

Response to New Health New Zealand's views on the Ministry of Health's NZBORA analysis

New Health New Zealand Inc. (New Health) considers that each of the 14 directions to local authorities to fluoridate one or more water supplies is not a reasonable limitation on the right to refuse medical treatment. New Health's submission articulates several reasons in support of its view.

This document provides high-level comment in relation to New Health's key reasons in support of its view. The Ministry of Health | Manatū Hauora (the Ministry) has carefully considered New Health's response and the supporting material provided by New Health.

- 1. There is now an undeniable risk of neurological harm to children in terms of lower IQ where the total intake of fluoride is equivalent to the WHO's maximum limit of ingesting 1 litre of water per day at 1.5mg/L fluoride, an intake proven to be reached and exceeded by a proportion of the population in communities fluoridated at 0.7 to 1mg/L. There is no identifiable lower threshold for such harm (NTP Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopmental and Cognition: A Systematic Review (August 2024))**

The detail of New Health's comments focuses largely on the recently published State of the Science review by the US National Toxicology Program (NTP) [1]. The Ministry has considered this NTP review in detail and does not consider that it alters conclusions regarding the safety and effectiveness of community water fluoridation (CWF). The NTP review concludes that there is "insufficient data to determine if the low fluoride level of 0.7 mg/L currently recommended for U.S. community water supplies has a negative effect on children's IQ." [1] While this review raises important questions about fluoride exposure above 1.5mg/L, there is no reliable, robust evidence that this applies to levels of fluoride exposure used in CWF.

The Ministry's detailed consideration of the NTP report can be found in the *Community water fluoridation: Additional information on recent publications* document.

New Health's submission also refers to other studies. The Evidence Brief undertaken by the Ministry identified five relevant systematic reviews that provided evidence relating to IQ as an outcome. All of these were limited by the nature of the primary studies included which were predominantly cross-sectional studies.¹ Very few of the original studies adjusted for important confounding factors, such as alcohol intake or other known neurotoxins. The lack of adjustment for confounders is a recognised shortcoming in the secondary analysis of data

¹ Cross-sectional studies collect information from a group or groups of people over a short time period. Comparisons of groups at a single point of time to assess the rates of non-communicable disease which have often developed over many years is an unreliable method to assess causation, as it is often impossible to control for risk factors spanning over a long period of time. It is in effect just a snapshot of population risk.

originally collected for another purpose such as the MIREC study.² Moreover, the systematic reviews all include studies from regions with high naturally occurring fluoride levels in drinking water which severely limits their generalisability and applicability to CWF.

New Health says that “[W]ith one exception these are poor quality reviews done by dentists. The exception is the Taher publication.” New Health does not explain why publications written by dentists should be disregarded, why the publication by Taher is of higher quality or why the other four studies are of poorer quality.

The Ministry’s Evidence Brief explains the limitations of all the reviews and provides the conclusions of each review. A summary of the conclusions with bold for emphasis is provided in the table below.

Study/country. Outcomes	Conclusions by the authors
Gopu et al (2022) [2] UK Cognitive outcomes ³	“...many low-quality studies and the lack of robust estimates of fluoride exposure from all sources make it difficult to provide definitive conclusions.”
Kumar et al (2023) [3] USA IQ scores	“These meta-analyses show that fluoride exposure relevant to community water fluoridation is not associated with lower IQ scores in children.”
Miranda et al (2021) [4] Brazil/Canada Neurological disorders ⁴	“...showed IQ impairment only for individuals under high fluoride exposure considering the World Health Organization criteria, without evidence of association between low levels and any neurological disorder.”
Taher et al (2024) [5] Canada Health effects ⁵	“The evidence supports a conclusion that fluoride exposure reduces IQ levels in children at concentrations close to those seen in North American drinking water, although there is some uncertainty in the weight of evidence for causality and considerable uncertainty in the point of departure.”
Veneri, Vinceti [6] [6] USA/Italy IQ scores	“...we found an overall indication of dose-dependent adverse effects of fluoride on children’s cognitive neurodevelopment, starting at rather low exposure. However, the limitations of most studies included in this meta-analysis, with particular reference to the risk of residual confounding, raise uncertainties about both the causal nature of such relation and the exact thresholds of exposure involved.”

