Adding fluoride to water supplies

Adding fluoride to water supplies to prevent dental caries is controversial. K K Cheng, Iain Chalmers, and Trevor A Sheldon identify the issues it raises in the hope of furthering constructive public consultation and debate.

Several countries add fluoride to water supplies to prevent dental caries (boxes 1 and 2). Since the 2003 Water Act, water companies are required to add fluoride to supplies when requested—after public consultation—by a health authority in England or the Welsh Assembly in Wales.

Plans to add fluoride to water supplies are often contentious. Controversy relates to potential benefits of fluoridation, difficulty of identifying harms, whether fluoride is a medicine, and the ethics of a mass intervention. We are concerned that the polarised debates and the way that evidence is harnessed and uncertainties glossed over make it hard for the public and professionals to participate in consultations on an informed basis. Here, we highlight problems that should be confronted in such consultations and emphasise the considerable uncertainties in the evidence.

Known benefits of adding fluoride to water

In 1999, the Department of Health in England commissioned the centre for reviews and dissemination at the University of York to systematically review the evidence on the effects of water fluoridation on dental health and to look for evidence of harm. The review was developed with input from an advisory committee, which included members who supported and opposed fluoridation, or who had no strong views on the matter. Exceptional steps were taken to avoid bias and ensure transparency throughout.

Given the certainty with which water fluoridation has been promoted and opposed, and the large number (around 3200) of research papers identified, the reviewers were surprised by the poor quality of the evidence and the uncertainty surrounding the beneficial and adverse effects of fluoridation.

Studies that met the minimal quality threshold indicated that water fluoridation reduced the prevalence of caries but that the size of the effect was uncertain. Estimates of the increase in the proportion of children without caries in fluoridated areas versus non-fluoridated areas varied (median 15%, interquartile range 5% to 22%). These estimates could be biased, however, because potential confounders were poorly adjusted for.

Water fluoridation aims to reduce social inequalities in dental health, but few relevant studies exist. The quality of research was even lower than that assessing overall effects of fluoridation. The results were inconsistent—fluoridation seemed to reduce social

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Inequalities in children aged 5 and 12 when measured by the number of decayed, missing, or filled teeth, but not when the proportion of 5 year olds with no caries was used.

Potential harms of fluoridation

The review estimated the prevalence of fluorosis (mottled teeth) and fluorosis of aesthetic concern at around 48% and 12.5% when the fluoride concentration was 1.0 part per million, although the quality of the studies was low. The evidence was of insufficient quality to allow confident statements about other potential harms (such as cancer and bone fracture). The amount and quality of the available data on side effects were insufficient to rule out all but the biggest effects.

Small relative increases in risk are difficult to estimate reliably by epidemiological studies, even though lifetime exposure of the whole population may have large population effects. For example, an ecological study from Taiwan found a high incidence of bladder cancer in women in areas where natural fluoride content in water is high. The authors attributed the finding to chance because multiple comparisons were made. Testing the hypothesis that drinking fluoridated water increases the risk of bladder cancer would need to take account of errors in estimating total fluoride exposures; potential lack of variation in exposure; the probable long latency between exposure and outcome; the
presence of strong confounders such as smoking and occupational exposures; and changes in diagnostic classification of bladder tumours. Therefore, a modest association between fluoridation and bladder cancer would be difficult to detect, both in communities and in individuals. This is of concern because a modest (for example, 20%) increase in risk of bladder cancer would mean about 2000 extra new cases a year if the entire UK population was exposed.

The methodological challenges of detecting harms of long term exposure to fluoridation are further illustrated by a case-control study on hip fracture in England.12 It reported “no increase” in risk associated with average lifetime exposure of 20.9 part per million fluoride in drinking water. Although exemplary in many other aspects, the study had less than 70% power to identify an odds ratio of 1.5 associated with exposure. If the odds ratio was only 1.2—which would mean more than 10 000 excess hip fractures a year in England if the population was so exposed—the study would have a less than one in five chance of detecting it.

Thus, evidence on the potential benefits and harms of adding fluoride to water is relatively poor. This is reflected in the recommendations of the Medical Research Council (MRC)13 and the Scottish Intercollegiate Guideline14 on preventing and managing dental decay in preschool children (box 3). We know of no subsequent evidence that reduces the uncertainty.

