TOPICAL FLUORIDES

Evidence-based guidance on the use of topical fluorides for caries prevention in children and adolescents in Ireland

Feidhmeannacht na Seirbhíse Sláinte
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This work was funded by the Health Research Board (Grant No. S/A013)

Recommended citation: Irish Oral Health Services Guideline Initiative. Topical Fluorides: Evidence-based guidance on the use of topical fluorides for caries prevention in children and adolescents in Ireland. 2008

Guideline and supplementary data available at: http://ohsrc.html/guidelines.html

What is an evidence-based guideline?

Evidence-based clinical practice guidelines are systematically developed statements containing recommendations for the care of individuals by healthcare professionals that are based on the highest quality scientific evidence available. Guidelines are designed to help practitioners assimilate, evaluate and apply the ever-increasing amount of evidence and opinion on current best practice, and to assist them in making decisions about appropriate and effective care for their patients. Their role is most clear when two factors are present: (a) evidence of variation in practice that affects patient outcomes, and (b) a strong research base providing evidence of effective practice.[1] It is important to note that guidelines are not intended to replace the healthcare professional's expertise or experience, but are a tool to assist practitioners in their clinical decision-making process, with consideration for their patient's preferences.

To assist the reader of this guideline, the key to the grading of evidence and recommendations is presented below.

LEVELS OF EVIDENCE	
1++	High quality meta-analysis, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion
GRADES OF RECOMMENDATIONS	
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population OR A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results OR Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population, and demonstrating overall consistency of results OR Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4 OR Extrapolated evidence from studies rated as 2+
GPP **Good Practice Point**	Recommended best practice based on the clinical experience of the Guideline Development Group

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Acknowledgements

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Acknowledgements

We would like to thank the following for their contribution to this guideline:

Sylvia Bickley, Trials Search Co-ordinator, Cochrane Oral Health Group, Manchester; Dr Morag Curnow, Clinical Dental Director, Community Dental Service, Perth, Scotland; Dr Gill Davis, Department of Dental Public Health, Manchester Primary Care Trust; Sarah Hall, PhD student, University College Cork.; Dr Valeria Marinho, Senior Lecturer in Bioinfomatics, Institute of Dentistry, Queen Mary University of London. Our thanks also to the staff of the Oral Health Services Research Centre for their assistance in hosting the Guideline Development Group meetings.

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Summary of Recommendations

Professionally Applied Topical Fluorides

The use of professionally applied topical fluorides for the prevention and control of dental caries in individual patients should be considered as part of an overall preventive programme for the patient, based on an assessment of the individual patient's risk for caries and their exposure to other sources of fluoride. A caries risk assessment checklist for Irish children has been developed for this purpose (Appendix 5).

FLUORIDATED AND NON-FLUORIDATED AREAS				
	Age 1– 7 years	**Grade of recommendation**	**Age 7–16 years**	**Grade of recommendation**
FLUORIDE VARNISH	Resin-based fluoride varnish application (22,600 ppm F) should be offered to children who are assessed as being at high caries risk [77,83, 89]	**A**	Fluoride varnish application (at least 22,600 ppm F) should be offered to children who are assessed as being at high caries risk [77,82,90]	**A**
	Varnish should be applied at intervals of 6 months or 3 months[77]	**A**	Varnish should be applied at intervals of 6 months [77,90] or 3 months[77]	**A**
	Because of its ease of application, the small amount used, and the precise application of the material to individual tooth surfaces, resin-based varnish (22,600 ppm F) can be used in very young children who are assessed as being at high caries risk	**GPP**		
	The introduction of a school-based fluoride varnish programme should be considered for children attending special schools			**GPP**
FLUORIDE GEL	Fluoride gel should not be used in children under the age of 7	**GPP**	Because of its ease of application and greater patient acceptability, fluoride varnish should be used in preference to fluoride gel for caries prevention in children who are assessed as being at high caries risk[95,104]	**D**
			In situations where operator or patient preference dictates the use of fluoride gel rather than fluoride varnish, gel application should be offered at 6 month intervals[98,99]	**A**
FLUORIDE VARNISH & GEL	Manufacturer's instructions regarding use of fluoride varnish and gel should be carefully followed, as these products have high concentrations of fluoride			**GPP**
	Every fluoride varnish or gel application should be recorded as a treatment item in the patient record and also in the day book, if used			**GPP**
FLUORIDE FOAM	There is insufficient evidence at this time on which to base a recommendation on the use of fluoride foam			
SLOW-RELEASE FLUORIDE DEVICES	There is insufficient evidence at this time on which to base a recommendation on the use of slow-release fluoride devices			

Community-Based Use of Fluoride Toothpaste

The use of topical fluorides for caries prevention should form part of an overall community-based preventive strategy, which should be population-specific and tailored to meet the needs and preferences of the population under consideration. The identification of high caries risk groups or populations in Ireland is currently based on local knowledge of disadvantaged schools or districts, special needs groups, geographic location (non-fluoridated areas) or, where available, on small area data on the distribution of caries.

FLUORIDATED AND NON-FLUORIDATED AREAS				
	Age < 2 years	**Grade of recommendation**	**From age 2 years**	**Grade of recommendation**
FLUORIDE TOOTHPASTE	Community-based programmes involving the use of fluoride toothpaste are not recommended for children under the age of 2 years	**GPP**	**Daily supervised toothbrushing programmes** should:	
			• Be considered for targeted populations of children who are at high risk of developing dental caries[117,147, 148]	**A**
			• Be undertaken in community settings such as	
			o crèches, nurseries, preschools[117,118,152]	**B**
			o primary schools[117,118,147]	**A**
			• Involve the use of toothpaste containing at least 1,000 ppm fluoride[117-120]	**A**
			• Support home use of fluoride toothpaste through provision of toothpaste, toothbrush and instructions for home use during school holidays[149]	**D**
			Programmes involving the distribution of fluoride toothpaste should**:**	
			• Be considered in targeted populations of children at high risk of caries[117,118,133] *Toothpaste distribution has the advantage of being cheaper[154,155], but is less effective than supervised brushing.*[117,118]	**A**
			• Involve the use of toothpaste containing at least 1,000 ppm fluoride[117-120]	**A**
			• Distribute toothpaste at 3-month intervals, with instructions for home use	**GPP**
			• Distribute toothpaste directly to parents/guardians of children under the age of 7 years	**GPP**
			Any community-based preventive programme should be conducted as an RCT to establish both the effectiveness and cost of the programme in Ireland	**GPP**

Community-Based Use of Fluoride Mouthrinse

NON-FLUORIDATED AREAS ONLY				
	Age < 7 years	**Grade of recommendation**	**Age 7–16 years**	**Grade of recommendation**
FLUORIDE MOUTHRINSE	Children under the age of 7 years should not participate in a school-based fluoride mouthrinsing programme because of the increased risk of the rinse being swallowed by young children[158]	**D**	Weekly fluoride mouthrinsing with 0.2% sodium fluoride rinse should be offered to children living in non-fluoridated areas (sub-group analysis of review by Marinho et al.[156])	**B**
			The target number of applications should be at least 30 per year	**GPP**
			Fortnightly mouthrinsing with 0.2% sodium fluoride rinse is effective at reducing caries, but appears to be less effective than weekly rinsing (sub-analysis of review by Marinho et al. [156])	**B**
			Children participating in a school-based fluoride mouthrinsing programme should rinse for two minutes with 0.2% sodium fluoride rinse	**GPP**
			Rinsing times of less than 2 minutes should be considered for new participants in a mouthrinsing programme to avoid excessive ingestion of fluoride mouthrinse	**GPP**
			Children should wait for at least 20–30 minutes after rinsing before eating or drinking[173,174]	**D**
			Staff responsible for administering the fluoride mouthrinse are an important part of the dental service and should be appropriately trained in the delivery of the fluoride mouthrinsing programme	**GPP**
			A standardised protocol should be developed for fluoride mouthrinsing programmes in Ireland, which should include an individual rinse record for each child, incident reporting, monitoring and evaluation of participation, and information for participants on the maintenance of good oral health when the programme ends	**GPP**

Section 1: Background

Fluoride has been the cornerstone of caries prevention in the Republic of Ireland since the introduction of water fluoridation in the mid 1960s. Currently, 71% of the population has fluoridated domestic water supplies.[2] The other main exposure to fluoride in the Republic of Ireland comes from the diet and from topical fluorides. Topical fluorides have been defined as "delivery systems which provide fluoride to exposed surfaces of the permanent and primary dentition, at elevated concentrations, for a local protective effect, and are therefore not intended for ingestion".[3] Topical fluorides generally fall into two categories: (a) self applied – e.g. toothpaste and mouthrinse, and (b) professionally applied – e.g. varnish and gel. Toothpaste is by far the most commonly used topical fluoride modality, with over 95% of toothpastes sold in the Republic of Ireland containing fluoride.[4]

1.1 Epidemiology

1.1.1 Dental caries

In line with trends in many developed countries, the prevalence and severity of dental caries among Irish children has declined dramatically since the 1960s. Much of this decline has been attributed to the availability of fluoride, through water fluoridation and also through the home use of fluoride toothpastes.[2,5] The North South Survey of Children's Oral Health 2002, found that children who had lifetime exposure to fluoridated water had significantly lower caries levels than children who lived in non-fluoridated areas.[2] (Table 1.1)

In spite of the overall improvement in dental health, caries remains a very common disease among Irish children. For example, among 5 year olds, 55% of children in non-fluoridated areas and 37% in fluoridated areas have experienced decay. At age 15, 73% of children in fluoridated areas and 79% in non-fluoridated areas have experienced decay (Table 1.1). Oral health goals for the year 2000 were set by the Department of Health in the first national health strategy *Shaping a Healthier Future.*[6] The goals for 5-year-old children were for at least 85% of children in fluoridated areas and at least 60% in non-fluoridated areas to be free of caries by the year 2000. These goals have not been achieved. The oral health goal for 12-year-olds in fluoridated areas to have, on average, no more than one decayed, missing or filled permanent tooth has also not been reached. No oral health goals were set for 15-year-olds.

Although the average caries levels of Irish children compare quite favourably with other European countries[2], the average caries figures conceal the fact that a considerable proportion of Irish children experience high levels of decay. The Significant Caries (SiC) Index represents the average decay experience, (measured at cavitation level), in the one third of the population with the highest caries scores.[7] Table 1.1 shows that the SiC Index score is substantially higher than the average caries levels (mean d_{3vc}mft/D_{3vc}MFT) for all age groups, in both fluoridated and non-fluoridated areas. For example, for 15-year-olds, the mean D_{3vc}MFT is 2.6 in fluoridated areas and 3.8 in non-fluoridated areas, whereas the SiC Index scores for this age group are 5.8 and 8.8 respectively.

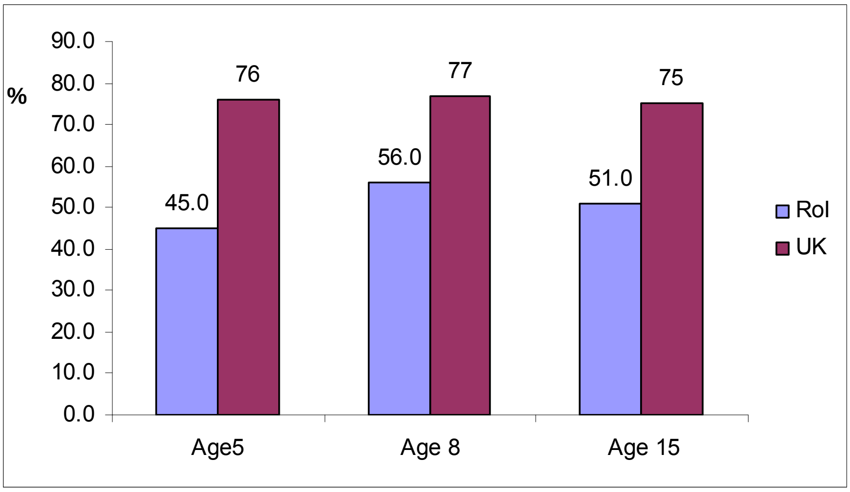
Table 1.1: Percent of children with caries experience*, average caries levels^, and SiC Index score at age 5-, 12- and 15- years by fluoridation status, 2002

	Age 5		Age 12		Age 15	
	Full F	Non-F	Full F	Non-F	Full F	Non-F
% of children with caries experience*	37%	55%	52%	60%	73%	79%
Average caries levels^	1.3	2.2	1.4	1.8	2.6	3.8
SiC Index score (for top third of children with worst decay)	4	5.8	3.6	4.3	5.8	8.8

*% with $d_{3v}cmft/D_{3vc}MFT > 0$
^mean $d_{3vc}mft/D_{3vc}MFT$

The oral health behaviours of Irish children compare unfavourably with other countries. Only 45% of Irish 5-year-olds brush twice a day[8] compared to 76% in the UK[9], while fewer than 60% of children aged 8 or 15 brush twice a day[2] compared to 75% or more in the UK (Figure 1.1). In an international comparison of health behaviour in school-aged children in 35 countries (HBSC survey), Ireland ranked in the bottom half of all participating countries for the percentage of children brushing more than once a day.[10] (Further details on the toothbrushing habits of Irish children can be found in Appendix 1). When it came to daily consumption of sweets, Ireland ranked 2nd for 13-year-olds and 1st for 15-year-olds.[10]

Figure 1.1: Percentage of children brushing twice a day in RoI[2,8] and UK[9]



Thus, for some Irish children, there is a need for strategies, additional to water fluoridation and home use of toothpaste, to prevent and control caries. The critical question for the Irish situation is whether preventive strategies that involve the use of topical fluorides provide any additional benefit in an environment which already has population exposure to two fluoride modalities (water and toothpaste) and, if so, how best to deliver these preventive strategies.

1.1.2 Dental fluorosis

In using fluoride for caries prevention, the aim is to maximise the benefits in terms of reduced caries levels while minimising the risk of dental fluorosis. Fluorosis is a disturbance in enamel formation which occurs when excess fluoride is ingested during tooth development. The appearance of fluorosis varies from almost imperceptible fine white lines on the tooth to pitting and discolouration of the tooth. The severity of fluorosis is related to the timing, duration of exposure and dose of fluoride ingested.[11]

Most research on fluorosis has focused on the permanent upper central incisors because of their prime aesthetic importance. Although some researchers have estimated very precise risk periods for the development of fluorosis in the upper central incisors (age 15–24 months for boys and age 21–30 months for girls)[12], a systematic review of the dental literature on risk periods for fluorosis concluded that no specific period of enamel formation could be singled out as being the most critical for the development of fluorosis in these teeth.[13] The author of the review concluded that the duration of fluoride exposure during enamel formation, rather than specific risk periods, would seem to explain the development of dental fluorosis in the upper permanent central incisors. Long exposure of more than 2 years during the first 4 years of life increased the risk of developing fluorosis in the upper central incisors.[13] A longitudinal study from the United States (the Iowa Fluoride Study) calculated total fluoride intake in a cohort of children at 3–4 month intervals during the first 4 years of life. Examination of these children at age 9 revealed that while fluoride intake during the first two years of life was most important to fluorosis development in the upper permanent central incisors, fluoride intake during each year of the first four years of life was also associated with fluorosis in these teeth.[14]

The chronology of the development of the permanent front teeth is shown in Table 1.2. The formation of the crowns of the upper central and lateral incisors is complete by age 4–5 years, while the crowns of the adjacent canine teeth are not complete until age 6–7 years. This suggests that, when considering the front teeth from canine to canine, and not just the central incisors, the first 5–7 years of life would seem to be the most important in terms of risk for fluorosis.

Table 1.2: Chronology of the development of the permanent dentition: Adapted from Berkovitz et al., 2002[15]

<table>
<tr><th rowspan="3">Stage of development</th><th rowspan="3">Time</th><th colspan="8">Permanent Dentition: Upper/Lower Arch</th></tr>
<tr><th colspan="2">Central Incisor</th><th colspan="2">Lateral Incisor</th><th colspan="2">Canine</th><th colspan="2">Premolar</th></tr>
<tr><th>U</th><th>L</th><th>U</th><th>L</th><th>U</th><th>L</th><th>U</th><th>L</th></tr>
<tr><td>First evidence of calcification</td><td>Months after birth</td><td colspan="2">3–4</td><td>10–12</td><td>3–4</td><td colspan="2">4–5</td><td>18–21</td><td>21–24</td></tr>
<tr><td>Crown completed</td><td>Years</td><td colspan="4">4–5</td><td colspan="2">6–7</td><td colspan="2">5–6</td></tr>
</table>

The threshold level of fluoride above which fluorosis of aesthetic concern may occur is not accurately known. However, empirical evidence suggests that the often quoted “optimal” value for fluoride ingestion of 0.05 to 0.07 mg F/kg body weight per day is a useful upper limit for fluoride intake in children[16], and this has become the standard reference range in investigations into fluoride intake.[17] Consumption of fluoridated water, ingestion of fluoride toothpaste, inappropriate use of fluoride supplements, and infant formula have all been implicated as individual risk factors for dental fluorosis.[18] The most important factor in determining the prevalence and severity of fluorosis is the total amount of fluoride ingested from all sources during the first few years of life, but this can be extremely difficult to measure accurately.

The Iowa Fluoride Study calculated the total fluoride intake from water, beverages, certain foodstuffs, fluoride toothpaste and fluoride supplements, based on questionnaire data returned by parents every 3–4 months over 4 years. This longitudinal study found considerable variation in fluoride intake across ages and among individuals, from birth to age 36 months, most of whom had exposure to fluoridated water. The study found that the thresholds for fluoride ingestion were substantially more likely to be exceeded by younger children.[17] For example, at age 9 months, 36% of children exceeded the upper threshold of 0.07 mg F/kg body weight, whereas between the ages of 12 and 36 months, the percentage of children exceeding this intake was consistently less than 17%. From ages 3 to 6 years, the average fluoride intake was around 0.05 mg/kg body weight – as the diet becomes relatively stable during these ages – and the percentages with estimated intake exceeding thresholds for dental fluorosis decreased.[19] A longitudinal study of 3–4 year old children from fluoridated and non-fluoridated areas of New Zealand directly measured total fluoride intake from diet and toothpaste at 6-month intervals over one year, and found that none of the children exceeded the upper threshold limit of 0.07 mg F/kg per day.[20] These studies highlight the variation that occurs in total fluoride ingestion among children during the early years of life.

As caries levels have fallen worldwide, there has been an increased focus on the balance between the benefits and the risks of fluoride, particularly in light of the increased availability of fluoride from multiple sources. The 2002 North South survey of children's oral health in Ireland found that the reduction in caries since 1984 (Figure 1.2a) was accompanied by an increase in the prevalence of fluorosis in 8- and 15-year-olds, particularly in fluoridated but also in non-fluoridated areas (Figure 1.2b). It is important to note that fluorosis was recorded using Dean's Index and that most of the fluorosis recorded was in the categories Questionable or Very Mild.[2]

Figure 1.2a: Average caries experience (recorded at cavitation level $d_3$mft/D_3MFT) in 5-, 12- and 15-year-olds in 1984 and 2002 by fluoridation status

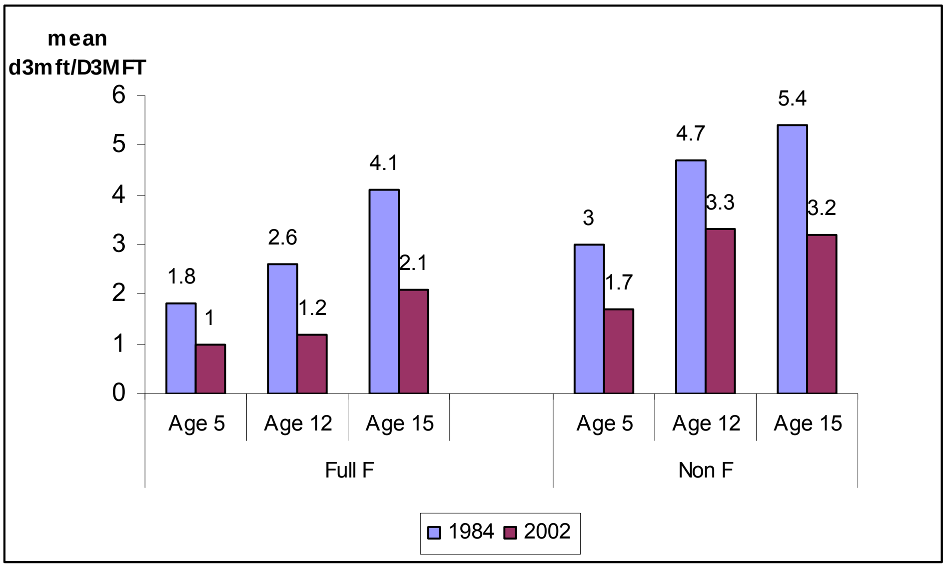
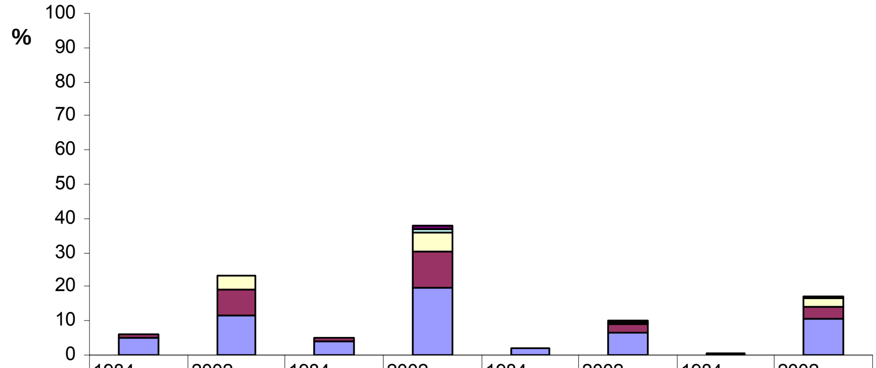


Figure 1.2b Prevalence of fluorosis in 8- and 15-year-olds in 1984 and 2002 by fluoridation status



Dean's Index of fluorosis	Full F, Age 8, 1984	Full F, Age 8, 2002	Full F, Age 15, 1984	Full F, Age 15, 2002	Non F, Age 8, 1984	Non F, Age 8, 2002	Non F, Age 15, 1984	Non F, Age 15, 2002
Severe				0.6				
Moderate		0.4		1.4		0.4		0.3
Mild		3.6	0.4	5.4		0.3		2.6
Very Mild	1	7.8	0.9	10.6		2.6		3.6
Questionable	5	11.6	4	19.7	1.9	6.6	0.6	10.5

In 2002, the Report of the Forum on Fluoridation recommended lowering the fluoride level in drinking water from 0.8–1.0 ppm to 0.6–0.8 ppm, with a target of 0.7 ppm, as part of a strategy to bring about "meaningful reductions in dental decay while reducing the risk of developing fluorosis".[4] The necessary change to the legislation was enacted in 2007.[21] As an additional measure to minimise the risk of fluorosis, the Forum on Fluoridation recommended that toothpaste should not be used for children under the age of 2 years, and that professional advice on the use of fluoride toothpaste should be sought for children under the age of 2 who are at high caries risk. For children aged 2–7 years, it was recommended that parents should supervise brushing, that a pea-size amount of toothpaste should be used and that swallowing the toothpaste should be avoided. Low fluoride paediatric toothpastes were not recommended. The Forum on Fluoridation recommended that guidelines on the use of oral health care products should be developed for use by all those involved in advising members of the public on healthcare matters.

