

# Effectiveness of topical fluorides – all modalities

## Systematic reviews

Marinho, V.C.C., Higgins, J.P.T., Logan, S., Sheiham, A. Topical fluoride (toothpastes, mouthrinses, gels or varnishes) for preventing dental caries in children and adolescents. The Cochrane Database of Systematic Reviews. 2003; (4): CD002782. DOI: 10.1002/14651858.CD002782.

Study type	Evidence level	No. of included studies	Patient characteristics	No. of patients in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1++	144 trials conducted between 1955 and 1996 included in the review.; 74 toothpaste trials, 36 mouthrinse trials, 25 gel trials and 9 varnish trials. 133 trials included in the meta analysis	Participants were aged 16 or less at the start of the study, irrespective of initial level of dental caries, background exposure to fluorides, dental treatment level, nationality, setting where intervention was received or time when it started. Studies where participants were selected on the basis of special oral or general health conditions were excluded	65,169 children	Topical fluoride therapy in the form of toothpastes, mouthrinses, gels or varnishes, using any fluoride agent, at any concentration, amount or duration of application, provided the frequency was at least once a year.	placebo or no treatment	At least one year	<p>Caries increment: change from baseline in the DMFS/de/mfs index.</p> <p>Dental caries was defined as being clinically and radiographically recorded at the dentine level</p> <p>Other effects e.g. pain/discomfort, fluorosis, stain, oral allergic reactions, adverse symptoms were also recorded.</p> <p>Unacceptability of treatment as measured by dropouts</p>	<p>DMFS PF (any TFT v placebo or no tx) 26% (95% CI 24% -29%, p&lt;0.0001)</p> <p>NNT=2 in a population with annual caries increment of 2.5 DMFS/year</p> <p>NNT=20 in a population with annual caries increment of 0.2 DMFS/yr</p> <p>defs PF (5 studies): 33% (95% CI 22%-44%)</p> <p>NNT = 2 in a population with annual caries increment of 1.9 defs/yr</p> <p>NNT = 4 in a population with annual caries increment of 0.8defs/yr</p> <p>The effect of topical fluoride varied according to :</p> <ul style="list-style-type: none"> <li>• Initial caries level: PF increased by 0.7% per unit increase in baseline caries (95% CI 0.2% to 1.2%, p&lt;0.004)</li> <li>• Type of TFT used: PF 14% higher (95% CI 2% to 29%, p&lt;0.025) in varnish trials compared to other modalities</li> <li>• Mode/setting of use: PF 10% lower (95% CI -17% to -3%) in trials of unsupervised home use compared to supervised self-applied or operator applied</li> <li>• Type of control group used: DMFS PF 14% higher (95% CI 5%to -23%, p&lt;0.002) in non-placebo controlled trials</li> </ul> <p>No clear relationship was detected between background exposure to other fluoride sources implying that use of topical fluoride may provide additional caries reduction in subjects from fluoridated areas.</p>

**Comments:** The review confirms the effect of topical fluorides at preventing caries in the permanent teeth of children and adolescents, but is unable to draw any conclusions about the relative effect of the different modalities. Direct head to head comparisons of the different modalities are required.

Marinho, V.C.C., Higgins, J.P.T., Sheiham, A., Logan, S. One topical fluoride (toothpastes, or mouthrinses or gels or varnishes) versus another for preventing dental caries in children and adolescents)

The Cochrane Database of systematic reviews. 2004; (1): CD002780. DOI: 10.1002/14651858.CD002780.pub2.

Study Type	Evidence level	No. of included studies	Patient characteristics	No. of patients inc in meta analysis	Intervention	Comparison	Outcome	Effect size
Systematic review	1++	17 (15 included in meta- analysis)	Age 14 or less at start of study. No special oral or health conditions.	6 trials n=2545	Toothpaste	Mouthrinse	DMFS PF	<b>DMFSPPF = 0.00</b> (CI -18% to 19%, p=0.97) No difference in effect and substantial heterogeneity
				3 trials n=1256	Toothpaste	Gel		<b>DMFSPPF= 0.00</b> (CI -21% to 21%, p=1.00) i.e. absolutely no differences in effect. Substantial heterogeneity
				9 trials n=3801	Toothpaste	Any TFT		<b>DMFSPPF= 1%</b> (CI -13% to 14% p=0.94) i.e. no significant difference detected. Significant and substantial heterogeneity
				1 trial n=183	Varnish	Toothpaste	dfsPF	<b>dfsPF= 5%</b> CI not available (inconclusive)
				4 trials n=952	Varnish	Mouth rinse	DMFSPPF	<b>DMFSPPF= 10%</b> (CI -12% to 32% p=0.4). Non significant result in favour of varnish. Result varied depending on type of meta-analysis performed. Fixed effects meta analysis produces a significant result (DMFSPPF 15% (CI 4% to 26%, p=0.007). Not robust to sensitivity analysis performed and heterogeneity was considerable.
				1 trial n=254	Varnish	gel		<b>DMFSPPF=14%</b> (CI -12% to 40% p=0.3) Non significant result in favour of varnish. Insufficient evidence to confirm or refute a differential effect in caries reduction
				1 trial n=257	Gel	Mouthrinse		<b>DMFSPPF= 14%</b> in favour of mouthrinse (CI -40% to 12% p=0.3). Insufficient evidence from this trial to confirm or refute a differential effect in caries reduction
							Adverse effects	no useful information in the trials about potential adverse effects such as fluorosis, tooth staining or oral allergic reactions

**Comment:** Toothpaste, mouthrinses and gels reduce decay in children and adolescents to a similar extent. There was no convincing evidence that fluoride varnishes offer a benefit over the other modalities. Toothpaste was the most acceptable modality in terms of no. of drop-outs. Although this review is likely to represent the totality of the available randomised evidence comparing the relevant TFTs directly, there are a relatively small number of trials in each main comparison/analysis. So a modest difference in treatment effect may have been missed for the most relevant comparisons. The lack of clear benefit may not indicate a priority for the performance of new studies. However, Because of the apparent benefits of varnish in terms of application time and low risk of ingestion, the author suggests high quality head to head comparison with other modalities

Marinho, V.C.C., Higgins J.P.T., Sheiham, A., Logan, S. Combinations of topical fluoride (toothpastes, mouthrinses, gels, varnishes) versus single topical fluoride for preventing dental caries in children and adolescents. Cochrane Database of Systematic Reviews 2004, Issue 1. Art. No.: CD002781. DOI: 10.1002/14651858.CD002781.pub2.

Study Type	Evidence level	No. of included studies	Patient characteristics	No. of patients inc in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1++	11	Participants were age 14 or less at the start of all trials. Most were around age 12.	Main meta-analysis 9 trials N= 4026	Toothpaste + any TFT	TP only	AT least one calendar/school year	DMFS PF	10% (95% 2 -17, p=0.01) (Heterogeneity in results not detected statistically)
								NNT with annual caries increment of 0.8 DMFS/yr	13 (CI 8-63)
								NNT with annual caries increment of 2.5 DMFS/yr	4 (CI 3-20)
				5 trials N=2738	TP+ MR	MR		DMFS PF	7% (95% CI 0 -13, p=0.06) Just non sig in favour of combined TP+MR
				2 trials N= 497	Gel + MR	TP		DMFS PF	23% (CI 4-43) p=0.02)
								Unacceptability	6 studies reported dropouts fully. Each of the 6 trials reported equivocal results for this outcome i.e. no demonstrated differential effect

**Comments:** Topical fluorides (mouthrinse, gel or varnish) used in addition to toothpaste achieve a modest reduction in caries compared to toothpaste alone. No conclusions about any adverse effects could be reached because data were scarcely reported in the trials. The lack of a significant difference between different modalities used in combination versus a single modality must be interpreted cautiously due to the small number of trials included in some of the analyses.

## Professionally applied topical fluorides: evidence tables

### Systematic reviews

Bader, J.D., Rozier, G., Lohr, K.N., and Frame, P.S. Physicians' Roles in Preventing Dental Caries in Preschool Children: A Summary of the Evidence for the U.S Preventive Services Task Force. Am J Prev Med 2004;26(4):326-329.									
Study type	Evidence level	No. of included studies	Patient characteristics	No. of patients in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic Review	1+	6 studies	3-6 year olds	<p>A summary of the evidence is based on five key clinical questions. Only the question relating to topical fluoride application is covered here.</p> <p><b>How effective is application of fluoride by the primary care clinician in terms of</b></p> <p>a. appropriateness of application decision?</p> <p>b. achieving parental agreement for the application?</p> <p>c. prevention of dental caries?</p>	<p>4 studies involve 2.2% Duraphat varnish application 2/yr</p> <p>2 studies involve 0.1% Fluor protector 2/yr</p>	Untreated controls	All 2 years except one study 0.75 year.	Caries increment dmfs, defs, dfs PF NNT	<p>Four studies including all 3 RCTs showed caries inhibiting effects.</p> <p>The strength of the evidence supporting the effectiveness of fluoride varnish in the prevention of dental caries in preschool-aged children is fair. No studies were available beginning at age 1 or 2 years (i.e., the time that children at high risk for dental caries need to begin treatment), but results of available clinical trials were consistent.</p>
<p><b>Comments:</b> These studies of fluoride varnish use in young children are supported by a larger body of evidence that provides good evidence of effectiveness in permanent teeth for topical application of both fluoride varnish and other fluoride compounds</p>									



Marinho, V.C.C., Higgins, J., Logan, S., Sheiham, A. Fluoride varnishes for preventing dental caries in children and adolescents. The Cochrane Database of Systematic Reviews 2002; (1) Art. No.: CD002279. DOI: 10.1002/14651858.CD002279.

