Regulatory Impact Statement:

Transferring decision-making on the fluoridation of drinking-water from local authorities to district health boards

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry of Health. It was developed to inform policy decisions on whether to transfer decision-making on the fluoridation of drinking-water supplies from territorial local authorities in order to improve oral health outcomes and reduce disparities between groups and communities.

The practice of fluoridation in New Zealand is based on the advice of the World Health Organisation and other international health authorities. The case for extending fluoridation is based on a number of studies, including those published by the Cochrane Collaboration, and the Prime Minister’s Chief Science Advisor and the Royal Society of New Zealand. The latter comments on “the compelling evidence that fluoridation of water at the established and recommended levels produces broad benefits for the dental health of New Zealanders”.

The case for extending fluoridation is also based on cost-effectiveness studies published by J. C. Wright et al (1999), the National Fluoride Information Service (2012) and the Sapere Research Group (2015). There is consistent evidence that the fluoridation of water-supplies for populations of more than 1,000 people is cost-effective (ie, the savings resulting from fluoridation exceed the costs). The Sapere report estimates that extending water fluoridation to those areas that are currently unfluoridated would be associated with net savings of over $600 million over twenty years, with most of the savings to consumers and a small amount to Vote Health. The conclusion that fluoridation and extended fluoridation would result in net savings was shown to be robust under a range of assumptions.

Sapere was not able to clearly isolate the incremental operating costs of adding fluoridation systems from general plant operations. It has estimated the annual costs of fluoridation for plants of various sizes, based on costing information from 17 water treatment plants.

The Ministry of Health has considered a range of options for managing fluoridation and increasing the proportion of the population having access to fluoridated water supplies. It concluded that the DHB option represents a significant advance on the current arrangements through territorial local authorities and could achieve the potential health gains that have been identified. The proposed regulatory framework would support DHBs and it would ensure that the process is more robust than it is at present. The Ministry also notes that the risk of legal challenge would remain, but that this is a feature of the status quo.

This analysis was conducted in light of the Government’s commitment to improvements in oral health, outlined in its strategic vision for oral health in New Zealand.

Cathy O’Malley
Acting Director
Service Commissioning
Ministry of Health

21 March 2016
Status quo and problem definition

Oral health in New Zealand

The burden and consequences of poor oral health

1 An emerging body of evidence suggests that poor oral health affects general health and has risk factors in common with other chronic diseases. The FDI World Dental Federation has commented that oral diseases are related to a number of risk factors and determinants that are common to many other chronic diseases, particularly cardiovascular diseases, cancer, chronic respiratory diseases and diabetes. Major risk factors include tobacco use, high sugar and alcohol consumption, as well as broader determinants such as socio-economic status which influence oral and general health. A common approach to reducing and preventing these risks would not only improve oral health but would also have an impact on the burden of non-communicable diseases, for individuals and health systems.

2 As with general health, oral health deteriorates with decreasing socio-economic status. The disparities are visible as people along a declining social gradient visit the dentist less often, have fewer fillings, more missing teeth, higher tobacco consumption, higher rates of oral cancer, higher rates of caries and untreated decay, and higher rates of gum disease than those with higher socio-economic status. These differences are seen both within and between countries.¹

3 Poor oral health has significant downstream consequences. For example, a study in the American Journal of Public Health² found that children with poorer oral health status were more likely to experience dental pain, miss school and perform poorly in school.

4 In New Zealand, the burden of poor oral health remains inequitable and is costly to individuals, the health system and society. Despite improvements in oral health over the last 30 years, tooth decay remains the most common disease among both children and adults. Māori and Pacific adults and children and those living in areas of high deprivation have significantly higher rates of tooth decay and poorer oral health than the general population. In 2013 more than 40 percent of all five year olds, and more than 60 percent of Māori and Pacific five year olds, had already experienced tooth decay. The Well Child / Tamariki Ora Quality Improvement Framework reports that these same children, and children in high deprivation areas, are also likely to have significantly lower levels of: newborn enrolment with primary care services; contact with Well Child services; enrolment with child oral health services; and completion of the B4 School Check. The 2013/14 New Zealand Health Survey reported that 35,000 children aged 1-14 years had had teeth extracted in the last 12 months due to tooth decay. Māori children were 1.6 times more likely than non-Māori to have had a tooth extracted in the last 12 months.

5 Tooth decay is one of the three leading causes of potentially avoidable hospitalisations among children with about 2,900 children aged 0 to 4 years, and

¹ FDI World Dental Federation, Geneva. Oral Health Worldwide

nearly 3,300 children aged 5 to 9 years being admitted in 2011/12 for the treatment of tooth decay and associated infection. The cost of such treatment under general anaesthetic is estimated to be around $4,000 per case.

**The response through treatment services and health promotion**

6 The Ministry of Health has a range of treatment and health promotion strategies in place for improving oral health outcomes and reducing oral health inequalities. Over the past six years, there has been a significant reinvestment in Community Oral Health Services (COHS). The new COHS infrastructure operates from 177 fixed clinics and 169 mobile clinics operating from 1263 sites around the country.

7 There are encouraging signs of improvement in child oral health outcomes from the reinvestment programme. Between 2005 and 2013, the proportion of five-year-olds free of tooth decay (caries-free) increased from 52 percent to 57.5 percent and the proportion of children caries-free at school year 8 increased from 44 to 54 percent. The proportion of Māori children who were caries-free at age five improved from 30 percent to 37 percent. In 2013, 73 percent of pre-schoolers were enrolled in the COHS, compared with 49 percent in 2009. In 2013, 74 percent of adolescents (school year 9 up to their 18th birthday) were seen by publicly-funded dental services, mostly provided by private dentists contracted by DHBs.

8 Early work is under way to implement a nationwide oral health promotion initiative targeting pre-schoolers and their families using funding appropriated in Budget 2014. The initiative will provide free toothbrushes and fluoride toothpaste to pre-schoolers and their families as well as delivering supportive messaging about maintaining good oral health appropriate for all age groups. Māori, Pacific and low income pre-schoolers are priority groups for this initiative.

9 Treatment services and health promotion activities are just two of the interventions that are possible, and fluoridation is another. Any improvements to oral health status would support the Government’s Health targets and other initiatives to improve participation in education and employment.

**Fluoride levels and fluoridation coverage in New Zealand**

10 Natural fluoride levels in New Zealand water supplies vary but are generally low compared with other countries, at less than 0.2 parts per million (ppm, equivalent to 0.2mg/L). In areas rich in fluoride-containing minerals, well water may contain up to about 10ppm. The World Health Organisation (WHO) reports naturally-occurring fluoride in drinking-water at less than 0.2ppm in water-supplies in the Netherlands and Canada, 2ppm in some US water supplies and as high as 8-9ppm in groundwater supplies at some localities in a number of countries. The Ministry of Health recommends adjusting fluoride levels to between 0.7 and 1.0ppm in drinking-water as the most effective and efficient way of preventing dental decay. This is in line with WHO guidelines.

11 Water fluoridation coverage in New Zealand is much lower than it could be. Public drinking-water supplies serve 3.8 million New Zealanders, or about 85 percent of the population. Of those on public water supplies, about 60 percent (or 54 percent of the total population) receive fluoridated water. Table 1 shows the total New Zealand population currently covered by water fluoridation, and the potential for an increase in coverage if all drinking-water supplies servicing over 1000 people were fluoridated.

Table 1: Potential for increase in water fluoridation coverage in New Zealand

<table>
<thead>
<tr>
<th>Drinking-water supply category</th>
<th>Total population provided fluoridated water</th>
<th>Total increase on current level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>2,272,832</td>
<td>-</td>
</tr>
<tr>
<td>If all communities with</td>
<td>3,726,922</td>
<td>+1,454,090</td>
</tr>
</tbody>
</table>
The large proportion of the population not having access to fluoridated drinking water contributes to oral health inequalities among regions and ethnic groups. Public health experts argue that one of the underlying causes of the disparity in oral health between Māori adults and children and the general population is lower access to fluoridated drinking water. Māori are more likely to live in unfluoridated areas (Northland, Onehunga, Rotorua, Wairoa, Tairawhiti and other rural or remote areas) than non-Māori.