1.2 Why do we need a guideline?

The Public Dental Service in Ireland provides free dental care to children and adolescents under the age of 16. The core element of the Public Dental Service is the School Dental Service (SDS), which targets specific classes for receipt of dental care, with particular emphasis on the provision of fissure sealants. The Public Dental Service also operates oral health promotion programmes, some of which involve the use of fluorides. In 2001, a survey of existing fluoride programmes operated by the Public Dental Service found that few dental areas offered formal advice or guidance to clinicians on the use of fluoride varnish or gel. The survey also found variation in procedures, such as rinsing time and disposal of waste rinse, in the 14 dental areas that operated fortnightly fluoride mouthrinsing programmes.[22]

In 2005/6, we carried out a new survey to determine if there had been any changes in the programmes, practices or policies relating to the use of topical fluorides in the Public Dental Service since 2001. Our questionnaire survey of the Principal Dental Surgeons (response 29/30) found that the majority of dental areas still offered no formal advice or guidance on the use of fluoride varnish or gel. In two dental areas, professionally applied fluorides were not used at all. There was considerable variation between dental areas in the extent to which varnish or gel was used, based on the number of recorded applications. Even the recording of applications was inconsistent, with some areas not collecting data on the number of topical fluoride applications.

Given the unfavourable toothbrushing habits of Irish children, a number of reports have stressed the need to promote the use of fluoride toothpaste among Irish children.[2,23] Our situation analysis sought information on oral health promotion programmes that promoted, or actively involved, the use of fluoride toothpaste. We found that over half of the dental areas surveyed provided school-based dental health education, which promoted the use of fluoride toothpaste. The oral health education activities involved over 40,000 children in 614 primary schools. Only a small number of areas targeted this dental health education at specific disadvantaged groups, as recommended in the National Health Promotion Strategy 2000–2005.[23] Three dental areas distributed toothpaste at regular intervals (i.e. more than once a year) to target groups. No dental area provided supervised toothbrushing programmes.

Our situation analysis also found that the number of children involved in fluoride mouthrinsing programmes had halved, from approximately 30,000 in 2001 to 14,500 in 2005/6. Some dental areas had ceased all or part of their mouthrinsing programmes, due to the extension of fluoridated water supplies or shortage of staff to deliver the mouthrinsing programme. Among the areas that continued to provide mouthrinsing programmes, there was variation – as there had been in 2001 – in the consent forms used, the age at which children entered the programme, the rinse time and the procedures for disposal of rinse. In all but one dental area, the mouthrinsing programmes targeted only primary school children.

A strong international research base exists on the use of topical fluorides for caries prevention. Given the lack of guidance and the variation in practice regarding the use of fluoride varnish and gel in the Public Dental Service, the substantial resources being directed towards the promotion of fluoride toothpaste, primarily through oral health education in primary schools, and the lack of a standardised approach for the delivery of the fluoride mouthrinsing programme, the development of evidence-based clinical practice guidelines offers a way for the Public Dental Service to adopt a more evidence-based approach to the use of topical fluorides.

Section 2: Methodology

2.1 Scope of the guideline

This guideline has been developed for the Public Dental Service in Ireland and provides evidence-based recommendations on the use of topical fluorides for caries prevention in children and adolescents. It is important to emphasise that topical fluorides are just one of many approaches to the prevention of dental caries; the recommendations in this guideline are offered for use as a component of an overall preventive approach for individual children and populations.

2.1.1 What the guideline covers

This guideline covers the use of the following topical fluoride modalities for caries prevention:

- Fluoride varnish, gel and foam
- Slow release fluoride devices
- Fluoride toothpaste used as part of community-based preventive programmes
- Fluoride mouthrinse used in school-based preventive programmes.

The recommendations cover children and adolescents under the age of 16, as they are the main population served by the Public Dental Service The upper age limit of 16 stated in the recommendations is based solely on the age at which universal eligibility for Public Dental Services ends, and does not imply that these recommendations are not valid for older adolescents.

2.1.2 What the guideline does not cover

The following areas are not covered by this guideline:

- Any form of systemic fluoride – For recommendations relating to water fluoridation, see the report of the Forum on Fluoridation 2002 (http://www.dohc.ie/publications/fluoridation_forum.html)
- Use of topical fluorides in adults
- Home-use of fluoride toothpaste or mouthrinse – For recommendations on the home use of toothpaste, see the report of the Forum on Fluoridation (http://www.dohc.ie/publications/fluoridation_forum.html) and Fluoride and Public Health from the Irish Expert Body on Fluorides and Health (http://www.dentalhealth.ie/download/pdf/fluorides_qanda.pdf)
- Use of topical fluorides in the management of dentine hypersensitivity, root caries or erosion
- Fluoride containing dental materials (including fissure sealants)
- Oral health promotion except in relation to community-based preventive programmes involving the use of topical fluorides.

2.2 Aim of the guideline

The aim of this guideline is twofold:

- To assist Public Dental Service clinicians in making decisions on the use of fluoride varnish, gel, foam and slow release fluoride devices for caries prevention in individual patients
- To assist policy makers and those responsible for planning public dental services for children and adolescents in making decisions on the provision of caries prevention programmes involving the use of topical fluorides as part of an overall caries-prevention strategy.

The guideline is of relevance to all clinical staff working in the Public Dental Service, those responsible for the planning and management of public dental services, oral health promoters, children using the Public Dental Service and their parents, and teachers. Although the guideline has been developed for the Public Dental Service, it will also be of interest to general dental practitioners and their dental teams.

2.3 Guideline methodology

2.3.1 Guideline Development Group

This guideline was developed in line with international best practice, as specified by the AGREE Collaboration and described in the AGREE Instrument.[24] A Guideline Development Group (GDG) was established, which represented key stakeholders in the guideline (see Appendix 2). All GDG members were asked to declare any interests that might be in conflict with the development of the guideline: No conflicting interests were declared. Stakeholder groups who were not represented were invited to contribute comments at the scoping stage and to comment on the consultation draft of this guideline.

2.3.2 Questions addressed by the guideline

The Guideline Development Group identified the questions that the guideline needed to address. These questions fell into two categories:

- **Background questions –** Background questions related to the mechanism of action of topical fluorides; age for risk of fluorosis in incisor, canine and premolar teeth; pattern of ingestion of fluoride by children; toothbrushing habits of children in Ireland (including type of toothpaste used); and estimated caries increment in Irish children. As these questions were to establish the context for topical fluorides, systematic searches were not undertaken. Instead, we consulted relevant textbooks, systematic reviews where available, narrative reviews by key researchers in the field, and relevant Irish studies.
- **Key questions** – Key questions related to the general effectiveness, relative effectiveness and risks of the included modalities, particularly in an environment with fluoridated water and toothpaste and with current levels of caries. Specific questions about frequency of application and

acceptability of the different modalities were also posed. Please see Appendix 3 for a full list of the key questions.

2.4 Search strategy

The Guideline Development Group was assisted by a research team, based at the Oral Health Services Research Centre, who systematically searched for evidence to answer the key questions. A comprehensive search strategy was developed to identify relevant systematic reviews, evidence-based guidelines and economic evaluations. The main search strategy was built around three groups of terms – dental caries, topical fluorides and age – and was initially run from January 1995 to December 2006 in Pubmed, Embase, Cinahl, and all databases of The Cochrane Library. The search was re-run in Pubmed on a monthly basis up to February 2008. Randomised trials published after the systematic reviews (1999 onwards) were also sought. The eligibility criteria for including RCTs were based on those used in the Cochrane summary review of the effectiveness of topical fluorides[3], i.e. randomised or quasi-randomised controlled trials with blind outcome assessment, of at least one year duration, involving children or adolescents aged 16 or under at baseline. The outcome measure was caries increment, reported either at the dentinal level or including both enamel and dentinal lesions. The websites of key guideline organisations were also searched to identify relevant guidelines. Appendix 4 contains the full search strategy and databases and websites searched.

While randomised trials are particularly suited to questions of effectiveness, they may be less suitable for considerations of safety or adverse effects.[25] Therefore, a separate search for studies of any design reporting adverse effects using the terms for each modality and "adverse effects" or "fluorosis" was also carried out in Pubmed and EMBASE. A decision was made at the outset to limit all searches to English. The quality of the identified systematic reviews and trials was independently appraised by two reviewers using the methodology checklists used by the Scottish Intercollegiate Guideline Network (SIGN) and the National Institute for Health and Clinical Excellence (NICE).[26,27] Using these methodology checklists, the quality of a paper was graded according to SIGN criteria (Table 2.1). Disagreement between the reviewers on the quality grading of a paper was resolved by discussion. Studies which had a high risk of bias (graded minus) were only considered if there was no other evidence available, but were not used as the basis for making recommendations. A number of guidelines on the use of topical fluorides and on caries prevention were identified.[28-37] The quality of these guidelines was appraised using the AGREE instrument.[24]

A summary of the evidence to answer each of the key questions was presented to the Guideline Development Group in structured abstracts and evidence tables. These were discussed and informal consensus methods were used to formulate recommendations. Recommendations were graded according to the level of evidence on which they were based, using the SIGN criteria (Table 2.2).

Table 2.1: Levels of evidence

LEVELS OF EVIDENCE	
1++	High quality meta-analysis, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analysis, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analysis, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion, formal consensus

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Table 2.2: Grades of recommendations

GRADES OF RECOMMENDATIONS	
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population *OR* A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results *OR* Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population, and demonstrating overall consistency of results *OR* Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4 *OR* Extrapolated evidence from studies rated as 2+
GPP **Good Practice Point**	Recommended best practice based on the clinical experience of the Guideline Development Group

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2.5 Funding for the guideline

The development of this guideline was funded through a Strategic Health Research and Development Research Award from the Health Research Board (HRB). The Guideline Development Project is a collaboration between the Health Service Executive (Public Dental Service), the Oral Health Services Research Centre (University College Cork) and the UK Cochrane Centre. The development of this guideline – from scoping to final recommendations – was not influenced in any way by the funding body.

2.6 Updating the guideline

It is essential that recommendations in guidelines are reviewed and updated, where necessary, in a timely fashion as new evidence becomes available. Two years after the publication of this guideline, the project team will re-run the main search strategy and the searches for adverse effects, for the period since the previous searches were conducted. Relevant systematic reviews and randomised trials will be identified and critically appraised. The opinion of the original Guideline Development Group will be sought on whether an update is needed and whether any new evidence impacts on the guideline recommendations. In general, the process for updating a guideline will follow that used for the development of the original guideline.

Section 3: Dental Caries and the Role of Fluoride in Caries Prevention

3.1 Introduction

Dental caries is a multifactorial disease which has been described as "a simple process in concept, but complicated in detail."[38] The basic prerequisites for caries to occur are:

- Plaque bacteria
- Fermentable carbohydrate (e.g. sugars) from the diet
- A susceptible tooth surface.

However, these factors are themselves influenced by other variables such as genetics, lifestyle, education, and socio-economic, cultural and environmental conditions, many of which lie beyond the control of the individual. It must be borne in mind that any preventive approach needs to address the underlying determinants as well as the immediate causes of ill health.[39]

3.2 The caries process

Teeth are covered by a microbial biofilm (plaque), which produces acids as a result of metabolising fermentable carbohydrates in food. These acids diffuse through the plaque and into the enamel, where they dissolve tooth minerals, principally calcium and phosphate. The loss of these minerals from the tooth is known as demineralisation. Demineralisation occurs each time carbohydrate is taken into the mouth and metabolised by the bacteria. The saliva plays numerous roles, including buffering (neutralising) the acid and providing minerals that can replace those dissolved from the tooth during demineralisation. This replacement of mineral is called remineralisation.[40] If the cumulative result of the demineralisation and remineralisation processes leads to net loss of mineral from the tooth, there is the potential for a clinically detectable lesion to develop. The current understanding of the caries process is that it is essentially a balance between factors that promote remineralisation and those that cause demineralisation.[41]

3.3 Role of fluoride in the prevention of caries

For many years, it was thought that the most important mode of action of fluoride was through incorporation of fluoride into the enamel during tooth formation.[42] However, the current consensus is that fluoride exerts its effect topically after the tooth has erupted, primarily by inhibiting demineralisation and enhancing remineralisation.[43] Although fluoride has been shown to interact with many metabolic and growth processes in bacteria, the current view is that this all occurs at fluoride levels far exceeding those prevailing in the oral cavity: therefore the hard tissue effects of fluoride are more important from a clinical point of view.[44] A low level of fluoride in the mouth, particularly at the plaque/saliva/enamel interface, is of most benefit in preventing dental caries.[40,44]

Demineralisation is markedly inhibited if fluoride is present at the time of the acid challenge. Fluoride diffuses with the acid from plaque into the enamel and acts at the crystal surface to reduce mineral loss. When the pH rises following demineralisation, fluoride present at the crystal surface can combine with dissolved calcium and phosphate ions to precipitate or grow fluorapatite-like crystalline material within the tooth. Fluoride enhances this mineral gain and provides a material which is more resistant to subsequent acid attack.[44] Regular use of fluoride toothpaste or mouthrinse results in sustained elevated fluoride concentrations in the oral fluids. Having this "external" source of fluoride means that, at low pH, fluoride is available during the demineralisation/remineralisation cycle. With high concentration topical fluoride vehicles (such as varnishes and gels), calcium fluoride, or a calcium fluoride-like material, is precipitated on the enamel surface and in the plaque. This calcium fluoride acts as a fluoride reservoir which is released when the oral pH falls.[45,46]

3.4 Risk factors for caries

Because dental caries is a dynamic process that can progress, reverse or remain inactive depending on the balance of factors that promote demineralisation and remineralisation, the ideal preventive strategy would target patients at a stage when the caries process is still reversible, thus avoiding the need for restorative treatment. However, accurately identifying children who are at risk of developing caries has proved to be problematic, not least because of the multifactorial nature of the disease. Caries risk has been defined as "the probability of an individual developing at least a certain number of carious lesions reaching a given stage of disease progression during a specified period." [47] This definition incorporates the concepts of the quantity and *activity* of carious lesions as an outcome. Prediction of caries risk has been based on assessment of risk factors (variables causally related to the disease, where the relationship has been established by prospective studies), and risk indicators or risk markers (variables where risk is imputed from cross sectional studies).[48]

In general, most risk factors/indicators for caries fall under the following headings:

➢ **Social history**

- A systematic review, which evaluated the evidence regarding the association between caries and socio-economic status, found fairly strong evidence for an inverse relationship between socio-economic status and caries in children under 12 years of age but relatively weak evidence for the same inverse relationship in older children.[49] **2+**

- Cross-sectional surveys in Ireland, which used medical card status as an indicator of disadvantage, found significantly higher levels of caries in disadvantaged children in primary and secondary school compared to those who were not disadvantaged.[2, 8] A similar relationship between medical card status and higher caries levels was also found in Irish preschool children.[50] **3**

➢ **Medical conditions**

- Medical conditions can put a patient at increased risk of developing caries. For example:

- o Conditions which cause dry mouth (xerostomia), either as a result of the disease itself or as a side effect of medication, can put a patient at increased risk of developing caries.[51]

- o Conditions that impair a patient's ability to maintain their own oral health, such as physical or mental disability, can impact on oral health.

- o For some medical conditions, the consequences of developing caries and/or the treatment of caries could put the patient's general health at risk (e.g. bleeding disorders such as haemophilia, immunosuppression).

➢ Dietary habits

- A systematic review evaluated the relationship between sugar intake and caries experience at a time when fluoride exposure is widespread.[52] The authors took the view that the evidence that sugars and other fermentable carbohydrates play a fundamental role in the initiation and progression of caries is overwhelming, and wanted to determine how the relationship between sugar and caries was influenced by fluoride. They concluded that the relationship between sugar consumption and caries is much weaker in the modern age of fluoride exposure, but added that controlling the consumption of sugar is a justifiable part of caries prevention. **2+**

- A systematic review of risk factors for caries in preschool children found that balance between "good" habits (i.e. toothbrushing) and "bad" (i.e. highly cariogenic diet) appear important with regard to caries.[53] **2+**

- Cross sectional surveys from Ireland have identified a number of diet-related indicators of caries risk. These include:

  - o Taking a baby bottle to bed [54]
  - o Drinking juice from a baby bottle[8]
  - o Weaning from the baby bottle after 2 years of age[8]
  - o Consumption of sweet snacks or drinks between meals more than twice a day.[2,8] **3**

➢ Fluoride

- Several systematic reviews have shown that exposure to fluoride, in the form of water fluoridation[55] or as topical fluoride[3] reduces caries experience. **1++**

- Cross sectional surveys in Ireland have found that:

  - o Children from fluoridated areas have significantly lower caries levels than children from non-fluoridated areas[2,8,54]
  - o Children who brush their teeth twice a day or more have less caries than those who brush less frequently.[2,8] **3**

➢ Bacteria

- Two systematic reviews found that the presence of Strep Mutans in preschool children was associated with an increased risk of caries.[53,56] **2+**

- The results of studies in older age groups suggest that the predictive power of salivary mutans streptococci testing is consistently modest and the test cannot be considered useful for the assessment of the risk of developing cavities.[47] **4**

➢ **Clinical evidence**

- A systematic review of 43 studies employing multivariate caries risk prediction models found that previous caries experience was an important predictor of caries risk in both the primary and the permanent dentition.[57] **2++**

3.5 Caries risk assessment

In recent years, there has been an increased emphasis on the concept of risk assessment to guide treatment planning decisions and recall intervals for individual patients.[58-60] The rationale behind caries risk assessment is that the treatment and preventive measures received by the patient will be tailored to their individual needs, thus directing appropriate restorative and preventive care towards those at "high" risk and avoiding unnecessary treatments for those at "low" risk. It has been suggested that such an approach not only benefits the patient, but also makes economic sense.[61] Recording caries risk status also allows changes over time to be monitored, and treatment and recall to be adjusted accordingly.

In spite of years of research developing caries risk prediction models, the predictive power of even the best measures that are currently available are modest.[47] Although the judgement of the experienced clinician has been shown to be an important predictor of caries[62-64], the fact remains that there is considerable variation between clinicians in their assessment and management of patients.[65]

A number of caries risk assessment checklists and tools have been developed[58,60,66-69] which incorporate the various known risk factors/indicators for caries, and are intended to assist clinicians in assessing their patient's caries risk and to encourage a systematic approach to caries risk assessment.

The Public Dental Service currently does not formally assess patients' caries risk on a routine basis. A caries risk assessment checklist has been developed as part of this guideline project, specifically for use in the Irish Public Dental Service. This risk assessment checklist combines elements of existing risk assessment tools and known risk factors for caries in Irish children. It was designed to be simple and quick to apply in the Public Dental Service setting. The aim of the checklist is to encourage a risk-based approach to the management of caries in Irish school-children. The checklist and accompanying notes for completing the checklist can be found in Appendix 5. Full details of the development process leading to the development of the checklist will be included in the guideline *"Identification of high caries risk children and preventive strategies for high caries risk children"* which is due to be published in 2009.

Section 4: Effectiveness of topical fluorides – all modalities

In formulating the key questions for the guideline, two categories of questions emerged: (1) those that related to the effectiveness of topical fluorides in general and (2) those that related specifically to a particular fluoride modality. Answers to the general effectiveness questions are presented in this section; specific details on the individual modalities are provided in the following sections.

- **How effective are topical fluorides at preventing caries?**

  A Cochrane systematic review of all topical fluoride modalities for preventing caries, analysed the results of 133 trials involving 65,169 children and found that the use of topical fluorides (varnish, gel, mouthrinse or toothpaste), compared to placebo or no treatment, was associated with an average reduction in caries increment of 26% (95% CI, 24–29%; p<0.0001) in permanent teeth and 33% (95% CI, 22–44%; p<0.0001) in primary teeth.[3] **1++**

- **Is any one modality superior to another?**

  The same review found that fluoride varnish seemed to be more effective than the other modalities, with varnish trials showing a 14% (95% CI, 2–26%; p=0.025) greater effect compared to the other modalities. No differences in effect were found between the three other modalities. The authors suggested that this could be an overestimate, due to the small number of placebo-controlled varnish trials included, and suggested that stronger evidence would come from trials in which the different modalities were compared head-to-head.[3]

  A subsequent Cochrane review, which compared the effect of the different modalities head-to-head, found that no modality was superior to another.[70] **1++**

- **In children already exposed to water fluoridation and home use of toothpaste, do topical fluorides confer any additional benefit?**

  The Cochrane review of all topical fluoride modalities found that the presence of background exposure to fluoride from other sources (e.g. water fluoridation, toothpaste or other fluoride sources) does not influence the size of the effect of topical fluorides. Therefore, the use of topical fluorides may provide additional caries reduction in subjects from fluoridated areas.[3] **1+**

  The question of whether combinations of topical fluorides provide any additional benefit over and above a single modality was addressed in another Cochrane review in the series. Overall, the review found an increase in effect of 10% (95% CI, 2–17%; p=0.01) with the combined use of toothpaste plus gel, varnish or mouthrinse compared to toothpaste alone.[71] **1++**

- **In children already exposed to water fluoridation and home use of toothpaste, do topical fluorides confer any additional risk?**

None of the systematic reviews included in this guideline provided any useful evidence on adverse effects of the different modalities, including the risk of fluorosis. Evidence of risk associated with the individual modalities is presented in the relevant section.

