

Response to South Central Strategic Health Authority Consultation on the Proposed Water Fluoridation for Southampton and Area

"...when we looked at the studies that have been done, we found that many of these questions [about the effects of fluoride] are unsettled and we have much less information than we should, considering how long this has been going on"

Professor John Doull - Chair of the Working Group on Fluorides in Drinking Water, National Research Council, USA (Quoted in Fagin 2008.)

1. Introduction

- 1.1 This paper has been prepared in response to the SHA consultation on the proposals to fluoridate public water supplies in Southampton, Eastleigh and Totton. In accordance with the guidelines set out in the consultation document this response deals with key issues of fact and draws on published reviews and research where necessary. This detailed response has been prepared by members of Hampshire Against Fluoridation.
- 1.2 Generally the epidemiological case for the proposed scheme is very weak and not based on good quality data and arguments that water fluoridation will significantly reduce rates of dental decay, are weak. After 70 years, there has not been a single randomized, clinically controlled trial conducted examining the effects of fluoride administered in drinking water. Such a study design is required for any new drug applications and is considered the "gold standard" for evidence and such a study was recommended by the MRC after the York Review (McDonagh et al 2000, MRC 2002).
- 1.3 The fact that the dental caries rate for 12 year olds is now 0.69 DMFT in Southampton and lower than in any study which has examined the effect of water fluoridation, challenges the central assumption of the proposal that water fluoridation will be effective in Southampton and the surrounding areas. Rates of dental decay for five and 12 year olds has been dropping over the last 10 years in common with decreases in decay rates in other areas whether fluoridated or non-fluoridated. The data on dental decay quoted by the PCT and SHA is for the city not for the area covered by the proposed scheme. It is not clear who will benefit from the proposed scheme and what level of decay will be achieved or how this will be attributable to water fluoridation alone and not other interventions such as the application of fluoride varnishes, teeth brushing, and changes in diet - especially consumption of sugary drinks and sweets (for example sweet and drink machines have only been removed from schools in the last couple of years) – all of which form part of the government's oral health strategy (DH 2005). The evidence examined by the York Review (McDonagh et al 2000) suggests that such factors may be the main cause for reductions in dental decay given that non-fluoridated areas have achieved similar, and in some cases larger, reductions in dental decay to fluoridated areas.

- 1.4 The economic analysis is also deeply flawed and does not present an accurate estimation of costs. Also, as it uses the epidemiological data for the city and applies it to the area to be fluoridated it over estimates caries rates. It underestimates capital costs and over estimates benefit and savings. It does not compare the cost of water fluoridation to other forms of intervention. Given these concerns and also Southern Water's concerns about cost and feasibility, a new economic analysis is required before any decision about water fluoridation can be made.
- 1.5 The consultation has focused on the claimed benefits and safety of water fluoridation. SHA staff and PCT staff have repeatedly claimed that water fluoridation is both safe and effective. There is no evidence upon which to base such confident statements about safety and effectiveness (McDonagh et al 2000). The systematic review undertaken by the NHS Centre for Research and Dissemination at York University cautioned against such confident statements and the chair of the review panel has repeatedly condemned such statements. In a recent review, Pizzo et al (2007) report that: "In most European countries, where [water fluoridation] has never been adopted, a substantial decline [75%] in caries prevalence has been reported in the last decades.." and "..... epidemiological studies conducted in fluoridated and non-fluoridated communities suggest that [fluoridation] may be unnecessary for caries prevention"(191). Their review also found that after the cessation of water fluoridation "... caries prevalence did not rise, remained almost the same or even decreased further." (191)
- 1.6 The consultation has not in any depth explored alternatives to water fluoridation. The PCT has reported that it has tried a number of other approaches but that these have failed. No details of the approaches and where they have been undertaken or what the results were have been presented – although at the final Question and Answer session a Headmaster of a city centre school reported reductions of some 2.0 DMFT in his school showing that targeted interventions can substantially reduce dental caries. There is consistent evidence that teeth brushing, using fluoride toothpaste, mouth washes, varnishes and gels are consistently more effective than water fluoridation when delivered effectively. While a number of studies have shown that interventions are not effective (DH 2007) it is clear that when intervention delivery conforms to best practice they are highly effective (Marinho et al 2008, Weyant 2004). They also form part of the Government's Oral Health Strategy and more attention should be paid to developing effective delivery systems that target children with the highest levels of dental caries (DH, 2005)
- 1.7 The proposal to add fluoride to the water supply is also unethical. There has been very selective quoting of ethical views to support the idea of water fluoridation rather than drawing on the analysis of the Nuffield Council on Bio-ethics report on public health ethics or other ethical frameworks guiding public health that attempt to provide guidance to policy makers about the process of ethical consideration (Gostin and Lazzarini 1997, Kass 2004, Childress et al 2002). Perhaps most importantly, the European Commission (2000) provides a guiding framework for public health interventions based on the precautionary principle. The proposal involves a universal mandatory intervention - the highest form of intervention on the Nuffield Council intervention ladder (Nuffield Council on Bioethics 2007). As such the proposed intervention should be supported

with clear and uncontested benefit with a minimum of potential for harm. Given the continuing scientific, medical and ethical debate about water fluoridation this intervention fails to meet this criterion and as such there is no ethical basis for supporting the policy.

1.8 Finally the consultation itself lacks neutrality and cogency. It has been biased in terms of the information provided to the public and the consultation document has been widely criticised for not presenting information in an unbiased way. There has been a failure to censure the PCT in its active promotion of water fluoridation costing tens of thousands of pounds. The huge advertising costs for billboard and newspaper adverts, production of leaflets, postcards, door to door delivery, road shows, use of public health staff time to promote water fluoridation in supermarkets, at meetings etc has come from NHS revenues. Yet there is a dearth of dental health promotion literature in chemists, doctor surgeries, and PCT walk-in centres. Clearly the only option that the PCT subscribes to appears to be water fluoridation.

1.9 This heavy one sided advertising and promotion by the NHS of water fluoridation has undermined any sense of balance in the Consultation. So the general public, who must be assumed not to know a great deal about the subject, are being heavily and unduly influenced by this one-sided behaviour. Therefore the Consultation cannot be considered to be a consultation at all but a heavily financed persuasion exercise.

1.10 These points are expanded upon in more detail in this submission. The overwhelming weight of evidence and ethical opinion suggests that a cautionary approach should be taken when considering water fluoridation. The evidence base is weak and there is increasing recognition of the harmful effect of fluoride. All the evidence points to the fact that water fluoridation will be ineffective in Southampton because the caries level in permanent dentition is already so low but will at the minimum contribute to some children getting moderate to severe dental fluorosis. The SHA should therefore reject the proposal.

2. Water fluoridation

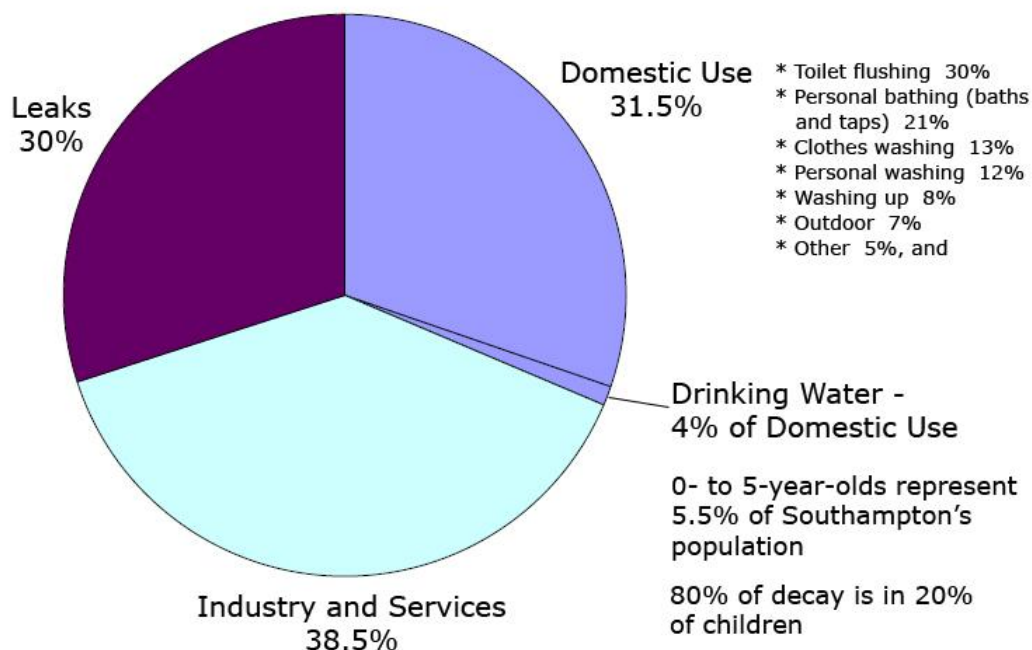
2.1 The current proposal is to add 112.3 tons per annum of hexafluorosilicic acid to two water supply systems covering the city and parts of Eastleigh, Test Valley and New Forest District council areas. The proposal is to increase the level of fluoride to 1ppm. This level is laid down by the government, but is often referred to as the 'optimum level'. However, there is no scientific basis for 1ppm as being an optimum level. Safety limits and ingestion levels are not measured by water concentration but as mg per Kg of bodyweight per day. As Locker (1999) states "The optimal level of 1.0 ppm was chosen, largely on an arbitrary basis, to achieve the maximum reduction in dental caries and the minimum prevalence of fluorosis There is a lack of contemporary data on dose-response relationships between fluoride concentrations in the water supply, dental caries and dental fluorosis. Nevertheless, it has been suggested that new and more flexible guidelines are needed which take into account the changing prevalence of dental caries, access to other sources of fluoride

and contemporary concerns with the cosmetic effects of fluorosis.” (60) In fact there is no universally accepted optimal level for daily intake of fluoride. The range most often cited by researchers is 0.05 to 0.07 milligram of fluoride per kilogram of body weight (Levy et al 1995). However, Professor Steven Levy of the Department of Preventive and Community Dentistry, University of Iowa has said "The optimal level of fluoride intake is not known with certainty" (Levy 2003).