Aim: To determine the effectiveness and safety of fluoride varnishes in the prevention of dental caries in children and to examine factors potentially modifying their effect

Study type	Evidence level	No. of included studies	Patient characteristics	No. of patients in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1++	9 5 from 1970s 3 from 1980s 1 from 1990s  1 study in a fluoridated area  1 study reported no exposure to fluoride toothpaste  (7 contributed to meta analysis)	age range: 3-15 yrs  no special general or oral health conditions	2709	NaF varnish (Duraphat or Lawefluor or Bifluorid 12 in all trials. Difluorsilane (Fluor Protector) in 1 trial  Concentration:  7000 ppm – 56,300 ppm  Application frequency:  2xyr – 4x yr	placebo or no treatment	At least one year	DMFS PF (7 trials) dfs PF (3 trials) NNT Permanent Increment 0.67 DMFS/yr 1.4 DMFS/yr  NNT deciduous Increment 0.82 dfs/yr  1.9 dfs/yr  Secondary outcomes  Unacceptability  Adverse effects	46% (95% CI 30-63, p<0.0001)  33% (95% CI 19-48)  3.2 (95% CI 2.4-5) 1.4 (95% CI 1-2)  3.7 (95% CI 2.5 – 6.4)  1.6 (95% CI 1.1- 2.8)  No significant association between DMFS PF and prespecified factors : baseline caries severity, exposure to F water, toothpaste or any reported F source  RR of dropping out from tx vs non tx group: 1.78 (CI 0.7-4.55, p=0.06)  No information found

**Comments:** This review suggests that the application of fluoride varnishes 2 to 4 times a year, either in the permanent or deciduous dentition is associated with a substantial reduction in caries increment. Small number of trials included in the analysis and substantial heterogeneity among trials – therefore interpret result with caution. No information on likelihood of side effects and inconclusive evidence on acceptability.

Marinho, V., Higgins, J., Logan, S., Sheiham, A. Fluoride gels for preventing dental caries in children and adolescents. Cochrane Database of Systematic Reviews 2003; Issue 3: Art. no.: CD002284. DOI: 10.1002/14651858. CD002284  
 Aim: To determine the effectiveness and safety of fluoride gels in the prevention of dental caries in children and adolescents and to examine factors potentially modifying their effect

Study Type	Evidence level	No. of included studies	Patient characteristics	No. of patients inc in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1++	25 (23 contributed to meta analysis)	All participants were under 15 years of age at start of studies (range 2-15) Five studies were conducted in areas with exposure to systemic fluoride (3 water, 2 salt). Baseline levels of caries in the participants ranged from 0.24 DMFS to 12.2 DMFS.	n= 7747	Fluoride gel, either professionally or self applied, with any fluoride agent (APF, SnF, AmF, NaF) and any concentration (range 2425 – 12,300).  14 trials involved professional application 4 times a year or less. 11 studies involved self-applied gel, applied 5 times a year or more.  APF used in at least 13 trials.  Application time, when reported, ranged from 2-10min (majority 3-5 min)	Placebo or no treatment	At least one year (majority were ~ 2yrs)	<p><i>Primary outcome:</i></p> <p>DMFS PF</p> <p>defs PF NNT annual caries increment 0.2 DMFS annual caries increment of 2.2 DMFS</p> <p><i>Secondary outcome:</i></p> <p>To examine the influence of baseline caries severity, background exposure to fluoride or fluoride concentration and frequency of use on effectiveness</p> <p>Signs of acute toxicity</p>	<p>28% (CI 19-37) all trials pooled</p> <p>21% (CI 14 – 28) placebo controls</p> <p>38% (CI 24 - 53) No treatment control</p> <p>39% (CI not reported) 1 study</p> <p>24 (CI 18 – 36) placebo controls</p> <p>2</p> <p>No association found between effectiveness and baseline caries severity or background exposure to fluoride. There was an association of frequency of application as well as of 'total intensity of application per year' (frequency x concentration) with the prevented fraction, but this result was dependent on the inclusion of a single study. No association was found when this study was removed from analysis.</p> <p>2 studies reported on adverse events. One had no events. The other showed no significant difference in risk of adverse effects between test and control. The review does not provide useful information on the likelihood of significant side effects.</p>

**Comments:** This review suggests that the application of fluoride gels, either by professionals or self-applied, is associated with a substantial reduction in caries increment. We found no evidence that this relative effect was dependent on baseline caries level or exposure to other fluoride sources, although this result should be interpreted with caution. A higher D(M)FS prevented fraction was shown with increased frequency, intensity of application and with the self-applied gel treatment (where a higher frequency of application is apparent), although these relationships were dependent on the inclusion of one study with particularly powerful effect. Unfortunately the review does not provide useful information on the likelihood of significant side effects with this treatment. We also found no information on other adverse effects such as fluorosis, tooth staining, or oral allergic reactions. This lack of evidence about adverse effects makes it more difficult for clinicians and policy makers to weigh the benefits of fluoride gels in preventing caries against possible side effects.

Strohmenger, L., and Brambilla E. The use of fluoride varnishes in the prevention of caries: a short review Oral Diseases. 2001;7(2)71-80

Aim: To review the current literature regarding the anti-caries efficacy of fluoride varnishes. To analyse a series of studies designed to detect the caries preventive efficacy of fluoride varnishes by means of meta-analysis.

Study Type	Evidence level	No. of included studies	Patient characteristics	No. of patients inc in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1+	3	Age 6-14 No special characteristics	934	Fluoride varnish applied twice a year	0.2% NaF MR	At least 1 year  (included studies had follow-up of 2, 3 and 4 years)	Standardised treatment effect  (difference in DMFS between V and MR group/ sum of DMFS  DMFS Weighted mean	-1.522 (CI -3.168-0.12)  Pooled estimate of effect favoured varnish  No statistically significant difference  4.09 in varnish group  5.07 in rinse group

**Comments:** The meta analysis showed no significant difference between varnish and 0.2% NaF rinses. The authors conclude that fluoride varnish is an efficacious caries preventive agent. Because of the rigorous inclusion criteria for the meta analysis only a small number of studies were included and none was varnish v placebo and so is a comparison of one modality v another. It supports the findings of the Marinho varnish review.



van Rijkom, H.M., Truin, G.J., van't Hof, M.A. A meta-analysis of clinical studies on the caries-inhibiting effect of fluoride gel treatment. Caries Res 1998; 32:83-92

Aim: To assess the overall caries-inhibiting effect of clinical fluoride gel treatment studies based on explicit selection criteria.

Study type	Evidence level	No. of included studies	Patient characteristics	No. of patients in meta analysis	Intervention	Comparison	Length of follow-up	Outcome measure	Effect size
Systematic review	1+	19 in meta analysis	6-15 years old ( at start of study)	8263	Application of fluoride gel to the permanent teeth (self-applied or professionally-applied)	No treatment or placebo treatment	Not stated	Prevented fraction  NNT	22% (95% CI 18-25%)  NNT 18 in a population with a caries increment of 0.25 DMFS per year NNT 3 in a population with a caries incidence of 1.5 DMFS per year  Baseline caries prevalence, general fluoride regimen, application method, and application frequency did not significantly affect the caries-inhibiting effect of fluoride gel treatment.

**Comments:** The authors question the additional effect of fluoride gel treatment in relation to cost in the current low and even moderate caries incidence child populations. The frequency of fluoride gel application varied from once a year to 360 times a year. The studies included range in publication date from 1967 to 1992 but the majority were published in the 1970s and 80s. Limiting the search to Medline means that relevant studies may have been missed.

## Randomised controlled trials

Hardman, M.C., Davies, G.M., Duxbury, J.T., Davies, R.M. A cluster randomised controlled trial to evaluate the effectiveness of fluoride varnish as a public health measure to reduce caries in children. Caries Res 2007; 41: 371-376 Aim: To assess the effectiveness of twice yearly application of Duraphat varnish as a public health measure to reduce dental caries in children living in relatively deprived areas																																																
Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome measure	Effect size																																								
Cluster randomised controlled trial	1-	Eligible at baseline: n=2,091 Consented: N=457 Test N=457 control  Examined at base and final: N= 334 test N=330 control  Loss to follow up: 67% test 69% control	Children aged 6-7 (Year 2) and 7-8 (Year 3) from 24 schools in relatively deprived areas of Manchester. Children were recruited from 24 schools in Manchester.  51% male  88% Caucasian  Baseline oral health status: Mean d <sub>3</sub> ft 2.53 test 2.26 control  % d <sub>3</sub> ft>0 67.7 test 60.9 control  % D <sub>3</sub> MFT>0 11.4% test 8.8% control	26 months	Application of fluoride varnish- Duraphat 22,600ppmF at school at 6-monthly intervals.	The comparison groups received no intervention. For test children in Year 2, the comparison group was Year 3 in the same school. For test children in Year 3, the comparison group was Year 2 in the same school.	Caries increment in the primary and permanent dentition, measured at enamel level: small lesions (D <sub>1</sub> ) and large lesions (D <sub>2</sub> ) as well as dentine level (D <sub>3</sub> )	The only statistically significant difference found was in small enamel lesion increment in the primary dentition in the test group compared to control. No significant differences were found in the primary teeth at the 2 other levels of diagnosis, or when broken down by school year and no significant differences were found in the permanent teeth at any of the three diagnostic levels.  <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Test</th> <th>Control</th> <th>p-value</th> <th>PF</th> </tr> </thead> <tbody> <tr> <td>% with d<sub>3</sub>fs increment &gt;0</td> <td>53%</td> <td>50%</td> <td>p=0.49</td> <td></td> </tr> <tr> <td>% with d<sub>1</sub>FS increment &gt; 0</td> <td>45%</td> <td>48%</td> <td>p=0.38</td> <td></td> </tr> <tr> <td>Mean d<sub>3</sub>fs increment</td> <td>1.52</td> <td>1.49</td> <td>p=0.94</td> <td>2%</td> </tr> <tr> <td>Mean d<sub>1</sub>fs increment</td> <td>0.71</td> <td>1.12</td> <td>p=0.03*</td> <td>36.6%</td> </tr> <tr> <td>% with D<sub>3</sub>FS increment &gt; 0</td> <td>16%</td> <td>19%</td> <td>p=0.22</td> <td></td> </tr> <tr> <td>% with D<sub>1</sub>FS increment&gt;0</td> <td>45%</td> <td>46%</td> <td>p=0.36</td> <td></td> </tr> <tr> <td>Mean DFS increment</td> <td colspan="4">Not reported at any diagnostic level</td> </tr> </tbody> </table>		Test	Control	p-value	PF	% with d <sub>3</sub> fs increment >0	53%	50%	p=0.49		% with d <sub>1</sub> FS increment > 0	45%	48%	p=0.38		Mean d <sub>3</sub> fs increment	1.52	1.49	p=0.94	2%	Mean d <sub>1</sub> fs increment	0.71	1.12	p=0.03*	36.6%	% with D <sub>3</sub> FS increment > 0	16%	19%	p=0.22		% with D <sub>1</sub> FS increment>0	45%	46%	p=0.36		Mean DFS increment	Not reported at any diagnostic level			
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<p><b>Comments:</b> This study failed to demonstrate that the twice yearly application of fluoride varnish provided at school reduced dental caries in children living in this community. The lack of effect is disappointing and seems to have been influenced selection bias, whereby those least likely to benefit were the ones who consented. The authors also made the point that the application of varnish was not done under optimum conditions and without control of eating and drinking post application and this may have resulted in suboptimal effects of the varnish. More than 50% of those randomized to test and control groups did not consent to participate in the study.</p>																																																

Jiang, H., Tai, B.J., Du, M.Q., Peng. Effect of professional application of APF foam on caries reduction in permanent first molars in 6-7-year-old children: 24-month clinical trial. Journal of Dentistry (2005) 33, 469-473  
 Aim: To evaluate the effect of 6-monthly professional application of APF foam on caries reduction in permanent first molars in 6-7-year-old children over 24 months and to compare the caries-preventive effect between APF foam and APF gel.