International context

Water fluoridation has been endorsed by the World Health Organization (WHO) and a number of international health authorities as the most effective public health measure for the prevention of dental decay. The US Centers for Disease Control and Prevention have recognised water fluoridation as one of the 10 great public health achievements of the twentieth century. There is a large body of evidence about the safety, efficacy and cost-effectiveness of water fluoridation, and this underpins the position of expert groups overseas and in New Zealand.

Water fluoridation has been practised internationally for over 60 years. Around 30 countries have fluoridated their water supplies, serving an estimated 370 million people. In addition, more than 50 million people drink water that is naturally fluoridated at or near the optimal level. In Australia, prevention of tooth decay through the extension of fluoridation to all communities with populations of 1000 or more was a major strategy under the National Oral Health Plan 2004-2013. Around 90 percent of Australians have access to fluoridated drinking water – an increase from 70 percent in 2006. (See Appendix One for more information on fluoridation in other countries).

Safety and efficacy of water fluoridation

The safety and efficacy of water fluoridation has been evaluated many times, and systematic reviews consistently find that it prevents and reduces dental decay and does not cause harmful health effects. The study published by the Cochrane Collaboration in June 2015, found that:

“The introduction of water fluoridation resulted in a 35 percent reduction in decayed, missing or filled baby teeth and a 26 percent reduction in decayed, missing or filled permanent teeth. It also increased the percentage of children with no decay by 15 percent. These results indicate that water fluoridation is effective at reducing levels of tooth decay in both children’s baby and permanent teeth”.

WHO and other international health bodies have identified water fluoridation as the most effective public health measure for reducing the burden of tooth decay, by preventing it and reducing its severity in affected individuals, and by allowing all of the population served to access the benefits of fluoride.

Data from the 2009 Oral Health Survey indicate New Zealand children and adolescents living in fluoridated areas had, on average, 40 percent less tooth decay than their peers living in non-fluoridated areas.

Public Health England, which has a statutory role in monitoring the effects of water fluoridation on health, found that in the fluoridated areas of England there were 45

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percent fewer hospital admissions of children aged one to four for dental caries (mostly for extraction of decayed teeth under a general anaesthetic) than in non-fluoridated areas.  

19 In 2014 the Prime Minister’s Chief Science Advisor and the Royal Society of New Zealand, assisted by a panel of experts, conducted a systematic analysis of the local and international scientific evidence for and against the efficacy and safety of fluoridation of public water supplies. The report, which was peer reviewed by appropriate international experts, concluded as follows.

“There is compelling evidence that fluoridation of water at the established and recommended levels produces broad benefits for the dental health of New Zealanders. In this context it is worth noting that dental health remains a major issue for much of the New Zealand population, and that economically and from the equity perspective fluoridation remains the safest and most appropriate approach for promoting dental public health.

The only side effect of fluoridation at levels used in NZ is minimal fluorosis, and this is not of major cosmetic significance. There are no reported cases of disfiguring fluorosis associated with levels used for fluoridating water supplies in New Zealand. The use of fluoridated toothpastes does not change these conclusions or obviate the recommendations.

Given the caveat that science can never be absolute, the panel is unanimous in its conclusion that there are no adverse effects of fluoride of any significance arising from fluoridation at the levels used in New Zealand.”

Cost-effectiveness of water fluoridation

20 Fluoridation of a water supply incurs modest costs, and has benefits that stretch into the future, in that it effectively averts both decay and associated dental costs. Cost-effectiveness analyses vary in the assumptions and measures they employ. These include:

- number and size of water treatment plants and population of communities being supplied
- costs for water treatment plant maintenance
- repair and replacement (eg 15 year lifespan)
- time span of uninterrupted supply of fluoridated water (eg over 30 years)
- the discount rate used (between 3-7 percent)
- inclusion versus exclusion of dental savings/costs averted for adults after a specified age.

New Zealand evaluations

21 The cost-effectiveness of water fluoridation in New Zealand was evaluated in 1999. The study assumed uninterrupted supply of fluoridated water over the years 2000-2030, a discount rate of 5 percent, a Māori population proportion of 15 percent, and no benefits of fluoridation after age 34 years nor cost savings after age 45 years (because of lack of quantitative data on this). Water fluoridation was found to be very cost-effective (dental cost savings exceeded water fluoridation costs) for communities above about one thousand people. This was still the case when different assumptions were applied (a higher discount rate, more injection sites, Māori being a larger

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proportion of the population). The authors noted that water fluoridation may be cost-effective even for smaller communities, depending on how much a prevented decayed tooth surface is valued.

In 2012, the National Fluoride Information Service reviewed nine economic evaluations undertaken between 2001 and 2012 (a period of increased availability of fluoride in all forms) in countries similar to New Zealand. The reviewers undertook a sensitivity analysis to compare the impact of the different assumptions used across the studies. All nine evaluations reported a cost saving from water fluoridation for communities of more than 1000 people. The review concluded that water fluoridation remains a cost-effective oral public health intervention in the New Zealand context, including for reduction of dental decay in populations such as Māori and low income groups.

Cost-benefit of water fluoridation

In 2014 the Ministry of Health commissioned an updated review of the costs and benefits of water fluoridation in the New Zealand context. The review by the Sapere Research Group, focuses on the national cost-effectiveness and cost-benefit of water fluoridation. The report confirms findings that water fluoridation is materially cost-saving for communities of more than 1000 and possibly also for smaller populations.

The Sapere report estimates that extending water fluoridation to those areas that do not currently have fluoridation would be associated with net savings of over $600 million over twenty years, with most of the savings to consumers and a small amount to Vote Health. This estimate takes into account the lower cost-effectiveness of fluoridating water at the smaller water treatment plants which represent a greater proportion of the currently non-fluoridated water supplies. The conclusion that fluoridation and extended fluoridation would result in net savings was shown to be robust under a range of assumptions.

The results of Sapere’s closer analysis of smaller treatment plants suggest that water fluoridation at even minor water treatment plants (serving a population of between 500 and 5,000) can result in net savings on average. There is some uncertainty as to whether every treatment plant in this range can adopt fluoridation cost-effectively. Some of the smaller plants are likely to require further economic evaluation on a case-by-case basis.

Sapere estimates that extending fluoridation to the rest of New Zealand’s networked water supplies would result in 4,400 to 6,850 QALYs gained over twenty years, with a proportionately larger benefit to Māori and the most deprived communities. Extending fluoridation to the rest of New Zealand’s networked water supplies is expected to result in over $5 million in savings for each million dollars invested.

Many intangible benefits from averted tooth decay are difficult to quantify and have not been included in cost-benefit analyses. These include the positive impact on general health, fewer days lost at school or work, better academic performance, reduced pain and improved social interactions. These are represented by the proxy of averted decayed surfaces.

Distribution of benefits

The Wright et al cost-effectiveness study (see above) concluded that where the community has a substantial proportion of Māori, a socio-economic status lower than average, or a high proportion of children and young people (aged 1-20 years) the economic argument is particularly persuasive. Another way to express this point is that water fluoridation is especially beneficial for people who are disadvantaged in terms of socio-economic or health status.

The findings of the Sapere report suggest that for people living in areas with fluoridated drinking-water there is a:

- 40 percent lower lifetime incidence of tooth decay among children and adolescents
- 48 percent reduction in hospital admissions for the treatment of tooth decay among children aged 0 to 4 years
- 21 percent reduction in tooth decay among adults aged 18 to 44 years
- 30 percent reduction in tooth decay among adults aged 45 years and over.

Fluoridation under current arrangements (local authority decision-making)

Roles

30 Local authorities fund drinking-water supplies from rates and they are responsible for decisions on fluoridation.

31 The Ministry of Health has no direct role in the decision-making process on water fluoridation. It reviews the literature on the safety and effectiveness of fluoridation of water supplies in New Zealand and overseas and actively supports local authorities looking to establish fluoridation schemes in their areas. It does this by providing information on the benefits of fluoridation and by making submissions during the public consultations carried out by local authorities.

32 The Ministry of Health also provides financial assistance with the set-up costs of fluoridation systems. Priority is given to regions that cover populations of high need, areas with particular oral health problems and/or to councils outside the main urban areas. To date, uptake of the subsidy has been low. Since 2007, five district councils have received subsidies ranging from $49,000 to $291,000. The Ministry of Health has also recovered funding from one of those councils when it ceased fluoridation two years later.

