

Extraordinary Whangarei District Council Meeting Agenda

Date: Wednesday, 18 December, 2024

Time: 10:00 am

Location: Civic Centre, Te Iwitahi, 9 Rust Avenue

Elected Members: His Worship the Mayor Vince Cucurullo
Cr Gavin Benney
Cr Nicholas Connop
Cr Ken Couper
Cr Jayne Golightly
Cr Phil Halse
Cr Deborah Harding
Cr Patrick Holmes
Cr Scott McKenzie
Cr Marie Olsen
Cr Carol Peters
Cr Simon Reid
Cr Phoenix Ruka
Cr Paul Yovich

For any queries regarding this meeting please contact the Whangarei District Council on (09) 430-4200.

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|---|-----|
| 1. Karakia/Prayer | |
| 2. Declarations of Interest / Take Whaipānga | |
| 3. Apologies / Kore Tae Mai | |
| 4. Decision Reports / Whakatau Rīpoata | |
| 4.1 Fluoridation Update | 3 |
| 4.2 NEST Lease Update | 175 |
| 5. Public Excluded Business / Rāhui Tangata | |
| 6. Closure of Meeting / Te katinga o te Hui | |

Recommendations contained in the Council agenda may not be the final decision of Council.

Please refer to Council minutes for final resolution.

4.1 Fluoridation update

Meeting: Extraordinary Whangarei District Council

Date of meeting: 18 December 2024

Reporting officer: Simon Weston - Chief Executive

1 Purpose / Te Kaupapa

To provide Elected Members with an update on recent correspondence from the Director-General of Health.

2 Recommendations / Whakataunga

That the Council:

1. Notes the continuation of community water fluoridation direction from the Director-General of Health (Attachment 1) dated 3 December 2024;
2. Notes the information provided with the Director-General's continuation of community water fluoridation direction including the full Bill of Rights assessment and new information review (contained in Attachments 2-7 of this Agenda item);
3. Notes the 9 December 2024 letter from the Director-General of Health in response to notification of the Council resolution dated 28 November 2024; and
4. Revokes point 1 of the resolution dated 28 November 2024 that states: "*Resolves to not add fluoride to the Whangarei District's water supplies as required by the directive from the Ministry of Health (MOH)*";

3 Background / Horopaki

On 28 November 2024, Councillors voted 7-6 (one abstention) to pass the following resolution: That the Council:

1. Resolves to not add fluoride to the Whangarei District's water supplies as required by the directive from the Ministry of Health (MOH);
2. This decision is based on recent court rulings and research that question the effectiveness, safety and legality of fluoridation; and
3. That the Mayor and the Chief Executive write to the Ministry of Health, the Minister of Health and the coalition government advising them of this decision.

This paper is to provide an update of communication with the Ministry of Health since that resolution was adopted.

Note: This agenda item does not repeat advice or issues dealt with in previous agenda items including legal risks, costs of non-compliance in terms of fines and penalties or the

implications of contractual breaches. More information on each of these can be found in the agenda reports listed in the footnote.¹

4 Discussion / Whakawhiti kōrero

4.1 Bill of Rights review

As a result of a finding by the High Court that an error of law had occurred in the issue of the directives to 14 local authorities to fluoridate local authority water supplies, the Director-General of Health had been instructed by the Court to reassess each of the 14 Directions in terms of Bill of Rights considerations.

On 3 December 2024, the Director-General confirmed the outcome of this review and notified Council of the Ministry's finding that in terms of section 5 of the New Zealand Bill of Rights Act 1990, "community water fluoridation in the Bream Bay and Whangarei water supplies is a justified limit on the right to refuse medical treatment" for the following reasons:

- due to the high prevalence and the potential for lifelong impacts of poor oral health, the oral health benefits gained from community water fluoridation are sufficiently important to justify the curtailment of the right.
- According to the available scientific evidence, water fluoridation within the optimal range provides protection against dental caries, so there is a rational connection between community water fluoridation and public health goals related to oral health.
- Community water fluoridation is an effective public health measure and impairs the right or freedom no more than is reasonably necessary, when fluoridation is kept within the optimum range, to achieve oral health benefits for a whole community.
- Taking into account the effectiveness of community water fluoridation as a public health measure, and its benefits in particular for the communities that need it most, and that the scientific evidence shows water fluoridation at optimal levels is safe and does not give rise to significant health risks, the limit on the right is in due proportion to the importance of the overall objective.

Further details on the reasons for this decision are outlined in the Director-General's letter (Attachment 1) and in the Bill of Rights Analysis prepared by the Public Health Agency (Attachment 2).

4.2 Notification of Council Resolution

On 4 December 2024, the Mayor and Chief Executive wrote to the Director-General of Health, Minister of Health and the coalition government as directed in the resolution dated 28 November 2024, informing them of:

- The steps that had been taken to date to comply with the Directive;
- The contents of the Council resolution dated 28 November 2024, including supporting documentation; and
- Asking to meet to discuss the concerns of Whangarei residents and elected members and what possible outcomes and solutions can be provided for Whangarei.

4.3 Reconfirmation of Directive

¹ See agenda items from Council meeting dated 28 November 2024 (legal risks of notice of motion) included as part of the Attachment 8 to this Agenda, Council briefing dated 13 November 2024 (summary of work to date and legal risks) and Council meeting dated 21 December 2023 (legal and contractual considerations).

On Monday 9 December 2024, Whangarei District Council received a response to the 4 December letter from the Director-General of Health (Attachment 8).

In that letter the Director-General states:

- The direction creates a mandatory legal obligation on Whangarei District Council to fluoridate by 28 March 2025 and this legal requirement applies despite any Council motion to the contrary.
- It is an offence to contravene or permit the contravention of the direction and outlines the penalties for such an offence;
- Outlines the Director-General's expectations that Council's comply with the directions and indicates the Ministry will consider enforcement action, which could include contractual remedies; and
- Responds to the reasons that Council members have cited in relation to the motion.

The Director-General stated that:

I expect councils to comply with their directions. The Ministry will consider whether to take enforcement action where there is evidence of non-compliance with directions by a council, particularly where there is deliberate or continuing non-compliance. In addition to the other options set out in the legal advice provided to the Council by the Council's legal advisor, the Ministry will also consider whether to seek contractual remedies in light of the significant funding support provided to the council to enable fluoridation.

It seems clear that the Director-General of Health does not intend to change their position relating to the Directive.

4.4 Financial Implications

There are a number of potential financial implications from a continuing refusal to comply with the Directive. These include:

- Under section 116J of the Health Act 1956, a local authority who commits an offence is liable on conviction of a fine not exceeding \$200,000 and a further fine of \$10,000 for every day or part of a day during which the offence continues;
- Cost of legal proceedings, including defending a charge under the Health Act 1956 or responding to other legal proceedings initiated by the Ministry. Council is likely to be held liable for the Ministry's costs as well as its own in any proceedings.
- The capital costs of fluoride equipment has been funded by the Ministry. This cost comes to \$4,557,856.88 (excl GST). Half of this, \$2,278,928.44, has already been paid to Council. The remaining \$2,278,928.44 is due for payment on completion of the commissioning of the sites. Staff have budgeted to receive this payment within this financial year. This funding is subject to contractual terms that Council undertake the fluoridation. If Council do not, the Ministry may demand the return of the money already paid and refuse to pay the outstanding amount.

Each of these costs are unbudgeted. Insurance will not cover any legal proceedings. The Ministry's latest letter indicates that continued refusal to comply with the directive will result in some kind of action.

Costs of beginning the fluoride dosing works out at approximately \$0.0022 per m³ of water, or between \$15,000 and \$20,000 per year. However, other costs such as power, calibrations, repairs, maintenance, monitoring and call outs are likely to make the annual cost closer to \$100,000 per year. No budget has been allowed for the fluoridation of Poroti water treatment

plant. If funding for the Poroti fluoridation is not obtained from the Ministry of Health staff will bring a paper back to Council to consider options.

4.5 Risks

1. The 9 December 2024 letter from the Director-General of Health gives Council an opportunity to reconsider its resolution based on new information. The Bill of Rights assessment and the additional information provided which includes scientific evidence and detailed information and responses to recent publications (including the recent US case), provides an opportunity for Councillors to reassess their position and reconsider whether their original concerns have been addressed. A further such opportunity for reconsideration may not occur. Delays in reconsidering or revoking the resolution, exposes Council to other legal risks such as judicial review proceedings from other parties.
2. Further refusal to comply with the Directive increases the potential for intervention by the Minister of Local Government. The broad powers of intervention of the Minister in a local authority outlined in the Local Government Act 2002 are based on the occurrence of a “problem”.
 - “Problem” is defined under section 256(a)(ii) of the LGA as a significant or persistent failure by the local authority to perform 1 or more of its functions or duties under any enactment.

A continued refusal or resolution not to comply with the directive meets the above definition and the threshold for intervention by the Minister

5 Significance and engagement / Te Hira me te Arawhiti

The decisions or matters of this Agenda do not trigger the significance criteria outlined in Council’s Significance and Engagement Policy, and the public will be informed via agenda publication on the website.

6 Attachments / Ngā Tāpiritanga

Bill of Rights review notification

Attachment 1: Director-General of Health to WDC - Continuation of community water fluoridation direction 3 December 2024

Documents provided by Ministry supporting Bill of rights analysis and reconsideration:

Attachment 2: Bill of Rights analysis

Attachment 3: Public Health Agency analysis 14 directions under NZBORA

Attachment 4: Update on scientific evidence relating to community water fluoridation

Attachment 5: New Health comments on scientific evidence and draft NZBORA analysis

Attachment 6: Public Health Agency response to New Health comments

Attachment 7: Ministry of Health additional information on recent publications

Correspondence with Ministry of Health

Attachment 8: Letter from WDC to Ministry re Council resolution 4 December 2024

Attachment 9: Letter from Director-General of Health response to WDC letter 6 Dec 2024



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3 December 2024

Simon Weston
Chief Executive
Whangarei District Council
Simon.weston@wdc.govt.nz

Tēnā koe Simon

Continuation of community water fluoridation direction

On 22 February I wrote to you to let you know that I would carry out an assessment under the New Zealand Bill of Rights Act 1990 (NZBORA), for each of the directions to fluoridate that were made in 2022.

I am now contacting you to let you know the outcome of my reconsideration of your direction as a result of that assessment.

My assessment is that, in terms of section 5 of the NZBORA, community water fluoridation in the Bream Bay and Whangarei water supplies is a justified limit on the right to refuse medical treatment that is provided for in section 11 of the NZBORA.

I consider that:

- a. due to the high prevalence and the potential for lifelong impacts of poor oral health, the oral health benefits gained from community water fluoridation are sufficiently important to justify the curtailment of the right.
- b. according to the available scientific evidence, water fluoridation within the optimal range provides protection against dental caries, so there is a rational connection between community water fluoridation and public health goals related to oral health.
- c. community water fluoridation is an effective public health measure and impairs the right no more than is reasonably necessary, when fluoridation is kept within the optimum range, to achieve oral health benefits for a whole community.
- d. taking into account the effectiveness of community water fluoridation as a public health measure, and its benefits in particular for the communities that need it most, and that the scientific evidence shows water fluoridation at optimal levels is safe and does not give rise to significant health risks, the limit on the right is in due proportion to the importance of the overall objective.

On this basis, I decided to continue the direction to fluoridate the Bream Bay and Whangarei drinking water supplies by 28 March 2025.

The NZBORA analysis will be published on the Ministry of Health | Manatū Hauora website, and you can find that at: <https://www.health.govt.nz/strategies-initiatives/programmes-and-initiatives/oral-health/implementation-of-community-water-fluoridation>.



To inform my assessment, Manatū Hauora also carried out a review of the latest scientific evidence relating to community water fluoridation. A copy of the report will also be published on the Manatū Hauora website at: <https://www.health.govt.nz/strategies-initiatives/programmes-and-initiatives/oral-health/community-water-fluoridation-policy>.

As you are aware, Part 5A of the Health Act 1956 empowers the Director-General of Health to direct local authorities to fluoridate water supplies, and provides that local authorities must comply with the Director-General's directions. Under Part 5A contravening a direction is an offence, and the statute provides for potentially significant penalties.

Manatū Hauora continues to support community water fluoridation as a safe, effective and affordable way to improve the oral health of communities in Aotearoa New Zealand.

I look forward to continuing to work with the Council to improve the oral health outcomes of the communities we serve.

Nāku noa, nā



Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora

Memo

New Zealand Bill of Rights Act 1990 analysis for 14 fluoridation directions

Date: 29 November 2024

To: Dr Diana Sarfati, Director-General of Health, Te Tumu Whakarae mō te Hauora

From: Dr Andrew Old, Deputy Director-General, Public Health Agency | Te Pou Hauora Tūmatanui

For your: Decision

Purpose of report

1. This memo provides advice to support your consideration of the 14 directions to fluoridate, specifically to assess whether the directions, in each case, constitute reasonable limits on the right to refuse medical treatment pursuant to the requirements of section 5 of the New Zealand Bill of Rights Act 1990 (NZBORA).
2. The following documents are appended to this memo:
 - a. Appendix 1: The Public Health Agency (PHA) analysis of the 14 directions under the NZBORA
 - b. Appendix 2: The Manatū Hauora Ministry of Health (the Ministry) update on the scientific evidence relating to community water fluoridation
 - c. Appendix 3: New Health New Zealand Inc. (New Health) comments on the scientific evidence and draft NZBORA analysis
 - d. Appendix 4: The PHA response to New Health's comments
 - e. Appendix 5: Additional information on recent publications
 - f. Appendix 6: Draft letters to each of the 14 local authorities to inform them of your decision following your decisions on the directions.

Background and context

3. In July 2022, the former Director-General of Health (Director-General) directed 14 local authorities to fluoridate some, or all, of their drinking water supplies. In total, local authorities were directed to fluoridate 19 water supplies.
4. In June 2023, New Health filed legal proceedings challenging the 2022 directions made by the Director-General.
5. In November 2023, Justice Radich found that the right to refuse medical treatment, provided for in section 11 of the NZBORA, should have been expressly taken into account by the Director-General when considering the directions. In a further judgment in February 2024,

Justice Radich kept the directions in place, but also directed the Director-General to assess whether the decision to put in place the 14 directions the Director-General made in 2022 was, in terms of section 5 of the NZBORA, a reasonable limit on the right to refuse medical treatment.

6. The PHA has carried out a comprehensive process to inform the analysis of each of the directions under the NZBORA. That process, and the PHA's recommendations, are set out in more detail below.

Process for the NZBORA analysis

Framework for the NZBORA analysis

7. To structure the NZBORA analysis, the PHA has used the common framework applicable to any analysis of whether a particular limit on a right is justified, under section 5 of the NZBORA. That framework consists of the following:
 - a. does the limiting measure serve a purpose sufficiently important to justify curtailment of the right or freedom?
 - b. is the limiting measure rationally connected with its purpose?
 - c. does the limiting measure impair the right or freedom no more than is reasonably necessary for sufficient achievement of its purpose?
 - d. is the limit in due proportion to the importance of the objective?

The Ministry has carried out a review of the recent scientific evidence on community water fluoridation

8. The Office of the Chief Science Advisor, in collaboration with the PHA Intelligence, Surveillance and Knowledge Group, has carried out a review of the scientific evidence relating to community water fluoridation since the 2021 Office of the Prime Minister's Chief Science Advisor's evidence review was carried out. The Ministry's updated evidence review has been peer reviewed by two external independent academic experts in oral health. The report has been signed off by the Ministry's Chief Science Advisor, Dr Ian Town.
9. The report aligns with the conclusion reached by the Prime Minister's Chief Science Advisor that community water fluoridation is a safe and effective public health intervention to prevent dental caries.

You provided local authorities with opportunity to comment

10. You also engaged with each of the 14 local authorities that received a direction to fluoridate. This was to give them an opportunity to review the local information the Ministry is considering and to invite them to inform you of any other local information they would like considered as part of the NZBORA analysis for the particular water supply/supplies that they have been directed to fluoridate.
11. Local authorities were provided 15 working days to respond. Three local authorities responded to the opportunity, and their input has been taken into consideration.
12. Hastings District Council provided a history of water fluoridation in Hastings. This information has been added to the NZBORA analysis in relation to the local considerations for the Hastings water supply.

13. Tauranga City Council provided the figure for the population of Tauranga. The population number used in the NZBORA analysis is the population served by each water supply, rather than the total population for the town or district, which may include people not served by the water supply such as those with a private water supply. This distinction has been made clear in the analysis.
14. Horowhenua District Council expressed a concern about the lack of consultation with the community, requested that historical data be taken into account, and asked about what else the Ministry is doing to support children's oral health.
15. Horowhenua District Council's letter did not specify what historical data it wanted to be considered. The oral health data used in the analysis is data collected for the Te Whatu Ora MidCentral district as this is the most relevant data that is available for the Levin water supply. The Ministry has looked at the rate of dental caries in the MidCentral district since 2000 and dental caries remains a highly prevalent disease. We have included a response on this point in the draft letter to the Council. We have also addressed the issue of consultation in the NZBORA analysis.
16. Additionally, prior to the consultation with local authorities, the Tararua District Council provided you with a petition that the Council received on 24 April 2024 from representatives of Fluoride Free Tararua relating to fluoridation. The Council advises that the petition was signed by 706 residents, which equates to approximately 12% of the population serviced by the Dannevirke water supply. The petition has also been taken into consideration in the NZBORA analysis.

The Ministry provided New Health with an opportunity to comment

17. Justice Radich ruled that the Director-General's NZBORA analysis should take into account the views of New Health. This has been done in two ways.
18. Firstly, New Health's submission to the High Court raised its concern that the safety and efficacy of community water fluoridation is not supported by the scientific evidence. The Ministry carried out a review of the scientific evidence on the safety and efficacy of community water fluoridation published since 2021. Its submission raised other matters including in relation to tikanga principles. The matters raised by New Health have been considered as part of the NZBORA analysis.
19. Secondly, the Ministry (through Crown Law) also provided New Health the opportunity to provide feedback on the scientific evidence review and a summary of the draft NZBORA analysis, and provided further information at New Health's request.
20. New Health's submission is attached in Appendix 3. New Health's submission focussed on 3 main points of view:
 - a. the view that there is risk of neurological harm from community water fluoridation
 - b. the view that tooth decay is not of functional significance
 - c. the view that there is insufficient evidence for the effectiveness of community water fluoridation, and alternative initiatives are preferable.
21. The PHA, together with Office of the Chief Science Advisor, carefully considered New Health's submission and has provided comment on the submission, engaging with New Health's key points, outlining where we have made amendments to the NZBORA analysis to reflect New

Health's comments, or where points raised have already been addressed in the NZBORA analysis. The Ministry's comments are attached in Appendix 4.

The Ministry has considered more recent publications

22. Since the Ministry's evidence review was completed, the following two noteworthy scientific publications relating to community water fluoridation have been published:
 - a. the US National Toxicology Program Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopmental and Cognition: A Systematic Review, published in August 2024
 - b. the Cochrane review of the evidence related to the prevention of dental decay by community water fluoridation, published in October 2024.
23. Additionally, in October 2024 the US District Court for the Northern District of California issued a ruling relating to community water fluoridation in the United States.
24. The US National Toxicology Program Monograph and District Court ruling were also provided to the Ministry by New Health, in additional responses to the consultation.
25. The Ministry has carefully considered all 3 of these documents as part of the evidence base underpinning the NZBORA analysis. We conclude that these documents do not change the overall conclusions reached. A detailed analysis of these 3 documents has been provided in Appendix 5 for your consideration.

Conclusions from NZBORA analysis

26. The NZBORA analysis comes to the following general conclusions about whether community water fluoridation is a reasonable limitation on the right to refuse medical treatment, as provided for by the NZBORA:
 - a. due to the high prevalence and the potential for lifelong impacts of poor oral health, the oral health benefits gained from community water fluoridation are sufficiently important to justify the curtailment of the right
 - b. according to the available scientific evidence, water fluoridation within the optimal range provides protection against dental caries, so there is a rational connection between community water fluoridation and public health goals related to oral health
 - c. community water fluoridation is an effective public health measure and impairs the right or freedom no more than is reasonably necessary, when fluoridation is kept within the optimum range, to achieve oral health benefits for a whole community
 - d. taking into account the effectiveness of community water fluoridation as a public health measure, and its benefits in particular for the communities that need it most, and that the scientific evidence shows water fluoridation at optimal levels is safe and does not give rise to significant health risks, the limit on the right is in due proportion to the importance of the overall objective.
27. In addition to the general conclusions, the NZBORA analysis considers local circumstances for each of the 19 water supplies that local authorities were directed to fluoridate, including population demographics, oral health data, cost-effectiveness and consultation responses.
28. Taking into consideration the general conclusions as well as the local considerations, the PHA considers that community water fluoridation is a reasonable limitation (under section 5 of the

NZBORA) on the right to refuse to undergo medical treatment provided for under section 11 of the NZBORA, for the populations serviced by each of the 19 water supplies.

29. Based on this, the PHA recommends that you reconfirm each of the 14 directions to fluoridate.

Next steps

30. We have attached a draft letter to each of the 14 local authorities to inform them of your decision relating to their water supply/supplies. This is to enable you to act on any decision you might make to reconfirm one or more of the directions to fluoridate. If you decide to not reconfirm the direction for one or more of the 19 water supplies, we will draft an alternative letter to inform the relevant local authority of your decision.
31. The PHA will work with local authorities to implement your decisions on the directions.
32. Note that we will publish the updated review of the scientific evidence on the Ministry website. We seek your agreement also to publish this memo and appendices on the Ministry website. Your decisions on the directions will be of high public interest, and publishing the supporting documentation will support openness and transparency in this area.

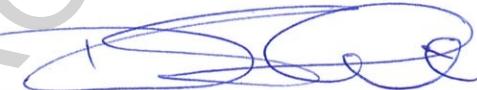
Recommendations

It is recommended that you:

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| 1. | Note | that the High Court has directed you to reconsider each direction to fluoridate issued under the Health Act 1956 and that you must consider the right to refuse medical treatment provided for in section 11 of the NZBORA in determining whether to confirm each direction | Noted <input checked="" type="checkbox"/> |
| 2. | Note | that fluoridation engages the right to refuse medical treatment that is protected by section 11 of the NZBORA | Noted <input checked="" type="checkbox"/> |
| 3. | Note | that before deciding that a direction to fluoridate should remain in place, you must be satisfied that this is a justified limitation on the right to refuse medical treatment pursuant to the requirements of section 5 of the NZBORA | Noted <input checked="" type="checkbox"/> |
| 4. | Note | that detailed NZBORA advice is provided in Appendix 1, and the Ministry scientific evidence review is provided in Appendix 2 | Noted <input checked="" type="checkbox"/> |
| 5. | Note | the feedback provided by New Health regarding its views on the issue of whether a direction is a justified limitation on the right to refuse medical treatment, which is provided in Appendix 3 | Noted <input checked="" type="checkbox"/> |
| 6. | Note | the Ministry's response to the feedback from New Health, which is provided in Appendix 4 | Noted <input checked="" type="checkbox"/> |
| 7. | Note | the Ministry's assessment of 3 additional publications relating to community water fluoridation that were published since the evidence review was carried out, which is provided in Appendix 5 | Noted <input checked="" type="checkbox"/> |

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| 8. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the New Plymouth District Council to fluoridate the New Plymouth drinking water supply | <input checked="" type="radio"/> Yes/No |
| 9. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Nelson City Council to fluoridate the Nelson drinking water supply by 31 December 2024 | <input checked="" type="radio"/> Yes/No |
| 10. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Auckland Council to fluoridate the Onehunga drinking water supply | <input checked="" type="radio"/> Yes/No |
| 11. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Auckland Council to fluoridate the Waiuku drinking water supply by 30 June 2026 | <input checked="" type="radio"/> Yes/No |
| 12. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Far North District Council to fluoridate the Kaitaia drinking water supply by 30 June 2024 | <input checked="" type="radio"/> Yes/No |
| 13. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Far North District Council to fluoridate the Kerikeri drinking water supply by 30 June 2024 | <input checked="" type="radio"/> Yes/No |
| 14. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Hastings District Council to fluoridate the Hastings drinking water supply by 30 June 2023 | <input checked="" type="radio"/> Yes/No |
| 15. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Horowhenua District Council to fluoridate the Levin drinking water supply | <input checked="" type="radio"/> Yes/No |
| 16. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Kawerau District Council to fluoridate the Kawerau drinking water supply by 30 September 2024 | <input checked="" type="radio"/> Yes/No |
| 17. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Rotorua Lakes Council to fluoridate the Rotorua Central drinking water supply by 28 March 2025 | <input checked="" type="radio"/> Yes/No |
| 18. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Rotorua Lakes Council to fluoridate the Rotorua East drinking water supply by 28 March 2025 | <input checked="" type="radio"/> Yes/No |
| 19. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Tararua District Council to fluoridate the Dannevirke drinking water supply | <input checked="" type="radio"/> Yes/No |

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| 20. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Tauranga City Council to fluoridate the Tauranga water supply by 30 November 2024 | <input checked="" type="radio"/> Yes/No |
| 21. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Waipa District Council to fluoridate the Cambridge drinking water supply by 31 July 2023 | <input checked="" type="radio"/> Yes/No |
| 22. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Waitaki District Council to fluoridate the Ōamaru drinking water supply | <input checked="" type="radio"/> Yes/No |
| 23. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Western Bay of Plenty District Council to fluoridate the Athenree drinking water supply by 31 July 2025 | <input checked="" type="radio"/> Yes/No |
| 24. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Western Bay of Plenty District Council to fluoridate the Wharawhara drinking water supply by 31 July 2025 | <input checked="" type="radio"/> Yes/No |
| 25. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Whangarei District Council to fluoridate the Bream Bay drinking water supply by 28 March 2025 | <input checked="" type="radio"/> Yes/No |
| 26. | Agree | having regard to the right protected by section 11 of the NZBORA, to reconfirm the direction to the Whangarei District Council to fluoridate the Whangarei drinking water supply by 28 March 2025 | <input checked="" type="radio"/> Yes/No |
| 27. | Sign | the draft letters that correspond to the decisions above | <input checked="" type="radio"/> Yes/No |
| 28. | Agree | to publish this memo and its appendices on the Ministry's website following your decision. | <input checked="" type="radio"/> Yes/No |

Signature 
Dr Diana Sarfati

Date: 3 Dec 2024

Director-General of Health
Te Tumu Whakarae mō te Hauora

PROACTIVELY RELEASED

Community water fluoridation: New Zealand Bill of Rights Act analysis

In 2018, the Supreme Court¹ held that the addition of fluoride to a water supply engaged the right to refuse to undergo medical treatment under s11 of the New Zealand Bill of Rights Act 1990 (NZBORA). The following analysis applies the well-established framework used to assess whether community water fluoridation is a justified limitation on that right for each of the 14 directions to fluoridate made by the Director-General of Health in 2022. That framework consists of the following:

- a. Does the limiting measure serve a purpose sufficiently important to justify curtailment of the right or freedom?
- b. Is the limiting measure rationally connected with its purpose?
- c. Does the limiting measure impair the right or freedom no more than is reasonably necessary for sufficient achievement of its purpose?
- d. Is the limit in due proportion to the importance of the objective?