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome measure	Effect size
RCT [Double blind]	1+	661  APF foam group: 205  APF gel group: 210  Control group: 246  Drop out rate: 7%	Aged 6-7 years at baseline	2 years	Bi-annual 4 minute APF foam application (in sponge lined tray)  Bi-annual 4 minute APF gel application (in sponge lined tray)	No treatment	DMFS increment (analysis only on those present for baseline exam, 4xtreatments and follow-up exam)	Smooth surface    Mean DMFS increment Foam                    0.16 Gel                      0.17 Control                0.27 p<0.05  Pit and fissure surface Foam                    0.22 Gel                      0.20 Control                0.23 NS  All surfaces Foam                    0.39 Gel                      0.38 Control                0.50 NS

**Comments:** Six-monthly professional application of APF foam is as effective as APF gel in reducing the incidence of dental caries in smooth surfaces of permanent first molars in 6-7 year old children. Intention to treat analysis should have been performed in addition to per protocol analysis. The authors do not report or take into account any differences between the study groups in eruption of first permanent molars at baseline.

Jiang H, Bian, Z, Tai, B.J., Du, M.Q., Peng, B. The effect of a biannual professional application of APF foam on dental caries increment in primary teeth: 24-month clinical trial. J Dent Res 84(3):265-268, 2005 Aim: To evaluate the effect of bi-annual professional application of acidulated phosphate fluoride (APF) foam on caries increment in the primary dentition over a two year period in the People's Republic of China.								
Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome measure	Effect size
RCT [Double-blind, placebo controlled]	1++	392  APF foam group: 209  Placebo control group: 183  Drop out rate: 20% test and 17% placebo	Aged 3-4 years at baseline	2 years	Bi-annual 4 minute (0.6-0.8g)APF foam application (in sponge lined tray)	Bi-annual 4 minute (0.6-0.8g) placebo foam application (in sponge lined tray)	dmfs increment (analysis only on those present for baseline exam, 4xtreatments and follow-up exam)	Mean caries increment: 3.8 dmfs in APF foam group 5.0 dmfs in the placebo control group 24.2% reduction in caries (p value = 0.03)  APF group had 37.5% caries reduction on approximal surfaces compared with placebo control group. (p value = 0.03)  Increment lower on buccolingual surfaces in APF foam group but not statistically significant (p value = 0.054)  No significant difference in the mean caries increment on occlusal surfaces (p=0.75)  No clinical side effects such as nausea and vomiting were reported.
<b>Comments:</b> A bi-annual professional application of APF foam was effective in reducing the increment of dental caries in the primary teeth. The analysis should have included intention to treat in addition to per protocol.								

Moberg Skold, U., Petersson, L.G., Lith, A., Birkhed, D. Effect of school-based fluoride varnish programmes on approximal caries in adolescents from different caries risk areas. Caries Res 2005. 39: 273-279

Aim: To determine which application frequency offers the best effect on approximal caries incidence and progression and if the effect differs between low, medium and high caries risk areas

Study Type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Results																																									
RCT	1+	Baseline N= 854 At end N=758 (89%)	Swedish adolescents aged 13 at start of intervention recruited from 9 secondary school in 3 geographic areas with differing socio-economic status and caries levels.  Low risk mean DFT = 0.6.  High risk Mean DFT = 2.65  Medium risk Mean DFT = 0.85  All had access to dental services which includes annual application of fluoride varnish.	3 years	NaF varnish (Duraphat) applied at 3 different frequencies: Group 1 – 2/yr 6mthly Group 2 – 3/yr, all within the one week Group 3 – 8/yr (monthly application during term)  Total applications during the 3 year study : Group 1: 6 applications Group 2: 9 applications Group 3: 24 applications	Group 4: No varnish at school	mean caries incidence on approximal surfaces  (no. sound surfaces at baseline developing caries)  Caries progression (no. of surfaces with lesions in enamel progressing to dentine lesions)  Prevented fraction  Adverse effects	<table border="1"> <thead> <tr> <th>Approximal Caries Incidence</th> <th>Control</th> <th>Group 1 (2/yr)</th> <th>Group 2 (3/yr all same wk)</th> <th>Group 3 (8/yr)</th> </tr> </thead> <tbody> <tr> <td>Low</td> <td>1.36</td> <td>1.09</td> <td>0.43</td> <td>0.68</td> </tr> <tr> <td>Med</td> <td>1.59</td> <td>0.54</td> <td>1.09</td> <td>0.27</td> </tr> <tr> <td>High</td> <td>3.05</td> <td>0.95</td> <td>1.40</td> <td>0.5</td> </tr> <tr> <td>Combined</td> <td>1.85</td> <td>0.79</td> <td>0.98</td> <td>0.45</td> </tr> </tbody> </table> <p>For medium and high risk groups, incidence of approximal caries in the varnish groups was significantly less than the control group. <math>p &lt; 0.001</math>. Incidence was also significantly less in group 3 than group 2.</p> <p>Caries progression was significantly higher in the control group in high risk areas compared to the 3 F varnish groups in high risk areas (<math>p &lt; 0.003</math>). (0.9 in control vs 0.18, 0.30 and 0.37 in Groups 1-3 respectively in the high risk area). There were no significant differences between the groups in low and medium risk areas.</p> <table border="1"> <thead> <tr> <th>Prevented fraction</th> <th>Group 1</th> <th>Group 2</th> <th>Group 3</th> </tr> </thead> <tbody> <tr> <td>Low</td> <td>20%</td> <td>68%</td> <td>50%</td> </tr> <tr> <td>Med</td> <td>66%</td> <td>31%</td> <td>83%</td> </tr> <tr> <td>High</td> <td>69%</td> <td>54%</td> <td>82%</td> </tr> </tbody> </table> <p>None found</p>	Approximal Caries Incidence	Control	Group 1 (2/yr)	Group 2 (3/yr all same wk)	Group 3 (8/yr)	Low	1.36	1.09	0.43	0.68	Med	1.59	0.54	1.09	0.27	High	3.05	0.95	1.40	0.5	Combined	1.85	0.79	0.98	0.45	Prevented fraction	Group 1	Group 2	Group 3	Low	20%	68%	50%	Med	66%	31%	83%	High	69%	54%	82%
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**Comments:** F varnish treatment every 6 months, performed at school, is excellent to prevent caries on approximal surfaces in 13-16 year olds in medium and especially high caries risk areas. The financial aspects of this study will be presented in a separate paper.

Truin, G.J., van't Hof, M.A. Caries Prevention by Professional Fluoride Gel Application on Enamel and Dentinal Lesions in Low-Caries Children. Caries Res 2005; 39:236-240.

Aim: Secondary analysis of data collected in the RCT 'To investigate the caries-reducing effect of semi-annual professional fluoride gel application in a low-caries child population initially aged 4.5-6.5 years during a 4-year follow-up period' [Van Rijkom et al 2004], to study caries-reducing effect of semi-annual professional fluoride gel application in low-caries children including incipient lesions.

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size				
								AR	PF	p value	PF	
RCT [Double Blind]	I	667	Low-caries children D <sub>3</sub> MFS =0, d <sub>3</sub> mfs=0 at baseline  aged 4.5-6.5 years  Enrolled in the dental clinics for children of four communities in the Netherlands. Per protocol subjects only.	4 years	Semi- annual check-up including OHI, supervised brushing with fluoridated toothpaste and application of 1% sodium fluoride gel (4500ppm) for 4 mins.	Semi- annual check-up including OHI, supervised brushing with fluoridated toothpaste and application of a placebo gel for 4 mins.	D <sub>2</sub> FS, d <sub>3</sub> mfs, D <sub>2,3</sub> FS and d <sub>2,3</sub> mfs assessed clinically and radiographically	<b>D<sub>2</sub>S</b>	0.14	20	0.14	
								<b>D<sub>3</sub>S</b>	0.05	71	<0.01	
								<b>FS</b>	0.04	16	0.44	
								<b>D<sub>2,3</sub>FS</b>	0.22	22	0.04	
								<b>D<sub>3</sub>FS</b>	0.08	26	0.11	
								<b>d<sub>3</sub>mfs</b>	0.36	20	0.06	
								<b>d<sub>2,3</sub>mfs</b>	0.54	23	0.02	

**Comments:** Based on the initial analysis, it was concluded that the treatment effect of fluoride gel application on dentinal caries lesions in low-caries children was statistically significant but considered not clinically relevant (based on NNT) [Van Rijkom et al. 2004]. Inclusion of non-cavitated lesions in the treatment effect statistics did not change this conclusion. The results suggest that enamel lesion progression was lower in the fluoride group than in the placebo group. The analysis of subjects is per protocol, not intention to treat. Intervention at semi-annual dental check-ups included a sealant application strategy where FS were placed over enamel caries lesions. The significantly higher number of sealants on occlusal surfaces and in buccal and palatal pits and fissures in the placebo group has likely distorted the difference between D<sub>2</sub>S and D<sub>3</sub>FS increment reported here. NNT was not calculated for this study.

