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Withdrawn



Public Health
England

Protecting and improving the nation's health

Improving oral health

A community water fluoridation toolkit
for local authorities

Withdrawn

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Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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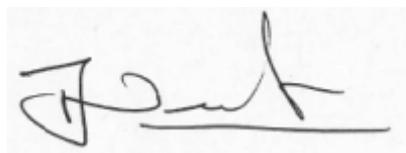
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Foreword

Tooth decay remains an important public health challenge for England, affecting many children and adults. The impact of this preventable disease on individuals can be severe, causing pain and suffering but also affecting their ability to function in other ways. Treatment is expensive and diverts critical NHS resources that could be devoted to other problems, for example far too many children still need to go to hospital to have teeth removed. Tackling this problem has been made more pressing by the increasing cost and difficulty of providing operative dental care.

Research around the world and from monitoring of the effects of Community Water Fluoridation in England have highlighted the benefits to individuals and to society of this important public health measure. All water contains some fluoride; having the right level helps create a healthy environment and helps people enjoy a healthier life. Community Water Fluoridation is an effective and safe way of achieving this.

This toolkit is designed to supplement the advice and support that PHE offers to those seeking to improve the health of the communities they serve, and I hope you find it useful. Further support can be obtained from your PHE centre.



Professor John Newton
Director of Health Improvement
Public Health England

Executive summary

The public health challenge of tooth decay prevention

Tooth decay is largely preventable, yet it remains a serious health problem affecting around 23%¹ of all 5-year olds and is the most common cause of hospital admissions among children aged between 6 and 10.

While there have been improvements in children's oral health over the past 40 years, the rate of reduction in tooth decay levels has slowed in the past decade. Major dental health inequalities remain. Children from the most deprived areas experience the highest levels of decay. The consequences of decay are lifelong; extracted teeth are lost for ever; fillings need to be replaced.

The contribution of water fluoridation to local oral health promotion strategies

Water fluoridation is one of a range of interventions available to improve oral health, and the only one that does not require behaviour change by individuals.

All water contains small amounts of naturally occurring fluoride. Fluoride in water at the optimal concentration (one part per million or 1mg fluoride per litre of water [1mg/l]) can reduce the likelihood of tooth decay and minimise its severity. Where the naturally occurring fluoride level is too low to provide these benefits, a water fluoridation scheme raises it to one part per million.

Reviews of studies conducted around the world confirm that water fluoridation is an effective and safe public health measure suitable for consideration in localities where tooth decay levels are of concern.

Reports published by Public Health England (PHE) in 2014² and 2018³ comparing a range of health indicators for local authorities in this country, found lower rates of tooth decay among children from fluoridated areas than those from non-fluoridated areas. No evidence of harm to the health of people supplied with fluoridated water was found. PHE will continue to keep the evidence under review and use these reports as part of

¹ National Dental Epidemiology Programme for England: oral health survey of 5-year-olds 2019. Accessed at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/873492/NDEP_for_England_OH_Survey_5yr_2019_v1.0.pdf

² Water fluoridation. Health monitoring report for England 2014. Public Health England 2014. Accessed at www.gov.uk/government/publications/water-fluoridation-health-monitoring-report-for-england-2014

³ Public Health England: Water Fluoridation Health Monitoring Report for England 2018. Accessed at <https://www.gov.uk/government/publications/water-fluoridation-health-monitoring-report-for-england-2018>

an ongoing dialogue with local authorities about ways of improving the oral health of their communities.

Legislation governing water fluoridation and the decision-making role of local authorities

Water fluoridation is expressly permitted in legislation by parliament, with decisions made at a local level. The Health and Social Care Act 2012, by amending the Water Industry Act 1991 (the Act), returned responsibility for those decisions to local authorities with public health responsibilities.

Many existing fluoridation schemes in England have been running for 40 years or more, with the oldest, serving the city of Birmingham, having existed for over 50 years. Some 6 million people in England now have a fluoridated water supply. Another third of a million have a water supply in which the naturally occurring background level of fluoride is around the optimal level. Worldwide, over 370 million people are served by water fluoridation schemes.

Local authorities have to exercise their responsibilities in accordance with legislation governing the way in which a new scheme can be introduced and how an established scheme may be modified or terminated.

The legislation sets out a process to be followed for formal public consultation on a fluoridation proposal; for collaborating with other local authorities whose populations may be affected by the proposal; and for taking account of a range of key factors when making final decisions.

Duties of the secretary of state for health and social care and PHE in respect of water fluoridation

Legislation assigns specific powers and duties to the secretary of state, particularly those of making and holding arrangements (normally documented in legal agreements) for schemes with water companies, monitoring at regular intervals the health effects of schemes and reporting publicly on those effects. The secretary of state's responsibilities are largely discharged on his or her behalf by PHE.

Informing local discussions

Debate on water fluoridation tends to focus on a few key questions: the level of dental health need in the community or communities affected; whether a fluoridation scheme would be effective in reducing tooth decay levels; whether it is safe (that is, does not cause harm to health); who will benefit; whether people want it; the ethical issues raised by such public health interventions; and cost-effectiveness.

The preparedness of a local authority to address these issues confidently and authoritatively from the outset of any public discussion of water fluoridation is likely to be vital to the whole process. PHE advises that any local authority minded to consider the possibility of water fluoridation should develop a thorough communications plan.

Local authorities with longstanding schemes, such as those in the West Midlands (the most extensively fluoridated part of England) may form a valuable source of advice on effectiveness, absence of harm and public acceptability to any local authority minded to consider water fluoridation.

Local NHS bodies and clinicians are well-placed to contribute to the health debate about water fluoridation in a locality and about its potential to reduce health inequalities, in respect of which NHS England and clinical commissioning groups have statutory responsibilities.

The costs of treating dental decay fall to NHS bodies, and dental clinicians (both primary and secondary-care based) provide the necessary treatment services. They are able to explain to lay decision-makers the impacts of that treatment. Medically qualified clinicians (GPs and hospital-based specialists) are able to describe the dentally-related workload impacting on out-of-hours and emergency department services, and the opportunity cost of providing general anaesthetic services for a preventable disease.

Medical specialists are also able to make a valuable contribution to debates about possible harms alleged from water fluoridation on the basis of clinical plausibility, their knowledge of the scientific literature, and their ability to consult relevant colleagues in other, fluoridated, areas.

In discussions about the impact on patients and carers of patients with high levels of dental decay, and the options for tackling that problem, it will be important to ensure that the voices of a diverse range of local people are heard in an appropriate way, including those in greatest dental need, and that their contribution to the debate is facilitated.

Health and wellbeing boards

Health and wellbeing boards (HWBs) have a key role in relation to consideration of fluoridation, through their duty to produce a joint strategic needs assessment (JSNA) for their area and a joint health and wellbeing strategy (JHWS).

It is anticipated that if dental decay levels are a source of serious concern in an area, the matter would feature in the JSNA and JHWS. In making decisions about proposals

for water fluoridation schemes, local authorities are required to have regard to the JNSA and JHWS published by the HWB.

The Act also recognises HWBs as one of the possible vehicles through which fluoridation functions may be exercised by local authorities, where more than one local authority is affected by proposed or actual fluoridation arrangements.

Local authorities with established schemes

Local authorities with established schemes⁴ are advised to:

- work with PHE and the water company to understand operating issues, scheme performance and costs
- ensure they commission appropriate dental surveys to monitor dental decay levels
- review the four-yearly health monitoring reports on water fluoridation published by PHE, and work with PHE on the design of the future monitoring programme
- equip themselves to be able to discuss the health effects of their scheme and respond to enquiries from residents
- work collaboratively on these issues with partner local authorities involved with the same scheme

Further advice and support from PHE

Local authorities can obtain advice and support on water fluoridation through their local PHE centre.

⁴ Listed in annex 1

Section 1. Introduction

Local authorities were the driving force behind the introduction of water fluoridation schemes in England in the 1960s. In 1974 the responsibility for fluoridation was transferred to the NHS and further schemes were introduced. Some 6 million people currently benefit from those decisions.

On 1 April 2013, when the Health and Social Care Act 2012 came into force, major responsibilities for water fluoridation were returned to local authorities.

Fluoridation schemes are governed by legislation⁵ which sets out how new schemes may be introduced, how established schemes are operated or modified and how they can be terminated.

This toolkit therefore provides information and advice to local authorities:

- that have established schemes, so they are aware of the issues relating to those schemes
- considering options for action to address levels of tooth decay in their populations, so they understand the evidence base and the processes they would be required by legislation to follow if they decided to propose a fluoridation scheme

The toolkit will be of particular interest to directors of public health and their staff, and to chairs and members of health and wellbeing boards and of health overview and scrutiny committees.

Most water boundaries, of companies and of local supply systems within companies, rarely match local authority boundaries. Modern investment in water systems to improve resilience against possible drought conditions means that particular water systems increasingly cover larger areas. Almost all existing fluoridation schemes cover more than one local authority area; some cover several. It is highly likely that any new schemes proposed for introduction would also cover more than one local authority area. It is therefore important that local authorities are prepared to work across boundaries, whether in relation to existing schemes or possible new schemes.

The toolkit covers the current legislation and evidence base for fluoridation and provides pointers to other issues which local authorities may wish to consider. It also indicates the support that PHE can offer to local authorities on this subject.

⁵ Relevant legislation is now the Water Industry Act 1991, Part III Chapter IV (the Act) and The Water Fluoridation (Proposals and Consultation) (England) Regulations 2013 (the regulations)

The legislation gives the secretary of state for health and social care powers and responsibilities for certain aspects of fluoridation. These include the holding of legal agreements with water companies for individual schemes which are managed on his or her behalf by PHE, and for monitoring the health effects of schemes. The toolkit provides information on the roles of the secretary of state and PHE and how these interface with local authority responsibilities.

It is important to note that while this toolkit offers advice to local authorities it has no legal status and does not represent legal advice. A local authority involved with or considering water fluoridation should familiarise itself with the relevant legislation and secure its own legal advice on the interpretation and implementation of that legislation.

The toolkit content was developed in-house by PHE with input from representatives of the Association of Directors of Public Health drawn from a range of those local authorities with fluoridation responsibilities.⁶

Note: Throughout this document, legislative references to 'the Act' refer to the Water Industry Act 1991, as subsequently amended. Part III, chapter IV, deals with water fluoridation. Similarly, references to a specific regulation are to ones within The Water Fluoridation (Proposals and Consultation) (England) Regulations 2013

⁶ Outside London, upper tier and unitary authorities

Section 2. Background

2.1 Tooth decay and its consequences

Tooth or dental decay (dental caries) is a common disease in the population. It is the most common oral disease affecting children and young people. While children's oral health has improved over the last 20 years, almost a quarter (23.4%) of 5-year olds still had tooth decay in 2019⁷. Poor oral health impacts on children and families' health and wellbeing.^{8 9 10 11} Children who have toothache or who need treatment may have to be absent from school. Parents may also have to take time off work to take their children to the dentist. Data on the proportion of 5-year-old children with dental decay was included in the November 2019 Public Health Outcomes Framework¹². Dental decay is progressive and can cause severe pain and sepsis, especially if left untreated. The treatment of dental decay may require the replacement of part of the decayed tooth with a filling to restore function and relieve pain. Such restorative treatment sometimes requires the tooth to be root filled, which involves removal of the inner soft tissue of the tooth and its replacement with a filling material. In some cases, extraction of the diseased tooth or teeth may be the only viable treatment option. This procedure, especially in young children, may necessitate hospital treatment under general anaesthesia. All of these treatment procedures are irreversible. Once a filling has been placed in an adult (permanent) tooth, it will typically need replacing periodically because of wear and tear; this may be every 10 to 20 years or even more frequently. Often, replacement fillings have to be larger than their predecessors, involving a greater part of the tooth and so are more complex to repair on the next occasion. A person with filled teeth is therefore locked into an ongoing cycle of repair throughout life, with cost to the individual and to the NHS.

Dental decay is not just a disease of childhood; adults get decay too. With age many adults experience receding gums which exposes the tooth root surfaces. These exposed roots are vulnerable to decay which can be challenging to treat. Added to this is the effect of many medicines often prescribed for older adults, which can reduce the protective effects of saliva in the mouth. Consequently, adults with previously healthy

⁷ Public Health England. National Dental Epidemiology Programme for England: oral health survey of 5-year-olds 2019 A report on the variations in prevalence and severity of dental decay, (2020)

⁸ Nuttall, N. & Harker, R. Impact of Oral Health: Children's Dental Health in the United Kingdom, 2003. (2004).

⁹ Health & Social Care Information Centre. Children's Dental Health Survey 2013. Report 1: Attitudes, Behaviours and Children's Dental Health. England Wales and Northern Ireland 2013.

¹⁰ Health & Social Care Information Centre. Children's Dental Health Survey 2013. Report 4: The burden of dental disease in children.

¹¹ Royal college of Paediatrics and child health: State of Child Health, 2017

¹² PHE, Public Health Outcomes Framework Data included in 5 November 2019 publication

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/845216/Table_of_PHOF_updates_November_2019.pdf

teeth may experience a gradual increase in decay. This situation adds to the dental care challenge posed by an ageing population who are retaining natural teeth. In many cases the results of past complex treatment may become increasingly difficult to maintain.

Despite reductions in the prevalence of the disease over the past 40 years, substantial inequalities remain. People from more deprived communities tend to experience more disease¹³. They are far more likely to have extensive tooth decay and signs of sepsis than their peers and are at greater risk of more extreme interventions such as extractions under general anaesthetic.¹⁴ Furthermore, the rate of reduction of tooth decay levels has slowed in the last decade.¹⁵ A 2015 publication¹⁶ from the International Centre for Oral Health Inequalities Research and Policy (ICOHIRP) gives a helpful overview of social inequalities in oral health.

As a substantial public health problem, tooth decay can result in significant diversion of health resources. For example, tooth decay is a very common reason for hospital admission in younger children. In 2017-2018 dental extraction was the most common reason for 6- to 10-year olds to be admitted to hospital.¹⁷ Delivering this hospital-based dental treatment is costly and uses resources such as specialist anaesthetic and operating theatre time that could be used to treat other conditions. The psychological impact of these tooth extractions under general anaesthesia on children and their parents may also be significant. In response, an oral health indicator has been included in the NHS outcome framework based on tooth extractions due to decay for children admitted as inpatients to hospital, aged 10 years and under¹⁸.

¹³ Health & Social Care Information Centre. Children's Dental Health Survey 2013. Report 2: Dental Disease and Damage in Children.

¹⁴ Goodwin, M., Sanders, C., and Pretty, IA. A study of the provision of hospital based dental general anaesthetic services for children in the north-west of England: Part 1 – A comparison of service delivery between six hospitals. BMC Oral Health, 2015. 15: p.50

¹⁵ Health & Social Care Information Centre. Children's Dental Health Survey 2013. Report 2: Dental Disease and Damage in Children.

¹⁶ Watt RG et al (Editors). Social inequalities in oral health: from evidence to action. ICOHIRP, University College London, 2015

¹⁷ Public Health England Dental Public Health Intelligence Programme Hospital Episode Statistics: Extractions data, 0-19 year olds, 2011-12 to 2017-18

¹⁸ NHS Digital, NHS Outcomes Framework Indicators - November 2019 Release: 3.7.ii Tooth extractions due to decay for children admitted as inpatients to hospital, aged 10 years and under

2.2 Tooth decay is largely preventable – interventions for prevention

Improving oral health and addressing inequalities requires a combination of strategies. These include preventing disease through measures which benefit the whole population, combined with measures specifically targeted at individuals with the greatest susceptibility to disease. Preventing oral diseases should be a priority at all stages of people's lives. Strategies are needed that will have a cumulative and significant impact on quality of life from childhood through to later years¹⁹.

