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The use of fluorides in Australia: guidelines

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PREFACE

In October 2005, the Australian Research Centre for Population Oral Health (ARCPOH) hosted a Workshop on the Use of Fluorides in Australia. The workshop was attended by 35 experts, university, jurisdictional and peak-body representatives from all states and territories of Australia.

ARCPOH hosted the workshop at the request of the National Advisory Committee on Oral Health (NACOH) which had considered the need for Australia to update its guidelines on the use of fluorides as part of promoting the oral health of the population in *Australia's National Oral Health Plan 2004–2013* (AHMC, 2004). One short-term national action in the *National Oral Health Plan* called for a 'consensus conference on use of discretionary sources of fluoride and other preventive agents, as a first step towards establishing an evidence-based suite of health promotion messages'. Therefore, the workshop was part of the implementation of the *National Oral Health Plan*. The two-day workshop in Adelaide, South Australia aimed:

- to update information on the nature and distribution of dental caries and fluorosis in Australia;
- to update information on the nature and distribution of use (or exposure) to fluorides in Australia;
- to consider the trade-off of the benefit of caries prevention versus the risk of dental fluorosis;
- to review the evidence of the efficacy/effectiveness of a range of individual fluorides in caries prevention and their risks for creation of dental fluorosis; and
- to develop guidelines for the use of fluorides in Australia.

Seventeen working papers were prepared by invited experts and distributed in advance of the workshop. These papers covered topics underpinned by Australian research ranging from exposure to fluorides in Australia, the effectiveness of water fluoridation, the prevalence of dental fluorosis, pre- and post-eruptive exposure to fluoride and the prevention of caries, and the relationship between fluoride exposure, fluorosis and caries. Further evidence built on systematic reviews in the literature was presented on a range of individual fluoride vehicles such as fluoride supplements, fluoridated toothpaste, fluoride gels, mouthrinses and varnish. Finally, a rationale was presented to underpin the guidelines. Guidelines had also been drafted and distributed prior to the workshop. The guidelines were extensively discussed and during the subsequent three months further comment was considered and editing completed. The resulting guidelines are presented below.

INTRODUCTION

The following guidelines have been informed by previous Australian reports plus research and scientific papers presented at the ARCPOH Workshop on the Use of Fluorides in Australia, Adelaide, 13–14 October 2005. In the few instances where scientific evidence was unavailable, a guideline reflected consensus of expert opinion.

Fluoride is the cornerstone in the prevention of dental caries. However, all fluoride vehicles need to be viewed in terms of their potential benefit (caries protection) and risk (causing dental fluorosis). Exposure to each fluoride vehicle should maximize the benefit in caries protection without causing an unacceptable prevalence of dental fluorosis. No adverse health effect is considered to arise from the use of fluoride vehicles at levels outlined in these guidelines.

Recommendations for some fluoride vehicles can be made for the population at large, while other recommendations are appropriate only for individuals or groups of individuals deemed to be at elevated risk of developing dental caries. The Centers for Disease Control and Prevention (CDC, 2001) provided broad guidelines for identifying individuals and groups with elevated risk of developing caries and proposed that the following forms of fluoride should be limited to them: fluoride mouthrinse, fluoride supplements, fluoride gel and fluoride varnish. When assessing caries risk, it is important also to consider availability of non-fluoride interventions that are efficacious in the prevention of caries including fissure sealants, polyol-based chewing gum, and antibacterial chlorhexidine varnish.

In the following guidelines, fluoride vehicles have been divided into community water fluoridation (section A), self-use fluoride products (section B), and products that are applied by dental or other health professionals (section C). Additional recommendations are presented in section D regarding monitoring and developing caries prevention strategies in the Australian population.

A. Community water fluoridation

Australia has relied on community water fluoridation as its main use of fluoride. While other forms of fluoridation exist, including salt fluoridation and milk fluoridation, the potential for widespread coverage of the Australian population that predominantly is served by public water supplies makes this approach the centrepiece of the population strategies for prevention of caries. Water fluoridation in Australia provides a universal caries-preventive benefit to individuals of all ages in communities via the public water supply.

The extent of the benefit historically has been estimated as between 50 to 60 per cent, and in some circumstances the

benefit is still of this magnitude. Studies of children and adolescents in the late 20th century revealed that the effects of water fluoridation in the permanent dentition had reduced, with the benefit ranging from 20 to 40 per cent less caries associated with lifetime exposure to fluoridation. This reduced benefit may be a result of low caries activity in the permanent teeth at these ages, compounded by difficulties in making unbiased comparisons that arise from the diffusion or halo effect. This effect results from the availability of fluoride spreading from fluoridated to non-fluoridated communities via foods and beverages manufactured in fluoridated areas. The dilution or mixing of effects of more than one fluoride vehicle also makes estimation of the independent benefit of water fluoridation methodologically difficult. Water fluoridation has also been found to benefit young adults. There is limited population evidence of a benefit existing in older age groups and none from Australia, partly reflecting the difficulties of such life-course research and methodological limitations with the measurement of dental caries in middle-aged and older adults.

