Caution needed in altering the ‘optimum’ fluoride concentration in drinking water


Abstract – The US Public Health Service has finalized its recommendation relating to community water fluoridation (Federal Panel on Community Water Fluoridation, US Department of Health and Human Services, 2015). It recommends an optimal concentration of 0.7 mg/l F based on their argument that this concentration provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. The rationale for this recommendation can be questioned, particularly given the contrasting etiologies and impact on the community. Uncertainty surrounds the key evidence considered by the panel. This study argues that the panel should have exercised more caution and called for further research before reducing the ‘optimal’ concentration of fluoride in water supplies. Up-to-date data on caries and fluorosis trend by age group or birth cohort, analyses on attributable risk for fluorosis, data on individual and population impact of caries and fluorosis, water intake over an extended period across the seasons, and the curvilinear relationship of fluoride concentration in water supplies and caries protection would have all been desirable to inform the panel, given the foreshadowing of the recommendation in late 2011. Further, a wider range of policy directions to achieve the best balance of protection from dental caries while limiting the risk of dental fluorosis are available from the international literature. Assessment of these should have been more evident. There is a public health policy responsibility to monitor water fluoridation programs so as to achieve a near maximum reduction in dental caries without unacceptable levels of dental fluorosis. However, recommendations to alter existing policy need to be cognizant of the balancing of risk and protective exposures across the entire population and potentially all ages and to be based on recent data that are purposefully collected, critically analyzed and carefully interpreted.

Key words: caries; dental health; fluoride; fluorosis; public health policy; water fluoridation

A. John Spencer, Australian Research Centre for Population Oral Health, The University of Adelaide
Adelaide, SA, Australia
Tel.: +61 8 8313 5029
Fax: +61 8 8313 3070
e-mail: john.spencer@adelaide.edu.au
Submitted 30 September 2015 accepted 9 November 2015

The Federal Panel on Community Water Fluoridation of the US Department of Health and Human Services (US HHS) has recommended an ‘optimum’ concentration of 0.7 mg fluoride per liter (mg F/l) in water supplies (1). It made this recommendation on the basis of that concentration providing the best balance of protection from dental caries while limiting the risk of dental fluorosis. The recommendation changes the previous US Public Health Service (US PHS) advice that fluoride concentrations should range between 0.7 and 1.2 mg F/l based on the outdoor air temperature of geographic areas.

The notice for the draft of the recommendation issued in 2011 (2) has been the subject of public consultation for a period of 4 years. A huge number of submissions were received and have no doubt occupied the time and energy of the panel. However, the final recommendation indicates that the vast majority of submissions questioned water fluoridation per se on general health grounds. These have been described in the overview of
public comments (1). What seems apparent is that either a limited number of submissions raised doubts about the rationale and/or evidence put forward to support the new ‘optimal’ concentration recommended or those doubts were not considered well founded.

It is our contention that the rationale for this action can be questioned and that considerable uncertainty surrounds the key evidence considered by the panel. The panel should have exercised more caution and called for more purposeful research before reducing the ‘optimal’ concentration of fluoride in water supplies. While the panel calls for monitoring of the implementation of the recommendation, this may well be too little too late in terms of ensuring the best balance of protection from dental caries while limiting the risk of dental fluorosis in the USA. Further, water fluoridation in other countries and balance in the protection from caries while limiting the risk of dental fluorosis will possibly be unnecessarily challenged as a result of the new ‘optimal’ fluoride concentration in the USA.

Balancing protection from dental caries while limiting the risk of dental fluorosis

Contrasting etiologies
Any intervention aimed at obtaining the best balance between caries and fluorosis should start with their contrasting etiology. Dental fluorosis shows a ‘critical period’ etiology. Whether one accepts the wide critical period put forward in support of the panel’s recommendation (birth to age 8 years) or a narrower critical period of say 18–30 months of age (3) makes little difference. It is widely accepted that dental fluorosis has a critical period in early childhood for its etiology.

