ORANGE COUNTY
HEALTH DEPARTMENT
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# Orange County Board of Health

# Community Water Fluoridation Health Recommendation to

# Orange Water and Sewer Authority

## March 2020

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# Board of Health 2019

| NAME | FIELD | APPOINTED | TERM EXPIRATION |
|---|---|---|---|
| Alison Stuebe, MD, MSc | At-Large | 6/18/19 (partial term to end 6/30/21) | 6/30/24 (1st )<br>6/30/27 (2nd)<br>6/30/30 (3rd) |
| Aparna Jonnal, MD, MPH | Physician | 6/18/19 | 6/30/22 (1st)<br>6/30/25 (2nd )<br>6/30/28 (3rd) |
| Bruce Baldwin, OD, PhD | Optometry | 6/20/17<br>(partial term to end 6/30/18) | 6/30/21 (1st)<br>6/30/24 (2nd)<br>6/30/27 (3rd) |
| Earl McKee | County Commissioner | 12/18/18 | N/A |
| Jennifer Deyo, PharmD | Pharmacy | 2/7/17 | 6/30/22 (2nd)<br>6/30/25 (3rd) |
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| Liska Lackey, RN | Nursing | 7/28/11 | 6/30/20 (3rd) |
| Quintana Stewart, MPA<br>Health Director | Health Director | Sworn in 12/18/17 | N/A |
| Sam Lasris, DDS | Dentist | 3/18/14 | 6/30/22 (3rd) |
| Timothy Smith, PLS, PE<br>Chairperson | Engineering | 9/15/15 | 6/30/21 (2nd)<br>6/30/24 (3rd) |

# Acknowledgements

This report, Orange County Board of Health Community Water Fluoridation Health Recommendation to Orange Water and Sewer Authority (OWASA), documents the process of the Orange County Board of Health to arrive at a health recommendation on fluoridation of community water provided by OWASA. The Board of Health appointed an Ad Hoc Fluoride Committee that oversaw the process. This process outlined steps for the Board to receive opinions from the general public and to have experts review and respond to those public opinions regarding fluoridation of drinking water.

Members of the Board of Health Ad Hoc Fluoride Committee were:

- Bruce Baldwin, OD, PhD
- Jessica Frega, MPH
- Liska Lackey, RN
- Dr. Michael Day, DDS – Dental Clinic Director
- Quintana Stewart, MPA – Health Director
- Beverly Scurry, MBA/MHA

Expert Reviewers

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  - Ann Newman Chelminski MPH, MD.
    Disclaimer - The views expressed in this document are my own and are not the opinions of my employers.
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# Executive Summary

In February 2017, Orange Water and Sewer Authority (OWASA) experienced an incident regarding overfeed of fluoride within the water treatment process. The overfeed was contained and no water with higher than normal fluoride levels reached the water pipe system supplying OWASA customers. OWASA made the decision to stop fluoridation of the drinking water for a period of eight months amid customers and residents voicing concerns regarding the health, safety and efficacy of fluoridation.

In April 2017, the Orange County Board of Health wrote OWASA's Board of Directors affirming OWASA's decision to continue fluoridation of the water supply and offering supportive resources and facts. See Attachment 1. In October 2017, after purchasing new equipment to monitor the fluoride feed system, OWASA resumed fluoridation of drinking water.

Due to continued community concerns, Ed Kerwin, Executive Director of OWASA and OWASA Board of Directors sent Dr. Dorothy Cilenti, Interim Orange County Health Director, a letter requesting that the Orange County Health Department assist OWASA in a periodic review process of drinking water fluoridation. The letter outlined key components for the review and requested feedback and recommendations. See Attachment 2.

Dr. Cilenti presented the request to the Board of Health during the November 29, 2017 Board meeting. The Board decided to review next steps at the February 2018 meeting once the new Health Director was on board. See Attachment 3.

On February 28, 2018 the Board of Health again discussed the letter from OWASA and voted unanimously to create a committee charged with developing a response plan. See Attachment 4. The Ad Hoc Fluoride Committee was finalized on March 25, 2018 and the first meeting was scheduled for June 6, 2018. Meeting outcomes included researching more about the public input process, researching

potential panelists to take part in the fluoride review process, and creating potential community survey questions. See Attachment 5.

During the June 27, 2018 meeting the Ad Hoc Fluoride Committee provided an update to the full Board outlining proposed methods to fulfill OWASA's request. See Attachment 6. The next Ad Hoc meeting was held on July 18, 2018. During that meeting, committee members decided to:

- Secure dental and medical experts to serve on a panel
- Compile public feedback from OWASA meetings
- Invite additional public comment
- Ask experts to respond to public comment and reference the latest science on fluoridation

See Attachment 7.

On August 22, 2018 the Ad Hoc Committee updated the full Board on the plan to move forward with the fluoride review process. The Board agreed with the plan as presented. See Attachment 8. The Board of Health then drafted a letter letting OWASA know of the review process plans that the Board agreed with. See Attachment 9.

The Ad Hoc Committee drafted a letter in order to secure medical, dental, and toxicology experts. The letter of request was emailed to recommended, local colleagues as well as statewide societies including the NC Society of Toxicologists, NC Neurological Society, and the Carolinas Chapter of the American Association of Clinical Endocrinologists. See Attachment 10. Another update was provided to the full Board on the progress of the committee during the October 24, 2018 BOH meeting. See Attachment 11.

The Ad Hoc Committee drafted a community survey intended to garner public comments on fluoridation of drinking water for OWASA customers. See Attachment 12. The committee presented the survey to the full board during the November 28, 2018 BOH meeting. See Attachment 13.

Due to the difficulty in securing experts to participate in the fluoride review process, the Ad Hoc Committee presented to the full Board additional options during the February 27, 2019 BOH meeting. During that meeting, the Board agreed to offer an honorarium of $1,000 per expert for up to three experts. See Attachment 14. The letter to secure experts was updated to reflect the honorarium and resent to various local professionals and again to statewide societies. See Attachment 15.

The OWASA Director contacted Health Director Quintana Stewart and expressed their Board of Director's interest in being involved in the fluoride review and survey development process. The Ad Hoc Committee addressed this request during the May 22, 2019 BOH meeting. The BOH decided to continue with the current plan to avoid undue influence. This was supported by OWASA Executive Director, Ed Kerwin. See Attachment 16.

By July 2019, the Ad Hoc Committee was able to secure three experts and one volunteer expert to participate in the fluoride review process. The committee, with assistance from Kristin Prelipp, Communication Manager, finalized the community questionnaire (see Attachment 17) and began promotion. The questionnaire was opened to the community from July 18 to July 31, 2019. The online questionnaire was promoted on social media platforms, sent to OWASA customers, and hard copies were available at the Health Department's medical and dental clinics. See Attachment 18.

An analysis of the survey was conducted by the BOH Strategic Plan Manager. There was a total of 170 online and hard copy surveys received; 72% responded that they supported OWASA fluoridation of water and 29% responded they were opposed to OWASA fluoridation of water. Of the respondents, 79% drink OWASA water regularly (14% did not) and 86% live in Chapel Hill/Carrboro area (7% did not).

Of all survey respondents who showed support, 68% support fluoridation of water because it is an important public health measure, in the right amounts, it is safe, and in the right amounts, it helps prevent dental decay. Other reasons respondents support fluoride include fluoridation being a social

justice issue for those who have trouble paying for dental care and because it's equitable and reaches all citizens.

Of all survey respondents who were opposed, 14% oppose fluoridation of water because it can affect the environment; 24% responded it can have a negative impact on personal health; and 19% responded it is not necessary to prevent tooth decay. Additional responses and comments from those who oppose fluoride were analyzed and grouped into major themes. Those themes are outlined in the Evaluation section of this report. The experts have responded to each theme using their expertise and scientific research.

## Board of Health Recommendation

The Orange County Board of Health supports the continued fluoridation of Orange Water and Sewer Authority's water supply at the current levels as deemed effective for prevention of tooth decay and for promotion of good oral health.

The Board of Health Ad Hoc Fluoride Committee conducted a process of:

- Obtaining public feedback on community water fluoridation
- Reviewing public feedback given at an OWASA public meeting
- Reviewing the latest recommendations from national health organizations including, but not limited to, the Centers for Disease Control and Prevention (CDC), North Carolina Department of Health and Human Services (NC DHHS), and American Dental Association (ADA)
- Reviewing medical, dental, and toxicological expert responses to public opposition of community water fluoridation

The committee also considered the lack of naturally occurring fluoride in OWASA's reservoirs. This detailed process and the recognition by the CDC that community water fluoridation is one of the greatest public health achievements of the 20th century, led to the support of OWASA continuing community water fluoridation.

# Public Health Framework for Community Water Fluoridation

During this process, Board of Health members considered the Board's duty as a governing body to protect and promote the health of the community and what ethical obligations the Board should consider in creating a recommendation. The Ad Hoc Fluoride Committee reviewed An Ethics Framework for Public Health [1] article by Nancy E. Kass, ScD. The framework poses six questions to consider when health professionals want to consider the morality in how to respond to a public health issue. (See Attachment 19) Those six questions were answered in regards to Community Water Fluoridation.

1. What are the public health goals of Community Water Fluoridation?

   Community water fluoridation has been a benefit to communities since the 1950s. The goal of community water fluoridation is prevention of tooth decay. While fluoride is found naturally in water, it is not found at high enough levels to be effective against tooth decay. In fact, according to OWASA, "Fluoride naturally present in groundwater ranges up to more than 12 parts per million (ppm). Fluoride in rivers and other surface water may range up to 1.4 ppm. Fluoride in OWASA's reservoirs is below the detectable level."[5] Adjusting the level of fluoride in community water through water supply systems has been researched and found to be an effective public health intervention.[2]

2. How effective is the Community Water Fluoridation in achieving its goals?

   According to the Centers for Disease Control and Prevention (CDC) [2], fluoridated water reduces tooth decay by 25% among children and adults. Fluoride also helps with reducing cavities, less severe cavities, less need for fillings and removing teeth, and less pain and suffering because of tooth decay.

3. What are the known or potential burdens of Community Water Fluoridation?

According to information provided by OWASA (M. Tiger, personal communication, February 5, 2020), the financial burden of community water fluoridation to OWASA ratepayers is minimal. In 2019, OWASA spent $16,140 on the fluoride that was added to drinking water. With 2.4 billion gallons treated at the Jones Ferry Road Water Treatment Plant in 2019, the unit cost equates to approximately $1.00 per 1.4 million gallons. Beyond chemical costs, the cost of maintaining the system is incorporated into overall plant operations. The fluoride feed system is flow-paced and does not require manual adjustment. The system is monitored as part of OWASA's larger facility monitoring. Following a 2017 investment by OWASA to increase the reliability of the system, the fluoride feed system requires minimal upkeep and preventative maintenance.

4. Can burdens be minimized? Are there alternative approaches?

According to OWASA (M. Tiger, personal communication, February 5, 2020), given that the cost of community fluoridation lies primarily in the cost of fluoride, there is little opportunity to minimize costs. The cost of purchasing community fluoridation represented a very small portion of OWASA's Fiscal Year 2020 $25.5 million operating budget.

According to, Fluoridation and Social Equity[3], by Brian A. Burt BDS, MPH, Ph.D., there is no practical alternative to water fluoridation for reducing disparities in the US for low socioeconomic communities.

There are additional ways in which communities can obtain fluoride such as through over-the-counter products (toothpaste and mouthwash) and prescription only products (supplements). These products are not as effective at preventing tooth decay because they are often not used enough and present an economic barrier to some.[2]

5. Is Community Water Fluoridation implemented fairly?

All residents, in states across the country that have Community Water Fluoridation programs, have the opportunity to access fluoride through the water supply system. Residents, who are burdened with poor water systems and cannot drink the water, will not have access to fluoridated water. Other residents may have hardships in keeping water turned on due to economic burdens therefore limiting access to fluoride.

6. How can the benefits and burdens of Community Water Fluoridation be fairly balanced?

Providing Community Water Fluoridation in communities leads to an economic savings not only for that community, but for the residents as well. According to the CDC, communities save on average $20 for every $1 invested annually on Community Water Fluoridation and residents save on average $32 by avoiding dental decay and cavities and the need for costly dental treatment for this preventable disease.[4]

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## Evaluation of Health-Related Public Comments and Concerns

Survey respondents oppose fluoridation of community water for a variety of reasons. A complete list of those reasons can be found in Attachment 20. The six concerns listed below are the major health-related themes from survey respondents and from residents who attended the OWASA Board meeting on October 27, 2017 at which Orange County Health Department's Communications Manager was in attendance and able to capture those concerns. See Attachment 21.

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## Assertion One: Disease/Health Concerns Caused by Fluoride

Disease and health related issues from community members who oppose fluoride include concerns about:

- disease states that cannot tolerate water fluoridation levels such as kidney disease/renal transplant and autoimmune diseases
- fluoride causes thyroid problems and skeletal fluorosis diagnosed as arthritis
- fluoride increases incidence of ADHD
- fluoride damages tooth enamel due to fluorosis
- fluoride increases incidence of certain cancers
- fluoride damages the brain, neurons, liver, and pineal gland
- fluoride makes bones brittle
- fluoride concentrates in the spines causing backaches.

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## Expert Evaluation by Tim Wright DDS, MS

- Disease states that cannot tolerate water fluoridation levels such as kidney disease/renal transplant and autoimmune diseases
    - National Kidney Foundation - https://www.kidney.org/atoz/content/fluoride (The National Kidney Foundation has not issued specific recommendations regarding fluoride intake and kidney disease due to the limited available research on the topic. The benefit of water and dental products containing fluoride is the prevention of tooth decay and dental cavities in people of all ages. The potential health risks are a rare bone disease called skeletal fluorosis, bone fractures and severe enamel fluorosis.)
- Fluoride causes thyroid problems and skeletal fluorosis diagnosed as arthritis
    - The only hits I get on arthritis are from the anti-fluoride website Fluoride Network. I don't see anything on Arthritis Foundation web site and don't see anything in scientific literature. Thyroid issue has publications but these are confounded similarly to the neurotoxicity issue. When evaluating very low fluoride communities to fluoridated communities, none of these health issues come to the surface as safety issues. Studies of communities in Canada concluded community water fluoridation was not associated with impaired thyroid functioning. [1]
- Fluoride damages tooth enamel due to fluorosis
    - At 0.7 ppm there is only a low % of people that have mild fluorosis (10-15%) and this has been shown to be associated with a decreased caries risk and in studies has not been shown to be esthetically objectionable.
- Fluoride increases incidence of certain cancers

- American Cancer Society - https://www.cancer.org/cancer/cancer-causes/water-fluoridation-and-cancer-risk.html (fluoride is not associated with cancer and evidence suggests it cannot be classified as carcinogen)

When evaluating possible adverse effects related to fluoride exposure it is critical to consider the dosage. It is well established that excessive consumption of fluoride can lead to alteration of mineralized tissues such as tooth enamel and bone (i.e. dental and skeletal fluorosis). Based on this knowledge it is required that communities not have a water source in excess of 4 ppm F in the drinking water as this can lead to skeletal fluorosis. Dental fluorosis occurs at a lower level of exposure with severe dental fluorosis occurring by consumption of water concentrations of 3-4 ppm F or higher in the drinking water. Multiple epidemiological studies investigating human exposure to different levels of fluoride in drinking water were used to establish a safe, yet caries reducing, dosage.[2] Neither dental fluorosis nor skeletal fluorosis is a problem at the level recommended for community water fluoridation (i.e. 0.7 ppm F).[3]

Large epidemiological studies at the community level have assessed issues related to the health of individuals with and without water fluoridation including cancer, increased risk of chromosome damage and having children with Down syndrome, skeletal fluorosis, dental fluorosis, IQ, kidney and thyroid problems and numerous other issues. To date, these studies have failed to show, that at the currently recommended levels of water fluoridation, any of these negative health outcomes are caused by fluoride.[4] The topic remains highly controversial and studies related to many of the issues raised by those opposed to community water fluoridation are ongoing. The National Toxicology Program report on IQ and diminished cognitive ability resulting from fluoride exposure concluded that there was not sufficient evidence to support an association of these conditions with fluoride exposure at the dosage levels recommended for community water fluoridation[5].

References:

1. Barberio AM, Hosein FS, Quinonez C, McLaren L. Fluoride exposure and indicators of thyroid functioning in the Canadian population: implications for community water fluoridation. J Epidemiol Community Health 2017;71(10):1019-25.
2. Pendrys D, Stamm J. Relationship of total fluoride intake to beneficial effects and enamel fluorosis. J Dent Res 1990;69((Spec Iss)):529-38.
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Expert Evaluation by Ann Newman Chelminski MPH, MD.

- Disease states that cannot tolerate water fluoridation levels such as kidney disease/renal transplant and autoimmune diseases
    - Renal toxicity – because fluoride is primarily renally excreted, it is clear that those with impaired renal function could be at risk of fluoride toxicity due to decreased excretion. There have been deaths in dialysis patients due to lethal cardiac arrhythmias after machine dysfunction caused abnormally high levels of fluoride in dialysate solution[12]. There have also been incidences of acute fluoride toxicity with inadvertent additions of large quantities of fluoride to public drinking water. At lower levels of exposure there is no apparent strong association between low level fluoride exposure and the development of chronic renal disease. Dialysis centers should follow professional recommendations for water quality for dialysis. Studies summarized in the CADTH[1] review suggest a protective effect of lower levels of fluoride on the incidence of kidney stones. A study of people with skeletal fluorosis (indicating long term high levels of exposure) found an association with reported kidney stones.
- Fluoride causes thyroid problems and skeletal fluorosis diagnosed as arthritis
    - Osteosarcoma – High levels of fluoride have known potential bone toxicity. Studies have looked at the risk of the bone cancer, osteosarcoma, related to fluoride exposure. Some studies have found higher levels of fluoride in the drinking water of patients with osteosarcoma than in that of controls, but often had water supplies containing fluoride levels higher than those found in American community drinking water. A study in the U.S. by Levy and Leclerc[2] found no association. A study by Blakey et al[3] reviewed 25 years of data on Ewing sarcoma and osteosarcoma in Great Britain and found no association with fluoride in

drinking water. The authors obtained fluoride information from the public water supplier associated with the cancer registry patient and found no increased risk in these two bone cancers over a 25-year period. The EPA Six-Year Review 3[4] included a study by Bassin (2006)[5] that found an increased risk of osteosarcoma in males exposed to higher levels of fluoride. The review authors note serious study design limitations. The EPA review also includes a study by Kim (2011)[6] that found no association between osteosarcoma and bone fluoride levels. The CADTH[1] review includes a case-control study done in Texas by Archer et al[7] that found no association.

Conclusion

The reports and studies reviewed do not clearly support an increased risk of the bone cancer, osteosarcoma, due to fluoride exposure from water in community water supplies with fluoride levels $\leq$ 0.7 ppm.

- Hypothyroidism – Previous reviews by the CADTH, NRC and EPA have not identified strong evidence of increased thyroid disorders and community water fluoridation at recommended levels. Since 2010, an ecological study of two metropolitan areas in England (Peckham et al, 2015[8]) reported higher rates of clinic patients diagnosed with hypothyroidism in two areas of England with fluoridated vs non-fluoridated water. Critiques of the study include using the General Practitioner's clinic office location for drinking water status rather than residence and not controlling for the potential confounder of iodine deficiency. A 2017 cross-sectional study by Barberio et al[9] found no association and used urinary fluoride or tap water measurements for the measure of exposure. A study in India in areas with levels of fluoride significantly higher than those found in fluoridated community water supplies in the U.S. found higher TSH levels in the areas with higher fluoride, but levels were still within normal.

Conclusion

There does not appear to be strong evidence for an association between higher rates of hypothyroidism and drinking water with fluoride levels ≤ 0.7 ppm. In future research, it would be important to control for family history of hypothyroidism.

- Fluoride increases incidence of certain cancers
    - Cancer (overall) risk – Fluoride is not listed as a chemical known to cause cancer or reproductive toxicity by the State of California's Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency (Proposition 65[10]).
- Fluoride makes bones brittle
    - Fracture risk- A meta-analysis of observational studies by Yin et al[11] found no increased fracture risk with fluoridated drinking water. The authors note that many studies did not control for potential confounders and had possible exposure misclassification. Large scale studies are needed.
- Fluoride concentrates in the spines causing backaches.
    - Musculoskeletal Pain – The CADTH[1] review addresses the question of increased musculoskeletal pain with higher levels of fluoride exposure. A cross sectional study in Thailand found an increased risk of low back pain being reported with fluoridated community water containing greater than 0.7 ppm compared to less than 0.7 ppm. An ecologic study in India found that study subjects had increased reported joint pain at >1.5 ppm fluoride in drinking water, but less joint pain reported in subjects with exposure to water containing 0.4-1.5 ppm fluoride than in subjects with exposure to water with less than 0.4 ppm fluoride. The review authors note concern about inadequate control for confounding variables studies. Skeletal fluorosis is known to be a risk of chronic, high level exposure to fluoride. An

association of increased joint pain and low-level exposure to fluoride is not clearly supported by these studies.

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## Assertion Two: Fluoride Reduces IQ

Community members responding to the survey also express concerns regarding a reduction in IQ level and children experience reduced IQ by 5 points.