Tooth decay starts when the outer surface of the tooth (the enamel) is attacked and dissolved by acid produced by bacteria on the surface of the tooth, in a thin layer called dental plaque. When sugars from food or drink enter the mouth, the bacteria in plaque quickly convert the sugars into acid. This process of attack on the enamel is called demineralisation. It is reversible but, depending on the length of exposure of the tooth to this acid attack, the balance between demineralisation and remineralisation may be unfavourable, leading to the formation of a cavity in the tooth. Low levels of fluoride in saliva and dental plaque encourage remineralisation of the tooth surface and thereby increase its resistance to decay. This is known as the topical effect of fluoride.

Fluoride can also have a further systemic effect, for example if fluoride in water is swallowed while the teeth are still developing in the jaws. The fluoride makes the developing enamel more resistant to the chemical attacks (demineralisation) which will occur once the teeth have erupted into the mouth.

Fluorides have an important role in a wide range of approaches, both upstream and downstream, to reduce dental decay.

Preventive interventions include self-help through regular use of a toothpaste containing fluoride and reducing the quantity and frequency of sugar intake.

Tooth decay can be prevented or minimised by adherence to an appropriate diet, which includes ensuring that consumption of sugars represents no more than 5% of total dietary energy.²⁰ The PHE report 'Sugar reduction: The evidence for action' (2015) notes: "Consumption of sugar and sugar sweetened drinks is particularly high in school age children. It also tends to be highest among the most disadvantaged who also experience a higher prevalence of tooth decay and obesity and its health consequences." Unfortunately, it is also the case that people who are poorer or more

¹⁹ Local Authorities improving oral health: commissioning better oral health for children and young people. An evidence informed-toolkit for local authorities. Public Health England 2014.

²⁰ Sugar reduction: The evidence for action. Public Health England, October 2015.

disadvantaged may face difficulty in adhering to recommended healthy eating approaches.²¹

When patients considered to be at risk of tooth decay are seen by dental professionals, they can be offered individual preventive treatments – for example, fluoride-containing varnishes. However, regular toothbrushing and dental attendance are less prevalent in poorer or more disadvantaged groups²². Supervised tooth brushing programmes using fluoride toothpaste may usefully be targeted at children in communities with a particularly high risk of tooth decay.

Since the resumption by local authorities of responsibilities for public health, including oral health, PHE has provided them with an evidence-informed toolkit on their commissioning responsibilities for oral health¹⁹ and, the Local Government Association, has provided advice on a whole systems approach to tackling childhood tooth decay providing a range of examples of the steps that need to be taken to achieve success²³. PHE has also published an evidence-based toolkit²⁴ for dental teams to use when giving preventive advice and treatment to their patients.

For success, all of the recommended measures require long-term commitment and consistently appropriate behaviours by individuals or their carers. For various reasons, including personal financial circumstances, many people are unable to enter into or maintain that level of commitment long-term. Adopting and sustaining the behaviours needed to maintain good oral health can therefore be problematical for those at the greatest risk of disease.

Water fluoridation, which has both topical and systemic effects, is the only intervention to improve dental health that does not require sustained behaviour change over many years. It is therefore particularly beneficial for individuals and communities at increased risk of tooth decay, such as those from more deprived backgrounds and other vulnerable groups.

2.3 The impact of fluoride in water

Fluoride in water can reduce the likelihood of experiencing dental decay and minimise its severity. Evidence reviews (see Section 3) confirm that it is an effective, safe public health measure suitable for consideration in localities where levels of dental decay are of concern.

²¹ McGill R, Anwar E, Orton L et al. Are interventions to promote healthy eating equally effective for all? Systematic review of socioeconomic inequalities in impact. BMC Public Health 2015 15:457 and Erratum at 15: 894

²² Health & Social Care Information Centre. Children's Dental Health Survey 2013. Report 1: Attitudes, Behaviours and Children's Dental Health.

²³ <https://www.local.gov.uk/whole-systems-approach-tackling-childhood-tooth-decay>

²⁴ Delivering Better Oral Health – an evidence-based toolkit for prevention. Public Health England 2017

Some fluoride occurs naturally throughout the world in water used for drinking, but the amount is highly variable. A very low level of natural fluoride, as found in most parts of England, has no documented impact on health. At the other extreme, as in parts of Africa, India and Asia, very high levels of naturally occurring fluoride in water consumed over the long-term can cause a serious condition called skeletal fluorosis. This is extremely rare in western countries.

Researchers²⁵ in the US in the first half of the last century observed a relationship between the concentration of fluoride in water, levels of tooth decay and levels of dental fluorosis, a condition affecting the appearance of individuals' teeth. Those researchers estimated the most advantageous level of fluoride in water, in temperate climates, to be one part of fluoride per million parts of water, or 1mg fluoride per litre of water (1mg/l). At this level the benefits of fluoride in reducing decay are optimal. Higher levels of fluoride confer little additional benefit in terms of decay reduction while increasing the risk of dental fluorosis. Water fluoridation schemes, where the naturally low fluoride is adjusted to the optimum level, mimic that naturally occurring optimum level of fluoride in public water supplies.

In the UK, the naturally occurring level of fluoride in water is typically around 0.1 to 0.2 mg/l, although in some localities (for example Hartlepool and Uttoxeter) it is about 1.0mg/l and in some private water supplies (springs, wells, boreholes) can reach 3 or 4mg/l before correction. About a third of a million people in England have a water supply in which the naturally occurring background level of fluoride is around the optimal level.

Water fluoridation is therefore a valuable public health intervention which can make an important contribution to reducing levels of dental decay and reducing inequalities in a local community. It is undertaken through the public water supply, so the communities in which it may be a viable option can be constrained by the specific water distribution arrangements in a given locality. Since water fluoridation requires capital investment, it is a measure which should be considered as a long-term investment to secure improvements in dental health.

Most of the community water fluoridation (CWF) schemes in England were introduced by local authorities. Birmingham City Council and Solihull established the first substantive scheme in 1964, and were followed by Worcestershire County Council in 1965 and Cumberland County Council in 1968, with Durham, Northumberland, Gateshead and Newcastle making fluoridation agreements the same year.

Further schemes, predominantly in the West Midlands, were introduced by the NHS from the late 1970s onwards. At 1 January 2020, 26 (unitary and upper tier) local authorities had CWF schemes covering the whole or parts of their area with some 6

²⁵ Dean, H.T. et al. Studies on mass control of dental caries through fluoridation of the public water supply. Public Health Rep, 1950. 65(43)pp1403-8

million people in England receiving a fluoridated water supply, principally in the North-East and in the West and East Midlands. Details are in annex 1 and these authorities – particularly those with extensive longstanding schemes such as in the West Midlands – may form a valuable source of advice on effectiveness, absence of harm and public acceptability, to any local authority minded to consider water fluoridation.

Box 1. Some of the cities and towns in England with water fluoridation schemes

Alnwick, Bedford, Birmingham, Bolsover, Bridgnorth, Bromsgrove, Burton-on-Trent, Cannock, Consett, Coventry, Crewe, Dudley, Evesham, Gateshead, Grantham, Hexham, Leamington Spa, Lichfield, Lincoln, Nantwich, Newcastle-upon-Tyne, Nuneaton, Mansfield, Redditch, Retford, Rugby, Scunthorpe, Solihull, Stratford-upon-Avon, Tamworth, Walsall, Warwick, West Bromwich, Whitley Bay, Wolverhampton, Worksop.

The following map²⁶ illustrates the approximate current area of coverage of fluoridation schemes in England and also shows areas with naturally fluoridated water at levels above 0.5mg/litre.

Withdrawn

²⁶ Map provided by the Drinking Water Inspectorate

Box 2. Some other countries with water fluoridation schemes

Ireland, Spain, Australia, New Zealand, Canada, the USA, Brazil, Argentina, Chile, Guyana, Malaysia and Singapore.

Box 3. Some of the major cities worldwide with water fluoridation schemes

New York, Los Angeles, Chicago, Houston, Phoenix, Washington DC, Philadelphia, San Antonio, San Diego, Dallas, Detroit, Indianapolis, Austin, Columbus, Seattle, Denver, Atlanta, Boston, Miami, Toronto, Winnipeg, Edmonton, Rio de Janeiro, Sao Paulo, Buenos Aires, Santiago, Valparaiso, Dublin, Cork, Seville, Bilbao, Hong Kong, Sydney, Melbourne, Brisbane, Adelaide, Perth, Darwin, Hobart, Canberra, Auckland and Wellington.

In recent years there has been an increase in fluoridation coverage around the world, particularly in the United States, Brazil, Chile, Australia and Malaysia, adding around 50 million more people who receive this public health measure. Worldwide, over 370 million people are included within CWF schemes.²⁷

Water fluoridation is supported by the World Health Organisation, the World Health Assembly, the Federation Dentaire Internationale, the International Association for Dental Research and health bodies in many countries around the world, including the US Centers for Disease Control and Prevention (which named water fluoridation as one of the 10 great public health achievements of the 20th century), the American Medical Association, the American Dental Association, the Canadian Medical Association, the Canadian Dental Association, the Canadian Paediatric Society and the Australian Dental Association.

Within the UK water fluoridation is endorsed as a public health intervention by PHE, the British Medical Association Board of Science, the Faculty of Public Health of the Royal College of Physicians, the Faculty of Dental Surgery of the Royal College of Surgeons of England, the British Dental Association, the British Society for Paediatric Dentistry and many bodies representing health professionals.

²⁷ Royal Society of New Zealand. Health effects of water fluoridation: A Review of the scientific evidence. 2014. Accessed at www.royalsociety.org.nz/media/2014/08/Health-effects-of-water-fluoridation_Aug_2014_corrected_Jan_2015.pdf

2.4 Assessing the need for fluoridation

Water fluoridation sits within a context of local oral health needs and as part of a likely range of interventions to improve oral health. JSNAs and strategies to improve oral health (see also section 5.4 and annex 2) are a key initial step when considering the role of water fluoridation. The early stages of strategy development will also facilitate dialogue with the NHS and local professional groups, both dental and medical, over the potential utility of different and combined approaches to oral health improvement. Where there are concerns over high levels of tooth decay among vulnerable children it may be useful to engage local children's safeguarding boards and any local fairness commissions in discussions. It might also be useful to ascertain whether neighbouring authorities, who may share water supplies, have similar concerns and priorities. Having an agreed and widely discussed position on need and the range of actions to be taken is likely to be valuable when discussions progress further.

To inform these discussions, local dental surveys will be required and should have a sufficient sample size to demonstrate variations in oral health within the local authority, for example, the nature and magnitude of oral health inequalities. Local authorities are responsible for providing, or making arrangements to secure the provision of, oral health surveys to facilitate the assessment and monitoring of oral health needs.²⁸ These surveys will establish the prevalence and incidence of oral disease, including dental decay, and include ones of 5-year-old children normally undertaken every other year to a national timetable. PHE centres are able to advise on appropriate survey design to ensure comparability with other authorities, and on quality assurance of a survey. Data from surveys of 5-year-old children is included in local authority health profiles.²⁹

2.5 Public debate on water fluoridation

The preparedness of a local authority to address issues confidently and authoritatively will be vital as it enters into local discussions. Public debate is likely to start at an early stage and may involve enquiries and challenges from interested parties within and outside the area potentially affected.

Experience over many decades of fluoridation in the UK and internationally has shown that there are people who make a range of untrue assertions and claims about fluoridation which can have a disproportionate impact on public opinion if unchallenged. Experience has also shown that in those parts of the country where fluoridation schemes have operated for many years it is not an ongoing issue of controversy for the

²⁸ The NHS Bodies and Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch) Regulations 2012. Part 4, Regulation 17(2)(b)(i)

²⁹ Local Authority Health Profiles, Public Health England. <https://fingertips.phe.org.uk/profile/health-profiles>

general population. PHE therefore strongly advises any local authority minded to consider the possibility of water fluoridation to:

- develop a thorough communications plan before the authority or its health and wellbeing board (HWB) embarks upon any substantive consideration of introducing a water fluoridation scheme – the development of a comprehensive questions and answers briefing may greatly facilitate timely and consistent responses to enquiries
- inform the communications plan with advice from other local authorities with experience of fluoridation and by advice from PHE
- develop the initial plan in the knowledge that the overall timescale for decision-making about the introduction of a fluoridation scheme will be measured in months or years, not weeks, and that appropriate communications activity would be necessary throughout that period

Those local authorities which have established schemes are advised to ensure that their HWBs are familiar with the subject including the results of the PHE health monitoring and reporting programme (see sections 6 and 7), and are able to provide authoritative commentary should any fluoridation-related issues be raised locally. The local PHE centre can provide advice and information on request.

PHE has health improvement and health protection responsibilities and expertise. It can, if requested by individual local authorities, provide advice on effectiveness, safety and costs or can sign-post the authorities towards other sources of such advice. A later section of this toolkit introduces these topics.

2.6 Procedural matters

Because of water distribution arrangements in a particular area, it may not be technically feasible to fluoridate only the area of initial dental health concern. It might be necessary to fluoridate a wider area if water fluoridation was desired for adoption. Additionally, those water distribution arrangements may extend into more than one local authority area which may as a consequence require additional steps. It is therefore essential to gain the earliest possible understanding of such matters through the procurement of a feasibility study from the water company concerned. Often a low-cost desk-top exercise will provide that initial information. This will inform preliminary discussions within the originating local authority and with any neighbouring authorities which might be affected. PHE can advise local authorities on these matters.

Local authorities should be aware from the outset that, if they initiate the procedures necessary to introduce a new scheme, or to vary or terminate an existing scheme, the legislation requires them to make their decisions after following specified procedures. At the conclusion of those deliberations, should the authority(ies) decide to put forward a

proposal, the secretary of state for health and social care has to be satisfied that the procedural requirements imposed by the Act have been met.

The legislation also requires local authorities to ensure their decisions have regard to a number of matters specified in the regulations. Those matters are described in the annexes to this toolkit.

There are, therefore, a number of procedural matters to which local authorities are advised to give close attention if they are to avoid the possibility of successful legal challenge to decisions made at the end of a lengthy process, be those decisions to introduce a new scheme or decisions to vary or terminate a scheme.

The procedural pathways and issues for consideration are quite similar whether the proposal is to introduce, vary or terminate a scheme.

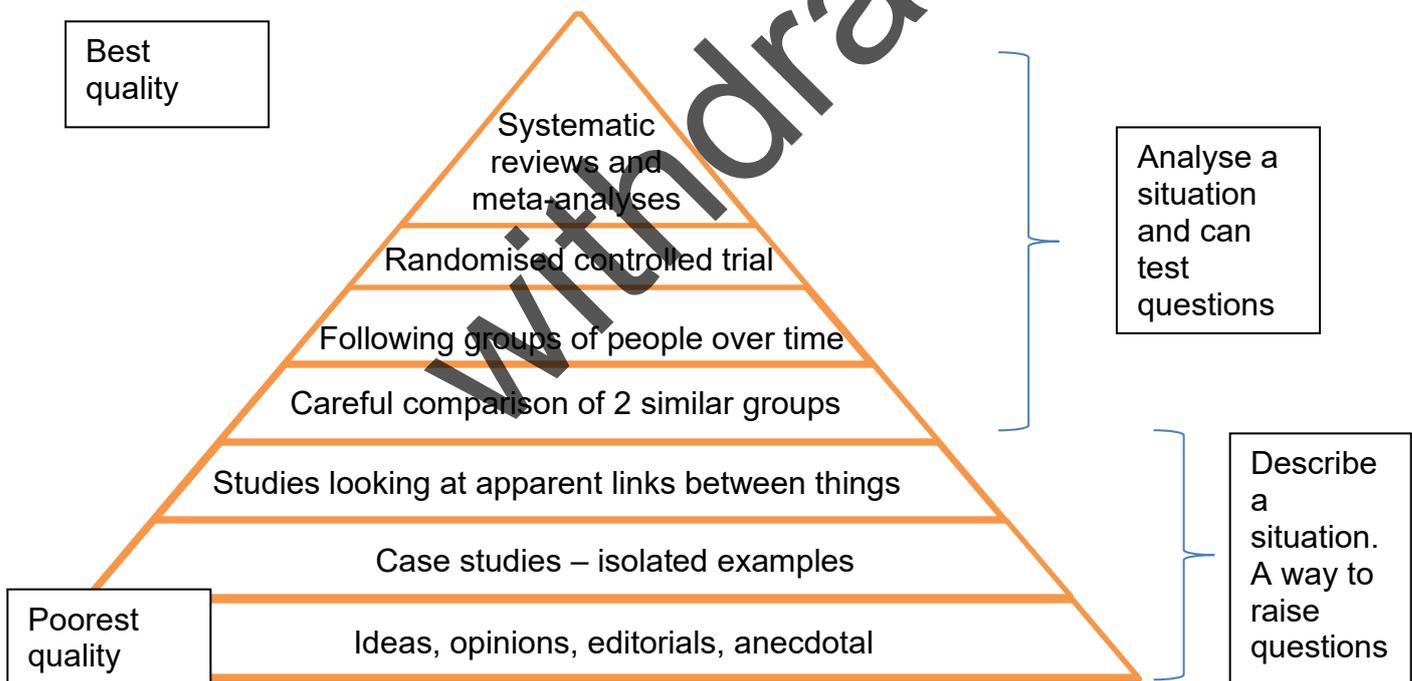
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Section 3. Community water fluoridation and health

3.1 The evidence base

Assessing the quality of evidence

The evaluation of scientific evidence should take into account a number of considerations, including the type of evidence and the research methods used, which should be appropriate to the question being studied. In order to assess whether a public health intervention is effective, it is useful to look at a range of research using different methods. It is also important to look at the quality of the evidence, as well as the quantity. The following diagram illustrates what is normally regarded in the scientific community as the hierarchy of evidence in terms of quality.



