



Hampshire
County Council

Report of the Water Fluoridation Panel

November 2008

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Foreword – by Chairman of the Review Panel Cllr Anna McNair Scott

I was warned at the outset that the Fluoridation debate is ‘tiger country’, and so it has proved! There can be few issues where opinions are as polarised, and the Review Panel is fully understanding of the conviction and sincerity of proponents on both sides of the argument. We have listened to the evidence and read widely, and what we learnt persuaded us of the value of looking at the whole picture rather than concentrating on the issues for Hampshire residents who would be affected by the proposal. In addition, this is the first time that the Water Act (2003) has been tested and we believed that the proposal should be scrutinised as thoroughly as was possible in the time available to us.



The picture is far from clear, and the most striking aspect of what we have found is the extent of ‘known unknowns’: John Doull, professor emeritus at the University of Kansas Medical Centre who chaired the American National Academy of Sciences committee reporting in 2006 on the subject, commented on the number of unsettled questions and the lack of certain information: ‘I think that’s why fluoridation is still being challenged so many years after it began. In the face of ignorance, controversy is rampant.’ For the same reason, we used as our benchmark the York Review of 2000 whose findings are still the most authoritative and are broadly confirmed by later studies such as the Australian Government’s systematic review of 2007.

A controversy that has bedevilled discussion of fluoridation in this country since 2000 is the misleading and selective use of the York Review to support arguments from both sides. Indeed, this was singled out for criticism by the Nuffield Council on Bioethics in their 2007 report on public health issues. We are disappointed that, despite this, the practice continues: it is a feature of the SHA’s consultation document, and the work of the British Fluoridation Society among others.

One question that the Review Panel felt had not been satisfactorily addressed is that of the ‘optimal’ dose. There are indications that this is an important ‘known unknown’. For example, there are now suggestions in the US that infant formula should not be made up using fluoridated tap water. When this was raised with witnesses, answers were dismissive and one cited the existence of Creationism in America as an explanation! Within memory we have seen rumours turn into known harms concerning asbestos, lead and aluminium: rampant controversy is inevitable while such questions remain unanswered.

The consultation offers no options apart from fluoridation at 1 part per million, and the Review Panel believes that this is a serious shortcoming. As things stand, there will be either winners or losers. One of our witnesses, Sir Iain Chalmers, a member of the advisory panel for the York Review, felt that there might be a positive way forward, and we are suggesting a third way which we believe has a real chance of addressing the needs of Southampton children without dosing the water supply for populations who do not share these problems.

The Review Panel would like to thank all those who have helped us to our conclusions: the witnesses who gave us their time and the benefit of their expertise, and those who provided invaluable written evidence. I would like to thank my colleagues and the observers for their support and for the thoughtful way they have contributed to the debate. Above all, the Review Panel would like to pay tribute to the Hampshire County Council officers for their unstinting work and without whom we might well have lost our way in the complicated jungle of tiger country.

Conclusions and Recommendations

The proposals to add fluoride to drinking water for parts of the population of Southampton City and south west Hampshire raised a number of complex issues. The Review Panel considered 7 distinctive but related themes in coming to its conclusions. These are set out below by theme.

Improving oral health:

- *Overall fluoride does have a beneficial impact on the prevalence of caries and improves oral health. In particular there is wide ranging evidence that the topical (surface) application of fluoride is beneficial.*
- *The Review Panel is not however of the view that the case put forward in the SHA consultation document is convincing in its argument that adding fluoride to drinking water is the only way to improve the oral health of 7 of the 11 deprived communities in Southampton City. In particular the Review Panel is concerned that:*
 - *There is little evidence of suitable quality to support the assertion that this action will reduce health inequalities.*
 - *Alternatives exist that are less intrusive and coercive.*
 - *The total exposure to fluoride in the population has not been evaluated and taken into account. The importance of this point has been emphasised by all the authoritative reference documents identified by the Review Panel as well as the WHO.*
 - *The introduction of fluoride to drinking water will result in some children within the population that have otherwise healthy teeth experiencing fluorosis. The extent to which this would be severe enough to be of aesthetic concern is disputed in the evidence, but a conservative (1 in 22) estimate based on the under nine population in the areas covered by the 2 schemes (source: Atkins) suggests that a total of 846 children in the area, of which 171 would be from south west Hampshire, could be affected by fluorosis of aesthetic concern. Taking a figure of 1 in 8, which is cited by the York Review, the number of children affected in this way would increase significantly.*
- *The consultation document does not give a complete picture of the oral health of the population affected, figures for 8, 12 and 15 year old children are not included.*

Ethics:

- *The balance of benefit and risk has not been presented in accordance with the findings of authoritative reports such as the York Review and MRC, nor has this been properly explained to local people.*
- *Other less coercive interventions are available to achieve the same goals.*
- *The conflicting principles involved meant that the Review Panel was unable to come to a consensus on the need for consent.*
- *The availability of other interventions and the inconclusive evidence relating to the impact of fluoridation on individual health requires that a precautionary approach be adopted.*

Impact on Health:

- *Adding fluoride to drinking water has the potential to result in an increase in moderate to severe fluorosis in the communities affected.*
- *There may be harms other than fluorosis as a result of adding fluoride to drinking water.*
- *The plausibility of other serious health impacts from the fluoridation of water reinforces the view of the Review Panel that a precautionary approach is needed until such time as additional research has been done. It is of serious concern that, despite this point being made repeatedly in the literature, credible research is still not available.*

Alternatives to adding fluoride to water:

- *Effective alternatives to adding fluoride to water do exist, with the potential to target those affected rather than the population as a whole.*
- *Particular opportunities exist for the creative use of skill mix to provide targeted support to vulnerable groups and using existing skills, such as those of health visitors more fully.*

Exposure to Fluoride:

- *Evidence has not been provided to demonstrate that adding fluoride to water at 1ppm equates to individuals receiving an optimal therapeutic dose. Current daily intake of fluoride from other sources may already exceed the equivalent of 1ppm in water.*
- *The recent decision of the Republic of Ireland to reduce the longstanding accepted dose for adding fluoride to water from 1 ppm to 0.7ppm brings into question the level of dosage for England as set out in the current legislation.*
- *Individual exposure will be affected by the addition of fluoride to drinking water at 1ppm as well as other sources.*
- *The conflicting information about using fluoridated water to reconstitute infant formula reinforces previous conclusions about the need to adopt a precautionary approach.*

Nature of Fluoride:

- *There is not sufficient evidence to show how individuals vary in the way in which they retain and excrete fluoride, or the impact that hard or soft water may have on this.*
- *There is not sufficient evidence to show that artificial fluoride acts in the same way as natural fluoride.*

Legal and Technical Issues:

- *The technical appraisals show that the options presented by the SHA for introducing fluoride to the water supplies of the full target population are neither viable nor effective.*

- *The projected costs are not sufficiently robust.*
- *The conflicting evidence received makes it difficult to determine if there are additional legal issues that need to be taken into account.*

Overall it is not clear what impact the addition of fluoride to the water will have on people living in Hampshire who will be affected by the schemes proposed. This population does not have the same dental health challenges as reported in Southampton City. There **may** be a benefit to Hampshire children living in the area affected but there is also a significant possibility that some children with otherwise healthy teeth could suffer from a degree of fluorosis, which **may** be of aesthetic concern and **may** be an indication of fluoride toxicity. Additionally there **may** be other health effects on the population as a result of adding fluoride to water at this level.

The proposals only cover 7 of 11 deprived areas identified by SCPCT in its population. If the evidence received is correct and one of the two schemes is not viable or cost effective this would reduce the deprived areas being covered to 6 out of 11. Other options exist for targeting the most vulnerable populations to improve the oral health of children and experience elsewhere has shown these to be effective.

As clearly stated in the following report the Review Panel is convinced by the sincerity, integrity and passion of all the stakeholders presenting evidence for consideration. The goal of eradicating poor oral health, particularly for children who may suffer significant pain and distress, is laudable. The Review Panel would also agree that the most vulnerable in our society should be protected and understands the notion that, in order to achieve the greatest good for the community as a whole preferences of individuals may be set to one side in some circumstances. However, where the evidence is unclear or equivocal about the impact of an action on individuals or communities, then those individuals and communities should be able to contribute to the discussion about the way forward in an informed and participative manner. The Review Panel has already made clear its concerns that this latter point has not been addressed in the consultation by the SHA. Equally it is apparent that the experience of the Review Panel in considering this matter replicates many of the concerns raised by Nuffield, and rehearses arguments that have taken place since the first fluoridation schemes were introduced over 60 years ago. To quote the comments of the Chairman of the U.S. National Academy of Sciences committee reported in a recent article in the journal *Scientific American* ‘in the face of ignorance controversy is rampant’.

Most significantly the Review Panel has been persuaded not to support the proposal by the lack of robust and reliable scientific evidence produced to support this proposal. It is clear that scientists and health professionals recognise that there are ‘unknowns’ with regard to the need to understand the effect of fluoride on the body (not just teeth). This work has simply not taken place. In the absence of scientific evidence of sufficient quality the Review Panel based its evaluation on the findings of the York Review informed by the work of the Nuffield Council on Bioethics.

In the light of the issues reviewed and the evidence received the Review Panel considers that this important debate needs to be held in a more mature and participative way than has been the case to date. The suggestion from Sir Iain Chalmers, that rather than simply asking if fluoride should be added to water supplies or not, communities should be engaged in contributing to research that is based on a more integrated approach to resolving problems of this nature, is one that the Review Panel would wish to see endorsed and commended to the SHA. It is therefore the view of the Review Panel that the following recommendations are made to the SHA on behalf of Hampshire County Council:

1. The SHA takes the lead, working with local stakeholders, communities and key national researchers in a way that conforms to the stewardship model advocated by the Nuffield Council, to understand better the options open to improving poor oral health in those affected and takes forward agreed programmes for achieving this objective. Initial approaches to recognised national commentators on this issue indicate a strong interest in, and willingness to contribute to, research of this nature.
2. Hampshire County Council agrees to actively engage with and support this work.
3. Taking account of the plausibility of harm a precautionary approach to the addition of fluoride to water be adopted until such time that clear evidence of benefit and harm has been established.
4. The alternatives to adding fluoride to water supplies to improve oral health are fully explored with a view to targeting the children affected rather than the population as a whole.
5. That further work be taken forward by the SHA and interested PCTs to establish the total daily exposure of populations to fluoride and understand the threshold at which this ceases to be therapeutic. This information should be accessible to all local people.
6. That the SHA and interested PCTs undertake further work to provide reliable information about the prevalence and severity of fluorosis in populations exposed to fluoride.
7. That the SHA actively and effectively promotes the publication of clear guidance about the use of fluoridated water to make up infant formula.
8. Taking account of the recent decision in the Republic of Ireland to reduce fluoride levels and the evidence base underpinning this the SHA lobbies the Department of Health to reconsider the level of 1 ppm set out in the legislation to ensure that this is robustly evidenced.
9. As a consequence of the evidence received by the Review Panel the projected cost and technical feasibility of the proposal is reviewed by the SHA.
- 10. Until such time as the further work outlined above has taken place the County Council does not support any proposal for adding fluoride to the water of people living and working in Hampshire.**

11. That the views of the County Council, which represents all Hampshire residents of Eastleigh, Test Valley and Totton affected by the proposals, are considered equally alongside those of other representative bodies. Additionally full account is taken of the range of evidence considered and the extensive engagement with local and national stakeholders that have informed the findings of the Review Panel.
12. That the Review Panel continues to evaluate the content and conduct of the consultation process, providing feedback to the SHA as appropriate.
13. That the Review Panel assesses the evaluation of the responses to the consultation, and the weighting given to feedback from the public and local authorities, to ensure that the views of the population affected are taken into account by the SHA Board.
14. That the Review Panel confirms whether or not it is satisfied with the balance of scientific and ethical issues considered by the SHA Board when coming to a decision, and reports back to full Council on this matter in order to allow Hampshire County Council to consider the scope for any further action required in the interests of the population of Hampshire that would be affected by the proposal.