- 2.2 In fluoridated areas there is an enormous variation in average daily dose of fluoride as fluoride is ingested from a wide range of sources. While the UK has fixed on 1ppm there is not universal agreement about the safe level of fluoride in drinking water. Following a major review in Ireland the level of fluoride has been reduced to 0.7ppm and in Canada the recommendation is that fluoride levels should be between 0.6 and 0.8ppm (Fluoride Expert Panel 2007, Locker 1999). Not only has water fluoridation been discontinued, banned or let lapse in most of Europe the relevant European guidelines on fluoride in water stipulate a level of 0.8ppm in fluoridated water supplies (European Union 2007).
- 2.3 In 2005 the European Food Safety Authority issued the opinion of its Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) following a request from the Commission about the tolerable upper limits of fluoride intake. The Scientific Committee on Food “recommended a maximum fluoride level of 0.6-0.7 mg/L in infant formula and follow on formula, equivalent to an intake of about 0.1 mg/kg body weight per day in infants during the first six months of life (body weight 5 kg). For powdered formula, this maximum will be exceeded if water containing more than 0.7 mg/L is used for its preparation.” (EFSA 2005).
- 2.4 There are very few countries that fluoridate their water supply and there is no real difference in dental decay rates between countries with or without water fluoridation. Many countries have either stopped or banned water fluoridation and 98% of the population of Europe does not have fluoridated water.
- 2.5 There is also increasing debate about what the correct level, if any, there is for the volume of fluoride in water supplies. It is widely recognised that volume of fluoride in water does not equate to dose (Kauffman 2005). In fact, administering fluoride via the water supply means that individual doses cannot be regulated despite concerns about levels of individual fluoride ingestion. Kauffman (2005) recommends a level of 0.4ppm.
- 2.6 Utilisation of water as a delivery system is also an inefficient delivery method. The majority of water is used for industrial or other domestic reasons and not for drinking. In Southampton 30% of water is lost through leaks and only 4% is drunk (see figure 1). Of this only one twentieth of this 4% will be drunk by 0-5 year olds. Much of the water will end up going into the local environment. The fluoride and other contaminants in the hexafluorosilicic acid will accumulate in the soil and local marine environment. There is no discussion of the environmental and safety issues in the consultation document.

Figure 1: Use of water

Where Southampton's water goes



Sources - Southern Water, OFWAT, National Statistics and Waterwise

3. The proposed scheme

3.1 Following the feasibility study undertaken by Atkins, two schemes have been selected that cover approximately 160,000 Southampton residents and 35,000 residents in Eastleigh, Totton and Test Valley. The proposed schemes cover 59% of the key target population of the city's under fives and seven of the 11 priority areas identified by Southampton PCT. The PCT cites the level of dental caries for five year olds and the number of extractions to children in the city as the main reason for requiring the scheme. However, no information has been given on how many of the 522 children will be covered by the scheme nor have accurate dental caries rates been provided for the area covered by the scheme. In particular dental caries rates in the New Forest, Test Valley and Eastleigh districts are lower than Southampton City.

3.2 Southampton is often compared to Birmingham and other West Midlands areas to demonstrate that water fluoridation is effective. However, if five year old rates are compared with North Tees the opposite is true (see table 1). These examples show no clear relationship between dmft/DMFT rates and water fluoridation and that Southampton appears to be doing better than fluoridated and non-fluoridated PCT areas.

Table 1: Comparing dmft/DMFT rates in non-fluoridated and fluoridated PCT areas				
PCT	Fluoridation status	dmft 5 year olds¹	DMFT 12 year olds²	Index of multiple deprivation
City and Hackney	Non fluoridated	1.64	0.46	44.91 (3 rd most deprived)
Islington	Non fluoridated	1.41	0.41	38.96 (8 th most deprived)
Blackpool	Non fluoridated	2.23	1.27	37.66 (12 th most deprived)
Newcastle	Fluoridated	2.28	0.87	31.36 (30 th most deprived)
Gateshead	Fluoridated	1.69	0.90	29.0 (41 st most deprived)
Coventry	Fluoridated	1.15	0.42	27.85 (47 th most deprived)
Peterborough	Fluoridated	1.77	0.34	24.29 (69 th most deprived)
Southampton	Non-fluoridated	1.76	0.69	24.31 (71 st most deprived)
Medway (Dartford and Gravesham)	Non-fluoridated	0.90	0.32	19.95 (93 rd most deprived)
Solihull	Fluoridated	0.65	0.67	16.16 (114 th most deprived)

Source: BASCD survey data: 1. 2005/06, 2. 2003/04

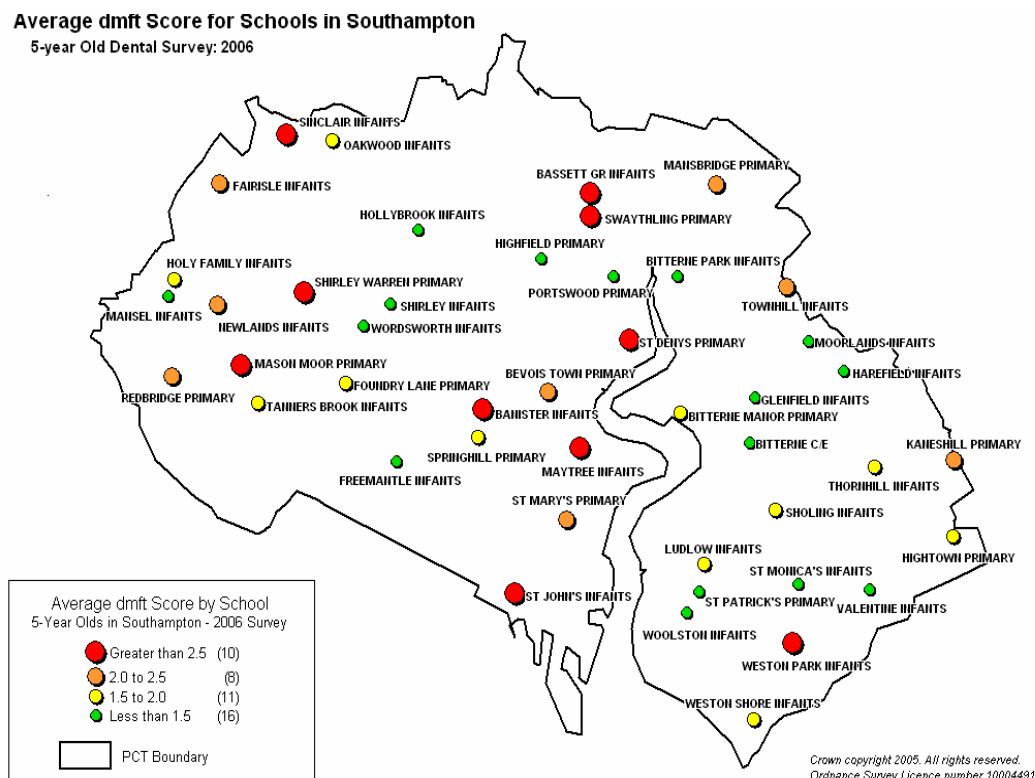
3.3 Only rates for five year olds are referred to in the proposal and consultation. The normal comparative rate used in public health dentistry is for 12 years olds as this relates to the permanent teeth. According to the latest British Association Survey of Community Dentistry (BASCD) 12 year old dental caries rates for the city (being 0.69DMFT) are about the English PCT average of 0.64DMFT. This rate is less than half what it was ten years ago. The dmft rates for five year olds have declined at a slower rate but are now some 25% below the rate ten years ago. Currently 42% of city five year olds experience tooth decay but there are variations in the percentage of caries free children and dmft rates across the city with the highest prevalence of dental caries in the city centre (51% of all 5 year olds and the lowest in the northern area 29%). Figure 2 shows the average dmft score for schools in Southampton. This clearly shows the variance between dmft rates in different areas of the city. The variance is related to deprivation but not exactly so while the Thornhill area has three Lower Super Output Areas dmft rates are not as high as other areas with less deprivation such as St Denys. Also we are not given median dmft rates and the variance for each school – these would provide a clearer picture.

3.4 One statistic often referred to in the PCT and SHA literature is that 522 children had 2900 extractions in 2007/08. This represents 1.3% of 0-14 year olds in the city but there is no data on how many of these children are in the area to be covered by the proposed scheme or whether this represents some children having one or two extractions and others substantially more than six extractions. Research suggests that between 75 and 80% of dental caries is associated with 20-25% of the population of five year olds so having good data on the numbers and location of children with the highest levels of dental caries is important. It would be useful to know as well if some of these

children are from the same families. The PCT has been unable to provide details of caries rates or numbers of children and therefore the epidemiological basis for the scheme is poor. There is substantial evidence that a small minority of people have the majority of dental decay. There is, however, very little evidence that fluoridation prevents decay in these high risk people. In particular, for young children, “baby bottle tooth decay” is a leading cause of serious decay (Barnes et al 1992, Bruerd and Jones 1996, Von Burg et al 1995). This occurs when young children are given a bottle with sweet liquids to suck on for long periods of time. Other key factors associated with early childhood caries early streptococcus mutans colonisation, high plaque accumulation and maternal sharing (Cogulu et al 2008). Fluoridation has no ability to prevent this type of serious dental decay. Education to avoid this practice is the only way to prevent it.

There has been a long problem of access to dental care in the City. While this appears to have improved in the last few years, in 2001/02 the care index for the City (indication of restorative treatment) was one of the lowest in the SHA. In a 1997 survey 75% of 4 to 18 year olds in the South East who had dental caries remained untreated. In addition, surveys show 35% of 4 to 18 year olds have unhealthy gums, 63 per cent of 10-year-olds have gum inflammation and 73 per cent of 10-year-olds have a build up of plaque and 40 per cent of 15 to 18 year-olds have gingivitis (Gregory et al 2000). These are all indicators of poor oral hygiene as while the aetiology of periodontal diseases is complex, it would appear to be episodic, there is some evidence that its effects may be minimised by thorough daily removal of dental plaque (Pilot 1997). 54% of adults have periodontal disease and this is the primary dental health problem and cause of loss of teeth (ONS 1998). Water fluoridation will have no impact on this. The only solution is good oral hygiene and dental checks.

Figure 2: Average dmft score for schools in Southampton



3.5 The poor epidemiological analysis is highly relevant to the feasibility of the scheme. The PCT is justifying the need for the scheme based on its assessment that dental decay rates are high and that the scheme will have a beneficial effect. However, there is no accurate data on the levels of dental caries or its distribution within the proposed scheme. This also has important implications for the economic assessment commissioned by the Strategic Health Authority.

4. The economic case

4.1 A major platform of the SHA's case for fluoridation of water supplies is the economic analysis undertaken by Abacus (2008). The report in fact shows that it costs more to fluoridate water than not to fluoridate, even on the very narrow cost-benefit terms it sets itself. Choosing a very high level of benefit to teeth (25% improvement) is not justified by the evidence, especially as the measures usually relate to five year old children only, and these statistics do not hold for the rest of the population. It also does not include any costs for dealing with extra dental fluorosis, nor for any costs at all for the various other negative health effects found by research (see below). Even where these health problems remain unproven in terms of 100% certainty, a cost analysis should allocate some sort of probability of other side effects, even if in the opinion of the authors this probability is low. The report also seriously underestimates the costs, as confirmed by Southern Water.

4.2 The Abacus Report is seriously flawed as it is clear that not only are the capital costs understated but the level of benefit and the estimated savings are overstated (points acknowledged in the report but not referred to in the consultation document) leading to a substantial underestimate of the costs overall and the £0.32 per carious lesion is clearly completely wrong and should not be referred to in the consultation document. There is no evidence that water fluoridation leads to lower dental costs or savings – a consistent finding since the original work on this by Douglas (1972). The report also does not follow best guidance and practice on economic analysis as it does not include all costs as recommended in guidance articles on the economic analysis of water fluoridation (see Birch 2005). It is clear that a new economic analysis will be required and should have been made available for the consultation.

