Authors' objectives
To review the safety and efficacy of the fluoridation of drinking water. Specifically, the review examined the effects of the fluoridation of drinking water on the incidence of caries and whether fluoridation has negative effects.

Searching
Twenty-five specialist databases were searched from inception to February 2000; these included MEDLINE, EMBASE, TOXLINE and Current Contents. In addition, searches of the World Wide Web were conducted and the bibliographies of all included studies were handsearched. Authors and experts in the field were also contacted. A dedicated website was used to seek additional references from individuals and organisations. Published and unpublished studies in any language were included. The full search strategy is available in the report.

Study selection
Study designs of evaluations included in the review
Any study design that compared populations exposed to different water fluoride concentrations was considered. In addition, the authors applied inclusion criteria relating to the level of evidence, based on the risk of bias. Studies rated below level B (moderate quality, moderate risk of bias) was not considered in the evaluation of efficacy. All levels of evidence were included in the assessment of safety.

Specific interventions included in the review
Any study that examined changes to water fluoridation levels was included. The inclusion criteria specified that the work had to be a primary study involving humans, relate directly to fluoride in drinking supplies, and involve two groups with different fluoride concentrations. Studies of caries had to evaluate two points in time, one of which was less than three years since the change in water fluoridation status in one of the two groups. The results obtained from areas using artificially and naturally fluoridated water supplies were compared to investigate any differences in effect.

Participants included in the review
Populations receiving fluoridated water (natural or artificial) and those with unfluoridated water were considered. The efficacy studies usually included children aged 5 to 15 years.

Outcomes assessed in the review
The efficacy outcomes were any measure of dental decay in primary or permanent teeth and the proportion of children with dental caries. Safety was measured by dental or skeletal fluorosis, hip fractures, cancer congenital malformation, mortality and any other negative effect reported in the literature.

How were decisions on the relevance of primary studies made?
Three reviewers independently assessed each title and abstract located through the searches, then independently assessed each paper for the predetermined inclusion criteria. Any disagreements were resolved through consensus.

Assessment of study quality
The authors assessed validity using a published checklist (CRD report 4) modified for this review. The level of evidence (A, B or C) is generic and was used to classify studies according to inclusion criteria based on overall quality and chance for bias. Each study was assigned a 'level of evidence' (see report for full description) and a validity score based on the number of checks achieved on the checklist. Two reviewers assessed study validity independently, with any disagreements resolved through consensus.

Data extraction
The data extraction was performed independently by two reviewers and checked by a third. Any disagreements were resolved through consensus.

**Methods of synthesis**

How were the studies combined?

Meta-analyses using random-effects models were used to combine the study results. A full description of the data analysis is provided in the report. A multi-level regression analysis was used to combine the studies and investigate the association between water fluoride concentration and the prevalence of dental fluorosis.

How were differences between studies investigated?

Heterogeneity was investigated both visually, by examination of plots, and statistically with the Q statistic. Meta-regression techniques were used to explain heterogeneity. Full details of the analyses are provided in the report.

**Results of the review**

A total of 214 studies were included, none of which were of evidence level A (high quality, bias unlikely). The review included 45 before-and-after studies, 102 cross-sectional studies, 47 ecological, 13 cohort and 7 case-control studies.

Efficacy: there were 39 studies of moderate to low quality. Water fluoridation was associated with an increased proportion of children without dental caries (median increase 14.6%) and a reduction in the number of teeth affected by caries (median reduction 2.25).

Safety: there were 176 studies (88 dental fluorosis, 29 fractures, 26 cancer, and 33 other effects); the majority were of a low quality. A dose dependent increase in dental fluorosis was found. At a fluoride level of 1 ppm, an estimated 12.5% (95% confidence interval: 7.0, 21.5) of exposed people would have an aesthetically concerning fluorosis from these studies. However, there is a risk of bias towards overestimation due to a lack of assessor blinding in many studies. There was no clear association between fluoridation and bone fractures, cancers or any other adverse effects.

**Authors' conclusions**

The evidence of a beneficial reduction in dental caries should be considered together with the increased prevalence of dental fluorosis. There was no clear evidence of other potential adverse effects.

**CRD commentary**

This was a well-conducted review with a clear review question. The searches were described in detail and there were no language restrictions. The authors appear to have made extensive attempts to seek out all relevant studies. A validity assessment was conducted and was well described. The meta-analysis appears to have been conducted appropriately, and the authors' conclusions follow from the findings presented.

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

Practice: The authors state that the evidence on positive and negative effects of water fluoridation needs to be considered alongside ethical, environmental, financial and legal issues when taking decisions.

Research: The authors state that future research should be carried out with appropriate methodology to improve the quality of the evidence-base.

**Bibliographic details**


**Original Paper URL**
Other publications of related interest
This additional published commentary may also be of interest. Water fluoridation [letters]. BMJ 2001;322:1486-9.

Indexing Status
Subject indexing assigned by CRD

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Record Status
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.