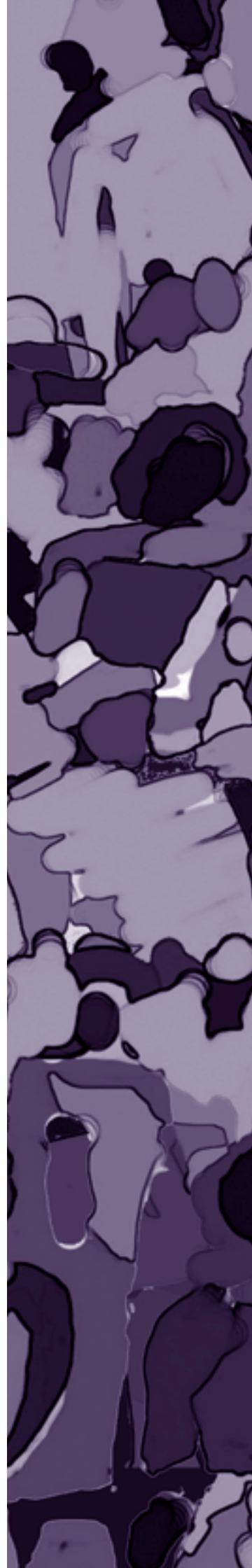


Chapter 7

Case study –
Fluoridation of water



Case study – Fluoridation of water

Introduction

- 7.1 Water fluoridation is an example of an intervention that directly affects whole populations, in this case for the purpose of improving dental health. Because of the relative difficulty of 'opting out', the measure raises ethical and policy issues: what is the justification for overriding the preferences of those people who wish to receive water that has not been fluoridated? Is the intervention justifiable even if it is not possible (or feasible) to obtain individual consent? In this chapter we begin by providing some background information on dental health, the technical principles behind water fluoridation, and alternative fluoride-based dental health measures. We then consider how different ethical principles outlined in Chapter 2 could potentially be used in support of, or against, water fluoridation, and how the principles should be weighed against one another. The case of fluoridation also raises particular issues about the nature and strength of evidence required in arguments about the acceptability of an intervention, and about ways in which evidence is, and should be, communicated. We therefore, finally, consider the role of evidence and information in policy, and the way different parties in this debate use and communicate evidence.
- 7.2 Although we focus here on fluoridation, we note that some similar ethical issues are raised about policies on the fortification of foods. Several such programmes are in place in the UK as means of improving the health of a population or sub-population, for example adding vitamins and

Box 7.1: Fortification of flour with folic acid

Folate, a B vitamin, is essential to everyone's health.¹ Insufficient levels during early pregnancy of folate or its synthetic substitute, folic acid, can lead to neural-tube defects in the newborn.² For some time, folic acid supplements have been recommended before and during pregnancy. However, research has found that only 55% of women planning a pregnancy increased their folate intake as recommended.³ Furthermore, because around 50% of pregnancies are unplanned, many women may not start taking folic acid sufficiently early. The recommended folate intake for women of child-bearing age is 600 micrograms (µg) per day, but the National Diet and Nutrition Survey indicates that 34% of women of child-bearing age have intakes of less than 200 µg per day, and this is particularly common in lower socio-economic groups.⁴

Because of this situation, consideration has been given in the UK to fortification of food with folic acid. In 2007 the Board of the Food Standards Agency recommended the mandatory fortification of either bread or flour.⁵ This followed a report by the Scientific Advisory Committee on Nutrition (SACN), which recommended fortifying flour with folic acid to a level that they estimated would result in 77–162 fewer pregnancies with neural-tube defects in the UK each year.⁶ They also estimated that this level of fortification would reduce the proportion of people across the population consuming less than the recommended amount of folate from 23% to 5%. Flour is already fortified with folic acid in the USA, Canada and Chile.⁷

There have been concerns that folic acid fortification may 'mask' vitamin B12 deficiencies in the elderly. However, SACN has suggested that this effect is not seen with doses of 1 mg/day or less, and that there are no reports of these effects in countries with mandatory folate fortification.⁸ The Committee also found insufficient evidence for several other adverse effects that it considered.

Although comparisons between folic acid fortification and water fluoridation are interesting, it should be noted, first, that folic acid fortification is not known to be associated with harms (see paragraphs 7.31–7.32); and secondly, that wholemeal flour/bread would be excluded from the policy, enabling individuals to opt not to receive the fortified foods.

¹ Food Standards Agency, *Folic Acid*, available at: <http://www.eatwell.gov.uk/healthydiet/nutritionessentials/vitaminsandminerals/folicacid/>.

² *Ibid.*

³ Scientific Advisory Committee on Nutrition (2006) *Folate and Disease Prevention*, available at: http://www.sacn.gov.uk/pdfs/folate_and_disease_prevention_report.pdf.

⁴ *Ibid.*

⁵ Food Standards Agency (2007) Press release: *Board recommends mandatory fortification*, available at: <http://www.food.gov.uk/news/newsarchive/2007/may/folatefort>. At the time this Report went to press, the Food Standards Agency was in the process of considering whether it should be bread or flour that was fortified and presenting its recommendations to UK Health Ministers.

⁶ Scientific Advisory Committee on Nutrition (2006) *Folate and Disease Prevention*, available at: http://www.sacn.gov.uk/pdfs/folate_and_disease_prevention_report.pdf. It is estimated that in 2003 there were 630–850 pregnancies with neural-tube defects in England and Wales, and at least 49 in Scotland and 11 in Northern Ireland. Of these pregnancies, varying proportions (generally at least 50%) were terminated in different UK countries, except in Northern Ireland, where none were terminated.

⁷ Scientific Advisory Committee on Nutrition (2006) *Folate and Disease Prevention*, available at: http://www.sacn.gov.uk/pdfs/folate_and_disease_prevention_report.pdf.

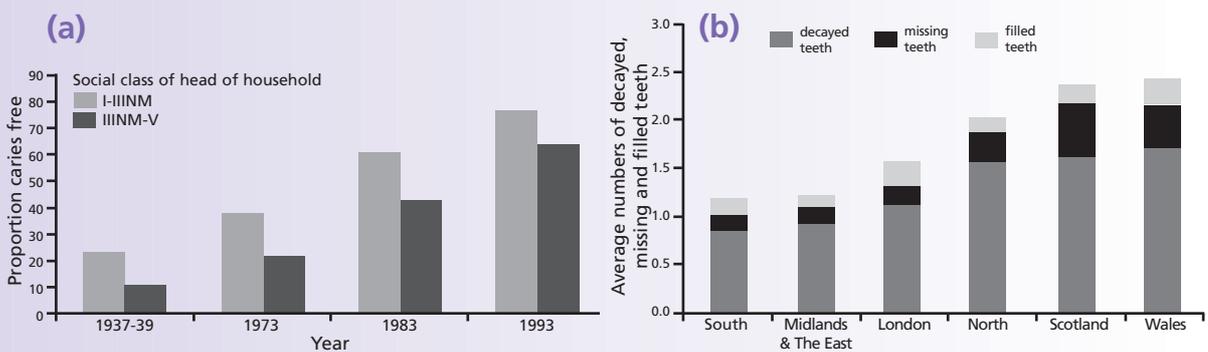
⁸ *Ibid.*

minerals to margarines and breakfast cereals, while a policy of fortifying flour with folic acid is, at the time of writing, under consideration (see Box 7.1).

Dental health in the UK

7.3 Children's dental health in the UK has been improving over recent decades (see Figure 7.1a). In 2003 the UK Children's Dental Health Survey reported lower levels of obvious dental decay (also called dental caries) than had previously been recorded in the permanent teeth of 8-, 12- and 15-year-olds.⁹ The proportions of children affected by decay in each age group were 14%, 34% and 49%, respectively, compared with 38%, 83% and 91% in 1983.¹⁰ In 2003 the mean numbers of teeth with obvious decay in these age groups were 0.2, 0.8 and 1.6, respectively, compared with 0.8, 3.1 and 5.9 in 1983. These figures are, however, UK averages, and dental health varies considerably across different social groups and areas of the UK (see Figure 7.1). Surveys by the British Association for the Study of Community Dentistry of 5-, 11-, and 14-year-old children in England, Wales and Scotland have all shown wide variation in caries prevalence in different areas (see Figure 7.1b).¹¹

Figure 7.1: Children's dental health in the UK*



(a) Oral health of children aged 5 in England, 1937–1993. Data: National Children's Dental Health Surveys, 1973 to 1993. Data for other UK countries for 1983 and 1993 indicate that similar trends over time and with socio-economic group were evident in these areas also. The 2003 survey used a different classification system, but indicated further improvements in dental health although socio-economic inequalities persisted.

(b) Occurrence of dental caries, measured as average numbers of decayed, missing and filled teeth, of children aged 5 in Great Britain. Data: The dental caries experience of 5-year-old children in England and Wales (2003/4) and in Scotland (2002/3); surveys co-ordinated by the British Association for the Study of Community Dentistry.

