



MANATŪ HAUORA

Guidelines for the Use of Fluorides

Guidelines for the **Use of Fluorides**

© Ministry of Health 2009

Published by: Ministry of Health

PO Box 5013, Wellington

ISBN (Print): 978-0-478-33930-7

ISBN (Online): 978-0-478-31972-9

HP4952

Copyright

The copyright owner of this publication is the Ministry of Health, which is part of the New Zealand Crown. Content may be reproduced in any number of copies and in any format or medium provided that a copyright acknowledgement to the New Zealand Ministry of Health is included and the content is neither changed, sold, nor used to promote or endorse any product or service, or used in any inappropriate or misleading context. For a full copyright statement, go to www.moh.govt.nz/copyright

Funding and independence

This guideline was funded by the Ministry of Health. The development of the guideline was researched and written by New Zealand Guidelines Group (NZGG) employees or contractors. The searching for the evidence and the review of the evidence were independent of the Ministry of Health. Recommendation formulation was completed by an independent expert advisory group, and their recommendations have not been altered by the Ministry.

Statement of intent

NZGG produces evidence-based best practice guidelines to help health care practitioners, policy-makers and consumers make decisions about health care in specific clinical circumstances. This document is not a fully evidence-based guideline in that the evidence was not systematically critically appraised and the recommendations are not graded to show the extent to which they are supported by the evidence. This document therefore provides best practice guidance that is informed by international evidence and placed within the New Zealand context.

While NZGG guidelines represent a statement of best practice based on the latest available evidence (at the time of publishing), they are not intended to replace the health practitioner's judgment in each individual case.

Citation: New Zealand Guidelines Group. Guidelines for the use of fluorides. Wellington: New Zealand Ministry of Health; 2009.

Currency review date: 2019

Cover concept: The cover image has been used to align with the 'Let's talk teeth' campaign.

Copies of the guideline are available online at www.moh.govt.nz and www.nzgg.org.nz

**Ma te huruhuru te manu ka rere,
ma te niho ora ka ora te tangata**

With feathers the bird will fly,
with good oral health, the person will thrive

Contents

About the guideline.....	iii
Summary	vii
1 Background	1
2 Fluoride toothpaste	11
3 Fluoride varnishes.....	21
4 Fluoride mouthrinse.....	33
5 Topical fluoride gels and foams.....	39
6 Fluoride tablets	47
7 Fluoride algorithm	51
8 Horizon scanning.....	53
Appendix A: Development process.....	55
Appendix B: Methods	57
Glossary	60
References	61

List of tables

1.1 Fluoride nutrient reference values for Australian and New Zealand populations.....	5
1.2 Estimated dietary intake of fluoride for New Zealand children, aged 1 to 10 years....	6
2.1 Fluoride toothpaste versus placebo/no treatment	12
2.2 Fluoride toothpaste versus other topical fluoride treatments	13
2.3 Included primary studies for fluoride toothpaste	15
2.4 Percentages converted to parts per million	19
3.1 Fluoride varnishes versus placebo/no treatment.....	23
3.2 Fluoride varnishes versus other topical fluoride treatments	23
3.3 Fluoride varnish versus placebo or no treatment	25
3.4 Fluoride varnish versus other topical fluoride treatment.....	28
3.5 Amount of fluoride and percentage of probable toxic dose	31

4.1	Fluoride mouthrinse versus placebo/no treatment	34
4.2	Fluoride mouthrinse versus other topical fluoride treatments	35
4.3	Included primary studies for fluoride mouthrinse	36
5.1	Gel versus placebo/no treatment	41
5.2	Fluoride gels versus other topical fluoride treatments.....	42
5.3	Included primary studies for fluoride gels and foams	43
6.1	Fluoride tablet recommendations	50

List of boxes

1.1	Risk categories that increase the risk of developing dental caries.....	9
-----	---	---

About the guideline

Purpose

This guideline provides an evidence-based summary of current New Zealand and overseas evidence to inform best practice in the use of fluoride. The Ministry wished to develop a guideline for the use of fluorides that would fit into the wider programme of work to improve oral health, reinvest in child and adolescent oral health services, build from the existing New Zealand guidelines, and use international evidence-based guideline development, as appropriate. Therefore, this guideline:

- is informed by new evidence from clinical trials, changing patterns of behaviour that alter the nature and amount of exposure to fluoride, and the emergence of new evidence about the epidemiology of dental caries and fluorosis
- provides useful information which can be shared with the broader oral health sector and provide practical assistance in oral health programme development and guidance, particularly for those involved in the care of groups that have disproportionately poorer oral health outcomes
- provides stronger guidance on the use of fluorides for at-risk populations that ultimately will aid in reducing inequalities in oral health
- can be used in training oral health professionals and non-oral health primary health practitioners in prevention and early intervention practices to reduce the prevalence and severity of dental caries.

Full methodological details can be found in Appendix A.

The need for the guideline

The overall standard of oral health in New Zealand has improved in the last 30 years. However, the trends in the pattern of early child oral health show signs of worsening and there remain high levels of dental caries (tooth decay) in vulnerable groups of the population.¹

The Ministry of Health recommends the adjustment of fluoride to between 0.7 parts per million (ppm) and 1.0 ppm in drinking water as the most effective and efficient way of preventing dental caries in communities receiving a reticulated water supply, and strongly recommends the continuation and extension of water fluoridation programmes where technically feasible. This document has not undertaken a further analysis and review of the policy and situation with water fluoridation.

With approximately one half of the population accessing fluoridated tap water and some people receiving fluoridated water remaining at increased risk of dental caries, guidelines for the discretionary use of topical fluoride treatments are also needed.

Scope of the guideline

This guideline specifically addresses the use of topical fluoride treatments (including fluoride toothpastes, fluoride varnishes, fluoride mouthrinse, fluoride gels and foams) and fluoride tablets. Appendix A provides further details of the scope, the inclusion and exclusion criteria, and clinical questions.

It should be noted that detailed analyses and discussion of water fluoridation (including bottled water) and dietary intake issues are beyond the scope of the guideline and are included as far as they relate to the context in which health professionals consider and apply topical fluoride treatments. Furthermore, the guideline does not cover all clinical scenarios or medical emergencies.

Target audience

The guideline is intended primarily for the providers of oral health care to New Zealanders, including primary care services where applicable. It is also expected that the guideline will have implications for health service provider organisations and funders, and may be accessed by patients, parents or caregivers, or children themselves.

Treaty of Waitangi

The New Zealand Guidelines Group (NZGG) acknowledges the importance of the Treaty of Waitangi to New Zealand, and considers the Treaty principles of partnership, participation and protection as central to improving Māori health.

NZGG's commitment to improving Māori health outcomes means it works as an organisation to identify and address Māori health issues relevant to each guideline. In addition, NZGG works to ensure Māori participation is a key part of the guideline development process. It is important to differentiate between involving Māori in the guideline development process (the aim of which is to encourage participation and partnership) and specifically considering Māori health issues pertinent to that guideline topic at all stages of the guideline development process.

While Māori participation in guideline development aims to ensure the consideration of Māori health issues by the guideline team, this is no guarantee of such an output; the entrenched barriers Māori may encounter when involved in the health care system (in this case guideline development) need to be addressed. NZGG attempts to challenge such barriers by specifically identifying points in the guideline development process where Māori health must be considered and addressed. In addition, it is expected that Māori health is considered at all points in the guideline in a less explicit manner.

Guideline development process

NZGG follows specific structured processes for guideline development. A general description of these processes in relation to this guideline is provided in Appendix A.

In brief, NZGG convened a multidisciplinary Expert Advisory Group (EAG). Members of the EAG were nominated for their knowledge of fluorides and fluoride use and by a range of stakeholder groups including the Royal New Zealand Plunket Society, Te Ao Marama (the New Zealand Māori Dental Association), academic institutions and District Health Boards. For a full list of group members, see Appendix A. Two, one-day, face-to-face meetings of the full EAG were held, where evidence was reviewed and recommendations were developed.

Summary

Summary of recommendations

Fluoride toothpaste

- Toothpaste should be labelled in parts per million (ppm) fluoride
- Toothpaste of at least 1000 ppm is recommended for all ages and should be used twice daily
- Parents and caregivers should be advised that a smear of fluoride toothpaste is recommended until 5 years of age. From age 6 years, a pea-sized amount should be used
- For children aged under 6 years living in fluoridated areas who are at low risk of dental caries, fluoride toothpaste less than 1000 ppm may be considered to reduce total fluoride intake
- In deciding whether to provide low fluoride toothpaste, parents and caregivers should be advised of the issues associated with reduced fluoride exposure (lesser dental caries protection) versus the risk of fluorosis
- Children should be supervised when using toothpaste
- Toothpaste should not be eaten

Fluoride varnishes

- Professionally-applied, high-concentration fluoride varnishes are not recommended in people with low risk of dental caries
- Professionally-applied, high-concentration fluoride varnishes may be used for people aged over 12 months who are at high risk of dental caries
 - Fluoride varnish applications should be applied at 6-monthly intervals as part of a preventive oral health plan
 - Fluoride varnish should be applied to all erupted teeth
 - Health practitioners applying fluoride varnish should have appropriate training

Fluoride mouthrinses

- Fluoride mouthrinses are not recommended for children aged under 6 years or people aged 6 years and over who are at low risk of dental caries
- Fluoride mouthrinse may be used by people aged 6 years and over who are at high risk of developing dental caries
- After rinsing, mouthrinse should be spat out, not swallowed
- Fluoride mouthrinse should be used as part of a preventive oral health plan

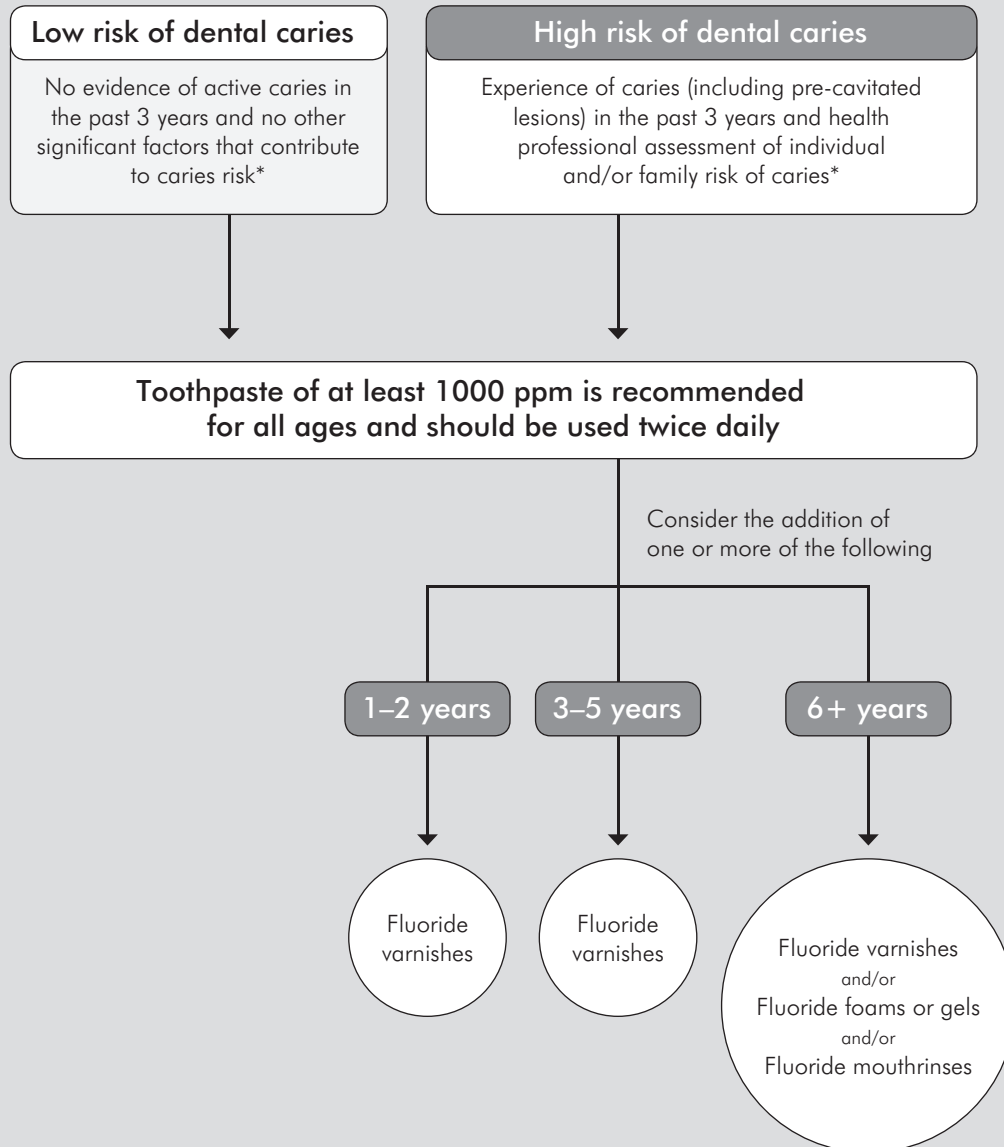
Topical fluoride gels and foams

- Professionally-applied, high-concentration fluoride gels and foams are not recommended for children aged under 6 years or people aged 6 years or over who are at low risk of dental caries
- Professionally-applied, high-concentration fluoride gels and foams may be used for people aged 6 years and over who are at high risk of dental caries
 - Fluoride gel applications should be applied at 3- to 6-monthly intervals as part of a preventive oral health plan
 - Neutral gels are preferable to acidulated gels in people with porcelain and composite restorations

Fluoride tablets

- Fluoride tablets are not recommended as a population health measure in New Zealand
- Fluoride tablets may be recommended for people aged 3 years and over at high risk of dental caries
- Tablets should be chewed or sucked, or dissolved in drinking liquid

Algorithm Guidelines for the use of fluorides



***Dental caries risk factors:** Socioeconomic deprivation, suboptimal fluoride exposure, ethnicity, poor oral hygiene, prolonged bottle feeding, poor family dental health, enamel defects, eating disorders, irregular dental care, high sugar diet, high carbohydrate diet (in people with complex medical conditions), active orthodontic treatment, low salivary flow

1 Background

Patterns of disease

In New Zealand as well as internationally, there has been a shift in the approach to oral health, with more focus on the pattern of disease than the classic biological model that focuses on the disease itself. Preschool caries affects children beyond the physical domain and has impacts on their development, school performance and behaviour; it also affects families and society in general.² One of the shifts necessitated by the New Zealand Oral Health Strategy is to focus on preschool and early primary school years, rather than just the primary school years.

A report to the Ministry of Health in 2003 showed that dental caries rates in New Zealand children had been declining up until the early 1990s, but had since remained either static or shown a slight increase.³

New Zealand dental caries data show that inequalities are more pronounced during the preschool period³ and following the loss of entitlement to state-funded dental care which occurs at age 18.

Part of the challenge of this guideline is to bring about awareness of the need to focus on the youngest age groups. There is a continuing need for effective strategies and treatment services to address the current levels of preschool caries. This guideline focuses on various topical fluoride treatments that have been shown to be effective (gels/foams and mouthrinses); however, these particular interventions are not recommended for children aged under 6 years.

The fluoride algorithm, created as part of the guideline development process, provides guidance regarding the right intervention for the right age group while taking the background risk factors into account.

Action of fluoride and delivery method

Action of fluoride

Tooth enamel (the outer surface of the tooth) is made of closely-packed mineral crystals. These minerals are lost and gained from inside the enamel crystals through the processes of demineralisation and remineralisation. Bacteria that collect on tooth enamel cause dental caries (tooth decay). Bacteria obtain their food from sugar and starch in a person's diet. When these foods are eaten, the bacteria can convert these foods to an acid that causes destruction (demineralisation) of the tooth enamel.