Current level of coverage

33 As at December 2014, 27 out of 66 territorial authorities were fluoridating their local drinking-water supply. This means that approximately 54 percent of the total population is receiving fluoridated water. This level of coverage has not increased over the last 15 years. A number of major cities and towns do not fluoridate their water supplies, including Whangarei, Rotorua, Tauranga, Whanganui, New Plymouth (ceased in 2011), Napier, Nelson, Blenheim, Christchurch and Timaru. The map in Appendix Two shows fluoridation status across the country.

Fluoridation an increasingly contentious issue for local authorities

34 Fluoridation has become an increasingly contentious issue for local authorities, because of active lobbying and court action against councils by anti-fluoridation groups and controversy at local body elections and around referendums.

35 A number of challenges in the High Court have been brought against local authorities that have adopted water fluoridation, notably:

- *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395

36 These cases tested both the legality of fluoridation programmes and councils’ decision-making processes where there had been a decision to start or recommence such programmes. In particular they considered the claims that:

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water fluoridation programmes were an unjustified breach of the right to refuse medical treatment under section 11 of the New Zealand Bill of Rights Act and the Council had failed to meet the obligations under Section 5 of the Act (ie, that any curtailment of human rights is demonstrably justified in a free and democratic society).

In rejecting the claims, the High Court found that fluoridation is not a medical treatment for the purposes of section 11 of the Bill of Rights Act; that a breach of section 11 requires a “direct interference with the body or state of mind of the individual”; and that section 11 does not cover public health interventions delivered to the population at large or inhabitants of a particular locality. It also found that, even if water fluoridation did engage section 11 of the Bill of Rights Act, councils’ power to fluoridate water is a justified restriction of the right to refuse medical treatment – because the benefits of fluoridation far outweigh its risks.

While the High Court found in favour of the local authorities in each of these cases, none of the Court’s decisions finally rule on the substantive merits of fluoridation. The issue therefore remains open for challenge by fluoride opponents. Councils find that they cannot make a decision “once and for all” but face the prospect of having to undertake further public consultations and to revisit decisions to fluoridate. They increasingly take the view that fluoridation is a public health issue that belongs in the Health sector. At the 2014 conference of Local Government New Zealand, local authorities called for either the Director-General of Health or district health boards to take responsibility for decisions on fluoridation.

The National Fluoridation Information Service’s Environmental Scan, referenced above, commented that:

“Councils (particularly those with current fluoridation programmes) are increasingly advocating that either DHBs or central government should have responsibility for decision-making about fluoridation, rather than local authorities. Key reasons are frustration at the time taken up by the issue, the divisive nature of the issue, and the expense of legal challenges currently being borne by councils. For the same reasons, some councils in un-fluoridated areas are shying away from even opening the issue for discussion.”

Policy objectives

The overarching policy objective is to make further improvements in oral health status and to reduce disparities in oral health status between groups and communities.

Authoritative basis for this regulatory impact analysis

The proposal supports Good Oral Health for All, for Life: The Strategic Vision for Oral Health in New Zealand, in particular:

- Action Area 2: Reduce inequalities in oral health outcomes and access to oral health services

Regulatory impact analysis

The model of decision-making around water fluoridation has a major influence on national water fluoridation coverage and therefore this is a major feature of the options outlined below. The options for decision-making range along a continuum from the status quo to a requirement in legislation to fluoridate drinking-water. Six options are described and each is assessed in terms of the criteria in the tables that follow.
Identification of policy options

Option 1: Maintaining the status quo: local authority decision-making

Description

Under the status quo, decision-making would remain the responsibility of local authorities, who would continue to set fluoridation requirements for water-suppliers, following local consideration of the issue.

Table 2: Assessment of Option 1, Status quo (local authority decision-making)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of alignment with criteria</th>
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</thead>
<tbody>
<tr>
<td>Improves oral health status and reduces disparities?</td>
<td>The status quo has not been effective at extending fluoridation coverage, which has remained static at around 54 percent of the population for 15 years or so. This is unlikely to change under the status quo. There is likely to be no improvement in oral health status – and health status more broadly – for the remainder of the population who do not have access to fluoridated water. The status quo has no impact on the disproportionate burden of ill health for the most disadvantaged groups in society.</td>
</tr>
<tr>
<td>Decisions informed by scientific evidence?</td>
<td>Although information on the scientific evidence in support of fluoridation is available to local authorities and their communities, they have had difficulty weighing and assessing conflicting advice about the usefulness and safety of fluoridation. The scientific evidence has been outweighed by councils’ concerns about the level of controversy surrounding the issue and potential legal disputes. Some councils have considered the fluoridation issue a number of times in recent years and have reversed their position. The current arrangements mean that councils will continue to be asked to revisit their decisions and there is no certainty that their current policy (either for or against fluoridation) would continue.</td>
</tr>
<tr>
<td>Decisions informed by local health priorities and circumstances?</td>
<td>Although local authorities have responsibility for some environmental health and public health issues, their current role in fluoridation is not linked to local (DHB) health priorities.</td>
</tr>
<tr>
<td>Costs?</td>
<td>Sapere was not able to clearly isolate the incremental operating costs of adding fluoridation systems from general plant operations. Based on costing information from 17 water treatment plants, Sapere estimates the annual cost of fluoridation for a medium-sized plant serving 5000 – 10,000 people to be in the region of $13,000. There are cost impacts for councils reviewing their position on fluoridation: these relate to referendums on the issue and, for some, the significant costs resulting from legal challenges from opponents of fluoridation.</td>
</tr>
<tr>
<td>Cost-effective?</td>
<td>The status quo is not cost-effective. It is achieving none of the very significant net savings that could result from fluoridation, through reduced treatment costs and savings on reduced absenteeism etc.</td>
</tr>
</tbody>
</table>
Option 2: Status quo plus guidelines

Description

Under this option, non-binding guidelines would be developed and promoted by the Ministry of Health with support from Local Government New Zealand (LGNZ). The guidelines would provide local authorities with advice on:

- when and how to involve DHBs in decision-making on fluoridation
- options for decision-making (e.g., expert advisory panel, poll, referendum)
- use of technical tools such as health impact assessment to evaluate the benefits of fluoridating, or impacts of not fluoridating water in an area
- public consultation and review of public submissions
- issues to be considered when cessation of water fluoridation is proposed
- frequency of review of decisions not to fluoridate water supply
- options for engaging with local opposition to fluoridation.

Central government would bear the cost of guideline development and local authorities would continue to cover community engagement costs and the costs of fluoridation. This option would not require legislative change.

Table 3: Assessment of Option 2, Status quo plus guidelines

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of alignment with criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improves oral health status and reduces disparities?</td>
<td>The development of guidelines would not provide significant new information to local authorities and would be unlikely to lead to any improvement in oral health status for the population who do not have access to fluoridated water.</td>
</tr>
<tr>
<td>Decisions informed by scientific evidence?</td>
<td>As for Option 1. Although information on the scientific evidence in support of fluoridation is available to local authorities and their communities, they have had difficulty weighing and assessing conflicting advice about the usefulness and safety of fluoridation.</td>
</tr>
<tr>
<td>Decisions informed by local health priorities and circumstances?</td>
<td>Although local authorities have responsibility for some environmental health and public health issues, their current role in fluoridation is not linked to local (DHB) health priorities.</td>
</tr>
<tr>
<td>Costs?</td>
<td>As for Option 1, except for the cost of developing and disseminating guidelines on fluoridation for local authorities, estimated at up to $150,000.</td>
</tr>
<tr>
<td>Cost-effective?</td>
<td>The status quo is not a cost-effective option and the provision of guidelines for local authorities would not change this.</td>
</tr>
</tbody>
</table>
Option 3: Financial incentives for water fluoridation

Description

Under this option local authorities would continue to make decisions about water fluoridation and central government would promote water fluoridation by:

- providing incentive payments to encourage local authorities to fluoridate. Incentives would be paid on the basis that, if fluoridation ceased, payments would be recouped on a pro rata basis.
- withholding subsidies and diverting incentive funds to local DHBs if local authorities did not fluoridate. This would be an option only where government already contributes or plans to contribute subsidies (for example, for capital works for small community water supplies).