*Figures reproduced under the terms of the Click-Use Licence, from: Department of Health (2005) *Choosing Better Oral Health: An oral health plan for England* (London: Department of Health), available at: <http://www.dh.gov.uk/assetRoot/04/12/32/53/04123253.pdf>.

⁹ National Statistics (2004) *Executive Summary of preliminary findings: 2003 Children's Dental Health Survey*, available at: http://www.statistics.gov.uk/downloads/theme_health/Executive_Summary-CDH.pdf.

¹⁰ National Statistics (2005) *Children's Dental Health in the United Kingdom, 2003 Summary Report*, available at: http://www.statistics.gov.uk/CHILDREN/dentalhealth/downloads/cdh_Summary.pdf.

¹¹ Pitts NB, Boyles J, Nugent ZJ, Thomas N and Pine CM (2007) The dental caries experience of 5-year-old children in Great Britain (2005/6). Surveys co-ordinated by the British Association for the Study of Community Dentistry *Community Dent Health* **24**: 59–63; Pitts NB, Boyles J, Nugent ZJ, Thomas N and Pine CM (2006) The dental caries experience of 11-year-old children in Great Britain. Surveys coordinated by the British Association for the Study of Community Dentistry in 2004 / 2005 *Community Dent Health* **23**: 44–57; Pitts NB, Boyles J, Nugent ZJ, Thomas N and Pine CM (2004) The dental caries experience of 14-year-old children in England and Wales. Surveys co-ordinated by the British Association for the Study of Community Dentistry in 2002/2003 *Community Dent Health* **21**: 45–57.

Water fluoridation

Background to fluoride and water fluoridation

- 7.4 The chemical element fluorine is found combined with other elements to form fluoride compounds in soil, rock, air and water.¹² Although all water contains dissolved fluoride, the concentrations at which it is present naturally in water vary considerably, from less than 0.5 parts per million (ppm) to, rarely, as high as 25 ppm.¹³ Fluoride can also be present in various food and drink products that people may consume, in particular tea.¹⁴
- 7.5 Fluoride is a mineral. It is unclear whether, in biological terms, it should be considered an essential mineral,¹⁵ but it does appear to be of benefit in the prevention of tooth decay, or dental caries (see Box 7.2). This benefit was first suggested in the 1930s and 1940s when researchers in the USA compared areas with different levels of natural fluoride in the water.¹⁶ In 1945 the first water fluoridation scheme was implemented in the USA, and this was followed by further schemes in the USA, the UK and elsewhere. The water fluoride level used in these schemes, and still widely used today, was 1 ppm. This was suggested to be a suitable level at which the prevalence of dental caries was reduced and adverse effects were rare.¹⁷

Box 7.2: How does fluoride work?

Current research suggests that fluoride affects demineralisation and remineralisation of the tooth, and has anti-bacterial effects. These properties alter the process by which dental caries may occur.¹⁸ It is estimated that most, if not all, anti-caries effects of fluoride occur through the presence of fluoride in the mouth, and that maintaining adequate levels of fluoride in the mouth is essential for preventing and controlling decay.¹⁹ It is unclear whether there is a systemic effect from fluoride that is ingested.²⁰

Benefits and harms of water fluoridation

- 7.6 The purpose of water fluoridation, where it is implemented, is to reduce dental caries. However, the extent of any reduction has been difficult to quantify on the current evidence. Some of the early studies on water fluoridation suggested that the measure was highly beneficial. For example, research into the scheme begun in 1945 concluded that water

¹² European Food Safety Authority (2005) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the tolerable upper intake level of fluoride *European Food Safety Authority Journal* **192**: 1–65, available at: http://www.efsa.europa.eu/etc/medialib/efsa/science/nda/nda_opinions/851.Par.0001.File.dat/nda_op_ej192_fluoride_corrigenum1.pdf.

¹³ Expert Group on Vitamins and Minerals (2001) *Review of Fluoride*, available at: <http://archive.food.gov.uk/committees/evm/papers/evm0103.pdf>. Consuming water with very high fluoride levels can be harmful (see paragraphs 7.7, 7.31–7.33 and Box 7.3), and consequently in some places the fluoride level in the drinking water supply is reduced. In the UK, the maximum level of fluoride permitted is 1.5 ppm under the Water Supply (Water Quality) Regulations 2000 and Water Supply (Water Quality) (Scotland) Regulations 1990. In the USA the guideline maximum contaminant level goal is 4 ppm, although there are some calls for this to be reduced. Committee on Fluoride in Drinking Water, National Research Council of the National Academies (2006) *Fluoride in Drinking Water* (Washington, DC: National Academies Press).

¹⁴ European Food Safety Authority (2005) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the tolerable upper intake level of fluoride *European Food Safety Authority Journal* **192**: 1–65, available at: http://www.efsa.europa.eu/etc/medialib/efsa/science/nda/nda_opinions/851.Par.0001.File.dat/nda_op_ej192_fluoride_corrigenum1.pdf.

¹⁵ Essential minerals are those that are required for human health, either for growth or to sustain life, and as such if insufficient amounts are consumed adverse health effects occur. It is unclear whether fluoride should be categorised as an essential mineral. Expert Group on Vitamins and Minerals (2003) *Safe Upper Levels for Vitamins and Minerals* (London: Food Standards Agency), available at: <http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf>.

¹⁶ Lennon MA (2006) One in a million: the first community trial of water fluoridation *Bull World Health Org* **84**: 759–60.

¹⁷ *Ibid.*

¹⁸ Clarkson J (Ed) (2000) International collaborative research on fluoride *J Dent Res* **79**: 893–904.

¹⁹ *Ibid.*; Aoba T and Fejerskov O (2002) Dental fluorosis: chemistry and biology *Crit Rev Oral Biol Med* **13**: 155–70.

²⁰ Clarkson J (Ed) (2000) International collaborative research on fluoride *J Dent Res* **79**: 893–904

fluoridation was “remarkably effective” in reducing the prevalence of dental caries among children.²¹ However, in many of the studies on fluoridation, particularly the early ones, the methodologies used have not been of high quality. A major review of the evidence on water fluoridation was published in 2000 by the Centre for Reviews and Dissemination at the University of York (hereafter referred to as the York review).²² It concluded that the best available evidence suggested that fluoridation of drinking water reduced the prevalence of caries, but found that the reduction was difficult to quantify from the evidence available.

- 7.7 Drinking fluoridated water can have adverse effects, the risks of which increase with higher levels of consumption. Dental fluorosis, a defect of the tooth enamel that causes visible markings on the teeth, is the most well known and frequently studied negative effect of fluoridation (see also Box 7.3).²³ It can vary from mild speckling to more substantial staining and pitting of the teeth, and may have a psychological effect on the children concerned. Estimates of the prevalence of fluorosis among people receiving fluoridated water vary. The York review and a report by the Medical Research Council suggested prevalences of 12.5% and 3–4%, respectively, for fluorosis serious enough to cause aesthetic concern at a fluoridation level of 1 ppm (see also paragraph 7.32).²⁴ Besides fluorosis, some have suggested other harms may be associated with water fluoridation, including bone fractures and cancer, although the evidence for such effects is generally weak; we discuss these further later (see paragraph 7.31).
- 7.8 We have not, in this chapter, sought to re-assess the evidence on fluoridation. In our discussions we have drawn on expert assessments by others, and in particular the York review, because this represents the most recent major review in this area.²⁵ We do, however, note a comment made by authors of the York review that: “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”.²⁶ This is particularly surprising as fluoridation has been implemented as an intervention in some areas of the country, and has been considered as a policy option in others, over several decades. Later in the chapter we return to consider further the reported benefits and harms of fluoridation in relation to the ethical principles and the stewardship model established in Chapter 2 (paragraphs 2.41–2.44, 7.29–7.33).

²¹ Lennon MA (2006) One in a million: the first community trial of water fluoridation *Bull World Health Org* **84**: 759–60.

²² McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

²³ Committee on Fluoride in Drinking Water, National Research Council of the National Academies (2006) *Fluoride in Drinking Water* (Washington, DC: National Academies Press).

²⁴ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination); Medical Research Council (2002) *Water Fluoridation and Health* (London: MRC).

²⁵ For more information on the methods used in the York review and for discussion of the rigorous approach taken, see: McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination); Medical Research Council (2002) *Water Fluoridation and Health* (London: MRC); Wilson PM and Sheldon TA (2006) Muddy waters: evidence-based policy making, uncertainty and the ‘York review’ on water fluoridation *Evidence and Policy* **2**: 321–31.