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## Expert Evaluation by Tim Wright DDS, MS

A recent publication concluded that males born to mothers that consumed fluoridated water had an IQ reduction of 5 points.[1] This study had many deficiencies and has been the subject of numerous editorials and reviews stating its shortcomings.[2-4] Overall, the study showed no change in the IQ level of the children exposed to higher levels of fluoride compared with low fluoride exposures. Girls in the high fluoride exposure group had IQ levels greater than girls in the low fluoride exposure group. In this study there was no accounting for the children's exposures or experiences from birth to IQ testing at age 3 years and there were numerous other issues. This paper states that fluoride is concentrated in the brain providing a possible mechanism for IQ reduction but they reference a rodent study where very high levels of fluoride exposure are used as there is no human data to support that fluoride is concentrated in any tissues other than mineralized tissues. There is no known or proposed mechanism by which fluoride would alter IQ or affect cognitive function in humans exposed to fluoride levels consistent with community water fluoridation. Evaluation and presentation of the data in the Greene study has been highly controversial and has drawn much concern and criticism from researchers across the globe.

The IQ of the population in the United States has continued to increase since water fluoridation began in the late 1940s.

References:


1. Till C, Green R, Lanphear B. Association Between Maternal Fluoride Exposure and Child IQ. JAMA Pediatr 2019.
2. Berezow AB. Association Between Maternal Fluoride Exposure and Child IQ. JAMA Pediatr 2019.
3. Bledsoe J, Breiger D, McKeever J. Association Between Maternal Fluoride Exposure and Child IQ. JAMA Pediatr 2019.

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Expert Evaluation by Ann Newman Chelminski MPH, MD.

There have been a number of studies published in this area in the past decade, some suggesting an association of lower IQ in children whose mothers had higher prenatal fluoride exposure. It should be noted that some of the studies listed in the CADTH[1] review (Table 36, p. 168) were conducted in countries with areas of very high levels of naturally-occurring fluoride in water. In some studies, the comparison (low exposure) subjects had drinking water with fluoride concentration higher than the US standard for community water supplies. Most of these studies found an association between high water fluoride concentrations and lower IQ. The high exposure groups had levels significantly higher than the US community water standard. A meta-analysis by Choi et al[2] in 2012 reviewed studies done in rural China in communities with some very high (>10ppm) levels of fluoride in drinking water. Higher fluoride exposure was associated with lower IQ measurements. The authors note that most of the studies were of poor quality. Another study by Choi et al[3] of 51 children in China found an association of moderate to severe dental fluorosis (indicating higher fluoride exposure) and poorer scores on a test of non-verbal learning and memory (digit span test). Aggeborn and Ohman[4] looked at subjects ≥ age 16 in Sweden and found no effect of water fluoridation on cognitive ability and math skills. A more recent study from 2019 by Green et al[5] in Canada is notable in that the level of exposure was comparable to the levels of fluoride found in U.S. community water systems. The authors conclude that increased maternal fluoride exposure is associated with decreased IQ in children at age 3-4 years. In October, 2019, the Canadian Agency for Drugs and Technology in Health (CADTH) issued a "Rapid Response Report" titled "Community Water Fluoridation: A Review of Neurological and Cognitive Effects. The CADTH[8] report's critical appraisal of the Green et al study notes that the conclusion regarding lower IQ in children of mothers with higher levels of urinary fluoride is not supported by the data presented. There was no association in girls, only in boys. For girls, the IQ scores were slightly higher in the exposed (fluoridated)

group. A 2017 study by Bashash et al[6] in Mexico City looked at women enrolled in different cohorts for a study of environmental exposures during pregnancy. The biomarker for fluoride exposure was maternal urinary fluoride adjusted for creatinine (spot samples) during one to all three trimesters of pregnancy and the primary outcomes were the results of intelligence testing in their children at ages 4 (General Cognitive Index, GCI, of the McCarthy Scales of Children's Abilities, in Spanish) and at age 6-12 (Wechsler Abbreviated Scale of Intelligence, Full-Scale IQ (WASI-FSIQ)). In the discussion, the authors state that, "The associations with GCI appeared to be linear across the range of prenatal exposures, but there was some evidence that associations with IQ may have been limited to exposures above 0.8 mg/L." It is unclear to me whether their statistical analysis adequately controlled for the differences in maternal lead levels among the cohorts. The authors acknowledge that they did not have information about iodine sufficiency.

While multiple studies have concluded that decrements in IQ are associated with exposure to high levels of fluoride in drinking water, there are far fewer studies that assess cognition and pre- or post-natal exposure to fluoride at low levels of exposure. The studies that show an adverse effect at high levels of exposure raise the question of adverse effects of low levels of exposure and concern for excessive exposure due to sources of ingested fluoride other than appropriately fluoridated drinking water. The study by Green et al[5] found an association with IQ in boys, but not girls; they do not provide a biological explanation for this finding. While some of the studies include maternal lead exposure as a source of prenatal exposure for children, none of the studies reviewed address post-natal exposure of the child to lead, a known neurotoxin. One study by Malin and Till[7] looked at the percentage of fluoridation in different parts of the U.S. and parent-reported diagnoses of Attention Deficit Hyperactivity Disorder (ADHD) in their children. An association between having more areas with fluoridated drinking water (particularly added, rather than naturally-occurring fluoride in water) and a

higher prevalence of children with a diagnosis of ADHD was found. The authors note the study limitation of lack of individual exposure data or information about whether the child lived in the same area at the time of diagnosis. They also note that certain types of added fluoride may increase the risk of lead leaching from older pipes and that the role of lead could not be assessed. A similar study by Barberio et al. cited in the CADTH[8] rapid response report on neurological and cognitive effects of water fluoridation found no increased reports of learning disability, including ADHD, in areas of Canada with community water fluoridation.

More studies of fluoride exposure at low levels, comparable to that found in fluoridated drinking water in the US and Canada are needed, particularly with control for potential confounders such as lead exposure. In the meantime, educational efforts should be continued regarding other sources of fluoride so that excessive exposure is avoided. Dental public health research should inform the discussion about whether lower concentrations of fluoride in drinking water will provide worthwhile protection from dental decay.

References:


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2. Choi AL, Sun G, Zhang Y, Grandjean P. Developmental fluoride neurotoxicity: a systematic review and meta-analysis. Environ Health Perspect. 2012;120(10):1362–1368. doi:10.1289/ehp.1104912
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exposure to fluoride and cognitive functions in Chinese children: A pilot study. Neurotoxicology and teratology. 47. 10.1016/j.ntt.2014.11.001.

4. Aggeborn, L. and Ohman, M. The Effects of Fluoride in the Drinking Water (working paper) , 2017 for the Institute for Evaluation of Labour Market and Education Policy https://www.ifau.se/globalassets/pdf/se/2017/wp2017-20-the-effects-of-fluoride-in-the-drinking-water.pdf
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6. Bashash M, Thomas D, Hu H, Martinez-Mier EA, Sanchez BN, Basu N, Peterson KE, Ettinger AS, Wright R, Zhang Z, Liu Y, Schnaas L, Mercado-García A, Téllez-Rojo MM, Hernández-Avila M. Prenatal Fluoride Exposure and Cognitive Outcomes in Children at 4 and 6-12 Years of Age in Mexico. Environ Health Perspect. 2017 Sep 19;125(9):097017
7. Malin AJ, Till C. Exposure to fluoridated water and attention deficit hyperactivity disorder prevalence among children and adolescents in the United States: an ecological association. Environ Health. 2015;14:17. Published 2015 Feb 27. doi:10.1186/s12940-015-0003-1
8. Community Water Fluoridation Exposure: A Review of Neurological and Cognitive Effects. Ottawa (ON): CADTH; 2019 October. (CADTH rapid response report: summary with critical appraisal Available from: https://www.ncbi.nlm.nih.gov/books/NBK551870/

## Assertion Three: Fluoride Is Only Effective Topically

Community members who oppose fluoride state that dental use of fluoride is meant to be applied directly to the teeth and that swallowing fluoride has no effect on dental health or that fluoride is only affective when applied topically.

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## Expert Evaluation by Gary D. Slade, BDSc, Dip DPH, PhD

### 1.1. Synopsis

- On average, throughout people's lifespan, most of the dental health benefits of fluoridated water are due to TOPICAL effects of the fluoride in preventing decay.
- The remaining benefit is due to pre-eruptive effects that occur when fluoride is incorporated into unerupted teeth as they are forming under the gums during childhood.
- Topical effects and pre-eruptive effects account for approximately equal portions of the preventive benefit in childhood, whereas in adulthood, the benefit is entirely due to topical effects.
- People experience the greatest preventive benefit when they experience both effects which happens when fluoridated water is consumed in childhood and throughout life.

### 1.2. Plain language summary

Throughout people's lifespan, fluoride in drinking water prevents dental decay mostly because of its topical effects on teeth that have erupted. This is called the post-eruptive effect. The remaining preventive benefit is due to fluoride being incorporated into unerupted teeth as they are forming under the gums during childhood. This is called the pre-eruptive effect.

When dental health benefits of fluoride were first discovered in the 1930s and 1940s, it was assumed that preventive effect was mostly pre-eruptive. It wasn't until the 1960s, when fluoride was first added to toothpaste, that researchers discovered that decay could be prevented by topical effects of fluoride on erupted teeth. Subsequent laboratory research and population studies showed that fluoride in drinking water has topical effects (in addition to its pre-eruptive effects). Those studies found two ways in which fluoride in drinking water prevents decay topically, on erupted teeth. Firstly, while the fluoridated water is in the mouth, some of the fluoride comes into contact with the soft dental

plaque that occurs naturally on the tooth surface. The second topical effect comes from fluoridated water that is swallowed. Some of it then enters the saliva via the bloodstream, which means the fluoride has another opportunity to become concentrated in dental plaque on the tooth surface.

By the end of the 20th century, when the topical and pre-eruptive effects of fluoride in drinking water were better understood, most researchers concluded that the main preventive effect of fluoridated drinking water was topical. One piece of evidence came from studies of people who started consuming fluoridated water as adults. By then, all of their permanent teeth had erupted, meaning that the preventive benefit of fluoridated water was due solely to post-eruptive effects. The fact that those adults developed decay at a lower rate than adults who lived in non-fluoridated areas indicated that fluoride in drinking water could prevent decay solely on account of its topical effects on erupted teeth.

However, those same studies found that decay rates were even lower in adults who had consumed fluoridated water in childhood AND in adulthood. This greater benefit from LIFETIME consumption of fluoridated water occurs because of the additional pre-eruptive effects of fluoride during childhood. It's difficult to be precise as to just how much additional benefit occurs because of the pre-eruptive effect in childhood. The best evidence in humans comes from a study of over 17,000 children aged 6-15 years who provided a lifetime history of their water consumption. Decay rates were measured in the first permanent molars, which erupt around six years of age. The study showed that fluoride in drinking water had an overall preventive benefit, reducing decay in by 28% overall, with about half of the effect being pre-eruptive and one half post-eruptive. In other words, the topical effect was equivalent to the pre-eruptive effect in this age group.

See Attachment 22 for a detailed response and references.

## Expert Evaluation by Tim Wright DDS, MS

The primary benefit from water fluoridation is the frequent contact of the fluoride ion in the water with the mineralized tooth tissue (enamel on crowns and cementum and dentin on root surfaces). This frequent contact allows tooth mineral to be re-deposited because fluoride is highly reactive, is attracted to the demineralized mineral where it binds and then the fluoride attracts deposition of calcium and phosphate ions that are deposited thus repairing the damaged tooth mineral. While it is believed that the primary anti-caries benefit of fluoride is from topical exposure on the tooth surface, there are other mechanisms that also contribute to caries reductions. When fluoride is consumed in drinking water, small amounts are secreted in saliva providing a continuous, albeit small, additional topical benefit (concentration in saliva is much lower than the level in community water). There is the additional benefit of fluoride exposure during tooth development that is associated with reduced dental caries. Epidemiological studies show that humans with mild to moderate fluorosis have a reduction in dental caries compared with similar control populations not having fluorosis.[1] Incorporation of fluoride into the tooth mineral makes the mineral less acid soluble and thus more resistant to dental caries.[2] The incorporation of fluoride into enamel can occur topically after the tooth erupts but also occurs during tooth formation as fluoride is taken up by developing mineralized tissues.

References:


1. McGrady MG, Ellwood RP, Maguire A, et al. The association between social deprivation and the prevalence and severity of dental caries and fluorosis in populations with and without water fluoridation. BMC Public Health 2012;12:1122.
2. Isaac S, Brudevold F, Smith FA, Gardner DE. Solubility rate and natural fluoride content of surface and subsurface enamel. J Dent Res 1958;37(2):254-63.

## Assertion: Four: Fluoride is a Neurotoxin

Community members also express concerns that fluoride is a neurological toxin/neurotoxin/developmental neurotoxin.

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## Expert Evaluation by Ann Newman Chelminski MPH, MD.

Fluoride is a neurotoxin – There does not appear to be data supporting an association of fluoride in fluoridated community water supplies with ADHD or Down's syndrome. The NTP Evaluation on Fluoride Exposure and Potential for Developmental Neurobehavioral Effects study of exposure in rats should yield more evidence regarding low level exposures in mammals.

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## Expert Evaluation by Michael Waalkes, Ph.D.

Recent studies and systematic literature reviews have stimulated debate about the potential neurotoxicity of excessive fluoride exposure, possibly indicating that prenatal or early life may be a sensitive period for exposure. For example, a recent study (Bashash et al., 2017[2]) looked at pregnant women and their offspring living in Mexico and found that higher prenatal fluoride exposure apparently caused slightly lower offspring cognitive function (IQ, etc.). In this study (Bashash et al., 2017[2]) fluoride intake was appraised in both mothers and children by urinary fluoride output, an indirect measure of consumption with unknown potential confounding factors including diet. In fact, in this study the levels of fluoride in the drinking water were never actually measured, and, unlike in the USA, in Mexico they add fluoride to salt for supplementation. The effect on IQ in this study was limited to higher levels of fluoride exposure. In addition, there was also significant exposure to mercury and lead in the study population, which are both potentially neurotoxic metals, and there was a lack of information about arsenic exposure, a neurotoxic element. The authors themselves could not rule out the impact of unmeasured variables, including total exposure to established neurotoxic agents, on their findings with fluoride (Bashash et al., 2017[2]). These confounding factors appear to largely limit the usefulness of this study and it is difficult to translate these findings at high levels to the levels used to fluorinate drinking water in the US particularly since drinking water exposure was never actually measured.

Systematic reviews are a type of literature review that uses systematic criteria to collect previously published scientific research studies, and then critically appraises the selected studies, and finally synthesizes findings into an overall set of conclusions. One such systematic review looked at human studies of fluoride exposure from the drinking water and how fluoride exposure might impact neurodevelopmental status from studies carried out primarily in rural China and mostly published in the Chinese scientific literature and “not widely disseminated” (Choi et al., 2012[3]). The authors indicate that

when they looked at low fluoride versus high fluoride exposure (up to 11.5 ppm or mg/L in drinking water) in children from these various studies (ranging age 4-14) they detected a very small reduction in IQ (0.5 points). The authors state that many of the reviewed studies had flaws, often rather serious, including that the actual exposure of the individual children to fluoride was never directly measured, that several of the studies provided evidence of co-exposure to arsenic (a neurotoxin) or did not apparently assess arsenic exposure, that iodine levels are high in some studies and low in others, which could impact fluoride metabolism, etc. Furthermore, the reason that the studies used in this compilation work are "not widely disseminated" is because they are often published in Chinese and/or Chinese regional journals not readily available to most scientists and this makes it difficult for an independent scientific reviewer to assess their quality (rigor of their methods, results, etc.). Overall the conclusions of this review are undercut by the unknown rigor of the studies assessed and the frequent flaws seen of the studies in this review.

Another recent systematic review looked at how fluoride exposure might be linked to neurotoxicity specifically in rodents (NTP, 2016[4]) and comes from the Office of Health Assessment and Translation (OHAT) of the National Toxicology Program (NTP), which is part of the US National Institutes of Health. In evaluating nearly 70 studies they determined that at levels at or near those used for community water fluoride supplementation (0.7 mg/L) there was little or no evidence of neurotoxic effects in experimental animals. In fact, few rodent studies even had data relevant to this fluoride dosage level. Furthermore, OHAT felt that any future additional studies using this low level of fluoride in the water would likely be a challenge to perform because fluoride is a micronutrient needed to support rodent growth, development and adult health and there would be a risk of deficiency. At high doses of fluoride the studies in this systematic review showed "low-to-moderate evidence of a pattern of evidence suggestive of an effect on learning or memory" (NTP, 2016[4]) although the studies reviewed

did not allow for quantitation. This suggestive effect appeared greater in adults than during development. The OHAT review stated most all studies suffered from key deficiencies, including problems with study design, statistics, bias, reporting, method descriptions, etc. Overall the conclusions of this review indicate the pool of available rodent data linking fluoride exposure with neurotoxicity is at best only suggestive, that it comes from studies that most all suffer from key and serious issues, and that it provides no evidence that it occurs at levels used for community water fluoridation.

Conclusion:

At present available data from studies in humans and rodents are consistent in indicating that fluoride, when used and consumed at the levels recommended for community water supplementation (0.7 mg/L), is not associated with neurotoxic effects. This includes systematic reviews of adverse effects in humans and rodents, which combine studies to help better define patterns. At high levels of exposure to fluoride there are data that provide some suggestive evidence of neurotoxicity, but these studies consistently have had confounding factors (human: unknown rigor, exposure to other neurotoxins, diet, etc.; rodent: problems with study design, statistics, bias, reporting, method descriptions, etc.) that overall seriously undercut any firm conclusion about fluoride exposure and neurotoxicity. Indeed one can readily find recent, well performed studies in humans that provide strong evidence that fluoride exposure does not cause neurotoxicity (for example: Barberio et al., 2017[1]).

References:


1. Barberio, et al., 2017: Fluoride exposure and reported learning disability diagnosis among Canadian children: Implications for community water fluoridation. Can. J. Public Health. 14;108:e229-e239.
2. Bashash et al., 2017: Prenatal Fluoride Exposure and Cognitive Outcomes in Children at 4 and 6–12 years of Age in Mexico. https://doi.org/10.1289/EHP655.

3. Choi et al., 2012: Developmental Fluoride Neurotoxicity: A Systematic Review and Meta-Analysis. Envron. Health Perspt. 120: 10 , 1362-68.
4. NTP, 2016: National Toxicology Program, 2016. Systematic literature review on the effects of fluoride on learning and memory in animal studies. NTP Research Report 1.

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## Expert Evaluation by Tim Wright DDS, MS

I address this issue under IQ but again it is critical to point out that exposure dose matters. One review on this topic stated fluoride exposure through drinking water was associated with a reduction in IQ but the studies cited were comparing optimal water fluoride levels to known toxic levels (10ppm in some communities).[1] Even at these extremes it is not clear that there is an association with IQ reduction that is caused by fluoride ion exposure. Many times, these populations (all were outside the US) have increased exposures to aluminum, lead, mercury and other well-known and well-characterized neurotoxins. There are numerous communities and populations around the world drinking fluoridated water that is excessive (compared with current US water fluoridation level recommendations) and there are not conclusive studies showing those populations have a diminished IQ or increased rate of neurological dysfunction unless the levels are well-above recommended and at levels known to be toxic.

References:

1. Choi AL, Sun G, Zhang Y, Grandjean P. Developmental fluoride neurotoxicity: a systematic review and meta-analysis. Environ Health Perspect 2012;120(10):1362-8.

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## Assertion Five: Fluoride is Not Approved by the FDA

Community members also state the FDA defines fluoride as an “unapproved drug” under the form sodium fluoride.

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## Expert Evaluation by Michael Waalkes, Ph.D.

A concern has been expressed by some that fluoride is not "approved" by the U.S. Food and Drug Agency (FDA) and therefore, implicitly, its use as a public health measure via addition to a drinking water system is inappropriate. In point of fact, the U.S. Environmental Protection Agency (EPA) has Federal regulatory oversight of public drinking water (tap water) under the 1974 Safe Drinking Water Act (SDWA; FDA 2017[1]). Thus, the FDA does not have Federal regulatory responsibility for drinking water quality or safety standards, including the use of fluoride in this specific fashion. Furthermore, the US EPA takes the view that fluoride is voluntarily added to drinking water systems by a State or local municipality as a safe public health measure in order to help reduce the incidence of cavities among the population drinking that water.

Consistent with its responsibilities mandated in the SDWA, the US EPA has performed extensive assessment of available data on any toxic or adverse effects published in the scientific literature concerning fluoride in the drinking water. The EPA concludes (EPA 2019[2]) there is no known or expected risk to health from drinking water fluoride levels drastically higher (4.0 mg/L) than the level of fluoride used at the recommended level for drinking water fluoridation (0.7 mg/L). Furthermore, when it comes to specific compounds of fluoride, sodium fluoride supplementation is considered by the United Nations World Health Organization to be both a highly safe and very effective agent in preventative dentistry and its use is considered critical to an effective health care system (WHO 2017[3]).

Conclusion:

In conclusion, a decision to fluoridate a water supply is made by a State or local municipality. It is not approved or mandated by any Federal Agency including the FDA, EPA or any other US Federal Government entity. Thus, the absence of Federal approval for the use of fluoride in this fashion has no bearing on the regulatory validity of its use in this manner.