The costs of the incentives and administration of the incentive scheme would be borne by central government, with the cost depending on the level of incentive provided.

Table 4: Assessment of Option 3, Financial incentives for fluoridation

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of alignment with criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improves oral health status and reduces disparities?</td>
<td>If financial incentives led to an extension of fluoridation coverage, some improvement in oral health status could be expected. Because the cost of fluoridation is not local authorities’ primary concern about fluoridation, it is uncertain what effect (if any) financial incentives would have on councils’ decision-making.</td>
</tr>
<tr>
<td>Decisions informed by scientific evidence?</td>
<td>As for Options 1 and 2. The provision of financial incentives for local authorities would not change the status quo as it relates to the scientific evidence to support fluoridation.</td>
</tr>
<tr>
<td>Decisions informed by local health priorities and circumstances?</td>
<td>Although local authorities have responsibility for some environmental health and public health issues, their current role in fluoridation is not linked to local (DHB) health priorities.</td>
</tr>
<tr>
<td>Costs?</td>
<td>As for Options 1 and 2, with the addition of the cost to central government of the incentive scheme and its administration. Further work on the costs of the incentive scheme would be required, but see comments on cost-effectiveness below.</td>
</tr>
<tr>
<td>Cost-effective?</td>
<td>Initial work on this option suggests that there may be only limited uptake of any financial incentives offered to local authorities, because the costs related to fluoridation are not the main driver of decision-making. Without further work on the likely costs to Government and uptake by local authorities, it seems unlikely that this option would be any more cost-effective than Options 1 and 2.</td>
</tr>
</tbody>
</table>

Comment

Significant further work would be required on the detail of an incentive scheme in order to assess the costs and benefits of this option. The work would need to assess the risk that the cost of fluoridation would shift from water suppliers to central government. For example, the incentive scheme would need to reflect the actual cost of fluoridating if it was to achieve buy-in from local authorities (given the low uptake of existing subsidies for the set-up costs of fluoridation). The work would also need to consider whether local authorities currently fluoridating community water supplies should receive incentive payments to continue to do so, given they are already making a positive contribution towards health outcomes in their communities.
Option four: Decision-making by district health boards

Description

47 This option would involve DHBs directing drinking-water suppliers to fluoridate water supplies, following an assessment of the circumstances related to any particular water-supply and the oral health status of the local community. It would require an amendment to the Drinking Water provisions in Part 2A of the Health Act 1956 and consequential amendments to the New Zealand Public Health and Disability Act 2000.

48 The Ministry of Health would develop a regulatory framework to support DHBs to take a structured and nationally consistent approach. This would require the use of standard tools to undertake:

- health status and needs assessment
- evaluation of water quality
- evaluation and application of scientific evidence
- cost benefit analysis taking account of local conditions
- decision-making criteria, including consultation requirements.

49 The role of the DHB would be to collect local data; apply the national tools to generate information about identified water supplies and the affected population groups/communities; and to make directions on the basis of this analysis. This approach would have the dual benefit of providing strong national supports for DHBs and would also limit judicial review to a DHB’s analysis of local data and its application within a regulated set of tools and decision-making criteria.

50 DHB Public Health Units would monitor compliance with directions to fluoridate through the existing system of drinking-water assessors and health protection officers.

Table 5: Assessment of Option 4, Decision-making by district health boards

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of alignment with criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improves oral health status and reduces disparities?</td>
<td>Decision-making by DHBs is expected to result in a significant increase in the population having access to fluoridated water. There is potential to extend coverage to an additional 1.45 million people, and Option 4 could achieve this. The Sapere report estimates that extending fluoridation to the rest of New Zealand’s networked water supplies would result in 4,400 to 6,850 QALYs gained over twenty years, with a proportionately larger benefit to Māori and the most deprived communities. Fluoridation coverage could increase relatively rapidly under this option, compared to the status quo. The regulatory framework that is proposed under this option would support the extension of fluoridation. It would also specify the limited circumstances under which a DHB might need to review its decisions on fluoridation.</td>
</tr>
<tr>
<td>Decisions informed by scientific evidence?</td>
<td>The scientific evidence on fluoridation would be a more significant factor in decision-making under this option than it is under the status quo. DHBs have a responsibility under national service specifications to promote water fluoridation.</td>
</tr>
<tr>
<td>Decisions informed by local health priorities and circumstances?</td>
<td>DHBs have a statutory mandate to improve, promote and protect the health of people and communities and to reduce health outcome disparities between various population groups. If DHBs could make decisions on fluoridation, as proposed under this option, they would have an additional public health intervention at their disposal and would link fluoridation to local health needs and priorities.</td>
</tr>
<tr>
<td>Costs?</td>
<td>The Sapere report estimates the total additional direct costs of extending fluoridation to populations not receiving fluoridated water to be $144 million over 20 years. This cost comprises around $48 million over 20 years related to upfront investment in capital works, and around $96 million over 20 years for the operational costs of water fluoridation.</td>
</tr>
<tr>
<td>Criteria</td>
<td>Level of alignment with criteria</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td></td>
<td>The one-off cost of developing and implementing the legislative changes is estimated to be in the range of $0.25m - $0.4m (excl GST). Under this option, administration costs may be similar to the status quo because individual DHBs would be involved in consultation and planning related to the decision to fluoridate water supplies. If DHBs were challenged on their decision-making process through judicial review, they could incur significant costs. Based on the recent South Taranaki case in the High Court, legal costs could range from $100,000 - $200,000 (excl GST) per challenge.</td>
</tr>
<tr>
<td>Cost-effective?</td>
<td>Extending fluoridation to the rest of New Zealand's networked water supplies is expected to result in over $5 million in savings for each million dollars invested. The Sapere report estimates that extending water fluoridation to those areas that do not currently have fluoridation would be associated with net savings of over $600 million over twenty years with most of the savings to consumers and a small amount to Vote Health. This estimate takes into account the lower cost-effectiveness of fluoridating water at smaller water treatment plants which represent a greater proportion of the currently non-fluoridated water supplies. The conclusion that fluoridation and extended fluoridation would result in net savings was shown to be robust under a range of assumptions.</td>
</tr>
</tbody>
</table>
Option five: Decision-making by the Director-General of Health

Description

51 This option would involve the Director-General of Health directing drinking-water suppliers to fluoridate water supplies, following an assessment of the circumstances related to any particular water-supply and the oral health status of the local community. It would require an amendment to the Drinking Water provisions in Part 2A of the Health Act 1956 and consequential amendments to the New Zealand Public Health and Disability Act 2000.

52 The Ministry of Health would develop a regulatory framework to take a structured and nationally consistent approach to decision-making. This would require the use of standard tools to undertake:

- health status and needs assessment
- evaluation of water quality
- evaluation and application of scientific evidence
- cost benefit analysis taking account of local conditions
- decision-making criteria, including consultation requirements.

53 DHB Public Health Units would monitor compliance with directions to fluoridate through the existing system of drinking-water assessors and health protection officers.