² <https://www.mirec-canada.ca/en/>

³ including IQ

⁴ all IQ except one study

⁵ including ADHD and IQ

As can be seen, all of the systematic reviews are cautious in their conclusions and overall raise concerns about residual confounding and causal inferences, particularly at lower fluoride levels used for CWF. A recent critique of the Taher publication noted that “[P]ractitioners should be aware the evidence base is much disputed with ongoing concerns regarding the validity, applicability, and the risk of bias in many of the studies.” [7] This critique also identifies that the dose response curve is not clear at lower concentrations of fluoride.

The Ministry keeps a watching brief over the scientific evidence on community water fluoridation, including evidence relating to fluoride used to set the maximum acceptable value (MAV) in the Drinking Water Regulations. The current MAV is set on the available body of evidence, which takes into account dietary intake of fluoride as well as intake from fluoride in water.

Further detailed analysis of the evidence in relation to fluoride and IQ can be found in the *Community water fluoridation: Additional information on recent publications* document.

2. Tooth decay is not of functional significance for the majority of New Zealanders, and for those that it is, fluoridation will make no functional difference.

It is widely known that poor oral health, including dental caries, is a common problem across the world including in New Zealand. As outlined in the NZBORA analysis, it is the most common non-communicable disease in New Zealand, and it can impact on wellbeing and quality of life throughout a person’s life.

The NZBORA analysis provides data on the rates of dental caries in children and adults in New Zealand. New Health focuses in on the low average number of decayed, missing or filled teeth (DMFT) at year 8 to say that dental caries is a relatively minor problem in New Zealand and is not of functional significance. This approach risks normalising what is a significant public health problem, which affects many people. New Health gives the example that in Counties Manukau 79.5% of year 8 children were caries free. This means that 20% of year 8 children experienced caries, which is 1 in 5 children. It is also important to recognise that DMFT only increases as people age, with the average of 13.9 DMFT for over 18-year-olds (2009 Oral Health Survey).

The lowest rate of dental caries across the age 5 and year 8 data for the relevant Te Whatu Ora districts (for all children and not disaggregated by ethnicity) is for year 8 children in the Nelson-Marlborough District, with 13.68% experiencing caries. For most of Te Whatu Ora districts looked at, at least 30% of the age 5 and year 8 children experienced caries. New Heath says that for children to have 2-3 DMFT is of no functional significance. Again, this risks normalising the issue, downplays the effects for those who suffer caries, and does not recognise that there will be a range of severity of caries and a range of resulting impacts. It is also important to observe that year 8s have just developed their permanent teeth, so that decay is irreversible.

Given dental caries is a very common problem in New Zealand, and can have much wider impacts on quality of life, the Ministry does not consider that any dental decay at this young age should be accepted and normalised by government or by health care providers.

It is also not possible to draw conclusions of functional significance from the data regarding DMFT, as that data does not indicate severity, level of pain, or any other impacts resulting from the dental caries. However, as outlined in the NZBORA analysis, other evidence goes to impact, such as the 2009 Oral Health Survey, which showed that 1 in 8 children and adolescents had taken time away from school or normal activities because of problems with their teeth or mouth.

The Ministry acknowledges that oral health is improving over time, and this trend is identified in the NZBORA analysis. However, the data still shows that poor oral health is a significant problem, particularly amongst certain population groups. That certain population groups are particularly impacted in turn is reflective of the meaningful link between oral health and equity concerns.

New Health's submission highlights that oral health for 75-year-olds reflects a range of practices such as potentially unnecessary fillings by school dental nurses. The Ministry agrees that data for 75-year-olds' oral health may have been influenced by many factors including decision making by oral health professionals, as well as by their historical water fluoridation status and has limited relevance to community water fluoridation today. As such this data has been taken out of the population demographics data in the NZBORA analysis for each local authority. The data is retained in the wider analysis that paints a picture of overall oral health in New Zealand.