Studies of the cost-benefit of water fluoridation document a very positive net saving to the community, based on a tapering of effectiveness with increasing age. Water fluoridation is also socially equitable. It provides the greatest absolute benefit to those of low socio-economic position who are at greatest risk of dental caries, with the consequence that socio-economic disparities in caries levels are less pronounced among those with exposure to fluoridated water compared with those with no such exposure. Given the strong commitment in Australia to reduce social inequalities in oral health, water fluoridation is a logical centrepiece in caries prevention.

Water fluoridation is safe. Water fluoridation at around 1mg/L in temperate climates is associated with a substantial reduction in caries experience. It is also associated with fluorosis at a very mild or mild level occurring in 22–29 per cent of children. Fewer than two per cent show more severe levels of dental fluorosis. This prevalence of fluorosis today is only marginally above that observed when water fluoridation was introduced in the 1940s in the United States.

Therefore,

(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) 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 labelled to indicate the concentration of fluoride in water consumed or resulting from the use of such products.

(5) 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.

Historically, infant formula powder was manufactured with a varying but relatively high fluoride content. When reconstituted with fluoridated water and consumed by infants, there was a potential for exposure to relatively high levels of fluoride in relation to body weight. Infant formula now has very low amounts of fluoride. While the workshop did not review information about fluoride content of infant formulas, evidence from Australian population-based studies reveal no association between consumption of infant formula and levels of dental fluorosis. Therefore,

(6) Infant formula nowadays is safe for consumption by infants when reconstituted using fluoridated or non-fluoridated water.

B. Self-use fluoride products

Fluoridated toothpaste

Fluoridated toothpaste is effective in the prevention of caries. While the use of fluoridated toothpaste is an individual dental health behaviour, the practice of tooth brushing by the overwhelming majority of Australians at least once per day and the predominance of fluoridated toothpaste in the toothpaste market both help this discretionary measure mimic a successful population strategy.

Clinical trials, most of them conducted for periods of 2–3 years, demonstrate that the absolute level of caries prevention associated with fluoridated toothpaste is lower than that of lifetime exposure to fluoridated water. However, it has been speculated that the lifetime caries preventive benefit of fluoridated toothpaste may, in fact, be closer to the lifetime benefit of community water fluoridation (CDC, 2001). Furthermore, there is evidence of an additive caries preventive effect between fluoridated water and fluoridated toothpaste, leading to a benefit among those who are exposed to both that is greater than either vehicle alone, although less than the sum of benefits.

As with other fluoride vehicles, there is a need to balance the caries preventive effect of fluoridated toothpaste with the risk of dental fluorosis. In Australia during the early 1990s, guidelines for the use of fluoridated toothpaste emerged that included age of commencement, parental supervision, using a pea-sized amount of toothpaste per brushing, spitting not swallowing and not rinsing after brushing. These guidelines were the same regardless of whether children use low fluoride concentration toothpaste (0.4–0.55mg/g of fluoride) or a standard toothpaste (1mg/g of fluoride). In the early 1990s, prior to those guidelines, the prevalence of dental fluorosis was unacceptably high. However, research approximately 10 years later has shown a halving in prevalence of fluorosis, bringing the prevalence of fluorosis to a far more acceptable level.

Wider compliance with recommended toothpaste use would further reduce the prevalence of fluorosis. In the population at large, commencement of tooth cleaning before

the first birthday is associated with reduced caries prevalence later in childhood compared with delayed tooth cleaning. Before the age of 18–24 months, the additional use of fluoridated toothpaste while cleaning teeth does not confer any further benefit in preventing caries later in childhood. In contrast, the risk of dental fluorosis is elevated among children who begin using fluoridated toothpaste before the age of 30 months. It should be noted, however, that these patterns have been observed in South Australia, where the majority of children drink fluoridated water. It is plausible that exposure to fluoridated toothpaste at younger ages may be more important in caries prevention among children in non-fluoridated areas.

Therefore,

(7) 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.

(8) For children aged 18 months to five years (inclusive), the teeth should be cleaned twice a day with toothpaste containing 0.4–0.55mg/g of fluoride. 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.

(9) For people aged six years or more, the teeth should be cleaned twice a day or more frequently with standard fluoride toothpaste containing 1mg/g fluoride. People aged six years or more should spit out, not swallow, and not rinse.

(10) 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.

(11) 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 1mg/g of fluoride).

Fluoride supplements

Fluoride supplements have long been advocated as an alternative source of fluoride in non-fluoridated areas. A 2.2mg sodium fluoride tablet provides 1mg of fluoride per day, equivalent to the consumption of 1 litre of water fluoridated with a fluoride concentration of 1mg/L. However, in contrast to the evidence on the effectiveness of water fluoridation, fluoride tablet use has been quite varied in its effectiveness. While some studies with supervised use, usually through school programmes, have shown benefits, many studies that rely more on compliance by parents and children at home have shown little benefit. The younger the children and greater the reliance on compliance, the weaker the benefit. Unfortunately, the younger the children the greater the risk of dental fluorosis. Fluoride supplement use in pre-school years is associated with a significant increase in the risk of dental fluorosis. This has led to revision of supplement guidelines over time so that age-specific daily regimens for children up to six years old have been substantially reduced. At the same time as the regimen has been reduced, others have strongly questioned whether the risk of fluorosis is outweighed by any benefit in caries protection. This has led to a number of guidelines not to use fluoride supplements.