A range of aspects related to community water fluoridation have been taken into account to inform the analysis, including the impact of poor oral health on people, benefits of community water fluoridation particularly for Māori, Pacific peoples and people living in the most deprived neighbourhoods, whether any alternatives are feasible, scientific evidence regarding community water fluoridation, and local circumstances.

The analysis concludes that the benefits resulting from community water fluoridation for each of the 19 water supplies under direction to fluoridate are sufficiently important to justify the limitation on the right to refuse medical treatment. The analysis concludes that:

- a. due to the high prevalence and the potential for lifelong impacts of poor oral health, the oral health benefits gained from community water fluoridation are sufficiently important to justify the curtailment of the right.
- b. according to the available scientific evidence, water fluoridation within the optimal range provides protection against dental caries, so there is a rational connection between community water fluoridation and public health goals related to oral health.
- c. community water fluoridation is an effective public health measure and impairs the right no more than is reasonably necessary, when fluoridation is kept within the optimum range, to achieve oral health benefits for a whole community.
- d. taking into account the effectiveness of community water fluoridation as a public health measure, and its benefits in particular for the communities that need it most, and that the scientific evidence shows water fluoridation at optimal levels is safe and does not give rise to significant health risks, the limit on the right is in due proportion to the importance of the overall objective.

¹ *New Zealand Inc v South Taranaki District Council [2018] NZSC 60*

1. Does the limiting measure serve a purpose sufficiently important to justify curtailment of the right or freedom?

Poor oral health is very common and can have negative impacts on quality of life

Dental caries is an irreversible disease and, according to the World Health Organization (WHO), is the most common noncommunicable disease worldwide, despite being largely preventable. While oral health has been improving over time, dental caries (also known as tooth decay or dental cavities) remains the most prevalent chronic disease in Aotearoa New Zealand affecting people of all ages. If left untreated, tooth decay can have lasting negative impacts throughout a person's life. Individuals who are adversely affected early in life tend to have pervasive decay by adulthood and are likely to suffer extensive tooth loss later in life. Emerging evidence also suggests that tooth decay and poor oral health can have negative consequences on a person's general health and are 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.

Oral disease causes pain and suffering, impairment of function and self-consciousness. Oral disease and its consequences can have profound effects on an individual's quality of life. Toothache, which may accompany many of the major oral diseases, is consistently rated among the most intense of pains. Impacts from oral diseases are often repeated experiences for individuals, resulting in physical, social and mental consequences. This can include impacts on self-confidence and self-esteem, which can lead to reduced social interaction. For children, untreated caries can affect a child's ability to eat, speak, learn and sleep, and severe untreated caries can affect nutrition, growth and weight gain.

In 2021, Parliament provided for a framework in legislation in Part 5A and Schedule 1AA of the Health Act 1956 which enables the Director-General of Health to direct local authorities to add fluoride to drinking water supplies for certain localities. The legislation also requires that local authorities that were fluoridating one or more water supplies upon commencement of the Act must continue to do so. The enactment of this legislation provides a clear signal from Parliament that community water fluoridation is considered an important public health measure.

Poor oral health affects people of all ages

Children are at risk of dental caries as soon as their teeth begin to break through the gum (around the age of 6 months) and this risk of decay continues through the life course. Findings from two New Zealand birth cohort studies concluded that 5-year-olds with greater caries were more likely to have poorer self-related general health by midlife.

The most recent New Zealand Oral Health Survey (Oral Health Survey), from 2009, found that 10.2% of adults aged 18-64 years had taken time off work or school over a 12-month period. The same survey also found that 1 in 8 (13%) children and adolescents aged 2-17 years had taken time away from school or normal activities because of problems with their teeth or mouth over a 12-month period. The prevalence of time taken away from school or normal activities was significantly higher among 12-17-year-olds (17.0%). The burden of time taken

away from school for 12-17-year-olds is significant because that is a key age for exams and preparation for life after school.

The Oral Health Survey found that overall, dentate adults (adults with at least one natural tooth) aged 18+ years had a mean of 13.9 decayed, missing, and filled teeth (DMFT²). This was higher among older dentate adults than younger dentate adults. Survey results showed that people aged 18-24 years had a mean DMFT of 3.7 teeth, while people aged 75 years and over had a mean DMFT of almost 25. Poor oral health among older people can negatively affect daily activities and contribute to overall frailty.

The Oral Health Survey also showed that the prevalence of having visited a dental professional in the last 12 months drops in both the younger (18-44) and the older (65+) adults, with the highest rate being 55.7% for the 45-64 year olds.

Poor oral health disproportionately affects Māori and Pacific people and people living in the most deprived neighbourhoods

Poor oral health disproportionately impacts Māori and Pacific people. The Community Oral Health Service provides annual oral health data for children at age 5 years and at year 8 in school (around 12-13 years of age)³. The 2022 data for children aged 5 show that, 56.0% of children aged 5 were caries free. When disaggregated by ethnicity, data shows that only 39% of Māori children and 33.5% of Pacific children were caries free, while 66.4% of non-Māori/non-Pacific children were caries free. Māori children had an average of 3.11 dmft and Pacific children had an average of 3.32 dmft, while non-Māori/non-Pacific children had an average of 1.36 dmft.

The same pattern was shown for children in year 8. Only 69% of children in year 8 were caries free. When disaggregated by ethnicity, data shows that only 59.2% of Māori children and 64.8% of Pacific children were caries free, while 73.3% of non-Māori/non-Pacific children were caries free. Māori children had an average of 1.15 DMFT and Pacific children had an average of 0.81 DMFT, while non-Māori/ non-Pacific children had an average of 0.55 DMFT.

The 2022/23 New Zealand Health Survey (Health Survey) found that those living in the least deprived neighbourhoods rated themselves as having better oral health than those living in the most deprived neighbourhoods, and were less likely to have had a tooth removed due to decay in the past 12 months.

Given the links between oral health and wider health and wellbeing including educational achievement, sustained employment, and social outcomes, community water fluoridation is an important contributor to health equity, as an effective means of reducing poor oral health

² Note:

- dmft = decayed, missing and filled teeth for baby teeth
- DMFT = decayed, missing and filled teeth for permanent teeth (permanent teeth start to erupt from approximately 6 years old)

³ This data is impacted by unequal provision of dental services and uneven geographic distribution of the sample population and therefore does not provide a reliable picture of trends in child oral health over time. A discussion on the limitations of the data can be found at:

<https://www.ehinz.ac.nz/assets/Reports/Oral-Health-Perspective.pdf>

in Māori and Pacific people, and also for those living in the most deprived neighbourhoods more generally.

Dental costs are burdens for individuals and the health care system

The burden of tooth decay can have direct financial costs to individuals. According to the New Zealand Dental Association, in October/November 2023, the average cost in New Zealand of a single tooth extraction was \$291, with each additional tooth extracted costing an average additional \$193. During this same time period, the average cost of a filling for one tooth surface ranged from \$201 to \$231 depending on the type of filling.

Tooth decay also has indirect cost to communities and society, in the form of time lost by individuals who need to take time off work or school to seek dental care, including for their dependents. A 2015 Sapere review of the costs and benefits estimated that if community water fluoridation was extended to cover those who do not currently have access to fluoridated water, this has the potential to result in estimated net savings of more than \$600 million over 20 years. These savings will mostly be seen by whānau in reduced costs for dental care, with some savings also to the health care system.

In 2022, approximately 6,957 0-14 year olds in New Zealand were hospitalised for dental treatment due to preventable decay and pulp and periapical issues. Rates of ambulatory sensitive hospitalisations (ASH) are a proxy measure of avoidable hospital admissions. ASH due to dental caries and diseases of pulp and periapical tissues are avoidable hospital admissions due to oral health issues that could be improved by use of fluoride and community water fluoridation. Given the pressure on health care services, ASH rates are measures not only of the impact that poor oral health has on individuals but also on the wider healthcare system. It is also of note that the average cost of a case addressed on the same day (i.e. not overnight) including general anaesthetic for dental care is just under \$5,000.

Conclusion

Due to the high prevalence and the potential for lifelong impacts of poor oral health, the oral health benefits gained from community water fluoridation are sufficiently important to justify the curtailment of the right.

2. Is the limiting measure rationally connected with its purpose?

Fluoride helps strengthen and repair teeth

Evidence supports that water fluoridation is effective at reducing incidence and severity of tooth decay.

Fluoride is a naturally occurring mineral that plays an essential role in preventing tooth decay. Every day, teeth go through demineralisation and remineralisation processes. Demineralisation occurs when the enamel, the protective outer layer of teeth, loses mineral due to acids in the mouth caused by bacteria, plaque, and sugars. Remineralisation is the

natural tooth repair process. Tooth decay is a result of too much demineralisation without enough remineralisation.

When fluoridated water is consumed, the concentration of fluoride in saliva and plaque fluid increases. 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 through remineralisation.

The enamel of 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 symmetrical and stack better than the hydroxyapatite crystals.

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 possible 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.

Other countries similar to New Zealand including Australia, Canada, Ireland, the United Kingdom, and the United States of America also add fluoride to drinking water, to levels within the recommended range to provide oral health benefits to the population. The recommended levels of fluoride are broadly consistent across these countries. Over 20 countries across the world add fluoride to drinking water.

Some countries have very high levels of fluoride in their water supplies either because of natural occurrence or because of industrial contamination (some of these countries include India, Estonia, China, and parts of South Africa). Where levels of fluoride in water supplies exceed recommended limits, some water supplies may have fluoride removed to lower content to recommended levels.

International and national scientific evidence shows that community water fluoridation is effective at preventing tooth decay

Water fluoridation is endorsed by the WHO and other international and national health and scientific experts as an effective public health measure for preventing dental decay.

Fluoride exists naturally within New Zealand's water, however the naturally occurring levels (~0.1-0.2 mg per litre in most parts of New Zealand) are not high enough to prevent tooth decay. Water fluoridation adjusts the natural level of fluoride in the water supply to between 0.7 mg per litre and 1.0 mg per litre. This is the optimal range recommended by the WHO that provides protection against tooth decay.

There have been a number of evidence reviews conducted in New Zealand and overseas assessing the efficacy of community water fluoridation at preventing tooth decay. These reviews include:

- 2015 review by Sapere Research Group (commissioned by the Ministry of Health | Manatū Hauora) on the benefits and costs of water fluoridation in New Zealand
- 2015 and 2024 Cochrane reviews which evaluated the effect of fluoride in water on the prevention of tooth decay and dental fluorosis
- 2014 review of scientific evidence on the health effects of water fluoridation carried out by the Royal Society Te Apārangi and the Office of the Prime Minister's Chief Science Advisor
- 2021 evidence update by the Office of the Prime Minister's Chief Science Advisor
- 2024 review of the scientific evidence since 2021, carried out by the Ministry of Health.

The findings of these evidence reviews are summarised below.

Review of benefits and costs of community water fluoridation in New Zealand

In 2015, the Ministry of Health commissioned an independent report titled “Review of the Benefits and Costs of Community Water Fluoridation in New Zealand” (the Sapere Report). The Sapere Report provided an evaluation of the benefits and costs of water fluoridation, in the New Zealand setting.

This report reviewed evidence found in many studies and reports both in New Zealand and overseas. It estimated the following benefits of water fluoridation:

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

The Sapere Report also estimated that provision of fluoridated water to all New Zealand reticulated water supplies over 20 years would result in between 8,800 and 13,700 quality adjusted life years (QALYs) gained. QALY is a measure of health outcomes pertaining to disease burden and is used to assess the value of medical interventions. It measures how many additional months or years of life of a reasonable quality a patient or person may gain due to treatment.

Cochrane review into the effect of fluoride in water on the prevention of tooth decay and dental fluorosis

A meta-analysis of the effectiveness of water fluoridation for the prevention of dental caries was published by the Cochrane Library in 2015 and updated in 2024 (the Cochrane review).

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 community water fluoridation on the prevention of tooth decay in children.

Since 1975 there have been relatively few studies which meet the inclusion criteria for inclusion in the Cochrane review. Due to the low numbers of studies meeting inclusion criteria, not all outcomes were statistically significant. Therefore the authors concluded that although "*studies conducted after 1975 showed that adding fluoride to water may lead to slightly less tooth decay in children's baby teeth. There was uncertainty about whether adding fluoride to water reduced tooth decay in children's permanent teeth or decay on the surfaces of permanent teeth.*"

In addition the authors reported that "*adding fluoride to water may slightly increase the number of children who have no tooth decay in either their baby teeth or permanent teeth. However, these results also included the possibility of little or no difference in tooth decay*".

The 2015 review also found that, where the fluoride level in water is 0.7 ppm, there is a chance of around 12% of people having dental fluorosis that may cause concern about how their teeth look.

Royal Society Te Apārangi/Office of the Prime Minister's Chief Science Advisor 2014 report

In 2014, a comprehensive report was published by the Royal Society Te Apārangi and the Office of the Prime Minister's Chief Science Advisor which reviewed the scientific evidence of the health effects of water fluoridation. This review assessed a range of international and New Zealand evidence.

The report concluded that from a financial and an equity perspective, community water fluoridation is the safest and most appropriate approach for promoting public dental health. The report also stated that there are no adverse effects of fluoride of any significance arising from fluoridation at the levels used in New Zealand.

The report found that water fluoridation reduces dental decay regardless of ethnicity, socio-economic status and age. In contrast, oral disease disproportionately affects poor and socially disadvantaged members of society with a strong association between socio-economic status and the prevalence and severity of oral disease. Because of this, it concluded that water fluoridation is especially important for the most deprived neighbourhoods to reduce the inequitable burden of poor oral health.

Office of the Prime Minister's Chief Science Advisor 2021 evidence update

In 2021, the Office of the Prime Minister's Chief Science Advisor examined new evidence on water fluoridation published since the Royal Society Te Apārangi report in 2014. After

considering new research on fluoridation and in a comprehensive review published subsequently, the Office of the Prime Minister's Chief Science Advisor found that the conclusions of the Royal Society Te Apārangi remain appropriate.

Ministry of Health's 2024 review of evidence

In 2024, the Ministry of Health carried out a review of the evidence regarding the risks and benefits of community water fluoridation published since the Office of the Prime Minister's Chief Science Advisor report in 2021. The Ministry's review concurs with the conclusions of the 2014 and 2021 reviews that community water fluoridation is a safe and effective health intervention to prevent dental caries, on the basis that:

- the evidence that has been published since 2021 indicates ongoing clear benefits from community water fluoridation including during the period when alternative forms of fluoride (such as fluoride toothpaste) are available and
- community water fluoridation promotes equity by decreasing the incidence and severity of dental caries in individuals in areas of high socioeconomic deprivation as much as, or more than, in individuals in areas of less deprivation and
- there has been no high-quality evidence published since those reviewed in 2014 and 2021 reports to suggest a causal link between fluoride exposure at the levels used in Aotearoa New Zealand for community water fluoridation and significant harm to health.

Conclusion

According to the available scientific evidence, water fluoridation within the optimal range provides protection against dental caries, so there is a rational connection between community water fluoridation and public health goals related to oral health.

3. Does the limiting measure impair the right or freedom no more than is reasonably necessary for sufficient achievement of its purpose?

Alternatives to community water fluoridation are of limited efficacy, particularly for Māori and Pacific communities and those living in the most deprived neighbourhoods

There have been recommendations that alternatives to fluoridation should be used instead because they are less intrusive on individuals' rights and freedoms. Alternatives to community water fluoridation that are often suggested include brushing teeth with fluoride toothpaste, taking fluoride tablets, regular dental care including professional application of fluoride varnishes, and reducing sugar intake.

However, these alternatives require behaviour change. In an ideal situation, people would regularly carry out behaviours that are protective for their oral health, but for many different reasons some people cannot or do not carry out these behaviours and therefore their oral health suffers. For example, the Health Survey 22/23 found that only 65.9% of children up to 14 years and 68.2% of adults 15+ brushed their teeth twice a day with standard fluoride

toothpaste. These behaviours are recommended in addition to water fluoridation, as complementary measures rather than as alternatives or substitutes.

The evidence that has been published indicates ongoing clear benefits from community water fluoridation even during the period when alternative forms of fluoride (such as fluoride toothpaste) are available.

Relying on these other oral health measures would disproportionately negatively impact Māori and Pacific people and those living in the most deprived neighbourhoods. The Health Survey results for tooth brushing twice a day or more with standard fluoride toothpaste among adults aged 15+ years with natural teeth showed that 51.9% of Māori, 61.9% of Pacific people, 69.9% of European/Other, and 73.5% of Asian people brush twice a day. A similar distribution was seen for children aged 14 and under.

The Health Survey also showed that 76.6% of the respondents from quintile 1 (least deprived) brushed twice a day, and that this progressively decreased with increasing deprivation to 58.0% of the respondents from quintile 5 (most deprived) brushing twice a day. The same pattern was shown for children aged 14 and under, with prevalence of brushing twice a day decreasing from 78.5% in quintile 1 to 57.4% in quintile 5.

The Health Survey also showed that 73.1% of children (aged 1-14 years) and 49% of adults (15+) had visited a dental health care worker in the previous 12 months. The cost of dental care is a barrier for some populations. Dental care is free for under 18-year-olds, so there must be other barriers than direct cost that operate to impede access to dental care for this cohort.

The Oral Health Survey showed that there were a range of reasons that adults aged 18+ years had not visited a dental professional in the last 12 months. The most common reason, almost on par with 'having no issues' (47.5% stated no issues) was cost, with 46.8% stating this reason.

Over half (56.8%) of people in quintile 5 (most deprived) neighbourhoods avoided dental care due to cost. This percentage decreases as the level of deprivation increases, but it is still a significant factor even for those in quintile 1, with 29.0% of adults in quintile 1 (least deprived) neighbourhoods avoiding dental care due to cost.

The Oral Health Survey showed that among adults aged 18+ years, 63.3% of those in quintile 1 had visited a dental professional in the last 12 months, compared to 33.9% of those in quintile 5.

The Oral Health Survey identified that Māori and Pacific people were much less likely to have visited a dental professional in the last 12 months (35.6 and 32.8% respectively) when compared to those who were European/Other (49.4%), and that Māori and Pacific people were more likely to have avoided dental care due to cost (61.5% and 66.3% respectively) than those who were European/Other (41.4%).

Community water fluoridation is beneficial and effective as a public health measure because it does not require any behaviour change or financial input from individuals. Individuals are

able to carry out their daily lives as they would otherwise, while also having the oral health benefits associated with fluoridated water.

Concentration of fluoride in drinking water is kept within the optimal range

Fluoridation of drinking water increases the concentration of a substance that already naturally exists in the water. Drinking water in New Zealand naturally has an average fluoride concentration of 0.2mg/L.

Fluoride concentration in drinking water is kept within the optimal range for oral health outcomes. This range ensures that it has maximum oral health benefit, while limiting any negative impact on health that could arise at higher fluoride concentrations. The recommended optimal range is generally consistent around the world, with ranges in individual countries all being taken from within the bracket of 0.5mg/L minimum and 1.2mg/L maximum. In New Zealand the optimum range is set at 0.7-1.0mg/L. The range was identified as optimal by the 2014 review of the scientific evidence carried out by the Office of the Prime Minister’s Chief Science Advisor, and subsequent reviews of evidence, such as the 2021 update and 2024 Ministry of Health review, are consistent with the 2014 report.

The maximum concentration set for the optimal range is also lower than the maximum acceptable value set in the Water Services (Drinking Water Standards for New Zealand) Regulations 2022 (which is 1.5mg/L). Water supplies are also regularly monitored to ensure fluoride levels do not exceed the maximum safe limits set in the Drinking Water Standards.

Conclusion

Community water fluoridation is an effective public health measure and impairs the right no more than is reasonably necessary, when fluoridation is kept within the optimum range, to achieve oral health benefits for a whole community.

4. Is the limit in due proportion to the importance of the objective?

Benefits of community water fluoridation

Over 60 years of international and New Zealand research shows water fluoridation is both a safe and effective way to reduce tooth decay. The major recent reviews have been discussed above.

New Zealand's Oral Health Survey shows that, on average, 40% less tooth decay was experienced among children and adolescents living in communities with fluoridated water, compared with children living in communities without fluoridated water.

In addition to significant oral health benefits, water fluoridation provides financial benefits. A 2015 Sapere review of the costs and benefits of community water fluoridation estimated that if community water fluoridation was extended to water supplies that were not fluoridated at that time, this had the potential to result in net savings of more than \$600 million over 20 years. The Sapere report also estimated the average ongoing cost of community water fluoridation is \$2.60 per person per year for water supplies that serve populations of over

500 people and that every dollar spent on water fluoridation will save around \$9 in dental care costs. These savings will mostly be seen by individuals and families in reduced costs for dental care, with some savings also to the health care system.

The cost effectiveness assessment of the 14 directions made in 2022 was based on an analysis undertaken by Sapere in 2015. The review estimated that for water supplies with populations over 5,000, community water fluoridation would be cost saving, and for populations over 500 it would likely be cost saving. Additionally, the Ministry of Health is funding the costs for capital works for the 14 directions being implemented.

As well as being cost effective, community water fluoridation is effective as a public health measure because, as has been discussed in detail above, it provides health benefits over and above those provided by individual oral health behaviours such as toothbrushing, it provides benefits for all ages, and it particularly benefits the communities that need it most including Māori and Pacific communities and those living in the lowest socioeconomic communities – thereby promoting health equity.

Community water fluoridation and Te Ao Māori

In a traditional Māori world view, water and its use has physical and spiritual importance. Some Māori may consider that fluoridating water spoils that water and causes it to become waikino (polluted or spoilt) or waimate (dead damaged or polluted). Some Māori may consider that fluoridated water is no longer pure (eg, that it conflicts with the concept of waiora – the water of life), as was identified by the Public Health Commission (1994). However, Māori views on this issue are diverse.

For example, Broughton (2009) reflects a wider Te Ao Māori view that recognises that for some Māori, fluoridation of water as a means of protecting oral health and wellbeing is complementary to traditional beliefs in the life-giving properties of water. Broughton also highlights that water used for customary practices and religious services is often obtained from particular wahi tapu (sacred sites) or waipuna (fresh spring water) rather than from the community water supply.