1 Introduction

- 1.1 The South Central Strategic Health Authority (SCSHA) is conducting a public consultation running from 8 September to 19 December 2008 regarding the proposal to add fluoride to the drinking water at two distribution points serving part of the population in Southampton and south west Hampshire. The proposal has been put forward by Southampton City Primary Care Trust (SCPCT) to help improve dental health, on the grounds that alternative strategies have so far failed to make a significant improvement in the oral health of 5 year old children living in the most deprived areas of the City. The oral health of other age groups affected by the proposals is not included in the figures put forward by either SCPCT or the SCSHA.
- 1.2 Fluoridation is presented as having the potential to reduce levels of tooth decay in the areas receiving fluoridated water. The proposal affects 36,000 Hampshire residents as the homes served by the water treatment facilities in question include areas of Eastleigh, Totton and Test Valley. These populations do not have the same dental health challenges as Southampton City.
- 1.3 Fluoridation is a controversial issue, with vociferous groups strongly supporting or opposing its introduction to water supplies. The Hampshire Health Overview and Scrutiny Committee (HOSC) is not considered a statutory consultee in this case, as the fluoridation of water comes under the Water Act (2003), and is therefore not considered a variation in health services. However, the HOSC and the County Council will wish to contribute their views to the SCSHA as part of the public consultation. The Leader of the County Council asked the HOSC to look into this issue, and report to Full Council on 20 November. This report sets out the views of the Review Panel, including a recommended position, to support an informed debate in Full Council, at which time the County Council will come to a view on the proposal. Both this report, and the agreed stance of the County Council, will then be submitted to the SCSHA. It is expected that the SHA will give full and appropriately weighted consideration to the comments made by the County Council as a representative body of the people in south west Hampshire who will be affected by the proposal.
- 1.4 *Aim of the Review Panel:* To provide an informed, considered opinion to Full Council for debate, and subsequently to the South Central Strategic Health Authority, regarding the suitability of the proposed fluoridation scheme which affects Hampshire residents.
- 1.5 *Approach:*
- Written evidence was gathered, from national and international sources, regarding the fluoridation issue
 - Key experts and local stakeholders were invited to provide written and oral evidence
 - The proposals and how they may impact on the population affected were considered
 - The conduct of the public consultation was observed and comment passed to the SHA
 - The Review Panel weighed up the case and came to a conclusion regarding the suitability/desirability of the scheme
- 1.6 *Scope:*
The terms of reference of the Review Panel were: to consider the benefits and risks associated with the artificial fluoridation of water supplies to people living in south west Hampshire, recognising the intended benefits for target populations in

Southampton City, and to reach a view on whether the proposal should be supported as a public health intervention.

- 1.7 This included consideration of:
- The effectiveness of water fluoridation in improving oral health and addressing inequalities
 - The availability of alternative strategies for securing this objective
 - The risks and benefits associated with the fluoridation of water, taking account of the available evidence
 - The ethical issues raised by the proposal
 - The legal and technical matters to be addressed
 - The views of relevant experts and key stakeholders
- 1.8 The Review Panel did not invite comment from the general public, as local people are able to make their views known directly to the SHA as part of the formal consultation. The final decision regarding whether to go ahead with the proposed scheme rests with the Board at the SHA. The Review Panel has been carefully monitoring the content and conduct of the consultation exercise, and will be following the way in which the feedback received is weighted and presented to the SHA Board.
- 1.9 *Members of the Review Panel:*
Cllr Anna McNair Scott, Chairman
Cllr Brian Dash
Cllr Glynn Davies Dear
Cllr Phrynnette Dickens
Cllr Keith Evans
Cllr Marion Kerley
Cllr Carol Leversha
Cllr Dennis Wright
- 1.10 In the interests of sharing information, the Review Panel invited observers from the other local authorities affected by the proposals and the Hampshire Local Involvement Network (LINK) to attend the meetings of the Review Panel. This included representatives from Eastleigh Borough Council, New Forest District Council, Test Valley Borough Council and Southampton City Council.
- 1.11 The Review Panel considered evidence from the available literature, written evidence provided by stakeholders and oral evidence from stakeholders received at two ‘select committee’ style sessions held on 25 September and 6 October 2008.
- 1.12 The following stakeholders/ relevant experts were invited to provide evidence either as a written submission and/or in person at one of the ‘Select Committee’ Sessions:
- British Association for the Study of Community Dentistry
 - British Dental Association
 - British Fluoridation Society
 - Hampshire Against Fluoridation
 - Hampshire Local Dental Committee
 - Hampshire Primary Care Trust
 - National Pure Water Association
 - Nuffield Council on Bioethics
 - Portsmouth University (Community Dentistry Project)
 - Sir Iain Chalmers

- Southampton City Primary Care Trust
- South Central Strategic Health Authority
- Southern Water
- UK Councils Against Fluoridation

1.13 A webpage was set up for the fluoridation review, enabling the work of the Review Panel to be publicly accessible: <http://www3.hants.gov.uk/scrutiny/scrutiny-committees/health-overview-and-scrutiny-committee-2/fluoridation-review.htm>

1.14 Links are provided on this webpage to the full versions of the key literature the Review Panel considered. The webpage also provides links to the relevant stakeholder's websites, and clearly sign posts to the SHA fluoridation consultation pages.

2 Background to Fluoridation

2.1 What is Water Fluoridation?

Fluoridation (in relation to water) is the name for the process by which fluoride is added (in some form) to water supplies at water treatment plants. The chemical is added until the agreed concentration is reached. Officially defined acceptable concentration levels vary in different countries. In England the accepted concentration is 1.0 part of fluoride per million parts of water (ppm). In Ireland the agreed limit of 1 ppm was recently reviewed and reduced to 0.7 ppm. In some places fluoride is naturally present in water at this level or above, however in the UK the water supplied to the majority of the population has much lower fluoride content. In the Southampton area the natural level is 0.08ppm (10, appendix 2).

2.2 History of Fluoridation

In the early 1900s it was noticed that people living in some areas of the United States had dental fluorosis and fewer cavities, and that these areas had high natural fluoride content in their water. A biochemist did a study of the effect of fluoride on rats and concluded that fluoride reduced cavities. Following this, and the backing of key organisations such as the American Dental Association, fluoridation was first started in the United States in 1945 (using Sodium Fluoride [NaF]). Today fluoridation is achieved almost exclusively through use of hexafluorosilicic acid (HSiF) and its sodium salt (NaSiF). (17)

2.3 Fluoridation Uptake Worldwide

To date approximately 60% of water supplies in the United States are fluoridated. Other countries that fluoridate include Australia (all but one state covered), New Zealand (nearly all water supplies covered) and Canada (approximately 40% coverage) among others (see the SHA consultation document for further details). However, the countries of the European Union have largely chosen not to fluoridate, with for example Austria, Denmark, Finland, Netherlands and Sweden having no fluoridated water supplies. Scotland recently considered fluoridation, but after significant public opposition decided against it (in their consultation 97% of the responses received from members of the public which gave a view were against fluoridation). Ireland is the most significant exception in Europe as 66% of Ireland's water supplies are fluoridated. France has opted for fluoridated salt (with approximately 40-50% of the population covered).

2.4 In some EU Countries a small proportion of the population receives fluoridated water, for example Spain (3%), Portugal (1%), Germany (1.9%). England currently falls in this category as at present approximately 10% of the public water supplies in England

are fluoridated, with most of this concentrated in the West Midlands and the North. The schemes operating in England were mostly set up in the sixties, with the most recent initiated in 1985.

2.5 *UK legislative context*

The Water Act 1991 allowed that where a District Health Authority has requested that the water in their area be fluoridated, the water undertaker *may* increase the fluoride content of the water supplied within that area. The Act specified that the following compounds must be used in fluoridation schemes: hexafluorosilicic acid [H₂SiF₆] and/or disodium hexafluorosilicate [Na₂SiF₆] to a level of 1ppm. Evidence provided to the Review Panel by Southern Water suggests in the Southampton case hexafluorosilicic acid would be used. In various cases in the 1990's where fluoridation was suggested by health authorities, water companies ignored or declined such requests.

2.6 The Water Act 2003 amended the previous act, to *require* water companies to comply with a request from the local Strategic Health Authority to fluoridate water. However, it added that water undertakers are not required to initiate fluoridation until they have been given legal indemnity in respect of liabilities they may incur by complying with the request. This act also sets out that the relevant authority (the SHA) must consult, according to The Water Fluoridation (Consultation) (England) Regulations 2005, before undertaking fluoridation. The specifications as to the compounds to be used and the dilution to 1ppm were left unchanged.

2.7 In February 2008, Health Secretary Alan Johnson called on SHAs to make use of the powers enshrined in the 2003 Act, which have not been used to date. Therefore this proposal affecting Southampton and parts of Hampshire is the first to make use of the recent legislation. The government report 'A Futures Study of Dental Decay in 5 and 15 year olds in England' (7) suggests the government may be hoping that the proportion of the population receiving fluoridated water in this country increases to 60% in order to help meet targets for reducing dental decay in the future.

2.8 In coming to a view on a proposal the SHA is required to undertake public consultation, and within this to 'have regard to the extent of support for the proposal and the cogency of the arguments advanced' (27). In doing so the SHA cannot base its decision on a simple count of the responses for or against, but needs to take account of:

- The quality of the evidence presented
- The relevance of the representation to the health arguments in relation to fluoridation
- The nature of the individual/body making the representations.

In particular 'attention may need to be given to representative bodies' and when analysing the responses to understand... 'the methodology used to gain members input into the responses' (28).

3 **The Local Proposals**

3.1 Historically fluoridation has been a controversial issue, and this is not the first time this subject has been considered in Hampshire. In September 1977 Hampshire County Council accepted a recommendation from the Policy and Resources Committee that proposals to fluoridate water put forward by the Health Authority 'did not command widespread support from the public at large and should not be pursued'. The

controversy has not diminished over time; there are passionate and articulate arguments put forward both for and against the addition of fluoride to water.

- 3.2 The current proposal originates from a request made in May 2005 by Southampton City Primary Care Trust that the SHA investigate the feasibility and cost of fluoridating water supplies in the Southampton area. An independent feasibility study and economic analysis were undertaken and according to the paper presented to the SHA Board in May 2008 ‘show that it would be both feasible and cost effective to adjust fluoride levels in the water supply to parts of Southampton’(10). The Executive Summary notes that ‘the available scientific evidence on fluoridation shows that it is effective at reducing tooth decay and can improve dental health inequalities; however it does increase levels of fluorosis’(10).
- 3.3 In accordance with the Water Act 2003, the SHA Board approved going out to public consultation on the subject and will decide whether to approve the scheme detailed in the proposals ‘after taking full account of the views expressed in the consultation’(10).
- 3.4 The Board paper notes that 5 year old children in Southampton City have some of the poorest dental health across the NHS South Central region and in the country. It explains that the average number of decayed missing or filled teeth (dmft) for 5 year olds in Southampton was 1.76 compared with the national figure of 1.47 (BASCD data from 2005/06 survey). However, dental health is said to be ‘substantially worse in socially deprived areas’, for example in six schools the average dmft was found to be more than 3.0. Figures for 12 year olds were not mentioned.
- 3.5 The report states that ‘Southampton City PCT has reviewed its existing oral health promotion initiatives and explored available options to improve oral health’(10). In giving evidence to the Review Panel SCPCT gave a list of the alternative initiatives it has undertaken to improve dental health, and indicated that these programmes had not achieved significant improvements.
- 3.6 The SHA Board paper explains that it is for PCTs to assess the health needs of their populations and, where they think it is justified, to ask the SHA to investigate the feasibility and cost of water fluoridation. The SHA should proceed to a consultation if:
 - It has been requested to do so by a local PCT
 - A technically feasible scheme has been identified
 - The cost of the scheme seems affordable
- 3.7 If the above have been met, it is the SHA’s responsibility to undertake a consultation to assess adequately the level of local support for the scheme. The SHA should then consider the representations it receives and decide whether or not the health arguments in favour of the scheme outweigh all arguments against proceeding with the scheme.
- 3.8 In line with Department of Health guidance, the SCSHA commissioned a communications company to assess existing attitudes and levels of knowledge on the issue of fluoridation in the local area. They found that opinions about fluoridation varied considerably and ranged from staunchly in favour, through agnostic, to strongly opposed.
- 3.9 A question on fluoridation was included in a large public engagement exercise being run for other purposes (between January and March 2008). According to the report to the SHA Board ‘the results showed that more local residents are in favour of fluoridation in Southampton than are opposed to it, although half expressed no opinion

or were neutral. Two thirds of the population said they know little about the issue. Those who knew more about water fluoridation were more likely to be in favour of it.' (10) When asked 'to what extent do you support or oppose fluoride being added to the water?' 30% said 'don't know', 22% said 'neither support or oppose', 21% said 'tend to support', 8% 'strongly support', 9% 'tend to oppose' and 10% 'strongly oppose'. According to the SHA report 'the engagement exercise and the public survey provide sufficient preliminary evidence of local support to justify proceeding to a consultation' (10).

3.10 The report goes on to explain that in 1993, a fluoridation scheme was proposed by the then Southampton Health Authority with support from the local population. The scheme was not introduced because the local water company did not agree to it. However, now the Water Act 2003 requires water undertakers to adjust fluoride levels if requested to do so by an SHA.

