INTRODUCTION

Communities throughout the United States have used the fluoridation of drinking water supplies for over 70 years as a strategy to reduce tooth decay (dental caries) 1-7. The observed decline in national averages for the prevalence and severity of dental caries since the initiation of the program in 1945 has been deemed one of the greatest modern public health successes of the 20th century3, 5-9. Despite these gains, a debate exists concerning the potential health risks of water fluoridation versus the observed benefit of the intervention1, 10, 11. As a result, Public Health Madison & Dane County occasionally receives phone calls, emails, and letters from residents expressing concern about the fluoridation of local water supplies. Therefore, this document was produced and regularly reviewed to provide a brief overview of the current status of public concerns and an overview of the scientific literature.

OVERVIEW

Naturally occurring fluoride is found in all water supplies across the United States; the concentration is dependent upon the geology of the water body and the occurrence of fluoride-bearing minerals and materials1, 6, 8. The discovery of the potential health applications of fluoride in the early 1930s led to the development of the first clinical trial of artificial fluoridation of community water supplies in Grand Rapids, MI in 1945. The trial was designed to last for 15 years prior to any potential recommendation for the expansion of water fluoridation to other communities; however, the popularity of the program led to its initiation in other cites the following year1. The City of Madison, Wisconsin began the fluoridation of drinking water supplies in 1948.

EFFECTIVENESS OF WATER FLUORIDATION TO PREVENT DENTAL CARIES

Opponents of water fluoridation of community water supplies cite two major issues to question the effectiveness of the program; a comparable reduction in dental caries in non-fluoridated communities and the improved availability of fluoride-containing products make the treatment of community drinking water unnecessary.

Research has demonstrated that differences in the rate of dental caries in fluoridated and non-fluoridated communities have gradually decreased since the inception of water fluoridation programs. Opponents have used this and similar research to question the continued effectiveness of water fluoridation but this argument ignores the diffusion effect of fluoride containing products including food, beverages, dietary supplements, and dental products that were manufactured in fluoridated communities and sold in non-fluoridated areas1, 6, 8. Therefore, the non-fluoridated communities also experience an indirect benefit derived from
water fluoridation programs resulting in the comparable reduction of dental caries observed in these areas. This argument also ignores the larger benefit repeatedly reported among lower income and minority populations and the noted increase in dental caries among communities that have discontinued water fluoridation\textsuperscript{3, 5, 6, 7, 12 - 17}.

Oral hygiene has gradually improved in the United States over the past several decades, including the increased use of fluoride-containing dental products such as rinses, toothpaste, and topical gels\textsuperscript{12-16}. However, disparities in use of and access to products and services promoting oral health remain, especially among low income and minority populations. The use of water fluoridation has provided an effective and cost efficient method to deliver preventative services to promote oral health to all residents within a community served by municipal water supplies, regardless of income, race or ethnicity, ability level, insurance status, or access to care\textsuperscript{3, 8, 12, 13, 17}. Currently, over 200 million Americans are served by drinking water supplies that contain the accepted levels of fluoride to reduce dental caries (approximately 75%); the Healthy People 2020 initiative calls for an expansion of this coverage to 80% of the population receiving drinking water from public water systems\textsuperscript{3, 6, 15, 16, 18}.

**POTENTIAL HEALTH CONCERNS**

The beneficial health effects of exposure to low concentrations of fluoride result from its ability to reduce tooth enamel solubility, decrease acid production of plaque-producing organisms, and promote the remineralization of the enamel\textsuperscript{1, 6, 16}. Efforts to prevent or remove water fluoridation in Dane County communities are most commonly motivated by concerns of fluorosis of teeth and bone, toxicity of fluoride, increased risk of hip fracture among the elderly, decreased IQ among children, hypothyroidism and cancer.