4.3 The model adopted by Abacus is reasonable for forecasting the costs and benefits to a point but more recent guidelines on economic analysis published by the National Fluoride Information Centre suggest a wider analysis of costs and benefits should have been undertaken (Birch 2005). In addition, the analysis is based on a number of key assumptions about the population and levels of dental decay, the degree of benefit provided by water fluoridation, levels of cost savings and the costs of the scheme that lack cogency. The authors of the Abacus report have referred to previous studies but have ignored recommendations made by Birch (2005) that updates his own model and that of the York Health Economics Consortium (YHEC) paper (Birch 1990, Sanderson and Wilson 1994). The YHEC review has been widely referred to - including by the British Fluoridation Society, the York Review (McDonagh et al 2000) and the government in providing a basis for the economic justification of water fluoridation. The conclusion of the YHEC was that water fluoridation is

economically justified in areas where DMFT was 2.0 or more with areas where DMFT exceeded 2.6 DMFT (Sanderson and Wilson 1994). However, research published since the review suggests that water fluoridation has little effect on reducing dental decay than earlier research that this review was based on suggesting that the rate of 2 DMFT is now inaccurate and should be higher.

- 4.4 The Abacus report uses dental decay figures for 5 and 12 year olds for the city of Southampton drawn from recent dental surveys giving rates of 1.76 and 0.69 respectively. The assumption is that these would be the same for the 160,000 people to be covered by the scheme. However the proposed scheme only covers 59% of 1-4 year olds – considered the main target group. Also caries rates vary significantly across the city with parts of the proposed coverage exceeding 70% of children caries free. No data has been given about what proportion of the children in the key target priority areas, that are covered by the scheme, have dental caries (i.e. how many of the 1-4 year olds in priority areas). In addition 35,000 people live outside the city where dental caries rates are substantially lower (1.08 for under fives and 0.36 for 12 year olds). By applying the city figures to the whole population the annualised model overstates the likely benefit for the actual population covered by the scheme.
- 4.5 The Abacus report acknowledges that the level of benefit of 25% is too high and therefore offers a further sensitivity analysis at 12% as well. Yet the PCT and SHA only quote the cost assuming a 25% benefit. This clearly overstates the expected benefit and is not supported by the best available evidence. The York Review estimated the benefit of water fluoridation as between -5.0% (i.e. no benefit) and 64% with an intra-quartile range of 5%-22% and a mean of 14.6%. The York Review is still considered by all subsequent analyses as the most reliable analysis of water fluoridation yet its findings are ignored for the economic analysis. Reference is made to benefits to adults but there is no reliable evidence to demonstrate benefits of fluoridation to adult dental health. No costs of the negative effects of fluoridation are incorporated into the report. Key costs will include private dental costs for the remedial treatment of dental fluorosis where expected rates of moderate to severe fluorosis will be in the range of 1.3% to 2% of each cohort of children born after the introduction of water fluoridation (Heller 1997, Hong et al 2006, Levy et al 2006, Irish dental health survey 2002).
- 4.6 Southern Water has already indicated (at SCC and HCC health scrutiny committee meetings) that the costs in the SHA figures are underestimated and the capital cost will be more. The Water Authority has also raised concerns about the feasibility of the element of the proposed scheme that covers Rownhams. In addition, costs for ongoing monitoring and the four yearly assessments of impact are not included. The costs of the consultation, NHS time and the cost of the PCTs advertising campaign are also not included. This increases both capital and revenue costs of the scheme and means that the cost per carious lesion is increased.
- 4.7 Abacus calculates the cost savings based on NHS dentistry costs and the profile of local utilisation. The authors make the assumption that all carious lesions would be treated in the following NHS bandings:

- 56% band 1 (generally preventive treatment)
- 39% band 2 (fillings)
- 6% band 3 (More intensive treatments)

However, as the authors themselves identify, this overestimates NHS use as many of the children would not have normally accessed NHS dental care and thus the report cautions that the savings are overestimated. Thus the numbers of lesions actually treated will be lower than that estimated in the report. In a pilot shopping centre project undertaken by Hounslow PCT for the application of fluoride varnishes 85% of the children seen had not had any previous contact with dental services (Secretary of State 2008). This will reduce the cost savings – in reality to zero - and increase the net overall cost per lesion. There is also a question of identifying the net benefit of the scheme over and above the current decline in dental caries. The costs should be taken, therefore at gross cost without estimated savings as these will not accrue. In addition the cost saving is based on an assumption that all lesions would be treated on the NHS and this would not be the case. Thus the total discounted cost of the scheme will be £5,940,328 (plus additional capital costs) with an average running cost of £286,429. This will be an additional cost to be deducted from the dental budget with no savings accruing based on existing economic analyses. Even if 36,032 lesions are saved this makes the cost £164.86 per carious lesion.

4.8 Overstating the benefit and overstating the level of need means that there will be less than 36,000 lesions saved. Due to over estimating the level of dental caries across the whole population to be fluoridated, the actual number of carious lesions saved will be less. Also the level of benefit is overstated and therefore it must be assumed that the figure of 36,032 carious lesions avoided is in fact substantially over estimated. Even the lower efficacy figure of 17,296 lesions may therefore also be over estimated increasing the total cost of the scheme and the cost per lesion saved to £343.45 per carious lesion and being more expensive than other treatments or prevention (one application of varnish costs 30p plus staff time). Given that Southern Water are also questioning the capital costs as being too low this further increases the cost to the NHS.

4.9 The proposed scheme is of course only being delivered to 59% of the under five years old target group. Additional costs will be required to be spent addressing the dental health needs of the remaining 41% of under fives - including a number of priority areas. The cost of the fluoridation scheme will be deducted from the PCT dental budget, but based on experience elsewhere, targeted services will still be required to prevent dental caries in the area being fluoridated so fluoridation costs should be considered additional costs.

4.10 There is no evidence that water fluoridation leads to lower dental costs or savings – a consistent finding since the original work on this by Douglas (see for example Douglas et al 1972). Dental costs have continued to rise in areas with fluoridated water and targeted schemes such as Coventry PCT's recently announced £1.5million investment in varnish applications, is clear evidence that water fluoridation is not a stand alone solution or likely to bring any major benefits. The report also does not follow best guidance and practice on economic analysis as it does not include all costs or

compare alternative approaches to reducing dental caries as recommended in guidance articles on the economic analysis of water fluoridation (Birch 2005). In particular Birch recommended changes to the YHEC model to "... accommodate the potential impact of fluoridation on other aspects of oral and general health and hence identify the effects of fluoridation to be the *net change* in oral health status of the population." (p7) Given that there is little clear evidence that water fluoridation is effective at reducing dental caries rates – especially when caries rates are below 2DMFT the cost of water fluoridation should be compared to other more effective prevention approaches.

4.11 It is clear that a new economic analysis will be required and should have been made available for the consultation. Overall the report over-estimates benefit, over-estimates cost savings and under-estimates costs. The combined effect of this is to render the estimates in the report of 32pence per lesion meaningless and suggests that the £45.23 figure is an underestimate of total costs per lesion. Real costs will be in excess of £164 per lesion. It is clear that a further economic analysis is required that more accurately reflects costs, benefits and savings before any decision on water fluoridation can be taken.

5. Evidence of benefit

5.1 The Government commissioned the NHS Centre for Reviews and Dissemination at the University of York to undertake a systematic review of the literature on human studies related to water fluoridation. This review (hereafter referred to as the York Review) was published in 2000 (McDonagh et al 2000). The aim of funding the review was to put an end to the uncertainties about water fluoridation, acknowledging that much of the evidence did not meet modern standards. The York Review was, surprisingly, the first and only *systematic* review that systematically examined the topic of water fluoridation in human studies. It adhered to internationally recognised criteria for selecting, assessing and grading the evidence, giving both rigour and transparency to a process in which every reader can see what studies were included and why, as well as - crucially - how reliable the evidence is.

5.2 The York Review found that studies of the effect of water fluoridation on dental caries were of moderate quality (level B) and of limited quantity. Their analysis concluded that the studies did not give clear evidence of caries reduction. The range of the mean difference in the proportion (%) of caries-free children was -5.0 to 64%, with a median of 14.6% (inter-quartile range 5.05, 22.1%). "Given the level of interest surrounding the issue of public water fluoridation, it is surprising to find that little high quality research has been undertaken. As such, this review should provide both researchers and commissioners of research with an overview of the methodological limitations of previous research conducted in this area." (McDonagh et al 2000: xiv). In addition while there appeared to be some effect on health inequalities the quality of the studies was low and the results should be interpreted with caution.