References:


1. FDA (2017): www.fda.gov/drugs/questions-answers/does-fda-regulate-fluoride-drinking-water
2. EPA (2019): www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations
3. WHO (2017): World Health Organization Technical Report Series; no. 1006; 2017; ISBN 978-92-4-121015-7


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## Expert Evaluation by Tim Wright DDS, MS

The FDA does not classify fluoride for community water as an "unapproved drug". The FDA classifies fluoride in drinking water as a contaminant and it is regulated to not exceed a concentration of 4 ppm (see FDA website: https://iaspub.epa.gov/tdb/pages/contaminant/contaminantOverview.do?contaminantId=10700) . Other fluoride compounds such as those used in toothpaste (e.g. Sodium fluoride, stannous fluoride etc.) are classified and regulated differently. These fluoride compounds are under FDA regulation using a formulary for composition and concentration of dental products.

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## Assertion Six: Fluoride is Not Science Based

Community members also assert that fluoride is not science based.

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## Expert Evaluation by Michael Waalkes, Ph.D.

The original scientific reports that linked the natural level of fluoride in drinking-water with reduced dental caries started appearing in the 1930s followed soon after by reports on cities adjusting the concentration of fluoride in drinking water to improve dental health in the 1940s. Since these initial successes, hundreds of millions of people worldwide have consumed water supplemented with fluoride and numerous scientific studies from various countries have shown a remarkable consistency in associating a substantial reduction in dental caries with consumption of fluorinated water. The United Nations (UN) World Health Organization (WHO) recently convened an expert panel to review the scientific literature on fluoride supplementation and oral health and concluded that studies overwhelmingly show the effectiveness of supplemental water fluoridation in reduction of tooth decay, taking into account an evidence-based approach and using the findings of more recent systematic reviews to reinforce the evidence (O'Mullane et al., 2016[1]).

Additionally, fluoride is considered a nutrient mineral and is included in the Dietary Reference Intake (DRI) system, a system of nutritional recommendations developed by the Institute of Medicine, which is part of US National Academy of Sciences. Within the DRI system a level of nutrient fluoride intake is set to prevent deficiency and the Academy recognizes that fluoride deficiency manifests primarily as an increase in dental cavities. In fact, the ability of fluoridation of water to prevent tooth decay is profound enough to be considered by the US Centers for Disease Control and Prevention (CDC) as "one of 10 great public health achievements of the 20th century". Indeed, in 2007 the UN's WHO World Health Assembly passed a resolution that universal access to fluoride supplementation for prevention of dental caries was to be part of the basic right to human health. These institutes represent some of the world's leading scientific, medical and public health organizations. They are all voicing

support for the use of fluoride supplementation based on truly extensive scientific evidence of improved dental health.

Conclusion:

Extensive amounts of published scientific data overwhelmingly support the use of fluoride supplementation to improve dental health, specifically to substantially reduce dental caries. Hundreds of millions of people have consumed water supplemented with fluoride and numerous studies from all round the world have found it safe and effective. Fluoride supplementation is supported the by world's leading scientific, medical and public health organizations and considered a top public health achievement of last century and part of a basic right to human health.

Reference:

1. O'Mullane, et al., Fluoride and Oral Health. Community Dental Health (2016) 33, 69–99

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## Expert Evaluation by Gary D. Slade, BDSc, Dip DPH, PhD

### 1.1 Synopsis

- There is more than a century of scientific evidence supporting addition of fluoride to drinking water, toothpaste and other dental health products in order to prevent dental decay.
- Nowadays, as new evidence is gathered, it is re-evaluated periodically using systematic reviews and meta-analysis.
- These represent the most rigorous methods to assess scientific evidence concerning human health and healthcare.
- Consistently, those systematic reviews endorse water fluoridation as a safe and effective method to prevent dental decay in the U.S. population.

### 2.2 Plain language response

Observational epidemiologic studies of children covering more than half a century provide compelling and consistent evidence that fluoride in drinking water is associated with substantial benefits in preventing dental caries. The benefits are seen in the primary and permanent dentitions, with the magnitude of relative benefit being greater in the former. Statistical analytic methods used in recent decades account for other sources of fluoride—such as toothpaste—and other factors that influence dental caries in populations such as race, ethnicity, parental income and education. Those studies also demonstrate a caries-preventive benefit of water fluoridation even in populations where virtually all children use fluoridated toothpaste. The most recent U.S. evidence, reported in 2018, is from a study of a nationally-representative sample of children and adolescents that found a substantial preventive benefit, both in the permanent and primary teeth. Notably, benefits were more pronounced for children in low-income families than in high-income families. Similar studies of adults likewise show that water fluoridation is associated with reduced extent of dental caries.

Evidence from observational studies fulfills all criteria for a causal interpretation that water fluoridation prevents caries:

- Findings are consistent, over time and in different populations;
- The strength of association is of public health importance, typically in the range of 30-40% reductions in caries;
- The preventive association applies specifically to dental caries, not to other oral diseases;
- Studies establish the required temporal sequence between exposure to the fluoridation and caries prevention;
- There is a biological gradient in which the benefit increases with increasing extent of exposure to fluoridation;
- Results are analogous to caries-preventive effects of other (non-water) sources of fluoride;
- Several features of an experimental study are reproduced in studies of fluoridation; and
- The causal interpretation is biologically plausible, with good evidence that dental caries prevention is due to a combination of pre-eruptive mechanisms (i.e., incorporation of fluoride into developing enamel which becomes more resistant to subsequent acid attacks) and post-eruptive mechanisms (i.e., concentration of intra-oral fluoride in dental biofilm, inhibiting demineralization and enhancing remineralization).

This evidence from observational studies is bolstered by findings from prospective, community-level intervention studies, showing greater reductions in decay rates in communities that implement fluoridation compared to communities that remain non-fluoridated. Most studies that have assessed changes following cessation of fluoridation report an increase in dental caries compared to comparison communities.

See Attachment 23 for a detailed response and references.

## Expert Evaluation by Tim Wright DDS, MS

Community water fluoridation is one of the few preventive therapies ever evaluated at the community level and there are over 100 years of science evaluating the beneficial effects of fluoride related to caries reduction. Systematic reviews evaluating the community based intervention trial on community water fluoridation and its beneficial effects on caries provide the highest level of scientific evidence achievable.[1, 2] Reviews also show that removing fluoride from the drinking water results in an increase in dental caries.[3] Anti-fluoridation advocates may refer to the 2015 Cochrane Review that there is little contemporary evidence meeting inclusion criteria … to determine effectiveness of water fluoridation in preventing caries in adults.[4] Cochrane reviews are based on randomized control trials and water fluoridation has been tested as a community based intervention as it does not lend itself to a randomized controlled trial design. This type of study would be very difficult to implement.

There are multiple guidelines developed using systematic reviews recommending fluorides in a variety of forms for effective caries prevention. There is a tremendous body of evidence showing that for 75 years community water fluoridation has provided a safe and effective method of preventing and arresting dental caries. Community assessment of water fluoridation also shows that it helps reduce the prevalence of dental caries in populations challenged with social deprivation.[5]

Reference:


1. McDonagh MS, Whiting PF, Wilson PM, et al. Systematic review of water fluoridation. BMJ 2000;321(7265):855-9.
2. Yeung CA. A systematic review of the efficacy and safety of fluoridation. Evid Based Dent 2008;9(2):39-43.

3. McLaren L, Singhal S. Does cessation of community water fluoridation lead to an increase in tooth decay? A systematic review of published studies. J Epidemiol Community Health 2016;70(9):934-40.
4. Iheozor-Ejiofor Z, Worthington HV, Walsh T, et al. Water fluoridation for the prevention of dental caries. Cochrane Database Syst Rev 2015(6):CD010856.
5. McGrady MG, Ellwood RP, Maguire A, et al. The association between social deprivation and the prevalence and severity of dental caries and fluorosis in populations with and without water fluoridation. BMC Public Health 2012;12:1122.

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# Abbreviations

| ABBREVIATION | DEFINITION |
|---|---|
| Ad Hoc | Created for a particular purpose |
| ADHD | Attention-Deficit Hyperactivity Disorder |
| BOH | Board of Health |
| Ca | Calcium |
| CADTH | Canadian Agency for Drugs and Technologies in Health |
| CDC | Centers for Disease Control |
| CWF | Community Water Fluoridation |
| CWS | Community Water Source |
| DRI | Dietary Reference Intake system |
| EPA | Environmental Protection Agency |
| F | Fluoride |
| FDA | Food and Drug Administration |
| GCI | General Cognitive Index (An IQ test) |
| GP | General Practitioner |
| IQ | Intelligence Quotient |
| LBP | Low Back Pain |
| Meta-Analysis | Large review of many research publications |
| NRC | National Research Council |
| NTP | National Toxicology Program |
| OHAT | Office of Health Assessment and Translation |
| OWASA | Orange Water and Sewer Authority |
| ppm | Parts Per Million (1 milligram in 1,000,000 milligrams) |
| RCT | Randomized Controlled Trial |
| SDWA | Safe Drinking Water Act |
| TSH | Thyroid Stimulating Hormone |
| UN | United Nations |
| US CWS | United States Community Water Source |
| WHO | World Health Organization |

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# Attachments

1. April 2017 Board of Health letter of support to OWASA in continuing fluoridation of drinking water

2. November 2017 OWASA letter requesting assistance from Board of Health

3. November 2017 Board of Health meeting minutes presenting OWASA request letter to Board of Health (Excerpt page 7 of 8)

4. February 2018 Board of Health meeting minutes in which board voted to create an ad hoc committee (Excerpt page 7 of 8)

5. June 2018 Ad Hoc Fluoride Committee meeting minutes discussing process

6. June 2018 Board of Health meeting minutes in which ad hoc committee provides an update (Excerpt page 3 of 5)

7. July 2018 Ad Hoc Fluoride Committee meeting notes in which a plan was proposed for the fluoride process

8. August 2018 Board of Health meeting minutes in which the board agree to the fluoride review process proposed by the ad hoc committee (Excerpt page 3 of 6)

9. Letter outlining BOH Fluoride Review process to OWASA director

10. Letter created by ad hoc committee to secure experts in the fluoride process

11. October 2018 Board of Health meeting minutes in which ad hoc committee provides an update (Excerpt page 7 of 8)

12. First draft of the community survey created by the ad hoc committee

13. November 2018 Board of Health meeting minutes in which ad hoc committee provides an update (Excerpt pages 3-4 of 5)

14. February 2019 Board of Health meeting minutes in which Board of Health decides to offer an honorarium to experts (Excerpt page 5 of 6)

15. Updated letter created by ad hoc committee to secure experts in the fluoride process

16. May 2019 Board of Health meeting minutes in which ad hoc committee provides an update (Excerpt 5-6 of 7)

17. Finalized community questionnaire

18. Promotional correspondence to the community to complete questionnaire

19. An Ethics Framework for Public Health

20. List of concerns expressed by survey respondents who oppose fluoride

21. List of concerns from residents who attended the OWASA Board meeting on October 27, 2017

22. Assertion Three detailed response and references provided by expert Gary Slade.

23. Assertion Six detailed response and references provided by expert Gary Slade.

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April 11, 2017

John Young
OWASA Board Chair
Orange Water and Sewer Authority
400 Jones Ferry Rd
Carrboro, NC 27510

Dear Mr. Young,

The Orange County Board of Health would like to offer our utmost support for the continuation of fluoridation of the Orange County water supply. First, we would like to thank OWASA for the quick actions taken to prevent excess fluoride from entering the water distribution system in February. We also appreciate and support the efforts you intend to take to prevent this occurrence in the future. The Board of Health would like to affirm the decision to continue fluoridation of the water supply by offering the following supportive resources and facts.

- "Given the dramatic decline in tooth decay during the past 70 years since community water fluoridation was initiated, the Centers for Disease Control and Prevention (CDC) named fluoridation of drinking water to prevent dental caries (tooth decay) as one of ten great public health interventions of the 20th Century". For more information on the CDC's position on fluoridation visit: https://www.cdc.gov/fluoridation/index.html
- According to the American Dental Association, "the accumulated dental, medical and public health evidence concerning fluoridation has been reviewed and evaluated numerous times by academicians, committees of experts, special councils of government and most of the world's major national and international health organizations. The verdict of the scientific community is that water fluoridation, at recommended levels, safely provides major oral health benefits". http://www.ada.org/en/public-programs/advocating-for-the-public/fluoride-and-fluoridation/fluoridation-facts
- The Environmental Protection Agency (EPA) was petitioned on November 23, 2016 to exercise its authority to "prohibit the purposeful addition of fluoridation chemicals to U.S. water supplies." The EPA denied this petition on February 17, 2017 primarily because there was "not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water…" Additional reasons can be found at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0763-0001

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- The NC Department of Health and Human Services Oral Health Section supports and provides educational material for fluoridation of community water. To view these materials visit: https://www2.ncdhhs.gov/dph/oralhealth/education/index.htm

The Orange County Board of Health agrees with the vast amount of evidence provided by accredited local, state, and federal agencies. After 70 years of practice, we know and believe that:

- Fluoride is recognized as an important nutrient for healthy teeth.
- Fluoridation of community water is the most cost effective method to prevent tooth decay.
- Fluoridation is an important public health measure and modest community-wide investment that benefits everyone.

We are glad that OWASA plans to continue fluoridation of the water system, introducing new safeguards to continue to prevent excess fluoridation, as soon as possible.

Sincerely,

Liska Lackey, RN
Board Chair

Susan A. Elmore

Susan Elmore, MS, DVM, DACVP, DABT, FIATP
Board Vice-Chair

**Agenda Item Number:**

# ORANGE COUNTY BOARD OF HEALTH
# AGENDA ITEM SUMMARY

**Meeting Date:** November 29, 2017

**Agenda Item Subject:** Periodic Review of Drinking Water Fluoridation

**Attachment(s):** OWASA Water Fluoridation Letter

**Staff or Board Member Reporting:** Dorothy Cilenti

**Purpose:** ____ Action
____ Information only
__X_ Information with possible action

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**Summary Information:**

Following public input and discussion at their meeting on October 26, 2017, the OWASA Board of Directors would like to explore with the Orange County Health Department a County-wide process for periodic review of drinking water fluoridation to evaluate the latest scientific findings on the benefits for oral health and any harmful effects it may have on any aspect of health.

**Recommended Action:** ___Approve
___Approve & forward to Board of Commissioners for action
___Approve & forward to _____
_X_Accept as information
___Revise & schedule for future action
___Other (detail):

# ORANGE WATER AND SEWER AUTHORITY

*A public, non-profit agency providing water, sewer and reclaimed water services to the Carrboro-Chapel Hill community.*

November 3, 2017

Dr. Dorothy Cilenti, DrPH
Interim Orange County Health Director
300 West Tryon Street
Hillsborough, NC 27278

**Subject: Water Fluoridation**

Dear Dorothy,

Following public input and discussion at their meeting on October 26, 2017 (meeting video), the OWASA Board of Directors would like to explore with the Orange County Health Department a County-wide process for periodic review of drinking water fluoridation to evaluate the latest scientific findings on the benefits for oral health and any harmful effects it may have on any aspect of health. While any future decision(s) on fluoridation for the Chapel Hill-Carrboro community will remain the responsibility of the OWASA Board, we recognize that the Orange County Health Department is a very important community resource for such health and safety matters.

The OWASA Board discussed the following key components for review of fluoridation:

- Open and transparent process that has been communicated to the public and stakeholders.
- Individuals and organizations that both support and do not support fluoridation will be invited to provide input.
- The latest science will be reviewed by dental and medical experts who have recognized credentials in their fields of expertise including all aspects of human health that could be affected by fluoridation.
- The review will specifically address key concerns raised by those who do not support fluoridation.
- The observations and findings of the review will be communicated to the public and stakeholders in a clear and understandable way.

As a next step, OWASA very much appreciates the Health Department's timely feedback and recommendations regarding a County-wide process for periodic review of fluoridation.

Thanks,

Ed Kerwin

Ed Kerwin
Executive Director

c: OWASA Board of Directors

400 Jones Ferry Road
Carrboro, NC 27510-2001



Voice (919) 968-4421
*www.owasa.org*

Mr. David Andrews, Carrboro Town Manager
Ms. Bonnie Hammersley, Orange County Manager
Mr. Eric Peterson, Hillsborough Town Manager
Mr. Roger L. Stancil, Chapel Hill Town Manager

***Motion to elect Timothy Smith to Vice-Chair for the 2018 calendar year was made by Jennifer Deyo, seconded by Barbara Chavious and carried without dissent.***

## VII. Reports and Disccussion with Possible Action

### A. Periodic Review of Drinking Water Fluoridation

Dr. Cilenti began by acknowledging Ed Kerwin, OWASA's Executive Director. She referred to the November 3rd letter from OWASA requesting feedback and recommendation regarding a County-wide process for periodic review of fluoridation. The letter was sent following public input and discussion at OWASA's meeting held on October 26th. Our Communications Manager, Kristin Prelipp, was also in attendance at that meeting. Dr. Cilenti stated that a discussion needs to be had to develop a process about how the OCHD/BOH is going to address key concerns from those opposed to fluoridation, the oral health benefits and risks, and make sure it's communicated to the public in a clear way.

Suggestions by BOH members included creating a subcommittee with the new health director, hiring an outside party to give the OCHD/BOH a recommendation and possibly having an expertise in toxicology be involved. As a response was needed to the OWASA letter, it was suggested that this topic be a future agenda item. It was determined that this would occur in February 2018. Mr. Kerwin thanked the Board for all of its help and stated that he will pass the information on to his Board of Directors.

***The BOH had questions that were addressed by Dr. Cilenti and Mr. Kerwin.***

### B. Health Director Report

In addition to the report, Dr. Cilenti invited all to the meet and greet taking place on December 19th at the Whitted Building Room 230 from 2-4pm to welcome the new health director, Quintana Stewart. Speakers are to include the county manager as well Vice-Chair, Susan Elmore and Commissioner Mia Burroughs.

The newly hired health director has also been invited to attend the OCHD All Staff meeting on December 15th at 2:30pm at the SHSC. Dr. Cilenti stated that it's an opportunity for staff to meet her before she starts on December 18th. Lastly, she expressed that it's been a great privilege to work at the OCHD again and that she will be available during Quintana's transition.

On behalf of the BOH, Chair Liska Lackey conveyed how thankful and appreciative the Board was for Dr. Cilenti and for the space she gave to the Board that allowed them to conduct the health director search eventhough it took longer than expected.

### C. Media Items

***Media items were in the packet which focused on Orange County's events and our involvement in various efforts.***

***At 8:55pm, Paul Chelminski motioned to move into closed session and Sam Lasris seconded.***

***County Manager and Board of County Commissioners for action was made by Sam Lasris, seconded by Jennifer Deyo and carried without dissent.***

***The BOH had questions that were addressed by Ms. Crawford.***

**VII. Reports and Disccussion with Possible Action**

A. Fluoridation Discussion

Quintana Stewart, Health Director, began by reiterating that this is a follow-up to the November 3rd OWASA letter to the BOH requesting help with a community review of fluoridation. It was determined, during the November 27, 2017 BOH meeting, that the Board will decide if they wish to create a subcommittee to plan for the Countywide review of fluoridation upon arrival of the new Health Director. Ms. Stewart informed the Board that she had previously spoken with Ed Kerwin, OWASA Executive Director. The subcommittee's focus will be solely on health concerns and not the ethical. The subcommittee duties will consist of the planning and reaching out to the experts. After the Board reviews the information, they will present it to the public. After some discussion, the Board voted on whether to create a subcommittee.

***Motion to create a planning subcommittee was made by Liska Lackey and seconded by Sam Lasris. Johanna Birckmayer abstained.***

B. Health Director Report

Ms. Stewart elaborated on the Health Department's activities that occurred in February as well as the upcoming activities that were in her Health Director's Report. There were no questions from the Board regarding the Health Director's Report included in the packet.

C. Media Items

***Kristin Prelipp, Communications Manager, distributed the Annual Report to the Board. Media items were in the packet which focused on Orange County's events and our involvement in various efforts.***

**VIII. Board Comments**

**None.**

**IX. Adjournment**

***Barbara Chavious moved to adjourn the meeting at 8:55pm and Liska Lackey seconded.***

**The next Board of Health Meeting will be held March 28, 2018 at the Orange County Health Department, 300 West Tryon Street, Hillsborough, NC at 7:00 p.m.**

Respectfully submitted,

# MEETING MINUTES

Board of Health

Ad Hoc Fluoride Committee

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***Wednesday, June 6, 2018***
***5:30 pm – 6:30 pm***
***BOH Conference Room***

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**Committee Purpose** At the request of the Orange County Water and Sewer Authority (OWASA), the BOH has put together an Ad Hoc Committee to review the benefits for oral health and any harmful effects of drinking water fluoridation. The BOH will ultimately make a recommendation to OWASA.

**Present:** Jessica Frega, Bruce Baldwin, Liska Lackey, Quintana Stewart, Beverly Scurry

**Items in Red** **Action steps to be completed before the next meeting**

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**Background**

- OWASA is requesting the following from the BOH:
  - Open and transparent process that has been communicated to the public and stakeholders.
  - Individuals and organizations that both support and do not support fluoridation will be invited to provide input.
  - The latest science will be reviewed by dental and medical experts who have recognized credentials in their fields of expertise including all aspects of human health that could be affected by fluoridation.
  - The review will specifically address key concerns raised by those who do not support fluoridation.
  - The observations and findings of the review will be communicated to the public and stakeholders in a clear and understandable way.

