

Legal aspects and decision-making

KEY POINTS

- Decisions about whether to introduce a water fluoridation scheme to reduce tooth decay have always been made at a local level in the UK either by local authorities or by health authorities.
- From 2013, the decision-making responsibility has rested with local authorities, as it did before 1974. Between 1974 and 2003, it rested with area and district health authorities, and between 2003 and 2013 with strategic health authorities.
- Legislation requires a full public consultation lasting at least three months to be undertaken before a final decision about whether or not to fluoridate water supplies is made.
- Water companies are required by law to accede to requests made by the 'relevant authority' to fluoridate specified water supplies.

1. Fluoridation schemes introduced by local authorities in the 1960s and early 1970s

Birmingham and Newcastle upon Tyne lead the way

In the United Kingdom decisions about whether or not to fluoridate public water supplies have always been made at a local level. Prior to 1974, local authorities made those decisions as part of their (then) responsibilities for promoting public health. For example, in 1964 Birmingham City Council introduced a scheme to fluoridate its supply. Four years later, Newcastle upon Tyne City Council followed suit.

Over 3 million people drinking fluoridated water by 1974

In the late 1960s and early 1970s, other local authorities that decided to implement new fluoridation schemes included Warwickshire County Council, Worcestershire County Council, West Bromwich County Borough, Derbyshire County Council, Derby City Council, Nottinghamshire County Council, Cumberland County Council, Northumberland County Council, Lincolnshire County Council, Cheshire County Council and Bedfordshire County Council.

By the mid-1970s, thanks to decisions made by these and other councils over the previous ten years, the number of people in the UK benefiting from a supply of artificially fluoridated water had grown to around 4 million.

2. Fluoridation schemes introduced by health authorities between the late 1970s and late 1980s

Transfer of responsibility to NHS

In 1974, the statutory responsibility for fluoridation passed to newly created area health authorities (AHAs) when local government and the NHS were reorganised in that year and the NHS assumed many of the public health functions that had previously been vested in local councils. Area health authorities inherited all previously existing fluoridation schemes at the same time as becoming responsible for deciding whether or not to introduce new ones. In 1982, area health authorities were replaced by district health authorities (DHAs), which assumed their predecessors' fluoridation responsibilities.

Over 5.5 million people drinking fluoridated water by 1990

Between the late 1970s and late 1980s and after extensive public consultation and debate, health authorities implemented many new fluoridation schemes. They included, for example, schemes to serve people living in Sutton Coldfield, Coventry, Nuneaton, Atherstone, Kenilworth, Dudley, Sandwell, Walsall, Wolverhampton, Lichfield, Tamworth, Burntwood, Cannock and Burton on Trent.

By 1990, the total UK population covered by water fluoridation schemes had grown to over 5.5 million and health authorities in many parts of the country were actively seeking to extend the benefits even further, especially in areas of high dental need.

Between 1987 and 1995, public consultations on the possibility of introducing new fluoridation schemes, or extending existing ones, were also conducted by health authorities in the North West of England, the North East, Merseyside, Cheshire, Yorkshire, Worcestershire, Southampton, Hampshire, Scotland, Wales and Northern Ireland.

3. Public information and consultation strategies

Techniques for maximising public involvement

A good public information and consultation strategy has long been considered the cornerstone of decision-making about water fluoridation proposals. Under the Water Fluoridation Act 1985, health authorities were required to consult local councils in the areas potentially affected by proposed new fluoridation schemes, and to publicise the proposals in local news media in the those areas (1). In practice, however, many health authorities have tended to go beyond the required minimum in order to maximise public involvement in the process.

