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s 9(2)(a)

Dear Jason

NEW HEALTH NZ INC'S VIEWS ON CROWN'S NZBORA ANALYSIS

Summary

1. Thank you for providing the Evidence Review and Summary of the draft NZBORA analysis. I note you have refused to provide the names of the authors of the Evidence Review and the peer reviewer(s). So New Health does not know the credentials and speciality area of those involved.
2. For the reasons set out below New Health says that each of the fluoridating directions is not a reasonable limit on the right to refuse medical treatment.
 - a. 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 1.5 mg/L fluoride, an intake proven to be reached and exceeded by a proportion of the population in communities fluoridated at 0.7 to 1 mg/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 NTP Review)).
 - b. 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.
 - c. There is a lack of demonstrated effectiveness of fluoridation.
 - d. There is no known biological mechanism of action by which fluoride at 0.7 to 1 mg/L can affect caries.

- e. Alternative measures such as toothbrushing programmes in schools are more targeted, efficacious, and cost-effective options.
- f. 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.
- g. Fluoridation is not a proportionate limitation on the right to refuse medical treatment.

Primary submission: Fluoridation poses an unacceptable risk of neurological harm in terms of lowering IQ and must be immediately stopped to protect public health

NTP Review (August 2024)

3. Subsequent to the Crown providing to New Health the Evidence Review and draft BORA analysis, the National Toxicology Program released its Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopmental and Cognition: A Systematic Review. Refer link below:

https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride_final_508.pdf
4. This is the highest quality systematic review in existence and represents the best evidence in relation to fluoride’s impact on neurodevelopment and cognition. It is highly significant and relevant to the draft BORA analysis.
5. The NTP Review directly contradicts the statement in the Evidence Review that there has been no high-quality evidence published since reports in 2014 and 2021 “to suggest a causal link between fluoride exposure at the levels used in Aotearoa New Zealand for CWF and significant harm to health”. The NTP Review’s authority now overrides and supersedes any of the material contained in the Evidence Review.
6. The NTP Review found with *moderate confidence* that higher *estimated fluoride exposures* (eg as in approximations of exposure such as drinking water fluoride concentrations that exceed World Health Organisation Guidelines for Drinking-Water Quality of 1.5 mg/L of fluoride) are *consistently associated with lower IQ in children*. It says more studies are needed to fully understand the potential for lower fluoride exposure to affect children’s IQ.
7. Additionally, it found with low confidence other neurodevelopment effects such as attention deficit disorder.
8. Put simply fluoride exposure equivalent to consuming water *at or above* 1.5 mg/L fluoride is likely to cause neurological harm to children in the form of lower IQ.
9. This is highly significant because the maximum allowable value (MAV) for fluoride in the Water Services (Drinking Water Standards for New Zealand) Regulations 2022 is 1.5 mg/L.

10. According to Tuamata Arowai (Drinking Water Standards for New Zealand (Draft) 20 December 2021) –

The MAV of a chemical determinand is the *highest concentration of the determinand expected, on the basis of present knowledge, not to cause any significant risk to the health of the consumer over 70 years of consumption of 2 litres per day of that water*. MAVs for carcinogenic determinands are conservatively set, where possible, as the concentration in drinking water associated with an estimated excess lifetime cancer risk of 10^{-5} (or one additional case of cancer per 100,000 of the population ingesting drinking water containing the substance at the guideline value for 70 years).

Advances in scientific knowledge may lead to changes in the MAVs. When evidence for these changes becomes available, revised MAVs will be included in later editions of the Standards.

11. The MAV of 1.5 mg/L is now known with moderate confidence to cause significant risk to children's IQ. It is no longer "safe" and must be urgently amended.
12. The US Environmental Protection Agency's standard is to apply a 10 fold "uncertainty factor" (also called a safety factor) to the No Observed Adverse Effect Level (NOAEL) for toxicants.¹ 1.5 mg/L is *not* the NOAEL. It is not even the Lowest Observed Adverse Effect Level (LOAEL). Even if it were the NOAEL, applying the USEPA's safety factor would result in an MAV of 0.15 mg/L fluoride in the drinking water.
13. Accordingly, New Health says that an appropriate margin of safety would be a factor of 10 which would be 0.15 mg/L. That may not be practicable given that some NZ water supplies contain fluoride at up to 0.3 mg/L.
14. So ultimately, amending the MAV would mean no additional fluoride could ever be artificially added to a water supply.
15. The Director-General cannot reasonably or lawfully disregard the NTP Review on the basis that the "optimal" range for fluoridation is 0.7 to 1 mg/L and this is lower than 1.5 mg/L.
16. While the NTP Review does not address whether the *sole exposure to fluoride* is drinking water fluoridated at 0.7 mg/L is associated with a measurable effect on IQ, it notes that "*total exposure can vary widely even in optimally fluoridated areas based on personal habits in the use of dental products and consumption of beverages such as black tea that can contain fluoride*".
17. Based on the Canadian studies there is little scientific doubt that fluoridation at 0.7 to 1 mg/L will be lowering the IQ of at least some, and likely many, children. *The size effect appears comparable to the IQ loss caused by leaded petrol (around 4 IQ points)*.