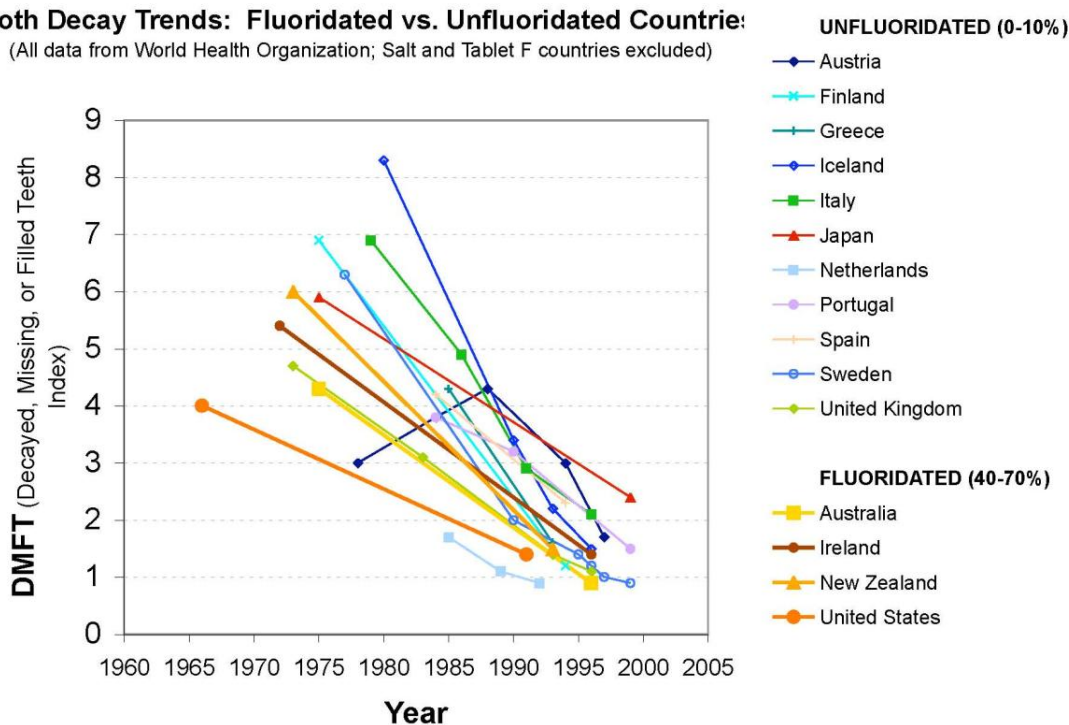
- 5.3 The importance of the York Review is dear and was acknowledged as the base study for the later Australian MRC Review in 2007 (NHMRC 2007). However, this later review restricted its search criteria more narrowly than the York Review limiting its searches to only Medline and Embase data bases (NHMRC 2007: 24). While a number of post-2000 studies were identified by the Australian MRC Review none were of good quality and, therefore, it did not alter the York Review's key conclusions or resolve any uncertainties. The Australian MRC Review did not cite the UK's Medical Research Council fluoridation report of 2002 as this did not have the reliability of a systematic review.
- 5.4 No other systematic reviews of the literature have been undertaken and, unsurprisingly, the Australian MRC review concurred with the findings of the York Review. It did not examine many of the studies included in a review of fluoride in drinking water undertaken by the National Research Council in the USA and nor did it include the scientific assessment within the review (NRC 2006). The Review identified 77 additional papers not considered by the York Review. On the whole the NHMRC review found no further research that would challenge the findings of the York Review and as such the York Review remains the key source for the analysis of the impact of water fluoridation.
- 5.5 The authors of the York Review and members of the Review Panel are very dear about the status and application of the findings of the York Review. While the York Review identified some benefit from water fluoridation "The research evidence is of insufficient quality to allow confident statements about other potential harms or whether there is an impact on social inequalities. This evidence on benefits and harms needs to be considered along with the ethical, environmental, ecological, costs and legal issues that surround any decisions about water fluoridation. All of these issues fell outside the scope of this review." (page xiv). The review authors also clearly state that: "An assessment of the effectiveness of fluoridation on the incidence of caries is difficult because there are a number of factors that may influence caries prevalence other than fluoride in water, and these have changed over time. These factors include the introduction of fluoridated toothpaste, mouth rinses and improved dental hygiene in general." (page 2)
- 5.6 In addition to these two systematic reviews two further reviews are of importance. The UK MRC review commissioned shortly after the publication of the York Review which was commissioned by the government to reanalyse some of the York data with less strict criteria. However, the MRC report generally concurs with the finding of the York Review but has weaker methodological standing. In 2004 the USA Environment Protection Agency (EPA) commissioned the National Research Council to undertake a review of evidence about whether the maximum allowable contaminant concentration for water fluoridation in the USA – then 4ppm – should be reduced. It should be noted that the US EPA has never promoted water fluoridation at 4 ppm and does not officially promote any level of water fluoridation. The NRC reported in 2006 and examined all studies pertaining to fluoride in drinking water. This review was the most detailed and widest of all reviews but was not designed as a systematic review but rather critically analysed and reviewed all studies examining the adverse effects of water fluoridation. The report is still being reviewed by the EPA.

- 5.7 The fact that 70% of the USA population receives water fluoridation has often been cited as a reason for supporting fluoridation. However, in the USA there is no regular collection of data on dental health. The largest and most comprehensive survey of dental caries in relationship to fluoridation was conducted in 1986-7 by the National Institute of Dental Research, a branch of NIH and the US Public Health Service, promoters of fluoridation (Brunelle and Carlos 1990). Numerous scientific papers have been written based on this study of almost 40,000 children (eg Yiamouyiannis 1990). The original study found a marginal benefit of a 20% reduction in DMFS in fluoridated areas: for a 12 year old this 20% reduction represents about half a cavity per person. There was virtually no benefit when measured as DMFT (Brunelle and Carlos 1990). Yiamouyiannis found that children who lived "partially fluoridated", that is, part of their lives in fluoridated areas, had lower DMFT than children living their entire lives in fluoridated areas. This undermines any conclusions claiming the apparent 20% reduction in DMFS is real. In addition the study did not consider socio-economic status (SES). The 80 study cities suffers from selection bias, such that the non-fluoridated cities tend to be poorer more rural cities and as the NIDR never gathered the relevant SES information nor ever acknowledged their lack of control for this very important factor in decay rates. As such even the minimal benefits claimed cannot be attributed to water fluoridation (Yiamouyiannis 1990).
- 5.8 Obtaining specific data on dental caries in the USA in fluoridated areas suggests that water fluoridation has not been a success. In Boston 90% of school aged children have some dental decay and in a study in Philadelphia 33% of 2 to 3 year olds, more than 50% of 4 and 5 year olds and 80% of 7 and 8 year olds had dental decay. A quarter of children had 6 or more decayed teeth and over a third had 5 or more decayed teeth. Paediatricians in Philadelphia are so concerned by rising levels of dental decay that they are calling for more community based dental programmes (Oral health Report 2002). In fact, in 2000 the US Surgeon General named dental caries as the most important childhood health problem in the USA and that it needed urgent action.
- 5.9 A key finding of all these reviews is that the evidence on the efficacy of water fluoridation for the prevention of dental carious lesions is uncertain and rates of effectiveness are confounded by sources of fluoride from fluoridated toothpaste, fluoride within the food chain etc. Estimates of the increase in the proportion of children without caries in fluoridated areas versus non-fluoridated areas varied between -5% and 64%. These estimates could be biased because potential confounders were poorly adjusted for. (York Review). The MRC report (2002) concluded that "Studies are needed to provide estimates of the effects of water fluoridation on children aged 3-15 years against a background of widespread use of fluoride toothpaste, and to extend knowledge about the effect of water fluoridation by . . . (socio-economic status), taking into account potentially important effect modifiers such as sugar consumption and toothpaste usage" (MRC 2002: 19). Comparisons of fluoridated and non-fluoridated areas demonstrate the lack of effect of water fluoridation. For example, overall there is little difference in the historical decline in rates of dental caries in fluoridated and non-fluoridated countries (See figure 3).

5.10 In the UK and USA areas with 100% fluoridation have high rates of dental caries as do non fluoridated areas (See table 1). In areas receiving 100% fluoridated water and non fluoridated water in the West Midlands the mean dmft for 5 year olds varied from 0.52 to 2.13 by PCT area in 2003. In fluoridated Newcastle mean dmft has increased from 1.60 in 2001 to 2.28 in 2005/06 (BASCD survey data).

Figure 3: Tooth Decay Trends: Fluoridated vs. Unfluoridated Countries

(All data from World Health Organization; Salt and Tablet F countries excluded)



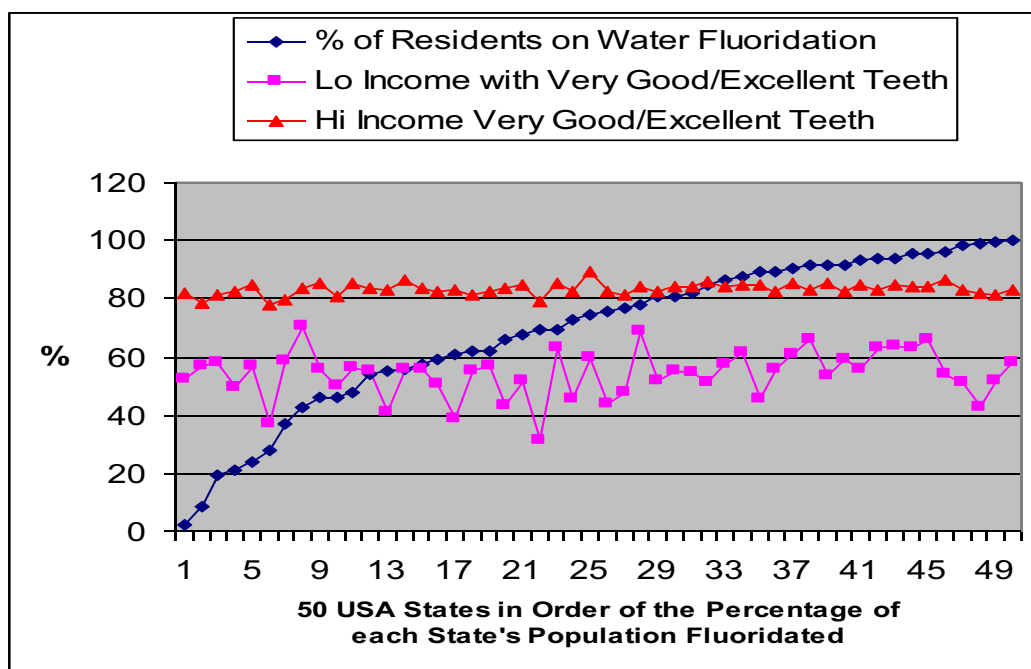
5.11 In a study in Georgia USA “No significant differences were seen in DMFS+dfs between children with or without fluoridated home water, nor for those with or without fluorosis No differences were found among MS and ES children in mean plaque (F) for those with or without fluorosis”. (Adair et al 1999). The York Review concluded that “Water fluoridation aims to reduce social inequalities in dental health, but few relevant studies exist. The quality of research was even lower than that assessing overall effects of fluoridation.” (Cheng et al 2006). The cohort study in Iowa has shown no difference in levels of dental caries at age five of those drinking bottled water with low levels or no fluoride and those drinking fluoridated water (Broffitt et al 2007).

5.12 In the largest US dental survey commissioned by the National Institute for Dental Research the dental health of 39,000 children in 84 communities was examined. The study compared DMFS (ie surfaces not teeth). While a statistically significant difference in average DMFS was found between children living in fluoridated and non-fluoridated communities (Brunelle and Carlos 1990) further analysis did not find evidence that the permanent teeth (DMFT) had any benefit from fluoridation (Yiamouyiannis 1990). He acknowledged the dmft were lower, but pointed out that this might have

been due to delayed eruption, which was not considered in the study. Also, the dmfs fluoridation benefit decreased rapidly with age, so that it became a tiny benefit by the time the children's permanent teeth were erupted.

5.13 A later study of dental decay in the USA by levels of fluoridation in each US State found no differences in DMFT between States but identified a clear difference between children from high and low income families (see figure 4).

Figure 4: Comparison of decay rates by US state and fluoridation status



The National Survey of Children's Health 2003 Rockville, Maryland: U.S.

5.14 Differences in dental decay rates are seen within fluoridated areas as well in non-fluoridated areas. For example, in Massachusetts where most communities have fluoridated water:

- 41.5% of kindergarten children from low-income families have been affected by dental caries, 1.9 times higher than kindergarten children from families with higher incomes.
- 60.8% of 3rd grade children from low-income families have been affected by dental caries, 1.9 times higher than 3rd grade children from families with higher incomes.
- 48.4% of 6th grade adolescents from low-income families have been affected by dental caries, 1.7 times higher than 6th grade adolescents from families with higher incomes.