1. **Acute fluoride toxicity**

   This condition has been reported when fluoridated drinking water supplies reach a level of 30ppm\textsuperscript{9}. Due to the utilization of well-designed fail-safe equipment, proper maintenance and calibration, and appropriate operating procedures these overdosing incidents are rare in the United States. Symptoms normally occur within hours of exposure and include skin irritation, nausea, vomiting, diarrhea, and muscle weakness. Depending upon severity, observable symptoms resolve quickly following cessation of exposure. In severe cases, fluoride poisoning may result in cardiac arrest\textsuperscript{19-21}.

2. **Dental and skeletal fluorosis**

   These conditions are well-documented results of prolonged exposure to excess fluoride\textsuperscript{1, 9, 15, 16}. The development of dental fluorosis and skeletal fluorosis are attributed to the toxicokinetic properties of fluoride following exposure. Following ingestion, 75-90% of the compound is absorbed and readily distributed throughout the body\textsuperscript{9}. Approximately 35-48% of the absorbed fluoride is retained by the body; an estimated 99% of the compound body burden is stored in the calcium rich areas of the bones and teeth (dentine and
enamel). This pattern of distribution and storage may lead to adverse impacts on the teeth and skeletal systems of individuals chronically exposed to excess natural and/or introduced levels of fluoride in public drinking water supplies.

Dental fluorosis is characterized by the staining and disruption of normal enamel formation of the teeth; the markings can range from unnoticeable in very mild cases (most common) to brown stains and pitting of the enamel in severe cases (rare). Although severe cases can lead to brittle teeth and more teeth wear, all forms of dental fluorosis are considered by the United States Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (DHHS) to be a cosmetic concern rather than an adverse health effect. Reported cases of dental fluorosis have increased in the United States since the widespread initiation of water fluoridation. Prior to the adoption of the program, the prevalence of dental fluorosis was 12-15%; modern rates of this condition have shown reported increases. A study conducted by the CDC reported that an estimated 23% of persons aged 6 to 39 years had a very mild or greater dental fluorosis while approximately 32% of children and adolescents aged 6 to 19 years were reported with the condition. The risk of dental fluorosis development is limited to children 8 years of age or younger; tooth development occurs during this age range and the enamel is susceptible to the effects of fluoride when chronically exposed to levels of fluoride larger than 2 ppm. The current optimal level of fluoride recommended for drinking water sources is 0.7 ppm. Children older than 8 years, adolescents, and adults are not susceptible to dental fluorosis.

Skeletal fluorosis is a disease characterized by increased density and brittleness of the skeletal system; the disease occurs in a range of severity dependent upon the level and duration of fluoride exposure. The mildest form of the disease can lead to arthritis-like symptoms including painful joints, limitations in movement, and reduced flexibility. Continual exposure to fluoride concentrations of 5 ppm or greater may lead to osteosclerosis. In the most severe cases, skeletal fluorosis can be a crippling disease, confining a patient to a wheelchair. The condition is extremely rare in the United States with only 5 confirmed cases reported in the last 35 years; each of these cases occurred in areas where natural fluoride levels were greater than 20 ppm.

3. Hip fracture

Both excessive and inadequate intake of fluoride has been associated with an increased risk of hip fracture among the elderly. However, research does not support an association between water fluoridation and increased rates of hip fracture. In fact, two systematic reviews of the literature published in 2000 and 2017 evaluating hip fracture and other types of bone fracture, respectively, also concluded that risk was not associated with water fluoridation.

4. Reduction of IQ in children

Concerns have also been raised that water fluoridation is associated with lowered IQ and
other neurological effects from exposure. However, this concern is not supported by the science-based evidence. A number of systematic reviews of the literature and individual investigations does not support this association; including the recent response by the US Environmental Protection Agency (US EPA) to a TSCA Section 21 petition and a study released in 2018 conducted by the National Toxicology Program (NTP)\textsuperscript{15, 16, 29 - 31}. Despite this fact, some published investigations continue to suggest or imply neurological impacts among communities with fluoridated water at recommended levels\textsuperscript{15, 16, 29 - 36}.