Truin, G.J., van't Hof, M.A. Professionally applied fluoride gel application in low-caries 10.5-year-olds. J Dent Res 2005; 84(5): 418-421.

Aim: To investigate the caries-reducing effect of semi-annual professional sodium fluoride gel application in a low-caries child population over a period of 4 years follow-up.

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size
RCT [Double Blind]	1 <sup>+</sup>	594	Low-caries children (D <sub>3</sub> MFS =0, at baseline) aged 9.5-11.5 years who were regular attenders at three paediatric clinics in three cities in the Netherlands.	4 years	Semi- annual check-up including OHI, supervised brushing with fluoridated toothpaste and application of 1% sodium fluoride gel (4500ppm) for 4 mins.	Semi- annual check-up including OHI, supervised brushing with fluoridated toothpaste and application of a placebo gel for 4 mins.	D <sub>3</sub> MFS assessed clinically and radiographically.	AR (per protocol) 0.2 D <sub>3</sub> MFS, p=0.39 PF for D <sub>3</sub> MFS 18% in permanent dentition and erupting second molars.
<p><b>Comments:</b> Professionally applied fluoride gel (4500ppm fluoride ion) showed no statistically significant effect on D<sub>3</sub>MFS increment in low-caries –active subjects initially aged 9.5 to 11.5 yrs over a four-year period. Quantitatively, the mean treatment effect was considered not clinically relevant.</p>								

Truin, G.J., van't Hof, M.A. The effect of fluoride gel on incipient carious lesions in a low-caries child population. Community Dent Oral Epidemiol 2007; 35: 250-254.

Aim: To study the cariostatic efficacy of semi-annual professional fluoride gel application on incipient carious lesions in low-caries children initially aged 9.5-11.5 years (secondary analysis of data from Truin, G.J., van't Hof, M.A. J Dent Res 84(5): 418-421, 2005).

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size
RCT [Double Blind]	1 <sup>+</sup>	594  Per protocol group included 255 children in the placebo group and 262 children in the fluoride group.	Low-caries children (D <sub>3</sub> MFS =0, at baseline) aged 9.5-11.5 years who were regular attenders at three paediatric clinics in three cities in the Netherlands.	4 years	Semi- annual check-up including OHI, supervised brushing with fluoridated toothpaste and application of 1% sodium fluoride gel (4500ppm) for 4 mins.	Semi- annual check-up including OHI, supervised brushing with fluoridated toothpaste and application of a placebo gel for 4 mins.	D <sub>2</sub> S, D <sub>3</sub> MFS, D <sub>2,3</sub> FS, D <sub>3</sub> FS assessed clinically and radiographically.  Second molars: D <sub>2</sub> S, D <sub>2,3</sub> FS, D <sub>3</sub> FS	(per protocol) PF      p value  D <sub>2</sub> S                    24                    0.05 D <sub>2,3</sub> FS                23                    0.05 D <sub>3</sub> FS                    18                    0.23  Results for second molars not statistically significant.

**Comments:** Professionally applied fluoride gel (4500ppm fluoride ion) showed no statistically significant caries-inhibiting effect on both enamel and dentine lesions in the permanent dentition of low-caries children.



van Rijkom, H.M., Truin, G.J., van't Hof, M.A. Caries-inhibiting effect of professional fluoride gel application in low-caries children initially aged 4.5-6.5 years.

Aim: To investigate the caries-reducing effect of semi-annual professional fluoride gel application in a low-caries child population initially aged 4.5-6.5 years during a 4-year follow-up period.

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size
RCT [Double Blind]	1 <sup>++</sup>	773	Low-caries children (D <sub>3</sub> MFS =0, d <sub>3</sub> mfs=0 at baseline) aged 4.5-6.5 years enrolled in the dental clinics for children of four communities in the Netherlands.	4 years	Semi- annual check-up including OHI, supervised brushing with fluoridated toothpaste and application of 1% sodium fluoride gel (4500ppm) for 4 mins	Semi- annual check-up including OHI, supervised brushing with fluoridated toothpaste and application of a placebo gel for 4 mins.	D <sub>3</sub> MFS and d <sub>3</sub> mfs assessed clinically and radiographically	<p>Attributive risk 0.08 D<sub>3</sub>MFS 95% CI -0.04 to 0.20, p=0.04.</p> <p>AR 0.36 d<sub>3</sub>mfs p=0.46, non-significant.</p> <p>Mean NNT to prevent 1 D<sub>3</sub>MFS after 1 year is 50(per protocol)</p> <p>Mean NNT to prevent 1 d<sub>3</sub>mfs after 1 year 11(per protocol)</p> <p>PF for D<sub>3</sub>MFS 26% (95% CI 0 to 52) PF for d<sub>3</sub>mfs 20% (95% CI 0 to 40)</p>

**Comments:** In the low-caries subjects generally using fluoride toothpaste, a statistically significant treatment effect was found on D<sub>3</sub>MFS and no significant effect on d<sub>3</sub>mfs. Based on the AR and NNT, the treatment effect for D<sub>3</sub>MFS as well as d<sub>3</sub>mfs was considered not clinically relevant.

Weintraub, J.A., Ramos-Gomez, F., Jue, B., Shain, S. et al. Fluoride varnish efficacy in preventing Early Childhood Caries J Dent Res, 85 (2) 172-176

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size																																								
RCT	1+	Baseline 376 12 months 261 24 months 202  Drop-outs: 12 months 30% 12-24 months 16%	Caries free at baseline. Mean age 1.8 yrs Resident in fluoridated area of San Francisco, recruited from public health centres serving primarily low income families 53% were girls, 47% Hispanic, 46% Asian and 7% other race/ethnicity. Children with medical conditions or medications that could affect their oral health were excluded.	2 years	Parental counseling + NaF varnish (Duraphat) twice a year Parental counseling + F varnish once a year	Parental counseling only	Caries incidence measured at the d <sub>2+</sub> (cavitated) and d <sub>1+</sub> (precavitated level). The presence of fillings was also recorded.  Prevented fraction	<table border="1"> <thead> <tr> <th></th> <th>No F</th> <th>F x 2 (intended)</th> <th colspan="2">F x 4 (intended)</th> </tr> </thead> <tbody> <tr> <td>Baseline (n)</td> <td>126</td> <td>124</td> <td colspan="2">126</td> </tr> <tr> <td>No. with no caries at 2 years</td> <td>48 (38.1%)</td> <td>59 (47.6%)</td> <td colspan="2">67 (53.2%)</td> </tr> <tr> <td colspan="5" style="text-align: center;">No. actual active treatments</td> </tr> <tr> <td></td> <td>0 (n=118)</td> <td>1 (n=79)</td> <td>2 (n=57)</td> <td>3-4 (n=26)</td> </tr> <tr> <td>Mean d<sub>2+</sub>fs*</td> <td>1.6</td> <td>0.8</td> <td>0.7</td> <td>0.1</td> </tr> <tr> <td>Mean d<sub>1+</sub>fs^</td> <td>2.8</td> <td>1.2</td> <td>1.2</td> <td>0.6</td> </tr> <tr> <td>PF</td> <td></td> <td>53%</td> <td>58%</td> <td>93%</td> </tr> </tbody> </table> <p>*excludes precavitated lesions ^ includes precavitated lesions</p> <p>The odds ratio by actual number of treatments for caries incidence in Control v 3-4 applications = 18.3 (95% CI 2.4-138.5) Control v 2 applications = 3.4 (95% CI 1.6-7.5) Control v 1 application = 2.5 (95% CI 1.3 -4.7)</p>		No F	F x 2 (intended)	F x 4 (intended)		Baseline (n)	126	124	126		No. with no caries at 2 years	48 (38.1%)	59 (47.6%)	67 (53.2%)		No. actual active treatments						0 (n=118)	1 (n=79)	2 (n=57)	3-4 (n=26)	Mean d <sub>2+</sub> fs*	1.6	0.8	0.7	0.1	Mean d <sub>1+</sub> fs^	2.8	1.2	1.2	0.6	PF		53%	58%	93%
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**Comments:** Fluoride varnish added to caregiver counseling is efficacious in reducing early childhood caries incidence. This study is complicated by the fact that placebo varnish was inadvertently used for part of the intervention trial. Results are therefore presented for the actual number of active applications and the intended number of applications. Drop-outs 46%.

## Slow-release fluoride devices: evidence table

### Systematic review

Bonner BC, Clarkson JE, Dobbyn L and Khanna S. Slow-release devices for the control of dental decay. Cochrane Database of Systematic Reviews 2006, issue 4. Art. No. CD005101 DOI: 10.1002/14651858.CD005101.pub2. Aim: To evaluate the effectiveness of different types of slow-release fluoride devices on preventing, arresting or reversing the progression of carious lesions on all surface types of deciduous and permanent teeth, compared to no treatment, placebo or alternative means of fluoride delivery.									
Study Type	Evidence level	No. of included studies	Patient characteristics	No. of patients inc in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1++	One study	174 high caries risk, low socio-economic children residing in a defined area of Leeds (post code LS11) and attending one of 7 schools in the area.  mean age at start of study = 8.8 years  having a dmft or DMFT >1  mutans streptococci count of > 1x10 <sup>6</sup> cfu/ml in saliva.	No meta analysis was performed as only one study included	Glass bead containing fluoride bonded onto the buccal surface of upper right first permanent molar.	Placebo glass bead, identical in appearance to the test bead but containing no fluoride.	2 years	Total loss to follow-up  Retention rate of beads  Mean Difference in DMFT increment  Mean Difference in DMFS increment	64%  63/132 = 47.7%  -0.72 (95% CI -1.23 to -0.21).  -1.52 (95% CI -2.68 to -0.36).  Analysis was carried out only on the 63 children with retained beads (31 test, 32 control).
<b>Comments:</b> The authors concluded that the one included trial had a high risk of bias, due to analysis, which included only those in whom the device was retained (less than 50% of participants at the end of the study). We conclude 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.									