New Health's submission also asserts that dental caries is caused by consumption of sugary foods and drinks. The Ministry is aware that consumption of sugary foods and drinks can cause health issues, not limited to oral health issues. The Heart Foundation is funded to work with industry to reduce levels of sugar and salt in our food supply. This includes incentivising reformulation and increasing uptake of the Health Star Rating labelling system, to support people to make healthy food choices. The Health Star Rating programme has also been strengthened to ensure products with high levels of sugar and salt are given lower ratings. These interventions are complementary to community water fluoridation, rather than alternatives. The Ministry also notes that poor oral health affects the whole population and not just those who consume sugary foods and drinks.

3. There is a lack of demonstrated effectiveness of fluoridation.

The Evidence Brief undertaken by the Ministry uses the accepted hierarchy of evidence to assess the effectiveness of community water fluoridation to reduce dental caries. In addition, the Evidence Brief was externally peer reviewed by two university professors expert in dental public health. The Ministry's Evidence Brief provides robust up to date evidence of the effectiveness of CWF.

New Health questioned the inclusion in the Evidence Brief of the review of fluoridation in Australia by Senevirathna et al [8], which identified 81 publications on a range of topics

related to fluoridation of which 24 represented a systematic review of CWF. The Ministry has changed the number of papers included in the review from 81 to 24.

As there have been no randomised trials of community water fluoridation published, systematic reviews and meta-analyses of observational studies were used to provide an initial robust assessment of the overall body of evidence. In line with accepted best practice, the aim of the Ministry's review was to assess all the available information as a whole. As outlined in the Evidence Brief, there were 6 systematic reviews published since 2021, all of which reported a significant decrease in the incidence of dental caries, particularly in children. The benefits of community water fluoridation have continued into the era of fluoridated toothpaste and other public health campaigns aimed at decreasing the rate of dental caries.

To provide a further layer of rigour for the conclusions drawn from the systematic reviews, all studies of the efficacy of community water fluoridation published since 2019 were identified. Again, these studies, which were undertaken in a wide range of countries and during the period of time that fluoridated toothpaste was available, overwhelmingly demonstrated that community water fluoridation decreased the rate of dental caries, a conclusion which is consistent with the previous reviews of 2014 and 2021 undertaken by the Royal Society and the Office of the Prime Minister's Chief Science Advisor.

Cochrane Review

New Health submits that the Cochrane reviews [9, 10] remains the best available evidence in relation to the efficacy of fluoridation. The 2015 meta-analysis reviewed 20 studies on the effects of fluoridated water on tooth decay and 135 studies on dental fluorosis. The review found that water fluoridation is effective at reducing levels of tooth decay among children, with the introduction of water fluoridation resulting in children having 35% fewer decayed, missing and filled baby teeth and 26% fewer decayed, missing and filled permanent teeth.

No studies that aimed to determine the effectiveness of water fluoridation for preventing caries in adults met the review's inclusion criteria. There was insufficient information to assess the effects of stopping water fluoridation or to determine whether initiation of a water fluoridation programme results in a change in disparities in caries across socioeconomic status.

The 2024 update re-affirmed the earlier 2015 finding that studies conducted in 1975 or earlier showed a clear and important effect of CWF on the prevention of tooth decay in children.

The Ministry's detailed consideration of the 2015 and 2024 Cochrane reviews can be found in the *Community water fluoridation: Additional information on recent publications* document.