The human epidemiology studies that are often cited to support this concern are typically conducted in areas of the world with high naturally occurring levels of fluoride in the drinking water (e.g. China and Iran) and imply or are used by opponents of fluoridation to imply an association with community water fluoridation programs at recommended fluoride levels. In addition, limitations in the methodology of many of these studies lead to unsupported conclusions due to the impact of potential confounding factors that were not controlled or considered during the investigation \textsuperscript{29, 34, 35, 37, 38}.

One important limitation is that many of these studies use a cross-sectional design; a type of study design that does not establish causality because it cannot be determined if the health conditions occurred before or after the exposure in question. Cross-sectional study designs are best suited to help generate potential causal hypotheses further evaluated by more robust epidemiological investigations \textsuperscript{29}. Another important limitation of these studies is that potential founding factors are not adequately recognized and/or controlled which results in the inability to attribute the reported conclusions to fluoride exposure or other factors or exposures potentially present and not accounted for by the investigation. Examples include, but are not limited to, estimated water intake and not actual consumption, a lack of standardized testing of mental IQ, the failure to address other potential exposures that are associated with neurological impacts (e.g. lead and arsenic), exposure to other sources of fluoride (e.g. burning coal for heating), social inequities of the study population (e.g. poverty, nutritional deficiencies, and parental educational attainment), and/or measuring fluoride delivery in salt and imply association with water fluoridation \textsuperscript{15, 16, 28, 29, 31-36, 38-40}.

5. Hypothyroidism

An association has also been suggested between exposure to community water fluoridation and the incidence of hypothyroidism; a condition in which the thyroid gland doesn’t produce a sufficient amount of hormones to function at a normal level\textsuperscript{41-43}. This suggested association is inconsistent with the literature and not supported by subsequent investigation of this potential association \textsuperscript{42, 44 - 46}.

Hypothyroidism is largely classified as an autoimmune disease (e.g. Hashimoto’s thyroiditis) that is strongly associated with age (over 50 years) and sex (female). However, the condition can also be attributed to other underlying variables including the use of certain medications (e.g. lithium), both an increased or decreased intake of dietary iodine,
socioeconomic status, pregnancy, family history of thyroid disease, surgery, and radiation therapy. Many of the studies that report an association between water fluoridation at the recommended optimal level and hypothyroidism fail to account for many of these potential confounding factors that could result in spurious associations that are not reliable, representative, or generalizable to communities with fluoridated water resources.

6. Cancer

According to the World Health Organization (WHO), a large number of studies exploring the issue demonstrate no consistent evidence of any association between the consumption of controlled fluoridated drinking water with an increased risk of cancer.

The majority of the concern about a potential cancer risk associated with the exposure to fluoridated drinking water is the development of osteosarcoma; a rare type of bone cancer typically diagnosed in children and teens in the United States. Similar to other types of cancers, the body of evidence does not display a consistent association between the consumption of drinking water fluoridated at recommended levels and the risk of osteosarcoma. For example, research performed by the Harvard School of Public Health in 2006 reported that water fluoridation was associated with a higher risk of osteosarcoma in males but not females. However, early results from the second half of this investigation did not match the initial findings and the researchers advised caution in interpreting the results. The second part of the Harvard study was published in 2011 and found no association between water fluoridation and osteosarcoma risk.

More recent studies have compared rates of osteosarcoma in areas of higher versus lower levels of water fluoridation in the United States, Great Britain, and Ireland; these studies have also not reported an increased risk in areas of water fluoridation.