²⁶ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

Box 7.3: Fluorosis

Dental fluorosis is a defect of the tooth enamel, typically characterised by visible effects on the teeth. The condition develops during tooth formation (from birth up to the age of about eight years) and is permanent. Several different types, with different ranges of severity, can be distinguished. Although mild fluorosis is often considered to be of fairly minor concern, for example involving mild whitish speckling on the teeth, more severe fluorosis, which is much less common, can cause serious aesthetic concern and there is some evidence of this leading to adverse psychological and social effects in those affected.²⁷ Severe fluorosis may require medical attention such as restorative treatments or fillings for pits. If enamel fluorosis affects the structure of the teeth, for example if pitting is present, the ability of the enamel to protect the internal structures of the tooth from decay and infection may be reduced.²⁸

Some respondents to our consultation commented on skeletal fluorosis, a condition characterised by skeletal abnormalities and joint pain, which is caused by long-term exposure to large amounts of fluoride. WHO suggests that skeletal fluorosis is observed when water fluoride levels are above 3 ppm, and the most severe form occurs when the level is over 10 ppm.²⁹ In the USA, where 2% of the population receives a water supply with a natural fluoride level at or above 4 ppm, a recent study found that the most severe form of skeletal fluorosis “appears to be a rare condition”, although it could not be determined whether a less severe form of skeletal fluorosis was associated with a fluoride level of 4 ppm.³⁰ In the UK the highest water fluoride level permitted is 1.5 ppm,³¹ and the Committee on Toxicity has advised that “there is no evidence of clinical skeletal fluorosis arising from exposures in the UK.”³²

Extent of water fluoridation in the UK and worldwide

- 7.9 Water fluoridation schemes are in place in around 30 countries, and it is estimated that more than 350 million people receive a fluoridated water supply worldwide (see Appendix 5).³³ However, in some countries, fluoridation schemes have been suspended and/or alternative dental health measures, such as the fluoridation of salt, have been adopted (see Appendix 5 and Box 7.4). In most areas where water is fluoridated, 1 ppm is still the target concentration, although in Ireland this has been reduced to 0.7 ppm.³⁴
- 7.10 Data from 2004 indicate that around six million people in the UK (10% of the population) receive a water supply that is either fluoridated to 1 ppm or is naturally fluoridated.³⁵ A small area of Scotland has a naturally fluoridated water supply, but all other areas receiving artificially or naturally fluoridated water are, at the time of writing, in England. The largest number of people receiving artificially fluoridated water is in the West Midlands and the North East of England.³⁶ In some areas, other fluoridation measures are in operation, such as schoolchildren receiving a daily portion of fluoridated milk.³⁷ Several organisations, including the British Dental Association and the British Fluoridation Society, have argued that water

²⁷ Committee on Fluoride in Drinking Water, National Research Council of the National Academies (2006) *Fluoride in Drinking Water* (Washington, DC: National Academies Press).

²⁸ *Ibid.*

²⁹ World Health Organization (2004) *Fluoride in Drinking Water*, available at: http://www.who.int/water_sanitation_health/dwq/chemicals/fluoride.pdf.

³⁰ Committee on Fluoride in Drinking Water, National Research Council of the National Academies (2006) *Fluoride in Drinking Water* (Washington, DC: National Academies Press).

³¹ Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (2003) *COT Statement on Fluorine in the 1997 Total Diet Study*, available at: <http://www.food.gov.uk/multimedia/pdfs/fluoride.pdf>.

³² *Ibid.* The Committee on Toxicity concluded in 2003 that: “based on the current information available and the dietary intakes estimated from the 1997 TDS [Total Diet Study], no adverse effects other than mild to moderate dental fluorosis would be expected to be associated with fluoride intake from food, either in adults or in children, at the intake levels in the UK.”

³³ Jones S and Lennon K (2004) *One in a Million: The facts about water fluoridation*, 2nd Edition (London: The British Fluoridation Society, The UK Public Health Association, The British Dental Association and The Faculty of Public Health).

³⁴ This move followed a report by the Forum on Fluoridation, a group established by the Minister for Health and Children, and was due to concerns over exposure to multiple sources of fluoride, increased rates of fluorosis and decreased rates of dental decay. Forum on Fluoridation (2002) *Forum on Fluoridation* (Dublin: The Stationery Office); Whelton H, Crowley E, O’Mullane D, Cronin M and Kelleher V (2003) *Children’s Oral Health in Ireland 2002: Preliminary results. A north–south survey coordinated by the Oral Health Services Research Centre, University College Cork* (Dublin: Department of Health and Children Dublin), available at: <http://www.dohc.ie/publications/pdf/coral.pdf?direct=1>.

³⁵ Jones S and Lennon K (2004) *One in a Million: The facts about water fluoridation*, 2nd Edition (London: The British Fluoridation Society, The UK Public Health Association, The British Dental Association and The Faculty of Public Health).

³⁶ *Ibid.* For a map of the areas receiving fluoridated water, see <http://www.dwi.gov.uk/consumer/concerns/fluoridemaps.pdf>.

³⁷ This is, for example, in operation in parts of Yorkshire^o and the Humber: see Department of Health (2007) *2006 Annual Report of the Chief Medical Officer: On the State of Public Health*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_076817.

fluoridation should be extended to other areas where dental disease levels are high, to cover around 25–35% of the population.³⁸

- 7.11 Where fluoridation schemes are in operation in the UK, fluoridation is performed at water treatment works, using hexafluorosilicic acid or its sodium salt, disodium hexafluorosilicate, as the source of fluoride. These chemicals are produced from co-products of the manufacture of phosphate fertilisers and are specifically manufactured to required standards.³⁹ The chemical is injected into the water at a suitable rate to achieve the concentration of 1 ppm, and a system of continuous monitoring (linked to an alarm and automated shut-down programme) protects against the fluoride concentration becoming too high.⁴⁰ The Drinking Water Inspectorate, whose responsibility is to monitor and check the quality of water in England and Wales, has published a code of practice on water fluoridation.⁴¹
- 7.12 The current legislative framework for fluoridation is the Water Industry Act 1991 and the Water Act 2003. The law requires water providers to fluoridate supplies where this is requested by strategic health authorities.⁴² These, in turn, must follow certain procedures, which include carrying out a consultation, before making such requests. The health authority has to bear the cost of the measure and of indemnifying the water supplier against any liabilities incurred.

Alternative fluoride-based measures

- 7.13 Other means of providing fluoride include adding it to salt or milk for consumption, fluoride supplements and topical applications such as toothpastes. We consider these alternatives further in Box 7.4, while Appendix 5 gives an overview of the international situation, outlining interventions adopted by different countries.

Box 7.4: Other means of using fluoride for dental health purposes

Alternative ways of providing fluoride include ingested interventions such as salt, milk and supplements, and topically applied interventions, including fluoride toothpastes.

Fluoridation of salt for human consumption

Typically, fluoride levels of 250–350 ppm are used. The proportion of salt that is fluoridated varies between 35% and over 90% in different countries. Fluoridated salt may be available just for use in the home, or may be used by the food industry also. Fluoridated salt is estimated to be available to almost 200 million people worldwide.⁴³

A review article, which considered evidence from early and more recent studies from around the world, suggested that salt fluoridation “was as effective as water fluoridation” but noted that: “The full potential of salt fluoridation ... is reached when most of the salt for human consumption is fluoridated”.⁴⁴ In Switzerland, where 87% of salt is fluoridated, data suggest that this measure decreases the prevalence of caries by around 30%.⁴⁵

One advantage of fluoridated salt is that the potential for consumer choice is, to some extent, retained where non-fluoridated salt can still be obtained. However, research has shown that a consequence of such consumer choice is that those from higher socio-economic groups are more likely to choose fluoridated salt, and hence this measure does not necessarily reach the whole population, and may miss those who are most likely to develop dental caries.⁴⁶ In terms

³⁸ Jones S and Lennon K (2004) *One in a Million: The facts about water fluoridation*, 2nd Edition (London: The British Fluoridation Society, The UK Public Health Association, The British Dental Association and The Faculty of Public Health).

³⁹ British Fluoridation Society, *Technical Aspects of Fluoridation*, available at: http://www.bfsweb.org/facts/tech_aspects/chem.htm.

⁴⁰ Drinking Water Inspectorate (2005) *Code of Practice on Technical Aspects of Fluoridation of Water Supplies 2005*, available at: <http://www.dwi.gov.uk/regs/infolett/2005/0505fluoridationCOP.pdf>.

⁴¹ *Ibid.*

⁴² Before the amendment in 2003, water providers were not obliged to provide fluoridation when requested to do so. In several cases they had refused to accede to such requests and the courts upheld their right to do so. *R v Northumbrian Water Ltd ex p. Newcastle and North Tyneside Health Authority* [1999] Env LR 715.

⁴³ National Fluoride Information Centre *Salt Fluoridation – The facts*, available at: <http://www.fluorideinformation.com/topic.aspx?main=6&sub=601>.

⁴⁴ Marthaler TM and Petersen PE (2005) Salt fluoridation – an alternative in automatic prevention of dental caries *Int Dent J* 55: 351–8.

⁴⁵ Marthaler TM (2005) Increasing the public health effectiveness of fluoridated salt *Schweiz Monatsschr Zahnmed* 115: 785–92.