This is in contrast to an accumulation etiology which better describes the etiology of dental caries—one of an ongoing tension between demineralization and remineralization of teeth from the crib to the grave (4). This starts with primary dentition caries in the preschool years, moves on to caries in both dentitions in the mixed dentition period in early school years, then caries in the permanent dentition of adolescents at high school, young adults at college or entering work and right on through adulthood. While the attack rate varies markedly among adults, the rate seems reasonably linear with age (5). Later in adulthood, caries of the exposed root surfaces of retained teeth becomes an added burden.

The fluoride intake of importance to dental fluorosis occurs across the early childhood years while the fluoride intake of importance to dental caries occurs across the whole life course. Developing policy to influence those intakes needs to take account of this fundamental difference. Actions to reduce fluorosis should be targeted at fluoride intakes that affect children in the early childhood years, while maintaining fluoride intake or exposure across life for the prevention of dental caries.

Impacts on the individual and society
Dental caries and dental fluorosis have markedly different impacts on both the individual and society. Caries is a disease with well-established sequela ranging from a noncavitated surface lesion to cavitation of the enamel and infection of deeper tissues, resulting in often considerable pain and discomfort. A caries diagnosis precedes the bulk of restorative or exodontic treatment provided either for repair or replacement of damaged teeth. Given its prevalence across the whole lifetime, it dominates estimates of the impact of oral diseases and cost analyses (6).

Dental fluorosis is a condition. Its presentation varies markedly in severity from barely discernable opacities predominantly at the incisal or cusp tips to whole surface opacities, with rare loss of enamel and/or pitting, at least with fluoride exposure at current levels in the USA and comparable countries. Individual reaction to any esthetic impact also varies. Dental researchers initially dismissed most low severity fluorosis as not readily discernable to the public and therefore of little individual or public health impact (7). However, as the prevalence of fluorosis increased in the 1970s and 1980s, its presence was much more widely noticed by children and their parents, and not infrequently accompanied by request for treatment (8). Research in the 2000s has documented that while the presence of fluorotic opacities is noted, reaction to low severity changes are muted or even positive in terms of self-rated oral health (9). This may coincide with the emergence of community expectations about ‘white’ teeth. Low severity dental fluorosis is rated as representing better oral health than no fluorosis. Where in the continuum of the severity of fluorosis its esthetic impact becomes a negative that is unclear, but it seems far closer to severe than mild. Given severe fluorosis is rare in the USA and comparable countries, its
impact on communities and costs of treatment are likely to be low. A further issue is the general lack of understanding of the natural history of dental fluorosis. Most research on fluorosis occurs among children in the mixed dentition or early permanent dentition stage. Rarely is its natural history followed. There are competing possibilities as to how the opacities of fluorosis might either become more or less noticeable with aging. Recent research has shown that approximately two-thirds of adolescents/young adults present with less severely rated fluorosis after an interval of 5–6 years. Only a few individuals present with more severely rated fluorosis; some of which could be random error in diagnosis and ratings by examiners (10). This introduces a further complication in weighting the impact of the prevalence and severity of the condition. Therefore, the calculus of a trade-off (11) to achieve the best balance of protection from dental caries while limiting the risk of dental fluorosis is no straightforward matter. In the absence of sufficient relevant data, caution should be exercised in under-rating the impact of caries and over-rating the impact of dental fluorosis.

Key research findings presented in support of the recommendation

Water consumption and outside air temperature

The relationship between water intake and outside (or ambient) air temperature was established many decades ago. Galagan and Vermillion (12) looked at the variation in water consumption of 0- to 10-year-olds measured over a 5-day period at different seasons across two different temperature zones in California. The relationship between water consumption and mean maximum daily temperature which was subsequently proposed was as follows:

\[
\text{Water intake per body weight (oz/lb)} = -0.038 + 0.0062 \times \text{Mean maximum daily temperature.}
\]

Using this equation with an ‘optimum’ fluoride concentration of 1 mg F/l (13) for a temperate climate like Chicago with a mean maximum daily temperature of 61.6° F led to an adjustment formula for fluoride concentration levels (Adjusted F) for different climates of:

\[
\text{Adjusted F ‘optimum’ fluoride concentration } = 0.34 / (\text{-0.038 + 0.0062 \times Mean maximum daily temperature (degrees Fahrenheit)})
\]

