Outcome of fluoride consensus workshop 2012

to review Fluoride Guidelines from 2005

Australia's fluoride guidelines were published in the Australian Dental Journal in 2006 following a consensus workshop of Australian and overseas experts (1). A second workshop was held in Adelaide in August 2012 to review those guidelines.

Two developments prompted an examination of the rationale for these proposals in light of both the international and Australian evidence and subsequently a re-examination of the Australian fluoride guidelines (1). The first was a proposal to change the recommended levels of fluoride in water in the United States of America and the second was a Cochrane review on the effectiveness of fluoride toothpaste.

The appropriate level of fluoride in water

In 2011 the United States Department of Health and Human Services (USHHS) proposed that the recommended level of 0.7 to 1.2 milligrams of fluoride per litre (ppm) be replaced by 0.7 milligrams of fluoride. This recommendation was developed for community consultation and to date no final decisions have been made. This announcement was made in conjunction with the United States Environment Protection Authority (US EPA) review into the maximum amount of fluoride allowed in drinking water. In combination these reviews are 'important steps to ensure that standards and guidelines on fluoride in drinking water continue to provide the maximum protection to the American people to support good dental health, especially in children' (2) This is being proposed on the basis of the following considerations:

- Americans now have access to more sources of fluoride than at the time when the optimal range was developed.
- An increase in the levels of dental fluorosis
- Recent social and environmental changes suggest that an increase in ambient temperature does not result in an increased intake of tap water

While these reviews are related, the US EPA review has limited relevance to Australia because the Australian maximum value of 1.5mg/L is already lower than the US maximum level of 4.0mg/L (or even the new proposed maximum level of 2.0mg/L? (US EPA 2006)). However, the USHHS proposal questions the background hypothesis of optimal fluoride levels which is applied in the Australian context. The following therefore will focus on the USHHS 'optimal level' proposal.

In Australia, the framework applied to the provision of safe drinking water is outlined in the Australian Drinking Water Guidelines (ADWG). With respect to fluoride it provides a health related guideline value "which is the concentration or measure of a water quality characteristic that, based on present knowledge, does not result in any significant risk to the health of the consumer over a lifetime of consumption" (3).

The health related value for fluoride is set at 1.5mg/L. This level recognises that levels between 1.5 and 2.0mg/L increase the risk of 'objectionable' dental fluorosis. Therefore the guideline value is set at the lower level to protect children from this risk. The ADWG also recognises there is some protective effect against dental caries from a level of 0.5mg/L while a level of 1mg/L in temperate

climates would provide the optimal benefit. It is important to note the ADWG maximum value of 1.5 mg/L is higher than that recommended for artificial fluoridation of water supplies, which in Australia is implemented in the 0.6–1.1mg/L range.

In the US, the addition of fluoride to public drinking water supplies is to achieve a level of fluoride in water between 0.7 to 1.2 mg/L which is referred to as the optimal range. In Australia, the 2006 fluoride guidelines from the first consensus workshop state the range for Australia should be 0.6 to 1.1mg/L (1), however in practice Australian states and territories have applied values between 0.5 to 1.0 mg/L.

1. Greater significance of toothpastes in the development of dental fluorosis

While the USHHS has proposed a revision of the fluoride level in water fluoridation programs, as a means of addressing a reported increase in dental fluorosis, it is important to note two things. Firstly, studies reveal development of dental fluorosis is more closely related to fluoride toothpaste and tooth brushing practices than to water fluoridation (4) and secondly, the US does not have any low fluoride children's toothpastes (5). A recent Cochrane review suggested fluoridated toothpaste as a significant risk factor for fluorosis (6).

Therefore it is important to address toothpaste and tooth brushing issues in order to tackle a reported increase in dental fluorosis. Australia successfully did this with the introduction of low-fluoride children's toothpastes in the early 1990s (7). In this way, we addressed the higher than expected prevalence of dental fluorosis without reducing the benefits of water fluoridation programs.

The US report does not consider either fluoride concentration in toothpaste or tooth brushing issues.

2. Dental fluorosis prevalence

The US proposal states that fluoride in water fluoridation programs should be revised due to increasing prevalence of dental fluorosis in the US (8). Australian dental health researchers have questioned the studies used to justify this claim (9).