Fluoride, along with calcium and phosphate, can cause the enamel crystals to reform and/or regrow. This results in repair of the caries when it is at an early stage. Remineralised enamel is more resistant to acid attack than the original enamel.³

While necessary to prevent dental caries from an early age, excessive fluoride consumption during tooth development can increase the risk of dental fluorosis. Dental fluorosis, a biomarker of exposure to fluoride among young children, results in an alteration in the appearance of the enamel. It ranges from mild white flecking (most common) to brown-stained enamel or, in extreme cases, enamel loss. The severity of dental fluorosis is related to the duration, timing and dose of fluoride intake. Long-term ingestion of large amounts can lead to potentially severe skeletal fluorosis. Acute high-level exposure to fluoride is rare and usually caused by accidental ingestion. This can cause immediate effects, such as abdominal pain, excess saliva, nausea and vomiting. Seizures and muscle spasms may also occur.⁴

The Expert Advisory Group (EAG) considered the risks and benefits of fluoride use when forming the following recommendations for the discretionary use of fluoride. The Group emphasised that, when health professionals are assessing levels of fluoride intake, it is the additive effect of fluoride that needs to be considered, rather than the exposure to one particular fluoride source.

Multiple sources of fluoride which need to be considered are: the fluoridation of the water supply, the diet, the frequency and strength of toothpaste used and the potential for ingestion of toothpaste, and the application of other topical fluoride interventions (such as fluoride gels, foams, and varnishes).

It is difficult to determine whether an enamel defect is fluorosis or whether it has another cause,^{5, 6} but it is important to note that there are numerous causes of tooth enamel defects and that many of them are not the result of exposure to fluorides.

Delivery method

The EAG agreed that fluoridated water and toothpaste provide the ideal foundation upon which the application of additional fluoride interventions (such as varnish, mouthrinse, gels/foams and tablets) may be considered.

To prevent dental caries, it was originally thought that fluoride had to be ingested to increase intake of fluoride during tooth development. However, during the 1970s laboratory studies showed that fluoride is able to act topically. Today, it is understood that fluoride is a key protective factor that acts directly on the tooth's surface.⁷

Unlike sources of fluoride intended for systemic use (such as fluoride tablets), the topically applied fluorides are not intended for ingestion. Fluoride is applied to exposed tooth surfaces at elevated concentrations for a local protective effect. For prevention, they are used either in low concentration and high frequency, or in high concentration and low frequency. However, for treating early stages of dental caries, it is recommended that fluoride is used in high frequency and high concentration.⁸

In the 1930s and 1940s, a series of international studies demonstrated that naturally occurring fluoride in water supplies was effective in preventing dental caries.⁹

The introduction of fluoride to some New Zealand regional water supplies began in 1954.¹⁰ Recent studies continue to support the benefits of water fluoridation as a public health measure in New Zealand,^{11, 12} with children continuously exposed to fluoridated water during their life having up to half the dental caries experience of those who do not.¹²

Various modes of fluoride use have evolved over recent decades. Fluoridated toothpastes, mouthrinses, gels and varnishes are the most widely used at present, either alone or in combination. A number of products are marketed in different countries and a variety of preventive programmes have been based on these interventions.¹³

Toothpastes and mouthrinses are the main forms of self-applied fluoride. Fluoridated toothpaste is the most widespread form of topical fluoride usage. Introduced to the United States market in the 1950s, there have been many studies reporting a significant reduction in dental caries for children and adults using such toothpastes.⁹ Fluoridated mouthrinses have been widely used for the past 30 years, with sodium fluoride mouthrinses being reported as early as 1960.¹⁴

Fluoride tablets were widely encouraged from the 1950s onwards. The rationale for the use of fluoride tablets was to replicate the intake of fluoride from 1 litre of water a day in a fluoridated area. Fluoride tablets have been shown to be a risk factor for dental fluorosis when not used appropriately⁹ and there have been problems with a lack of compliance, with those least in need of using them being most likely to do so. There is also a risk of acute toxicity from fluoride tablets if excessive numbers are ingested.

Fluoride gels and varnish are typical methods of professional application of topical fluoride. Varnishes are becoming increasingly popular as a method of preventing dental caries. One of the advantages of this product is that it can be used on younger age groups without the adverse risk of ingestion that is associated with the other topical fluoride products. The literature on varnishes is also generally of better quality than that on fluoride gels, because the latter studies were conducted approximately 20 years earlier, and investigatory techniques have improved.

A Cochrane systematic review conducted by Marinho et al¹⁵ shows that most of the studies on gels were published in the late 1960s and 1970s. In contrast, the studies on varnishes were mostly published twenty years later, in the 1980s and 1990s. This is despite the fact that fluoride varnishes were first developed and marketed in the 1960s in the form of sodium fluoride, and in the 1970s in the form of silane fluoride.¹⁶

Dietary intake of fluoride

Water fluoridation in New Zealand

The New Zealand drinking water standards recommend that drinking water contains a target fluoride range of 0.7–1 mg/L.¹⁷ Approximately 89% of the New Zealand population has access to a community water supply; of those, approximately 61% receive fluoridated drinking water. Therefore, approximately 52% of the New Zealand population has access to a fluoridated water supply. Actual concentrations of fluoride in reticulated water in New Zealand average around 0.8–0.9 mg/L in fluoridated areas and around 0.15 mg/L in non-fluoridated areas.¹⁸

Balancing the risk and benefit of fluoride use

Young children are currently exposed to numerous sources of fluoride.

- Fluoride from water
- Fluoride from toothpaste
- Fluoride from supplements
- Fluoride from professional dental applications

One of the concerns expressed about fluoridation of the water supply relates to increasing rates of fluorosis in children seen in some communities over the same period that fluoridation has been practised.¹⁹

A nutrition risk assessment report undertaken by Foods Standards Australia New Zealand (FSANZ) published in 2009 observed that the prevalence of very mild and mild fluorosis was 10% to 25% in Australian and New Zealand children.¹⁸ This is associated with exposure from several sources, both individually and collectively, including fluoridated water, toothpaste, other dental products and supplement use. The prevalence is usually higher in fluoridated than non-fluoridated areas. The FSANZ report did not identify any evidence of more severe forms of fluorosis.

Nutrient reference values for Australia and New Zealand fluoride

Drawing from a number of sources, including the United States, the National Health and Medical Research Council (NHMRC) and New Zealand Ministry of Health have adopted fluoride nutrient reference values (see Table 1.1).¹⁹ For fluoride, an adequate intake (AI)ⁱ and an upper level (UL)ⁱⁱ have been set for various age groups. The AI (used when the recommended dietary intake [RDI]ⁱⁱⁱ cannot be determined) reflects average daily intakes based on observed or experimental studies for healthy populations assumed to be adequate.

ⁱ AI is defined as the average daily nutrient intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.

ⁱⁱ UL is defined as the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.

ⁱⁱⁱ The average RDI level that is sufficient to meet the nutrient requirements of nearly all (97–98%) healthy individuals in a particular life stage and gender group.¹⁹

Table 1.1 Fluoride nutrient reference values for Australian and New Zealand populations

Population subgroup	Adequate intake (mg/day)		Upper level (mg/day)	
	Males	Females	Males	Females
Infants 0–6 months	0.01		0.7	
Infants 7–12 months	0.5		0.9	
1–3 years	0.7		1.3	
4–8 years	1.0		2.2	
9–13 years	2.0		10.0	
14–18 years	3.0		10.0	
Adults 19+ years (including pregnant/lactating women)	4.0	3.0	10.0	10.0

Source: Food Standards Australia New Zealand. Final assessment report: application A588: voluntary addition of fluoride to packaged water. Wellington: Food Standards Australia New Zealand 2009. Copyright Food Standards Australia New Zealand; reproduced with permission.

Analysis of New Zealand fluoride intakes

Two reports have recently assessed fluoride intake levels in New Zealand.^{18,20} A draft report by the Institute of Environmental Science and Research Limited (ESR) found that (excluding formula-fed infants) all population groups' mean fluoride estimates were below the AI level for dental caries protection and, in most cases, the additional fluoride contribution from toothpaste would be insufficient to bring the total fluoride exposure above the AI.²⁰

Table 1.2 summarises estimates of dietary intake of fluoride for New Zealand children, aged 1 to 10 years, based on total diet calculations and dietary modelling.

Table 1.2 Estimated dietary intake of fluoride for New Zealand children, aged 1 to 10 years

Age	Guideline levels (mg/day)		Mean estimated dietary fluoride intake (95th percentile*) (mg/day)			
	AI [†]	UL [†]	Total diet		Dietary modelling	
			Fluoridated water	Unfluoridated water	Fluoridated water	Unfluoridated water
6–12 month old infant	0.5	0.9	0.71	0.18		
1–3 year old toddler	0.7	1.3	0.57	0.25		
5–6 year old child	1	2.2	0.86	0.36	0.84 (1.74)	0.38 (0.73)
7–10 year old child	1–2	2.2–10			0.99 (1.80)	0.45 (0.82)

AI=adequate intake; UL=upper level of intake

* 95th percentile intakes are only available from the dietary modelling approach

[†] National Health and Medical Research Council and Ministry of Health. Nutrient reference values for Australia and New Zealand including recommended dietary intakes. Canberra and Wellington: NHMRC; 2006.

Source: Cressey P, Gaw S, Love J. Estimated dietary fluoride intake for New Zealanders. ESR Client Report FW0651. Christchurch: ESR; 2009. Reproduced with permission.

The estimates from ESR's fluoride intake assessment (see Table 1.2) are higher than those calculated by Chowdhury et al in a much earlier study.²¹ The ESR study used a duplicate diet approach to estimate the dietary fluoride intake of 31 New Zealand children (aged 11–13 months) from areas with fluoridated water and 29 children from non-fluoridated areas. The mean fluoride intakes from food and drinks were 0.263 mg/day in the fluoridated area and 0.082 mg/day in the unfluoridated area.

The duplicate diet approach was also used in a 1996 study of the dietary fluoride intake of 66 New Zealand children (aged 3–4 years).²² The mean estimated dietary fluoride intakes were 0.36 mg/day in fluoridated areas and 0.15 mg/day in low fluoride areas.

The group at greatest risk of exceeding the UL are the very young, particularly the fully formula-fed infant where fluoridated water has been used to prepare the formula. The ESR report estimated that a fully formula-fed infant exceeds the UL approximately one-third of the time for formula prepared with water at 0.7 mg fluoride/L and more than 90% of the time for formula prepared with water at 1.0 mg fluoride/L.²⁰

The risk assessment conducted by FSANZ also estimated that a proportion of children up to 8 years could exceed the UL of intake when fluoridated water (0.6–1.0 mg/L) from any source is consumed. However, they also identified that UL values were based upon the best available information at the time, that the absence of any increase in moderate dental fluorosis in the Australia or New Zealand populations indicates that current intakes do not constitute a safety concern, and that the current information indicates that the UL will need to be reviewed.¹⁸

Ethnicity

Ethnic inequalities in oral health status in New Zealand were reported more than 20 years ago,²³ and numerous studies have subsequently reported that Māori children have a higher prevalence and severity of dental caries than other New Zealand children.^{23–27}

The need to achieve equity in terms of Māori oral health status is a right affirmed by the tangata whenua status of Māori in New Zealand and reconfirmed by the Treaty of Waitangi.²⁸ Access and utilisation of dental health services has been identified as a problem for Māori children^{29, 30} and Māori adolescents in particular.^{31, 32} The strategic vision for oral health in New Zealand acknowledges that inequalities between non-Māori and Māori appear to be worsening.¹ Indeed, improving the oral health status of those currently disadvantaged (Māori, Pacific peoples and other individuals from lower socioeconomic groups) is a priority for improvements to oral health.

Although genetic predisposition and behavioural/lifestyle factors are often cited as contributing towards health inequalities, it is now recognised that wider determinants of health (such as social, cultural, historical, political and economic factors) influence these individual factors.³³ Māori are more likely to belong to lower socioeconomic groups than non-Māori.^{34, 35} The association between dental caries and socioeconomic status has long been recognised, both in New Zealand and internationally.³ A socioeconomic gradient in the prevalence and severity of dental caries has been shown to exist, with disadvantaged people having a higher dental caries experience than those who are less deprived.

Over the past 25 years many studies have shown that community water fluoridation reduces oral health inequalities among children of different ethnic and socioeconomic backgrounds.^{3, 36} The Ministry of Health and Te Ao Marama (the New Zealand Māori Dental Association) actively support and encourage community water fluoridation.³⁷ With approximately one half of the population accessing fluoridated tap water, there remains a need to utilise other methods to reduce oral health inequalities. The use of topical fluoride treatments is one such method. The EAG considers that the appropriate use of topical fluorides, in addition to community water fluoridation, will help to reduce oral health inequalities for Māori, particularly those living in communities with non-fluoridated water supplies.

Epidemiology of dental caries and fluorosis in New Zealand

Dental caries in children/adolescents

Data on 5-year olds and Year 8 (age 12–13 years) students is the only systematic collection of information about the oral health of New Zealand children. Information on the dental health of adolescents is less comprehensive, because it is not routinely collected. Moreover, underutilisation of dental services by some groups of adolescents is a concern.³

Several indices or classification systems are used in surveys for classifying and measuring levels of enamel defects. The most recently developed system – the Developmental Defects of Dental Enamel (DDE) index – allows for the recording of a broad range of defects, including fluorotic and nonfluorotic enamel defects. Up-to-date reviews of enamel defects

show that those living in fluoridated areas have more diffuse enamel opacities and fewer dental caries (tooth decay) than those living in non-fluoridated areas, but the prevalence of diffuse opacities has not increased compared to earlier studies and is largely unchanged from estimates reported within New Zealand over the last 25 years.^{11, 12}

A 2002 cross-sectional survey of New Zealand children living in fluoridated and non-fluoridated areas in Southland found that children who had lived in fluoridated areas all their lives had half the dental caries experience of those who had not.¹² Furthermore, children in unfluoridated areas had a greater prevalence of diffuse opacities.

In 2008, a study of Auckland children found that 28% had diffuse opacities.¹¹ Significant regional differences by fluoridation status were recorded, with diffuse opacity rates of 29% and 15%, respectively ($p < 0.001$). Conversely, the prevalence of dental caries in the primary dentition was significantly lower in fluoridated areas (55%) than in non-fluoridated areas (62%), $p = 0.05$.

Both of these studies reported that there was no difference in the prevalence of demarcated or hypoplastic defects of dental enamel in fluoridated and non-fluoridated areas.

Dental caries in adults

There is a scarcity of longitudinal studies of oral health, especially those of adults. The information available from the small number of studies that have been conducted suggests that the dental caries increment (ie, the rate at which new lesions develop over time) in the permanent dentition is relatively constant through the life-course, at between 0.8 and 1.0 surfaces per year, on average. Data from the Dunedin Study³⁸ show a mean rate of 0.8 surfaces per year in the permanent dentition from age 5 through to age 32 years (the most recent assessment age), with no evidence of a higher rate during childhood or late adolescence (as has previously been believed).

Nothing yet is known of the dental caries increment between that age and the early 50s, but information from a small number of longitudinal studies of community-dwelling older adults suggests an annual increment of about 1.0 surfaces per year (made up mostly of coronal dental caries).³⁹ Information from the only longitudinal study of dental caries increments among institutionalised older people shows that increment rate to be twice as high among residents of nursing homes, and twice as high again among those with dementia.⁴⁰

Risk categories

Teeth are at risk of dental caries from the time they erupt; therefore, children from approximately 6 months of age onwards are at risk of developing dental caries. The influences of the oral health of the child's main caregiver, access to water fluoridation and oral health-related behaviours (including regularity of brushing teeth with fluoride toothpaste, diet content and dietary habits) play a large role in determining whether a child acquires dental caries, and if so, how severely.⁴¹ Complex medical conditions or disabilities may be associated with greater dental caries risk because of higher occurrence of factors such as poor oral hygiene, irregular dental care or low salivary flow in people on particular medications.

