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Commentary

Science, Politics, and Communication: The Case of Community Water Fluoridation in the US

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A B S T R A C T

Community water fluoridation (CWF) and its effect in reducing the burden of dental caries (tooth decay) is considered one of the 10 public health achievements in the 20th century. In the U.S., three-quarters (74.4%) of people on community water supplies have optimally fluoridated water, and each year approximately 90 communities actively consider starting or discontinuing CWF. CWF exists within the policy environment and includes actions taken by local community councils, health and water boards, and groups; state legislatures and health departments; national regulatory and science agencies; independent science entities; and professional and nonprofit organizations. Epidemiologists have been in the forefront of CWF. Experience with the past 70 years reveals that the coming decades will bring additional questions, recommendations, and challenges for CWF. The continued involvement of epidemiologists as part of multidisciplinary teams is needed in research, surveillance, peer review of studies, assessment of systematic review findings, and in the translation and communication of science findings to audiences with limited science/health literacy. This chapter's purpose is to 1) examine how epidemiologic evidence regarding CWF has been translated into practice and policy, 2) examine how recommendations for and challenges to CWF have affected epidemiologic research and community decision-making, and 3) identify lessons learned for epidemiologists.

Introduction

Community water fluoridation (CWF) was named by the Centers for Disease Control and Prevention (CDC) as one of the 10 great public health achievements in the 20th century [1,2]. CWF is recognized for its ability to prevent the occurrence (incidence) and reduce the burden (prevalence) of dental caries (tooth decay), the most common chronic disease among both children and adults [3]. Dental caries was extremely prevalent in the mid-century and one that persists today at high levels, especially in vulnerable and compromised populations. The primary prevention of dental caries reduces pain, infection, and the need for, the cost of, and trauma related to treatment. CWF's safety, effectiveness, ease and low cost of implementation, and its ready access to all who reside in the community, regardless of socioeconomic status, are the key attributes that reflect an intervention that supports health equity. As its name implies, CWF is a community-wide intervention that reflects

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the critical interface between science, policy, and practice. As such, CWF exists within an extensive policy environment and includes actions at local, state, and national levels. Findings from early clinical trials starting in the 1940s demonstrated that adjusting the fluoride concentration of the water supply prevented between 50% and 70% of dental caries in the community's population of children over the subsequent years. These findings, and others, have informed community-level policy-maker decisions to adjust ("add") fluoride in their community water supply to an optimal concentration. Despite CWF's role in addressing some of the inequalities in dental caries prevalence in communities throughout the United States (and elsewhere) for over 70 years, this intervention still requires the active engagement of epidemiologists working with others in research, surveillance, policy, education, and communication. The purpose of this article is to examine how epidemiologic evidence regarding CWF has been translated into practice and policy; examine how recommendations for and challenges to CWF have affected epidemiologic research and community decision-making; and to identify lessons learned from this community-wide intervention. The CWF-specific lessons learned are interspersed throughout the article, identifying what epidemiologists can and should do to help maintain and continue to build the science base for water fluoridation. In addition, this case highlights general lessons learned that have relevance to other long-standing community-based preventive interventions.

Background

Fluoride and dental caries

Fluoride is a naturally occurring ion found in soil and water, usually in very low concentrations. Dental caries is a destructive and potentially life-threatening disease in which acids, produced by bacterial breakdown of dietary carbohydrates in dental plaque, dissolve (demineralize) the surfaces of teeth. Fluoride acts in a variety of ways to protect teeth from the continued challenges of bacterial acids. Epidemiologic research has determined the concentration of fluoride in water needed to protect teeth, while minimizing the prevalence of dental fluorosis. Dental fluorosis is a change in the appearance of the tooth enamel, most commonly appearing as symmetrical lacy white markings in its milder forms. Most dental fluorosis from CWF is mild and not noticeable to the layperson. Noticeable fluorosis (i.e., moderate or severe) is usually due to the chronic use of naturally occurring high fluoride concentrations in drinking water, chronic excess fluoride toothpaste ingestion, or inappropriate fluoride prescriptions for children. Dental fluorosis only develops while the teeth are growing in young children and does not progress to be more noticeable; older children and adults cannot acquire dental fluorosis. CWF is the process of upwardly adjusting the amount of fluoride occurring naturally in community water supplies to achieve the current recommended level of fluoride in the water supply, which is 0.7 mg/L (parts per million [ppm]) [4]. CWF contributes to dental caries prevention through all ages, and prevents the occurrence (incidence) of dental caries and reduces the burden (prevalence) of dental caries in children and adults by about 25% [5].

Role of epidemiologists and other key players

Epidemiologists have played, and continue to play, many roles in the implementation and dissemination of science, policy development, and communication (see Fig. 1). Epidemiologists have contributed to the evidence-based foundation: identifying the role of fluoride in water and association with dental fluorosis, dental caries and dental caries prevention; monitoring and documenting trends; establishing the scientific basis for safety and effectiveness of CWF; studying emerging issues; and communicating findings. They have been primary developers of research methods (including epidemiologic disease indices) and have been lead or coinvestigators of numerous studies. Epidemiologists remain key members of multidisciplinary teams contributing to ongoing surveillance, regulatory science, review of scientific manuscripts, and communication to the public, providers, and policy-makers. With the increased focus on dissemination and implementation science, epidemiologists are also involved in studying and testing strategies that would support integration of evidence-based approaches into clinical and community settings. It is important to note that the research outcomes of epidemiology are routinely used by public health–trained dental and other health professionals and others who use the evidence-base of CWF to recommend policy and communicate results to the public and to policy-makers.

