TOPICAL FLUORIDES

Guidance on the use of topical fluorides for caries prevention in children and adolescents in Ireland

Summary Guideline

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HRB
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The full guideline is available at: http://ohsrc.ucc.ie/

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Contents

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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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 3).

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[17-19]	**A**	Fluoride varnish application (at least 22,600 ppm F) should be offered to children who are assessed as being at high caries risk[17,20,21]	**A**
	Varnish should be applied at intervals of 6 months or 3 months[17]	**A**	Varnish should be applied at intervals of 6 months[17,21] or 3 months[17]	**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[29,30]	**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[22,24]	**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[50,52,60]	**A**
			• Be undertaken in community settings such as	
			o crèches, nurseries, preschools[52,53,59]	**B**
			o primary schools[50,52,53]	**A**
			• Involve the use of toothpaste containing at least 1,000 ppm fluoride[52-55]	**A**
			• Support home use of fluoride toothpaste through provision of toothpaste, toothbrush and instructions for home use during school holidays[61]	**D**
			Programmes involving the distribution of fluoride toothpaste should:	
			• Be considered in targeted populations of children at high risk of caries[52,53,57] *Toothpaste distribution has the advantage of being cheaper[62,63], but is less effective than supervised brushing[52,53]*	**A**
			• Involve the use of toothpaste containing at least 1,000 ppm fluoride[52-55]	**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	**GPP**	Weekly fluoride mouthrinsing with 0.2% sodium fluoride rinse should be offered to children living in non-fluoridated areas (sub-analysis of review by Marinho et al.[68])	**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. [68])	**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[71,72]	**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**

Introduction

Fluoride has been the cornerstone of caries prevention in the Republic of Ireland since the introduction of water fluoridation in the mid 1960s. In line with trends in many developed countries, the prevalence and severity of dental caries among Irish children has declined dramatically since the 1960s, and much of this decline has been attributed to the availability of fluoride, through water fluoridation and also through the home use of fluoride toothpaste.[2,3] Currently 71% of the population in the Republic of Ireland has fluoridated domestic water supplies[2] and over 95% of toothpastes sold in Ireland contain fluoride.[4]

In spite of the overall improvement in children's dental health, caries remains a very common disease among Irish children. Approximately half (55%) of all 5-year-old children in non-fluoridated areas and approximately one third (37%) in fluoridated areas have experienced decay. Over half of all 12-year-olds and approximately three quarters of all 15-year-olds in fluoridated and non-fluoridated areas have experienced decay.[2] (Table 1) For a sizeable proportion of children, the burden of disease experienced is considerable. 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.[5] Table 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: 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 $d_{3vc}mft/D_{3vc}MFT > 0$*
^mean $d_{3vc}mft/D_{3vc}MFT$

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 were not 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 was also not reached. No oral health goals were set for 15-year-olds.

In recent times, there has been an increased focus, both in Ireland and internationally, on the balance between the benefits and the risks of fluoride, particularly in light of the general decline in caries levels and the increased availability of fluoride from multiple sources. Dental fluorosis is a disturbance in enamel formation which occurs when excess fluoride is ingested during tooth development. The North

South Survey of Children's Oral Health 2002 showed that the prevalence of fluorosis among 8- and 15-year-old children in the Republic of Ireland had increased since 1984, particularly in fluoridated but also in non-fluoridated areas.[2] It is important to note that most of this increase in fluorosis was in the Questionable and Very Mild categories.

The dietary and toothbrushing habits of Irish children compare unfavourably with those of children in other countries[7,8] and a number of reports have stressed the need for new preventive strategies to improve the oral health of children in Ireland.[2,9] The critical question for the Irish situation is whether preventive strategies that involve the use of topical fluorides provide any additional benefit, or pose any additional risk of fluorosis, in an environment which already has population exposure to two fluoride modalities - water and toothpaste.

Scope and aim of this guideline

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".[10] Topical fluorides generally fall into two categories: (a) self applied – e.g. toothpaste and mouthrinse, and (b) professionally applied e.g. fluoride varnish and gel.

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 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.

The aim of this guideline is to:

- Assist Public Dental Service clinicians in making decisions on the use of professionally applied topical fluorides (varnish, gel, foam and slow-release fluoride devices) for caries prevention in individual patients
- Assist policy makers and those responsible for planning public dental services for children and adolescents in making decisions on the provision of community-based caries prevention programmes involving the use of topical fluorides.

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.