Furthermore, in the US there are areas where drinking water contains naturally occurring high levels of fluoride acceptable to levels of 4mg/L which could be a contributing factor to the perceived increase in dental fluorosis rates. In Australia where areas have high levels of naturally occurring fluoride, this must be held at or below 1.5mg/L. However, most Australian water supplies have naturally low levels that do not confer dental health benefits. In those locations that apply fluoride at a level of 1.0mg/L irrespective of climate variations, the rates of dental fluorosis are not considered to be a public health issue in Australia. Studies in Western Australia and South Australia found a marked decrease in fluorosis prevalence between the early 1990s and 2000s (4; 7). There is strong anecdotal evidence that the prevalence and severity of dental fluorosis is generally not an issue associated with tap water at or around 1.0mg/L to children or their parents' assessment of their self-rated oral health. While there have been studies (10), more dental fluorosis data would be useful to confirm this.

Furthermore, it is recognised that dental fluorosis in its very mild, mild or moderate form, is not considered to be a toxic effect and numerous studies have shown that teeth that present such signs of dental fluorosis are more cavity-resistant (11).

3. Dental decay experience

Australian dental health researchers have also questioned the omission of recent studies which have identified an increase in dental decay experience in young children in the US (9). Further to this is emerging evidence from Australia of an increase in dental decay rates (9). A regular national child

oral health survey for both dental caries and dental fluorosis would be useful to confirm these trends. This would assist with the future direction of Australia wide water fluoridation policy.

It is also important to note that the risk of developing dental caries is life-long; people can develop dental decay at any age while the risk of developing dental fluorosis is in the early years of life (9). In Australia public health departments recognise the need to ensure people have life-long exposure to optimal fluoride levels in water fluoridation programs while at the same time working to minimise the prevalence of fluorosis initiated in childhood. The ability to alter fluoride levels in both toothpastes and water are ways to achieve this.

4. Air temperature and fluid consumption

Traditionally, fluoride levels in water fluoridation programs were set according to the average maximum daily air temperature (12). The fluoride level in water fluoridation programs in cooler climates is higher than that in warmer climates as people in cooler climates consume fewer fluids than people in warmer climates (12). In the US the hottest climates had fluoride in water fluoridation programs set at 0.7mg/L; the coldest climates had fluoride set at 1.2mg/L.

We don't have (or we haven't seen) any evidence that fluid consumption, or more importantly tap water consumption, varies somewhat by ambient temperature. Further we don't have any evidence that at a population level there is more fluorosis in lower temperature/higher [F] areas than in higher temperature/lower [F] areas (which one would expect if micro-climates were bringing fluid consumption back to some mid-range). It does not seem that the US HHS put forward any evidence linking temperature/ [F] to varying levels of fluorosis.

In Australia too, a number of states apply a range of fluoride values based on climate. This was undertaken to balance protection from dental caries while minimising dental fluorosis. This practice was further confirmed as recently as 2004 where the WHO Guidelines for Drinking-water Quality 2004 state that "*In warmer areas, because of the greater amounts of water consumed, dental fluorosis can occur at lower concentrations in the drinking-water"* (13).

Should we be cautious and simply reduce the fluoride concentration [F]?[1]

This is in effect what the US HHS has done. It is quite reasonable to want to reduce risk, but the target should be the fluoride vehicle with the higher population attributable risk (and conversely the lowest population preventive benefit) at critical ages. The benefit should not be reduced for all ages. The US HHS view of benefit not being reduced rests on the flat dose-response to [F] between 0.7 and 1.2mg/L by Heller et al. for school-aged children (14). That is a result that is contrary to both the logic of dose-response, and a body of empirical evidence (admittedly within extended ranges of [F]). Further there is no information that a similar flat dose-response result would be obtained among young adults or middle-aged adults.

The release of this proposal has however generated discussion amongst the Australian dental, research, public health policy, and water sectors. To assist with responses to questions about the US proposal the Victorian Department of Health, in collaboration with Australian Research Centre for Population Oral Health (ARCPOH), undertook an analysis of the proposal to consider its relevance to Australia. In order to consider the US proposal against the Australian situation a number of differences have been identified.