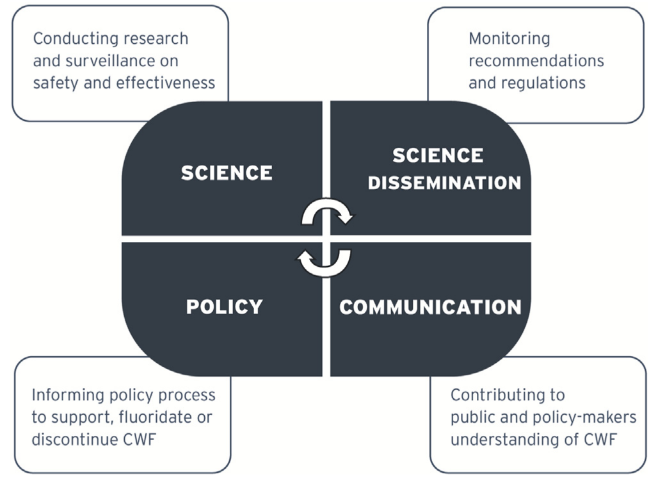

Fig. 1. Landscape of CWF science and policy is ever-changing. Epidemiologists have taken, and will take, part in all of these areas/processes.

Many other key players and organizations contribute to CWF, and reveal the extent of the policy environment in which CWF exists. For purposes of this article, policy is defined broadly and includes actions taken by local health and water departments, community councils and groups; state health departments and legislatures; national regulatory and science agencies; independent science entities; and professional and nonprofit associations. Given that the community water supply, a public utility, provides the delivery method for fluoride, the public has a major role in supporting or rejecting CWF, working with and through their state and local governments, elected officials, and community decision-makers. Once CWF is approved, trained water engineers play a critical role in implementation, operation, and maintenance according to set protocols. Regulation of water safety is under the direction of the U.S. Environmental Protection Agency (EPA), the agency responsible for setting standards for drinking water quality as specified by the Safe Drinking Water Act [6]. Research, surveillance, and critical scientific review is in the domain of the Department of Health and Human Services (U.S. Public Health Service and agencies, Centers for Disease Control and Prevention, and National Institutes of Health). These agencies contribute to the conduct and funding of these activities. In addition, nonprofit organizations and foundations provide support for educating the public and for CWF implementation. Professional organizations integrate the science and regulatory input and develop guidelines for care, resulting in recommendations for public education and patient clinical care for use by healthcare providers.

Extent of community water fluoridation

In the United States, 74.4% of people on community water supplies in 2014 had access to optimally fluoridated water (Fig. 2) which represented approximately 66% of the total US population [7]. In addition, it is estimated that each year approximately 90 communities in the U.S. consider starting, maintaining, or discontinuing water fluoridation [8]. For example, Templeton, Massachusetts has been fluoridated since 1951, yet this public health practice has been challenged each year from 2012 to 2016.

The implementation and support for CWF requires efforts from all sectors. A vignette of California's experience with CWF provides an example of the strength of collaborative efforts, one that benefited from actions of local and state policy-makers, community groups, the dental profession, epidemiologists, and foundations.

California vignette

In 1992, only 15.7% of California's population on public water systems received fluoridated water, ranking 48th among states. By 2014, the percentage climbed to 63.7% and the number of Californians receiving fluoridated water was almost 5 times higher—increasing from less than 5 million in 1992 to 24.7 million in 2014. The California legislature and the Governor enacted the 1995 fluoridation drinking water act (Assembly Bill 733) that authorized water systems with 10,000 or more service connections to fluoridate once funding from an outside source was provided. In 1998, The California Endowment, a private foundation, provided $15 million dollars in grants to water utilities through the California Dental Association Foundation to leverage the state law. More recently, other sources of grant support have assisted additional communities to cover initial implementation costs.

Early history of research, policy, and practice

Ruth Roy Harris, author of *Dental Science in the New Age, A History of the National Institute of Dental Research*, documented that "In the case of fluoridation, epidemiology rather than basic research helped to identify the inhibitor of dental caries." [9] Harris contrasted CWF to other mass public health achievements in mid-20th century, stating that it was the only one at that time that resulted from the use of epidemiology and then was followed by basic research to elucidate the mechanism of action. The history of CWF parallels the history of the scientific method and the evolution of epidemiologic methods and study designs. It also reflects the serendipitous nature of science.

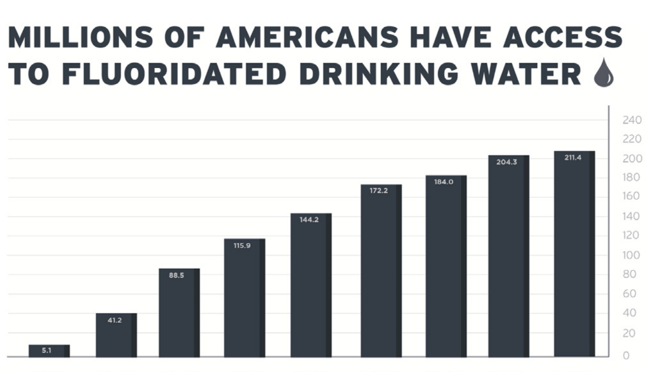

Fig. 2. Fluoridation has steadily expanded in the U.S. Centers for Disease Control and Prevention. Community Water Fluoridation. http://www.cdc.gov/fluoridation/statistics/2014stats.htm; 2016 [accessed 21.12.16].