There have been several analyses of the relationship of water intake and temperature as that of Galagan and Vermillion (12). These have included Ershow and Cantor who used the 1977–78 Nationwide Food Consumption Survey data to show that water intake was slightly greater in summer (14). There were also regional differences that were larger than the seasonal pattern. Heller et al. (15) used the 1994–96 Continuing Survey of Food Intakes by Individuals (CSFII). They observed that while Galagan and Vermillion found a 60% increase in water intake between the coldest and warmest conditions, the CSFII data showed only a 20% difference between the winter and summer months in certain regions of the US. Sohn et al. (16) used the National Health and Nutrition Estimates Survey (NHANES) III (1988–94) data to examine the relation of water intake and mean maximum daily temperature. No significant association was found between water intake and mean maximum daily temperature. While the association was not significant, water intake was 11.6% higher at the top end of the temperature range compared to the lower end. Beltran-Aguilar et al. (17) continued the use of NHANES data, analyzing data over 1999–2004, and again found no significant relationship between water intake and daily, monthly or yearly outside maximum temperature.

It is possible that the type of data collected and analytic approach used in many of these studies may favor a null finding. NHANES has used a 24-h diet recall. While this approach has been verified, such a short observation period increases the individual variation in water intake. The original work of Galagan and Vermillion used a 5-day observation period repeated across the seasons. It would be informative if the water intake data for 24-h diet recall could be compared with that on 5 days from a diet diary repeated at several times of a year. A further possible concern with most of this cited research is the focus on an individual-level analysis using linear regression techniques. This approach tests for an association between individual water intake and outside temperature allocated to the individual through their residence in some defined small area. Hence, the analysis seeks an association within a population. In such circumstances, the finding quoted by the panel that temperature explained <1% of variation in plain water intake is
not unexpected, but it should not have been regarded as sufficient to support one target fluoride concentration across the USA. The analytic focus might better be across populations and temperature zones measured for intake at multiple times over a year long period. After all, fluoride concentration for a treated water supply is set for a ‘catchment’ area and maintained at that level all year round.

The empirical findings do support a plausible hypothesis that a combination of technological changes controlling the microclimate and behavioral changes in terms of outdoor activities has reduced the systematic variation in water intake by outside air temperature. This would support a truncation in the range of the ‘optimum’ concentration toward the mean. However, it might be considered that the controlled microclimate has unevenly reduced the extreme differences in temperature. This would imply that the truncation might not remain centered on the ‘optimum’ set at 1.0 mg/l for a temperature for Chicago of 61.6° F. A further complication arises from trends in water intake over time. A decreasing proportion of water intake is contributed by tap water. There has been a substantial increase in soda (soft) drinks and bottled water consumption. The manufacturing of soda (soft) drinks has moved to use of distilled water reducing the potential fluoride exposure from fluoridated water in the area of production, and the fluoride content of bottled waters, while varied, is more frequently low. A reduction in tap water intake would justify an increase in the fluoride concentration regarded as ‘optimal’. This introduces added uncertainty to how to respond to any substantiated change in the relationship between water intake and outside air temperature.

Reducing the prevalence of dental fluorosis

The panel has rationalized the elimination of the range and lowering of the ‘optimal’ level on the grounds that it would reduce the prevalence of dental fluorosis without a reduction in the protection for caries.

There is widespread evidence of an increase in the prevalence of ANY fluorosis in many countries across the 1980s and 1990s. This coincided with an increased number of fluoride vehicles available for both home use and for professional application. Initial attention in most countries was on fluoride supplements, drops or tablets (18). Many countries provided more and more conservative advice on regimens for supplements use. Guidelines on the use of other fluorides, especially fluoridated toothpaste by infants and young children, emerged across the late 1990s and 2000s (19). Only in a limited number of countries was the fluoride concentration in water supplies the focus on policy to reduce the prevalence of dental fluorosis (3).