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. The recommendations cover children and adolescents under the age of 16. The upper age limit of 16 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.

How this guideline was developed

This guideline was developed in line with international best practice, as described in the AGREE Instrument.[11] A Guideline Development Group (GDG) was established, which represented key stakeholders in the guideline. Stakeholder groups who were not represented on the GDG were invited to contribute comments at the scoping stage and to comment on the consultation draft of this guideline. A full list of stakeholders can be found in Appendix 1. The draft guideline was also reviewed by five external reviewers (see Acknowledgements for list of external reviewers).

The key questions to be addressed by the guideline were developed by the GDG and a systematic search was undertaken for evidence-based guidelines, systematic reviews, economic evaluations and randomised controlled trials to answer these questions. A decision was made at the outset to limit all searches to English. Details of the search strategy and the databases and websites searched can be found in Appendix 2. A separate search for studies of any design reporting adverse effects was also conducted in Pubmed and EMBASE. The quality of evidence was independently appraised by two reviewers, and a summary of the evidence was presented to the GDG. Following discussion of the evidence presented, recommendations were made by the GDG using informal consensus.

The development of this guideline was funded through a Strategic Health Research and Development Research Award from the Health Research Board (HRB). The content of this guideline was not influenced by the funding agency. The guideline will be updated in 2010.

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 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.[10] **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.[10]

  A subsequent Cochrane review, which compared the effect of the different modalities head-to-head, found that no modality was superior to another.[12] **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.[10] **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.[13] **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 the 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.[10] 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.

Professionally Applied Topical Fluorides

Professionally applied fluoride varnish, gel and foam are high concentration fluoride vehicles which are applied by healthcare professionals intermittently for caries prevention. The professionally applied topical fluorides considered in this guideline are:

- Fluoride varnish
- Fluoride gel
- Fluoride foam
- Slow-release fluoride devices

Of these, fluoride varnish is the most widely used professionally applied topical fluoride in the Public Dental Service. Although the fluoride concentration of varnish is typically very high, the nature of varnish lends itself to controlled, precise application to specific tooth surfaces, and only a small amount of the product is required. A typical application of 5% sodium fluoride varnish (22,600 ppm F) requires 0.25 – 0.5 ml, and contains 5.65 - 11.3 mg of fluoride. In contrast, fluoride gel (12,300 ppm F), which has a viscous texture and is most commonly applied in a tray, requires 3-5 mls of gel per application, which contains 36.9 - 61.5mg of fluoride. The probably toxic dose of fluoride for a 20 kg child is contained in only 8 mls of gel.[14] Fluoride gel is not widely used in the Public Dental Service. Fluoride foam is a relatively recent product which has the same fluoride concentration and method of application as 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. The fluoride content and formulations of various professionally applied topical fluoride products are summarised in Table 2.

Table 2: Fluoride formulation and concentration of a selection of fluoride varnish, gel and foam products

Fluoride Product	Fluoride formulation	Product name	Fluoride concentration (ppm F)
Varnish	**Resin-based:** 5% Sodium Fluoride	Duraphat (Colgate Palmolive)	22,600
	Aqueous: 1% difluorsilane	Fluor Protector (Ivoclar-Vivadent)	1,000
	6% sodium fluoride plus 6% calcium fluoride	Bifluorid 12 (VOCO GmbH)	56,300
Gel	1.23% acidulated phosphate fluoride	NUPRO® Fluoride gel	12,300
	2% neutral sodium fluoride	NUPRO® Fluoride gel	9,050
Foam	1.23% acidulated phosphate fluoride	Denti-Foam (Medicom)	12,300
	2% sodium fluoride neutral	Denti-Care Foam (Medicom)	9,050

Slow-release fluoride devices have been developed as vehicles to deliver a consistent level of fluoride intra-orally, during a long period of time (at least one year), without the need for regular professional involvement or patient compliance.[15] Two main types of intra-oral device for caries prevention have

been described – (a) the copolymer membrane and (b) fluoride-containing glass beads – both of which have been shown to increase salivary fluoride levels.[16]

Summary of evidence on the effectiveness of 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. **1++**

  A Cochrane systematic review of seven trials involving 2,278 children reported an average reduction in caries increment of 46% (95% CI 30-63%, p<0.0001) in permanent teeth and 33% (95% CI 19-48%, p<0.0001) in primary teeth, with the use of fluoride varnish compared to placebo or no treatment.[17] A subsequent systematic review[18] and an RCT[19], both of which looked at the effectiveness of fluoride varnish at preventing caries in preschool children, supported the efficacy of fluoride varnish at preventing caries in the primary dentition.

