

# PUBLIC BOARD PAPER HA09/020 MEETING – 26 FEBRUARY 2009

## Water fluoridation – the scientific evidence

<b>2008/9 Annual Plan key area of responsibility to which the paper relates (please mark in bold):</b>				
<b>Health and Well-Being / Inequalities</b>	Improve Clinical Standards	System Reform	Workforce and Capability	SHA Leadership
Finance	Information Technology-Enabled Transformation	<b>Knowledge Management</b>	Governance	Performance
<b>Links to SCSHA Risk Register / Board Assurance Framework (please complete):</b>				
Risk Register Reference	4.1			
Risk Description	PCTs fail to commission prevention and treatment services and address the inequalities in oral health, particularly for children, young people and vulnerable adults in parts of NHS South Central			

<p><b>Legal Implications (if any)</b></p> <p>The Board need to be aware of the overall conclusions of scientific studies of water fluoridation in order to determine whether the health arguments in favour of water fluoridation outweigh all arguments against water fluoridation.</p>
<p><b>Equality and Diversity Implications (if any)</b></p> <p>Fluoridation of the water supply is intended to reduce inequalities in dental health and has been formally assessed using standard Equality Impact Assessment processes.</p>
<p><b>Links to partnership working / public engagement (if any)</b></p> <p>Results of the consultation are not covered by this paper except that certain scientific arguments raised in the consultation are considered in relation to the scientific evidence. New scientific material presented to the authors during the consultation as relevant to the proposal was sent for independent critical appraisal and the results are reported in this paper.</p>

**Key Issues and Points for Discussion:**

*This paper summarises the scientific evidence on water fluoridation and addresses issues highlighted in discussion during the consultation process.*

*The available scientific evidence on water fluoridation suggests that it is effective at reducing tooth decay and can improve dental health inequalities. There is no reason to believe that water fluoridation is unsafe after widespread use for many decades. However, fluoridation does increase the level of dental fluorosis.*

*Primary Care Trusts are responsible for deciding on the most effective health promotion strategies for their population based on need. The scientific evidence supports Southampton City PCT's choice of water fluoridation against other options as an effective community public health intervention to reduce dental decay and reduce inequalities.*

*The consultation identified two major pieces of research that had not been adequately considered prior to consultation – a set of papers on the potential effect of water fluoridation on IQ and the US National Research Council report into the safety of fluoride in water supplies at more than 2 parts per million. This paper presents an independent critical appraisal of this research by Bazian. The paper also considers some of the other scientific arguments raised by those who oppose fluoridation.*

**Actions requested from / recommendations to the SHA Board:**

The Board is asked to consider the information and views expressed in this paper and use them to help determine whether the health arguments in favour of water fluoridation outweigh all arguments against water fluoridation.

The Board is asked to consider the Equality Impact Assessment recommendations on page 9 of Appendix 1.

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**Other committees / groups where this paper / item has been considered:**

None

**Date of paper:**

19 February 2009

# Water fluoridation – The scientific evidence

## Introduction and scope of this paper

1. The Nuffield Council on Bioethics published a report in November 2007 on the ethics of population-based public health interventions such as fluoridation. The Council emphasised the need for responsible authorities to justify their decisions by reference to peer-reviewed evidence of potential benefits and avoidance of harm. There was recognition in the report that the assessment of technical evidence was not well suited to a public consultation.

*“stewardship is not exercised simply by following the public vote, especially where issues involve complex scientific evidence”.*

2. The SHA therefore needs to take account of the level of support from scientific evidence when assessing the strength of the health arguments in favour of the proposals. It also needs to consider the cogency of arguments against the proposals by reference to the available scientific evidence, amongst other things.
3. This paper is a report to the Board by the Regional Director of Public Health and his staff and serves to:
  - briefly restate our view of the evidence as presented to the Board in May 2008, as summarised in the CDO’s letter of February 2008, and as summarised in the consultation document;
  - report the result of a formal equality impact assessment;
  - consider certain scientific issues raised with us during the consultation (although we do not have access to the full report of the consultation responses at the time of writing);
  - report the results of independent critical appraisal of evidence submitted to us during the consultation;
  - consider whether issues have been raised during the consultation that alter our earlier view of the scientific evidence in relation to this proposal.
  - provide full text versions of the two main reviews of the evidence and other key reports;
4. The conclusions presented in this report represent the professional opinion of the Regional Director of Public Health.

## Background

5. Results from surveys show that children in Southampton have some of the poorest dental health in the South Central SHA region and in the country. Dental decay can cause pain, requires repeated dental treatments, including the use of general anaesthetics, and can compromise eating, speaking and self confidence.

6. In 2005/6, the average number of decayed missing or filled teeth for 5 year-olds in Southampton was 1.76, compared with the national figure of 1.47. The average number of teeth affected in those children with decay was more than four teeth. A census of schoolchildren showed that dental health is substantially worse than this in socially deprived areas of Southampton.
7. Southampton City Primary Care Trust reviewed its existing oral health promotion initiatives and explored available options to improve oral health. In May 2005, the PCT asked the former Hampshire and Isle of Wight SHA to investigate the feasibility and costs of fluoridating the water supplies to the Southampton area, and subsequently asked South Central SHA to formally consult on a fluoridation scheme for the Southampton area.
8. In February 2008, the Chief Dental Officer wrote to Strategic Health Authorities and Primary Care Trusts<sup>1</sup> to:
  - show how fluoridation can reduce health inequalities and encourage PCTs to consider water fluoridation among other measures to improve the oral health of their populations;
  - give updated guidance on the respective roles of Strategic Health Authorities and Primary Care Trusts in planning, consulting upon and implementing fluoridation schemes;
  - provide guidance on the legislative framework governing the consultations and assessment of public opinion that SHAs need to undertake where they propose to make arrangements with a water undertaker to increase the fluoride content of a water supply; and
  - provide guidance on the technical and legal issues SHAs need to address in conducting consultations and making arrangements with water undertakers including the means by which water undertakers may be indemnified against any liabilities arising from the fluoridation of water.
9. In May 2008, the SHA was sufficiently persuaded of the feasibility and potential desirability of water fluoridation in Southampton to conduct a consultation on the proposal. The analysis of responses and a survey of those covered by the proposal are now available to the SHA and will be considered by the Board alongside this paper on the available scientific evidence.

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<sup>1</sup>[http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH\\_082666](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_082666)

## The evidence on water fluoridation

10. Water fluoridation is defined as the controlled addition of a fluoride compound to a public water supply in order to bring the fluoride concentration up to a level that effectively prevents caries. The recommended concentration of fluoride for this purpose is 1 part per million (ppm) in this country.

