# A Systematic Review of Public Water Fluoridation

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## EXECUTIVE SUMMARY

This systematic review has been commissioned by the Chief Medical Officer of the Department of Health to 'carry out an up to date expert scientific review of fluoride and health' (Paragraph 9.20, Our Healthier Nation).

Overall, the aim has been to assess the evidence on the positive and negative effects of population wide drinking water fluoridation strategies to prevent caries. To achieve this aim five objectives were identified:

**Objective 1:** What are the effects of fluoridation of drinking water supplies on the incidence of caries?

**Objective 2:** If water fluoridation is shown to have beneficial effects, what is the effect over and above that offered by the use of alternative interventions and strategies?

**Objective 3:** Does water fluoridation result in a reduction of caries across social groups and between geographical locations, bringing equity?

**Objective 4:** Does water fluoridation have negative effects?

**Objective 5:** Are there differences in the effects of natural and artificial water fluoridation?

### Methods

A search of 25 electronic databases (with no language restrictions) and the world-wide-web was undertaken. Relevant journals and indices were hand searched and attempts were made to contact authors for further information.

Quality inclusion criteria were based on a pre-defined hierarchy of evidence (A, B, and C). Studies of efficacy were included if they were of evidence level A or B. In order to allow the broadest search for evidence on potential adverse effects, studies of all levels of evidence were included. Objective specific inclusion criteria, based on selection of participants, intervention, outcomes assessed, and study design appropriate for a given objective were then applied. Study validity was formally assessed using a published checklist modified for this review (CRD Report 4, 1996).

Inclusion criteria were assessed independently by at least two reviewers. Extraction of data from, and validity assessment of, included studies was independently performed by two reviewers, and checked by a third reviewer. Disagreements were resolved through consensus.

Where the data were in a suitable format, measures of effect and 95% confidence intervals (Cl) were plotted. Heterogeneity was investigated by visual examination and statistically using the Q-statistic. Where no evidence of heterogeneity was found a meta-analysis was conducted to produce a pooled estimate of the measure of effect. Statistically significant heterogeneity was investigated using meta-regression. Multiple regression analysis was used to explore the relationship between fluoridation and fluorosis.

### Results

214 studies met full inclusion criteria for one or more of the objectives. No randomised controlled trials of the effects of water fluoridation were found. The study designs used included 45 'before and after' studies, 102 cross-sectional studies, 47 ecological studies, 13 cohort (prospective or retrospective) studies and 7 case-control studies. Several studies were reported in multiple papers over a number of years.

**Results by Objective**

***Objective 1***

A total of 26 studies of the effect of water fluoridation on dental caries were found. For this objective, the quality of studies found was moderate (no level A studies). A large number of studies were excluded because they were cross-sectional studies and therefore did not meet the inclusion criteria of being evidence level B or above. All but three of the studies included were before-after studies, two included studies used prospective cohort designs, and one used a retrospective cohort design. All before-after studies located by the search were included. The most serious defect of these studies was the lack of appropriate analysis. Many studies did not present an analysis at all, while others only did simple analyses without attempting to control for potentially confounding factors. While some of these studies were conducted in the 1940's and 50's, prior to the common use of such analyses, studies conducted much later also failed to use methods that were commonplace at the time of the study.

Another defect of many studies was the lack of any measure of variance for the estimates of decay presented. While most studies that presented the proportion of caries-free children contained sufficient data to calculate standard errors, this was not possible for the studies that presented dmft/DMFT scores. Only four of the eight studies using these data provided estimates of variance.

The best available evidence suggests that fluoridation of drinking water supplies does reduce caries prevalence, both as measured by the proportion of children who are caries free and by the mean change in dmft/DMFT score. The studies were of moderate quality (level B), but of limited quantity. The degree to which caries is reduced, however, is not clear from the data available. The range of the mean difference in the proportion (%) of caries-free children is -5.0 to 64%, with a median of 14.6% (interquartile range 5.05, 22.1%). The range of mean change in dmft/DMFT score was from 0.5 to 4.4, median 2.25 teeth (interquartile range 1.28, 3.63 teeth). It is estimated that a median of six people need to receive fluoridated water for one extra person to be caries-free (interquartile range of study NNTs 4, 9). The best available evidence from studies following withdrawal of water fluoridation indicates that caries prevalence increases, approaching the level of the low fluoride group. Again, however, the studies were of moderate quality (level B), and limited quantity. The estimates of effect could be biased due to poor adjustment for the effects of potential confounding factors.

Objective 2

To address this objective, studies conducted after 1974 were examined. While only nine studies were included for Objective 2, these would have been enough to provide a confident answer to the objective's question if the studies had been of sufficient quality. Since these studies were completed after 1974, one might expect that the validity assessments would be higher than the earlier studies following the introduction of more rigorous study methodology and analytic techniques. However, the average validity checklist score and level of evidence was essentially the same for studies after 1974 as those conducted prior to 1974. Hence, the ability to answer this objective is similar to that in Objective 1.

In those studies completed after 1974, a beneficial effect of water fluoridation was still evident in spite of the assumed exposure to non-water fluoride in the populations studied. The meta-regression conducted for Objective 1 confirmed this finding.