In their fluoride recommendations, the American Dental Association⁴² (ADA) listed factors that increase the risk of developing dental caries. These factors were considered and the EAG amended the ADA list to reflect risks pertinent to the New Zealand population. The risk categories for development of dental caries (see Box 1.1) were developed and agreed by the EAG. These categories include both an assessment of current prevalence of dental caries and assessment of risk factors for dental caries in the individual being evaluated.

Box 1.1	Risk categories that increase the risk of developing dental caries
Risk factors	Description
High risk of dental caries	Experience of dental caries (including pre-cavitated lesions) in the past 3 years and health professional assessment of individual and/or family risk of dental caries*
Low risk of dental caries	No evidence of active dental caries in the past 3 years and no other significant factors that contribute to dental caries risk*
* Dental caries risk factors: socioeconomic deprivation, suboptimal fluoride exposure, ethnicity, poor oral hygiene, prolonged bottle feeding, poor family dental health, enamel defects, eating disorders, irregular dental care, high sugar diet, high carbohydrate diet (in people with complex medical conditions), active orthodontic treatment, low salivary flow	

The EAG also discussed the fact that oral health professionals need to consider the collective risk of these factors; there is not enough evidence to individually weight each risk factor, but rather the cumulative effect of these factors together is important.

Age categories

Given the stages of child development, the changing nature of the developing dentition and contemporary information about dental caries activity, the EAG decided that guidelines about the use of topical fluorides should be considered for the following age groups:

- 0–<3 years
- 3–<6 years
- 6–17 years
- 18+ years.

These age categories also correspond easily with the delivery of oral health services in New Zealand. However, advice in this document about age groups for the recommendations of use of the various fluoride delivery methods may vary from these age bands based on the available evidence.

2 Fluoride toothpaste

The most widely known and used topical fluorides are incorporated into toothpastes. In many countries, over 90% of the marketed toothpastes contain fluoride as sodium monofluorophosphate (SMFP), sodium fluoride, stannous fluoride or amine fluoride. Most fluoridated toothpastes on sale in New Zealand contain 1000 ppm of fluoride. Low-strength (400–550 ppm) fluoride toothpaste is available and is marketed for use by children aged under 6 years.

Body of evidence

Guidelines

The Australian consensus guidelines⁴³ were used as a base to develop the following New Zealand-specific recommendations. For full methodological details, see Appendix A. One additional guideline was identified which made recommendations on the use of fluoride toothpaste; this was an American conference paper by Adair.⁴⁴

Three systematic reviews were identified which reported on the use of fluoride toothpaste: the National Health and Medical Research Council (NHMRC) review,⁴⁵ a review of programmes for prevention of early childhood caries⁴⁶ and a review of the risk factors for fluorosis.⁴⁷ The guidelines and systematic reviews include reviews by Marinho¹⁵ and Twetman.⁴⁸ Three additional primary studies were identified and are summarised below.

The Australian consensus guidelines present the recommendations for the use of fluoridated toothpastes listed below.⁴³

- From the time that teeth first erupt (about 6 months of age) to the age of 17 months, children's teeth should be cleaned by a responsible adult, but not with toothpaste
- For children aged 18 months to 5 years (inclusive), the teeth should be cleaned twice a day with toothpaste containing 0.4–0.55 mg/g of fluoride. Toothpaste should always be used by children under the 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
- For people aged 6 years or more, the teeth should be cleaned twice a day or more frequently with standard fluoride toothpaste containing 1 mg/g fluoride. People aged 6 years or more should spit out (not swallow) and not rinse
- For children who do not consume fluoridated water or who are at elevated risk of developing dental 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 at a younger age or earlier commencement of use of standard toothpastes containing 1 mg/g fluoride
- For teenagers, adults and older adults who are at elevated risk of developing dental caries, oral health professional advice should be sought to determine if they should use toothpaste containing higher concentration of fluoride (ie, greater than 1 mg/g of fluoride)

An American conference paper presented guidelines for the use of fluoride toothpastes in children.⁴⁴

- Oral cleanings after feedings should begin prior to primary tooth eruption, but certainly as soon as teeth have erupted. Non-fluoride, all-natural tooth cleaning gels are available for use in low-dental caries-risk children at this age. Due to the association between fluorosis and fluoride toothpaste use in children younger than 2 years of age, use of fluoridated dentifrices prior to the age of 2 should be based on a dental caries risk assessment. Parents should be apprised of the risks and benefits of fluoride dentifrice use in the age group
- Tooth-brushing should be supervised by an adult, especially once fluoride dentifrice use has begun. Pea-sized dabs of dentifrice should be used, and the caregiver should brush the child's teeth until this is no longer practicable. At that point, the parent should continue to dispense the dentifrice and the child should have their tooth-brushing checked by the caregiver
- Tooth-brushing with a fluoridated toothpaste should be done twice daily. Twice-daily brushing is associated with additional benefits over once-daily brushing; the benefits of more frequent cleanings are not well established
- Older children who are able to expectorate should use more than a pea-sized dab to increase their salivary fluoride levels

Systematic reviews

The NHMRC review based much of its review on a previous review by Marinho 2003¹⁵ and cited summary tables in its text (see Tables 2.1 and 2.2).

Table 2.1 Fluoride toothpaste versus placebo/no treatment

Outcome	Comparison	Number of included studies	Heterogeneity	Prevention fraction (95%CI)
DMFS increment	Fluoride toothpaste vs placebo	70	$p < 0.001$	PF 0.24 (0.21–0.28) $p < 0.001$
DMFT prevention fraction	Fluoride toothpaste vs placebo	53	$P < 0.001$	PF 0.23 (0.19–0.28) $p < 0.001$

DMFS=decayed, (missing) and filled surfaces prevented fraction; PF=prevention fraction; DMFT=decayed, (missing) and filled teeth prevented fraction

Source: National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation: Australian Government. Copyright Commonwealth of Australia; adapted with permission.

Compared to placebo or no treatment, fluoride toothpastes improve the prevention fraction for dental caries. The pooled prevented fraction for DMFS was 24%. The dental caries-preventive effect of fluoridated toothpaste was greater with:

- higher baseline DMFS levels
- higher fluoride concentration in the toothpaste
- greater frequency of use
- supervised brushing.

Table 2.2 Fluoride toothpaste versus other topical fluoride treatments

Outcome	Comparison	Number of included studies	Prevention fraction (95%CI)
DMFS	Toothpaste vs gel	3	PF 0.00 (-0.21–0.21)
DMFS	Toothpaste vs mouthrinse	6	PF 0.00 (-0.18–0.19)
DMFS	Toothpaste vs other	9	PF 0.01 (-0.13–0.14)
Withdrawals	Toothpaste vs mouthrinse	5	PF 0.89 (0.78–1.00)

DMFS=decayed, (missing) and filled surfaces prevented fraction; PF=prevention fraction

Source: National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation: Australian Government. Copyright Commonwealth of Australia; adapted with permission.

Evidence for the effectiveness of fluoride toothpaste compared to other treatments is limited. There is no evidence that toothpaste is more or less effective than other topical fluoride treatments.

There is limited evidence relating to the primary dentition or dental fluorosis.

Two studies (rated poor quality) were identified in the NHMRC review investigating the impact of fluoridated toothpastes and dental fluorosis. The findings of one of these studies showed that fluoridated toothpaste might be associated with 'any fluorosis'.⁴⁹ However, when 'fluorosis of aesthetic concern' was examined no significant difference between the higher fluoride concentration group and the control group was found and the prevalence of fluorosis in the higher concentration toothpaste group was low (<2%). This study was conducted in an area with fluoride in the drinking water at <0.1 ppm.

The NHMRC review also located four cross-sectional or case-control studies assessing the impact of various fluoride types. The results of these studies were mostly consistent with three of the four studies showing a statistically significantly greater risk of fluorosis (any fluorosis) associated with the use of fluoride.

A systematic review of the literature on the risk factors for fluorosis identified the following fluoride toothpaste variables that have been associated with fluorosis: beginning toothbrushing at a relatively early age, and the amount of toothpaste used (measured as either toothbrushing frequency, amount swallowed or the amount of paste used at each brushing).⁴⁷

Fluoride concentration

The NHMRC review found mixed evidence on the benefit of higher fluoride concentration toothpaste. Of the four studies included in this review, three studies showed no difference between lower versus higher fluoride concentrations (ie, 500 ppm vs 1100 ppm, 500 ppm vs 1450 ppm and 1100 ppm vs 2800), while one study showed higher concentrations to be more effective than lower concentrations (ie, 2200 ppm and 2800 ppm vs 1100 ppm).

The authors of the NHMRC review also analysed the findings of one further study, calculating the change in the dental caries score between lower versus higher fluoride concentrations.⁵⁰ The results of this study showed that the proportion of dental caries-free children after 5 years was significantly greater in the 1450 ppm toothpaste group (50%) compared with the 440 ppm toothpaste and no toothpaste groups (both 42%).

It should be noted that the NHMRC used the results of a combination of four previously conducted Cochrane reviews as a basis for their systematic review with the addition of 16 systematic reviews and 17 randomised controlled trials (RCTs) published between 2000 and 2006. The individual reviews are not included in the NHMRC review. The original Cochrane review of fluoride toothpaste aimed to examine whether the effect of fluoride toothpaste is influenced by fluoride concentration or application features such as frequency of use. This review found that the dental caries-preventive effect of fluoridated toothpaste was greater with higher fluoride concentration in the toothpaste. There was a clear 8% increase in the prevention fraction per 1000 ppm F concentration.¹³

Fluoridated toothpastes were included in a systematic review of programmes for prevention of early childhood dental caries.⁴⁶ Two of the studies included in the review (also included in the NHMRC review) compared differing strengths of toothpaste. According to their study's results, the authors concluded that at 250 ppm fluoride toothpaste is less effective for dental caries prevention in permanent dentition than toothpaste containing 1000 ppm fluoride or more.

No studies were found investigating the efficacy of toothpaste containing 5000 ppm fluoride concentration.

Primary studies

The three primary studies that were identified are summarised in Table 2.3.

Table 2.3 Included primary studies for fluoride toothpaste

Citation and type of study	Type of study and number and age of participants	Intervention	Comparison	Outcome measures and follow-up	Results	Summary
Fan 2008 China Double blind, parallel group RCT Method of randomisation not reported	Age: recruited at 4 years of age n=998 Participants: children living in the Chengdu area (drinking water 0.3 ppm fluoride) Brushing instructions reinforced at school Baseline dental caries data indicated no significant difference in DFS scores (mean DFS score 3.54)	Group A: 1.14% SMFP calcium carbonate-based fluoride toothpaste twice/day Group B: 1.14% SMFP silica-based fluoride toothpaste twice/day	Non-fluoride calcium carbonate-based toothpaste twice/day	Mean DFS increment (visual and probe procedure) Follow-up: 1 and 2 years	1-year follow-up DFS increment scores: • intervention group A: 1.53 ± 3.09 , $p < 0.05$ • intervention group B: 1.69 ± 3.12 , $p < 0.05$ • comparison 2.19 ± 4.12 not significant (ns) 2-year follow-up DFS increment scores: • intervention group A: 2.75 ± 4.43 , $p < 0.05$ • intervention group B: 2.98 ± 4.42 , $p < 0.05$ • comparison 4.73 ± 5.17 ns	Both fluoridated toothpastes provided statistically significant 42% (calcium carbonate-based) and 37% (silica-based) reductions in dental caries increment compared to non-fluoride-based toothpaste

continued over...

Table 2.3 continued...

Citation and type of study	Type of study and number and age of participants	Intervention	Comparison	Outcome measures and follow-up	Results	Summary
Pine 2007 UK Single (examiner) blind RCT Randomisation on a school class basis	Age: recruited at 5 years of age n=534 Participants: children in deprived areas with a history of above average numbers of children with dental caries experience at school entry	Supervised brushing once/day at school with 1000 ppm F and a home support package encouraging twice-daily brushing	No brushing at school and no home support package received	All visible cavitated and non-cavitated lesions in enamel and dentine (D ₃ FS) Follow-up: 7 years	Intervention group D ₃ FS caries increment 1.62 Comparison group D ₃ FS caries increment 2.65 P<0.05	Prolonged benefits were found for intervention children with fewer dental caries in first permanent molars
Zantner 2006 Germany Single (examiner) blind RCT	Age: 12–18 years n=44 Participants: good general health, good oral hygiene (approximal plaque index <25%), at least one tooth with a visible (not newly formed) long-existing white spot lesion	1500 ppm NaF toothpaste	1250 ppm AmF toothpaste	Mean fluorescence loss – ΔQ (% x mm ²) Follow-up: 6 months	Intervention group ΔQ1 –20.31 (±41.06) Comparison group ΔQ10 –26.2 (±47.69) Intervention group ΔQ1 –22.28 (±43.86) Comparison group ΔQ10 –26.39 (±46.4)	Within 6 months the long standing white spot lesions are stable concerning fluorescence loss over the lesion area

RCT = randomised controlled trial; n = number; SMFP = sodium monofluorophosphate; DFS = decayed and filled tooth surfaces; ppm = parts per million; NaF = sodium fluoride; AmF = amine fluoride; ΔQ = fluorescence loss integrated over the lesion area (% X mm²)

A Chinese study investigated the efficacy of three toothpastes commercially available in China. The intervention groups were encouraged to brush their teeth twice a day using either 1.14% SMFP calcium carbonate-based fluoride toothpaste or 1.14% SMFP silica-based fluoride toothpaste. The comparison group was given non-fluoride calcium carbonate-based toothpaste and also encouraged to brush twice a day. The children were aged 4 years at baseline with a similar mean DFS (decayed and filled tooth surfaces) score. The results of the study showed significantly lower dental caries increments in those using the fluoride-based toothpaste than in those brushing with non-fluoride toothpaste.⁵¹

A UK study investigated the efficacy of a supervised toothbrushing programme conducted in 12 primary schools. During the 30-month duration of the randomised controlled trial (RCT), the intervention group received supervised toothbrushing once a day at school with 1000 ppm fluoride toothpaste and a home support package encouraging twice-daily toothbrushing. The comparison group did not brush at school or receive the home support package. Children were aged 5 years at baseline and were examined every 6 months during the trial, then at 6, 18, 30 and 54 months after the end of the trial. Significantly fewer dental caries developed in the permanent molars of the intervention children.⁵²

A German study investigated the effect of fluorides on long-existing white spot lesions. In this study, the intervention group brushed their teeth with 1500 ppm sodium fluoride toothpaste and the comparison group brushed using 1250 ppm amine fluoride toothpaste. Findings indicated no significant differences in respect of these (already arrested) lesions.⁵³

Summary of findings

Compared to placebo or no treatment, fluoride toothpastes are effective in preventing dental caries. Fluoride toothpastes have been found to improve the prevention fraction for dental caries (DMFS) by 24%.

Evidence for the effectiveness of fluoride toothpaste in comparison with other treatments is limited. There is also limited evidence relating to the primary dentition or dental fluorosis.

The NHMRC review reported mixed evidence as to the benefit of higher fluoride concentration toothpaste. They reported that three studies showed no difference when comparing lower and higher fluoride concentration, while they also reported that two studies showed higher fluoride concentrations to be more effective than lower strength. The Cochrane review of fluoride toothpaste found that the dental caries-preventive effect of fluoridated toothpaste increased with higher fluoride concentration in the toothpaste.

No studies that investigated the efficacy of 5000 ppm fluoride toothpaste were found.

Recommendation development

The Expert Advisory Group (EAG) agreed that fluoridated water and toothpaste provide the ideal building blocks upon which the option of applying additional fluoride interventions may be considered (varnishes, mouthrinse, gels or foams or tablets).

