue to smoke. The majority of people who need such information most—those in low-income groups and those with lower levels of education—also are the ones who lack the information and skills (oral health literacy) to ask for and obtain specific preventive services or treatment options. Health professionals are in an ideal position to provide up-to-date health information and care to their patients. They also have an opportunity to enhance their knowledge and practices as well as increase their communication to patients about the procedures they provide and the reasons for these procedures.

Few national studies of public and professional knowledge, attitudes, and practices exist. Highlights from these as well as from state and local studies that evaluated the prevention of dental caries, periodontal diseases, and oral cancers are provided below. Generally, the public is unable to discriminate between methods that prevent dental caries and those that prevent periodontal diseases (Corbin et al. 1985, Gift et al. 1994). This confusion has been attributed to the prevailing marketing message that refers to them as "plaque diseases" preventable by thorough tooth cleaning with a toothbrush and floss. In addition, the general public and health care providers are not fully informed about the relative value of fluoride and the appropriate recommended applications of regimens to prevent dental caries (Corbin et al. 1985, Gallup 1992, Gift et al. 1994, O'Neil 1984). More work is needed to improve knowledge and practices related to oral cancer prevention as well. As with other areas of investigation, additional survey research is needed to better understand findings to date and to develop tailored interventions. Research is ongoing to improve the design of survey instruments and the wording of questions to address cultural and ethnic differences and interpretations.

Dental Caries Prevention

The Public

Most members of the general public, regardless of socioeconomic level, tend to believe that the best way to prevent dental caries is by brushing their teeth (Corbin 1985, Gift et al. 1994, O'Neil 1984). In the 1990 National Health Interview Survey (NHIS), respondents were asked the purpose of adding fluoride to public drinking water. About two thirds of the respondents 25 to 65 years of age knew that water fluoridation helps prevent caries, compared with only 51 percent and 49 percent of those 65 and older and 18 to 24 years of age, respectively. Blacks and Hispanics were less likely to know the value of this preventive procedure than whites. In the same survey, when asked to indicate the one best way to prevent tooth decay from five answers (limiting sugary snacks, using fluorides, chewing sugarless gum, brushing and flossing the teeth, and visiting the dentist every 6 months), only 7 percent of the respondents answered correctly that fluoride was the most effective (Gift et al. 1994). More than two thirds said tooth brushing and flossing were the most effective. These results paralleled those of earlier studies (Gift et al. 1994, O'Neil 1984). A lower perceived value of fluorides by the public in preventing dental caries also was seen in the 1985 NHIS (Corbin et al. 1985). In a survey of knowledge and beliefs of the public, dentists, and dental researchers about the best way to prevent dental caries, the public and the dentists identified tooth brushing, whereas dental researchers unanimously ranked fluorides, as most important (O'Neil 1984). A small study among Latina mothers showed that they believed that brushing with baking soda is a good way to prevent dental caries; they knew little about brushing with a fluoride-containing dentifrice (Watson et al. 1999).

Dental sealants and appropriate use of fluoride are critical for caries prevention. In the 1990 NHIS, about 32 percent of the public had heard of dental sealants, but among those only three fourths knew the purpose of this preventive measure (Gift et al. 1994). In 1991 the Gallup Organization conducted a poll for the American Academy of Pediatric Dentistry among a national sample of 1,200 parents of children 16 years and younger. The results indicated that only 58 percent believed fluoride to be very important to a child's oral health; another 36 percent considered it to be somewhat important. Eight of 10 parents did not know when a child should be prescribed fluoride supplements, and virtually no one knew when supplements should be stopped. Only 25 percent of parents in non-fluoridated communities reportedly give their children fluoride supplements (Gallup 1992).

Health Care Providers

In a national survey of U.S. dental hygienists' knowledge, opinions, and practices regarding dental caries etiology and prevention, over 90 percent agreed that "adults benefit from the use of fluorides" and that "root surface caries is an emerging problem." A little less than one third did not provide fluoride treatments to adults. This same survey found that only 57 percent of the respondents recognized remineralization as fluoride's most important mechanism of action; rather, flossing was selected as the most effective procedure for preventing caries in adults. Also, only 18 percent reported providing the recommended time for acidulated phosphate fluoride (APF) gel treatment (Forrest 1998). A city-based survey of dentists and dental hygienists found that nearly 70 percent of the offices used lower than recommended topical fluoride application times and that some of the fluoride products reportedly used had not been clinically tested (Warren et al. 1996).

Periodontal Disease Prevention

The Public

In the 1990 NHIS the majority of household respondents (79 percent) could identify one common sign of "gum" disease. Level of education was directly related to knowledge of gum disease. Eighty-nine percent of those with more than a high school level of education were able to name a common sign of gum disease, compared with 79 percent of those with a high school education and 60 percent of those with less than a high school education (Gift et al. 1994).