- Fluoride varnish is effective at preventing caries in high caries risk children. **1+**

  A systematic review of professional caries prevention methods graded the strength of evidence for the efficacy of fluoride varnish at preventing caries in high caries risk individuals as fair.[20] Two subsequent RCTs, one involving adolescents from areas with low, moderate and high caries levels[21] and the other involving high caries risk preschool children[19], both reported significantly lower caries increments in the high caries risk varnish group compared to the control group.

- Fluoride gel is effective at preventing caries in permanent teeth. **1++**

  A Cochrane review involving 14 placebo-controlled trials reported a reduction in caries increment of 21% (95% CI 14-28%, p<0.0001) with the use of fluoride gel.[22] Another systematic review[23] and one meta-analysis[24] have reported average caries reductions of 18%.and 22% respectively, with the use of fluoride gel compared to placebo or no treatment.

- Fluoride varnish or gel applications may not benefit children who are at low risk of developing dental caries. **1+**

  Reports from 2 RCTs that involved the use of fluoride gel in low caries risk children found no clinically relevant difference in caries increment between the gel and control group at the end of the trials.[25,26-28] An RCT of the effect of fluoride varnish on approximal caries in adolescents found no statistically significant difference in approximal caries incidence or progression between the varnish and control group in low-caries risk adolescents.[21]

- Evidence for the comparative effectiveness of fluoride varnish versus fluoride gel is inconclusive.[12] **1++**

  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.

- Two observational studies reported that fluoride varnish is easier to apply, takes less time, and results in fewer signs of discomfort in children than fluoride gel or foam.[29,30] **3**
- None of the systematic reviews provided evidence on adverse effects associated with the use of fluoride varnish or gel. A retrospective cohort study found no association between the prevalence of fluorosis and age at which gel was applied or the frequency with which it was applied.[31] **3**
- No studies on the risk of fluorosis with the use of fluoride varnish were identified. Allergy to the colophony (resin) component of resin-based varnish has been reported[32-34], and is extremely rare. **3**
- Evidence of the effectiveness of fluoride foam is limited to 2 clinical trials[35,36] which provide insufficient evidence on which to base a recommendation.
- A Cochrane review of the effectiveness of slow-release fluoride devices for the control of dental caries identified only one RCT that met its inclusion criteria, and 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.[37]

Recommendations on the use of 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 has been developed as part of this guideline project, specifically for use in the Irish Public Dental Service. The aim of the checklist is to encourage a risk-based approach to the management of caries in Irish school children. This risk assessment checklist combines elements of existing risk assessment tools[38-42] and known risk factors for caries in Irish children.[2,43,44] The checklist and accompanying notes can be found in Appendix 3.

Recommendations

- ***Fluoride varnish application should be offered to children in fluoridated and non-fluoridated areas who are assessed as being at high caries risk*** **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**
- ***Fluoride varnish should be applied at intervals of 6 months or 3 months*** **A**

- ***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**

  The cut-off age of 7 for fluoride gel use was agreed by the Guideline Development Group, based on the age of eruption of the first permanent molars and also on the mean body weight of Irish children, which increases sharply between age 6 and age 7[45], thus reducing the risk of exceeding the threshold for fluoride ingestion if fluoride gel was inadvertently ingested.

- ***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**

- ***There is insufficient evidence at this time on which to base a recommendation on the use of fluoride foam***

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

As well as covering the use of professionally applied topical fluorides for individual patient care, the Guideline Development Group also considered the use of fluoride varnish as a public health measure for the prevention of caries in certain groups of the population e.g. children with special needs, children living in non-fluoridated areas, children living in disadvantaged areas or attending designated disadvantaged schools, or those who might face barriers to accessing surgery-based dental care. An economic evaluation of the cost of delivering a school-based fluoride varnish programme in a non-fluoridated area was conducted for this guideline. The estimated cost of 6-montly school-based fluoride varnish applications ranged from €23 to €62 per child per year. Most of the variation in cost related to the number of children treated per day. Further details on the economic evaluation of the fluoride varnish programme can be found in Appendix 4.

The Guideline Development 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.

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

Community-based Fluoride Toothpaste Programmes

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.[46] 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.[47,48]

In Ireland, 95% of toothpastes on the market contain fluoride.[4] 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.[49] However, as with all self-administered interventions, it relies on patient compliance to achieve optimum results.