The group discussed the trade-off between improved oral health and the (arguably minimal) aesthetic impact of diffuse opacities in children who are continuously resident in communities with fluoridated water. The risk of fluorosis needs to be considered, taking into account the total amount of fluoride consumed from all sources during the critical period of tooth development (the first 3–4 years of a child's life).¹²

The EAG also highlighted the issue of children eating toothpaste. A significant association has been found between the prevalence of hypoplastic enamel defects and children reportedly eating toothpaste up to 3 years of age.¹²

In considering the evidence for the various strengths of fluoride toothpastes available in New Zealand (see Table 2.4), the EAG noted that the Cochrane review of toothpaste¹³ found that the dental caries-preventive effect of fluoridated toothpaste was greater with higher fluoride concentrations. This corresponds with the known dose-response relationship established in the 1940s in the 21-city study.⁵⁴

In deciding whether to provide low fluoride toothpaste, parents and caregivers may need to be advised of the issues associated with reduced fluoride exposure (lesser dental caries protection) versus the risk of dental fluorosis.

Plain English summary

Evidence for fluoride toothpastes

- Fluoride toothpaste helps to prevent dental caries (tooth decay) and is better at preventing dental caries than non-fluoride toothpaste
- Prevention of dental caries is greater with higher concentrations of fluoride in the toothpaste, greater frequency of brushing and supervised toothbrushing
- Toothpaste should not be eaten

Issues associated with toothpaste use

- Consuming fluoride during the period of tooth development (0–4 years of age) is associated with higher risk of dental fluorosis (mottling of the teeth)
- Child-strength fluoride toothpastes provide less protection against dental caries but reduce the exposure to fluoride and the potential risk of dental fluorosis

The Expert Advisory Group (EAG) noted that the labelling of toothpaste is confusing for parents and caregivers because of the different forms of toothpaste used and the use of percent/weight/volume measures. Table 2.4 presents examples of the most common strengths of toothpaste available in New Zealand with a conversion to parts per million (ppm).

Table 2.4 Percentages converted to parts per million

Percentages (%)	Parts per million (ppm)
0.304% sodium monofluorophosphate	400 ppm
0.117% sodium fluoride	500 ppm
0.4% sodium monofluorophosphate	526 ppm
0.221% sodium fluoride	1000 ppm
0.76% sodium monofluorophosphate	1000 ppm
1.1% sodium fluoride	5000 ppm

In developing the recommendations, the EAG expressed concern that widespread use of low-fluoride-strength toothpastes in New Zealand could lead to increased dental caries. Therefore, the lower-strength toothpaste (400–550 ppm) was not recommended for use, but may be considered for use in those who are at low risk of dental caries.

continued over...

Plain English summary continued...

Unlike the Australian consensus guideline, the EAG decided against endorsing the widespread use of low-fluoride-strength toothpaste and advocating for young children to have their teeth cleaned without the use of toothpaste. This decision was reached in view of (1) the fact that New Zealanders have lower levels of overall access to fluoridated water than Australians, and (2) recent studies in New Zealand showing that the prevalence of diffuse opacities among children living in fluoridated areas has not increased.

The EAG is also mindful of the finding in some dietary intake studies which using dietary modelling shows that there is a potential for some young children to exceed the recommended upper levels of dietary fluoride intake at times. The EAG also noted that there is a discrepancy between studies examining duplicate actual diets (which suggest lower dietary fluoride intake) and studies that have used dietary estimates to model dietary fluoride intake. They also noted that Food Standards Australia New Zealand (FSANZ) has indicated that the upper level recommendations for fluoride intake will need to be reviewed.

Recommendations

Toothpaste should be labelled in ppm fluoride
Toothpaste of at least 1000 ppm is recommended for all ages and should be used twice daily
Parents and caregivers should be advised that a smear of fluoride toothpaste is recommended until 5 years old. From 6 years, a pea-sized amount should be used
For children aged under 6 years living in fluoridated areas who are at low risk of dental caries, fluoride toothpaste less than 1000 ppm may be considered to reduce total fluoride intake
In deciding whether to provide low fluoride toothpaste, parents and caregivers should be advised of the issues associated with reduced fluoride exposure (lesser dental caries protection) versus the risk of fluorosis
Children should be supervised when using toothpaste
Toothpaste should not be eaten

3 Fluoride varnishes

Fluoride varnish contains 22.6 mg/ml fluoride ion suspended in an alcohol and resin base.⁴³ This high-concentration fluoride varnish is applied directly to dried teeth by oral health (or other health care) professionals directly onto the teeth where it forms a waxy layer that adheres to the teeth until it is worn off by chewing or brushing.⁴³ It is not intended to adhere permanently. Varnishes are reapplied at regular intervals to retain efficacy, usually with at least two applications per year.

Body of evidence

Guidelines

The Australian Consensus Guidelines⁴³ report that fluoride varnishes are efficacious for the prevention of dental caries in both the primary and permanent dentition. Application twice-yearly has not been linked to a higher risk of fluorosis and it is able to be applied by health professionals other than dentists.

The Australian consensus guidelines⁴³ present the following recommendation for the use of fluoridated varnishes:

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

Two additional guidelines were identified which made recommendations on the use of fluoride varnish: guidelines from the American Dental Association⁴² and an American conference paper by Adair.⁴⁴

Four systematic reviews were identified reporting use of fluoride varnishes: the National Health and Medical Research Council (NHMRC) review,⁴⁵ a Health Canada review focusing on high-risk groups,¹⁶ a Cochrane review of pit and fissure sealants versus fluoride varnish,⁵⁵ and a review comparing silver diamine fluoride and fluoride varnish.⁵⁶

Six additional primary studies were identified and are summarised in the section titled, 'Primary studies'.

Guidelines from the American Dental Association⁴² draw the following conclusions from the evidence reviewed: fluoride varnishes applied every 6 months are effective in preventing dental caries in the primary and permanent dentition of children and adolescents; two or more applications of fluoride varnish per year are effective in preventing dental caries in high-risk populations; and fluoride varnish applications take less time, create less patient discomfort and achieve greater patient acceptability than fluoride gel, especially in preschool-aged children. They go on to recommend the following:

- moderate-risk children younger than 6 years, aged 6–18 years and adults over 18 years should receive fluoride varnish applications at 6-monthly intervals. Fluoride varnish contains a smaller quantity of fluoride compared to fluoride gels; and, therefore, its use reduces the risk of inadvertent ingestion in children younger than 6 years
- high-risk children younger than 6 years should receive fluoride varnish applications at 3- to 6-month intervals
- high-risk children aged 6–18 years should receive fluoride varnish or gel application at 6-monthly intervals; 3-monthly intervals may provide additional dental caries prevention benefit
- high-risk adults over 18 years should receive fluoride varnish or gel application at 3- to 6-month intervals.

An American conference paper presents guidelines for the use of fluoride varnishes in children.⁴⁴

- The current best practice with fluoride varnish is application at 6-month intervals for reducing the dental caries incidence in the permanent teeth of children residing in optimally fluoridated and fluoride-deficient communities. (The evidence for fluoride varnish's effectiveness in the primary dentition is inconclusive, but currently there is no reason to assume that it would not provide a similar level of dental caries protection in younger children.)
- Have the patient refrain from eating or drinking for 30 minutes after the application. Have the patient postpone brushing the teeth until the morning following varnish application
- Until further evidence suggests otherwise, frequent periodic applications of fluoride varnish to open dental caries lesions in very young children (as often employed in the 'alternative restorative technique') should continue to be utilised as a means of controlling early childhood dental caries
- When a choice of professionally-applied fluoride is available, it appears that fluoride varnish may be superior to fluoride gels and foams in dental caries reduction

Systematic reviews

The NHMRC review based much of their review on work by Marinho¹⁵ and cited summary tables in their text (see Tables 3.1 and 3.2).

Table 3.1 Fluoride varnishes versus placebo/no treatment

Outcome	Comparison	Number of included studies	Heterogeneity	Prevention fraction (95% CI)
DMFS increment	Fluoride varnish vs placebo	3	p<0.001	PF 0.40 (0.09–0.72) p=0.01
	Fluoride varnish vs no treatment	4	p=0.07	PF 0.52 (0.35–0.69) p<0.001
DMFT prevention fraction	Fluoride varnish vs placebo	2	p=0.001	PF 0.49 (0.02–0.96) p=0.04
	Fluoride varnish vs no treatment	1	n/a	PF 0.60 (0.36–0.84) p<0.001
Defs prevention fraction	Fluoride varnish vs placebo	1	n/a	PF 0.20 (0.02–0.38) p=0.03
	Fluoride varnish vs no treatment	2	p=0.64	PF 0.41 (0.26–0.55) p<0.001

DMFS=decayed, (missing) and filled surfaces prevented fraction; p=p-value; PF=prevention fraction; DMFT=decayed, (missing) and filled teeth prevented fraction; n/a=not applicable

Source: National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation: Australian Government. Copyright Commonwealth of Australia, adapted with permission.

Compared to placebo or no treatment, fluoride varnishes improve the prevention fraction for dental caries.

Table 3.2 Fluoride varnishes versus other topical fluoride treatments

Outcome	Comparison	Number of included studies	Prevention fraction (95% CI)
DMFS	Varnish vs gel	1	PF 0.14 (-0.12–0.40)
DMFS	Varnish vs mouthrinse	4	PF 0.10 (-0.12–0.32)
Withdrawals	Varnish vs mouthrinse	2	PF 1.18 (0.85–1.64)
Withdrawals	Varnish vs toothpaste	1	PF 1.28 (0.37–4.41)

DMFS=decayed, (missing) and filled surfaces prevented fraction; PF=prevention fraction

Source: National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation: Australian Government. Copyright Commonwealth of Australia; adapted with permission.

Evidence for the effectiveness of fluoride varnishes compared to other fluoride treatments is limited. There is no clear evidence that professionally-applied fluoride varnish is more effective than other agents.

One further systematic review conducted as part of a report for the First Nations and Inuit Branch of Health Canada¹⁶ examined the effectiveness of fluoride varnish in preventing dental caries in high-risk populations, particularly young children. Five randomised and two non-randomised control trial studies were included, two of which^{57, 58} are described further in the next section titled, 'Primary studies'.

The authors concluded that there was clear evidence showing that the use of fluoride varnish prevents dental caries in children and adolescents. As for the combined effectiveness of varnishes and sealants, toothpastes and oral health counselling, the authors made the following recommendations:

- any use of fluoride varnish should be based on risk assessment, with the best predictor of risk being previous or current dental caries experience
- evidence of efficacy with two applications in a year but insufficient evidence to support three applications within a short interval such as 1 or 2 weeks
- for predominantly high-risk populations (eg, people with low socioeconomic status [SES], new immigrants and refugees, all First Nations and Inuit children and adolescents), fluoride varnish should be applied twice a year, unless the individual has no risk of dental caries, as indicated by past and current dental caries history.

A Cochrane review⁵⁵ compared the effectiveness of fluoride varnish and pit-and-fissure sealants, including whole-mouth and split-mouth designs. Three studies were identified with participants ranging in age from 5 to 9 years old at the start of treatment and follow-up ranging from 1 to 9 years.

A meta-analysis and calculation of overall effectiveness was not possible because of diversity in the study designs and interventions, but there was some evidence that pit-and-fissure sealants were more effective than fluoride varnish in the prevention of occlusal caries. The magnitude of the benefit could not be calculated and the authors recommended that the decision to use sealants or fluoride varnish should be made locally.

Rosenblatt et al.⁵⁶ conducted a systematic review of studies comparing the effectiveness of silver diamine fluoride (SDF) with fluoride varnish in the prevention of dental caries. One study was located comparing the effectiveness of treatment with SDF (44.8 ppm F), fluoride varnish (22.6 ppm F) or water in carious primary maxillary anterior teeth. SDF was more effective in arresting and preventing dental caries than fluoride varnish; however, this limited dataset limits the conclusions that can be made regarding the comparative effectiveness of the two treatments and any clinical recommendations.⁵⁶

Primary studies

Primary studies that were identified are summarised in Tables 3.3 and 3.4.

Table 3.3 Fluoride varnish versus placebo or no treatment

Citation and type of study	Type of study and number and age of participants	Intervention	Comparison	Outcome measures and follow-up	Results	Summary
Lawrence et al. 2008	n=915 fluoride varnish (FV)	DuraFluor 22.6 mg fluoride	Oral health counselling alone	2 year dental caries increment (dmfs)	Dental caries increment:	No significant difference in dental caries increment for all Aboriginal children, but difference for 4–5 year age group
RCT-cluster randomised at community level	n=328 No FV	0.3–0.5 ml applied to primary dentition every 6 months for 24 months plus oral health counselling for caregivers		Prevention fraction (PF)	Aboriginal children FV=11.0±0.5 No FV=13.47 ±0.9 p=0.184	
Northern Canada	Additional non-randomised group of 150 children received FV			OR dental caries incidence NNT	PF= 18.3% All children FV=10.17±0.5 No FV=13.47 ±0.9 p=0.07	18.3% prevention fraction for dental caries increment
	20 rural communities randomised			Regression for dental caries incidence over 2 years	Dental caries incidence: Aboriginal children: OR 1.38 (0.80–2.36) p=0.03 NNT=26.3	The authors combined the results for the randomised Aboriginal population and the non-Aboriginal non-randomised children recruited as a further control group
	6 month–5 year olds				All children: OR 1.95 (1.08–3.56) p=0.03 NNT=12.2	The results in this table are for the randomised children only

continued over...

Table 3.3 continued...

Citation and type of study	Type of study and number and age of participants	Intervention	Comparison	Outcome measures and follow-up	Results	Summary
Stecksén-Blicks et al. 2007 RCT Sweden	n=302 12–16 year olds with fixed orthodontic brackets	FluorProtect 0.1% F as difluorasilane varnish every 6 weeks until debonding	Placebo varnish (PV)	Change in white spot lesions (WSL) at debonding ARR NNT	WSL score: Mean progression FV=0.8 +/- 2.0 PV= 2.6 +/- 2.8 p<0.001 Incidence FV=7.4% PV=25.7% p<0.001 ARR=18% NNT=5.5	FV group had significantly less progression and fewer WSL at debonding than a placebo varnish group Measurement of WSL was by examination of photos
Weintraub et al. 2006 RCT San Francisco, United States	n=376 6–44 month olds, dental caries free Low income communities Chinese and Hispanic (93%) 24-month intervention	4FV group: twice yearly application of Duraphat (0.1 mL per arch) plus caregiver counselling 2FV group: once yearly application plus caregiver counselling	0FV group: caregiver counselling alone	Dental caries incidence: • cavitated, decayed (d2+) on all primary teeth • filled surfaces (d2+fs) on all primary teeth	Mean d2+fs at last follow-up: 4FV=0.7 (SD 2.1) 2FV=0.7 (SD 1.8) 0FV=1.7 (SD 3.1) PF 4FV=61% PF 2FV=58%	Either once yearly or twice yearly fluoride varnish resulted in fewer dental caries at 24-months follow-up No difference between twice and once yearly fluoride varnish All children were dental caries-free at beginning of study

continued over...

Table 3.3 continued...

