EXECUTIVE SUMMARY

Background
Decision-makers are sometimes uncertain about the oral health effects of the main forms of fluoride interventions intended to control dental caries in children. This is because evidence has been summarised in traditional narrative reviews. It was not until recently that information based on rigorous reviews of the relevant research evidence existed. The information from up-to-date systematic reviews should inform decisions about population-wide use of fluoride to prevent caries and guide further research.

The seven Cochrane reviews on the effects of topical fluoride administration - toothpastes, mouthrinses, gels and varnishes, used alone or in conjunction with one of the others - have been published from April 2002 to January 2004 (See Annex for references and main findings). All these systematic reviews are based upon thorough searches of published and unpublished evidence.

Whilst a variety of study designs have been used over the past five decades to evaluate the effectiveness of fluorides in preventing caries, the various topical fluoride interventions have been subjected to intensive clinical testing in controlled trials, the type of evidence regarded as the best to be included in systematic reviews, because they are considered the strongest study design for prospective research into effectiveness.
Main findings

Single topical fluoride interventions compared to placebo/no treatment

- The evidence on the beneficial effects of topical fluorides is consistent and strong. Research involving more than 65,000 children and adolescents shows that fluoride toothpastes, mouthrinses gels and varnishes can reduce dental caries irrespective of water fluoridation or other sources of fluoride exposure. There is a clear reduction in caries increment in both the permanent (for all forms of topical fluorides examined) and the deciduous dentition (for fluoride gels and varnishes).
  - *The benefits of fluoride toothpaste are firmly established.* Taken together, the trials, which included more than 42,000 children provide clear evidence that fluoride toothpastes used at least once a day are efficacious in preventing dental caries in permanent teeth. The caries preventive effect of fluoride toothpaste increased with higher initial levels of decayed, (missing), and filled permanent teeth (D(M)FS), higher fluoride concentration, and supervised brushing, but was not influenced by exposure to water fluoridation.
  - A clear reduction in caries increment in children is associated with supervised regular use (daily or weekly) of fluoride mouthrinse. This conclusion is based on the direct evidence from clinical trials involving more than 14,000 children.
  - The application of fluoride gels, either by professionals (once every few months) or self-applied under supervision, does prevent dental caries. The review as a whole contains information from nearly 8000 children.
  - *Fluoride varnishes* applied by professionals two to four times a year, either in the permanent or deciduous dentition, appears to lead to large reductions in caries increment, but there is less research on this type of topical fluoride intervention.

One type of topical fluoride therapy (TFT) compared to another

- Fluoride toothpaste used every day can protect children and adolescents against dental caries as much as other forms of topical fluoride treatments (mouthrinses and gels; relevant direct comparisons of fluoride toothpaste with varnish are lacking).
- Young people are more likely to persist with using toothpaste than with using fluoride mouthrinses, or having gels or varnishes applied.
Combined topical fluoride therapy compared to one type alone

- Research showed that children and adolescents who used another form of topical fluoride in addition to fluoride toothpaste experienced additional reduction in dental caries compared with children who only used fluoride toothpaste. However, the additional benefit was less substantial.

Conclusions on fluoride toothpaste

1. **Supported by more than half a century of research, the benefits of fluoride toothpastes are firmly established.**

2. **The caries preventive effect of fluoride toothpaste increased with higher initial levels of decayed, (missing), and filled permanent teeth (D(M)FS), higher fluoride concentration, and supervised brushing, but was not influenced by exposure to water fluoridation.**

3. **Every effort should be made to make affordable fluoride toothpastes available to the general population.**
Annex

References to seven large Systematic Reviews on topical fluorides
(The reviews are based upon 371 clinical trials which included 136,451 children)


Main results: Supported by more than half a century of research, the benefits of fluoride toothpastes are firmly established. The trials provide clear evidence that fluoride toothpastes are efficacious in preventing caries. For the 70 studies that contributed data for meta-analysis (involving 42,300 children) the D(M)FS pooled PF was 24% (95% confidence interval (CI), 21 to 28%; p<0.0001). This means that 1.6 children need to brush with a fluoride toothpaste (rather than a non-fluoride toothpaste) to prevent one D(M)FS in populations with caries increment of 2.6 D(M)FS per year. In populations with caries increment of 1.1 D(M)FS per year, 3.7 children will need to use a fluoride toothpaste to avoid one D(M)FS. The effect of fluoride toothpaste increased with higher baseline levels of D(M)FS, higher fluoride concentration, higher frequency of use, and supervised brushing, but was not influenced by exposure to water fluoridation.


