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BMJ 2007;335:699-702  
doi:10.1136/bmj.39318.562951.BE

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# 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.<sup>1</sup>

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.<sup>9</sup> 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,<sup>9</sup> 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.<sup>9</sup>

Water fluoridation aims to reduce social inequalities in dental health,<sup>10</sup> 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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Accepted: 15 July 2007

**No water fluoridation**

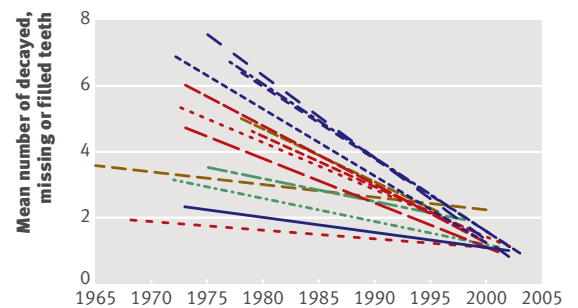
- Austria
- - - Denmark
- - - Finland
- - - Netherlands
- - - Sweden
- - - Greece
- - - Italy

**Water fluoridation (% population covered)**

- - - Germany
- - - Ireland (74%)
- - - Portugal (1%)
- - - Spain (3%)
- - - UK (9%)

**Data not given**

- - - France (40-50%)
- - - Belgium



Tooth decay in 12 year olds in European Union countries<sup>2</sup>

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,<sup>9</sup> 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.<sup>11</sup> 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

**Box 1 | Dental caries****What is dental caries?**

Dental caries is a process of demineralisation of dental hard tissue caused by acids formed from bacterial fermentation of sugars in the diet. Demineralisation is countered by the deposit of minerals in the saliva—remineralisation. Remineralisation is a slow process, however, which has to compete with factors that cause demineralisation. If remineralisation can effectively compete the enamel is repaired. If demineralisation exceeds remineralisation a carious cavity finally forms. Fluoride prevents caries by enhancing remineralisation.

**How common is caries?**

The figure shows the average numbers of decayed, missing, and filled teeth in 12 year old children for several European countries. In most countries this number is around 1.5 and 50% of children have no caries. Although the prevalence of caries varies between countries, levels everywhere have fallen greatly in the past three decades, and national rates of caries are now universally low. This trend has occurred regardless of the concentration of fluoride in water or the use of fluoridated salt, and it probably reflects use of fluoridated toothpastes and other factors, including perhaps aspects of nutrition.

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

**“Against this backdrop of one sided handling of the evidence, the public distrust in the information it receives is understandable”**

**Box 2 | Exposure to fluoride****How common are water supplies containing fluoride?**

About 9-10% of water supplies in England and Wales contain 0.5-1 mg/l fluoride, either naturally or as an additive.<sup>2-4</sup> Limited fluoridation trials were introduced in England from the mid-1950s, but resistance by water companies curtailed their spread. Currently, 1.5 million people receive water containing fluoride drawn from ground that is relatively high in the mineral. Another five million people in parts of the West Midlands, Yorkshire, and Tyneside receive water with added fluoride (1 mg/l). Fluoride is not added to water supplies in Scotland, Wales, or Northern Ireland.

In Western Europe 12 million people receive water with added fluoride, mainly in England, Ireland, and Spain.<sup>5</sup> In the United States, just under 60% of the population receive fluoridated water.<sup>6</sup> Water fluoridation has also been introduced in Australia, Brazil, Chile, Colombia, Canada, Hong Kong Special Administrative Region of China, Israel, Malaysia, and New Zealand. Worldwide, about 5.7% of people receive water containing fluoride to around 1 mg/l.<sup>5</sup> In some countries such schemes have been withdrawn. These include Germany, Finland, Japan, the Netherlands, Sweden, and Switzerland. Systematic information on the rationale behind these decisions is not available. In the Swiss canton of Basel-Stadt, the fluoridation scheme was withdrawn in 2003 after 41 years of operation because other measures were of “comparable effectiveness” to “compulsory medication”.<sup>7</sup>

**What are the sources of fluoride exposure?**

Before the widespread use of fluoride containing toothpastes, fluoride in water (natural or fluoridated) was the main source of exposure in adults and children.<sup>8</sup> Although the relative contribution from toothpaste has increased, in fluoridated areas drinking water remains the main source of exposure. Young children are more likely to ingest fluoridated toothpaste, so its relative importance as a source of exposure is higher in children than in adults.



illustrated by a case-control study on hip fracture in England.<sup>12</sup> It reported “no increase” in risk associated with average lifetime exposure of  $\geq 0.9$  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)<sup>13</sup> and the Scottish Intercollegiate Guideline<sup>14</sup> 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 flourides. Analysis of 70 randomised trials of 42 300 children yielded a pooled preventive fraction for decayed, missing, or filled teeth of 24% (21% to 28%).<sup>15</sup> 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?

#### Box 3 | Key recommendations for future research on water fluoridation

- “Studies are needed to provide estimates of the effects of water fluoridation on children aged 3-15 years against a background of widespread use of fluoride toothpaste, and to extend knowledge about the effect of water fluoridation by . . . (socio-economic status), taking into account potentially important effect modifiers such as sugar consumption and toothpaste usage”<sup>13</sup>
- “A robust evaluation of the benefits of water fluoridation, as well as the potential risks of fluorosis . . . should be a health priority”.<sup>14</sup>

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.”<sup>16</sup>

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.<sup>17</sup> An important distinction also exists between removing unnatural exposures (such as environmental tobacco smoke) and adding unnatural exposures (such as drugs or preservatives).<sup>18</sup> 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<sup>19</sup> (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.<sup>20</sup> 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 26).<sup>19</sup> Potential benefit must therefore be balanced against uncertainty about harms, the lower overall prevalence of caries now than a few decades

**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.

ago (and smaller possible absolute benefit), the availability of other effective methods of prevention, and people's autonomy. Research on areas suggested by the MRC is needed.<sup>13</sup> Methodological challenges due to problems of measuring fluoride exposure, long latency in chronic disease, and modest effect sizes will need special attention.

**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.<sup>21</sup> On the other hand, the Department of Health's objectivity is questionable—it funded the British Fluoridation Society, and along with many other supporters of fluoridation it used the York review's findings<sup>9</sup> selectively to give an overoptimistic assessment of the evidence in favour of fluoridation.<sup>22</sup> In response to MRC recommendations,<sup>13</sup> 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,<sup>23</sup> this report formed the basis of a series of claims by government for the safety of fluoridation.<sup>24</sup>

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.

We thank Edward Baldwin, June Jones, Aubrey Sheiham, and David Sloan for their comments on the manuscript.

**Contributors and sources:** All authors contributed to the original idea of the paper and its writing. TAS chaired the CRD fluoridation review advisory panel. IC was a member of the same panel. KKC lives in Birmingham where the water is fluoridated. The sections on potential benefits and harms of water fluoridation are largely based on a systematic review and recent materials identified through Medline searches. The rest of the paper reflects the authors' opinion. KKC is guarantor.

**Competing interests:** Please see the Contributors and sources section.

**Provenance and peer review:** Not commissioned; externally peer reviewed.

**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

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