Citation and type of study	Type of study and number and age of participants	Intervention	Comparison	Outcome measures and follow-up	Results	Summary
Hardman et al. 2006 RCT-cluster randomised at the class level	n=914 children 7-8 year olds at 24 randomly selected schools in relatively low SES communities	Duraphat FV (22,600 ppm F) twice yearly	No treatment	Proportion of children with increment in dmf/DMF Magnitude of increment of dmf/DMF 24-month follow-up	24-month dental caries increment: d3fs FV=1.49 No FV=1.52 NS d2fs FV=0.72 No FV=0.97 NS d1fs FV=0.71 No FV=1.12 P=0.03 No differences in permanent teeth	Significantly smaller increment in small enamel lesions in fluoride varnish group. No difference in medium enamel or dentine lesions or in lesions in permanent teeth High drop-out rate Both groups continued to have routine dental care in usual way

RCT=randomised controlled trial; n=number; OR=odds ratio; NNT=number needed to treat; p=p-value; ARR=absolute risk reduction; SD=standard deviation; PF=prevention fraction; SES=socioeconomic status

Table 3.4 Fluoride varnish versus other topical fluoride treatment

Citation and study type	Type of study and number and age of participants	Intervention	Comparison	Outcome measures and follow-up	Results	Summary
de Amorim 2008 RCT Brazil	RCT n=80 3-5 year olds Rural, non-fluoridated community in Brazil	1. Chlorhexidine varnish (CV) 2. Fluoriz fluoride varnish (FV) 3. Alternate treatment with both Application once a week for 4 weeks	No treatment	Change in white spot lesions (WS) between T1 (1 month) and T3 (3 months) after treatment Change in visible plaque index % (VPI)	WS: T1 – T3 Gp 1 = -0.89 Gp 2 = -1.05 Gp 3 = -1.40 Gp 4 = 0.37 VPI: T1 – T3 Gp 1 = -8.05 Gp 2 = -1.58 Gp 3 = -8.75 Gp 4 = 1.58	Treatment with CV or FV or a combination of both reduced VPI and WSL at T3. Trend towards better response with combination treatment No blinding or allocation concealment
Ersin 2006 RCT	n=90 12-15 year old children with intellectual disabilities	Fluoride varnish (Bifluorid 12) at baseline and 1 year	Chlorhexidine varnish (Cervitec) baseline and every 3 months for 1 year or fluoride gel (NaF gel) baseline and 1 year	1 year follow-up: • dental caries increment DMFS • mutans streptococci • lactobacilli • plaque scores	Dental caries increment: FV = 1.38 ± 2.03 NaF = 1.06 ± 2.26 CV = 0.74 ± 1.5 Not significant	No difference in plaque scores, lactobacilli or mean dental caries increment at the end of 1-year follow-up

RCT = randomised controlled trial; n = number; NaF = sodium fluoride; DMFS = decayed, (missing) and filled surfaces prevented fraction

A study⁵⁷ of young First Nations children (ranging in age from 6 months to 5 years) living in non-fluoridated, rural communities in Northern Canada randomised 20 communities to either a fluoride varnish group, where children received treatment every 6 months and caregivers were counselled about oral health, or a control group who received counselling alone.

There was no significant difference in overall dental caries increment over 2 years (FV=11.0±0.5, control=13.47±0.9, p=0.184) for the Aboriginal children. The prevented fraction was 18.3%. Further analyses including a group of non-Aboriginal children from a nearby urban area indicated a significantly lower DMFS increment for the children receiving fluoride varnish treatment (FV=4.22±1.02, control=8.52±2.24, p=0.014) compared to control group. The prevented fractions for 0- to 1-year olds, 2- to 3-year olds, and 4- to 5-year olds were 27.6%, 18.4% and 50.5%, respectively, when all children were included in analyses. A regression analysis yielded a significant effect of fluoride varnish on 2-year dental caries incidence (adjusted OR 1.96, 95% CI 1.08–3.56, p=0.027).

A study of 6 to 44 month old children living in low-income areas in San Francisco⁵⁸ randomised 376 children to receive either a twice-yearly application of fluoride varnish plus caregiver counselling, a once-yearly application of fluoride varnish plus caregiver counselling, or counselling alone. Treatments were applied for 24 months, and a significantly lower dental caries increment was found for the fluoride varnish groups (2FV and 4FV=0.7) compared to the control group (0FV=1.7), with a prevented fraction of 58% and 61% for the once-yearly and twice-yearly fluoride varnish groups, respectively. No difference was found between the two fluoride groups. The children included in this study were dental caries-free at baseline.

A third study of children in low-income areas⁵⁹ randomised 48 classes of 5- to 9-year old children to either a twice-yearly fluoride varnish group or no treatment. There was no significant difference in either medium enamel or dentine lesions in either primary or permanent teeth at the 24-month follow-up. In primary teeth only, there was a significant difference in small enamel lesions, with the fluoride varnish group displaying a smaller increment in lesions (FV=0.71) than the control group (No FV=1.12, p=0.03).

Two studies investigated changes in white spot lesions following treatment with fluoride varnish. A study of 12- to 15-year olds who were having orthodontic brackets fitted⁶⁰ randomised participants to have either a fluoride varnish 0.1% F or a placebo varnish (of identical composition aside from the fluoride component) applied to their brackets at bonding and then every 6 weeks until removal of the brackets. Participants, treating clinicians and examiners were blind to the treatment allocation, and changes in white spot lesions were measured by examining photographs taken before and after the intervention. Adolescents in the fluoride varnish group developed significantly fewer white spot lesions between baseline and debonding, and had significantly less progression in white spot lesions than the placebo varnish group.

A second study⁶¹ examined changes in white spot lesions in 3- to 5-year old children living in rural, non-fluoridated communities who received a 4-week treatment with either chlorhexidine varnish, fluoride varnish or a combination of the two, compared with children who received no treatment. Treatment in any of the varnish groups increased white spot lesion remineralisation between 1 and 3 months after treatment compared with the control group. There was some evidence that alternate treatment with chlorhexidine and fluoride

varnishes was more effective than either treatment alone. The performance of the two single varnish treatment groups was similar, with chlorhexidine varnish alone resulting in a lower visible plaque index than fluoride varnish alone, and fluoride varnish having a slightly greater improvement in white spot lesions.

A similar study compared the effectiveness of chlorhexidine varnish, fluoride gel and fluoride varnish in preventing dental caries in children with intellectual disabilities over a 12-month period.⁶² There was some evidence for a higher reduction in mutans streptococci with chlorhexidine varnish, but no difference in plaque scores or 1-year dental caries increment among any of the three treatment agents.

Summary of findings

Compared to placebo or no treatment, fluoride varnishes are effective in preventing dental caries. The magnitude of the benefit appears to vary, with prevention fractions ranging from approximately 20% to 60%, depending on the population and setting. There was little evidence regarding the effectiveness of different frequencies of application, but the current recommendations are for applications twice a year in most groups, possibly increasing this to three applications a year for very-high-risk groups. A twice-yearly application schedule over a period of 24 months was used in most of the larger primary studies.

Several studies have been conducted with high-risk groups: especially young children; those living in low-income, rural or non-fluoridated areas; or those coming from minority communities. In these studies, fluoride varnish was reported as being easy and quick to apply and having a high degree of acceptability with very few adverse effects reported.

One of the included studies included measures of fluorosis, but the Australian consensus guidelines report that there is no increase in fluorosis with the use of fluoride varnish. A Cochrane review protocol⁶³ has been developed for the investigation of fluorosis with the use of fluoride varnishes.

Evidence for the effectiveness of fluoride varnishes compared to other fluoride treatments is limited. There is no clear evidence that professionally-applied fluoride varnish is more effective than other fluoride treatment agents.

Recommendation development

The Expert Advisory Group (EAG) discussed the fact that fluoride varnishes are prescription medicines and should be used by practitioners consistent with the requirements of the Medicines Act and associated regulations.

The Group also discussed the need for training in the use of fluoride varnishes and agreed on the importance of practitioners understanding the mechanism of action, carrying out a risk assessment, having knowledge of toxicology and its safe use and handling, and also the clinical techniques to be used.

The EAG discussed the appropriate application of fluoride varnishes and considered the evidence that there is no demonstrated benefit for more than twice-yearly application; three to four applications per year does not add any benefit and less frequently than twice per year does not provide adequate dental caries benefit. There was no evidence supporting the spot application of fluoride varnish, and the EAG agreed that application to all teeth was appropriate. It was decided that fluoride varnish should be applied at 6-monthly intervals and that it was beneficial to apply the varnish to all erupted teeth.

In developing the recommendations, the EAG considered what the appropriate lower age limit was for fluoride varnish use. There was a greater volume of evidence showing its effectiveness in younger age groups and the EAG also took practicality into account; there are usually enough teeth erupted by 12 months, and this age fits with the oral health assessments both in the Well Child programme and early childhood dental caries-preventive approaches in the oral health services.

It was decided that fluoride varnish could be applied to children from the age of 12 months.

Table 3.5 provides a guide to the amounts of fluoride varnish and the percentage of the probable toxic dose (PTD) for each formulation for children weighing 10 kg or 20 kg.

Table 3.5 Amount of fluoride and percentage of probable toxic dose

Formulation	Fluoride concentration (mg/ml)	Amount dispensed*	Fluoride content	Percentage of PTD for 10 kg child [§]	Percentage of PTD for 20 kg child [§]
5% NaF varnish	22.6	0.25 ml [†]	5.7 mg	11.40%	5.7%
5% NaF varnish	22.6	0.4 ml [‡]	9.0 mg	Not recommended	9.0%
1.23% APF gel	12.3	5 ml [†]	61.5 mg	Not recommended	61.5%
2% NaF gel	9.1	5 ml [†]	45.5 mg	Not recommended	45.5%

NaF=sodium fluoride; APF=acidulated phosphate fluoride

* Maximum amount required to provide a fluoride treatment to all erupted teeth

[†] Deciduous dentition

[‡] Following eruption of first permanent molars

[§] The probable toxic dose (PTD) is considered to be 5 mg/kg. Average weight for a 1-year old child is 10 kg, and 20 kg for a 5- to 6-year old child

Recommendations

Professionally-applied, high-concentration fluoride varnishes are not recommended in people with low risk of dental caries

Professionally-applied, high-concentration fluoride varnishes may be used for people aged over 12 months who are at high risk of dental caries

- Fluoride varnish applications should be applied at 6-monthly intervals as part of a preventive oral health plan
- Fluoride varnish should be applied to all erupted teeth
- Health practitioners applying fluoride varnish should have appropriate training

4 Fluoride mouthrinse

The most common fluoride compound used in mouthrinse is sodium fluoride. Over-the-counter solutions with concentrations less than 0.05% sodium fluoride (225 ppm fluoride) for daily rinsing are available for public use. However, this section focuses on professionally-prescribed mouthrinses specifically for dental caries control (where the only active ingredient is fluoride), rather than those available in supermarkets. The use of mouthrinse is an adjunct and does not replace the need for brushing with fluoride toothpaste.

Prescription mouthrinses are more effective for those at high risk for dental caries.

Body of evidence

Guidelines

The Australian consensus guidelines⁴³ indicated that some of the research underpinning fluoride mouthrinse comes from international trials of supervised mouthrinse programmes for particular sub-populations (such as school children), but that no such programmes were being pursued in Australia at the time of publication. The guidelines also highlighted the appeal of mouthrinse in the adolescent age groups and warned that this should not be a substitute for tooth-brushing. Ingestion of fluoride mouthrinses by children younger than 6 years is concerning due to possible adverse effects in that age group.

The Australian Consensus Guidelines presented the following recommendations for the use of fluoridated mouthrinse:⁴³

- children below the age of 6 years should not use fluoride mouthrinse
- fluoride mouthrinse may be used by people aged 6 years or more who have an elevated risk of developing dental 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.

One additional guideline was identified which made recommendations on the use of fluoride mouthrinse; an American conference paper by Adair.⁴⁴ One systematic review by the National Health and Medical Research Council (NHMRC) was identified reporting on fluoride mouthrinse.⁴⁵ Both the guideline and systematic review include reviews by Marinho¹⁵ and Twetman.⁶⁴ Two additional primary studies were identified^{65, 66} and are summarised in the section titled, 'Primary studies'.

An American conference paper presented guidelines for the use of fluoride mouthrinse in children.⁴⁴ The guidelines highlighted the issue of swallowing mouthrinse and suggested that they only be used in children older than 6 years.

- Fluoride mouthrinses should be reserved for use with children judged to be at moderate or high risk for dental caries, including children with fixed orthodontic or prosthetic appliances and those with reduced salivary flow
- Daily use of an over-the-counter 0.05% NaF rinse in a swish-and-expectorate regimen is as effective as a prescription rinse that is swallowed after rinsing
- Little additional benefit should be expected from fluoride mouthrinses in low-dental caries-risk children who are already using fluoridated toothpaste
- Fluoride mouthrinses should be recommended only for those children who have demonstrated mastery of their swallowing reflex
- Where available, alcohol-free preparations should be recommended over those containing alcohol

Systematic reviews

The NHMRC based much of its review on work by Marinho¹⁵ and cited summary tables in their text (see Tables 4.1 and 4.2).

Table 4.1 Fluoride mouthrinse versus placebo/no treatment

Outcome	Comparison	Number of included studies	Heterogeneity	Prevention fraction (95%CI)
DMFS increment	Fluoride mouthrinse vs placebo	30	p=0.009	PF 0.26 (0.22, 0.29), p<0.001
	Fluoride mouthrinse vs no treatment	4	p=0.79	PF 0.33 (0.27, 0.40), p<0.001
DMFT prevention fraction	Fluoride mouthrinse vs placebo	13	p=0.01	PF 0.24 (0.18, 0.30), p<0.001

DMFS=decayed, (missing) and filled surfaces prevented fraction; p=p-value; PF=prevention fraction; DMFT=decayed, (missing) and filled teeth prevented fraction

Source: National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation: Australian Government. Copyright Commonwealth of Australia; adapted with permission.

Compared to placebo or no treatment, fluoride mouthrinse improves the prevention fraction for dental caries.

Table 4.2 Fluoride mouthrinse versus other topical fluoride treatments

Outcome	Comparison	Number of included studies	Prevention fraction (95% CI)
DMFS	Varnish vs mouthrinse	4	PF 0.10 (-0.12–0.32)
Withdrawals	Varnish vs mouthrinse	2	PF 1.18 (0.85–1.64)
DMFS	Gel vs mouthrinse	1	PF -0.14 (-0.40–0.12)
DMFS	Toothpaste vs mouthrinse	6	PF 0.00 (-0.18–0.19)
Withdrawals	Toothpaste vs mouthrinse	5	PF 0.89 (0.78–1.00)

DMFS=decayed, (missing) and filled surfaces prevented fraction; PF=prevention fraction

Source: National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation: Australian Government. Copyright Commonwealth of Australia; adapted with permission.

Evidence for the effectiveness of mouthrinse compared with other fluoride treatments is limited and inconclusive.

Primary studies

The two primary studies that were identified are summarised in Table 4.3.

Table 4.3 Included primary studies for fluoride mouthrinse

Citation and type of study	Type of study and number and age of participants	Intervention	Comparison	Outcome measures and follow-up	Results	Summary
Ogaard 2006 Sweden Double blind RCT	Age: Not reported n = 115 Participants: scheduled to receive fixed orthodontic appliances	AmF/SnF ₂ toothpaste and mouthrinse	NaF toothpaste and NaF mouthrinse	White spot lesion (WSL) development, plaque and gingivitis Follow-up: 1.5 years	Increase in WSLs on upper anterior teeth was 4.3% in AmF/SnF ₂ and 7.2% in the NaF group	Combined use of AmF/SnF ₂ toothpaste and mouthrinse had a slightly more inhibitory effect on WSL development, plaque and gingivitis compared with NaF
Duarte 2009 Brazil Double-blind RCT	Age: 11–15 years n = 170 Participants: children with active smooth surface dental caries lesions	0.05% NaF	NaF + Chlorhexidine digluconate	Arrested lesions defined as a white spot situated far from a healthy gingival margin Follow-up: 28 days	Arrested lesions NaF = 84.4% NaF + CHX = 85.3% p = 0.71	No significant differences were found between the groups. Taking into account age and gender did not alter results

RCT = randomised controlled trial; n = number; AmF = amine fluoride; SnF₂ = stannous fluoride; NaF = sodium fluoride; CHX = chlorhexidine; p = p-value

A Swedish study investigated the combined effect of toothpaste and mouthrinse on the development of white spot (initial dental caries) lesions. There was no significant difference in white spot lesions in the group assigned to AmF/SnF₂ at bonding of orthodontic appliances and de-bonding (1.02 vs 1.05, p=0.14) while the group assigned to NaF combination treatment showed a significant increase (1.00 vs 1.08, p=0.01) following de-bonding. The actual increase in white spot lesions on upper anterior teeth was 4.3% in the AmF/SnF₂ group and 7.2% in the NaF group.⁶⁶

A Brazilian study carried out in a public school investigated the additional effect of adding chlorhexidine (CHX) to a sodium fluoride (NaF) mouthrinse for arresting active enamel dental caries lesions. Although both solutions showed high arrestment proportions, the addition of CHX did not improve the arrestment capacity of the NaF mouthrinse.⁶⁵

Summary of findings

Compared to placebo or no treatment, fluoride mouthrinse solutions containing strengths at or above 0.05% sodium fluoride (225 ppm fluoride) are effective in preventing dental caries. There is no evidence of therapeutic benefit from low-strength fluoride mouthrinse preparations available without prescription. Compared to other fluoride interventions and in combination with other interventions, the place of fluoride mouthrinse is unclear.