Māori oral health organisations including Te Ao Mārama (the New Zealand Māori Dental Assoc) and Te Rōpu Niho Ora strongly support community water fluoridation for its oral health benefits at low cost to communities. These Māori health organisations consider community water fluoridation has a positive impact on equity. These organisations note the mana and mauri of water, and consider that fluoridation doesn't diminish the overall mauri of the water because fluoridated water improves health and wellbeing for all.

A National Māori Oral Health Equity Symposium was held in 2019 which was attended by representatives from a range of Māori oral health providers, the wider health sector, Māori health and other non-health sector stakeholders. The recommendations from that symposium led to the development of the Māori Oral Health Equity Action Plan 2020-2023 which called for increased community water fluoridation coverage including for Māori communities and marae. Te Rōpu Niho Ora also noted in its 2023 position statement on community water fluoridation that improvement of Māori oral health and reduction of oral

health inequities can result in improvements in other areas such as educational achievement and sustained employment.

Concerns relating to community water fluoridation

For community water fluoridation to have benefits for the community, it needs to be the public water supplies that are fluoridated. It is not practicable to get informed consent from everyone that could be impacted when it comes to community interventions, and we acknowledge that it is unlikely that 100% of a population supplied by any individual water supply will want fluoride in their water. However, it is impossible to supply differently treated water to different dwellings from one water supply, and the legislative scheme governing fluoridation of water supply recognises this. The Bill of Rights, by section 5, recognises that there is a responsibility to make decisions that balance the best possible community health outcomes with individual rights.

For an individual that does not wish to consume fluoridated water, community water fluoridation significantly restricts their options for accessing non-fluoridated water. However, it does not fully restrict such access. In general, private water supplies are not fluoridated. Individuals may also purchase bottled water, which is typically not fluoridated. However, we acknowledge that these alternatives will not be practical for many people due to accessibility and cost, and are likely to be less accessible to those in the most deprived neighbourhoods. Section 116F(3) of the Health Act provides that the Director-General may allow a local authority to supply water to which fluoride has not been added at specified sites, for example public taps. Any public tap provided by a local authority must meet the Drinking Water Standards. Requests for such sites will be considered.

Some people are concerned about the impact of ingesting fluoride on their health, and these concerns are also raised by New Health. Risks to health that are commonly raised include neurodevelopmental and cognitive risks, cancer, skeletal fluorosis, and dental fluorosis. The 2014 evidence review by the Office of the Prime Minister's Chief Science Advisor and Te Apārangi considered the evidence around health concerns and concluded that these are not supported by the evidence. The report noted that it is important to distinguish between effects of apparent fluoride toxicity at very high concentrations, and effects that may occur at the much lower concentrations from community water fluoridation. These conclusions were supported by updated evidence reviews carried out in 2021 by the Office of the Prime Minister's Chief Science Advisor and in 2024 by the Ministry of Health. The Ministry continues to review new evidence on an ongoing basis.

Dental fluorosis is a condition that causes changes in the appearance of tooth enamel. Dental fluorosis reflects overall fluoride absorption from all sources at a young age and is a known effect of drinking water containing naturally very high concentrations of fluoride. The levels of fluoride used for community water fluoridation in New Zealand are relatively low in the range that is known to cause minimal risk for cosmetically problematic fluorosis. Other factors contribute more significantly to increasing risk, such as young children regularly swallowing fluoridated toothpaste.

No severe form of fluorosis has ever been reported in New Zealand. The Oral Health Survey indicated that fluorosis prevalence is not increasing, and that levels of fluorosis are similar between fluoridated and non-fluoridated areas, confirming that a substantial proportion of the risk is attributable to the intake of fluoride from sources other than water.

Conclusion

Taking into account the effectiveness of community water fluoridation as a public health measure, and its benefits in particular for the communities that need it most, and that the scientific evidence shows water fluoridation at optimal levels is safe and does not give rise to significant health risks, the limit on the right is in due proportion to the importance of the overall objective.

Assessment of proportionality in relation to each water supply under direction

In addition to the considerations already outlined, this section outlines the considerations specific to each local authority which are relevant to determining whether the limit on the right is in due proportion to the benefits for each individual community under direction.

The following key local factors have been taken into account when determining costs and benefits of community water fluoridation for individual communities:

- Population demographics
 - Size of population serviced by the water supply
 - Age distribution
 - Ethnicity
- Neighbourhood deprivation
- Oral health data
- Cost-effectiveness

The relevance of each of these factors has been discussed previously in this analysis. In addition to these factors, this section outlines any additional considerations relevant to the assessment of community water fluoridation in each individual community. The Director-General engaged with local authorities when considering whether to make a direction to fluoridate and has continued to maintain regular communication with these local authorities. For the purposes of this Bill of Rights assessment the Director-General provided a further round of consultation with local authorities, in response to which Horowhenua, Hastings, and Tauranga Councils provided further information. Tararua District Council also provided information prior to the consultation which has been taken into account.

Kawerau District Council – Kawerau water supply

Population demographics Kawerau district

The population of the Kawerau district includes 61.7% Māori, and 4.6% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Kawerau district includes 24.0% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Kawerau water supply

Population serviced by the Kawerau water supply is 7,078⁴.

For the population that receives water from the Kawerau water supply specifically, 61.8% are Māori. This is much higher than the national average of 17.3% and means that Māori would have a disproportionately greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Kawerau water supply specifically, 95.2% are considered to be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Bay of Plenty District Health Board⁵

The 2022⁶ Community Oral Health Service data shows that in the Bay of Plenty District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 53.0% | 2.57 |
| | Māori children | 68.3% | 3.72 |
| | Pacific children | 74.5% | 3.98 |
| Year 8 | All children | 42.1% | 1.05 |
| | Māori children | 54.4% | 1.59 |
| | Pacific children | 51.6% | 1.28 |

For the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Bay of Plenty District Health Board show:

⁴ This analysis uses population numbers served by the water supply rather than population of the whole town or district, which may include people not served by the water supply.

⁵ Data used in this analysis was collected prior to the establishment Health New Zealand | Te Whatu Ora (on 1 July 2022) and therefore refers to district health boards. The boundaries of the district health boards are the same as the boundaries for the Te Whatu Ora districts currently in place.

⁶ We note that the 2023 Community Oral Health Data has now been published. Because oral health outcomes generally change slowly, this data is not likely to differ significantly from the 2022 data.

- 50.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 6.8% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Bay of Plenty District Health Board due to dental caries and diseases of pulp and periapical tissues was 3,535 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations.

Cost effectiveness

Kawerau water supply population is 7,078. Based on the Sapere report Kawerau is a medium-sized supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Kawerau water supply will provide oral health benefits to the Kawerau district population and likely improve equity in health outcomes, in due proportion to the limitation on the right.

Hastings District Council – Hastings Urban water supply

Population demographics Hastings district

The population of the Hastings district includes 27.3% Māori and 8.0% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Hastings district includes 21.7% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Hastings Urban water supply

Population serviced by the Hastings water supply is 60,402

For the population that receives water from the Hastings Urban water supply specifically, 29.5% are Māori. This is higher than the national average of 17.3% and means that Māori would have a disproportionately greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Hastings Urban water supply specifically, 51.3% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Hawke's Bay District Health Board

The 2022 Community Oral Health Service data shows that in the Hawke's Bay District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 43.4% | 1.96 |
| | Māori children | 59.3% | 2.92 |
| | Pacific children | 62.3% | 3.40 |
| Year 8 | All children | 35.6% | 0.77 |
| | Māori children | 46.4% | 1.12 |
| | Pacific children | 46.2% | 1.09 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Hawke's Bay District Health Board show:

- 53.1% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 9.1 % of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Hawke's Bay District Health Board due to dental caries and diseases of pulp and periapical tissues was 3,580 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Hastings Urban water supply population is 60,402. Based on the Sapere report Hastings is a large supply and providing community water fluoridation is cost saving.

Additional information

Hastings District Council provided further information on fluoridation in Hastings. The Council highlighted that it was one of the first in the country to add fluoride to its drinking water, with fluoridation of the main urban Hastings water supply in the early 1950s. In 2016, a campylobacter outbreak in the water supply occurred in the Havelock North area which is part of the main Hastings Urban water supply. In response to this outbreak, the Council had to stop adding fluoride to the water supply in order to introduce chlorine, as the Council's infrastructure at the time would only allow one element to be added to the water supply at a time.

Ceasing fluoridation to allow chlorination of the water supply at that time was based on the need to manage the immediate health risk the campylobacter outbreak caused to the community, and not because of a decision by elected members to cease fluoridation. The Chief Executive stated that it was not foreseen that fluoridation would be paused for as long as has transpired.

The Council also highlighted that water fluoridation has been put to a local referendum twice (1990 and 2013) and both times the majority voted in favour.

Hastings District Council currently partially fluoridates the Hastings water supply. Hastings District Council has implemented fluoridation at two major water treatment plants but is still to complete capital works at the Wilson Road water treatment plant to fully meet the direction.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Hastings Urban water supply will provide oral health benefits to the Hastings population that are in due proportion to the limit of the right.

Horowhenua District Council – Levin water supply

Population demographics Horowhenua district

The population of the Horowhenua district includes 24.5% Māori and 5.7% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Horowhenua district includes 18.3% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Levin water supply

Population serviced by the Levin water supply is 20,239

For the population that receives water from the Levin water supply specifically, 24.6% are Māori. This is higher than the national average of 17.3% and means that Māori would have a disproportionately greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Levin water supply specifically, 71.6% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data MidCentral District Health Board

The 2022 Community Oral Health Service data shows that in the MidCentral District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 43.3% | 2.01 |
| | Māori children | 61.9% | 2.98 |
| | Pacific children | 65.9% | 3.70 |
| Year 8 | All children | 43.2% | 1.26 |
| | Māori children | 55.3% | 1.86 |
| | Pacific children | 48.0% | 2.04 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the MidCentral District Health Board show:

- 51.3% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 7.9% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the MidCentral District Health Board due to dental caries and diseases of pulp and periapical tissues was 4,706 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

The Levin water supply population is 20,239. Based on the Sapere report Levin is a medium supply and providing community water fluoridation is cost saving.

Additional information

The Council provided further information raising a concern over community consultation and voice. It is acknowledged water fluoridation attracts a range of views. Part 5A of the Health Act 1956 creates a relationship between the Director-General and local authorities, as the community's representatives, and as part of that scheme provides that local authorities are not under a legal obligation to consult.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Levin water supply will provide oral health benefits to the Horowhenua district population that are in due proportion to the limit of the right.

New Plymouth District Council – New Plymouth water supply

Population demographics New Plymouth district

The population of the New Plymouth district includes 17.8% Māori and 2.2% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the New Plymouth district includes 20.4% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics New Plymouth Urban water supply

Population serviced by the New Plymouth Urban water supply is 65,176.

For the population that receives water from the New Plymouth water supply, 19.2% are Māori. This is higher than the national average of 17.3% and means that Māori would have a

greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the New Plymouth water supply specifically, 33.8% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Taranaki District Health Board

The 2022 Community Oral Health Service data shows that in the Taranaki District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 44.3% | 2.03 |
| | Māori children | 66.2% | 3.33 |
| | Pacific children | 64.7% | 3.71 |
| Year 8 | All children | 36.9% | 0.71 |
| | Māori children | 32.6% | 0.54 |
| | Pacific children | 37.5% | 1.38 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Taranaki District Health Board show:

- 52.9% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 8.9% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Taranaki District Health Board due to dental caries and diseases of pulp and periapical tissues was 2,980 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

New Plymouth water supply population is 65,176. Based on the Sapere report New Plymouth is a large supply and providing community water fluoridation is cost saving

Conclusion

Taking all of these factors into account, we conclude that fluoridating the New Plymouth water supply will provide oral health benefits to the New Plymouth district population that are in due proportion to the limit of the right.

Waipa District Council – Cambridge water supply

Population demographics Waipa district

The population of the Waipa district includes 20.7% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Cambridge water supply

Population serviced by the Cambridge water supply is 18,833.

The population of the Waipa district includes 14.9% Māori and 1.8% Pacific. For the population that receives water from the Cambridge water supply specifically, 10.8% are Māori. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

For the population that receives water from the Cambridge water supply specifically, 8.3% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Waikato District Health Board

The 2022 Community Oral Health Service data shows that in the Waikato District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 45.4% | 2.01 |
| | Māori children | 62.7% | 3.03 |
| | Pacific children | 67.8% | 3.62 |
| Year 8 | All children | 22.9% | 0.66 |
| | Māori children | 23.1% | 1.01 |
| | Pacific children | 17.0% | 0.74 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Waikato District Health Board show:

- 50.0% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 7.1% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Waikato District Health Board due to dental caries and diseases of pulp and periapical tissues was 3,713 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Cambridge water supply population is 18,833. Based on the Sapere report Cambridge is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Cambridge water supply will provide oral health benefits to the Waipa district population that are in due proportion to the limit of the right.

Whangarei District Council – Bream Bay water supply

Population demographics Whangārei district

The population of the Whangārei district includes 30.1% Māori, and 3.9% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Whangārei district includes 21.0% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Bream Bay water supply

Population services by the Bream Bay water supply is 7,072.

For the population that receives water from the Bream Bay water supply specifically, 25.0% are Māori. This is higher than the national average of 17.3% and means that Māori would have a greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Bream Bay water supply specifically, 30.7% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Northland / Te Tai Tokerau District Health Board

The 2022 Community Oral Health Service data shows that in the Northland / Te Tai Tokerau District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 56.9% | 3.29 |
| | Māori children | 70.3% | 4.52 |
| | Pacific children | 47.8% | 2.35 |
| Year 8 | All children | 41.2% | 1.22 |
| | Māori children | 50.6% | 1.64 |
| | Pacific children | 45.5% | 1.00 |

For the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Northland / Te Tai Tokerau District Health Board show:

- 57.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 9.2% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Northland / Te Tai Tokerau District Health Board due to dental caries and diseases of pulp and periapical tissues was 4,318 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Whangarei district Bream Bay water supply population is 7,072. Based on the Sapere report Bream Bay is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Bream Bay water supply will provide oral health benefits to the Whangarei district population that are in due proportion to the limit of the right.

Whangarei District Council – Whangārei water supply

Population demographics Whangārei district

The population of the Whangārei district includes 30.1% Māori, and 3.9% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Whangārei district includes 21.0% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Whangārei water supply

Population serviced by the Whangārei water supply is 57,831.

For the population that receives water from the Whangārei water supply specifically, 34.0% are Māori. This is double the national average of 17.3% and means that Māori would have a disproportionately greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Whangārei water supply specifically, 59.1% are considered be living in high deprivation. We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Northland / Te Tai Tokerau District Health Board

The 2022 Community Oral Health Service data shows that in the Northland / Te Tai Tokerau District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 56.9% | 3.29 |
| | Māori children | 70.3% | 4.52 |
| | Pacific children | 47.8% | 2.35 |
| Year 8 | All children | 41.2% | 1.22 |
| | Māori children | 50.6% | 1.64 |
| | Pacific children | 45.5% | 1.00 |

For the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Northland / Te Tai Tokerau District Health Board show:

- 57.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 9.2% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Northland / Te Tai Tokerau District Health Board due to dental caries and diseases of pulp and periapical tissues was 4,318 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Whangārei district Whangārei water supply population is 57,831. Based on the Sapere report Whangārei is a large supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Whangārei water supply will provide oral health benefits to the Whangārei district population that are in due proportion to the limit of the right.

Rotorua Lakes District Council – Rotorua Central water supply

Population demographics Rotorua Lakes district

The population of the Rotorua Lakes district includes 40.1% Māori and 5.4% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Rotorua Lakes district includes 22.4% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts

Population demographics Rotorua Central water supply

Population serviced by the Rotorua Central water supply is 43,064.

For the population that receives water from the Rotorua Central water supply specifically, 43.2% are Māori. This is much higher than the national average of 17.3% and means that Māori would have a disproportionately greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Rotorua Central water supply specifically, 65.8% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Lakes District Health Board

The 2022 Community Oral Health Service data shows that in the Lakes District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 54.3% | 2.79 |
| | Māori children | 68.1% | 3.82 |
| | Pacific children | 79.0% | 4.00 |
| Year 8 | All children | 50.6% | 1.62 |
| | Māori children | 59.9% | 2.38 |
| | Pacific children | 61.8% | 1.26 |

For the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Lakes District Health Board show:

- 52.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 8.9% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Lakes District Health Board due to dental caries and diseases of pulp and periapical tissues was 4,519 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Rotorua Central water supply population is 43,064. Based on the Sapere report Rotorua Central is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Rotorua Central water supply will provide oral health benefits to the Rotorua Lakes district population that are in due proportion to the limit of the right.

Rotorua Lakes District Council – Rotorua East water supply

Population demographics Rotorua Lakes district

The population of the Rotorua Lakes district includes 40.1% Māori and 5.4% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Rotorua Lakes district includes 22.4% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Rotorua East water supply

Population serviced by the Rotorua East water supply is 11,179.

For the population that receives water from the Rotorua East water supply specifically, 38.7% are Māori. This is much higher than the national average of 17.3% and means that Māori would have a disproportionately greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Rotorua East water supply specifically, 41.5% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Lakes District Health Board

The 2022 Community Oral Health Service data shows that in the Lakes District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 54.3% | 2.79 |
| | Māori children | 68.1% | 3.82 |
| | Pacific children | 79.0% | 4.00 |
| Year 8 | All children | 50.6% | 1.62 |
| | Māori children | 59.9% | 2.38 |
| | Pacific children | 61.8% | 1.26 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Lakes District Health Board show:

- 52.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 8.9% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Lakes District Health Board due to dental caries and diseases of pulp and periapical tissues was 4,519 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Rotorua East water supply population is 11,179. Based on the Sapere report Rotorua East is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Rotorua East water supply will provide oral health benefits to the Rotorua Lakes district population that are in due proportion to the limit of the right.

Nelson City Council – Nelson water supply

Population demographics Nelson district

The population of the Nelson district includes 10.7% Māori and 2.3% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Nelson district includes 17.7% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Nelson water supply

Population serviced by the Nelson water supply is 46,936.

For the population that receives water from the Nelson water supply specifically, 11.1% are Māori.

For the population that receives water from the Nelson water supply specifically, 30.8% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Nelson Marlborough District Health Board

The 2022 Community Oral Health Service data shows that in the Nelson Marlborough District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 33.8% | 1.56 |
| | Māori children | 46.0% | 2.33 |
| | Pacific children | 48.2% | 2.89 |
| Year 8 | All children | 13.7% | 0.69 |
| | Māori children | 22.5% | 1.01 |
| | Pacific children | 21.4% | 1.04 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Nelson Marlborough District Health Board show:

- 51.3% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 6.2% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Nelson Marlborough District Health Board due to dental caries and diseases of pulp and periapical tissues was 2,327 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Nelson water supply population 46,936. Based on the Sapere report Nelson is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Nelson water supply will provide oral health benefits to the Nelson district population that are in due proportion to the limit of the right.

Far North District Council – Kaitaia water supply

Population demographics Far North district

The population of the Far North district includes 48.3% Māori and 4.8% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Far North district includes 21.6% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Kaitaia water supply

Population serviced by the Kaitaia water supply is 6,079.

For the population that receives water from the Kaitaia water supply specifically, 65.6% are Māori. This is much higher than the national average of 17.3% and means that Māori would have a disproportionately greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Kaitaia water supply specifically, 98.3% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Northland / Te Tai Tokerau District Health Board

The 2022 Community Oral Health Service data shows that in the Northland / Te Tai Tokerau District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 56.9% | 3.29 |
| | Māori children | 70.3% | 4.52 |
| | Pacific children | 47.8% | 2.35 |
| Year 8 | All children | 41.2% | 1.22 |
| | Māori children | 50.6% | 1.64 |
| | Pacific children | 45.5% | 1.00 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Northland / Te Tai Tokerau District Health Board show:

- 57.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 9.2% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Northland / Te Tai Tokerau District Health Board due to dental caries and diseases of pulp and periapical tissues was 4,318 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Kaitaia water supply population 6,079 Based on the Sapere report Kaitaia is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Kaitaia water supply will provide oral health benefits to the Far North district population that are in due proportion to the limit of the right.

Far North District Council – Kerikeri water supply

Population demographics Far North district

The population of the Far North district includes 48.3% Māori and 4.8% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Far North district includes 21.6% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Kerikeri water supply

Populations serviced by the Kerikeri water supply is 4,972.

For the population that receives water from the Kerikeri water supply specifically, 19.0% are Māori. This is higher than the national average of 17.3% and means that Māori would have a greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Kerikeri water supply specifically, 30.3% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Northland / Te Tai Tokerau District Health Board

The 2022 Community Oral Health Service data shows that in the Northland / Te Tai Tokerau District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 56.9% | 3.29 |
| | Māori children | 70.3% | 4.52 |
| | Pacific children | 47.8% | 2.35 |
| Year 8 | All children | 41.2% | 1.22 |
| | Māori children | 50.6% | 1.64 |
| | Pacific children | 45.5% | 1.00 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Northland / Te Tai Tokerau District Health Board show:

- 57.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 9.2% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Northland / Te Tai Tokerau District Health Board due to dental caries and diseases of pulp and periapical tissues was 4,318 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Kerikeri water supply population 4,972. Based on the Sapere report Kerikeri is a minor supply and providing community water fluoridation is likely to be cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Kerikeri water supply will provide oral health benefits to the Far North district population that are in due proportion to the limit of the right.

Auckland Council – Onehunga water supply

Population demographics Auckland district

The population of the Auckland district includes 11.5% Māori and 15.5% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Auckland district includes 20.0% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Onehunga water supply

Population serviced by the Onehunga water supply is 23,855.

For the population that receives water from the Onehunga water supply specifically, 10.9% are Māori.

For the population that receives water from the Onehunga water supply specifically, 34.9% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Auckland District Health Board

The 2022 Community Oral Health Service data shows that in the Auckland District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 45.3% | 2.06 |
| | Māori children | 62.4% | 3.05 |
| | Pacific children | 68.3% | 3.17 |
| Year 8 | All children | 19.8% | 0.40 |
| | Māori children | 24.2% | 0.58 |
| | Pacific children | 31.7% | 0.64 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for Auckland District Health Board show:

- 36.9% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 5.3% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Auckland District Health Board due to dental caries and diseases of pulp and periapical tissues was 2,146 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Onehunga water supply population 23,855. Based on the Sapere report Onehunga is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Onehunga water supply will provide oral health benefits to the Auckland district population that are in due proportion to the limit of the right.

Auckland Council – Waiuku water supply

Population demographics Auckland district

The population of the Auckland district includes 11.5% Māori and 15.5% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Auckland district includes 20.0% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Waiuku water supply

Population serviced by the Waiuku water supply is 9,177.

For the population that receives water from the Waiuku water supply specifically, 19.9% are Māori. This is higher than the national average of 17.3% and means that Māori would have a greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Waiuku water supply specifically, 33.1% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Counties Manukau District Health Board

The 2022 Community Oral Health Service data shows that in the Counties Manukau District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 58.6% | 2.75 |
| | Māori children | 73.3% | 3.59 |
| | Pacific children | 72.4% | 3.76 |
| Year 8 | All children | 25.9% | 0.52 |
| | Māori children | 32.1% | 0.71 |
| | Pacific children | 33.9% | 0.73 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for Counties Manukau District Health Board show:

- 43.1% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 7.2% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Counties Manukau District Health Board due to dental caries and diseases of pulp and periapical tissues was 3,001 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Waiuku water supply population 9,177. Based on the Sapere report Waiuku is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Waiuku water supply will provide oral health benefits to the Auckland district population that are in due proportion to the limit of the right.

Tararua District Council – Dannevirke water supply

Population demographics Tararua district

The population of the Tararua district includes 24.6% Māori and 1.9% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Tararua district includes 21.6% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Dannevirke water supply

Population serviced by the Dannevirke water supply is 5,973.

For the population that receives water from the Dannevirke water supply specifically, 32.1% are Māori. This is much higher than the national average of 17.3% and means that Māori would have a disproportionately greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Dannevirke water supply specifically, 75.6% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data MidCentral District Health Board

The 2022 Community Oral Health Service data shows that in the MidCentral District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 43.3% | 2.01 |
| | Māori children | 61.9% | 2.98 |
| | Pacific children | 65.9% | 3.70 |
| Year 8 | All children | 43.2% | 1.26 |
| | Māori children | 55.3% | 1.86 |
| | Pacific children | 48.0% | 2.04 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the MidCentral District Health Board show:

- 51.3% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 7.9% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the MidCentral District Health Board due to dental caries and diseases of pulp and periapical tissues was 4,706 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Dannevirke water supply population 5,973. Based on the Sapere report Dannevirke is a medium supply and providing community water fluoridation is cost saving.