11. Water fluoridation is seen as one of the major achievements of public health in the last half of the twentieth century and its efficacy and safety as a dental public health measure has entered the professional orthodoxy. For example, the following is a quote from a review published in 2000 by the US Centres for Disease Control and Prevention:

*“Fluoridation of community drinking water is a major factor responsible for the decline in dental caries (tooth decay) during the second half of the 20th century. The history of water fluoridation is a classic example of clinical observation leading to epidemiologic investigation and community-based public health intervention. Although other fluoride-containing products are available, water fluoridation remains the most equitable and cost-effective method of delivering fluoride to all members of most communities, regardless of age, educational attainment, or income level.”<sup>2</sup>*

12. The safety and efficacy of water fluoridation has also been declared publicly by authoritative institutions internationally, such as the World Health Organisation, and by all those organisations in the UK (such as the British Medical Association and the Royal College of Physicians) that one might expect to have a legitimate view on it (see page 23, SHA consultation document for a list).

13. Approximately 10% of the UK population (6 million people) currently receive water with fluoride content at the optimal level (including naturally and artificially fluoridated areas). The West Midlands is the most extensively fluoridated area, followed by parts of the North East. The USA is the most widely fluoridated country in the world with approximately 70% of the population drinking artificially fluoridated water. Many other people receive fluoride in different forms as part of community-based dental public health strategies, for example via fluoridated salt in Germany, France and Switzerland.

14. Fluoride reduces dental disease by altering the balance between remineralisation and demineralisation of enamel away from breakdown and decay, towards repair. Much of this effect may be topical rather than systemic. However, regardless of how it acts, the body of evidence in support of fluoridation is based on direct observation that there is less dental disease in people who drink fluoridated water compared with those

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<sup>2</sup> Centers for Disease Control. 2000 Achievements in Public health, 1900 – 1999: Fluoridation of Drinking Water to Prevent Dental Caries. *JAMA*. 283(10):1283-1286.

who do not. Given that the first fluoridation scheme was introduced in the USA in 1945, and given that there are now over 300 million people worldwide who have received fluoridated water supplies for decades, there is plenty of such experience to draw on.

15. The questions that arise in relation to that evidence mostly relate to two fundamental issues. Firstly, critics question the inference that people in fluoridated areas have better teeth because they drink fluoridated water and not for some other reason (so-called confounding), and secondly they question whether there is sufficient evidence to confirm that water fluoridation is safe.

### **Does water fluoridation reduce caries and reduce inequalities in dental health?**

16. The proper assessment of a wide body of evidence requires a systematic review. More weight is given in such reviews to studies of better quality and unreliable or irrelevant studies are excluded. The Chief Medical Officer commissioned such a systematic review of the evidence on water fluoridation from the York Centre for Reviews and Dissemination in 2000.<sup>3</sup> A more recent systematic review was carried out by the Australian Government's National Health and Medical Research Council in 2007<sup>4</sup>. The findings from these reviews are central to the case supporting water fluoridation as a public health measure. The summaries of both reports are reproduced in full at the end of this paper.

17. On the key question of the effect of water fluoridation on dental caries, the York report (page xii) found that:

*“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.”*

18. The York review therefore concluded that water fluoridation was likely to be effective but it was difficult to say by how much. The review merged primary data from many studies to estimate that an additional 14.6% of the population were likely to be dental disease free as a result of water fluoridation. The range among individual studies was from a reduction of 5%, to an increase of 64%. The average reduction in number of affected

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<sup>3</sup> University of York NHS Centre for Reviews and Dissemination. Mc Donagh M. et al. A Systematic Review of Water Fluoridation. York: NHS Centre for Reviews and Dissemination. University of York, 2000. Available at URL [www.york.ac.uk/inst/crd/fluores.htm](http://www.york.ac.uk/inst/crd/fluores.htm)

<sup>4</sup> Australian National Health and Medical Research Council. A systematic review of the safety and efficacy of Fluoridation. Canberra. 2007. <http://www.nhmrc.gov.au/publications/synopses/eh41syn.htm>

teeth was likely to be 2.25 teeth (the range was 0.5 to 4.4).

19. The review also concluded that water fluoridation is likely to have effects over and above those of alternative preventive interventions and strategies. This was because studies conducted after 1974 still showed a beneficial effect despite the assumed availability of fluoride toothpaste in non-fluoridated areas.
20. Water fluoridation by its nature has at least the potential to produce universal benefits across all individuals in a population. Whereas approaches that rely on behaviour change, for example in relation to diet or dental hygiene, or compliance with a therapeutic intervention such as topical fluoride applications, are likely to fail in some cases however well they are promoted<sup>5</sup>. The York review concluded that there was some evidence that water fluoridation reduces inequalities in dental health across social classes in children using the dmft/DMFT measure. However, there were few studies and the reviewers considered them of low quality.
21. While drawing these conclusions the York review also described at length the limitations of the studies on which it based them. These were mainly due to the lack of randomised designs, or even of before and after designs, of the type more common in the assessment of clinical interventions, and the lack of measurement of potential confounding variables. The authors suggested that further studies should be conducted in such a way as to address these weaknesses in order to provide more reliable and precise results. The significance of these criticisms is discussed below.
22. The Australian National Health and Medical Research Council published a systematic review in 2007. They searched for any relevant additional research studies completed after the York review. This review confirmed and endorsed the results of the York review as follows:

*“The existing body of evidence strongly suggests that water fluoridation is beneficial at reducing dental caries. After adjustment for potential confounding variables, McDonagh et al (2000a) [the York review] showed in their systematic review that the introduction of water fluoridation into an area significantly increased the proportion of caries-free children, and decreased mean dmft/DMFT scores compared with areas which were non-fluoridated over the same time period. The findings of McDonagh et al (2000a) also suggest that cessation of fluoridation resulting in a narrowing of the difference in caries prevalence between the fluoridated and non-fluoridated populations. Only one additional relevant original study was identified in the current review and this did not change the conclusion of the existing systematic review.”*