As a general rule, the best evidence comes from systematic reviews of scientific evidence published in the scientific literature, particularly meta-analyses of randomised controlled trials. Systematic reviews set often tight criteria for what will be acceptable research in terms of quality and then seek to summarise what the accepted research says. At the other end of the scale there is opinion or anecdote. While there is a generally accepted hierarchy of evidence as above, the quality of individual studies or reviews is crucial; for example, a well-designed and interpreted cohort study can be

more informative than a poorly executed trial and it has been argued that systematic reviews should be removed from the top of the pyramid and use them “as a lens through which other types of studies should be assessed seen”³⁰. Much of the evidence in relation to any health question sits somewhere in the middle of the hierarchy, involving studies that compare groups of people and ask why they might be different.

Another useful indicator of research quality is to look at who sponsored or commissioned the research and to consider whether these groups may have biases either in favour or against the issue being studied.

Sources of evidence

A common, but not exclusive, source of evidence is research published in peer-reviewed scientific journals, where the research has been looked at by other independent scientists (reviewers) before it is accepted for publication. This is a helpful way of stopping bad science being published and creates an open forum for the wider scientific community to comment on research. The system is not, however, infallible and, occasionally, there may be valid concerns over research published in the peer-reviewed literature. In such circumstances it is useful for journals to publish commentaries or letters that criticise the research, with an opportunity for the authors to respond. In extreme cases the authors or the journal editors might withdraw the paper. In this way we can have more faith in published scientific literature, particularly the journals with a reputation for rigorous peer review, than in what appears on websites or in newspapers, though it may take several months for a published paper to be assessed by the wider scientific community.

Evidence for community water fluoridation

The evidence for community water fluoridation sits towards the top of the hierarchy outlined above. The reviews identified in the table below acknowledge that there are limitations to the quality of the evidence on dental effects since, in particular, much of the evidence comes from observational cross-sectional studies rather than the epidemiological gold standard of prospective longitudinal (long term “before and after”) studies. While it is often suggested that the preferred study design for any intervention is the randomised controlled trial, this is not necessarily appropriate to public health interventions in complex contexts.^{31 32} In addition, randomised controlled trials are often not feasible with many public health measures - including water fluoridation and it is

³⁰ Murad MH, Asi N, Alsawas M, Alahdab F: New evidence pyramid, Evid Based Med. 2016 Aug;21(4):125-7. doi: 10.1136/ebmed-2016-110401. Epub 2016 Jun 23

³¹ Westhorp G. Realist impact evaluation. An introduction. Methods Lab 2014. Accessible on www.odi.org/sites/odi.org.uk/files/odi-assets/publications-opinion-files/9138.pdf

³² Pawson, R. and Tilly, N. (1997). Realistic Evaluation. London: Sage

acknowledged that such public health interventions have to be assessed in other ways.³³

The common finding of the reviews looking at dental health is that levels of tooth decay are lower in fluoridated areas and, for reviews which looked at general health effects, that there is no credible scientific evidence that at permitted levels water fluoridation is harmful to health. Table 1 lists the main systematic and other substantive reviews of the evidence on water fluoridation since 2000.

Table 1. Systematic and other reviews of water fluoridation since 2000

Report	Reference	Web link
NHS Centre for Reviews and Dissemination (2000). * †	McDonagh M, Whiting P, Bradley M, Cooper J, Sutton A, Chestnutt I, Misso K, Wilson P, Treasure E, Kleinjen J. A Systematic Review of Public Water Fluoridation. National Health Service Centre for Reviews and Dissemination, University of York 2000.	www.nhs.uk/conditions/fluoride/documents/crdreport18.pdf
US Community Preventive Services Task Force (2002) * †	Task Force on Community Preventive Services. Recommendations on Selected Interventions to Prevent Dental Caries, Oral and Pharyngeal Cancers, and Sports-Related Craniofacial Injuries. Am J Prev Med 2001; 23 :16-20	www.thecommunityguide.org/oral/oral-ajpm-recs.pdf
National Health and Medical Research Council (Australian Government) (2007) * †	A Systematic Review of the Efficacy and Safety of Fluoridation; National Health and Medical Research Centre, Australian Government 2007	www.nhmrc.gov.au/guidelines/publications/eh41
Review by Griffin et al. (adults) * ‡	Griffin SO, Regnier E, Griffin PM, Huntley V. Effectiveness of Fluoride in Preventing Caries in Adults. J Dent Res. 2007; 86 :410-5.	http://jdr.sagepub.com/content/86/5/410.abstract
(European) Scientific Committee on Health and Environmental Risks - SCHER (2011) †	Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water.	http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_139.pdf
US Community Preventive Services Task Force (2013) * ‡	Community Preventive Services Task Force. Preventing Dental Caries: Community Water Fluoridation. Atlanta: Community Preventive Services Task Force 2013	www.thecommunityguide.org/oral/supportingmaterials/RRfluoridation.html
Royal Society of New Zealand (2014) †	Health effects of water fluoridation: A review of the scientific evidence, The Royal Society of New Zealand, 2014	https://s3.amazonaws.com/s3.documentcloud.org/documents/1278925/fluoride.pdf

³³ Guidelines: Systematic Reviews of Health Promotion and Public Health Interventions. The Cochrane Collaboration Health Promotion and Public Health Field. 2007. Accessed at http://ph.cochrane.org/sites/ph.cochrane.org/files/uploads/Guidelines%20HP_PH%20reviews.pdf

Cochrane Oral Health Group (2015) *‡	Water fluoridation for the prevention of dental caries. Iheozor-Ejiofor Z, Worthington HE, Walsh T, O'Malley L, Clarkson JE, Macey R, Alam R, Tugwell P, Welch V, Glenny A. Cochrane Library 2015	http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010856.pub2/abstract
Health Research Board (Ireland) (2015) ~	Sutton M, Kiersey R, Farragher L, Long, J. Health Effects of Water fluoridation: An evidence review. Health Research Board 2015.	www.hrb.ie/uploads/tx_hrbpublicati ons/Health_Effects_of_Water_Flu oridation.pdf
National Health and Medical Research Council (Australian Government) (2016) *†	Jack B, Ayson M, Lewis S, et al. <i>Health Effects of Water Fluoridation. Evidence Evaluation Report</i> . Canberra: National Health and Medical Research Council; 2016.	https://www.nhmrc.gov.au/about-us/publications/water-fluoridation-dental-and-other-human-health-outcomes#block-views-block-file-attachments-content-block-1
Review by McLaren and Singhal (Cessation) *†	McLaren L, Singhal S. Does cessation of community water fluoridation lead to an increase in tooth decay? A systematic review of published studies. <i>J Epidemiol Community Health</i> . 2016;70(9):934-940.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5013153/pdf/jech-2015-206502.pdf
Canadian Agency for Drugs and Technologies in Health (2019) *†	CADTH. <i>Community Water Fluoridation Programs: A Health Technology Assessment-Review of Dental Caries and Other Health Outcomes</i> . Ottawa; 2019.	https://cadth.ca/sites/default/files/pdf/HT0022 CWF - Clinical report.pdf
Review by Moynihan et al. to inform WHO manual on prevention of early childhood caries (2019) *‡	Moynihan P, Tanner LM, Holmes RD, et al. Systematic Review of Evidence Pertaining to Factors That Modify Risk of Early Childhood Caries. <i>JDR Clin Transl Res</i> . 2019;(July):202-216.	https://www.ncbi.nlm.nih.gov/pubmed/30931717

* Systematic review of scientific literature

† Dental and general health effects

‡ Dental effects only

~ General health effects only

While reviews of the literature agree that water fluoridation has reduced levels of tooth decay in populations, the research designs included in the reviews and ways of expressing the impact tend to vary. The 2015 Cochrane review³⁴ looked at before and after studies that met the reviewers' criteria for inclusion, concluding that the introduction of water fluoridation resulted in children having 35% fewer decayed, missing and filled baby teeth and 26% fewer decayed, missing and filled permanent teeth. They also found that fluoridation led to a 15% increase in children with no decay in their baby teeth and a 14% increase in children with no decay in their permanent teeth. However, their very specific inclusion criteria led to a focus on older studies associated with the introduction of new schemes which often pre-dated the introduction

³⁴ Iheozor-Ejiofor Z et al. Water fluoridation for the prevention of dental caries. Cochrane Library 2015

of fluoride toothpaste, leading the authors to question how applicable the results might be to populations exposed to this measure today.

Another way of assessing the impact of water fluoridation is to compare populations with and without this measure, controlling for other factors that might affect levels of decay, particularly social deprivation. The 2012 review of studies published after 1990 (therefore after the introduction of fluoride toothpaste) by Rugg-Gunn and Do³⁵ found that substantial reductions were reported. The systematic review by Griffin³⁶ (2007) concluded, from studies published since 1979, that water fluoridation was effective in reducing dental decay levels in adults, both in the crowns and root surfaces of teeth (prevented fraction 27.2%). This is significant since, as the authors stated, increased tooth retention in older adults' results in more teeth at risk of decay, making population-based efforts at prevention even more important.

Evidence from monitoring the effects of community water fluoridation in England

PHE, on behalf of the secretary of state for health and social care, is required by legislation to monitor the effects of water fluoridation schemes on the health of people living in the areas covered by these arrangements, and to produce reports at no greater than four-yearly intervals. PHE's 2014 health monitoring report² compared the results of contemporary dental epidemiological surveys undertaken in fluoridated and non-fluoridated communities. It showed that, when deprivation and ethnicity were taken into account, 5-year olds in fluoridated areas were 28% less likely to have had tooth decay in their baby teeth than those in non-fluoridated areas and 12-year olds in fluoridated areas were 21% less likely to have had tooth decay in their permanent teeth than those in non-fluoridated areas. This report also looked at child hospital admissions for dental decay, concluding that there was statistically strong evidence of lower rates of admission for children aged 1-4 years (55% fewer) in fluoridated areas when deprivation was taken into account. Similar findings were reported in the 2018 report (see below).

Oral health inequalities

The evidence for water fluoridation reducing oral health inequalities is generally found in more recent cross-sectional studies comparing fluoridated and non-fluoridated populations, as research involving before and after studies of schemes established some years ago tended to look at whole population effects. For this reason the 2015 Cochrane review concluded that, on the basis of the studies they reviewed, there was insufficient information regarding the impact on oral health inequalities, though the

³⁵ Rugg-Gunn A and Do L. Effectiveness of water fluoridation in caries prevention. *Community Dentistry and Oral Epidemiology* 2012; 40(Suppl. 2): 55-64

³⁶ Griffin SO, Regnier E, Griffin PM, Huntley V. Effectiveness of Fluoride in Preventing Caries in Adults. *Journal of Dental Research* 2007; 86: 410-415

earlier review by the NHS CRD (2000),^{37 38} with different criteria, suggested that there was some evidence that water fluoridation reduced these. In 2019 Weston-Price et al³⁹ published analysis utilising a representative national sample of 5 year old children across England, which assessed the role of water fluoridation on population caries (dental decay). The results found the greatest impact of exposure to fluoridated water was seen in the most deprived children.

The PHE Water Fluoridation Health monitoring report for England 2018³ compared populations in receipt of public water supplies with a fluoridation scheme where the fluoride concentration averaged $\geq 0.7\text{mg/l}$, versus populations where fluoride concentration averaged $< 0.2\text{mg/l}$. Finding a reduction in the number of 5-year-olds experiencing caries and a decrease in the severity of this dental disease as significant in those receiving a fluoridated water supply, and most clearly so in more deprived areas, narrowing differences in dental health between more and less deprived children. The effect of fluoridation on admission for tooth extraction was also substantial. A larger number of the most deprived children and young people benefited, again lessening differences in dental health between more and less deprived children and young people.

When considering the context of water fluoridation and oral health inequalities, it is worth noting that the research evidence for the impact of other population-based oral health interventions on inequalities is often uncertain. Some interventions, which rely on a degree of behaviour change, may even increase inequalities by impacting on more affluent people only¹⁹. Water fluoridation is the only intervention, for oral health, which does not require such change.

Dental fluorosis

There is a well-established adverse association between levels of fluoride in water and the prevalence of dental fluorosis. Dental fluorosis is one of a number of different conditions that can affect the appearance of teeth. In England it is usually seen as paper-white flecks or fine white lines, but it can vary in appearance from barely visible white lines to patches which may be of aesthetic concern. The risk period for the development of dental fluorosis in permanent (adult) teeth is when the teeth are growing in the jaws; dental fluorosis cannot develop after teeth are formed. The first 2 to 3 years of life are generally accepted to be the period of highest susceptibility for fluorosis affecting the front teeth (the incisors).

³⁷ McDonagh et al. A Systematic Review Of Public Water Fluoridation. NHS Centre for Reviews and Dissemination. University of York (2000)

³⁸ Hausen H. Some evidence that water fluoridation reduces inequalities in dental health across social classes. Evidence-Based Dentistry 2003;3:41-42

³⁹ Weston-Price S, Copley V, Smith H and Davies GM A multi-variable analysis of 4 factors affecting caries levels among five-year-old children; deprivation, ethnicity, exposure to fluoridated water and geographic region, Community Dental Health (2018) 35, 217–222

The impact of milder forms fluorosis on measured quality of life (using the Oral Health Related Quality of Life scale) is certainly less than that of tooth decay, and may be non-existent or even positive.⁴⁰ ⁴¹A positive effect on quality of life may seem counter-intuitive but may be explained by the fact that the white flecking of enamel associated with very mild fluorosis can give the impression of having teeth that are whiter than average.⁴² More severe dental fluorosis can cause brown staining and pitting of teeth but is generally seen in those countries with very high naturally occurring levels of fluoride in groundwater rather than in areas with community water fluoridation schemes. It should be noted that dental fluorosis can also occur in the absence of water fluoridation, through ingestion of other sources of fluoride during tooth formation, particularly toothpaste and other fluoride supplements. The most recent reporting of fluorosis prevalence and severity in England was commissioned by PHE to inform the 2018 health monitoring report. The population under examination was drawn from 4 cities; Newcastle upon Tyne (fluoridated), Birmingham (fluoridated), Liverpool (non-fluoridated) and Manchester (non-fluoridated)⁴³. The prevalence of any positive score for fluorosis was greater in the fluoridated cities (Newcastle and Birmingham 61%) compared to the non-fluoridated cities (Manchester and Liverpool, 37%). Fluorosis of a severity that might be of aesthetic concern affected 10.3% of children from the fluoridated cities and 2.2% in the non-fluoridated cities. There was, however, no difference in satisfaction with dental appearance between the 2 groups. Further research in adults in England has suggested that the aesthetic impact of fluorosis diminishes with age⁴⁴.