The LOTUS Study

The LOTUS Study [11], cited by New Health, is a secondary analysis of NHS dental claim data. Although the utilisation of a dataset for purposes other than what it was collected for can lead to a wide range of biases and confounding, the LOTUS Study did demonstrate a benefit

from fluoride in water supplies⁶. This is despite the lack of inclusion of groups known to experience higher rates of tooth decay and dental caries. In addition, the LOTUS Study is not an assessment of community water fluoridation, but a comparison of caries experience and tooth decay in areas with different levels of fluoridation from both artificial and naturally occurring water supplies. The level of fluoridation for each area was calculated by averaging the annual mean fluoride concentration in the water supply over the 10-year period to produce a "grand-mean". The validity of this approach and the application to CWF is highly questionable. For example, the concentration of fluoride in water samples from Stratford-upon-Avon ranged from 0.05 to 1.01 mg/L. The "grand-mean" of 0.47 mg/L resulted in a classification as a non-fluoridated region, when clearly the concentration of fluoride in the water supply was within levels known to improve oral health during the study period. The authors of the LOTUS study stated that there is a benefit on a population basis, but possibly not on an individual basis. Community water fluoridation is a population intervention. Population based interventions can be highly effective even with small improvements in overall health indices as the improvements occur over the entire population and are not limited to small subgroups. Population interventions also target those individuals who are difficult to reach through individually targeted interventions. Population based and individual based interventions should be considered as being synergistic and not antagonistic.

Therefore, the LOTUS study is not applicable to a New Zealand population for multiple reasons:

1. The treatment and control populations are not clearly delineated, with a known therapeutic benefit within the areas classified as non-fluoridated.
2. The analysis was based on NHS claim data, not on direct evidence of dental caries in the population.
3. The analysis was based on only 63% of the population with those in lower socioeconomic deciles under-represented.
4. Individuals who were not resident in the same location for more than 10 years were excluded. The younger population tends to be more mobile.
5. The fluoridation status of individuals prior to the start of data collection is not considered.

The CATFISH Study

The CATFISH Study [12], cited by New Health, also demonstrated an improvement in oral health in those individuals living in areas with community water fluoridation which was reintroduced in a contemporary setting in which fluoridated toothpaste was widely available.

The global use of fluoridation

New Health says that "New Zealand is one of a tiny minority of countries that add fluoride to drinking water. Other countries include the US, UK, Canada, Australia and Hong Kong."

Approximately 25 countries fluoridate water supplies [13, 14]. Fluoride supplementation is achieved in some countries by fluoridating milk or salt, however this is less effective than water fluoridation. Other countries have adequate or even elevated natural levels of fluoride

⁶ The study combined areas with fluoridated drinking water from naturally occurring sources and CWF.

in water, including both the Asian subcontinent and China, which account for 40% of the world's population. Fluoride is available in the water through natural or artificial means throughout most of North, Central and South America.

In addition, while not intended to measure effects of fluoridation specifically, the New Zealand 2009 Oral Health Survey [15] showed a significant difference in decay rates in communities with fluoridated and non-fluoridated water supplies, despite most people also using fluoridated toothpaste. For example, children aged 2-17 years old had on average 1.7 times as many decayed, missing or filled teeth than those living in fluoridated areas.

4. There is no known biological mechanism of action by which fluoride at 0.7 to 1mg/L can affect caries.

The biological mechanisms for the action of fluoride in decreasing tooth decay is clear and proven. [16]

The enamel of your teeth is made of mainly hydroxide, calcium and phosphate ions, a structure called hydroxyapatite. Fluoride reacts strongly with these ions in developing teeth and results in strong teeth with enamel that is more resistant to decay. In this reaction, fluoride replaces hydroxide, converting hydroxyapatite to fluorapatite. These fluorapatite crystals are more symmetric and stack better than the hydroxyapatite crystals.

With topical exposure through fluoridated toothpaste and other sources (including water), fluoride is bound to enamel. With consistent exposure, this reduces the rate at which enamel demineralises (i.e. when tooth decay is occurring) and also promotes remineralisation of early caries lesions.

The benefit of community water fluoridation is that there is a constant low level of fluoride in the saliva and plaque fluid creating topical application of fluoride on the teeth, which helps strengthen teeth over and above the once or twice a day application of fluoride toothpaste.