Recommendation development

In developing the recommendations, the Expert Advisory Group (EAG) discussed the differences between high strength fluoride mouthrinses prescribed by oral health professionals for preventing dental caries, and mouthrinse available for public use which can be bought at supermarkets or pharmacies. For children and adults at high risk of dental caries, a fluoride mouthrinse for home use may be beneficial provided that the patient is motivated to use it.

Several mouthrinses are available for retail purchase that contain low levels of fluoride. There is no evidence of therapeutic benefit from these low-strength fluoride preparations.

The EAG discussed the timing of using fluoride mouthrinses, particularly considering some of the international literature advocates using toothpaste and mouthrinses at different times (ie, not both together, at the same time of day). Although some guidelines recommend not using these products at the same time, the EAG did not find evidence of harm and discussed the potentially higher rate of compliance when used with toothpaste. It was decided that, if people are using mouthrinse, then there was no harm in using it at the same time as brushing.

The EAG considered and agreed with the statement from the Adair conference paper that 'where available, alcohol-free preparations should be recommended over those containing alcohol'.

Although Medsafe reports no problems with small amounts of alcohol in fluoride mouthrinses, the EAG preferred that younger children were not exposed to it. A further statement from the Adair paper was discussed and the EAG agreed that 'fluoride mouthrinses should be recommended only for those children who have demonstrated mastery of their swallowing reflex'.

Although there is always going to be some ingestion with this method of topical fluoride application, the group decided that children under the age of 6 years (or who could not expectorate the mouthrinse) should not use such preparations. The 6-year age limit was decided upon, mainly because packaging of such products is usually labelled for people aged 6 years and over.

Recommendations

Fluoride mouthrinses are not recommended for children aged under 6 years or people aged 6 years and over who are at low risk of dental caries

Fluoride mouthrinse may be used by people aged 6 years and over who are at high risk of developing dental caries

- After rinsing, mouthrinse should be spat out, not swallowed
- Fluoride mouthrinse should be used as part of a preventive oral health plan

5 Topical fluoride gels and foams

Fluoride gels and foams contain a high concentration of fluoride and are applied by oral health professionals using trays which retain the gel or foam on the teeth for the prescribed time.⁶⁷ Fluoride gels are available in a neutral sodium fluoride (NaF) preparation and an acidulated phosphate fluoride preparation. The neutral sodium fluoride oral solution is a non-acidic fluoride that is safe for patients with porcelain or composite restorations and sealants. Most fluoride gel and foam applications are delivered in a dental office by an oral health professional; if these high strength products are used at home, they must be prescribed by a dentist or physician. New Zealand supermarkets can sell fluoride gels at 1000 ppm, the same strength as toothpaste. Another gel product, with the higher concentration of 5000 ppm, is available as a pharmacy only medicine for home use.

Body of evidence

Guidelines

The Australian consensus guidelines⁴³ highlighted the effectiveness of fluoride foams and gels in children, but also recognised their contraindication for children aged under 10 years where large amounts could be ingested. The guideline also reported that fluoride gels and foams are more efficacious in preventing dental caries in the permanent than primary dentition.

The Australian consensus guidelines present the following recommendation for the use of fluoride gels and foams:⁴³

- high concentration of fluoride gels and foams (those containing more than 1.5 mg/g fluoride ion) may be used for people aged 10 years or more who are at an elevated risk of developing dental caries in situations where other fluoride vehicles may be unavailable or impractical.

For topical fluoride gels, two additional guidelines were available which make recommendations on the use of fluoride gels: the American Dental Association⁴² and American conference report.⁴⁴ One systematic review by the National Health and Medical Research Council (NHMRC)⁴⁵ was identified investigating the use of fluoride mouthrinse.

Both American guidelines and the NHMRC review include the systematic reviews by Marinho¹⁵ and van Rijkom.⁶⁸ It is unclear which reviews were included in the development of the Australian consensus guidelines.

Two additional primary studies were identified^{65, 66} and are summarised in the section titled, 'Primary studies'.

For fluoride foams, one guideline by the American Dental Association,⁴² one systematic review by the NHMRC⁴⁵ and one additional primary study⁶⁹ investigating the use of fluoride foams were identified.

For topical fluoride gels, guidelines from the American Dental Association⁴² conclude that fluoride gel is effective in preventing dental caries in school-aged children. They go on to recommend the following:

- that high-risk children younger than 6 years be given fluoride varnish treatment over fluoride gel because of the higher concentration of fluoride found in gel and because it reduces the risk of ingestion
- high-risk children aged 6–18 years should receive fluoride varnish or gel application at 6-monthly intervals; 3-monthly intervals may provide additional dental caries prevention benefit
- adults over 18 years at moderate risk should receive fluoride varnish or gel application at 6-monthly intervals. For higher-risk persons, 3- to 6-monthly intervals
- application time for fluoride gel should be 4 minutes.

An American conference paper presents guidelines for the use of fluoride gels and foams in children.⁴⁴

- Use a dental caries risk assessment to determine the need for and frequency of professionally-applied fluoride gel/foam
- Follow a pumice prophylaxis with a topical fluoride application to replace the surface fluoride layer removed by the prophylaxis
- During professional application of fluoride gel or foam, reduce the likelihood of unwanted ingestion by using properly fitted application trays. Fill the trays with only enough product to cover the teeth. Seat the patient upright, and place a saliva ejector in the mouth between the upper and lower trays during administration. Have the patient lean forward slightly and allow excess saliva to drip into a cup. Apply the fluoride gel/foam for 4 minutes
- Allow the patient to expectorate freely after application. Have the patient refrain from eating or drinking for 30 minutes following the application

For fluoride foams, guidelines from the American Dental Association⁴² conclude that 4 minutes fluoride foam applications are effective in dental caries prevention in the primary dentition and newly erupted permanent first molars. However, the panel was reluctant to make a recommendation for the use of foams due to a lack of evidence.

Fluoride foam requires a smaller amount for application than fluoride varnish and gel, resulting in lower fluoride concentration, thereby reducing the risk associated with inadvertent ingestion.

Systematic reviews

The Australian NHMRC review⁴⁵ aimed to investigate the effectiveness of topical fluoride treatments and was based mainly around one comprehensive systematic review by Marinho¹⁵ which took into account four previously-conducted Cochrane reviews and 144 primary trials. The main findings of the fluoride gel comparisons are presented in Tables 5.1 and 5.2.

Table 5.1 Gel versus placebo/no treatment

Outcome	Comparison	Number of included studies	Heterogeneity	Prevention fraction (95% CI)
DMFS	Fluoride gel vs placebo	13	$p=0.07$	PF 0.21 (0.14, 0.28) $p<0.001$
	Fluoride gel vs no treatment	9	$p<0.001$	PF 0.38 (0.23, 0.52) $p<0.001$
DMFT	Fluoride gel vs placebo	4	$p=0.35$	PF 0.18 (0.09, 0.27) $p<0.001$
	Fluoride gel vs no treatment	6	$p<0.001$	PF 0.43 (0.29, 0.57) $p<0.001$
Defs prevention fraction [†]	Fluoride gel vs placebo	2	$p=0.11$	PF 0.26 (-0.11, 0.63) $p=0.2$

DMFS=decayed, (missing) and filled surfaces prevented fraction; p = p -value; PF=prevention fraction; DMFT=decayed, (missing) and filled teeth prevented fraction; Defs prevention fraction=decayed, (missing/extraction indicated), and filled surfaces prevented fraction [d(m/e)fs PF]

Source: National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation: Australian Government. Copyright Commonwealth of Australia; adapted with permission.

Compared to placebo or no treatment, fluoride gel improves the prevention fraction for dental caries.

Table 5.2 Fluoride gels versus other topical fluoride treatments

Outcome	Comparison	Number of included studies	Prevention fraction (95% CI)
DMFS	Varnish vs gel	1	PF 0.14 (-0.12, 0.40)
DMFS	Gel vs mouthrinse	1	PF -0.14 (-0.40, 0.12)
DMFS	Toothpaste vs gel	3	PF 0.00 (-0.21, 0.21)

DMFS=decayed, (missing) and filled surfaces prevented fraction [d(m)fs pf]; PF=prevention fraction

Source: National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation: Australian Government. Copyright Commonwealth of Australia; adapted with permission.

There is no clear evidence that any other topical fluoride treatment is more or less effective than fluoride gels.

In addition to the Marinho review, the NHMRC review identified two studies that assessed the use of fluoride gel compared with no treatment in children with low risk of dental caries by Truin⁷⁰ and van Rijkom.⁷¹ Children were aged a mean 5.5 years in one study and 10.5 years in the other and both studies followed children for 4 years. Truin found no difference between fluoride gel and placebo ($p=0.30$), while van Rijkom found gel to be significantly beneficial ($p=0.03$). Two further studies compared a combination of fluoride toothpaste and gel with no toothpaste or gel; one study showed significant benefit of toothpaste and gel,⁷² the other showed no significant differences.⁷³

For fluoride foams, the Australian NHMRC review⁴⁵ identified one study that assessed the use of fluoride foam and gel compared to no treatment in children aged 6 to 7 years old.⁷³ This study had a follow-up time of 2 years and found no significant differences between those receiving fluoride foam and those who did not.

Primary studies

Two recent additional studies were identified and are summarised in Table 5.3.

Table 5.3 Included primary studies for fluoride gels and foams

Citation and study quality	Type of study and number and age of participants	Intervention	Comparison	Outcome measures and follow-up	Prevention fraction	Summary
Truin, 2007 Netherlands Qual: +	Double blind RCT n = 516 Age: 9.5–11.5 years	Fluoride gel 0.4%–0.6% (n = 261)	Placebo (n = 255)	Enamel and dentine dental caries lesions Follow-up: 4 years	Enamel dental caries 0.23 (SE, 0.10) Dentinal dental caries 0.18 (SE 0.12)	Fluoride gel showed no statistically significant effect on enamel or dentine dental caries in the permanent dentition of low-dental caries children
Xu, 2009 China Qual: +	Double-blind RCT n = 61	Povidine-iodine/ fluoride foam Applied once a week for 4 weeks	Fluoride foam	Follow-up: 12 months	Mean values of DIAGNOdent readings in permanent first molars Experimental group: 14.20 ± 7.29 Control group 14.40 ± 6.93:	No statistically significant difference Note: Study was powered to determine the difference in bacteria levels and the authors state that a follow-up time of 18 months is required to detect a change in dental caries level

RCT = randomised controlled trial; n = number; SE = standard error

A study conducted in The Netherlands investigated the cariostatic efficacy of semi-annual professional fluoride gel application on incipient carious lesions in low-dental caries children aged 9.5 to 11.5 years; this study is a more recent report of the earlier 2005 publication reported in the NHMRC systematic review (see previous section, 'Systematic reviews'). Fluoride gel continued to show no statistically significant effect on enamel or dentine dental caries in the permanent dentition of low-dental caries children.⁷⁴

For fluoride foams, one study was found comparing povidine-iodine/fluoride foam with fluoride foam in a high-dental caries-risk population, (defined as children with at least one active dental caries lesion within the last year).⁶⁹ No statistically significant differences were evident between the two groups in dental caries lesions over a period of 1 year. The authors concluded that the evidence is lacking for the use of povidone-iodine and fluoride to achieve a better dental caries-prevention effect in high-dental caries-risk populations.

Summary of findings

Previous guidelines have considered fluoride gels to be effective in preventing dental caries. Systematic reviews by Marinho¹⁵ and van Rijkom⁶⁸ on which the guidelines and NHMRC review were based, found overall reductions in dental caries incidence in low dental caries children; however, evidence is lacking for the primary dentition. The effectiveness of fluoride gel is unknown in children who are at high risk of dental caries.

There is limited evidence for the effectiveness of fluoride foam. Previous guidelines and systematic reviews have identified one RCT that found no significant difference between fluoride gel and foam. For younger age groups the risk of inadvertent ingestion of fluoride foam is an important consideration. The Australian guideline recommends the use of fluoride foams for those at high risk (over 10 years of age).

No information was available on the risk of fluorosis.

Recommendation development

The Expert Advisory Group (EAG) agreed that fluoride gels should be professionally applied. Home use of fluoride gels is not recommended because of the risk of ingesting excessive fluoride, and it may cause gastritis. The EAG also discussed the availability of gels in New Zealand. Acidulated and neutral gels are available; however, there is no evidence that one is more effective than the other, and there are safety concerns with acidulated gels. It was decided that neutral gels are preferable in patients with porcelain and composite restorations.

In developing the recommendations, the EAG considered and agreed with the American Dental Association Guideline statement that 'high-risk children aged 6 to 18 years should receive fluoride gel application at 6-monthly intervals; 3-monthly intervals may provide additional caries prevention benefit',⁴² and also with the statement from the Adair conference paper that 'fluoride foam requires a smaller amount for application compared with fluoride varnish and gel, resulting in lower fluoride dose thereby reducing the risk associated with inadvertent ingestion. There are fewer studies showing effectiveness of fluoride foams than fluoride gels.'⁴⁴

The EAG discussed the appropriate application of gels and foams and discussed two studies conducted in the 1970s, where trays were filled to the top (ie, they were overloaded) and where the excess was not suctioned or wiped out of the mouth. The EAG expressed concern that the inappropriate application of gels and foams could cause fluorosis, and increase the risk of ingesting high amounts of fluoride. The Adair conference paper provides useful instructions on the application of fluoride gels and/or foams that the EAG saw as a valuable adjunct to the recommendations.

During professional application of fluoride gel or foam, reduce the likelihood of unwanted ingestion by using properly fitted application trays. Fill the trays with only enough product to cover the teeth. Seat the patient upright, and place a saliva ejector in the mouth between the upper and lower trays during administration. Have the patient lean forward slightly and allow excess saliva to drip into a cup. Apply the fluoride gel/foam for 4 minutes.

Recommendations

Professionally-applied, high-concentration fluoride gels and foams are not recommended for children under 6 years or people aged 6 years and over who are at low risk of dental caries

Professionally-applied, high-concentration fluoride gels and foams may be used for people aged 6 years and over who are at high risk of dental caries

- Fluoride gel applications should be applied at 3- to 6-monthly intervals as part of a preventive oral health plan
- Neutral gels are preferable to acidulated gels in people with porcelain and composite restorations

6

Fluoride tablets

Fluoride tablets have long been advocated in areas without water fluoridation. Some studies with supervised use have shown benefits; however, other studies relying on compliance have not shown the same benefits. The possible risk of fluorosis in children, particularly in preschoolers, has led to the Australian guidelines not recommending their use. Since the early 1990s, New Zealand (along with Australia) agreed that fluoride tablets were no longer suitable as a public health measure. There are still cases where fluoride tablets may be beneficial to individuals and recommended by oral health professionals, although the availability of fluoride tablets in New Zealand is limited.

Body of evidence

Guidelines

The Australian consensus guidelines⁴³ reported varied effectiveness of fluoride supplements; studies with supervised use have shown greater benefit (eg, school programmes) while studies relying on at-home compliance have shown little benefit. The guidelines also report the significant increase of fluorosis in preschool-aged children and revision of the supplement guideline over time where age-specific daily intakes of fluoride for children under 6 years have been substantially reduced.

The Australian consensus guidelines present the following recommendation for the use of fluoride supplements:⁴³

- fluoride supplements in the form of drops or tablets to be chewed and/or swallowed should not be used.

One additional guideline, an American conference paper by Adair,⁴⁴ and one systematic review⁷⁵ were identified which made recommendations on the use of fluoride tablets.