Table 5: Assessment of Option 5, Decision-making by the Director-General of Health

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of alignment with criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improves oral health status and reduces disparities?</td>
<td>Decision-making by the Director-General of Health is expected to result in a significant increase in the population having access to fluoridated water. There is potential to extend coverage to an additional 1.45 million people, and Option 5 could achieve this. The Sapere report estimates that extending fluoridation to the rest of New Zealand’s networked water supplies would result in 4,400 to 6,850 QALYs gained over twenty years, with a proportionately larger benefit to Māori and the most deprived communities. Fluoridation coverage could increase relatively rapidly under this option, compared to the status quo.</td>
</tr>
<tr>
<td>Decisions informed by scientific evidence?</td>
<td>The scientific evidence on fluoridation would be a more significant factor in decision-making under this option than it is under the status quo.</td>
</tr>
<tr>
<td>Decisions informed by local health priorities and circumstances?</td>
<td>If the Director-General of Health made decisions on fluoridation, as proposed under this option, there would only be limited local input on fluoridation. There would also be only limited links between fluoridation decision and other local health priorities.</td>
</tr>
<tr>
<td>Costs?</td>
<td>The Sapere report estimates the total additional direct costs of extending fluoridation to populations not receiving fluoridated water to be $144 million over 20 years. This cost comprises around $48 million over 20 years related to upfront investment in capital works, and around $96 million over 20 years for the operational costs of water fluoridation. The one-off cost of developing and implementing the legislative changes is estimated to be in the range of $0.25m - $0.4m (excl GST). If the Ministry of Health was challenged on its decision-making process under this option, significant costs could result. Based on the recent South Taranaki case in the High Court, legal costs could range from $100,000 - $200,000 (excl GST) per challenge.</td>
</tr>
<tr>
<td>Cost-effective?</td>
<td>Extending fluoridation to the rest of New Zealand’s networked water supplies is expected to result in over $5 million in savings for each million dollars invested.</td>
</tr>
<tr>
<td>Criteria</td>
<td>Level of alignment with criteria</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td></td>
<td>The Sapere report estimates that extending water fluoridation to those areas that do not currently have fluoridation would be associated with net savings of over $600 million over twenty years with most of the savings to consumers and a small amount to Vote Health. This estimate takes into account the lower cost-effectiveness of fluoridating water at smaller water treatment plants which represent a greater proportion of the currently non-fluoridated water supplies. The conclusion that fluoridation and extended fluoridation would result in net savings was shown to be robust under a range of assumptions.</td>
</tr>
</tbody>
</table>
**Option six: A legislative requirement to fluoridate**

**Description**

54 Under this option, the Health Act 1956 would be amended to require drinking-water suppliers to fluoridate all water supplies above a certain threshold (eg supplying 1,000 people or more). A review or appeal process could be included to allow drinking-water suppliers to seek an exemption for a particular water supply if they could demonstrate that it was not practical to fluoridate due to cost or other reasons. The Minister of Health or Director-General of Health could make decisions on these applications.

55 The Public Health Units of DHBs would monitor compliance through the existing requirements for drinking-water supply safety and quality.

Table 6: Assessment of Option 6, A legislative requirement to fluoridate

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of alignment with criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improves oral health status and reduces disparities?</td>
<td>A legislative requirement to fluoridate would result in a substantial increase in the population having access to fluoridated water. This option is likely to achieve a higher level of coverage, and more rapidly, than the other options, with a potential 1.45 million additional people getting access to fluoridated water. The Sapere report estimates that extending fluoridation to the rest of New Zealand’s networked water supplies would result in 4,400 to 6,850 QALYs gained over twenty years, with a proportionately larger benefit to Māori and the most deprived communities. A legislative requirement to fluoridate would be the most effective option for increasing fluoridation coverage, because all water supplies over a certain threshold would be required to be fluoridated. Any exceptions would require approval by the Minister or Director-General of Health.</td>
</tr>
<tr>
<td>Decisions informed by scientific evidence?</td>
<td>A legislative requirement to fluoridate legislation would ensure decisions are made using the best available evidence. Decisions on specific applications from water suppliers for an exemption would be informed by the goal that fluoridation should take place if at all practicable.</td>
</tr>
<tr>
<td>Decisions informed by local health priorities?</td>
<td>As this option would require the fluoridation of all water-supplies (with some exceptions), decisions would not be informed by local health priorities. The basis for any exemption would be practicality or cost rather than consideration of more suitable alternatives to fluoridation for a particular community.</td>
</tr>
<tr>
<td>Costs?</td>
<td>The costs of fluoridation would be higher than the status quo due to greater coverage. The Sapere report estimates the total additional direct costs of extending fluoridation to populations not receiving fluoridated water to be $144 million over 20 years. This cost comprises around $48 million over 20 years related to upfront investment in capital works, and around $96 million over 20 years for the operational costs of water fluoridation. The one-off cost of developing and implementing the legislative changes is estimated to be in the range of $0.25m - $0.4m (excl GST). Once the regime under this option is in place, administration costs would be lower than currently because individual local authorities and DHBs would not be involved in consultation and planning related to the decision to fluoridate water supplies. If the Ministry of Health was challenged on its decision-making process under this option, significant costs could result. Based on the recent South Taranaki case in the High Court, legal costs could range from $100,000 - $200,000 (excl GST) per challenge.</td>
</tr>
<tr>
<td>Cost-effective?</td>
<td>Extending fluoridation to the rest of New Zealand’s networked water supplies is expected to result in over $5 million in savings for each million dollars invested. As outlined under Option 4, the Sapere report estimates that extending water fluoridation to those areas that do not currently have fluoridation would be associated with net savings of over $600 million over twenty years, with most of the savings to consumers and a small amount to Vote Health. This estimate takes into account the lower cost-effectiveness of fluoridating water at smaller water treatment plants which represent a greater proportion of the currently non-fluoridated water supplies. The conclusion that fluoridation and extended fluoridation would result in</td>
</tr>
<tr>
<td>Criteria</td>
<td>Level of alignment with criteria</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td></td>
<td>net savings was shown to be robust under a range of assumptions.</td>
</tr>
<tr>
<td></td>
<td>Option 6 is the most likely to achieve the greatest gains and is also likely to achieve these more rapidly than the other options.</td>
</tr>
</tbody>
</table>
Discussion of options

Policy objective

56 The policy objective is to improve oral health status and reduce the burden and disparities associated with poor oral health. This objective supports the Government’s strategic vision for oral health and, in particular:

- Action Area 2: Reduce inequalities in oral health outcomes and access to oral health services

There is a body of evidence which suggests that poor oral health affects general health and is related to a number of risk factors and determinants that are common to other chronic diseases, particularly cardiovascular diseases, cancer, chronic respiratory diseases and diabetes.

57 Although significant improvements have already been made through health promotion activities and oral health treatment services, there are substantial additional gains to be made through fluoridation. The evidence for improved oral health status and the cost benefits resulting from fluoridation is very solid.

58 The options in this Regulatory Impact Statement cover a broad range of possible responses to the issues of poor oral health status and the poor level of access to fluoridated water for almost half the population.

The three status quo options

59 The first three options are variations on the status quo, where local authorities, who are responsible for drinking water supplies, continue to make decisions on fluoridation. These options are unlikely to increase water fluoridation coverage, which has hovered around the same level for decades. They also provide little certainty about extended fluoridation coverage because a number of local authorities have decided not to fluoridate or have introduced fluoridation and then reversed their decisions, local authorities have difficulty assessing opposing arguments about the safety and usefulness of fluoridation, and decisions by local authorities are being contested frequently. Territorial authorities do not themselves support the status quo, as they consider water fluoridation to be a health issue and best decided by health authorities.

- The status quo is not an effective way of managing and implementing fluoridation policy. It is not achieving the potential benefits (improvements in oral health status and savings) and, based on experience in recent years, is not likely to result in any extension of fluoridation coverage. There is some risk that coverage will contract, if local authorities decide to stop fluoridation. Through LGNZ, they have stated their view that decisions on this issue should be made by the health sector. Under current arrangements, decision-making is not linked to local health priorities.

- The introduction of guidelines would not substantively alter the existing situation and is consequently unlikely to achieve any significant increase in coverage, or the associated health benefits, when compared to Options 4, 5 and 6. This option is unlikely to be effective, or cost-effective.

- The provision of financial incentives for local authorities to fluoridate water supplies may have a small impact on fluoridation coverage. If incentives led to an extension of fluoridation coverage, some improvement in oral health status could be expected. Because the cost of fluoridation is not local authorities’ primary concern about fluoridation, however, it is uncertain what effect financial incentives would have on councils’ decision-making. It seems unlikely, however, that this
option would make any significant change to the status quo, or that it would achieve any notable improvement in fluoridation coverage and oral health status.

As noted earlier, fluoridation has become an increasingly contentious issue for local authorities, because of active lobbying and court action against councils by anti-fluoridation groups and controversy at local body elections and referendums. While the High Court found in favour of the local authorities in each of the recent cases, none of the Court’s decisions finally rule on the substantive merits of fluoridation. The issue therefore remains open for challenge by fluoride opponents. Councils find that they cannot make a decision “once and for all” but face the prospect of having to undertake further public consultations and to revisit decisions to fluoridate. The National Fluoridation Information Service’s Environmental Scan 2013-14 commented that:

“Councils (particularly those with current fluoridation programmes) are increasingly advocating that either DHBs or central government should have responsibility for decision-making about fluoridation, rather than local authorities. Key reasons are frustration at the time taken up by the issue, the divisive nature of the issue, and the expense of legal challenges currently being borne by councils. For the same reasons, some councils in un-fluoridated areas are shying away from even opening the issue for discussion.”