3.11 The report also notes 'the Regional Director of Public Health's advice is that water fluoridation is effective at reducing tooth decay and reducing inequalities in dental health. Water Fluoridation has not been shown to have untoward effects other than an increase in the level of fluorosis, despite very widespread use for many decades.' (10)

4 Technical Details

4.1 Southampton's population is currently served through 5 water distribution zones. The Atkins feasibility study (14) evaluated 9 possible schemes for fluoridating the water at different points, and short listed 2 viable schemes, which together would supply approximately 160,000 residents of Southampton. (67% of the population of SCPCT).

4.2 SCPCT has identified 11 neighbourhoods which are considered a priority for fluoridation because of the level of tooth decay. The 2 viable schemes together cover 7 of these. According to the report presented to the SHA Board 'SCPCT is planning additional oral health promotion initiatives for those priority neighbourhoods not covered by the 2 schemes' (10), though no further information on this is provided.

4.3 The structure of local water supplies is such that some people living beyond the city boundaries would also be included in the schemes (approximately 36,000 Hampshire residents for the combined scheme). The report affirms that 'Hampshire residents involved in the scheme would have an opportunity to respond to the consultation' (10).

4.4 The two schemes identified as viable are referred to as 1 and 7:

- **1 involves the Otterbourne Indirect and Direct Distribution Zones**

(fluoridation to take place at the Water Treatment Plant)

Capital Costs: £210,000 **Revenue Costs per annum:** £40,800 (approx)

Coverage: indicated in red on the Map (Appendix One)

The area indicated in green on the map would occasionally receive fluoridated water due to water being exported from the fluoridated Otterbourne zone to this area.

- **7 involves Rownhams Distribution Zone**

(fluoridation to take place within the distribution system)

Capital Costs: £261,000 **Revenue Costs per annum:** £19,700 (approx)

Coverage: indicated in blue on the Map (Appendix One)

The Department of Health will pay the capital costs of the schemes if they go ahead. SCPCT would be responsible for the ongoing revenue costs.

5 Economic Implications

- 5.1 Economic Modelling was carried out by an independent company (Abacus). According to their report ‘the model suggests that the majority of the cost of the water fluoridation scheme would be offset by a reduction in the cost of dental treatment due to prevention of tooth decay. The net additional cost over a 20 year period is estimated to be £11, 526 or £576.30 per year.’ (13) Therefore, ‘Abacus suggest treating the economic picture as cost neutral, with a potential downside of a net cost of £782,000 over 20 years and a potential upside of £226,000 dental healthcare cost savings.’ (10)
- 5.2 Economic modelling suggested that a total of 36,032 carious lesions would be avoided over a 20 year period, at a cost per carious lesion prevented of £0.32. However, the report notes ‘results are most sensitive to the assumed efficacy of the water fluoridation scheme and this is difficult to predict with certainty.’ (13) These figures were based on an estimated reduction in caries of 25%. Abacus were referring to the work of Griffin et al who estimate the reduction in caries due to fluoridation to be between 12% and 29%. If the lower figure is used in the model (12%), the cost to the NHS would be £782, 271 or £45.23 per carious lesion avoided.
- 5.3 The report also notes that patients have to pay part of the cost of NHS treatment of tooth decay and therefore stand to benefit financially from prevention of tooth decay. However, it recognises there would be no saving for patients who are exempt from dental charges, such as children and those on benefits. As the population most likely to benefit from fluoridation are likely to fall into this category, it is arguable that cost savings for patients would be minimal as a result of this scheme.

6 Public Consultation arrangements

- 6.1 The Water Consultation (England) Regulations (2005) require a minimum of 3 months consultation and a ‘demonstrably conscientious consideration to the outcome of consultation’ particularly with regard to the ‘extent of support’ and ‘cogency of arguments advanced’ (10). The engagement process needs to be rigorous.
- 6.2 According to the SHA ‘Water fluoridation does not constitute a substantial development or change to health services within the terms of the Local Authority Regulations 2002’ (10), which means the HOSC is not a statutory consultee in this case.
- 6.3 The SHA developed a consultation strategy following the advice of the Chief Dental Officer. A paper containing details of their plans went to the SHA Board on 24 July 2008. The consultation period is due to run from Monday 8 September to Friday 19 December. (this was changed from the original anticipated start point of 4 August after feedback from local authorities). The report is clear that ‘no decision on adjusting the levels of fluoride in the local area will be made until a full and independent analysis of the responses received has been collated and reported to the SHA Board.’ (9).
- 6.4 The report also states ‘it is of paramount importance that people living and working in Southampton and South West Hampshire feel they have had a genuine opportunity to have their say’ (9). It notes ‘it is important that those people responding to the

consultation do so having received accurate and relevant information on the proposal and the consultation process'. (9)

- 6.5 The public are able to find out information and make their views known to the SHA in a variety of ways. Written responses can be sent to a free post address, via an online form on the website or by email. There is also a phone number people can ring to request a copy of the consultation document. The report recognises that the information provided to support the consultation 'needs to be clear, concise, accurate, informative and balanced' (9). The challenge in this case is that the issues around this topic often rely on complex scientific information. The Review Panel has provided early feedback to the SHA, and the Department of Health Review Team about the extent to which the SHA was successful in presenting a balanced case to the public (Appendix 5).
- 6.6 The SHA consultation document sets out the proposals, the issues and how people can find out more and have their say. The document is also available in the top three non-English languages used in Southampton (Punjabi, Urdu and Polish). Focus groups were carried out, involving a representative cross section of the local population, to test the language used in the document to make sure it is accessible. All material is available from the website www.southcentral.nhs.uk/fluoridation and has been distributed to key stakeholders.
- 6.7 The website includes a postcode checker so residents can find out if where they live will be affected, alongside a map of the proposed scheme. The website uses technology (RSS), so the public can 'subscribe' to the site and be alerted when new items are added. The website includes a short podcast giving a visual overview of the proposals and issues. A live webchat is also available for debate. The SHA plans to attend meetings of community groups, with a particular focus on 'hard to reach' groups.
- 6.8 The SHA is holding café style drop in events hosted in the local area to allow opportunities for discussion. According to the report, at these events information will be on display and SHA staff will be on hand to answer questions. These are located in easy to access locations with high footfall e.g. community halls and shopping centres. They run from noon through to 8 p.m. and it is proposed that some will be held on a Saturday. The details are due to be advertised in the local press in advance. Leaflets and posters are being used to raise awareness of the consultation, on display in GP practices, dental surgeries, libraries and other community locations and areas of high footfall.
- 6.9 The SHA is also holding 'Question Time' style events featuring representatives who are proponents and opponents of fluoridation, and these events will be independently chaired. Members of the public can attend and use the opportunity to ask questions of experts on each side. The discussion from these events will be recorded as part of the consultation process.
- 6.10 The report acknowledges the challenge that 'those who live in the priority neighbourhoods and who would benefit most from adjusted fluoride levels are perhaps least likely to respond to a consultation' (9), therefore activity will be targeted at these areas. The SHA will be writing to large employers in the area affected asking them to disseminate information about the consultation among their employees. The SHA will also be in regular contact with local media covering newspapers, radio and TV.
- 6.11 The SHA plans to carry out a phone poll across a representative sample of at least 1,000 people in the areas covered by the proposal, selected at random. This will be considered

a representative measure of public opinion, and will be fed into the overall response analysis.

- 6.12 It is anticipated that the final decision on whether to fluoridate will be made at an SHA Board meeting in public at the end of February 2009. The decision will be publicised through local media and directly to those people who have given their contact details as part of the consultation.

7 Evidence Base

- 7.1 A large proportion of the literature in this area consists of scientific studies assessing the impact of fluoridation on the human body. There is a vast quantity of information about fluoridation available on the internet, however much of this is contradictory and needs to be interpreted with caution. Key documents from authoritative sources have been identified which cover the range of issues involved in this debate, although there are disputed areas in each, particularly with regard to the weighting given to different areas of research.
- 7.2 What is known as ‘the York Review’ (1) published in 2000 is the most important document. This is a systematic review, which used internationally recognised criteria for selecting, assessing and grading all available published research from international sources. A systematic review is the most rigorous and reliable way of assessing any evidence base.
- 7.3 It is noted in the executive summary of the York Review that ‘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’. It goes on to suggest that ‘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’ (1).
- 7.4 A more recent systematic review was undertaken by the Australian National Health and Medical Research Council, published in 2007 (5). This review found little new evidence of sufficient quality beyond what was considered by York, and overall did not find anything to suggest the findings of York needed updating. Therefore, the Review Panel recommends that in terms of the scientific evidence relating to fluoridation the York Review be considered the primary source of evidence.
- 7.5 Fluoridation also raises ethical issues. It is proposed on the basis of promoting public health and reducing health inequalities, but there are ethical arguments both for and against pursuing this intervention to achieve these goals. The ethical considerations involved in public health measures have recently been studied by a body of academics specialising in medical ethics. Their report ‘public health: ethical issues’ (2) provides a good grounding in what policy makers need to weigh up when considering fluoridation. This is the key text the Review Panel used to inform their understanding of the ethics in relation to fluoridation.
- 7.6 After the publication of the ‘York Review’, the Medical Research Council was asked to identify any gaps in the research base around fluoridation. Their report (3) highlighted areas of continued uncertainty. This report was considered by the Review Panel.

- 7.7 Another useful recent review of the fluoride evidence was produced by the American National Academy of Sciences (4), which reviewed its recommendations regarding safe levels of fluoride to be added to water. This report was considered by the Review Panel.
- 7.8 A relatively short and accessible article was written in the British Medical Journal (6) by Sheldon, Chalmers and Cheng which serves to ‘emphasise the considerable uncertainties in the evidence’. This provides an introduction to the scientific discrepancies around fluoridation and provided an update on progress since the publication of the York Review as well as the issues that need to be considered in contemporary discussions about the potential benefits and disbenefits of adding fluoride to drinking water.
- 7.9 Selective interpretation of the research by both the proponents and opponents of fluoridation makes the evaluation of the evidence by non experts particularly difficult. Evidence provided to the Review Panel by stakeholders often cited individual studies or outdated research. The Review Panel has considered the evidence provided by the range of stakeholders, however Members were cautious not to rely on individual examples, as evidence provided by different stakeholders was contradictory.
- 7.10 Some stakeholders indicated that they have been convinced of the benefits of fluoridation through the evidence of observation of areas that have been consuming fluoridated water for many years. However, observation of real world situations does not enable sufficient consideration of what other factors may be influencing the trend being observed, and comparison between areas is difficult given the range of differences between populations.
- 7.11 The Review Panel have considered the observational evidence presented, however Members appreciate the limitations of this type of evidence and gave greater weight to information gathered via systematic reviews. Where the Review Panel felt there was uncertainty, or contradictory information they have referred back to the York Review as the most reliable source of evidence.

8 Evidence by Theme

- 8.1 The Review Panel were mindful of the weighting that the SHA was placing on arguments that are cogent and the use of ‘peer reviewed’ evidence wherever possible. These requirements place a considerable burden on a lay body and make it difficult for members of the public who are not familiar with this way of working to respond.
- 8.2 Additionally, although in coming to a view the Review Panel has sought to understand the needs of the population in Southampton, it is for Southampton City Council to comment on any aspect of SCPCT’s work in this area. The Hampshire population affected do not have the same dental challenges as Southampton, and Hampshire PCT has a clear oral health strategy for continuing to improve the oral health of the population. The co-operation between the Southampton City Health Committee and this Review Panel in considering this complex matter has been greatly appreciated, as has the willingness of SCPCT to respond so fully to all the questions raised by Members.
- 8.3 The Review Panel’s findings and conclusions are presented below under seven broad themes, each of which has been referenced as appropriate.