⁴⁶ *Ibid.*

of cost, it has been suggested that the start-up costs for salt fluoridation are similar to those for water fluoridation, and the running costs are 10–100 times lower.⁴⁷

WHO favours fluoridation of water over salt, in part because this measure generally ensures that all consumers receive the fluoridated product.⁴⁸ However, it recognises that fluoridation of salt may be more appropriate in some circumstances, for example, in places where people tend to drink bottled water rather than tap water, or where fluoridation of water is unsuitable for political reasons or for technical reasons such as in some rural areas. Various medical authorities in the UK have opposed the fluoridation of salt, in part because of the possibility of this leading to people consuming more salt, which can have adverse effects on health.⁴⁹ However, in countries that have been using fluoridated salt for some time, such changes in salt consumption have not been seen.⁵⁰

Fluoridation of milk

Examples of schemes for fluoridation of milk include: providing a daily portion of fluoridated milk or yoghurt to children, usually through schools, and distributing powdered fluoridated milk for young children through health clinics.

A systematic review of fluoridated milk as a means of preventing caries concluded that: “There are insufficient studies with good quality evidence examining the effects of fluoridated milk in preventing dental caries. However, the included studies suggested that fluoridated milk was beneficial to school children, especially to their permanent dentition.”⁵¹

Fluoride supplements

Generally the use of fluoride supplements is not encouraged except for children at a high risk of developing caries, although in a few countries fluoride tablets are recommended, with the dosage dependant on the fluoride level of the drinking water.⁵²

Topical application of fluoride

Examples of topically applied fluorides include fluoridated toothpastes and mouth rinses, and professionally applied fluoride gels and varnishes.

A systematic review of topically applied fluoride products found that: “children aged 5 to 16 years who applied fluoride in the form of toothpastes, mouth rinses, gels or varnishes had fewer decayed, missing and filled teeth regardless of whether their drinking water was fluoridated,” and concluded that “benefits of topical fluorides have been firmly established on a sizeable body of evidence”.⁵³

Fluoride toothpaste

A systematic review that compared fluoride toothpastes, mouth rinses and gels found that they all “reduce tooth decay in children and adolescents to a similar extent”. However, it indicated that toothpastes were more likely to be regularly used, suggesting that this made them more advantageous.⁵⁴

Fluoride toothpastes are the most widely used of the topical applications, and their use is endorsed by various medical and dental organisations around the world including WHO and the British Dental Association.⁵⁵ They are endorsed regardless of whether fluorides are also ingested in water, salt or milk.

⁴⁷ Gillespie GM and Marthaler TM (2005) Cost aspects of salt fluoridation *Schweiz Monatsschr Zahnmed* 115: 778–84.

⁴⁸ Marthaler TM and Petersen PE (2005) Salt fluoridation – an alternative in automatic prevention of dental caries *Int Dent J* 55: 351–8; Petersen PE & Lennon MA (2004) Effective use of fluorides for the prevention of dental caries in the 21st century: the WHO approach *Community Dent Oral Epidemiol* 32: 319–21.

⁴⁹ National Fluoridation Information Centre, *Salt Fluoridation – Safety and Effectiveness*, available at: <http://www.fluorideinformation.com/topic.aspx?main=6&sub=602>.

⁵⁰ National Fluoridation Information Centre, *Salt Fluoridation – Safety and Effectiveness*, available at: <http://www.fluorideinformation.com/topic.aspx?main=6&sub=602>. For example, in Germany, Bergmann KE and Bergmann RL (1995) Salt fluoridation and general health *Adv Dent Res* 9: 138–43.

⁵¹ Yeung CA, Hitchings JL, Macfarlane TV, Threlfall AG, Tickle M and Glenny AM (2005) Fluoridated milk for preventing dental caries *Cochrane Database of Systematic Reviews* Issue 3. Art. No.: CD003876. DOI: 10.1002/14651858.CD003876.pub2.

⁵² European Food Safety Authority (2005) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the tolerable upper intake level of fluoride *European Food Safety Authority Journal* 192: 1–65, available at: http://www.efsa.europa.eu/etc/medialib/efsa/science/nda/nda_opinions/851.Par.0001.File.dat/nda_op_ej192_fluoride_corrigenm1.pdf; Árnadóttir IB, Ketley CE, van Loveren C *et al.* (2004) A European perspective on fluoride use in seven countries *Community Dent Oral Epidemiol* 32 (Suppl. 1): 69–73; Committee on Fluoride in Drinking Water, National Research Council of the National Academies (2006) *Fluoride in Drinking Water: A Scientific Review of EPA's Standards* (Washington, DC: The National Academies Press).

⁵³ Marinho VCC, Higgins JPT, Logan S and Sheiham A (2003) Topical fluoride (toothpastes, mouthrinses, gels or varnishes) for preventing dental caries in children and adolescents *Cochrane Database of Systematic Reviews* 2003, Issue 4. Art. No.: CD002782. DOI: 10.1002/14651858.CD002782.

⁵⁴ *Ibid.*

⁵⁵ Petersen PE and Lennon MA (2004) Effective use of fluorides for the prevention of dental caries in the 21st century: the WHO approach *Community Dent Oral Epidemiol* 32: 319–21; British Dental Association (2003) *Seven Point Plan for Healthy Teeth Launched*, available at: <http://www.bda.org/advice/news.cfm?ContentID=938>.

Ethical considerations in fluoridation of water

7.14 The fluoridation of water supplies illustrates how tensions can arise between competing principles and values within the stewardship model developed in Chapter 2 (paragraphs 2.41–2.44). Here we set out three main principles that might justify fluoridation (reducing risks of ill health, protecting the vulnerable and reducing inequalities), and three further principles that might be referred to in opposing it (not coercing people to live healthy lives, respecting important personal values and the requirement of consent). These principles touch on many of the issues on water fluoridation raised by respondents to our consultation (see Box 7.5). We then present the Working Party's analysis of the merits and weights of the different arguments.

Box 7.5: Quotations from respondents to the consultation

"There are two principal issues – firstly, the balance between the population good and the risk of individual harm and secondly, the matter of individual choice. Fluoridation of water is particularly contentious ... because the ubiquity of the water supply severely curtails individual choice and there is the possibility, albeit small, of individual harm." *MRC Human Nutrition Research*

"It is reasonable to restrict the freedom of individuals [in order] to protect the health of children, but only when the health threat is serious. I don't think fluoridation qualifies." *Anon*

"Those from the more vulnerable sections of the community are likely to experience more tooth decay and thus potentially receive the greatest benefit from water fluoridation. [...] Being provided with water containing 1 ppm fluoride does not infringe any human right ... although some people may have an individual preference with regard to the concentration of fluoride in their water. Where parliament has determined that a measure should be permitted and consultation demonstrates public acceptance then a restriction of personal choice is acceptable for the sake of the common good." *British Fluoridation Society*

"As water is one of the most vital elements of life, surely our water supply should only be treated with chemicals that are necessary to make it safe to drink." *Anon*

Principles that may be used in favour of water fluoridation

Reduction of risks of ill health

7.15 One of the arguments that could be made in favour of fluoridation is that the liberal state has a duty to provide interventions that reduce ill health, as outlined in paragraphs 2.8–2.9 and 2.41–2.44. However, for this principle to carry weight, several empirical questions need to be considered, including the extent of the benefits to health and of any risks or harms. We noted above (paragraphs 7.6–7.7) that evidence in relation to these questions is not straightforward to interpret, and we consider this further in our discussion below (paragraphs 7.29–7.33).

7.16 In Chapter 2 we discussed the principle of reducing of ill health in particular through ensuring environmental conditions that sustain good health (paragraph 2.38). This could potentially be called upon in the fluoridation of mains water. We noted in Chapter 1 the considerable contribution made to public health through housing and sanitation programmes in the 19th and early 20th Centuries, and noted in Chapter 5 the importance of infrastructural policies such as cycle lanes or pedestrian zones as components of strategies to reduce obesity. Along similar lines, it could be argued that the fluoridation of water might be a way of improving environmental conditions in such a way as to promote people's health. Just as water may be treated in several ways to improve safety, such as by adding chlorine to kill bacteria and by filtering out harmful substances (see Box 7.8), the claim could be made that it would be legitimate to alter the quality of drinking water by adding fluoride, if it were shown to promote improved health for the population.

Special care for the health of children

7.17 Children represent an especially vulnerable group in many public health contexts (see paragraphs 2.16, 2.44). This is true in the area of dental health, because they are susceptible

to dental caries, are less able to make informed choices about their dental health, and are dependent on parents and carers to assist with or promote preventative measures such as tooth brushing.

- 7.18 The discussions on vaccinations, obesity, and smoking and alcohol (Chapters 4, 5 and 6) has demonstrated that despite the vulnerability of children, for ethical and policy reasons, it is usually not appropriate for the state to seek to promote the health of children in such a way that would infringe on the liberties of their parents (see paragraphs 4.30–4.32, 5.39, 6.14–6.15). However, water fluoridation may be a special case in which children could be reached directly without major infringements on their parents' liberties.