¹ <https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments>

18. New Health is particularly concerned about the total exposure to unborn and formula fed babies. These two groups were the subject of the USNIH-funded Canadian studies by Green and Till respectively (both assessed as high quality by the NTP reviewers).
19. *In short, New Health says that a conclusion of ‘moderate confidence’ of neurotoxic effects, especially on unborn and newborn children, requires an immediate cessation of water fluoridation. Failure to do so would endanger public health.*
20. New Health also says that this risk was well known to the authors of the 2014 report from the Royal Society of New Zealand but was obfuscated– refer paragraphs [90] – [99] of the statement of claim dated 12 June 2023.
21. In terms of the Evidence Review, there are six “systematic reviews” of neurotoxicity listed in Table 3. With one exception these are poor quality reviews done by dentists. The exception is the Taher publication. This paper was commissioned by Health Canada and includes evidence that IQ was lowered when water fluoridation was even below 1.5 mg/L.
22. The authors of the Evidence Review – whom you refuse to identify – criticise the Taher paper on two grounds. First, by claiming Taher used a study quality tool (risk of bias RoB assessment) of “uncertain validity” and then misattributing an association at low fluoride levels with lower IQ when in fact the association is with higher levels of fluoride than those used in CWF.
23. These are false grounds. The Taher RoB has as much validity as any of the other reviews, and second, the study did find an association at fluoridation levels below 1.5 mg/L.
24. New Health also notes that the Evidence Review relies on a systematic review by Kumar (2023). The NTP review at p 101 seriously criticises the Kumar review and its validity is challenged.

There are several serious concerns and limitations of these analyses which failed to report many details critical to the conduct of a systematic literature review and meta-analysis. These missing details include, but are not limited to: lacking a predefined protocol; providing rationale or criteria for the risk-of-bias assessments; providing details about how the SMDs were calculated; reporting the data from the individual studies that were used to calculate the SMDs; describing the selection process for which data to use if a study reported results of multiple models; describing assessment of heterogeneity (other than reporting I2 values); describing the method for assessment of publication bias; and describing rationale for choice of sensitivity analyses.

Other comments

Tooth decay is not of functional significance to most people

25. The draft BORA analysis provides unquantified claims such as “[i]f left untreated, tooth decay can have lasting negative effects throughout a person’s life, causing pain and suffering, impairment of function and self-consciousness.”

26. The analysis fails to specify what proportion of people experience this and to what degree.
27. The 2009 Oral Health Survey provides an alleged saving of 0.7 Decayed Missing or Filled Surfaces (DMFS) which it states as not statistically significant for those over 18. This equates to 0.55 % of the 128 surfaces typically found in the adult mouth.
28. In Counties-Manukau 79.5% unfluoridated Year 8 children and 74% fluoridated children are completely caries-free (2022 School Dental statistics).
29. Between 2000 and 2022 the percentage of caries-free Year 8 children rose from 42% to 69%. The average DMFT decreased from 1.61 to 0.72. There was no material change to fluoridation coverage over that time.
30. Reference to 75 years olds having high DMFT scores does not establish that there is an issue at that age. It is well known that the cohort born prior to 1970 were subjected to many unnecessary fillings by school dental nurses.²
31. According to school dental data from 2012 to 2016 around 80% of decay is in people with 4 DMFT or less (“other” ethnicity) or 6 DMFT or less (Maori) whether fluoridated or not. 50% of decay typically occurred in children with 2-3 DMFT or less. This is of no functional significance.
32. The reality is that untreated tooth decay is of concern to a small subset of the population only. That population includes children who suck on bottles filled with sugary drinks. It is well established that water fluoridation cannot address this issue.
33. The draft BORA analysis refers to 6957 0 to 14 years olds being hospitalised in 2022 for dental treatment due to preventable decay and pulp and periapical issues. What is not disclosed is the fluoridation status of the regions these children came from. But in any case these issues are not the result of a lack of water fluoridation and cannot be prevented by water fluoridation. They are almost certainly fundamentally an issue of systemic consumption and exposure to sugary foods and drinks and a lack of twice daily toothbrushing. No data on this issue have been published in the reports on this.
34. The additional information provided in relation to the Councils in letters dated 5 June 2024 is revealing. The vast majority of decay in 5 years olds is between 2 and 4 DMFT but with Year 8 children is consistently under 2 DMFT apart from Horowhenua with 2.04 DMFT for Pacific children, Rotorua Lakes with 2.38 DMFT for Maori children, and Tararua with 2.04 DMFT for Pacific children.
35. But most of the Year 8 children in these districts have negligible DMFT. For example:
 - a. Auckland
 - i. All children 0.52 DMFT
 - ii. Maori children 0.71 DMFT