**Discussion**

- Members of the Ad Hoc Committee. OWASA would like to include a community resident who opposes fluoridation of the drinking water. Beverly sent Ed Kerwin, Executive Director of OWASA, an email requesting recommendations for someone who opposes fluoridation as well as a resident who supports fluoridation.
- Beverly presented the Committee with two documents from the American Dental Association – Responses to Misconceptions About Community Water Fluoridation, March 2015 & Frequently Asked Questions on Community Water Fluoridation, February 2017.
- Beverly also presented the Committee with a journal titled An Ethics Framework for Public Health by Nancy E. Kass (2001). *American Journal of Public Health.* This document outlines the following questions for the committee to remember during this process:
  1. What are the public health goals of the proposed program?
  2. How effective is the program in achieving its stated goals?
  3. What are the known or potential burdens of the program?
  4. Can burdens be minimized? Are there alternative approaches?

5. Is the program implemented fairly?
6. How can the benefits and burdens of a program be fairly balanced?

- The Committee discussed having a panel of experts seems the best way to help formulate a recommendation.
- The Committee discussed the best way to get public comment on the issue. The committee will develop a survey and post it on the OCHD website for public feedback.
- The Committee would review the comments from the survey and find the major themes.
- The expert panel would be presented with those themes and respond keeping in mind the 6 questions above.
- A set of questions will be developed specifically to ask the panel. Questions will be based on themes as well.
- After the panel, a formal report will be written to give to OWASA and make public.

**Final Thoughts**

- Due to the fact that all residents and committee stakeholders will be given a chance to respond online, there will be no need to have residents as part of the panel or Ad Hoc Committee.
- Suggested panelists include:
  - OWASA Board/Staff member
  - Hydrogeologist at the North Carolina Department of Environment and Natural Resources
  - Chief or staff member of the NC Department of Health and Human Services, Oral Health Section
  - Chair of the UNC School of Dentistry – Pediatric Dentistry
  - Medical Person – MD, PhD
- Confirm panelists by the end of June
- First week in July make electronic survey available to the public – open for 2 weeks
- The committee will meet again third week in July to review public comments and pick themes
- Panelists will be sent themes from public comment in early August as well as the ethics of public health framework
- Panelist will present at the August meeting or committee will ask for electronic responses from panelists to present a PPT to BOH
- August would be ideal to finish process, but September may be more realistic

**Action Steps**

- **Ask Donna and Coby how they previously set up an online public survey during the E-cig/Tobacco work**
- **Beverly will contact potential panelists**
- **Beverly will work with Committee to formulate questions for the electronic survey (open ended and close ended questions)**
- **Beverly will find out from county lawyer what are the guidelines around public comment**
- **Beverly will send out July meeting date for committee**
- **Jessica will give the Board an update on this meeting at the June BOH meeting**

Sexually Transmitted Diseases – Chlamydia is on the rise. Syphilis is also very high. HIV cases have stayed constant and are low in comparison to national and state numbers.

Outbreaks – There were four in 2017. There was a school influenza outbreak that resulted in 38 cases over 3 months. There were also 2 separate Noro Virus-like outbreaks at a sorority and a fraternity house. The last outbreak involved Pertussis.

***The BOH members had questions that were addressed by Ms. Vann.***

C. Fluoride Ad Hoc Committee Update

Jessica Frega, BOH member, gave an update on the first ad hoc fluoride committee meeting. Highlights are below:

- OWASA requests - have medical/dental experts weigh in by recruiting experts outside of the OCHD, public comments by having an online poll/survey and one public comment hearing, address those that oppose fluoridation, receive a clear understandable final report that is comprised once the ad hoc committee synthesize themes, forward it to the experts and reports to the BOH.
- Discussion was had amongst BOH members regarding methods to fulfill OWASA's requests.
- The next ad hoc meeting will be held on July 18th.

***The BOH members had questions that were addressed by Ms. Frega.***

D. NALBOH Annual Conference

Quintana Stewart, Health Director, gave an overview of the upcoming 2018 NALBOH conference scheduled for August 8-10, 2018 at the Marriot Raleigh Crabtree Valley in Raleigh. There will be great networking opportunities, public health governance, national attendees and discussion on the roles and responsibilities of local BOH. This year's topics include the opioid epidemic and Accreditation. Registration rates vary dependent on whether you attend the pre-conference, full conference or just one day.

Ms. Susan Elmore added she goes every year and leaves energized. As a member on the ANCBH, she stated that there are $500 scholarships that assist with registration. She requested that those interested notify her. She also stated that it's the first time it's being held in Raleigh and is a great opportunity.

**VI. Action Items (Non-Consent)**

A. Strategic Plan 2018-2020

Beverly Scurry, BOH Strategic Plan Manager, revealed the final look for the 2018-2020 Strategic Plan. BOH members commented that the Strategic Plan was visually appealing. Thanks were given to Kristin Prelipp, Communications Manager, for the new look and branding of the Strategic Plan.

Fluoride Sub-Committee's proposal for BOH plan to review fluoridation of water – 7.18.18

After BOH's approval of the plan, the Fluoride Sub-Committee will respond to OWASA's Nov 3, 2017 letter, as follows:

1. Recognizing that there is public dissent on the issue of fluoridation, we welcome OWASA's request for our review

2. Present a summary of our planned review process, to include:
    a. Secure review panel to include dental and medical experts

    b. Compile community feedback already provided to OWASA

    c. Invite public comment:
        i. Public announcement of BOH review
        ii. Two-week on-line opportunity for public to provide comment

    d. Request expert panel address fluoridation and provide their observations and findings, to include:
        i. Address key concerns provided through public comment (both to OWASA and BOH)
        ii. Reference latest science on the effects of fluoridation on all aspects of human health
            1. For example, evidence of human health benefits from public water fluoridation, especially as this pertains to oral health
            2. For example, evidence of potential human harms, with special focus on possible adverse neurologic and endocrinological effects
        iii. Utilize public health framework in the review process

    e. The Fluoride Committee will review the expert panel's report and present to BOH for consensus on endorsement

    f. The BOH will submit the BOH-endorsed report to OWASA

    g. The BOH will assist OWASA in communicating the report to the public & stakeholders
        i. After report is received, OWASA can decide on the process of how to share with public and consult with BOH on their role in assisting in that process

- **Total Billing Accuracy**: Continuing with the goal of 90% billing accuracy set in FY 14-15, the average billing accuracy rate for medical for FY 17-18 was 91% as compared to the year-end average of 96% in FY 16-17. The average billing accuracy rate for dental for FY 17-18 was 101% as compared to 100% in FY 16-17.

- **Dental Earned Revenue by Source:** The FY 17-18 average monthly revenue ($42.5/month) for the fourth quarter is below our budget projection ($43.4k/month) but above our FY 16-17 average of $39.8/month. FY 17-18 dental earned revenue totaled $511k at the end of the fiscal year, compared to $478k at the end of FY 16-17.

- **Medical Earned Revenue by Source:** Medical earned revenue for the fiscal year was below the budgeted projection for FY 17-18 ($686k) at $609k since we had a provider on maternity leave until the end of December, provider turnover at the end of the fiscal year, and reduced appointments available to allow for Epic preparation.

- **Grants Fund Revenue:** FSA received a multi-year grant for $100k per fiscal year for 3 years at the end of FY 17-18. These funds will carry through FY 18-19 and FY 19-20. We'll track these and any other multi-year grants through this section of the financial report on an ongoing basis.

- **Note for FY 18-19 Revenue:** FAS (Finance and Administrative Services Division) anticipates medical revenue will be delayed for the first 3 months of FY 18-19 as we close out billing in the Patagonia Electronic Medical Record System (EMR) and begin billing in the new Epic EMR. UNC has built an incredible billing system for the Health Department, however it is the first system like it they have ever built and we continue to work through anticipated system issues, which will delay billing to commercial insurance and Medicaid. Patients are still being seen so revenue will catch up in the latter part of the Fiscal Year.

  FAS also anticipates a potential delay in Environmental Health revenue as the division transitions to a new Central permitting system in October. Staff are training frequently now to reduce the impact on county residents and prepare for the upcoming Go Live.

***The BOH members had questions that were addressed by Ms. Crawford.***

C. Fluoride Ad Hoc Committee Update

Liska Lackey, BOH member, began by reminding the Board that the role they have in reviewing a policy in which they have no authority is due to their duty to protect the public's health while recognizing that OWASA has that authority. Ms. Lackey then reviewed the proposed plan for addressing key components in the November 3, 2017 letter in which OWASA requested a review of fluoridation. Ms. Lackey acknowledged and praised the fluoride committee members that provided input into this proposed plan. Board suggestions included making sure there is focus on the at-risk population and having local experts (e.g. those in the triangle area) participate. The Board came to a general consensus and all agreed on the proposed plan. Ms. Lackey will generate a letter for the Board chair's signature to be sent to OWASA.

***The BOH members had questions that were addressed by Ms. Lackey.***

[DATE]

Ed Kerwin, Executive Director
Orange Water and Sewer Authority
400 Jones Ferry Road
Carrboro, NC 17510-2001

**Subject: BOH review of water fluoridation**

Dear Ed,

Recognizing that there is public dissent on the issue of fluoridation, the Orange County Board of Health (BOH) welcomes OWASA's request for a review of water fluoridation. Our review plan is based on our responsibility to protect and promote the public health of Orange county while recognizing that OWASA has authority over water fluoridation.

Our planned review process, which addresses the key components listed in your letter of November 3, 2017, is as follows:

a. Secure review panel to include dental and medical experts
b. Invite public comment:
    i. Public announcement of BOH review
    ii. Two-week on-line opportunity for public to provide comment
c. Request the expert panel address water fluoridation and provide their observations and findings, to include:
    i. Address key concerns provided through public comment (both to OWASA and BOH)
    ii. Reference latest science on the effects of fluoridation on all aspects of human health, including those in the population who may be at most risk of harm
        1. For example, evidence of human health benefits from public water fluoridation, especially as this pertains to oral health
        2. For example, evidence of potential human harms, with special focus on possible adverse neurologic and endocrinological effects
    iii. Utilize public health framework in the review process
d. The BOH will review the expert panel's report
e. The BOH will submit the BOH-endorsed report to OWASA
f. The BOH will assist OWASA in communicating the report to the public & stakeholders

Thank you for requesting that the BOH review water fluoridation. We look forward to working with you.

Sincerely,

Susan Elmore, DVM
Chairperson, Orange County Board of Health

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October 16, 2018

**Subject: Expert review of water fluoridation**

To Whom It May Concern,

As a member of the Orange County Board of Health, I am contacting you to see if you can serve as an expert in your field to address water fluoridation.

Recognizing that there is public dissent on the issue of fluoridation, Orange Water and Sewer Authority (OWASA) requested that the Orange County Board of Health (BOH) address this issue. The BOH's review plan is based on our responsibility to protect and promote the public health of Orange County while recognizing that OWASA has authority over water fluoridation.

We will ask the environmental, dental and medical experts to address water fluoridation and to provide their observations and findings in a summary report, that:

1. Addresses key concerns provided through public comment to OWASA and BOH
2. References latest science on the effects of fluoridation on all aspects of human health,
    a. Including potential harm to those in the population who may be at most risk (in utero, children and elderly
    b. For example, evidence of human health benefits from public water fluoridation, especially as this pertains to oral health
    c. For example, evidence of potential human harms, with special focus on possible adverse neurologic and endocrinological effects
3. Utilizes a public health framework in the review process

Would you consider serving as an expert by submitting a formal response to the items listed above? If you need further information before deciding, please let me know.

We appreciate your consideration of this request and look forward to hearing from you.

Sincerely,

Liska Lackey, MSN, FNP-BC
Chair, Board of Health, Water Fluoridation Committee
llackey@email.unc.edu
919-968-2796

## VII. Reports and Discussion with Possible Action

### A. Fluoride Ad Hoc Committee Update

BOH member, Liska Lackey, provided an update on the recruitment of subject matter experts. She stated that they've acquired a dental expert, Dr. Lewis Lampiris, Assistant Dean for Community Engagement and Outreach at the UNC School of Dentistry. The committee is still in need of an expert in toxicology and a medical expert with a background in neurology and endocrinology. Beverly Scurry, Strategic Plan Manager, added that she will be reaching out to professional organizations.

### B. Presentation of 2019 Vice-Chair

The Board members shall elect a Chair and Vice-Chair by majority vote each year at the last meeting of the calendar year. Jessica Frega had expressed interest in the Vice-Chair position. Prior to the BOH meeting, Timothy Smith and Liska Lackey, members of the Vice-Chair selection committee, extended an invitation to Ms. Frega for Vice-Chair which she accepted.

***Motion to elect Timothy Smith to Chair and Jessica Frega to Vice-Chair for the 2019 calendar year was made by Jennifer Deyo, seconded by Keith Bagby and carried without dissent.***

### C. Health Director Report

In addition to her report, some of the highlights Ms. Stewart gave are below:

- October 12th - OCHD Annual Picnic. Although attendance was low (this was a day after Tropical Storm Michael occurred), a great time was had. BOH member, Keith Bagby, made an appearance.
- October 15th – Attorney General Josh Stein announced that he has launched an investigation into Juul, the e-cigarette company.
- October 16th – BOCC unanimously agreed with the option to alter the capital building improvement plan and replace the original plans to build a dental clinic with the mobile clinic (dental van).
- NCALHD voted to support the ABC Boards to avoid privatization of alcohol sales. The NCALHD acknowledged the ABC Boards' contributions including to Orange County. BOH member and ABC Chair, Keith Bagby, added that most people aren't aware of what the ABC Board does outside of liquor sales regulation. Mr. Bagby continued by stating that the ABC Board contributes significantly to multiple agencies including law enforcement and mental health.
- On October 25th, Ms. Stewart and April Richard, Tobacco Prevention and Control Coordinator, will be attending "Vision 2020" in Raleigh which is sponsored by the American Cancer Society.
- Ms. Stewart thanked the BOH for the recommendation of taking the Municipal and County Administration course and that classes are going well.

### D. Media Items

Kristin Prelipp, Communications Manager, briefly mentioned the article in the News of Orange regarding suicide prevention which was included in the Media Items packet.

Water Fluoridation Survey

Orange Water and Sewer Authority (OWASA) recognizes that there is public dissent on the issue of water fluoridation and has requested that the Orange County Board of Health (BOH) review this policy. The BOH's review plan includes inviting public comment on water fluoridation. Public comments will be provided to a panel of dental and medical experts and they will be asked to address the public's key concerns, referencing the latest science on the effects of fluoridation on all aspects of human health.

We appreciate your participation in this short survey.

I support OWASA's fluoridation of water Yes No

If respondent answers "no", cue the following questions:

1. I am opposed to fluoridation of water because (check all that apply):
    - It can affect the environment
    - It is an infringement of individual rights
    - It can have a negative impact on personal health
    - It is not necessary to prevent tooth decay
2. What questions do you have about water fluoridation?
3. What other comments do you have with water fluoridation?

If respondent answers "yes", cue the following questions:

1. I support the fluoridation of water because (check all that apply):
    - It is an important public health measure
    - In the right amounts, it is safe
    - In the right amounts, it helps prevent dental decay
2. What questions do you have about water fluoridation?
3. What other comments do you have with water fluoridation?

Ms. Moore explained that the Fair Housing section of her department is equivalent to Housing and Urban Development (HUD). HUD refers cases to them and pays them as well. There were 84 Fair Housing Assistance Program (FHAP) agencies. For FY 2017, there were 6,878 complaints filed and 7,985 completed investigations. In Orange County, there were 11 cases closed last year. There are many disability cases filed in Orange County as well as nationally. Percentages of the cases filed are:

Disability – 59.4%
Race – 26.0%
Familial Status – 10.6%
Retaliation – 10.2%
National Origin – 10.1%
Sex – 9.8%
Religion – 2.8%
Color – 2.3%

Statistics on hate crimes were also given. There were 7,175 reported in the U.S. in 2017 which was a 17% increase from 2016. It was the 3rd worst year since the FBI starting collecting data in 1992. Of the 50 states, Hawaii is the only one that does not report hate crimes.

Ms. Moore continued by noting that there are some instances of underreporting as some of the new immigrant populations are afraid. Ms. Moore's department is working with translators to help with this issue. Sex discrimination is also underreported.

Ms. Moore reminded us that we have to change methods and practices; how we do our work. She reiterated that we cannot continue doing the same thing and expecting change to occur. She stated that we need to stop acting in silence and that there needed to be 1 Orange 1 community. She also stated that there needs to be strategic planning for how we're going to heal our community; we need to talk to each other and be vulnerable together. Lastly, Ms. Moore shared that we also need to ensure that there are community resources and tools for everybody.

***The BOH had questions that were addressed by Ms. Moore.***

## VI. Reports and Discussion with Possible Action

### A. Fluoride Ad Hoc Committee Update

BOH member, Liska Lackey, provided an update on the recruitment of subject matter experts. She stated that they're still working on acquiring experts for the panel. Although a dentist has been secured, Beverly Scurry, BOH Strategic Planning Manager, stated that she has been reaching out to several professional organizations including the Society of Toxicologist to recruit the additional experts in the field of toxicology and a medical expert with a background in neurology and endocrinology. Susan Elmore, BOH Chair, requested the CV of those interested including the acquired dentist so that it can be assured that they're experts. Beverly Scurry, BOH Strategic Plan Manager, added that she will be reaching out to professional organizations.

Ms. Lackey also presented a draft of the Water Fluoridation Survey and asked for feedback/edits. The survey would be available to be completed online. Discussion included:

- Brevity of the survey
- Free form section – determining the limit of text characters, possibility to upload documents
- Defining fluoridation
- Notifying the public that the water is currently fluoridated
- Ensuring that the only individuals completing the survey are the OC residents that are being affected (only Carrboro and Chapel Hill)
- Removing "Survey" and replacing it with "Questionnaire"
- OWASA will disseminate the notice allowing a 2 week opportunity to comment after panel approves the questionnaire.

B. Health Director Report

In addition to her report, some of the highlights Ms. Stewart gave are below:

- Ms. Stewart briefly discussed the water main break that occurred the first week of November in front of the treatment center in Chapel Hill and smaller water break in Carrboro.
  - Water pressure dropped; a boil water advisory was issued; schools closed; patients couldn't be seen.
  - Victoria Hudson and Kristin Prelipp were praised for their efforts during this event.
  - Chatham, Durham and Hillsborough piped in water.
  - OCHD participated in a debriefing with OWASA that was attended by UNC school and hospital representatives, Carrboro Chamber, Chapel Hill elected officials and several business owners. It was mentioned that the health department improved their communication since the water main break that occurred in February 2017.
  - Lessons learned from 2017 were integrated.
  - EMS is still looking to improve the OC Alerts.
- REI Groundwater Presentation will take place on December 4th at Whitted. An offer to cover the BOH members' participation was extended.
- An invitation to attend the OCHD Holiday Breakfast on December 5th was extended to the BOH members.

C. Media Items

Kristin Prelipp, Communications Manager, briefly mentioned articles regarding the boil water advisory and the appointment of our medical director, Dr. Erica Pettigrew, to the NC Commission for Mental Health, Developmental Disabilities and Substance Abuse Services which was included in the Media Items packet.

***Media items were in the packet which focused on Orange County's events and our involvement in various efforts.***

Before going into closed session, Ms. Elmore presented a plaque of appreciation to Commissioner Burroughs, who was thanked by all for her service.

***At 8:10pm, Paul Chelminski motioned to move into closed session and Jessica Frega seconded.***

levels of complexity and time involved for the procedures. Finally, the division requests to implement scheduled adjustments to the fees for 340B drugs (Family Planning drugs not including birth control pills) to make them match the county's cost to purchase them, as required by the state and federal government. The total financial impact from Personal Health fee changes is projected to be a maximum of $39,449.

***The BOH had questions that were addressed by Ms. Crawford and Quintana Stewart.***

***Motion to approve the total budget in the amount of $10,575,428 for FY 2019-2020 and to approve all fee changes for FY 2019-2020 as presented and forward to the County Manager and Board of County Commissioners for action was made by Liska Lackey, seconded by Keith Bagby and carried without dissent.***

**VII. Reports and Discussion with Possible Action**

A. Fluoride Ad Hoc Committee Update

BOH and Fluoridation Subcomittee member, Liska Lackey, gave an update on the status of recruitment of fluoride panel experts. Three experts were requested – an expert in toxicology, dental and medical/endocrinology. So far, only a dental expert has been obtained. Discussion followed regarding the best methods to ensure the goal of attaining a panel of 3 experts including paying consultants and the promotion of these requested experts. It was determined that various BOH members will reach out to their colleagues and professional organizations with the added paid benefit to the panel experts of $125/hour in hopes of obtaining the additional experts needed to complete the panel.

B. Board of Education Letter of Support

Earlier this month, BOH member, Jennifer Deyo, met with Orange County Board of Education (OC BOE) member, Hillary MacKenzie, to discuss the BOH's letter of support for their equity policy. Historically, the OC BOE wasn't happy with how it has handled racial equity. All of the OC BOE members will have to complete racial equity training. Ms. Deyo reported that the OC BOE recently voted and approved the equity policy this month. Discussion followed including whether it would be helpful to fulfill OC BOE's request to have a letter of support from the BOH. The proposed requested letter of support would point out the benefits to the county employees, the students and the teachers as well as applaud the approval of the equity policy.

***Motion to move forward to write the letter of support for the OC Board of Education's Equity Policy was made by Liska Lackey and seconded by Bruce Baldwin and carried without dissent.***

C. Health Director Report

In addition to her report, some of the highlights Ms. Stewart gave are below.