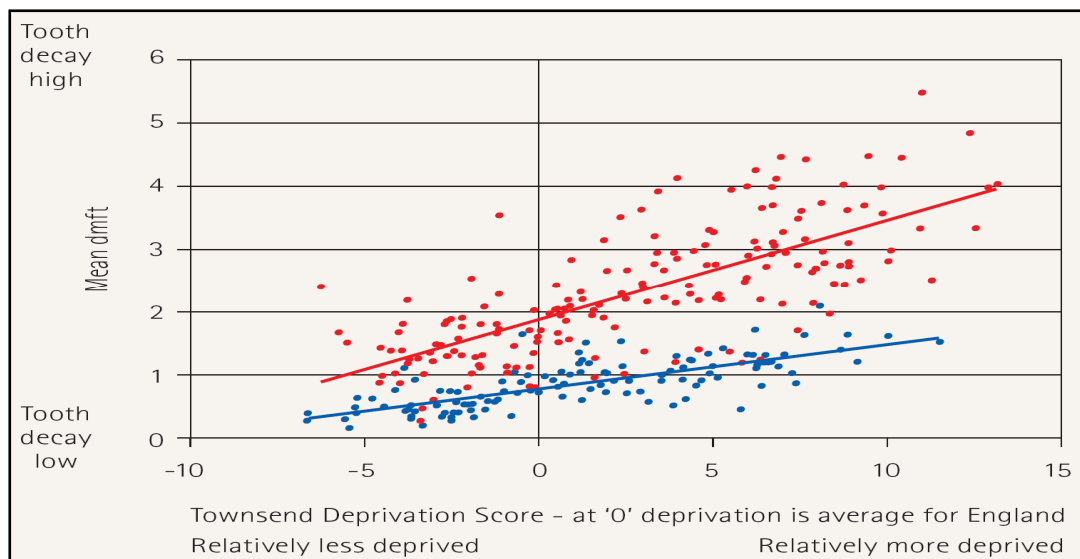
23. To illustrate the nature of the available evidence, data from one of the

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<sup>5</sup> <http://www.nice.org.uk/niceMedia/documents/effectivenessoralhealth.pdf>

studies included in the York review is reproduced with permission in Figure 1, below. Riley et al reported levels of dental decay in five year olds for electoral wards in fourteen Districts of England. These Districts were paired for potential confounders such as ethnicity and results compared according to the level of deprivation of the ward and the presence of water fluoridation. The Figure suggests not only that dental health was generally better in fluoridated areas but also that the effect of deprivation was mitigated by fluoridation (the gradient of the line is less for the fluoridated wards).

24. This is a study of low quality according to the York review because it is a cross sectional study (based on a survey not an experiment), because it is an ecological study (comparisons are made at the level of electoral wards not individuals) and because other possible causes of differences in the observed dental health were not measured for each ward (such as ethnicity or levels of use of fluoride supplements).



Source = Riley et al, 1999<sup>6</sup> Graph reproduced by permission of Oxford University Press

**Figure 1: Relationship between tooth decay and social deprivation in fluoridated (labelled blue) and non-fluoridated (labelled red) communities.**

25. In addition to the formal research studies considered in these reviews, information is available from direct observation of patterns of dental health in Britain and routine surveillance of health in fluoridated and non-fluoridated areas.
26. Large scale national child dental health surveys are conducted each year, co-ordinated by the British Association for the Study of Community Dentistry.<sup>7</sup> This survey shows that in areas where there is fluoride in the water, children generally have less decay than in areas of similar demographic profile where there is no fluoride in the water.
27. The majority of the available evidence looks at the effects of water fluoridation on dental disease levels in children. A recent systematic review however has found that the best available evidence suggests that water fluoridation is also effective in reducing dental caries in adults.<sup>8</sup>

## Dental fluorosis

28. There is a well established association between the prevalence of dental fluorosis (a form of discolouration of teeth) and the concentration of

<sup>6</sup> Riley JC, Lennon MA, Ellwood RP (1999) The effect of water fluoridation and social inequalities on dental caries in 5-year-old children. *International Journal of Epidemiology*, 28: 300-305.

<sup>7</sup> *NHS Dental Epidemiological Survey of 5 year old children in 2005/06* coordinated by the British Association for the Study of Community Dentistry <http://www.bascd.org/>

<sup>8</sup> Griffin SO, Regnier E, Griffin PM, Huntley V. 2007 Effectiveness of Fluoride in Preventing Caries in Adults. *J Dent Res* 86(5):410-415.

fluoride in the water. The York Report states that, at a concentration of 1ppm fluoride in the water supply, fluorosis of aesthetic concern is likely to be present in 12.5% of the population. Following the York Report, the Medical Research Council considered the likely prevalence of dental fluorosis in the UK<sup>9</sup>. The Council reports states:

*“In the UK, the prevalence of aesthetically important dental fluorosis is probably lower than that reported in the York Review. For example, a study by Tabari et al., (2000) found prevalence of fluorosis (in upper permanent incisor teeth) to be 3% in fluoridated Newcastle and 0.5% in non-fluoridated Northumberland. An EU BIOMED funded study (O’Mullane et al., 1999) reported the prevalence of aesthetically important fluorosis (based on photographic diagnosis) in seven European countries, including the UK. Results are reported in Table 3 [presented below as Table 1]. Only in Cork was the drinking water artificially fluoridated.”*

	Number of children photographed	Prevalence of aesthetically important fluorosis
Cork (Ireland) Fluoridated	325	4%
Knowsley (UK)	314	1%
Haarlem (Netherlands)	303	4%
Athens (Greece)	283	0%
Almada (Portugal)	210	1%
Reykjavic (Iceland)	296	1%
Oulu (Finland)	315	0%

Table 1: Prevalence of aesthetically important fluorosis in seven European countries. Source: EU BIOMED study, report to EU July 1999

29. The majority of cases of dental fluorosis are mild and the aesthetic concern is slight to the individuals concerned (see Figure 2).<sup>10</sup> The impact of mild fluorosis on measured quality of life (using the Oral Health Related Quality Of Life scale) is certainly less than that of dental caries, and may be non-existent or even positive.<sup>11</sup>

<sup>9</sup> Medical Research Council Working Group Report: Water fluoridation and health. London, MRC: 47. Available at URL <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002482>

<sup>10</sup> Rozier RG. 1999 The prevalence and severity of enamel fluorosis in North American children. J Public Health Dent. Fall;59(4):239-46

<sup>11</sup> Do LG, Spencer A. 2007 Oral health-related quality of life of children by dental caries and fluorosis experience. J Public Health Dent. 67(3):132-9.