- **Which patients or groups of patients are likely to benefit most from the use of topical fluorides?**

Topical fluorides in general have a greater effect in children with higher initial caries scores. The review of all topical fluoride modalities found a significant 0.7% (95% CI, 0.2–1.2%; p=0.04) increase in the caries preventive effect of topical fluorides per unit increase in baseline caries.[3] The corollary of this is that as caries levels fall in a population, the size of reduction of the caries increment from the use of topical fluorides will also fall. **1++**

(Note: The above association between baseline caries levels and effect was not found for all individual modalities when analysed singly in separate reviews, due to the smaller number of trials involved and the consequent loss of statistical power.)

- **Which patients or groups of patients are likely to be at increased risk of harm from the use of topical fluorides?**

None of the systematic reviews provided any useful information on the adverse effects associated with the use of topical fluorides for caries prevention in children and adolescents. The adverse effects associated with each individual modality will be presented in the following sections.

Section 5: Professionally applied topical fluorides

5.1 Summary of evidence on professionally applied topical fluorides

• Fluoride varnish application two or four times a year, either in the permanent or primary dentition, is associated with a substantial reduction in caries increment.[77]	1++
• Fluoride varnish is effective at preventing caries in high caries risk children.[82,89,90]	1+
• Fluoride gel is effective at preventing caries in permanent teeth.[98,99]	1++
• Fluoride varnish or gel applications may not benefit children who are at low risk of developing dental caries.[90,100-103]	1+
• Evidence for the comparative effectiveness of fluoride varnish versus fluoride gel is inconclusive.[70]	1++
• Fluoride varnish takes less time to apply and results in fewer signs of discomfort in children than fluoride gel or foam.[95,104]	3
• The evidence on the effectiveness of fluoride foam is limited to 2 clinical trials, which provide insufficient evidence on which to base a recommendation.	

5.2 Introduction

Professionally applied fluoride varnish, gel and foam are high concentration fluoride vehicles which are applied by healthcare professionals intermittently for caries prevention. Their caries preventive effect is topical and although they should not be ingested, small amounts will inevitably be swallowed by patients.

Fluoride varnishes may be aqueous solutions (e.g. Bifluorid) or non-aqueous solutions of natural resins (e.g. Duraphat, Lawefluor). Resin-based varnishes have a sticky texture, which prolongs the contact time between the fluoride and the enamel. The concentration of fluoride in varnish ranges from 1,000 ppm (Fluor Protector) to 56,300 ppm (Bifluorid 12). The fluoride formulations that are found in most commercially available varnishes are:

- 5% sodium fluoride (Duraphat, Colgate Palmolive)
- 1% difluorsilane (Fluor Protector, Ivoclar-Vivadent)
- 6% sodium fluoride plus 6% calcium fluoride (Bifluorid 12, VOCO GmbH).

Although the fluoride concentration of varnishes is typically very high, the nature of varnish lends itself to controlled, precise application to specific tooth surfaces. A single 0.25 ml application of fluoride varnish with 22,600 ppm F contains 5.65 mg of fluoride ion, which is well below the probably toxic dose (PTD) for fluoride of 5 mg/kg body weight[72], even if all the varnish dispensed is swallowed.

The concentration of fluoride in gel typically ranges from 5,000 ppm to 12,300 ppm. It has a viscous texture which allows its professional application in a tray, with cotton wool or with dental floss. The most commonly used formulation of gel is 1.23% acidulated phosphate fluoride (APF) containing 12,300 ppm fluoride. A typical fluoride gel treatment using APF gel involves the application of 3 to 5 ml of gel, containing 36.9 to 61.5mg of fluoride ion. However, the probably toxic dose – which is 100 mg of fluoride for a 20 kg child – is contained in only 8 ml of APF fluoride gel (12,300 ppm F). It has been reported that 2.8% to 78% of the initial dose of fluoride may be retained following fluoride gel application. The amount of fluoride retained depends on the amount of gel used, the age of the subject and the application technique.[73] Peak plasma fluoride levels are reached within a shorter space of time and reach higher levels with fluoride gel application than with fluoride varnish application.[74,75]

Recommendation:

- ***Manufacturer's instructions regarding use of fluoride varnish and gel should be carefully followed, as these products have high concentrations of fluoride.*** **GPP**
- ***Fluoride gel should not be used in children under the age of 7.*** **GPP**

The cut-off age of 7 for fluoride gel use was agreed by the Guideline Development Group based on age of eruption of the first permanent molars and also on the mean body weight of Irish children, which increases sharply between 6 age 7 years of age[76], thus reducing the risk of exceeding the threshold for fluoride ingestion if fluoride gel was inadvertently ingested.

Fluoride foam is a relatively recent product which has the same fluoride concentration (12,300 ppm), pH (3–4) and method of application (tray) as conventional APF gel. The advantage of foam over gel is that less material needs to be used, and therefore the patient's risk of ingesting excess fluoride is reduced.

5.3 Fluoride varnish and gel use in Ireland

Our situation analysis, carried out in 2005, showed that Duraphat (22,600 ppm F) was the fluoride varnish most commonly used by the Irish Public Dental Service, with Bifluorid (56,300 ppm F) used to a lesser extent. Twenty seven out of the 29 dental areas reported using fluoride varnish, and two of the dental areas that used fluoride varnish also reported using fluoride gel (Mirafluor gel; 12,300 ppm F). Two out of the 29 dental areas did not use fluoride varnish or gel. The extent to which varnish or gel was used, based on the number of recorded applications, varied widely between dental areas. The recording of applications between dental areas was also inconsistent. We have no information on whether fluoride foam is used in the Public Dental Service.

Recommendation:

- ***Every fluoride varnish or gel application should be recorded as a treatment item in the patient record and also in the day book, if used.*** **GPP**

5.3.1 Availability of fluoride varnish and gel in Ireland

Fluoride gels and varnishes are classified as medicinal products and, as such, are subject to authorisation control by the Irish Medicines Board (IMB). They are also subject to prescription-only control.[22] None of the commonly used fluoride varnish or gel products (e.g. Duraphat, Lawefluor, Bifluorid 12 or Mirafluor) are listed on the IMB website, which means they do not have product authorisation in the Republic of Ireland.

The lack of product authorisation does not mean that a product cannot legally be used in the Republic of Ireland. Under recent legislation governing the marketing of medicinal products, there is provision for a practitioner, registered in Ireland, to prescribe an unauthorised medicinal product for use by his individual patients, on his direct responsibility, in order to fulfil the special needs of those patients (Paragraph 2 of Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007). It can be assumed that this exemption also applies to the situation where the practitioner administers the product to the patient, as in the case of a dental professional applying fluoride varnish or gel (personal communication, Compliance Department, IMB). The use of fluoride varnish or gel, which has always been the responsibility of the prescribing dentist, is clearly a more controlled situation than that which is allowed by the exemption.

An unauthorised product must be ordered from a licensed wholesaler, with written confirmation that the product is for use as specified above. A practitioner may not order an unauthorised product from outside the EEA. This function has to be carried out by the holder of a Manufacturing Authorisation, whose licence refers to this specific activity.

5.4 Effectiveness of fluoride varnish for caries prevention

A number of systematic reviews[77-80] and one meta-analysis[81] on the effectiveness of fluoride varnish have been published, based on a small number of trials of relatively low quality. In addition, three systematic reviews of selected caries prevention and management strategies, which included fluoride varnish, have also been published.[82-84] Most of the trials included in the reviews involved the use of resin-based varnish containing 5% sodium fluoride (22,600 ppm F).

The results from these systematic reviews support the use of fluoride varnish for caries prevention in permanent teeth. The Cochrane review of fluoride varnish reported a mean reduction in caries increment of 46% (95% CI, 30–63%; $p<0.0001$) in permanent teeth, based on the results of seven trials involving 2,278 children. This corresponds to a NNT of 3.2 to prevent one DMFS in a population with a caries increment of 0.67 DMFS/year, and an NNT of 1.4 to prevent one DMFS in a population with a caries increment of 1.6 DMFS/year.[77] **1++**

5.4.1 Effectiveness of fluoride varnish in primary teeth

There is less evidence for the effectiveness of fluoride varnish in the prevention of dental caries in primary teeth. The conclusions drawn from the systematic reviews that address this issue vary. This is primarily due to (a) the small number of studies addressing the effectiveness of fluoride varnish in primary teeth, (b) differences in the inclusion criteria employed by the different reviewers and (c) differences in methods of grading the quality of the evidence, which resulted in the evaluation of different combinations of studies in each systematic review.

The Cochrane varnish review was the only systematic review to report a prevented fraction for the use of fluoride varnish in primary teeth. Although based on only three trials involving 1,107 children[85-87], the pooled reduction in caries increment in primary teeth was 33% (95% CI, 19–48%; p<0.0001).[77] **1++**

Petersson[79] and Rozier[84] in their respective systematic reviews, reported the evidence for the effectiveness of fluoride varnish in primary teeth to be inconclusive and insufficient. Bader et al.[83] found the strength of the evidence supporting the effectiveness of fluoride varnish in preschool-aged children to be fair. The authors based their conclusion on six studies of generally good quality, including three randomised controlled trials.[86-88] **1+**

Subsequently, a randomised controlled trial involving preschool children, found that fluoride varnish (22,600 ppm F) applied once or twice a year over a 24 month period, in addition to oral health counselling, was effective at reducing caries increment in the primary teeth of low income children (mean age 1.8 years at baseline).[89] The mean number of decayed (pre-cavitated or cavitated) or filled surfaces was 1.3 in children who were assigned to receive one application per year and 1.4 in children assigned to receive two applications a year, compared to 2.7 in the control group which received oral health counselling only (p≤ 0.01). **1+**

5.4.2 Application frequency

The most common application frequency for fluoride varnish in clinical trials is twice a year, although application at 3 monthly intervals has also been tested. The Cochrane varnish review concluded that fluoride varnish application two or four times a year, either in the permanent or primary dentition, is associated with a substantial reduction in caries increment. [77] **1++**

Clinical trials evaluating the relative effectiveness of various application frequencies, including ‘intensive’ fluoride varnish application, i.e. three times per week in one week once or twice a year, are of varying quality and have produced conflicting results.[90-93] The most recent of these trials tested the effect of three different fluoride varnish application frequencies on the incidence and progression of approximal caries in 758 Swedish adolescents aged 13—16, from areas with high, medium and low levels of caries.[90] The application frequencies were:

- twice a year, at 6 month intervals (Group 1)
- once a year, three times in one week (Group 2)
- eight times a year at one month intervals during school semesters (Group 3).

Treatment once a month (Group 3) showed the best result, especially in the high risk area. Total approximal caries experience (incidence and progression) in the high risk area was 0.9 DFS in Group 3 (varnish once a month during term time), 1.1 in Group 1 (varnish twice a year), 1.7 in Group 2 (3 applications in one week) compared to 4 in the control group. Application twice a year was considered by the authors to be the most cost effective treatment option.[90] **1+**

5.4.3 Effectiveness of fluoride varnish in high caries risk children

The Cochrane systematic review of fluoride varnish did not find the effectiveness of fluoride varnish to be dependant on baseline caries severity. However, as there were only seven studies included in the regression analysis, the authors advised caution in the interpretation of this finding.[77] **1+**

A systematic review of selected caries prevention methods among high caries risk individuals judged the evidence for efficacy to be fair for fluoride varnish, and insufficient for fluoride gel and fluoride mouthrinse.[82] **1+**

The Swedish randomised controlled trial that compared the effect of three different fluoride varnish application frequencies on the incidence and progression of approximal caries in teenagers from areas with high, medium and low levels of caries, found that the impact of varnish application was greatest in the high caries risk areas.[90] The incidence of new caries lesions on approximal surfaces was significantly lower for all fluoride application frequencies in the high risk group compared to the control (average number of new lesions: 0.95, 1.40 and 0.54 in varnish Groups 1, 2 and 3 respectively, compared to 3.05 in the high risk control group, $p<0.001$). The average number of enamel lesions progressing to dentine or fillings on approximal surfaces was also significantly lower in the high risk areas for the three varnish application frequencies compared to the control (0.18, 0.30 and 0.37 in varnish Groups 1, 2 and 3 respectively, compared to 0.90 in the control group, $p<0.003$). In the medium and low risk areas, although the average number of lesions progressing was lower in all varnish groups compared to the control group, the differences were not statistically significant. **1+**

A recent randomised controlled trial evaluating the use of fluoride varnish in high caries risk preschool children from a fluoridated area of California, showed reductions in caries increment of 58% in children assigned to receive one varnish application a year and 61% in those assigned to receive 2 applications a year during the 24 month study period, compared to children who did not receive varnish.[89] **1+**

Recommendation:

- ***Fluoride varnish application should be offered to children in fluoridated and non-fluoridated areas who are assessed as being at high caries risk.*** **A**
- ***Fluoride varnish should be applied at intervals of 6 months or 3 months.*** **A**
- ***Because of its ease of application, the small amount used and the precise application of the material to individual tooth surfaces, resin-based varnish (22,600 ppm F) can be used in young children (aged 1-7 years) who are assessed as being at high caries risk.*** **GPP**

5.5 Fluoride varnish in community-based programmes

The use of fluoride varnish as a public health measure for the prevention of caries in certain groups of the population has the potential to maximise access to high caries risk children who might otherwise not attend the dental surgery. Many of the trials included in the systematic reviews do not specify the setting for the application of the varnish, i.e. dental surgery-based or outreach. Three recent RCTs were all conducted outside of the dental surgery setting. Two of these studies reported significant caries reductions for children receiving fluoride varnish application compared to the control group.[89,90] The third study found a non-significant result, which was attributed to participation bias.[94] Although this latter trial was conducted in a high caries area in Manchester, the children who consented to participate in the study had caries levels at baseline (average age 6.9) that were lower than the average caries levels of 5-year-olds in the area (mean d_3ft = 2.39 at age 6.9 compared to 2.48 in 5-year-olds). Apart from a statistically significant reduction in small enamel lesions in the primary dentition (0.71 v 1.12, p=0.03), the study failed to demonstrate a reduction in dental caries in the children receiving the fluoride varnish applications. The low level of consent to take part in the study – less than 45% of those who were randomised to test and control groups actually consented to participate – and the lower than expected caries increment in the control group were considered by the authors to explain the lack of effectiveness of the fluoride varnish treatments.[94] 1-

The Guideline Development Group considered the use of fluoride varnish as a targeted population intervention for high caries risk groups, e.g. children with special needs, children living in non-fluoridated areas, children living in disadvantaged areas or attending designated disadvantaged schools. A small number of studies were identified which included economic evaluation of fluoride varnish application[95,96,97], none of which were directly applicable to the Irish setting. Therefore, an economic evaluation was conducted to estimate the cost of introducing a school-based fluoride varnish programme in Ireland.

The cost of such a programme was estimated as the cost per child per year, based on 2 fluoride varnish applications per year delivered by a dental team of one hygienist and one dental nurse. The variables included in the cost analysis were labour, travel, subsistence and materials. A sensitivity analysis was conducted to allow for variable travel distances and productivity (number of children treated per day). We considered it likely that, to reduce travel costs, the hygienist would be assisted by a dental nurse who was based closest to the school being visited. We made provision for this in the sensitivity analysis by calculating costs for both members of the team travelling equal distances (20, 33 and 50 miles), and for the dental nurse travelling half the distance of the hygienist (10, 17.5 and 25 miles). An upper limit of 50 children per day was set, following consultation with one of the authors of the Manchester Fluoride Varnish project.[94] The figure of 33 children per day was reached based on the published application time of 6 minutes[95] and the amount of school time actually available for seeing children, excluding breaks and the 30 minutes leading up to break times. The minimum number of children seen per day was arbitrarily set at 20. Table 5.1 shows the cost per child per year for the various scenarios described above. The estimated cost per child per year ranged from €23 to €62, with productivity having the greatest influence on costs. The greatest cost efficiency was seen when 50 children per day were seen and when the distance travelled by the hygienist was 20 miles, with the nurse travelling 10 miles. Further cost savings could be made if the dental team worked for a half day (one session on the varnish programme, seeing approximately 20 children per session), leaving them free for other duties for the second session in the day. A full description of how the costs were calculated can be found in Appendix 6.

Table 5.1: Sensitivity analysis of the cost per child per year of a bi-annual school-based fluoride varnish programme, delivered by a hygienist/nurse dental team

	Assumption 1: Nurse and hygienist travel equal distances			Assumption 2: Nurse travels half the distance of hygienist		
	50 miles	**33 miles**	**20 miles**	**50 miles**	**33 miles**	**20 miles**
20 children/day	€62.15	€58.75	€56.15	€59.65	€57.20	€55.15
33 children/day	€37.67	€35.61	€34.03	€36.15	€34.67	€33.43
50 children/day	€26.16	€24.80	€23.76	€25.16	€24.18	€23.36

The Group concluded that a school-based fluoride varnish programme should initially be considered for a discrete target group, such as children attending special schools. The effectiveness and true cost of this type of programme would need to be evaluated before extension to other high risk groups could be considered.

Recommendation:

- ***The introduction of a school-based fluoride varnish programme should be considered for children attending special schools.*** **GPP**

5.6 Effectiveness of fluoride gel for caries prevention

We identified a Cochrane systematic review[98] and a meta-analysis[99] on the effectiveness of fluoride gel for caries prevention. The included studies involved both professionally-applied and self-applied fluoride gel at a variety of different concentrations and application frequencies. However, most of the studies involving professionally applied fluoride gel used 1.23% APF gel (12,300 ppm F) applied with a tray, once or twice a year. The Cochrane review reported a reduction in caries increment of 21% (95% CI, 14–28%; p<0.0001) in permanent teeth of children and adolescents, based on 14 placebo-controlled trials that involved the use of both professionally applied and self-applied topical fluoride gel. This corresponds to an NNT of 2 to avoid 1 DMFS in a population with a caries increment of 2.2 DMFS/year, or an NNT of 24 based on an increment of 0.2 DMFS/year. The authors concluded that there is clear evidence of a caries-inhibiting effect of fluoride gel.[98] **1++**

The meta-analysis reported a similar reduction in caries increment of 22% (95% CI, 18–25%; p value not reported).[99] However, in a separate review by Rozier et al., which analysed only studies from the meta-analysis that involved professionally applied fluoride gel, a more modest reduction in caries increment of 18% (unweighted) was reported.[84] **1+**

Subsequently, two randomised controlled trials from the Netherlands measured the effectiveness of semi-annual applications of fluoride gel (4,500 ppm F) in two groups of low-caries children, initially aged 4.5–6.5[100] and 10.5 years[101]. The results of these two studies and two further publications which re-analysed the results to include enamel lesions[102,103] suggest that semi-annual application of fluoride gel (4,500ppm F) may not benefit children who are at low risk of caries. **1+**

5.6.1 Effectiveness of fluoride gel in primary teeth

The authors of the Cochrane systematic review of fluoride gels found little useful information concerning the effectiveness of fluoride gel in primary teeth.[98]

5.7 Fluoride varnish versus fluoride gel for caries prevention

In making recommendations on the use of fluoride varnish and gel, the Guideline Development Group considered evidence on the relative effectiveness, acceptability, adverse effects and costs of varnish and gel. The relative safety of the two modalities has been covered in section 5.2.

5.7.1 Effectiveness

The Cochrane review of trials that compared one fluoride modality directly with another included only one trial that compared varnish directly with gel. This trial found a non-significant increase in effect of 14% (95% CI, -12 to 40%; p=0.3) in favour of varnish. The researchers concluded that there was insufficient evidence from this trial to confirm or refute a differential effect in caries reduction for fluoride varnish versus fluoride gel.[70] **1++**

5.7.2 Acceptability

Fluoride varnish may have an advantage over fluoride gel in terms of operator and patient acceptability. In an evaluation of dental hygienist and patient comparisons of fluoride varnish to fluoride gel, fluoride varnish was rated as superior to fluoride gel in terms of need for moisture control, control of ingestion, efficiency, comfort and taste. However, the patients in the study were all aged 12 years or older, and some of the patients objected to the temporary discoloration caused by the fluoride varnish (Duraphat).[104] In a similar study which compared fluoride varnish with fluoride foam, varnish applications were found to take less time and to result in fewer signs of discomfort for patients aged 3–15 years when compared to a four minute fluoride foam application.[95] 3

Recommendation:

- ***Because of its ease of application and greater patient acceptability, fluoride varnish should be used in preference to fluoride gel for caries prevention in children who are assessed as being at high caries risk.*** **D**
- ***In situations where operator or patient preference dictates the use of fluoride gel rather than fluoride varnish for children aged 7 years and over, gel application should be offered at 6 month intervals.*** **A**

5.7.3 Adverse effects

None of the systematic reviews provided evidence on adverse effects associated with the use of fluoride varnish or gel. Adverse effects such as nausea, vomiting and gastrointestinal pain have been reported following professional application of fluoride gel in observational studies.[74,105] However, these studies were conducted without precautions such as suction. The subsequent introduction of a standard protocol for professional application of fluoride gel has undoubtedly led to a reduction in the risk of adverse effects with the use of fluoride gel.[106] 3

5.7.4 Fluorosis

We identified a retrospective cohort study, conducted in a low fluoride area in Denmark, which found no increased prevalence of dental fluorosis in the teeth of children who were given fluoride gel treatments during the formation of the teeth, compared to those who received the fluoride treatment exclusively after tooth formation was completed.[107] Additionally, there was no increased prevalence of dental fluorosis in the teeth of those who received fluoride gel treatments four times a year compared to those who received semi-annual fluoride gel treatments. 3

We did not identify any studies on the risk of dental fluorosis associated with the use of fluoride varnish. Further research is required to establish if the use of varnish, particularly in very young children, is associated with fluorosis.