During the late 1980s, for example, health authorities in the North West of England mounted *very vigorous information programmes* to explain why they were proposing new fluoridation schemes in the geographical areas for which they had statutory responsibilities for public health, and to stimulate responses to the consultation from as many local people and organisations as possible. Similar activities were undertaken in the 1990s by health authorities in the North East and West Midlands. Techniques used in these consultations, included:

- pre-consultation *information campaigns* (through the media and through leaflets and posters widely distributed to dental surgeries, GP practices, health centres, clinics, hospital out-patient departments and libraries) on the state of local dental health, inequalities between different geographical areas or sections of the community, and the options for reducing those inequalities;
- offers to make *presentations on the state of dental health* to elected representatives, community organisations, parents' groups, schools and other interested bodies;
- *circulation to local authorities, community health councils, MPs and town or parish councils of an information pack* containing copies of the formal consultation document supported by detailed background information and scientific evidence of the dental benefits and safety of fluoridation;
- an *initial press conference to announce the proposals*, followed up by a series of news releases and editorial features to explain the issues in greater detail and deal with queries and concerns which are raised during the three month consultation period;
- a willingness to supply *well-informed spokespersons for radio and television programmes and debates*;
- extensive circulation of a *summary version of the consultation document in leaflet form* on a door-to-door basis to local residents (subject to feasibility and cost) as well as to dental surgeries, GP practices, health centres, clinics, hospitals, libraries, council offices, schools, colleges and other public places;
- insertion of *advertising features in major local newspapers* to summarise the key points from the consultation document;

- *poster displays* in NHS premises;
- independently conducted *opinion surveys* asking a demographically representative sample of the population concerned whether they think fluoride should be added to water to reduce tooth decay;
- *briefing materials* distributed widely to health care professionals in order to enable them to respond to their patients' questions about fluoridation;
- establishment of a *free telephone information line* for people to obtain further information;
- provision of *speakers* on request for public meetings arranged by local community organisations to discuss the merits of fluoridation.

Lack of progress due to ambiguity about who had the legal power to make the final decision

Despite successful outcomes in these and other public consultations in terms of the levels of public support expressed for health authorities' fluoridation proposals, no schemes were actually implemented.

During the 1990s, newly privatised water companies in England and Wales – including North West Water, Northumbrian Water and Southern Water – exercised their discretion under the legislation in force at the time and declined to accede to health authorities' requests for fluoridation. Two companies – Yorkshire Water and Welsh Water – went further by halting two existing fluoridation schemes in Huddersfield and Anglesey, despite the relevant health authorities wishing to see those schemes continue in operation.

In 1991, the Water (Fluoridation) Act 1985 was consolidated into a new Water Industry Act dealing with a much wider range of water-related issues (2). However, there was no change in the wording of the relevant section of the original Act that had prevented progress from being achieved on fluoridation.

The wording specified that, when a water company had been requested in writing by a health authority for water to be fluoridated, the company concerned 'may increase the fluoride content of the water' specified. To a large extent, therefore, it was disagreement between health authorities and water companies over the meaning of the word 'may' that blocked progress on fluoridation in the UK for many years. Health authorities thought the final decision-making power lay with them, whilst water companies thought it lay with them.

4. Change to legislation in 2003 to resolve the decision-making impasse

Throughout the 1990s the decision-making impasse in England and Wales remained unresolved. However, in 2003 some sections of the relevant legislation pertaining to fluoridation were amended by Parliament in order to clarify beyond any doubt that, in law, water companies were required to accede to health authorities' requests for fluoridation. Water UK, the industry body representing water companies, had strongly supported a change in the wording of the legislation so that responsibility for deciding whether or not to fluoridate water supplies could be placed firmly in the hands of the relevant health authorities.

Water Act 2003

The Water Act 2003, which became law on 20th November 2003, stated *inter alia* that: *"If requested to do so by a relevant authority, a water undertaker shall enter into arrangements with the relevant authority to increase the fluoride content of the water supplied by that undertaker to premises specified in the arrangement"*. (3) Here, the critical word is 'shall', which replaced 'may' in the preceding legislation.