Reducing health inequalities

- 7.19 As we have seen in paragraph 7.3 and Figure 7.1, there are considerable inequalities in dental health in the UK, which, for example, vary according to socio-economic group and geographical area. In Chapter 2 we noted that reducing health inequalities should be considered central to the goals of public health, and prioritarian programmes that address inequalities can, in principle, be ethically justified (see paragraphs 2.27–2.32). This justification could be used for fluoridation of water given that it may potentially improve dental health across the population including in lower socio-economic groups.⁵⁶

Principles that may be used against water fluoridation

Not intervening without the consent of those affected

- 7.20 We noted in Chapter 2 the importance of consent in medical interventions, especially where there is the possibility of a risk to the health of the person involved (paragraphs 2.22–2.25). For water fluoridation it could be argued that this measure is only acceptable if all those receiving fluoridated water agree individually to whatever level of risk there may be, both for themselves, and for those in their care, especially children. Here, drinking fluoridated water might be perceived in the same way as taking a medicine, and represent 'forced medication' of the population if consent is not obtained from everyone (see Box 7.6). However, because of the nature of the intervention it is not possible to provide each individual affected with a choice. This is both because its implementation across whole areas means that it would not be possible to accommodate the differing choices of every individual in that area, and because people from outside the area who visit or move there after its introduction would be affected by the measure. Considerations about consent could hence be used to argue that the measure should not be introduced either where some individuals, however few, were opposed to it, or where individuals who had not agreed to it might be affected by it, such as those from outside the area. However, this would presuppose clear evidence about risks of harms and in the absence of such evidence give too much weight to the importance of choice and consent, allowing them automatically to override any collective good that might be achieved through the measure. Further to our general observations on individual consent and procedural justice arrangements in Chapter 2, we consider in our discussion below how the requirement for consent might be addressed (see paragraphs 7.38–7.41).

⁵⁶ All Party Parliamentary Group on Primary Care and Public Health (2003) *Inquiry into Water Fluoridation*, available at: <http://www.bfsweb.org/APPCPH%20report.pdf>.

Box 7.6: Fluoridated water – food or medicinal product

Several respondents to our consultation raised concerns over whether fluoridated water was a fortified food or a medicinal product, and where this fitted within the regulatory system in the UK. The legal situation is that while in principle drinking water is considered a food, the addition of fluoride is not considered a food supplementation process. This is because, from a legal viewpoint, water provided by the local water supply is only considered a food once “it emerges from the taps that are normally used for human consumption”,⁵⁷ and because water is not considered a food at the point at which fluoride is added, the process is not considered supplementation of food.⁵⁸

The UK Medicines and Healthcare Products Regulatory Agency (MHRA), which licenses medicinal products in the UK, has indicated that fluoridation of water is not within its remit: “As drinking water is quite clearly a normal part of the diet the MHRA does not regard it to be a medicinal product.”⁵⁹ Fluoridation of water at the water treatment stage also does not fall within the remit of the Food Standards Agency as a fortified food, because it is not legally considered to be such a food, as outlined above.⁶⁰ However, this is not to say that the content of drinking water is unregulated, because it is covered by legislation on water quality, which includes levels of fluoride and processes for implementation of fluoridation. Drinking water safety and quality, including the water fluoride level, is checked by the UK Drinking Water Regulators.⁶¹ Policy on water fluoridation is determined by the Department of Health in England, the Welsh Assembly Government in Wales and by the Scottish Executive in Scotland.⁶²

Minimise interventions that affect important areas of personal life

7.21 Another argument that might be made against fluoridation is that, although individual consent may not be required, the intervention could be seen to restrict the choices of individuals in some significant way (see paragraphs 2.19, 2.44), because individuals are able to exercise little choice over the water they consume. Fluoridation might thus be seen to interfere with important values of personal life, but the precise nature of these values may not always be clear. For some, the value may relate to being able to have a choice about what to ingest.⁶³ For others, the value may be about a certain conception of health, or water may be considered to be ‘special’. For example, some respondents to the consultation suggested that water could be regarded as intrinsically pure and natural, or as a public good that should be provided in as ‘neutral’ a form as possible (see Box 7.7).

Box 7.7: Is water special?

Several respondents to our consultation suggested that water fluoridation measures were, or could appear to be, different to those of food fortification because water was in some way ‘special’ or different from other foods.

“I believe that people have an emotional attachment to the purity of water [...] However, with food, people are often more than happy to tolerate quite extensive manipulation.” *Mr Robert Warwick*

“Water is unique among nutrients. It makes up nearly three quarters of the human body and brain. It is essential to life and there is no substitute for water.” *Elizabeth A McDonagh*

“Water is not for supplementing. Water ... is primarily an essential for life on this planet. [...] Without water we die very quickly.” *Richard Carruthers*

⁵⁷ Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, available at: http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf; Council Directive 98/83/EC on the quality of water intended for human consumption, available at: http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_330/l_33019981205en00320054.pdf.

⁵⁸ Several respondents to our consultation raised concerns about the currently used source of fluoride for water fluoridation, fluorosilicates, not being included in the list of permitted vitamins and minerals for food supplementation that is found in EU legislation. Some suggested that this meant that fluoridation by this means was illegal; however, as described in the text above the process is not legally considered to be supplementation of food. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (see Annex II), available at: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_404/l_40420061230en00260038.pdf.

⁵⁹ Personal communication, MHRA.

⁶⁰ Personal communication, FSA. Furthermore, the FSA’s Expert Group on Vitamins and Minerals concluded that drinking water and dental products containing fluoride were “neither foods or food supplements”; Expert Group on Vitamins and Minerals (2003) *Safe Upper Levels for Vitamins and Minerals* (London: Food Standards Agency), available at: <http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf>.

⁶¹ This includes the Drinking Water Inspectorate for England and Wales, the Drinking Water Quality Regulator for Scotland and the Drinking Water Inspectorate for Northern Ireland. For further information see: Drinking Water Inspectorate, *Fluoridation of Drinking Water*, available at: <http://www.dwi.gov.uk/consumer/concerns/fluoride.shtm>.

⁶² Department of Health, *Oral Health*, available at: http://www.dh.gov.uk/en/Aboutus/Chiefprofessionalofficers/Chiefdentalofficer/DH_4138822; Welsh Assembly Government, *Information Briefing on Fluoridation*, available at: <http://new.wales.gov.uk/topics/health/professionals/dental/oral-health/programmes/fluoridation/?lang=en>; Scottish Executive (2002) *Towards Better Oral Health in Children*, available at: <http://www.scotland.gov.uk/consultations/health/ccoh.pdf>.

⁶³ However, few people would probably follow up this argument by maintaining that naturally occurring fluoride should be removed from water supplies in areas where this occurs at low levels.

Not coercing ordinary adults to lead healthy lives

7.22 In presenting the stewardship model we noted that it can be acceptable to require members of society to sacrifice some freedom in order to secure benefits for those who cannot make effective choices about their health, but that it should not normally be considered acceptable to restrict freedoms in such a way as to force individuals into leading healthy lives (paragraphs 2.44–2.45). The acceptability of a public health intervention should therefore depend on the amount of freedom to be sacrificed and how this relates to the extent of the benefits across society (see paragraphs 3.18, 3.37–3.38). In the case of fluoridation the question is whether the intervention is overly coercive, given the potential benefits to certain groups within society.

Discussion of arguments

7.23 Having outlined the different arguments for and against fluoridation, we now consider these further, and engage them with each other, where relevant.

Personal values

7.24 The arguments about not coercing ordinary adults to lead healthy lives and minimising interventions that affect important areas of personal life both, in this context, relate to the degree to which it is acceptable to modify water for the purposes of health benefits for the population. We find the argument that water is ‘special’, and that it should never be altered (paragraph 7.21), to be problematic. The composition of tap water varies from one place to another and is already altered in various respects during the water treatment processes, for example by the removal of potentially harmful chemicals and adding chlorine to kill bacteria (see Box 7.8).⁶⁴ It seems unlikely that those who argue that ‘water is special’ would maintain that it should never be treated, but instead be provided in its untreated form.

Box 7.8: Treatment of water

Some of the water treatment processes that are most commonly used include the following.⁶⁵

Clarification for the removal of silt, algae, colour, manganese and aluminium, and some pathogens from raw water. A coagulant is added to the water, usually an iron or aluminium salt, which combines with these other materials to form larger particles that can then be removed.

Filtration removes any particles remaining in raw water after clarification and is used on ground water to remove iron and manganese. There are different types of filter; the most common is a gravity filter, which uses a bed of sand to filter the water.

Disinfection to kill bacteria. In the UK the most common method of disinfection is the use of chlorine, but can include the use of ozone and ultraviolet light. In all cases, however, chlorine remains in the water after it leaves the treatment works to keep the water free of bacteria as it is distributed through the water supply.

Ion exchange to remove nitrate from ground water, and in some cases for softening of water. Ion exchange is similar to the process used in water softeners in the home, in which water is passed through special particles.

Activated carbon and ozone to remove organic substances, for example from pesticides. The substances are broken down by the ozone and then adsorbed on the surface of the carbon.

7.25 **The principles of avoiding coercive interventions and minimising interventions in personal life could be used to argue against the addition of any substance to the water supply. However, we do not accept that the addition of potentially beneficial substances to the water supply should always be prohibited. Rather, we seek to identify the situations in which this may be appropriate.**

⁶⁴ Drinking Water Inspectorate, *Tap water*, available at: <http://www.dwi.gov.uk/pubs/tap/index.htm>.