Community water fluoridation and general health

Regarding claims that water fluoridation might be a cause of ill health, some 370 million people worldwide, including 6 million in England and 200 million (70% of the population) in the United States⁴⁵, have an artificially fluoridated water supply and there is over 50 years' experience of the measure in England. Routine monitoring of health in these areas has not revealed any health problems associated with water fluoridation.

A judgement has to be made as to the likelihood that any adverse effect would by now have come to light had it been present. The likelihood of detecting such a problem through routine surveillance depends on its severity and the level of risk. The more serious the effect and the greater the risk attributable to water fluoridation the more

⁴⁰ Do LG, Spencer A. Oral health-related quality of life of children by dental caries and fluorosis experience. *Journal of Public Health Dentistry* 2007;67(3):132-139

⁴¹ Chankanka O, Levy S, Warren JJ, Chalmers JM. Fluorosis and relationships with psychological aspects/ oral health-related quality of life. *Community Dentistry and Oral Epidemiology* 2010; 38:97-109

⁴² Hawley GM, Ellwood RP, Davies RM. Dental caries, fluorosis and the cosmetic implications of different TF scores in 14-year-old adolescents. *Community Dental Health* 1996;13:189-192

⁴³ Pretty IA, Boothman N, Morris J, MacKay L, Liu Z, McGrady M, et al. Prevalence and severity of dental fluorosis in 4 English cities. *Community dental health*. 2016;33(4):292-6.

⁴⁴ Macey R., Tickle M, MacKay L, McGrady M, Pretty IA. A comparison of dental fluorosis in adult populations with and without lifetime exposure to water fluoridation. *Community Dentistry and Oral Epidemiology* 2018;46:608-614

⁴⁵ Centers for Disease Control, Atlanta, Georgia, U.S. Accessed at: www.cdc.gov/fluoridation/basics/index.htm

likely that it would have been detected by now. Were there to be concerns over the general health effects of fluoride in water, at the levels permitted by legislation, this would also apply to areas where fluoride is present naturally at such levels.

Given the substantial number of people exposed to this intervention for many decades, during which any adverse effects might have been expected to be reliably documented, it has to be concluded that if there are any undetected adverse effects they are minor and/or the effect is small.

The 2014 PHE report² compared a range of dental and non-dental health indicators in fluoridated and non-fluoridated areas in this country. A summary of the report was published in the scientific literature.⁴⁶ The authors concluded that the report provided further reassurance that water fluoridation is a safe and effective public health measure.

The PHE Water Fluoridation Health monitoring report for England 2018³ agreed with the view that water fluoridation is an effective and safe public health measure to reduce the frequency and severity of dental decay, and narrow differences in dental health between more and less deprived children and young people. Nevertheless, PHE will continue to keep the evidence base under review and use the report as part of an on-going dialogue with local authorities.

Internationally the US Centers for Disease Control and Prevention (CDC) stated that “water fluoridation is beneficial for reducing and controlling tooth decay and promoting oral health across the lifespan”⁴⁷. Their statement draws on scientific reviews by expert panels which have concluded that community water fluoridation is a safe and effective way to promote good oral health and prevent decay.

3.2 Ethical considerations

As with many other public health interventions such as restrictions on where people can smoke, water fluoridation involves taking action to achieve population-wide benefits – in this case by helping to reduce risk of tooth decay, particularly among children. Naturally occurring fluoride exists in all water supplies. Community water fluoridation ensures that, where the natural fluoride concentration is too low to provide dental health benefits, it is raised to and maintained at the optimum level (one part per million or 1mg/litre).

Parliament has given its express consent to the deployment of water fluoridation as a public health measure, by passing legislation to that end. However, parliament has also decreed that decisions about particular water fluoridation schemes should be made

⁴⁶ Young N et. al. Community water fluoridation and health outcomes in England: a cross-sectional study. *Comm Dent Oral Epidemiol* 2015; DOI: 10.1111/cdoe.12180. Accessed at <http://onlinelibrary.wiley.com/doi/10.1111/cdoe.12180/full>.

⁴⁷ Centers for Disease Control and Prevention (CDC) 2018: Statement on the Evidence Supporting the Safety and Effectiveness of Community Water Fluoridation <https://www.cdc.gov/fluoridation/guidelines/cdc-statement-on-community-water-fluoridation.html>

locally, not nationally, and only through a rigorous process defined in legislation. From April 2013 the decision-makers are the local authorities defined in the legislation.⁴⁸ When a local authority runs a public consultation on a proposal to introduce a scheme, it is likely that those holding strong views against the principle of fluoridation – regardless of its dental health benefits – will raise ethical concerns about adding even this relatively tiny amount of fluoride to local water supplies. They may claim that individuals have a right to drink water without added fluoride and that the local authority would somehow be interfering with this right.

On the other hand, members of the dental and other health professions, together with local groups campaigning for improvements to the dental health of children and other vulnerable groups in the population, may present a counter argument that focuses on the need to prevent avoidable pain and suffering from tooth decay. They are likely to argue that combating tooth decay through a safe and effective public health measure intended for the common good is a necessary and highly ethical course of action to take. Equally, they may object to any proposals put forward to terminate an existing fluoridation scheme, arguing that such a move would deprive children and other vulnerable groups in the community of the positive health benefit (protection against tooth decay) they are currently receiving.

Ethical issues have been formally considered since the early days of water fluoridation. Reports on fluoridation by a number of independent bodies (for example, a New Zealand Commission of Inquiry in 1957, the Irish Forum on Fluoridation in 2002, and the Nuffield Council on Bioethics (2007)), together with important legal judgements taken about it (for example, the Irish Supreme Court in 1964), have commented on the ethical dimensions.^{49 50 51 52 53} In addition, PHE and NHS England have produced a briefing on community-centred approaches to health and wellbeing that may be helpful to local authorities when considering ethical questions related to water fluoridation and other public health initiatives.⁵⁴ A further resource is the 2017 PHE ethics in practice publication which provides an introduction to public health ethics both as a philosophical field of enquiry and as an applied area that guides practice and policy⁵⁵.

⁴⁸ Water Industry Act 1991, Part III, Chapter IV, s87(7B)

⁴⁹ Report of the New Zealand Commission of Inquiry into the Fluoridation of Public Water Supplies (1957): Wellington, Department of Health.

⁵⁰ Kenny MJ (1963): FLUORIDATION. Judgement delivered by Mr Justice Kenny in the High Court, Dublin, 1963. Dublin. Department of Health.

⁵¹ Chief Justice O'Dalaigh (1964). Judgement of the Supreme Court of Ireland delivered by Chief Justice O'Dalaigh on 3rd July, 1964. Dublin: Department of Health.

⁵² Forum on Fluoridation (2002): Forum on Fluoridation in Ireland. Irish Department of Health and Children. Dublin. www.fluoridationforum.ie

⁵³ Nuffield Council on Bioethics (2007). Public health: ethical issues. London

⁵⁴ A guide to community-centred approaches for health and wellbeing: Briefing. Public Health England and NHS England, February 2015.

⁵⁵ Public Health England: Public health ethics in practice: An overview of public health ethics for the UK Public Health Skills and Knowledge Framework (PHSKF). 2017

Any consultation on proposals for a water fluoridation scheme will raise a number of important issues, not least the level of need in the local population for dental health improvements, the potential scale of improvement that could be achieved by introducing this measure (that is, its effectiveness in reducing tooth decay), and the safety of adjusting the fluoride content of water in this way. The ethical factors – and the different views held about them – may also need to be considered by local authorities within the wider context of need, effectiveness and safety.

3.3 Cost and cost-benefit

Although provided by water companies through the public water supply, the costs of fluoridation do not fall on their customers through water charges. Rather, the entire costs are covered by local authorities in their public health role and/or by the secretary of state for health and social care.

The secretary of state is required to meet the reasonable capital and operating costs incurred by water undertakers operating water fluoridation schemes in England. The secretary of state has the power to require local authorities whose populations are served by those schemes to make payments to the secretary of state to meet these costs. At present PHE meets the capital cost of schemes and recovers the operating costs from local authorities. Local authorities also pay for the cost of feasibility studies.

Affordability is a key consideration when a new scheme is proposed, and it is important that the principles of funding of a new fluoridation scheme are agreed between the local authority(ies) concerned and PHE, on behalf of the secretary of state, before a scheme is formally proposed by the local authority(ies).

The capital and operating costs of an individual scheme will flow from the design of that scheme to reflect local water supply arrangements. In particular the number of dosing sites required, and the size of population served by each of those sites, will have a material effect on capital and operating costs. PHE has considerable experience in dealing with water companies on the capital and operating costs of established schemes and can advise local authorities as to the financial reasonableness of water company proposals.

Illustratively, the operating costs of established schemes in 2018-2019 averaged approximately 52p per head of population served per year, though the costs for individual schemes will vary depending upon the design of the scheme. In particular, the number of fluoridation plants required will affect running costs.

With regard to value for money, the key drivers will be levels of dental disease in a particular area, the direct costs associated with treating that disease (be it in primary

care or in a hospital setting), and the indirect or social costs of the disease and its consequences.

Levels of dental decay are not uniform across England but, like many diseases, vary in line with demography, with affluent populations generally having much better dental health than deprived communities. Cost-benefit will also vary and should be considered in the early stages of evaluation of the possible options for tackling high levels of dental decay. It should be noted that, because the footprint of a fluoridation scheme is heavily influenced by the water distribution system in that locality, it may not be possible to design a scheme which is entirely focused on the highest priority target area for action. The local authority's HWB, bringing together interested parties locally, will be a useful forum in which to discuss the healthcare and financial impacts of strategies for reducing levels of dental decay.

The financial benefit of water fluoridation schemes will fall primarily to NHS bodies and to individual patients as a consequence of the commissioning arrangements for dental services.

Costs of treating dental decay in a particular locality may be obtained from NHS Digital⁵⁶ NHS representatives on the HWB may be a useful source of advice and have an interest in the opportunity to take action on health inequalities, given their legal duty in that respect.⁵⁷

Public Health England's (PHE) return on investment (ROI) tool allows effectiveness data on oral health interventions to be used to estimate the potential economic benefits from oral health interventions including water fluoridation⁵⁸. Local authorities can use the ROI tool to inform their commissioning decisions, providing an estimate of the return on investment of programmes using the oral health profile of their local population.

Internationally, a systematic review was undertaken and published⁵⁹ in 2015 by the US CDC. This review examined studies from the US, Canada, Australia and New Zealand. Although the detailed findings cannot be directly transferred to England because of the different dental care systems, the review found that per capita annual cost of schemes was mainly attributable to community population size. The review concluded that the economic benefits of CWF exceeded the intervention costs, and that the cost-benefit ratio increased with the size of the population served.

⁵⁶ <https://digital.nhs.uk/>

⁵⁷ Guidance for NHS commissioners on equality and health inequalities legal duties. NHS England, December 2015

⁵⁸ Public Health England: Improving the oral health of children: cost effective commissioning Resources to support local authorities investing in the local commissioning of oral health improvement programmes for pre-school children.

⁵⁹ Ran, Tao et al. Economic evaluation of community water fluoridation – a Community Guide systematic review. *Am J Prev Med* 2015. In press: doi:10.1016/j.amepre.2015.10.014 Accessed 8th February 2016.

Section 4. The governance of community water fluoridation

4.1 The regulation of fluoride in water

As one of the normal components of water, fluoride falls within the regulatory framework for water quality.

In England and Wales, regulations made under the Act separately cover public and private water supplies. In England, these are the Water Supply (Water Quality) Regulations 2016⁶⁰ [as amended] and the Private Water Supplies (England) Regulations 2016⁶¹ [as amended]. The Water Supply (Water Quality) Regulations govern the quality of drinking water supplied by water companies and are enforced by the Drinking Water Inspectorate (“DWI”). They can be accessed at www.legislation.gov.uk/ukxi/2016/614/contents/made

The Private Water Supplies Regulations govern the quality of drinking water supplied privately - for example, from springs, wells, or private boreholes, and are enforced by local authorities, advised by the DWI. They can be accessed at www.legislation.gov.uk/ukxi/2016/618/contents/made

Both sets of regulations provide for a maximum permitted level of fluoride in water of 1.5mg/l, mirroring the Directive. In summary, therefore, drinking water naturally containing less than 1.5mg/l fluoride is compliant with relevant domestic and EU law.

4.2 Water fluoridation schemes: primary and secondary legislation.

Water fluoridation schemes in England are explicitly permitted by parliament through the Water Industry Act 1991 (the Act), which incorporated the content of the Water (Fluoridation) Act 1985. The relevant sections are within Part III, Chapter IV of the Act, which is titled ‘Fluoridation’ and has been repeatedly and significantly amended since 1991.

The Water Act 2003 placed a duty on water companies to comply with a fluoridation request made in accordance with the requirements of the legislation by the then relevant NHS body (strategic health authorities). It also introduced a requirement for monitoring and reporting at four-yearly intervals on the health effects of schemes.

⁶⁰ SI 2016/614

⁶¹ SI 2016/618

More recently, the Health and Social Care Act 2012 has introduced further changes to fluoridation responsibilities. The decision-making and consultation responsibility for schemes was transferred from 1 April 2013 to unitary and upper-tier local authorities. The responsibility for making, varying or terminating fluoridation agreements with water companies was transferred to the secretary of state for health and social care, to be exercised by him or her in accordance with the proposals of the affected local authority(ies) made in accordance with the legislation. The secretary of state has also become responsible for health monitoring and reporting. The functions of the secretary of state are largely exercised on his or her behalf by PHE, an executive agency of the Department of Health.

Each amended form of the Act has brought all fluoridation schemes operating at the relevant time into the scope of the amended Act, so that all existing schemes are now subject to the Act in its current form since being amended in 2012.

A consolidated version of the Act in its current form is available online, or via legal advisers.

The Act permits the secretary of state to make regulations on certain matters relating to fluoridation. Two sets of regulations are currently in force: the Water Supply (Fluoridation Indemnities) (England) Regulations 2005⁶² and the Water Fluoridation (Proposals and Consultation) (England) Regulations 2013.⁶³ The former set out the terms of an indemnity to be provided by the secretary of state to water companies operating fluoridation schemes, and can be found at www.legislation.gov.uk/uksi/2005/920/pdfs/uksi_20050920_en.pdf The latter impose requirements on how local authorities must exercise their powers to propose, vary or terminate fluoridation schemes. They can be found at www.legislation.gov.uk/uksi/2013/301/pdfs/uksi_20130301_en.pdf

4.3 Water fluoridation schemes: technical guidance and standards

The technical aspects of water fluoridation schemes are the responsibility of the relevant water undertaker/company providing the public water supply to a particular area. A company has no decision-making role as to whether a scheme should be introduced, varied or terminated. In designing and operating water fluoridation equipment, water companies are required to exercise those responsibilities in accordance with a technical code of practice published by the DWI, the body responsible for assuring the quality of public water supplies in England and Wales. The DWI published an updated code of practice in January 2016. This can be accessed at www.dwi.gov.uk/stakeholders/information-letters/2016/01-2016-annexa.pdf.

⁶² SI 2005/920

⁶³ SI 2013/301

The only 2 chemical compounds permitted to be used in fluoridation schemes are specified in the Act. Their quality and purity have to comply with the relevant British (EN) Standards. These standards are:

- disodium hexafluorosilicate BS EN 12174: 2013 (supplied as a powder)
- hexafluorosilicic acid BS EN 12175: 2013 (supplied as a liquid).

British Standards are available for purchase at www.shop.bsigroup.com .

4.4 Fluoridation scheme legal agreements

The legislation is couched in terms of “arrangements” to increase the fluoride content of water supplied by a water company.⁶⁴ Such arrangements are initially proposed by local authorities but, if agreed, are made between the secretary of state for health and social care and the relevant water company. Each set of arrangements for every established fluoridation scheme is described and codified in a legal agreement for that scheme made between the responsible public health body and the relevant water company. For any new scheme started since 1 April 2013 the public health body is the secretary of state , acting on a duly made request of the appropriate local authority(ies).