Under the 2003 Act and its associated regulations, newly created strategic health authorities (SHAs) became the bodies in England responsible for conducting public consultations on fluoridation and making the final decisions on whether to proceed with a scheme. In Wales, it is the National Assembly that fulfils this role. The position is different, however, in Scotland and Northern Ireland, as explained later.

The Water Act 2003 requires that, as far as reasonably practicable, the concentration of fluoride in water covered by legal agreements entered into between water companies and Strategic Health Authorities should be 1 milligram per litre (one part per million).

However, the Act permits the fluoride concentration to be lower than 1mg/L if it is not practicable to achieve this concentration in an area, or part of an area, covered by the legal agreement. The Act also permits the Secretary of State for Health to vary the target concentration of fluoride in water fluoridation schemes, subject to approval by both Houses of Parliament.

Consultation regulations and guidance

In England, detailed consultation regulations and guidance were issued by the Department of Health to ensure that people and relevant organisations in the areas potentially affected would have the opportunity to express their views before any final decisions were taken (4).

Local authorities whose populations (or parts of whose populations) fall within the area(s) where it is proposed to add fluoride to water were among the

organisations that had to be consulted. SHAs were also expected to take account of:

- letters received from individual members of the public (in the area potentially affected);
- letters received on behalf of community organisations;
- resolutions passed by or letters received from professional organisations;
- resolutions passed by or letters received from NHS Patient and Public Involvement Forums/Local Involvement Networks;
- letters received from community representatives, including MPs and individual councillors;
- representations from all relevant bodies;
- results of any public opinion surveys the SHA/PCT has commissioned from a recognised independent research body.

5. Consultation undertaken in 2008/09 on proposals to fluoridate water supplies in parts of Southampton and south west Hampshire

In 2008, South Central Strategic Health Authority became the first SHA in England to undertake a public consultation under the provisions of the Water Act 2003 (5). In this instance, the proposal was to fluoridate water supplies to large parts of Southampton and neighbouring areas of south west Hampshire served by the same water sources.

Weighing the level of dental need, the cogency of the scientific arguments regarding the safety and efficacy of water fluoridation, and the responses received during the consultation, the board of South Central SHA decided in February 2009 to proceed with the implementation of its fluoridation proposals.

Judicial review of South Central Strategic Health Authority consultation

The decision by South Central Strategic Health Authority to proceed with fluoridation of water supplies in the Southampton area prompted a legal challenge from local opponents of the scheme. One of them, Geraldine Milner, sought a judicial review of the way in which the SHA had conducted the consultation. Implementation of the scheme was therefore delayed while the legal process took its course.

At a hearing in the High Court in London on 11th February 2011, Mr Justice Holman dismissed a claim by Ms Milner that the decision taken two years earlier by South Central Strategic Health Authority (SHA) to add fluoride to the Southampton's water supply had been unlawful (6).

Ms Milner argued that South Central SHA had ignored what she alleged was a government policy that no new fluoridation schemes should proceed without the support a majority of local people. But the judge said it was not clear that such a policy existed and, even if it had existed (which he did not accept), it would have been inconsistent with the relevant regulations approved by Parliament and subsequent guidance issued by the Chief Dental Officer.

Secondly, Ms Milner argued that the SHA had failed properly to assess the cogency of the arguments against fluoridation made by respondents to the consultation. This was dismissed by Mr Justice Holman, who said her claim was not even arguable.

Court decides that South Central Strategic Health Authority had not acted unlawfully

In conclusion, Mr Justice Holman said the SHA had not acted unlawfully and no court could interfere with its decision. He also offered guidance to any SHA about making post-consultation decisions on fluoridation under the legislation in force at the time:

1. They needed to ascertain and make a judgement or assessment as to the cogency of all the arguments (not merely the health arguments) advanced both for and against proceeding with the proposal.
2. They needed to weigh very carefully those arguments which were health arguments in favour of proceeding against all the arguments (not merely any health arguments) against proceeding.
3. If they were not satisfied that the health arguments (and none other) in favour outweighed all the arguments against, then that was the end of the matter.
4. If they were satisfied that the health arguments in favour did outweigh all the arguments against, they then needed to have regard to the extent of support for, or opposition to, the proposal, and decide whether, in the light of the extent of support/opposition, the health arguments in favour were still so weighty that they should prevail.