Ideally policy on what fluoride vehicle to target for reducing fluorosis should be based on the knowledge of the pattern of use of each vehicle, its strength of association with the incidence of dental fluorosis, and calculations of the attributable risk and population attributable risk from multivariable analyses. Such research seems quite limited, but is available for some situations. For instance, Do and Spencer have published on the population attributable risk of dental fluorosis in South Australian children 8–13 years old in 2002–03 (11). A greater rate of excess cases per 1000 children was attributed to tooth brushing and toothpaste factors: using a standard 1000 ppm fluoride toothpaste, swallowing slurry, and eating or licking toothpaste (11). Further, there is research within the USA that comments on these considerations (20). In a nonfluoridated area, 65% and 34% of fluorosis cases were attributed to use of fluoride supplements and tooth brushing practice, respectively. Among children who grew up in fluoridated areas, 68% of fluorosis cases were attributed to the use of a larger than a pea-size amount of toothpaste per brushing during the first year of life.

A common thread in the population level etiology of dental fluorosis is the ingestion of fluoride as a result of tooth brushing with fluoridated toothpaste. Such ingestion can be overt as in the licking or eating of toothpaste, or covert as with the swallowing of toothpaste foam during brushing or during the rinsing process. Reflex swallowing may play a greater role in younger preschool children.

As fluoride ingestion associated with toothpaste is attributed with approximately two-thirds of cases of fluorosis, it is not surprising that many countries have either introduced and promulgated guidelines for the practice of tooth brushing to limit fluoride ingestion by young children (parental supervision of tooth brushing, age of commencement of brushing without toothpaste, with toothpaste, size of brush head, amount of toothpaste applied to tooth brush head, spitting out but not rinsing) and/or introduced lower concentration fluoridated toothpaste for use by children up to 6 years old (500–550 ppm F) (21). There is an increasing body of research around the success of such approaches to reducing the incidence of
dental fluorosis. For instance, Riordan (19) as well as Spencer and Do (22) has reported on the action taken in Australia post-1993 to reduce the risk of dental fluorosis associated with children’s fluoride supplements, use of fluoridated toothpaste, and also fluoride in infant formula powder. The dental community ceased its support for fluoride tablets as their use was associated with fluorosis, but compliance seemed insufficient to provide a benefit for the prevention of caries. Low-fluoride children’s toothpaste was introduced and better guidance given to parents on age of commencement of use, amount to use, spitting out, and not swallowing toothpaste foam. Elimination of fluoride in infant formula powder was a move that ‘industry’ took on board. These actions to reduce the risk of fluorosis led to a remarkable reduction in the prevalence and severity of dental fluorosis. For instance, the prevalence of any fluorosis in fluoridated Adelaide decreased from 49% to 30%. Likewise, the prevalence of fluorosis halved in nonfluoridated areas from 30% to 15%. The decrease was similar in both fluoridated and nonfluoridated areas. These outcomes point to a crucial issue in choice of fluoride vehicle to target to reduce fluorosis. Only if the vehicle targeted is a risk factor across both fluoridated and nonfluoridated areas will substantial reductions in the prevalence of fluorosis occur across the whole population.

One complication with the package of approaches pursued by Australia to reduce fluoride intake associated with tooth brushing and fluoridated toothpaste is disentangling which element of the package contributes and how much to any subsequent change in dental fluorosis. One interpretation is that various elements might obviate the need for others in the package. Recent Norwegian research has reported on the adoption of guidelines for tooth brushing with a pea-sized amount of toothpaste alone being associated with no cases of mild-to-moderate dental fluorosis (23). This supports altered toothpaste use alone being sufficient to bring about a reduction in fluorosis. However, such behavioral change is not easily achieved across the population of young children. In such a situation, the use of low-fluoride toothpaste up to the age of 6 years provides a level of insurance in reducing the prevalence of dental fluorosis.

The panel’s failure to consider guidelines for the use of fluoridated toothpaste or the introduction of low-fluoride toothpaste for children might reflect the widely held view that fluoridated toothpaste is the common element in caries reductions over time across many countries. However, this commonality alone is not sufficient justification for the use of toothpaste not to receive greater attention. It is recognized that countries differ in the regulatory environment that surrounds toothpastes as a therapeutic good. There are also questions about equivalency in efficacy in the prevention of caries with low-fluoride toothpastes that give rise for caution, but evidence in this area is limited and not conclusive (24).