***Objective*** 3

No level A or B studies examining the effect of water fluoridation on the inequalities of dental health between social classes were identified. However, because of the importance of this objective, level C studies conducted in England were included. A total of 15 studies investigating the association of water fluoridation, dental caries and social class in England were identified. The quality of the evidence of the studies was low, and the measures of social class that were used varied. Variance data were not reported in most of these studies, so a statistical analysis was not undertaken.

There appears to be some evidence that water fluoridation reduces the inequalities in dental health across social classes in 5 and 12 year-olds, using the dmft/DMFT measure. This effect was not seen in the proportion of caries-free children among 5 year-olds. The data for the effects in children of other ages did not show an effect. The small quantity of studies, differences between these studies, and their low quality rating, suggest **caution** in interpreting these results.

### *Objective* 4

#### *DENTAL* ***FLUOROSIS***

Dental fluorosis was the most widely and frequently studied of all negative effects. The fluorosis studies were largely cross-sectional designs, with only four before-after designs. Although 88 studies of fluorosis were included, they were of low quality. The mean validity score for fluorosis was only 2.8 out of 8. All, but one, of the studies were of evidence level C. Observer bias may be of particular importance in studies assessing fluorosis. Efforts to control for the effects of potential confounding factors, or reducing potential observer bias were uncommon.

As there may be some debate about the significance of a fluorosis score at the lowest level of each index being used to define a person as 'fluorosed', a second method of determining the proportion 'fluorosed' was selected. This method describes the number of children having dental fluorosis that may cause 'aesthetic concern'.

With both methods of identifying the prevalence of fluorosis, a significant dose-response relationship was identified through a regression analysis. The prevalence of fluorosis at a water fluoride level of 1 .0 ppm was estimated to be 48% (95% CI 40 to 57) and for fluorosis of aesthetic concern it was predicted to be 12.5% (95% CI 7.0 to 21.5). A very rough estimate of the number of people who would have to be exposed to water fluoride levels of 1 .0 ppm for one additional person to develop fluorosis of any level is 6 (95% CI 4 to 21), when compared with a theoretical low fluoride level of 0.4 ppm. Of these approximately one quarter will have fluorosis of aesthetic concern, but the precision of these rough estimates is low. These estimates only apply to the comparison of 1 .0 ppm to 0.4 ppm, and would be different if other levels were compared.

#### *BONE FRACTURE AND BONE DEVELOPMENT PROBLEMS*

There were 29 studies included on the association between bone fracture and bone development problems and water fluoridation. Other than fluorosis, bone effects (not including bone cancers) were the most studied potential adverse effect. These studies had a mean validity score of 3.4 out of 8. All but one study were of evidence level C. These studies included both cohort and ecological designs, some of which included analyses controlling for potential confounding factors. Observer bias could potentially play a role in bone fracture studies, depending on how the study is conducted.

The evidence on bone fracture can be classified into hip fracture and other sites because there are more studies on hip fracture than any other site. Using a qualitative method of analysis (Figure 8.1), there is no clear association of hip fracture with water fluoridation. The evidence on other fractures is similar. Overall, the findings of studies of bone fracture effects showed small variations around the 'no effect' mark. A meta-regression of bone fracture studies also found no association with water fluoridation.

#### ***CANCER STUDIES***

There were 26 studies of the association of water fluoridation and cancer included. Eighteen of these studies are from the lowest level of evidence (level C) with the highest risk of bias.

There is no clear association between water fluoridation and overall cancer incidence and mortality. This was also true for osteosarcoma and bone/joint cancers. Only two studies considered thyroid cancer and neither found a statistically significant association with water fluoridation.

Overall, no clear association between water fluoridation and incidence or mortality of bone cancers, thyroid cancer or all cancers was found.

*OTHER POSSIBLE NEGATIVE EFFECTS*

A total of 33 studies of the association of water fluoridation with other possible negative effects were included in the review. Interpreting the results of studies of other possible negative effects is very difficult because of the small numbers of studies that met inclusion criteria on each specific outcome, and poor study quality. A major weakness of these studies generally was failure to control for any confounding factors.

Overall, the studies examining other possible negative effects provide insufficient evidence on any particular outcome to permit confident conclusions. Further research in these areas needs to be of a much higher quality and should address and use appropriate methods to control for confounding factors.

***Objective 5:***

The assessment of natural versus artificial water fluoridation effects is greatly limited due to the lack of studies making this comparison. Very few studies included both natural and artificially fluoridated areas, and direct comparisons were not possible for most outcomes. No major differences were apparent in this review, however, the evidence is not adequate to make a conclusion regarding this objective.

**Conclusions**

This review presents a summary of the best available and most reliable evidence on the safety and efficacy of water fluoridation.

Given the level of interest surrounding the issue of public water fluoridation, it is surprising to find that little high quality research has been undertaken. As such, this review should provide both researchers and commissioners of research with an overview of the methodological limitations of previous research conducted in this area.

The evidence of a benefit of a reduction in caries should be considered together with the increased prevalence of dental fluorosis. The research evidence is of insufficient quality to allow confident statements about other potential harms or whether there is an impact on social inequalities. This evidence on benefits and harms needs to be considered along with the ethical, environmental, ecological, costs and legal issues that surround any decisions about water fluoridation. All of these issues fell outside the scope of this review.

Any future research into the safety and efficacy of water fluoridation should be carried out with appropriate methodology to improve the quality of the existing evidence base.