Main results: Topical fluorides (mouthrinses, gels, or varnishes) used in addition to fluoride toothpaste achieve a modest reduction in caries compared to toothpaste used alone. For the 9 trials that provided data for the main meta-analysis on the effect of fluoride mouthrinses, gels or varnishes used in combination with toothpaste (involving 4026 children) the D(M)FS pooled PF was 10% (95% CI, 2% to 17%; p = 0.01) in favour of the combined regimens.


Main results: Fluoride toothpastes in comparison to mouthrinses or gels appear to have a similar degree of effectiveness for the prevention of dental caries in children. There is no clear suggestion that fluoride varnish is more effective than mouthrinses and the evidence for the comparative effectiveness of fluoride varnishes and gels, and mouthrinses and gels is inconclusive. 15 studies contributed data for the meta-analyses. Fluoride toothpaste was not significantly different from mouthrinse (pooled DMFS PF 0%; 95% CI, -18% to 19%; p = 0.94), or gel (pooled DMFS PF 0%; 95% CI, -21% to 21%; p = 1), or both gel and mouthrinse (pooled DMFS PF 1%; 95% CI, -13% to 14%; p = 0.94); heterogeneity was substantial.

4. Marinho VCC, Higgins JPT, Logan S, Sheiham A. *Topical fluoride (toothpastes, mouthrinses, gels or varnishes) for preventing dental caries in*
children and adolescents (Cochrane Review).
http://www.cochrane.org/cochrane/revabstr/ab002782.htm

Main results: The benefits of topical fluorides have been firmly established on a sizeable body of evidence from randomized controlled trials. For the 133 studies that contributed data for meta-analysis (involving 65,169 children) the D(M)FS pooled prevented fraction estimate was 26% (95% CI, 24% to 29%; p < 0.0001).

http://www.cochrane.org/cochrane/revabstr/AB002284.htm

Main results: This review suggests that the supervised regular use of fluoride mouthrinse at two main strengths and rinsing frequencies is associated with a clear reduction in caries increment in children. In populations with caries increment of 0.25 D(M)FS per year, 16 children will need to use a fluoride mouthrinse (rather than a non-fluoride rinse) to avoid one D(M)FS; in populations with a caries increment of 2.14 D(M)FS per year, 2 children will need to rinse to avoid one D(M)FS. For the 34 studies that contributed data for meta-analysis (involving 14,600 children) the D(M)FS pooled PF was 26% (95% confidence interval (CI), 23% to 30%; p < 0.0001).

http://www.cochrane.org/cochrane/revabstr/AB002279.htm

Main results: The review suggests a substantial caries-inhibiting effect of fluoride varnish in both the permanent and the deciduous dentitions based largely on trials with no treatment controls. Nine studies were included, involving 2709 children. For the seven that contributed data for the main meta-analysis, the D(M)FS pooled prevented fraction estimate was 46% (95% CI, 30% to 63%; p<0.0001). The pooled d(e/m)fs prevented fraction estimate was 33% (95% CI, 19% to 48%; p<0.0001).

http://www.cochrane.org/cochrane/revabstr/AB002280.htm

Main results: There is clear evidence of a caries-inhibiting effect of fluoride gel. The best estimate of the magnitude of this effect, based on the 14 placebo-controlled trials, is a 21% reduction (95% CI, 14 to 28%) in D(M)FS. This corresponds to an NNT of 2 (95% CI, 1 to 3) to avoid 1 D(M)FS in a population with a caries increment of 2.2 D(M)FS/year, or an NNT of 24 (95% CI, 18 to 36) based on an increment of 0.2 D(M)FS/year. Twenty-five studies were included, involving 7747 children. For the 23 that contributed data for meta-analysis, the D(M)FS pooled prevented fraction estimate was 28% (95% CI, 19% to 37%; p<0.0001).