**Figure 2: Very mild (left) and mild (right) fluorosis**

30. The positive effect on quality of life may seem counter-intuitive but is explained by the fact that the white flecking of enamel associated with very mild dental fluorosis can give the impression of having whiter than average teeth.
31. Severe dental fluorosis causes unpleasant brown staining and pitting of teeth but is seen in those countries with very high natural levels of fluoride rather than areas with water fluoridation schemes. Dental fluorosis can also occur in the absence of water fluoridation, for example if someone swallows large amounts of fluoride toothpaste.
32. Although the majority of fluorosis cases are mild and seem to be of little aesthetic consequence,<sup>12</sup> it is a known adverse consequence of water fluoridation. The risk of increased perceived aesthetic problems attributable to fluoridation must be weighed against its likely benefits. Experience in fluoridated areas of the UK is reassuring in that fluorosis remains a relatively uncommon presenting problem in the West Midlands and can be addressed if required by cosmetic dentistry as an NHS procedure.

## **Safety of fluoridation**

33. Although fluoride is a naturally occurring substance that is ubiquitous in the natural environment (sea water for example has 1.0 to 1.5 ppm of fluoride) it is important to for health professionals to establish that water fluoridation schemes are safe, and that there is no evidence of harm due to artificially increasing the content of fluoride in water supplies.
34. The York review considered this question and in particular reviewed available research studies of the effect of water fluoridation on the incidence of bone fractures and of cancers.
35. There were 29 studies that met the inclusion criteria for bone fracture and other bone development problems. The review found that:

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<sup>12</sup> Rozier RG. 1999 The prevalence and severity of enamel fluorosis in North American children. *J Public Health Dent.* Fall;59(4):239-46

*“there is no clear association of hip fracture and water fluoridation. The evidence on other fractures is similar. Overall the findings of studies of bone fracture effects showed small variation around the ‘no effect’ mark.”*

36. There were 26 studies looking at whether water fluoridation caused cancer. The York authors concluded that:

*“There is no clear association between water fluoridation and overall cancer incidence and mortality. This was also true for osteosarcoma and bone/ joint cancers. Two studies considering thyroid cancers did not find a statistically significant association with water fluoridation.”*

37. The Australian NHMRC report identified four additional studies which looked at cancer, one of which was a case control study of a subset of patients from a larger group. The results of this smaller study suggested an increased risk of osteosarcoma amongst young males (but not females) with water fluoridation<sup>13</sup> the same result is not seen in the bigger study. The authors of the larger study have cautioned readers not to over interpret the results of the smaller study.

38. In summary, the York systematic review found no association between water fluoridation and bone fractures, other bone development problems or cancer, however as before the review was critical of the quality of the research available and called for further projects to be carried out to higher scientific standards. The review also looked at a total of 33 other studies on the possible association of water fluoridation with other negative effects, including dementia, congenital malformations, Down syndrome, low IQ and thyroid disease. Overall these studies examining other possible harmful effects provide insufficient evidence on any particular outcome to make confident conclusions.

39. Demonstrating with certainty that any intervention is completely safe is intrinsically problematic. The best one can hope to achieve is a level of assurance that sufficient observations have been made that important adverse effects would have come to light had they been present.

40. The systematic reviews and the underlying research studies provide a good level of assurance in respect of bone fractures and cancer, although further studies would still be welcome. In addition in the UK, around 6 million people (approx 10%) currently receive fluoridated water and have done for more than two decades, the West Midlands being the most fluoridated region. Routine monitoring of the health of this region for example by cancer registries and through hospital morbidity statistics has not revealed any unusual health problems associated with water fluoridation.

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<sup>13</sup> Bassin EB, Wypij D, Davis RB & Mittelman MA. 2006. Age-specific fluoride exposure in drinking water and osteosarcoma (United States). *Cancer Causes and Control*. 17(4):421-428.

41. In countries where fluoridation is widespread (the USA has almost 70% of the population receiving fluoride) levels at 1ppm fluoride have not appeared to cause harm to the population.
42. A judgement has to be made as to the likelihood that a significant effect would by now have come to light were it to be present. The likelihood of detecting such a problem through routine surveillance depends on its severity and the level of risk (strength of association with fluoridation). The more serious the effect and the greater the risk attributable to water fluoridation the more likely it would have been apparent by now.
43. Given the huge (possibly uniquely large) number of people exposed to this intervention for many decades, during which adverse effects might have been expected to be reliably documented, one can conclude that if there are remaining undetected adverse effects they are minor or the effect is small.
44. This problem of small risks is not unique to water fluoridation. A study of over a million women was required to quantify the effect of hormone replacement therapy on breast cancer (a 20% increase in risk). Public health authorities must balance the theoretical risk that there are as yet undetected small or rare adverse effects of an intervention against the known benefits of that intervention and therefore the certainty of adverse outcomes if it is withheld.

## Equality Impact Assessment

45. In line with NHS good practice, the SHA commissioned an Equality Impact Assessment from the Public Health Research Unit based in Oxford in order to ensure that any inadvertent discrimination resulting from this proposal could be anticipated and if possible mitigated<sup>14</sup>.
46. The assessment is generally reassuring in that the authors predict definite or probable reductions in inequality as a result of water fluoridation in relation to ethnicity, gender, disability and age with speculative equality benefits also in relation to sexual orientation and religion.
47. Of the possible adverse equity impacts considered most are speculative or of low impact. The most important predicted adverse equity impacts were as follows:
- Potential for ethnically based inequalities in babies' intake of fluoride (due to differences in breastfeeding prevalence).
  - Some geographical areas with high prevalence of dental caries are not covered by the proposed scheme.
  - People with disabilities who receive non-oral fluids and nutrition may not get the benefit of fluoridation (impact depends on fluoride content of feeds).
48. A number of possible mitigating actions are suggested to tackle these predicted impacts if water fluoridation goes ahead and the Board is asked to consider the recommendations on page 9 of the Equality Impact Assessment in Appendix 1.

### Significant scientific issues raised with us directly in the consultation

During our participation at drop-ins, Question Time events and Local Authority Scrutiny Committee meetings, a number of scientific questions were raised by those concerned about fluoridation, including the declared anti-fluoridation campaigners. This section considers some of these questions in relation to the relevant scientific evidence.