9 Improving oral health

- 9.1 Overall there is evidence in the literature that fluoride (as opposed to fluoridation) can help reduce the incidence of caries in teeth and there are particular benefits for children. (7, 26)
- 9.2 The evidence relating to benefits from topically applied fluoride is established (5,7,26). Other ways of controlling decay are also effective when used in conjunction with topical fluoride. Pit and fissure sealants can have an additional beneficial impact on the oral health of children who have persistent poor oral health (7), as ingested fluoride is not particularly effective in controlling dental decay on all surfaces of a tooth, such as pits and fissures (17).
- 9.3 The evidence for benefit from ingested fluoride is more variable in the extent of the improvements achieved (1, 2, 3, 4, and 5). The benefits attributed to water fluoridation date back to the 1940s and guidelines setting the level of fluoride to be added to water were introduced by the U.S. Public Health Service more than 40 years ago (4). The York Review suggested that ‘water fluoridation does appear to reduce caries’ however ‘interpreting from this data the degree to which water fluoridation works to reduce caries is more difficult’ (1, 4.9).
- 9.4 According to the York Review, the studies on the efficacy of fluoridation undertaken over the years indicate a large range of effect from a slight disbenefit to a substantial benefit. The analysis of this data gave a mean estimated effect of a 14.6% increase in caries free children in fluoridated areas. However, the York Review stresses that the existing evidence is not clear cut: ‘to have clear confidence in the ability to answer the question in this objective [what are the effects of fluoridation of drinking water supplies on the incidence of caries?] the quality of the evidence would need to be higher. The failure of these studies to deal with potential confounding factors or to provide standard error data means that the ability to answer the objective is limited’ (1, 4.9).
- 9.5 One of the ‘confounding factors’ identified by the York Review since the introduction of water fluoridation schemes is the considerable change in diet and lifestyle, with the

result that populations are now exposed to much greater levels of fluoride, including for example fluoride in toothpaste and mouth rinses, as well as rich sources from different foodstuffs, such as tea, fish and mechanically reclaimed meat.

- 9.6 It has not been possible for the Review Panel to determine how much fluoride needs to be ingested (regardless of source) in order to secure a therapeutic effect on the incidence of caries, or at what point the amount ingested increases the risk of possible harm. The suggestion of 1ppm is based on a historic situation when water was the main source of fluoride. There have been no subsequent controlled experiments and it has not been possible to evaluate variation in the amount of fluoride ingested at an individual level.
- 9.7 There is evidence of significant improvement over the past 30 years in oral health across populations regardless of whether they have fluoridated water. This trend is continuing, particularly in permanent dentition (5,7, 8). It is not clear if this has any implications for the case made for adding fluoride to water supplies, although the York Review noted that ‘the greater the population prevalence of tooth decay at the baseline examination the greater the effect of water fluoridation in decreasing this decay’. This point is particularly important in the context of the proposals from SCPCT and the economic modelling that has been undertaken to support the current consultation.
- 9.8 In some countries water fluoridation 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. However, it is suggested that in the Swiss canton of Basel-Stadt, the fluoridation scheme was withdrawn in 2003 after 41 years of operation in part because other measures were considered of ‘comparable effectiveness’ to ‘compulsory medication’ (6).
- 9.9 A recent article in the British Medical Journal reported that ‘levels [of caries] everywhere have fallen greatly in the past three decades, and national rates of caries are now universally low. This trend has occurred (see Figure 1 below) 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’ (6) .
- 9.10 The major contributory factor to the decline in caries in England over the last 20 years is the increased use of fluoride toothpaste (7), although it is recognised that broader socio-economic factors have a significant impact on the dental health of young people and that social class influences treatment choices. However, the Office of Public Management notes that ‘social factors only account for a small proportion of the variance in decay; 12 and 15 year olds who have decay have almost as much decay if they are from affluent as from deprived backgrounds.....there is a strong case for arguing that any targeting should be at the affected rather than the deprived’ (7).
- 9.11 There is evidence that in England overall dmft is improving, but those children from deprived backgrounds are likely to have a greater number of caries and are less likely to have ever visited a dentist. The Care Index for England suggests that there has been a decline in restorative care of primary teeth, although this trend is reversed for permanent teeth (7). Local health comparisons produced for south west Hampshire in 2004 note that ‘the Central area of Southampton has been shown to have the highest levels of dental decay amongst 5 years olds but also the lowest level of treatment’. It has not been possible to ascertain if this position has changed.

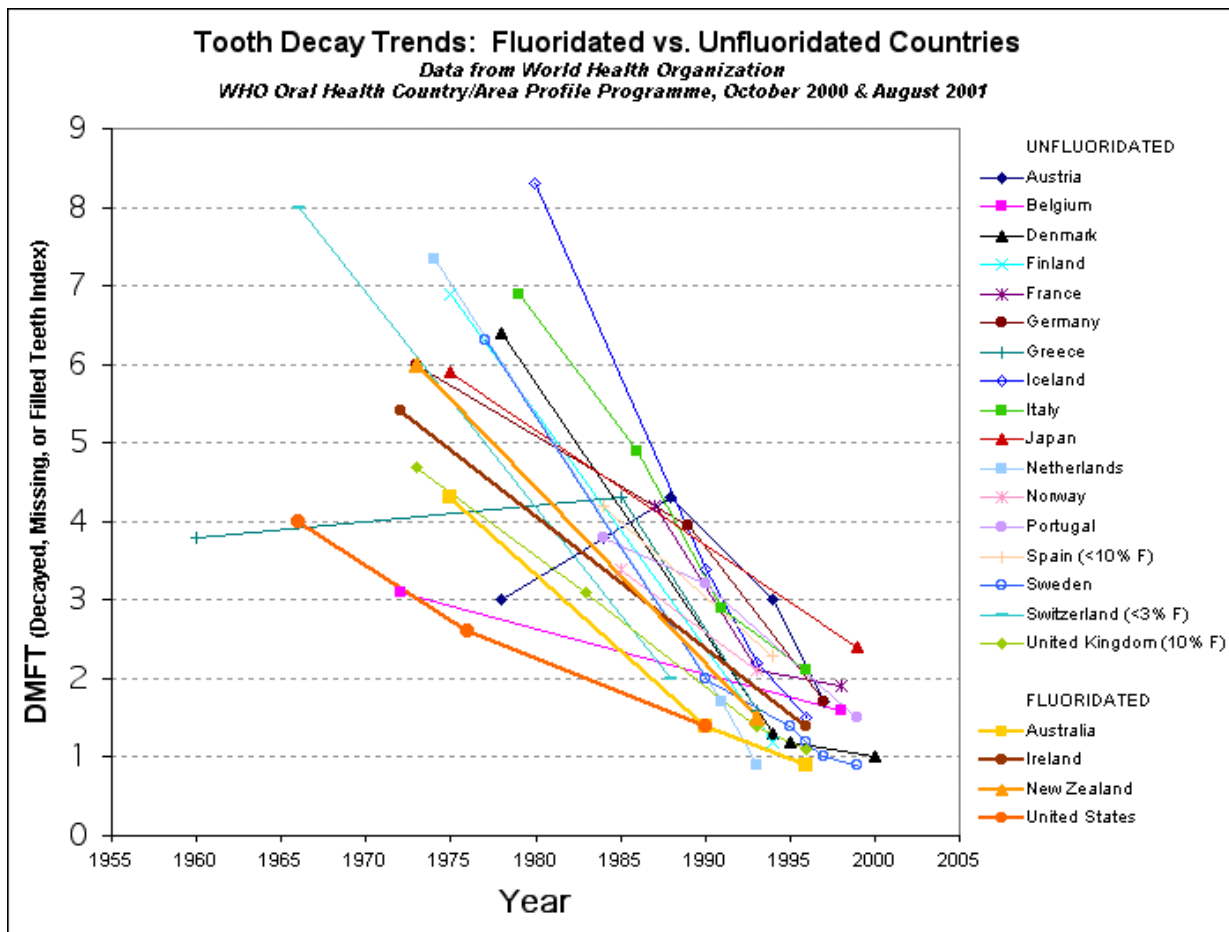


Figure 1 (Source – Sir Iain Chalmers presentation to the Review Panel)

- 9.12 Evidence was provided to the Review Panel by stakeholders comparing the dmft rates of areas in the UK receiving fluoridated water and non-fluoridated areas. This data indicated less decay was present in the fluoridated areas than the comparison areas. However, the Review Panel was cautious not to come to a view using this data alone, as statistics can be used selectively, and an association does not indicate a cause (as explained in an article ‘Causes, associations and evaluating evidence; can we trust what we read?’ published in the journal Evidence Based Dentistry in 2000).
- 9.13 The most frequent comparisons presented to the Review Panel compared SCPCT data to data from the fluoridated West Midlands such as Heart of Birmingham PCT (fluoridation in Birmingham was initiated in 1964). The table below demonstrates that although dmft was lower in Birmingham in 2005/06 than in Southampton, the situation was reversed in 2001/02. Other figures show a different trend, for example the rate of dmft in fluoridated Newcastle has increased over the same time period to over 2.00 (21). The Review Panel is of the view that a variable picture can be painted of the impact that the fluoridation of water can have on populations, depending on how the data available is interpreted. This brings into question the extent of improvement the proposed scheme would bring. The fact that fluoridated areas dmft rates are not universally and consistently low suggests that the differences observed in any particular year cannot be attributed to fluoridation alone and that other factors are playing a part.

Average dmft of 5 year olds by area, fluoridation status and year:

Area	2001/02	2005/06	Fluoridated
Southampton PCT	1.23	1.76	No
Heart of Birmingham PCT	1.57	1.35	Yes
Newcastle PCT	1.60	2.28	Yes

9.14 It is worth noting that the data provided by the SCPCT to support this proposal is based on decay rates of 5 year olds teeth. This relates to deciduous (milk) teeth which are replaced during childhood by permanent teeth. Data is also collected on the state of 12 year olds' teeth (by age 12 usually only permanent teeth remain). The situation is far better in this age group, indeed 'in England (in 2003) the mean DMFT in 12 year olds was 0.7, the lowest since records were first established. 12-year-old children in England now have the best dental health of their age in Europe' (22). The table below demonstrates the rates in Southampton (and the same 2 fluoridated areas as above) for 11/12 year olds teeth (21).

Average DMFT of 11/12 year olds by area, fluoridation status and year:

Area	2000/01 (12 yr olds)	2004/05 (11 yr olds)	Fluoridated
Southampton	0.84	0.69	No
Birmingham	0.52	0.36	Yes
Newcastle	0.84	0.87	Yes

9.15 The Review Panel could find no reported evidence that tested the impact that the changes to the dental contract have had on the way in which people access NHS dental services. SCPCT had no details of the children from the target areas that were registered with an NHS dentist, although they did report that six dentists in the City were able to accept NHS patients. Findings of the Health Select Committee do however suggest that a lower number of people are able to access NHS dental care as a result of the introduction of the contract, with some courses of treatment (such as single fillings) becoming more expensive. This can lead to some low income patients delaying visiting their dentist and 'storing up' dental problems. Additionally some complex work has decreased and there has been an increase in the number of teeth extracted (19). In its response to the Select Committee the Government noted that 'in Southampton some dental practices that are able to see patients report difficulty in getting uptake by patients' (15).

9.16 The Review Panel noted that the trends in oral health in England have mirrored the experience of the United States, where a majority of the population has had fluoridated water since the middle of the last century. Research indicates that there has been no change in the prevalence of dental caries in primary teeth in America in two time periods examined (1988-1994 and 1999-2002) with 41% of children experiencing dental caries. The incidence of caries in permanent teeth had however declined and the level of total tooth loss had reduced (8).

9.17 The Review Panel could find no credible evidence to support the claim that water fluoridation reduces oral health inequalities, particularly when the rates of decay were looked at across all age groups. Socio-economic factors are the main influence on health inequalities and health gradients: arguably it would make a greater impact on reducing dental health inequalities if these issues were targeted.

9.18 The York Review found that 'for all age groups and all social classes the proportion of caries free children is higher in the fluoridated than in the non fluoridated areas' (1, 6.1) and that 'caries experience is higher in the lower social classes than the higher social classes in both fluoridated and non fluoridated areas' (1, 6.1). From data relating to caries free children the York Review notes 'there is no evidence from these studies to suggest that fluoridation reduces the social gradient' (1,6.1) (see Figure 2 below).