Given that the frequency of toothbrushing among Irish children compares unfavourably with that of children from other countries[2,7,8], the Guideline Development Group (GDG) focused on the use of fluoride toothpaste as part of community-based caries preventive programmes, to support or supplement home use. Guidelines on the home use of toothpaste have been issued by the Irish Expert Body on Fluorides and Health, and are available at http://www.dentalhealth.ie/download/pdf/fluorides_qanda.pdf.

The two community-based toothpaste interventions considered by the GDG 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.[50]

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. However, 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.[51]

Summary of evidence on the effectiveness of fluoride toothpaste

- Fluoride toothpaste is effective at preventing caries in children and adolescents. **1++**

  A Cochrane review of 70 trials involving over 42,300 children reported an average reduction in caries in permanent teeth of 24% (95% CI 21-28, p<0.0001) with the use of fluoride toothpaste compared to placebo or no treatment.[52] A similar estimate of effect (24.9%) was reported in a Swedish systematic review of 54 toothpaste trials.[53]

- Brushing twice a day is more effective than brushing once a day. **1+**

  The Cochrane review found a 14% increase in the effect of fluoride toothpaste, moving from brushing once a day to twice a day.[52]

- The effect of fluoride toothpaste is not influenced by exposure to water fluoridation. **1+**

  The Cochrane review found that the effect of fluoride toothpaste was not influenced by exposure to other sources of fluoride, including water fluoridation, and concluded that use of fluoride toothpaste provides additional caries reduction in subjects from fluoridated areas.[52]

- There is a dose/response effect with increasing fluoride concentration in toothpaste: **1+**

  - *A systematic review[54] and a meta-analysis[55] found that toothpaste containing 1,000 ppm F is more effective than toothpaste containing 250 ppm F at preventing caries in permanent teeth.*
  - *The Swedish systematic review of the effectiveness of fluoride toothpaste found that toothpaste containing 1,500 ppm F is more effective than standard 1,000/1,100 ppm F toothpaste at preventing caries in permanent teeth.[53]*

- Evidence on the effectiveness of low fluoride toothpaste (containing less than 600 ppm F) at preventing caries in primary teeth is limited to 3 randomised controlled trials, which differ in quality, design, populations studied and results.[56-58]

- 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 higher baseline levels of caries. **1+**

  The Cochrane review found a increase of 0.7% (95% CI 0.3-1.17%) in effect per unit increase in caries.[52] *The Swedish review also reported an increase in effect with higher baseline levels of caries.*[53]

- Supervised toothbrushing (in a school setting) is more effective than unsupervised toothbrushing (i.e. toothpaste distribution). **1+**

  Both the Cochrane and Swedish systematic reviews reported increased effectiveness with supervised toothbrushing compared to unsupervised brushing. The Cochrane systematic review reported a 10% (95% CI -17 to -4%; p=0.001) reduction in effectiveness with unsupervised use[52], *while the Swedish review reported an average reduction in caries of 31% with supervised brushing and 23.3% with unsupervised brushing. A subsequent RCT from China reported a 30.6% reduction in caries increment in the primary teeth of children,*

age 3 at baseline, who participated in a kindergarten-based preventive programme involving twice daily supervised brushing with 1,100 ppm F toothpaste.[59]

- Long term benefits of school-based supervised toothbrushing have been reported. **1+**

  A 30% reduction in caries increment in first permanent molars was found in children who had participated in a 30 month school-based supervised toothbrushing trial in Scotland, compared to the control group, 4.5 years after the programme had stopped.[60]

- The provision of motivators such as toothbrushing charts, to encourage children to brush twice daily at home and during the school holidays, plays an important role in supervised toothbrushing programmes.[61] **3**

- There is no evidence that educative programmes aimed at reducing caries are effective if they do not involve fluoride.[51] **2++**

Recommendations on the use of fluoride toothpaste in community-based programmes

The variation in the prevalence of caries between dental areas in Ireland would suggest that community-based programmes may be more relevant to some dental areas than others. 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. The cost of a school-based supervised toothbrushing programme and a toothpaste distribution programme was estimated for Ireland, based on reported costs of these programmes in Scotland[62] and England[63] (Appendix 5 and 6). This cost estimate shows that school-based supervised toothbrushing is substantially more expensive, but appears to be more effective than toothpaste distribution at reducing caries in high caries risk children. 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 of the distribution of caries.