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<sup>14</sup> [www.southcentral.nhs.uk/fluoridation/page.php?area\\_id=9996&id=6](http://www.southcentral.nhs.uk/fluoridation/page.php?area_id=9996&id=6)

Issue	Point raised	Comment
<p><b>Studies showing an effect on IQ not considered</b></p>	<p>A number of papers and a systematic review have shown that water fluoridation reduces IQ. This research has not been considered in the consultation document.</p>	<p>The SHA commissioned a specialist expert organisation (Bazian) to undertake a critical appraisal of this review. Their advice was that the studies are unreliable and do not constitute convincing evidence of harm. Bazian states:</p> <p><i>“In our appraisals we found that the study design and methods used by many of the researchers had serious limitations. The lack of a thorough consideration of confounding as a source of bias means that, from these studies alone, it is uncertain how far fluoride is responsible for any impairment in intellectual development seen. The amount of naturally occurring fluoride in drinking water and from other sources and the socioeconomic characteristics in the areas studied is different from the UK and so these studies do not have direct application to the local population of Southampton.</i></p> <p><i>Specifically:</i></p> <ul style="list-style-type: none"> <li>• <i>The authors of the primary observational studies have not consistently adjusted for the following confounding factors: the differences in environmental arsenic and iodine in water, parental education, and socioeconomic measures between the populations. There is a possibility that some or all of the impairment in IQ can be explained by these or other unmeasured or unknown factors.</i></li> <li>• <i>The authors of one of the systematic reviews have combined the results of these confounded observational studies into summary measures by meta analysis in a way that is not</i></li> </ul>

		<p><i>statistically appropriate or valid. The authors' interpretation of the results is incorrect.</i></p> <ul style="list-style-type: none"> <li>• <i>The findings are unlikely to be directly applicable to the population of Southampton because the level of fluoride found in the high fluoride areas in this research was generally higher than that intended for use in water fluoridation schemes (1ppm), or was confounded by varying levels of other chemicals in drinking water that are not a problem in the UK (iodine or arsenic).</i></li> <li>• <i>Sources of fluoride exposure exist in these settings that do not exist in the UK setting, for example, burning high fluoride coal and eating contaminated grain, which can substantially contribute to fluoride exposure."</i></li> </ul> <p>(see <a href="http://www.southcentral.nhs.uk/fluoridation/page.php?area_id=9996&amp;id=6">www.southcentral.nhs.uk/fluoridation/page.php?area_id=9996&amp;id=6</a> for the full critical appraisal).</p>
<p><b>US NRC report not considered</b></p>	<p>The consultation document does not adequately present the evidence of harm from water fluoridation. The US National Research Council review demonstrates harm to the pineal gland, bones, cancer, thyroid disorders, Down's syndrome, severe dental fluorosis, IQ and child development due to fluoride ingestion at close to 1ppm.</p>	<p>The SHA commissioned the same specialist expert organisation (Bazian) to undertake a critical appraisal of the National Research Council report. Their conclusion was that the report is not relevant to the proposed scheme because it considers much higher levels of fluoride (4ppm) than those envisaged in Southampton (1ppm). Bazian states:</p> <p><i>"In our assessment we found that the methods used by the book's authors had some important limitations and that the question it examines does not have direct relevance to the issue of fluoridation in Southampton.</i></p>

		<p><i>Specifically:</i></p> <ul style="list-style-type: none"> <li>• <i>The book was not a systematic review. The gold standard way of addressing questions about the effects of exposure is by using a systematic review, as this ensures that all evidence is identified and assessed in a transparent way using replicable methods.</i></li> <li>• <i>The maximum levels of water-borne fluoride for cosmetic or health safety recommended by the EPA, and examined in the book, are two to four times higher than the level of water fluoridation proposed for Southampton and higher than the 1.5ppm maximum level laid down by the European Union.</i></li> <li>• <i>The purpose of this book was to assess the risks of environmental contamination with fluoride at the maximum levels recommended by the EPA, and not to assess the health effects of water fluoridation schemes.”</i></li> </ul> <p>(see <a href="http://www.southcentral.nhs.uk/fluoridation/page.php?area_id=9996&amp;id=6">www.southcentral.nhs.uk/fluoridation/page.php?area_id=9996&amp;id=6</a> for the full critical appraisal).</p> <p>In fact the lay summary of NRC book<sup>15</sup> states:</p> <p><i>“The committee did not evaluate the risks or benefits of the lower fluoride concentrations (0.7 to 1.2 mg/L) used in water fluoridation. Therefore, the committee’s conclusions regarding the potential for adverse effects from fluoride at 2 to 4 mg/L in drinking water do not apply at the lower water fluoride levels commonly experienced by</i></p>
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<sup>15</sup> [dels.nas.edu/dels/rpt\\_briefs/fluoride\\_brief\\_final.pdf](http://dels.nas.edu/dels/rpt_briefs/fluoride_brief_final.pdf)

		<i>most U.S. citizens."</i>
<b>ADA advice on baby milk ignored</b>	The consultation document ignores the fact that baby milk formula would have to be made up with bottled (non-fluoridated) water, as recommended by the American Dental Association.	The American Dental Association states that the risk of developing significant dental fluorosis by making baby formula with fluoridated water is low. Their advice is that if parents were particularly concerned about the possibility of fluorosis then they could make baby formula up with bottled water that was low in fluoride to reduce their risks further <sup>16</sup> (a sample of bottled waters in the UK showed fluoride concentrations between 0.01 and 0.37 mg per litre). It is not a recommendation to avoid fluoridated water.
<b>Need to measure personal intake of fluoride from other sources</b>	<p>The SHA has not surveyed the current total fluoride intake of people in Southampton. In its <i>Guidelines for drinking water quality, 3rd Ed (2006)</i> the WHO stated that "<i>It was also emphasised that in setting national standards for fluoride, it is particularly important to consider ... volume of water intake and intake of fluoride from other sources.</i>"</p> <p>Dr Peter Mansfield found that 20.2% of the adult population</p>	<p>The Food Standards Agency has responded to Dr. Mansfield on the British Medical Journal website.</p> <p>Current COMA Dietary Reference Values are low compared with equivalent limits in Europe<sup>17</sup> and the US. They represent the level of intake known to be safe in relation to dental fluorosis. It does not follow that intake above that level is necessarily unsafe. The Committee on Toxicity reviewed the evidence then available on fluoride intake in 2003<sup>18</sup> and concluded that no adverse effects other than mild to moderate dental fluorosis would be expected to be associated with fluoride intake from food, either in adults or in children at the intake levels in the UK.</p> <p>The Department of Health keeps the target water fluoride dose in water fluoridation schemes under review to ensure the balance</p>

<sup>16</sup> [www.ada.org/prof/resources/topics/fluoride\\_letter\\_interim.pdf](http://www.ada.org/prof/resources/topics/fluoride_letter_interim.pdf)

<sup>17</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178633962601.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178633962601.htm)

<sup>18</sup> [cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2003/fluorine](http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2003/fluorine)