- Ms. Stewart gave a brief update on Medicaid Transformation . The NC DHHS announced the four Prepaid Health Plan (PHP) contracts (AmeriHealth Caritas North Carolina, Inc., Blue Cross and Blue Shield of North Carolina, United Healthcare of North Carolina, Inc. and WellCare of North Carolina, Inc.) that will serve the entire state of North Carolina. The Health Department has attested to tier 3 – Advanced Medical

ORANGE COUNTY
HEALTH DEPARTMENT
*Improving health. Inspiring change.*

March 5, 2019

**Subject: Expert review of water fluoridation**

To Whom It May Concern,

As a member of the Orange County Board of Health, I am contacting you to see if you can serve as an expert in your field to address water fluoridation. The Orange County Health Department Board of Health would like to offer an honorarium of $1,000 for your assistance.

Recognizing that there is public dissent on the issue of fluoridation, Orange Water and Sewer Authority (OWASA) requested that the Orange County Board of Health (BOH) address this issue. The BOH's review plan is based on our responsibility to protect and promote the public health of Orange County while recognizing that OWASA has authority over water fluoridation.

We will ask the environmental, dental and medical experts to address water fluoridation and to provide their observations and findings in a summary report, that:

1. Addresses key concerns provided through public comment to OWASA and BOH
2. References latest science on the effects of fluoridation on all aspects of human health,
    a. Including potential harm to those in the population who may be at most risk (in utero, children and elderly
    b. For example, evidence of human health benefits from public water fluoridation, especially as this pertains to oral health
    c. For example, evidence of potential human harms, with special focus on possible adverse neurologic and endocrinological effects
3. Utilizes a public health framework in the review process

Would you consider serving as an expert by submitting a formal response to the items listed above? If you need further information before deciding, please let me know.

We appreciate your consideration of this request and look forward to hearing from you.

Sincerely,

Liska Lackey, MSN, FNP-BC
Chair, Board of Health, Water Fluoridation Committee
llackey@email.unc.edu
919-968-2796

- Lastly, Ms. Richard stressed that this is a county initiative not just a health department initiative.

***The BOH members had questions that were addressed by Ms. Richard.***

## VI. Action Items (Non Consent)

A. Board Reappointments

Due to the absence of a quorum at April's board meeting, the BOH voted on member reappointments.

***Motion to reappoint Jennifer Deyo was made by Susan Elmore, seconded by Jessica Frega, and carried without dissent. Jennifer Deyo abstained.***

***Motion to reappoint Sam Lasris was made by Paul Chelminksi, seconded by Jennifer Deyo, and carried without dissent. Sam Lasris abstained.***

Mr. Smith thanked both members for their continued service. He then announced that BOH member, Barbara Chavious, has notified him that, due to caring for her ill husband, she will, regretfully, issue a letter of resignation.

Susan Elmore announced that, as of tonight's meeting, she will be stepping down from both the OCHD BOH and Animal Services Boards. She has held her position on the Animal Services Board for 13 years, 9 years on the OCHD BOH and still serves on 2 other state boards. She stated that it has been a pleasure working with everyone. Everyone thanked her for her service.

After serving 11 years (3 full three-year terms and having finished the term of the person before him) BOH member Paul Chelminski's last meeting will be next month, June. The BOH members stated that they'll miss him and thanked him for his service.

Timothy Smith and Jessica Frega (Chair and Vice-Chair, respectively) will form a subcommittee that will review applications for the physician seat held by Paul Chelminski and conduct phone interviews. They asked for volunteers to which Jennifer Deyo and Sam Lasris offered to do so.

As time is of the essence, Vice-Chair Jessica Frega suggested that the board informed any interested applicants to complete their application for the physician seat by Friday, May 31st to allow for interviews to be scheduled and a recommendation turned into the clerk's office by June 7th for the BOCC's agenda review. The BOH can send their comments on the physician seat candidates via email to the 4 subcommittee members.

Quintana Stewart stated that she'll speak with Bob Marotto, Animal Services Director, regarding a Veterinary liaison.

B. Fluoride Update

BOH member, Bruce Baldwin, substituted for BOH Liska Lackey and provided a brief update on the progress of the Fluoride Ad Hoc Committee. He began by stating that many documents dating back to November 2017 have been reviewed. He also read a summary of what's occurred since November 2017 to the present. Baldwin commented that OWASA not being

involved in the process avoids any potential influence. OWASA Executive Director, Ed Kerwin, has instructed the BOH to proceed as it sees fit. Various BOH members agreed with Mr. Kerwin noting that there was no need to be hasty in the continuation of the Committee's process.

## VII. Reports and Discussion with Possible Action

A. Health Director Report

In addition to her report, highlights given by Ms. Stewart are below.

- The NC Attorney General, Joshua Stein, announced that the state of NC is suing Juul over allegations that it's marketing its products to youth and misled the public about risks associated with its products.
- Thanks were given to those that assisted with the Community Health Assessment (CHA) surveys including BOH member Bruce Baldwin and BOH member Susan Elmore's daughter. Mr. Baldwin encouraged all to volunteer. Ms. Stewart noted that there are more opportunities for those that are able to volunteer and that there may be a change in the proposed schedule.
- June 6th is the budget session with the BOCC.
- On June 21st at the SHSC, the Health Equity Commission Forum will take place from 9am-12pm with breakfast starting at 8:30am. There will be a gallery walk that will display health equity data and provide a visual image.
- Earlier today, Ms. Stewart met with Elinor Landess, Director, Campus & Community Coalition. She felt that HB 536, which includes language that would create a new exception to authorize the issuance of permits for the sale of alcoholic beverages at stadiums, athletic facilities, or arenas on the campus or property of a public college, will most likely pass; however, it will be up to the UNC trustees to decide if they will sell alcohol at collegiate sports facilities. It was mentioned that some other state universities use some of the proceeds from the alcohol sales to go towards funding other school programs. A letter of support from the BOH detailing best practices will probably be requested by Ms. Landess.
- Ms. Stewart referred to the NALBOH newsletters that were on the table and revealed that the national conference will be held in Denver, Colorado this year. She indicated that there are funds available if a BOH member would like to attend. BOH Chair, Timothy Smith stated that the NALBOH conference is a very good event.

B. Media Items

Kristin Prelipp, Communications Manager, briefly mentioned articles regarding the whooping coughs cases at Glenwood Elementary and the Family Success Alliance were included in the Media Items packet.

***Media items were in the packet which focused on Orange County's events and our involvement in various efforts.***

## VIII. Board Comments

**None.**

Water Fluoridation Survey

Orange Water and Sewer Authority (OWASA) recognize that customers may have differing opinions on the issue of water fluoridation and has requested that the Orange County Board of Health (BOH) review this policy. The BOH's review plan includes inviting public comment on water fluoridation. Public comments will be provided to a panel of dental and medical experts and they will be asked to address the public's key concerns, referencing the latest science on the effects of fluoridation on all aspects of human health. We appreciate your participation.

I support OWASA's fluoridation of water Yes No

If respondent answers "no", answer the following questions:

1. I am opposed to fluoridation of water because (check all that apply):
   - It can affect the environment
   - It can have a negative impact on personal health
   - It is not necessary to prevent tooth decay
   - Other _____
2. What questions do you have about water fluoridation?

3. What other comments do you have with water fluoridation?

If respondent answers "yes", answer the following questions:

1. I support the fluoridation of water because (check all that apply):
   - It is an important public health measure
   - In the right amounts, it is safe
   - In the right amounts, it helps prevent dental decay
   - Other _____
2. What questions do you have about water fluoridation?

3. What other comments do you have with water fluoridation?

I use OWASA supplied drinking water.

- Yes
- No

I live or work in the Chapel Hill/Carrboro area.

- Yes
- No

Questions? Email Beverly Scurry, Board of Health Strategic Plan Manager at bscurry@orangecountync.gov

# We want to hear from you!

Please tell us what you think about fluoride in water.

**Take the survey at:**

bit.ly/32mxPRs

***Thanks!***

ORANGE COUNTY
HEALTH DEPARTMENT

# An Ethics Framework for Public Health

Nancy E. Kass, ScD

More than 100 years ago, public health began as an organized discipline, its purpose being to improve the health of populations rather than of individuals. Given its population-based focus, however, public health perennially faces dilemmas concerning the appropriate extent of its reach and whether its activities infringe on individual liberties in ethically troublesome ways. In this article a framework for ethics analysis of public health programs is proposed.

To advance traditional public health goals while maximizing individual liberties and furthering social justice, public health interventions should reduce morbidity or mortality; data must substantiate that a program (or the series of programs of which a program is a part) will reduce morbidity or mortality; burdens of the program must be identified and minimized; the program must be implemented fairly and must, at times, minimize preexisting social injustices; and fair procedures must be used to determine which burdens are acceptable to a community. (*Am J Public Health.* 2001;91:1776–1782)

Public health as an organized discipline began more than 100 years ago, with the goal of improving the health, primarily, of populations rather than of individuals. Given its population-based focus, however, public health continually faces dilemmas concerning the appropriate extent of its reach and at what point the work of public health professionals is infringing on individual liberties in ethically troublesome ways. Nonetheless, there have been few attempts to articulate an ethics of public health.

Bioethics, as a discipline, helps health care professionals identify and respond to moral dilemmas in their work. In this article I suggest that the contexts out of which bioethics emerged—medical care and human research—were oriented toward a different set of concerns than those typically arising in public health. While the founders of bioethics articulated principles equally relevant for public health, the more specific action guides and codes of health care ethics that have followed are an imperfect fit for public health. Codes of medical and research ethics generally give high priority to individual autonomy, a priority that cannot be assumed to be appropriate for public health practice.

A framework of ethics analysis geared specifically for public health is needed, both to provide practical guidance for public health professionals and to highlight the defining values of public health, values that differ in morally relevant ways from values that define clinical practice and research. A first attempt at such a framework is offered here.

## PUBLIC HEALTH

Public health is the societal approach to protecting and promoting health. Generally through social, rather than individual, actions, public health seeks to improve the well-being of communities. By maintaining a safe water supply, immunizing schoolchildren, or engaging in epidemiologic research, public health seeks to ensure societal conditions under which people can lead healthier lives,[1] minimizing threats to our health "that can be averted or lessened only through collective actions aimed at the community."[1(p20)] The providers of public health interventions often are governments, rather than private practitioners. Indeed, the provision of health services, generally the domain of medicine, becomes the responsibility of public health departments when services are provided by public clinics or hospitals.

Public health interventions date back more than 3 centuries. In 1701, Massachusetts passed laws for isolation of smallpox patients and quarantine of ships.[1(p57)] In the early 1800s, Edward Chadwick demonstrated in England that differences in social conditions led to a more than 2-fold difference in life expectancy between upper and lower classes. Also in the 1800s, Lemuel Shattuck, in Massachusetts, implemented the first system of vital health statistics.[2] Governments began conducting investigations of housing conditions and garbage heaps and mapping them in relation to outbreaks of disease,[2] and by the end of the 19th century, state and local boards of health were being created to enforce sanitary regulations.[1(pp60–61)]

By the early 20th century, public health was seen as cost-effective as well as useful,[2] and more money was directed to public health programs. During World War II, given the need for a healthy population for the military, the US Public Health Service established the Center for Controlling Malaria in the War Areas, later the Centers for Disease Control and Prevention. Epidemiology developed as the science of public health, to study "the distribution and determinants of health-related states or events in defined populations and [to apply this knowledge] to the control of health problems."[3(p42)]

Today, public health practitioners use tools in addition to epidemiology to accomplish their work, still focusing primarily on communitywide, typically prospective, approaches to improve health. Some public health functions—surveillance, vital statistics, disease and injury reporting, and disease registries—relate to epidemiology and the collection of data. In addition, practitioners investigate outbreaks, conduct contact tracing, provide health education and other preventive interventions, and conduct research related to public health. Last, public health professionals sometimes create or enforce health-related regulations and legislation, for example, mandating screening, treatment, immunizations, or—rarely—quarantine.

States' authority to pass laws to improve the public's health dates to the 19th century and is referred to as the "police power": "coercive action under state authority to encourage educational efforts. . .seize property, close businesses, destroy animals, or involuntarily treat or even lock away individuals."[4(p42)] These various public health tools and functions, while together successful in decreasing morbidity and mortality, nonetheless raise ques-

tions of ethics in terms of the means by which these successes are achieved.

## BIOETHICS AND PUBLIC HEALTH

Bioethics helps health professionals and public policymakers recognize moral dilemmas in health care and biomedical research and provides principles and moral rules with which to navigate through these dilemmas. (A framework of bioethics based on principles, as put forward by Beauchamp and Childress,[5] will be used here. However, there are many other bioethical frameworks, including, for example, ethics of care, casuistry, and virtue-based ethics.)

Dating to the 1960s and 1970s, bioethics grew out of questions of fairness in resource allocation, moral issues raised by new technologies, and a lack of oversight in human-subjects research. The public was swept up in debate about whether the first artificial kidney center should allocate scarce resources on the basis of social criteria and whether Karen Ann Quinlan should be kept alive artificially when she had no meaningful cognition.

In 1969, the Institute of Society, Ethics, and the Life Sciences (now the Hastings Center) was created to address questions of bioethics and to provide frameworks with which to analyze contemporary moral dilemmas in medicine and science.[6] In 1974, after several reports of US government–sponsored research that compromised the rights and welfare of study subjects, a new national commission issued the Belmont Report, which included ethics principles to guide the conduct of human subjects research—beneficence, respect for persons, and justice.[7] Early framers of bioethics elaborated on these principles and provided examples of how they were useful in analyzing dilemmas from other areas of health care, not just research.[5]

These early framers argued that, a priori, no principle ought to have moral superiority over any other. At the same time, the issues that animated bioethics in the early years—the need to tell patients and research subjects the truth, the patient's right to refuse care or research participation—were ones in which the principle of respect for autonomy, perhaps given too little moral attention previously, was now given preeminent moral status.[8–10] Informed consent, a practical application of the autonomy principle, became a hallmark of the new bioethics, and codes of ethics for clinical practice, while still emphasizing the need not to harm the patient, added clauses requiring physicians to "best care for the dignity of man in patients or research subjects."[11(p21)]

That contemporary medical ethics or research codes have made the right to noninterference central is understandable, given the context out of which they emerged. That public health practitioners, lacking guidelines of their own, must turn to these same codes for professional moral direction, however, is more problematic. In rare instances, existing medical or research codes do discuss traditional public health functions, such as breaching patient confidentiality to report diseases to the state.[12] In such instances, however, the physician's behavior is presented as an allowable exception to usual ethics rules in the name of public health.

At best, this leaves public health professionals needing to muddle through most other situations on their own; at worst, it could lead them, or even the public, to assume that public health is the branch of health care sanctioned by bioethics to make exceptions to existing ethics rules at will, in the name of public health and safety. Indeed, it is in great part *because* such power is vested in public health by law that a code or framework of ethics designed specifically for public health is so very important. The need for a code of ethics for public health, then, might be viewed as a code of restraint, a code to preserve fairly and appropriately the negative rights of citizens to noninterference.

A code or framework of public health ethics must emphasize positive rights as well, however. Public health has affirmative obligations to *improve* the public's health and, arguably, to reduce certain social inequities. A code of public health ethics is needed to address such social justice functions of public health. While frameworks have been put forward in medicine to help clinicians think through the ethical issues in a clinical case,[13,14] no analogous framework is available for public health practitioners.

We live in a morally pluralistic society, and it is inevitable that moral appeals will conflict when attempts are made to determine appropriate public policy. A framework for public health ethics will help public health professionals recognize the multiple and varied moral issues in their work and consider means of responding to them.

## AN ETHICS FRAMEWORK FOR PUBLIC HEALTH

A 6-step framework is proposed for consideration. Components of this framework were proposed in an earlier article,[15] and a similar framework was proposed for public health and human rights by Gostin and Lazzarini.[16] This is not a code of professional ethics, which more likely would address general norms and expectations of professional behavior and probably would be the product of a professional society. Rather, this is an analytic tool, designed to help public health professionals consider the ethics implications of proposed interventions, policy proposals, research initiatives, and programs.

### 1. What are the public health goals of the proposed program?

The first step for any proposed public health program is to identify the program's goals. These goals generally ought to be expressed in terms of public health improvement, that is, in terms of reduction of morbidity or mortality. For example, an HIV screening program should have as its ultimate goal fewer incident cases of HIV, not simply that a certain proportion of individuals will agree to be tested. A health education program in cardiac risk reduction should have as its ultimate goal (or the ultimate goal of a larger program of which it is a part) that individuals will have fewer heart attacks, not simply that individuals will learn new information or even that they will change their behavior. A research study should have as its ultimate goal (or the ultimate goal of a larger trajectory of which it is a part) that findings, if positive, will be implemented with the target population and improve its health status.

While more proximate and process goals (such as whether individuals will learn health information or whether they will

agree to be tested) are critical pieces of program planning and evaluation and may be crucial to achieving health improvement, the fundamental goal of decreased morbidity and mortality is the outcome by which the program or series of programs ultimately must be assessed. This is not to say that each individual program or research study must achieve this end. Epidemiologic studies may provide descriptive data that lead scientists years later to develop an intervention that will result in a reduction in morbidity or mortality; a health education program may be one of multiple and varied interventions that together reduce risks and ill health. The argument put forth here, however, is that public health programs, interventions, or studies must be designed with an awareness of the relationship between this program and an ultimate reduction in morbidity or mortality.

Of course, other types of benefits, generally social benefits, can accrue from public health programs as well. Public health programs can result in greater employment, for example, as well as less tangible benefits, such as coalition-building or the strengthening of communities. These benefits are extremely important and should be given strong consideration. They are, however, the incidental or intermediary outcomes of public health programs, rather than the programs' final goal. If a program has as its goal to increase employment as an end in itself (rather than, for example, to increase employment as a means to lower psychological morbidity or as a means to improve socioeconomic status and therefore lead to improved health) or to strengthen communities (rather than to strengthen communities as a means to decrease interpersonal violence or as a means to help watch out for the well-being of the young or old persons in the community), then the program is primarily a social program, not a public health program.

As described further below, a reduction in morbidity and mortality need not and could not be the goal of every individual public health intervention or program; however, individual public health programs should not be undertaken that are not part of a larger package of programs whose combined goal is the reduction of morbidity and mortality.

According to this view, an intervention whose goal is to improve access to care among hard-to-reach populations has an extremely relevant public health goal, assuming, of course, the program is effective in improving access. Other examples of interventions designed to reduce social inequalities will be discussed further in step 5.

Also relevant when we consider public health goals and benefits is to whom the benefit will accrue. Public health interventions often are targeted to one set of individuals to protect *other* citizens' health. Partner notification programs and directly observed therapy for tuberculosis are designed primarily to protect citizens from the health threats posed by others. In some contexts, public health programs are designed primarily to protect individuals from themselves, revealing that much of public health is inherently and unabashedly paternalistic. Health education campaigns, blood pressure screening, seat belt laws, and 55-mile-per-hour speed limits, while motivated in part by social concerns about costs, are, I suggest, motivated primarily to further individuals' ability to protect their own health. Restricting someone's liberty to protect him- or herself and restricting liberty to protect another person pose different ethical burdens, discussed further in step 3.

### 2. How effective is the program in achieving its stated goals?

Proposed interventions or programs are based on certain assumptions that lead us to believe the programs will achieve their stated goals. Step 2 asks us to examine what those assumptions are and what data exist to substantiate each of them. A cardiac risk reduction program has as its ultimate goal the reduction of fatal and nonfatal cardiac events. The assumptions of this education program (or the larger effort of which it is a piece) are that the program will reach individuals at risk for cardiac events; those individuals will learn the risk reduction messages; individuals will change their behavior (e.g., stop smoking, change diets, increase exercise) in ways suggested by the program; these changes would not have occurred without the program; and the behavior change in itself will result in fewer cardiac events.

While many health education programs are very effective at transmitting information that recipients learn and understand, programs generally are less successful at inducing behavior change.[17,18] Thus, while a rather narrow evaluation may demonstrate success (in terms of participants' understanding the message), a program ultimately cannot claim success if behavior is unaffected and morbidity and mortality rates remain unchanged.

This is not to suggest that each program must reduce morbidity by itself. Individual health education or screening programs, for example, might be pieces of larger initiatives to reduce cardiac morbidity and mortality. Data may show that multiple education campaigns in different formats and with different messages are required to induce widespread behavior change. Multidimensional efforts are appropriate and useful, if data show that the combination is likely to evoke the desired result. Again, however, if the multiple approaches are simply hypothesized or assumed to reduce illness events, then further research must be done; a public health program is not yet justified.

This step of examining existing data to challenge our assumptions and implement only data-based policies or programs is often neglected in public health. One can assume that this is not because professionals are indifferent to whether their methods relate to their outcomes, but because we simply assume that they do, and we neglect to find data that prove us right or wrong. Thus, we introduce a program based on the assumption that some number of people who learn that cigarettes cause asthma and lung cancer will quit smoking, or we call for HIV screening because we assume that individuals who learn they are infected will begin to use condoms in sexual relationships. It is when our assumptions seem most intuitively obvious that we are at greatest risk of neglecting to determine to what extent they are supported by real evidence.