**FLUORIDATION COMPOUND SOURCES AND POTENTIAL CONTAMINATES**

There are three basic compounds that are utilized for water fluoridation; sodium fluoride, sodium fluorosilicate, and fluorosilicic acid. Each of these compounds is derived from phosphorite rock, a source that is primarily used in the production of phosphate fertilizer. Phosphorite contains a mixture of calcium phosphate, calcium carbonate (limestone), and apatite; the mineral apatite contains approximately 3 to 7% fluoride overall and is considered the primary source of the fluoride used in water treatment. The association of water fluoridation additives and the production of phosphate fertilizer have led to safety concerns by opponents of the intervention. The majority of these concerns center on potential impurities entering the drinking water supply as a result of the water fluoridation; specifically lead, arsenic, and radionucleotides.

Regulatory processes are in place to protect community water supplies that either restricts and/or prevents the introduction of impurities from the fluoridation of drinking water. The U.S.
Environmental Protection Agency (US EPA) is responsible for the regulation of drinking water and to assure its safety in accordance with the Safe Drinking Water Act (SDWA). The SDWA requires that all additives used in water treatment plants, including fluoride additives, must meet strict regulatory standards in regards to their production, maintenance, and application. Each additive is subject to a system of standards, testing, and certification by the American Water Works Association (AWWA) and the National Sanitation Foundation/ American Standards Institute (NSF/ ANSI). Testing by the NSF for water quality has demonstrated that the vast majority of fluoride additive samples do not have detectable levels of arsenic derived from the addition of these compounds; water samples that do test positive are much lower than the EPA allowable levels. Other impurities, including lead and radionucleotides, are typically reported at levels lower than the detected arsenic levels. Aside from the testing of impurities, the recommended optimum fluoride concentration is 0.7 ppm; these levels are monitored to ensure appropriate concentrations are maintained in communities that fluoridate drinking water supplies.

The water fluoridation program for the City of Madison currently utilizes hydrofluorosilicic acid as its primary source for the fluoridation of community drinking water supplies. The compound is obtained from Hawkins Chemical, Inc. via an annual renewable contract. In addition to the federal requirements to ensure water quality, the City of Madison Water Utility has also designed and initiated additional safe guards to maintain safe water supplies. Standard operating procedures (SOPs) were designed in cooperation with Public Health Madison and Dane County to govern the operation of water fluoridation, routine maintenance of all equipment associated with the fluoridation process, and the daily monitoring of the water fluoride levels to ensure optimal recommended levels of fluoridation. Impurities, including potential impurities introduced by water fluoridation are also monitored in order to ensure that water quality standards are in accordance with regulatory policies; samples are derived from water entering the distribution center, which occurs after fluoridation to ensure the accurate reporting of water quality.

SUMMARY AND RECOMMENDATIONS

The occurrence of dental caries has been substantially reduced in the United States in recent decades, predominately through the widespread use of fluoride. Unfortunately, disparities among low income and minority populations are still quite prevalent. This trend has also been reported in Wisconsin including Dane County; especially among populations of color. For example, between September 2014 and June of 2015, the Madison Metropolitan School District (MMSD) reported that 47% of students reporting urgent dental needs were African American children. In 2013, the rates for patients visiting hospital emergency departments in Dane County for dental pain were also higher for African Americans than for Whites, Hispanics, or other racial groups; similar findings were reported in 2015 providing further evidence of the persistence of oral health disparities. These inequities underline the need for continued intervention efforts to address this inequity; water fluoridation is one of these tools.

To reach children and other at-risk populations for dental caries, water fluoridation is still the most efficient method of delivering safe and effective levels of fluoride. Therefore, Public
Health Madison and Dane County supports and recommends water fluoridation using the optimum fluoride concentration of 0.7 ppm as recommended by the United States Department of Health and Human Services\textsuperscript{3,15,16}. However, it should be recognized that drinking water fluoridation is a complex process that must be well monitored and controlled.

Careful review of the scientific literature and consultation with local and national experts has identified no evidence for adverse health impacts associated with water fluoridation at recommended levels. This fact and the continued high prevalence of dental caries and associated pain, expense and potentially serious medical consequences make the continuation and expansion of well controlled drinking water fluoridation a public health necessity in Dane County.

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REFERENCES


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