⁶⁵ *Ibid.*

7.26 We note that a distinction could be made between adding chlorine to avoid harms that could be caused by the water itself, and adding fluoride to promote benefits that are unrelated to the water. The Working Party members were divided over whether the distinction between these different intentions was ethically relevant or not. However, we agree 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.** In the case of fluoridation of water, there are considered to be potential benefits in reducing ill health and inequalities, although currently these are difficult to quantify (see paragraph 7.31). There are also potential harms (see paragraphs 7.32–7.33), and there is therefore a need to consider in what sense consent is relevant, as well as the possibility of alternative approaches (Box 7.4).

Reducing inequalities

7.27 We noted above that considerable inequalities in dental health remain (see paragraph 7.3 and Figure 7.1),⁶⁶ and therefore the potential for water fluoridation to reduce inequalities could, in principle, be an important argument in favour of the intervention. It could be argued conceptually at least that those expected to have lower levels of dental health had a greater potential to benefit, and that inequalities in outcome might therefore be reduced. However, the evidence on this point is not clear-cut. The York review of 2000 found that “The research evidence is of insufficient quality to allow confident statements about ... whether there is an impact on social inequalities”.⁶⁷ It concluded that “[although] the available evidence... appears to suggest a benefit in reducing the differences in the severity of tooth decay, ... the quality of evidence is low and based on a small number of studies”.⁶⁸ For now, we note that based on the best available evidence it is not straightforward to conclude that water fluoridation reduces dental health inequalities as measured by outcomes.

7.28 On inequalities in access, because water fluoridation is an intervention that is provided directly to everyone owing to the mechanism by which it is distributed, it is an intervention that, in principle, provides equal access for all. However, this principle needs to be weighed against other considerations, in particular the potential for harms, and the likelihood and extent of benefits.

Reducing ill health by ensuring environmental conditions that sustain health, and caring for the health of children

7.29 Another strong argument, in principle, in favour of water fluoridation would be that of reducing ill health, particularly given that children could be some of those to benefit. Figure 7.2 and our discussion in paragraph 7.3 above show that there have been improvements in oral health in recent decades in the UK. An analysis of data from 14 European countries (see Figure 7.2) shows that oral health has improved across all these countries over the past 30 years, and the average levels of decayed, missing or filled teeth are now similar irrespective of whether water (or salt) fluoridation is in operation.⁶⁹ It would seem, therefore, that the potential for benefit from fluoridation of water may have decreased, although this may vary in different areas given the regional variations in dental health (paragraph 7.3).

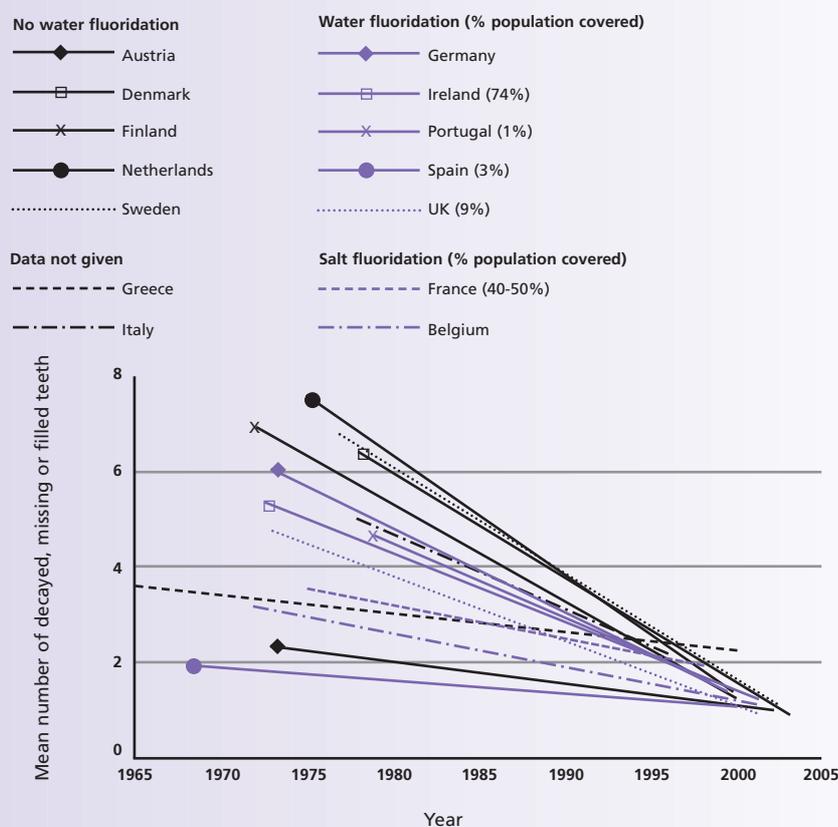
⁶⁶ Note also that just 10% of the UK population have received artificially or naturally fluoridated water; Jones S and Lennon K (2004) *One in a Million: The facts about water fluoridation*, 2nd Edition (London: The British Fluoridation Society, The UK Public Health Association, The British Dental Association and The Faculty of Public Health).

⁶⁷ McDonagh M, Whiting P, Bradley M et al. (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

⁶⁸ *Ibid.*

⁶⁹ Cheng KK, Chalmers I and Sheldon TA (2007) Adding fluoride to water supplies *Br Med J* 335: 699–702.

Figure 7.2: Mean number of decayed, missing or filled teeth in 12 year olds in European Union countries (1965–2003)*



*Source: Cheng KK, Chalmers I and Sheldon TA (2007) Adding fluoride to water supplies *Br Med J* 335: 699–702. Figure reproduced with permission from the BMJ Publishing Group.

7.30 The York review concluded that: “The best available evidence suggests that fluoridation of drinking water does reduce caries prevalence”.⁷⁰ However, the degree to which it was found to be reduced was “not clear from the data”, with results of individual studies ranging from a substantial reduction in caries prevalence to a slight increase in prevalence. Of the 30 studies assessed, twelve had not detected a statistically significant difference between the populations receiving fluoridated and non-fluoridated water. An average of the studies included in the York review suggested that water fluoridation may lead to an additional 14.6% of the child population having no caries.

7.31 In relation to whether any harms result from the fluoridation of water, the York review investigated fluorosis, bone fractures and other bone problems, cancer and other possible adverse effects. The York review study group concluded (from analyses of almost 30 studies most of which were assessed as being of low quality) that on the basis of the best available evidence no clear association could be established between either bone problems or cancers and fluoridation.⁷¹ However, both a review of the evidence and a large study published shortly after the York review suggested that fluoridated drinking water did not adversely

⁷⁰ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

⁷¹ *Ibid.*

affect bones.⁷² The York group also found a small number of studies on other health risks, including Alzheimer's disease, malformations and mental retardation, but concluded that: "interpreting the results of the other possible negative effects is very difficult because of the small number of studies that met inclusion criteria on each specific outcome, the study designs used and the lower study quality".⁷³ For several reasons, it may be difficult to determine whether particular harms are caused by fluoridation,⁷⁴ for example because of the presence of other confounding factors, because of the difficulties in estimating people's total fluoride exposure and where there is a long lag time between exposure and occurrence of harm.

- 7.32 The York review included 88 studies that investigated the association between fluorosis and water fluoridation, of which almost all were considered to be of low quality. A significant dose-response relationship was found to exist between fluoride levels and the prevalence of fluorosis. It was estimated that with a water fluoride level of 1 ppm⁷⁵ the overall prevalence of fluorosis would be 48%, and the prevalence of fluorosis of aesthetic concern would be 12.5%.⁷⁶ However, a later report by the Medical Research Council suggested a lower estimate of fluorosis of aesthetic concern of 3–4%.⁷⁷ In the York review it was also estimated that for roughly every six people receiving water fluoridated to 1.0–1.2 ppm, one extra person would have some form of dental fluorosis compared with those receiving water with a fluoride level of 0.4 ppm, and a quarter of these individuals would have fluorosis of aesthetic concern.
- 7.33 In summary, on the benefits and risks to health of fluoridation, we conclude that there is evidence to show that fluoridation programmes are associated with benefits, although these are difficult to quantify, particularly in the context of the current historically low population caries levels. Similarly, there is evidence of harm, although there is debate over the extent and significance of the harm. This gives rise to the potential for two alternative, and opposing, applications of the precautionary approach (paragraphs 3.15–3.19). On the one hand, it could be suggested that because fluoridation offers the possibility of some benefits to health, it should be implemented. Conversely, given that fluoridation raises the possibility of some risks to health, perhaps its implementation should be prohibited as a precaution. However, in our discussion of the precautionary approach and proportionality (see paragraphs 3.15–3.19), we also highlighted the need to compare the policy in question with alternative approaches, and we consider these next.