While all programs must be based on sound data rather than informed speculation, the quality and volume of existing data will vary. The question for policy and ethics analysis, then, is what quantity of data is enough to justify a program's implementation? As a rule of thumb, the greater the burdens posed

by a program—for example, in terms of cost, constraints on liberty, or targeting particular, already vulnerable segments of the population—the stronger the evidence must be to demonstrate that the program will achieve its goals. Indeed, because many public health programs are imposed on people by governments and not sought out by citizens, the burden of proof lies with governments or public health practitioners to prove that the program will achieve its goals. Thus, if at least some data do not exist that demonstrate the validity of a program's assumptions, the analysis can stop right here, and, ethically, the program should not be implemented. Conversely, the presence of good data alone does not justify the program; it allows us to move to the next stage of the analysis.

### 3. What are the known or potential burdens of the program?

If data suggest that a program is reasonably likely to achieve its stated goals, then the third step of the framework asks us to identify burdens or harms that could occur through our public health work.

Although a variety of burdens or harms might exist in public health programs, the majority will fall into 3 broad categories: risks to privacy and confidentiality, especially in data collection activities; risks to liberty and self-determination, given the power accorded public health to enact almost any measure necessary to contain disease; and risks to justice, if public health practitioners propose targeting public health interventions only to certain groups. Different types of burdens are more or less likely to result from different types of public health activities.

*Disease surveillance and vital statistics,* designed to monitor health and population trends, raise potential privacy concerns, especially since data collection is mandatory and data often are individually identifiable and, in many cases, publicly available. Although the types of data collected are not considered very personal or sensitive by most persons, everyone has his or her own boundary of privacy. Further, for some individuals, particular elements of vital statistics, such as paternity or cause of death, could be seen as invasions of their privacy. Finally, vital statistics and other publicly collected data can reveal patterns about ethnic groups or neighborhoods that may be stigmatizing or otherwise harmful.

*Communicable disease reporting* raises privacy concerns as well, but the infringement and risks potentially are greater, since names are reported only of those who have reportable (and often socially stigmatizing) conditions. Given that individuals typically want the ability to control whether and to whom private information is disclosed, disease reporting carries the additional risk of a breach of confidentiality if security measures are not followed or do not work. For some, there is a risk of privacy infringement only to the extent that confidentiality is not maintained and harms such as social stigma or loss of employment ensue from unwarranted disclosure. For others, the privacy infringement is viewed as a wrong in itself, regardless of whether any tangible harm ensues.

Disease reporting is an example of a public health function that, at least on its face, is distributionally unfair, in that the burdens of the program are borne by those with the disease, generally for the benefit of others who do not have the disease. This unevenness of burdens and benefits may be justified in certain instances, when the benefits are important and when there are no less burdensome ways to achieve them. Unevenness in benefits and burdens is never appropriate, however, if groups are burdened in ways that are arbitrary and without public health justification. Further, a program that does not target particular groups explicitly may, in fact, lead to targeting in its implementation. One study, for example, suggested that doctors are more likely to report a patient with HIV to the health department if the patient is Black and male,[19] despite language in the statute requiring the reporting of *all* persons with HIV. The appropriateness of creating targeted public health programs justified by epidemiologic data is discussed further in step 6.

*Contact tracing,* which sometimes accompanies communicable disease reporting, poses additional privacy risks. Not only are an individual's name and condition reported, but individuals are asked to provide the names of other (usually sexual) contacts they have had. Obviously a privacy infringement in itself, contact tracing also invades the privacy of individuals whose names are disclosed, who are not able to decide for themselves whether to release their names to officials. As stated above, harms can occur if confidentiality protections fail, and individuals can feel wronged simply by virtue of the violation of their privacy. Justice concerns also arise if contact tracing programs are not implemented fairly.

*Health education* poses interesting questions in terms of ethics. In certain ways, health education is the ideal public health intervention, since it is completely voluntary and seeks to empower people to make their own decisions regarding their health once they are equipped with accurate information. From an ethics perspective, education clearly is preferable to other preventive strategies, to the extent that they are equally effective, because it poses few, if any, burdens.

Health education, however, although an essential component of most public health campaigns, will not be appropriate for all situations. First, education may not work in all settings, and more burdensome measures may be required. Second, to increase effectiveness, educational programs may introduce ethically questionable practices, such as manipulation or even coercion. A smoking cessation program, for example, may try to manipulate attitudes by suggesting that smokers are unpopular and by providing only partial or even false information to achieve its ends.[20]

Third, all health education campaigns are potentially paternalistic, suggesting that certain ways of being (e.g., in greater aerobic health) are universally valued. Additional work is needed to examine when and where paternalism in public health is justified, especially since biomedical ethics generally has steered professionals away from paternalism except when it is specifically requested by patients. (See Bernard Lo for a discussion of paternalism in which he concludes that "when disagreements persist after repeated discussions, the patient's informed choices and definition of best interests should prevail,"[21[pp39–43]] and a discussion of patients who do not want to make their own decisions.[21[p29]])

Fourth, health education programs may target messages to certain audiences. Although such targeting is often justified on public health grounds (e.g., epidemiologic data demonstrate that members of this population are

at greatest risk, so their pictures will go on the billboards and messages will be promoted on the radio stations they listen to), the social and even public health ramifications of targeting must be seriously considered. Social stigma can result if, for example, certain subgroups of the population are assumed to be the ones who carry sexually transmitted diseases, and opportunities for public health intervention will be missed entirely if we all come to believe, through well-intentioned media campaigns, that only certain groups are at risk for domestic violence or HIV.

Finally, health education campaigns may be accompanied by incentives. Incentives generally are considered ethically less problematic than coercive measures or threats, but even incentives could be ethically questionable in certain contexts, such as when financial incentives are given for using particular types of birth control or avoiding pregnancy.[22]

*Public health research* carries burdens. Human subjects regulations already describe the types of harms that could occur through research participation. These include medical risks if the research is clinical, and psychological or social risks if the research is epidemiologic or social science. In recent years there has also been increased attention to the personal and social burdens that can result from injustice or exploitation in research when certain populations are disproportionately disadvantaged or privileged through research participation.

In addition to these well-articulated risks, however, is the harm that can occur if public health research findings are never implemented in public health policy or practice. Any study conducted imposes, at the very least, the burden of inconvenience on those who participate, and may, of course, pose more significant risks to the individuals or communities who volunteer. An institutional review board allows research to go forward because of the benefits expected to emerge from study findings. If research findings are never translated into policy, however—a situation that occurs far too often—no benefits accrue from the research. In such instances, participants were wronged through a misleading (albeit not deliberately so) informed consent process, and the risk-to-benefit ratio could rarely be considered favorable.

*Regulations and legislation,* strictly speaking, are coercive, since they impose penalties for noncompliance. As such, they pose risks to liberty and self-governance. While many of these measures, such as reduced speed limits, childproof bottles, and immunization, have demonstrated efficacy, they nonetheless are the most intrusive approach to public health. Edmund Pellegrino and David C. Thomasma write:

> Involuntary and coercive measures must be undertaken with a clear perception of the dangers they pose to a democratic society: loss of personal freedom to choose a lifestyle, dependence upon governments to define values and concepts of the good life, and the imposition of cultural homogeneity. Involuntary measures also assume a benign, wise, and responsive government—something history finds singularly rare.[10(p375)]

While threats to autonomy are the most obvious threats posed by public health regulations and legislation, such regulations and legislation can, in some circumstances, be associated with physical risks, or risks to individuals' health, as well. Federally approved and mandated vaccinations carry health risks to individuals; widespread spraying to prevent the spread of mosquito-borne viruses can cause proximate health problems to some individuals who inhale the chemicals. Finally, in this instance as well, the law can impose, by design or inadvertently, threats to justice if regulations impose undue burdens on particular segments of society.

### 4. Can burdens be minimized? Are there alternative approaches?

This piece of the framework requires us to minimize burdens once they have been identified. If step 3 suggests that a program or policy carries potential or actual burdens, we are ethically required to determine whether the program could be modified in ways that minimize the burdens while not greatly reducing the program's efficacy. Public health professionals, for example, when ready to report a patient's name and disease to the state, should inform patients that their names, by law, must be reported to public health authorities but that the law also requires that they be reported confidentially. Although reporting programs are not optional, the policy is more respectful of patients if patients are adequately informed.

Contact tracing programs, similarly, pose threats to privacy and confidentiality. Yet contact tracing programs, strictly speaking, are voluntary, in that no sanctions are imposed on citizens who refuse to cooperate. It is ethically incumbent on public health practitioners to inform individuals sought for contact tracing of their right to refuse to disclose the names of their partners, as well as of their right to inform partners themselves, have a known health care provider do it, or have partners contacted by an agent of the state.

If 2 options exist to address a public health problem, we are required, ethically, to choose the approach that poses fewer risks to other moral claims, such as liberty, privacy, opportunity, and justice, assuming benefits are not significantly reduced. Making this assessment relies on the existence of sound data. If data show that a voluntary screening program will test essentially the same number of individuals as a mandatory one, because almost no one refuses testing when asked, then it would be ethically improper to implement a mandatory program.[23(chap6)] If disease surveillance is equally effective with unique identifiers or with names, a program of unique identifiers is the morally preferable choice.

### 5. Is the program implemented fairly?

This piece of the framework corresponds to the ethics principle of distributive justice, requiring the fair distribution of benefits and burdens.[5(pp326–394)] Public health benefits, such as clean water, cannot be limited to one community, nor can a single population be subjected to disproportionate burdens. HIV screening programs, for example, cannot be implemented only in poor or minority communities without strong justification (see Stoto et al.[23] for a discussion of why universal HIV screening programs are ethically preferable to targeted programs); cardiac risk reduction programs cannot be targeted exclusively to White men when women and minorities are also at substantial risk of heart disease.

That programs be implemented fairly is even more important if restrictive measures are proposed. Injustice is wrong for its own sake, and also for the material harms it can evoke. Social harms result if social stereotypes are created or perpetuated, such as the stereotype that only certain segments of the population are vulnerable to sexually transmitted diseases. In addition, real public health

harms result when individuals do not believe that they are at risk for disease because they were never targeted in education campaigns, or because their own doctors never screened them for a condition because they didn't fit the popular risk profile.[24] This does not mean that programs or resources must be allocated equally to all communities—rather, the allocations must be fair. That is, differences cannot be proposed arbitrarily or on the basis of historical assumptions about who might be at risk. Again, unequal distributions of programs must be justified with data. Moreover, the social consequences must be considered if a community is allotted resources unequally, and these consequences must be balanced against the benefits to that community or others.

Discussed less frequently is whether, or the degree to which, public health has any explicit role in righting existing injustices, especially given the strong link between poor living conditions and poor health outcomes. To what extent is there a positive responsibility on the part of public health professionals to advocate better housing, better jobs, and better access to food programs, since such advocacy might be the best route to improving the public's health?

Several notions of justice allow and even require unequal allocation of benefits to right existing inequities. John Rawls posits that justice requires us to allocate our resources unequally to help the least well-off.[25] Norman Daniels discusses the need for all members of society to be brought to a level of "species-typical normal functioning,"[26] which also could result in the unequal distribution of certain resources. Admittedly, not all philosophers have adopted this notion of justice; some make a distinction between preexisting societal inequities that are unfair (because they resulted from a person or community having been wronged by an identifiable source), where intervention is owed, and inequities that are merely unfortunate (that is, due to acts of God or circumstance), where no intervention is morally required.[27]

Public health, I would argue, does have a positive responsibility to engage in programs and interventions that seek to lessen societal inequalities, at the very least when those inequalities relate (as essentially all do) to health outcomes. Indeed, it is hard to find a more powerful predictor of health than class,[28,29] and it is thus an appropriate, if not obligatory, function of public health to reduce poverty, substandard housing conditions, and threats to a meaningful education—if for no other reason than to reduce the incidence of disease.

### 6. How can the benefits and burdens of a program be fairly balanced?

If it is determined that a proposed public health intervention, policy, or program is likely to achieve its stated goals, if its potential burdens are recognized and minimized, and if the program is expected to be implemented in a nondiscriminatory way, a decision must be reached about whether the expected benefits justify the identified burdens. Recognizing, of course, that public policy is based on multiple considerations in addition to ethics, the question must still be asked whether, from an ethics perspective, the program should go forward. Health department officials and other public health professionals may not have the power to implement all programs they think would be beneficial, but they do have a responsibility both to advocate programs that do improve health and to remove from policy debate programs that are unethical, whether because of insufficient data, clearly discriminatory procedures, or unjustified limitations on personal liberties.

And yet while most reasonable people will agree, in the abstract, that burdens and benefits must be balanced, and that the most burdensome programs should be implemented only in the context of extensive and important benefits, disagreements are all but guaranteed over the details. Depending on one's perspective, there will be differing views over how burdensome various programs are, such as having one's name reported to the state or being required to immunize children before they start school. Citizens can be expected to differ over how important it is to protect a water supply for future generations, particularly if it means significantly higher taxes or prohibiting recreational use of a public body of water—which is clearly a benefit, not only in terms of individual pleasure, but also in terms of community cohesiveness.

Solutions to these inevitable disagreements must be reached through a system of fair procedures. Procedural justice requires a society to engage in a democratic process to determine which public health functions it wants its government to maintain, recognizing that some infringements of liberty and other burdens are unavoidable. There should be open discussion of what a society gains from good public health and why such benefits often cannot be obtained through less communal or more liberty-preserving methods. The discussion, of course, should also address why other interests also have moral claim. Such a process, even when procedurally fair by most standards, must not result in decisions based solely on the will of the majority. Indeed, deliberations, particularly around significantly burdensome proposals, must be scrutinized to ensure that the views of the minority are given due consideration. Highly burdensome programs should be preceded by public hearings, not just votes, so that minority views can be heard and considered.

At the same time, it is important to acknowledge that there will always be some number of persons who do not want their water fluoridated, do not want their children immunized, do not want to wear seat belts, and do not want speed limits on public roads. That there is dissent is insufficient justification for blocking a public health program; indeed, dissent is inevitable in all proposals. Dissent must be considered, however, and it deserves special attention if it is raised exclusively by a particular identified subgroup such as an ethnic minority, a particular age group, or residents of a particular neighborhood.

In balancing values and interests, the greater the burden imposed by a program, the greater must be the expected public health benefit, and the more uneven the benefits and burdens (that is, burdens are imposed on one group to protect the health of another), the greater must be the expected benefit. Programs that are coercive should be kept to a minimum, should never be implemented when a less restrictive program would achieve comparable goals, and should be implemented only in the face of clear public health need and good data demonstrating effectiveness. Nonetheless, we are a pluralistic society, including with regard to our notions of ethics. Different states and communities will decide differently which public health activities are appropriate and which are

overly burdensome. Ultimately, that different communities will enact different public policies, based on their own balancing of benefits and burdens, may be indicative of a fair process, or at least a pluralistic process, steering local public health policy.

## CONCLUSION

Of course, public policy is based on many factors in addition to public health goals and ethical reasoning. Weighing alternatives according to this public health ethics framework should lead to an ethically acceptable option, but it may not lead to the politically preferable option for a given time. That politics often takes a divergent and somewhat unpredictable path, however, is not an excuse for abandoning ethics analysis when a public health proposal is up for discussion. An ethics analysis must always be conducted, both because bringing truth, fairness, and respect to our work is right in itself and also because, from a more utilitarian perspective, public health work will be more effective if we do.

Engaging in the steps of an ethics analysis makes us meticulous in our reasoning, requiring us to advocate interventions on the basis of facts and not merely belief. Further, an ethics analysis holds us to high standards, not only for scientific method but also for how respectfully we communicate with and involve constituent communities. The involvement of communities will help identify the public health threats divergent groups face and will create, if not partnerships, at least—one can hope—a reasonable amount of trust. To succeed, the field of public health must gain the public's trust that the inevitable higher proportions of government involvement and population targeting imposed by public health, relative to other branches of health care, are appropriate and in these various communities' best interests.

Public health professionals must go through the steps of an ethics analysis to assure the public of their integrity. The public must feel confident that public health professionals will offer only those proposals that will improve the health of the public, that proposed measures are minimally burdensome, and that a fair procedure has determined that the magnitude of the problem and the ensuing benefits justify overriding conflicting moral claims. It is reasonable to assume that the public will be concerned about which functions are necessary and which are overly burdensome, offensive, or simply wasteful. This process, then, must be integrated, constant, and ongoing. The most important asset that public health can have is the public's trust that work is being done on its own behalf. In such a context, public health professionals can and must advocate what they believe, on balance, are the ethically best approaches for furthering social justice and the public's health. ■

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- It represents a violation of the Nuremberg principle of informed consent.
- There are no benefits to fluoridation. We actually pay the phosphate fertilizer industries for their crude hazardous waste.
- There are many disease states where water fluoridation levels of fluoride are not tolerated. Such as kidney disease/renal transplant. Fluoridation is supplying a medicine without ability to control dose and without informed consent. It is a gross violation of our right to control what goes into our own bodies. Over 50 studies link the levels of fluoride found in community water fluoridation with reduced IQ. They can be found on the **Fluoride Action Network** website. Please review them and the other information there.water
- it's not science-based
- Causes thyroid problems, causes skeletal fluorosis that is diagnosed as arthritis, reduces IQ, increases incidence of ADHD, damage to tooth enamel due to fluorosis, increases incidence of certain cancers.
- It is toxic waste. It's not even the kind of fluoride that dentists recommend. Dental use of fluoride is applying it directly to the teeth. Swallowing it has no effect on dental health. Meanwhile, swallowing it does have deleterious effect on mental health and long-term health.
- Fluoride is effective against tooth decay only when applied topically. Systemically it is a neurotoxin and there are no systemic levels of fluoride that are innocuous.
- It's neurological toxin.9
- It is an FDA defined drug, "unapproved drug" under the form sodium fluoride. Hexafluorosilicic acid is an analog.
- Fluoride used has many toxic impurities, in addition to the toxicity of the fluoride itself.
- Even if it were to have some benefits for teeth, putting it in the public drinking supply is an imprecise, uncontrolled, and potentially dangerous way to deliver the medicine.
- It is unethical to expose all citizens to a neurotoxin with increasing evidence of negative health impacts without their consent.
- It contaminates our precious bodily fluids
- It is known to reduce IQ.
- Aren't these enough?!
- Fluoridation of the public water supply is medication without informed consent, which is a violation of our basic. Fluoride is classified as a developmental neurotoxin, linked to decreased IQ and numerous health problems (see **fluoridealert.org** for tons of info about that)
- impact on developing brains, skeletal fluorosis, neurotoxicity to name a few
- It's expensive for the public to pay for this, AND none of us get to opt out if the water system contains it. Removal via filtration is expensive. Most people have access to fluoridated toothpaste and topical products. Those have been shown to be most effective to prevent caries. We'd save money and do better for overall health and the environment by offering free fluoride toothpastes, etc. to our neighbors who need and request them. Also, the poisoning of the water system that happened 2 years ago at OWASA due to accidental overfluoridation (and resulting shutdown of the system) would NOT happen again.
- Fluoride (F) is a neuro-toxin

Periodic Fluoride Review at OWASA board meeting 10/26/17

Speakers against fluoridation (F) of water: 22

Speakers in favor: 2

Reasons why they do not consent to have fluoride in their water:

- Fluoride (F) is a neuro-toxin
- F damages the brain, neurons and the pineal gland (3rd eye)
- Putting F in the water is a diversion so we won't notice that the government is stealing money
- F reduces IQ in children by 5 points
- F is already in sodas we drink, so no need
- Toothpaste has F so no need
- F damages environmentally fragile kids- makes them feel nauseous and break out in hives
- F is an industrial byproduct from phosphate plants, so this whole thing is just a way to get rid of industrial waste and make money
- Money would be better spent on toothpaste and dental care for kids
- F contains arsenic, lead and aluminum and soaks into the skin
- CDC says kids with F in their water also have elevated levels of lead because F corrodes the pipes
- The OWASA board is racist for putting F in the water (said by Claire Viadro)
- F is bad for people with auto immune diseases
- Violates informed consent (this was said many times)
- Makes bones brittle
- F is a corrosive, toxic, poisonous chemical
- It is very expensive to filter F out of water and economically disadvantage people cannot do it
- If people want F they can just buy it
- F damages the thyroid
- F concentrates in the spine and gives people backaches
- F damages the liver

Reasons why OWASA should continue to fluoridate the water:

- No good evidence that F is hurting children
- Most cost effective public health victory in last 100 years
- Because it has greatly improved the dental health of citizens

Things brought up that have to do with OCHD:

- Dental department is not knowledgeable about the brain and thyroid so they should not be the authority on F.
- Asking the OCHD to convene a panel about F is just using the Delphi method to stage a debate to get their desired outcome.

- OWASA is responsible for this decision, not OCHD.
- To delegate this decision or no? It is an ethical, moral and scientific question. Needs consideration and input from all, including neurologists, rheumatologists, lawyers and ethicists.
- OWASA board is not a scientific review panel. This needs a holistic review, not just dental.
- What is informed consent? What does the community as a whole think, not just these 20+ activists?
- Why wait until 2020 to review? That would not be sensitive to citizens' concerns. These 20 activists do not feel as if they are being heard.
- What does Healthy Carolinians have to do with F?