However, as at January 2016, it so happens the only schemes in operation in England are ones which pre-date all of the fluoridation legislation – that is, they were made before 20 December 1984 between a health body and a water company. The earliest agreements were made in the 1960s and early 1970s by local authorities acting in their then public health role, and were made with often quite small water companies which have since been subsumed into the major utilities now operating in England. Further agreements were made in the late 1970s and early 1980s by NHS bodies acting in a public health role. In accordance with current legislation, the secretary of state is the successor body to the originating public health body for each agreement, irrespective of whether the originator was a local authority or an NHS body.

The content of these agreements typically includes the area to be fluoridated and/or the works at which fluoridation will take place, the financial arrangements for reimbursing the water company, and the period of notice required should it be desired to terminate the scheme. Individual agreements, while generally similar in approach, vary in scope and detail. It is therefore essential to inspect the relevant agreement for a particular scheme closely to understand the detailed legal status and obligations of that scheme. Local authorities may benefit from taking legal advice when doing so.

Some of the established schemes cover large areas and may be subject to several legal agreements reflecting their evolution.

⁶⁴ Water Industry Act 1991 Part III, Chapter IV, s87(1)

Section 5. Key agencies and their roles

5.1 Roles of local authorities, water companies and secretary of state for health

The legislation as it stands prescribes specific roles for and duties of various actors in all aspects of water fluoridation. The 3 principal actors in the legislation are as follows.

Upper tier and unitary local authorities⁶⁵

Upper tier and unitary local authorities propose and make decisions to implement new schemes, make decisions about existing schemes and bear the running costs of schemes. Fluoridation schemes normally extend into more than one local authority area, some into several, and it is important that all the local authorities affected by a scheme, or a proposed scheme, work together effectively on that scheme. The legislation prescribes the ways in which local authorities must work together if there is a live proposal for a fluoridation scheme (a possible new scheme or a variation to or termination of an existing scheme) and how they must make joint decisions. A later part of this section of the toolkit discusses joint decision-making in more detail.

Water companies

Water companies advise on the technical feasibility of schemes and, when requested to do so, implement and operate them in accordance with the Act and regulations.

The secretary of state for health and social care

The secretary of state for health and social care:

- determines whether the arrangements which would result from a local authority's initial proposal for a fluoridation scheme would be operable and efficient
- confirms that the necessary procedural steps have been taken by the proposing local authority, and, if so, requests a water undertaker to enter into arrangements with him to implement the scheme (or to vary it) or giving notice to the water undertaker to terminate arrangements (as applicable)

⁶⁵ The full definition of responsible local authorities, including those in London, is in the Water Industry Act 1991, Part III, Chapter IV, s87(7B)

- enters into arrangements with the water undertaker, negotiates the terms of those arrangements and consults the Water Services Regulation Authority (OFWAT) and affected local authorities in relation to those terms
- notifies local authorities in relation to maintenance of schemes in certain circumstances and gives notice to the water company to terminate the scheme where the local authorities affected decide not to propose maintaining the scheme
- monitors the health of populations covered by CWF schemes and reporting the results

The secretary of state currently also provides the capital funds for new schemes and the refurbishment of established schemes, but may choose to recover these from local authorities.

5.2 The NHS and clinicians

Local NHS bodies and clinicians are well-placed to contribute to the health debate about water fluoridation in a locality and about its potential to reduce health inequalities, in respect of which NHS England and clinical commissioning groups have statutory responsibilities.⁶⁶ The costs of treating dental decay fall to NHS bodies, and dental clinicians (both primary and secondary-care based) provide the necessary treatment services. They are able to explain to lay decision-makers the impacts of that treatment.

Medically-qualified clinicians (GPs and hospital-based specialists) are able to describe the dentally-related workload impacting on out-of-hours and emergency department services, and the opportunity cost of providing general anaesthetic services for a preventable disease. Medical specialists are also able to make a valuable contribution to debates about possible harm alleged from water fluoridation, on the basis of clinical plausibility, their knowledge of the scientific literature, and their ability to consult relevant colleagues in other fluoridated areas.

5.3 Patients and their carers, and patient representative groups

In discussions about the impact on patients and carers of patients with high levels of dental decay, and the options for tackling that problem, it will be important to ensure that the voices of a diverse range of local people are heard in an appropriate way, including those in greatest dental need, and that their contribution to the debate is facilitated. As the distribution of disease in any locality will tend to be skewed towards those from more deprived backgrounds, it will be particularly important to ensure that there is equitable involvement in the debate. Local Healthwatch organisations will have a role to play, and parents of children who have needed dental extractions under general

⁶⁶ 'Guidance for NHS commissioners on equality and health inequalities legal duties'. NHS England, December 2015

anaesthetic (or the children themselves) will be well-placed to speak about the impact of dental disease and may be willing to act as advocates for change. Active measures are advised to engage with these populations, so that any local decision is truly inclusive.

5.4 Health and wellbeing boards

Health and wellbeing boards (HWBs) are established by Section 194(1) of the Health and Social Care Act 2012 and governed by Sections 194-199 (inclusive) of the same Act, when read in conjunction with Sections 116, 116A, and 116B of the Local Government and Public Involvement in Health Act 2007.

HWBs provide strategic influence and oversight, briefing the leader and relevant portfolio holders. They also have a key role in relation to consideration of fluoridation, through their duty to produce a joint strategic needs assessment (JSNA) for their area and a joint health and wellbeing strategy (JHWS). It is anticipated that, if dental decay levels are a source of serious concern in an area, the matter would feature in the JSNA and JHWS. In making decisions about proposals for water fluoridation schemes, local authorities are required⁶⁷ to have regard to the JSNA and JHWS published by their HWB.

The Act also recognises HWBs as one of the possible vehicles through which fluoridation functions may be exercised by local authorities, where more than one local authority is affected by proposed or actual fluoridation arrangements.⁶⁸

HWBs include representatives from clinical commissioning groups and NHS England. Together with local Healthwatch organisations and other agencies, including the voluntary, community and social enterprise sector, they can provide a valuable forum in which all relevant views can be captured. HWBs may also provide a vehicle for discussions about the possibility of joint funding of fluoridation, given that the costs of treating dental disease fall to NHS England and to CCGs.

5.5 Public Health England

PHE, as an executive agency of the Department of Health, does not appear by name in the legislation. However, most fluoridation functions of the secretary of state for health and social care are exercised on his or her behalf by PHE.

In particular PHE:

- provides evidence-based advice about the safety and effectiveness of fluoridation

⁶⁷ The Water Fluoridation (Proposals and Consultation) (England) Regulations 2013, regulations 6(b) and 12(b)

⁶⁸ Water Industry Act 1991. Part III, Chapter IV, s88F

- monitors the performance of water companies in meeting legal agreements for established fluoridation schemes
- provides advice on request to local authorities interested in establishing the technical feasibility of new fluoridation schemes
- negotiates the terms of legal agreements for new schemes
- monitors and pays water company bills for the running costs of fluoridation schemes, recovering these costs from the local authorities whose populations are benefiting from the schemes
- monitors and manages fluoridation capital investment
- undertakes monitoring of the health effects of water fluoridation schemes and reports at four-yearly intervals on those effects including inequalities
- provides support, through PHE centres, to local authorities in developing strategies to improve oral health and reduce inequalities in oral health, including the use of fluoride

Local authorities can access support and advice from PHE via their PHE centre director, whose team includes consultants in dental public health, and who can also access national support from PHE.

5.6 Joint working on fluoridation

The legislation necessitates close working between local authorities, PHE and water companies. The relationship between local authorities and PHE is particularly crucial, both in the development of proposals regarding schemes and in the operation of schemes. That relationship needs to reflect operational practicality and, very importantly, to acknowledge and respect the separate legal roles of local authorities and PHE (on behalf of the secretary of state for health and social care) in CWF schemes. The importance of joint working between local authorities when more than one is affected by a scheme or by a proposal for a scheme is discussed more fully below.

5.7 Other agencies

5.7.1 The Drinking Water Inspectorate (DWI)

DWI, an agency of the Department for Environment, Food and Rural Affairs, does not feature in the fluoridation legislation. However, as the body responsible for assuring the quality of public drinking water supplies in England and Wales, and for advising local authorities on the quality of private water supplies, it has a central role in monitoring levels of fluoride in water, be those naturally or artificially occurring, and taking or advising on compliance action in the event of breaches of the drinking water standard for fluoride. DWI also publishes the technical code of practice on the design and operation of fluoridation plant and may provide technical advice to PHE on such matters.

5.7.2 The Water Services Regulation Authority

The Water Services Regulation Authority (OFWAT) is a non-ministerial government department and is the economic regulator of the water sector in England and Wales. Its role in water fluoridation is that of a statutory consultee on the terms to be included in the proposed legal agreement for a new fluoridation scheme and, in particular, terms which affect the operation of the water undertaker's supply system.

5.8 Joint decision-making by local authorities

Because their boundaries are defined by water distribution systems, not by administrative boundaries, water fluoridation schemes usually extend beyond the boundary of a single local authority. All formal consideration of proposals for fluoridation arrangements covering more than one authority has to involve each of the affected local authorities in a way prescribed in the fluoridation legislation, and in the absence of unanimity about a particular proposal, has to be determined in a way again prescribed in the legislation.

In a multi-authority situation where one or more of the authorities concerned believes that a new scheme should be introduced, or an existing scheme varied or terminated, it is necessary for at least one of the affected authorities initially to make a formal proposal to the secretary of state for health and social care for the desired action. Except in circumstances⁶⁹ where it would not be necessary to undertake a public consultation about the proposal, the proposer first has to consult and secure the support of the other affected authorities to undertake public consultation.

It will be important to ensure that all affected authorities are actively involved in that consultation. In the absence of unanimity the regulations prescribe that the matter should be resolved by a process of weighted voting between the authorities, each authority having in effect a single block vote the size of which is determined by the proportion of the whole population affected by the proposal which is resident in the area of that authority. It is necessary for the proposal to secure at least 67% of the total block vote to succeed. The method of calculating the voting is set out in the schedule to the regulations.

Should it be determined that the formal proposal should proceed to public consultation, it is then necessary for the authorities affected to agree on and establish joint committee arrangements for progressing the matter. The options for joint committee arrangements are defined in s88F of the Act.

⁶⁹ Limited to relatively minor changes to established fluoridation schemes. See Regulation 15 of the regulations

Following public consultation, decisions about the outcome are taken in the joint committee established for that purpose and have to take account of certain matters prescribed in the legislation. In the absence of unanimity, the outcome decision is again taken by the process of weighted voting between the affected local authorities. Each authority represented on the joint committee has a single block vote the size of which is determined by the proportion of the whole population affected by the proposal which is resident in the area of that authority. It is again necessary for the proposal to secure at least 67% of the total block vote to succeed.

5.9 Academia and research funding bodies

The role of academic research concerning water fluoridation and its impacts is recognised by both the academic community and research funding bodies. There is a constant flow of new research, which will need evaluating in line with the considerations outlined in section 3.1 above. New and existing water fluoridation schemes both provide opportunities for research; local authorities might find it helpful to develop links with local academic units to promote additions to the evidence base.

Withdrawn

Section 6. Management of established schemes

Working with the water company

Once a scheme is established, PHE (on behalf of the secretary of state for health and social care) is responsible for working with the water company and the DWI regarding the operational aspects of the scheme. There are distinct reporting mechanisms from companies to PHE and to DWI regarding the performance of plants and the achievement of the correct level of fluoride in the water supply.

For all public water supplies, whether fluoridated or not, the DWI checks that water companies comply with all drinking water regulations. This includes checking that water supplies do not contain more than 1.5mg/l of fluoride. If the standard of 1.5mg/l is breached, then DWI has the power to take enforcement action that requires the water company to rectify the breach. Enforcement relates equally to water supplies naturally containing fluoride and to those where the level is adjusted. DWI also carries out independent audits of water company fluoridation facilities for compliance with the code of practice.

PHE meets regularly with water companies operating fluoridation schemes and reviews the performance of individual fluoridation plants and the scheme as a whole. The reasonable capital and operating costs incurred by companies are also reviewed and any necessary capital investment agreed. Local authorities are routinely invited to these meetings.

Cost of running the scheme

PHE, on behalf of the secretary of state for health and social care, is required to meet the reasonable capital and operating costs incurred by the water companies. Section 88H of the Act gives the secretary of state the powers to require all local authorities affected by the arrangements to make payments to the secretary of state to meet any costs incurred by the secretary of state under the terms of the arrangements. At present PHE meets the capital costs of schemes and recovers only the operating costs from local authorities, but PHE will keep this arrangement under continuous review. The same provisions allow for determining the share of costs across local authorities where a scheme covers more than one authority. The operating costs may vary from year to year dependent upon:

- the amount of (fluoridated) water supplied in that year

- the operational status of the fluoridation plants, including times out of operation or ongoing maintenance costs
- changes in unit cost of materials, particularly the fluoridation chemicals

In addition, should there be a desire to vary an established scheme, it is likely that a feasibility study will need to be carried out by the water company. At present the costs of feasibility studies are met by local authorities. PHE can advise individual authorities, based on experience elsewhere in England, of the reasonableness of costs for such exercises.

Monitoring the effects of the scheme

As with all other health programmes, it is important that the effects of a water fluoridation scheme are monitored and that those effects are understood by the local authority and its health and wellbeing board. This will help ensure good governance of the scheme and equip the authority to be able to respond to enquiries.

As described in section 7 PHE, on behalf of the secretary of state for health and social care, is responsible for fulfilling his or her statutory obligation to monitor and report publicly at four-yearly intervals on the health effects of water fluoridation schemes. That programme of work has to be undertaken in consultation with local authorities.

One important component of health monitoring is that of understanding levels of dental decay in the scheme area and in similar non-fluoridated areas. Local authorities have a statutory responsibility⁷⁰ for commissioning or providing the necessary surveys and can obtain advice and support from PHE to ensure that their surveys are appropriately designed and conducted.

Schemes which cross local authority boundaries

Most established schemes, because of the boundaries of water distribution systems, extend into more than one local authority area. Some involve multiple authorities. This increases the complexities of scheme governance. In such situations, PHE recommends that the affected authorities work collectively and closely with PHE to ensure effective management of the entirety of the scheme across the range of issues described above.

⁷⁰ SI 2012 No. 3094. The NHS Bodies and Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch) Regulations 2012

Section 7. Monitoring the health effects of fluoridation schemes

Under section 90A of the Act the secretary of state for health and social care is under a duty to monitor the effects of fluoridation schemes on the health of people living in those areas and report within four-yearly intervals on those effects. For existing schemes, the first report fell due in March 2014. In respect of the area of any subsequent new scheme the four-yearly reporting cycle would start within 4 years of the date when the new arrangements came into force. The monitoring and reporting duty is discharged by PHE on behalf of the secretary of state.

The legislation requires that local authorities with fluoridation schemes are consulted about the health monitoring programme. PHE undertakes this as part of its health monitoring work.

The programme includes consideration of levels of tooth decay and possible adverse effects, taking into account the current scientific evidence, biological plausibility, and availability of appropriate data. Health monitoring reports have been published by PHE in 2014² and 2018³. Further iterations of this work will be informed by relevant new research published internationally and through discussion with local authority directors of public health.

Local authorities are responsible for securing the provision of oral health surveys to provide the dental epidemiological information necessary to facilitate the monitoring and reporting programme.⁷¹

⁷¹ The NHS Bodies and Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch) Regulations 2012 – Regulation 17(2)(b)(iv)

Section 8. Key steps towards introducing a new fluoridation scheme

Upper tier and unitary local authorities are responsible for determining the need for new fluoridation schemes. They are required to undertake public consultations before they make a final decision. This applies when just a single local authority is involved and when a number of authorities receiving water from the same sources are involved. In the latter case, they must form a joint committee to oversee the process and make the decision.