[1]Acknowledgement for the section: Helen Walsh, Department of Health, Victoria

While the US proposal assumes impacts from societal changes that are also relevant to Australia, the proposal does not consider other factors such as modern dietary options. It is recognised that the increased use of bottled non fluoridated water coupled with sugar dense drinks are increasing in Australia and the US and is being reflected in rising rates of dental caries (15, 16). A comparison of ingestion by various sources indicates that community water comprises 75% of the total water ingested by individuals in the U.S. population, followed by bottled water which constitutes 13 % of total water ingested while 12% is attributable to water from other sources (17). For Australia to assess the merit of a similar approach on this basis requires further research into dietary changes, both in terms of amount of fluid intake (which also considers environmental influences) and types of fluid. This research would also be useful to validate the original link between climate and fluid consumption.

While the lower fluoride levels are in place as a mechanism for minimising dental fluorosis, this must be balanced against dental caries rates. In Australia, the application of an optimal value of 1.0mg/L with the ability to apply lower rates in warmer climates has not resulted in any significant dental fluorosis trends to suggest that this should be changed. Likewise we also suspect that lower fluoride levels in warmer climates is not linked to the overall trending rise in the dental caries experience of children. However, further research would be useful to confirm this. Furthermore, Australia's trending evidence of rising caries rates would suggest a cautious approach if there was a future consideration similar to the US proposal to adopt an overall lower value.

Conclusion regarding water fluoridation

This paper identifies a number of instances where Australian researchers question the methodology used in developing the US proposal. The US proposal appears to be weighted toward reducing dental fluorosis but may do this at the expense of increasing dental caries. In Australia however the dental decay experience is of primary concern which means the current water fluoridation policy in Australia remains appropriate for Australia. This does not preclude possible future changes to water fluoridation policy in Australia however current evidence indicates that while dental fluorosis is not a public health concern, increased dental decay rates are of concern.

Toothpaste

Careful consideration of the Cochrane reviews of fluoridated toothpastes (18; 19) was undertaken. A number of problems with the evidence supporting the recommendation on the use of 'standard' toothpaste for young children were identified. The first problem was the lack of data on the primary dentition and the extrapolation of findings in the permanent dentition to the primary dentition. Secondly, there was insufficient consideration of other fluoride vehicles. Over 90% of young children in Australia live in areas with water fluoridation which is much higher coverage than for most other countries. In addition, in 2013 'low fluoride' toothpaste in Australia has 500-550 PPM fluoride, which has been found equivalent to 1000PPM toothpaste in the Cochrane review. The lower concentration fluoride toothpaste (250 ppm) reviewed by the Cochrane group is not available in Australia. In addition, there was little consideration of fluorosis associated with use of higher fluoride concentration toothpastes by very young children. Do et al (2007) (20) has shown the risk-benefit balance in relation to caries and fluorosis in Australia, with no significant increase in caries with use of low fluoride toothpaste. Fluorosis levels in Australia have halved since the introduction of a number of measures in the early 1990s, including the use of low fluoride concentration toothpastes by very young children (4; 7).

Also toothpaste manufacturers in Australia have changed the fluoride concentration some of their standard toothpastes from 1000ppm to 1450ppm in line with the new maximum level of 1500ppm approved by the Therapeutics Goods Administration, Australia.. This was considered to increase the risk of fluorosis if used by young children.