## 1.3. Detailed response

Cariologists recognize two biological mechanisms by which fluoride affects the dental caries process.[1]

a) The pre-eruptive mechanism occurs when fluoride from the bloodstream is incorporated into a developing tooth, altering its mineral structure, making it more resistant to acid-dissolution when the tooth later erupts. Because most calcification of the primary teeth occurs *in utero*, the contribution of the pre-eruptive mechanism to caries prevention in the primary dentition is dependent predominantly on the amount of fluoride ingested by the mother during pregnancy. In contrast, most of the mineralization of developing permanent teeth occurs from birth to about eight years of age, and hence the contribution of the pre-eruptive mechanism to caries prevention in the permanent dentition is dependent predominantly on the amount of fluoride ingested during early childhood.

b) The post-eruptive mechanism occurs when fluoride in the mouth comes into contact with erupted teeth. This is aided by fluoride's affinity for dental biofilm (i.e., "dental plaque", the film of salivary components that adhere to a tooth surface and the microbes that grow in the film). Fluoride is selectively concentrated in biofilm affecting two processes critical to dental caries: (i) fluoride in biofilm inhibits acid-demineralization of enamel and increases the efficacy of re-mineralization, and (ii) fluoride in biofilm inhibits bacterial enzymes, and hence acid production by those bacteria. The contribution of these post-eruptive mechanisms to caries prevention potentially can occur from the moment of tooth eruption and throughout life.

### *1.3.1 Methods of administrating fluoride for caries prevention*

Fluoride consumed via drinking water or in beverages and foods containing water is often characterized as a "systemic" method of administration because the intention is that the fluoride be swallowed. (That same is true for fluoride delivered in tablets, supplements, and in fortified salt and milk.) Alternatively, fluoride in toothpaste is often characterized as a "topical" method of administration because the intention is that it be spat out, not swallowed, after use. (The same is true for fluoride delivered in mouth rinse and professionally-applied products.)

### *1.3.2. Method of administration does not neatly distinguish between biological mechanisms of action*

Most of the fluoride administered in drinking water or in foods or beverages prepared with fluoridated water is swallowed. At first appearance, this, suggests that its caries prevention via this mode of administration is due solely to pre-eruptive effects of the fluoride. However, that is a misnomer for two main reasons:

- some of the fluoride is not swallowed; instead, it is concentrated in the biofilm of erupted teeth in the mouth during consumption; and
- when ingested on a daily basis, the consumed fluoride increases the concentration of fluoride in circulating plasma which, in turn, increases the concentration of fluoride in the saliva,[2] with the fluoride then being concentrated in the biofilm of erupted teeth in the mouth.

Conversely, it is almost inevitable that some of the fluoride in toothpaste and other topically-applied products is swallowed, and if that occurs in childhood, it contributes to the pre-eruptive mechanism of caries prevention. However, the amount of fluoride swallowed during tooth brushing varies considerably among children,[3] making it difficult to quantify the overall contribution of toothpaste to pre-eruptive effects of fluoride occurring in the population.

### *1.3.2 Evolution of evidence concerning the relative contribution of pre- and post-eruptive effects*

According to the biological reasoning outlined above, fluoride in drinking water can, in principle, prevent dental caries via a pre-eruptive mechanism, post-eruptive mechanism, or both mechanisms. Scientific thinking has changed considerably over the decades as to the relative contribution of each mechanism, reflecting the evolution in research about dental health effects of fluoride itself.

By the middle of the 20th century, it was assumed that that the caries-preventive effect of fluoridated drinking water was due entirely to pre-eruptive mechanisms. The evolution of this thinking aligned with sequence of discoveries about fluoride and dental health made in the first half of the century.[4] In summary: (i) Colorado brown stain was found to be endemic in some communities, but absent in others; (ii) co-incidentally, where Colorado brown stain was endemic, rates of dental caries were noticeably lower; (iii) further studies established that Colorado brown stain was attributable to the community's drinking water, specifically in children who had consumed the drinking water since birth; (iv) high concentrations of fluoride in the drinking water were then isolated as the cause of Colorado brown stain, which was renamed dental fluorosis; (v) further studies established that lifetime exposure to lower levels of fluoride in drinking water of around 1 mg/L F was associated with lower rates of dental caries compared to a negligible concentration, and with little significant dental fluorosis; (vi) in subsequent intervention studies that added around 1 mg/L F to drinking water, dental caries experience was lessened in cohorts born after implementation of fluoridation; (vii) by then, it had been established that high concentrations of fluoride in drinking water affected the developing teeth to cause dental fluorosis seen in epidemiologic studies; (viii) by deduction, it was reasonable to believe that caries preventive benefits of lower concentrations of fluoride in drinking were likewise due to its effects on the developing enamel.

In fact, there was already some evidence to question the assumption that fluoride prevented caries solely be a pre-eruptive mechanism. In the Grand-Rapids study, caries experience of 16 year olds 10 years after implementation of fluoridation was lower than the level seen prior to fluoridation. Commenting on the significance of this finding, Arnold alluded to a post-eruptive effect of water fluoridation noting "It is to be remembered that these children in most cases were those who presumably had the coronal portion of their permanent teeth already calcified when fluoridation started."[5]

By the 1960s, the premise that fluoridated water prevented caries predominantly via a pre-eruptive mechanism was being challenged by biological studies. In one study of 36 premolar teeth extracted for orthodontic reasons, there was little correlation between fluoride concentration of surface enamel and caries experience of the study participants' other teeth.[6] Although a larger study reported an inverse correlation,[7] the finding cast into doubt the prognostic importance of fluoride's incorporation into surface enamel. This was around the time that randomized controlled trials

of topically-applied fluorides were showing clear evidence of efficacy, representing proof-of-principle that fluoride's post-eruptive mechanisms of caries prevention could be significant. There was also a marked increase in microbiological, in-vitro, and animal-experimental studies of post-eruptive mechanisms in dental caries. By the 1980s, a narrative review of the limited epidemiologic evidence and the extensive biological studies concluded that the "major cariostatic effect of water fluoridation, fluoride tooth paste and mouth rinses can probably be ascribed to regular increases in fluoride ion activity in the oral fluids".[8]

The first persuasive epidemiological study to address the question came from re-analysis of data from the Tiel-Culemborg study.[9] A unique feature of the study was its recording of pre-cavitated carious lesions (in addition to the conventional recording of caries experience at the level of cavitation). The re-analysis first confirmed the original finding[10] that fluoridation was associated with a significant benefit in preventing caries at the cavitation threshold. However, when pre-cavitated lesions were included in the re-analysis, caries experience in fluoridated Tiel did not differ appreciably from non-fluoridated Culemborg.[9] The author concluded that fluoridated water did not alter the total caries attack rate (manifesting as pre-cavitated AND cavitated caries), and deduced that difference in cavitation-level caries must have been due to a post-eruptive effect, namely, that fluoride from drinking water favored remineralization of initial, pre-cavitated lesions, preventing their progression to cavitated lesions. By the turn of the century, another prominent narrative review concluded that the predominant caries-preventive effect of fluoridated drinking water was through post-eruptive mechanisms.[11] This represented an evolution in scientific thinking that was characterized as a "paradigm shift".[1]

This century, the "predominantly post-eruptive" explanation for caries preventive benefits of fluoridated water has been corroborated by findings from two groups of epidemiologic studies:

- In studies of children conducted this century, [12-15] sequential cross sectional studies conducted during a relatively short period after a change in community water fluoridation (i.e., addition or removal of fluoride) reported changes in caries experience even in age-groups born years before the change in fluoridation. Because pre-eruptive mechanisms are an implausible explanation in such children, the observed trends in disease that are best explained in terms of post-eruptive effects of water fluoridation.
- In studies of adults conducted this century, [16-21] greater lifetime exposure to fluoridation was associated with less caries experience, even among those born approximately one decade or more after implementation of fluoridation. Again, because pre-eruptive mechanisms are an implausible explanation, the observed trends in disease that are best explained in terms of post-eruptive effects of water fluoridation.

The more persuasive evidence comes from epidemiologic studies that were designed specifically to test hypotheses about relative contributions of pre- and post-eruptive effects. One is the study summarized above, that re-analyzed the Tiel-Culemborg data, demonstrating that fluoridation prevented caries by promoting remineralization of initial carious lesions - a hallmark of post-eruptive mechanisms.

However, the other epidemiologic studies investigating relative contributions provide evidence favoring the *pre*-eruptive mechanism. Three such publications[22-24] re-analyzed data from a single survey[25] in which each child's periods of exposure- and non-exposure to fluoridated water were determined retrospectively. The re-analysis was restricted to first-permanent molars because they have an established chronology of crown mineralization during the first eight years of life, and because caries occurs most frequently in first molars. Residency in fluoridated areas during and after defined-periods of mineralization of first molars was used to classify exposure periods that plausibly are dominated by pre- or post-eruptive caries-preventive mechanisms. The analysis further investigated potential differences according to the anatomical location of caries on the tooth, and according to exposure during discrete phases of mineralization. The findings were consistent in showing that both pre- and post-eruptive mechanisms of caries prevention were necessary to explain observed caries preventive benefits of water fluoridation. Specifically:

- Considering overall caries experience of first permanent molars, pre-eruption exposure was required for a caries-preventive effect whereas exposure only after eruption did not lower caries levels significantly;[23]
- More detailed analysis of the period of pre-eruptive exposure showed that exposure during crown completion was important for caries prevention irrespective of the effect of exposure at crown maturation and at post-eruption.[24]
- More detailed analysis of the anatomical location of dental caries found that, in surfaces with pits and fissure, greater pre-eruption exposure reduced caries levels significantly, whereas at other tooth surfaces, both high pre- and post-eruption exposure were required to prevent caries.[22]

Another epidemiologic study designed specifically to test hypotheses about pre- and post-eruptive mechanisms was a cross-sectional study of n=1,485 South Korean children sampled either from an intervention community that ceased fluoridation seven years earlier or a comparison community that had never been fluoridated.[26] Among 11 year olds, caries experience was lower in the intervention community (where the children had been exposed to fluoridation for the first four years of life) than in the control community. This was in contrast to equivalent levels of caries experience observed in the primary dentition, suggesting that the two communities had a similar risk for developing caries after cessation of fluoridation. The results in the permanent dentition are consistent with fluoridation in the intervention community producing a pre-eruptive effect that conferred caries-protection seen several years later, after the teeth erupted despite being unexposed to fluoridation after eruption.

Another relevant consideration is the 2011 Cochrane systematic review of fluoride supplements.[27] It concluded that "use of fluoride supplements is associated with a reduction in caries increment when compared with no fluoride supplement in permanent teeth." This is relevant because virtually all fluoride in fluoride supplements is swallowed, and because the recommended schedule is that they be discontinued within a few years after the permanent teeth first erupt. Hence, their observed caries preventive benefits must be due almost entirely due to pre-eruptive effects. Likewise, there is some evidence that fluoride supplementation of milk is effective in preventive caries,[28, 29] with studies suggesting that both pre- and post-eruptive mechanisms account for the effect.[30]

### *1.3.4 Critical appraisal of pre- and post-eruptive caries-preventive effects of fluoride in drinking water*

The initial belief that fluoridation prevented caries solely via pre-eruptive mechanisms was a deduction based on the historical epidemiologic studies that discovered fluoride's contributions to both dental fluorosis and dental caries. The subsequent "paradigm shift" in thinking that favored a predominantly post-eruptive mechanism occurred near the end of the 20th century. It was based on an upsurge in biological studies and re-analysis of the historical epidemiologic data. This century, new studies of adults and other studies designed specifically to test relative contributions of each mechanism offer support for the pre-eruptive mechanism. Also, findings from studies of fluoride supplements and milk fluoridation provide in-principle support that pre-eruptive mechanisms are important for population-level prevention of dental caries.

Overall, the studies of caries preventive mechanisms support a combination of pre-eruptive and post-eruptive effects of fluoride in drinking water. Over time, scientific opinion has altered as to whether the "predominant" contribution is via one or the other mechanism, with studies this century suggesting that it is probably a draw. Logically, the share attributable to pre-eruptive effects is greatest in childhood (where little time has elapsed in order for a post-eruptive effect to accrue) and it is necessarily predominant in adulthood. It seems unlikely that any single biological experiment or observational epidemiological study will resolve the question definitively. Instead, the most defensible conclusion is that both mechanisms are important in understanding caries preventive benefits of fluoridation. It follows that the greatest caries-preventive benefit is achieved when both mechanisms operate, which occurs for individuals who have lifetime exposure to fluoridation.[4]

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## 2.3 Detailed response

### *2.3.1 Early scientific findings*

The scientific discovery that fluoride in drinking water prevents dental caries has been described as a "classic epidemiological study".[4] It began with studies of a completely different dental condition, now known as dental fluorosis, and which was first described in the early 20th century as "mottled" teeth and "Colorado brown stain". By the 1920s, dentist in the U.S. Public Health Service observed that dental caries occurred infrequently, if at all, in children with mottled teeth. In contrast, at that time, dental caries was rampant in children unaffected by mottling. With the aid of the new photospectrographic method of measuring fluoride concentration, new epidemiologic studies investigated the association between concentration of fluoride in drinking water and dental caries.

### *2.3.2 U.S. Public Health Service studies conducted in the first half of the 20th century*

The first observational study of an association between exposure to fluoride in drinking water and dental caries was reported by Dean in 1938.[31] It compared dental caries of nine-year olds exposed to 0.6-1.5 mg/L F or 1.7-2.5 mg/L F in drinking water, with the analysis limited to continuous residents of the six cities studied. In the primary dentition, the prevalence of dental caries (i.e., children having 1 or more teeth with caries experience) was 69 percent among those exposed to the higher concentration compared to 89 percent among children exposed to the lower concentration. In the permanent dentition, prevalence was 51 percent and 74 percent, respectively.

By 1942 Dean and co-investigators reported associations between dental caries and fluoride using data from 21 cities where the concentration of fluoride in drinking water ranged from undetectable amounts to 2.6 mg/L F.[32] Dental examiners also assessed dental fluorosis. When examined ecologically (i.e., by plotting community-average levels of caries and community-average levels of fluorosis), the findings identified a range of 1.0-1.2 mg/L F as the "optimal" concentration at which the occurrence of dental caries was lessened, but without elevated prevalence of dental fluorosis. Chapter 23 of Burt et al[4] summarizes this extensive set of studies, commenting on their strengths, limitations and implications.

Those association studies provided the rationale for subsequent intervention studies designed to determine if dental caries could be prevented by adding fluoride to drinking water. The first such study was conducted in Grand Rapids, MI, where fluoride was added to the public water supply to a concentration of 1mg/L in 1945. In that year, epidemiologists conducted dental examinations of 28,614 school children, virtually the entire child population of the city at the time. After fluoridation, they repeated examinations annually for 10 years, selecting samples of children from five school grades in each year (i.e., not necessarily the same individuals from one year to the next). Five years after fluoridating the water, mean deft index in the primary dentition reduced by one third in 5 year olds who were continuous residents (and who represented 73% of the population).[33] After 10 years, the mean DMFT index in the permanent dentition had halved in 12-year-olds.[34] In contrast, over the same period, dental decay levels reduced by less than 20% in samples of continuous residents of non-fluoridated Muskegon, MI, where Dean and colleagues likewise conducted annual dental

examinations. By 1946, studies to evaluate fluoridation were underway in four other pairs of cities in Illinois, New York, Canada and the Netherlands. Results were published in the 1950s, replicating the effects seen in the Grand Rapids-Muskegon study (Table 1).

**Table 1: Summary of findings from children aged 14-15 years in five intervention studies***

| Country (baseline year) | United States (1947) | United States (1946) | United States (1944) | Canada (1944) | Netherlands (1952) |
|---|---|---|---|---|---|
| Test city | Grand Rapids | Evanston | Newburgh | Brantford | Tiel |
| Control city | Muskegon | Oak Park | Kingston | Sarnia | Culemborg |
| Mean DMFT: Test city | 12.4 | 11.3 | 10.4 | 8.0 | 13.9 |
| Mean DMFT: Control city | 6.2 | 5.9 | 6.0 | 3.9 | 6.8 |
| % difference | 50 | 48 | 42 | 51 | 51 |

Data are from Backer-Dirks[35] and Ast and Fitzgerald[36] as tabulated in the 1991 National Health and Medical Research Council report[37]

### *2.3.3 Studies and narrative reviews in the second half of the 20th century and the first decade of the 21st century*

In 1962, based primarily on evidence from studies discussed above, the U.S. Public Health Service first recommended fluoridation of public water systems to prevent dental caries.[38] Communities responded quickly, and by 1970, 49% of the U.S. population was served by a fluoridated public water system.[39] This rapid spread of fluoridation motivated a new round of observational epidemiologic studies, both in the U.S. and in other countries that had adopted fluoridation. There are three comprehensive narrative reviews that evaluated studies in children during the period: a) one was a review of 55 studies reported primarily before the 1980s;[40] b) another review assessed 24 studies reported between the late 1970s and 1980s;[41] and c) another review focused primarily on 58 studies reported after 1990.[42] In each instance, the reviews concluded that children living in communities with fluoridated water had significantly less dental caries that children living in non-fluoridated areas.

### *2.3.4 Systematic reviews of dental caries preventive effects of fluoridated drinking water in children*

The reviews cited above[40-42] are nowadays classified as *narrative* reviews to distinguish them from *systematic* reviews. The distinguishing features are methodological: systematic reviews begin by defining a structured research question; strategies to search bibliographic sources and database are then specified; before the search, criteria are developed for inclusion and exclusion of studies; researchers conduct an initial review of study titles and abstract to determine those that meet selection criteria; and each study is synthesized according to a checklist of features that appraise the quality of the studies. The compiled review summarizes findings, comments on the scientific quality of each study, and creates tabular and graphical summaries. In some instances, systematic reviews combine results from two or more studies using meta analysis, a statistical method that pools quantitative results published from different studies. Methods for systematic reviews were first developed in the 1990s, spearheaded by the Cochrane collaboration, which aims to improve rigor in evaluating healthcare, and in particular, the results from clinical trials comparing treatments. While any

researcher with the requisite skills and resources can conduct a systematic review, reviews undertaken by the Cochrane collaboration are often valued for their rigor and objectivity.

The criteria used to select studies and rate their methodological quality are critical components of systematic reviews. Virtually all systematic reviews use a similar "hierarchy of study designs" when judging quality of the evidence: properly conducted randomized controlled trials are at the top of the hierarchy, observational studies are given lower quality ratings, and case reports or expert opinions are at the bottom of the hierarchy. Nonetheless, systematic reviews vary in the details and application of the evidence hierarchy. For example, a recent Cochrane review of water fluoridation applied GRADE criteria to evaluate quality of studies, commenting that "when applying GRADE to non-randomised studies, the quality of the evidence automatically starts at 'low', as opposed to 'high'." [43] In contrast, the U.S. Preventive Services Task Force considers a broader set of characteristics in rating the quality of evidence, particularly when evaluating preventive public health interventions for which randomized trials are not feasible.[44]

The first systematic review of fluoridation was conducted in 2000 by the United Kingdom's National Health Service Centre for Reviews and Dissemination.[45] The research question was defined thus: "What are the effects of fluoridation of drinking water supplies on the incidence of caries". While the search criteria placed no historical restrictions on studies to be reviewed, only 26 met the investigators' inclusion criteria which stipulated that studies had to report changes in caries over time, comparing one community where fluoride was added to or removed from drinking water with a control community that did not change its fluoridation status. Specifically, it required that communities be assessed at "two points in time, one of which is less than one year since the change of water fluoridation status in one of the groups". The review, which included meta analysis to quantitatively combine the published results, concluded that introduction of fluoridation was effective in reducing dental caries, with the mean difference between communities in changes in dmft/DMFT ranging from 0.5 to 4.4 teeth per child. The review also found that withdrawal of water fluoridation led to an increase in prevalence of caries. It noted that most of the included studies were of moderate quality (level B). That rating was driven by the fact that there have been no randomized controlled trials of fluoride in drinking water for dental caries prevention. Instead, the 26 studies reviewed used observational study designs which ranked lower in the evidence hierarchy applied by the reviewers when evaluating quality.

Other systematic reviews soon followed, although they varied in the number of studies reviewed. A 2007 review by Australia's National Health and Medical Research Council updated the U.K. review with two additional studies, concluding that introduction of fluoridation reduced cares while removal of fluoridation increased caries.[46] In 2013, the U.S. Community Preventive Services Taskforce updated the U.K. review with its own evaluation of 28 studies, endorsing fluoridation "based on strong evidence of effectiveness in reducing dental caries across populations."[47] It also found that fluoridation was effective in reducing caries across all socioeconomic groups. Meanwhile, a review of systematic reviews and practice guidelines concluded that water fluoridation is effective in reducing caries in children, with some evidence that it can "reduce the oral health gap between social classes."[48]

In contrast, the 2015 review by the Cochrane collaboration was more restrictive than other systematic reviews, using results from only nine studies that evaluated primary dentition caries following addition of fluoride to drinking water, and 10 studies that evaluated permanent dentition caries.[43] Although it concluded that fluoridation led to a 35% reduction in dmft and a 26% reduction in DMFT, it found that all studies had a high risk of bias. It also found insufficient evidence to determine the effect of stopping water fluoridation or the effect of fluoridation on dental health disparities.

### *2.3.5 Studies of fluoridation and dental caries in children reported since the 2015 Cochrane systematic review*

Several new epidemiologic studies of children have been reported since the Cochrane review, as summarized in Table 2. Each study found dental caries preventive benefits associated with exposure to water fluoridation. Results therefore are consistent with the main finding of the reviews summarized above.