5.7.5 Hypersensitivity

Adverse effects in the mouth from the use of fluoride varnish appear to be very rare. Our search identified three papers which reported cases of hypersensitivity to Duraphat. The first paper[108] contained two case reports: the first was a case of contact dermatitis on the hand of a dental nurse who had chronic dermatitis on her hand, which possibly was aggravated by accidental exposure to

Duraphat. The second case report was an allergic stomatitis in a dental patient with an allergy to colophony. Colophony (rosin) is a natural resin with adhesive properties derived mainly from pine and spruce trees. It is found in Duraphat varnish and is responsible for its sticky texture. The colophony component of Duraphat was cited as the most likely cause for these adverse reactions. The authors concluded that dental personnel are at risk of developing contact allergy to Duraphat and that patients already hypersensitive to colophony can acquire allergic contact stomatitis from Duraphat.[108] The second paper reported a case of contact stomatitis after Duraphat application, in a patient allergic to sticking plasters.[109] The author advised that dentists should be encouraged to ask their patients about allergies to colophony or sticking plasters prior to treatment with Duraphat varnish. It is also noted that allergy to colophony is uncommon in children. The third paper described a case of severe disseminated acute urticaria and angioedema in an 8-year-old girl 7 hours following an application of sodium fluoride varnish (Duraphat) – her third ever application, and the second within a 4 month period. Patch testing with a standard series, plastics, resins and Duraphat showed only mild erythema and oedema at 2 days, and at 4 days a slight erythema persisted. Patch tests with Duraphat and sodium fluoride 1% aq. in 14 controls were negative The child had a history of other allergies, leading the authors to conclude that in some atopic patients, painting the teeth with sodium fluoride can lead to severe and potentially dangerous reactions.[110] **3**

The product information leaflet for Duraphat contraindicates its use in patients with ulcerative gingivitis, stomatitis or known sensitivity to colophony. It states that in extremely rare instances, attacks of dyspnoea have occurred in asthmatic children following its application. We found no reports of this in the literature. A randomised controlled trial evaluating the use of fluoride varnish in high caries risk preschool children reported no adverse events for 21 asthmatic children (5.6% of the baseline sample) included in the trial.[89] **1+**

5.8 Fluoride Foam

Our literature search identified only two RCTs which evaluated the effect of fluoride foam on caries increment in primary teeth[111] and in the first permanent molars[112] In both trials, fluoride foam (12,300 ppm) was applied in trays for 4 minutes, twice a year for two years.

The first trial, a double–blind RCT on the effect of fluoride foam in primary teeth of children aged 3–4 years at baseline, found a significantly lower caries increment after two years in the foam group compared to the placebo group for approximal surfaces (mean dmfs: 1.2 v 1.9, p=0.002) and on all surfaces combined (mean dmfs: 3.8 v 5.0, p=0.03).[111] **1++**

The second trial measured the effect of fluoride foam on caries increment in the first permanent molars of children aged 6–7 years at baseline, and also compared the effect of foam with that of fluoride gel. After two years, the caries increment on smooth surfaces in the control group was significantly higher than that of the foam or gel groups (mean DMFS increment (smooth surfaces): 0.27 control compared to 0.16 foam and 0.17 gel, p= 0.01). Although the mean caries increment for all surfaces was lower in the foam and the gel groups than in the control group, the difference was not statistically significant (mean DMFS increment (all surfaces): 0.39 foam, 0.38 gel compared to 0.50

control p>0.05).[112] A weakness of the study is that it did not consider the possible effect that variations in eruption time of the first molars across the three study groups could have on the reported results. 1+

- ***Given the limited evidence on the effect of fluoride foam, the Guideline Development Group concluded that there was insufficient evidence on which to base a recommendation on the use of fluoride foam.***

Section 6: Slow-release fluoride devices

6.1 Summary of evidence on slow release fluoride devices

- There is, as yet, only weak and unreliable evidence that slow-release fluoride devices in the mouth may provide a measure of protection against dental disease progression.[113]

The objective of a slow-release fluoride device is to produce a consistent level of fluoride intraorally, during a long period of time (at least one year), without the need for regular professional involvement or patient compliance. Slow-release fluoride devices have been suggested as an ideal way to provide fluoride to high caries risk groups, who tend to be irregular attenders with poor oral hygiene habits.[114] The properties of the ideal slow-release fluoride device have been described as follows:

- Safe to administer
- Cheap and cost effective
- Easily manufactured
- Easy and quick to apply
- Robust
- Fluoride release of at least one year
- Provides continuous low concentration of intra-oral fluoride
- Acts topically at the tooth surface
- Does not rely on patient compliance or motivation
- Prevents dental caries clinically.[114]

We found one systematic review of the effectiveness of slow-release fluoride devices for the control of dental caries.[113] This review identified a single randomised-controlled trial that met its inclusion criteria.[115] The included trial involved 174 high caries risk children, with a mean age of 8.8 years, living in a deprived area of Leeds. The slow-release device was a glass bead constituted with fluoride, which was designed to be released slowly as the glass bead dissolved. Placebo devices without fluoride, which were indistinguishable from the fluoride-containing beads, were used as controls. The test and control devices were randomly assigned to children, and bonded to the buccal surface of the right maxillary first permanent molar. After two years, 132 children were available for assessment; of these, only 63 children (47.7%) still had beads retained (31 test, 32 control). Among those who retained the beads, a significant difference in salivary fluoride levels between the test and control groups was found (0.11 mg L^{-1} v 0.03 mg L^{-1} respectively, $p< 0.001$). Mean caries increment was significantly lower in the test group compared to the control group (DMFT mean difference -0.72, $p<0.01$; DMFS mean difference -1.52, $p<0.01$). However, the exclusion of the majority of the participants from the statistical analysis marked the evidence presented as weak and unreliable.

The authors of the systematic review concluded that there is, as yet, only weak and unreliable evidence that slow-release fluoride devices in the mouth may provide a measure of protection against dental disease progression. They questioned the generalisability of the results to general practice due to the difficulties of retention of the device – which is fundamental to its effectiveness – and suggested that future studies consider bonding methods and contouring of the device to match that of the tooth surface.[113]

A subsequent observational study, which measured the fluoride release and retention of slow-release fluoride glass beads with a modified shape, found that 93% of beads were retained at six months.[116]
The authors concluded that the new shape of the devices improved their retention enormously. 3

- ***There is insufficient evidence at this time on which to base a recommendation on the use of slow-release fluoride devices.***

Section 7: Community-based Fluoride Toothpaste Programmes

7.1 Summary of the evidence on fluoride toothpaste

• Fluoride toothpaste is effective at preventing caries in children and adolescents.[117,118]	**1++**
• The effect of fluoride toothpaste is not influenced by exposure to water fluoridation, i.e. fluoride toothpaste use provides additional caries reduction in subjects from fluoridated areas.[117]	**1+**
• The effect of fluoride toothpaste is influenced by the level of caries in the population, i.e. greater caries reductions are seen in populations with high levels of caries.[117, 118]	**1+**
• Supervised brushing is more effective at preventing caries than unsupervised brushing.[117, 118]	**1++**
• There is a dose/response effect with increasing fluoride concentration in toothpaste:	
o Toothpaste containing 1,000 ppm F is more effective than toothpaste containing 250 ppm F at preventing caries in permanent teeth.[119, 120]	**1+**
o Toothpaste containing 1,500 ppm F is more effective than standard 1,000/1,100 ppm F toothpaste at preventing caries in permanent teeth.[118]	**1+**
• Brushing twice a day is more effective than brushing once a day.[117]	**1+**
• There is no evidence that educative programmes aimed at reducing caries are effective if they do not involve fluoride.[121]	**2++**

7.2 Introduction

Throughout the world, fluoride toothpaste is by far the most widely used method of applying fluoride. The consensus view is that the use of fluoride toothpaste has been a very important factor in the decline in dental caries in many western countries over the past 30 years.[122] The effectiveness of fluoride toothpaste has been firmly established in two systematic reviews, which reported caries reductions in permanent teeth of 24% [117] and 24.9%[118] with the use of fluoride toothpaste compared to placebo or no treatment. **1++**

The effect of fluoride toothpaste was not influenced by background exposure to water fluoridation, i.e. use of fluoride toothpaste provides additional caries reduction in subjects from fluoridated areas.[117] **1+**

In Ireland, 95% of toothpastes on the market contain fluoride.[8] It has been suggested that toothbrushing with fluoride toothpaste is close to an ideal public health method in that its use is convenient, inexpensive, culturally approved and widespread.[123] However, as with all self-administered interventions, it relies on patient compliance to achieve optimum results. Given the unfavourable toothbrushing habits of Irish children (Section 1.1.1 and Appendix 1), the Guideline Development Group focused on the use of fluoride toothpaste as part of community-based caries preventive programmes, as a means of supporting or supplementing home use. Before considering the community use of toothpaste, it is important to consider the evidence supporting the optimum use of fluoride toothpaste, specifically in relation to the fluoride concentration of toothpaste, frequency of brushing, age of commencing brushing and risk of fluorosis.

7.3 Fluoride concentration of toothpaste

The European Union (EU) limit for fluoride concentration in over-the-counter toothpastes is 1,500 ppm; these toothpastes are classified as cosmetic products. Toothpastes containing higher levels of fluoride (up to 5,000 ppm) are available on prescription. Low fluoride toothpastes, usually containing less than 600 ppm F, are marketed specifically for young children who, because of their inability to spit out effectively, tend to swallow much of the toothpaste that is placed on the brush.[124,125]

7.3.1 Toothpastes containing 1,000 ppm F or more

There is a dose/response effect with increasing fluoride concentration in toothpaste. A Cochrane review found a 7.7% increase in effectiveness per 1,000 ppm fluoride, which was non-significant (95% CI, -0.03–15%; p=0.051).[117] A Swedish review found a 9.7% (range 0–22%) increase in caries prevention in favour of 1,500 ppm F compared to 1,000/1,100 ppm F toothpaste, and concluded that there was strong evidence that toothpastes with 1,500 ppm fluoride had a superior caries-preventive effect in the young permanent dentition compared to standard toothpastes with 1,000 ppm fluoride.[118] **1+**

The Swedish review also included six trials which compared high fluoride toothpastes containing 2,000 ppm F or more with standard toothpastes containing 1,000 ppm F. Three of these trials reported significant results in favour of the high fluoride toothpaste, with reported reductions in caries of 9%[126], 6%[127], and 11%.[128] The other three trials had non-significant results.[129-131]

7.3.2 Low fluoride toothpaste

A systematic review[119] and a meta-analysis[120] have reported higher caries increments in permanent teeth of children using 250 ppm F toothpaste compared to those using 1,000 ppm F toothpaste. The systematic review identified seven randomised controlled trials that met its inclusion criteria, only four of which could be included in the meta-analysis. The analysis of these four studies found a statistically significantly higher mean caries increment with the low fluoride (250 ppm F) toothpaste compared to the standard 1,000 ppm F toothpaste (mean DFS increment 0.6 higher (95% CI, 0.22–0.99; p=0.002) with monofluorophosphate toothpaste, and 0.7 higher (95% CI, 0.3–1.09; p=0.0005) with sodium fluoride paste. The reviewers concluded that toothpastes containing 250 ppm fluoride were not as effective as toothpastes with 1,000 ppm fluoride at preventing caries in the permanent dentition.[119] **1+**

The meta-analysis by Steiner et al. analysed the same four trials using different statistical techniques, and calculated lower caries increments of 13% or 14% (depending on the meta-analysis model used) in children using 1,000 ppm F toothpaste compared to those using 250 ppm F.[120] **1+**

Evidence on the caries-preventive effect of low fluoride toothpaste in young children is extremely sparse. We found only three trials which tested the effect of low fluoride toothpastes at preventing caries in the primary teeth of preschool children. Given the scarcity of the evidence, it is worth considering each trial in turn.

A double-blind RCT by Winter et al. compared the effectiveness of 550 ppm F versus 1,055 ppm F toothpaste at preventing caries in the primary teeth of 2,177 children from a non-fluoridated area of England.[132] The children were aged 2 at the start of the trial, which lasted 3 years. At the end of the trial, the average caries experience of children in the 550 ppm F group was higher than that of children in the 1,055 ppm F group (mean dmft = 1.72 v 1.45; mean dmfs = 2.52 v 2.29), but the differences were not statistically significant. The only statistically significant finding relating to caries was the percentage of children who were caries free, which was significantly lower in the 550 ppm F group compared to the 1,055 ppm F group (52% v 58%, difference 6% (95% CI, 0.33–13.3%). Based on the totality of the results, the authors concluded that the low fluoride toothpaste was likely to be as equally effective as a standard paste at preventing caries in young children, and could therefore be recommended for use by this age group. A weakness of this trial, however, was that there was no baseline measure of caries and the baseline characteristics of the test and control groups were not described. **1-**

An RCT by Davies et al., conducted in non-fluoridated, deprived areas of north west England, tested the effect of postal distribution of fluoride toothpaste, containing either 1,450 ppm F or 440 ppm F, at 3 month intervals to 7,422 children from the age of 12 months to 5.5 years, on caries levels in the primary teeth at age 5-6 years.[133] At the end of the trial, when analysis was restricted to data from children who had been supplied with toothpaste throughout the trial, those who received the 1,450 ppm F toothpaste had significantly less caries than the control group, which received no toothpaste (2.15 v 2.57, p=0.002, PF = 16%). Caries levels were also significantly lower for children in the 1,450 ppm F group compared to the 440 ppm F group (2.15 v 2.49, p=0.02, PF = 14%). There was no significant difference in mean dmft between the 440 ppm F group and the control group (2.49 v 2.57, p=0.08). **1+**

Further analysis of this data showed a social gradient in the effectiveness of the two fluoride concentrations. In the least deprived quartile (which had the lowest caries levels), the mean dmft of the high fluoride (1,450 ppm F) group was significantly lower than that of the low fluoride (440 ppm F) group (1.4 versus 2.2, p<0.05). In the most deprived quartile (which had the highest caries levels), the provision of both low and high fluoride toothpaste tended to reduce caries, compared to the control group, although the differences in mean dmft were not significant (mean dmft 2.7, 2.9 and 3.2 in the 1,450 ppm F, 440 ppm F and control groups respectively).[134] **1+**

The third trial was conducted in a low-income, low fluoride (<0.3 ppm F) area of Brazil. It tested the effect of supervised toothbrushing in preschools with low fluoride (500 ppm F) toothpaste and 1,100 ppm F toothpaste in preventing caries in young children (age range 2–4 years) who were "caries active" or "caries inactive" at baseline.[135] At one year follow-up, there was no significant difference in the mean number of new caries lesions that developed in children receiving the low and high fluoride toothpaste in the caries inactive group (0.33 v 0.52, p=0.28). In the caries active group, net caries increment (number of lesions progressing minus number of lesions arresting) was significantly lower in the 1,100 ppm F group compared to the 500 ppm F group (-0.6 v 2.5, p=0.005). The authors concluded that in a low fluoride area, the anti-caries effect of low fluoride toothpaste was similar to that of conventional toothpaste for caries inactive children. However, in children with active caries lesions, the low fluoride toothpaste was less effective than the 1,100 ppm F toothpaste at controlling the progression of lesions.

A weakness of this study is that at baseline, the mean number of active, non-cavitated lesions was twice as high in the 1,100 ppm F group compared to the 500 ppm F group (5.3 ± 6.5 v 2.5 ± 1.5), while the number of cavitated lesions was lower (4.7 ± 5.5 v 5.7 ± 5.0). The relevance of the differences between the two caries active groups at baseline was not considered by the authors, so it is unclear if the baseline differences could have influenced the results. **1-**

Recommendation:

- ***Toothpaste containing at least 1,000 ppm F should be used*** **A**

The Guideline Development Group concluded that there is insufficient evidence to make a recommendation on the use of low fluoride toothpaste for the prevention of caries in preschool children, given the limited number of trials that address this issue, and the differences in the quality, design, populations studied and results of these trials.

7.4 Frequency of brushing

Brushing twice a day is more effective than brushing once a day. The Cochrane toothpaste review found that the effect of fluoride toothpaste increased with higher frequency of use, with a 14% increase in prevented fraction moving from brushing once a day to twice a day.[117] **1+**

In Ireland, cross sectional surveys have found that children who brush twice a day or more have significantly less caries in their primary teeth[2,8] and in their permanent teeth[2] than those who brush less frequently. **3**

Recommendation:

- ***Children should brush their teeth twice a day.*** **B**

7.5 Toothpaste use and the risk/benefit balance

Toothpaste is undoubtedly effective at preventing dental caries, but its use is also associated with an increased risk of developing fluorosis. Young children can ingest considerable amounts of fluoride during toothbrushing with fluoride toothpaste[124,125], which can contribute substantially to total daily fluoride intake for children in both fluoridated and non-fluoridated areas.[19,20,136,137]

Most studies which have investigated the association between toothpaste use and fluorosis have relied on retrospective assessment of fluoride intake, years after the exposures occur, and are open to recall bias. With this limitation, a narrative review which included 15 studies that quantified the risk of fluorosis associated with the use of fluoride toothpaste, concluded that of all the toothpaste variables, the best indicator of fluorosis was use of fluoride toothpaste before 2 years of age.[18] The odds of fluorosis with toothpaste use before age 2 was reported in 9 studies, and ranged from 1.34 ($p<0.05$)[138] to 11 (95% CI, 4.83–25.22).[139] Differences in the indices used to measure fluorosis and also in exposures to multiple sources of fluoride account for this wide variation in the estimates of risk. **3**

A longitudinal study, which collected data from parental questionnaires on total fluoride ingestion for a cohort of children at age 16, 24 and 36 months, found that fluoride ingestion from toothpaste at age 24 months remained a significant risk factor for fluorosis in the upper permanent incisors at age 9–11, when controlling for fluoride ingestion from diet and supplements.[140] **3**

The concentration of toothpaste used has also been associated with higher levels of fluorosis. In the follow-up of the trial by Winter et al. [132], in which toothpaste containing 550 ppm F or 1,055 ppm F was provided from age 2 years to age 5 years, the prevalence of fluorosis ($TF\geq2$) at age 9 years was 9% in the 1,055 ppm F group and 5% in the 550 ppm F group, ($p<0.05$). The fluoride concentration of the toothpaste remained significant in logistic multiple regression analysis, which controlled for other sources of fluoride and age of commencing toothbrushing.[141] In the follow-up of the trial by Davies et al.[133], in which toothpaste containing 440 ppm F or 1,450 ppm F was provided from age 12 months to age 5 years, the prevalence of fluorosis ($TF\geq2$) at age 9/10 years was 7% in the 1,450 ppm F toothpaste group and 2.1% in the 440 ppm F toothpaste group, ($p<0.003$).[142] **2+**

Other factors associated with increased risk of fluorosis with the use of toothpaste include:

- Swallowing toothpaste[143,144] **3**
- Brushing frequency[145] **3**

Assessment of the fluorosis/caries balance for a population must be based on that population's fluoride exposure profile, oral health status and socio-economic status. It is made more complex when more than one source of fluoride is available, as is the case within the Republic of Ireland where fluoridated water and toothpaste are both widely available.

Irish cross sectional studies have found that commencing toothbrushing before 12 months of age is significantly associated with lower caries levels in the primary teeth at age 5 and at age 8 after controlling for water fluoridation.[2,8] Creedon and O'Mullane found that age of commencing toothbrushing was significantly associated with caries levels at age 5, and reported a 42% increase in the predicted odds of having caries for every unit (~ 1 year) increase in the age of commencing toothbrushing.[54]

On the other side of the equation, the prevalence of fluorosis in the permanent teeth of Irish children and adolescents has increased in both fluoridated and non-fluoridated areas between 1984 and 2002, while levels of caries have fallen in the same time period (Figure 1.1). The prevalence of fluorosis was significantly higher in fluoridated areas, which is not unexpected as a certain degree of fluorosis is an inevitable consequence of water fluoridation. Caries levels were also significantly lower in fluoridated areas.[2] Further research is required to investigate the contribution of fluoride toothpaste to enamel fluorosis in Ireland. Research is also needed to measure prevalence and severity of caries in Irish children aged 2-3 years, as this is the age group most directly affected by the caries/fluorosis balance, and yet there is little Irish data available on the oral health of young children.

In 2002, the Forum on Fluoridation recommended lowering of the fluoride level in water in Ireland from 0.8–1.0 ppm to 0.6–0.8 ppm as part of a strategy to bring about “meaningful reductions in dental decay while reducing the risk of developing fluorosis”.[4] Recommendations on the use of fluoride toothpaste were also issued, as an additional measure to minimise the risk of fluorosis. These recommendations were updated by the Expert Body on Fluorides and Health in 2008[146] and are presented in Table 7.1.

Table 7.1 Irish Expert Body on Fluorides and Health recommendations on the use of fluoride toothpaste, 2008

From 0 until 2 years old

- Start to clean a baby’s teeth as soon as the first tooth appears
- Brush a baby’s teeth with a soft toothbrush and water only
- Do Not Use Toothpaste*

**Professional advice on the use of fluoride toothpaste should be considered when a child below 2 years of age is thought to be at high risk of developing dental decay, e.g. children with special needs.*

From 2 until 7 years old

- Use a small pea-sized amount of fluoride toothpaste 1,000–1,500 ppm.

(Paediatric toothpastes with low concentrations of fluoride (e.g. 500 ppm) require further research before their use can be recommended).

- Supervise brushing twice a day, in the morning and at night just before bedtime
- A child under seven years needs help from an adult when brushing teeth
- A child should never eat or swallow toothpaste
- Clean the teeth thoroughly twice every day with fluoride toothpaste

7.6 Fluoride Toothpaste Preventive Programmes

The Guideline Development Group focused on the use of fluoride toothpaste as part of community-based caries preventive programmes, to support or supplement home use. Currently, in the Public Dental Service, most oral health promotion activities that promote the use of fluoride toothpaste are education-based and are delivered through schools. While simple educative interventions can improve knowledge, there is no evidence that changes in knowledge are causally related to changes in behaviour. There is also no evidence that educative programmes aimed at reducing caries are effective if they do not involve fluoride.[121] **2++**

The two community-based toothpaste interventions considered by the Guideline Development Group were school-based supervised toothbrushing and toothpaste distribution (referred to in some studies as *unsupervised* toothbrushing). Community-based supervised toothbrushing ensures compliance and also reduces the risk of fluoride ingestion by overseeing the amount of toothpaste dispensed. The rationale behind toothpaste distribution is that the provision of free toothpaste will encourage its use. An advantage of community-based interventions that involve toothpaste is that they put the means of preventing decay into the hands of the individual, rather than having it imposed by professional intervention.[147]

In the 1970s, caries preventive programmes involving fluoride toothpaste took the form of either school-based supervised toothbrushing or formal distribution of fluoride toothpaste on a regular basis. More recent studies have evaluated the effectiveness of supervised toothbrushing at preventing caries in targeted populations such as preschool children and school children who are at particularly high risk of decay.

7.6.1 Populations likely to benefit from community-based fluoride toothpaste preventive programmes

The Cochrane systematic review found that the effect of fluoride toothpaste significantly increased with higher baseline levels of caries, with a 0.7% (95% CI, 0.3–1.17%; p=0.002) increase in effect per unit increase in caries. The review also found that the effect of fluoride toothpaste was not influenced by background exposure to water fluoridation, which implies that fluoride toothpaste use provides additional caries reduction in subjects in fluoridated areas.[117] **1+**

Therefore, in both fluoridated and non-fluoridated areas, a community-based intervention involving the use of toothpaste is likely to be most effective in populations with high levels of caries. At national level, the wide variation in the prevalence of caries in different dental areas would suggest that community-based programmes may be more relevant to some dental areas than others. It has been suggested that where the proportion of high caries risk individuals exceeds 40% of the target population, for practical purposes, preventive efforts should be targeted at the whole population rather than at individuals.[47] As few dental areas collect data on caries levels in the populations served, there is very little data at small area level on caries experience in Ireland. This makes the identification of high caries risk groups more difficult. However, from their ongoing contact with schools through the school dental service, many dental areas have built up a local knowledge of the caries profile of different districts within the dental area, which provides some basis for identifying high risk groups. All dental areas prioritise services for children with special needs as a specific high caries risk group; many areas also target designated disadvantaged schools.