In 1901, Frederick S. McKay, a dentist in Colorado Springs, Colorado, noted an unusual permanent stain or "mottled enamel" (termed "Colorado brown stain" by area residents) on the teeth of many of his patients [10]. This observation led to a series of studies that ultimately led to discovery of fluoride's role in both this cosmetic condition and the prevention of dental caries and the recommendation to adjust the level of fluoride in central water supplies to promote health. McKay's systematic examinations of his community schoolchildren revealed that over 80% had this condition. Similar findings were found in surrounding areas and reports came in from dentists in other states as well. In 1925, McKay, who concluded that this condition was due to an agent in the water, convinced residents of Oakley, Idaho to change their water supply. He returned 7 years later to examine the permanent teeth of children who were raised using the new water supply since birth, and reported that none had any "Colorado stain."

In Bauxite, Arkansas, similar findings were noted in children who accessed water from a deep well, which was subsequently abandoned. In 1931, a chemist with the Aluminum Company of America, tested the water from that well, using a new method at that time—spectrographic analysis—and noted high concentrations of fluoride (13.7 ppm). This news led McKay to send water samples from affected communities. The results revealed levels of fluoride ranging from 2.0 ppm to 12.0 ppm.

McKay also noted that teeth affected by mottled enamel seemed less susceptible to dental caries [11], and national interest focused on finding whether there was a threshold concentration of fluoride in water below which mottling is not observed. In 1930, H. Trendley Dean became the first dental scientist at the then National Institute of Health and his research focused on this association. He renamed the condition to "fluorosis," developed the Fluorosis Index, and documented the prevalence of this condition by conducting observational epidemiologic surveys throughout the United States [12]. Additional indices were developed to measure the extent and severity of dental caries, given that most individuals had this disease. Rather than noting the presence or absence of dental caries, these indices included assessments of the number of decayed, missing, or filled teeth (DMFT), or surfaces (DMFS) [13]. The use of these indices provided the capacity to cross-sectionally compare the prevalence and severity of fluorosis with dental caries prevalence and severity among children in 26 states that had naturally occurring different levels of fluoride, and revealed an inverse relationship between fluoride levels and dental caries [14]. This was confirmed in a subsequent 21-city study [15]. Fluorosis prevalence/severity was low at fluoride levels of 1.0 ppm, and the prevalence/severity of dental caries was low. This led to a "pioneering" prospective field study using intervention and control cities [16]. Follow-up surveys in these cities revealed a reduction of dental caries by 50%–70% among children in the communities where fluoride levels were adjusted to levels of 1.0 ppm–1.2 ppm and dental fluorosis prevalence/severity in these cities was comparable to cities whose water had naturally occurring levels of fluoride at 1.0 ppm.

Although the National Institutes of Health (NIH) did not complete the Grand Rapids study until 1960, the prevalence of dental caries was so high, the health burden was so great, and the degree of prevention noted after only 5 years of the trial was so large, leading health organizations were eager to replicate the early findings. In 1950, the American Dental Association, the American Public Health Association, and the Association of State and Territorial Health Officers all endorsed fluoridation of community water supplies. On April 24, 1951, Surgeon General Leonard Scheele announced that the Public Health Service's scientific studies had reached the point where he could give an unqualified endorsement of fluoridation as a means of reducing tooth decay by two-thirds.

During that year, over 3.5 million people in the U.S. received fluoridated drinking water for the first time [9].

Based on previous epidemiologic investigations of water consumption, caries, and fluorosis, an optimum range of fluoride concentration based on climate (0.7 ppm–1.2 ppm) was recommended by the US Public Health Service and guided technical action of water engineers [17]. Prior to 1965, policy decisions were made exclusively community-by-community, and remain the primary decision-making entity. In 1965, the Connecticut legislature required that all communities of 20,000 persons or more adjust the fluoride content to the optimal level. Thirteen states now have laws encouraging equitable access to fluoridated water, unless state law dictates otherwise. A decision to fluoridate is made by the local entity under whose jurisdiction the water supply falls [18]. Yet, since about 1950, concerns about safety raised at the community level have lead many city councils, health and water boards to defer the decision until they have a clear indication of public opinion, which often means holding a referendum or a town meeting, a method of policy-making that is becoming more common in public health.

Surveillance, regulation, and research: a focus on safety and benefits

National surveys, critical federal and other independent reviews and regulatory agencies have regularly assessed CWF by reviewing disease trends, scientific literature, and regulatory standards. The national Healthy People Health Promotion and Disease Prevention Initiative, launched in 1979, provided additional incentives to promote CWF access and its health effects. This initiative relies on a consortium of public- and private stakeholders that set and evaluate progress to national health promotion and disease prevention objectives each decade, and has inspired practices to prevent disease and promote health and related federal, state, and local policies. Objectives for CWF have been included in each decade of this initiative, starting with the first goal for 1990 to provide fluoridation to 95% of persons on community water systems [19]. Currently, the target for 2020 is 79.5% [20].

The federal government provides leadership in conducting surveys to monitor progress on the national objectives. Inasmuch as both the prevalence and severity of dental caries and enamel fluorosis are both expected to be influenced by fluoridation, methods to assess these conditions have been included in several national surveys whose design and analyses are guided by epidemiologists [21–23]. The population receiving fluoridated water is monitored at the state level, from which progress toward the national objective can be calculated. There is no federal authority to start or maintain fluoridation programs. Consequently, there are eight states in which most residents served by community water systems lack access to optimally fluoridated water [7].