## Table 2: Studies reported since the 2015 Cochrane systematic review

| Year(s) and setting for data collection | Methods (row 1)<br>Results (row 2) |
|---|---|
| 1986 to 2003 Brazil, DMFT of 12-yr-old children [12] | Time-series analysis of ecological data (550 records from 428 locations) linked to area-level measures of fluoridation and socio-economic status.<br>Compared to non-fluoridated communities, mean DMFT was 0.94 lower in fluoridated communities. |
| 1999-2008 and 2011-2012 Australia, dmft of 4-9 yr olds [13] | Sequential cross-sectional surveys of dental examination and radiograph records recorded pre-fluoridation (1998-2008; n=201) and 3-years post-fluoridation (2011-2012, n=256) n= children living in a remote Indigenous community of Australia before (n=393) and after fluoridation (n-263).<br>Significant three year reductions in mean dmft (4.54 to 3.66). |
| 1999-2014 United States, dmfs and DMFS of 2-17 yr olds[49] | National, cross-sectional surveys of 16,718 children whose county-of-residence was classified according to percentage of the population served by community water fluoridation.<br>Mean dmfs of 2-8 yr olds was less in counties with ≥75% of population served by fluoridated water (mean =3.3) than in counties with <75% of population served by fluoridated water (mean = 4.6). Mean DMFS of 6-17 yr olds was likewise lower (1.9 versus 2.2, respectively) |
| 1999-2014 United States, dmfs and DMFS of 2-17 yr olds [50] | National, cross-sectional surveys of 16,718 children listed above, where household income-to-poverty ration was used to compute absolute- and relative measures in income-related inequality in caries.<br>In the primary dentition, there was a statistically significant interaction between county-coverage of fluoridation and income that attenuated the income-gradient in dental caries. In the permanent dentition, the gradient was also attenuated, but no to a statistically significant degree. (See Figure 1) |
| 2003 and 2008, Alaska, Medicaid claims for dental caries treatment | Medicaid dental treatment claims for 0-18 yr olds analyzed in 2003 (n = 853) during fluoridation and five years later (n = 1052), five years after cessation of fluoridation.<br>Following cessation of fluoridation, there were significant increases number of caries-related procedures per child (2.35 vs. 2.02) and in treatment costs (varying according to age group from 28% to 111%. |
| 2005 and 2012, Australia, dmft and DMFT of 4-12 yr olds [14] | Sequential cross-sectional surveys of children living in a remote Indigenous community of Australia before (n=393) and after fluoridation (n-263).<br>Significant seven-year reductions in mean dmft (4.44 to 2.76) and mean DMFT (2.08 to 1.32) |
| 2008-2012, Australia, dmft of 5-7 year olds [51]* | Three sequential cross-sectional surveys in one city before and after fluoridation (average n=827 per survey year) and in a control location which had no fluoridation throughout (average n=610 per survey year)<br>Four-year reduction in mean dmft was greater in city that implemented fluoridation (2.02 to 0.72) than in non-fluoridated comparison area (2.09 to 1.21) |
| 2011-2012 Australia, dmft and DMFT of 5-12 year olds[52] | Cross-sectional study of 10,825 children classified as living either in the fluoridated metropolitan area or the non-fluoridated south-west area of Western Australia<br>Mean dmft was significantly greater in non-fluoridated (e.g., 5-yr-old dmft=1.6) than fluoridated area (5-yr-old dmft =1.1). Mean DMFT was greater, though not statistically significantly so, in non-fluoridated (e.g., 12-yr-old DMFT=0.82) than in fluoridated area (12-yr-old DMFT=0.60) |
| 2012-2014, Australia, income-inequality in dmfs and DMFS of 5-14 yr olds [53] | National, cross-sectional study of 21,328 children classified as living either in the fluoridated or non-fluoridated areas; absolute measure of income inequality in dental caries computed as the regression-slope index of inequality<br>Absolute income-related inequality in dmfs of 5-9 yr olds was less in fluoridated areas (−4.18) than in non-fluoridated areas(−6.20). Absolute inequality in DMFS of 9-14 yr olds was less in fluoridated areas (−0.60) than in non-fluoridated areas(−1.66) |
| 2009-2014, Canada, socioeconomic inequalities in caries of grade 2 children[15] | Sequential cross-sectional surveys in 2009-10 (n=511) when Calgary water was fluoridated and in 2013-14, (n=2980), 2-3 years after defluoridation. Socio-economic inequities in dmft and DMFT gradients were computed according to a) small-area measures of socio-economic deprivation; and b) dental insurance<br>Inequities in caries experience according to dental insurance status and by small area material deprivation were more apparent in 2013/14 than in 2009/10. |
| 2009-2012, England, multiple caries-related outcomes in children [54] | Cross-sectional, ecological analysis of n= 32,482 local statistical areas, 12% of which were fluoridated. Dental caries measured in 5-year-olds (dmft) and 12-year olds (DMFT) in the National Dental Epidemiology Program. Rates of dentally-related hospitalization were from national hospital episode statistics (HES) for children aged 1-4 years.<br>After adjustment for ethnicity and socio-economic deprivation, there was 28% lower likelihood of dental caries in fluoridated areas versus non-fluoridated areas for 5-year olds, and 21% lower likelihood for 12-year olds. Fluoridated areas had 45% fewer dental-caries related hospital admissions of 1-4 year olds compared to non-fluoridated areas. |
| 2015, South Korea education-inequality in dmf | Examination survey of 6-, 8- and 11-year-old South Korean children living in fluoridated Okcheon and non-fluoridated Yeongdong.<br>Questionnaires determine educational attainment of parents.<br>Education-associated inequalities in dental caries were statistically significant in Okcheon but absent in Yeongdong. |

* Prior to publication, results from this study were used in the Cochrane systematic review

The studies in Table 2 include time-series cross-sectional studies in communities that either added or removed fluoride from drinking water. Others used a single-cross sectional study design, focusing on the association between exposure to fluoridation and the extent of income-inequalities in caries. One study warrants further emphasis because of its timeliness in being the first study in 30 years to investigate water fluoridation and dental caries in the U.S. child population. The cross-sectional study used data from five cycles of the National Health and Nutrition Examination Survey (NHANES) conducted between 1999 and 2014. Dental caries experience of 16,718 sampled children was measured by trained examiners who recorded dfs and DMFS indices. Sociodemographic characteristics and dental health behaviors were reported by parents/guardians during the NHANES interview. Information about fluoridation in each child's county-of-residence was obtained from the Water Fluoridation Reporting System (WFRS). This database contains information about fluoride concentration and population size served by each of approximately 54,000 U.S. public water systems.

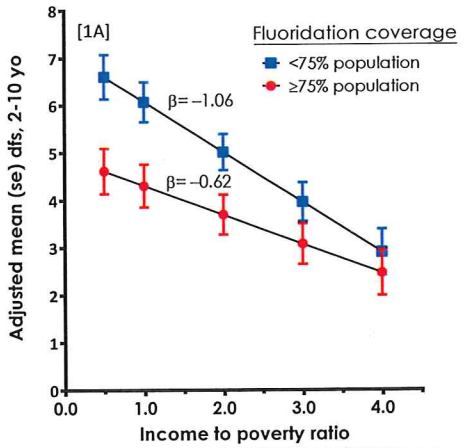
The first publication from the study compared caries experience according to the percentage of county population served by a fluoridated public water system. For descriptive purposes, mean levels of caries experience were compared between two groups classified according to the percentage of county population served by public water containing ≥0.7 mg/L F: <75% or ≥75%. Separate analysis used a linear regression model to estimate a "dose-response" gradient between caries experience and the proportion of the county's population that was fluoridated (modeled as a continuous variable, ranging from 0 to 1). The rationale was that the dichotomous classification of fluoridation (<75% or ≥75%) provides an estimate of the association at a pragmatic public health level, recognizing that many counties have some fraction of the population that does not use a public water system, making 100% fluoridation unattainable. In contrast, the continuous measure of fluoridation estimates the likely impact of fluoridation in situations where 100% coverage is attainable.

For primary dentition caries, mean dfs was 4.6 in counties with <75% fluoridation compared to 3.3 in counties with ≥75% fluoridation and the covariate-adjusted group difference between the two groups was 1.39 (i.e., after adjusting for socio-demographics and dental behaviors). Using the continuous measure of county-level fluoridation, the adjusted difference associated with 0% versus 100% fluoridation was 2.1. In the permanent dentition, mean DMFS was 2.2 and 1.9 in <75% fluoridation and ≥75% fluoridation counties, the fully-adjusted difference was 0.25, while, using continuous measure of fluoridation, the difference between 0% versus 100% fluoridation was 0.88. However, it is more informative to consider those effect estimates for groups of children, rather than for individuals. To that end, Table 3 summarizes the same effect estimates for an average group of 30 children in the U.S. population (i.e., the approximate number of children in a school classroom). Based on the contrast of 0% with 100%, fluoridation is associated with 62 fewer cavities in primary teeth per thirty 2-8 year olds, and 26 fewer cavities in permanent teeth per thirty 6-17 year olds (Table 3).

**Table 3: Caries experience expressed as number of affected tooth surfaces per 30 children in the U.S. child and adolescent population***

| Age-group, caries index | Observed means in counties with <75% fluoridation | Observed means in counties with ≥75% fluoridation | Covariate-adjusted mean difference <75% vs. ≥75% fluoridation | Covariate-adjusted mean difference 0% vs. 100% fluoridation |
|---|---|---|---|---|
| 2-8 yr olds, dfs per 30 children | 138 | 100 | 42 | 62 |
| 6-17 yr olds, DMFS per 30 children | 66 | 57 | 7 | 26 |

* Based on observed means reported in Table 4 and regression-model adjusted differences reported in Table 5 of Slade et al. [49]




| Reduction: | Income to poverty ratio | | | | |
|---|---|---|---|---|---|
| <75% vs. ≥75% | 0.5 | 1 | 2 | 3 | 4 |
| Absolute | 2.0 | 1.8 | 1.3 | 0.9 | 0.4 |
| Relative | 30% | 29% | 26% | 22% | 15% |

Figure 1: Income-gradients in dental caries of U.S. children are attenuated by fluoridation. [50]

The second publication from the same study investigated income-associated inequality in dental caries experience, comparing counties where <75% of the population was served by fluoridated water with counties where ≥75% of the population was served by fluoridated water. In the primary dentition, there was a statistically significant interaction between county-coverage of fluoridation and household income. The interaction provided statistical evidence that the income-gradient in dental caries was attenuated by 41% in predominantly fluoridated counties compared to communities with <75% fluoridation (i.e., gradients of -1.06 and -0.62, respectively; see Figure 1). In the permanent dentition, the gradient was also attenuated, but not to a statistically significant degree.

As such, fluoride in drinking water represents a rare preventive intervention that is associated with greater preventive benefits in low-income groups than in high-income groups.

In addition to the original studies reported in Table 2, there have been two systematic reviews reported since the 2015 Cochrane systematic review (Table 4).

**Table 4: Systematic reviews reported since the 2015 Cochrane systematic review**

| Year(s) and setting for data collection | Methods (row 1)<br>Results (row 2) |
|---|---|
| 2016, Australia, Evidence evaluation of fluoridation and dental caries [55] | Review of previous systematic reviews (through 2015) and subsequently-published association studies through 2016 (n=15 studies of primary dentition caries; n=21 studies of permanent dentition) by the Fluoride Reference Group of the Australian National Health and Medical Research Council.<br>Main conclusions:<br>• "water fluoridation reduces tooth decay by 26-44% in children, teenagers and adults".<br>• "there is consistent evidence that water fluoridation reduces tooth decay for all socio-economic groups"<br>• "there is some additional evidence that suggests water fluoridation reduces inequality in tooth decay experienced by those in lower socio-economic groups and those living in regional areas. |
| 2016, Canada, Systematic review of fluoridation cessation [56] | Systematic review of n=15 studies that investigated caries experience before- and after-cessation of community water fluoridation.<br>Of 9 studies that met criteria for methodological quality, five showed an increase in caries after cessation of fluoridation, 3 studies did not show an increase, and one could not be adjudicated. |

### *2.3.6 Critical appraisal of studies reported since the 2015 Cochrane systematic review*

In each instance of primary studies reported since 2015 (Table 2), the study designs were of the type that did not meet the criteria for study selection in the 2015 Cochrane review. That is, the subsequently reported studies either used a cross-sectional design or sequential cross-sectional surveys before and after fluoridation (or defluoridation), but with no comparison community. Hence, if a systematic review were to be repeated today using the same study selection criteria as applied for the Cochrane review,[43] none of the new studies would be included. Yet, other systematic reviews conducted since 2015 were more inclusive in their selection criteria than the 2015 Cochrane systematic review. In each instance, those other systematic reviews evaluated a considerably larger body of evidence, and they were more affirmative in concluding that fluoridation was associated with lower levels of dental caries than was the 2015 Cochrane systematic review. Specifically, the Australian evidence review considered cross-sectional studies excluded by the 2015 Cochrane systematic review, along with 26 studies published since the 2015 Cochrane systematic review, concluding that fluoridation reduces tooth decay by 26-44% (a higher upper bound than the 26-35% reported in the 2015 Cochrane systematic review). The Australian review was also more affirmative with respect to effects of fluoridation on socio-economic inequalities in dental caries. Likewise, the systematic review of fluoridation cessation,[56] in concluding that "overall, the published research points more to an increase in dental caries post-CWF [community water fluoridation] cessation than otherwise", was more assertive than the 2015 Cochrane systematic review which concluded "there is insufficient information to determine the effect of stopping water fluoridation programmes on caries levels".

In summary, studies reported since 2015 continue to show dental caries preventive benefits associated with exposure to fluoridated drinking water. The two new systematic reviews used more inclusive selection criteria than the 2015 Cochrane systematic review and were more affirmative in their conclusions of a caries-preventive benefit.

### *2.3.7 Epidemiologic studies of water fluoridation and dental caries in adults*

Epidemiologic studies in adults of the association between water fluoridation and dental caries date back to 1948[57] when a markedly lower-than expected rate of dental decay and tooth extraction was seen in adults who were lifetime residents of Colorado Springs, CO, where drinking water contained 2.6 mg/L F. When later compared with lifetime

resident of non-fluoridated Bolder, CO, [58] the rates in Colorado Springs were approximately 60 percent lower. Ironically, those two studies were not included in a 2007 systematic review of the fluoridation and dental caries in adults because the search was limited to studies published since 1966. Instead, that 2007 systematic review[59] used results from nine published studies: one was a prospective cohort study, one was a an ecological study, and seven were cross-sectional studies of adults who were lifetime residents of either fluoridated or non-fluoridated areas. Pooled results from meta-analysis revealed a reduction of one third (34.6%, 95%CL: 12.6%, 51.0%) in caries experience associated with lifetime exposure to approximately 1mg/L F (range 0.7 to 2.0 mg/L F).

Since that systematic review, six cross-sectional studies of adults have investigated the relationship, as summarized in Table 5. The one U.S. study during that period investigated tooth loss, not total caries experience, using a nationally-representative sample of adults.

**Table 5: Studies published since 2007 examination associations between fluoridation and dental caries experience in Adults**

| Year(s) and setting for data collection | Methods (row 1)<br>Results (row 2) |
|---|---|
| 2006 Australia, DMFT of 17-56 yr olds [16] | Cross-sectional clinical and radiographic examination survey of n=876 armed forces recruits. Fluoridation status of each residential location was determined from a national database of fluoridation history of public water supplies.<br>Mean DMFT in recruits with ≥50% lifetime exposure was 24% lower than recruits with the <10% lifetime exposure group. |
| 2008, Australia, DMFT of 17-35 yr olds[17] | Cross-sectional clinical and radiographic examination survey of n=1084 army recruits. A questionnaire asked about socio-demographic characteristics and residential locations throughout life. Fluoridation status of each residential location was determined from a national database of fluoridation history of public water supplies.<br>Mean DMFT in recruits with lifetime exposure to fluoridated drinking water was 3.02 compared to 3.87 for recruits with no exposure. |
| 1992-1999, U.S. missing teeth of 23-49 yr olds[18] | Cross-sectional telephone interview survey with 81,337 adults in the Behavioral Risk Factor Surveillance System Survey, where tooth loss due to dental disease was reported in four categories. The 1992 Fluoridation Census was used to calculate each respondents county-of-residence at the time of the survey, 20 years earlier, and at birth.<br>Lower levels of tooth loss were significantly associated with residence in fluoridated counties at the time of the respondent's birth, but not to fluoridation at the time of the survey. |
| 2004-06, Australia, DMFT and DFS of 18->65 yr olds[19] | Cross-sectional dental examination survey of a nationally representative sample of n=3,779 adults who also completed a questionnaire asking about socio-demographic characteristics and residential locations throughout life. Fluoridation status of each residential location was determined from a national database of fluoridation history of public water supplies.<br>After adjustment for sociodemographic characteristics, adults with >75% of lifetime exposure to fluoridation had 10% fewer DMFT compared to adults with < 25% of lifetime exposure. The percentage difference was similar for people who were exposed to fluoridation before- and after birth, and for people exposed only after birth. |
| 2012, Brazil, DMFT of 20-59 yr olds[20] | Cross-sectional dental examination survey of n= 1,140 people born in Florianópolis where fluoridation was implemented in 1982 and 1986 in different parts of the city. Questionnaires asked about residential locations throughout life.<br>Relative to people with access to fluoridated water for >75% of their lifetime, DMFT was greater for people with 50%-75% lifetime exposure (ratio=1.34) and for people with <50% lifetime exposure (ratio=1.34) |
| 2006-2011, Australia, DMFS in 20-35 yr olds[21] | Cross-sectional dental examination survey of n=1,221 people in South Australia who had first participated in a 1991-1992 survey. Questionnaire asking about socio-demographic characteristics and residential locations throughout life were administered and percentage of lifetime with access to fluoridation was determined from a national database of fluoridation history of public water supplies.<br>Relative to people with 100% lifetime exposure to fluoridation, people with <75% lifetime exposure had greater DMFS (ratio=1.26). Relative effects were of a similar when fluoridation exposure was calculated separately as percentage of childhood exposed and percentage of adolescence/adulthood exposed. |

### *2.3.8 Critical appraisal of studies of water fluoridation and dental caries in adults*

Overall, findings from studies of adults corroborate results from studies of children: exposure to water fluoridation is associated with lower levels of dental caries experience. There is also some indication that the magnitude of preventive

benefit was greater in historical studies. For example, the 2007 systematic review[59] of studies reported since 1966 estimated an overall relative difference of one third, whereas most of the subsequent studies summarized in Table 5 report smaller relative differences. Also, as seen in studies of children, the systematic review in adults[59] used more inclusive selection criteria than the 2015 Cochrane systematic review which also included studies of adults, but which concluded that "no studies that aimed to determine the effectiveness of water fluoridation for preventing caries in adults met the review's inclusion criteria".[43]

Some studies of adults distinguish between preventive benefits from exposure in childhood and in adulthood, suggesting that both periods of exposure are important. Consistently, though, the studies reviewed in Table 5 conclude that lifetime exposure to fluoridation confers the greatest caries-preventive benefit. This finding is considered in further detail in the next section, which reviews hypothesized biological mechanisms underlying the preventive benefits observed in association studies.

### *2.3.9 Causal inference and biological mechanisms of action*

There are well-established criteria to evaluate whether or not an association between exposure and disease is causal. For example, when judging the health effects of smoking (which, on ethical grounds, can never be tested in an experimental study of humans), the 2004 U.S. Surgeon General's Report[60] applied seven criteria. Those criteria as they apply to caries-preventive benefits of water fluoridation are reviewed briefly below.

1. *Consistency: results from association studies should be replicated in different studies and populations.*
   As reviewed above, systematic reviews from studies spanning more than half a century and conducted in multiple countries are consistent in concluding that exposure to water fluoridation is associated with lower levels of dental caries in children.
2. *Strength of association: a greater magnitude of effect suggests an association that is more likely causal.*
   The first association studies, conducted at a time when dental caries was rampant, and when fluoride was available only in drinking water demonstrated profound reductions in dental caries experience associated with lifetime exposure to fluoridation.
3. *Specificity[1]: the exposure should be associated with only one or a few diseases.*
   While fluoridation has been investigated for potential preventive effects in other oral diseases (including gingivitis and periodontal disease), no association was found.
4. *Temporality: exposure to the putative cause should precede development of the disease.*
   As noted in above, this criterion is satisfied in studies that measure lifetime caries experience in lifetime residents of either fluoridated or non-fluoridated areas.
5. *Biological gradient: incremental effects on disease are observed with incrementally greater exposure*
   This was demonstrated first in Dean's "21-cities" study,[32] where the concentration of fluoride varied, and has

[1] The Surgeon General's report gives least credence to the specificity criterion when evaluating chronic diseases, noting that its existence can strengthen a causal claim, but its absence does not weaken it.

been verified in later studies that expressed the degree of exposure as a percentage of lifetime living in places fluoridated at around 1 mg/L F (see Section 2.3.3)

6. *Experiment: studies of natural variation that plausibly imitate conditions of a randomized experiment.*
   This criterion was addressed most convincingly in the five "twin-cities" trials (Section 2.3.2) where intervention and control cities were studied in parallel, over multiple years, making them equivalent to experimental trials in many aspects, although not with respect to random allocation. Subsequent studies with comparable, non-randomized designs were reviewed and given the highest quality ratings in systematic reviews reported this century.
7. *Coherence, plausibility and analogy: a proposed causal relationship should not violate known scientific principles.*
   The causal interpretation is *biologically plausible*, with good evidence that dental caries prevention is due to a combination of pre-eruptive mechanisms (i.e., incorporation of fluoride into developing enamel which becomes more resistant to subsequent acid attacks) and post-eruptive mechanisms (i.e., concentration of intra-oral fluoride in dental biofilm, inhibiting demineralization and enhancing remineralization).

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