6. Preparatory work undertaken in the North West of England to explore feasibility of new fluoridation schemes

Between 2006 and 2009, work took place in the North West of England to assess the feasibility of fluoridating water supplies to large parts of Greater

Manchester, Lancashire, Cumbria and Cheshire. Within that region, existing fluoridation schemes served parts of Cumbria, including the communities of Workington, Whitehaven and Cockermouth, and parts of Cheshire, including the communities of Crewe, Nantwich and Alsager.

Discharging their duties for disease prevention and health promotion, the 24 NHS primary trusts (PCTs) in the region formed a consortium to explore the potential benefits of extending fluoridation. Having reviewed the relative efficacy of different strategies for reducing tooth decay, in 2008 they submitted their report to the North West Strategic Health Authority (7).

The North West SHA then set about the task of exploring the feasibility and cost of specific fluoridation schemes and preparing the way for a possible public consultation. However, with judicial review proceedings having started in 2009 with regard to the outcome of the South Central SHA consultation on proposals to fluoridate water supplies in the Southampton area, significant further progress in the North West was not possible.

Similarly, primary care trusts in Yorkshire and other parts of England had been looking at whether fluoridation of water supplies might help to reduce unacceptably high levels of children's tooth decay in their areas. As in the South Central and North West regions, however, the judicial review on the Southampton consultation put everything on hold.

7. The legal position in Scotland

In Scotland, the 1985 Water (Fluoridation) Act, and subsequent guidance issued as NHS Circular No 1991(GEN)16, remain in force. The Act and guidance give health boards the power to decide whether or not to apply for fluoridation of supplies in their area, and set out the procedure to be followed.

Scotland has its own Parliament, with health among its devolved powers. A further major difference between England and Scotland is that Scottish water supplies are under public, not private, ownership. Since February 2001, that ownership has been vested in a single water authority – Scottish Water which, unlike the privatised water industry in England and Wales, remains a publicly owned organisation directly answerable to the Scottish Parliament.

8. The legal position in Northern Ireland

The Water Act (2003) does not cover Northern Ireland. Legislation enabling fluoridation of the public water supplies in Northern Ireland is based on the Water Order (1987), which empowers the Department of the Environment (NI), on application from a health board, to fluoridate the water supplied within the area (or part of the area) of that board (8).

9. Decision-making on fluoridation – changes in the Health and Social Care Act 2012

In a White Paper on the future structure of the NHS in England, the coalition government that came to power in May 2010 made clear its intention to abolish strategic health authorities (SHAs) (9). Specific provisions to this effect, together with the transfer of public health responsibilities from the NHS to local authorities, were included in the Health and Social Care Act 2012.

Under this legislation and with effect from April 2013, 'upper tier' local authorities (county councils, metropolitan boroughs, London boroughs and unitary authorities) assumed the responsibilities of the former strategic health authorities for conducting public consultations and making decisions on fluoridation schemes. The local authorities' responsibilities in relation to community water fluoridation are laid out in more detail in The Water Fluoridation (Proposals and Consultation) Regulations 2013.

From the same date a new national body – Public Health England – came into being with a wide range of functions, including the management of existing and future fluoridation schemes. Public Health England is an executive agency of the Department of Health and, in the context of fluoridation, discharges the statutory duties of the Secretary of State for Health under the 2012 Act.

In practice, Public Health England's tasks include:

- advising local authorities whether fluoridation schemes they are proposing would be 'operable and efficient';
- providing information and expertise on fluoridation matters;
- entering into a legal agreement with the relevant water company when, following public consultation, a local authority or group of local authorities formally request the Secretary of State to implement a new fluoridation scheme or extend an existing one;
- working with water companies to ensure the safe and efficient operation of all fluoridation schemes in England.