	<p>between 19 and 64 yrs old across all of England, Wales and Scotland is already exposed to above safe intakes of fluoride. In those areas with fluoridated drinking water, the proportion above the safe intake rises to 65% of adults. Safe intake has been set by the Committee on Medical Aspects of Food (COMA) as 0.05mg F /kg body weight/ per day. Above this safe level fluoride accumulates in the body and the bones to such an extent that by the time of retirement people can expect serious adverse health effects, even if they have avoided them successfully until that age.</p>	<p>between achieving maximum dental benefits and minimum prevalence of dental fluorosis is maintained. The UK Government and its scientific advisers continue to believe that, on the basis of experience in existing fluoridated areas in the West Midlands, North East and other regions, the target of 1 part per million should be retained. This will be kept under review as part of the overall process of monitoring the effects of current and future fluoridation schemes.</p>
<p><b>Alternatives have not been tried or not given sufficient attention</b></p>	<p>Other things should be tried first, such as oral health promotion. The NHS should be working with the less affluent families to reduce obesity and address other health issues before considering water fluoridation.</p>	<p>Before the SHA agreed to consult on the water fluoridation scheme, it was assured by Southampton City PCT that they had already assiduously pursued other approaches but that these had not been fully effective. Preventive strategies that rely on targeted work with those at most risk (the 'high risk' approach) are rarely as effective as strategies that address the underlying problem by reducing risk in all members of a population. In the case of dental caries, significant disease is not confined to subgroups at high risk. Strategies limited to those individuals would</p>

		fail to help the majority of cases. A population approach is therefore likely to be both more effective and more cost-effective than a 'targeted-population' approach alone. However, the combination of the two may be even more effective still. The evidence that oral health promotion interventions are effective is in fact weak. The Health Development Agency produced a useful review of the effectiveness of oral health promotion interventions <sup>19</sup> .
<b>The children concerned do not drink enough tap water</b>	Water fluoridation will not help the poorest children as they do not drink enough water.	The research suggests that water fluoridation is just as effective in the most disadvantaged areas. Even in those most socially disadvantaged, or those who consume very unhealthy diets, fluoridated water will still be used in preparing food and cooking, diluting squashes and when food outlets make up carbonated drinks on site.
<b>Inadequate research base</b>	Some scientists say the existing evidence is of poor quality and that research that adequately addresses the efficacy and safety issues has not been done.	Many authorities and professional organisations are completely satisfied with the evidence base in support of water fluoridation and have stated so in their publications.  The York review took an explicitly sceptical approach in order to fully test the strength of the evidence base. They set stringent standards for inclusion and rejected many studies as inadequate. Nevertheless, they were able to find 214 studies that met their criteria. The studies were graded A, B or C. The studies of efficacy were of grade B (moderate quality). Safety studies were more often of grade C (low quality). Safety is intrinsically difficult to demonstrate in research studies because they tend to have limited data collection periods and scope. For example, the pharmaceutical industry relies heavily on on-going surveillance

<sup>19</sup> <http://www.nice.org.uk/niceMedia/documents/effectivenessoralhealth.pdf>

		<p>systems to confirm the safety of drugs beyond initial clinical trials. In the case of water fluoridation, there has been decades of surveillance of the health of large populations exposed to fluoridated water. No harmful effects have been confirmed other than dental fluorosis, which is clearly demonstrable using the study designs that are said by critics to be unable to detect adverse effects reliably.</p> <p>Specific criticisms included the absence of randomised studies, that assessments of dental health were not blind to fluoridation status, and that confounding is inadequately allowed for in the observational epidemiological studies.</p> <p>There were 45 studies using a non-randomised before and after design. Randomisation would be extremely difficult to accomplish in practice, the legal and regulatory framework may not allow it, a number of schemes would need to be included simultaneously and the people would not be able to consent. Also, since the York review concluded that fluoridation was effective it may well be deemed unethical to withhold fluoridation from the control groups. It would be unfeasible to assess the dental health of a population in the UK without being reasonably well aware of the fluoridation status of the relevant water supply. There has been no change in fluoridation patterns for twenty years and these patterns are well known to dentists.</p> <p>Confounding occurs when a factor appears to be associated with an effect but is not in fact the true cause of that effect. It occurs when the actual cause is also associated with the apparent (false) cause. For example, consumption of tonic water is associated with</p>
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		<p>liver disease but is not the cause of it (the confounder in this case is gin). The York review criticised many studies for not measuring potential confounders. This is technically a valid criticism of any epidemiological study. However, in order for this to be a real rather than a potential problem, one must conceive that there is a strong association between these unmeasured causes (or preventers) of dental disease and water fluoridation, that is leading to an apparent effect due to the latter. The reviewers suggest that confounders that should have been measured included age, gender, social class, mean daily temperature, intake of fluoride, and use of fluoride in other forms. (They also mention method of measurement and training of examiners which would not be confounders but causes of measurement bias.)</p> <p>I am not convinced that there is evidence to support the contention that, for example, the variation in oral health that seems in these studies to be due to water fluoridation could actually be caused by variation in (say) level of intake of fluoride from other sources because it is closely correlated for some reason with patterns of water fluoridation. The same would be true for the other potential confounders – why would mean daily temperature be expected to be correlated with water fluoridation status and what evidence is there that it is? Two associations with the confounder need to hold for confounding to move from potential to actual, one with the effect and the other with the “false” cause, in this case, as it is proposed by the York reviewers, with water fluoridation. We believe the potential for the results of these studies to be explained by confounding although theoretically correct has been overplayed in the York review. The Australian review takes a significantly less sceptical view.</p>
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		<p>This is an important point and another example may help to explain our position. The tobacco industry argued for years that smoking did not cause lung cancer and the apparent relationship (they claimed) was confounded by socio-economic status. Smoking, they argued, was strongly associated with lung cancer because poorer people were more likely to have lung cancer due to a poor diet or the jobs they were likely to do, and poorer people smoked more. The contention was that if studies adjusted adequately for socio-economic status there would be no association with lung cancer. At least in this case there was some evidence that smoking was correlated with social class.</p>
<b>Further research is required</b>	No decision should be made until more research has been conducted	<p>It is not at all unusual for reviews to conclude that more research is needed.</p> <p>Following the York Review, the Medical Research Council (MRC) reported on what further research was required to improve knowledge about fluoridation and health.<sup>20</sup> The MRC report concluded that there was no evidence for any significant adverse health effects, but the need for better research prompted them to make a number of recommendations for the future.</p> <p>The important question is not whether further good quality research would help, but what does the existing research tells us we should do now?</p>
<b>If in doubt do not act</b>	As the evidence of safety is poor, you should apply the precautionary principle and not	<p>The precautionary principle has gained ground recently as a means of providing additional protection for health and the environment. It places greater responsibility on an activity proponent to establish</p>

<sup>20</sup> Medical Research Council Working Group Report: Water fluoridation and health. London, MRC: 47. Available at URL <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002482>