Fluoride Guidelines for Australia 2012

Unchanged recommendations as no new evidence was available to warrant amendment

1) Water fluoridation should be continued as it remains an effective, efficient, socially equitable and safe population approach to the prevention of caries in Australia
2) Water fluoridation should be extended to as many people as possible living in non-fluoridated areas of Australia, ideally supported by all levels of government.
3) The level of fluoride in the water supply should be within the range 0.6–1.1mg/L with variation within that range according to the mean maximum daily temperature.
4) From the time that teeth first erupt (about six months of age) to the age of 17 months, children's teeth should be cleaned by a responsible adult, but not with toothpaste
5) For teenagers, adults and older adults who are at elevated risk of developing caries, dental professional advice should be sought to determine if they should use toothpaste containing a higher concentration of fluoride (i.e., greater than 1000–1500ppm up to 5000 ppm of fluoride)
6) Fluoride supplements in the form of drops or tablets to be chewed and/or swallowed, should not be used
7) Children below the age of six years should not use fluoride mouth-rinse.
8) Fluoride mouth-rinse may be used by people aged six years or more who have an elevated risk of developing caries. Fluoride mouth-rinse should be used at a time of day when toothpaste is not used, and it should not be a substitute for brushing with fluoridated toothpaste. After rinsing, mouth-rinse should be spat out, not swallowed.
9) High concentration fluoride gels and foams (those containing more than 1.5mg/g fluoride ion) may be used for people aged 10 years or more who are at an elevated risk of developing caries in situations where other fluoride vehicles may be unavailable or impractical There is a need to support further studies that examine the impact of fluoride vehicles in the Australian population including: studies of the epidemiology of dental caries and dental fluorosis; investigations of the impact of both conditions on people's well-being and quality of life; risk factors for dental caries and dental fluorosis; use of fluoride vehicles in dental practice and the population; and the efficacy, effectiveness and cost effectiveness of fluoride vehicles.
10) Research is needed to develop new preventive interventions including new vehicles for fluoride delivery as well as other preventive strategies that are not based on fluoride. New interventions should be judged for their equivalency or superiority to existing preventive approaches that have documented efficacy.

Amended recommendations

Recommendations have been changed in order to clarify the guideline, or because of new evidence or a change in the environment.

11) So people can choose to consume bottled or filtered waters containing fluoride, manufacturers should be encouraged to market bottled water containing approximately 1.0mg/L fluoride and water filters that do not remove fluoride. An integral part of this guideline is that all bottled water and water filters should be *clearly* labeled to indicate the concentration of fluoride in water consumed or resulting from the use of such products.

The context in relation to bottled water has changed, with the availability of bottled water with fluoride and the concern about the very limited availability of sodium fluoride as a supplement. Since the 2005 fluoride guidelines Food Standards of Australia and New Zealand 2011 changed the code relating to bottled water and now allows between 0.6 and 1.0 milligrams of fluoride (including naturally occurring and added fluoride) per litre of bottled water.

12) *So people in non-fluoridated areas can obtain the benefits of fluoride in water it is recommended that people buy bottled water with fluoride at approximately 1mg/L for drinking.* (This replaces: So people can choose to consume fluoridated water, sodium fluoride should be marketed as a water supplement, for addition to non-fluoridated water sources, thereby achieving a fluoride concentration of approximately 1mg/L.)

13) For children aged 18 months to five years (inclusive), the teeth should be cleaned twice a day with toothpaste containing 0.5–0.55mg/g of fluoride (500–550ppm). Toothpaste should always be used under supervision of a responsible adult, a small pea-sized amount should be applied to a child-sized soft toothbrush and children should spit out, not swallow, and not rinse. *Young children should not be permitted to lick or eat toothpaste.*

14) For people aged six years or more, the teeth should be cleaned twice a day or more frequently with standard fluoride toothpaste containing 1- 1.5mg/g fluoride (1000–1500ppm). People aged six years or more should spit out, not swallow, and not rinse. *Standard toothpaste is not recommended for children under six years of age unless on the advice of a dental professional.*

15) For children who do not consume fluoridated water or who are at elevated risk of developing caries for any other reason, guidelines about toothpaste usage should be varied, as needed, based on dental professional advice. Variations could include more frequent use of fluoridated toothpaste, commencement of toothpaste use at a younger age, or earlier commencement of use of standard toothpaste containing 1mg/g fluoride (1000ppm). *This guideline may apply particularly to preschool children at high risk of caries.*

Studies on fluoride varnish including a 2013 Cochrane review (21) have confirmed the efficacy of fluoride varnish.

16) Fluoride varnish should be used for people who have elevated risk of developing caries, including children under the age of 10. *(The following was deleted: in situations where other professionally applied fluoride vehicles may be unavailable or impractical).*

Conclusion

These guidelines on the use of fluorides in Australia have been reviewed using critical reviews of the latest national and international evidence and amended accordingly. As new evidence emerges, this process will need to be repeated.

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Consensus workshop attendees

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