10. European law and fluoridation

Drinking Water Directive specifies maximum permitted level of fluoride in water, whether naturally occurring or added

Under EU law and regulations, the supply of water for human consumption is governed by a Drinking Water Directive (10). The purpose of the Directive is to protect the health of people throughout the EU by ensuring that the water they drink is wholesome and clean. It sets standards for the concentrations of

certain substances in water, including fluoride. The maximum level permitted anywhere in the EU is 1.5 parts of fluoride per million parts of water, whether occurring naturally or artificially added.

It follows that any fluoridation schemes implemented by individual EU Member States must keep the fluoride level in the water supplies concerned within the 1.5 ppm maximum at all times. In the UK, the level agreed by Parliament in the Water Act 2003 is 1 ppm. Levels of naturally occurring fluoride in some parts of the UK may exceed 1 ppm. However, they are not allowed to exceed 1.5 ppm.

Decisions vested in individual Member States on whether or not to add fluoride to water

Under EU law, individual Member States can decide whether or not to implement fluoridation schemes as part of their oral health promotion strategies. Similarly, they can decide whether to add fluoride to salt or milk.

There is no EU-wide obligation to add fluoride to any product, including water, consumed by humans. Nor is there an EU-wide obligation *not* to add fluoride to water or to any other product. The discretion to add or not to add fluoride lies with the government of each Member State.

Four EU countries currently practise water fluoridation:

- the UK (where around 5.5 million people are supplied with fluoridated water);
- Spain (where 4 million people are served by local schemes);
- Ireland (where fluoridation of all public water supplies has been mandatory since the 1960s and where approximately 2.4 million are currently receiving fluoridated supplies);
- Poland (where an estimated 80,000 people drink artificially fluoridated water).

Several EU countries, including France, Germany, Austria, Belgium, the Czech Republic and Slovakia, practise salt fluoridation. Children in some communities in the UK, Bulgaria, Macedonia and Russian Federation receive fluoridated milk.

Locally made decisions on public health initiatives to combat tooth decay

Whatever anti-fluoridation groups may claim to the contrary, none of the Member States supplying fluoridated water to all or part of their populations is contravening EU legislation in any way. They have each made local public health decisions to adjust the fluoride content of water in all or parts of their territories in order to reduce what they consider to be unacceptably high levels of tooth decay.

No European Court judgement has changed the legal status of fluoridated water in the EU. Indeed, if anything, European Court judgements over recent

years have confirmed that it is for individual Member States to decide whether particular substances used in their territories should or should not be classified as 'medicines'. Such decisions, says the European Court, must necessarily be made on a case by case basis.

References

1. HM Government (1985): *Water (Fluoridation) Act 1985*. HMSO: London.
2. HM Government (1991): *Water Industry Act 1991*. HMSO: London.
3. HM Government (2003): *Water Act 2003*. HMSO: London.
4. HM Government (2005): *The Water Fluoridation (Consultation) (England) Regulations 2005*.
5. South Central Strategic Health Authority (2008): *Public consultation on the proposal for water fluoridation in Southampton and parts of south west Hampshire*.
6. Judgement delivered by Mr Justice Holman at the Royal Courts of Justice, London on 11th February 2011 in the case of *Geraldine Milner v South Central Strategic Health Authority and the Secretary of State for Health*.
7. North West Primary Care Trusts (2008): *Report of the North West Primary Care Trusts' Fluoridation Evaluation Group*.
8. HM Government, (1987): *Water (Fluoridation) (Northern Ireland) Order 1987, in Statutory Instrument 1987 No.2052 (N.I. 21)*. HMSO: London.
9. Department of Health (2010): White paper, *Equity and excellence – Liberating the NHS*.
10. EU Drinking Water Directive 98/83/EC.