	<p>proceed with water fluoridation.</p>	<p>that the proposed activity will not (or is very unlikely to) result in significant harm. The February 2, 2000 European Commission Communication on the Precautionary Principle notes: <i>"The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU"</i>.</p> <p>However, we do not believe the principle should be applied in the case of water fluoridation in Southampton. Although it operates in the context of scientific uncertainty, it is applicable only when, on the basis of the best scientific advice available, there is good reason to believe that harmful effects might occur. In this case there is a clear scientific consensus based on a body of evidence that water fluoridation is in fact safe and effective. It would also seem very odd to apply the principle to a single fluoridation scheme in Southampton when 300 million people are receiving water fluoridation around the world without any apparent harm coming to them.</p> <p>The SHA must weigh the evidence of harm (due to dental fluorosis) against the harm of dental caries and extractions under anaesthetic at the rates they occur now if we do not act.</p> <p>The principle also reinforces the need to continue to be vigilant and to put in place adequate surveillance processes to monitor the health of populations receiving fluoridated water as required by the Water Act 2003.</p>
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## **Discussion**

49. Water Fluoridation is a well established and widespread public health intervention designated one of the top ten public health interventions of the last century.
50. There is a considerable body of evidence on the safety and efficacy of water fluoridation. This evidence has been extensively and recently reviewed. Those reviews conclude that water fluoridation prevents dental disease and is likely to reduce inequalities in dental health. There is no reason to believe that water fluoridation causes any harm to health other than dental fluorosis. In most cases fluorosis is a mild condition and only rarely a cause of significant aesthetic concern.
51. The evidence has been criticised but those criticisms are not sufficient to detract from the overall conclusions of the reviews. In particular, it is not credible that the apparent effect of water fluoridation in observational studies could be explained by strong confounding effects due to other unmeasured factors.
52. The NRC report and the studies suggesting a link between water fluoridation and IQ presented to us during the consultation have been independently assessed and do not provide any reason to change the above view.

## **Conclusions**

53. The balance of evidence in the systematic reviews from Centre for Reviews and Dissemination in York and the Australian National Health and Medical Research Council is in favour of the effectiveness and safety of water fluoridation. The new evidence presented as part of the consultation does not change the balance of the evidence.
54. In my view, the additional concerns described in this paper are of interest and the SHA has considered them but for the reasons stated they do not constitute cogent arguments that outweigh the health arguments in favour of water fluoridation.

Professor John Newton  
Regional Director of Public Health

19 February 2009

## **The University of York Review (2000) – Executive Summary in full**

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 (CI) 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 metaregression. 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.

## **Australian NHMRC review (2007) – Executive Summary in full**

The current systematic review considers the recent evidence relating to the efficacy and safety of fluoride interventions, with emphasis upon those able to be delivered as a widespread public health initiative. Therefore, the systematic review's research questions relate to the caries-reducing benefits and associated potential health risks of providing fluoride systemically (via addition to water, milk and salt) and the use of topical fluoride agents (such as toothpaste, gel, varnish and mouthrinse).

Whilst the review summarises the recent evidence, it does not constitute health policy or clinical practice recommendations.

A search of the literature was undertaken in the MEDLINE and EMBASE databases using EMBASE.com. In addition, the Cochrane Systematic Review and Clinical Trial Databases were searched to help identify additional systematic reviews and original studies. Due to the availability of recent systematic reviews, searches were limited to publications from 1996 onwards, with the intention that the current review would update the most relevant existing systematic review. Searches were also limited to English-language publications. The search was conducted in December 2006.

In total, 5418 non-duplicate citations were identified. After reviewing the potentially eligible, 77 citations were included in the review.

Based on type of intervention (ie, individual or population) and the outcomes assessed (efficacy or safety), the hierarchy of study designs considered most relevant for answering each of the clinical questions was defined. As the aim of the current review was to build upon the most relevant and recent existing systematic review for each research question, the lowest level of evidence accepted was also determined by the criteria that had been applied in the existing systematic review.

The findings of the systematic review are present in the context of the research questions:

Research question: *Is intentional water fluoridation more efficacious than no water fluoridation in the prevention of dental caries?*

The existing body of evidence strongly suggests that water fluoridation is beneficial at reducing dental caries. After adjustment for potential confounding variables, McDonagh et al (2000a) showed in their systematic review that the introduction of water fluoridation into an area significantly increased the proportion of caries-free children, and decreased mean dmft/DMFT scores compared with areas which were non-fluoridated over the same time period. The findings of McDonagh et al (2000a) also suggest that cessation of fluoridation resulting in a narrowing of the difference in caries prevalence between the fluoridated and non-fluoridated populations. Only one additional relevant original study was identified in the current review and this did not change the conclusion of the existing systematic review.

Research question: *Is intentional milk fluoridation more efficacious than no milk fluoridation in the prevention of dental caries?*

The results of the systematic review suggest that milk fluoridation is beneficial in the prevention or reduction of caries, although there is less good quality evidence than is the case for water fluoridation. The results of the two included original studies represent low levels of evidence; however, the results are consistent with milk fluoridation being associated with caries prevention, and cessation of milk fluoridation associated with worsening dental health.

Research question: *Is intentional salt fluoridation more efficacious than no salt fluoridation in the prevention of dental caries?*

No studies were identified which met the criteria for inclusion in this review. The results of the three before-and-after cross-sectional studies suggest that salt fluoridation reduces caries in populations of children aged from 6-15. However, it should be noted that these studies were considered to be of poor methodological quality, primarily due to the lack of assessment of, and adjustment for, potential confounding factors.

Research question: *Is the use of topical fluoride supplementation more efficacious than no topical fluoride supplementation in the prevention of dental caries?*

There is consistent Level I evidence from existing systematic reviews and a review of additional original studies that topical fluoride agents reduce caries in children, when compared to no topical fluoride supplementation. When compared to placebo/no treatment the magnitude of the effect achieved with varnish is greater than the other topical agents. However, when compared directly to each other, there is no significant difference between agents.

Research question: *Is a combination of topical fluoride supplementation products more efficacious than a single topical fluoride supplementation product in the prevention of dental caries?*

There is Level I evidence that some combinations of topical agents may be more effective at preventing/reducing caries than single agents.