# Community-based use of fluoride toothpaste: evidence tables

## Systematic reviews

Ammari, A. B., Bloch-Zupan, A., Ashley, P.F. Systematic review of studies comparing the anti-caries efficacy of children's toothpaste containing 600ppm of fluoride or less with high fluoride toothpastes of 1,000ppm or above. Caries Res 2003; 37: 85-92

Study Type	Evidence level	No. of included studies	Patient characteristics	No. of patients inc in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1+	7 trials were included in the review, of which 4 (one of which had two arms) were included in the meta analysis	Children age range 6-13 Only one study involved preschool children, but it could not be included in the meta analysis as it did not report the baseline level of caries or the SE or SD.	2601	Toothpaste containing 600ppmF or less	Toothpaste containing 1000ppm or more	24 or 36 months	Mean difference in caries increment between test and control group measured as dmft/DMFT or dmfs/DMFS or DFS/DFT.	<p><b>250ppm v 1000ppm.</b> (4 trials) Weighted mean DFS increment was <b>0.6</b> (95% CI 0.22 – 0.99, p=0.002) greater in the 250ppm group than in the 1000ppm group (MPF as the control paste).</p> <p>Weighted mean DFS increment was <b>0.7</b> (95% CI 0.3 – 1.09, p=0.0005) greater in the 250ppm group than in the 1000ppm group (NaF as the control paste).</p> <p><b>500-550ppm v 1000-1055ppm</b> (2 trials) One trial found results in favour of the 1000ppm group, but did not test the result for statistical significance. The other study concluded that both dentifrices had the same anti-caries efficacy but mean caries increments were greater in the 550ppm group and there were significantly more caries free children in the 1050 group.</p> <p><b>150ppm with 1055ppm</b> (1 trial) Mean caries increment at end was not reported</p>

**Comments:** Meta analysis of the available data indicates that 250ppm F toothpastes are not as effective at preventing dental caries in the permanent dentition as 1,000 ppm F pastes. Data comparing 500-1000ppm F pastes are very limited. More studies are required. The only evidence available on the effectiveness of low fluoride toothpastes relates to their use in permanent teeth in children who are old enough not to be at risk of fluorosis if toothpaste is swallowed. Only one of the 7 studies identified by the reviewers involved preschool children and this study was not included in the meta analysis as it was missing data.

Marinho VCC, Higgins JPT, Logan S, Sheiham A. Fluoride toothpastes for preventing dental caries in children and adolescents. The Cochrane Database of Systematic Reviews 2003, Issue 1. Art. No.: CD002278. DOI: 1002/14651858. CD002278.

Study type	Evidence level	No. of included studies	Patient characteristics	No. of patients in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1++	74 70 contributed to meta analysis  11 studies were conducted in fluoridated communities. 56 trials unsupervised (home use):18 supervised (school or institution). Fluoride concentration ranged from 250 to 2500ppm, but in the majority of studies was 1000/1100ppm	Children or adolescents aged 16 or less at the start of the study (range 5-16). No special general or oral health conditions. At least 49 trials included children who were aged 12 at the start of the trial, 4 trials included children younger than 6 and 18 trials included children who were 5 or 6	42,300	Toothpaste only, containing NaF, SMFP, SNF <sub>2</sub> , APF, amine fluoride, with any compatible abrasive system at any concentration (ppm F), frequency of use, amount or duration of application and with any technique of toothbrushing or post brushing procedure.	Placebo or no treatment	At least one year/school year (most lasted 2 or 3 years)	DMFS PF NNT          dmfs PF (1 study)  Adverse effects	24% (95% CI 21-28, p<0.0001). 1.6 with caries increment of 2.6 DMFS/year NNT = 3.7 with caries increment of 1.1 DMFS/year  Effectiveness was greater with: <ul style="list-style-type: none"> <li>• <b>Higher baseline caries rates</b> (0.7% increase in the PF per unit increase in baseline caries, (95% CI 0.3-1.17% p=0.002)</li> <li>• <b>Higher fluoride concentration</b> Just non – significant 7.7% increase in PF per 1000ppm (95% CI -0.03 to 15%, p=0.051)</li> <li>• <b>Greater frequency of application</b> (14% increase in PF moving from once to twice a day frequency of brushing with fluoride toothpaste.)</li> <li>• <b>Supervision of toothbrushing</b> (10% reduction in PF with unsupervised use (95% CI -17 to -4%, p=0.001)</li> </ul> The effect of fluoride toothpaste was not influenced by exposure to water fluoridation.  37% (CI not available)  Tooth staining reported in early trials using SnF  Lack of data on fluorosis
<p><b>Comments:</b> Supported by more than half a century of research, the benefits of fluoride toothpastes are firmly established. Taken together, the trials are of relatively high quality and provide clear evidence that fluoride toothpastes are efficacious in preventing caries. Unfortunately the review provides little information on the effects of fluoride toothpaste other outcomes such as caries incidence in the deciduous dentition, and provides no useful information on the likelihood of adverse effects such as enamel fluorosis.</p>									



## Randomised controlled trials

<p>Curnow, M.M.T, Pine, C.M., Burnside, G., Nicholson, J.A., et al. A randomised controlled trial of the efficacy of supervised toothbrushing in high caries risk children. Caries Res 2002; 36:294-300.          Aim: To determine the reduction in 2 year caries increment that can be achieved by daily supervised toothbrushing on school days with 1000ppm, combined with recommended daily home use, compared to a control receiving no intervention.</p>																																											
Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size																																			
RCT [single blind]	1+	Baseline: 534 children  279 test 255 control  At end: 461  239 test 222 control  Losses to follow-up:  14.3% test 12.9% control  6% test and 14% control did not consent/missed baseline exam/excluded after randomization before the start of the trial.	Mean age = 5.3 at baseline 65% of sample came from 2 most deprived areas (DEPCAT 5 & 6)  Baseline d3mfs = 8.63 ± 11.82 (test) and 8.75 (control) (significance of difference not reported)  Children from most deprived areas of Tayside, Scotland.	2 years	School-based toothbrushing, once a day after lunch, using 1000ppm sodium monofluorophosphate toothpaste.  Local mothers recruited to project.  Toothpaste and toothbrush provided for home use also.	Parallel class in the same school did not receive the intervention	Difference in caries increment in primary teeth (cde only) and first permanent molars between test and control groups. Caries was recorded at D1 and D3 level, with and without FOTI. Intra examiner K = 0.88 – 0.96	<p><b>Primary teeth</b>            Mean d<sub>3</sub>fs increment was 4.86 (SD 5.44) for all children. Difference between test and control was not significant at d<sub>1</sub> or d<sub>3</sub> level.</p> <p><b>First permanent molars</b>            At the end of the study, significantly less caries had developed in FPMs in the intervention group at the D3 level (and at the D1 level on clinical data excluding FOTI) when the data were stratified by dental immaturity. Children who erupted their FPMs earlier than their peers were more likely to experience decay in these teeth by the end of the study.</p> <p><b>Mean 2 year caries increment</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <thead> <tr> <th></th> <th>Test</th> <th>Control</th> <th>Difference</th> <th>P value*</th> <th>P value^</th> <th>NNT</th> </tr> </thead> <tbody> <tr> <td>Mean D<sub>1</sub>FS</td> <td>0.669</td> <td>1.104</td> <td>0.435</td> <td>0.01</td> <td>0.04</td> <td>2.3</td> </tr> <tr> <td>Mean D<sub>3</sub>FS</td> <td>0.192</td> <td>0.455</td> <td>0.263</td> <td>0.01</td> <td>0.02</td> <td>3.8</td> </tr> <tr> <td>D<sub>1</sub>FS inc FOTI</td> <td>0.808</td> <td>1.194</td> <td>0.386</td> <td>0.02</td> <td>0.12 NS</td> <td>2.6</td> </tr> <tr> <td>D<sub>3</sub>FS inc FOTI</td> <td>0.205</td> <td>0.477</td> <td>0.272</td> <td>0.01</td> <td>0.015</td> <td>3.7</td> </tr> </tbody> </table> <p>* without stratification by dental maturity i.e. number of FPMs erupted at baseline            ^ after stratification by dental maturity            Absolute difference in caries at D1FS level = 0.435            PF at D<sub>1</sub>FS inc FOTI = 32% (95% CI 4-60%)            PF at D<sub>3</sub>FS inc FOTI = 56% (95% CI 13-101%)</p>		Test	Control	Difference	P value*	P value^	NNT	Mean D <sub>1</sub> FS	0.669	1.104	0.435	0.01	0.04	2.3	Mean D <sub>3</sub> FS	0.192	0.455	0.263	0.01	0.02	3.8	D <sub>1</sub> FS inc FOTI	0.808	1.194	0.386	0.02	0.12 NS	2.6	D <sub>3</sub> FS inc FOTI	0.205	0.477	0.272	0.01	0.015	3.7
	Test	Control	Difference	P value*	P value^	NNT																																					
Mean D <sub>1</sub> FS	0.669	1.104	0.435	0.01	0.04	2.3																																					
Mean D <sub>3</sub> FS	0.192	0.455	0.263	0.01	0.02	3.8																																					
D <sub>1</sub> FS inc FOTI	0.808	1.194	0.386	0.02	0.12 NS	2.6																																					
D <sub>3</sub> FS inc FOTI	0.205	0.477	0.272	0.01	0.015	3.7																																					
<p><b>Comments:</b> School-based supervised toothbrushing, with support for home use, commencing at age 5, is effective at reducing caries in first permanent molars, in children at high risk of caries. The study is well conducted and analysed. The absolute reduction in caries is modest (0.435 DFS over 2 years at D1FS level) and the confidence intervals around the estimate of the prevented fraction are very wide, indicating a high level of imprecision around the estimate. It is unfortunate that no information is provided on why 1000ppm toothpaste was chosen rather than toothpaste with a higher fluoride concentration, given that this was such a high risk population. There is also no information on the cost of the study, or on the acceptability of the programme to school teachers.</p>																																											

Davies, G.M., Worthington, H.V., Ellwood, R.P., Bentley, E.M., Blinkhorn, A.S., Taylor, G.O., Davies, R.M. A randomised controlled trial of the effectiveness of providing free fluoride toothpaste from the age of 12 months on reducing caries in 5-6 year old children. Community Dental Health (2002) 19, 131-136

Aim: To assess the impact of regularly supplying free fluoride toothpaste to children initially aged 12 months and living in deprived areas of the north west of England on the level of caries in the deciduous dentition at 5-6 years of age.