Recommendation:

Supervised Toothbrushing

Under age 2 years

- ***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, preschools*** **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 years

- ***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

- ***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**

School-based Fluoride Mouthrinsing Programmes

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. With the decline in caries seen in many developed countries, school-based fluoride mouthrinsing is generally reserved for targeted populations with high caries levels. 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 (230 ppm F) rinse is also practiced.

In the Republic of Ireland, fortnightly school-based fluoride mouthrinsing with 0.2% sodium fluoride rinse was first introduced in the late 1960s to bring the caries-preventive benefits of fluoride to children living in rural areas where it would not be possible to fluoridate the water supply. In 2005/06, 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 in primary and (where resources permit) 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. Irish cross sectional studies from the 1970s to the 1990s, have shown that, at age 12, caries levels in the fluoride mouthrinsing groups were significantly lower than caries levels in the no-rinse comparison groups.[64-66] In the most recent study from 2001, the difference between the two groups fell just short of statistical significance.[67] In all studies that included a fluoridated comparison group, there was no significant difference in average caries levels (mean DMFT) at age 12 between the rinse group and the fluoridated group.

The benefits of fluoride mouthrinsing that are seen at age 12 fade after children leave the programme. An Irish study compared caries levels in three groups of 16-year-olds: those who had participated in a school-based mouthrinsing programme up to age 12; those who had not been part of a mouthrinsing programme and those who had lifetime exposure to water fluoridation. This study found no significant difference in caries levels between the former rinse and no-rinse group (mean DMFT 4.0 and 4.7 respectively, p>0.05), but both groups had significantly more caries than the fluoridated group (mean DMFT 2.7). [66] The results of this study would suggest that the home use of fluoride toothpaste by Irish teenagers in non-fluoridated areas is insufficient to achieve the same level of caries control as the combined use of fluoride toothpaste and fluoridated water.

Summary of evidence on the effectiveness of fluoride mouthrinsing

- Fluoride mouthrinsing is effective at reducing caries in children and adolescents.[68,69] **1+**

  A 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.[68] A similar estimate was given in a Swedish systematic 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.[69]

- Fortnightly mouthrinsing with 0.2% sodium fluoride (900 ppm F) rinse is beneficial, but weekly rinsing appears to be much more beneficial (meta-analysis based on a subset of studies in the systematic review by Marinho et al., 2003[68]). **2++**

  At the request of the Guideline Development Group, a special meta-analysis was carried out of the fourteen mouthrinse trials that involved the use of 0.2% sodium fluoride rinse included in the Cochrane systematic review[68] 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. The average reduction in caries increment was 18% (95% CI, 9–27%; p<0.0001) for fortnightly rinsing (4 trials) and 32% (95% CI, 27–37%, p<0.00001) for weekly rinsing (10 trials) compared to placebo or no treatment. A lower level of evidence was assigned to the new meta-analysis due to the indirect nature of the comparison between the subgroups.

- The evidence on the effectiveness of fluoride mouthrinse with background exposure to fluoride is conflicting.[68,69]

  The Cochrane review of mouthrinses found no significant association between the effectiveness of fluoride mouthrinse and background exposure to fluoride.[68] 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.[69]

- The effectiveness of fluoride mouthrinse is not influenced by baseline levels of caries.[68] **1+**

  The Cochrane review found no significant association between baseline level of caries and the effectiveness of fluoride mouthrinse at preventing dental caries.

- The efficiency of fluoride mouthrinsing programmes is greater in populations with a high annual caries increment.[68] **1+**

  In populations with a low caries increment of 0.25 DMFS/year, the NNT (Numbers Needed to Treat) 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.

- Younger children tend to swallow more rinse than older children.[70] **3**

  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).

- 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.

Recommendations on the use of fluoride mouthrinse in school-based fluoride mouthrinsing programmes

Under age 7 years

- ***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*** **D**

  The cut-off age of 7 for the use of fluoride mouthrinse was agreed by the Guideline Development Group, based on the age of eruption of the first permanent molars and also on the mean body weight of Irish children, which increases sharply between age 6 and age 7[45], thus reducing the risk of exceeding the threshold for fluoride ingestion if fluoride rinse was inadvertently ingested.

From age 7 years up to age 16 years

- ***Weekly fluoride mouthrinsing with 0.2% sodium fluoride (900ppm 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**

  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.