Therefore,

(12) Fluoride supplements in the form of drops or tablets to be chewed and/or swallowed, should not be used.

Fluoride mouthrinses

A minority of mouthrinse products purchased by Australian consumers contain fluoride ion at a concentration of 200–900mg/L for daily and weekly use respectively. Some overseas research has examined daily or weekly supervised fluoride mouthrinse programmes as a strategy for particular sub-populations such as school children. However, no such programmes are being pursued in Australia. Instead, fluoride mouthrinses offer an additional fluoride vehicle for individuals with elevated risk of caries. Population data reveal that the use of fluoride mouthrinse increases among adolescents. This suggests that it may represent an appealing additional source of fluoride among adolescents deemed to be at elevated risk of developing caries. However, it would be important to ensure that any such use of mouthrinse would not merely represent a substitute for toothbrushing with fluoridated toothpaste. Children aged less than six years should not use fluoride mouthrinses because of the probability of its ingestion and risk of dental fluorosis.

Therefore,

(13) Children below the age of six years should not use fluoride mouthrinse.

(14) Fluoride mouthrinse may be used by people aged six years or more who have an elevated risk of developing caries. Fluoride mouthrinse 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, mouthrinse should be spat out, not swallowed.

C. Professionally applied fluoride products

Fluoride varnishes

Fluoride varnish contains 22.6mg/ml fluoride ion suspended in an alcohol and resin base. It is applied by dental and other health professionals directly to dried teeth where it forms a waxy film that adheres to the teeth until it is worn off by chewing or brushing. There is evidence that varnish is effective for prevention of dental caries in children, including children under the age of 10 years, where other forms of professionally applied fluoride are contra-indicated. Like all forms of professionally provided fluoride, varnish offers an alternative vehicle for caries protection for individuals deemed to be at an elevated risk and in whom other fluoride modalities are not available or suitable. Fluoride varnishes are efficacious for the prevention of caries in the deciduous dentition and permanent dentition. Their application twice a year has not been linked to an increased risk of dental

fluorosis. They may also be successfully applied by health professionals other than dentists. This broadens the opportunity for their use, where they would otherwise be impractical if they had to be applied by dentists.

Therefore,

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

Fluoride gel and foam

Fluoride gels and foams contain a high concentration of fluoride, typically up to 12.3mg/g fluoride. They are applied by dental professionals using trays that retain the material on the teeth for four minutes, during which time suction is used to evacuate the excess material that mixes with saliva. After removal of trays, patients must spit out the residual gel or foam. There is evidence of their effectiveness in children, however, they are contra-indicated for use in children under the age of 10 because large amounts can be ingested. Further, fluoride gels appear more efficacious in the permanent dentition. Like all forms of professionally provided fluoride, gels and foams offer an alternative vehicle for caries prevention for individuals deemed to be at an elevated risk and in whom other fluoride modalities are not available or suitable. Fluoride gel and foam are efficacious for the prevention of caries in the permanent dentition.

Therefore,

(16) 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.

D. Monitoring and developing caries prevention strategies in the population

There will be a continuing need to review and revise guidelines for the best strategies to prevent dental caries. Many of the preceding guidelines for fluorides represent modifications of guidelines developed little more than a decade ago. As noted above in the review of several fluoride vehicles, modifications become necessary for reasons including new evidence from clinical trials, changing patterns of behaviour that alter the nature and amount of exposure to fluoride, and emergence of new evidence about the epidemiology of caries and fluorosis. In anticipation of the need for future revisions to these guidelines, it will be important, as in the present instance, to strengthen the evidence-base about individual fluoride vehicles, dental clinical practice, population exposures, and the distribution of oral conditions, particularly the prevalence of caries and fluorosis and the psychosocial impact of both conditions.

Concurrently, it is important to identify and evaluate new preventive strategies, including caries-preventive agents that are not based on fluoride. Dentists, their patients and the community need to be informed about the potential advantages and disadvantages of new interventions, and whether those new interventions should be used in addition to, or as a substitute for, existing preventive interventions. Interventions that appear promising need to be subjected to randomized controlled clinical trials among the target populations in whom they would be intended for use. Any new preventive agents should be adopted only if they are superior to existing preventive strategies, or if they are shown to provide benefits in addition to existing preventive strategies. It is not sufficient to adopt interventions merely because they appear promising, even if they are known to cause no harm, because their use may forego opportunities to provide other care that is effective. After adoption of efficacious interventions in clinical practice or public health settings, their community effectiveness should be monitored through population-based studies.

Therefore, it is recommended that,

(17) 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.

(18) 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.

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DISCLAIMER

These guidelines reflect the consensus view of the 35 attendees at the workshop, drawn from all states and territories and representing academics from Australian dental schools, jurisdictional health authorities and peak organizations in dentistry. While the guidelines reflect the views of those attending the workshop, they may not reflect the views of the organizations with which those attendees are affiliated.

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