5.15 Again these are rates of dental caries that are substantially higher than many areas in the UK. Recent reviews of dental caries prevention acknowledge the poor effectiveness of water fluoridation compared to other approaches (See table 2) and Pizzo et al (2007) argue that water fluoridation

should only be considered in areas where dental caries rates are very high. More recently the Iowa cohort study measured dental caries rates in a cohort of children and compared those who drank bottled water with those who drank fluoridated drinking water. They found no significant difference (Broffitt et al 2007).

Table 2: Effectiveness of different approaches to dental caries prevention			
Topic	Source of evidence	Overall quality of studies	Summary findings
Water fluoridation	Systematic reviews	Quality of studies low or moderate	14% reduction in primary dentition
Topical fluorides	Cochrane reviews	Good	24% reduction for fluoride toothpastes 26% for mouth rinses, 28% for gels, 46% for varnishes. Overall 26% in permanent dentition and 33% in primary dentition (ie over twice as effective as water fluoridation)
Fissure sealants	Cochrane review	Good	Caries reduction ranging from 86% at 12 months to 57% at 48 months.
Dental health education	Effectiveness review	Low to moderate	Mainly short term improvement

Source: Watt 2005.

5.16 Water fluoridation has been shown to have a poor effect on the prevention of dental caries. There are two main reasons why water fluoridation has a weak effect. The first is that fluoride only helps prevent dental decay topically – i.e. when applied directly to the teeth: "[L]aboratory and epidemiologic research suggests that fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children" (CDC, 1999). Most water is ingested and only a small proportion washes over the teeth. Yet as Warren and Levy (2003) argue "Current evidence strongly suggests that fluorides work primarily by topical means through direct action on the teeth and dental plaque. Thus ingestion of fluoride is not essential for caries prevention."

5.17 The second reason is that dental caries mainly occurs in the pits and fissures in the molars and fluoride has little preventive effect in these tooth surfaces (Pinkham 1999). "Fluoridation and the use of other fluorides have been successful in decreasing the prevalence of dental caries on the smooth surfaces of teeth. Unfortunately, these efforts have much less effect on dental caries that occur in the pits and fissures of teeth (particularly on the biting surfaces of teeth) where more than 85 percent of dental caries now occur." (White 1993). Examination of children in the Iowa fluoride study supports the view that water fluoridation has no impact on pit and fissure lesions. In the

cohort study an examination of non-cavitated smooth surface and non-cavitated pit and fissure lesions and their progression to cavitated lesions **was not associated with fluoride**, socio-economic status or beverages. Generally smooth surface lesions rarely progressed to cavitated lesions while pit and fissure lesions led to frank decay or fillings (Warren et al 2006).

5.18 There is increasing widespread caution about the claimed benefits of water fluoridation. In 2001 the USA Centres for Disease Control stated that “The prevalence of dental caries in a population is not inversely related to the concentration of fluoride in enamel, and a higher concentration of enamel fluoride is not necessarily more efficacious in preventing dental caries”. In Canada there has also been a recognition of the limited benefits “The magnitude of [fluoridation’s] effect is not large in absolute terms, is often not statistically significant, and may not be of clinical significance.” (Locker 1999). Increasingly researchers are finding no differences in dental caries rates between fluoridated and non fluoridated areas, and are now expressing concern about potential problems arising from water fluoridation. While rates of dental erosion remain high only that which exposes the dentine is of real concern with regard to dental caries. Al Dilaigan et al (2001) compared erosion between a number of areas and found that dentine exposure was higher in fluoridated Birmingham than in non-fluoridated Liverpool and London. As with dental caries, socio-economic status was strongly associated with levels of dental erosion.

5.19 The evidence of benefit in preventing dental caries is weak and there is a lack of good quality studies that have demonstrated any benefit that have adequately controlled for all other factors that affect dental caries rates. Studies comparing fluoridated and non-fluoridated populations produce conflicting outcomes of either no difference, some benefit or some disbenefit. The quality of studies also remains poor (McDonagh et al 2000, NHMRC 2007). There is no high quality research that demonstrates a positive impact on health inequalities and the finding of the York Review that it is not possible to make confident statements about the benefits of water fluoridation remain true. The action of water fluoridation on the teeth is minimal with little water consumed actually passing over the teeth. In addition research demonstrates that most early childhood caries is related to feeding habits such as bottle caries or high levels of streptococcus mutans and not helped by water fluoridation (Cogulu et al 2008,). In addition the majority of caries arises from pit and fissure problems which are also not helped by water borne fluoride but need direct brushing and topical application of fluorides.

5.20 It is now widely accepted and recognised that the action of fluoride is topical and not systemic (Warren and Levy 2003). Thus the action of water fluoridation is poor and it is not surprising that it is ineffective. It has little impact on the main causes of caries or the predominant types of caries. As water fluoridation has relatively little topical effect and does not have sufficient strength to act as an anti bacterial agent to reduce levels of streptococcus mutans it is unlikely to reduce severe caries. As Naylor (1985) has argued, any reduction of less than 1.0dmft/DMFT, such as from 1.0 to 0.7 dmft, may be statistically significant but a reduction of less than 1.0 is not clinically significant.

6. Evidence of harm

- 6.1 It has long been recognised that there is a relationship between water fluoridation and dental fluorosis. There have been a number of studies that suggest that moderate to severe fluorosis is of more than aesthetic concern and is indicative of too much fluoride being ingested. In addition, moderate to severe fluorosis can require expensive remedial treatment and where teeth are pitted, lead to dental caries (Cunha-Cruz and Nadanovsky 2005). This view is supported by a leading USA agency: “In more severely fluorosed teeth, the enamel is pitted and discoloured and is prone to fracture and wear. Several studies have found significant increases in the number of decayed missing, or filled tooth surfaces in children with severe dental fluorosis.” (US Agency for Toxic Substances and Disease Registry 2003)
- 6.2 At least one study states that fluorosis is ‘a toxic effect’ (NRC 2006). 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’. (Hansard, 20 Apr 1999 : WA 158.). 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. While the Medical Research Council suggested that this would be lower (approximately 3-4%) the more recent Australian systematic review supports the findings of the York Review. In the USA, studies have found that the level of dental fluorosis in fluoridated areas has increased over time with Jackson et al (1999) finding a 20% increase in fluoridated areas. In particular the levels of moderate to severe fluorosis are increasing. In 1997 Heller and colleagues found that in areas of water fluoridation at 0.7ppm to 1.2ppm there was 1.3% of moderate fluorosis increasing to 7.3% moderate and severe fluorosis when levels exceeded 1.2ppm. The total level of fluorosis also increases as levels of fluoride increase as shown in table 3.

Table 3: Levels of fluorosis in the USA

Fluoride (ppm)	Severity of dental fluorosis				Total levels of dental fluorosis
	1	2	3	4	
<0.3	10.7	2.4	0.4	0.1	13.6
0.3-<0.7	17.3	3.1	1.2	0.0	21.6
0.7-<1.2	22.5	5.8	1.3	0.0	29.6
>1.2	27.2	7.0	5.3	2.0	41.5

Source: Heller et al 1997

- 6.3 Rozier (1999) concluded that because the prevalence of fluorosis is now higher than 50 years ago, we can conclude that fluoride availability to the developing enamel during critical periods when enamel is at risk of fluorosis has increased in North American children. In a more recent cohort study in Iowa 1.6% of children had level 3 or higher fluorosis (Levy et al 2006). Concern about fluorosis was a key factor in the reduction of fluoride levels in Eire. In the light of both international

and Irish research which shows that there is an increasing occurrence of dental fluorosis, Irish Forum on Fluoridation (2002) recommended the lowering of the fluoride level in drinking water to a range of 0.6 to 0.8ppm, with a target of 0.7ppm. (p15). A study of Irish dental health in children in 2002 found that levels of fluorosis in Southern Ireland are substantially higher than in Northern Ireland where the water is not fluoridated (see figures 3 and 4) (Whelton et al 2004). The Irish and Canadian governments have paid attention to the increasing evidence on the negative effects of water fluoridation in combination with other sources of fluoride (see Bottenberg et al 2004).

Figure 3:

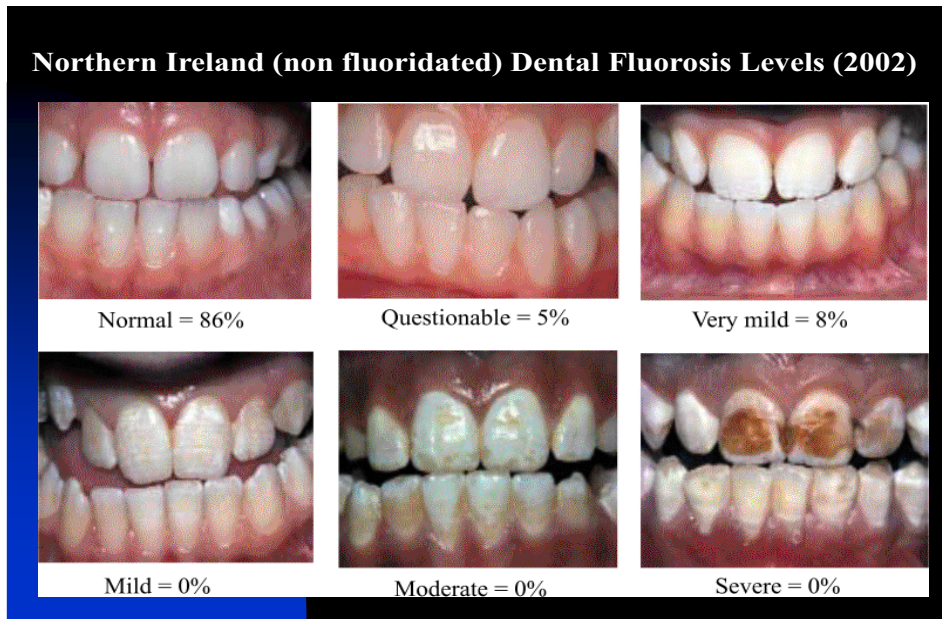
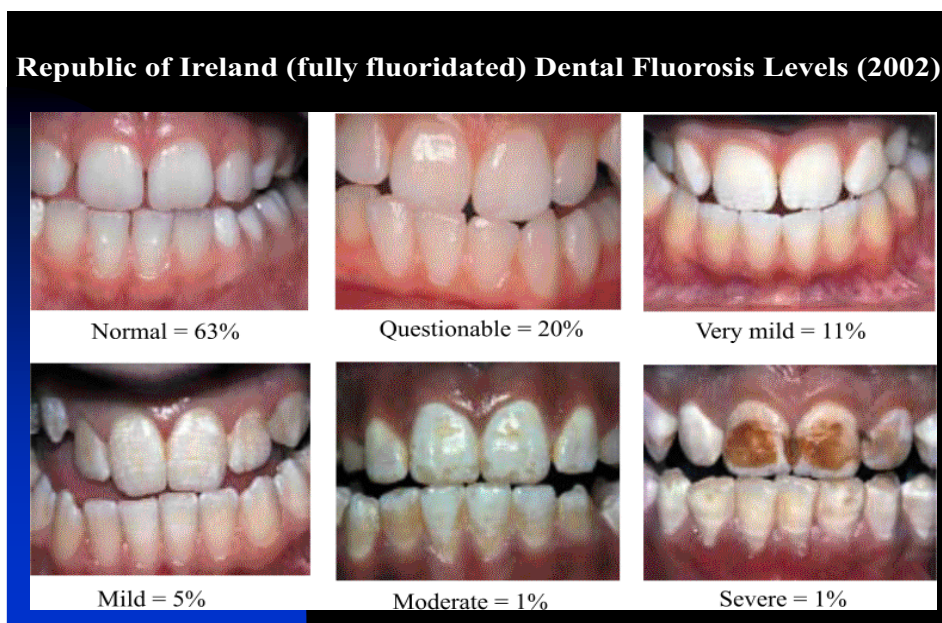