Whelton and Parnell have documented the range of tooth brushing and toothpaste measures promoted to reduce dental fluorosis in some ten countries (21). There are many common directions in the measures pursued, although the specifics tend to vary. It is surprising that there is no discussion of these by the panel. Instead, the panel seems to have moved from the questioning of the recommended range of optimal fluoride levels in a water supply to the additional step of reducing the optimal fluoride concentration to reduce fluorosis. The initial draft recommendation rationalized that the ‘optimal’ fluoride concentration was the midpoint of the range, 0.9 mg F/l, reduced by 0.1 mg/l to reduce fluorosis, and a further 0.1 mg/l as a precautionary step because of uncertainty. This reduction in ‘optimal’ was accepted on the basis that protection against caries would be maintained even though the optimal concentration was lowered.

Maintaining the protection for dental caries

There is a history to the curvilinear relationship between fluoride concentration and protection against caries in the USA and in other countries. The relationship was initially examined through Dean and others’ studies of two groups of cities in the USA in the 1930s (25,26). Collectively, the cities constituted the 21 cities study (27). This research was replicated in a number of countries, for instance, Sweden, Denmark, and England (28). While the curvilinear relationship was similar across different countries, the level of caries experienced varied as a result of context-specific factors indicating the need for their control within analyses. The relationship has continued to be described in the USA by Eklund and Striffler in 1980 (29) and the US Environment Protection Agency (US EPA) in 2010 (30). The US EPA included data from studies by Driscoll et al. (31,32) and Jackson et al. (33). The US EPA report describes the dose–response relationship between fluoride concentration and caries experience measured as either DMFS or
DMFT as a decrease in caries experience through to about 3 mg/l, but then a levelling off, or even subsequent increase. The interpretation of this later research does not seem to have influenced the panel’s interpretation of fluoride concentration and protection against caries.

In justifying the maintenance of the protection against caries, despite the lowering of the optimal fluoride concentration, the panel has placed an emphasis on the findings of Heller et al. (34) using data from the 1986/1987 National Survey of Oral Health of US Schoolchildren (4–22 years old) in a secondary analysis. Analysis was restricted to those children for whom there was a single continuous residence. This reduced the number of children available in the analysis of caries from 40,693 to 18,755. Exposure to fluoride in water supplies was categorized into four categories <0.3, 0.3–0 < 0.7, 0.7–1.2, >1.2 mg F/l. The initial analysis showed a dose–response for primary decayed and filled surfaces (dfs) among 5- to 10-year-old and DMFS among 5- to 17-year-old children across the four categories at least up to >1.2 mg F/l. There was a scarcity of data for the fluoride concentration category >1.2 mg F/l.

Heller et al. (34) went on to focus on the dose–response relationship between 0.0 and 1.6 mg F/l. Regression models for dfs and for DMFS showed a significant negative regression coefficient for fluoride (mg F/l) in the presence of several potential modifiers such as fluoride drops or tablets, school-based fluoride rinses or professionally applied fluoride treatments. However, it should be noted that there was no statistical adjustment for variations in socioeconomic contextual characteristics of sites or of the socioeconomic status of children included in the data. A graph of the dose–response relationship across the fluoride concentration range of 0.0–1.6 mg F/l indicated a relationship, but with some fluctuation and only a little additional decline in caries between 0.7 and 1.2 mg F/l, the range previously recommended for US water supplies. No specific analysis of the relationship within the 0.7–1.2 mg F/l range is presented.

The 1986–1987 National Survey of Oral Health of US Schoolchildren was a population sample drawn from the entire USA, including adjusted fluoridation areas and areas with naturally varying fluoride levels in the local water supply. Some 50.4% of children resided in areas with 0.7–1.2 mg/l fluoride in the water supply, the previously recommended range for adjusted water fluoridation programs. Most will have had the ‘optimum’ fluoride concentration of 1.0 mg/l adjusted to suit their mean maximum daily temperature according to the Galagan and Vermillion formula. In each of these situations, the aim was to produce the same prevention of dental caries given different water consumption associated with mean maximum daily temperature.