There is no such thing as absolute certainty on safety. While the quality of evidence on potential long term harms of fluoridated water may be no worse than that for some common clinical interventions, patients can weigh potential benefits and risks before agreeing to treatments. In the case of fluoridation, people...
should be aware of the limitations of evidence about its potential harms and that it would be almost impossible to detect small but important risks (especially for chronic conditions) after introducing fluoridation.

**Alternative ways to prevent caries**
The evidence from systematic reviews of randomised trials is strong for alternative ways of preventing caries—mainly toothpastes containing fluorides. Analysis of 70 randomised trials of 42,300 children yieded a pooled preventive fraction for decayed, missing, or filled teeth of 24% (21% to 28%). However, the use of toothpaste depends on individual behaviour, which has implications for reducing inequality.

**Is fluoride added to water supplies a medicine?**
Fluoride is not in any natural human metabolic pathway. Because it mainly reduces caries by remineralisation of demineralised enamel (box 4), some people regard water fluoridation as a form of mass medication. Other people point out that fluoride occurs naturally at concentrations comparable to those used in fluoridation programmes and is therefore not a medicine. If viewed as a medicine, water fluoridation would require approval from a relevant authority.

**Is fluoride toothpaste sufficient to prevent dental caries?**

The legal definition of a medicinal product in the European Union (Codified Pharmaceutical Directive 2004/27/EC, Article 1.2) is any substance or combination of substances “presented as having properties for treating or preventing disease in human beings” or “which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.” Furthermore, in 1983 a judge ruled that fluoridated water fell within the Medicines Act 1968, “Section 130 defines ‘medicinal product’ and I am satisfied that fluoride in whatever form it is ultimately purchased by the respondents falls within that definition.”

If fluoride is a medicine, evidence on its effects should be subject to the standards of proof expected of drugs, including evidence from randomised trials. If used as a mass preventive measure in well people, the evidence of net benefit should be greater than that needed for drugs to treat illness. An important distinction also exists between removing unnatural exposures (such as environmental tobacco smoke) and adding unnatural exposures (such as drugs or preservatives). In the second situation, evidence on benefit and safety must be more stringent. There have been no randomised trials of water fluoridation.

**Ethical implications**
Under the principle of informed consent, anyone can refuse treatment with a drug or other intervention. The Council of Europe Convention on Human Rights and Biomedicine 1997 (which the UK has not signed) states that health interventions can only be carried out after free and informed consent. The General Medical Council’s guidance on consent also stresses patients’ autonomy, and their right to decide whether or not to undergo medical intervention even if refusal may result in harm.

This is especially important for water fluoridation, as an uncontrollable dose of fluoride would be given for up to a lifetime, regardless of the risk of caries, and many people would not benefit.

The convention makes provision for exceptions to the principle of informed consent if necessary for public safety, to prevent crime, or to protect public health (article 20). Potential benefit must therefore be balanced against uncertainty about harms, the lower overall prevalence of caries now than a few decades ago.
Box 4 | Effect of fluoride on the association between sugar and caries

Fluoride is the main factor that alters the resistance of teeth to acid attack and interacts with sugars in plaque. Fluoride affects tooth structure during and after development. It reduces caries in three ways:

- It reduces and inhibits dissolution of enamel
- It promotes remineralisation; remineralisation in the presence of fluoride not only replaces lost mineral but also increases resistance to acids and to subsequent demineralisation
- It affects plaque by altering the ecology of the dental plaque and reducing acid production

Fluoride is most effective when used topically, after the teeth have erupted.

Trust in the dissemination of evidence

Public and professional bodies need to balance benefits and risks, individual rights, and social values in an even-handed manner. Those opposing fluoridation often claim that it does not reduce caries and they also overstate the evidence on harm. In response to MRC recommendations, the department commissioned research on the bioavailability of fluoride from naturally and artificially fluoridated drinking water. The study had only 20 participants and was too small to give reliable results. Despite this and the caveats in the report's conclusion, this report formed the basis of a series of claims by government for the safety of fluoridation.

Against this backdrop of one-sided handling of the evidence, the public distrust in the information it receives is understandable. We hope this article helps provide professionals and the public with a framework for engaging constructively in public consultations.

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SUMMARY POINTS

Water fluoridation is highly controversial

Evidence is often misused or misinterpreted and uncertainties glossed over in polarised debates

Problems include identifying benefits and harms, whether fluoride is a medicine, and the ethical implications

This article provides professionals and the public with a framework for constructive public consultations

2 WHO. WHO oral health country/area profile programme. www.who.int/ohcp/areas/profile/regions.html.