The consultation process is defined in the legislation. It is essential that a local authority considering a fluoridation scheme understands the legislation and obtains independent legal advice throughout the whole process. A local authority should be aware of the risk of legal challenge and consider appropriate steps to mitigate that risk. The requirements of the legislation need to be read alongside the practicalities of how a fluoridation scheme is designed and operated. PHE cannot offer legal advice to local authorities but can, if requested, advise on how the legislation interfaces with operational practicalities.

Successful implementation requires careful adherence to a sequential process of steps which are briefly outlined below and in more detail in annex 2, which covers the main legislative requirements relevant to each step. Aspects on which PHE can provide advice to local authorities are identified, but it is important to note that on aspects where the secretary of state for health and social care has a role PHE will need to maintain a distinct separation from the local authority.

Table 2. Summary of key steps towards a new scheme

Phase	Content
1	Preliminary scoping phase (non-statutory) and informal discussion with any other affected local authorities.
2	Commencement of statutory process – making an initial proposal, perhaps with multiple proposers.
3	Assessment of operability and efficiency, including agreement of secretary of state to proceed.
4	Consultation with other affected local authorities (if any), and securing their consent to proceed.
5	Public consultation and subsequent decision-making including, in the case of multiple local authorities, joint committee arrangements. In the latter instance, decisions may need to be made by a process of weighted population voting (see section 5.8 and annex 2)
6	Making an agreement between the secretary of state and the water company including issuing an indemnity to the company.
7	Scheme implementation.

Section 9. Changes to established schemes

9.1 Varying (modifying) a scheme

Once a scheme is established - that is, once the secretary of state for health and social care and water company have made arrangements for a new scheme – or once the secretary of state has inherited an agreement for a scheme already in existence at 1 April 2013, it may subsequently be desired to modify the scheme in some way. Depending on the terms of the legal agreement for a particular scheme, such alteration may require that the legal agreement is modified to reflect the changed circumstances.

A proposal to vary a scheme can only come from a local authority and could arise for one of a number of reasons, some examples of which are outlined below. PHE, as the holder of the agreement on behalf of the secretary of state, and as the agency in regular touch with both the affected local authority(ies) and the water company, may be the conduit through which the proposed change is notified to the other parties.

A water company might wish to vary a scheme to reflect changes it needs to make to its water supply arrangements - for example, to introduce fluoridated water into an area, or to cease fluoridating from a particular location but substituting a different location. In such a case the company would need to discuss the matter with PHE and the local authority, with any proposal for change having to be made by the local authority.

A local authority might wish to seek a variation to an existing scheme to include a greater part of its area in the scheme or, in a multi-local authority scheme, to withdraw from the scheme. An authority might wish to join an adjacent existing scheme.

Any of these possible changes would require detailed consideration with PHE, acting on behalf of the secretary of state as party to the legal agreement, to establish whether the proposed change would trigger the requirements of the Act and Regulations for varying the arrangements. Should those requirements apply to a particular change, a local authority or authorities would become the proposer of the intended variation and public consultation. Where a variation is proposed to a multi-authority scheme, joint committee procedures and weighted population voting would be necessary (see section 5.8 and annex 3). As with a proposed new scheme, consideration would initially be required with the water company and secretary of state as to whether the proposal would be operable and efficient. It would also be necessary to have regard to any relevant clauses of the existing legal agreement(s) should the proposal affect more than one local authority. Regulation 15 sets out the circumstances in which a proposed variation would not require certain procedures, like formation of a joint committee and consultation, to be followed.

In summary, the joint committee and consultation procedures would not be required if the proposed change to the agreement:

- did not concern the boundary of the area defined in the agreement
- did concern the boundary of the area, but the proposed change (to increase or decrease the boundary) affected 20% or less of the number of houses within the area at the time the proposal was made

A more detailed description of the relevant processes is at annex 3.

9.2 Maintaining a scheme

The Act, at s88O, makes provision for another process of consultation and ascertainment of opinion to apply to established schemes if the scheme in question requires the upgrading or replacement of fluoridation plant to maintain the existing arrangements otherwise than for the purpose of meeting operational requirements or health and safety standards. The necessary process is introduced in Regulation 18.

In practice, it is difficult to envisage such a situation arising but, on receiving proposals from a water company for a capital scheme of works without such justification, PHE would investigate the company proposals more fully. If necessary, PHE would notify the local authority or local authorities that they would need to go through the prescribed processes of public consultation, joint committee arrangements and decision-making set out in Regulations 19 to 23 in order to secure the continuation of the arrangements.

9.3 Terminating a scheme

Under s88I to 88N of the Act (inclusive), a local authority or local authorities may propose terminating an established scheme. The procedure essentially replicates that for the introduction of a new scheme, that is:

- initial consultation by the proposer(s) with the water company and the secretary of state for health and social care as to whether it would be reasonably practicable to terminate the arrangements – if the secretary of state were not of that opinion, no further steps could be taken to terminate the arrangements
- initial consultation with all other affected local authorities (if any) as to whether the proposed termination should go forward to formal public consultation – the outcome would if necessary be decided by weighted population voting by the local authorities concerned; the terms of the existing legal agreement might also need to be taken into account
- joint committee (if applicable) and public consultation procedures as stipulated in Regulation 11, including a period of no less than 3 months for representations to be made

- decision-making by the proposer or joint committee having regard to the matters specified in Regulation 12, with (if necessary) weighted population voting and including consideration of the costs of giving effect to the termination which would/might need to be borne by the local authority(ies)

If following that process it is decided by the local authority or joint committee that the scheme be terminated, it has to give notice to the secretary of state, who is then required to notify the water undertaker that the scheme is to be terminated (Regulation 14).

Should a termination proposal for a particular scheme be made but not succeed, then no further termination proposal may be made in respect of that scheme for a period of 20 years from the date when the secretary of state is notified by the proposing local authority – or joint committee of local authorities – about the decision of the proposer or joint committee in relation to the termination proposal (Regulation 17).

A more detailed description of the relevant processes is at annex 4.

Withdrawn

Section 10. Sources of further advice

Local authorities seeking further advice on water fluoridation should contact their PHE centre in the first instance.

Members of the public with queries should contact the PHE enquiry line via email to enquiries@phe.gov.uk or in writing to PHE Enquiries, 5th Floor, South Wing, Public Health England, Wellington House, 133-155 Waterloo Road, London, SE1 8UG.

Withdrawn

Annex 1. Unitary and upper tier local authorities with established community water fluoridation schemes – at 1 January 2020

Local authority	PHE Centre
Bedford Borough Council	East of England
Birmingham City Council	West Midlands
Cambridgeshire County Council	East of England
Central Bedfordshire Council	East of England
Cheshire East Council	North West
Cheshire West and Chester Council	North West
Coventry City Council	West Midlands
Cumbria County Council	North West
Derbyshire County Council	East Midlands
Dudley Metropolitan Borough Council (MBC)	West Midlands
Durham County Council	North East
Gateshead Council	North East
Hertfordshire County Council	East of England
Leicestershire County Council	East Midlands
Lincolnshire County Council	East Midlands
Newcastle City Council	North East
North East Lincolnshire Council	Yorkshire and Humber
North Lincolnshire Council	Yorkshire and Humber
North Tyneside Council	North East
Northumberland County Council	North East
Nottinghamshire County Council	East Midlands
Sandwell MBC	West Midlands
Shropshire Council	West Midlands
Solihull MBC	West Midlands
Staffordshire County Council	West Midlands
Walsall Council	West Midlands
Warwickshire County Council	West Midlands
City of Wolverhampton Council	West Midlands
Worcestershire County Council	West Midlands

Note – some of these local authorities may only have small areas served by a scheme

Annex 2. Process for proposing and establishing a new fluoridation scheme

Phase 1 – preliminary scoping

Needs assessment.

As part of its wider responsibility for improving the health of the public, a local authority will assess the health of its population, including oral health aspects. These may be documented in a JSNA, or in addition to a JSNA. Local dental epidemiological data to support the needs assessment process will come from the oral health surveys commissioned by the local authority pursuant to its responsibilities under The NHS Bodies and Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch) Regulations 2012. This process should identify any particular concerns about levels of tooth decay in the area, or in a locality within the authority area. Local authority health profiles²⁹ include data on tooth decay in 5-year-old children and provide a useful benchmarking tool. The public health outcomes framework (2019) includes tooth decay in 5-year-old children as an outcome indicator. Other indicators, such as the number of children having a hospital admission for general anaesthetic for tooth extraction, might also be informative.

Scoping options for action on high levels of tooth decay.

Where levels of tooth decay are identified as cause for concern, the local authority and its health and wellbeing board will wish to consider options for action to address those concerns. The PHE publication “Local authorities improving oral health: commissioning better oral health for children and young people: an evidence-informed toolkit for local authorities”¹⁹ sets out principles for commissioning better oral health in children and young people. It advocates looking at a range of opportunities and methods to prevent decay at all stages of life. Section 3 describes the strength of evidence for a range of approaches to reducing tooth decay, one of which is water fluoridation. It assesses water fluoridation as an intervention having strong evidence of effectiveness and recommends it as a measure to be considered within a wider oral health promotion strategy. Similarly, water fluoridation is one of the recommended interventions in PHE’s 2018 toolkit for local authorities “Commissioning better oral health for vulnerable older people”⁷².

⁷² Commissioning better oral health for vulnerable older people. An evidence-informed toolkit for local authorities. Public Health England, 2018

Assessing the feasibility of water fluoridation in the target area

Should a local authority wish to include water fluoridation in its approach to tooth decay prevention, the first necessary step is to gain an understanding of the public water supply arrangements in the area. Key initial questions are:

- is it technically practicable for the responsible water company to fluoridate the geographic area of concern?
- will doing so necessitate also fluoridating other adjacent localities and, if so, will this involve other local authority areas?
- are the likely costs affordable?

These questions can only be answered by commissioning a suitably specified feasibility study from the relevant water company, which the local authority would need to fund. PHE staff have considerable experience of working with water companies on fluoridation schemes and can, if requested by a local authority, provide it with advice and support on the feasibility process, including providing a draft specification for the feasibility study.

Subject to discussion with the water company about the specific target locality of interest it may be possible to adopt an incremental approach to exploring technical feasibility. For example, an initial desk-top feasibility exercise to map water supply arrangements against priority areas for oral health improvement can often be carried out at relatively low cost using information already available to the water company and requiring no additional investigation. This might allow an early appreciation of potential options for scheme design.

Under this approach, should the local authority decide to investigate further, a more detailed study would be needed to investigate options identified in the first stage. As more information becomes available a discussion will be needed with the water company to clarify what level of detail will be necessary to allow the company to give a view on whether any particular option would be operable and efficient. PHE can provide support for these discussions.

At the time of commissioning feasibility studies, the local authority may wish to emphasise to interested parties that this is purely a fact-finding process to support subsequent decision-making and that it does not represent a decision by the local authority to proceed substantively with fluoridation.

Assessing the implications of the feasibility study results

The feasibility study (or studies, if an incremental approach is taken) will tell the local authority:

- whether fluoridation of the public water supply to a selected area is technically achievable
- whether this would necessitate the boundaries of the fluoridation scheme extending more widely than the initially anticipated priority area
- broadly, what fluoridation works would be required at water company sites to deliver the scheme
- identify any significant constraints or other issues
- the likely capital and revenue costs

Should, ultimately, the secretary of state enter into arrangements with the water company, PHE will commission studies to finalise aspects such as fluoridation plant design to ensure that any equipment installed meets contemporary requirements and best practice (see section 4.3).

Involvement of other local authorities

Of considerable significance to any further steps on fluoridation is whether it would be necessary, because of water supply arrangements, to include parts of other local authority areas in the scheme. This is because, under the legislation, the proposing local authority would need to consult any other affected local authorities as to whether they were willing to proceed with public consultation on a scheme affecting their areas. Should there be a mixture of views between the authorities, then the legislation provides that the matter would be determined by “voting” between the local authorities concerned, with each local authority having a number of “votes” equating to the number of people in their population who would be affected by the proposed scheme. For the proposed scheme to proceed to further stages that are prescribed in legislation including public consultation, there would need to be a 67% or greater majority in favour of proceeding. This process prevents any local authority having an automatic veto about proceeding including about going to public consultation, but also prevents any local authority from being able automatically to impose fluoridation on unwilling neighbours. The detailed process for decision-making is set out in the regulations.

Multi-local authority decision-making

In the event that the feasibility study demonstrated that a proposed scheme could only be introduced on a multi-local authority basis, it would be advisable for the prospective initiating authority to discuss the matter with the other affected authorities. This would establish the likely level of support or opposition to the proposed scheme, and the

extent to which that would be reflected if the matter had to be tested through the prescribed “voting” procedure, the details of which are in the Schedule to the regulations. The formal voting procedure is not required to be undertaken until later in the process, but the methodology could be used at this stage to gauge indicative levels of support.

The following table gives a simple worked example, for illustrative purposes only.

Table 3. Multi-authority “voting”

	Proposer		Other affected authorities	
Local authority	A	B	C	Total population affected by scheme
Affected population	200,000	120,000	65,000	385,000
LA % of total affected population (rounded)	51.9%	31.2%	16.9%	100.0%
Examples of application of weighted voting procedure				
Supporters of proposal	% of affected population represented:		Outcome:	
A and B	83.1% (that is 51.9% + 31.2%)		Succeeds	
A and C	68.8% (that is 51.9% + 16.9%)		Succeeds	
A alone	51.9%		Fails	

This assessment would form part of the decision-making process by the local authority following receipt of the feasibility study from the water company. The outcome of this would either be to decide that the local authority (perhaps jointly with at least some other affected authorities) would now formally proceed to initiate the process for establishing a fluoridation scheme, or that it would not give further consideration to water fluoridation as part of the solution to its acknowledged problem of high levels of tooth decay.

In these early discussions with other affected local authorities it would be important to decide whether, if it is intended to proceed towards the statutory process, the formal proposal should be made by one or more local authorities (section 88B(3) of the Act).

Phase 2 – commencing the statutory process by making a formal proposal to the secretary of state for health and social care

Should the local authority, perhaps with partner affected local authorities, decide in the light of the feasibility study that it wished to proceed to the statutorily prescribed stages towards establishing a scheme, then the first necessary step would be for the proposer local authority(ies) to make a proposal to the secretary of state that he or she enter into arrangements with the water company under s.88B of the Act “to increase the fluoride content of the water supplied by the undertaker...to premises within such area or areas in England as may be specified in the proposal.”.

It would be good practice, for the purpose of clarity and avoidance of subsequent doubt, that the proposal be made in writing to the secretary of state, with a copy direct to PHE. Having made that formal proposal, the local authority(ies) would then need to move to the next stage of the legislative process, namely undertaking “Initial consultation” and other actions, as required, required regarding the fluoridation proposal.

Phase 3 – Initial consultation with the water company and secretary of state for health and social care

Section 88C of the Act requires a proposer (local authority or authorities) to consult the secretary of state as to whether the proposed scheme would be “operable and efficient”. The proposer must also consult the water company as to whether the scheme, insofar as it might affect the company, would be “operable and efficient”.

Both the secretary of state and the water undertaker(s) are required to give the proposing local authority(ies) their opinion on operability and efficiency. The proposer must give the secretary of state the opinion of the water company.

This phase of the process will be aided and expedited by early engagement with the water company and the results of the feasibility study recommended as part of phase 1. Early engagement with PHE will also be helpful, since PHE may be in the position of adviser to the secretary of state on this proposal.

Should the secretary of state be of the opinion that the proposed scheme would not be operable and efficient, then the local authority may not progress the matter any further.

Should the secretary of state be of the opinion that the proposal would be operable and efficient then, if no other local authority area would be affected by the proposal, the proposing local authority can move direct to phase 5 – undertaking public consultation.

Phase 4 – consultation with all other affected local authorities (if applicable)

If the secretary of state for health and social care has given his or her approval to proceed, and other local authorities would be affected and are not co-proposers, the proposer next needs to formally consult the other local authorities as to whether the matter should proceed to the next stage, that is public consultation. Section 88D of the Act and Regulation 3 of the regulations detail the process which must be followed, including the information which must be supplied to the affected local authorities. Consultee local authorities must be given up to 3 months to consider the matter and give their opinion to the proposer. Should a consultee not respond within 3 months then they are taken to have withdrawn from this phase of the decision-making process.