Additional information

On 24 April 2024, the Tararua District Council received a petition from representatives of Fluoride Free Tararua relating to fluoridation. The Council advises that the petition was signed by 706 residents (noting that not all entries include a complete address and/or contact details). That would equate to approximately 12% of the population serviced by the Dannevirke water supply. The petition seeks to:

1. Advise the Tararua District Council they do not want fluoride added to our drinking water.
2. Remind the Tararua District Council that its duty is to the communities it serves, not central government policy.
3. Call the Tararua District Council to seek an interim injunction restraining the Director-General of Health from issuing a directive under s116E of the Health Act 1956 on the Tararua District Council to fluoridate the drinking water until the court case against the Director-General by New Health NZ currently before the High Court is decided.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Dannevirke water supply will provide oral health benefits to the Tararua district population that are in due proportion to the limit of the right.

Waitaki District Council – Ōamaru water supply

Population demographics Waitaki district

The population of the Waitaki district includes 8.2% Māori and 3.8% Pacific.

The population of the Waitaki district includes 18.2% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Ōamaru water supply

Population serviced by the Ōamaru water supply is 16,553.

For the population that receives water from the Ōamaru water supply specifically, 8.7% are Māori. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

For the population that receives water from the Ōamaru water supply specifically, 36.7% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through

toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Southern District Health Board

The 2022 Community Oral Health Service data shows that in the Southern District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|---------------------------|-----------------------|
| Aged 5 | All children | 33.0% | 1.39 |
| | Māori children | 40.7% | 1.81 |
| | Pacific children | 53.0% | 2.59 |
| Year 8 | All children | 34.3% | 0.74 |
| | Māori children | 40.5% | 1.05 |
| | Pacific children | 54.6% | 1.15 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Southern District Health Board show:

- 47.6% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 7.1% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Southern District Health Board due to dental caries and diseases of pulp and periapical tissues was 3,099 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Ōamaru water supply population 16,553. Based on the Sapere report Ōamaru is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Ōamaru water supply will provide oral health benefits to the Waitaki district population that are in due proportion to the limit of the right.

Tauranga City Council – Tauranga water supply

Population demographics Tauranga district

The population of the Tauranga district includes 18.2% Māori and 2.9% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Tauranga district includes 20.2% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for

children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Tauranga water supply

Population serviced by the Tauranga water supply is 136,604.

In response to the consultation with local authorities, Tauranga City Council provided an updated figure for the population of Tauranga (157,900). The population number used in the NZBORA analysis is the population served by each water supply, rather than the total population for the town or district, which may include people not served by the water supply such as those with a private water supply.

For the population that receives water from the Tauranga water supply specifically, 18.2% are Māori. This is higher than the national average of 17.3% and means that Māori would have a greater level of access to fluoridated water through fluoridation of this supply, likely increasing equity in oral health outcomes.

For the population that receives water from the Tauranga water supply specifically, 25.3% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Bay of Plenty District Health Board

The 2022 Community Oral Health Service data shows that in the Bay of Plenty District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 53.0% | 2.57 |
| | Māori children | 68.3% | 3.72 |
| | Pacific children | 74.5% | 3.98 |
| Year 8 | All children | 42.1% | 1.05 |
| | Māori children | 54.4% | 1.59 |
| | Pacific children | 51.6% | 1.28 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for Bay of Plenty District Health Board show:

- 50.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 6.8% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Bay of Plenty District Health Board due to dental caries and diseases of pulp and periapical tissues was 3,535 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Tauranga water supply population 136,604. Based on the Sapere report Tauranga is a large supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Tauranga water supply will provide oral health benefits to the Tauranga district population that are in due proportion to the limit of the right.

Western Bay of Plenty District Council – Athenree water supply

Population demographics Western Bay of Plenty district

The population of the Western Bay of Plenty district includes 19.2% Māori and 2.7% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Western Bay of Plenty district includes 18.6% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Athenree water supply

Population serviced by the Athenree water supply is 4,139.

For the population that receives water from the Athenree water supply specifically, 15.9% are Māori.

For the population that receives water from the Athenree water supply specifically, 20.7% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Bay of Plenty District Health Board

The 2022 Community Oral Health Service data shows that in the Bay of Plenty District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 53.0% | 2.57 |
| | Māori children | 68.3% | 3.72 |
| | Pacific children | 74.5% | 3.98 |
| Year 8 | All children | 42.1% | 1.05 |
| | Māori children | 54.4% | 1.59 |
| | Pacific children | 51.6% | 1.28 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Bay of Plenty District Health Board show:

- 50.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 6.8% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Bay of Plenty District Health Board due to dental caries and diseases of pulp and periapical tissues was 3,535 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Athenree water supply population 4,139. Based on the Sapere report Athenree is a minor supply and providing community water fluoridation is likely to be cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Athenree water supply will provide oral health benefits to the Western Bay of Plenty district population that are in due proportion to the limit of the right.

Western Bay of Plenty District Council – Wharawhara water supply

Population demographics Western Bay of Plenty district

The population of the Western Bay of Plenty district includes 19.2% Māori and 2.7% Pacific. As we have seen, Māori and Pacific peoples have higher rates of dental decay.

The population of the Western Bay of Plenty district includes 18.6% children aged 0-14-years. As previously mentioned, tooth decay can affect all ages, however the data show that for children this can result in missed school days which has the potential to have lifelong impacts.

Population demographics Wharawhara water supply

Populations serviced by the Wharawhara water supply is 8,334.

For the population that receives water from the Wharawhara water supply specifically, 11.8% are Māori.

For the population that receives water from the Wharawhara water supply specifically, 30.8% are considered be living in high deprivation (score 8-10 on the 2018 NZDep Index). We know that people living in areas with higher deprivation have less exposure to fluoride through toothpaste and are less likely to use oral health services compared to people who live in areas with less deprivation.

Oral health data Bay of Plenty District Health Board

The 2022 Community Oral Health Service data shows that in the Bay of Plenty District:

| | | Experienced caries | Mean dmft/DMFT |
|--------|------------------|--------------------|----------------|
| Aged 5 | All children | 53.0% | 2.57 |
| | Māori children | 68.3% | 3.72 |
| | Pacific children | 74.5% | 3.98 |
| Year 8 | All children | 42.1% | 1.05 |
| | Māori children | 54.4% | 1.59 |
| | Pacific children | 51.6% | 1.28 |

For the rest of the population aged 15-years or older, the 2017-2020 New Zealand Health Survey results for the Bay of Plenty District Health Board show:

- 50.5% of adults (15-years or older) had one or more teeth removed in their lifetime due to decay, an abscess, infection or gum disease
- 6.8% of adults (15-years or older) had one or more teeth removed in the last 12 months due to decay, an abscess, infection or gum disease.

In 2022 the ASH rate for the Bay of Plenty District Health Board due to dental caries and diseases of pulp and periapical tissues was 3,535 per 100,000 population. Water fluoridation could have contributed to preventing these hospitalisations in this district.

Cost effectiveness

Wharawhara water supply population 8,334. Based on the Sapere report Wharawhara is a medium supply and providing community water fluoridation is cost saving.

Conclusion

Taking all of these factors into account, we conclude that fluoridating the Wharawhara water supply will provide oral health benefits to the Western Bay of Plenty district population that are in due proportion to the limit of the right.

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Community Water Fluoridation: An Evidence Review

1. Executive Summary

The 2014 report from the Royal Society of New Zealand (RSNZ) and the 2021 report from the Office of the Prime Minister's Chief Science Advisor (OPMCSA) on the risks and benefits of community water fluoridation (CWF) concluded that CWF is a safe and effective public health intervention to prevent dental caries.

This current review updates the evidence regarding CWF published since the OPMCSA report of 2021.

- The current review supports that conclusion on the basis that:
 - the evidence that has been published since 2021 indicates ongoing clear benefits from CWF even during the period when alternative forms of fluoride (such as fluoride toothpaste) are available and
 - CWF promotes equity by decreasing the incidence and severity of dental caries in individuals in areas of high socioeconomic deprivation as much as, or more than individuals in areas of less deprivation and
 - there has been no high-quality evidence published since those 2014 and 2021 reports to suggest a causal link between fluoride exposure at the levels used in Aotearoa New Zealand for CWF and significant harm to health.
- Individuals living in countries with high naturally occurring fluoride in drinking water, are at greater risk of dental fluorosis. However, the risk and severity of this complication in the setting of CWF is very low. Aotearoa New Zealand does not have high naturally occurring fluoride levels in drinking water.

2. Background

In June 2023, New Health New Zealand Inc (NHNZ) filed legal proceedings challenging the Director-General of Health's 2022 directions to 14 local authorities to add fluoride to one or more of their drinking water supplies. That challenge has two components: (i) a "procedural" aspect, that the Director-General should have explicitly considered the New Zealand Bill of Rights Act (NZBORA) in making a decision on each direction; and (ii) a "substantive" challenge to the directions, alleging that the scientific evidence on CWF does not support its safety or efficacy. Only the first component has been heard to date.

In November 2023, the High Court ruled, on the first component, that the Director-General should have explicitly considered the NZBORA in the decision to make the directions. In

February 2024, the High Court Judge kept the 14 directions in place and directed the Director-General to carry out a NZBORA analysis. The Judge also directed the Director-General to consider the views of NHNZ as part of the analysis. As part of its submission to the Court, NHNZ referred to several scientific studies, which have been included in this review, if not already referenced in the earlier reviews by OPMCSA and RSNZ. The studies referred to by NHNZ are listed in Appendix 8.

The Royal Society of New Zealand (RSNZ) and Office of the Prime Minister's Chief Science Advisor (OPMSCA) have published reports on the risks and benefits of water fluoridation, in 2014 and 2021 respectively. The 2014 report recommended a review of the evidence be repeated every 10 years. However, given the outcome of the judicial review, the Public Health Agency (PHA) Ope Aorangi team requested that an update of the evidence be carried out now in order to inform the NZBORA analysis. A review of the evidence of the safety and effectiveness of CWF was undertaken by the Office of the Chief Science Advisor (OCSA) in collaboration with the PHA Intelligence, Surveillance and Knowledge Group (ISK). The document produced was peer reviewed by subject matter experts external to the Ministry of Health.

3. Conclusions from the review by the OPMCSA (2021)

The review of the risks of fluoridation undertaken by the OPMCSA in 2021 supported the conclusions of the report undertaken by RSNZ published in 2014.

The key points from the 2021 OPMCSA report are as follows:

- The low levels of fluoride that occur naturally in Aotearoa New Zealand's water do not contribute to better dental health.
- How much fluoride a person is exposed to depends on their diet, how much water they drink, the level of fluoride in the water supply, and their oral hygiene routines.
- Adding fluoride to water helps reduce the incidence of dental caries in Aotearoa New Zealand and is particularly important in reducing socioeconomic inequities in health.
- Excessive fluoride intake can cause dental fluorosis (a tooth enamel defect resulting in opaque white spots on the teeth). However, at the levels used for water fluoridation in Aotearoa New Zealand, this is generally mild (i.e., of no health concern and little-to-no cosmetic concern) and the incidence of dental fluorosis is generally similar between fluoridated and non-fluoridated areas.
- Some groups may be exposed to higher levels of fluoride than what is necessary to gain oral health benefits, in particular formula-fed infants living in areas with fluoridated water supplies. This may put them at higher risk of experiencing mild dental fluorosis, but no other health concerns are expected.

- Recent studies suggest that at very high levels and with chronic exposure, fluoride could have negative neurodevelopmental and cognitive impacts. However, this is not a concern at levels used in fluoridation of water supplies in Aotearoa New Zealand.

Reports outlining the risks and benefits of CWF from Australia, Europe, Canada, the United States, and the World Health Organisation (WHO) were included in the OPMCSA 2021 review.

4. Scope of Current Review

The scope of the current review was to assess whether or not the evidence regarding CWF published since the 2021 OPMCSA report significantly shifts the overall balance of evidence to suggest that CWF is no longer a safe and effective public health measure.

5. Limitations of this evidence review

There is always a risk that not all studies have been identified and included in this report. However, collating published studies from systematic reviews and regularly supplementing this information with newly published data from original studies using robust search criteria provides an effective mechanism for ensuring inclusion of relevant studies. In addition, the use of systematic reviews is a way of identifying and synthesising a body of evidence, that is, it looks at the overall evidence, identifies sources of bias and makes conclusions about that body of evidence. In this situation, it is very unlikely that a single study published after the search date for this report (or not identified in the search) would alter the conclusions based on the body of evidence.

6. Methods

a. Study design

Systematic reviews¹ and meta-analyses² were given priority in synthesising the evidence. Evidence from randomised trials and observational trials was also assessed for completeness and to ensure that evidence presented by NHNZ was addressed as requested by the Court. Publications that were not peer reviewed, editorials, opinion pieces and review articles which did not use a systematic methodology (that is, narrative reviews) were not incorporated into this review.

b. Identification of Evidence

The review was performed by undertaking a systematic review of the evidence regarding the risks and benefits of CWF published between January 2019 and April 2024. Search criteria are

¹ an objective, reproducible method to find answers to a certain research question, by collecting all available studies related to that question and reviewing and analysing their result

² the statistical process of analysing and combining results from several similar studies

provided in Appendix 7. The start date was extended earlier than the 2021 publication date of the OPMCSA report to ensure all the relevant literature was identified.

The categorisation of evidence covered the following issues:

1. Benefits of fluoridation
 - a. Prevention of dental caries
 - b. Equity
2. Risks of fluoridation
 - a. Neurodevelopmental delay
 - b. Dental fluorosis
 - c. Hypothyroidism

Skeletal fluorosis and cancer were not assessed in detail. Economic analyses of CWF were also not considered in this evidence review.

Skeletal fluorosis, a summary of which was published in the 2021 OPMCSA report, occurs only after many years of exposure to very high levels of fluoride. The OPMCSA report stated that skeletal fluorosis does not occur in the setting of CWF and has not been reported to occur in New Zealand.

A single study assessing the risks of bone diseases (hip fracture, osteoporosis, and bone cancer) in an area in which CWF had been implemented from 1982 to 2004, compared to a non-fluoridated adjacent region, did not identify any association between hip fracture or bone cancer. (Lee et al., 2020)

The role of fluoride in skeletal physiology is complex and dose-dependent. At low dose, fluoride has been demonstrated to improve bone mineral density. (Skalny et al., 2023)

c. Exclusions and Inclusions

Evidence of the risks and benefits of CWF was assessed. Systematic reviews of water supplies with naturally occurring fluoride were included where appropriate. However, as many naturally occurring water sources contain concentrations of fluoride above that used for CWF and the concentrations of fluoride vary over time, the relevance of individual studies reporting naturally fluoridated water is limited. Papers which were referenced in the OPMCSA report of 2021 were excluded from this report as they informed the existing evidence base. Non-English language publications were excluded³.

d. Risk of Bias

Bias is an important concept to understand when it comes to evaluating the quality of research. Bias is a systematic mistake in the planning, execution, or analysis of a study that

³ Only one study was excluded on this basis

results in inaccurate conclusions. This makes the assessment of the risk of bias important when interpreting research findings. One important source of bias is confounding factors. Confounding factors are associated with both the exposure and the outcome and, if not accounted for, can cause spurious results in a study.⁴ Systematic reviews aim to minimize bias by using explicit, systematic methods documented in advance with a protocol for inclusion and exclusion.

Confounders and the risk of bias were identified in publications where possible. Confounders related to the outcomes of dental caries, dental fluorosis, and neurodevelopmental delay/IQ are as follows;

1) Dental caries

The caries-preventive benefits of fluoride may be obtained from multiple other sources including fluoride toothpaste, gels, mouthwash and foods which contain fluoride. The risks of tooth decay are influenced by a wide range of behaviours and dietary factors, along with structural and contextual factors as with any non-communicable disease (NCD). Where possible these confounders were identified.

2) Dental fluorosis

The risks of dental fluorosis can be influenced by sources of fluoride products other than CWF, including fluoride toothpaste, tablets and varnish.

3) Neurodevelopmental delay/IQ

The risks of neurodevelopmental delay, including low IQ, are influenced by a wide range of factors such as established neurotoxins, including alcohol (Giordano & Costa, 2012), congenital disorders, complications of pregnancy and the newborn period, nutritional status, residence and sociodemographic variables such as parental educational levels.

7. Results

Studies of the risks and benefits of CWF are presented as summaries of systematic reviews followed by summaries of trials and studies.

a. Dental caries

Dental caries is determined by systematically examining the dentition and noting the presence of cavities and restorations (along with missing teeth). The usual practice in dental epidemiological studies is to determine the status of the tooth surfaces and to record the number of decayed, missing or filled surfaces (DMFS for permanent dentition or dmfs for deciduous dentition) or teeth (DMFT / dmft). This report has attempted to accurately refer to

⁴ For example, intelligence is known to be sensitive to a range of demographic variables which can interact. If an unmeasured variable, such as alcohol use in pregnancy (a known neurotoxin) is associated with both the exposure location (a city with CWF) and the outcome measure (neurodevelopmental delay) a false association will be identified between the exposure and the outcome.

dental experience as the relevant DMFT indices and caries prevalence as the percentage of individuals who experience any caries, which can be expressed as DMFT >0.

1) Systematic reviews and meta-analyses

Twenty-six systematic reviews and meta-analyses were identified in the search. Twenty publications were excluded for the following reasons: did not assess CWF (n=13); were not systematic reviews (n=9); and did not assess dental caries as an outcome (n=4). Some publications were excluded for more than one reason. Of the six publications remaining, three undertook a meta-analysis. Two publications identified original studies published after 2020 and both were identified in the search of observational and randomised controlled trials. A table of the systematic reviews not included is provided in Appendix 1.

A summary of the publications included is provided in Table 1.

Table 1. List of systematic reviews included in this review

| No | Study | Number of included studies | Years of included studies | Author's Summary | Reviewer's Comment |
|----|--|----------------------------|---------------------------|--|---|
| 1 | Al Rasheed, et al (2024). (Al Rasheed & Jones, 2024) | 9 studies | 1956 - 1998 | Water fluoridation was effective in improving dental caries among the Scottish child population. | Similar results to the 2015 Cochrane review demonstrating the effectiveness of fluoridation prior to widespread introduction of fluoridated toothpaste. |
| 2 | Belotti, et al (2022). (Belotti & Frazao, 2022) | 10 studies | 1998 - 2018 | Fluoridated areas exhibited lower mean dmft/DMFT than non-fluoridated areas. The caries prevalence was 1.4 times and 57% lower, respectively, in primary and permanent dentitions in fluoridated areas | CWF remains effective in preventing dental caries in children younger than 13 years, even with the widespread use of fluoride toothpaste. |
| 3 | Moynihan, P., et al. (2019) (Moynihan et al., 2019). | 32 studies | 1965 - 1997 | Meta-analysis of data on the impact on ECC ⁵ from living in a fluoridated area showed a significant effect (mean difference, -1.25; 95% CI, -1.24 to -0.36). Providing access to fluoridated water and raising awareness among caregivers are justified approaches to ECC prevention. | CWF remains effective in preventing dental caries in a metanalysis pooled from four studies. |
| 4 | Senevirathna, L., et al. (2023). (Senevirathna et al., 2023) | 24 studies | 1960 - 2022 | Studies report that water fluoridation has reduced dental caries by 26-44% in children, teenagers, and adults, benefiting everyone regardless of age, income, or access to dental care. CWF is a cost-effective intervention to prevent dental caries, especially in rural and low-income areas. | CWF remains effective in preventing dental caries and decreases inequality. |

⁵ early childhood caries

| | | | | | |
|---|--|------------|-----------------|---|---|
| 5 | Sharma, V., et al. (2024). (Sharma et al., 2024) | 31 studies | Up to June 2022 | Dental caries in children has consistently declined in the Republic of Ireland in the last seven decades. Since the introduction of CWF, a greater reduction in dental caries has been reported among children living in areas with CWF than among those without CWF. | CWF remains effective in preventing dental caries in the presence of declines in the prevalence of dental caries. |
| 6 | Shen, A., et al. (2021). (Shen et al., 2021) | 4 studies | 2007 - 2020 | The quality of included papers was moderate. The overall findings suggest that whole population interventions such as water fluoridation are more likely to reduce inequalities in children's caries than target population and individual interventions. | CWF remains effective as a public health intervention to decrease dental caries even in the presence of other existing individually focussed interventions. |

i. Outcomes

All six systematic reviews reported a lower rate of dental caries associated with CWF. Five of the six studies (all except Al Rasheed et al) (Al Rasheed & Jones, 2024) analysed data published during a period when additional vehicles for fluoride application such as fluoride toothpaste were widely available. Benefits were observed for both the primary (or deciduous) and permanent teeth but were more pronounced for primary dentitions.

ii. Equity

Two systematic reviews reported the effect of CWF in the context of greater equity in outcomes. (Senevirathna et al., 2023; Shen et al., 2021) One review reported that CWF was associated with a lower rate of dental caries in all groups irrespective of age, income and access to dental care, consistent with greater equity for oral health outcomes. (Senevirathna et al., 2023) The second study reported that CWF resulted in less inequality for children's oral health than targeted approaches. (Shen et al., 2021)

2) Observational Studies⁶

i. Study selection

Fifty-nine studies were identified in the search and reviewed by title and abstract to identify those assessing the benefits of CWF. A full review was undertaken of all studies relating to CWF or when a title and abstract did not provide sufficient information to determine inclusion.

Thirty-one studies assessing CWF published since 2018 which were not included in the OPMCSA 2021 report were identified from the search. Of these 31 papers, three did not have sufficient information in the abstract to classify and the originals could not be sourced. (Pollick, 2019a, 2019b; Sanders et al., 2019) A further six studies were excluded after a full review. One paper was in Portuguese without an available English translation, (Corrêa et al., 2020) one paper combined results from both naturally occurring and actively fluoridated

⁶ An observational study is a type of investigation used in clinical research to simply observe a group of people or study participants without intervening or influencing them, for example, by allocating a treatment

groups, (Moore et al., 2024) one paper did not provide sufficient information regarding fluoridation status of the comparison groups, (Dixit et al., 2024) two papers were duplications of the same data (L. McLaren et al., 2022; Meyer et al., 2018) and one paper was an economic analysis of CWF without associated clinical data. (Cronin et al., 2021)

A table of the observational studies not included is provided in Appendix 2.

ii. Types of studies

Of the remaining 22 papers, three were prospective observational studies, three retrospective observational studies and 16 were cross-sectional studies. A summary of the studies is included in Table 2.

Table 2. List of observational studies included in this review

| No | Study / Country | Type of study | Author's Summary | Reviewer's Comment |
|----|---|-----------------|---|---|
| 1 | Batsos, et al., 2021. (Batsos et al., 2021) Canada | Cross-sectional | Residence in a municipality with water fluoridation was associated with a lower caries experience in a national sample of newly enrolled Canadian Armed Forces members. The benefits of water fluoridation were uniform across neighbourhood income and military rank classes. | The socioeconomic class of recruits was relatively uniform. |
| 2 | Brito, et al., 2020. (Brito et al., 2020) Brazil | Cross-sectional | Water fluoridation was associated with a lower DMFT index ($OR_P^7 = 0.766$). Dental caries experience is still associated with social inequalities at different levels. | CWF is effective in a modern setting. CWF addresses inequities in oral health |
| 3 | Cruz, et al., 2018. (Cruz & Narvai, 2018) Brazil | Cross-sectional | Exposure to fluoridated water is associated with lower mean values for the DMFT and SiC ⁸ indices, even in the presence of the concomitant exposure to fluoridated toothpaste, in a scenario of low prevalence of the disease, and with a similar pattern of caries distribution in the populations analysed. | CWF is effective in a modern environment and low prevalence of tooth decay. |
| 4 | Della Nora, et al., 2020. (Dalla Nora et al., 2020) Brazil | Cross-sectional | In conclusion, this cross-sectional study found that urban schoolchildren showed greater caries experience than rural students, and that this increment was related to active non-cavitated lesions. | No difference between groups using WHO criteria for DMFT. No adjustment for variables known to influence the incidence of dental caries. |
| 5 | Do, et al., 2018. (Do et al., 2018) Australia | Cross-sectional | Caries experience was higher in non-fluoride (NF) than fluoride (F) strata. Race- and income-related gradients in caries experience were observed in both F and NF areas. All indices of inequality indicated that caries experience was concentrated among lower income groups. Absolute inequalities were consistently lower in F than in NF areas. | CWF effective in a modern setting. CWF reduces inequities in oral health |

⁷ OR_P = Odds ratio using Poisson regression analysis.