7.7 School-based supervised toothbrushing

Two of the systematic reviews mentioned earlier considered the effects of supervised toothbrushing in caries prevention.[117, 118] In both reviews, the supervision mainly took place in a school setting and was carried out by teachers. Toothpaste was also provided for home use in most trials. Fourteen of the 18 supervised trials in the Cochrane review used 1,000 ppm F toothpaste; only one used 500 ppm F toothpaste.[117] In the Swedish review, all 14 of the supervised trials used 1,000 ppm F toothpaste.[118] The Cochrane review reported a 10% (95% CI -17 to -4%; p=0.001) reduction in effectiveness with unsupervised use. The absolute effect size for each mode of use was not reported. The researchers attributed the increased effectiveness of supervised toothbrushing to better compliance in the use of toothpaste.[117] **1+**

The Swedish systematic review reported reductions in caries increment of 31.0% with supervised toothbrushing and 23.3% with unsupervised toothbrushing for placebo controlled trials.[118] **1++**

Neither review included any trials that involved a direct randomised comparison of supervised versus unsupervised toothbrushing with the same toothpaste formulation.

Long term benefits of school-based supervised toothbrushing have been reported 4.5 years after the cessation of the programme.[148] The effect of the programme was tested in a randomised controlled trial, in which disadvantaged, high caries Scottish children, aged 5 at baseline, brushed daily in school with 1,000 ppm F toothpaste. The school-based toothbrushing was supervised by trained local mothers. Toothpaste and toothbrushes were also provided for home use. After two years, a significant reduction in caries on the first permanent molars was reported: 32% (95% CI, 4–60%) for enamel and dentine lesions combined (D_1), and 56% (95% CI, 13–101%) for dentine lesions only (D_3). The trial ran for 30 months, after which the supervised toothbrushing programme was discontinued.[147] **1+**

Seven years after the start of the trial and 4.5 years after its cessation, the caries increment in first permanent molars in children who had participated in the programme and who were successfully followed up was 1.6 D_3FS compared to 2.65 D_3FS in the control group ($p<0.05$) – a percentage reduction of 39%. Analysis of the results on an intention-to-treat basis, produced a slightly more conservative, but still substantial, estimate of 30% reduction in caries increment (D_3FS) in first permanent molars for all children completing the 30 month programme.[148] **1+**

An important feature of the Scottish supervised toothbrushing trial was the use of motivators such as toothbrushing charts, to encourage children to brush twice daily at home and during the school holidays. The dental charts and other motivators (e.g. novelty toothbrushes, small gifts) given to the children for regular toothbrushing were greatly appreciated by parents. Ninety seven percent of parents reported using the toothbrushing charts during the holidays; 96% said that their child enjoyed using them.[149] **3**

7.7.1 Effectiveness of school-based supervised toothbrushing in primary teeth

Limited evidence was available on the effectiveness of supervised toothbrushing at preventing caries in primary teeth. The Swedish systematic review[118] included two studies of supervised toothbrushing in preschool children in China, both of which had results that suggested a reduction in caries increment in primary teeth with the use of fluoride toothpaste containing 1,000 or 1,100 ppm F compared to placebo or no treatment. However, both studies were of low quality. [150, 151]

A subsequent RCT, also from China, reported a reduction in the 2-year caries increment of 30.6% (mean dmfs: 2.47 (test) v 3.56 (control); p=0.009) in children, aged 3 at baseline, who participated in a kindergarten-based caries preventive programme involving twice daily supervised toothbrushing for one minute with 1,100 ppm F toothpaste and oral health education.[152] **1+**

The limited number of trials on supervised toothbrushing in preschool children is indicative of the general lack of good quality research on the effectiveness of toothpaste in this age group. Extrapolating from the evidence of its effectiveness in the permanent teeth, it can be inferred that supervised toothbrushing in preschool with fluoride toothpaste containing at least 1,000 ppm F would offer benefits, not only in reducing caries levels but also in controlling the amount of toothpaste dispensed and thereby the amount of fluoride swallowed.

7.8 Toothpaste distribution

Another approach to increasing the frequency of toothbrushing in a population is to provide free or subsidised toothpaste to the target population. The rationale is that increasing the availability of toothpaste will encourage its use and thereby reduce caries. In the two systematic reviews cited earlier, the trials that were not supervised involved the distribution of toothpaste, usually to the homes of the trial participants. In both reviews, unsupervised toothbrushing (i.e. toothpaste distribution) was less effective at preventing caries than supervised brushing.[117, 118] **1++**

Although the Cochrane review did not provide estimates of the effect size for supervised and unsupervised toothbrushing[117], the Swedish review calculated that unsupervised toothbrushing reduced the caries increment by 23.3% – which still represents a considerable effect – compared to 31% with supervised toothbrushing.[118] **1++**

In Ireland, an oral health promotion programme (Winning Smiles), which involved the 3-monthly distribution of toothpaste containing 1,450 ppm F to 7–8 year-old children attending disadvantaged schools in a fluoridated area, found significantly increased mean salivary fluoride levels at 12 months in the children receiving the toothpaste compared to the control group who received no intervention. The increased salivary fluoride level was taken as an objective indicator of increased frequency of brushing. The results from another arm of the trial, which was set in a non-fluoridated area and involved oral health promotion without the distribution of toothpaste, did not show any difference in mean salivary fluoride levels between the intervention and control groups at 12 months.[153] **2+**

An RCT that involved the postal distribution of 1,450 ppm F or 440 ppm F toothpaste at 3-monthly intervals to a cohort of children from the age of 12 months until the children were aged 5 years, found a 16% reduction in caries increment in the group randomly assigned to receive 1,450 ppm F toothpaste compared to the control group which received no intervention (mean dmfs increment: 2.15 v 2.57; p=0.002). There was no significant difference in caries increment between the control group and the group receiving 440 ppm F toothpaste.[133] 1+

Distribution of high fluoride toothpaste on a population scale does not reduce deprivation-related oral health inequalities. Though the provision of 1,450 ppm F toothpaste resulted in lower caries levels compared with the control group in all four deprivation-related quartiles of the study population, the absolute caries reduction was the same (0.5 dmft) for both the least and most deprived quartiles. However, compared with the control group, the caries reduction was 26% in the least deprived quartile but only 16% in the most deprived quartile.[134] 1+

The relationship between the fluoride concentration of toothpaste, deprivation status and the prevalence of fluorosis was shown in a follow-up study of a sample of children aged 8–10 years who had participated in the randomised controlled toothpaste distribution trial from age 12 months up to age 5–6 years. The researchers found that the overall prevalence of fluorosis (TF>0) was significantly higher among children who received 1,450 ppm F toothpaste compared to those who received 440 ppm F toothpaste (30.4% v 21.8%, p<0.003). The prevalence of fluorosis at the level that might be considered aesthetically objectionable (TF≥2 and TF≥3) was low overall, but was significantly higher in the group that had received the high fluoride toothpaste compared to those receiving the low fluoride toothpaste. In the 1,450 and 440 ppm F groups respectively, the percentages of children with TF≥2 were 7% and 2.1% while the percentages with TF≥3 were 2.2 and 0.2% (p<0.003). For the group receiving 1,450 ppm F toothpaste, there was a trend for the prevalence of fluorosis (TF>0) to decrease with increasing deprivation, being 40% in the least deprived quintile versus 24% in the most deprived quintile. The authors concluded that high fluoride 1,450 ppm F toothpaste should not be provided on a community basis to very young children in less deprived communities. [142] 2+

7.9 Cost of community-based fluoride toothpaste interventions

7.9.1 Cost of supervised toothbrushing

We obtained data on the costs of school-based supervised toothbrushing from the main author of the Scottish school-based supervised toothbrushing programme.[154] The total 2-year cost of this programme (1997–1999) was £28,504 for 279 children, or £51 per child per year, and resulted in a 56% reduction in caries increment in the first permanent molars after 2 years. Labour costs accounted for 65% of the total cost. Sustained caries reductions of 30% were reported 4.5 years after the programme ended.[148] When the 2-year cost is converted to euro and updated to current (2008) prices, the cost per child per year corresponds to €99.

We calculated the costs of delivering a school-based supervised toothbrushing programme in Ireland, based on the Scottish RCT model which provided a sealable, washable tray for storing the toothbrush, toothpaste and cup for each child and paid local mothers for 1 hour per day for toothbrushing supervision and clean-up. The provision of motivators to children to encourage home brushing accounted for 20% of the total programme cost, and we allocated the same amount in our calculation. Using the 2007 minimum wage (€8.65) as the basis for salary costs, we estimated that a school-based supervised toothbrushing programme involving 100 children (4 classes of 25 children, each supervised by a mother) would cost €105 per child per year. Full details of how these costs were calculated can be found in Appendix 7. Reductions in the cost of delivering a supervised toothbrushing programme could be achieved if it were possible to include supervision as part of the normal duties of non-teaching personnel in schools or of carers in preschools. The amount spent on motivators could also be reduced.

The high cost of running a supervised toothbrushing programme needs to be offset against the long-term benefits from establishing a habit of daily toothbrushing in children. In Scotland, supervised toothbrushing has been rolled out to preschools and schools as a preventive programme (ChildSmile). By streamlining the delivery of the programme and reducing the number of hours required for supervision and clean-up, costs have been reduced to £500 per class (up to 30 children) per year, or approximately £16.60 (€23.20) per child per year (personal communication).

As community-based supervised toothbrushing is untested in Ireland, any intervention would need to be initially introduced as a randomised controlled trial, in order to define the logistics of providing the intervention in Ireland, and to provide a measure of the effectiveness in Irish children and cost of delivering a supervised toothbrushing programme in Ireland.

7.9.2 Cost of toothpaste distribution

The total programme cost per child of the 4-year toothpaste distribution programme in north west England was £27.93, which corresponds to £6.98 per child per year, over 4 years. The cost of reducing the mean dmft by 1 was £80.83. The cost per child kept free of caries was £424.38, and the cost of preventing extraction experience was £679.01 per child.[155] Assuming that these costs were calculated for 2002 (the year in which the paper was submitted for publication), the cost per child per year converts to €11.91 at 2008 prices. The authors suggested that costs could be reduced by commencing the programme when children were aged 2–2.5 years rather than at age 12 months, as approximately 90% of the caries incidence involved the primary molars, which are not fully erupted until age 2–2.5 years.

The calculations in this study tended to overestimate the costs while underestimating the benefits of the programme. As caries was only recorded at age 5.5 years, the incremental effect of the programme and any longer term benefits arising from continued, regular use of toothpaste could not be calculated. In addition, the study evaluated the effect of postal distribution of toothpaste as a population intervention, which may have resulted in the lower average reduction in caries increment (16%) compared to the 23% reported in the Swedish toothpaste systematic review for unsupervised brushing.[118]

A comparison of the costs and effectiveness of supervised toothbrushing and toothpaste distribution is presented in Table 7.2. Supervised toothbrushing is expensive relative to postal distribution of toothpaste, but it must be borne in mind that these are the costs of an RCT establishing the effectiveness of the intervention under "gold standard" conditions. Costs have been effectively reduced by 75% since the intervention has been rolled out as a preventive programme in Scotland. Long-term benefits of supervised brushing have been recorded in a follow-up study which reported a 30% reduction in caries in first permanent molars.[148] This figure is close to the average caries reduction of 31% with supervised brushing reported in the Swedish toothpaste systematic review.[118] The effect of the toothpaste postal distribution study may be underestimated, due to the design of the study.[133] Unfortunately, no long term data are available from the toothpaste distribution study to allow a comparison to be made.

Table 7.2 Comparison of costs and effectiveness of community-based toothpaste programmes (updated to current rates)

	Intervention	Actual cost per child per year (£)	Current cost per child per year (€)	Duration of programme	Prevented fraction	Long term effect
Curnow, 2002[154] Curnow et al., 2002[147]	Supervised brushing	£51	€99	2 years	PF= 56% (FPMs)	PF=30% (FPMs)
Davies et al., 2003[133]	Toothpaste distribution	£6.98	€11.91	4 years	PF=16% (primary dentition)	N/A

A full description of the cost calculations for toothpaste programmes can be found in Appendix 7.

Recommendation:

➢ **Supervised Toothbrushing**

Under age 2

- ***Community-based toothbrushing programmes are not recommended.*** **GPP**

From age 2 years

In fluoridated and non-fluoridated areas, daily supervised toothbrushing programmes should:

- ***Be considered for targeted populations of children who are at high risk of developing dental caries*** **A**
- ***Be undertaken in community settings such as***
  - ***crèches, nurseries, preschool*** **B**
  - ***primary schools*** **A**
- ***Involve the use of toothpaste containing at least 1,000 ppm fluoride*** **A**
- ***Support home use of fluoride toothpaste through provision of toothpaste, toothbrush and information for home use during school holidays.*** **D**

➢ **Toothpaste Distribution**

Under age 2

- ***Community-based toothpaste distribution programmes are not recommended.*** ***GPP***

From age 2 years

Programmes involving the distribution of fluoride toothpaste should:

- ***Be considered in targeted populations of children at high risk of caries*** **A**
  Toothpaste distribution has the advantage of being cheaper, but is less effective than supervised toothbrushing
- ***Involve the use of toothpaste containing at least 1,000 ppm fluoride*** **A**
- ***Distribute toothpaste at 3-month intervals, with information for home use*** **GPP**
- ***Distribute toothpaste directly to the parents/guardians of children under the age of 7 years.*** **GPP**

➢ **Any community-based preventive programme should be conducted as an RCT to establish both the effectiveness and cost of the programme in Ireland.** **GPP**

Section 8: School-based Fluoride Mouthrinsing Programmes

8.1 Summary of evidence on school-based fluoride mouthrinsing programmes

• Fluoride mouthrinsing is effective at reducing caries in children and adolescents.[156, 157]	**1+**
• Fortnightly mouthrinsing with 0.2% sodium fluoride (900 ppm F) rinse is beneficial, but weekly rinsing appears to be much more beneficial. (based on a meta-analysis of a subset of studies in the systematic review by Marinho et al.[156])	**2++**
• The evidence on the effectiveness of fluoride mouthrinse with background exposure to fluoride is conflicting.[156,157]	
• The effectiveness of fluoride mouthrinse is not influenced by baseline levels of caries.[156]	**1+**
• The efficiency of fluoride mouthrinsing programmes is greater in populations with a high annual caries increment.[156]	**1+**
• Younger children tend to swallow more rinse than older children.[158]	**3**
• There is no reliable evidence on adverse effects associated with school-based fluoride mouthrinsing.	
• The optimum rinse time for school-based mouthrinsing programmes has not been determined.	

8.2 Introduction

School-based fluoride mouthrinsing programmes were popular in North America and Scandinavia in the 1970s and 1980s as a public health strategy to prevent caries in children. During this period, fluoride mouthrinsing programmes were carried out in fluoridated as well as non-fluoridated areas.[159] In the mid 1980s, a large scale evaluation of school-based preventive regimens – the National Preventive Dentistry Demonstration Program (NPDDP) in the United States – demonstrated only a minor preventive effect for school-based fluoride mouthrinsing[160-162], giving rise to uncertainty about the effectiveness and costs of these programmes. The low effectiveness of fluoride mouthrinsing programmes was attributed to the secular decline in caries that had occurred around the time of the NPDDP, leading researchers to suggest that fluoride mouthrinses should be redirected towards those at high risk of decay.[163]

The most commonly used fluoride mouthrinse regimen for school-based mouthrinsing programmes is 0.2% sodium fluoride (900 ppm F) rinse applied either weekly or fortnightly. Daily rinsing with 0.05% sodium fluoride rinse (230 ppm F) is also practiced.

8.2.1 School-based fluoride mouthrinsing programmes in Ireland

In Ireland, school-based fluoride mouthrinsing was introduced in rural areas to bring the caries-preventive benefits of fluoride to children living in areas where it would not be possible to fluoridate the water supply.[164] In 2005, fluoride mouthrinsing programmes were provided by the Public Dental Service in nine dental areas, and involved over 14,000 primary school children. These fluoride mouthrinsing programmes run parallel to the School Dental Service, which targets specific classes (usually three) in primary and some secondary schools for receipt of dental care. Given the intermittent nature of the targeted School Dental Service, fluoride mouthrinsing programmes offer a way to provide a caries-preventive service to children who might not have regular access to dental services.

Fortnightly school-based mouthrinsing using 0.2% sodium fluoride (900 ppm F) rinse was first introduced in the non-fluoridated Portlaw area of North Waterford in 1968. It has been running continuously since that time, making it one of the longest-running school-based fluoride mouthrinsing programmes in the world. The effectiveness of the North Waterford mouthrinsing programme has been evaluated in a number of cross-sectional studies. The results of these studies are summarised in Table 8.1 and are described in detail in Appendix 9. Table 8.1 shows that the caries levels of 12-year old children, in all groups (rinse, non-rinse and fluoridated) have fallen dramatically since the 1970s, but caries levels in the rinse group were significantly lower compared to the no rinse group in all but the most recent study, where the difference fell just short of statistical significance (p value not provided). In all studies that included a fluoridated comparison group, the mean DMFT at age 12 was not significantly different in the rinse group compared to the fluoridated group.

Table 8.1: Summary of result of Irish cross sectional studies of the effectiveness of fortnightly fluoride mouthrinsing (mean DMFT at age 12)

	Fluoridation Group			Absolute difference in DMFT	Percent difference in DMFT	Level of evidence
	Rinse	**No Rinse**	**Fluoridated**	**rinse vs. no rinse**	**rinse vs. no rinse**	
Holland and O'Leary, 1978[165]	4.4	6.9	-	2.5 [a]	36.2%	3
Holland et al., 1987[166]	2.5	4.5	2.3	2.0 [b]	44.4%	
Holland et al., 1995[167]	1.2	1.9	1.2	0.7 [c]	36.8%	
Holland et al., 2001[164]	1.3	1.8	1.25	0.5 [ns]	27.8%	

a: p<0.01, b: p<0.001, c: p<0.05, ns: not statistically significant

8.3 Effectiveness of fluoride mouthrinsing programmes

A weakness of the above Irish studies is that they are all cross-sectional and did not take into account possible confounders that could explain the differences between the groups, such as socio-economic status, toothbrushing and dietary habits and exposure to fissure sealants. In addition, only one of the studies[166] reported blind outcome assessment. More robust evidence on the effectiveness of fluoride mouthrinsing is available from two systematic reviews.[156,157] Most of the trials included in the Cochrane review date from the 1960s and 1970s[156], while most of the trials in the Swedish review from the

1970s and 1980s.[157] Both reviews pooled the results of trials – which mainly involved daily use of low fluoride mouthrinses (230 ppm F) or weekly/fortnightly use of high fluoride mouthrinses (900 ppm F) – to produce a single measure of effectiveness. The Cochrane review reported an average reduction in caries of 26% (95% CI, 23–30%; $p<0.0001$) with supervised use of fluoride mouthrinses, compared to placebo or no treatment.[156] The estimate was based on the analysis of 34 trials involving 14,663 children and adolescents. Most of the trials involved 230 ppm F rinse used daily, or 900 ppm F rinse used weekly or fortnightly. **1++**

A similar estimate was given in the Swedish review, which reported a mean reduction in caries increment of 29% (range 14–53%) for children with limited background exposure to fluoride, using daily or weekly sodium fluoride mouthrinses compared to placebo[157]. This estimate was based on the analysis of eight trials, all of which were included in the Cochrane review. **1+**

The difference between the two estimates is likely due to the different inclusion criteria applied in each review.

8.3.1 Influence of background exposure to fluoride

In Ireland, the majority of children who participate in fluoride mouthrinsing programmes are also exposed to fluoride through the use of toothpaste at home and through the consumption of foods and drinks processed in fluoridated areas (the "halo-effect"). Therefore, it is important to know if the effectiveness of fluoride mouthrinse is influenced by background exposure to fluoride. The Cochrane review of mouthrinses found no significant association between the effectiveness of fluoride mouthrinse and background exposure to fluoride. However, the reviewers advised caution in the interpretation of this result, due to the relatively small number of trials (34) included in the review and the assumptions made regarding exposure to toothpaste.[156] **1+**

The Swedish review, analysing many of the same trials as the Cochrane review, judged that the evidence was inconclusive for the effectiveness of fluoride mouthrinses in children and adolescents exposed to additional fluoride sources, owing to the mixed and contrasting results of the included studies.[157]

The differences between the findings of the two systematic reviews could be due to the different inclusion criteria for the two reviews, the use in the Cochrane review of both published and unpublished data for many of the trials, and the use of statistical methods to test for the association between background exposure to fluoride and effectiveness in the Cochrane review but not in the Swedish review.

Another Cochrane review which compared the effect of combinations of two topical fluoride modalities against a single modality, found that the use of any topical fluoride (gel, varnish, or daily fluoride mouthrinse) along with toothpaste was associated with an average 10% (95% CI, 2–17%) additional reduction in caries increment compared to toothpaste use alone.[71] This review did not include any trials which involved the use of 900 ppm F rinse. **1++**

8.3.2 Comparison of effectiveness of fluoride mouthrinse with other fluoride modalities

The Cochrane review in which different topical fluoride modalities were compared directly against each other concluded that fluoride toothpaste and mouthrinse appeared to be effective to the same degree, while the benefits of mouthrinse versus gel and mouthrinse versus varnish were unclear.[70] **1++**

The inconclusive finding in relation to mouthrinses versus varnishes was supported by a systematic review on the effectiveness of fluoride varnish, which found a non-significant treatment effect in favour of varnish.[80] **1+**

8.3.3 Populations likely to benefit from the use of fluoride mouthrinse

The Cochrane mouthrinse review found no significant association between baseline level of caries and the effectiveness of rinsing with fluoride mouthrinse. However, the review showed that fluoride mouthrinsing was more efficient in populations with a higher annual caries increment: For example, in populations with a caries increment of 0.25 DMFS/year, the NNT would be 16 (i.e. 16 children would have to rinse with fluoride mouthrinse to avoid one DMFS); whereas in a population with a high caries increment of 2.14 DMFS/year, the NNT would be 2.[156] **1++**

The authors of the Swedish mouthrinse review concluded that fluoride mouthrinsing programmes should still be considered as a school-based collective measure in vulnerable populations with irregular fluoride exposure, wherein caries has been identified as a public health problem by epidemiological studies.[157] **1+**

8.3.4 Age for commencing mouthrinsing

The age of a child affects their ability to rinse and spit out effectively. A cross-sectional study of the rinsing capabilities of preschool children showed that the risk of swallowing the rinse increased with lower age, greater rinse volume and longer rinse time ($p<0.05$). Among 3-year-olds, approximately one fifth to one third of the fluoride in the rinse was ingested, while in 5-year-olds, less than a quarter of the fluoride was ingested.[158] **3**

A later study from Japan reported fluoride ingestion levels of 12% and 10.7% in 4- and 5-year-old children respectively, who were participating in a daily mouthrinsing programme with a low fluoride rinse.[168] Although this study showed low fluoride ingestion in young children, the Guideline Development Group did not consider that daily mouthrinsing programmes for this age group were applicable to the Irish setting.