² De Liefde NZDJ 94: 109-113, 1998

- iii. Pacific children 0.73 DMFT
- b. Waipa
 - i. All children 0.66 DMFT
 - ii. Maori children 1.01 DMFT
 - iii. Pacific children 0.74 DMFT
- c. Nelson
 - i. All children 0.69 DMFT
 - ii. Maori children 1.01 DMFT
 - iii. Pacific children 1.04 DMFT

36. This demonstrates that tooth decay is not a prevalent or serious issue for these communities.

There remains no high quality evidence that fluoridation meaningfully reduces tooth decay

- 37. The draft BORA analysis states that the 2015 Cochrane review which evaluated the effect of fluoride in water on the prevention of tooth decay and dental fluorosis found that “water fluoridation is effective at reducing levels of tooth decay among children”.
- 38. This is misleading. The Cochrane Review found that the majority of studies (71%) supporting claims of benefit were conducted prior to 1975 and the widespread introduction of the use of fluoride toothpaste. The Review noted there is very little contemporary evidence meeting the review’s inclusion criteria that has evaluated the effectiveness of water fluoridation for the prevention of caries.
- 39. The review noted there is insufficient information to determine whether the initiation of a water fluoridate programme results in a change in disparities in caries across socioeconomic status (SES) level, and that there was insufficient information to determine the effect of stopping water fluoridation programmes on caries level. Further, no studies that aimed to determine the effectiveness of water fluoridation for preventing caries in adults met the review’s inclusion criteria.
- 40. The Cochrane Review and York Review remain the best evidence in relation to efficacy of fluoridation. Both found that the evidence in support of fluoridation is of low quality and as a consequence the precise scale of benefits is unclear.
- 41. The latest studies from the UK (CATFISH and LOTIS) found with low confidence a benefit of up to 4% which LOTUS described as “may not be meaningful for individuals” and found was not cost effective over the lifetime of a fluoridation plant.³

³ CATFISH: <https://bmcoralhealth.biomedcentral.com/articles/10.1186/s12903-016-0169-0>
 LOTUS: <https://onlinelibrary.wiley.com/doi/10.1111/cdoe.12930>

42. The Evidence Review purports to have done a review of recent systematic review – refer Table 1. This material is of low quality. We selected one review – Senevirathna et al (2023) which is listed with 81 studies – to look at in more detail.
43. What stood out is that it not in fact a systematic review of fluoridation effectiveness. It is only a systematic review of how many studies have been done on fluoridation effectiveness over the past 70 years, including time trends in number of studies per decade. But it never tried to rate the studies for quality and synthesise their findings. It merely produced graphs of the number of studies by each decade in the past 70 years. Furthermore, it was limited strictly to Australia. We have to question the credentials and ability of the authors of the Evidence Review to conduct a scientifically robust review in light of this fact.

