CRD summary
This review concluded that fluoride varnish may be effective in preventing dental caries in preschool children, but more randomised controlled trials with better methods are necessary to provide conclusive evidence. There were several methodological limitations in the review process, but these conclusions appear reasonable considering the data available.

Authors' objectives
To investigate whether the professional application of fluoride varnish decreases the incidence of dental caries in preschool children.

Searching
MEDLINE, LILACS, Brazilian Bibliography of Dentistry and the Cochrane Library were searched to December 2008 for trials published in English, Spanish or Portuguese (search terms were reported). The bibliographies of retrieved systematic reviews were also examined for further trials.

Study selection
Randomised controlled trials (RCTs) or quasi-RCTs were selected if the assess application of topical fluoride varnish to primary dentition and incidence of caries in primary dentition. Trials of children aged six years or younger (regardless of caries experience at the start of the trial) were eligible for inclusion. The fluoride varnish could be given in any quantity, or concentration or at any application interval, on selected or unselected surfaces using any application technique. Trials that used a split-mouth design and intentionally administered other fluoride products in addition to varnish for the intervention or control group were excluded.

The included trials were conducted in China, USA, Poland and Sweden. The participants were aged six months to five years and follow-up ranged from nine to 30 months. The interventions were Duraphat and Fluor Protector. Varnish was applied to all of the primary teeth in all but one trial. The application of varnish and the use of concomitant fluoride containing products varied across trials. The control groups received no treatment, oral health counselling, or water. The frequency of treatments ranged from three months to one year.

Two reviewers selected trials for inclusion. Disagreements were resolved by consensus.

Assessment of study quality
Methodological quality was assessed in terms of sample selection, randomisation, allocation concealment, interventions and controls used, comparability of groups, blinding, outcome assessment, trial duration, attrition and adherence to treatment. The Jadad scale was used to give a quality score out of five (based on randomisation, blinding, withdrawals and dropouts).

Two reviewers assessed trial quality.

Data extraction
The mean and standard deviation of decayed, missing and filled surfaces at the start and end of each trial were extracted and the difference in the mean additional caries between test and control groups was calculated. The percentage of caries prevented (the difference in the caries increment between intervention and control as a percentage of the caries increment of the control group) was calculated.

The authors did not report how many reviewers performed data extraction.

Methods of synthesis
The trials were synthesised narratively and individual trial details were presented in tables. The authors stated that meta-analysis was not used as there appeared to be a major asymmetry in the data, missing standard deviations, heterogeneity...
between trials and the raw data were not available (for all trials).

**Results of the review**

Eight controlled clinical trials were included in the review (2,501 participants). Two trials had a Jadad score of zero, three a score of 1, two a score of 2 and one a score of 4. One trial was double-blind and one adequately described randomisation and allocation concealment.

The authors reported there was broad diversity in the caries increment between the intervention and control groups; the average increase in cavitated carious surfaces ranged from 0.5 to 6.3 in the intervention group and 1.4 to 6.7 in the control group. The difference between the intervention and control groups ranged from 0.30 to 1.64. The percentage of caries prevented across trials ranged from five to 63% and higher values were reported in more recently published trials. Two reported that no side-effects were observed.

**Authors' conclusions**

Fluoride varnish may be effective in preventing dental caries in preschool children, but more randomised controlled trials with better methods are necessary to provide conclusive evidence.

**CRD commentary**

The research question was supported by well-defined inclusion criteria. As only published trials in three languages were included, the review was open to publication language bias. Trial selection was performed by two reviewers but it was unclear whether similar steps were taken to prevent bias in assessing trial quality and extracting data. Quality was assessed using appropriate criteria; trials were generally of poor quality. The reasons for not undertaking meta-analysis appear reasonable. There were several methodological limitations in the review process, but the authors’ conclusions appear to be reasonable considering the data available.

**Implications of the review for practice and research**

**Practice:** The authors stated that professional use of fluoride varnish may be useful within a caries control strategy based on population targeting. However, the use of fluoride varnish resulted on average one less carious dental surface in treated children.

**Research:** The authors stated a need for well-designed randomised controlled trials that assess whether there is an ideal interval for the application of varnishes (considering the cost-benefit ratio, whether the magnitude of benefit is associated with prior caries experience, and what additional benefit is derived in populations already exposed to fluoridated water and toothpastes). The acceptability of fluoride varnishes to children and their parents and any possible side-effects should be investigated.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.