⁸ the Mean DMFT of the one third of the study group with the highest caries score

| | | | | |
|----|---|--|---|---|
| 6 | Foley, et al., 2022. (Foley et al., 2022) Australia | Cross-sectional | Longer lifetime exposure to fluoridated drinking water is causally associated with a lower childhood dental caries prevalence and more positive parental ratings of child oral health. The associations are stronger for younger children. | CWF is effective in a modern setting. The associations are stronger for younger children. |
| 7 | Gnanapragasam, et al., 2024. (Gnanapragasam et al., 2024) Malaysia | Retrospective longitudinal | After controlling for confounders, partial exposure to CWF remained a strong predictor for mean caries increment over a five-year study period. This study showed greater mean caries increment in permanent dentition among schoolchildren in Pahang after CWF ceased. | CWF is effective in a modern setting and has a positive impact on permanent dentition. |
| 8 | Goodwin, et al., 2022. (Goodwin et al., 2022) United Kingdom | Prospective longitudinal | The evidence, after adjusting for deprivation, age and sex, with an adjusted odds ratio of 0.74 (95% confidence interval 0.56 to 0.98), suggested that water fluoridation was likely to have a modest beneficial effect. | CWF is effective in a modern setting. The authors state that the low response rate to the questionnaires limited the power of this study |
| 9 | Gussy, et al., 2020. (Gussy et al., 2020) Australia | Prospective longitudinal | Independent protectors of surface cavitation included water fluoridation, and older age of mothers. | Well-conducted multi-year prospective study identified risk factors at a population, household and individual level. |
| 10 | Kim et al., 2019. (Kim et al., 2019) South Korea | Prospective observational ⁹ | The caries-reducing effect was so high that health policy makers should consider CWF as a priority policy for caries-reducing in Korean children and adolescents. | CWF was effective in a modern setting in deciduous and permanent dentition. |
| 11 | Kroon, et al., 2019. (Kroon et al., 2019) Australia | Cross-sectional | Between the pre- & post-CWF surveys age-weighted mean dmft decreased by 37.7% & DMFT decreased by 35%. Between the 1- & 4-year post-CWF surveys DMFT/dmft increased by 25% & 7.7%, respectively. | CWF is effective in a modern setting. |
| 12 | Levy, et al., 2023. (Levy et al., 2023) Israel | Cross-sectional | The findings indicated that subjects exposed to fluoridated water during their childhood had significantly lower rates of caries-related treatment, regardless of access to free dental care. | CWF is effective in a modern setting and is more effective than free oral care. |
| 13 | Matsuo, et al., 2020. (Matsuo et al., 2020) United States | Cross-sectional | Among the children without any CWF lifetime exposure, statistically significant caries disparities by parental educational attainment were observed. Socioeconomic disparities in dental caries were not observed among 10-19-year-old schoolchildren with lifetime CWF exposure. CWF seemed to reduce dental caries disparities. | CWF is effective in a modern setting. CWF decreases inequities in oral health. |
| 14 | McLaren, et al., 2022. (Lindsay | Cross-sectional | Social inequities in dental caries were present in both Calgary and Edmonton. Those inequities | CWF is beneficial in a modern setting. |

⁹ Data from Korean National Health and Nutrition Examination Survey. (KNHANES)

| | | | | |
|----|---|-----------------|--|---|
| | McLaren et al., 2022) Canada | | tended to be worse in Calgary where fluoridation was ceased. | CWF decreases inequities in oral health. |
| 15 | Melough, et al., 2023. (Melough et al., 2023) United States | Cross-sectional | Free sugars intake, especially in the form of added sugars and specifically in sweetened beverages, was associated with higher dental caries. Water fluoride exposures modify these associations, reducing caries risk in the primary dentition of children whose home water meets recommended fluoride levels., | CWF is effective in a modern setting and can ameliorate risks from sugar-sweetened beverages. |
| 16 | Meyer et al, 2022. (Meyer et al., 2022). United States | Cross-sectional | The results are consistent with previous research that has demonstrated a significant protective effect of CWF against dental caries. | CWF is effective in a modern setting |
| 17 | Silva, et al., 2021. (Silva et al., 2021) Brazil | Cross-sectional | Children and adolescents who consumed fluoridated water had lower dental caries prevalence and severity than those who used only fluoridated toothpaste as the source of fluoride. There is an association between water fluoridation and very mild/mild and moderate fluorosis in adolescents. | CWF is effective in a modern setting for both deciduous and permanent dentition |
| 18 | Silveira, et al., 2021. (Silveira Schuch et al., 2021) Brazil | Cross-sectional | In crude analysis, children who consumed bottled water ¹⁰ had a lower risk of decayed teeth, lower experience of dental caries and less severe disease. No associations were observed after adjustments for socioeconomic conditions. Drinking fluoridated tap water is as effective in dental caries prevention as bottled water with acceptable levels of fluoride, with the advantage of being accessible to all. | CWF is effective in a modern setting. CWF decreases inequities in oral health. |
| 19 | Slade, et al., 2018. (Slade et al., 2018) United States | Cross-sectional | Statistically significant associations were seen when % CWF was modelled as a continuum, and differences tended to be greater in covariate-adjusted analysis and in sensitivity analysis. These findings confirm a substantial caries-preventive benefit of CWF for U.S. children and that the benefit is most pronounced in primary teeth. | CWF is effective in a modern setting |
| 20 | Tobias, et al., 2024. (Tobias et al., 2024) Israel | Cross-sectional | Based on DMFT, the caries experience was significantly higher in non-fluoridated cities (1.38 vs 0.98 in fluoridated cities) and there were more caries-free children in fluoridated cities (56.4% vs 40.6% in non-fluoridated). | CWF is effective in a modern setting. CWF decreases inequities in oral health. |
| 21 | Tuan, et al., 2018. (Tuan et al., 2023) United States | Retrospective | Children living in rural and non-fluoridated water communities had 1.7 to 1.8 times greater rates of developing early childhood caries. | CWF is effective in a modern setting. CWF decreases inequities in oral health. |

¹⁰ In this study, bottled water contained a variable amount of fluoride which was generally within therapeutic range for prevention of dental caries.

| | | | | |
|----|--|---------------|--|--|
| 22 | Yazdanbakhsh, et al., 2024. (Yazdanbakhsh et al., 2024) Canada | Retrospective | Discontinuing water fluoridation appears to negatively affect young children's oral health, potentially leading to a significant increase in caries-related dental treatments under general anaesthesia and oral health disparities in this paediatric population. | CWF is effective in a modern setting. CWF decreases inequities in oral health. |
|----|--|---------------|--|--|

iii. Location of Studies

The location of studies was as follows; Brazil (n = 5), United States (n=5), Australia (n=4), Canada (n = 3), Israel (n = 2) and one study each in Malaysia, South Korea and the United Kingdom.

iv. Study periods

The study periods for data collection ranged from the 1999 through to 2021. Data collection often spanned many years. All but three studies collected data in the decade from 2000 to 2009 (8 studies) or from 2010 to 2019 (21 studies).

v. Outcomes

Dental Caries

Twenty-one of the 22 observational studies of CWF reported that CWF was associated with a lower dental caries experience in groups studied. The CWF exposure in all studies occurred during the last 25 years, when fluoridated toothpaste was widely available¹¹. One study identified a positive association between CWF and a greater dental caries experience using a modification of the WHO criteria for dental caries when comparing an urban (CWF) and rural (non-CWF) samples. No association was identified using the standard WHO criteria¹². However, that study did not adjust for socioeconomic variables (known to be associated with dental caries) or diet. In addition, the water fluoride concentration in some locations without CWF was within the therapeutic range (range: 0.17 – 0.52 ppm), which would have provided some oral health benefits to individuals living in non-CWF areas. (Dalla Nora et al., 2020)

Equity

Of the 22 included studies, 17 collected some sociodemographic data. Dental caries in children was positively associated with socioeconomic deprivation or lower socioeconomic status in the majority of studies. (Brito et al., 2020; Do et al., 2018; Hobbs et al., 2020; Matsuo et al., 2020; Lindsay McLaren et al., 2022; Silveira Schuch et al., 2021; Tobias et al., 2024; Tuan et al., 2023; Yazdanbakhsh et al., 2024)

CWF was associated with better oral health in children with greater levels of socioeconomic deprivation in 7 studies (Do et al., 2018; Hobbs et al., 2020; Levy et al., 2023; Matsuo et al.,

¹¹<https://www.cdc.gov/fluoridation/basics/timeline.html#:~:text=1956,over%20the%20next%20few%20decades>.

¹²<https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3812>

2020; Tobias et al., 2024; Tuan et al., 2023; Yazdanbakhsh et al., 2024) but not in one study (Goodwin et al., 2022).

b. Risks of CWF

1) Neurodevelopment

The effect of CWF on neurodevelopment and cognition (including IQ) was specifically investigated.

A search for relevant research identified 43 publications of which 10 met the inclusion criteria for this review. Of the ten publications, six were systematic reviews and four were primary studies not included in any of the other reviews.

Thirty-three publications were excluded. Nineteen were already included in a systematic review (including the OPMCSA (2021) review), nine were of the wrong study/publication type (including editorials, letter, and conference proceedings) and five were of an outcome other than neurodevelopmental or cognitive outcomes. A list of the excluded publications is provided in Appendix 3.

An evidence table with more details of the publications included is provided in Appendix 4.

i. Systematic reviews and meta-analyses

Two systematic reviews investigated ADHD as an outcome (Fiore et al., 2023; Taher et al., 2024) and found no association with fluoride levels in drinking water.

Five systematic reviews provided evidence relating to IQ as an outcome. (Gopu et al., 2022; Kumar et al., 2023; Miranda et al., 2021; Taher et al., 2024; Veneri et al., 2023) Three of those concluded there was no association between lower IQ and fluoride in drinking water at levels comparable to that used in Aotearoa New Zealand for CWF. (Gopu et al., 2022; Kumar et al., 2023; Miranda et al., 2021) The other two reviews reported a negative association between water fluoride concentration and IQ. (Taher et al., 2024; Veneri et al., 2023) However, there are significant limitations and concerns about the methodological quality and robustness of results of these two reviews. Many of the included studies had exposures to fluoride of levels well above that used for CWF and are not relevant to a review of the risks of CWF. There are serious concerns regarding the risk of bias assessment in the review by Taher et al. (Taher et al., 2024) where most studies have been assessed as being of 'high quality' using a modified assessment tool of uncertain validity. This is at odds to other risk of bias assessments of the same studies by different authors. Moreover, they have mis-attributed an association at low fluoride levels (as used in CWF) with lower IQ where, in fact, the association is with much higher levels of fluoride than those used in CWF. There are similar issues with the publication by Veneri et al. (Veneri et al., 2023) However, the authors were more cautious in their conclusions, stating that the limitations of most of the primary studies (particularly residual confounding) raises uncertainties about the causal nature of the findings and the exact thresholds of exposure involved.

A brief summary of the findings from the systematic reviews is provided in Table 3.

Table 3. Summary of the systematic reviews investigating neurodevelopmental outcomes

| Study/country Outcomes | Results | Conclusions by the authors |
|--|---|---|
| Fiore et al (2023) (Fiore et al., 2023) Italy/USA ADHD spectrum disorder | 3/7 studies suggest an association 4/7 found no association | “...heterogeneity in study designs and results from human studies did not allow us to reliably identify fluoride exposure as a risk factor for ADHD development. ” |
| Gopu et al (2022) (Gopu et al., 2022) UK Cognitive outcomes ¹³ | 25/31 studies found mean IQ lower for exposure to ≥ 2 mg/l compared to < 2 mg/l | “...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) (Kumar et al., 2023) USA IQ scores | 2 studies found no association between IQ and community fluoridation 8 studies in non-endemic areas (mean fluoride 0.90 vs. 0.30 mg/l) found no association | “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) (Miranda et al., 2021) Brazil/Canada Neurological disorders ¹⁴ | Odds of “low IQ” significantly greater in high fluoride area (> 2 mg/l) compared to low fluoride area (0.5-1.0 mg/ml) | “...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) (Taher et al., 2024) Canada Health effects ¹⁵ | 16/21 studies found an association between fluoride levels in water and reduced IQ Insufficient evidence for any association between water fluoride and ADHD | “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 et al. (2023) (Veneri et al., 2023) USA/Italy IQ scores | Mean difference in IQ score (highest vs. lowest fluoride level in each included study) for water fluoride level -5.60 (95% CI: -7.76 to -3.44) $I^2 = 91.69\%$ | “...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. ” |

ii. Additional primary studies¹⁶

Four additional studies were identified that were not included in the systematic reviews above. (Dewey et al., 2023; Do et al., 2023; Ibarluzea et al., 2023; Krzeczkowski et al., 2024)

Three used data from longitudinal cohort studies and considered a number of confounding factors. A summary of additional studies is presented in Table 4.

¹³ including IQ

¹⁴ all IQ except one study

¹⁵ including ADHD and IQ

¹⁶ One additional publication was identified after the completion of this review and is discussed in Appendix 9.

An evidence table of the included additional primary publications is provided in Appendix 5.

Table 4. Summary of the additional studies of neurodevelopmental outcomes

| Study/country Outcomes | Results | Conclusions by the authors |
|---|---|--|
| Dewey et al (2023) (Dewey et al., 2023) Ecological study Canada IQ and executive function | No association between exposure to CWF during pregnancy and IQ Exposure to CWF was associated with poorer inhibitory control and cognitive flexibility. | No associations were found between exposure to drinking water from a community water supply fluoridated at 0.7 mg/L throughout pregnancy and measures of intelligence at 3–5 years of age. Maternal exposure to drinking water throughout pregnancy fluoridated at the level of 0.7 mg/L was associated with poorer inhibitory control and cognitive flexibility, particularly in girls, suggesting a possible need to reduce maternal fluoride exposure during pregnancy |
| Do et al (2023) (Do et al., 2023) Cohort Australia/UK Emotional, behavioural development, and executive functioning | Comparable scores for those fully exposed and never exposed to CWF | Exposure to fluoridated water by young children was not negatively associated with child emotional, behavioural development, and executive functioning in their adolescent years |
| Ibarluzea et al (2023) (Ibarluzea et al., 2023) Cohort Spain/UK Probable cognitive problems/inattention, hyperactivity/impulsivity, & ADHD | Non-significant associations were observed between MUFc ¹⁷ levels and cognitive outcomes at age 8 years. Significant reduction in risk of probable cognitive problems/inattention scores at 11 years of age for maternal urinary fluoride levels at 32 weeks gestation and all of pregnancy. All other associations non-significant. | Higher levels of maternal urinary fluoride levels in pregnant women were associated with a lower risk of cognitive problems/inattention at 11 years . |
| Krzeczkowski et al (2024) (Krzeczkowski et al., 2024) Cohort Canada Visual acuity & heart rate variability | Poorer visual acuity and one measure of heart rate variability at 6 months associated with water fluoride levels and maternal fluoride intake | Fluoride in drinking water was associated with poorer visual acuity and differences in cardiac autonomic function in infancy , adding to the growing body of evidence suggesting fluoride's developmental neurotoxicity. |

One study found no association between CWF exposure during pregnancy and the infants' IQ at 3-5 years of age. (Dewey et al., 2023) The same study found an association between CWF and poorer inhibitory control (using some assessment tools) and cognitive flexibility in girls only. The clinical significance of the observed differences was not placed in a clinical context, so are not clear.

¹⁷ maternal urinary fluoride concentration (adjusted for creatinine)

An Australian study found no effect of CWF on the emotional and behavioural development and executive functioning of adolescents. (Do et al., 2023) This was a nationwide population-based follow-up study with relevant and valid outcome and exposure measurement.

A Spanish study found no association between maternal urinary fluoride levels and ADHD. (Ibarluzea et al., 2023) Interestingly, the study did find an association between maternal urinary fluoride levels and lower risk of cognitive problems/inattention at 11 years. This result should not be interpreted as suggesting that antenatal exposure to fluoride decreases the risk of ADHD, but that maternal urinary fluoride is an unreliable measure of antenatal exposure and that neurodevelopmental outcomes are primarily determined by factors other than fluoride.

The final study, also using the MIREC dataset, used three different methods to estimate maternal fluoride intake and found an association between both water fluoride levels and estimated fluoride consumption, but not maternal urinary fluoride concentration and lower visual acuity and heart rate variability. (Krzczkowski et al., 2024)

The use of the MIREC dataset for multiple analyses in multiple subgroups raises concerns regarding the reliability of the findings and the relevance of the results to other populations. Repeated analysis of a single dataset will result in the identification of associations by chance. It is also possible that within the MIREC dataset, fluoride is a marker for a range of known causes of neurotoxicity, such as alcohol, pregnancy complications and sociodemographic variables. The over-reliance on a single dataset will provide a distorted view of the strength of possible associations.

2) Thyroid function

A recent systematic review and meta-analysis was identified that investigated the effect of fluoride exposure on thyroid function. (Iamandii et al., 2024) This review included 33 studies of variable quality (risk of bias) and compared measures of thyroid function at the highest fluoride concentration with those at the lowest concentration. With regards to fluoride sourced from drinking water, there was some difference in thyroid function but whether this was significant clinically is very uncertain. No test of statistical significance was conducted and levels of statistical heterogeneity¹⁸ were all very high. This is extremely concerning because it is an indication that the studies in the meta-analysis are not comparable. In addition, there was no exploration of the reasons for this high heterogeneity. It is very likely that the source is the variation in the populations, exposures and outcomes of the included studies. It is certainly clear that the fluoride concentrations were not comparable as the authors used the highest fluoride concentration in any single study and compared it to the lowest fluoride concentration. This makes the generalisability and applicability of these

¹⁸ Heterogeneity refers to any kind of variability among studies in a systematic review including variability in the participants, interventions, outcomes, study design, risk of bias, and intervention effects. Statistical heterogeneity is where the observed intervention effects being more different from each other than one would expect due to chance alone.

findings to CWF in Aotearoa New Zealand weak. An evidence table with more details of the publications included is provided in Appendix 6.

A dose-response meta-analysis was also conducted in this systematic review which is more applicable and generalisable to CWF in Aotearoa New Zealand as it covers all water fluoride concentrations in the included studies. The results of these dose-response meta-analyses show that at levels comparable to CWF, there is no effect on thyroid function; any effect on thyroid-stimulating hormone (TSH) levels occurred only above 2ppm (or 2.5 ppm when the highest quality studies are considered).

3) Dental fluorosis

Dental fluorosis is an abnormality of the tooth enamel due to fluoride. The severity of fluorosis is assessed by a range of methods. (Mohd Nor, 2017) Mild degrees of fluorosis may cause cosmetic concern, but are of no functional significance. Mild degrees of dental fluorosis often resolve with time due to surface abrasion and ongoing mineralisation. (Do et al., 2016)

i. Systematic reviews and meta-analyses

Three systematic reviews assessing the relationship between fluoride in drinking water and dental fluorosis were identified. (Akuno et al., 2019) (Taher et al., 2024) (Umer, 2023). All three studies reported findings primarily from naturally occurring fluoride at different concentrations and were not relevant to CWF in Aotearoa New Zealand. Analyses were not undertaken based on the severity of fluorosis.

ii. Observational studies

Ten studies were identified which analysed the risk of fluorosis associated with fluoride in drinking water. Only two of these studies were undertaken in the presence of CWF.

A study in Brazil, reported that the prevalence of fluorosis in 12-year-olds was higher in those groups who were provided with CWF. (Silva et al., 2021) Very mild/mild and moderate fluorosis increased from 15.2 % and 3.3% in the group without fluoridated water, to 41.6% and 18.0% with fluoridated water respectively. The concentration of fluoride in CWF samples was reported to be between 0.5 and 0.6 mg/l.

The second study (undertaken in Israel) reported the prevalence of fluorosis in adolescents as 10.3%, of which 9.3% were classified as questionable or mild fluorosis. (Tobias et al., 2024)

One further study, the United States National Health and Nutrition Survey (NHANES), which included both CWF and non-CWF sources is included in the review. (Hung et al., 2023) NHANES recorded the concentration of fluoride in the drinking water, the fluoride concentration in serum and the use of fluoride supplementation.

The most recent data from the 2015/16 NHANES survey reported an adjusted¹⁹ odds ratio (OR) for dental fluorosis for increasing concentrations of fluoride using a concentration of less than 0.30 mg/l as the reference value. For a water fluoride concentration of 0.31 to 0.50, the OR (95% CI)²⁰ was 1.105 (0.377 – 3.469), at a concentration of 0.51 to 0.70 mg/l, OR = 1.828 (0.735 to 4.909) and for a concentration of greater than 0.70 mg/l, OR = 2.378 (1.218 – 5.249) (Hung et al., 2023). These data suggest that CWF at a concentration of less than 0.7 mg/l is not associated with a significantly greater risk of fluorosis compared to non-fluoridated water. The severity of fluorosis, which was identified by a visual inspection, was collected in the NHANES data in a four point scale from 0 = no fluorosis to 4 = severe fluorosis. However, the study reported fluorosis as yes or no and will include mild and transitory degrees of dental fluorosis.

¹⁹ Adjusted for age, sex, race, ethnicity, family educational level, ratio of family income to area poverty level and period of survey.

²⁰ 95% CI = 95% confidence interval.