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size										
								Completers	Mean dmft	Difference Test v Control	PF	NNT	%dmft >0					
RCT	1+	Baseline: 7422 1450ppmF=2488 440ppmf=2472 Control=2462  At end: 3,467 1450ppmF=1186 440ppmf=1176 Control=1369  Losses to follow-up: 1450ppmF=52% 440ppmf =52% Control =44%	Birth cohort during two 3mth periods from high caries deprived areas of North England	4.5 years (age 12mths to age 5-6)	Postal distribution of TP 1450ppmF or 440ppmF every 12 wks + Toothbrush 1/yr.  Information leaflet on brushing	No intervention	Mean dmft Calculated for those completing the study, for those who were randomised by imputing the caries levels based on the increment in the controls % caries free Caries recorded at dentinal level	<b>Completers</b>										
								1450ppm	2.15 (2.96)	0.42, p=0.002	16%	2.3	50*					
								440ppm	2.49 (3.16)	0.08, p~1			58					
								control	2.57 (3.16)				58					
								Difference between 1450ppm and 450ppm was 0.34, p=0.020 * p< 0.001										
								<b>Intention to treat</b>										
								1450ppm	2.21	0.39, p=0.001	15%	2.6						
								440ppm	2.47	0.13, p=0.71								
								control	2.6									
								Difference between 1450ppm and 450ppm was 0.26, borderline significant p=0.049										

**Comments:** The provision of free fluoride toothpaste in a programme of this type can significantly reduce caries levels in 5 year old children. This benefit was apparent only when 1450ppm toothpaste was provided



Ellwood, R.P., Davies, G.M., Worthington, H.V., Blinkhorn, A.S., et al. Relationship between area deprivation and the anticaries benefit of an oral health programme providing free fluoride toothpaste to young children. Community Dent Oral Epidemiol 2004; 32: 159-65.

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size				
RCT	1+	Baseline 7422 1450ppmF=2488 440ppmf=2472 Control=2462  In analysis: 3,467 1450ppmF=1093 440ppmf=1096 Control=1278  Drop-outs/no postcode available 1450ppmF=56% 440ppmf =56% Control =48%	Age 12 months Non-F Deprived High caries England (Nth West)  Subjects grouped into quartiles based on Townsend deprivation score of area of residence	4.5 years	440 v 1,450ppmF  Home use Postal distribution	Control (no intervention)	Mean dmft Calculated for those completing the study, for those who were randomised by imputing the caries levels based on the increment in the controls % caries free Caries recorded at dental level		Quartile	440 ppm F	1,450 ppm F	Control
								Mean dmft (SD)	Least deprived	2.2 (3.0)	1.4* (2.5)	1.9 (2.9)
									Most deprived	2.9 (3.6)	2.7 (3.0)	3.2 † (3.4)
									*440 v 1,450, p<0.05 †NS difference between groups			
										440	1,450	Control
								% dmft=0	Least deprived	49	60	56*
									Most deprived	39	41	32*

**Comments:** For the most deprived groups postal provision of either a low or high fluoride toothpaste tended to decrease caries although the differences in mean dmft were not significant. In the less deprived groups only provision of high fluoride toothpaste provided a benefit. The programme did not reduce deprivation related health inequalities.

Lima, T.J., Ribeiro, C.C.C., Tenuta, L.M.A, Cury, J.A. Low fluoride dentifrice and caries lesion control in children with different caries experience: a randomised controlled trial. Caries Res 2008; 42: 46-50

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size																																
RCT	1-	120 baseline (30 in each of 4 groups) 70 at end Losses to follow up: 22% in caries inactive group 28% in caries active group	Age range: 2-4 (mean ~3.3 years) Low income, low fluoride (<0.3ppmF) area in Brazil Children screened allocated to one of 2 groups: caries inactive and caries active i.e. 1 or more cavitated or non-cavitated active lesions.  Higher mean number of active, non cavitated lesions in 1100ppmF group compared to 500ppmF group at baseline (5.3 ± 6.5 v 2.5 ± 1.5). (significance of this difference not mentioned in the article)	1 year	500ppmF toothpaste supervised brushing in preschool. Home use at least twice a day also encouraged. Toothbrushes and toothpaste provided Caries active and caries inactive children randomly assigned to 500ppm toothpaste or	1100ppmF toothpaste	Caries inactive group: New lesions  Caries active group:  Net caries increment	<table border="1"> <tr> <td colspan="3">Caries inactive (n=47)</td> </tr> <tr> <td></td> <td>Lesions/child</td> <td>P</td> </tr> <tr> <td>500ppm (n=24)</td> <td>0.33 ± 0.92</td> <td>0.28</td> </tr> <tr> <td>110ppm (n=23)</td> <td>0.52 ± 0.99</td> <td></td> </tr> </table> <table border="1"> <tr> <td colspan="4">Caries active (n=43)</td> </tr> <tr> <td></td> <td>Lesions progressing</td> <td>Lesions arresting</td> <td>Net increment</td> </tr> <tr> <td>500ppm (n=22)</td> <td>3.0 ± 2.9</td> <td>0.5 ± 0.9</td> <td>2.5 ± 3.3</td> </tr> <tr> <td>110ppm (n=21)</td> <td>1.5 ± 2.4</td> <td>2.1 ± 3.2</td> <td>-0.6 ± 2.3</td> </tr> <tr> <td>P</td> <td>0.0014</td> <td>0.19</td> <td>0.0052</td> </tr> </table>	Caries inactive (n=47)				Lesions/child	P	500ppm (n=24)	0.33 ± 0.92	0.28	110ppm (n=23)	0.52 ± 0.99		Caries active (n=43)					Lesions progressing	Lesions arresting	Net increment	500ppm (n=22)	3.0 ± 2.9	0.5 ± 0.9	2.5 ± 3.3	110ppm (n=21)	1.5 ± 2.4	2.1 ± 3.2	-0.6 ± 2.3	P	0.0014	0.19	0.0052
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**Comments:** The anticaries effect of low fluoride toothpaste was similar to the conventional fluoride toothpaste when used by caries inactive children. However, in children with active caries lesions, the low fluoride toothpaste was less effective than the 1100ppmF toothpaste in controlling the progression of lesions. At baseline, the 500ppmF group had half the number of active non-cavitated lesions as the 1100ppmF group, which suggests some bias in the method of randomisation.

Pine, C.M., Curnow, M.M.T, Burnside, G., Nicholson, J.A., et al. Caries prevalence four years after the end of a randomized controlled trial. Caries Res 2007; 41: 431-436

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size																									
RCT	1+	<p><b>Baseline:</b> 534 children</p> <p>279 test 255 control</p> <p><b>At baseline 30 months and 84 months:</b> 175 test 154 control</p> <p><b>At all time points (BL, 6, 12, 18, 24, 30, 36, 48, 60, 84):</b> 153 test 138 control</p>	<p>12 years of age at follow up.</p> <p>Mean age 5.3 at baseline</p>	<p>30 months</p> <p>Follow-up 4.5 years after cessation of the intervention.</p>	<p>School-based toothbrushing, once a day after lunch, using 1000ppm sodium monofluorophosphate toothpaste.</p> <p>Local mothers recruited to project.</p> <p>Toothpaste and toothbrush provided for home use also</p>	Parallel class in the same school did not receive the intervention	<p>Caries was recorded at D1 and D3 level with and without FOTI</p>	<p><b>0-84 month increments in first permanent molars</b></p> <table border="1"> <thead> <tr> <th></th> <th>Test</th> <th>Control</th> <th>%Difference</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>Mean D<sub>1</sub>FS</td> <td>2.60</td> <td>3.86</td> <td>33</td> <td>0.001</td> </tr> <tr> <td>Mean D<sub>3</sub>FS</td> <td>1.58</td> <td>2.62</td> <td>40</td> <td>0.002</td> </tr> <tr> <td>D<sub>1</sub>FS inc FOTI</td> <td>2.75</td> <td>3.95</td> <td>30</td> <td>0.001</td> </tr> <tr> <td>D<sub>3</sub>FS inc FOTI</td> <td>1.62</td> <td>2.65</td> <td>39</td> <td>0.002</td> </tr> </tbody> </table>		Test	Control	%Difference	P value	Mean D <sub>1</sub> FS	2.60	3.86	33	0.001	Mean D <sub>3</sub> FS	1.58	2.62	40	0.002	D <sub>1</sub> FS inc FOTI	2.75	3.95	30	0.001	D <sub>3</sub> FS inc FOTI	1.62	2.65	39	0.002
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**Comments:** Seven years after the start of the trial and 4.5 years after its cessation, children in the intervention group had developed significantly less caries in their first permanent molar teeth than those in the non-intervention group.

Rong, W.S., Bian, J.Y., Wang, W.J., Wang, J.D. Effectiveness of an oral health education and caries prevention programme in kindergartens in China. Community Dent Oral Epidemiol 2003; 31: 412-6

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size
RCT	1+	Baseline: 731 361 test 370 control  At end: 514 258 test 256 control  Drop out 30%  Baseline dmft/s of dropouts was not significantly different from those who completed the study.	Mean age 3 at baseline  Baseline mean dmfs: 5.24 ± 7.08 Test 5.96 ± 7.74 control NS  Water fluoride= 0.2ppm  Miyun county, Beijing  Most toothpaste on market non fluoridated  Socio economic status included in stratification of kindergartens prior to randomisation	2 years	OHE training for teachers  3 mthly OHE to children  Supervised toothbrushing with 0.5g 1100ppm NaF toothpaste for 1 minute 2/day  Supervisor: teacher  TP & TB given 3 monthly for home use.	Non-fluoridated toothpaste for home use. No oral health education was provided	1. Difference in caries increment (dmft/dmfs) reported at cavitation level 2. Changes in parental reported behaviour, attitudes and knowledge Intra examiner kappa >0.84 (1 examiner)	Mean dmfs increment after 2 years: Test: 2.47 ± 4.09 Control: 3.56 ± 5.30 Difference: 1.09, p = 0.009  Prevented fraction: 30.6%
<b>Comments:</b> The study involves the supervised use of fluoride toothpaste as part of an oral health promotion programme. The programme was effective in reducing the development of new carious lesions.								