Decision-making by DHBs

Option 4 – transferring decision-making to DHBs – would address most of the shortcomings of the status quo options, that is –

- the scientific evidence for fluoridation would be a more prominent factor in decision-making than it is at present
- decisions would be linked to local health priorities
- fluoridation coverage would be extended significantly
- significant improvements in oral health status would result
- this approach would be cost effective and would lead to substantial net savings.

There is a risk that DHBs would face the same opposition to their fluoridation proposals as local authorities. The boards of DHBs would face the same scrutiny that territorial local authorities have experienced at election time and the election of anti-fluoride advocates could lead to a stalemate or a reversal of fluoridation in some areas. Secondly, DHB decision-making would not rule out a series of locally-fought campaigns over fluoridation. The great majority of DHBs would need to consider introducing or extending fluoridation in their areas.

The regulatory framework that is proposed under Option 4 would help to manage these risks but it would not remove them altogether. While DHBs would have to respond to the critics of fluoridation and face legal challenges to their decisions, High Court rulings in recent cases have reduced the grounds available for future challenges.

The discussions we have had with DHBs suggest – because of boundary overlaps with territorial local authorities – that DHBs would work together to plan and coordinate the extension of fluoridation. This could mean that the unfluoridated areas in any region become fluoridated as part of a regional initiative. It also means that, with DHB decision-making, the extension of fluoridation could occur relatively rapidly.

The DHB option represents a significant advance on the current arrangements through territorial local authorities and is likely to achieve the potential health gains that have been identified. The DHB view is that fluoridation is closely related to their role and that they should take on the decision-making role. The regulatory framework outlined above would support DHBs and would ensure that the process is more robust than it is at present. While the risk of legal challenge would remain, it is a feature of the status quo.
Option 5 would address some of the shortcomings of the status quo options, that is –

- the scientific evidence for fluoridation would be a more prominent factor in decision-making than it is at present
- fluoridation coverage would be extended significantly
- significant improvements in oral health status would result
- this approach would be cost effective and would lead to substantial net savings.

However the significant disadvantage is that there would only be limited local input on fluoridation.

There would also be only limited links between fluoridation decision and other local health priorities. It can be argued that fluoridation is just one element of a strategy to improve oral health and that the DHB is in the best position to implement a comprehensive approach. There may be circumstances where fluoridation is not the best intervention for a particular community. The DHB is in the best position to assess this and to tailor a response. Option 5 would centralise the decision on fluoridation and separate it from local action on oral health.

The Ministry of Health would also be required to establish a new function to manage the decision-making process and to work with DHBs and local authorities. This is not deemed as efficient as Option 4, as DHBs already have established relationships with local authorities.

A legislative requirement to fluoridate

Option 6 would address the shortcomings of the status quo options, just as Options 4 and 5 would. It could lead to a rapid extension of fluoridation and result in earlier improvements in oral health than under the other options.

It would also transfer the risks identified under Option 4 by locating decision-making on exceptions with the Director-General of Health or the Minister of Health. While decisions to fluoridate water supplies could still be contested and legal challenges would still be likely, the Director-General or the Minister would be the respondent to the court action rather than, potentially, each of the 20 DHBs in the context of many separate decisions.

The disadvantage of Option 6 is the absence of a link between local health priorities and decisions on fluoridation. It can be argued that fluoridation is just one element of a strategy to improve oral health and that the DHB is in the best position to implement a comprehensive approach. There may be circumstances where fluoridation is not the best intervention for a particular community. The DHB is in the best position to assess this and to tailor a response. Option 6 would centralise the decision on fluoridation and separate it from local action on oral health.

Community views on fluoridation

Under Options 4, 5 and 6, there would be less consultation on the community’s preferences about fluoridating the water-supply, or about their views on the merits of fluoridation. Under Option 4, DHBs might seek public comment as part of a broader planning process. Under Options 5 and 6, the Ministry of Health would seek the views of local authorities and DHBs on technical issues related to the fluoridation of particular water-supplies. Limited consultation is justified because the scientific evidence in support of fluoridation is very solid and there is a strong case for intervening: the potential benefits go beyond oral health and have much broader positive effects, especially for more disadvantaged groups and communities, on health and on participation in education and employment. It is also apparent from experience under the current arrangements that local communities cannot make good decisions on this issue.
Table 7: Fluoridation options, summary of assessment against criteria

<table>
<thead>
<tr>
<th></th>
<th>1: Status quo</th>
<th>2: Status quo plus guidelines</th>
<th>3: Financial incentives for TLAs</th>
<th>4: Decision-making by DHBs</th>
<th>5: Decision making by Director-General of Health</th>
<th>6: Mandatory fluoridation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Improves oral health status and reduces disparities?</strong></td>
<td>No</td>
<td>Unlikely</td>
<td>Only limited improvement</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Decisions informed by scientific evidence?</strong></td>
<td>To a limited extent</td>
<td>To a limited extent</td>
<td>To a limited extent</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Decisions informed by local health priorities and circumstances?</strong></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Costs?</strong></td>
<td>Operational costs of managing fluoridation. Consultation and litigation costs</td>
<td>Operational costs of managing fluoridation. Consultation and litigation costs</td>
<td>Incentive scheme to be costed. Limited uptake expected.</td>
<td>$48 million capital investment + $96 million over 20 years to extend coverage</td>
<td>$48 million capital investment + $96 million over 20 years to extend coverage</td>
<td>$48 million capital investment + $96 million over 20 years to extend coverage</td>
</tr>
<tr>
<td><strong>Cost-effective?</strong></td>
<td>No</td>
<td>No</td>
<td>Unlikely</td>
<td>$5m+ savings per $1m invested $600m net savings/20yrs (mostly to consumers)</td>
<td>$5m+ savings per $1m invested $600m net savings/20yrs (mostly to consumers)</td>
<td>$5m+ savings per $1m invested $600m net savings/20yrs (mostly to consumers)</td>
</tr>
</tbody>
</table>

**Conclusion**

Preferred approach: transfer decision-making from territorial local authorities to DHBs

74 Table 7 sets out the level of alignment of each of the potential policy options with the Ministry of Health’s policy objectives. While Options 4, 5 and 6 deliver a relatively high level of alignment with the objectives, there are trade-offs required between objectives when it comes to selecting the preferred option, the one that delivers the greatest net benefits to society.

75 Options 4, 5 and 6 address most of the short-comings of the status quo. Option 4 would also link decisions about fluoridation to local health priorities and the needs of the affected communities. Options 4, 5 and 6 are likely to achieve the same benefits in terms of improvements in oral health status and net savings, although it may take longer to do so for Options 4 and 5. There are risks of controversy and legal challenge associated with Options 4, 5 and 6 but they are more significant for Options 4 and 5 and they cannot be avoided altogether.

76 Options 5 and 6 would focus any legal challenge at the centre – through either the Director-General of Health or the Minister of Health – and this may lead to a more rapid settlement of issues related to fluoridation. The disadvantage of Options 5 and 6 is the separation of fluoridation from local health priorities and local oral health initiatives in particular. There may be very little difference between Options 4, 5 and 6 in relation to the extension of fluoridation and the achievement of improvements in oral health status and the associated net savings.
Deciding on a preferred option depends on the weight that is given to the relative strengths and risks associated with DHB decision-making and a legislative requirement to fluoridate. In our view, the benefits of linking fluoridation with local action to achieve health gains outweigh the advantages of the legislative option. The DHB option represents a significant advance on the current arrangements through territorial local authorities. The Ministry of Health notes the DHB view that fluoridation is closely related to their role. The regulatory framework outlined above would support DHBs and would ensure that the process is more robust than it is at present. It also notes that the risk of legal challenge would remain with both of these options, but that is a feature of the status quo. On balance, the Ministry of Health’s preference is to transfer decision-making to DHBs.