Alternatives to water fluoridation

- 7.34 Box 7.4 provided details on several other means of administering fluoride, including through toothpastes and mouth rinses, and supplementation of salt. These alternatives all rank lower than water fluoridation on the intervention ladder that we introduced in Chapter 3 (paragraphs 3.37–3.38). Implementing measures that may be perceived as coercive can have a major effect on the acceptability of public health measures more generally, contributing unhelpfully to concerns about the 'nanny state', and this may influence policy decisions. For water fluoridation to be acceptable it must be shown that there is justification for this level

⁷² Phipps KR, Orwell ES, Mason JD and Cauley JA (2000) Community water fluoridation, bone mineral density, and fractures: prospective study of effects in older women *Br Med J* 321: 860–4; Demos LL, Kazda H, Cicuttini FM, Sinclair MI and Fairley CK (2002) Water fluoridation, osteoporosis, fractures—recent developments *Aust Dent J* 46(2): 80–7.

⁷³ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

⁷⁴ Cheng KK, Chalmers I and Sheldon TA (2007) Adding fluoride to water supplies *Br Med J* 335: 699–702.

⁷⁵ This is the level generally proposed in artificial fluoridation schemes.

⁷⁶ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

⁷⁷ Medical Research Council (2002) *Water Fluoridation and Health* (London: MRC).

of intervention. Factors to consider include the costs, benefits, harms and effectiveness of the different options in comparison to any reduction in liberty. Water fluoridation is considered to be relatively cost-effective,⁷⁸ but how does it otherwise compare with the alternatives?

- 7.35 The lowest-ranking fluoride interventions are those of fluoride-containing dental products, such as toothpastes, mouth rinses and tablets. Many of these products have been widely used in the UK and other industrialised countries since the early 1970s, and it might be questioned whether such measures negate any need for other fluoridation interventions. The York review sought to establish whether health benefits of water fluoridation were still reported after this time, in order to determine whether water fluoridation had a beneficial effect over and above these interventions. The conclusion, based on the findings of ten studies of “moderate quality”, was that: “a beneficial effect of water fluoridation was still evident in spite of the assumed exposure to non-water fluoride in the populations studied.”⁷⁹ We note also that water fluoridation has the advantage over toothpaste and mouth rinse of ensuring complete uptake of the measure, and of not requiring individuals to change their behaviour, which can be difficult to achieve (see paragraph 2.33).
- 7.36 The strongest case for an alternative intervention ranking lower than water fluoride can perhaps be made for salt fluoridation (see Box 7.4). This has been suggested to be “as effective” as water fluoridation if a large enough proportion of the salt is fluoridated,⁸⁰ and is typically similar to or lower than water fluoridation in setting-up and running costs.⁸¹ One particular advantage is that it allows consumer choice to be retained, to some extent, if non-fluoridated salt can still be obtained by consumers who wish to do so. However, some groups may then choose against fluoridated salt, and hence this measure can miss groups that are likely to develop dental caries.⁸² The concern may also be raised that salt fluoridation could cause individuals to increase their salt intake, which can be unhealthy, although in other countries that have been using fluoridated salt for some time, changes in overall salt consumption have not been reported.⁸³
- 7.37 We note that a range of alternative interventions that rank lower on the ‘intervention ladder’ exist, and that the relative costs and benefits both to population health and individual liberty should be assessed when considering water fluoridation. We previously discussed the variation in dental health across different areas of the UK, and note here that the alternatives should be considered in terms of the context in which they may be applied, because, for example, greater health need of a particular subgroup of the population may play an important role in justifying a higher-ranking intervention.

Consent

- 7.38 The nature of water fluoridation measures is such that whole areas either receive fluoridated water or do not, and it is therefore not possible to provide each individual with a choice. Some might argue that the impossibility of individual consent must, in principle, rule out a

⁷⁸ An analysis on the cost-effectiveness of water fluoridation notes that the financial benefits, such as reduced treatment costs, can be greater than the financial costs, although the costs vary for example according to the size of the population and the level of caries present and case-by-case assessment is needed. York Health Economics Consortium (1998) *Water Fluoridation – An Economic Perspective* (York: York Health Economics Consortium).

⁷⁹ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

⁸⁰ Marthaler TM and Petersen PE (2005) Salt fluoridation – an alternative in automatic prevention of dental caries *Int Dent J* 55: 351–8.

⁸¹ Gillespie GM and Marthaler TM (2005) Cost aspects of salt fluoridation *Schweiz Monatsschr Zahnmed* 115: 778–84.

⁸² Marthaler TM (2005) Increasing the public health effectiveness of fluoridated salt *Schweiz Monatsschr Zahnmed* 115: 785–92.

⁸³ National Fluoridation Information Centre, *Salt Fluoridation – Safety and Effectiveness*, available at: <http://www.fluorideinformation.com/topic.aspx?main=6&sub=602>. For example, in Germany: Bergmann KE and Bergmann RL (1995) Salt fluoridation and general health *Adv Dent Res* 9: 138–43.

proposed intervention (paragraph 7.20). As we have observed in Chapter 2 and subsequent case study chapters (see paragraphs 2.22–2.25, 4.38–4.40 and Box 4.4), requirements for individual consent can sometimes be over-emphasised in the context of public health. This is especially problematic where there is a very low risk of harm to a person and where refusal to give consent would prevent others from accessing important benefits.

7.39 This is not to say that reducing choices requires no justification. As we have said (paragraph 2.25), procedural justice arrangements can form an appropriate means of reconciling different preferences within a population, even if the final policy does not meet with everyone's approval. However, consideration needs to be given to the situations in which it would be acceptable to replace individual consent with such an approach, and whether fluoridation of water qualifies. We consider these questions in relation to two hypothetical situations for fluoridation.

7.40 First, if there were robust evidence that fluoridation of water was associated with a substantial likelihood of significant harm to individuals, individual consent would certainly be required. Alternatively, if there are no harms, but clear benefits, it might be argued that fluoride should be added by default without individual consent, in the same way as chlorine. Neither of these situations represents the current situation, in which there is some evidence of possible harms, and some evidence of benefits, though both are difficult to quantify. Thus, both action (adding fluoride) and inaction (not adding it) might disadvantage some groups of people, either through limiting personal choice or through preventing individuals from receiving any possible health benefits of the measure. Overall, the prevalence of caries has reduced considerably over recent decades, but inequalities between regions persist, and therefore the extent to which these costs materialise varies in different regions. **The most appropriate way of deciding whether fluoride should be added to water supplies is to rely on democratic decision-making procedures. These should be implemented at the local and regional, rather than national level,⁸⁴ because the need for, and perception of, water fluoridation varies in different areas. Account should be taken of relevant evidence, and of alternative ways of achieving the intended benefit in the area concerned. Whatever policy is adopted, dental health and any adverse effects of fluoridation should be monitored.**

7.41 We commented in Chapter 2 that procedural justice approaches are characterised by: transparency of decision-making processes; a focus on rationales that those affected recognise as being helpful in meeting health needs fairly; and involvement of individuals and stakeholder groups in decision-making processes, with opportunities to challenge such interventions (paragraph 2.25). These will typically involve: publishing plans for fluoridation programmes in ways and formats that are suitable for the public; a period of consultation; and a response to the issues raised during the consultation. The outcome should be a justification of a policy proposal which engages the scientific and health-related evidence on the benefits of water fluoridation for the respective regions in relation to alternative approaches, the consultation responses and relevant ethical considerations. Two important elements that feature in the process are the evidence base for an intervention (and its alternatives) and the availability of information for policy makers and individuals, particularly where they are to be asked to vote or contribute to policy decisions through these approaches.

Evidence and information

Evidence

7.42 We noted in Chapter 3 the importance of taking an evidence-based approach to public health policy (paragraphs 3.3–3.12). We also commented above on the lack of high quality

⁸⁴ Within the constraints of the water supply network.

research on fluoridation, which is particularly noteworthy given the interest in this intervention and the length of time over which it has been considered and implemented as a policy option (paragraphs 7.8, 7.29–7.33). Nevertheless, we recognise that, as in the case of obesity (Chapter 6), and in many other areas of public health more generally, inconclusive evidence by itself is not necessarily a sufficient reason to halt an otherwise promising strategy. Such strategies may be pursued as long as there is mandate for the intervention and appropriate monitoring is conducted. Therefore, **the UK health departments should monitor the effects of water fluoridation, including the incidence and severity of fluorosis and other possible harms.**⁸⁵ We note also that other research priorities have previously been suggested in the York review, and by the MRC, WHO and National Research Council of the National Academies in the USA.⁸⁶ These have included investigating total fluoride exposure, and how this relates to harm, and the impact of using lower levels of fluoride in water. **Water fluoridation policy should be objectively reviewed by the UK health departments on a regular basis in light of the findings of ongoing monitoring and further research studies. Furthermore, the conclusions and their basis should routinely be published.**

Information

- 7.43 In Chapter 3 we highlighted the importance of considering the robustness of scientific evidence, of not over-interpreting it, and of accurately portraying the current evidence. The need for accurate reporting of the evidence is especially important for debates such as the one about fluoride where the public would otherwise have great difficulty in establishing the benefits and the risks of the intervention.
- 7.44 There have been particular problems with the communication of the results of the York review (see paragraphs 7.27, 7.30–7.32).⁸⁷ These have been used by both proponents and opponents of fluoridation to support their case, by focusing on different aspects or interpretations of the findings. Soon after the report's publication (in 2000), its authors began to draw attention to their view that the report had been "widely misinterpreted."⁸⁸ The York review team sought to correct the record and expressed their concern over statements by groups including the British Fluoridation Society, British Dental Association, and the National Alliance for Equity in Dental Health which "mislead the public about the review's findings".⁸⁹ The reported problems included overstating the potential benefits of fluoridation, understating the potential harms, and the inaccurate claim that the review concluded water fluoridation to be "safe".⁹⁰
- 7.45 One example is that of *One in a Million: The facts about water fluoridation*, which was funded by the British Fluoridation Society (BFS), and published in a second edition in 2004 by

⁸⁵ Consideration should, however, be given to possible difficulties in detecting harms, as noted above (see paragraph 7.31).