There is no demonstrated biochemical action by which fluoride at concentration used in CWF reduces tooth decay

44. The draft analysis says that “when fluoridated water is consumed the concentration of fluoride in saliva and plaque increases. The fluoride helps to prevent tooth decay by strengthening the enamel, interfering with the growth of acid producing bacteria and helps to repair the early stages of tooth decay.”
45. This statement confirms that the mechanism of action is topical and that the benefit is not derived from ingesting fluoridated water.
46. But more importantly what has never been explained is how fluoridated water with a concentration of 0.7 to 1 mg/L is sufficient to provide cariostatic effect when combined with plaque and saliva when it is well known that to have any cariostatic effect toothpaste must have a concentration of 1000 mg/L. Moreover, the US Center for Disease Control and Prevention has confirmed that fluoridated water does not result in such levels.
47. But in any case even if fluoridated water could provide benefit, the plaque coating would have to be exceedingly thin (approximately 50 microns), ie immediately after toothbrushing. Once the plaque coating started to build up fluoride of 0.7 mg/L could never penetrate into the enamel.
48. That might explain why the best evidence on contemporary efficacy is so inconclusive.

Alternatives to water fluoridation are much more effective

49. The draft BORA analysis states that “alternatives to community water fluoridation are of limited efficacy”.
50. This statement is patently false.
51. Supervised school brushing programmes in NZ and overseas have proved to be very effective.
52. For example, the Director-General will be well aware that the Scottish Childsmile programme has been very successful in reducing tooth decay and is cost effective.

53. Counties Manukau contracted Mighty Mouth Dental between 2016 and December 2020 and again in 2021 to provide preschool oral health education and tooth-brushing programmes in 150 pre-schools and kohanga reo facilities. The Counties-Manukau positive dental statistics referred to above may be a result of this targeted early childhood intervention.
54. In 2022 a number of schools in the Far North region successfully implemented a tooth brushing programme. This was created by the Northland DHB.
55. In July 2024 the Byte charitable trust commenced a toothbrushing pilot at Te Komanawa Rowley School for six and seven year olds with the intention of expanding the pilot nationally.
56. The evidence of efficacy and cost effectiveness of such programmes is shown by the TDB Report: The Costs and Benefits of a National Tooth Brushing Education Programme for Children commissioned by New Health in 2016. New Health also refers to TDB's critique of the Sapere Report which TDB says both grossly over-calculated benefits and under-calculated costs. This under-calculation of fluoridation costs is set out in the statement of claim at pages 44 to 48. We further understand that the actual costs have in many cases exceeded even the Council's estimates.
57. Other alternatives include fluoride enamels and gels and fluoride tablets, twice daily brushing with fluoridated toothpaste, and reducing the consumption of sugary foods and drinks.

Fluoridation internationally


58. NZ is one of a tiny minority of countries that add fluoride to the drinking water. Other countries include the US, UK, Canada, Australia and Hong Kong. Only 5% of the world's population receive fluoridated drinking water, half of which are in the US. 97% of Western Europe does not add fluoride and fluoridation is banned in Germany, Austria and Sweden.
59. The 2012 WHO data shows no meaningful difference in tooth decay rates between fluoridated and unfluoridated countries.

Summary

60. New Health says that the limiting measure does not serve a sufficiently important purpose to justify the curtailment of the right to refuse medical treatment. Tooth decay is of limited functional significance for the vast majority of the population. The tooth decay rates of children in those 14 council areas are overall very low.
61. The measure is not rationally connected to its purpose. The evidence of efficacy is ultimately inconclusive as shown by the Cochrane Review and York Report which remain the highest quality evidence on this issue.
62. Fluoride does not work by swallowing so the delivery mechanism through water is irrational.

63. The limiting measure impairs the right more than is necessary because there are effective alternatives, such as toothbrushing programmes in schools, and fluoride tablets and gels.
64. Further, the limiting measure affects people who won't benefit from the intervention – those who have no teeth, including babies (who only suffer harm from fluoridation) and those with false teeth – and affects the majority of the population for whom dental decay is not of any functional significance.
65. To the extent that the Director-General appears to be concerned primarily with Maori and Pacifica children, these populations can be targeted through pre-school and school toothbrushing programmes. Such programmes instil oral hygiene skills for life and are highly cost-effective.
66. The limiting measure risks lowering children's IQ by around 4 IQ points, and on that point alone, can never be justified. This level of cognitive effect is well known to be associated with reduced educational attainment, employment status, productivity, earned wages, reflecting substantial public health concerns.
67. *New Health says the evidence of fluoride's effect on IQ is now sufficiently clear, that the only lawful exercise by the Director-General of her powers under s 116E of the Health Act requires her to immediately rescind the 14 directions, and further issue directions to all councils not to fluoridate.*

s 9(2)(a)



Lisa Hansen