Figure 4:



- 6.4 Rates of 1.3% to 2% “moderate” to “severe” fluorosis in populations with “optimally fluoridated” water are unacceptable in a mandatory measure which is difficult for people to avoid and which affects the entire population. It may sound like a small percentage, but if you are the one in fifty with deformed enamel or brown spots, you and your parents are going to be very unhappy. Moderate fluorosis definitely harms self-esteem and detracts from people’s physical attractiveness. Current research on the effects of fluoride (funded by the Department of Health) show that fluorosis is of more than aesthetic concern and for those with brown staining, the condition is viewed as worse than having dental decay (Williams et al 2006). Similar views have been expressed in the USA and Australia (see for example Lawson et al 2008, Spencer et al 1996) and a study in Southern Ireland found that fluorosis gave rise to embarrassment among girls more than boys (Browne et al 2006). Fluorosis is also considered by the WHO as a health problem not an aesthetic one (WHO 2001, 2002).
- 6.5 In 2000, the Newcastle NHS Trust found that the prevalence of dental fluorosis among 8 - 9-year-old children in fluoridated Newcastle was 54%. They also found that in "fluoride-deficient" Northumberland, 23% of 8 - 9-year-old children have dental fluorosis. They concluded that the prevalence of "aesthetically important" dental fluorosis in the fluoridated area was 3% - six times higher than was found in the non-fluoridated area, where 0.5% of the children were affected.
- 6.6 Dental fluorosis is an indication of the level of fluoride toxicity in the body. Increasing levels of fluoride ingestion are due to an increase in all sources of fluoride, including water fluoridation. In the Iowa study, 90% of 3-month-olds consumed over their recommended 0.01 mg/kg bodyweight/per day daily-fluoride-dose from water, supplements and/or dentifrice (Levy et al 2001). Some babies ingest over 6 mg fluoride daily, above what the Environmental Protection Agency says is safe to avoid crippling skeletal fluorosis. Mean intake per unit body weight (bw) was about 0.075 mg F/kg bw through 3 months of age, 0.06 mg F/kg bw at 6 and 9 months, 0.035 mg F/kg bw at 12 and 16 months, and 0.043 mg F/kg bw from 20-36 months. Depending on the threshold chosen (e.g., 0.05 or 0.07 mg F/kg bw), variable percentages of the children exceeded the levels, with percentages greatest during the first 9 months. (Levy et al 2001) There is an increasing scientific literature identifying that ingestion levels of fluoride are increasing and this is of particular concern in babies and young children (Levy et al 1995, Erdal and Buchanan 2005, Marshall et al 2004).
- 6.7 The World Health Organisation is aware of over-exposure to fluorides and recommends that “Dental and public health administrators should be aware of the total fluoride exposure in the population before introducing any additional fluoride programme for caries (tooth cavities) prevention.” (*Fluoride and Dental Health* 1994). This has not been done in Southampton. In addition many authorities including the American Dental Association and US Public Health Departments have cautioned parents not to use fluoridated water for formula milks because of the potential over exposure to fluoride (American Dental Association). Fomon et al (2000) have recommended that the most important measures that should be undertaken in relation to over exposure :

- use, when feasible, of water low in fluoride for dilution of infant formulas;
- adult supervision of tooth brushing by children younger than 5 years of age; and
- changes in recommendations for administration of fluoride supplements so that such supplements are not given to infants and more stringent criteria are applied for administration to children.

7. Other health effects

7.1 The harmful effects of fluoride have been scientifically recognised for many years. For example, McClure (1943) stated that "With few exceptions the biochemistry of fluorine [fluoride] emphasizes its toxic features. The production of endemic dental fluorosis (mottled enamel) in human beings by drinking water is an outstanding example of the toxic effect of the excessive intake of the element." And twenty years later "Mottled enamel is an endemic hypoplasia of permanent teeth produced by toxic quantities of fluoride in drinking water. . . . There is a direct quantitative relation between the fluoride content of drinking water and clinical manifestations of dental fluorosis." (McClure 1962).

7.2 The toxicity of fluoride in the body is also accepted by the government. In response to a written question in Parliament Baroness Hayman responded for the Government: "We accept that dental fluorosis is a manifestation of systemic toxicity. . . ." (Hansard, 20 Apr 1999 : WA 158.).

7.3 The York Review examined the existing literature on health effects of water fluoridation. It only examined human studies and excluded consideration of fluoride intake from other sources. With regard to the safety of water fluoridation the authors concluded that "Overall, the studies examining other possible negative effects provide insufficient evidence on any particular outcome to permit confident conclusions. Further research in these areas needs to be of a much higher quality and should address and use appropriate methods to control for confounding factor." (McDonagh et al 2000:xiv) They recommended that further research was needed to address the many areas of concern and the lack of reliable evidence. This necessary research has not been done, meaning that mass water fluoridation is being proposed based on seriously inadequate knowledge and in defiance of the 'precautionary principle'.

7.4 Since the York Review, another rigorous analysis of the health effects of water fluoridation was undertaken in the USA. The National Research Council (NRC) reviewed the evidence on fluoride in drinking water and a panel of 12 experts spent three and half years reviewing the literature and produced a 507-page report with over 1000 references (NRC, 2006). While the focus of the review was to examine the effects of water fluoridation at between 2 and 4ppm, it identified a number of studies demonstrating health effects at levels lower than 2ppm. These included effects:

- To the central nervous system and the brain at 1.8 ppm
- Brittle bones at <1.2 ppm
- Osteosarcoma (bone cancer) in young men – 1 ppm
- Thyroid gland – <1 ppm

- Pineal gland – 1 ppm
- Still births & miscarriages – 1 ppm
- Genetic Damage – 1 ppm
- Hypersensitivity reactions – 1% at 0.25 ppm

7.5 The NRC report deals with each of these areas at some length. During the consultation the NRC report has been dismissed with the PCT and SHA arguing that it was specifically examining problems associated with between 2ppm and 4ppm levels of fluoride in drinking water. However, the studies examined by the NRC committee included all studies at differing levels of fluoride including many below the 2ppm level. Also by necessity, many human and animals studies must be conducted at levels above what is commonly experienced, otherwise it is very difficult to detect subtle health problems. But this does not mean that the adverse health effects found at higher levels will not occur to at least some people at lower exposure levels such as in fluoridation. In addition there have been subsequent studies demonstrating associations between water fluoridation and health problems. For example Bassin et al (2006) concluded that there "... exploratory analysis found an association between exposure to fluoride in drinking water and the incidence of osteosarcoma, demonstrating a peak in the odds ratio for exposure at ages 6–8 years among males diagnosed less than 20 years old, but no consistent association among females." (p427). To date no contrary studies have been published that refute these findings.

7.5 One area that was of particular concern to the NRC committee was endocrine effects. The committee concluded that: "The chief endocrine effects of fluoride exposures in experimental animals and in humans include decreased thyroid function, increased calcitonin activity, increased parathyroid hormone activity, secondary hyperparathyroidism, impaired glucose tolerance, and possible effects on timing of sexual maturity. Some of these effects are associated with fluoride intake that is achievable at fluoride concentrations in drinking water of 4 mg/L or less, especially for young children or for individuals with high water intake. Many of the effects could be considered subclinical effects, meaning that they are not adverse health effects. However, recent work on borderline hormonal imbalances and endocrine-disrupting chemicals indicated that adverse health effects, or increased risks for developing adverse effects, might be associated with seemingly mild imbalances or perturbations in hormone concentrations. Further research is needed to explore these possibilities." (NRC 2006: 8).

7.6 Since the publication of the report, members of the scientific committee have publically expressed their concerns about the effects of water fluoridation. The Chair of the scientific committee has highlighted thyroid impacts: "The thyroid changes do worry me. There are some things here that need to be explored.... What the [NRC] committee found is that we've gone with the status quo regarding fluoride for many years – for too long really – and now we need to take a fresh look" (John Doull Professor Emeritus of Pharmacology and Toxicology, University of Kansas Medical School, Chair of the NRC Committee on Fluoride in Drinking Water).

7.7 The NRC study found that "In humans, effects on thyroid function were associated with fluoride exposures of 0.05-0.13 mg/kg/day when iodine intake was adequate and 0.01-0.03 mg/kg/day when

iodine intake was inadequate.” (NRC 2006: 218) Fluoride's potential to impair thyroid function is perhaps best illustrated by the fact that -- up until the 1970s -- European doctors used fluoride as a thyroid-suppressing medication for patients with HYPERTHYROIDISM (over-active thyroid). Fluoride was utilized because it was found to be effective at reducing the activity of the thyroid gland - even at doses as low as 2 mg/day. Today, many people living in fluoridated communities are ingesting doses of fluoride (1.6-6.6 mg/day) that fall within the range of doses (2 to 10 mg/day) once used by doctors to reduce thyroid activity in hyperthyroid patients. Currently in the USA synthroid (used to treat hypothyroidism) is the second most widely prescribed drug.

- 7.8 In England it is now possible to obtain good prevalence data for hypothyroidism in the community. Initial analysis of hypothyroidism prevalence rates by PCT area, adjusted for age, has demonstrated a statistically significant relationship with water fluoridation. This is a preliminary analysis and was undertaken by the Environmental Epidemiology Unit at the London School of Hygiene and Tropical Medicine. Further data is being sought on water fluoride exposure to develop a more sensitive analysis but based on the preliminary analysis, there is sufficient evidence to hypothesise a link between water fluoridation and hypothyroidism prevalence in England and a paper is currently in preparation.
- 7.9 Much of the debate about the harmful effects of fluoride to health rest on the levels of fluoride ingestion. While water fluoride delivers a level of fluoride by volume it does not relate to ingested levels of fluoride. With the introduction of fluoride in toothpaste and dentrifice, in addition to fluoride in foods and beverages, the addition of water fluoridation tends to increase the overall levels of fluoride in the environment and in food chains leading to increasing ingestion levels. There are widely differing views about the accepted levels of maximum fluoride ingestion.
- 7.10 In particular, it is not clear what the point at which the threshold of therapeutic benefit is reached and toxic effects begin to manifest themselves. The MRC review cautioned 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’ (MRC 2002: para 3.6).
- 7.11 The World Health Organisation has identified potential adverse health effects at 6mg/kg per day for adults: “... long-term exposure to higher amounts may have deleterious effects on tooth enamel and bone; single doses of 5–10 mg/kg body weight cause acute toxic effects, and death was reported following ingestion of 16 mg/kg” (WHO 2000:4). The most important long-term adverse effect of fluorides on human populations is endemic skeletal fluorosis. It is therefore of crucial importance to gather information on fluoride sources in the diet, especially water, the aetiology of early skeletal fluorosis as related to bone mineralization, and dose–response relationships (WHO 1984, 2000).