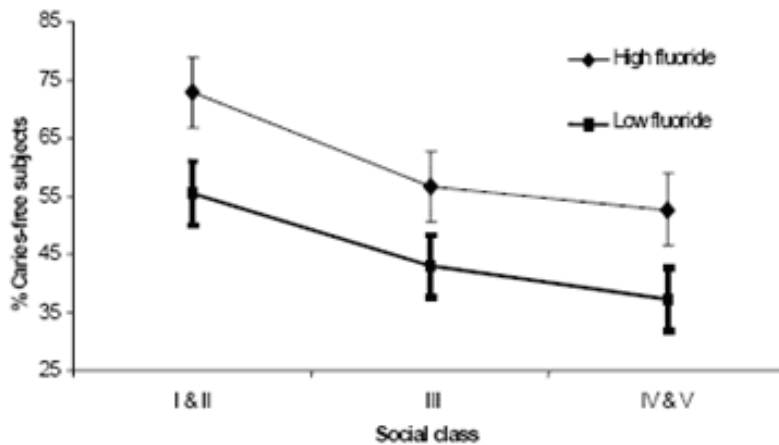


Figure 2: Proportion of (%) caries-free five-year old children (95%CI) by social class in high and low fluoride areas (source – York Review)

- 9.19 By dmft/DMFT the York Review states that ‘these data from 5 year old children suggest that water fluoridation is leading to a decrease in dmft across the social classes and reducing the inequalities in dental health between the social classes. However this trend is not seen in the other age groups. It may be a finding peculiar to the younger age group or it may be because only a very small number of studies were included in the older age groups’ (1, 6.2). In terms of evidence the authors were of the view that ‘while these studies provide an indication of the effect, the ability to answer this question is low’ (1, 6.4) and that ‘the small quantity of studies, differences between these studies, and their low quality rating, suggest caution in interpreting these results’ (1, 6.4). In assessing the impact on social inequalities the York Review considers that ‘the association between water fluoridation, caries and social class needs further clarification’ (1, 12.3). This point was subsequently reinforced in a statement from the authors in October 2003 which states that ‘the evidence about reducing inequalities in dental health was of poor quality, contradictory and unreliable’ (see Appendix Two).
- 9.20 There is evidence that targeted programmes can help change behaviours and improve oral health as exemplified by the progress achieved in Scotland (12) . Other initiatives such as the dental outreach work being piloted by Portsmouth University (see evidence received by the Review Panel, 25 September 2008) are able to target populations with accessible programmes. Members also noted the work being taken forward by Hounslow PCT which enables children to have fluoride varnish applied to their teeth while their parents do the weekly shop. This is undertaken by an extended dental nurse and is expected to cost 30p per application. In the pilot study approximately 85% of the children seen had no previous contact with the dental health system (15).
- 9.21 There is evidence of increased fluorosis across populations with fluoridated water but uncertainty about the extent of this. The Review Panel has heard that information about the extent of fluorosis in populations is not routinely collected by dental health professionals.
- 9.22 A number of studies suggest that moderate to severe fluorosis is of aesthetic concern and is indicative of too much fluoride being ingested. At least one study states that fluorosis is ‘a toxic effect’(4). Baroness Hayman in her response to questions in the House of Lords on 20 April 1999 stated that ‘we accept that dental fluorosis is a manifestation of systemic toxicity, since it is partially caused by blood borne fluoride’. It is not known if fluorosis is indicative of any other effects of fluoride on an individual.

- 9.23 The York Review suggests that up to 1 in 8 children may suffer fluorosis of ‘aesthetic concern’ as a result of water being fluoridated at 1ppm. The Medical Research Council suggests this is 3-4% and the more recent Australian systematic review supports the findings of the York Review.
- 9.24 The evidence received from stakeholders on this point was very contradictory therefore the Review Panel are of the view that the findings of the systematic review should be given precedence. It was deeply disappointing that this matter had not been subject to further evidential review since the York Review was published in 2000.
- 9.25 The Republic of Ireland has reduced its dosing level from 1ppm to 0.7 ppm to minimise the potential for fluorosis, and the Canadian Paediatric Society states that ‘a suitable trade-off between dental caries and fluorosis occurs around 0.7ppm. As the action of fluoride is topical no fluoride should be given before teeth have erupted’. As a result of these concerns, which were shared by the American Dental Association, American instructions for making up infant formula advise against using fluoridated tap water. The Review Panel did ask for the evidential base of the request for 1ppm to be added to drinking water in Southampton and south west Hampshire, and if there was evidence to suggest this was more efficacious than 0.7ppm. In response the SCPCT confirmed that the level of 1ppm is determined by the Water Act 2003. The Review Panel could find no systematic evidence that supported the level of dosing required by the legislation.
- 9.26 Diet has the greatest impact on oral health both directly and indirectly as teeth are influenced by diet prior to eruption. The frequent consumption of sugar is a major cause of tooth decay (1, 7). There has been an increase in sugar consumption in the population, particularly in the lower socio economic groups. Milk has been displaced from the diets of many children and young people by soft drinks and juices, with a corresponding effect on dental health from the sugars and acidity. The 1995 National Diet and Nutrition Survey suggests that children in England consume large quantities of carbonated drinks, squashes and fruit juices. Sales of soft drinks have increased since that time and it is therefore likely that the levels of consumption have increased. Night time drinking of soft drinks and the consumption of sugar between meals increase the risk of caries, as do the eating patterns of some families. One report suggests that caries incidence ‘can be reduced by up to 35% by increasing the use of sugar free chewing gum amongst young people’ (7, 6.1). Diet and oral hygiene can interact to help control caries.
- 9.27 The Review Panel was able to obtain a general list of the action taken by SCPCT to improve oral health in the population but was not clear what actual impact any programmes have had on the population most at risk. In response to questions about the basis for requesting such a coercive level of intervention for this population SCPCT commented that ‘oral health promotion programmes which include supervised tooth brushing schemes, promoting the use of high fluoride toothpaste, targeted fluoride varnish applications and dietary interventions for more than 10 years have not had measurable improvement at a population level’. A figure of 42000 was quoted by SCPCT when asked about the number of children living in the areas covered by the two schemes (see written evidence). Other evidence presented at the SHA public meeting on 20 October suggested that there had been significant improvements in children’s oral health in Southampton over the last ten years. This related to both primary and permanent dentition.

Conclusions: Given the discussions set out above the Review Panel is of the view that

- *Overall fluoride does have a beneficial impact on the prevalence of caries and improves oral health. In particular there is wide ranging evidence that the topical (surface) application of fluoride is beneficial.*
- *The Review Panel is not however of the view that the case put forward in the SHA consultation document is convincing in its argument that adding fluoride to drinking water is the only way to improve the oral health of 7 of the 11 deprived communities in Southampton City. In particular the Review Panel is concerned that:*
 - *There is little evidence of suitable quality to support the assertion that this action will reduce health inequalities.*
 - *Alternatives exist that are less intrusive and coercive*
 - *The total exposure to fluoride in the population has not been evaluated and taken into account. The importance of this point has been emphasised by all the authoritative reference documents identified by the Review Panel as well as the WHO.*
 - *The introduction of fluoride to drinking water will result in some children within the population that have otherwise healthy teeth experiencing fluorosis. The extent to which this would be severe enough to be of aesthetic concern is disputed in the evidence, but a conservative (1 in 22) estimate based on the under nine population in the areas covered by the 2 schemes (source: Atkins) suggests that a total of 846 children in the area, of which 171 would be from south west Hampshire, could be affected by fluorosis of aesthetic concern. Taking a figure of 1 in 8 , which is cited by the York Review, the number of children affected in this way would increase significantly.*
- *The consultation document does not give a complete picture of the oral health of the population affected as figures for 8, 12 and 15 year old children are not included.*

10 Ethics

- 10.1 There are strongly held opposing views about the addition of fluoride to water. The published research is contradictory and both proponents and opponents have used data selectively to make their case.
- 10.2 The Review Panel is convinced by the sincerity, integrity and passion of all the stakeholders presenting evidence for consideration. The goal of eradicating poor oral health and the pain and distress this condition can cause, especially to children, is laudable. The Review Panel would agree that the most vulnerable in our society should be protected and understands the notion that, in order to achieve the greatest good for the community as a whole preferences of individuals may be set to one side in some circumstances. However, where the evidence is unclear or equivocal about the impact of an action on individuals or communities, then those individuals and communities should be able to contribute to the discussion about the way forward in an informed and participative manner.

- 10.3 The polar opposite views on the addition of fluoride to drinking water are not new: many of the arguments presented have been well rehearsed for a number of years. The York Review, the most authoritative and objective assessment of all the available evidence, has been used and quoted selectively and misleadingly by both proponents and opponents. The Review Panel noted in particular the disclaimer published by the authors of the York Review in 2003 (see Appendix Two). It is deeply disappointing and unhelpful that this situation seems to have been perpetuated from the highest level rather than addressed since this publication. Further, where agreement exists about the need for additional research or clarification of the evidence, this has not taken place in such a way that evidence can replace emotion.
- 10.4 The experience of the Review Panel suggests that it is unlikely for the public to be able to come to an informed view on the proposals, taking account of both the possible benefits and plausible adverse effects. In the absence of consensus about the science underpinning the fluoridation of water it has been helpful to be able to refer to the ethical framework developed by the Nuffield Council on Bioethics (2). This considers public health ethics in depth, setting out some principles and a framework for guiding thinking on specific issues. It proposes a ‘stewardship model’ (see Appendix Three) and a ‘ladder of intervention’ (see Appendix Four) to guide decision makers in the area of public health policy. The authors support a ‘precautionary approach’ to public health decision making, replacing the less flexible ‘precautionary principle’, recognising that in the area of public health in particular there may be competing or conflicting ethical considerations or emerging empirical evidence.
- 10.5 The issues relating to water fluoridation create tensions between different principles. Accordingly the Nuffield Council suggests that ‘The acceptability of any public health policy involving the water supply should be considered in relation to:
- The balance of risks and benefits
 - The potential for alternatives that rank lower on the intervention ladder to achieve the same intended goals
 - The role of consent where there are potential harms.
- In the case of fluoridation there are considered to be benefits in reducing ill health and inequalities although these are difficult to quantify. There are also potential harms and therefore there is a need to consider in what context consent is relevant as well as the possibility of alternative approaches’ (2, 7.26).
- 10.6 When considering the benefits and risks to health of water fluoridation the report concludes that ‘there is evidence to show that fluoridation programmes are associated with benefits, although these are difficult to quantify, particularly in the context of the current historically low population caries levels. Similarly, there is evidence of harm, although there is debate over the extent and significance of the harm. This gives rise to the potential for two alternative, and opposing, applications of the precautionary approach. On the one hand, it could be suggested that because fluoridation offers the possibility of some benefits to health, it should be implemented. Conversely, given that fluoridation raises the possibility of some risks to health, perhaps its implementation should be prohibited as a precaution’ (2, 7.33).
- 10.7 When looking at alternatives to water fluoridation the Review Panel noted that other models did exist, some of which were not known to the SHA (e.g. the Portsmouth University Dental Outreach Project) and the wealth of evidence that states that fluoride is most effective when applied topically, rather than systemically. Progress achieved in Scotland (21, 2005/06 data) demonstrates that improvements can be achieved through targeting areas, and other work relating to oral health in England (7) points to the fact

that when looking at the incidence of caries it is better to target those affected rather than those that are deprived.

- 10.8 The Review Panel noted that no work had been done with the target population in Southampton City to ascertain the cause of continued poor oral health and how this may best be addressed. The Scottish Consumer Council (18) undertook work of this nature in 2005. This suggests that disadvantaged parents ‘would support approaches that addressed the root causes of oral health problems (including poverty and poor diet) rather than a ‘sticking plaster’ approach’ (for example adding fluoride to water). Concerns about fluoride expressed by these parents related to choice, information and safety, including the ability to ‘add up’ fluoride from different sources in order to judge their child’s need. The Consumer Council reported that targeted teeth cleaning schemes in Tayside and Glasgow in nursery and primary schools had led to a reduction of up to 37% in the incidence of tooth decay in two years. The Review Panel agrees this is an impressive result.
- 10.9 Another approach to improving oral health in Scotland which the Review Panel felt may be of note was the development of a coherent oral health strategy that set out a clear way forward supported by a detailed action plan (12). The Review Panel is not aware of any such approach underpinning the current proposal in Southampton, although Hampshire PCT does have a detailed oral health strategy. When asked about plans to address the oral health needs in the population not covered should the proposals to fluoridate water in Southampton City proceed the PCT stated they expect existing programmes to be supplemented.
- 10.10 Turning to the issue of consent, the Nuffield Council is clear that ‘if there were robust evidence that fluoridation of water was associated with a substantial likelihood of significant harm to individuals, individual consent would certainly be required. Alternatively, if there are no harms, but clear benefits, it might be argued that fluoride should be added by default without individual consent, in the same way as chlorine. Neither of these situations represent the current situation, in which there is some evidence of possible harms, and some evidence of benefits, though both are difficult to quantify’ (2,7.40). This point highlights the need for a clear and balanced account of the evidence: the absence of this is a significant concern as set out in the Review Panel’s letter to the SHA dated 13 October (see Appendix Five).
- 10.11 The Nuffield report is clear that ‘the most appropriate way of deciding whether fluoride should be added to water supplies is to rely on democratic decision-making procedures. Account should be taken of relevant evidence, and of alternative ways of achieving the intended benefit in the area concerned. Whatever policy is adopted, dental health and any adverse effects of fluoridation should be monitored.’ (2, 7.40). The Review Panel was concerned that despite this recommendation, the legislation requires that the decision regarding the addition of fluoride to drinking water be taken by an unelected body. Given this situation it is particularly important that the consultation process is thorough and balanced, providing a full opportunity for all affected to share their views. The SHA Board needs to satisfy itself that the content and conduct of the consultation process has provided local people with the information necessary to come to an informed view, and to take into account the extent of support for the proposal indicated by the population of Southampton and south west Hampshire through this process. This may be different from the views expressed by some professional interests.
- 10.12 The Director of the Nuffield Council on Bioethics, when giving oral evidence, indicated that in his view science may never give us a clear answer on the efficacy and

safety of fluoridation. Therefore, an element of judgement will inevitably be required. The Review Panel is concerned by the emphasis on peer reviewed evidence suggested in the SHA arrangements for evaluating responses to the consultation. In a situation where the science is not clear, personal judgement on whether the potential benefits are worth the risk of the potential harms, is a valid contribution to the debate.