⁸⁶ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination); Medical Research Council (2002) *Water Fluoridation and Health* (London: MRC); WHO (2002) *Environmental Health Criteria 227 Fluoride* (Geneva: WHO); Committee on Fluoride in Drinking Water, National Research Council of the National Academies (2006) *Fluoride in Drinking Water* (Washington, DC: National Academies Press).

⁸⁷ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

⁸⁸ *Hansard* text of letter from Professor Trevor Sheldon, Chair of the Advisory Group for the systematic review on the effects of water fluoridation at the University of York; *Hansard* (29 January 2001) column 146, available at: <http://www.publications.parliament.uk/pa/cm200001/cmhansrd/vo010129/debtext/10129-40.htm>.

⁸⁹ *Ibid.*

⁹⁰ For example, on safety, Professor Trevor Sheldon comments: "The review did not show fluoridation to be safe. The quality of the research was too poor to establish with confidence whether or not there are potentially important adverse effects in addition to the high levels of fluorosis." Further examples of discrepancies between the findings of the review and other groups' reporting of the findings have been noted, and can be found at: *Hansard* (29 January 2001), column 148–149, available at: <http://www.publications.parliament.uk/pa/cm200001/cmhansrd/vo010129/debtext/10129-40.htm>. See also: NHS Centre for Reviews and Dissemination (2003) *What the York Review on the fluoridation of drinking water really found*, available at: <http://www.york.ac.uk/inst/crd/fluoridnew.htm>.

the BFS, the UK Public Health Association, the British Dental Association and the Faculty of Public Health.⁹¹ On the benefits and harms of fluoridation, the executive summary states that: “Many studies have confirmed that water fluoridation reduces tooth decay, and has no harmful side effects.” The main discussion on the York review describes its conclusions without sufficiently drawing out of the degree of cautiousness that was central to the report’s findings.⁹² As such, the publication gives a potentially misleading account of the state of the evidence on fluoridation. This is disappointing given that the members of the York review team had previously raised their concerns about misinterpretation of the report, and that this specific issue had been raised in the House of Lords in 2001, where Lord Hunt, on behalf of the Government, said: “We accept that the York review identified a need for more good-quality evidence and have asked the British Fluoridation Society to ensure that this is reflected in future briefings.”⁹³ It is of particular concern that at the time of the publication of this report the BFS was receiving Government funding,⁹⁴ and we consider that as such its publications bore a special responsibility for accurately informing debate.

7.46 At the same time, in the view of the Working Party, some of the information materials of groups opposed to fluoridation could be considered to overstate the risks of the intervention, and this too is problematic. For example the National Pure Water Association website reports that fluoride “causes” brain damage and lowered IQ in children, and abnormalities to sperm and eggs,⁹⁵ where other groups have been considerably more cautious. The York review noted in relation to IQ that there was not “enough good quality evidence ... to reach conclusions”;⁹⁶ and the National Research Council of the National Academies in the USA noted in relation to reproductive and developmental effects that although existing studies showed that “high concentrations” of fluoride “might” have negative effects, “design limitations make those studies insufficient for risk evaluation.”⁹⁷

7.47 **Neither the public nor policy makers are helped by information that makes it difficult for the non-expert to obtain a good understanding of current evidence.⁹⁸ 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.** As in the case of inaccurate reporting on the alleged link

⁹¹ Jones S and Lennon K (2004) *One in a Million: The facts about water fluoridation*, 2nd Edition (London: The British Fluoridation Society, The UK Public Health Association, The British Dental Association and The Faculty of Public Health).

⁹² *Ibid.*, p.4; Wilson PM and Sheldon TA (2006) Muddy waters: evidence-based policy making, uncertainty and the ‘York review’ on water fluoridation *Evidence and Policy* 2: 321–31.

⁹³ *Hansard* (12 Feb 2001), column WA16, available at: www.publications.parliament.uk/pa/ld200001/ldhansrd/vo010212/text/10212w04.htm.

⁹⁴ The BFS has received grants from the Department of Health for England, the Scottish Executive Health Department, the National Assembly for Wales and the Northern Ireland Health Department, given “to support the BFS in promoting the benefits of the fluoridation of water in reducing tooth decay”. Between 1998 and 2005 these grants totalled between £90,000 and £104,500 per financial year. We note, however, the Department of Health for England, which was the largest contributor, has ceased to give these grants; the last, of £90,000, was in 2005–6. Department of Health (8 Feb 2007) *Grants, resources or donations to dental bodies*, available at: www.dh.gov.uk/en/Publicationsandstatistics/Freedomofinformationpublicationscheme/feedback/FOIreleases/DH_4111162; *Hansard* (8 March 2007), column 2205W, available at: www.publications.parliament.uk/pa/cm200607/cmhansrd/cm070308/text/70308w0020.htm; *Hansard* (18 April 2006), column 216W, available at: <http://www.publications.parliament.uk/pa/cm200506/cmhansrd/cm060418/text/60418w57.htm>.

⁹⁵ National Pure Water Association, *Adverse effects of fluoride*, available at: http://www.npwa.freereserve.co.uk/adverse_effects.html.

⁹⁶ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination).

⁹⁷ Committee on Fluoride in Drinking Water, National Research Council of the National Academies (2006) *Fluoride in Drinking Water* (Washington, DC: National Academies Press).

⁹⁸ Cheng KK, Chalmers I and Sheldon TA (2007) Adding fluoride to water supplies *Br Med J* 335: 699–702.

between MMR and autism (paragraphs 4.33–4.34 and Box 4.3), **we consider that researchers, journalists and others who report research have a duty to communicate findings in a responsible manner. Those who report research should take account of the Guidelines on Science and Health Communication published by the Social Issues Research Centre, the Royal Society and the Royal Institution of Great Britain.⁹⁹ In particular we emphasise that the source and the status of scientific evidence alluded to should be identified (including, for example, whether it is preliminary or based on a conference presentation, and whether it has been peer reviewed).**

Summary

- 7.48 Water fluoridation has the potential to contribute to three central goals of the stewardship model: first, the principle of reducing health inequalities between different regional and socio-economic groups; secondly, the possibility of reducing ill health through environmental measures; and thirdly, concern for the health of children, who constitute a vulnerable group. Although the best available evidence suggests that fluoridation is beneficial, the evidence on the extent of benefits and harms is weak overall, particularly in the context of the current historically low levels of caries in the population; these are therefore difficult to fully evaluate and quantify.
- 7.49 The principles of consent, minimising interventions that affect important areas of personal life, and not coercing adults to lead healthy lives could in principle be used to argue against water fluoridation. We reject the view that, on the basis of arguments about interference in personal life and coercing ordinary adults, the fluoridation of water should be prohibited outright. Instead the acceptability of any policy involving the water supply should be considered in relation to the balance of risks and benefits, the potential of alternatives, and, where there are harms, to the role of consent.
- 7.50 Regarding consent, it is clear that an approach requiring individual consent is not feasible in practice. However, both the decision to introduce fluoridation programmes and a decision not to do so would require justification. Both action and inaction are policy options with the potential to have advantages and disadvantages to some groups of people. Therefore, a mechanism is needed for considering the views of the public in providing a mandate for either option. We suggest the adoption of local decision-making procedures that take into account the context in each area in which a decision is to be taken. In particular the health needs, the degree of benefit anticipated in a given community, the local perceptions of the measure, and possible alternatives need to be considered. The latter is particularly important as there are potential alternatives that rank lower on the intervention ladder, although the evidence on these is also limited.
- 7.51 Evidence, and information materials conveying that evidence, are important in any policy decisions, but particularly so when scientific knowledge is complex and a procedural justice approach involving the public is to be taken. We noted that the evidence base for fluoridation is not strong, and that as such ongoing monitoring and further research, particularly on risks, are recommended. Policy makers and the public need to have access to clear and accurate information, and uncertainties and the strength or weakness of the evidence should be explicitly recognised.

⁹⁹ Social Issues Research Centre, the Royal Society and the Royal Institution of Great Britain (2001) *Guidelines on Science and Health Communication*, available at: http://www.sirc.org/publik/revise_d_guidelines.pdf.