In Ireland, fluoride mouthrinsing programmes commence in either first or second class (average age 6 and 7 respectively), with one dental area stipulating a minimum age of 7 for entry into their programme. Since mouthrinsing programmes in Ireland are aimed at preventing caries in the permanent teeth, the key factors to be considered when trying to decide the best age to start are the age of eruption of the first permanent molars and the risk of ingesting more than the daily "threshold" dose of fluoride (0.05–0.07 mg/kg body weight). Prospective studies of the eruption time of permanent teeth have reported the mean age of eruption of first permanent molars to range from 6.1 years[169,170] to 6.4 years.[171] Between the age of 6 and 7 years, the average body weight of Irish children increases sharply from 23 kg to 28.2 kg for boys and from 22 kg to 29.1 kg for girls.[76] Therefore, for any given fluoride ingestion, the intake in terms of mg/kg will be less in the older, heavier children. Based on this rationale, the Guideline Development Group agreed that children under the age of 7 should not participate in fluoride mouthrinsing programmes. **4**

Recommendation*:*

- ***Children under the age of 7 years should not participate in a fluoride mouthrinsing programme because of the increased risk of the rinse being swallowed by young children.*** **D**

8.3.5 Frequency of application

At the request of the Guideline Development Group, a special meta-analysis of the fourteen mouthrinse trials from the Cochrane review that involved the use of 0.2% sodium fluoride (900 ppm F) was carried out. The objective of the meta-analysis was to determine the effectiveness of this specific fluoride concentration and to examine whether the frequency of application (weekly versus fortnightly) influenced effectiveness. Four of the fourteen trials involved fortnightly rinsing. All of the trials in the analysis used a sodium fluoride formulation (0.2% NaF).

We found an overall reduction in caries increment of 28% (95% CI, 23–34%; p<0.0001) with the use of 0.2% sodium fluoride (900 ppm F) mouthrinse compared to placebo or no treatment. When the trials were grouped by frequency of application, the average reduction in caries increment was 18% (95% CI, 9–27%; p<0.0001) for fortnightly rinsing and 32% (95% CI, 27–37%, p<0.00001) for weekly rinsing compared to placebo or no treatment. The systematic review did not include any randomised trials that directly compared the effectiveness of weekly versus fortnightly rinsing.

The percent reduction in caries increment for fortnightly rinsing was influenced greatly by the inclusion of a study from 1965[172] in which the participants had extremely high levels of caries (the caries increment over two years in the control group was 10 DMFS). This study contributed about half of the evidence to the estimate for fortnightly mouthrinsing; without it, the estimate for fortnightly mouthrining was 13% (95% CI -2 to 28%, p=0.09). Based on the meta-analyses, the Guideline Development Group concluded that fortnightly rinsing is beneficial but that weekly rinsing appears to be much more beneficial. The statistically significant result of the test for the difference between the two subgroups was supportive of this (p=0.01). A lower level of evidence was assigned to the new meta-analysis due to the indirect nature of the comparison between the subgroups. **2++**

The Guideline Development Group had agreed at the outset that participation in a fluoride mouthrinsing programme would be worthwhile if it provided a benefit at least as great as that from lifetime exposure to water fluoridation. The percentage difference in mean DMFS between children in fluoridated and non-fluoridated areas in Ireland is 24% at age 12, and 36% at age 15.[2] If the estimates of effectiveness from the meta-analysis of weekly and fortnightly fluoride mouthrinsing are applied to the estimated caries increment for Irish children (from the cross-sectional North South survey) and assuming rinsing starts around age 8, an 18% reduction in caries increment with fortnightly rinsing would result in a mean DMFS at age 12 of 2.5 compared to 2.9 without fluoride mouthrinse. With weekly mouthrinsing, and a 32% reduction in caries increment, the mean DMFS at age 12 would be 2.2, which is the same as that for 12-year-olds with water fluoridation. Full details of how these estimates were calculated are found in Appendix 10. Calculation of the effect of fluoride mouthrinsing from age 8 to age 15 is unreliable due to the wide time-span involved.

The estimated annual caries increment for Irish children of 0.55 DMFS (see Appendix 10) would translate into an NNT of 10 using the estimate of effect of 18% for fortnightly 900 ppm F mouthrinses, and an NNT of 6 using the estimate of effect of 32% for weekly 900 ppm F mouthrinse. The number of fluoride mouthrinse applications that could reasonably be expected within a school year was discussed by the Guideline Development Group. Primary schools are required to open for a minimum of 183 days per year, which corresponds to just over 36 weeks. The Guideline Development Group agreed that a target of at least 30 applications per year for a weekly fluoride rinse programme would be reasonable.

Recommendation:

- ***Weekly fluoride mouthrinsing with 0.2% sodium fluoride (900 ppm F) rinse should be offered to children living in non-fluoridated areas.*** **B**
- ***The target number of applications should be at least 30 per year.*** **GPP**
- ***Fortnightly mouthrinsing with 0.2% sodium fluoride (900 ppm F) rinse is effective at reducing caries, but appears to be less effective than weekly rinsing.*** **B**

8.3.6 Duration of rinsing

Most of the 900 ppm F studies included in the Cochrane review used rinsing times of one minute; the review does not include a direct comparison of different fluoride frequencies or intensities. The Guideline Development Group discussed the practicalities of co-ordinating the simultaneous mouthrinsing by all children in a class. Using informal consensus, the Group agreed that rinsing should be for two minutes, to ensure that all children are exposed to the mouthrinse for at least one minute.

Recommendation:

- ***Children participating in a school-based fluoride mouthrinsing programme should rinse for two minutes with 0.2% sodium fluoride mouthrinse.*** **GPP**
- ***Rinsing times of less than two minutes should be considered for new participants in the mouthrinsing programme, to avoid excessive ingestion of fluoride mouthrinse.*** **GPP**

8.3.7 Eating following mouthrinsing

Unstimulated salivary fluoride levels peak immediately after rinsing with fluoride mouthrinse, then fall dramatically in the 20–30 minutes after rinsing. Therefore eating or drinking should be avoided for at least 20 minutes following rinsing.[173, 174] **3**

Recommendation:

- ***Children should wait for at least 20-30 minutes after rinsing before eating or drinking.*** **D**

8.3.8 Disposal of waste from school-based mouthrinsing programmes

Healthcare waste is the solid or liquid waste arising from healthcare. There are two categories of healthcare waste: risk waste and non-risk waste. Healthcare risk waste is classified as "potentially hazardous or dangerous to those who come in contact with it, by nature of its infectious, biological, chemical or radioactive content, or by being categorised as a sharp". In Ireland, two overlapping definitions of infectious waste apply, based on two European Council Directives – Protection of Workers: 90/679/EEC, as amended; and Hazardous Waste 91/689 EEC. Essentially, under both definitions, infectious waste must contain a biological agent that can cause disease in man or other living organisms. Further information can be found in the Department of Health publication: Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste.[175]

Health care non-risk waste does not present as an infectious risk to those who handle it and, provided it is secured appropriately, is suitable for landfill.[175] Waste generated by most fluoride mouthrinsing programmes would not be expected to include microbiological waste, blood or blood products, pathological waste or sharps. Thus, under most circumstances, the collection of mouthrinsing waste does not require special precautions.[176] **4**

8.3.9 Cessation of fluoride mouthrinsing programmes

The effect of cessation of a fluoride mouthrinse programme is influenced by the prevalence of caries in a population, and exposure to other sources of fluoride.

Two randomised controlled trials conducted in Denmark[177] and Sweden[178] demonstrated that the termination of a fluoride mouthrinsing programme did not result in an increase in caries among adolescents who stopped rinsing compared to those who continued. Both studies were conducted on low caries populations which had annual access to dental care and used fluoride toothpaste. In the Swedish study, children were also treated with fluoride varnish at least once a year. **1+**

The situation is somewhat different in Ireland: Mouthrinsing programmes cease at the end of primary school and, unlike Sweden and Denmark, free routine dental care is not readily available for Irish children once they leave primary school. Although the effect of cessation has not been tested in a randomised-controlled trial in Ireland, a cross-sectional study found that among 16-year-olds, there was no significant difference in caries levels between those who had rinsed up to age 12 and those who had never rinsed (mean DMFT: 4.0 v 4.7 respectively).[167] Both groups had significantly higher DMFT scores than 16 year olds in fluoridated areas (mean DMFT: 2.7, $p<0.05$). This contrasted with the finding from the same study for 12-year-olds, where the mean DMFT of those who had rinsed from age 6/7 was significantly lower than that of non-rinsers (mean DMFT: 1.2 v 1.9, $p<0.05$) and was the same as that of children from fluoridated areas. The results of this study would suggest that the home use of fluoride toothpaste by teenagers in non-fluoridated areas is insufficient to achieve the same level of caries control as the combined use of fluoride toothpaste and water fluoridation. **3**

Recommendation:

- ***Where possible, fluoride mouthrinsing should be offered to children in non-fluoridated areas up to the age of 16.*** **D**

The Guideline Development Group agreed that school-based fluoride mouthrinsing constituted a form of treatment, and therefore a treatment log should be kept to record the date of rinsing and any incidents of swallowing the mouthrinse for each child.

Recommendation:

- ***A standardised protocol should be developed for the fluoride mouthrinsing programme in Ireland, which should include an individual rinse record for each child, incident reporting, monitoring and evaluation, and information for participants on the maintenance of good oral health when the programme ends.*** **GPP**
- ***Staff responsible for administering the fluoride mouthrinse are an important part of the dental service and should be appropriately trained in the delivery of the fluoride mouthrinsing programme.*** **GPP**

8.3.10 Adverse effects

There is a wide margin of safety with 0.2% sodium fluoride (900 ppm F) mouthrinse in terms of acute toxicity. The probably toxic dose of fluoride for an average 5-year-old child weighing 20 kg is 100 mg, whereas the usual volume of rinse used in school mouthrinsing programmes is 10 ml (i.e. 9 mg of fluoride). Thus, the toxic dose is more than 10 times the fluoride contained in a single rinse. The main concern with the use of 0.2% sodium fluoride (900 ppm F) mouthrinse is that persistent swallowing of the rinse could increase a child's risk of developing fluorosis.

Neither of the systematic reviews provided evidence on the possible adverse effects from the use of fluoride mouthrinse, and our search for any studies involving fluoride mouthrinse and fluorosis found no reliable evidence of risk of fluorosis with the use of fluoride mouthrinse. (We did find one study which reported the prevalence and severity of fluorosis in adolescents aged 16-17, who had participated in an eight-year fluoride mouthrinsing programme from age 5–6. However, the losses to follow-up were so great in this study (73%) that we did not include it.[179])

8.4 Cost-effectiveness of fluoride mouthrinsing programmes

The annual cost of a fortnightly fluoride mouthrinsing programme in Ireland, serving a population of 2,180 children has been calculated as IR£3.26 (€4.14) per child.[164] Updated to current prices (2008), the annual cost per child for a programme serving the same number of children is €5.32 for fortnightly rinsing. We estimated that doubling the frequency of application to weekly would double the costs, to €10.64. The expected reduction in caries with weekly rinsing is 32%, based on the special meta-analysis conducted for this review, and 18% for fortnightly rinsing. A comparison of the cost effectiveness of the various community-based programmes covered in this guideline can be found in Appendix 8.

Section 9: Implementation and Audit

This guideline contains recommendations on the use of topical fluorides in two distinct situations:

- For individual children – based on an assessment of the individual child's risk for caries and current exposure to fluorides;
- For groups of children who are considered to be at increased risk of developing dental caries – based on fluoridation status, epidemiological data, or deprivation status of a community.

The approach to implementation of guideline recommendations and to audit of implementation will differ in each situation.

9.1 Audit of use of professionally applied topical fluorides

In order to measure changes in the use of professionally applied topical fluorides for caries prevention, it will be necessary to carry out a detailed assessment of current practice, particularly in relation to the type of patients selected for topical fluoride application, frequency of application, and total number of applications. Developments in dental information technology (IT) should facilitate both the collection of this data and the generation of reports at dental clinic, Local Health Office Area, HSE area and national levels. To measure changes in behaviour, a similar assessment should be made following dissemination of the guideline.

Suggested audit criteria for recommendations on the use of professionally applied topical fluorides are:

- Number of fluoride applications in children and adolescents;
- Percentage of patients with a caries risk assessment recorded on the patient chart;
- Percentage of children assessed as being at high risk receiving an application of fluoride varnish at six monthly intervals.

9.1.1 Potential barriers to implementation

One potential barrier to implementation of the recommendations on the use of professionally applied fluorides could be the availability of fluoride varnish: At the time of writing, we found no fluoride varnish or gel with product authorisation in Ireland.

The recommended frequency of application of professionally applied fluorides is at intervals of 3 or 6 months. Chronic staff shortages could make the regular recall of high risk children difficult. A service that is based on the needs of patients is a key principle of the national health strategy, however, and should be supported through policy.

9.2 Audit of topical fluoride programmes

The key audit criterion for fluoride programmes will be the number of dental areas identified as needing a fluoride programme and which have a fluoride mouthrinse or toothpaste programme in place. Different audit criteria will apply depending on the specific type of programme.

9.2.1 Fluoride mouthrinsing programmes

Suggested audit criteria for fluoride mouthrinsing programmes include:

- Number of dental areas with a fluoride mouthrinsing programme;
- Number of dental areas achieving at least 30 applications per year;
- Number of dental areas with up-to-date rinse participation log;
- Percentage of eligible children who consent to participate in the programme;
- Number of dental areas with a fluoride rinse programme in secondary school;
- Number of dental areas providing training for staff involved in delivering the mouthrinsing programme.

9.2.2 Toothpaste programmes

Suggested audit criteria for toothpaste programmes include:

- Number of dental areas operating supervised toothbrushing in preschools or primary schools;
- Number of children involved in supervised toothbrushing programmes in non-fluoridated areas and in fluoridated areas;
- Number of dental areas operating a toothpaste distribution programme for children aged >2 years in primary school and/or in secondary school.

9.2.3 Potential barriers to implementation

With mouthrinsing programmes, the recommendation that the frequency of rinsing should be increased in order to maximise the effectiveness of the programme will present a resource problem for the Public Dental Service. Areas with existing mouthrinse programmes are experiencing difficulty maintaining the current fortnightly schedule due to staff shortages. Some mouthrinse programmes have been stopped because of lack of staff. Increasing the mouthrinsing frequency will increase costs but since the effectiveness of the programme will also increase, the ratio of cost to effectiveness will remain unchanged. For the participating schools, the increased frequency could prove to be too disruptive to normal school activities. Extending fluoride mouthrinsing to secondary school children could also pose problems, as access to secondary schools is more difficult than access to primary school. Also, the population of students attending a particular secondary school is likely to be drawn from a larger catchment area, with greater variation in exposure to other fluorides than that found in primary school.

The guideline group discussed in detail the implications of the recommendation to introduce school-based supervised toothbrushing programmes for children in preschool and primary school. The group was very conscious that this intervention is untested in the Republic of Ireland, but given the lack of dental services for preschool children and the limited services for primary school children in their first and second years at school, the group considered that such a programme should be implemented as a randomised controlled trial. This would allow the effect of the programme in Irish children to be evaluated and other important outcomes such as acceptability of the programme, barriers to implementation and cost to be evaluated. Any area wishing to implement a school-based supervised toothbrushing programme will require considerable support in planning and financing such a study.

Section 10: Recommendations for Future Research

During the guideline development process, a number of gaps in the evidence were identified. Further research is needed in the following areas:

- The prevalence and severity of dental caries in children aged between 2 and 3 years in the Republic of Ireland;
- Toothpaste use by children under the age of 2 years
- The effectiveness of toothpastes containing less than 1,000 ppm F at preventing caries in the primary dentition of children under the age of 6 years;

Evidence	3 RCTs of varying quality with different results. Winter[132] found equal efficacy of low and standard fluoride toothpaste, Davies[133] found greater caries reductions with 1,450 ppm F toothpaste compared to 440 ppm F toothpaste overall and Lima[135] found no difference in effect between high and low F toothpaste in caries inactive children but caries increment was significantly lower in the 1,100 ppm F caries active group compared to the 500 ppm F caries active group.
Population	Children aged 12 months in fluoridated and non-fluoridated areas.
Intervention	Toothpaste containing 500 ppm F from age 2 years. Toothpaste containing 250 ppm F from age 2 years. Toothpaste containing 750 ppm F from age 2 years.
Comparison	Toothpaste containing 1,000 ppm F from age 2 years.
Outcome	Caries increment at age 5, measured at enamel and dentinal level of involvement. Prevalence of fluorosis in central incisors at age 8 measured using TF and Deans indices.

- The effectiveness, acceptability, and cost of school-based supervised toothbrushing in Irish preschools;

Evidence	Two systematic reviews showed that supervised toothbrushing was more effective than unsupervised toothbrushing.[117,118]
Population	Children aged 2 and over attending playschool, community preschools, Early Start programmes or crèches in high caries risk areas.
Intervention	Daily toothbrushing with 1,000 ppm F toothpaste, supervised by trained preschool staff or parent volunteer.
Comparison	No daily toothbrushing in the preschool setting.
Outcome	Caries increment at age 5, fluorosis at age 8. Acceptability of programme to staff and parents. Cost of programme.

- The effectiveness, acceptability, and cost of school-based supervised toothbrushing in Irish primary schools;

Evidence	Two systematic reviews showed that supervised toothbrushing was more effective than unsupervised toothbrushing.[117,118]
Population	Children in Junior Infants class (age 5) attending primary school in high caries areas.

Intervention	Daily toothbrushing with 1,000 ppm F toothpaste, supervised by trained parent or class room assistant.
Comparison	No daily toothbrushing in the school setting.
Outcome	Caries increment in the permanent teeth at age 8 and 12. Proportion of children with no obvious decay at age 8 and 12. Acceptability of programme to staff and parents. Cost of programme.

- the cost-effectiveness of weekly fluoride mouthrinsing, school-based supervised toothbrushing and toothpaste distribution in non-fluoridated areas;

Evidence	Three systematic reviews have shown that all three fluoride interventions are effective. [117,118,156] However, there is limited evidence on the cost-effectiveness of each of these programmes. [154,164]
Population	Children attending primary schools in non-fluoridated areas.
Intervention	Daily supervised toothbrushing with 1,000 ppm F toothpaste from Junior infants. Toothpaste distribution (1,000 ppm F) every three months from age 7. Weekly mouthrinsing with 0.2% sodium fluoride rinse from age 7.
Comparison	No intervention non-fluoridated control and no intervention fluoridated control.
Outcome	Cost per surface saved.

- The effectiveness of rinsing for one minute versus two minutes with a fluoride mouthrinse;
- The risk of fluorosis associated with use of fluoride varnish in young children;
- Effective methods to encourage twice-daily home use of toothpaste;
- Effective methods to reduce oral health inequalities.

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Glossary of Terms

Approximal caries	Decay occurring on the surface of a tooth where it contacts the tooth beside it.
Caries	Tooth decay.
Controlled clinical trial	A clinical trial that has a control group. Such trials are not necessarily randomised.
dmft/DMFT	An index which is used to describe the level of dental caries in individuals or groups. It counts the number of teeth which are decayed, missing or filled. By convention, dmft in lower case letters refers to primary teeth and DMFT in capital letters denotes permanent teeth.
d_{3c}mft/ D_{3c}MFT	Caries recorded at cavitation level.
d_{3vc}mft/ D_{3vc}MFT	Caries recorded at the dentine level, with or without cavitation.
$d_1$mft/D_1MFT	Caries recorded in enamel and dentine.
Meta-analysis	The use of statistical techniques in a systematic review to integrate the results of included studies.
Meta-regression analysis	A technique used to explore the relationship between study characteristics (e.g. concealment of allocation, baseline risk, timing of the intervention) and study results (i.e. the magnitude of effect observed in each study) in a systematic review.
Numbers needed to treat (NNT)	An estimate of how many people need to receive a treatment before one person would experience a beneficial outcome.
Observational study	A study in which the investigators simply observe the course of events and do not seek to intervene.
Caries increment	The amount of caries developing during a specific period of time, usually from the start of a study (baseline) to the end of the study.
Prevented fraction	The difference in caries increment at the end of the study between the control and treatment group, divided by the caries increment in the control group. (Also called the percent caries reduction.)
Probably toxic dose (fluoride)	The dose of ingested fluoride that should trigger immediate therapeutic intervention and hospitalization because of the likelihood of serious toxic consequences (5mg/kg).
Randomised controlled trial (RCT)	An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants.
Systematic review	A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyze and summarize the results of the included studies.
Significant Caries Index	The SiC index is designed to focus attention on those individuals with the highest caries scores in each population. It is calculated as follows: Individuals are sorted according to their d_{3vc}mft/D_{3vc}MFT scores, the one third of the population with the highest caries scores is selected and the mean d_{3vc}mft/D_{3vc}MFT score for this subgroup is calculated.
Cross sectional study	A study measuring the distribution of some characteristic(s) in a population at a particular point in time. This type of study design is also known as a survey.
Fluorosis	Fluorosis is a specific disturbance in tooth formation that is caused when excess fluoride is ingested during tooth development and

	results in an altered appearance of the tooth, which ranges from almost imperceptible fine white lines to pitting or staining of the enamel.
ppm F	Parts per million fluoride. A commonly used measure of the concentration of fluoride in a product.
Intention-to-treat (ITT) analysis	A strategy for analysing data from a randomised controlled trial. All participants are included in the arm to which they were allocated, whether or not they received (or completed) the intervention given to that arm. Intention-to-treat analysis prevents bias caused by the loss of participants, which may disrupt the baseline equivalence established by randomisation and which may reflect non-adherence to the protocol.
95% confidence interval	A measure of the uncertainty around the main finding of a statistical analysis. Estimates of unknown quantities, such as the odds ratio comparing an experimental intervention with a control, are usually presented as a point estimate and a 95% confidence interval. This means that if someone were to keep repeating a study in other samples from the same population, 95% of the confidence intervals from those studies would contain the true value of the unknown quantity. Alternatives to 95%, such as 90% and 99% confidence intervals, are sometimes used. Wider intervals indicate lower precision; narrow intervals, greater precision. (Also called CI.)