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Appendix 1: Systematic reviews not used in this review

| Reference | Summary |
|--|--|
| Akuno, M. H., et al. (2019). "Factors influencing the relationship between fluoride in drinking water and dental fluorosis: a ten-year systematic review and meta-analysis." <i>Journal of water and health</i> 17(6): 845-862. | Studies were of naturally occurring fluoridation in Asia and Africa, not CWF. Publication bias identified. |
| Anopa, Y., et al. (2020). "Systematic Review of Economic Evaluations of Primary Caries Prevention in 2- to 5-Year-Old Preschool Children." <i>Value in health</i> , 23(8): 1109-1118. | Did not include studies on CWF |
| Chou, R., et al. (2023). "Screening, Referral, Behavioral Counseling, and Preventive Interventions for Oral Health in Children and Adolescents Ages 5 to 17 Years: A Systematic Review for the U.S. Preventive Services Task Force." | Did not include studies on CWF |
| Chou, R., et al. (2021). "Screening and Interventions to Prevent Dental Caries in Children Younger Than Age Five Years: A Systematic Review for the U.S. Preventive Services Task Force." | Did not include studies on CWF |
| Davidson, K. W., et al. (2021). "Screening and Interventions to Prevent Dental Caries in Children Younger Than 5 Years: US Preventive Services Task Force Recommendation Statement." <i>JAMA</i> 326(21): 2172-2178. | Did not include studies on CWF |
| Ivančáková, R. K. et al. Exogenous Intake of Fluorides in Caries Prevention: Benefits and Risks. <i>Acta Medica</i> 2021 Vol. 64 Issue 2 Pages 71-76 | Not a systematic review. |
| Kathuria, N. S., et al. (2022). "Patterns and Distribution of Dental Caries and Dental Fluorosis in Areas with Varying Degrees of Fluoride Ion Concentration in Drinking Water: A Systemic Review and Meta analysis." <i>International Journal of Toxicological and Pharmacological Research</i> 12(4): 201-205. | Did not include studies on CWF. Did not assess benefits, only risks |
| Koberova Ivancakova, R., et al. (2021). "Exogenous Intake of Fluorides in Caries Prevention: Benefits and Risks." <i>Acta medica (Hradec Kralove)</i> 64(2): 71-76. | Not a systematic review. Only briefly mentions CWF. Duplicate of Ivancakova et al. |
| Skeie, M. S. and K. S. Klock (2018). "Dental caries prevention strategies among children and adolescents with immigrant - or low socioeconomic backgrounds- do they work? A systematic review." <i>BMC oral health</i> 18(1): 20. | Did not include studies on CWF |
| Peng, S.-M. and C. McGrath (2020). "What can we do to prevent small children from suffering from tooth decay?" <i>Evidence-based dentistry</i> 21(3): 90-91. | A review of Moynihan, P., et al. (2019). "Systematic Review of Evidence Pertaining to Factors That Modify Risk of Early Childhood Caries." <i>JDR clinical and translational research</i> 4(3): 202-216. |
| Taher, M. K., et al. (2024). "Systematic review of epidemiological and toxicological evidence on health effects of fluoride in drinking water." <i>Critical reviews in toxicology</i> 54(1): 2-34. | Did not include studies on CWF. Did not assess benefits. |
| Takahashi, R., et al. (2017). "Fluoride supplementation (with tablets, drops, lozenges or chewing gum) in pregnant women for preventing dental caries in the primary teeth of their children." <i>Cochrane Database Syst Rev</i> 10(10): Cd011850. | Did not include studies on CWF |

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| Toumba, K. J., et al. (2019). "Guidelines on the use of fluoride for caries prevention in children: an updated EAPD policy document." <i>European archives of paediatric dentistry : official journal of the European Academy of Paediatric Dentistry</i> 20(6): 507-516. | Did not include studies on CWF |
| Umer, M. F. (2023). "A Systematic Review on Water Fluoride Levels Causing Dental Fluorosis." <i>Sustainability</i> (Switzerland) 15(16). | Not CWF. Did not include studies on CWF. Studies from endemic fluorosis areas. |
| Valkenburg, C., et al. (2019). "Is plaque regrowth inhibited by dentifrice?: A systematic review and meta-analysis with trial sequential analysis." <i>International journal of dental hygiene</i> 17(1): 27-38. | Did not include studies on CWF |
| Veneri, F., et al. (2024). "Fluoride and caries prevention: a scoping review of public health policies." <i>Annali di igiene : medicina preventiva e di comunità</i> 36(3): 270-280. | Did not include studies on CWF Scoping review of public policies, not evidence |
| Zanatta, R. F., et al. (2020). "Protective effect of fluorides on erosion and erosion/abrasion in enamel: a systematic review and meta-analysis of randomized in situ trials." <i>Archives of oral biology</i> 120: 104945. | Did not include studies on CWF |

Appendix 2: Table of observational studies not included in this review

| Reference | Exclusion indication |
|--|---|
| Ambarkova, V. et al 2022 The Correlation Between the DMFT of the 15-year-old Children and the Concentration of Fluoride in Drinking Water from the East Region of the Republic of Macedonia. Open Access Macedonian Journal of Medical Sciences, 10 260-266 | Not CWF |
| Anisha, M, et al, 2020 The effect of fluoride in the prevention of dental caries and prevalence of dental fluorosis among high and low fluoridated areas of Tamil Nadu - a cross-sectional survey Indian Journal of Public Health Research and Development 2020 Vol. 11 Issue 7 Pages 62-67 | Not CWF Fluoride concentrations above CWF |
| Arheiam et al, 2020 Changes in dental caries and sugar intake before and during the conflict in Libya: A natural experiment. Community dentistry and oral epidemiology 2020 Vol. 48 Issue 3 Pages 201-207 | Not CWF |
| Arheiam et al 2022 Dental Fluorosis and Its Associated Factors Amongst Libyan Schoolchildren. International dental journal 2022 Vol. 72 Issue 6 Pages 853-858 | Not CWF Fluorosis, not caries |
| Corrêa, et al 2020 Factors associated with dental caries in adolescents: A cross-sectional study, São Paulo State, Brazil, Epidemiologia e Servicos de Saude 2020 Vol. 29 Issue 5 | In Portuguese |
| Garcia-Perez, et al. Impact of diseases of the hard tissues of teeth on oral health-related quality of life of schoolchildren in area with a high concentration of fluoride in drinking water. Community dental health 2022 Vol. 39 Issue 4 Pages 240-246 | Not CWF. Assessed QOL not dental caries. |
| Gousalya et al 2023 Effect of Fluoride on Oral Health Status Among General Population Residing in High- and Low-Level Fluoride Blocks in Erode District, Tamil Nadu, India: A Cross-Sectional Study. Journal of pharmacy & bioallied sciences 2023 Vol. 15 Issue Suppl 1 Pages S752-S755 | Not CWF High natural fluoride levels |
| Hearnshaw et al. 2023 Comments on recent community water fluoridation studies. British dental journal 2023 Vol. 235 Issue 8 Pages 639-641 | Not primary study Commentary on CATFISH study |
| Hobbs et al 2020. Area-level deprivation, childhood dental ambulatory sensitive hospitalizations and community water fluoridation: evidence from New Zealand International journal of epidemiology 2020 Vol. 49 Issue 3 Pages 908-916 | Included in OPMCSA 2021 report |
| Lee et al 2020 The Association between Community Water Fluoridation and Bone Diseases: A Natural Experiment in Cheongju, Korea. International journal of environmental research and public health 2020 Vol. 17 Issue 24 | Assessed risk of cancer and bone disease. Did not assess caries. |
| Matsuyama et al, Tap water natural fluoride and parent-reported experience of child dental caries in Japan: Evidence from a nationwide birth cohort survey Community dentistry and oral epidemiology 2023 Vol. 51 Issue 6 Pages 1141-1149 | Not CWF |
| Miranda-Rius, et al 2020 Periodontal and dental conditions of a school population in a volcanic region of Tanzania with highly fluoridated community drinking water | Assessed fluorosis. Did not assess caries. |

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| African health sciences 2020 Vol. 20 Issue 1 Pages 476-487 | |
| Montanha-Andrade et al, 2019 Dental health status and its indicators in adult Brazilian Indians without exposition to drinking water fluoridation: a cross-sectional study. Environmental science and pollution research international 2019 Vol. 26 Issue 33 Pages 34440-34447 | Not CWF |
| Moore, D., et al. 2024 How effective and cost-effective is water fluoridation for adults and adolescents? The LOTUS 10-year retrospective cohort study. Community Dentistry and Oral Epidemiology. https://onlinelibrary.wiley.com/doi/abs/10.1111/cdoe.12930 | Not CWF. |
| Munoz-Milan et al 2018. Effectiveness of fluoride varnish in preventing early childhood caries in rural areas without access to fluoridated drinking water: A randomized control trial. Community dentistry and oral epidemiology 2018 Vol. 46 Issue 1 Pages 63-69 | Not CWF Assessed benefits of fluoride varnish |
| Nguyen, T. M., et al. (2023). Economic Evaluations of Preventive Interventions for Dental Caries and Periodontitis: A Systematic Review. Applied health economics and health policy 21(1): 53-70. | Economic Evaluation |
| Perez et al 2020. Marginalization and fluorosis its relationship with dental caries in rural children in Mexico: A cross-sectional study Community Dental Health 2020 Vol. 37 Issue 3 Pages 216-222 | Not CWF |
| Ramesh et al. A cross-sectional study to find the correlation between the level of fluoride in drinking water, dental fluorosis and associated risk factors Journal of Pharmacy and Bioallied Sciences 2023 Vol. 15 Issue 5 Pages 651-655 | Not CWF. |
| Rani et al 2022 Prevalence of dental fluorosis and dental caries in fluoride endemic areas of Rohtak district, Haryana Journal of the Indian Society of Pedodontics and Preventive Dentistry 2022 Vol. 40 Issue 2 Pages 140-145 | Not CWF High levels of fluoride |
| Rezki et al 2023 Effect of Drinking Water Fluoride on Gingivitis and Caries: A Study in Peat and Non-Peat Land: A Comparative Cross-Sectional Study Journal of International Society of Preventive & Community Dentistry 2023 Vol. 13 Issue 6 Pages 509-515 | Not CWF |
| Saunders et al 2018 Blood Lead Levels and Dental Caries in U.S. Children Who Do Not Drink Tap Water. American journal of preventive medicine 2018 Vol. 54 Issue 2 Pages 157-163 | Not CWF Tested lead levels in drinking water |
| Schluter et al 2020 Association Between Community Water Fluoridation and Severe Dental Caries Experience in 4-Year-Old New Zealand Children JAMA pediatrics 2020 Vol. 174 Issue 10 Pages 969-976 | Included in OPMCSA 2021 report. |
| Whittaker et al 2024 Economic evaluation of a water fluoridation scheme in Cumbria, UK Community dentistry and oral epidemiology 2024 | Economic analysis |

Appendix 3: Exclusion table for neurodevelopmental outcomes

| Reference | Reason for exclusion |
|--|---|
| Bashash, M., et al., Prenatal fluoride exposure and attention deficit hyperactivity disorder (ADHD) symptoms in children at 6-12 years of age in Mexico City. Environ Int, 2018. 121(Pt 1): p. 658-666 DOI:10.1016/j.envint.2018.09.017. | ELEMENT project Included in the Fiore et al 2023 and Gopu et al 2022 systematic reviews |
| Bashash, M., et al., Prenatal Fluoride Exposure and Cognitive Outcomes in Children at 4 and 6-12 Years of Age in Mexico. Environ Health Perspect, 2017. 125(9): p. 097017 DOI:10.1289/ehp655. | ELEMENT project Included in the PMCSA update |
| Broadbent, J.M., et al., Community Water Fluoridation and Intelligence: Prospective Study in New Zealand. Am J Public Health, 2015. 105(1): p. 72-76 DOI:10.2105/ajph.2013.301857. | Dunedin Multidisciplinary Health and Development study Included in the PMCSA update and the Gopu et al 2022 systematic review |
| Canadian Agency for Drugs and Technologies in Health. Community Water Fluoridation Exposure: A Review of Neurological and Cognitive Effects – A 2020 Update. CADTH Rapid Response Report: Summary with Critical Appraisal 2020; Available from: https://www.ncbi.nlm.nih.gov/books/NBK567579/ . | HTA update Included in the OPMCSA update |
| Canadian Agency for Drugs and Technologies in Health. Community Water Fluoridation: A Review of Neurological and Cognitive Effects. CADTH rapid response report: summary with critical appraisal 2019; Available from: https://americanfluoridationsociety.org/wp-content/uploads/2019/12/cadth-evaluation-of-green-till-study.pdf . | HTA Included in the OPMCSA update |
| Cantoral, A., et al., Dietary fluoride intake during pregnancy and neurodevelopment in toddlers: A prospective study in the progress cohort. Neurotoxicology, 2021. 87: p. 86-93 DOI:10.1016/j.neuro.2021.08.015. | PROGRESS cohort Included in Kumar et al 2023 |
| Choi, A.L., et al., Association of lifetime exposure to fluoride and cognitive functions in Chinese children: a pilot study. Neurotoxicol Teratol, 2015. 47: p. 96-101 DOI:10.1016/j.ntt.2014.11.001. | Pilot study Included in Gopu et al 2022 systematic review |
| Duan, Q., et al., Association between water fluoride and the level of children's intelligence: a dose-response meta-analysis. Public Health, 2018. 154: p. 87-97 DOI:10.1016/j.puhe.2017.08.013. | Meta-analysis Included in the OPMCSA update |
| Farmus, L., et al., Critical windows of fluoride neurotoxicity in Canadian children. Environ Res, 2021. 200: p. 111315 DOI:10.1016/j.envres.2021.111315. | MIREC cohort Included in the Veneri et al 2023, Kumar et al 2023, and Taher et al 2024 systematic reviews |
| Goodman, C.V., et al., Domain-specific effects of prenatal fluoride exposure on child IQ at 4, 5, and 6-12 years in the ELEMENT cohort. Environ Res, 2022. 211: p. 112993 DOI:10.1016/j.envres.2022.112993. | ELEMENT project Included in the Veneri et al 2023, , and Taher et al 2024 systematic reviews |
| Grandjean, P., Developmental fluoride neurotoxicity: an updated review. Environ Health, 2019. 18(1): p. 110 DOI:10.1186/s12940-019-0551-x. | Integrated literature review Included in the OPMCSA update |
| Grandjean, P., Updated review by Grandjean of developmental fluoride neurotoxicity. Fluoride, 2020. 53 | Editorial Wrong study design |
| Grandjean, P., et al., A Benchmark Dose Analysis for Maternal Pregnancy Urine-Fluoride and IQ in Children. Risk Anal, 2022. 42(3): p. 439-449 DOI:10.1111/risa.13767. | ELEMENT and MIREC cohort data Wrong outcome (benchmark dose analysis) Both primary studies used for this paper already included |
| Grandjean, P. and P.J. Landigan, Neurobehavioural effects of developmental toxicity. The Lancet Neurology, 2014. 13(3): p. 330-338 DOI:10.1016/S1474-4422(13)70278-3. | Narrative review Wrong study design |
| Grandjean, P., et al., Dose dependence of prenatal fluoride exposure associations with cognitive performance at school age in three prospective studies. Eur J Public Health, 2024. 34(1): p. 143-149 DOI:10.1093/eurpub/ckad170. | Added Odense Child Cohort to ELEMENT and MIREC cohort data Wrong outcome (benchmark dose analysis) |
| Green, R., et al. Effects of Trimester-Specific Prenatal Fluoride Exposure and Childhood IQ in a Canadian Birth Cohort. in BIRTH DEFECTS RESEARCH. 2019. WILEY 111 RIVER ST, HOBOKEN 07030-5774, NJ USA. | Wrong article type (Conference proceedings) |
| Green, R., et al., Association Between Maternal Fluoride Exposure During Pregnancy and IQ Scores in Offspring in Canada. JAMA Pediatr, 2019. 173(10): p. 940-948 DOI:10.1001/jamapediatrics.2019.1729. | MIREC cohort Included in the PMCSA update and Gopu et al 2022 systematic review |
| Green, R., et al., Sex-specific neurotoxic effects of early-life exposure to fluoride: A review of the epidemiologic and animal literature. Curr Epidemiol Rep, 2020. 7(4): p. 263-273 DOI:10.1007/s40471-020-00246-1. | Wrong study design i.e., not a systematic review Wrong outcome (difference in mean IQ between boys and girls) |
| Guth, S., et al., Contribution to the ongoing discussion on fluoride toxicity. Arch Toxicol, 2021. 95(7): p. 2571-2587 DOI:10.1007/s00204-021-03072-6. | Reply Wrong study type |

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| Hirzy, J.H., et al., Developmental Neurotoxicity of Fluoride: A Quantitative Risk Analysis Toward Establishing a Safe Dose for Children. <i>Fluoride</i> , 2016. 49(4): p. 379-400 DOI:10.5772/intechopen.70852. | Wrong outcome (benchmark dose analysis) |
| Ibarluzea, J., et al., Prenatal exposure to fluoride and neuropsychological development in early childhood: 1-to 4 years old children. <i>Environ Res</i> , 2022. 207: p. 112181 DOI:10.1016/j.envres.2021.112181. | "Infancia y Medio Ambiente" (INMA) birth cohort Included in the Kumar 2023 systematic review |
| Khairkar, P., et al., Outcome of Systemic Fluoride Effects on Developmental Neurocognitions and Psychopathology in Adolescent Children. <i>Indian J Pediatr</i> , 2021. 88(12): p. 1264 DOI:10.1007/s12098-021-03903-5. | Case-control Included in the Fiore et al 2023 systematic review |
| Kjellevold, M. and M. Kippler, Fluoride - a scoping review for Nordic Nutrition Recommendations 2023. <i>Food Nutr Res</i> , 2023. 67 DOI:10.29219/fnr.v67.10327. | Scoping review Wrong study design and outcome |
| Mustafa, D.E.Y., U.M. and S.A. Elhaga, The relationship between the fluoride levels in drinking water and the schooling performance of children in rural areas of Khartoum state, Sudan. <i>Fluoride</i> , 2018. 51(2): p. 102-113 | Included in Taher et al 2024 systematic review |
| National Academies of Sciences, E., et al. Review of the Draft NTP Monograph: Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. 2020; Available from: https://nap.nationalacademies.org/catalog/25715/review-of-the-draft-ntp-monograph-systematic-review-of-fluoride . | Review of systematic review Included in the PMCSA update |
| Riddell, J.K., et al., Association of water fluoride and urinary fluoride concentrations with attention deficit hyperactivity disorder in Canadian youth. <i>Environ Int</i> , 2019. 133(Pt B): p. 105190 DOI:10.1016/j.envint.2019.105190. | Canadian Health Measures Survey Included in the Fiore et al 2023 systematic review |
| Saeed, M., et al. (2021). "WITHDRAWN: Co-exposure effects of arsenic and fluoride on intelligence and oxidative stress in school-aged children: A cohort study." <i>Environmental research</i> 196: 110168 DOI: https://dx.doi.org/10.1016/j.envres.2020.110168 | Withdrawn Included in the Gopu et al 2022 systematic review |
| Spittle, B., Fluoride, IQ, and advice on type I and II errors. <i>Fluoride</i> , 2014. 47(3): p. 188-190 | Wrong article type (Editorial) |
| Spittle, B., Development of fluoride toxicity including cognitive impairment with reduced IQ: Pathophysiology, interactions with other elements, and predisposing and protective factors. <i>Fluoride</i> , 2016. 49(3): p. 189-193 | Wrong article type (Editorial) |
| Spittle, B., Reviews of developmental fluoride neurotoxicity by Grandjean and Guth et al. <i>Fluoride</i> , 2020. 53(2): p. 204-219 | Wrong article type (Editorial) |
| Thomas, D.B., et al., Urinary and plasma fluoride levels in pregnant women from Mexico City. <i>Environ Res</i> , 2016. 150: p. 489-495 DOI:10.1016/j.envres.2016.06.046. | ELEMENT Wrong outcome (fluoride levels in urine and plasma) |
| Till, C., et al., Fluoride exposure from infant formula and child IQ in a Canadian birth cohort. <i>Environ Int</i> , 2020. 134: p. 105315 DOI:10.1016/j.envint.2019.105315. | MIREC Included in the Gopu et al 2022 systematic review |

Appendix 4: Evidence table of included systematic reviews for neurodevelopmental outcomes

| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
|--|---|---|--|--|
| <p>Fiore et al. (2023) (Fiore et al., 2023) Systematic review Italy/USA</p> <p>Journal Medicina</p> <p>Funding: This study was supported by the grant “Dipartimenti di Eccellenza 2018–2022” to the UNIMORE Department of Biomedical, Metabolic and Neural Sciences from the Italian Ministry of Education, University and Research. T.F. was also supported by the grants “UNIMORE FAR 2021 and 2022, FOMO Line” by University of Modena and Reggio Emilia and Fondazione di Modena.</p> <p>Conflicts of Interest: The authors declare no conflict of interest.</p> | <p>Search: PubMed, EMBASE and Web of Science on the 31st March 2023</p> <p>Inclusion criteria: a healthy child and adolescent population (P), fluoride exposure of any type (E), comparison with low or null exposure (C), ADHD spectrum disorder (O), and ecological, cross-sectional, case-control and cohort studies (S).</p> <p>No exclusion criteria or limits on language or data [sic]</p> <p>Studies included:</p> <ul style="list-style-type: none"> • Bashash et al 2018 • Malin and Till 2015/Perrott 2018 • Riddell et al 2019 • Adkins et al 2022 • Wang 2022 • Barberio et al 2017 • Khairkar et al 2021 <p>Appraisal: No appraisal of quality conducted</p> | <p>Exposure: fluoride exposure of any type (water, toothpaste, diet)</p> <p>Comparator: Lowest fluoride exposure in cohort or no exposure</p> <p>Each study used different methods to assess fluoride exposure and diagnose ADHD: 5 used urinary fluoride levels and 2 fluoride water levels; only 3 used validated questionnaires for ADHD</p> <p>Outcome: ADHD</p> | <p>N=7 studies included (1 cohort, 1 case control, 5 cross-sectional) Two from USA and Canada, one from Mexico, China and India</p> <p>Findings: Overall, 3 studies suggest an association between fluoride exposure and ADHD and 4 studies find no association. Malin and Till 2015, Riddell et al., 2019 and Khairkar et al., 2021 suggest there is a positive correlation between fluoride exposure and ADHD diagnosis. Bashash et al., 2018 found an association between maternal fluoride exposure and inattention, whereas no association is found between maternal fluoride exposure and hyperactivity or impulse control dysfunctions. Conversely, Barberio et al., 2017 and Perrott 2018 observe no association between fluoride exposure and ADHD. Adkins and Wang note an association between fluoride exposure and the development of internalizing symptoms such as somatization, but they do not find any significant connection with ADHD.</p> | <p>Significant heterogeneity in populations, fluoride levels, and outcome assessment and small number of studies limits ability to make any general conclusions.</p> <p>Of note, it is not possible to attribute causality in studies with a cross-sectional design.</p> <p>Quality of this systematic review: Adequate search and selection criteria, however, there has been no discussion of methodological quality of the included studies. Likely risk of misclassification and residual confounding and study design also precludes drawing of definitive conclusions.</p> <p>Authors' conclusions: Current epidemiological evidence indicates that fluoride exposure may have neurotoxic effects on neurodevelopment, including behavioral alterations, cognitive impairment and psychosomatic issues. However, the heterogeneity in study designs and results from human</p> |

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| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
|---|--|--|---|---|
| | | | | studies did not allow us to reliably identify fluoride exposure as a risk factor for ADHD development. |
| Gopu et al. (2022) (Gopu et al., 2022) Systematic review UK <u>Journal</u> International Journal of Environmental Research and Public Health. <u>Funding:</u> This research was funded by Teesside University Ph.D. Studentship. <u>Conflicts of Interest:</u> The authors have no conflicts of interest to declare. | <p><u>Search:</u> MEDLINE, Embase, and CINHAL via EBSCO host, PubMed, Web of Science, Scopus, and PsycINFO using MeSH</p> <p><u>Inclusion criteria:</u></p> <ul style="list-style-type: none"> Population: pregnant women and children >18 years Exposure: fluoride through sources including groundwater, tea and milk, diet, toothpaste, mouthwash, industrial emissions, coal-burning for fuel, supplements, pesticide residues, and certain pharmaceuticals; Outcome: cognitive outcomes measured with a validated tool²¹ Study design: Longitudinal, cross-sectional, and experimental studies Only publications in the English language. <p><u>Exclusion criteria:</u> animal studies; studies in adults over 18 years; case studies; narrative reports; expert opinions; reviews; abstracts; conference proceedings</p> <p><u>Studies included:</u></p> <ul style="list-style-type: none"> Chen et al 2008 Choi et al 2015 | <p><u>Exposure:</u> fluoride exposure of any type (water, toothpaste, diet)</p> <p><u>Source of fluoride:</u> coal (N=4 studies); drinking water (N=42 studies)</p> <p><u>Fluoride levels:</u></p> <ul style="list-style-type: none"> 0.13 to 9.4 mg/L in the drinking water 0.03 to 2.33 mg/m³ through coal burning ≥2 mg/l in 27 studies <2 mg/l in 13 studies 6 studies did not report level <p><u>Duration of exposure:</u></p> <ul style="list-style-type: none"> from birth (N=28) not reported (N=18) <p><u>Outcomes:</u> cognitive outcomes</p> | <p>N=46 studies included (6 longitudinal; 40 cross-sectional)</p> <p>23 from China; 9 from India; 6 from Mexico; 3 Canadian; 2 Iranian; one each from NZ, Mongolia and Pakistan</p> <p><u>Quality of studies:</u></p> <ul style="list-style-type: none"> Excellent N=5 Good N=7 Fair N=14 Poor N=20 <p><u>Findings:</u> 31 out of the 46 included studies reported mean IQ scores alone:</p> <ul style="list-style-type: none"> Of these, 25 studies found mean IQ levels of children exposed to fluoride ≥2 mg/L were significantly lower than those exposed to <2 mg/L, while the remaining 6 studies found no significant association <p>The remaining 15 studies reported on various outcomes:</p> <ul style="list-style-type: none"> 11 found a negative association between fluoride exposure and mental and psychomotor development index (N=1 study), neonatal behavioural neurological assessment scores (N=1), intelligence ranking (N=2), mean intelligence grades (N=2), and intelligence assessment scores (N=4) 4 found no effect on self-reporting learning ability, the mean general cognitive index, the strengths and difficulty questionnaire, or intelligence deficiency <p><u>Subgroup analysis:</u></p> <ul style="list-style-type: none"> study design: more likely to report a negative effect with cross-sectional studies age: no difference for ≤8 years vs. >8 years old | <p>Some clinical heterogeneity in population, fluoride exposure levels, and outcomes, therefore narrative synthesis (i.e., no meta-analysis conducted)</p> <p><u>Quality of this systematic review:</u> Adequate search and selection criteria with appraisal of quality. Appropriate subgroup analysis and narrative synthesis. Generalisability and applicability is limited due to fluoride exposures above that used for water fluoridation in Aotearoa New Zealand (0.7 – 1.0 mg/l).</p> <p>Other limitations include: preponderance of cross-sectional studies which make it difficult to attribute causality; the use of mean IQ to measure cognition ignores the complexity of cognition and the factors influencing it; risk of residual confounding by not including other factors that influence IQ such as maternal IQ, nutrition, education,</p> |

²¹ Various tools used including Raven's Standard progressive matrices; official IQ Tests; Raymond B Cattell test; Chinese Binet IQ test etc