Public policy decision-makers also have benefited from the work of the independent Community Preventive Services Task Force established in 1996 and comprised nonfederal, unpaid public health and prevention experts. This panel reviews the scientific evidence on the effectiveness and economic benefit of community preventive services to make recommendations for individuals and organizations delivering these services [24]. Its members, several of whom are epidemiologists, represent a broad range of research, practice, and policy expertize in community preventive services and public health. Moreover, epidemiologists serve on the multidisciplinary teams that complete reviews of evidence as directed by the Task Force to inform their deliberations on effectiveness, safety, and cost-effectiveness. The Task Force completed reports regarding CWF in 2000 and 2013 and recommended it based on strong evidence of its effectiveness, and identified evidence gaps to guide further research [24].

Under the Safe Drinking Water Act, the U.S. Environmental Protection Agency sets regulatory standards for drinking water quality including the maximum concentration of fluoride allowed in drinking water [6]. Currently, the enforceable standard is set at 4.0 mg/L to protect against severe *skeletal* fluorosis, which is a rare condition in the US [25,26]. The EPA requested extensive reviews of the health effects of ingested fluoride by the National Research Council (NRC), which were published in 1993 and in 2006, to inform its periodic review of these standards [26,27]. Both reviews focused on the safety and risks of naturally occurring fluoride in water at concentrations of 2–4 mg/L—levels higher than concentrations of 0.7 mg/L currently recommended for CWF in the US. The NRC committee concluded in its 2006 review that exposure at these higher levels placed children at an increased risk of severe *dental* fluorosis [4,26]. The committee also noted that important gaps in knowledge hampered some evaluations about risks of naturally occurring fluoride at 2 mg–4 mg/L and identified research needs focused on improving the design of epidemiologic studies that can inform policy decisions [26]. These research needs include: improved assessment of fluoride exposure (e.g., from all sources, for various populations and subgroups with different sociodemographic conditions, at the individual instead of the community level, by exposure level rather than by source of exposure); additional studies of dental fluorosis (e.g., the relationship of moderate or severe fluorosis and dental caries, objective assessment methods); and studies of other possible nondental health effects with exposures appropriately documented.

In 2015, the USPHS released updated recommendations for those community water systems that add fluoride to achieve the optimal concentration of fluoride in drinking water for the prevention of dental caries. As mentioned earlier, the optimal fluoride concentration in drinking water is now set at 0.7 mg/L to provide the best balance for protection against tooth decay while limiting the chance of dental fluorosis [4,28]. For the USPHS review and update, a federal panel of scientists, including epidemiologists, accepted the conclusion of the extensive 2006 NRC review that severe dental fluorosis is the only adverse health effect of exposure to naturally-occurring fluoride at 2–4 mg/L in drinking water during childhood. The reason that severe dental fluorosis was deemed an adverse health effect is because the pitting of tooth enamel raises the risk of dental caries. This is not the case for nonsevere forms of dental fluorosis. The need for ongoing monitoring of exposure and outcomes is critical to any intervention. US Department of Health and Human Services aims to continually enhance surveillance activities to detect changes in the prevalence and severity of dental caries and dental fluorosis, to learn more about the nature and extent of exposure to CWF and other fluoride modalities at the child level, and to improve the validity and reliability of dental fluorosis measures [4].

Even with ongoing surveillance, critical reviews and regulatory oversight, and the reaffirmation of the safety and benefits of CWF, it has continued to face multiple challenges. Some challenges have come from a general distrust of government as a source of scientific information for community decision-making [29]. Other challenges have come from limited public knowledge about the benefits of CWF, due, in part, to failure of health professions to educate the public about this resource [30]. In addition, many people may have limited access to and understanding of scientific information and have low health literacy. Thus, making decisions regarding CWF can benefit from the advice of individuals who are familiar with the challenges of CWF and the weak scientific foundation of these critiques. One can categorize the challenges into two distinct categories: questions about claims of adverse health effects and questions about CWF's continued benefits for different cohorts.

Assessing claims of adverse health effects

Claims of adverse health effects persist, despite the evidence assessed by multiple systematic and comprehensive reviews that have concluded that the only potentially unwanted effect of CWF is the milder forms of dental fluorosis. In fact, early investigations into the physiologic effects of fluoride in drinking water predated the completion of the first community field trials. A 1953 update of the study by NIH's Medical Investigations unit of two Texas towns where the water had contained 8-ppm fluoride since 1901 revealed nothing adverse in the residents' health condition. Consistent with increases in other sources of ingested fluoride since the introduction of CWF in the 1940's, the prevalence and severity of dental fluorosis—mostly in the milder forms—have increased [4,31]. The severe form of dental fluorosis with pitting of the enamel surface, however, remains rare in the United States with prevalence near zero at fluoride concentrations less than 2 mg/L—a concentration notably higher than the current recommendation of 0.7 mg/L [4,26,32]. The 2013 review by the Community Preventive Services Task Force did find a dose-response relationship between fluoride concentrations in drinking water and dental fluorosis, but also concluded that there was no evidence that CWF results in severe dental fluorosis. The Task Force clearly stated that evidence does not support claims that CWF causes other unwanted health effects [32].

The evolution of scientific evidence on CWF follows a logical course as research questions are identified, refined, and methods developed. Epidemiologists can look to the expert reviews for guidance about where their research efforts might be best directed; knowing that no single study will answer the question or completely fill the research gap. It is insufficient to simply look for some database to use to consider potential adverse effects of CWF, irrespective of the biological plausibility. Through incrementally and collectively using different research methods, new information is collected to help future scientists and expert panels make more definitive recommendations on policy.