An American conference paper presents guidelines for the use of fluoride tablets in children.⁴⁴ The guidelines highlight the difficulties in obtaining high-quality research in this area because the majority of studies on fluoride supplements were carried out between 1950 and 1970; this was a time when other fluoride sources were limited, many studies lacked randomisation or control groups and there were often vast differences in baseline dental care between study groups.

The guideline makes the recommendations below.

- Prior to prescribing fluoride supplements, assay the child's primary drinking water supply for fluoride content. In addition, practitioners should consider other sources of fluoride exposure for their patients, particularly toothpaste use. For example, children in rural communities may be exposed to fluoride-deficient water at home, but may receive optimally fluoridated water at school or day-care settings. Consider supplementing only those children residing in fluoride-deficient communities with inadequate exposure to other fluoride sources who are at risk of dental caries, as demonstrated by a dental caries risk assessment
- Consider delaying supplementation until after the eruption of the permanent first molars. Evidence for the effectiveness of systemic fluoride supplementation prior to this age is not strong and does not support a specific recommendation for use prior to age six. On the other hand, the age group at highest risk for fluorosis supplements appears to be 3 to 6 years
- Ensure parents understand the risks and benefits of systemic fluoride supplementation. If supplements are prescribed, ensure that the parents understand the importance of complying with the supplementation regimen
- Prescription directions should state that fluoride supplements are to be dissolved in the mouth or chewed and swished prior to swallowing to enhance the topical effect
- As a safety factor, a maximum of 120 mg of fluoride ion should be prescribed at one time. This amount would be a certainly lethal dose only for those children weighing less than 8 kg and would be a probably toxic dose in children weighing 24 kg or less
- No good evidence exists to support fluoride supplements for pregnant women. Supplementation is not likely to cause harm. Data from a single RCT in a fluoride deficient community indicated that prenatal fluoride supplementation is of no benefit to the primary teeth of offspring, provided that the children receive postnatal fluoride exposure via toothpaste and supplements

Systematic reviews

A systematic review prepared for the American Dental Association Council for use in the 2009 guidelines (anticipated publication, summer 2009) investigated the effectiveness of fluoride supplements in preventing dental caries and their association with fluorosis.⁷⁵

For children aged under 3 years, the review identified limited evidence showing a reduction in dental caries, but the quality of included studies was poor. In children aged 3 to 6 years, there is evidence that children who received fluoride tablets had significantly fewer dental caries; however, the majority of studies were conducted in the 1970s when fluoride toothpaste was not commonplace. A more recent study in children aged 12 years showed that daily use of fluoride supplements over a 5-year period was not effective in reducing dental caries.

Five studies were identified investigating the risk of fluorosis in children receiving fluoride supplements. All five studies showed greater fluorosis incidence in children who had taken supplements, particularly in young children.

Summary of findings

Evidence for dental caries prevention using fluoride tablets is limited. Previous guidelines and systematic reviews have shown inconsistent evidence of effectiveness in different age groups, and, overall, the quality of the reviewed studies was low.

The evidence for greater fluorosis in children who receive fluoride supplements is fairly consistent. Fluoride supplement use during the first few years of life is associated with a higher risk of fluorosis. There is some evidence that the first year of life is the most important for this.

Recommendation development

Fluoride provided in tablet form (most commonly sodium fluoride) when used constantly and reliably, has been shown to have approximately the same effectiveness in dental caries prevention as for water fluoridation.

As with fluoridated water, research shows that the effect of fluoride from tablets is primarily topical, both from dissolving in the mouth, and systemically, from increasing fluoride in the saliva. They should therefore be chewed or sucked to enhance their topical effectiveness.

However, unlike water fluoridation – which delivers frequent low levels of fluoride to the saliva – fluoride tablets deliver occasional episodes of higher levels of fluoride to the saliva. Scientific knowledge about the risk period and mechanisms for developing fluorosis indicates that prescribing fluoride tablets for children under the age of three years is not desirable.

Furthermore, it has been shown that fluoride supplements have a limited application as a population health measure because compliance with the daily regimen is poor and the children who use them are normally from the more health-conscious families. Because there is no firm evidence of benefit from use of fluoride tablets by pregnant women (and in line with the general policy that unnecessary tablets should be avoided during gestation), fluoride tablets should not be taken during pregnancy.

Thus, fluoride tablets have a very limited application and are no longer recommended as a population health measure in New Zealand. Fluoride tablets should now be considered to be a personal health measure for individual recommendation by oral health professionals for at-risk individuals. In areas where there is less than 0.3 parts per million (ppm) fluoride in the water supply, fluoride tablets still have a useful role and can be recommended throughout an individual's lifetime for use during particular periods when there is a high risk of dental caries.

Tablets should be chewed, sucked or dissolved in drinking liquid. A 1.1 mg sodium fluoride tablet contains 0.5 mg fluoride ion, and therefore 2 x 1.1 mg sodium fluoride tablets dissolved in New Zealand drinking water that has not been adjusted to the optimal water fluoridation level will result in water with approximately 1 mg/L fluoride (1 ppm).

There are few studies showing effectiveness of fluoride tablets in adults; indeed, given the mechanism of action for fluoride, there is reason to believe that fluoride tablets may be beneficial in adults with high dental caries risk.

Table 6.1 provides a guideline to the required amount of fluoride tablet by age.

Table 6.1 Fluoride tablet recommendations		
Age	Daily fluoride intake	Tablet equivalent (1.1 mg NaF)*
3–5 years	0.25 mg fluoride/day	½ tablet
6–8 years	0.5 mg fluoride/day	1 tablet
9 years and over	1.0 mg fluoride/day	2 tablets

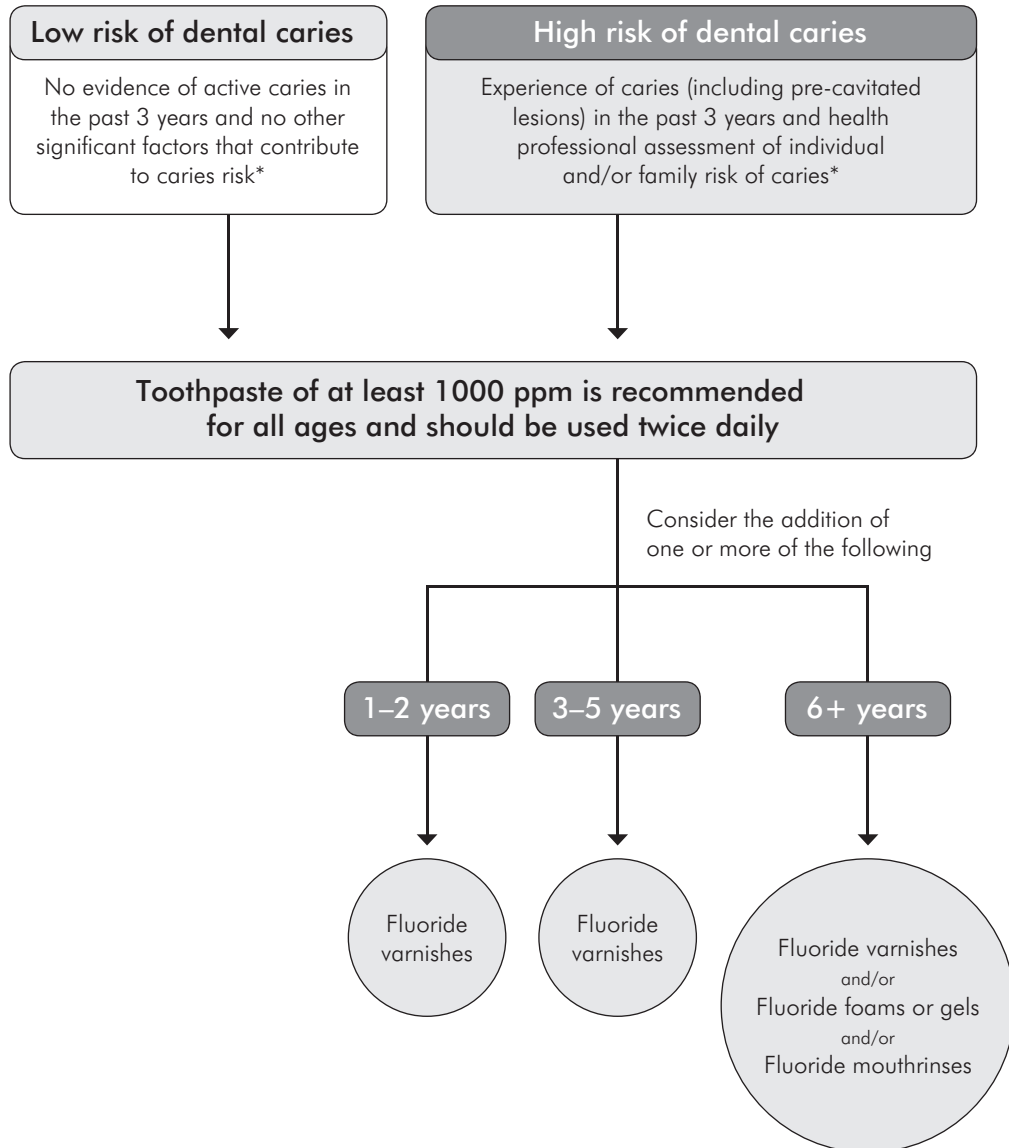
NaF=sodium fluoride

* Each 1.1 mg NaF tablet contains 0.5 mg fluoride ion

Recommendations
Fluoride tablets are not recommended as a population health measure in New Zealand
Fluoride tablets may be recommended for those aged 3 years and over at high risk of dental caries (see Table 6.1)
Tablets should be chewed or sucked, or dissolved in drinking liquid

7 Fluoride algorithm

Algorithm Guidelines for the use of fluorides



***Dental caries risk factors:** Socioeconomic deprivation, suboptimal fluoride exposure, ethnicity, poor oral hygiene, prolonged bottle feeding, poor family dental health, enamel defects, eating disorders, irregular dental care, high sugar diet, high carbohydrate diet (in people with complex medical conditions), active orthodontic treatment, low salivary flow

8 Horizon scanning

Fluoride drops are not currently available in the New Zealand market and were not included as part of this review. The Expert Advisory Group expects the evidence for drops to be similar to the evidence for fluoride tablets. They are designed for use in children aged under 3 years and are in the same dose range as tablets, and should be used subject to the same guidance should they become available.

Appendix A:

Development process

The Ministry of Health suggested using the Australian Consensus Guidelines⁴³ as a base to develop New Zealand specific recommendations. This guideline was updated with a systematic review of international literature published since 2006 restricted to randomised controlled trials (RCTs) or systematic reviews (please see Appendix B for a list of search databases used).

Guidelines identified were appraised using the Appraisal of Guidelines Research and Evaluation (AGREE) tool,⁷⁶ and systematic reviews and RCTs using the Scottish Intercollegiate Guidelines Network (SIGN) tools for appraising study quality. Because of the complexity of fluoride use in New Zealand, specifically different dental caries risk groups and dietary intake issues, searches were supplemented with New Zealand-specific research (mid-1970s onwards) and additional literature was identified and put forward by Expert Advisory Group members.

Evidence was summarised as it applied to various age groups, level of risk and dietary intake, and recommendations were developed through a consensus process over two meetings. The inclusion criteria in Appendix B were applied when selecting articles for review.

Members of the Expert Advisory group

Dr Robin Whyman (Chair)

Chief Dental Officer, Ministry of Health, Wellington

Erin Beatson

Clinical Advisor, Royal New Zealand Plunket Society, Wellington

Claire Caddie

Service Manager, Audiology, Oral and Preventative Programmes, Maternal, Child and Youth Continuum, Hawkes Bay

Bernadette K Drummond

Associate Professor, Paediatric Dentistry, Associate Dean Postgraduate Studies, University of Otago, Faculty of Dentistry, Dunedin

Barbara Hegan

Analyst, Nutrition and Physical Activity Policy, Health and Disability Services Policy Group, Population Health Directorate, Ministry of Health, Wellington

Debbie Jennings

Clinical Team Leader, School Dental Service, Hutt Valley DHB

Dr Pauline Koopu

Public Health Dentist, Tumuaki, Te Ao Marama (The New Zealand Māori Dental Association), Rotorua

Dr Martin Lee

Public Health Dentist, Clinical Director, Community Dental Service,
Canterbury District Health Board, Christchurch

W. Murray Thomson

Professor Dental Epidemiology and Public Health, Department of Oral Sciences,
Sir John Walsh Research Institute, Faculty of Dentistry, The University of Otago, Dunedin

New Zealand Guidelines Group Team

Jessica Berentson-Shaw, Research Manager (until July 2009)

Anne Lethaby, Interim Research Manager (from July 2009)

Catherine Coop, Researcher

Anita Fitzgerald, Senior Researcher

Meagan Stephenson, Researcher

Margaret Paterson, Information Specialist

Leonie Brunt, Publications Manager

Peer reviewers

Sathananthan Kanagartanam, Dental Public Health Specialist, Clinical Director,
Auckland Regional Dental Service, Auckland

Wendell Evans, Colgate Associate Professor, Population Oral Health,
Univeristy of Sydney; Centre for Oral Health, Westmead Hospital, Sydney

Appendix B:

Methods

Inclusion and exclusion criteria

Groups that were covered include:

- the New Zealand population – all age groups
- a strong focus on children and at-risk populations – especially Māori.

Health care setting covered include:

- oral health services
- primary care.

Interventions that were covered include:

- fluoride tablets
- fluoridated toothpastes
- topical fluoride gel
- fluoride foams
- fluoride varnish
- fluoride mouthrinses.

The development of recommendations relating to the majority of these interventions were drawn from existing guidelines and systematic reviews with an update of key publications; however three topic areas were more thoroughly reviewed:

- fluoridated toothpastes
- fluoride varnish
- dietary intake of fluoride (note that this will not be developed into a discrete set of recommendations, rather the purpose of reviewing this literature is to provide data that will inform all the other recommendations, that is, ensuring the recommendations are within safe level for dietary intake of fluoride).

Topics that were not covered include:

- fluoridation of community water supplies
- fluoridation of bottled water.

Clinical questions

1. What is the effectiveness of fluoride toothpaste in the prevention of dental caries?
2. Does the use of fluoride toothpaste increase the risk of dental fluorosis?
3. What is the effectiveness of fluoride varnishes in the prevention of dental caries?
4. Does the use of fluoride varnishes increase the risk of dental fluorosis?
5. What is the effectiveness of fluoride mouthrinse in the prevention of dental caries?
6. Does the use of fluoride mouthrinse increase the risk of dental fluorosis?
7. What is the effectiveness of fluoride gel in the prevention of dental caries?
8. Does the use of fluoride gel increase the risk of dental fluorosis?
9. What is the effectiveness of fluoride tablets in the prevention of dental caries?
10. Does the use of fluoride tablets increase the risk of dental fluorosis?

Search strategy

Searches were completed in May 2009 using the following criteria:

- **Participants:** all ages, living in fluoridated and non-fluoridated water areas, with particular focus on high-risk and young children (0–2 years)
- **Interventions:** gels, foams, tablets mouthrinse, toothpaste, varnish
- **Comparison:** placebo, no treatment, other topical fluoride intervention
- **Outcomes:** dental caries, fluorosis
- **Study type:** systematic reviews and randomised controlled trials
- **Years:** 2006 onwards.

For fluoride mouthrinse, gels, foams and tablets, 132 papers were identified from which there were 122 exclusions. Of the 10 relevant articles, 3 were guidelines, 2 were systematic reviews and 5 were primary studies.

For fluoride toothpastes and varnishes, 232 papers were identified from which there were 214 exclusions. Of the 18 relevant articles, 3 were guidelines, 6 were systematic reviews and 9 were primary studies.

The majority of evidence identified in the guidelines and systematic reviews was based on previous work by *Marinho and colleagues*;¹³ several reviews have been undertaken by this group investigating topical fluoride treatments both alone and in combination, the most recent work being a Cochrane review including all topical interventions. Where much of the evidence has stemmed from this review, and where it has been the underpinning of guideline recommendations, the results directly from the review have been cited.