7.12 The World Health Organisation identifies that levels of fluoride above 6mg/kg per day will lead to significant health problems. However, levels for children are of particular concern given that in many cases they exceed 0.05mg/kg per day and also 0.07mg/kg per day. There is little good data on the accumulated effects of fluoride in the human system. However, changes to bone structure (including brittle bones), endocrine effects, allergic reactions, etc. are widely accepted as resulting from levels of fluoride that people in areas of water fluoridation are subjected to due to high levels of ingested fluoride from all sources (NRC 2006). Currently exposure levels in the UK are not as high as in Eire and the USA but water fluoridation is limited to 10% of the population. Recent analysis of fluoride exposure in the National Diet and Nutrition Survey (Henderson et al 2003) has identified that even in the UK we should be concerned about increasing fluoride levels. 14% of this sample, regardless of water fluoride, consumes more than 5 mg fluoride daily and 1.3% more than 10 mg daily, which is indisputably sufficient to cause concern (Mansfield 2008, unpublished data). In relation to children the situation is more worrying. Between age 6 months and six years the safe intake of fluoride is considered by CoMA to be 0.12mg/kg/day, and in younger infants 0.22mg/kg/day. Small children retain up to 70% of ingested fluoride, making them more vulnerable to the long-term disbenefits of over-consumption (Levy et al 1995, Levy et al 2001, Erdal and Buchanan 2005).

7.13 The York Review concluded that it would be sensible for future studies of water fluoridation to measure the total fluoride exposure in areas being researched due to the potential toxicity of high doses of fluoride. It is estimated that water fluoridation at 1ppm could increase normal dietary intakes by 54%. (Walters et al 1983). Studies are now showing substantial increases in fluoride ingestion from all sources and water fluoridation should not be considered in isolation from other sources of fluoride. The overall conclusion of the NRC report is that '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. In addition, links with cancer need further investigation as do the effects of fluoride on the endocrine system. Similarly the UK MRC review committee were concerned about increasing fluoride exposure and made recommendations about needing new studies and also monitoring of future fluoride exposure (MRC 2002).

8. Alternative interventions to reduce dental decay

8.1 There is little reference within the consultation process to alternatives to water fluoridation. An evidence based approach to caries prevention would compare evidence on the different types of intervention. This has not been done. If a drug regime was being introduced it would be compared to current treatment regimes or other interventions. This should also be the case for water fluoridation. There are a number of alternative interventions to reduce dental caries and as table 2 has shown water fluoridation is one of the weakest interventions. There is good evidence that different types of approach work.

- 8.2 We would not support interventions such as salt fluoridation or other ingested approaches to fluoride delivery (eg milk fluoridation or provision of bottled fluoridated water) as the main aim should be to reduce fluoride ingestion. However, a number of non fluoride approaches and the topical application of fluoride interventions have been proved to be effective. Insufficient information has been provided by the PCT to ascertain what interventions and how they were delivered have already been undertaken.
- 8.3 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' (Secretary of State for Health 2008). 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 (Irish Fluoridation Forum 2002).
- 8.4 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% (Scottish Consumer Council 2005). Daily, weekly and fortnightly mouth rinsing programmes have been shown to be effective but cost more than water fluoridation (Irish Fluoridation Forum 2002). 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.' (Mahrinho et al 2003). Additionally, mouth rinses 'have been shown to reduce dental decay in adult teeth by 26%' (Mahrinho et al 2003).
- 8.5 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.' (Weintrub et al 2006). In its response to the Health Select Committee report on dental services the Government argued that "One of the most beneficial and evidence-based preventive procedures available is the application of topical fluoride varnishes to children's teeth. Evidence to support this has been available for 30 years, but there is no evidence of its widespread adoption under the old contract system. There is now growing evidence of its use, initiated both by individual dental practices and through PCT schemes. We have made this one of the measures in the enhanced clinical data set, and early evidence shows that it is increasing. It is covered by band 1 and can be provided by suitably trained dental professionals." (Secretary of State for Health 2008).
- 8.6 The Governments own dental health strategy advocates many community based oral health interventions based on the principle of a whole health approach to oral health. This aims to tackle

issues of diet, health living alongside oral health promotion. Community approaches such as Glasgow's community oral health promotion programme, Hounslow shopping centre based services and US programmes delivering services in schools have been shown to be effective (Blair et al 2006, DH 2005, 2007, Niederman et al 2008). There is high quality research to support these interventions as being effective when delivered appropriately. The Glasgow programme, while targeted at specific areas of deprivation was found to have a positive impact on city wide caries rates indicating that the programme was highly effective (Blair et al 2006). Poor outcomes are often associated with poor service delivery.

9. Ethics

- 9.1 The Nuffield Council Bioethics report on public health ethics (2007) has been mentioned several times in the consultation process. However, no reference has been made to the fact that the Council accepted the highly contentious nature of water fluoridation and the obvious problems of lack of good scientific evidence. In discussing the ethics and legality of water fluoridation the consultation document draws on selected references that are positive but ignores legal rulings and ethical opinions that are contrary. The paper's reference to the Nuffield Bioethics report is brief and fails to mention the fact that the Council accepted the highly contentious nature of water fluoridation and the obvious problems of lack of good scientific evidence. In addition, there is a curious reference to the 1964 Irish Supreme Court ruling in 4.9.2 about water fluoridation not being mass medication but there are other legal and ethical views that are contrary to this position (e.g. Opinion of Lord Jauncey in *causa Mrs Catherine McColl (A.P) against Strathclyde Regional Council*. The Court of Session, Edinburgh, 1983). In addition in the Netherlands a Supreme Court ruling of 1973 stated that there was no legal basis for water fluoridation.
- 9.2 Water fluoridation involves no choice – it is akin to mass medication. As such it is unethical to use the public water supply as a means of delivering a medicine that no one can avoid. Normal medical practice is for a doctor to assess a patient's need, prescribe for him or her as an individual and supervise the treatment. At any stage of this procedure the patient is free to accept or refuse to follow the doctor's orders. Fluoridation entirely flouts this ethical procedure. Under the Charter of Fundamental Rights of the European Union, 2000 (of which our Government is a signatory) Article 3 referring to the right to the integrity of the person states that "Everyone has the right to respect for his or her physical and mental integrity and that in the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned . . .". In particular water fluoridation does not provide a controllable dose of fluoride to individuals.
- 9.3 The Nuffield Bioethics report accepted that there is evidence of harm even though the extent and significance of harm required further research, echoing the conclusions of the two systematic reviews, the UK MRC report and the NRC report (McDonagh et al 2000, MRC 2002, NRC 2006, NH MRC 2007). The Nuffield Council concluded that "The acceptability of any public health policy involving the water supply should be considered in relation to: (i) the balance of risks and benefits;

(ii) the potential for alternatives that rank lower on the intervention ladder to achieve the same intended goals; and (iii) the role of consent where there are potential harms” (paragraph 7.26). In particular the Council further recommended that “All the groups involved in the fluoridation debate should ensure that the information they produce presents a balanced account of risks and benefits, and indicates accurately the strengths and weaknesses of the evidence base.” (Paragraph 7.47)

9.4 The European Commission (2000) has identified five elements to the precautionary principle applied to assessments of public interventions. These are

- Scientific assessment of risk, acknowledging uncertainties and updated in the light of new evidence
- Fairness and consistency
- Consideration of costs and benefits of actions
- Transparency
- Proportionality

9.5 While these elements are apparently self evident and provide a clear framework the problems occur in their application and interpretation. However, all five elements are of pertinence to water fluoridation but there are two key elements where particular problems occur. The first is in terms of evidence of effect and the other relates to the concept of proportionality. There is scientific debate about the nature or extent of benefits and harms of water fluoridation as a public health intervention. In particular the most recent evidence suggests that the effect of water fluoridation is minimal and unlikely to contribute to reductions in dental decay. Thus given the evidence on harmful effects the key question is one of proportionality. Is the proposed scheme likely to bring more benefit than harm? Considering the existing state of the evidence the conclusion must be that it will not. Other interventions are more likely to produce benefit and do not produce wider harm to the general population. Clearly, public health professionals and policy makers should ensure that any intervention is supported by the best evidence. Kriebel and Tickner (2001) argue that while the Rio Declaration was addressing environmental concerns the principle equally applies to public health actions. They cite four central components to the principle:

- (1) taking preventive action in the face of uncertainty;
- (2) shifting the burden of proof to the proponents of an activity;
- (3) exploring a wide range of alternatives to possibly harmful actions; and
- (4) increasing public participation in decision making.

9.6 Water fluoridation is banned in many countries. Many Western European countries have experimented and carried out detailed research into fluoridation and all but Ireland, the UK and Spain have stopped the practice, usually citing health and ethical concerns.

9.7 The Nuffield Council on Bio-ethics recommended in their report on public health ethics that “*Policy makers and the public need to have access to clear accurate information, and uncertainties and the*

strength or weaknesses of the evidence should be explicitly recognized.” (Nuffield Council para 7.51). The Council’s report also highlights the need to consider the issue of consent alongside balancing risks and benefits and the potential alternatives. As Locker and Cohen argue “Standards regarding the optimal level of fluoride in the water supply were developed on the basis of epidemiological data collected more than 50 years ago. There is a need for new guidelines for water fluoridation that are based on sound, up-to-date science and sound ethics. In this context, we would argue that sound ethics presupposes sound science.” (579) Furthermore Locker and Cohen argue that as there is an absence of comprehensive, high-quality evidence about the benefits and risks of water fluoridation “...the moral status of advocacy for [water fluoridation] is, at best, indeterminate, and could perhaps be considered immoral.” (579).

10. The consultation process

10.1 In conducting the consultation the SHA has asked the general public for their views “.. about the pros and cons of this proposal and any evidence that you might feel support your views”. Given that the SHA has stated that only high quality peer reviewed evidence will be considered ‘cogent’, I am not sure how local people are supposed to access and assess the evidence given that scientists, doctors and dentists cannot agree on the interpretation of the evidence. The consultation documents provide only a brief summary of the issues and do not assess the full range of evidence – particularly about the harmful effects and safety of water fluoridation. The consultation document has been widely criticised for not presenting information in an unbiased way.