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| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
|---|---|--|---|--|
| | <ul style="list-style-type: none"> • Chunyuan & Olsen 2011 • Cui et al 2018 • Ding et al 2011 • Guo et al 2008 • Li et al 2008 • Lou et al 202 • Lu et al 2000 • Qin et al 2008 • Ren et al 2008 • Wang et al 2020 • Wang et al 2008 • Wang et al 2019 • Wang et al 2008b • Wang et al 2007 • Wei et al 2014 • Xiang et al 2003 • Xu et al 2020 • Yang et al 2008 • Yu et al 2018 • Zhao et al 2021 • Zhao et al 1996 • Aravind et al 2016 • Eswar et al 2011 • Kumar et al 2021 • Kundu et al 2015 • Razdan et al 2017 • Saxena et al 2012 • Sebastian et al 2015 • Sharma et al 2016 • Trivedi et al 2007 • Bashash et al 2018 • Jimenez et al 2017 • Martinez et al 2016 • Rocha-Amador et al 2007 • Soto-Barreras et al 2019 • Barberio et al 2017 • Green et al 2019 • Till et al 2020 • Karimzade et al 2014 • Seraj et al 2012 • Li et al 2008 • Broadbent et al 2015 • Saeed et al 2020 <p><u>Appraisal:</u> STROBE-M tool</p> | | <ul style="list-style-type: none"> • fluoride level: more likely to report negative association with fluoride ≥ 2 mg/l exposure • study quality: more likely to report a negative association with fair or poor quality study | <p>maternal depression, and deficiencies in iron and iodine.</p> <p><u>Authors' conclusions:</u> The overall evidence from this systematic review suggests that exposure to fluoride at a level of more than 2 mg/L in drinking water may result in impaired cognitive outcomes among children. However, the inclusion of many low quality studies and the lack of robust estimates of fluoride exposure from all sources make it difficult to provide definitive conclusions.</p> |
| Kumar et al. (2023) (Kumar et al., 2023) Systematic review USA | <u>Search:</u> <ul style="list-style-type: none"> • N=26 studies from Duan et al. (2018) systematic review up to Nov 2016 | <u>Source of fluoride:</u> drinking water or urinary F | N=33 studies included overall <u>SMD meta-analysis:</u> | Well conducted systematic review overall. Small number of studies (N=8) relevant to |

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| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
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| Journal Public Health Funding: Funding was not sought for this project. Conflicts of Interest: J.V.K. is a member of the American Dental Association's National Fluoridation Advisory Committee. He was a reviewer of the National Academies of Sciences, Engineering, and Medicine report Review of the Revised NTP Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects: A Letter Report (2021). S.F.-O. is a member of the American Academy of Pediatrics' Section on Oral Health. She was a co-author of 'Fluoride Use in Caries Prevention in the Primary Care Setting' and 'Review of Safety, Frequency and Intervals of Preventive Fluoride Varnish Application for Children.' She consults for Arcora Foundation on medical/dental integration and has research funding for medical/dental integration from Health Resources Services Administration | <ul style="list-style-type: none"> N=46 studies from the National Toxicology Program (NTP) (2022) review PubMed, Google Scholar, and Mendeley (May 2020-Dec 2021) <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Population: children 1-18 years Exposure: water or urinary F Outcomes: info to calculate SMD and/or regression coefficient for change in cognition and IQ scores Study design: observational (cohort and cross-sectional) Available in English <p>Exclusion criteria: (for assessing the effect at low fluoride levels)</p> <ul style="list-style-type: none"> Exposure >1.5 mg/l (endemic fluorosis areas) Source other than water or urinary fluoride Overlapping publications <p>Studies that used dental fluorosis as exposure were also excluded, as well as studies that used different IQ and dental fluorosis measurement format than other studies</p> <p>Studies included: SMD meta-analysis (N=8)</p> <ul style="list-style-type: none"> Xu 1994 Zhang 1998 Xiang 2003 | <p>Exposure:</p> <ul style="list-style-type: none"> Mean water fluoride 0.90 mg/l vs. 0.30 mg/l [non-endemic areas] Mean water fluoride 3.7 mg/l vs. 0.7 mg/l [endemic areas] Urinary fluoride (children and maternal) <p>Outcomes: IQ</p> | <p>Three studies from China and one each from India, New Zealand, Mexico, Canada and Spain.</p> <p>Quality of studies:</p> <ul style="list-style-type: none"> Probably low risk N=2 Probably high risk N=3 Definitely high risk N=3 <p>Non-endemic areas (N=8 studies)</p> <ul style="list-style-type: none"> SMD=0.07 (95%CI: -0.02 to 0.17) $I^2=0\%$ <p>Endemic areas (N=23 studies)²²</p> <ul style="list-style-type: none"> SMD=-0.46 (95%CI: -0.58 to -0.35) $I^2=81\%$ <p>Regression coefficient meta-analysis: Two studies from Canada, one each from Mexico, China and Spain.</p> <p>Quality of studies:</p> <ul style="list-style-type: none"> Probably low risk N=1 Probably high risk N=3 <p>[One study not appraised for RoB]</p> <p>Child urinary fluoride: Non-endemic areas (N=3 studies)</p> <ul style="list-style-type: none"> $\beta=0.16$ (95%CI: -0.40 to 0.73); $p=0.57$; $I^2=0\%$ <p>Maternal urinary fluoride: Non-endemic areas (N=3 studies)</p> <ul style="list-style-type: none"> $\beta=-0.92$ (95%CI: -3.29 to 1.46); $p=0.45$; $I^2=72\%$ <p>Community water fluoridation (N=2)</p> <ul style="list-style-type: none"> $\beta=0.12$ (95%CI: -2.45 to 2.68) $I^2=63\%$ <p>Salt fluoridation (N=1)</p> <ul style="list-style-type: none"> $\beta=-3.15$ (95%CI: -5.43 to -0.87) $I^2=\text{not applicable}$ <p>Further regression analysis by standardizing absolute mean IQ scores from lower fluoride areas did not show a relationship between F concentration and IQ scores (Model Likelihood-ratio test: P-value = 0.34.)</p> | <p>community water fluoridation. Overall, a preponderance of studies with high risk of bias.</p> <p>Confounding factors in primary studies for SMD meta-analysis not reported.</p> <p>Quality of this systematic review: Adequate search and selection criteria with appraisal of quality. Appropriate meta-analyses. Sensitivity analyses conducted of random-effects SMD and regression coefficient (Beta) estimates of child's intelligence score with higher fluoride exposure. Tested for publication bias. Generalisability and applicability to Aotearoa New Zealand good with restriction to community water fluoridation levels used here.</p> <p>Authors' conclusions: These meta-analyses show that fluoride exposure relevant to community water fluoridation is not associated with lower IQ scores in children. However, the reported association observed at higher fluoride levels in endemic areas</p> |

²² NB: studies not listed here as levels in water much greater than that used for community water fluoridation in Aotearoa New Zealand (0.7 to 1.0 mg/l)

NB2: 22 studies 'definitely high risk of bias' and one 'probably high risk of bias'

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| (HRSA) D88HP37553. She serves on an independent DSMB for a study funded by Colgate. | <ul style="list-style-type: none"> Broadbent 2015 (child) Sebastian 2015 Bashash 2017 Green 2019 Ibarluzea 2021 <p><u>Child urinary fluoride:</u></p> <ul style="list-style-type: none"> Bashash 2017 Yu 2018 Farmus 2021 <p><u>Maternal urinary fluoride:</u></p> <ul style="list-style-type: none"> Green 2019 Ibarluzea 2021 Bashash 2017 <p><u>Appraisal:</u> Office of Health Assessment and Translation Risk of Bias rating tool</p> <ul style="list-style-type: none"> probably low risk (+) probably high risk (-) definitely high risk (- -) | | | requires further investigation. |
| <p>Miranda et al. (2021) (Miranda et al., 2021) Systematic review and meta-analysis Brazil/Canada</p> <p><u>Journal</u> Scientific Reports</p> <p><u>Funding:</u> This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES) – Finance Code 001. The funder was not involved in the design of the study, data collection, analysis, and interpretation of the data and the writing of the manuscript. The APC was funded by Pró-Reitoria de Pesquisa e Pós-graduação da Universidade</p> | <p><u>Search:</u> PubMed, Scopus, Web of Science, Lilacs, Cochrane and Google Scholar (Jan 2021).</p> <p>No restrictions on date or language</p> <p><u>Inclusion criteria:</u></p> <ul style="list-style-type: none"> observational studies in humans (P) exposed to high concentrations of F (E) and low concentrations (C) in which the associations between F and neurological damage (O) were investigated. <p><u>Exclusion criteria:</u></p> <ul style="list-style-type: none"> Case reports, descriptive studies, review articles, opinion articles, technical articles, | <p><u>Exposure:</u> >2mg/l fluoride in drinking water ("high" level)</p> <p><u>Comparator:</u> 0.5-1.0 mg/ml fluoride in drinking water ("low" level)</p> <p><u>Outcome:</u> neurological disorders (all IQ except one study)</p> <p>Note that IQ results have been dichotomised into "low IQ" and "normal IQ" to calculate an odds ratio. There is no description of how a "low IQ" was assigned.</p> | <p>N=27 studies included (all cross-sectional)</p> <p>Eleven studies from China, 13 from India, and 3 from Iran</p> <p><u>Risk of bias:</u></p> <ul style="list-style-type: none"> Low N=19 High N=8 <p><u>Findings:</u> Odds of "low IQ" significantly greater in high fluoride area (>2mg/l) compared to low fluoride area (0.5-1.0 mg/ml)</p> <ul style="list-style-type: none"> OR=3.88 (95%CI: 2.41 to 6.23); p<0.00001; I²=77% N=10 studies with total of 2,839 participants significant publication bias GRADE Quality of evidence: very low (downgraded due to serious imprecision) | <p><u>Quality of this systematic review:</u> Some concerns about appropriateness of data analysis especially how "low IQ" was ascertained. Conclusions limited by methodological quality of primary studies, high statistical heterogeneity and evidence of publication bias. In addition the cross-sectional nature of the studies precludes determination of any causal relationship. Other concerns include the variety of tools used to measure IQ and residual confounding (particularly from co-contamination of</p> |

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| Federal do Pará (PROPESP-UFPA). Conflicts of interest: The authors declare no competing interests. | <p>guidelines, animal and <i>in vitro</i> studies</p> <p>Studies included:</p> <ul style="list-style-type: none"> • Aravind 2016 • Chen 1991 • Eswar 2011 • Guo 1991 • Hong 2001 • Karimzade 2014 • Khan 2015 • Kundu 2015 • Lu 2000 • Nagarajappa 2013 • Poureslami 2011 • Qin 2008 • Raxdan 2017 • Saxena 2012 • Sebastian 2015 • Seraj 2012 • Sharma 2009 • Shivaprakash 2011 • Sudhir 2009 • Trivedi 2007 • Trivedi 2012 • Wang 2006, 2007, 2008 • Xiang 2003 • Yu 2018 • Zhao 1996 <p>Appraisal methods:</p> <ul style="list-style-type: none"> • Checklist of Fowkes and Fulton (low or high risk) for risk of bias • GRADE approach used for assessment of the quality of evidence overall | | | <p>water supply by other substances and nutritional status etc.</p> <p>Authors' conclusions: Ten studies were included on the meta-analysis, which showed IQ impairment only for individuals under high fluoride exposure considering the World Health Organization criteria, without evidences of association between low levels and any neurological disorder. However, the high heterogeneity observed compromise the final conclusions obtained by the quantitative analyses regarding such high levels. Furthermore, this association was classified as very low-level evidence. At this time, the current evidence does not allow us to state that fluoride is associated with neurological damage, indicating the need for new epidemiological studies that could provide further evidence regarding this possible association.</p> |
| Taher et al. (2024) (Taher et al., 2024) Systematic review Canada Critical Reviews in Toxicology | <p>Search: Human studies</p> <ul style="list-style-type: none"> • Updating previous SRs: Canadian Agency for Drugs and Technologies in | <p>Exposure: fluoride at any level in drinking water (added or naturally occurring)</p> | <p>N=89 human studies (of which 21 concern cognitive dysfunction)</p> <p>Seven studies from China; 3 from Mexico; 2 from Canada, India, and Pakistan; one each from Indonesia, Peru, Spain, Sudan and USA.</p> | Serious concerns about the conduct of this systematic review including: the validity of the risk of bias assessment using a |

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| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
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| <p>Funding: This work was requested by Health Canada under a competitive master standing offer agreement, which includes RSI as a provider of health risk assessment services. The contract report on which this manuscript is based was completed during the period from January 2020 to March 2023.</p> <p>Conflicts of interest: All authors who contributed to the current systematic review report no conflict of interest existed at any stage of planning or preparation for this review, as well as the drafting, critical review, and approval of the aforementioned manuscript.</p> | <ul style="list-style-type: none"> • Health (2019, 2020) and Jack B (2016) • 10 bibliographic databases; 6 clinical trial registries; 18 grey literature sources and web-based materials were also examined, including relevant national and international authoritative and technical health agencies, academic dissertations, major scientific hubs, and international conference proceedings. • NB: also updated systematic reviews of animal studies [NTP-National Toxicology Program (2016)] and <i>in vitro</i> studies [Health Canada (2010)] <p>Inclusion criteria: review articles and original human studies that examined the association between exposure to fluoride in drinking water (community water fluoridation or naturally occurring) with any health risks published between 2016 and July 2021.</p> <p>Exclusion criteria: studies that examined other fluoride formulations or mixtures, assessed dental outcomes other than dental fluorosis, reported irrelevant assessments (e.g. hazard quotient), or published in a non-Latin language, as well as study types such as commentaries, editorials, case reports, case series, books and</p> | <p>Outcomes:</p> <ul style="list-style-type: none"> • Cognitive dysfunction including ADHD, dementia, Down syndrome, IQ, and trouble working • Others including thyroid, kidney, and cancer | <p>Cognitive dysfunction:</p> <ul style="list-style-type: none"> • ADHD (2 studies; all high quality) • Dementia (1 study; high quality) • Down syndrome (no new studies) • IQ reduction (17 studies; N=12 high quality; N=5 acceptable quality) • trouble working (1 study; acceptable quality) <p>NB: there is a discrepancy between the number of studies stated for IQ in various places of the article</p> <p>Findings:</p> <p>ADHD</p> <ul style="list-style-type: none"> • Insufficient evidence to evaluate any association <p>IQ reduction</p> <ul style="list-style-type: none"> • Positive relationship <p>“Current review evidence synthesis: Based on the available literature to date, the cumulative body of evidence suggests a positive association of reduced IQ scores for children and fluoride exposures relevant to current North American drinking water levels.”</p> | modified tool which has likely inflated the quality assessment of studies by not taking into account the innate limitations of observational studies especially cross-sectional studies. Other concerns are the external validity of the included studies especially the levels of fluoride in drinking water being above that used for water fluoridation in Aotearoa New Zealand. In addition, six IQ studies are missing from relevant tables and parts of the text. Moreover, the authors appear to be not always correctly reporting the exact nuanced findings of some studies in detail. <p>Quality: Some serious concerns regarding the conduct of this review (see above) and concerns that the aim of this review is not correctly aligned with the aim of this evidence review.</p> <p>Authors' conclusions: 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</p> |

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| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
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| | <p>general informational materials</p> <p>Studies included: NB: human studies (IQ)</p> <ul style="list-style-type: none"> • Ahmad et al. (2022) • Bashash et al. (2017) • Cui et al. (2018) • Cui et al. (2020) • Farmus et al. (2021) • Feng et al. (2022) • Goodman et al. (2022) • Heck (2016) • Ibarluzea et al. (2022) • Kaur et al. (2022) • Kousik and Mondal (2016) • Mustafa et al. (2018) • Saeed et al. (2022) • Soto-Barreras et al. (2019) • Till et al. (2020) • Wang et al. (2020) • Wang et al. (2021) • Yani et al. (2021) • Yu et al. (2018) • Yu et al. (2021) • Zhao et al. (2021) <p>Appraisal methods: risk of bias assessed with a modified OHAT risk of bias tool</p> <ul style="list-style-type: none"> • high quality (1) • acceptable quality (2) • low quality (3) | | | <p>evidence for causality and considerable uncertainty in the point of departure.</p> |
| <p>Veneri et al. (2023) (Veneri et al., 2023)</p> <p>Systematic review</p> <p>USA/Italy</p> <p>Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.</p> <p>Conflicts of interest: The authors declare that they have no</p> | <p>Search: PubMed/MEDLINE, Web of Science, and Embase (inception up to December 30, 2022)</p> <p>No language or date restrictions were applied.</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • (P) children ≤18 years of age • (E) early or prenatal fluoride exposure from any source | <p>Exposure:</p> <ul style="list-style-type: none"> • fluoride in drinking water (0.13 to 5.55 mg/l) • urinary fluoride (0.16 to 7 mg/l) • hair/nail fluoride (6.9 and 27.8 µg/g, and 8.3 and 57 µg/g) | <p>N=33 studies (N=30 in meta-analysis)</p> <p>N=29 cross-sectional studies and N=4 cohort</p> <p>Total population of 12,263 children were enrolled in 7 countries (China N=15, India N=7, Canada N=2, Iran N=4, Mexico N=3, Pakistan N=1, New Zealand N=1).</p> <p>Risk of bias:</p> <ul style="list-style-type: none"> • High in 11 studies • Moderate in 19 studies • Low in 3 studies | <p>Serious concerns regarding the appropriateness of conducting a meta-analysis of highly heterogeneous studies (particularly in terms of fluoride level comparisons and exposure source) and the external validity of said studies.</p> <p>Statistical heterogeneity was extremely high for all meta-analyses</p> |

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| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
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| known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. | (e.g. water, dietary, and supplemental intake, topical dental products) or evaluating a biomarker of exposure (e.g. urinary, bone, hair fluoride) <ul style="list-style-type: none"> • (C) exposure to any lower dose of fluoride • (O) neurodevelopmental function • (S) observational studies and clinical trials <u>Exclusion criteria:</u> <ul style="list-style-type: none"> • conference proceedings, abstracts, letters to the editor, commentaries, case reports, reviews, and meta-analysis • exposure to fluoride from coal-burning or volcanic eruptions • specific populations, such as children born preterm and institutionalized children • specific health conditions including autism, Down's syndrome, attention-deficit/hyperactivity disorder (ADHD) or other behavioral issues, anxiety, and depression <u>Studies included:</u> <ul style="list-style-type: none"> • Ahmad et al., 2022 • Aravind et al., 2016 • Bashash et al., 2017 • Broadbent et al., 2015 • Chen et al., 2008 • Das and Mondal, 2016 • Ding et al., 2011 • Eswar et al., 2011 | <p>respectively)</p> <ul style="list-style-type: none"> • serum fluoride (0.04 to 0.18 mg/l) <p><u>Comparator:</u></p> <ul style="list-style-type: none"> • any lower dose of fluoride <p><u>Outcome:</u></p> | <p>NB: main source of high RoB was lack of adjustment for potential confounders (N=11) as well as potential selection bias (selected based on fluoride exposure N=25)</p> <p><u>Findings:</u></p> <p>Mean difference (MD) in IQ scores (highest vs. lowest F level)</p> <ul style="list-style-type: none"> • All F sources: -4.68 (95% CI: - 6.45 to - 2.92) $I^2 = 98.75\%$ • Water F: -5.60 (95% CI: -7.76 to -3.44) $I^2 = 91.69\%$ • Urinary F: -3.84 (95% CI: -7.93 to 0.24) $I^2 = 96.22\%$ <p><u>Dose-response analysis:</u></p> <p>A</p> <p>B</p> | <p>with little exploration of the reasons for this. In addition, many studies had a high risk of bias mainly due to lack of controlling for important confounders e.g., nutrition status (maternal and child), co-contaminants (e.g., lead, arsenic), education levels of parents, birth weight, income, presence of iron and/or iodine deficiency, alcohol and substance use, and comorbidities, among others.</p> <p>Note the dose-response curves with no effect on IQ for drinking water fluoride levels below about 1.25 mg/l and urinary fluoride levels below about 1.5mg/l.</p> <p><u>Quality:</u> Some serious concerns regarding the conduct of this review (see above), particularly the appropriateness of conducting a meta-analysis in the presence of significant statistical heterogeneity and risk of residual confounding.</p> <p><u>Authors' conclusions:</u> In conclusion, we found an overall indication of dose-dependent adverse effects of fluoride on children's</p> |

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| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
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| | <ul style="list-style-type: none"> • Farmus et al., 2021 • Feng et al., 2022 • Goodman et al., 2022 • Hong et al., 2008 • Karimzade et al., 2014 • Li et al., 1995 • Li et al., 2008 • Lu et al., 2000 • Poureslami et al., 2011 • Rocha-Amador et al., 2007 • Saxena et al., 2012 • Sebastian and Sunitha, 2015 • Seraj et al., 2012 • Seraj et al., 2007 • Shivaprakash et al., 2011 • Till et al., 2020 • Trivedi et al., 2007 • Wang et al., 2008 • Wang et al., 2021 • Wang et al., 2007 • Xiang et al., 2003 • Xiang et al., 2011 • Yu et al., 2021 • Zhang et al., 2015 • Zhao et al., 1996 <p><u>Appraisal methods:</u> ROBINS-E tool</p> | | | 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. |

Appendix 5: Evidence table of included primary studies for neurodevelopmental outcomes

| Author/year Study design/Country Funding Conflicts of interest | Participants Inclusion/exclusion criteria Characteristics | Exposure Outcome measures Confounders | Results | Comments Quality Authors' conclusions |
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| <p>Dewey et al. (2023) (Dewey et al., 2023)</p> <p>Ecological study</p> <p>Canada</p> <p>Journal: Science of the Total Environment</p> <p>Funding: Dewey, Giesbrecht, Letourneau, APrON Study Team</p> <p><u>Conflicts of interest:</u> The authors have no conflicts of interest to declare.</p> | <p>n=616 maternal-child pairs enrolled in the Calgary cohort of the Alberta Pregnancy Outcomes and Nutrition (APrON) study between 2009 and 2012.</p> <p>Water fluoride level = 0.7mg/l</p> <p>On May 19, 2011, Calgary, Canada stopped fluoridating its drinking water. The background fluoride level in the Calgary water source is reported to be 0.1 – 0.4 mg/L²³</p> <p><u>Eligibility criteria:</u> Women were eligible if they could communicate in English, were <27 weeks gestational age and were ≥16 years of age.</p> <p>A subset of 616 maternal-child pairs from Calgary whose children participated in cognitive and executive function assessments at 3 to 5 years of age ($M = 4.24$ SD = 0.51)</p> <p><u>Characteristics:</u></p> <ul style="list-style-type: none"> Significant differences in the rate of maternal smoking during pregnancy and the proportion of mothers born in | <p>Exposures: n=295 fully exposed to fluoridated drinking water throughout pregnancy²⁴</p> <p>n=220 exposed during part of pregnancy²⁵</p> <p>n=101 not exposed during pregnancy²⁶</p> <p>Outcome measures: IQ: Canadian Wechsler Preschool and Primary Scale of Intelligence (WPPSI-IV^{CDN}). Executive functions: Working memory - WPPSI-IVCDN Working Memory Index. Inhibitory control Gift Delay, NEPSY-II Statue subtest. Cognitive flexibility Boy-Girl Stroop, Dimensional Change Card Sort (DCCS).</p> | <p>IQ:</p> <ul style="list-style-type: none"> no association between exposure group and full IQ for boys or girls. <p>Executive Function</p> <p>Working Memory</p> <ul style="list-style-type: none"> No associations were noted for the overall group. Sex-stratified analyses also revealed no associations. <p>Inhibitory Control</p> <ul style="list-style-type: none"> Full exposure vs. no exposure was associated with reduced Gift Delay ($B = 0.53$, 95 % CI = 0.31, 0.93). Sex-stratified models showed that girls in the fully exposed group ($AOR = 0.30$, 95 % CI = 0.13, 0.74) displayed lower odds of passing the Gift Delay compared to girls in the not exposed group. No associations were found between exposure group and children's scores for the NEPSY-II Statue subtest. <p>Cognitive Flexibility</p> <p>For the DCCS, no associations were found between fluoride exposure group and odds of passing the DCCS in the overall group or for boys. Girls in the fully ($AOR = 0.34$, 95 % CI = 0.14, 0.88) and partially</p> | <p>Quality: innate risk of bias due to observational cross sectional study design. Adjusted for smoking but not for alcohol use, preterm birth or maternal diabetes²⁷</p> <p>Removal of children with low birthweight altered the magnitude of some associations, but no details provided.</p> <p>Authors' conclusions: “...no associations were found between exposure to drinking water from a community water supply fluoridated at 0.7 mg/L throughout pregnancy and measures of intelligence at 3–5 years of age.”</p> <p>Maternal exposure to drinking water throughout pregnancy fluoridated at the level of 0.7 mg/L was associated with poorer inhibitory control and cognitive</p> |

²³ The article referenced does not provide a valid link to the background fluoride concentration. Naturally occurring fluoride levels reported as 0.1 – 0.4 mg/L from the Calgary Water Supply Authority. <https://www.calgary.ca/water/drinking-water/fluoride.html#:~:text=Fluoride%20naturally%20occurs%20in%20the,0.1%20and%200.4%20mg%2FL>.