A Roper report on oral health surveyed more than 1,000 adults 18 and older. Eighty percent reported that they did not believe they have had periodontal disease. However, 70 percent reported having experienced at least one symptom of gum disease—bleeding gums; swollen, painful, or receding gums; a change in bite; or loose teeth. Although 41 percent of the respondents said that losing their teeth was their greatest fear regarding oral health, only 38 percent who had bleeding gums said they told their dentists about the problem. Further, only 30 percent of the respondents who had experienced warning signs of gum disease were worried about developing periodontal problems in the future. Fifty-eight percent knew that plaque is the main cause of gum disease and that flossing alone will not prevent gum disease, whereas 77 percent knew that brushing alone would not prevent gum disease. The majority (90 percent) knew that gum disease could strike anyone at any age (Roper Report 1994).

In a recently reported study on the oral hygiene practices of a convenience sample of 34,897 users and nonusers of tobacco products who obtained dental care in 75 dental practices, 74 percent reported brushing twice a day and 36 percent reported flossing once daily (Andrews 1998). Tobacco users brushed and flossed much less frequently than nonusers. Patients with more than a high school education were less likely to use tobacco products and more likely to brush at least 2 times a day and floss daily than were those with less education.

A 1996 study of 1,000 U.S. adults showed that nearly one third (29 percent) of respondents were extremely or very concerned about getting gum disease. Concern was highest among younger respondents 18 to 49 years of age and those who very or somewhat frequently experienced bleeding gums. Only 6 percent said they frequently suffered from bleeding gums (2 percent very frequently and 4 percent somewhat frequently). Only 13 percent said a dental professional had diagnosed them with any kind of periodontal disease (gingivitis, pyorrhea, and periodontitis). Older respondents were somewhat more likely than younger ones to have been diagnosed with gum disease, and 17 percent reported experiencing gingival bleeding occasionally (Andrews 1998).

Health Care Providers

Studies of dental professionals regarding periodontal disease prevention practices are limited. In 1989, Dental Products Report launched a study to determine the involvement of general practitioners in periodontal care. Overall, general dentists and their hygienists have become more involved in the periodontal exam phase of patient treatment. This positive trend suggests that periodontal diagnosis and treatment are well integrated into general practice. For example, when asked “what phases of periodontal treatment are you providing at present?” 100 percent reported gingival exam and evaluation, 97 percent reported pocket probing, and 88 percent reported providing patient education. The majority of dentists (67 percent) used as many as six measurement sites per tooth. Nearly all (93 percent) reported having a referral relationship with a periodontist (Dental Products Report 1996).

Oral Cancer Prevention and Early Detection

The Public

U.S. adults generally are ill-informed regarding risk factors for and signs and symptoms of oral cancers. Further, a 1990 national survey found that only 14 percent of adults 40 and older reported that they had ever had an oral cancer examination. Of those, only 7 percent had had an exam within the last year (Horowitz et al. 1995). In a statewide survey in Maryland, 85 percent of the adults claimed to have heard of oral or mouth cancer, but only 28 percent reported ever having an oral cancer examination (Horowitz et al. 1996). A state-based study of veterans—a population at high risk for oral cancers—found that they were ill-informed and misinformed about these cancers (Canto et al. 1998a). Finally, a study among Latino youths who reported use of tobacco and alcohol found that they, too, were not knowledgeable regarding risk factors for oral cancers (Canto et al. 1998b).

Health Care Providers

A recent national pilot survey of U.S. dentists found that the respondents’ knowledge regarding risk factors for and signs and symptoms of oral cancers and their reported practice of examination procedures were limited (Yellowitz et al. 1998). Most respondents believed they were adequately trained to provide oral cancer examinations, and 70 percent provided annual oral cancer exams to patients 40 and older. Seventy-four percent reported their knowledge of oral cancers to be current, yet only 30 percent correctly identified the age cohort most frequently diagnosed with oral cancers. Further, less than 50 percent correctly identified the stage at which most oral cancer lesions are diagnosed, and nearly one third of respondents could not identify the two most common sites of these lesions. Although 86 percent claimed to assess their patients' current tobacco use, only 50 percent assessed current alcohol use; relatively few dentists assessed past alcohol or tobacco use. There was a modest amount of misinformation as well. For example, 65 percent believed, incorrectly, that ill-fitting dentures and partials were a risk factor for oral cancers, and 47 percent believed, also incorrectly, that poor oral hygiene was a risk factor. Further, although the majority of dentists claimed to provide oral cancer examinations to the majority of their patients, a large proportion did not palpate the lymph nodes—part of a comprehensive oral cancer examination. These results confirm an earlier study conducted among a convenience sample of Maryland dentists and physicians in that both groups believed their knowledge and skills related to oral cancer prevention and early detection to be wanting (Yellowitz and Goodman 1995).