Conclusions: Given the discussions set out above the Review Panel is of the view that

- *The balance of benefit and risk has not been presented in accordance with the findings of authoritative reports such as the York Review and MRC, nor has this been properly explained to local people*
- *Other less coercive interventions are available to achieve the same goals*
- *The conflicting principles involved meant that the Review Panel was unable to come to a consensus on the need for consent*
- *The availability of other interventions and the inconclusive evidence relating to the impact of fluoridation on individual health requires that a precautionary approach be adopted*

11 Impact on Health

- 11.1 The toxicity of fluoride is clear in the research: above certain levels a range of toxic effects can be demonstrated. What is less clear is the point at which the threshold of therapeutic benefit is reached and toxic effects begin to manifest themselves. The MRC notes that ‘with regard to dental caries and fluorosis, fluoride has a relatively low ‘therapeutic ratio’ (the ratio between biologically effective dose and toxic dose). There is a need to address the aggregate rate of accumulation of fluoride in target tissues and assess whether this is fast enough to incur the risk of pathology within a reasonable life span in more than a small (and defined) minority of those exposed’ (3, 3.6)
- 11.2 A review of fluoride in the Republic of Ireland notes that a third of a tube of fluoridated toothpaste can be fatal to a child (17). Experiments in animals have suggested a range of effects of fluoride on different systems including bone and hormones, however these effects are at levels currently much higher than those suggested are added to water supplies. Whilst there are some studies that suggest similar effects in humans these are not generally accepted as being of high enough quality to give a conclusive picture. The York Review noted that the effects of substances on animals were not always the same in humans.
- 11.3 ***Fluorosis***
Dental fluorosis was the most common adverse effect identified as a result of adding fluoride to drinking water, although as discussed above in the section on oral health, there were widely varying views on both the incidence and severity of fluorosis when fluoride is added to water at 1ppm.
- 11.4 The York Review considered 88 studies on fluorosis although the quality of these was generally poor. The views on the degree of fluorosis judged to be of aesthetic concern were informed by children aged 14 shown pictures. The authors reached the conclusion that ‘as water fluoride concentration increases so does the prevalence of dental fluorosis in the population’ (1, 7.1.) and that ‘the differences in the prevalence of dental fluorosis at 1.0 and 1.2 compared with 0.4ppm are statistically significant’ (1, 7.2).

- 11.5 York estimates the % of populations with fluorosis of aesthetic concern at 1ppm is 12.5% (1, 7.7) and that ‘increasing the water fluoride level from 0.4 to 1 ppm... would mean that 1 additional person for every 22 people that receive water fluoridated to this level would have fluorosis of aesthetic concern. However, the confidence limits around this value include infinity, which means that it is possible that there is no risk’ (1, 7.8). These findings have been confirmed by the recent Australian systematic review.
- 11.6 Although some stakeholders suggested that the incidence of fluorosis was due to children swallowing toothpaste or mouthwash the York Review disagreed, demonstrating that when comparing the prevalence of fluorosis data pre 1975 and post 1985 (when the use of fluoridated tooth paste could be assumed), little difference was evident (1, 7.5) (see Figure 3 Below)

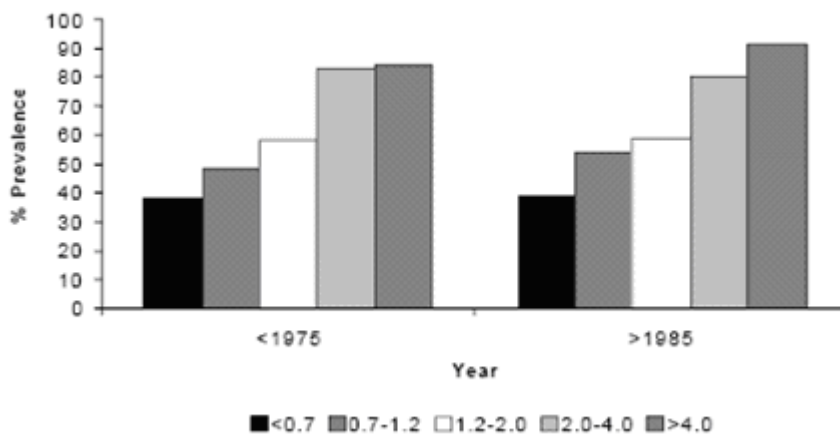


Figure 3: Prevalence of dental fluorosis at different water fluoride levels before 1975 and after 1985 (Source – York Review)

- 11.7 Figure 3 does indicate a clear dose-response relationship between level of fluoride in water and the prevalence of fluorosis. Subsequent reports highlight ‘better information is needed on the prevalence of different forms of dental fluorosis (and their visual/aesthetic impact)’ (3, lay summary).
- 11.8 American research published in 2006 (4) points to significant damage to teeth that are severely fluorosed and that ‘the committee finds the rationale for considering severe enamel fluorosis only a cosmetic effect to be much weaker for discrete and confluent pitting than for staining...severe enamel fluorosis compromises that health protective function by causing structural damage to the tooth. The damage to teeth caused by severe enamel fluorosis is a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effects’ (4).
- 11.9 Additionally the report notes that ‘the committee finds that it is reasonable to assume that some individuals will find moderate enamel fluorosis on front teeth to be detrimental to their appearance and that it could affect their overall sense of well being’ (4).
- 11.10 **Hip Fracture**
Hip fracture is another area reported to have an increased risk resulting from the addition of fluoride to water. The York Review considered this carefully finding generally poor quality research and conflicting results. As a result they reported that ‘using a qualitative method of analysis, there is no clear association of hip fracture with water fluoridation’ (1, 8.5).

- 11.11 The American National Academy of Sciences (4) called for more research into the relationship between fluoride ingestion, fluoride concentrations in the bone and stages of skeletal fluorosis before any conclusions about risk can be reached. The report suggests that although fluoride might increase bone volume there is less strength per unit volume. Biological and physiological data indicate a biologically plausible mechanism by which fluoride could weaken bone. As some people - such as those with renal disease - are prone to accumulate fluoride in their bones, they could be more vulnerable to any such effect. Additionally ‘overall, there was consensus among the committee that there is scientific evidence that under certain conditions fluoride can weaken bone and increase the risk of fractures. The majority of the committee concluded that lifetime exposure to fluoride at drinking water concentrations of 4mg/L or higher is likely to increase fracture rates in the population, compared with exposure to 1mg/L, particularly in some demographic subgroups prone to accumulate fluoride into their bones (e.g. people with renal disease).’ It should be noted that this review looked at higher levels of fluoride in water than is currently proposed by SCPCT. However, this is relevant when considering the total exposure of individuals to fluoride (see section 13), which could take them over the equivalent of 4mg/L.
- 11.12 A recent article in the British Medical Journal (6) highlights ‘the methodological challenges of detecting harms of long term exposure to fluoridation are further illustrated by a case-control study on hip fracture in England. It reported ‘no increase’ in risk associated with average lifetime exposure of around 0.9 ppm 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 1 in 5 chance of detecting it’. This indicates that small increases in the risk within a population would be hard to detect although the plausible harm to an individual may be significant.
- 11.13 **Cancer**
Links with fluoride and cancer, particularly bone cancer is a third recurring theme in the debates about the possible health impact of adding fluoride to water supplies. Again the York Review explored this carefully, considering research of mixed to poor quality that gave conflicting results. As a result the authors came to the view that ‘overall these studies do not appear to show any association between overall cancer incidence and water fluoride exposure’ (1, 9.1). Looking specifically at bone cancer again produced conflicting results leading to the conclusion that none of the studies found a statistically significant association’ (1, 9.2). Studies relating to osteosarcoma yielded one that suggested a statistically significant association between fluoridation and increased prevalence of osteosarcoma in males (1, 9.2)
- 11.14 Since the publication of the York Review other research has been published suggesting a plausible link between osteosarcoma in male children and water fluoridation, however the Australian systematic review cautions ‘the results of Bassin et al (2006) suggest an increased risk of osteosarcoma amongst young males (but not females) with water fluoridation. However... a Letter to the Editor by co-investigators of Bassin in which the authors point out that they have not been able to replicate these findings in the broader Harvard study... 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’ (5, page 12).

- 11.15 Other cancers were considered by the York review but no clear association was identified. The recent BMJ article suggests one of the reasons for this may be that ‘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 ... would mean about 2000 extra new cases a year if the entire UK population was exposed’ (6).
- 11.16 In terms of understanding the potential impact of adding fluoride to water on other aspects of individual health the Review Panel noted that other findings of the National Academy of Sciences (4) included:
- The Environmental Protection Agency assumes that adults drink 2 litres of water per day. Certain populations drink far more or are exposed to other important sources of fluoride (e.g. athletes, outdoor workers and those with certain medical conditions such as diabetes). On a per body weight basis children and infants have approximately three to four times greater exposure than do adults.
 - The best available study, from Finland, suggested an increased rate of hip fracture in populations exposed to fluoride at concentrations above 1.5 ppm
 - More research is required to clarify any effects of fluoride on intelligence as well as brain chemistry and function
 - Some effects of fluoride on the endocrine system are associated with fluoride concentrations in drinking water at 4ppm or less, especially for young children and individuals with high water intake. Further research is required to explore if adverse health effects or the risk of developing adverse health effects might be associated with seemingly mild imbalances or perturbations in hormone concentrations.
 - Bone is the most plausible site for cancer associated with fluoride because of its deposition into bone and its mitogenic effects on bone cells in culture.

Conclusions: Given the discussions set out above the Review Panel is of the view that

- *Adding fluoride to drinking water has the potential to result in an increase in moderate to severe fluorosis in the communities affected.*
- *There may be harms other than fluorosis as a result of adding fluoride to drinking water.*
- *The plausibility of other serious health impacts from the fluoridation of water reinforces the view of the Review Panel that a precautionary approach is needed until such time as additional research has been done. It is of serious concern that, despite this point being made repeatedly in the literature, credible research is still not available.*

12 Alternatives to adding fluoride to water

- 12.1 There are a number of different options for providing fluoride to improve oral health. Some of these are ingested interventions, such as the addition of fluoride to salt, milk or supplements. Others are applied interventions, such as fluoride varnishes or gels and fluoridated toothpaste.
- 12.2 In Switzerland, where 87% of salt is fluoridated, it is seen as being as effective as water fluoridation and that the prevalence of caries is reduced by 30%. Fluoridation of salt is seen as a reasonable alternative to water fluoridation (17). Fluoridated salt would come lower on the Nuffield ‘intervention ladder’ than water fluoridation because consumer choice can be preserved. Some argue that fluoridating salt may lead to an increase in

salt consumption which can be detrimental to health for other reasons. However, experience in countries using fluoridated salt does not indicate higher consumption of salt. The Australian systematic review considered the evidence relating to salt fluoridation to be of poor quality, although significant reductions in DMFT (up to 73%) were reported. None of this research was considered to be of a standard suitable for inclusion in the review (5).