CWF-related research and studies investigating possible harms are a vital part of continued oversight and investment. The government has supported scientists to assure public safety by periodically convening experts to conduct independent reviews. While the lay public may wish there were studies to prove that fluoridation does not cause some adverse effect, epidemiologists know it is not possible to prove a negative. However, research can be carefully designed and conducted to assess the level of evidence supporting an alleged harm. The *osteosarcoma vignette* reveals how focused attention to a likely potential problem can ultimately provide that reassurance. It demonstrates how epidemiologists can perform an essential role in improving the design and conduct of relevant studies, including the development and consistent use of valid and reliable exposures and outcome measures for exploring possible relationships between CWF and other health conditions.

Exploratory epidemiologic research must be carefully evaluated. An important aspect of the science base is the integrity of the peer review process for research funding and for manuscripts published in peer-reviewed journals, particularly for a very widespread and highly polarizing public health intervention like CWF. These manuscripts and studies are used to inform science, clinical practice, policies, and the public. The *fluoride and IQ vignette* recognizes that journal editors cannot control assertions that individuals may make, but they can provide critical information to policymakers. Epidemiologists have a critical role when they serve as reviewers of peer-reviewed journals and research proposals. There is a responsibility to ensure that study design and analytic methods are appropriate and that limitations and conclusions are articulated appropriately and clearly.

Osteosarcoma vignette

Scientists have studied, with a variety of methods, the concern that exposure to water fluoridation could cause osteosarcoma and have built an evidence base that provides ever greater confidence that CWF does not increase the risk of cancer. Yiamouyiannis and Burk first claimed an association between fluoride in drinking water and cancer in 1977 [33]. They reported a higher rate of all cancer mortality in 10 U S. cities with fluoridated drinking water than in 10 nonfluoridated cities, findings subsequently criticized for being at high risk for bias [27,34,35]. That study and others shortly after it [36–38] did not account for potential differences in fluoride health effects on different body organs and systems. By the 1990s, epidemiologists had begun to study fluoridation and cancer in specific organ systems.

Osteosarcoma, a rare cancer with about 400 newly diagnosed cases among U.S. children and adolescents each year [39], has been studied more than any other cancer, primarily because of its biological plausibility, with fluoride being a mitogen and having affinity for bone. In 1990, the National Toxicology Program (NTP) published equivocal evidence from animal studies of an increased incidence of osteosarcomas in male rats administered high levels of fluoride [40]. Because most epidemiologic studies were ecological studies [41–45], in 1993, the NRC recommended studies of humans with better information about individuals' fluoride exposures. In 1995, Gelberg et al. reported that fluoride exposure did not increase the risk of osteosarcoma based on a case-control study in which they determined the lifetime dietary fluoride exposures from interviews of subjects identified in the New York State Cancer Registry and age- and sex-matched controls from birth records [46].

A 2000 systematic review of seven studies on osteosarcoma and CWF conducted in the previous decade found no association in the six studies that included a statistical analysis [47]. Most of the studies during this period relied on cancer registries and area fluoridation information providing limited opportunities to assess person-level fluoride exposures or adjust for confounders [41–46,48]. The 2006 NRC report concluded that the literature did not clearly indicate whether fluoride was carcinogenic in humans [26].

Investigators at Harvard University improved on measurement of fluoride exposures in their multicenter, hospital-based case-control study [49,50]. The second of the two publications from this study used results of assays for fluoride content in bone segments of tumor-adjacent bone and iliac crest bone obtained from 137 subjects with primary osteosarcoma and 51 controls that had other malignant bone tumors. No statistically significant association was found between fluoride levels in bone and osteosarcoma risk [50].

In 2016, the National Health and Medical Research Council (NHMRC) of Australia updated two previous reviews (2000 York [47] and 2007 NHMRC reviews [51]) and identified six studies published between 2006 and 2015 [52–57]. It maintained its previous conclusion that there is no clear association between water fluoridation and osteosarcoma [58]. Water fluoridation prevents disease in teeth but also exposes other organs and systems to fluoride in the process. Over time, increasingly sophisticated studies have found no convincing evidence that links fluoride in drinking water in cancers [41–45,48,50–53,55–57,59,60] providing policy makers with sound scientific support for its safety.

IQ vignette

A review of findings of recent publications examining the relationship between fluoride in drinking water and IQ, reveal weaknesses in the design and conduct among included studies in the body of evidence, unsubstantiated assertions, and inconsistent findings. These findings have contributed to public uncertainty about risk. For example, the 2012 a meta-analysis [61] was published that focused on studies conducted in rural China, Iran, and Mongolia. The review found an association between high fluoride concentrations in drinking water, ranging up to 11.5 mg/L, and lower IQ scores. The authors stated that the quality of the included studies was low, especially related to measures of exposure, and that other explanatory factors could not be ruled out. While these limitations were ignored when this analysis was used to support the assertion that "raised fluoride concentrations" in drinking water were a developmental neurotoxicant [62], they were influential in considering these findings in the context of other studies [4]. In contrast, and more relevant to fluoridation policy, a prospective study of a birth cohort in New Zealand also published in 2014 did not find a relationship between residence in a fluoridated area in early childhood and IQ measured during childhood and at age 38 years [63]. This investigation was designed to study several potential influences on multiple measures of IQ, enabling statistical adjustments to take account of factors such as birthweight, socioeconomic status, and educational achievements of individuals.

Growing demands on the quality of science will continue to justify further investigations. Epidemiologists are well positioned to communicate with the public and policy-makers about the difficulties of studying rare diseases or conditions where the risk, if at all present, is very small and the exposure is ubiquitous. Epidemiologists can monitor trends and look for clusters of cases if they occur. In addition, they can collaborate with other scientists to understand the biologic mechanism, and use that information to design studies that will help to elucidate cause-and-effect conclusions, thus providing the policymakers with sound and clear evidence.