Search databases

The literature search was conducted on the basis of the areas noted above. The following search bibliographic, HTA and Guideline databases were included in the search:

1. MEDLINE
2. EMBASE
3. CINAHL
4. Cochrane Library
5. National Guideline Clearing House (NGC) www.guideline.gov
6. U.S. Preventive Services Task Force (USPSTF) www.ahrq.gov/clinic/uspstfix.htm
7. Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov
8. Health Services Technology/Assessment Text (HSTAT) <http://hstat.nlm.nih.gov>
9. CMA Infobase: Clinical Practice Guidelines (CPGs) www.cma.ca
10. Scottish Intercollegiate Guidelines Network (SIGN) www.sign.ac.uk
11. National Institute for Health and Clinical Excellence (NICE) www.nice.org.uk
12. Guidelines International Network (G-I-N) www.g-i-n.net
13. Canadian Agency for Drugs and Technologies in Health (CADTH) www.cadth.ca
14. Turning Research into Practice (TRIP) www.tripdatabase.com
15. International Network of Agencies for Health Technology Assessment (INAHTA) www.inahta.org
16. Medical Services Advisory Committee (MSAC) www.msac.gov.au
17. Australian and New Zealand Horizon Scanning Network (ANZHSN) www.horizonscanning.gov.au
18. New Zealand Health Technology Assessment (NZHTA) <http://nzhta.chmeds.ac.nz>
19. National Health and Medical Research Council (NHMRC) www.nhmrc.gov.au

Glossary

Aesthetic	concerned with beauty or the appreciation of beauty
Amelogenesis	the formation of the enamel of the teeth
Dental caries	tooth decay
Dentifrice	toothpaste
Enamel	the outer surface of the tooth
Fluorosis	a condition caused by excessive intake of fluorine, characterised chiefly by mottling of the teeth
Public health measure	publicly available and the MOH recommend that people use this intervention
Personal health measure	you/your family have a dental caries problem and your dental practitioner recommends a particular intervention
Skeletal fluorosis	skeletal condition caused by long-term ingestion of excessive amounts of fluoride
Tangata whenua	indigenous people of New Zealand

References

1. Ministry of Health. Good oral health for all, for life: the strategic vision for oral health in New Zealand. Wellington: Ministry of Health; 2006.
Available from: www.moh.govt.nz/moh.nsf/indexmh/good-oral-health-for-all-for-life-fulltext
2. Casamassimo PS, Thikkurissy S, Edelstein BL, et al. Beyond the dmft: the human and economic cost of early childhood caries. *J Am Dent Assoc.* 2009;140(6):650–657.
3. National Health Committee. Improving child oral health and reducing child oral health inequalities. Wellington: National Advisory Committee on Health and Disability; 2003.
4. World Health Organization. Water-related diseases: fluorosis. Geneva: World Health Organization; 2009. Available from: www.who.int/water_sanitation_health/diseases/fluorosis/en/print.html
5. Mackay T. Enamel defects among Southland 9-year-olds [Masters thesis]: The University of Otago; 2003.
6. Cutress TW, Suckling GW. Differential diagnosis of dental fluorosis. *J Dent Res.* 1990;69 Spec No:714–720.
7. Tubert-Jeannin S, Tramini P, Gerbaud L, et al. Fluoride supplements (tablets, drops, lozenges or chewing gums) for preventing dental caries in children (Protocol). *Cochrane Database Syst Rev.* 2009(1):CD007592.
8. Ferreira de Oliveira MA, Celeste R, Rodrigues C. Topical fluoride for treating dental caries (Protocol). *Cochrane Database Syst Rev.* 2002(1):CD003454.
9. Public Health Commission. Fluoride and oral health: the Public Health Commission’s advice to the Minister of Health. Wellington: Public Health Commission; 1995.
10. Public Health Commission. Water fluoridation in New Zealand. Wellington: Public Health Commission; 1994.
11. Schluter P, Kanagaratnam S, Durward C, et al. Prevalence of enamel defects and dental caries among 9-year old Auckland children. *NZ Dent J.* 2008;104(4):145–152.
12. Mackay T, Thomson W. Enamel defects and dental caries among Southland children. *N Z Dent J.* 2005;101(2):35–43.
13. Marinho VCC, Higgins JPT, Logan S, et al. Fluoride toothpastes for preventing dental caries in children and adolescents. *Cochrane Database Syst Rev.* 2003(1):CD002278.
14. Marinho VCC, Higgins JPT, Sheiham A, et al. Fluoride mouthrinses for preventing dental caries in children and adolescents. *Cochrane Database Syst Rev.* 2003(3):CD002284.
15. Marinho VCC, Higgins JPT, Logan S, et al. Topical fluoride (toothpastes, mouthrinses, gels or varnishes) for preventing dental caries in children and adolescents. *Cochrane Database Syst Rev.* 2003(4):CD002782.
16. Azarpazhooh A, Main PA. Fluoride varnish in the prevention of dental caries in children and adolescents: a systematic review. *Today's FDA.* 2008;20(7):21–25.
17. Ministry of Health. Drinking-water standards for New Zealand 2005 (revised 2008). Wellington: Ministry of Health; 2008. Available from: www.moh.govt.nz/moh.nsf/pagesmh/8534
18. Food Standards Australia New Zealand. Final assessment report: application A588: voluntary addition of fluoride to packaged water. Wellington: Food Standards Australia New Zealand; 2009.
19. National Health and Medical Research Council and Ministry of Health. Nutrient reference values for Australia and New Zealand including recommended dietary intakes. Canberra and Wellington: National Health and Medical Research Council and Ministry of Health; 2006.
20. Cressey P, Gaw S, Love J. Estimated dietary fluoride intake for New Zealanders. ESR Client Report FW0651. Christchurch: ESR; 2009.

21. Chowdhury NG, Brown RH, Shepherd MG. Fluoride intake of infants in New Zealand. *J Dent Res.* 1990;69(12):1828–1833.
22. Guha-Chowdhury N, Drummond BK, Smillie AC. Total fluoride intake in children aged 3 to 4 years: a longitudinal study. *J Dent Res.* 1996;75(7):1451–1457.
23. Hunter P. The prevalence of dental caries in 12- and 13-year-old children in New Zealand in 1977 and 1982. *N Z Dent J.* 1984;80:16–18.
24. Broughton J. Te niho waiora me te iwi Māori: dental health and Māori people. *N Z Dent J.* 1993;88:15–18.
25. Brown RH, Treasure E. Inequities in oral health: implications for the delivery of care and health promotion. *N Z Dent J.* 1992;88:132–138.
26. Treasure E, Dever J. The prevalence of caries in 5-year-old children living in fluoridated and non-fluoridated communities in New Zealand. *N Z Dent J.* 1991;88:9–13.
27. Treasure E, Whyman R. Changing patterns of dental disease and the implications for dental practice. *N Z Dent J.* 1995;91:8–11.
28. Koopu PI. Kia pakari mai nga niho: oral health outcomes, self-report oral health measures and oral health service utilisation among Māori and non-Māori Dunedin: University of Otago; 2004.
29. Fergusson DM, Horwood LJ. Relationships between exposure to additional fluoride, social background and dental health in 7-year-old children. *Community Dent Oral Epidemiol.* 1986;14(1):48–52.
30. Thomson WM. Ethnicity and child dental health status in the Manawatu-Wanganui Area Health Board. *N Z Dent J.* 1993;89(395):12–14.
31. de Liefde B. Longitudinal survey of enamel defects in a cohort of New Zealand children. *Community Dent Oral Epidemiol.* 1988;16(4):218–221.
32. Te Puni Kōkiri (Ministry of Māori Development). Oranga niho Māori: issues paper for discussion. Wellington: Ministry of Māori Development; 1996.
33. National Health Committee. The social, cultural and economic determinants of health in New Zealand: action to improve health. Wellington: National Advisory Committee on Health and Disability; 1998.
34. Ministry of Health. Reducing inequalities in health. Wellington: Ministry of Health; 2002.
35. Howden-Chapman P, Tobias M. Social inequalities in health: New Zealand 1999. Wellington: Wellington School of Medicine; 2000.
36. Lee M, Dennison PJ. Water fluoridation and dental caries in 5- and 12-year-old children from Canterbury and Wellington. *N Z Dent J.* 2004;100(1):10–15.
37. Broughton J. Te waiora: the water of life. *N Z Dent J.* 2008;104(4):144.
38. Broadbent J, Thomson W, Poulton R. Trajectory patterns of dental caries experience to the fourth decade of life. *J Dent Res.* 2008;87:69–72.
39. Thomson W. Dental caries experience in older people over time: what can the large cohort studies tell us? *Br Dent J.* 2004;196:89–92.
40. Chalmers J. Caries incidence and increments in community-living older adults with and without dementia. *Gerodontology.* 2002;19:80–94.
41. Ministry of Health. Early childhood oral health: a toolkit for District Health Boards, primary health care and public health providers and for oral health services relating to infant and preschool oral health. Wellington: Ministry of Health; 2008. Available from: www.moh.govt.nz/moh.nsf/indexmh/early-childhood-oral-health-a-toolkit
42. American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: evidence-based clinical recommendations. *J Am Dent Assoc.* 2006;137(8):1151–1159.
43. Australian Research Centre for Population Oral Health. The use of fluorides in Australia: guidelines. *Aust Dent J.* 2006;51(2):195–199.
44. Adair SM. Evidence-based use of fluoride in contemporary pediatric dental practice. *Pediatr Dent.* 2006;28(2):133–142.

45. National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation. Canberra: Australian Government; 2007.
46. Ammari JB, Baqain ZH, Ashley PF. Effects of programs for prevention of early childhood caries: a systematic review. *Med Princ Pract*. 2007;16(6):437–442.
47. Mascarenhas AK. Risk factors for dental fluorosis: a review of the recent literature. *Pediatr Dent*. 2000;22(4):269–277.
48. Twetman S, Axelsson S, Dahlgren H, et al. Caries-preventive effect of fluoride toothpaste: a systematic review. *Acta Odontol Scand*. 2003;61(6):347–355.
49. Tavener JA, Davies GM, Davies RM, et al. The prevalence and severity of fluorosis and other developmental defects of enamel in children who received free fluoride toothpaste containing either 440 or 1450 ppm F from the age of 12 months. *Community Dent Health*. 2004;21(3):217–223.
50. Davies G, Worthington H, Ellwood R, et al. A randomised controlled trial of the effectiveness of providing free fluoride toothpaste from the age of 12 months on reducing caries in 5–6 year old children. *Community Dent Health*. 2002;19(3):131–136.
51. Fan X, Li X, Wan H, et al. Clinical investigation of the anticaries efficacy of a 1.14% sodium monofluorophosphate (SMFP) calcium carbonate-based dentifrice: a two-year caries clinical trial on children in China. *J Clin Dent*. 2008;19(4):134–137.
52. Pine CM, Curnow MMT, Burnside G, et al. Caries prevalence four years after the end of a randomised controlled trial. *Caries Res*. 2007;41(6):431–436.
53. Zantner C, Martus P, Kielbassa AM. Clinical monitoring of the effect of fluorides on long-existing white spot lesions. *Acta Odontol Scand*. 2006;64(2):115–122.
54. Dean H, Arnold F, Elvove E. Domestic water and dental caries V: additional studies of the relation of fluoride domestic waters to dental caries experience in 4,425 white children, aged 12–11 years, of 13 cities in 4 states. *Pub Health Rep*. 1942;57(32):1155–1179.
55. Hiiri A, Ahovuo-Saloranta A, Nordblad A, et al. Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents. *Cochrane Database Syst Rev*. 2006(4):CD003067.
56. Rosenblatt A, Stamford TCM, Niederman R. Silver diamine fluoride: a caries “silver-fluoride bullet”. *J Dent Res*. 2009;88(2):116–125.
57. Lawrence HP, Binguis D, Douglas J, et al. A 2-year community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children. *Community Dent Oral Epidemiol*. 2008;36(6):503–516.
58. Weintraub JA, Ramos-Gomez F, Jue B, et al. Fluoride varnish efficacy in preventing early childhood caries. *J Dent Res*. 2006;85(2):172–176.
59. Hardman MC, Davies GM, Duxbury JT, et al. A cluster randomised controlled trial to evaluate the effectiveness of fluoride varnish as a public health measure to reduce caries in children. *Caries Res*. 2007;41(5):371–376.
60. Steckslen-Blicks C, Renfors G, Oscarson ND, et al. Caries-preventive effectiveness of a fluoride varnish: a randomized controlled trial in adolescents with fixed orthodontic appliances. *Caries Res*. 2007;41(6):455–459.
61. de Amorim RG, Leal SC, Bezerra ACB, et al. Association of chlorhexidine and fluoride for plaque control and white spot lesion remineralization in primary dentition. *Int J Paediatr Dent*. 2008;18(6):446–451.
62. Ersin NK, Oncag O. A comparison of the effectiveness of chlorhexidine varnish, fluoride varnish and fluoride gel in children with intellectual disability. *Journal of Disability & Oral Health*. 2006;7(1):10.
63. Wong M, Glennly A, Tsang B, et al. Topical fluoride as a cause of dental fluorosis in children (Protocol). *Cochrane Database Syst Rev*. 2009(2):CD007693.
64. Twetman S, Petersson L, Axelsson S, et al. Caries-preventive effect of sodium fluoride mouthrinses: a systematic review of controlled clinical trials. *Acta Odontol Scand*. 2004 Aug;62(4):223–230.
65. Duarte AR, Peres MA, Vieira RS, et al. Effectiveness of two mouth rinses solutions in arresting caries lesions: a short-term clinical trial. *Oral Health Prev Dent*. 2008;6(3):231–238.

66. Ogaard B, Alm AA, Larsson E, et al. A prospective, randomized clinical study on the effects of an amine fluoride/stannous fluoride toothpaste/mouthrinse on plaque, gingivitis and initial caries lesion development in orthodontic patients. *Eur J Orthod.* 2006;28(1):8–12.
67. Spencer AJ, Davies M, Slade G, et al. Caries prevalence in Australasia. *Int Dent J.* 1994;44(4 Suppl 1):415–423.
68. van Rijkom H, Truin G-J, van't Hof MA. A meta-analysis of clinical studies on the caries-inhibiting effect of fluoride gel treatment. *Caries Res.* 1998;32(2):83–92.
69. Xu X, Li JY, Zhou XD, et al. Randomized controlled clinical trial on the evaluation of bacteriostatic and cariostatic effects of a novel povidone-iodine/fluoride foam in children with high caries risk. *Quintessence Int.* 2009;40(3):215–223.
70. Truin G-J, van't Hof M. Professionally applied fluoride in low-caries 10.5 year-olds. *J Dent Res.* 2005;84(5):418–421.
71. van Rijkom HM, Truin GJ, van 't Hof MA. Caries-inhibiting effect of professional fluoride gel application in low-caries children initially aged 4.5–6.5 years. *Caries Res.* 2004 Mar-Apr;38(2):115–123.
72. Madlena M, Nagy G, Gabris K, et al. Effect of amine fluoride toothpaste and gel in high risk groups of Hungarian adolescents: results of a longitudinal study. *Caries Res.* 2002 Mar-Apr;36(2):142–146.
73. Jiang H, Tai B, Du M, et al. Effect of professional application of APF foam on caries reduction in permanent first molars in 6–7-year-old children: 24-month clinical trial. *J Dent.* 2005 Jul;33(6):469–473.
74. Truin G-J, van't Hof M. The effect of fluoride gel on incipient carious lesions in a low-caries child population. *Community Dent Oral Epidemiol.* 2007;35(4):250–254.
75. Ismail AI, Hasson H. Fluoride supplements, dental caries and fluorosis: a systematic review. *J Am Dent Assoc.* 2008;139(11):1457–1468.
76. AGREE Collaboration. The appraisal of guidelines for research and evaluation (AGREE) instrument. London: The AGREE Research Trust; 2001.



www.nzgg.org.nz



www.moh.govt.nz