- ***Fortnightly mouthrinsing with 0.2% sodium fluoride (900ppm F) rinse is effective at reducing caries, but appears to be less effective than weekly rinsing*** **B**

- ***Children participating in a school-based fluoride mouthrinsing programme should rinse for two minutes with 0.2% sodium fluoride (900ppm F) rinse*** **GPP**

  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.

- ***Rinsing times of less than 2 minutes should be considered for new participants in the 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*** **D**

  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.[71,72]

- ***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, 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**

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.

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 level. 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.

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 and gel: 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.

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.

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.

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 preschool, primary school and/or in secondary school.

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 it a priority 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.

The distribution of fluoride toothpaste to school children has been tested in Ireland through the Winning Smiles programme, and therefore the only potential barrier to the implementation of such a programme would be resources.

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 Irish 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 and with different results. Winter[58] found equal efficacy of low and standard fluoride toothpaste, Davies[57] found greater caries reductions with 1,450 ppm F toothpaste compared to 440 ppm F toothpaste overall and Lima[56] 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.[52,53]
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.[52,53]
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.[52,53,68] However, there is limited evidence on the cost-effectiveness of each of these programmes.[63,67]
Population	Children attending primary schools in non-fluoridated areas.
Intervention	Daily supervised toothbrushing with 1,000 ppm F toothpaste from age 5 (Junior infants class). Toothpaste distribution (1,000 ppm F) every three months from age 5 (Junior infants class). Weekly mouthrinsing with 0.2% sodium fluoride rinse from age 7 (First class).
Comparison	No intervention non-fluoridated control and no intervention fluoridated control.
Outcome	Cost per permanent tooth surface saved, at age 12

- 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.
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.
Case-control study	A study that compares people with a specific disease or outcome of interest (cases) to people from the same population without that disease or outcome (controls), and which seeks to find associations between the outcome and prior exposure to particular risk factors. Case control studies are usually retrospective, but not always.
Cohort study	An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared, to examine people who were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor of interest.
Controlled clinical trial	A clinical trial that has a control group. Such trials are not necessarily randomised.
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.
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.
$d_1$mft/D_1MFT	Caries recorded in enamel and dentine.
d_{3vc}mft/ D_{3vc}MFT	Caries recorded at the dentine level, with or without cavitation.
d_{3c}mft/ D_{3c}MFT	Caries recorded at cavitation level.
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.
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.
ppm F	Parts per million fluoride. A commonly used measure of the concentration of fluoride in a product.
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 (PTD)	The dose of ingested substance that should trigger immediate therapeutic intervention and hospitalisation because of the likelihood of serious toxic consequences. The PTD for fluoride is 5mg/kg.
Randomised controlled trial	An experiment in which two or more interventions, possibly

(RCT)	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.
95% confidence interval (CI)	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: 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 2: 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 3: Caries Risk Assessment Checklist

Dentist's name: _____ Date: _____

Child's name: _____ School: _____ First assessment Y / N

Risk Factors / Indicators **A "YES" in the shaded section indicates that the child is likely to be at high risk of developing caries**	Please circle the most appropriate answer	
• 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 twice a day or more	**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[73] and the dentist's own assessment.[74,75] 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.[76] 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.[75]

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.[77] 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.[52,53,78,79] The absence of protective factors could increase a child's risk for developing caries.

Appendix 4: 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 A4.1.

Table A4.1: 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 A4.2

Table A4.2: 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 A4.3.

Table A4.3: 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.[80] The figure of 33 children per day was reached based on the published application time of 6 minutes.[29] 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 A4.4 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. 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. The variation in travel distances has a relatively minor impact on costs.

Table A4.4: 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 5: 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[a]	Inflate to 2008 prices[b]	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. It is important to note that this cost estimate is based on an RCT to establish the efficacy of a supervised toothbrushing programme. Supervised toothbrushing programmes have subsequently been rolled out across Scotland as part of the ChildSmile programme, and by streamlining the delivery of supervised toothbrushing, costs have been reduced to approximately £16.60 (€23.20) per child per year. (Personal communication)

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 6: Comparison of the cost and 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 A6.1. 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 5. The cost of the varnish programme is estimated, as described in Appendix 4. 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[68] 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.[60] 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 A6.1: 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[62] Curnow et al., 2002[50]	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[60]
Davies et al., 2003[63]	Toothpaste distribution	£6.98 Stg (2002)	€11.91	4 years	PF=16% (primary dentition)	Unknown
Holland et al., 2001[67]	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[66]
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)[17]	Unknown

**FPMs: First permanent molars*