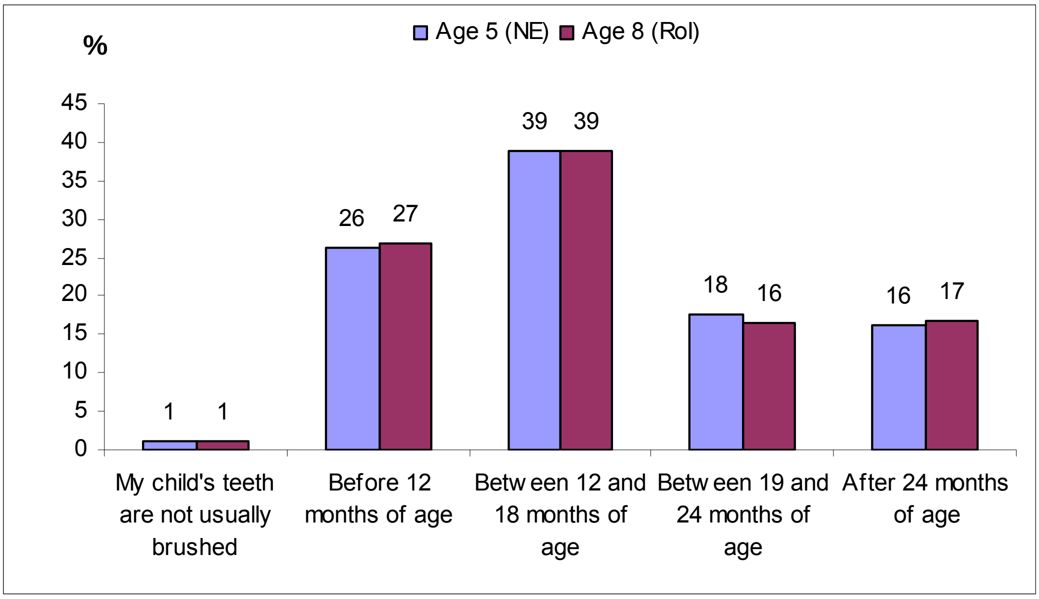
Definitions of terms relating to study design and research terms are taken from the glossary of the Cochrane Collaboration, available online at: http://www.cochrane.org/resources/glossary.htm.

Appendix 1: Brushing habits of Irish Children

Age of Commencing Toothbrushing

There is wide variation in the age at which Irish children commence brushing (Figure A5.1). Two dental surveys conducted in 2001/02 found that that for both the 5- and 8-year-old age groups, brushing started between 12–18 months of age for 39% of children and before 12 months of age for approximately one quarter of children.[2,8]

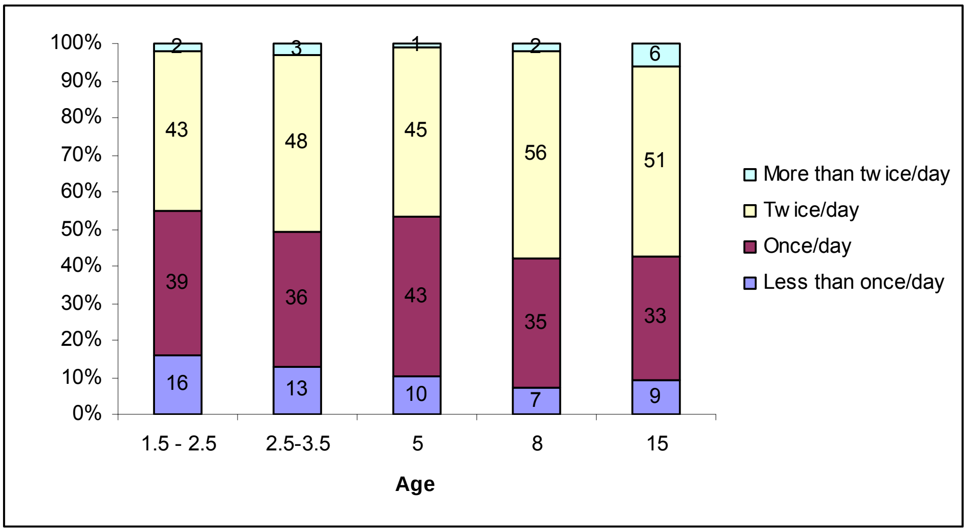
Figure A1.1: Frequency distribution of age of commencing toothbrushing in Irish children at age 5[8] and 8[2] years.



Frequency of Toothbrushing

Approximately 50% of Irish preschool children[180] and 5-year-olds[8] brush twice a day or more, while fewer than 60% of children aged 8 or 15 brush twice a day or more[2] (Figure A5.2).

Figure A1.2: Frequency of toothbrushing among Irish children at various ages.
Data sources: Age 1.5-3.5: Cochran et al., 2004[180], Age 5: Parnell et al., 2007[8], Age 8&15: Whelton et al., 2006[2]



The frequency of toothbrushing of Irish children compares unfavourably, not only with their nearest neighbours in the UK[9], but also with other countries[10] (Figure A5.3). In an international comparison of health behaviour in school-aged children in 35 countries (HBSC survey), Ireland ranked in the bottom half of all participating countries for the percentage of children brushing more than once a day. With the exception of 13 year old boys, the percentage of Irish children at age 11, 13 and 15 who brushed once a day fell short of the survey average.10 (Table 5A.1)

Figure A1.3: Percentage of children brushing twice a day in RoI and UK. RoI from: Parnell et al., 2007[8], (age 5) and Whelton et al., 2006[2] (age 8 and 15); UK figures from: Lader et al., 2005[9].

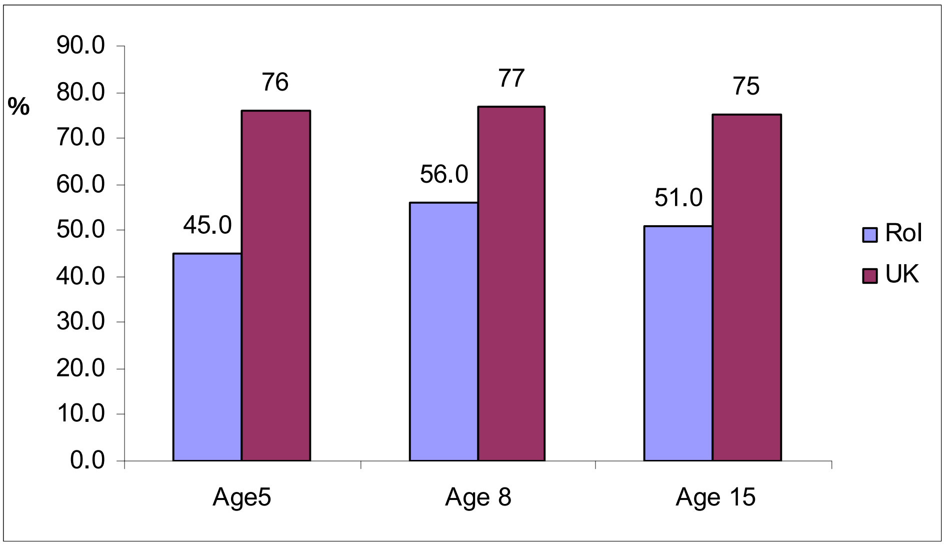


Table A1.1: Percentage of Irish children brushing more than once a day, compared to the HBSC average[10]

	Ireland		HBSC average	
	Female	**Male**	**Female**	**Male**
Age 11	64%	50%	67%	56%
Age 13	67%	54%	69%	54%
Age 15	72%	47%	73%	52%

Type of Toothpaste Used

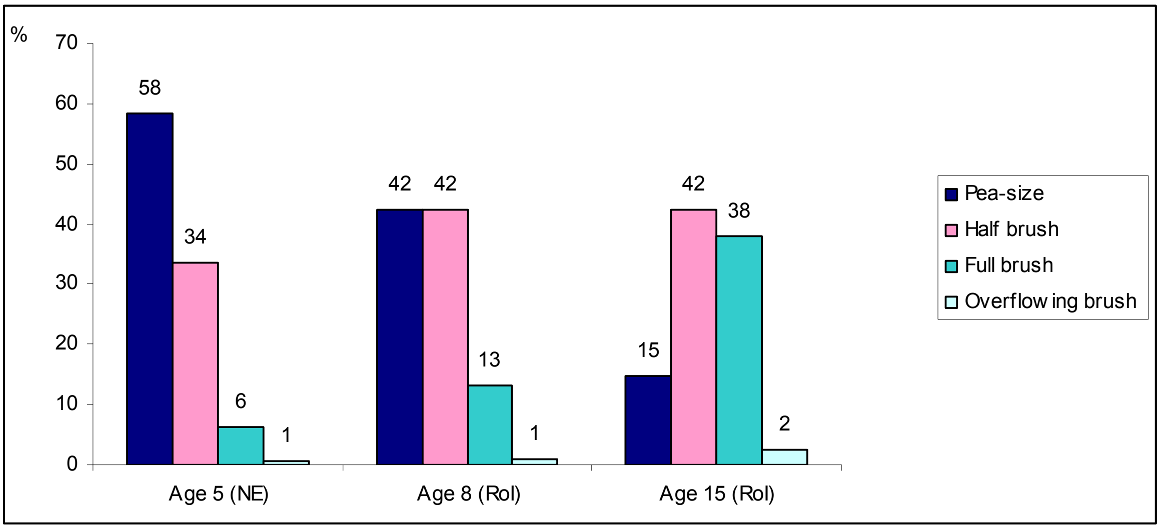
Two studies conducted in different parts of Ireland have found that approximately two thirds of children aged 5 years and under, use children's toothpaste.[8,180] However, not all toothpaste marketed as children's toothpaste contain low fluoride (<1000 ppm F).

A European, multi-centre observational study of fluoride ingestion from toothpaste recorded the fluoride content of the toothpaste used by young children: Among the sample of Irish children studied, the majority used low fluoride toothpaste containing under 800 ppm F (51% of 1.5–2.5 year-olds, 59% of 2.5–3.5 year-olds).[180]

Amount of Toothpaste Used

The amount of toothpaste used when brushing is particularly important for younger children, who are more likely to swallow the toothpaste on the brush. Data from 2001/02 show that a higher proportion of 5-year-olds used a pea-size amount of toothpaste when brushing[8], compared to the 8 and 15 age groups.[2] However, 41% of 5-year-olds still used more than the recommended pea-sized amount of toothpaste, which suggests that further work is needed in disseminating the message about minimising the amount of toothpaste that is used, particularly for young children.

Figure A1.4: Amount of toothpaste used by Irish children at age 5, 8 and 15 years of age. Data sources: Age Age 5: Parnell et al., 2007[8], Age 8&15: Whelton et al., 2006[2]



Appendix 2: Stakeholder Organisations

- Society of Chief & Principal Dental Surgeons
- Expert Body on Fluorides & Health
- Dental Health Foundation
- Dublin Dental School and Hospital
- Cork Dental School and Hospital
- Irish Dental Association
- Oral Health Promotion Research Group - Irish Link
- Irish Society for Disability and Oral Health
- Irish Society of Dentistry for Children
- Oral Health Managers' Society of Ireland
- Community Action Network
- National Parents Association
- National Consumer Agency
- Consumer Association of Ireland
- Irish National Teachers Organisation
- Office of the Minister for Children
- National Disability Authority
- St Michael's House
- Commercial companies - Colgate & GSK

Appendix 3: Key Questions

Background Questions

1. What is the mechanism of action of topical fluoride
   i. varnish
   ii. gel
   iii. mouthrinse

   in caries prevention?
2. What are the stages of development of teeth and the age for risk of fluorosis in incisor, canine and premolar teeth?
3. What is the safe daily allowance of fluoride for children?
4. What is the pattern of ingestion of fluoride (from all sources) by children residing in fluoridated and non-fluoridated areas
   i. internationally
   ii. in Ireland?
5. What are the brushing habits of Irish children, including:
   i. age of commencement
   ii. frequency of brushing
   iii. amount of toothpaste used
   iv. rinsing
   v. ingestion of fluoride from toothpaste?
6. What is the effect of toothbrush size on the
   i. effectiveness of toothpaste in caries prevention
   ii. risk of ingestion of fluoride toothpaste?
7. What is the extent of use of low fluoride paediatric toothpaste, regular fluoride toothpaste and non-fluoridated toothpaste in Ireland?
8. What is the estimated caries increment of Irish children?

Key Questions

General Topical Fluoride Questions

9. How effective are the different topical fluoride modalities at preventing caries in children under the age of 16? Is any one modality superior to another?
10. Which patients, or groups of patients, benefit most from the use of topical fluorides?
11. In children already exposed to water fluoridation and home use of toothpaste, do topical fluorides confer any additional benefit? (i.e. Is there a role for topical fluorides in fluoridated areas?)
12. In children, who have a fluoridated domestic water supply and exposure to home use of toothpaste, do additional topical fluorides further increase the risk of fluorosis?
13. What is the youngest age at which topical fluoride can be applied to the teeth of children to prevent caries and, at the same time, minimise the risk of fluorosis? *(ties in with Q2)*

Specific School-Based Toothbrushing Questions

14. Does school-based supervised toothbrushing reduce dental caries in children under the age of 16, compared to no school-based supervised brushing?
15. Does school-based toothbrushing have a role in Ireland? If so, what groups are most likely to benefit? *(To be discussed once evidence of effectiveness has been presented.)*

Specific Toothpaste Distribution Questions

16. Does the formal distribution of toothpaste to children under the age of 16, at regular intervals, reduce the level of caries compared to children who do not receive toothpaste or who receive toothpaste at less frequent intervals?

17. How effective is the distribution of toothbrush and toothpaste to children compared to toothpaste alone?
18. What is the effect of toothbrush size on the
    i. effectiveness of toothpaste in caries prevention
    ii. risk of fluorosis?

Specific Professionally-Applied Fluoride Questions

19. For individual patients, what is the
    i. relative safety
    ii. effectiveness
    iii. patient acceptability of fluoride gels vs. varnishes?
20. What is the most effective frequency of application of gels or varnishes for children at high and low risk?

Specific Mouthrinsing Questions

21. What is the most effective frequency of application of school-based fluoride mouthrinsing?
22. What is the optimum duration of rinsing for school-based mouthrinsing?
23. How long after rinsing (or professional application of fluoride) should the child wait before eating?
24. What is the best way to dispose of used mouthrinse?
25. What is the best age for commencing mouthrinsing? *(see also Q27)*
26. How acceptable are school-based mouthrinsing programmes to
    i. schools
    ii. parents
    iii. service providers?
27. Is there evidence that school-based fluoride mouthrinsing is effective and acceptable for adolescents in second level education in terms of caries prevention?
28. How does the cost of fluoride mouthrinsing compare with the cost of another fluoride intervention (e.g. school based supervised toothbrushing)?

Specific Slow-Release Fluoride Device Questions

29. How effective are slow-release fluoride devices at preventing caries in children and adolescents?

Appendix 4: Search Strategy

A search strategy was developed in PubMed around the concepts of dental caries, topical fluorides and children/adolescents and was initially run from 1995 to December 2006. This strategy was then filtered by systematic review in clinical queries. The search was also filtered by RCT in clinical queries and restricted to January 1999 to December 2006 to identify any RCTs that had been carried out since the systematic reviews. The search was updated monthly in Pubmed, and was re-run from 1995 to February 2008. The search was also run in EMBASE, Cinahl and all databases of the Cochrane Library. A separate search for adverse effects was also run in Pubmed and Embase using the terms for each of the modalities and the following terms: adverse effects or adverse reaction or toxicity or stomatitis or staining or poisoning or nausea or vomiting or fluorosis.

The main search strategy is given below:

(((fluoride* OR topical fluoride* OR fluoride gel* OR fluoride varnish* OR fluoride mouth*rinse* OR fluoride mouthrinse* OR fluoride mouth*wash* OR fluoride mouthwash* OR fluoride toothpaste* OR fluoride dentifrice* OR SnF OR NaF) OR (fluoride slow*releas* AND device*) OR (glass slow fluoride*releas* AND device*) OR (glass bead*)) OR (("Bifluorid 12"[Substance Name]) OR ("Duraphat"[Substance Name]) OR ("Fluorides"[MeSH]) OR ("Fluorides, Topical"[MeSH]) OR ("amine fluoride solution"[Substance Name]) OR ("amine fluoride gel"[Substance Name]) OR ("Acidulated Phosphate Fluoride"[MeSH]) OR ("Dentifrices"[MeSH]) OR ("Sodium Fluoride"[MeSH]) OR ("Tin Fluorides"[MeSH]) OR ("Mouthwashes"[MeSH]) OR ("Elmex"[Substance Name]) OR ("Fluor Protector"[Substance Name])))

AND

((("Dental Caries"[MeSH]) OR (DMF) OR ("DMF Index"[MeSH]) OR ("Dental Caries Susceptibility"[MeSH]) OR ("Tooth Demineralization"[MeSH]) OR ("Tooth Remineralization"[MeSH])) OR (dental caries OR caries OR dental cavit* OR dental decay OR tooth decay OR demineralis* OR remineralis* OR caries increment))

AND

((child* OR preschool* OR preschool child* OR toddler* OR teenager* OR young adult* OR young person* OR baby OR babies OR infant*) OR (("Child"[MeSH]) OR ("Child, Preschool"[MeSH]) OR ("Infant"[MeSH]) OR ("Adolescent"[MeSH])))

Results of main search

	No. hits (unsifted)	**Systematic reviews/meta-analyses**	**Evidence based guidelines**	**RCTs (1999–2008)** (sifted)	**Economic evaluations**
1995–Feb 2008	1,144	19	10	127	5

In addition, the following websites of guideline organisations and other health information databases were searched for relevant guidelines on the use of topical fluorides:

	Web address
The National Library for Health (NLH)	http://www.library.nhs.uk/
National Institute for Health and Clinical Excellence (NICE)	http://www.nice.org.uk/
Scottish Intercollegiate Guidelines Network (SIGN)	http://www.sign.ac.uk/
NZ Guideline Group	http://www.nzgg.org.nz/
Australian National Health and Medical Research Council	http://www.nhmrc.gov.au/publications/subjects/oral.htm
National Guideline Clearinghouse	http://www.guideline.gov/
Centre for Disease Control	http://www.cdc.gov/OralHealth/guidelines.htm
Guidelines International Network (G-I-N)	http://www.g-i-n.net/index.cfm
TRIP Database	http://www.tripdatabase.com/index.html
FDI	http://www.fdiworldental.org/home/home.html

Appendix 5: Caries Risk Assessment Checklist

Dentist's name: ___________________ Date: __________ First assessment Y / N

Child's name: _____________________ School: _________ Date of birth: _______

Risk Factors / Indicators	Please circle the most appropriate answer	
A "YES" in the shaded section indicates that the child is likely to be at high risk of developing caries		
• Age 0-3 with caries (cavitated or non-cavitated)	**Yes**	No
• Age 4-6 with dmft>2 or DMFT > 0	**Yes**	No
• Age 7 and over with active smooth surface caries (cavitated or non-cavitated) on one or more permanent teeth	**Yes**	No
• New caries lesions in last 12 months	**Yes**	No
• Hypomineralised permanent molars	**Yes**	No
• Medical conditions where dental caries could put the patient's general health at increased risk	**Yes**	No
• Medical conditions that could increase the patient's risk of developing dental caries	**Yes**	No
• Medical conditions that may complicate dental treatment or reduce the patient's ability to maintain their oral health	**Yes**	No
The following indicators should also be considered when assessing the child's risk of developing caries		
• Age 7–10 with dmft >3 or DMFT >0	**Yes**	No
• Age 11–13 with DMFT >2	**Yes**	No
• Age 14–15 with DMFT >4	**Yes**	No
• Deep pits and fissures in permanent teeth	**Yes**	No
• Full medical card	**Yes**	No
• Sweet snacks or drinks between meals more than twice a day	**Yes**	No
Protective Factors		
A "NO" in this section indicates the absence of protective factors which may increase the child's risk of developing caries		
• Fissure sealants	Yes	**No**
• Brushes twice a day or more	Yes	**No**
• Uses toothpaste containing 1000ppm F or more	Yes	**No**
• Fluoridated water supply	Yes	**No / Don't know**

Is this child at high risk of developing caries?	**YES**	**NO**

Notes on the Caries Risk Assessment Checklist

Introduction

The approach taken during the development of this checklist was that all children are at risk of developing caries but some children are at high risk, and these are the ones we want to identify. The assessment of caries risk is something that every dentist does, usually informally or implicitly. The aim of the checklist is to encourage a formal, systematic approach to identifying individual children who may be at high risk of developing decay. Caries risk assessment should form the basis of a risk-based approach to patient treatment and recall, with repeat assessments indicating if the child's risk status is changing over time.

The checklist is divided into 2 sections: risk factors/indicators and protective factors. The shaded part contains the risk factors/indicators that the Guideline Development Group considered most important for identifying high caries risk children. A score in the shaded part indicates that a child is likely to be at high risk for caries. Other indicators that should be taken into account when assessing the child's risk status complete this section. The presence or absence of protective factors should also be considered. The checklist combines the two most consistent predictors of future caries: previous caries experience[57] and the dentist's own assessment.[63,64] The dentist makes the final decision about caries risk status, based on their overall assessment of the patient. The following notes give some pointers on filling in the checklist.

Risk Factors/Indicators

Age 0-3: Any child under the age of 4 who shows any evidence of caries - with or without cavitation - should be considered high risk, as the consequences of any caries for this age group can mean recourse to general anaesthesia for treatment.