Following Cabinet’s approval of the approach officials have outlined, the Ministry of Health would undertake further work with DHBs and local authorities on the details of the regime for DHB decision-making.

Consultation

The Ministry of Health consulted the following agencies as it developed a policy proposal for Cabinet: Ministry for Business, Innovation and Employment, Office for Disability Issues, Department of Internal Affairs, Ministry of Justice, Te Puni Kokiri, Ministry for Pacific Island Affairs, Ministry of Social Development, Ministry for Women and The Treasury. The Department of Prime Minister and Cabinet was informed.

There has not yet been any consultation with representatives of territorial local authorities or the general public. While this has constrained the development of this Regulatory Impact Statement, it has been an appropriate course of action in this instance, as the Government has not yet indicated whether it would consider transferring decision-making responsibility from territorial local authorities. The Ministry of Health would consult DHBs and local authorities following Cabinet’s decision. Wider consultation on the proposal would occur through the Select Committee process following the introduction of an amendment bill.

Consultation with Māori

Te Ao Marama (the New Zealand Māori Dental Association) strongly supports community water fluoridation and has provided support to the Ministry policy and fluoridation debates throughout the country. Some Māori support fluoridation because of the positive health impacts while some others oppose it on the grounds that fluoridated water is no longer pure (eg, that it conflicts with the concept of waiora – the water of life). Engagement and consultation with Māori is critical whichever option is chosen.

Implementation, monitoring, evaluation and review

Implementation

Officials estimate that, if Cabinet agrees to this proposal early in 2016, amending legislation could be introduced by the end 2016. If legislation was passed before the end of the parliamentary term in 2017, it could come into force from April or June 2018. DHBs would then need to undertake the necessary planning before new fluoridation schemes could be implemented. It is likely, therefore, that DHB decision-making on fluoridation – and subsequent implementation by local authorities – could lead to an extension of fluoridation coverage from calendar year 2019.

Monitoring, evaluation and review

The Ministry would monitor implementation of the law change and subsequent changes in access to fluoridated water supplies. This would involve monitoring data about the number of fluoridated water supplies and the proportion of the population having access to fluoridated water. It would include ongoing review of the oral health status of the population as a whole and of groups who have been disadvantaged
when compared to the general population. The Ministry would also assess the
effectiveness of the new arrangements in improving fluoridation coverage and
achieving the expected health gains and savings.

The Ministry would report to the Minister of Health and, if indicated, to Cabinet. The
effectiveness of the policy approach would be monitored and reviewed as
appropriate.
Fluoridation in overseas jurisdictions

Around 30 countries worldwide have intentionally fluoridated water supplies, serving an estimated 370 million people. In addition, more than 50 million people drink water that is naturally fluoridated at or near the optimal level. Factors that influence the cost-effectiveness and implementation of fluoridation include:

- size of community (the greater the population, the lower the per capita cost)
- number of fluoride injection points in a water supply system (the fewer injection points the easier it is to implement fluoridation)
- amount and type of system feeder and monitoring equipment used
- amount and type of fluoride chemical used, its price and its costs of transportation and storage
- expertise of personnel at the water point.

There are a number of countries that do not fluoridate their water supplies. In many parts of the world, fluoridation is not feasible for a number of reasons, such as:

- the lack of a central water supply
- the presence of more urgent health needs
- lack of sufficient funds for capital and maintenance costs
- other technical and political reasons.

Different jurisdictions throughout the world demonstrate different approaches to effecting water fluoridation. This includes legislation at the local, state and national level, with each approach bringing its own complexities. A brief overview of fluoridation for overseas jurisdictions is presented in Table Two and a detailed examination of fluoride implementation for relevant international case studies is presented overleaf.

Australia, the United States and Canada have no federal legislation covering water fluoridation. States have the independence to legislate as their communities see fit. This approach allows territories to choose according to their circumstances and practicality, but local officials are sometimes subject to local pressure based on spurious and incorrect views on water fluoridation. This is evident in Canada where fluoridation coverage is only at 44 percent.

Ireland, Singapore, Hong Kong and Malaysia have national legislation concerning water fluoridation. Singapore and Hong Kong both have achieved 100 percent coverage as they both have a single water supplier and small territories which make fluoridation coverage and uniformity much easier. Ireland and Malaysia have struggled to achieve 100 percent coverage even though water fluoridation is nationally mandated. In Ireland there is a growing opposition movement that focuses its efforts on halting expansion of the fluoridation programme. In Malaysia there are issues with the infrastructure of the water supply system, with some water suppliers choosing to cut costs rather than expanding water fluoridation.

In the United Kingdom, local government makes the decision about water fluoridation. Coverage is only at 11 percent due to a number of issues faced by local government including: lack of expertise and funding to fulfil the requirements of consultation. In the United Kingdom private water companies normally supply more than one local authority which further complicates the issue of fluoridation.

In some cases there is no legislation involved. For example, neither South Australia nor the Australian Northern Territories have legislation on water fluoridation but have 90 percent and 70 percent water fluoridation coverage respectively. In both states, the Departments of Health strongly support water fluoridation through position statements and in strategic documents.
<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Instruments allowing water fluoridation</th>
<th>Population coverage (%)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>N/A</td>
<td>18M, (80%)</td>
<td>No Federal legislation. The Department of Health Australia supports fluoridation.</td>
</tr>
<tr>
<td>ACT</td>
<td>State legislation</td>
<td>0.38M (100%)</td>
<td>Small size of Territory. Single water supplier.</td>
</tr>
<tr>
<td>VIC</td>
<td>State legislation</td>
<td>5.2M (90%)</td>
<td>Secretary to the Department of Human Services has the power to direct water authorities to commence water fluoridation.</td>
</tr>
<tr>
<td>NSW</td>
<td>State legislation</td>
<td>7.2M (96%)</td>
<td>A water utility cannot start fluoridation of public water supplies without an approval or direction from the Director General of NSW Health.</td>
</tr>
<tr>
<td>QLD</td>
<td>Local legislation</td>
<td>3.7M (80%)</td>
<td>Was made mandatory in 2008 and reversed in 2012.</td>
</tr>
<tr>
<td>SA</td>
<td>No legislation</td>
<td>1.5M (90%)</td>
<td>Public Health South Australia supports water fluoridation and is looking into expanding coverage.</td>
</tr>
<tr>
<td>NT</td>
<td>No legislation</td>
<td>0.17M (70%)</td>
<td>A position statement has been put out by the Department of Health.</td>
</tr>
<tr>
<td>WA</td>
<td>State legislation</td>
<td>2.3M (92%)</td>
<td>Advisory Committee for the Fluoridation of Public Water Supplies advises and makes written recommendations to the Minister who makes the final decision.</td>
</tr>
<tr>
<td>TAS</td>
<td>State legislation</td>
<td>0.42M (83%)</td>
<td>Fluoridation committee provides a recommendation to the Health Minister, who makes the final decision.</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Local legislation</td>
<td>5.7M (11%)</td>
<td>Similar to NZ now, previously a health authority level decision. Private water companies.</td>
</tr>
<tr>
<td>Ireland</td>
<td>National legislation</td>
<td>3.2M (73%)</td>
<td>Mandatory. Supported by the Irish Expert Body on Fluorides and Health.</td>
</tr>
<tr>
<td>Israel</td>
<td>National legislation</td>
<td>0 (0)</td>
<td>New Minister of Health banned water fluoridation late in 2014, the Deputy Health Minister announced plans to resume mandatory fluoridation in mid-2015.</td>
</tr>
<tr>
<td>Canada</td>
<td>Local legislation</td>
<td>14.2M (44%)</td>
<td>Health Canada has non-binding guidelines on drinking water quality which includes fluoride.</td>
</tr>
<tr>
<td>USA</td>
<td>Local and state legislation</td>
<td>210M (67%)</td>
<td>The United States is complicated by the many types of relevant legislation, with no Federal legislation.</td>
</tr>
<tr>
<td>Singapore</td>
<td>National legislation</td>
<td>5M (100%)</td>
<td>Small size of Territory, single water supplier, water supply connected to Malaysia.</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>National legislation</td>
<td>7M (100%)</td>
<td>Small size of Territory, single water supplier.</td>
</tr>
<tr>
<td>Malaysia</td>
<td>National legislation</td>
<td>20.7M (75.5%)</td>
<td>Two distinct regions that make up country. Private water companies.</td>
</tr>
<tr>
<td>South Africa</td>
<td>National legislation</td>
<td>0 (0)</td>
<td>Government passed law to begin water fluoridation but has been put on hold with concerns over quality and reliability of water supply generally.</td>
</tr>
</tbody>
</table>
Case studies of fluoridation in other countries

Australia

There is no federal legislation for water fluoridation in Australia. Individual states deal with water fluoridation separately. However, the Commonwealth Department of Health supports water fluoridation and advises states and communities to pursue the practice where practicable. Water fluoridation in the states of New South Wales, Victoria, Tasmania and Western Australia are similar to option four (where the decision is delegated to either the DHB or the Director General) with variances between the states.