Should any of the consultee local authorities not be in favour of progressing the matter then a decision as to whether to proceed would be taken by the proposer in accordance with the affected population-based voting procedure set out in Regulation 4 and the schedule to the regulations.

Should the proposer determine that there is sufficient support to proceed, the affected local authorities then undertake public consultation and the ascertainment of public opinion in accordance with s88E of the Act and Regulation 5 of the regulations.

Phase 5 – Public consultation on a fluoridation proposal and subsequent decision-making, including joint committee arrangements

Public consultation

Where the only local authority affected is also the proposer, it can proceed to a public consultation in accordance with Regulations 5(2) and 5(3), giving a period of not less than 3 months for individuals and bodies with an interest to make representations.

Joint committee

Where any affected local authority other than the proposer informs the proposer that it wishes to participate in the decision-making process (in the Act this is described as “the exercise of the fluoridation functions”), then the affected local authorities must adopt a decision-making structure of an inter-authority joint committee. The options for doing so are specified in s88F of the Act and are:

- arranging for an existing joint committee of the authorities to exercise the fluoridation functions
- establishing a joint committee of the authorities for that purpose

- arranging for their health and wellbeing boards to exercise the fluoridation functions, in which case the boards must establish a joint subcommittee of the boards to exercise those functions

The joint committee then undertakes the public consultation process set out in Regulations 5(2) and 5(3) of the regulations.

Decision-making

At the conclusion of the consultation process the proposing local authority has to decide whether to modify the proposal pursuant to s88E(3) of the Act. Any modification to the area to be fluoridated can only be in the circumstances prescribed in Regulation 15(1)(b).

The proposing local authority (in the case of there being no other affected local authorities) or the joint committee of affected local authorities then has to decide whether to proceed with the implementation of the proposed scheme, which would require the proposer or the joint committee to request the secretary of state for health and social care to lodge a formal request with the water company to fluoridate the specified area.

In making that decision the proposer or joint committee is required to have regard to the matters specified in Regulation 6, namely:

- the extent of support for the proposal
- the strength of any scientific evidence or ethical arguments advanced in relation to the proposal
- any assessment of relevant needs set out in a joint strategic needs assessment in relation to the area of a local authority affected by the proposal
- any joint health and wellbeing strategy published by such an authority
- the capital and operating costs likely to be incurred
- any other available scientific evidence in relation to the proposal, including any evidence of benefit to the health and wellbeing of individuals who would be affected by the proposal

Unless the joint committee can agree unanimously as to whether to request the secretary of state to proceed, the joint committee must vote on the decision to implement the fluoridation proposal in accordance with Regulation 7 (3) and 7(4) which prescribes a population-weighted voting procedure by the joint committee.

Unless the proposing LA could command 67% or more of eligible “votes” (including its own) the proposal would progress no further.

The proposer (in the case of there being no other affected local authorities) or the joint committee of affected local authorities must notify the secretary of state of its decision (Regulation 8).

Phase 6 – making an agreement between the secretary of state for health and social care and the water company

Having received a formal request to proceed, the secretary of state, advised by PHE, has to be satisfied that the local authority or joint committee has complied with the requirements of s88B to 88F of the Act, except for those matters listed in s88G(3).

Having done so, the secretary of state (through PHE) will make a formal request to the water company to enter into a fluoridation agreement for the area specified in the proposal. Subject to receiving an indemnity from the secretary of state, the water company is required to enter into such an agreement. The secretary of state, with the consent of HM Treasury, will therefore arrange for the company to receive an indemnity. The form of the indemnity is set out in The Water Supply (Fluoridation Indemnities) (England) Regulations 2005.

Through PHE, a suitable legal agreement will be negotiated between the secretary of state and the water company. The agreement will include matters stipulated in s87(5) and (6) of the Act, including that the water company will be reimbursed all the reasonable costs of fluoridating the water supply. The secretary of state, through PHE, is required to consult the affected local authorities about the terms of the proposed agreement, and also the Water Services Regulation Authority (OFWAT). Following consultation, an agreement will be made between the secretary of state and the water company for the scheme as proposed.

Phase 7 – scheme implementation

Once the legal agreement takes effect, the water company will in consultation with PHE finalise the detailed design and cost of implementing the scheme. PHE will place an order with the company for the necessary works and the company will arrange installation and commissioning of the necessary fluoridation plant.

Following successful commissioning, the scheme will become operational. Before that date, PHE and the local authority(ies) will provide advice to the public and health professionals about the impending change to the fluoride concentration of the water.

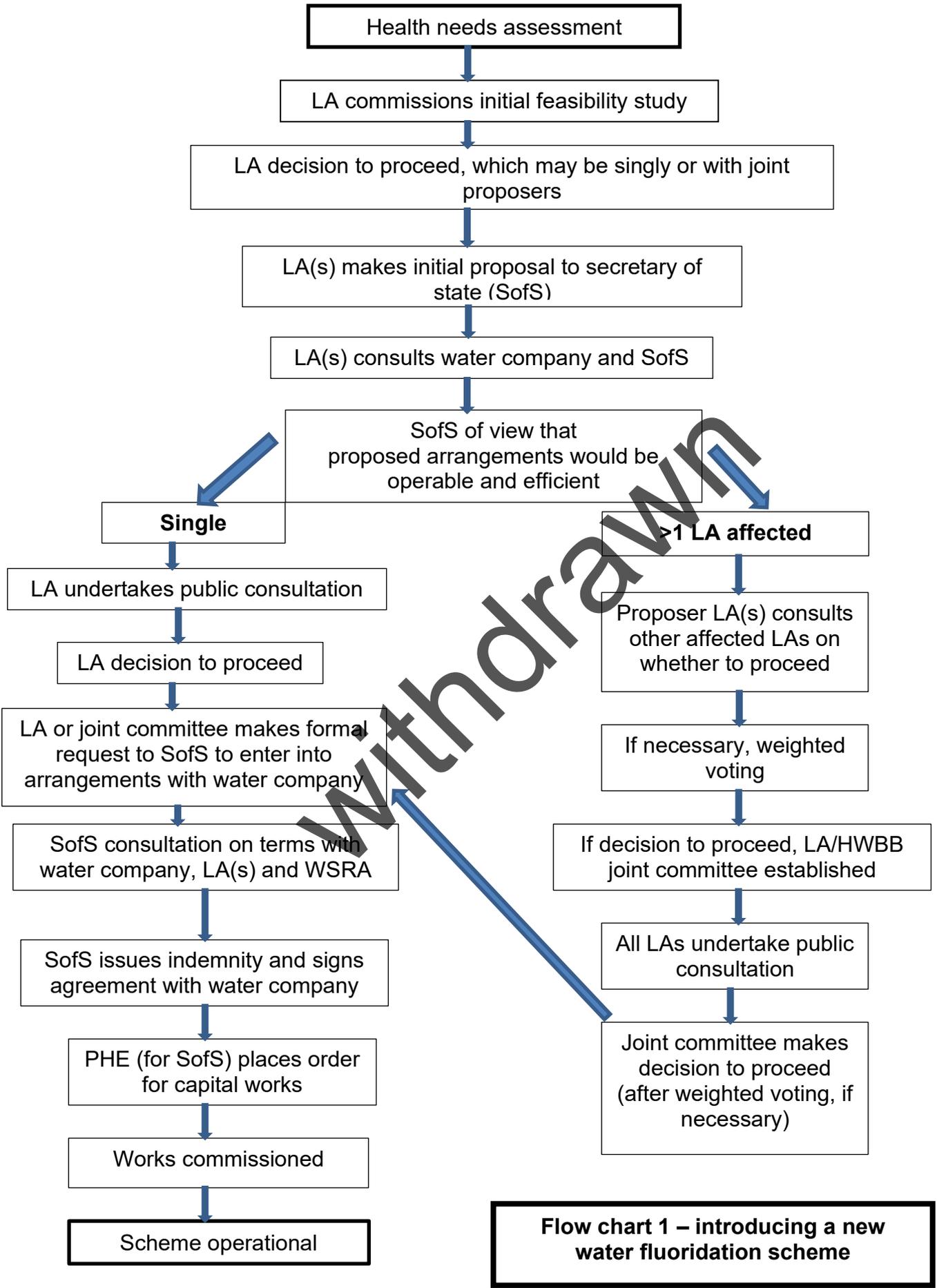
PHE, as part of its duty to undertake regular health monitoring of affected populations, will arrange in consultation with the local authority baseline measurements of key health indicators.

PHE will make arrangements to pay the ongoing revenue costs of the scheme and to re-charge those costs to the affected local authority(ies) in accordance with s88H of the Act.

Summary overview of process

Flow chart 1 below gives a visual summary of the main elements of the process needed to introduce a new community water fluoridation scheme.

Withdrawn



Annex 3. Process for proposing a variation to an established scheme

Introduction

Once a CWF scheme is established, that is, once the secretary of state and water company have entered into arrangements for a new scheme, or once the secretary of state has inherited arrangements for a scheme already in existence at 1 April 2013, it may subsequently be desired to vary the scheme in some way. Depending on the terms of the legal agreement for a particular scheme, such variation may require that the legal agreement is modified to reflect the changed circumstances.

A proposal to vary a scheme comes from a local authority⁷³ and could arise for one of a number of reasons. PHE, as the agency in regular touch with both the affected local authority(ies) and the water company, may be the conduit through which the proposed change is notified to the other parties.

Scheme variation will invariably be complicated because almost all current schemes extend across more than one local authority area, meaning that all of those authorities would need to be involved in, and might need to agree to, the proposed variation. Given the complexities of water supply arrangements in most parts of England it is also likely that subsequent variation to any new scheme would involve more than one local authority.

It is not practical to list all possible reasons for a party to wish to vary an established scheme. However, possible scenarios include:

- a desire to extend the geographical coverage of a scheme, either within a local authority which is already partly-fluoridated, or into one or more adjacent authorities
- the desire of one local authority in a multi-authority scheme to withdraw from that scheme

In any variation event, a key determinant of the process to be followed is the size of the change to the area to be fluoridated, since this determines whether or not there is a requirement for consultation including, if in a multi-authority scheme, joint committee procedures. In a multi-authority scheme, it would also be necessary to have regard to

⁷³ Definition of local authority is contained in the Water Industry Act 1991, s87(7B)

the terms of the existing agreement(s) for that specific scheme, since this might impose constraints upon the actions of individual parties.

Variation to extend an established scheme

A proposition to extend an established scheme might emerge from either:

- the desire of a local authority to extend the boundaries of a scheme in order that greater numbers of residents might benefit from CWF, and/or
- changes the water company wishes to make to its water distribution system that would necessitate introducing fluoridated water into a greater part of its supply area other than for emergency purposes

Variation to reduce the size of an established scheme

A proposition to reduce the size of an established scheme might emerge from:

- the desire of a local authority in a multi-authority scheme to withdraw from that scheme and/or
- changes the water company wishes to make to its water distribution system that would necessitate reducing the area to which it could supply fluoridated water other than for emergency purposes

Procedure to be followed

As in the case of a proposal for a new scheme, it is essential that proper procedure, as set out in the Act and regulations, is followed. Legal advice is strongly recommended.

The initial, preliminary scoping, phase is non-statutory but provides the essential building-blocks of information which will enable the parties (local authority(ies), water company, PHE on the secretary of state's behalf) to proceed into the statutorily-defined phases.

Phase 1 – preliminary scoping

The opening phase necessitates all 3 parties being clear about a number of factors which are:

- which parties desire the change, and the reasons for the change
- what the change would entail for the scheme, including the impact on the number of houses served by the amended scheme
- the number and identity of affected local authorities

- the number of affected people⁷⁴ in each local authority area
- technical feasibility, operability and efficiency of the change
- capital and revenue implications of the change including, if relevant to the proposed change, costs of de-commissioning any redundant fluoridation plant and/ or making changes to water supply arrangements

Feasibility study

It is likely that the water company would need to be commissioned to undertake a feasibility study to provide much of the necessary information, including the size of the affected area and the number of houses currently within it, the number which would be affected by the proposed variation and the nature and cost of any associated capital works.

As the holder on behalf of the secretary of state of the existing legal agreement PHE would be able on request to coordinate this activity and ensure that all necessary information is acquired. Costs of a feasibility study or studies would fall to the LA(s) concerned.

Phase 2 – commencing the statutory process by making a formal proposal to the secretary of state for health

The statutory process for decision-making starts with a formal variation proposal to the secretary of state under s88I of the Act. The proposer must be one or more of the affected local authorities. It would be good practice, for the purpose of clarity and avoidance of subsequent doubt, that the proposal be made in writing to the secretary of state, with a copy direct to PHE.

Were the water company the originator of the desired variation, the company would need to secure the agreement of an affected local authority to act as proposer, since the company cannot itself act as such.

Phase 3 – initial consultation with the water company and secretary of state for health

Section 88J of the Act requires a proposer (which may be one or more of the affected local authorities) to consult the secretary of state and the water undertaker as to whether the arrangements as varied in accordance with the proposal would be “operable and efficient”. Both consultees are required to provide the proposer with their

⁷⁴ The phrase “Individuals who would be affected” is defined in Regulation 2(2)(b)

opinion on that matter, and the proposer must notify the secretary of state of the opinion of the water company.

Should the secretary of state form the opinion that the proposed variation *would not* be operable and efficient, then the proposing local authority(ies) may not progress the matter any further.

Should the secretary of state be of the opinion that the arrangements as varied would be operable and efficient then, if no other local authority area would be affected by the proposal, the proposing local authority would move direct to phase 5 – determining the need for and undertaking public consultation.

Phase 4 – consultation with all other affected local authorities

If the secretary of state has given his or her approval to proceed, and other local authorities would be affected and are not co-proposers, the proposer next needs to notify any other local authority which is affected by the variation proposal to determine whether the matter should proceed to the next stage, which may (but may not) be public consultation. Section 88K of the Act and Regulation 9 of the regulations detail the process which must be followed, including the information which must be supplied to the affected local authorities.

It is strongly recommended that, if not done at an earlier stage, the proposer shares with other affected local authorities an analysis of the number of houses which would be affected by the proposal, so as to establish whether or not joint committee procedures and public consultation would be required in accordance with Regulation 15. This stipulates that if the number of additional houses which would be brought within the area or (in the case of a variation to reduce the area affected) removed from the area is 20% or less than the number of houses within the fluoridated area at the time the variation proposal is made then there is no requirement under the regulations to consult and ascertain opinion. Nor is there a requirement for affected local authorities to make decisions under joint committee procedures (Regulation 15).

Consultee local authorities must be given up to 3 months to consider the proposal and give their opinion to the proposer. Should a consultee not respond within 3 months then it is taken to have withdrawn from this phase of the decision-making process.

Should any of the consultee local authorities not be in favour of progressing the matter then a decision as to whether to proceed would be taken by the proposer in accordance with the affected population-based voting procedure set out in Regulation 10 and the schedule to the regulations.

Should the proposer determine that there is sufficient support to proceed and if the proposed variation is not exempt from public consultation in accordance with Regulation 15, the affected local authority(ies) would then undertake public consultation and the ascertainment of public opinion in accordance with s88L of the Act and Regulation 11.

Phase 5 – public consultation (when required) on a variation proposal and subsequent decision-making, including joint committee arrangements

Public consultation

Where the only local authority affected is the proposing authority the proposer can proceed to undertake public consultation (if required – see Regulation 15 for exemptions from consultation) in accordance with Regulations 11(2) and 11(3), giving a period of not less than 3 months for individuals and bodies with an interest to make representations.

Joint committee

Where an affected local authority (other than the proposer) informs the proposer that it wishes to participate in the decision-making process (in the Act this is described as “the exercise of the fluoridation functions”), then the affected local authorities must adopt a decision-making structure of an inter-authority joint committee. Note that Regulation 15(1) specifies circumstances when a joint committee is not required and the decision is made solely by the proposer.