- 12.3 There is insufficient research to demonstrate the impact of fluoridated milk on dental caries, but it is suggested that school children do benefit, especially their permanent teeth. In the U.K. milk fluoridation was first introduced in 1993 and is able to reach children in areas that suffer some of the highest levels of dental decay, such as Greater Manchester (17). The recent Australian systematic review notes that whilst the evidence relating to the effectiveness of milk fluoridation is generally low, research comparing populations in Sefton and the Wirral show less dental disease in children attending school with a milk fluoridation programme. This ‘suggests that milk fluoridation may be an effective method for preventing dental caries’ (5).
- 12.4 Fluoride supplements are not generally recommended except where there are significant risk factors and only provided to children over three years of age. The effectiveness of supplements is uncertain as compliance may be difficult to guarantee (17).
- 12.5 Fluoride gels, toothpastes and mouth rinses reduce DMFT regardless of whether water is fluoridated. Tooth cleaning schemes in Tayside and Glasgow in nursery and primary schools have shown a reduction in tooth decay of up to 37% (18). Daily, weekly and fortnightly mouth rinsing programmes have been shown to be effective but cost more than water fluoridation (17). According to the National Fluoride Information Centre ‘in countries where toothpastes are more or less the only form of fluoride available, general levels of dental decay have fallen by over 50%. Dental experts have agreed this is almost entirely due to the use of fluoride toothpaste. Similarly, a recent review of clinical studies lasting two to three years showed that fluoride toothpastes reduced decay in baby teeth by 37% and in permanent teeth by 24% when compared to non-fluoride toothpaste.’ (16). Additionally, mouth rinses ‘have been shown to reduce dental decay in adult teeth by 26%’ (16).
- 12.6 Fluoride varnish is another effective preventative measure ‘if applied twice a year fluoride varnish can reduce decay in baby teeth by 33% and by 46% in the permanent teeth. It is usual to apply fluoride varnish to the teeth of children who already have decayed teeth or are considered to be at increased risk of developing tooth decay. If used correctly, there are no negative effects of using a fluoride varnish.’ (16). According to the Government fluoride varnish is ‘one of the most beneficial and evidence-based preventive procedures available’ (15).
- 12.7 Regular professional care and good oral hygiene improve dental health as do plaque control and chewing sugar free gum. Research suggests access to NHS dentists is problematic in some areas, and that uptake, among deprived communities in particular, can be poor. For example, ‘in Southampton some dental practices that are able to see patients report difficulty in getting uptake by patients’ (15). Studies from Scandinavia have shown that the deployment of dentists and auxiliary dental workers can help reduce the levels of dental decay in the population although the cost of such an approach is significant (17).
- 12.8 As discussed above diet is also a factor. It is suggested that restricting sugar intake to meal times reduces the likelihood of caries. There is some evidence to suggest that

advice to new mothers regarding appropriate weaning habits can reduce caries. Oral health habits such as teeth brushing are also important to prevent caries developing. A study of health inequalities in childhood dental caries by the WHO indicated that further research was needed regarding the parental skills required to instil regular tooth brushing in children, and how these skills could be developed.

- 12.9 The efficacy rates of these alternatives are more reliable than the efficacy of water fluoridation, and these measures can be targeted at those most at risk.
- 12.10 ***Scotland's Oral Health Strategy***
Children's dental health in Scotland is among the worst in the UK, with the average dmft across the 15 PCT areas 2.40 in 2001/02 (highest 3.51, lowest 1.39) [at that time the dmft in Southampton was 1.23].
- 12.11 A consultation was undertaken regarding the options for improving this situation, including the possibility of fluoridating the water. This was entitled 'towards better oral health in children' and an independent analysis of responses to the consultation was published in March 2005. 'Where respondents indicated clearly their views for or against water fluoridation, it was possible to gauge relative levels of opinion. Of those 852 responses where individuals expressed a definite view, (excluding the 151 pre printed responses and 5 petitions), only 3% were pro-fluoridation of water.' The resultant action plan produced by the Scottish Executive did not take forward the option of water fluoridation, but instead promised action in other areas such as oral health promotion, healthy eating measures supported by schools and ensuring that oral health is an integral part of children and young people programmes such as Sure Start.
- 12.12 According to the most recent BASCD data (2005/06) Scotland is making progress on reducing its dmft (12 of the 15 areas scores are down compared to 01/02, the average is now 2.00 with highest 2.68, lowest 1.33). Scotland chose not to fluoridate water so these decreases have presumably been achieved through other methods. The Review Panel is of the view that there may be lessons here that could support SCPCT to achieve its ambitions for improving oral health in its population.

Conclusion: Given the discussions set out above the Review Panel is of the view that

- ***Effective alternatives to adding fluoride to water do exist, with the potential to target those affected rather than the population as a whole.***
- ***Particular opportunities exist for the creative use of skill mix to provide targeted support to vulnerable groups and using existing skills, such as those of health visitors more fully.***

13 Exposure to Fluoride

- 13.1 The current recommended levels of 1ppm of fluoride in water were set at a time when there was less availability of fluoride in diet and oral health products. There is conflicting information about the impact that changing life styles and exposure to fluoride have had on populations. In particular the Review Panel was concerned by the frequent use of the term 'optimal' to describe a level of fluoride in water at 1ppm. This takes no account of other sources of exposure to fluoride that may result in individuals being exposed to much higher levels of fluoride.

- 13.2 The American National Academy of Sciences (4) is very specific: ‘the Committee concluded that children living in communities with levels of fluoride of 4ppm or more were at risk of developing severe fluorosis. The majority of the Committee were also of the view that people drinking water at this level over a lifetime were at increased risk of bone fractures’. Although this report related to exposure to fluoride at levels up to 4ppm, considerably higher than that suggested by the SHA proposal, this is an important point when total exposure is considered, particularly as on a per body weight basis, infants and young children have approximately 3 to 4 times greater exposure than do adults’ (4, summary).
- 13.3 Similar concerns are expressed by other research such as the Medical Research Council: ‘up until the 1960’s, the ingestion of fluorides from water...probably represented the bulk of fluoride exposure for both adults and children...since then however, the availability of fluoride from other sources has changed significantly, and fluoride in drinking water is now recognised as just one component of an individual’s total fluoride intake.’ (3, 3.2).
- 13.4 If individuals are exposed to fluoride from multiple sources over time it is not possible to measure the actual dose that is being received, thus ‘the effects of fluorides are probably related to total exposure, not just fluoride in drinking water. There are very few data relating total fluoride exposure to health effects’ (3, 3.6).
- 13.5 Research published in 2006 (23) suggests that the average dietary intake per person of fluoride in the United Kingdom is estimated to be 1.82 mg per day. Beverages account for 71% of the total dietary intake and tea contributes most to the intake from the beverages group. Above average consumption of tea, as recorded in Great Britain, could result in fluoride intakes as high as 8.9 mg per day. It is estimated that tap water containing 1 mg of fluoride per litre could increase normal dietary intakes by 54%. Individual foods were analysed and the results show that tea infusions and foods containing skin or bone have higher fluoride concentrations than other foods.
- 13.6 The York Review notes that ‘because of potential toxicity of very high doses of fluoride, it would seem sensible that any future studies should attempt to measure total fluoride exposure in areas being researched’ (1, 12.7) and that ‘exposure to fluoride from sources other than water may alter the amount required in water for optimum caries reduction’ (1, 12.7). Additionally ‘because sources of fluoride exposure vary, this may be a difficult issue to examine, in that exposure would need to be measured at the person level, rather than at the population level’ (1, 12.7).
- 13.7 Other reports follow with similar calls for further research ‘because of the wide use of toothpastes and other dental health care products containing fluoride, and the potential for fluoride exposure from a number of other sources, it is especially important to understand better the total exposure that individuals are experiencing’ (3, lay summary) and that ‘in order to assess the specific benefits and/or hazards that might arise from the fluoridation of water, it is necessary to take account of the different sources and routes of human exposure to fluoride and to understand the absorption, distribution and metabolism of fluoride in the human body. This information is relevant for several reasons:
- Estimates of the impact of water fluoridation on total exposure to fluoride may otherwise be inaccurate or misleading
 - The effects of water fluoridation might be confounded or modified by exposure to fluoride from other sources.

- Knowledge of the distribution and metabolism of fluoride may provide pointers to the measures of exposure (e.g. recent or cumulative) that are most relevant to different health outcomes, and to the plausibility of effects in different tissues’ (3, 3).
- 13.8 Regarding exposure studies ‘several studies have found considerable variation, especially in children among whom individual intakes may far exceed the mean value, owing to ingestion of dentifrice, for example’ (3, 3.4).
 - 13.9 Most recently the Australian systematic review is clear that ‘the results suggest that the introduction of water fluoridation is strongly associated with an improvement in dmft/DMFT scores. However it should be noted that the analyses did not take into account the use of other sources of fluoride, including topical agents’ (5).
 - 13.10 Total exposure to fluoride will vary from person to person, depending on lifestyle, diet, use of oral health products and individual biological makeup. The bioavailability study undertaken by Maguire et al after the MRC report recommended this as a priority for further research, looked at the retention of fluoride in 20 subjects comparing naturally fluoridated hard and soft waters, artificially fluoridated hard and soft waters and a reference water. Although the study used too small a group of subjects to produce reliable results, an interesting finding was ‘large within and between subject variations in F absorption’. This suggests individuals vary significantly in the amount of fluoride retained in the body. This is important because an intervention such as fluoridation covers the population indiscriminately and cannot take account of individual variation in reaction to the dose. Most medical interventions are prescribed on an individual basis in order to take account of individual circumstances.
 - 13.11 The Review Panel sought to get a clear response to the work that had been done to understand the total exposure of the target population to fluoride. Although no local population information was available SCPCT did report that the 1997 Total Diet Study estimated exposure in the population to be 1.2 mgs/kilo. (SCPCT written evidence point 6). The economic model produced by the SHA highlights the potential for exposure to fluoride ‘from other sources to reduce the efficacy of the approach’ (13). The Review Panel could find no evidence to indicate what this might mean in terms of the proposal currently out for consultation.
 - 13.12 The evidence relating to the impact on infants being fed on formula reconstituted with fluoridated water was contradictory and for the Review Panel immensely frustrating given that this represents such a vulnerable population. The MRC makes the point that ‘breast fed children in fluoridated areas are likely to have below optimal intakes of fluoride. The individuals most likely to have above optimal fluoride intakes are formula fed infants in fluoridated areas, infants in non fluoridated areas fed on high fluoride containing formula and individuals with excessive toothpaste ingestion and use’. (3,3.4). It is not clear what the ‘optimal fluoride intake’ is for infants or the point at which this would cease to be therapeutic. Other research suggests that infants up to six months should not be exposed to fluoride.
 - 13.13 The American Dental Association changed its policy in 2006 to recommend that fluoridated water not be used for preparing infant formula; their policy is (with breast feeding as the best option) ‘Ready-to-feed formula is preferred over formula mixed with water containing fluoride during the first year of life to help ensure that infants do not exceed the optimal amount of fluoride intake.’ (29). The Irish Fluoridation Forum simply suggests that water used to make up infant formula is boiled (17).

- 13.14 The British Fluoridation Society briefing on this issue notes that ‘the difference in unsightly fluorosis in bottle fed as against breast fed children in fluoridated districts in the UK is not known and should be researched. Until such data are available for the UK it would probably not be justified to run a public awareness campaign in fluoridated districts’. If approached by parents on this issue the BFS suggest that advice from dental health professionals includes the following points.
- That breast feeding is the best option
 - That ready to use infant formula has a low fluoride content
 - That powdered formula could be made up with suitable bottled water
- 13.15 The Review Panel were of the view that this conflicting advice was deeply unhelpful, particularly given the vulnerability of mothers in the more deprived areas that may be affected by the proposals. It was also of concern to note that the public in fluoridated districts may not be made aware of this as a potential effect of fluoridation that may affect their children.

Conclusions: Given the discussions set out above the Review Panel is of the view that

- *Evidence has not been provided to demonstrate that adding fluoride to water at 1ppm equates to individuals receiving an optimal therapeutic dose. Current daily intake of fluoride from other sources may already exceed the equivalent of 1ppm in water.*
- *The recent decision of the Republic of Ireland to reduce the longstanding accepted dose for adding fluoride to water from 1 ppm to 0.7ppm brings into question the level of dosage for England as set out in the current legislation.*
- *Individual exposure will be affected by the addition of fluoride to drinking water at 1ppm as well as other sources.*
- *The conflicting information about using fluoridated water to reconstitute infant formula reinforces previous conclusions about the need to adopt a precautionary approach.*

14 Nature of Fluoride

- 14.1 The fluoride used as an additive to water supplies is not pharmaceutical grade. It is a by-product of the phosphate fertiliser industry and carries with it a range of impurities such as phosphate, hydrogen fluoride, antimony, arsenic, cadmium, chromium, lead, mercury, nickel and selenium. This is a source of major concern amongst opponents of fluoridation. However, when Southern Water gave oral evidence to the Review Panel, they indicated that when diluted to 1ppm, the contaminants present in the water as a result of the addition of the hexafluorosilicic acid do not exceed the levels given as allowable maximums in the water quality standards.
- 14.2 As it is not classified as a food or a medicine the fluoride added to water has not been subject to the rigorous controlled trials that establish the safety of new foods or medicines.
- 14.3 Because it combines easily with calcium there may be a difference in the bioavailability of fluoride in areas of hard or soft water. Additionally individuals will absorb fluoride at different rates. It is not clear if artificial fluoride reacts differently in the body compared to natural fluoride, due to its different chemical composition.