The addition of fluoride to public water supplies in NSW is controlled by the NSW Fluoridation of Public Water Supplies Act 1957. The fluoridation of Public Water Supplies Advisory Committee provides the Minister of Health with recommendations for making, altering or repealing any regulation; and recommendations relating to the administration of the Act and proposals for the addition of fluoride to public water supplies. Under the Act a water utility cannot start fluoridation of public water supplies without an approval or direction from the Director-General of NSW Health. A water utility makes either an application to the Director-General to fluoridate the water supply or seeks a direction from the Director-General. Once fluoridation has started, a water utility cannot stop fluoridating the water without the Director-General revoking the approval or direction. Coverage of water fluoridation is 96 percent in NSW.

The fluoridation of Victoria's drinking water supplies is regulated by the Department of Health, under the Health (Fluoridation) Act 1973. The Act provides the Secretary to the Department of Human Services with the power to direct water authorities to commence water fluoridation. A code of practice was established to support fluoridation of drinking water supplies.

The fluoridation of drinking water supplies in Tasmania is regulated by the Fluoridation Act 1968. Coverage in Tasmania is 83 percent. Under the Act, the need to add fluoride to a water supply is assessed by a Fluoridation Committee, which then provides a recommendation to the Health Minister. The principal functions of the Fluoridation Committee are to act as an expert advisory committee to interested parties, including the Minister, on matters relating to fluoridation of drinking water. The Committee also provides strategic oversight of fluoridation works in Tasmania and reports on the performance and outcomes of the fluoridation plants throughout the State. The Health Minister again has the final say on fluoridation matters.

Water fluoridation was introduced to Western Australia in Perth in 1968, and is regulated by the Fluoridation of Public Water Supplies Act 1966. The Act established the Advisory Committee for the Fluoridation of Public Water Supplies. The Committee considers, advises and makes written recommendations to the Minister relating to: any proposal to add fluoride to any public water supply; any proposal for making, amending or revoking any regulation contained in the Act; and matters relating to the Act and its administration. The Committee provides advice and the final decision rests with the Minister of Health.

The situation in Queensland is similar to the status quo in New Zealand, though fluoridation was mandatory for a short period of time. Legislation was introduced in 2008, requiring all water supplies serving 1,000 or more people to implement water fluoridation. A schedule of water supplies with dates by which fluoridation must be implemented was included in a schedule of the Regulation. The implementation was fully funded by the State Government and was managed by the then Department of Employment, Economic Development and Innovation. This was a very long and difficult process and resulted in some delays in the mandated time frames. Ongoing operational costs (eg, fluoride chemical and maintenance) are funded by service providers. The legislation was amended in December 2012 and the requirement for mandatory fluoridation of relevant supplies was replaced with a clause allowing local governments to decide if fluoridation was in the best interests of their communities. This change resulted in many local governments ceasing to fluoridate water supplies, including in major cities such as Cairns.
Fluoride has been added to Canberra water supplies in the Australian Capital Territory (ACT) since 1964. The addition of fluoride is regulated by the Electricity and Water Act 1989 and the Public Health (Drinking Water) Code of Practice 2007. As only one water supplier provides all of the water for the ACT, the percentage of the population with access to fluoridated water has always been 100 percent.

There is no legal requirement to fluoridate water supplies in the Northern Territory. Water fluoridation reaches 70 percent of the population in the Northern Territory. A position statement has been issued by the Department of Health urging water suppliers to pursue water fluoridation where practicably possible.

As for the Northern Territory, South Australia has no legislation regarding water fluoridation. Water fluoridation has spread to cover 90 percent of the population. Public Health South Australia, in its Oral Health Plan for 2010-2017, supports water fluoridation and is looking into expanding the water fluoridation programme.

**The United Kingdom**

The decision-making process for water fluoridation in the United Kingdom is similar to the current situation in New Zealand.

Local authorities currently have the decision making power. Before 2012, legislation required district health authorities in England, Wales and health boards in Scotland to consult widely in determining their policy on water fluoridation, and allowed water companies to accede to health authority requests to fluoridate, but did not oblige them to do so.

Before fluoridation could commence, the district health authority had to apply to the water company. The law included a stipulation that the health authority, over a period of three months, was required to consult with community health councils, local authorities, and the public (PHC, 1994). Government grants were available to health authorities to help meet a substantial proportion of the initial capital costs. However, while water companies were keen to work alongside health authorities and the National Health Service, the water industry’s position was to refuse any request to fluoridate until ‘legally obliged to’ (British Fluoridation Society website).

Since the inception of the Water (Fluoridation) Act 1985, almost half of all health authorities in England have requested water companies to introduce water fluoridation – none of those requests have been accepted. It is further suggested that if these requests had been acceded to, around 20 percent or more of the population would now be fluoridated.

The introduction of the Water Act in 2003 sought to rectify the situation. The Act made provision for the fluoridation of water supplies at the request of health authorities by inserting a new section 87, which put water suppliers under an obligation to accede to requests from strategic health authorities (SHAs) to enter into arrangements to fluoridate water supplies where an indemnity is provided (British Fluoridation Society website).

Legislation passed in 2012 shifted responsibility for conducting public consultations on fluoridation from SHAs to first tier local authorities. The Health and Social Care Act 2012 disestablished SHAs and established Public Health England (PHE) to monitor the health effects of fluoridation status; therefore a shift of responsibility was needed. The Government has placed that with local authorities and has also supplied a set of regulations to work with (ie, The Water Fluoridation (Proposals and Consultation) (England) Regulations 2013).

The current situation is similar to that in New Zealand, though there are complexities with private water companies and from the previous system that are not relevant to the New Zealand situation. There is strong advocacy from PHE for water fluoridation with the released *Water fluoridation: health monitoring report for England 2014.*
Canada

In Canada non-binding guidelines are in place. The decision to fluoridate water supplies is made by local authorities, with the federal, provincial and territorial governments setting the guidelines (Rabb-Waytowich 2009).

Health Canada has produced non-binding drinking water guidelines which includes fluoridation. The official position of Health Canada is:

Fluoride is a beneficial mineral nutrient that occurs naturally in most sources of drinking water. It is the responsibility of municipalities, or the appropriate provincial or territorial authorities, to decide whether to fluoridate their drinking water. Although Health Canada supports water fluoridation as a public health measure to prevent dental decay, the department does not participate in those decisions (Health Canada).

There is considerable variation in fluoridation rates across Canada (from nil to 76 percent), as the regulations are non-binding.

Republic of Ireland

Ireland currently has legislation mandating nationwide water fluoridation. In 2012, Ireland had 73 percent population coverage for water fluoridation (British Fluoridation Society).

Various health authorities are ultimately responsible for the fluoridation of water supplies. However, as the overall functions of sourcing, treatment and distribution of drinking water rest with the sanitary authorities (borough corporations, county councils and urban district councils) it has been the case from the outset that the latter bodies undertake fluoridation on an agency basis.

In 2014, numerous local authorities passed motions to end water fluoridation but remain bound by law to implement the policy.
WATER FLUORIDATION STATUS FOR RETICULATED WATER SUPPLIES, BY DISTRICT COUNCIL, AT JANUARY 2014

Source: Data supplied by the Institute of Environmental Science and Research; figure created by Sapere.
Source List


World Health Organisation 2004. *Fluoride in Drinking-water: Background document for development of WHO Guidelines for Drinking-water Quality*