Schwartz, E., Lo, E.C.M., Wong, M.C.M. et al. Prevention of early childhood caries – results of a fluoride toothpaste demonstration trial on Chinese preschool children after 3 years. J Public Health Dent 1998; 58 (1) :12-18								
Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size
Non-randomised controlled trial	2-	Baseline: 289 168 test 121 control  At end: 251 152 test 99 control  Drop out: 10% test 19% control  Baseline dmfs of those remaining in study at end was recalculated and there was no significant difference.	94% were age 3 at baseline  Baseline mean dmfs: 4.9 (SE 0.56) Test 6.8 (SE 0.75) control Significance of difference not reported  Water fluoride 0.1ppm  Chonghua County, Guangdong.  Mostly rural. Middle level income for China  F TP not available on market  No organized preventive or treatment services	3 years	OHE training for teachers  Supervised toothbrushing with 0.2 -0.4g 1000ppm MPF toothpaste for 2-3 minute 1/day Supervisor: teacher TP dispensed by teacher or class prefect	No intervention	1. Difference in caries increment (dmft/dmfs) reported at cavitation level and including category <i>arrested caries</i> 2. Plaque score and gingival bleeding  2 examiners K ~0.9 for caries	Mean dmfs increment after 3 years: Without arrested caries (SE) Test: 6.2 Control: 8.4 Difference: 2.2 p=0.016 PF = 26.2%  Excluding arrested caries and examiner reversals Test: 3.6 Control: 6.3 Difference: 2.7 p=0.002 PF = 42.9% Control group had significantly more plaque at end (28% v 22%) No significant difference in gingival bleeding
<b>Comments:</b> Daily toothbrushing with limited involvement of professional staff was feasible in Chinese kindergarten and that caries development was significantly slowed in the test children. This study was a feasibility study, and was not randomized. The examiners were not blind to the allocation of the children and this could have introduced bias into the outcome assessment. Applicability of the findings to the Irish context is doubtful as the severity of decay in these children is much higher than that of Irish children.								

Winter, G.B., Holt, R.D., Williams, B.F., Clinical trial of a low fluoride toothpaste for young children. International Dental Journal 1989; 39: 227- 235

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size				
RCT	1-	Baseline: 3040 families  At end: 2412 families  Drop out of families: 21%  No. of children at baseline unclear  At end: 2177 children 1104 ( 500ppmF ) 1073 (1100ppmF )	Age 2 years at baseline Non fluoridated England (Norwich)	3 years	550ppmF NaF & NaMPF toothpaste  Delivered to child's home at 3 monthly intervals.	1100ppmF NaMPF toothpaste	% with dmft>0 Mean dmft/s Mean ds/ms		550ppmF	1100ppmF		
								% caries free	58%	63%		Significant
								% with incisor caries	1.5%	1.4%		-
								% with dmft>5	11%	10%		-
								Mean dmft	1.48	1.29		NS
								Mean dmfs	2.45	2.21		NS
								Mean ms	0.46	0.52		NS
								Mean fs	0.43	0.34		NS
<p><b>Comments:</b> There appeared to be little or no difference between the children who had used test or control pastes. At age 5, the mean dmft of the children in the study was 1.5 (550ppm) and 1.3 (1100ppm), which is lower than the mean dmft of Irish 5 year olds in both fluoridated and non fluoridated areas in 1984 and lower than the mean dmft of Irish 5 year olds in non fluoridated areas in 2002. Therefore it is likely that these children were at low risk of caries. The authors assumed that the children were caries free at baseline.</p>												

You, B.J., Jian, W.W., Sheng, R.W., Jun, Q. et al. Caries prevention in Chinese children with sodium fluoride dentifrice delivered through a kindergarten-based oral health program in China. J Clin Dent 2002; 13: 179-184.

Study Type	Evidence level	Patient characteristics	No. of patients in study	Length of follow-up	Intervention	Comparison	Outcome	Results
RCT	1-	<p><b>Baseline</b> Mean age 3 dmfs = 6.24 ± 8.06 (test) 6.24 ± 7.95 (control)</p> <p>Water fluoride= 0.2-0.35ppm</p> <p>24 kindergartens in 2 districts (Miyun and Huairou)</p> <p>Most toothpaste on market non fluoridated</p> <p>Socio economic status included in stratification of kindergartens prior to randomisation</p>	<p>Baseline 1334 682 test 652 control</p> <p>At end 916 <i>(of which 85 had been involved in another oral care study and were excluded)</i></p> <p>386 test 445 control</p> <p>Drop out 31.3% 43.4% test 31.7% control</p>	2 years	<p>Toothbrushing with ~0.48g 1100ppm NaF toothpaste for 1 minute 2/day</p> <p>Supervisor: teacher</p> <p>TP &amp; TB given for home use</p> <p>OHE to teachers and children</p> <p>Audio visual materials shown to children at least every 2 weeks</p>	<p>Non-fluoridated toothpaste for home use. No oral health education was provided</p>	<p>1. Difference in caries increment (dmfs) reported using criteria of Radike.</p> <p>2. Urinary fluoride excretion</p>	<p>Mean dmfs increment after 2 years:</p> <p>Examiner 1 Test: 3.81 (0.24) Control: 4.817 (SE 0.26) Difference: 1, p = 0.004</p> <p>PF 20.7%</p> <p>Examiner 2 Test: 3.67 (SE 0.31) Control: 4.71 (SE 0.29) Difference: 1.04 , p = 0.014 PF 22.1%</p> <p>A county by treatment interaction was found for examiner 2 (the percent reduction in one county was not significant 6.8% compared to 39.9% in the other)</p> <p>There was no measure of inter examiner reliability</p> <p>Urinary fluoride levels at 24 hours 0.442 Test and 0.313 control</p>

**Comments:** Although this study is double blind, calibration of examiners is not mentioned in the report, which could account for the examiner variability found at county level. This casts doubt over the reliability of the results. The study is useful, however in that it provides information on urinary fluoride excretion at baseline and during the programme. The authors report that urinary fluoride levels were within acceptable levels at 24 hours and there was no difference between groups at year 1 or year 2

# Fluoride mouthrinsing programmes: evidence tables

## Systematic Reviews

Marinho, V.C.C., Higgins, J.P.T., Logan, S., Sheiham, A. Fluoride mouthrinses for preventing dental caries in children and adolescents. Cochrane Database of Systematic Reviews 2003; Issue 3. Art. no.: CD002284. DOI: 10.1002/14651858. CD002284									
Study Type	Evidence level	No. of included studies	Patient characteristics	No. of patients in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1++	36 trials 34 included in meta-analysis	Age range of children at start of trials 5-14 yrs  No special general or oral health conditions  Caries prevalence at baseline ranged from 0.94-14.7DMFS  4 studies were conducted in fluoridated areas & 30 studies were not  Of the 30 studies conducted in non-fluoridated areas, exposure to fluoride toothpaste reported in 6 studies and assumed in 16 studies. There was no/low exposure to F toothpaste in 8.	14,600	Supervised use of fluoride mouthrinse in school programmes (2 also tested their use at home)  <i>fluoride agent:</i>  NaF (32 trials) APF, SnF2, SMFP, AmF, NH4F  <i>Concentration:</i>  Range – 100-3000ppm  Majority  230/250ppm or 900/1000ppm 5-10ml volume  <i>Frequency of application:</i>  3-330 times a year  <i>Rinsing time</i>  1-2 mins (21 studies)	Placebo or no treatment	At least 1yr/school year  Majority 2-3 years  3 trials lasted < 2 yrs	<i>Primary outcome:</i>  DMFS PF  DMFT PF  DMFS PF for 900/1000 ppm MRs (personal communication)  NNT annual caries increment 0.25 DMFS  annual caries increment of 2.14 DMFS  <i>Secondary outcome:</i>  <i>Acceptability:</i>  Mean drop out rate  Odds of dropping out from MR group vs control group  <i>Side effects</i>	26% (CI 23-30)  24% (18-30)  29% (CI 22-36)  16 ( CI 14-18)  2 (CI 1.6-2)  No clear relationship between baseline caries severity, background exposure to fluoride or fluoride concentration and frequency of use.  32%  1.26 (0.60-2.64)  The review does not provide useful information on the likelihood of significant side effects.
<b>Comments:</b> Twenty-nine of the 36 trials were conducted in the 1960s and 70s when caries levels were much higher. Although the review indicates that baseline caries level does not influence effectiveness, the NNT, based on caries increment, shows decreasing efficiency of the intervention with decreasing caries increment. Information is needed on local caries prevalence and caries increment to allow the results of this study to be applied in a public health setting.									



Strohmenger, L., and Brambilla E. The use of fluoride varnishes in the prevention of caries: a short review Oral Diseases. 2001; 7 (2) 71-80

Aim: To review the current literature regarding the anti-caries efficacy of fluoride varnishes. To analyse a series of studies designed to detect the caries preventive efficacy of fluoride varnishes by means of meta-analysis.

Study Type	Evidence level	No. of included studies	Patient characteristics	No. of patients inc in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1+	3	Age 6-14 No special characteristics	934	Fluoride varnish applied twice a year	0.2% NaF MR	At least 1 year  (included studies had follow-up of 2, 3 and 4 years)	Standardised treatment effect  (difference in DMFS between V and MR group/ sum of DMFS  DMFS Weighted mean	-1.522 (CI -3.168-0.12)  Pooled estimate of effect favoured varnish  No statistically significant difference  4.09 in varnish group  5.07 in rinse group

**Comments:** The meta analysis showed no significant difference between varnish and 0.2% NaF rinses. The authors conclude that fluoride varnish is an efficacious caries preventive agent. Because of the rigorous inclusion criteria for the meta analysis only a small number of studies were included and none was varnish v placebo and so is a comparison of one modality v another. It supports the findings of the Marinho varnish review.