Research question: *Does intentional water fluoridation result in dental fluorosis over and above no intentional water fluoridation?*

There is consistent Level III/IV evidence from existing systematic reviews that water fluoridation results in the development of dental fluorosis. However, the majority of dental fluorosis is mild and is not considered to be of 'aesthetic concern'. The number needed to harm (NNH) with water fluoridation at an optimal level compared with no fluoridation to get one additional person with 'any fluorosis' is approximately 6. The corresponding NNH to get one additional person with 'fluorosis of aesthetic concern' is approximately 22. Meta-analysis of additional original studies provides results consistent with those seen in the existing systematic reviews.

Research question: *Does intentional milk fluoridation result in dental fluorosis over and above no intentional milk fluoridation?*

One study provided Level IV evidence that milk fluoridation is not associated with significant levels of fluorosis. A statistically significant increase in fluorosis was seen in a number of age groups following the introduction of milk fluoridation; however, the majority of this fluorosis was mild and would not be considered to be of aesthetic concern.

Research question: *Does intentional salt fluoridation result in dental fluorosis over and above no intentional salt fluoridation?*

One level IV study provided evidence of a significantly increased risk of 'any fluorosis' associated with salt fluoridation. Two additional supportive studies which did not strictly meet the inclusion criteria were in agreement with the included study. There was no data relating to the risk of 'fluorosis of aesthetic concern'.

Research question: *Does topical fluoride supplementation result in dental fluorosis over and above no topical fluoride supplementation?*

Two level IV studies provide evidence regarding the impact of the use of topical fluorides on dental fluorosis. One study showed that fluoridated toothpaste may be associated with 'any fluorosis'. However, when 'fluorosis of aesthetic concern' was examined, no statistically significant difference between the higher fluoride dose group and the control group was found, and the prevalence of fluorosis in the higher dose toothpaste group was low (< 2%). One poor quality study in which fluorosis was measured after a campaign was implemented to reduce the amount of topical fluoride use in children suggested that a decrease in fluorosis was seen.

Research question: *Does a combination of topical fluoride supplementation products result in dental fluorosis over and above a single topical fluoride supplementation product?*

There is currently no evidence comparing combinations of topical agents with a single topical agent.

Research question: *Does intentional water fluoridation result in fracture over and above no intentional water fluoridation?*

The authors of the three existing systematic review concur that water fluoridation at levels aimed at preventing dental caries has little effect on fracture risk - either protective or deleterious. The results of the subsequent original studies support this conclusion, although suggest that optimal fluoridation levels of 1 ppm may indeed result in a lower risk of fracture when compared to excessively high levels (well beyond those experienced in Australia). One study also indicated that optimal fluoridation levels may also lower overall fracture risk when compared to no fluoridation (the latter was not the case when hip fractures were considered in isolation).

Research question: *Does intentional milk fluoridation result in osteoporosis or fracture over and above no intentional milk fluoridation?*

There is currently no evidence available to determine the impact of milk fluoridation upon fracture risk.

Research question: *Does intentional salt fluoridation result in osteoporosis or fracture over and above no intentional salt fluoridation?*

There is currently no evidence available to determine the impact of salt fluoridation upon fracture risk.

Research question: *Does topical fluoride supplementation result in osteoporosis or fracture over and above no topical fluoride supplementation?*

There is currently no evidence available to determine the impact of topical fluoride supplementation upon fracture risk.

*Does a combination of topical fluoride supplementation products result in osteoporosis or fracture over and above a single topical fluoride supplementation product?*

There is currently no evidence available to determine the impact of combination topical fluoride supplementation upon fracture risk.

Research question: *Does intentional water fluoridation increase the risk of cancer over and above no intentional water fluoridation?*

The existing systematic review by McDonagh et al (2000a) concluded that there is no clear association between water fluoridation and overall cancer incidence or mortality (for 'all cause' cancer, and specifically for bone cancer and osteosarcoma). The authors state that the evidence relating fluoridation to cancer incidence or mortality is mixed, with small variations on either side of the effect. The current literature review identified four additional studies that investigated the relationship between water fluoridation and cancer incidence or mortality, including three Level IV ecological studies and one Level II-3 matched case-control study (Bassin et al, 2006). The latter study compares the fluoride exposure of histologically-confirmed osteosarcoma cases with that of matched controls - a sub-set of patients from a larger case-control study initiated by the Harvard School of Dental Medicine that is yet to report its findings. After adjusting for significant differences at baseline between the cases and controls, the results of Bassin et al (2006) suggest an increased risk of osteosarcoma amongst young males (but not females) with water fluoridation. However, the attention of the reader is drawn to a Letter to the Editor by co-investigators of Bassin in which the letter authors point out that they have not been able to replicate these findings in the broader Harvard study, that included prospective cases from the same 11 hospitals. Furthermore, the bone samples that were taken in the broader study corroborate a *lack* of association between the fluoride content in drinking water and osteosarcoma in the new cases. The final publication of the full study is not yet available, and the authors of the Letter caution readers not to over-interpret the results of Bassin and colleagues in the interim.

Research question: *Does intentional milk fluoridation increase the risk of cancer over and above no intentional milk fluoridation?*

There is currently no evidence available to determine the impact of milk fluoridation upon cancer risk.

Research question: *Does intentional salt fluoridation increase the risk of cancer over and above no intentional salt fluoridation?*

There is currently no evidence available to determine the impact of salt fluoridation upon cancer risk.

Research question: *Does topical fluoride supplementation increase the risk of cancer over and above no topical fluoride supplementation?*

There is currently no evidence available to determine the impact of topical fluoride supplementation upon cancer risk.

Research question: *Does a combination of topical fluoride supplementation products increase the risk of cancer over and above a single topical fluoride supplementation product?*

There is currently no evidence available to determine the impact of combination topical fluoride supplementation upon cancer risk.

Research question: *Is intentional water fluoridation associated with other adverse effects over and above no intentional water fluoridation?*

The authors of previous systematic reviews concluded that the studies examining other possible negative effects of water fluoridation provide insufficient evidence to reach a conclusion.

Research question: *Is intentional milk fluoridation associated with other adverse effects over and above no intentional milk fluoridation?*

There is currently no evidence available to determine the impact of milk fluoridation upon other harms.

Research question: *Is intentional salt fluoridation associated with other adverse effects over and above no intentional salt fluoridation?*

There is currently no evidence available to determine the impact of salt fluoridation upon other harms.

Research question: *Is topical fluoride supplementation associated with other adverse effects over and above no topical fluoride supplementation?*

There is currently no evidence available to determine the impact of topical fluorides upon other harms.

Research question: *Is a combination of topical fluoride supplementation products associated with other adverse effects over and above a single topical fluoride supplementation product?*

There is currently no evidence available to determine the impact of combination topical fluorides upon other harms.



## Appendix 1. Equality Impact Assessment