Age 7 and over: Caries is a dynamic process that can progress or arrest. The concept of lesion activity is becoming increasingly important in assessing a patient's risk of developing future caries. There is currently no international consensus on the diagnosis of active lesions, and for the purposes of this caries risk assessment checklist, we are suggesting a modified version of the criteria defined by Nyvad et al.[181] An active lesion is one which is likely to progress if nothing is done. It is more than just a "white spot" lesion. An active, non cavitated enamel lesion is characterised by a whitish/yellow opaque surface with loss of lustre and exhibiting a "chalky" appearance. Inactive lesions tend to be shiny and smooth.

New lesions: New caries in the last 12 months, or progression of non-cavitated lesions (clinical or radiographic) is a good indicator of high caries activity.

Smooth surface caries: At least 70% of caries in permanent teeth in Irish children occurs on pit and fissure surfaces.[2] The occurrence of caries on smooth surfaces i.e. proximal, buccal or palatal (excluding the respective pits) or lingual surfaces, indicates a different pattern of disease and potentially a greater risk of developing further decay. The presence of approximal lesions on bitewing (if available) should also be considered when assessing smooth surface lesions (although it will not be possible to assess the activity of the lesion from radiographs taken at a single timepoint).

Hypomineralised molars: These teeth can decay rapidly and in more severe cases, present a restorative and long term management challenge.

Deep pits and fissures: The morphology of the occlusal surface has been shown to be a good predictor of caries risk.[64]

Medical history: The medical history section is meant to be a formal summary of the medical history that you normally take for your patient, expressed as a risk factor for caries. Some examples of conditions that could be included in each of the categories are shown below.

Medical History	Examples
Conditions where dental caries could put the patient's general health at increased risk	Cardiovascular disease Bleeding disorders Immunosuppression
Conditions that could increase the patient's risk of developing dental caries	Salivary hypofunction Medications that reduce saliva flow Long term use of sugar-containing medicine
Conditions that may complicate dental treatment or that reduce the patient's ability to maintain their oral health	Anxious*, nervous* or phobic conditions, behavioural problems Certain physical and intellectual disabilities, cleft lip/palate

**Over and above what would be considered "normal" anxiety or nervousness for children*

DMFT (Decayed/Missing/Filled Teeth): In calculating the dmft/DMFT, only teeth that have been extracted due to caries should be counted as missing. Similarly, only fillings that have been placed due to caries should be counted. The DMFT cut-offs in the checklist are based on the mean DMFT of the top one third of children with the highest caries levels from the North South survey.[2] In the North South survey, caries was recorded without the use of (bitewing) radiographs; therefore caries detected on (bitewing) radiographs should not be included in the dmft/DMFT calculation. Smooth surface caries detected on radiographs can be included as 'Active smooth surface caries (cavitated or non-cavitated) on one or more permanent teeth.'

Dietary habits: Diet is one of the main risk factors for dental caries, and it can be the most difficult and sensitive area on which to get accurate information. We are suggesting that the question could be phrased along the lines of the question on diet that was included in the North South survey.

Dietary habits	Suggested question
Sweet snacks or drinks twice a day or more between meals	How often does your child eat sweet food or drinks e.g. biscuits, cakes, sweets, fizzy drinks/squash, fruit drinks etc between normal meals?

Medical Card: There is fairly strong evidence of an inverse relationship between socio-economic status and oral health in children under 12 years of age.[49] Medical card status has been used in Irish studies as an indicator of disadvantage. Medical card status may be a particularly useful indicator of caries risk where children are too young for their risk to be based on caries history. Since the introduction of the GP Visit card, which has higher income thresholds for eligibility, it is necessary to establish if the patient has a Full medical card. Very often this data is collected as part of the medical history or patient details, and data from these sources can be used to complete the checklist.

Protective Factors

The effectiveness of the protective factors listed in the checklist at reducing caries has been established in various systematic reviews.[55,117,118,182] The absence of protective factors could increase a child's risk for developing caries.

Appendix 6: Estimated cost of a school-based fluoride varnish programme in Ireland

Costs were calculated for a hypothetical school-based fluoride varnish programme involving twice-yearly varnish application, based on a dental team comprising a dental hygienist and a dental nurse attending schools within a 25 mile radius from the hygienist's base clinic. Travel distances of 20, 33 and 50 miles (round trip) were selected to represent possible variation in travel distances.

Labour and Subsistence Costs

Labour costs were estimated using the 6th point on the salary scale for hygienists and the 7th point on the salary scale for dental nurses with a qualification. The salary cost per day was calculated by dividing the annual salary by 52 weeks to get the weekly rate, and then dividing by 5 to get the daily rate. Five-hour subsistence rates (€16.95) were taken from the HSE Circular 21/2006 and rounded up to the nearest euro. Estimated total daily staff costs (labour and subsistence) are shown in Table A6.1.

Table A6.1: Estimated daily staff costs (labour and subsistence) for a fluoride varnish programme

STAFF COSTS			
	Hygienist	**Nurse**	**Both**
Basic Salary	€45,861.00	€31,028.00	
Employer's Contribution (25%)	€11,465.25	€7,757.00	
Total Salary	€57,326.25	€38,785.00	
Salary Cost /Day	€220.49	€149.17	€369.66
Subsistence/Day	€17	€17	€34.00
Total daily staff costs	€237.49	€166.17	**€403.66**

Travel Costs

Travel rates were taken from the HSE HR Circular 20/2006, based on an engine capacity of between 1,201 cc and 1,500 cc and annual travel of less than 4,000 miles. This rate – 102.58 cent – was rounded down to the nearest euro. We considered it likely that, to reduce travel costs, the hygienist would be assisted by a dental nurse who was based closest to the school being visited. We made provision for this by calculating costs for both members of the team travelling equal distances (20, 33 and 50 miles), and for the dental nurse travelling half the distance of the hygienist (10, 17.5 and 25 miles). Total daily staff and travel costs, for different distances travelled, are shown in Table A6.2

Table A6.2: Estimated daily staff and travel costs, for variable travel distances

Assumption 1: Equal travel distances for hygienist and nurse			
	50 miles	**33 miles**	**20 miles**
Total staff costs	€403.66	€403.66	€403.66
Travel - hygienist	€50.00	€33.00	€20.00
Travel - nurse	€50.00	€33.00	€20.00
Total daily staff and travel cost	**€503.66**	**€469.66**	**€443.66**
Assumption 2: Nurse travels half distance of hygienist			
	50 miles	**33 miles**	**20 miles**
Total staff costs	€403.66	€403.66	€403.66
Travel - hygienist	€50.00	€33.00	€20.00
Travel - nurse	€25.00	€17.50	€10.00
Total daily staff and travel cost	**€478.66**	**€454.16**	**€433.66**

Materials Costs

Materials were costed to include a portable dental chair and stool and a dental light. An average lifespan of 3 years was assumed for the dental chair and it was assumed that the chair would be in daily use during school term time (not necessarily as part of the varnish programme). With this assumption, the cost of fluoride varnish was the main influence on daily material costs. It was assumed that 1.5 x 10 ml tubes of fluoride varnish would be required to treat 20–33 children and that 2 tubes would be required to treat 50 children. Value added tax (VAT) was applied at the rate of 21% to all materials. The calculation of materials costs per day is shown in Table A6.3

Table A6.3: Estimated cost of materials for a fluoride varnish programme

Materials	Unit Cost (inc VAT@21%)		Quantity/day	Cost using 1.5 tubes varnish/day (20-33 children)	Cost using 2 tubes varnish/day (50 children)
Varnish	€65.00	per tube		€97.50	€130.00
Gloves	€4.84	per box of 100	2 boxes	€9.68	€9.68
Masks	€5.45	per box of 60	10 masks	€0.91	€0.91
Portable Chair	€1,378.51		1	€2.08	€2.08
Portable Stool	€682.22		1	€1.03	€1.03
Light	€502.44		1	€0.76	€0.76
Paper roll	€1.19	per roll	1/2 roll	€0.59	€0.59
Wipes	€8.76	per tub	1/4 tub	€2.19	€2.19
Cotton Wool	€6.99	per 1000	1/5 box	€1.40	€1.40
Tissues	€0.62	per box	one box	€0.62	€0.62
Administration Costs	€121.00	per year		€0.66	€0.66
Plastic bags - yellow	€0.18	per bag	one bag	€0.18	€0.18
Pastic bags - white	€0.13	per bag	one bag	€0.13	€0.13
Plastic bags - blue	€0.15	per bag	one bag	€0.15	€0.15
Total materials cost per day				**€117.87**	**€150.37**

Sensitivity Analysis

A sensitivity analysis was conducted to allow for variable travel distances (described above) and variable productivity (number of children treated per day). An upper limit of 50 children per day was set, following consultation with one of the authors of the Manchester Fluoride Varnish project.[94] The figure of 33 children per day was reached based on the published application time of 6 minutes.[95] The minimum number of children seen per day was arbitrarily set at 20. The expected working time within the school was estimated at 3.2 hours (190 minutes). The estimated annual cost per child for a school-based varnish programme is presented in Table A6.4 for each of the variations in travel, productivity and materials described above. It can be seen that the estimated annual cost per child is most influenced by the number of children seen per day. The variation in travel distances has a relatively minor impact on costs.

Table A6.4: Estimated annual cost per child for a school-based fluoride varnish programme

Assumption 1: Equal distances travelled by nurse and hygienist				Assumption 2: Nurse travels half distance of hygienist			
	50 miles	**33 miles**	**20 miles**		**50 miles**	**33 miles**	**20 miles**
20 children				**20 children**			
Staff costs	€503.66	€469.66	€443.66	Staff costs	€478.66	€454.16	€433.66
Materials	€ 117.87	€ 117.87	€ 117.87	Materials	€ 117.87	€ 117.87	€ 117.87
Total costs/day	€621.52	€587.52	€561.52	Total costs/day	€596.52	€572.02	€551.52
Cost/child/day	€31.08	€29.38	€28.08	Cost/child/day	€29.83	€28.60	€27.58
Cost/child/year	**€62.15**	**€58.75**	**€56.15**	**Cost/child/year**	**€59.65**	**€57.20**	**€55.15**
33 children				**33 children**			
Staff costs	€503.66	€469.66	€443.66	Staff costs	€478.66	€454.16	€433.66
Materials	€ 117.87	€ 117.87	€ 117.87	Materials	€ 117.87	€ 117.87	€ 117.87
Total costs/day	€621.52	€587.52	€561.52	Total costs/day	€596.52	€572.02	€551.52
Cost/child/day	€18.83	€17.80	€17.02	Cost/child/day	€18.08	€17.33	€16.71
Cost/child/year	**€37.67**	**€35.61**	**€34.03**	**Cost/child/year**	**€36.15**	**€34.67**	**€33.43**
50 children				**50 children**			
Staff costs	€503.66	€469.66	€443.66	Staff costs	€478.66	€454.16	€433.66
Materials	€ 150.37	€ 150.37	€ 150.37	Materials	€ 150.37	€ 150.37	€ 150.37
Total costs/day	€654.02	€620.02	€594.02	Total costs/day	€629.02	€604.52	€584.02
Cost/child/day	€13.08	€12.40	€11.88	Cost/child/day	€12.58	€12.09	€11.68
Cost/child/year	**€26.16**	**€24.80**	**€23.76**	**Cost/child/year**	**€25.16**	**€24.18**	**€23.36**

Appendix 7: Estimated cost of a school-based supervised toothbrushing programme in Ireland

The 2-year costs of delivering a school-based supervised toothbrushing programme in Scotland were obtained from the main author of the study, Dr Morag Curnow.[62] This study was conducted between 1997 and 1999, so costs were converted to euro and updated to current prices (2008) to determine the estimated cost of establishing a similar programme in Ireland (Table A5.1).

Table A5.1: Cost of a 2-year supervised toothbrushing programme in Scotland, converted to euro and updated to current prices (as of Jan 2008)

No. children = 279	Total 2-year Cost £stg (1997-1999)	Cost per year £stg	Convert to Euro	Inflate to 2008 prices	Cost per child per year (2008)
Supervisor's wages	£18,626.40	£9,313.20	€13,015.20	€18,039.06	€64.66
Cleaning materials	£802.67	£401.34	€560.87	€777.36	€2.79
Trays, toothbrushes and toothpaste	£3,338.83	£1,669.42	€2,333.01	€3,233.55	€11.59
Motivators for the children	£5,736.00	£2,868.00	€4,008.03	€5,555.13	€19.91
Total	£28,503.90	£14,251.95	€19,917.10	€27,605.10	**€98.94**

a: Exchange rate Bank of Canada website http://www.bankofcanada.ca/cgi-bin/famecgi_fdps: Based on an average exchange rate of £1=1.40
b:Inflation rate Base Year 1996 = 100 from CPI CSO website http://www.cso.ie/px/pxeirestat/Dialog/Saveshow.asp base year=1996.

The Scottish costs did not state the number of supervisors that were involved in the programme, so it was impossible to establish the hourly labour rate that was used. To determine if Irish labour costs would substantially influence the cost estimate of the supervised brushing programme, we estimated costs for a hypothetical school-based supervised toothbrushing programme in Ireland, involving 4 classes of 25 children, each with its own supervisor, paid at the minimum wage (€8.65 as of July 1, 2007):Source:http://www.citizensinformation.ie/categories/employment/employment-rights-and-conditions/pay-and-employment/pay_inc_min_wage).

We used 183 as the minimum number of school days available for the brushing programme (Department of Education and Science Primary Branch Primary Circular 11/95. Available at: http://www.into.ie/descirculars/DESCircularsPre1996/filedownload,2904,en.doc).

Cleaning materials were costed at €454 per year in total. Allowance was made for 3 tubes of toothpaste and 3 toothbrushes to be provided to each child per year, and in line with the Scottish study, 20% of the total budget was allocated to motivators for the children. The estimated cost of a supervised toothbrushing programme is €104.55 per child per year at 2008 prices.

Table A5.2: Estimated Irish costs for a hypothetical supervised toothbrushing programme (based on 4 classes of 25 children, 4 supervisors and 183 days/year, based on 2008 prices)

Supervisors' wages*		€6,870.00
Cleaning materials		€454.80
Trays	1 per child @ €3 ea	€300.00
Toothbrushes	3 per child @ €1 ea	€300.00
Toothpaste	3 per child @ €1 ea	€400.00
Motivators for the children	20% of total budget	€2,130.00
Total annual cost		€10,454.80
Estimated cost per child per year at 2008 prices		**€104.55**

** (Minimum wage (€8.65) x 4 supervisors x 5 days/week x 8.5% employer's PRSI) x 36.6 weeks*

Appendix 8: Comparison of the cost-effectiveness of community-based topical fluoride programmes

This guideline considered four possible community–based interventions involving the use of topical fluorides for preventing caries in children and adolescents: fluoride varnish, supervised toothbrushing, toothpaste distribution and fluoride mouthrinsing. A comparison of the costs and effectiveness of the various different community-based preventive programmes is presented in Table A8.1. The costs for the toothpaste and mouthrinse programmes are taken from actual trials, and have been converted to euro and updated to current (2008) prices, as described in Appendix 7. The cost of the varnish programme is estimated, as described in Appendix 6. The measure of effectiveness for the toothpaste programmes is taken from the published results of the trials from which the costs derive. In the case of the mouthrinse study, which was not an RCT, the measure of effectiveness is taken from the sub-analysis of the Cochrane fluoride mouthrinse systematic review[156] that was conducted for this guideline. Supervised toothbrushing is the most expensive option, but has the greatest effect for the shortest programme duration (2 years). The long term benefits of supervised toothbrushing have been reported: 30% reduction in caries in the first permanent molars, 4.5 years after the cessation of the programme.[148] Costs for this programme have been reduced by 75% since the programme was rolled out to preschools and primary schools in Scotland, mainly by reducing the labour costs. Cost reductions could also be achieved in preschools, if trained carers could supervise toothbrushing as part of their daily work. Fortnightly fluoride mouthrinsing is the cheapest option, but is less effective and is unsuitable for children under the age of 7 years. The estimated costs for a fluoride varnish programme fall between those of supervised brushing and toothpaste distribution. Varnish programme costs are particularly sensitive to the number of children seen per day. The choice of preventive programme for a particular community needs to be based on the caries profile, needs and preferences of that community, as well as the cost of the programme.

Table A8.1: Comparison of costs and effectiveness of various community-based caries preventive programmes involving topical fluorides

	Intervention	Actual cost per child per year (£)	Cost per child per year (€) at 2008 prices	Duration of programme	Prevented fraction	Long term effect
Curnow, 2002[154] **Curnow et al., 2002[147]**	Supervised brushing	£51 Stg (1999)	€99	2 years	PF= 56% D_3FS PF=32% (D_1FS) FPMs*	PF=30% D_3FS (FPMs) 4.5 years after programme stops[148]
Davies et al., 2003[155]	Toothpaste distribution	£6.98 Stg (2002)	€11.91	4 years	PF=16% (primary dentition)	Unknown
Holland et al., 2001[164]	School-based fluoride mouthrinsing	£ 3.26 IR (fortnightly) (2002)	€5.32 fortnightly €10.64 weekly	6 years	18% fortnightly 32% weekly	No benefit 4 years after programme stops[167]
Guideline Economic Model	Community-based fluoride varnish	2008	€23 to €62 (depending on travel and productivity)	Continuous	33% primary dentition 46% Permanent dentition (Marinho et al, 2002)[156]	Unknown

**FPMs: First permanent molars*

Appendix 9: Irish Fluoride mouthrinse studies

Three cross sectional studies have been conducted, which evaluate the effectiveness of fortnightly fluoride mouthrinsing at preventing caries in children participating in fluoride mouthrinse programme in County Waterford.

In the first study[165], significant differences in caries levels were found at each year of age, from age 7 up to age 12 years, in children who had been participating in the mouthrinsing programme since they started school, compared to children from non-fluoridated areas who were not part of a fluoride mouthrinsing programme. At age 12, the mean DMFT in the rinse group was 4.4 compared to 6.9 in the no-rinse group ($p<0.01$). 3

In 1984, the effectiveness of the mouthrinsing programme was re-examined in the light of the general decline in the prevalence of dental caries.[166] This study found that, overall, the level of caries in North Waterford had declined since 1978 and significant differences in caries levels between the rinse group and no-rinse groups were seen only at age 11 and 12. The mean DMFT of the rinse group at age 12 was 2.5 versus 4.5 in the no-rinse group ($p<0.001$). No significant difference was found in caries levels between 12-year-olds in the rinse group and children of the same age who had lifetime exposure to fluoridated water (mean DMFT 2.5 v 2.3). 3

The next study investigated the effects of the same fluoride mouthrinsing programme four years after children had left the programme at the end of primary school.[167] The study involved three groups of 12-year-old children and three groups of 16-year-old children. These groups were:

- children who had participated in the mouthrinsing programme from age 6 (rinse group)
- children attending non-participating nearby schools (no-rinse group)
- lifetime residents of a fluoridated community (fluoridated group).

The rinse group in the 16-year-old sample represented children who had participated in the mouthrinsing programme until they left primary school (age 12), at which point the programme ceased.

Among 12-year-olds, caries levels in the rinse group were the same as in the fluoridated group (mean DMFT 1.2) but were significantly lower than the no-rinse group (mean DMFT 1.2 v 1.9; $p<0.05$). Among 16-year-olds, there was no significant difference in caries levels between the former rinse group and the no-rinse group (mean DMFT 4.0 and 4.7, respectively, $p>0.05$). Both groups had significantly more caries than the fluoridated group (mean DMFT 2.7). These findings suggest that the benefits conferred by participation in a school-based mouthrinsing programme fade after the children leave the programme. The researchers recommended that the cessation of mouthrinse programmes should be reappraised and recommended a combination programme of school-based fluoride mouthrinsing with fissure sealing, since most of the caries in both age groups occurred in occlusal surfaces of molar teeth. 3

The main aim of the final study in this series was to compare the cost-effectiveness of a fluoride mouthrinsing programme and water fluoridation. It also compared caries levels in three groups of 12-year-olds: fluoridated, non-fluoridated and mouthrinsing. There was no significant difference in the mean DMFT of 12-year-old children in the mouthrinsing group compared to the fluoridated group (1.32 and 1.25 respectively). The non-fluoridated group had significantly higher caries levels than the fluoridated group (mean DMFT 1.82 v 1.25 ($p<0.05$), but the difference between the rinse and non-fluoridated group was not statistically significant (mean DMFT 1.32 v 1.82 respectively). The researchers concluded that water fluoridation and the fluoride mouthrinsing programme had similar effectiveness at age 12. [164]

The present value cost (PVC) of achieving similar reductions in caries for children at age 12 was calculated for a fluoride mouthrinsing programme and water fluoridation. The PVC is the amount that would have to be invested now to ensure that annual payments could be made to deliver each of the programmes up to age 12. The approach taken in this study was to calculate 12 years of costs in the case of water fluoridation, from age 0–12. For fluoride mouthrinsing, 7 years of costs, from age 6 to age 12, were calculated. The population size of 12 year olds for which both programmes cost the same was 3,168, and the cost was €54,920. Therefore, below this population threshold figure, fluoride mouthrinsing would be more cost effective. **3**

Appendix 10: Caries Increment Calculation

Ideally, caries increment should be measured in a longitudinal study which records the change in caries levels from baseline to the endpoint of the study in the same group of subjects. As we have no recent studies that measure caries increment in a representative sample of Irish children from non-fluoridated areas, we had to estimate the figure using the most recent data available to us – i.e. the cross-sectional North South survey. The caries increment for Irish children between age 8 and 12 in non-fluoridated areas was calculated by subtracting the mean DMFS for 8-year-olds from the mean DMFS for 12-year-olds. This calculation only provides an estimate, as it is based on two different cohorts of children and assumes that the conditions that led to the 12-year-olds having a DMFS of 2.9 in 2002 will also apply to the 8-year-old children over the next four years.

Bearing these limitations in mind, the caries increment age 8–12 was calculated as follows:

Non-Fluoridated areas

Mean DMFS age 8 = 0.7

Mean DMFS age 12 = 2.9

Estimated four year caries increment = 2.9 – 0.7 = 2.2

Reduction in caries increment with **fortnightly** 900 ppm NaF mouthrinse = 18%

Caries increment less 18% = 2.2 – 0.396 = 1.8

Assuming mouthrinsing started at age 8, the mean DMFS at age 12 with 18% reduction in caries increment = 0.7 + 1.8 = **2.5**

Reduction in caries increment with **weekly** 900 ppm NaF mouthrinse = 32%

Caries increment less 32% = 2.2 – 0.704 = 1.5

Assuming mouthrinsing started at age 8, the mean DMFS at age 12 with 32% reduction in caries increment = 0.7 + 1.5 = **2.2**

Fluoridated areas

Mean DMFS age 12 = **2.2**