In addition, for younger children when teeth are forming, fluoride can work systemically to strengthen teeth.

The Ministry has added more detail on these mechanisms of action into the NZBORA analysis to ensure that this is clear.

5. Alternative measures such as toothbrushing programmes in schools are more targeted, efficacious, and cost-effective options.

Community water fluoridation is one of a range of initiatives that the government is implementing to help improve the oral health of New Zealanders. These initiatives are summarised below. The Ministry recognises the success of programmes such as the Scottish Childsmile programme, as well as Health New Zealand's Oral Health Toothbrush and Toothpaste initiative. These types of programmes empower tamariki and their families to support their own oral health and create habits that will benefit them for life.

However, evidence for community water fluoridation shows that it provides an additional benefit over and above toothbrushing. In addition, as outlined in the NZBORA analysis, other

initiatives rely on changing behaviours in children and their whanau and this is not sufficient to address public health concerns and inequities. Community water fluoridation is effective because it doesn't require any behaviour change. It is also an equitable and cost-effective initiative, providing more benefit to those communities that need it most such as those living in the most deprived neighbourhoods. Community water fluoridation also benefits people of all ages, whereas most other oral health initiatives are targeted to under 18-year-olds.

Oral health initiatives that are being implemented by Health New Zealand | Te Whatu Ora (Health NZ) are:

- Government funding for oral health services focused on universal services for all children from birth up until their 18th birthday.
 - Government funded dental services for those over 18 years is limited to eligible people needing emergency dental care for the relief of pain and infection. Emergency Dental Service for Low Income Adult funding is available for community services card holders needing emergency dental care for the relief of pain and infection. These services may be provided by some Health NZ hospital dental facilities and in some regions, these services are provided by contracted oral health providers. The Ministry of Social Development (MSD) Dental Special Needs Grant allows for eligible people to access up to \$1,000 annually for 'immediate and essential' dental treatment.
 - Health NZ invests in the provision of free toothbrushes and toothpaste to Māori, Pacific and low-income pre-schoolers and their whānau. More than 2 million toothbrushes and toothpaste products have been distributed since December 2021, through Kaupapa Māori and Pacific health providers, Well Child Tamariki Ora providers including Whānau Āwhina Plunket, Family Start, immunisation outreach and Healthy Homes providers.
 - Budget 2022 included \$12 million for investment in new mobile dental clinics to increase access to assessment and treatment for young people in communities with the highest health need. Officials have been working with providers to develop service models, agree specifications and purchase the first tranche of new mobile dental clinics.
- 6. Even if fluoridation provided a modest reduction in tooth decay (denied), that benefit is significantly outweighed by the risk of neurological harm. Tooth decay is easily treatable and preventable. Neurological harm in the form of lowered IQ is permanent and causes lifelong disadvantage.**

The NZBORA analysis, the updated review of scientific evidence, the *Additional information* document and the above responses in this document show that the current preponderance of scientific evidence on community water fluoridation does not show any neurological harm at the levels of fluoride used for water fluoridation in New Zealand.

While the statement that tooth decay is easily treatable and preventable is technically true from a scientific standpoint, it does not recognise the other influences on oral health and

oral health behaviours, as discussed in more detail in the NZBORA analysis. If it was that simple, we would not see such high rates of dental caries in New Zealand.

In addition, dental caries is irreversible. Dental caries can be treated, but once a tooth is decayed this treatment may need to be maintained for the rest of the person's life. Dental caries, as well as treatment, can be painful and expensive. Prevention of any disease is always better than treatment.

7. Fluoridation is not a proportional limitation on the right to refuse medical treatment.

The Public Health Agency has had regard to the points raised by New Health. For the reasons set out in this document as well as in the detailed NZBORA analysis undertaken and the Additional information on recent publications document, the PHA Public Health Agency remains satisfied that fluoridation is a justified and proportional limitation on the right to refuse medical treatment.

PROACTIVELY RELEASED

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