10.2 No effort has been made by the SHA to ensure that relevant material such as the York Review and the National Research Council, is made available for people to read either at the Drop-In sessions, local libraries etc. There is only a link on the web site to various documents but many people do not have access to the internet. It is not clear whether those people who express an ethical objection to water fluoridation will have a cogent point of view and how will the SHA assess the difference, for example, between someone who holds a valid ethical position that they should not be forced to drink fluoridated water to someone who has a religious objection, such as a Muslim? It is also not clear what weight will be given to the responses in the telephone survey? Will these responses be given more weight than other responses? These things are still very unclear. With regard to the monitoring of responses it is still unclear what weight will be given to individual responses and how these will be credited as responses. There is no space for people to put their name and address on the response forms so anyone can respond putting in simply whether they live or work in the area – this is clearly open to abuse. There is no way that multiple copies of the forms or on-line submissions have not been done by the same person or organisation or persons outside the area. For example at the Question and Answer sessions there were a large contingent of West Midlands and other non local NHS and DH professionals in attendance and allowed to speak.

10.3 The consultation material makes selective use of ‘evidence to support a particular standpoint’ rather than providing an unbiased presentation of facts. Little if no reference is made to the

extensive literature on the health effects of fluoride. It appears that greatest weight is given to dental research with toxicology and chemistry papers ignored. The consultation paper also refers in section 2.8 to the fact the paper "Considers some of the environmental issues around water fluoridation". These in fact are not addressed anywhere in the consultation paper.

10.4 There are also repeated claims of safety that are not supported by the best evidence. Emphasis is placed on countries that have water fluoridation and not on the majority of countries that do not. No reference is made to the fact that some countries and communities have abandoned water fluoridation (e.g. The Netherlands, Quebec City) or that levels of fluoride added to water in the Irish Republic, Canada and Hong Kong have been reduced due to concerns about increasing levels of dental fluorosis. In particular, the paper repeats the claim of "adjusting or topping up" naturally occurring fluoride in the water when in fact it is increasing the level of fluoride some 12.5 times by the ADDITION of hexafluorosilicic acid. It also repeats the assumption that 1ppm is the optimum level of fluoride despite no evidence to support this and with the majority of scientific opinion only referring to safe levels of 0.05mg to 0.07mg per kilogram of body weight. Many authorities including US Public Health Departments, the American Dental Association and even the British Fluoridation Society are expressing caution regarding use of fluoridated water for baby milk but again is this not referred to in the consultation document.

10.5 We are concerned that the SHA is not observing its own advice within the consultation paper and is not conforming with the strict guidance laid down by Parliament to undertake an impartial public consultation on public water fluoridation. In accordance with the guidance issued in the Water Act 2003 and by the Cabinet Office on public consultations the SHA should be conducting an informative, fair and balanced process that presents all the facts to the public. The SHA is not providing unbiased information, nor is it relying only on the best scientific evidence. The SHA has been providing biased information and has, therefore, been misleading the public and clearly does not comply with the guidance. This is particularly important as the PCT has also been actively promoting water fluoridation using the NHS logo giving rise to confusion that the SHA is actively promoting water fluoridation as well. People do not distinguish between the SHA and PCT as both are the NHS.

10.6 The SHA has not made it entirely clear to the public how their views will be considered. The adverts and publicity material explicitly ask for people to make their views known but does not require evidence. However, nowhere on the forms or adverts does it say that only views supported by 'cogent evidence' will be considered despite this being explicit in SHA reports and in the letter by Olga Senior. It would seem that anyone who states that they simply do not want fluoride added to their water or that they feel it takes away their freedom of choice or consent will be ignored.

10.7 The consultation document does not reflect this cautionary approach. It makes no mention of the more recent research, post the York Review on the problems associated with water fluoridation except the UK MRC report which was not a systematic review but, nevertheless, identified the need for further research, and the Australian MRC report which essentially endorsed the findings of the

York Review. Yet the consultation document does not reflect these findings in any balanced way. The discussion of fluorosis does not reference the most recent research examining fluoride ingestion and fluorosis nor is there reference to the fact that concern about fluorosis was a key factor in the reduction of fluoride levels in Eire. Current research on the effects of fluoride (funded by the Department of Health) show that fluorosis is of more than aesthetic concern and for those with brown staining the condition is viewed as worse than having dental decay.

10.8 It is not made clear in the consultation document that the figures for decay rates do not correspond to the area covered by the scheme. Parts of this area have lower decay rates (especially Eastleigh and Test Valley) and some areas of Southampton, while other parts covered by the scheme have higher rates. No mention is made of dental decay rates for other ages even though the rate for 12 year olds is recommended by community dentists as the most appropriate rate to consider when comparing dental decay rates. Nor is reference made to the dramatic fall in rates of dental decay rates in Southampton and the surrounding areas over the last ten years. The focus on the last three years is not a sufficient time period to monitor rates of dmft/DMFT. The fact that the rate for 12 year olds is now 0.69 DMFT in Southampton and lower than in any study which has examined the effect of water fluoridation, challenges the central assumption of the proposal that water fluoridation will be effective. You acknowledge that the data quoted in the consultation document is for the city not for the area covered by the proposed scheme but this is not made clear in any of the consultation literature.

10.9 The Abacus Report is seriously flawed as it is clear that not only are the capital costs understated but the level of benefit and the estimated savings are overstated (points acknowledged in the report but not referred to in the consultation document) leading to a substantial underestimate of the costs overall and the £0.32 per carious lesion is clearly completely wrong and should not be referred to in the consultation document. There is no evidence that water fluoridation leads to lower dental costs or savings but none of this is referred to in the consultation document.

10.10 Within the consultation document there is no discussion of environmental concerns despite a clear statement in the document that these are addressed. Also there is a lack of reference in the consultation document to what is being added to the water supply and like the PCT the SHA uses the words "topping up" when in fact the proposal is to **add** hexafluorosilicic acid. There is also no discussion about recent concerns about fluoride ingestion for children and babies under 3 years old and, in particular the use of fluoridated water for reconstituting formula baby milk.

10.11 A key problem in the consultation has been the action of the PCT in promoting water fluoridation at the expense of any other activity to promote good oral health. The PCT has funded adverts in newspapers, at station billboards, undertaken door to door delivery of postcards promoting "Healthier teeth on Tap" with no reference to cogent or actual research evidence. They have run road shows in supermarkets and in the city centre handing out the leaflets on water fluoridation and post cards to return supporting water fluoridation. These have also been put in every dental and GP surgery, chemists and the walk-in centres. None of these activities has included

general dental health education or material. The PCT has spent thousands of pounds on these activities that should have been used for more bona fide NHS activities and people assume that this is the same as the SHA consultation. This excludes the enormous amount of staff time involved in the PCT with public health staff 'working flat out on water fluoridation' for the past few months (personal communication from PCT employee). The PCT cards have no evidence to support the "Healthier teeth on tap" message but as they carried the official NHS logo, people have returned them thinking that they should simply because they were distributed by the NHS. In contrast, the Hampshire Against Fluoridation cards, produced in response to the door to door delivery of the PCT post cards (although we were unable to fund the same number as the PCT or fund door to door delivery), were designed to introduce some balance into the debate by referring to evidence and cogent reasons for not supporting water fluoridation. We estimate that the PCT produced some 70,000-80,000 cards compared to our 15,000. The Hampshire Against Fluoridation cards should therefore, be given higher status than the PCT cards.

10.12 Since before the consultation began Hampshire Against Fluoridation expressed its concerns about the nature of the consultation process. Some of these have been borne out in practice. The consultation material has not been balanced and even in the last weeks of the consultation many residents are unaware that a consultation process was being conducted. As an unfunded group much of our activity has been trying to raise people's awareness of the consultation and that people should respond to the consultation. In addition, many people felt that as the NHS had been actively promoting water fluoridation in the local area it was going to happen anyway and therefore it was not something they could have a say in or that their views would not be influential. The SHA did not conduct any door to door distribution of material about the consultation and it was only at our suggestion that a leaflet was distributed with the Advertiser and this did not occur until the end of November. This should have done earlier and on more than one occasion.

10.13 A number of complaints have been made to the Advertising Standards Authority about PCT promotional and marketing material. These complaints have been deemed of substance and are currently under investigation by the ASA. In addition a complaint has been made to the Parliamentary and Health Ombudsman about the whole consultation process as it has been biased and undermined by the PCT.

11. Conclusion:

11.1 Given the weight of evidence, Hampshire Against Fluoridation is opposed to the proposal to fluoridate the water supply in the Southampton area. There are no strong scientific grounds for supporting the proposal. There is no strong data on the need for the scheme and there is no economic justification for the proposal. The proposal is also ethically unsound and the consultation process has not presented a fair and balanced case. Water fluoridation has minimal benefit and any benefit is in populations where caries rates are high. Given that the chief dental officer has commented " ...that the oral health of English children was comparable with the best in the world"

(Health Select Committee 2008:12), there cannot be any circumstances in which water fluoridation should be considered in this area. As Pizzo et al (2007) conclude: “ ... water fluoridation may still be a relevant public health measure in populations where oral hygiene conditions are poor, lifestyle results in a high caries incidence, and access to a well-functioning oral health care system is limited. Instead, topical fluoride offers an optimal opportunity to prevent dental caries among people living in both industrialized and developing countries, and the use of fluoride-containing products, particularly the toothpaste, needs to be maintained and expanded.”(192). The weight of scientific opinion is shifting against water fluoridation. The key concern is that it is ineffective at addressing dental caries where caries rates are low. Also as it is widely accepted that caries rates are low and that the main caries problems relate to bottle caries, children with high levels of streptococcus mutans and children with pit and fissure caries. Oral hygiene and topical fluoride applications are substantially more effective. The value of systemic fluorides has been shown to be poor.

11.2 The PCT has not provided a credible case to justify water fluoridation. It is clear that targeted approaches if delivered effectively will have more effect on caries rates in young children. The economic case has not justified the cost effectiveness of water fluoridation in the current proposal and it is clear that water fluoridation will be an additional cost burden on the existing dental budget leading to reductions in services in other areas unless funding is increased (as has happened in the West Midlands). There has been no balanced analysis of the harmful effects of water fluoridation or the impact on increasing fluoride exposure. There is good evidence to demonstrate that at a minimum water fluoridation will lead to increased levels of dental fluorosis of a moderate or severe nature. In addition, the weight of evidence suggests that further health problems are likely to occur due to over exposure to fluoride. This is of particular concern in infants and babies. The ethical case is not clear and there has been no discussion of the complex ethical issues that water fluoridation gives rise to. The Nuffield Council Report does not provide a clear ethical basis for the SHA to support water fluoridation. Nor does reference to the views of a particular ethicist or the Irish Supreme Court – particularly since such views were expressed before more recent scientific opinion had been published. Finally Hampshire Against Fluoridation remains concerned that the consultation process has not been conducted in a fair and balanced way. The consultation material has not been neutral or provided a balanced discussion of the relevant evidence. The actions of the PCT have been unconstrained and led to a substantial amount of misinformation about the proposal which has fatally undermined any notion of ‘consultation’ with a properly and widely informed public.

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