Twetman S, Petersson L, Axelsson, S., Dahlgren, H. et al. Caries preventive effect of sodium fluoride mouthrinses: a systematic review of controlled clinical trials. Acta Odontol Scandinavica 2004; 62(4) 223-30  
 Aim To report the findings concerning the effect of FMRs in non-selected populations of all ages, with special reference to background fluoride exposure.

Study type	Evidence level	No. of included studies	Patient characteristics	No. of patients in meta analysis	Intervention	Comparison	Length of follow-up	Outcome	Effect size
Systematic review	1+	22 studies involving children	age range 10-14 for 'no fluoride exposure group' 5-15 for 'other fluoride exposure' group "non-selected populations" i.e. excluding compromised or disabled	No formal meta analysis n= 7332 in 'no other fluoride exposure' group	NaF rinse without any other assumed fluoride exposure concentration range 0.025-0.4% Frequency: 1/day to 1/wk	Placebo	At least 2 years	weighed mean PF decayed surface saved /yr % dropouts	29% (CI not provided) Range: 14-53% 1.06 (range 0.4-2.55) range 9% - 56%
				n=10,276 in 'other fluoride exposure' group	NaF rinse under conditions with other fluoride sources e.g. piped water or toothpaste Concentration range: 0.05-0.2% Frequency: 1/wk or 2/wk (except 1 study)	Placebo or other fluoride intervention		PF (placebo trials only) % drop outs	6% Range: 0-30% (*4/15 studies had significant results favouring FMR. 1 favoured another F regime and the remainder were NS 0-59%

**Comments:** "Limited evidence that daily or weekly NaF MRs had a significant caries –reducing effect in young permanent teeth compared to placebo when no additional background fluorides were present or used. In contrast, the evidence for caries prevention by FMR in school children exposed to additional fluoride sources, such as regular use of fluoride toothpaste was rated as inconclusive". Only 2 databases were searched (Cochrane Library and Medline) although hand-searching of reference lists carried out. Heterogeneity of the various studies is not statistically addressed. Formal meta-analysis was not performed. There is no description of how the weighed mean PF was calculated in this systematic review.

**Notes:** Papers published prior to 1970 were excluded. The level of evidence was judged according to the protocol of the Swedish Council on Technology Assessment in health Care. Coding of evidence level was based on the number of studies of each quality category e.g. strong evidence = at least 2 studies with level A evidence to inconclusive evidence, Moderate evidence= One study with level A and at least 2 with level B, Limited evidence = At least 2 studies with level B, Inconclusive evidence= less than 2 studies with level B evidence

## Randomised controlled trials

Heidmann J, Poulsen S, Arnbjerg D, Kirkegaard E, Laurberg L. Caries development after termination of a fluoride rinsing program. Community Dent Oral Epidemiol 1992; 20:118-21 Aim: To determine whether the disuse of fluoride mouthrinses would have any measurable effect on caries development in a Danish population of schoolchildren.								
Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size
RCT	1+	Baseline 1306 At end 1083	Children age 6 to 12 attending four major schools in the municipality of Vaerloese near Copenhagen, Denmark. All children rinsed with 0.2% neutral sodium fluoride every second week during the school year, and all received systematic dental care with dental examination and treatment at least once a year. Non-fluoridated drinking water. F supplements not commonly used. Fluorides not added during commercial food production.	3 years	Fluoride rinse substituted with distilled water (slightly flavoured with peppermint) in a group of randomly selected children.	Fluoride group who continued rinsing with 0.2% sodium fluoride solution (slightly flavoured with peppermint)	<p>Clinical caries increment calculated as number of surfaces with no DMF score at baseline and DMF score at the end of the trial.</p> <p>Caries progression calculated as number of surfaces which showed development of new lesions or progression of existing lesions (measured radiographically).</p> <p>All surfaces with FS excluded from analysis.</p>	<p>PF 5% CI -19 to 30</p> <p>Faster caries progression in the water rinse group.  (90% of radiographically recorded lesions in enamel- majority less than half way through)</p>
<p><b>Comments:</b> Caries increment in the two groups was the same with pits and fissures containing 94% of the DMFS. Caries progression was higher in the water group than in the fluoride group.            Reviewers comments: There appears to be a trend of higher mean caries progression (subclinical) for surfaces erupting during the study in the placebo group <math>P &lt; 0.05</math>. However the size of the effect is small and is greatest in the 10 and 11 age group at the start of the study. Our population does not have access to the annual dental service and it is possible that a greater effect may be seen in our population.</p>								

Moberg Skold, U., Lindvall, A.M., Rasmusson, C.G., Birkhed, D., Klock, B. Caries incidence in adolescents with low caries prevalence after cessation of weekly fluoride rinsing. Acta Odontologica Scandinavica 2001; 59: 69-73.

Aim: To determine whether cessation of weekly fluoride rinsing leads to an increase in caries incidence in a group of adolescents with low caries prevalence.

Study type	Evidence level	No. participants	Patient characteristics	Length of follow-up	Intervention	Comparison	Outcome	Effect size															
RCT	1+	Baseline 120	12-14 year olds in neighboring elementary schools in the county of Bohuslan on Swedish West coast.  Socioeconomic factors similar according to municipal authorities.  0.1-0.2mgF/l in drinking water.  Participated in school-based mouthrinsing since age 6.	3 years	Test group stopped school-based mouthrinsing.	Control group continued to rinse with 0.2% sodium fluoride solution once a week during school terms.	Mean caries increment as measured clinically and radiographically and mean caries progression.	<table border="0"> <tr> <td></td> <td>TEST</td> <td>CONTROL</td> </tr> <tr> <td>Mean caries increment (open + incipient)</td> <td>5.52 ± 5.32</td> <td>4.72 ± 4.69 NS</td> </tr> <tr> <td>Mean caries increment (open lesions)</td> <td>1.58 ± 1.73</td> <td>1.48 ± 1.8 NS</td> </tr> <tr> <td>Mean caries increment (incipient lesions)</td> <td>3.13±3.63</td> <td>4.03± 4.23 NS</td> </tr> <tr> <td>Mean caries progression</td> <td>0.92±1.34</td> <td>0.72± 1.03 NS</td> </tr> </table> <p>Drop-outs 3% from control group.</p>		TEST	CONTROL	Mean caries increment (open + incipient)	5.52 ± 5.32	4.72 ± 4.69 NS	Mean caries increment (open lesions)	1.58 ± 1.73	1.48 ± 1.8 NS	Mean caries increment (incipient lesions)	3.13±3.63	4.03± 4.23 NS	Mean caries progression	0.92±1.34	0.72± 1.03 NS
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**Comments:** The results indicate that cessation of fluoride rinsing with a 0.2% sodium fluoride solution did not lead to increased caries activity in adolescents who used fluoridated toothpaste daily, who saw a dentist yearly, and who rinsed with a 0.2% NaF solution during a period of 7 years before the study started. Method of randomisation not described. Single blind. No definition of incipient caries as detected clinically or explanation of method used to obtain the final score of clinical and radiological findings. No description of method used to measure caries progression. Clinicians at the dental clinic who treated the control group “seemed to be more positive towards fissure sealant treatment”.

Moberg Skold, U, Birkhead D, Petersson LG. Approximal caries development in adolescents with low to moderate caries risk after different 3 year school-based supervised fluoride mouth rinsing programmes. Caries Research 2005; 39:529-536

Aim: To evaluate supervised school-based fluoride mouthrinse programmes with different rinse frequencies on approximal caries incidence and caries progression in adolescents with low/moderate caries risk.

Study Type	Evidence level	No. participants	Patient characteristics	Length of follow up	Intervention	Comparison	Outcome	Effect size
RCT	1-	788 at baseline 622 at analysis	Swedish adolescents aged 13 at start of study from 5 secondary schools in Molndal city.  Low to moderate caries risk  Mixed socio-economic background  Difference in caries prevalence at baseline NS  All reported brushing 2xd & received 3 varnish applications during the course of the study through dental service	3 years 1999-2003	Supervised 10ml 0.2% NaF mouthrinse applied at 4 different frequencies:  Group 1-FMR first 3 schooldays every semester (18 rinses)  Group 2-FMR first 3 and last 3 days every semester (36 rinses)  Group 3-FMR 3 consecutive days once a month during the semesters (81 rinses)  Group 4- FMR fortnightly during semester (60 rinses)	No rinse	On approximal surfaces only:	>90% of new lesions were in enamel
							Mean caries prevalence	Group 1-4 2.60 ± 3.99 p= 0.132 (NS) Control 3.29 ± 4.45
							Mean caries incidence <sup>^</sup>	Group 1 - 1.12 ± 2.10 Group 2 0.65 ± 1.57* Group 3 0.84 ± 1.62* Group 4 0.94 ± 1.81* Groups 1-4 0.88 ± 1.78* Control 1.59 ± 2.6 * statistically significant compared to control p < 0.01
							Mean caries progression <sup>^</sup>	Group 1-4 0.16 ± 0.79 Control 0.27 ± 0.71
							Prevented fraction <sup>^</sup>	Group 1 30% Group 2 59% Group 3 47% Group 4 41%
							% developing no new lesions	Group 1 - 69% Group 2 76% Group 3 68% Group 4 68% Control 55%

**Comments:** Various school-based FMR significantly affects caries incidence on approximal surfaces in adolescents in a region with low to moderate caries incidence rate. The method of randomization is not clearly described and results were not analysed on an intention to treat basis. 166 subjects were excluded from final analysis - 62 (37%) of all exclusions were because the participants had not carried out the required number of rinses. The % exclusions by group were 6% (group 1), 17% (group 2 & 3) and 57% (group 4). Failure to analyse on an intention to treat basis could overestimate the effect of the intervention, since only those who participated as prescribed are included. Dropouts who refused to rinse varied from 5% in group 4 to 23% in group 3. Because of the lack of detail about randomization, we cannot be sure that the groups were not fundamentally different.