Documenting benefits

With the availability of fluoride dental products targeted at individuals and the decline in dental caries in children in developed countries, the need for CWF has been questioned. However, measuring current benefits of proven community-wide interventions to control diseases like dental caries is difficult. Earlier studies were prospective field studies of intervention and control cities—these type of investigations are not possible today and cannot control for other effects. Randomized controlled trials are unlikely to be conducted for ethical and feasibility reasons. The 2015 Cochrane review of CWF stated that RCT's of CWF are infeasible. [64] Emerging methods in assessing and grading quality of science are identifying study designs that may not be possible to implement in the United States today due to cost, time, and ethical reasons.

In the past, cross-sectional studies have been used to assess differences in outcomes such as caries prevalence, tooth loss or extraction rates, dental pain, use of general anesthesia in hospital operating rooms, cost of treatment or claims for dental caries related treatment procedures. The main sources of data for such analyses are national and local surveys and administrative records, such as school dental records or Medicaid expenditures [65] or hospital records [66]. Retrospective cohort studies of population living in fluoridated and nonfluoridated communities have assessed the cumulative incidence of dental caries. The National Preventive Dentistry Demonstration Program (NPDDP) used a cohort study design to determine the cost and effectiveness of multiple clinical or classroom interventions in fluoridated and nonfluoridated communities [67]. This allowed the investigators to compare the occurrence of new dental caries (incidence) in different groups including a concurrent control group that was not exposed to these additional interventions. The conclusion of the NPDDP was that CWF was the most effective strategy for caries prevention.

With the movement toward the "evidence-based practice" of public health [68], some groups have applied the methods appropriate for drug trials and clinical interventions for assessing the effectiveness of CWF. Although cross-sectional and cohort studies with varying designs conducted among different population groups have shown that CWF helps prevent dental caries, most of these studies did not meet the strict inclusion criteria used in systematic reviews conducted by the National Health Service (NHS) Centre for Reviews and Dissemination, York University or the more recent Cochrane review [47,64]. The 2015 Cochrane review stimulated scientific debate regarding the inclusion criteria used in systematic reviews and highlighted the importance of critically reviewing the detailed methods and inclusion criteria used by different groups for such reviews. Epidemiologists need to understand the relevant merits of systematic review methodologies, including design of inclusion criteria and the grading protocols for different types of studies.

The 2015 Cochrane systematic review evaluated the effects of water fluoridation (artificial or natural) on the prevention of dental caries and on dental fluorosis. The review found that the initiation of water fluoridation resulted in reductions in the order of 1.8 dmft and 1.2 DMFT for deciduous (primary) and permanent dentitions that translated to reductions of 35% and 26% compared with the median control group mean values. However, 71% of the studies included in the review were conducted before 1975, when fluoride toothpaste was not as widely used and dental sealant applications were rare. Based on the inclusion criteria, the authors concluded that there was very little contemporary evidence on the effectiveness of water fluoridation for the prevention of dental caries. In contrast, the economic evaluation of CWF conducted by the U.S. Community Preventive Services Task Force (CPSTF) concluded that the recent evidence continued to indicate that the economic benefit of CWF exceeds the intervention cost [69]. The key question that has been raised is whether there is still a need to invest in CWF given that the rates of disease is going down, and there are other ways for individuals to get fluoride. Of particular concern is the impact on the underserved of ending a public health practice that has decreased the burden of dental caries.

It is important to ask how then these two reputable groups, Cochrane and the U.S. Community Preventive Services Task Force, appear to have come to such different conclusions. According to Lennon, the Cochrane group used the methodology appropriate for evaluating the randomized clinical trials for new drugs and clinical interventions, instead of using their own guidelines for conducting systematic reviews of public health interventions [70]. This method led the authors to reject all cross-sectional studies. Rugg-Gunn and Do's analysis of 59 mostly cross-sectional studies revealed a 30%–59% lower dmft (decayed, missing, filled primary teeth) in fluoridated areas; and, a 40%–49% lower DMFT [71]. They observed that even after adjusting for confounders, a potential concern with these types of studies, the percentage dental caries reduction was not affected.

Rugg-Gunn et al. provided a well-documented critique of the 2015 Cochrane review [72]. The authors highlight the strict inclusion criteria that included only prospective studies with a concurrent control, comparing at least two populations, one receiving fluoridated water (within 3 years of the baseline survey) and the other nonfluoridated water, with at least two points in time evaluated. Groups had to be comparable in terms of fluoridated water at baseline. Rugg-Gunn et al. point out the obvious challenge of designing studies to meet these standards. For example, they state, "This comes *ad extremis* in the Cochrane Review, in identifying the effect in adults. Thus, for an evaluation of the possible benefits for

50-year-olds, baseline information on the caries experience of people of this age would be required in the community to be fluoridated and in a comparable reference community, as well as information to be collected 50 years later on the caries experience of people from the same age group in the same communities which have continued to remain fluoridated or non-fluoridated for the whole of that very long period. Such requirements are unfeasibly stringent given the potential for community demographic characteristics to change over time, and render 50 year historical comparability of intervention and reference communities meaningless for present-day comparisons."

The focus of the Cochrane review appears to be to ensure internal validity for answering questions about whether the intervention works. Therefore, the Cochrane group emphasized the adoption of the GRADE system for observational studies [73]. Of importance for policy-makers, the real need is to determine what has happened with the introduction of CWF in different communities and what has been the return on investment. Toward that end, epidemiologists should consider planning rigorous evaluation studies of ongoing CWF programs to address policy-maker needs. An example of a policy-relevant question that could be addressed is: What is the total fluoride exposure to individuals that includes all sources (e.g., fluoridated dental products)?