The options for joint committee structures are specified in s88M of the Act and are:

- arranging for an existing joint committee of the authorities to exercise the fluoridation functions
- establishing a joint committee of the authorities for that purpose
- arranging for their health and wellbeing boards to exercise the fluoridation functions, in which case the boards must establish a joint subcommittee of the boards to exercise those functions

It is for the local authorities to determine the membership of the joint committee for fluoridation purposes.

The joint committee then undertakes the public consultation process set out in Regulations 11(2) and 11(3).

Decision-making

By s.88L(6) of the Act the proposing local authority is not permitted to modify the proposal after the conclusion of the consultation process.

The proposing local authority (in the case of there being no other affected local authorities) or the joint committee of affected local authorities then has to decide whether to proceed with the variation proposed to the scheme, which would require the proposer or the joint committee to request the secretary of state to lodge a formal request with the water company to vary the existing arrangements as described in the proposal (Act, s88I(1)).

In making that decision the proposer or joint committee is required to have regard to the matters specified in Regulation 12, including:

- any assessment of relevant needs set out in a joint strategic needs assessment in relation to the area of a local authority affected by the proposal
- any joint health and wellbeing strategy published by such an authority
- the capital and operating costs likely to be incurred in giving effect to the proposal
- any other available scientific evidence in relation to the variation proposal, including any evidence of benefit to the health and wellbeing of individuals who would be affected by the proposal

In addition, if the proposal has been subject to public consultation because of the scale of the change to the population served (see Regulation 15(1)(b) for when a consultation is not required) 2 additional factors have to be considered which are:

- the extent of support for the proposal
- the strength of any scientific evidence or ethical arguments advanced in relation to the proposal

Unless a joint committee can agree unanimously as to whether to request the secretary of state to proceed with a request to the water company to vary the existing arrangements, the joint committee must vote on the decision to implement the fluoridation proposal in accordance with Regulations 13(3) and 13(4), which prescribe a population-weighted voting procedure by the joint committee. The schedule to the regulations provides the formulae for calculating the percentage points allocated to local authorities for this purpose. Each local authority would need to determine for itself how to decide to cast its weighted vote.

Note that the definition of affected individuals (and therefore affected authorities) comprises 2 elements - see Regulation 2(2)(b)(ii) which are:

- individuals already within the arrangements, plus (if applicable to the variation being proposed)
- individuals who would be brought within the arrangements if the variation were made.

This could affect both the weighting power of each affected local authority and, in situations where a proposed variation would extend the boundary of a scheme into a neighbouring authority not already included in the arrangements, the number of local authorities which would need to be involved in consultation and decision-making.

Unless the proposing LA could command 67% or more of eligible votes (including its own) the proposal would progress no further.

Notification to the secretary of state

The proposer (in the case of there being no other affected local authorities) or the joint committee of affected local authorities must notify the secretary of state of its decision (Regulation 14).

Phase 6 – varying the agreement between the secretary of state and the water company

Having received a formal request to proceed with the variation, the secretary of state (advised by PHE) has to satisfy himself or herself that the local authority or joint committee has complied with the requirements of s88I to 88M of the Act, except for those matters listed in s88N(3).

Having done so, the secretary of state through PHE will make a formal request to the water company to vary the fluoridation arrangements for the area specified in the proposal. It may also be necessary to vary the legal agreement for the scheme in question.

Phase 7 – implementing the scheme variation

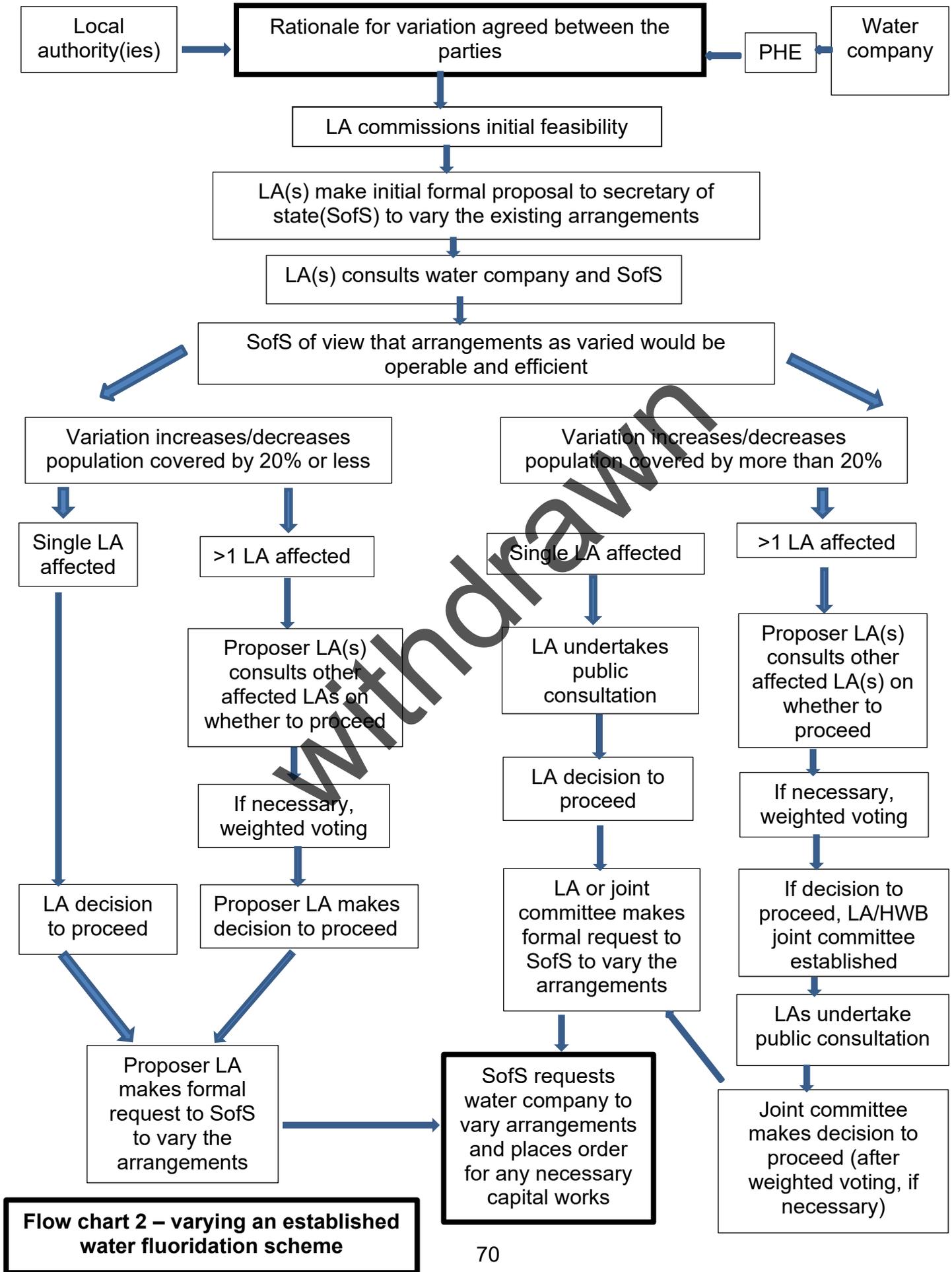
Once the arrangements have been appropriately modified to reflect the requested variation, the water company will in consultation with PHE finalise the detailed design and costs of any works necessary to vary the arrangements as specified in the proposal. PHE will place an order with the company for such works and the company will then arrange installation and commissioning of any additional fluoridation plant or the decommissioning of redundant plant, as appropriate.

PHE will make arrangements to pay the ongoing revenue costs of the amended scheme and, under S88H of the Act, may recover those costs from the affected local authorities. PHE may also require local authorities to bear any decommissioning costs.

Summary overview of process

Flow chart 2 below gives a visual summary of the main elements of the process needed to vary an established community water fluoridation scheme.

Withdrawn



Annex 4. Process for proposing the termination of an established scheme

Introduction

Once a CWF scheme is established, that is, once the secretary of state and water company have agreed arrangements for a new scheme, or once the secretary of state has inherited an agreement for a scheme already in existence at 1 April 2013, the scheme must continue unless and until the affected local authorities request the secretary of state to give notice to the water company under s87C(7) of the Act to terminate the arrangements. The procedure which the local authority(ies) must follow before that formal request is set out in the Act and regulations.

A water company has no power to terminate a scheme and the secretary of state has no independent power to instruct a water company to terminate a scheme, with the exception of very specific circumstances set out in Regulation 16. It follows that, unless and until the secretary of state receives the appropriate request from the local authorities concerned, the water company and PHE on behalf of the secretary of state are obliged to use their best endeavours to ensure the continued operation of the fluoridation arrangements in question, which may include capital expenditure and will include revenue expenditure which the local authorities are required to meet by way of re-charge from PHE. A local authority has no power to terminate a scheme by asking or instructing the water company or PHE to do so.

Procedure to be followed

As in the case of a proposal for a new scheme or a variation to an established scheme, it is essential that proper procedure, as set out in the Act and regulations, is followed. Legal advice is strongly recommended.

The initial, preliminary scoping phase is non-statutory but provides the essential building-blocks of information which will enable the parties (local authority(ies), water company, PHE) to proceed into the statutorily-defined phases.

Phase 1- preliminary scoping

The opening phase necessitates the local authority(ies) being clear about a number of factors which are:

- which local authority(ies) desire the scheme termination, and the reasons for that termination
- the number and identity of affected local authorities
- the number of people in each LA area who would be affected⁷⁵ by the termination of the scheme
- the health impact of the proposed termination
- technical feasibility, operability and efficiency of the change
- capital and revenue implications of the change including costs of de-commissioning any redundant fluoridation plant

It is likely that the water company would need to be commissioned to provide some of the necessary information.

As the holder, on behalf of the secretary of state, of the existing legal agreement PHE would be able on request to coordinate this activity and ensure that all necessary information is acquired.

Phase 2 – commencing the statutory process by making a formal proposal to the secretary of state for health

The statutory process for decision-making starts with a formal proposal under s88I of the Act to the secretary of state for the desired termination of the fluoridation arrangements.

The proposer must be one or more of the affected local authorities. It would be good practice, for the purpose of clarity and avoidance of subsequent doubt, that the proposal be made in writing to the secretary of state, with a copy direct to PHE.

Phase 3 – initial consultation with the water company and secretary of state for health

Section 88J of the Act requires a proposer (which must be one or more of the affected local authorities) to consult the secretary of state and the water undertaker as to whether it would be reasonably practicable to terminate the arrangements.

⁷⁵ People who would be affected by a termination proposal is defined in Regulation 2(2)(b)

Both consultees are required to provide the proposer with their opinion on that matter, and the proposer must notify the secretary of state of the opinion of the water company.

Should the secretary of state form the opinion that it would not be reasonably practicable to terminate the arrangements, then the proposing local authority(ies) may not progress the matter any further.

Should the secretary of state be of the opinion that the proposed termination would be reasonably practicable then, if no other local authority area would be affected by the proposal, the proposing local authority would move direct to phase 5 – undertaking public consultation.

Phase 4 – consultation with all other affected local authorities

If the secretary of state has given his or her approval to proceed, and other local authorities would be affected and are not co-proposers, the proposer next needs to notify any other local authority affected by the termination proposal (Act, s 88K) to determine whether the matter should proceed to the next stage, that of public consultation. Section 88K of the Act and Regulation 9 detail the process which must be followed, including the information which must be supplied to the affected local authorities, as listed in Regulation 9(3).

Consultee local authorities must be given up to 3 months to consider the proposal and give their opinion to the proposer. Should a consultee not respond within 3 months then it is taken to have withdrawn from this phase of the decision-making process.

Should any of the consultee local authorities not be in favour of progressing the matter then a decision as to whether to proceed would be taken by the proposer in accordance with the affected population-based voting procedure set out in Regulation 10 and the schedule to the regulations.

Should the proposer determine that there is sufficient support to proceed the affected local authority(ies) would then undertake public consultation and the ascertainment of public opinion in accordance with s88L of the Act and Regulation 11.

Phase 5 – public consultation on a termination proposal and subsequent decision-making, including joint committee arrangements

Public consultation

Where the only local authority affected is that of the proposer the proposer can proceed to undertake public consultation in accordance with Regulations 11(2) and 11(3), giving

a period of not less than 3 months for individuals and bodies with an interest to make representations.

Joint committee

Where any affected local authority other than the proposer informs the proposer that it wishes to participate in the decision-making process then the affected local authorities must adopt a decision-making structure of an inter-authority joint committee. The options for joint committee structures are specified in s88M of the Act and are:

- arranging for an existing joint committee of the authorities to exercise the fluoridation functions
- establishing a joint committee of the authorities for that purpose
- arranging for their health and wellbeing boards to exercise the fluoridation functions, in which case the boards must establish a joint subcommittee of the boards to exercise those functions

It is for the local authorities to determine the membership of the joint committee for fluoridation purposes.

The joint committee then undertakes the public consultation process set out in Regulations 11(2) and 11(3), the former detailing how the proposal must be publicised and the latter detailing the information which must be published.

Decision-making

The proposing local authority (in the case of there being no other affected local authorities) or the joint committee of affected local authorities then has to decide whether to proceed with the termination of the scheme, which would require the proposer or the joint committee to request the secretary of state to give notice to the water company under s87C(7) of the Act to terminate the arrangements. In making that decision the proposer or joint committee is required to have regard to the matters specified in Regulation 12, namely:

- the extent of support for the proposal to terminate the arrangements
- the strength of any scientific evidence or ethical arguments advanced in relation to the proposal
- any assessment of relevant needs set out in a joint strategic needs assessment in relation to the area of a local authority affected by the proposal
- any joint health and wellbeing strategy published by such an authority
- the capital and operating costs likely to be incurred in giving effect to the proposal, which may include decommissioning costs

- any other available scientific evidence in relation to the termination proposal, including any evidence of benefit to the health and wellbeing of individuals who would be affected by the proposal

Unless a joint committee can agree unanimously as to whether to request the secretary of state to proceed with giving notice of termination to the water company, the joint committee must vote on the decision to implement the termination proposal in accordance with Regulations 13(3) and 13(4) which prescribes a population-weighted voting procedure by the joint committee. The schedule to the regulations provides the formula for calculating the percentage points allocated to local authorities for this purpose. Each local authority would need to determine for itself how to decide to cast its weighted vote.

Unless the proposing LA could command 67% or more of eligible “votes” (including its own) the proposal would progress no further.

Note that, should a termination proposal be made but not gain the requisite support, no further termination proposal may be made in relation to those arrangements until the end of a period of 20 years after the date when the secretary of state received the notification of the decision not to proceed with the termination proposal w (Regulation 17).

Notification to the secretary of state

The proposer (in the case of there being no other affected local authorities) or the joint committee of affected local authorities must notify the secretary of state of its decision (Regulation 14).

Phase 6 – terminating the agreement between the secretary of state and the water company

Having received a formal request to proceed with the termination, the secretary of state advised by PHE has to satisfy himself or herself that the local authority or joint committee has complied with the requirements of s88I to 88M of the Act, except for those matters listed in s88N(3).

Having done so, the secretary of state (through PHE) will terminate the arrangements pursuant to s.87C(7) of the Act, after giving reasonable notice to the water company.

Phase 7 – implementing the termination

Once notice has been served on the water company of the termination of the arrangements, the water company will in consultation with PHE finalise the detailed

design and costs of any works necessary to give effect to the termination. PHE will place an order with the company for such works and the company will then arrange the decommissioning of redundant plant, as appropriate.

PHE will continue to reimburse the water companies for the revenue costs of the scheme until it ceases operation and, on behalf of the secretary of state, recover those costs from the affected local authorities. PHE may also require local authorities to bear any decommissioning costs and/ or a proportion of the original capital costs where equipment is being decommissioned before expiry of its normal lifespan.

Summary overview of process

Flow chart 3 below gives a visual summary of the main elements of the process needed to terminate a community water fluoridation scheme.

Withdrawn