Ershow and Cantor described regional differences in water intake at the time that the 1986–1987 National Survey of Oral Health of US Schoolchildren was undertaken (14). To the extent that the Galagan and Vermillion formula had relevance to the time immediately preceding the 1986–1987 National Survey of Oral Health of US Schoolchildren, it is not surprising that little additional decrease in caries was noted across the 0.7 to 1.2 mg/l range for adjusted water fluoridation programs.

What is surprising is that no more recent data were analyzed by the panel to test the relationship between fluoride concentration of water supplies and caries in US children. However, if the 1986–1987 National Survey of Oral Health of US Schoolchildren data were the best data to be used in the 2010, further analyses excluding those sites with adjusted community water fluoridation should have been conducted.

**Selectivity from the wider research literature**

There is a strong reliance by the panel on two studies to help set the context and then substantiate the proposition that fluoride concentration can be reduced to 0.7 mg/l without a consequent increase in dental caries. The first is the US EPA estimates of toothpaste swallowed inadvertently accounting for about 21% of total fluoride intake in very young children (1–3 years old). However, this is based on brushing only once a day. It also seems low in comparison with other fluoride intake research. Cresssey et al. (35) in New Zealand estimate that for 1- to 3-year-old children, toothpaste (1000 ppm F) contributes 34% of total fluoride intake in a fluoridated area and 45% in a nonfluoridated area. Zohoori et al. (36) estimated the fluoride intake from toothpaste to range from 24% to 78% of total daily fluoride intake for children 1–12 months old.

Yet most intake research shows a peak intake during the ages 1–3 years old. The interpretation of the US EPA data is part of the rationale for the panel to focus on fluoride intake from fluoridated water supplies.

The second study used selectively is the lowering of the fluoride concentration in water supplies in Hong Kong. The panel reports that a lowering of the fluoride concentration from 0.82 to 0.64 mg/l
was associated with the detectable reduction in fluorosis without a concurrent increase in caries. However, this is misleading in its implied strength of the association with the prevalence of fluorosis. Wong et al. (37) report that between 1961 and 1967, Hong Kong’s water supply was adjusted seasonally with summer levels of 0.7 mg F/l and winter 0.9 mg F/l. In 1967 through to 1978, the fluoride concentration was increased to 1.0 mg F/l. In 1978, it was decreased to 0.7 mg F/l and decreased again in 1988 to 0.5 mg F/l. The panel describes this as a small decrease of about 0.2 mg/l. It is clear that the magnitude of the decrease across the range of changes is much more than small. The panel acknowledged that while no concurrent increase in caries in Hong Kong was noted, one cannot answer the question on what the caries levels would have been if the fluoride concentration had remained at one of the higher levels.

**Monitoring of the implementation of the new recommendation**

The panel has called for enhanced surveillance of caries and fluorosis. It would have been all the more prudent to set about further research before finalizing the recommendation rather than seeking to validate it post hoc, in both the case for caries and fluorosis, many years later.

Somewhat ironically, the extension of NHANES data collections in 2013–2014 to collect home water samples and residential history, and the use of other fluoride modalities were noted. This would be welcomed data. However, unless such data collections are purposefully planned and analyzed, it will not be possible to attribute change in either caries or fluorosis to any particular change in fluoride exposure in US communities.

Improved up-to-date data on caries and fluorosis trend by age group or birth cohort, analyses on attributable risk for fluorosis, data on individual and population impact of caries and fluorosis, water intake over an extended period across the seasons in different climate zones, and the curvilinear relationship of fluoride concentration in naturally fluoridated water supplies and caries protection would all be desirable to support the direction the panel has proceeded along.

**Conclusion**

There is a public health policy responsibility to monitor fluoride programs so as to achieve a near maximum reduction in dental caries without unacceptable levels of dental fluorosis. The panel’s recommendation seems precautionary in approach but premature in terms of its rationale and use and interpretation of sometimes dated data. Recommendations to alter existing policy need to be cognizant of the balancing of risk and protective exposures across the entire population and potentially all ages and to be based on recent data that are purposefully collected, critically analyzed and carefully interpreted.

**References**


13. McClure FJ. Ingestion of fluoride and dental caries: quantitative relations based on food and water