- 14.4 The MRC commented that ‘a major area of uncertainty concerns the bioavailability of fluoride. This is particularly important with respect to the possible differential absorption of fluoride from naturally and artificially fluoridated water and the role of water hardness (calcium levels)’ (3,3.6). The subsequent research in this area highlighted by the Chief Dental Officer in February 2008 and sent to the Review Panel by the BFS relates to a small cohort of 20 individuals (one of whom was excluded) and as such it is not possible to demonstrate the necessary confidence intervals for a reliable response to this question. Other doubts about the standard of this research were drawn to the attention of the Review Panel and it is disappointing that it has not been followed up with more robust work to provide some reliable evidence.
- 14.5 The York Review found only one study of suitable quality, from 1965, that compared an area with relatively high levels of naturally fluoridated water, an artificially fluoridated area and a control area which found that ‘at the baseline survey, caries experience...was relatively high in the control area and the area that had recently started to receive fluoridated water. In the survey conducted 7 years later, caries experience remained high in the control area and low in the naturally fluoridated area. In the artificially fluoridated area, decay had declined to levels approaching those seen in the naturally fluoridated area. This suggests that naturally and artificially fluoridated water have similar effects on dental decay’ (1,11.1) and that ‘this variable did not show an association with fluorosis incidence, suggesting that there is no difference in the effects of artificially and naturally fluoridated water on the incidence of dental fluorosis’ (1, 11.2).
- 14.6 Regarding other possible negative effects ‘there were no studies in which an area with water naturally fluoridated to around 1ppm was compared with an area artificially fluoridated to this level. It was therefore not possible to make a direct comparison of the effects’ (1, 11. 2).

Conclusions: Given the discussions set out above the Review Panel is of the view that

- *There is not sufficient evidence to show how individuals vary in the way in which they retain and excrete fluoride, or the impact that hard or soft water may have on this*
- *There is not sufficient evidence to show that artificial fluoride acts in the same way as natural fluoride*

15 Legal and Technical Issues

- 15.1 A number of concerns were raised with the Review Panel about the way in which fluoride is classified, particularly in relation to whether it is a medicine or a food.
- 15.2 Cheng, Chalmers and Sheldon commented that ‘the legal definition of a medicinal product in the EU 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’ (6). The Review Panel received conflicting information about the legality of adding fluoride to water. The United Kingdom Councils against Fluoridation

produced significant evidence to suggest that there is at least a question mark over this point.

- 15.3 Additionally ‘if fluoride is a medicine, evidence on its effects should be subject to the standards of proof expected of drugs, including evidence from randomised trials. If used as a mass preventive measure in well people, the evidence of net benefit should be greater than that needed for drugs to treat illness. An important distinction exists between removing unnatural exposures and adding unnatural exposures. In the second situation, evidence on benefit and safety must be more stringent. There have been no randomised trials of water fluoridation’ (6).
- 15.4 The Medicines and Healthcare Products Regulatory Agency (MHRA), which is the body responsible for regulating medicines in the UK, was approached for a view on this issue and confirmed that they had not been asked to classify fluoride in this way.
- 15.5 The lack of clarity about the classification of fluoride, particularly given the legal judgements referred to above, are somewhat perplexing to the Review Panel. It would be helpful if this issue could be addressed at the earliest opportunity.
- 15.6 Overall the Review Panel was satisfied that Southern Water had sufficiently robust mechanisms in place to allow for the accurate monitoring of the level of fluoride being added to drinking water. However, it was of concern to note that the suggested dosing scheme at Rownhams was not considered to be either ‘practical or reasonable’ (see evidence 6 October 2008). Additionally there were concerns about the costs of undertaking this work and a view that these may have been significantly underestimated.
- 15.7 If the Otterbourne scheme only were to go ahead this would mean that just 48% of under 4 year old children in the target population would receive fluoridated water (14).
- 15.8 According to the University of York Health Economics Consortium (‘Water Fluoridation - An Economics Perspective’ 1998), benefits of water fluoridation are likely to be greater than the costs in areas where the average dmft for 5 year olds is 2.0 or more (especially if there are districts where it is over 2.65) and where the local water treatment works serve populations of 200,000 people or more. This is not the case in this proposal.
- 15.9 The Atkins ‘Fluoridation Feasibility Study’ (14) did not assess the benefits of the scheme (paragraph 1.2.) and therefore solely focused on costs. Paragraph 3.1 of the study sets out the way in which it assesses dmft across groups of people. This looks at the dmft rate as across a population. Thus a postcode with a dmft rate of 48 could be made up of 16 children with a dmft of 3, or 8 children with a dmft rate of 6. This study concludes that ‘without any knowledge of the benefits that each scheme will deliver it is not possible to fully assess which schemes are cost effective and which are not’. It recommends that each of the schemes is reviewed once the dental benefits are known. SCPCT say this is an incorrect presentation of the incidence of dental caries (see SCPCT written evidence).
- 15.10 The Abacus report on the economic implications of the proposed scheme (13) notes that the efficacy of the fluoridation of water may be confounded by other external factors, such as the use of fluoridated toothpaste. Any reduced efficacy due to these factors would have a significant impact on the likely cost effectiveness of the intervention. It uses research that suggests a reduction in caries of between 12% and 29%, assuming a

reduction of 25% in caries for the purposes of the modelling. It is not clear why this estimate was used in preference to the findings of the York systematic Review. Furthermore, the model used (Griffin et al) is based on permanent teeth in children over six years of age; it is not clear how this relates to the 5 year old child's primary dentition which is the target population in this proposal.

15.11 For the purposes of the economic model, fluorosis is considered to be cosmetic and have no impact on NHS costs, but the basis on which this assumption has been made is not clear. The model works across averages in the population, not individual disease profiles so there is no evidence that those actually affected are being targeted. It assumes all children are equally exposed to water fluoridation (the impact of uncontrolled variables is not quantifiable). SCPCT were not able to give any indication of the amount of fluoride that has to be consumed to have an impact on the incidence of caries (see written evidence) and the Review Panel has not been able to find this information in any of the literature reviewed. Using the figures produced by the PCT it would seem that the population may already be exposed to above the 'optimal' dose (see SCPCT written response). Specific points of note in the Abacus report are:

- As the relationship between water fluoridation can be confounded by external factors (such as the widespread use of toothpaste containing fluoride) it is necessary to consider whether the reduction in the future incidence of carious lesions ... is applicable to the people of Southampton (p5)
- ...in the worst case scenario (an efficacy of water fluoridation of 12%) the additional cost to the NHS is ...£45.23 per carious lesion avoided (p5)
- The evaluation did not consider any alternatives, such as milk or salt fluoridation (p8)
- Working across populations rather than individual disease profiles it is assumed that the risk of caries is independent of any previous decay experience (p9)
- The assumed efficacy of 25% was derived from studies performed before fluoride was routinely added to tooth paste and used by the population over a sustained period of time, and where the baseline prevalence of caries was higher, [so] the efficacy estimate may be smaller today (p16).

15.12 If the efficacy of water fluoridation is dependent on the baseline level of decay (as suggested by the York Review) and the total exposure to fluoride in a population has not been evaluated, it is difficult to see the suggested cost benefit of introducing this scheme as anything but speculative.

15.13 In summary, the technical case underpinning the proposal and the economic modelling do not seem to be able to support the case for adding fluoride to drinking water for people living and working in parts of Southampton City and south west Hampshire.

Conclusion: In considering the above points the Review Panel came to the view that:

- *The technical appraisals show that the options presented by the SHA for introducing fluoride to the water supplies of the full target population are neither viable nor effective.*
- *The projected costs are not sufficiently robust.*
- *The conflicting evidence received makes it difficult to determine if there are additional legal issues that need to be taken into account.*

16 Consultation Content and Process

16.1 Consultation Content

The Review Panel has expressed concerns to the SHA about the content of the consultation document and the lack of balance contained in the information this provided for consideration by local people (see Appendix Five). Members are aware that similar concerns have been raised with the SHA by other stakeholders and in a detailed critique of the consultation document that was published by Earl Baldwin, member of the York Review Advisory Panel and co-chairman of the All Party Parliamentary Group Against Fluoridation (25). In particular, references in the SHA document to research that were not considered of suitable quality to be included in the York Review were deeply unhelpful and gave a significant bias to the information presented.

16.2 Taking account of the evidence considered by the Review Panel, the issue of fluorosis was dealt with in a superficial and inaccurate manner. The way in which the document gave assurances relating to other plausible harms that may be associated with the fluoridation of drinking water was misleading and took no account of the work of the NAS (4) in this area or other relevant research. It was helpful to have an assurance from the SHA at the Hampshire PCT Board meeting that the NAS work would be included in feedback to the SHA Board, but this is too late to ensure that local people are aware of these issues, and the dismissive way in which questions related to this research were dealt with by the SHA at the Review Panel's evidence day on 6 October was cavalier and inappropriate.

16.3 The focus of the SHA document, and the case made by SCPCT, were based exclusively on the primary dentition of 5 year old children. No figures were included, such as the figures for 8, 12 and 15 year olds which give a very different picture of overall oral health in the population. Equally no reference was made to oral health problems that are not affected by the addition of fluoride to drinking water, such as pit and fissure decay and gum disease. The Review Panel understands that it is normal to present dmft/DMFT when referring to oral health within populations.

16.4 Consultation Process

The Review Panel welcomed the opportunity to provide feedback to the SHA on the planned consultation period and the willingness of the SHA to delay the start of consultation until the main holiday period (August) was over. Additionally the SHA extended the planned period of consultation to 14 weeks to accommodate the need for local authorities to provide formal feedback. Requests for additional 'drop in' sessions were accommodated.

16.5 The Review Panel received conflicting information about the number of copies of the consultation document that were distributed. In oral evidence the figure quoted was 5000, in written evidence from the SHA dated 28 October a figure of 2500 is suggested. It is not clear how many individuals in the area affected would have had access to these. The promotional campaign run by SCPCT reached many more local households and the Review Panel was concerned that many local people would not be able to distinguish between the pro fluoridation position adopted by the PCT and the consultation process being run by the SHA.

16.6 The Review Panel will come to a conclusion on the content and conduct of the consultation process once this is complete.

GLOSSARY

(includes acronyms and relevant scientific terms)

BASCD – British Association for the Study of Community Dentistry

BFS – British Fluoridation Society

Bioavailability – extent to which the body is able to absorb the substance

BMJ – British Medical Journal

Confidence Intervals (CI) – A statistical term for an estimate of the range within which a parameter falls. Usually presented as a 95% CI. This indicates there is 95% certainty that the effect lies within those margins, based on the data gathered.

Confounding factors – other things that may be affecting the phenomena being studied e.g. age may be a factor in certain diseases, diet may have an impact etc

Deciduous teeth – otherwise known as milk teeth, baby teeth, temporary teeth, or primary teeth are the first set of teeth in the growth development of humans. They develop during the embryonic stage of development and erupt — that is, they become visible in the mouth — during infancy. The eruption of these teeth begins at the age of six months and continues until twenty-five to thirty-three months of age. The process of shedding deciduous teeth and the replacement by permanent teeth may last from age six to age twelve. By age twelve there are usually only permanent teeth remaining.

Dental caries - is a disease which damages the structures of teeth. Tooth decay or cavities are consequences of caries. If left untreated, the disease can lead to pain, tooth loss, and infection.

Dental fluorosis – condition resulting from excess fluoride intake which has the effect of mottling of the teeth. Often considered a merely cosmetic effect, however some argue it is evidence of fluoride toxicity. ‘mild’ fluorosis can take the form of white flecks on the teeth; ‘severe’ fluorosis can be brown marks on the teeth. Severe fluorosis can be of ‘aesthetic concern’ if it is a noticeable affect, which affects the individuals appearance, which may therefore affect their confidence and wider well being

DMFS – Decayed Missing or Filled Surfaces

DMFT – Decayed Missing or Filled Teeth (capitals indicates permanent/adult teeth)

dmft – decayed missing or filled teeth (lower case indicates deciduous/‘baby’ teeth)

HOSC – Health Overview and Scrutiny Committee

MRC – Medical Research Council (UK)

NAS – National Academy of Sciences (US)

NHS – National Health Service

PCT – Primary Care Trust (if pre-fixed with SC = Southampton City)

Permanent dentition – second/adult teeth, once these come through they remain for life, if they are removed replacement teeth will not grow

ppm – parts per million (measure of concentration of fluoride in water, indicates how much fluoride is present e.g. 1 part fluoride to 1million parts water)

SHA – Strategic Health Authority (if pre-fixed with SC = South Central)

WHO – World Health Organisation

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