A recent national survey among U.S. dental hygienists found that although 98 percent agreed that oral cancer examinations should be provided annually for adults 40 and older, only 64 percent reported performing such an exam 100 percent of the time, and nearly 17 percent reported not performing an exam at any time (Forrest 1998). Further inconsistencies were found between knowledge of risk factors and performance. For example, although 94 percent correctly identified alcohol use as a risk factor for oral cancer, only 49 percent asked about alcohol use.

Less than a majority (45 percent) reported their knowledge of oral cancers to be current. A majority (61 percent) believed they were adequately trained to palpate lymph nodes; still, only 24 percent reported routine palpating of lymph nodes, while 51 percent indicated they did not do so at any time.

Summary

Findings from national surveys, together with those from local studies, suggest that there are opportunities for enhanced educational efforts for both the public and health professionals to improve oral health. These studies focus on the public and the dental profession for selected diseases. New research is needed to assess knowledge, attitudes, and practices of all health professionals and for other conditions and risk factors related to oral health as well.

Building Upon Success

As research and technology advance our understanding of the causes of major craniofacial diseases and disorders and lead to improved methods of diagnosis, treatment, and prevention, opportunities for new community-based prevention programs will grow. Ultimately, the application of any preventive intervention is driven by a combination of individual behaviors, community interventions, and professional practice. Only a few studies have taken into account all three spheres of action in determining health outcomes in a community (Arnljot et al. 1985, Chen et al. 1997). Our knowledge of the effects of multiple interventions is limited because most interventions were developed and tested singly.

In the past half century, however, advances in our understanding of oral diseases and the application of multiple preventive measures have resulted in continuing declines in the prevalence and severity of both dental caries and periodontal diseases for a sizeable majority of Americans. For dental caries, for example, experts now believe that most people can maintain a low risk of the disease by a combination of drinking fluoridated water and brushing daily with a fluoride dentifrice. They recommend that additional provider- and community-based dental prevention programs be targeted to high-risk individuals and groups.

Many of the studies reviewed in this chapter were conducted when higher rates of caries prevailed, community water fluoridation was less widespread, and use of fluoride dentifrices and supplements was not as common as today. These facts must be taken into consideration in contemporary decision making by public health professionals and policymakers. The validity and reliability of recommendations will benefit from the systematic reviews of the scientific evidence by the Task Force on Community Preventive Services (2000) to be included in a Guide to Community Preventive Services. Oral health promotion strategies are among those currently being evaluated.

Future innovations include implementing programs in new settings, such as workplaces, senior centers, and nursing homes, where individuals at high risk can be reached. Even if these programs are more expensive, the yield may be worth it if they reach those at high risk for disease. Similarly, focusing community-based interventions on populations at greatest risk will make optimal use of available resources. However, continued research to understand risk and improve ways to measure it is equally important for the success of these ventures.

A review of progress in reaching the Healthy People 2000 oral health objectives reveals relatively little gain across many of the objectives (Table 7.8). Progress in the next decade will require diligent efforts to identify public health problems, mobilize resources, and ensure that the necessary conditions are in place and crucial services received. Public health agencies will be instrumental in carrying out these functions, and state and local dental directors can perform a leadership role. Box 7.3 describes the public health services that are essential if a community is to realize fully the benefits of available disease prevention and health promotion interventions.

Findings

- Community water fluoridation, an effective, safe, and ideal public health measure, benefits individuals of all ages and socioeconomic strata. Unfortunately, over one third of the U.S. population (100 million persons) are without this critical public health measure.

- Effective disease prevention measures exist for use by individuals, practitioners, and communities. Most of these focus on dental caries prevention, such as fluorides and dental sealants, where a combination of services is required to achieve optimal disease prevention. Daily oral hygiene practices such as brushing and flossing can prevent gingivitis.

- Community-based approaches for the prevention of other oral diseases and conditions, such as oral and pharyngeal cancers and oral-facial trauma, require intensified developmental efforts.

- Community-based preventive programs are unavailable to substantial portions of the underserved population.

- There is a gap between research findings and the oral disease prevention and health promotion practices and knowledge of the public and the health professions.

- Disease prevention and health promotion approaches, such as tobacco control, appropriate use of fluorides for caries prevention, and folate supplementation for neural tube defect prevention, highlight opportunities for partnerships between community- based programs and practitioners, as well as collaborations among health professionals.

- Many community-based programs require a combined effort among social service, health care, and education services at the local or state level.

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