Although ongoing surveillance in the US through NHANES monitors health effects and takes into account practices of individuals, sample size limitations often preclude examination by communities. In the United States, a large number of school-based dental disease prevention programs currently operate in fluoridated and nonfluoridated communities. This provides an opportunity to develop a public health collaborative approach to evaluating ongoing programs. This would require developing protocols, training staff to collect data, and reporting the findings from multiple sites in a uniform way. As urged by Green, there is a need to shift the focus in public health away from "evidence-based practice" to the more relevant "practice-based evidence" [68]. It is the perspective of the "practice" of public health interventions, such as CWF, that the public and policy-makers experience. Addressing the questions posed by the public and by policy-makers, and providing information in a manner that they can use, will facilitate and inform their decision-making.

Communication and policy

The integrity of the public dialogue surrounding fluoride increasingly relies on the appropriate interpretation of data or research. The Internet and social media are leading sources for misinformation and attacks on CWF [74], and many of these claims can appear valid to a public with limited understanding of scientific methods. In his book Explaining Research, science writer Dennis Meredith observed: "Researchers consistently overestimate what the lay public understands about science" [75]. Epidemiologists are in a crucial position to clarify the scientific evidence for journalists, elected officials, other community stakeholders and the public. They also can play a role in enhancing the public's health literacy. These roles are strengthened by recognizing that language shapes the public's understanding and reaction, and narratives can complement data to enhance understanding. Epidemiologists trained in methods of clear communication are better prepared to translate epidemiologic data to audiences with limited science and/or health literacy.

Using "plain language" communication, understanding the dynamics that drive policy making, and working with people in other disciplines to inform messages that accurately reflect the evidence are important skills for epidemiologists and others involved with CWF. Epidemiologists can strengthen the quality of community-based decision-making about fluoridation in several ways. Clear communication of data requires reassessing the terms used. For example, when reporting health data to elected officials and the public, technical terms such as "cohort" and "longitudinal" which are unfamiliar to lay audiences, should be avoided [76] (Table 1).

When fluoridation becomes the subject of public debate, epidemiologists have an opportunity to be actively involved in a health department's conversation about the likely questions that will arise and contribute the appropriate data or analysis needed to answer those questions. By being part of the policy dialogue, they can temper instincts by some public information officers or other spokespersons to give blanket responses that might not be supported by the data. Epidemiologists can raise awareness, for example, that tooth decay, while at a lower prevalence and severity than in decades past, remains as the most common chronic disease among both children and adults [3]. When communicating data to the public, even minor variations in word choices can prompt significantly different reactions. For example, in scientific circles "chemical" is a neutral term that doesn't inherently convey danger. Yet, this word can be a source of anxiety among lay persons [77]. The Portland, Oregon group that led the defeat of a fluoridation ballot measure in 2013 likely benefited by consistently using the word "chemical" to describe fluoride [78]. Indeed, their yard signs urged voters to reject the addition of "fluoridation chemicals" to their water supply [79]. In addition to using plain language, the development of reports or fact sheets should reflect the cultural needs and norms of the populations that comprise their communities. As the *American Scientist* blog observed, "Many scientists speaking to the public do not spend enough time studying the lexicon and concerns of their audience to meet them where they are" [80].

Sharing oral health surveillance data and other statistics can provide an important context for a community's discussion about fluoridation. Even data from nongovernmental sources can shape local decisions. This was demonstrated in 2011, when a water district board voted unanimously in support of fluoridating the drinking water supplied to San Jose, California [81]. The successful campaign was spearheaded by The Health Trust, which operated two dental clinics for low-income children. For more than a year before the vote, The Health Trust engaged community stakeholders and made its case that investing more in prevention could lessen the consequences of dental disease, citing the roughly 7400 root canals and 4500 tooth extractions performed at its children's clinics [82]. The Health Trust's CEO later noted the crucial role these data played by helping proponents "put a face on the issue" of poor oral health [82].

Data can be complemented by story-telling and other forms of narrative. As Meisel and Karlawish [83] concluded, "narratives, when compared with reporting statistical evidence alone, can have uniquely persuasive effects in overcoming preconceived beliefs and

Table 1
Terms can have very different meanings

Terms	What scientists and epidemiologist mean	What the public might hear
Theory	A scientific understanding	A "hunch" or a guess
Positive trend	Upward trend	Good trend
Bias	Factors that could affect study results	Distortions or prejudice
Intervention	A health/medical strategy or procedure	Government exercises new authority
"More research is needed"	More research is always helpful	They aren't sure what to think

Adapted from Somerville and Hassol, "Communicating the Science of Climate Change," Physics Today, Oct. 2011.

cognitive biases." Stories should include explanations of how scientists reached their conclusions, and these are most helpful if individuals can identify with people featured in these stories. One example is the NIH's "Story of Fluoridation," which offers a condensed history of the pioneering epidemiologic investigations connecting fluoride and dental caries rates [84].

Even the briefest of stories can put data in an important context for the public. In 2016, weeks before residents of Rutland, VT cast votes on whether to continue water fluoridation, the city's daily newspaper published a letter from a local dentist. "When I started practice 41 years ago," he wrote, "the decayed, missing and filled teeth in the population at large were unmanageable. My reception room played loud music to muffle the sound of children crying as their teeth were drilled, filled, redrilled and refilled" [85].

By working with communications staff to brief health reporters on research, epidemiologists can provide context and lessen the likelihood that studies are misinterpreted. When fluoridation becomes the subject of media coverage, epidemiologists have a unique opportunity to explain to journalists how a study's design, its sample size, and other factors can shape conclusions. Indeed, the Shorenstein Center on Media, Politics and Public Policy, has warned reporters that "not examining the (fluoride) dose in question—levels of fluoridation proposed or studied—can lead to faulty reporting" [86].

Pinellas county vignette

A temporary cessation of CWF in Pinellas County, Florida illustrates the dividends that can accrue from outreach to reporters and editors. In October 2011, county commissioners voted 4–3 to end CWF for the water system's 700,000 customers. Local health professionals built positive relationships with local reporters and clarified research that helped to inform a series of editorials in the Tampa Bay Times, summarizing the scientific evidence of CWF's safety and effectiveness. A local dentist directed journalists to appropriate resources from the CDC, the Florida Department of Health, and the ADA. The Tampa Bay Times won a Pulitzer Prize for its coverage of this issue. In its nominating letter, the newspaper explained that it devoted such extensive coverage to CWF because county commissioners "ignored established science and the public health when they voted in 2011." CWF was reinstated in a November 2012 commission vote. [87].

Taking time to play a meaningful, proactive role in raising the public's fluoride literacy contributes to informed public decision-making. The public's understanding of CWF is low. For example, although Maryland ranks among the top five states for the percentage of residents served by fluoridated water systems, a 2011 survey revealed that nearly six in 10 Marylanders could not identify the purpose of adding fluoride to drinking water [88]. An NIH guide explains that understanding of a public health intervention "can be refreshed on important anniversaries or when new relevant reports or studies are published" [89]. These can include National Children's Dental Health Month (February), Public Health Week (April), Drinking Water Week (May), and the 75th anniversary of fluoridation that will be celebrated in January 2020. These events offer ideal situations for sharing fact sheets with recent or historic research with city councils, health departments, water boards, civic organizations, older adults, children's advocates, and other stakeholders.

Conclusion

CWF exists within the policy environment, whether it is decision-makers at the local community or state level, or at the level of state and national regulatory and science agencies. The experiences with the past 70 years of CWF reveal that the coming decades will bring additional challenges and questions and require continued involvement of epidemiologists. The expertize, contributions, and participation of epidemiologists, increasingly as members of multidisciplinary teams, will be needed to inform and conduct research and surveillance, implementation science and dissemination, regulatory assessments, and to communicate

Table 2
Highlights of lessons learned from CWF case

Conducting research and surveillance on safety and effectiveness
Surveillance findings, changes in regulatory standards, and outcomes of systematic reviews will continue to generate new research questions, some of which may call for RCT-type designs and question the quality of alternative study designs. However, the use of "gold standard" RCT study designs is not ethically possible for existing, effective, community-wide interventions, and large-scale cohort studies are costly and take time. Expert input is needed to guide where efforts might be best directed and to design research studies that address the most critical issues.
Even established interventions, such as CWF, require national and local investments to support a continuous surveillance infrastructure and process. This process should include continued development of tools/measures to monitor health outcomes as well as analyses and reporting of surveillance results.
Translating science into regulations and policy recommendations
Science to inform regulatory action and new knowledge depends on the quality of published peer-reviewed publications and peer-reviewed research awards. The critical assessment of study findings is essential since they inform policy-makers, the public, and scientists. Participation as a reviewer in the peer-review of submitted manuscripts and research proposals comes with the responsibility to ensure that study design and analytic methods are appropriate and that limitations and conclusions are articulated appropriately and clearly.
Systematic reviews also inform policy-makers and the public. To place the conclusions of these reviews in context for decision-makers, detailed knowledge of evaluation criteria and grading protocols for different types of studies is important as well as the implications of the inclusion criteria are needed.
Contributing to public and policy-makers understanding of CWF
The integrity of the public dialogue increasingly relies on the appropriate interpretation of data or research. Epidemiologists are in a crucial position to clarify the scientific evidence and related study design issues for journalists, elected officials, other community stakeholders, and the public.
Epidemiologists play an important role as essential members of the interdisciplinary team that informs the public and policy-makers. The advice of individuals who are familiar with the critiques of CWF and the weak scientific foundation of these critiques inform decisions regarding CWF implementation and monitoring.
Training in methods of clear communication enhances the capacity of epidemiologists and other scientists to translate epidemiologic findings effectively to audiences with limited science and/or health literacy.
Using "plain language" communication, understanding the dynamics that drive policy making, and working with people in other disciplines to inform messages that accurately reflect the evidence are essential skills. By working with communications staff to brief health reporters on research, they can provide context, provide information in a manner that can be used, and lessen the likelihood that studies are misinterpreted.
Informing the management decision-making of community interventions
Policy-makers and the public experience the "practice" of public health interventions. Addressing their questions, such as data to define the "return on investment," would benefit from evaluation studies of ongoing programs to assess their impact on overall costs, such as Medicaid spending, and in the context of other investments. In addition, epidemiologists can contribute to program-specific performance management and quality improvement activities.

science findings to the public and policy-makers. This article highlights how epidemiologic evidence has been translated into practice and policy, and how the experience with CWF since the 1950s has affected epidemiologic research, regulatory standards, and community decision-making. CWF-specific lessons learned are interspersed throughout this article. This case also provides several general lessons learned emanating from work with CWF, but also that have relevance to other long-standing community-wide and community-based interventions (Table 2). Epidemiologists have been in the forefront of this “great public health achievement” of the 20th century and their role is as critical today and tomorrow as it was in the early 1900s.

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