²⁴ Includes women who gave birth prior to cessation of CWF on 19 May 2011.

²⁵ Includes women who gave birth from 19th May 2011 to 13 May 2012.

²⁶ Includes women who gave birth after May 13, 2012

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| Author/year Study design/Country Funding Conflicts of interest | Participants Inclusion/exclusion criteria Characteristics | Exposure Outcome measures Confounders | Results | Comments Quality Authors' conclusions |
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| | <p>Canada.51.3% were boys</p> <ul style="list-style-type: none"> • 71.29% not exposed born in Canada compared to 83.64% partially exposed and 84.75% fully exposed | | <p>exposed groups (AOR = 0.29 95 % CI = 0.12, 0.73) were approximately one third less likely to pass the DCCS compared to girls in the not exposed group.</p> <p>No associations were found between fluoride exposure group and scores on Boy-Girl Stroop.</p> | flexibility, particularly in girls, suggesting a possible need to reduce maternal fluoride exposure during pregnancy. |
| <p>Do et al. (2023) (Do et al., 2023)</p> <p>Cohort</p> <p>Australia/UK</p> <p><u>Funding:</u> The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The follow-up study was funded by a National Health and Medical Research Council Project Grant APP1161581.</p> <p><u>Conflicts of interest:</u> The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.</p> | <p>Data is from Australia's National Child Oral Health Study (NCOHS) 2012–14 (total participants with both questionnaire and oral exam data n=24,664)</p> <p>n=15,793 participants included as they were <18 years old in 2018-19</p> | <p><u>Exposure:</u> individual-level percentage of lifetime exposure to fluoridated water from birth to age 5 years (%LEFW)</p> <ul style="list-style-type: none"> • 0% LEFW • >0% to <100% LEFW • 100% LEFW <p><u>Outcome measures:</u></p> <ul style="list-style-type: none"> • Strength and Difficulties Questionnaire Total Difficulties Score (SDQ TDS) • Behavior Rating Inventory of Executive Function Global Executive Composite (BRIEF GEC) <p>Note SDQ TDS 16+ and BRIEF GEC 65+ indicate clinically significant mental health issues and greater level of executive dysfunction</p> <p><u>Confounders measured:</u></p> <ul style="list-style-type: none"> • child's age at follow-up • sex • Indigenous identity • household income • parental education • country of birth • area-level remoteness status • neurodevelopmental diagnosis • breastfeeding | <p>n=2,682 completed the SDQ and BRIEF</p> <p>Note retention rates were higher in 100% LEFW, parents with tertiary education, and high income households</p> <p><u>Multivariable regression model results:</u></p> <ul style="list-style-type: none"> • comparable SDQ TDS and BRIEF GEC scores for 0% LEFW vs. 100% LEFW • higher prevalence rate (PR) of SDQ TDS 16+ and BRIEF GEC 65+²⁸ in the 0% LEFW compared to 100% LEFW • mean scores of SDQ TDS and BRIEF GEC were associated with household income, Indigenous identity, and neurodevelopmental diagnosis • prevalence of SDQ16+ and GEC65+ was also associated with those factors as well as with parental education | <p><u>Quality:</u> Probable low risk of bias due to representative sampling, and good coverage of actual and potential confounders.</p> <p>Good exposure and outcome measures.</p> <p><u>Authors' conclusions:</u> This nationwide population-based follow-up study has provided consistent evidence that exposure to fluoridated water by young children was not negatively associated with child emotional, behavioral development, and executive functioning in their adolescent years. Children who had been exposed to fluoridated water for their whole early childhood had their measures of emotional, behavioral development, and executive</p> |

²⁸ not statistically significant

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| Author/year Study design/Country Funding Conflicts of interest | Participants Inclusion/exclusion criteria Characteristics | Exposure Outcome measures Confounding | Results | Comments Quality Authors' conclusions |
|---|---|--|--|---|
| | | <ul style="list-style-type: none"> toothbrushing with fluoride toothpaste in early childhood | | functioning at least equivalent to that of children who had no exposure to fluoridated water. |
| Ibarluzea et al. (2023) (Ibarluzea et al., 2023) Cohort Spain/UK <u>Funding:</u> This study was funded by grants from Instituto de Salud Carlos III, CIBERESP, Department of Health of the Basque, the Provincial Government of Gipuzkoa and annual agreements with the municipalities of the study area <u>Conflicts of Interest:</u> The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. | <p>Data from the Spanish Environment and Childhood: INfancia y Medio Ambiente (INMA) mother-infant cohort. n=255 and 236 mother-child pairs for 8 years and 11 years follow-up, respectively had both ADHD outcome measures and maternal urinary fluoride data</p> <p><u>Inclusion criteria for the INMA cohort:</u></p> <ul style="list-style-type: none"> maternal age ≥ 16 years old, singleton pregnancy, recruitment during the first antenatal visit, pregnancy achieved without assisted reproduction techniques, planned to give birth in the referral hospital and no communication problems in Spanish or Basque <p><u>Selection criteria for this study (subsample of INMA cohort):</u></p> <ul style="list-style-type: none"> children with data on neuropsychological assessment at 8 or 11 year of age mothers with data on maternal urinary F level adjusted for creatinine (MUFcr) at the first and third trimesters <p><u>Characteristics:</u></p> <ul style="list-style-type: none"> mean birth age: 31 years pre-pregnancy BMI 22.8-23 kg/m² 58.9-60.0% nulliparous | <p><u>Exposures:</u></p> <ul style="list-style-type: none"> Maternal urinary fluoride (creatinine adjusted) Drinking water <p><u>Outcome measures:</u> Conners' Parent Rating Scale-Revised: Short Form (CPRS-R:S).</p> <p><u>Confounders measured:</u></p> <ul style="list-style-type: none"> maternal age, social class, education, BMI, birth country, smoking, alcohol, drinking water source and amount, maternal IQ, breastfeeding infant sex, birth order, premature birth, small for gestational age, daycare attendance family context: Haezi-Etxadi Scale (HES) maternal urine: arsenic, manganese umbilical blood: mercury, lead | <p><u>Fluoride exposures:</u></p> <ul style="list-style-type: none"> Mean maternal urine 0.62 and 0.64mg/g for 8 year and 11 year follow-up similar mean values for 8 year and 11 year follow-up for each zone and type of drinking water <p><u>Cognitive outcomes at 8 and 11 years:</u> Probable cognitive problems/inattention <ul style="list-style-type: none"> 9.8% and 6.8%, respectively Probable Hyperactivity-Impulsivity <ul style="list-style-type: none"> 9.8% and 8.5% Probable ADHD <ul style="list-style-type: none"> 6.7% and 5.5% </p> <p><u>Association between F exposure and ADHD scores:</u> Non-significant associations were observed between MUFcr levels and cognitive outcomes at age 8 years Significant reduction in risk of probable cognitive problems/inattention scores at 11 years of age for maternal urinary fluoride levels at 32 weeks gestation and all of pregnancy. All other associations non-significant.</p> <p><u>Sensitivity analysis:</u> Analysis including neurotoxicants, family context, alcohol, and community water fluoridation did not change the overall picture or the ORs substantially</p> | <p><u>Quality:</u> Probable low risk of bias due to cohort design, extensive consideration of potential confounders (including alcohol) and sensitivity analysis. Good exposure and outcome measures.</p> <p><u>Authors' conclusions:</u> Higher levels of MUFcr in pregnant women were associated with a lower risk of cognitive problems-inattention at 11 years. These findings are inconsistent with those from previous studies and indicate the need for other population-based studies to confirm or overturn these results.</p> |

COMMUNITY WATER FLUORIDATION

| Author/year Study design/Country Funding Conflicts of interest | Participants Inclusion/exclusion criteria Characteristics | Exposure Outcome measures Confounders | Results | Comments Quality Authors' conclusions |
|--|---|---|--|--|
| | <ul style="list-style-type: none"> • 49.3–51.7% uni degree • 59.6–59.7% non-manual social class • 9% smoked in pregnancy • infants: 49.8% and 54.2% were females, 2.7% and 2.5% were preterm and 7.8% and 8.0% were small for gestational age. <p>No significant differences between the follow-ups, with the exception to the zone of residence (fluoridated vs non-fluoridated), type of drinking water consumed, parity and order between brother/sister at the age of 8.</p> | | | |
| Krzczkowski et al. (2024) (Krzczkowski et al., 2024) Cohort Canada <u>Funding:</u> This research was funded by the National Institute of Environmental Health Science, grant number R01ES030365, 2020–2025. The Maternal-Infant Research on Environmental Chemicals Study was funded by the Chemicals Management Plan at Health Canada, the Ontario Ministry of the Environment, and the Canadian Institutes for Health Research (grant MOP-81285). The funding source had no involvement in any aspect of the study. | <p>A subsample of 525 mothers were invited to participate in the MIREC infant development (MIREC-ID) follow-up study, which involved the assessment of infant health at 6-months of age.</p> <p>90 (16.8 %) did not complete the visual assessment. Another six (1.1 %) were excluded due to suspected ocular abnormality, including congenital cataract or retinoblastoma.</p> <p><u>Final sample:</u> n=429 had visual acuity data and n=390 had heart rate variability (HRV) data</p> <p><u>Eligibility criteria:</u> infant was born from a singleton pregnancy and was free of birth defects and/or neurological disorders</p> <p><u>Characteristics:</u></p> <ul style="list-style-type: none"> • mothers mean age 31.6 years; 94.6% | <p><u>Exposures:</u></p> <ul style="list-style-type: none"> • fluoride concentration in drinking water (mg/L) • maternal urinary fluoride adjusted for specific gravity (MUFSG; mg/L) and averaged across pregnancy • maternal fluoride intake ($\mu\text{g}/\text{kg}/\text{day}$) from consumption of water, tea, and coffee, adjusted for maternal body weight (kg). <p><u>Outcome measures:</u></p> <ul style="list-style-type: none"> • Teller Acuity Cards II (TAC-II) • ECG: RMSSD²⁹ and SNDD³⁰ <p><u>Confounders measured:</u></p> <ul style="list-style-type: none"> • infant age at testing (months), • birthweight (g), • sex, • maternal age (years), • pre-pregnancy BMI, | <p><u>Fluoride exposure:</u></p> <ul style="list-style-type: none"> • Median water fluoride (n=337) 0.2 mg/l • Median daily fluoride intake (n=280) 4.82$\mu\text{g}/\text{kg}/\text{day}$ • Median maternal urinary fluoride (n=424) 0.44 mg/l <p><u>Visual acuity:</u> (adjusted)</p> <ul style="list-style-type: none"> • water F $\beta = -1.51$; 95 % CI: $-2.14, -0.88$, $p < 0.001$. • maternal F intake $\beta = -0.82$; 95 % CI: $-1.35, -0.29$, $p = 0.003$. <p><u>Heart rate variability:</u> (adjusted)</p> <ul style="list-style-type: none"> • maternal urinary F $\beta = 0.11$; 95 % CI: $0.51, p = 0.60$. <p><u>RMSSD</u></p> <ul style="list-style-type: none"> • water F $\beta = -1.60$; 95 % CI: $-2.74, -0.46$, $p = 0.006$. • maternal F intake $\beta = -1.22$; 95 % CI: $-2.15, -0.30$, $p = 0.01$. | <p>Water fluoride and daily intake associated with reduced TAC score and RMSSD. Unclear whether these reductions are clinically relevant. Retesting at other ages would give more meaningful data i.e., whether the visual acuity changes. Authors conclusions overstated.</p> <p><u>Quality:</u> Unclear risk of bias due to potential residual confounding and uncertain meaningful difference in outcome measures (visual acuity and HRV) at 6 months</p> <p><u>Authors' conclusions:</u> Fluoride in</p> |

²⁹ root mean square of successive differences³⁰ standard deviation of N-N intervals

COMMUNITY WATER FLUORIDATION

| Author/year Study design/Country Funding Conflicts of interest | Participants Inclusion/exclusion criteria Characteristics | Exposure Outcome measures Confounders | Results | Comments Quality Authors' conclusions |
|--|--|---|--|--|
| <u>Conflicts of interest:</u> The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [Disclosure: Dr. Lanphear (co-author) served as a non-retained expert witness in the federal fluoride case to describe the results of the fluoride studies using the MIREC cohort (Food & Water Watch, et al. vs. U.S. Environmental Protection Agency, United States District Court for the Northern District of California at San Francisco. He received no payment for his service. All authors report no conflict of interest.]. | married; 66.1% bachelor's degree +; 91.3% white <ul style="list-style-type: none">• infants mean age 6.81 months; 48% female; 5.2% <37 weeks gestation; 6.1% low birth weight; mean TAC score 5.75 cpd; RMSSD 15.25 and SDNN 39.10 Compared to full MIREC sample (n=1,983) there were some differences in the sub-sample <ul style="list-style-type: none">• less smokers, more likely white and greater gestational age in those with maternal urine fluoride, all confounders and visual acuity data• less likely income >\$100,000 in those with visual acuity data• less likely married in those with HRV data• mothers more likely married, white, higher birthweight infants in those with both infant outcomes• higher birthweight in infants born in fluoridated areas | <ul style="list-style-type: none">• smoking in trimester 1 (never, former, quit during pregnancy/current),• education,• race (white vs. other),• birth country (Canada vs elsewhere),• parity,• family income,• marital status,• self-reported ratings of warmth/affection | <ul style="list-style-type: none">• maternal urinary F $\beta = 0.22$; 95 % CI: -0.47, 0.92, $p = 0.53$. SNDD• water F $\beta = -1.31$, 95 % CI: -4.70, 2.09, $p = 0.45$• maternal F intake $\beta = -2.13$, 95 % CI: -4.98, 0.72, $p = 0.14$• maternal urinary $\beta = 0.10$, 95 % CI: -0.20, 2.20, $p = 0.92$; No significant interaction by sex except for water F in boys and RMSSD | drinking water was associated with reduced visual acuity and alterations in cardiac autonomic function in infancy, adding to the growing body of evidence suggesting fluoride's developmental neurotoxicity. |

Appendix 6: Evidence table for thyroid function

| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
|---|---|---|--|--|
| Iamandii et al. (2024) (Iamandii et al., 2024) Systematic review Italy/USA/Netherlands/Denmark/Iceland <u>Funding:</u> This study did not receive any specific funding. | <u>Search:</u> PubMed/MEDLINE, Web of Science, and Embase from inception up to November 15, 2023 <u>Inclusion criteria:</u> (P) population of any | <u>Exposure:</u> Highest fluoride exposure of any type (water, toothpaste, diet and/or urinary or serum fluoride) <u>Comparator:</u> Lowest fluoride | N=33 studies included (1 cohort, 5 case control, 27 cross-sectional) Three studies from Europe, 3 in Africa, 2 in Canada, 25 from Asia (including 8 in China and 10 in India) <u>Risk of bias of studies:</u> Very high N=5 | Significant statistical heterogeneity without investigation is concerning. Highest fluoride levels vs. lowest fluoride for each included study concerning as not comparing like with like. |

COMMUNITY WATER FLUORIDATION

| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
|---|---|--|---|--|
| <u>Conflicts of Interest:</u> The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. | <p>age; (E) assessment of long-term fluoride exposure through drinking water or diet, and/or assessment of biomarkers of exposure (urinary or serum fluoride); (C) comparison of at least two categories of fluoride exposure; (O) biomarkers of thyroid function (e.g., TSH, T4, T3 hormones), thyroid disease risk (e.g., hypothyroidism, goitre) or thyroid volume as endpoints in (S) both nonexperimental (observational) or experimental (clinical trial) study design.</p> <p><u>Exclusion criteria:</u> studies that did not present original data (e.g., review articles, editorials, comments, or guidelines) or were written in languages other than English</p> <p><u>Studies included:</u></p> <ul style="list-style-type: none"> • Ahmed et al., 2022; • Andezhath et al., 2005; • Bachinsky et al., 1985; • Barberio et al., 2017; • Cui et al., 2020; • Day and Powell-Jackson, 1972; • Du et al., 2021; • Eltom et al., 1984; • Hall et al., 2023; • Hong et al., 2008; • Jooste et al., 1999; • Karademir et al., 2011; | <p>exposure in cohort or no exposure</p> <p>Outcome: thyroid function (e.g., TSH, T4, T3 hormones), thyroid disease risk (e.g., hypothyroidism, goitre) or thyroid volume</p> | <p>High N=10 Some concerns N=17 Low N=1</p> <p>Findings: TSH (thyroid stimulating hormone) Mean difference (MD) in TSH for highest fluoride level compared to lowest level in children (6-18 years)</p> <ul style="list-style-type: none"> • Water fluoride (N=13 studies) MD=1.17 µIU/ml $I^2=99.84\%$ • Urinary fluoride (N=15 studies) MD=0.97 µIU/ml $I^2=99.57\%$ • Serum fluoride (N=8 studies) MD=1.46 µIU/ml $I^2=98.83\%$ • MD are 1.06, 0.52 and 1.09 µIU/ml, respectively when very high and high risk of bias studies are removed <p>T4 total (children)</p> <ul style="list-style-type: none"> • Water (N=6) MD=0.63 µg/dl • Urinary (N=7) MD=-0.05 µg/dl • Serum (N=2) MD=-0.01 µg/dl • all $I^2>96\%$ <p>Other outcomes: T3-free, T3-total, T4-free, goitre, hypothyroidism – see full text.</p> <p>Dose-response meta-analysis:</p> <p>The graph plots 'TSH difference (µIU/L)' on the y-axis (ranging from -1.0 to 8.0) against 'Water F (mg/L)' on the x-axis (ranging from 0.0 to 6.5). A solid line represents the fitted curve, which starts near zero, remains relatively flat until about 2 mg/L, and then rises sharply, indicating a non-linear relationship. A shaded area around the line represents the confidence interval.</p> | <p><u>Quality of this systematic review:</u> Adequate search and selection criteria, with risk of bias assessment with validated tool. Very high statistical heterogeneity with very little explanation/investigation for the sources. Concerns about using highest vs. lowest fluoride level in each primary study which are not the same. Sensitivity analysis with removal of studies with a 'high' and/or "very high" risk of bias.</p> <p><u>Authors' conclusions:</u> “...we found a clear pattern of association between fluoride content in drinking water consumed by the study participants and their circulating TSH concentrations. However, this occurred only above 2 mg/L of water fluoride (2.5 mg/L when the studies with the best quality were considered), thus confirming the hypothesis of a non-linear, dose-dependent pattern of association,...”</p> |

COMMUNITY WATER FLUORIDATION

| Author/year Study design/Country Funding Conflicts of interest | Search methods Inclusion/exclusion criteria Studies included Appraisal method | Exposure Comparator Outcome | Results | Comments Quality Authors' conclusions |
|--|--|-----------------------------------|---------|---|
| | <ul style="list-style-type: none"> • Khandare et al., 2017, 2018; • Kheradpisheh et al., 2018; • Kumar et al., 2018; • Kutlucan et al., 2013; • Lathman and Grech, 1967; • Michael et al., 1996; • Peckham et al., 2015; • Siddiqui, 1960; • Szczuko et al., 2019; • Wang et al., 2020, 2022; • Xu et al., 2022; • Yang et al., 2008; • Yasmin et al., 2013; • Zhang et al., 2015 • Hosur et al., 2012; • Shaik et al., 2019; • Singh et al., 2014; <p>Zulfiqar et al., 2019, 2020</p> <p><u>Appraisal:</u> ROBINS-E tool</p> | | | |

Appendix 7: Search Strategies

Appendix 7a: Search Strategy systematic reviews of benefit

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to April 19, 2024>, adapted for Embase, Cochrane, Scopus

Search Strategy:

- 1 Meta-Analysis as Topic/
- 2 meta analy*.ab,ti.
- 3 metaanaly*.ab,ti.
- 4 Meta-Analysis/
- 5 (systematic adj (review\$1 or overview\$1)).ab,ti.
- 6 1 or 2 or 3 or 4 or 5
- 7 Fluoridation/
- 8 exp Fluorides/
- 9 Fluorine/
- 10 (fluorid\$ or fluorin\$ or flurin\$ or flurid\$).mp.
- 11 7 or 8 or 9 or 10
- 12 Water supply/
- 13 water\$.mp.
- 14 12 or 13
- 15 11 and 14
- 16 6 and 15
- 17 exp TOOTH DEMINERALIZATION/
- 18 (caries or carious).mp.
- 19 (teeth adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 20 (tooth adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 21 (dental adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 22 (enamel adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 23 (dentin\$ adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 24 (root\$ adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 25 Dental plaque/
- 26 ((teeth or tooth or dental or enamel or dentin) and plaque).mp.
- 27 exp DENTAL HEALTH SURVEYS/
- 28 ("DMF Index" or "Dental Plaque Index").mp.
- 29 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
- 30 16 and 29
- 31 limit 30 to (english language and yr="2018 -Current")

Medline = 34

Embase = 24

Scopus = 25

Cochrane = 2

Total = 85

Total After Duplication and False Drops Removed by Librarian = 26

Appendix 7b: Randomised trials and Observational Studies

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to April 19, 2024>

Search Strategy:

- 1 Epidemiologic Studies/
- 2 exp case-control studies/
- 3 exp cohort studies/
- 4 cross-sectional studies/
- 5 (epidemiologic adj (study or studies)).ab,ti.
- 6 case control.ab,ti.
- 7 (cohort adj (study or studies)).ab,ti.
- 8 cross-sectional.ab,ti.
- 9 cohort analy*.ab,ti.
- 10 (follow up adj (study or studies)).ab,ti.
- 11 longitudinal.ab,ti.
- 12 retrospective.ab,ti.
- 13 prospective.ab,ti.
- 14 (observ\$ adj3 (study or studies)).ab,ti.
- 15 adverse effect*.ab,ti.
- 16 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
- 17 Randomized Controlled Trials as Topic/
- 18 randomized controlled trial/
- 19 Random Allocation/
- 20 Double Blind Method/
- 21 Single Blind Method/
- 22 controlled clinical trial.pt.
- 23 randomized controlled trial.pt.
- 24 ((singl\$ or doubl\$ or treb\$ or tripl\$) adj (blind\$3 or mask\$3)).ab,ti.
- 25 randomly allocated.mp.
- 26 (allocat* adj2 random*).mp.
- 27 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
- 28 16 or 27
- 29 exp TOOTH DEMINERALIZATION/
- 30 (caries or carious).mp.
- 31 (teeth adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 32 (tooth adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 33 (dental adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 34 (enamel adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 35 (dentin\$ adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 36 (root\$ adj5 (cavit\$ or caries\$ or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
- 37 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
- 38 28 and 37
- 39 Fluoridation/
- 40 exp Fluorides/
- 41 Fluorine/
- 42 (fluorid\$ or fluorin\$ or flurin\$ or flurid\$).mp.
- 43 39 or 40 or 41 or 42
- 44 38 and 43
- 45 Water supply/ or water*.mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]
- 46 44 and 45

Medline = 182

Embase = 100

Scopus = 112

Cochrane = 39

Total= 433

Total after duplicates and obvious false drops removed by librarian=59

Appendix 7c: Search strategy for neurodevelopmental outcomes

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to March 15, 2024>

Search Strategy:

- 1 exp case-control studies/
- 2 exp cohort studies/
- 3 case control.ab,ti.
- 4 (cohort adj (study or studies)).ab,ti.
- 5 Longitudinal Studies/
- 6 longitudinal.ab,ti.
- 7 retrospective.ab,ti.
- 8 prospective.ab,ti.
- 9 Randomized Controlled Trials as Topic/
- 10 randomized controlled trial/
- 11 Random Allocation/
- 12 Double Blind Method/
- 13 Single Blind Method/
- 14 controlled clinical trial.pt.
- 15 randomized controlled trial.pt.
- 16 ((singl\$ or doubl\$ or treb\$ or tripl\$) adj (blind\$3 or mask\$3)).ab,ti.
- 17 randomly allocated.mp.
- 18 (allocat* adj2 random*).mp.
- 19 Meta-Analysis as Topic/
- 20 meta analy*.ab,ti.
- 21 metaanaly*.ab,ti.
- 22 Meta-Analysis/
- 23 (systematic adj (review\$1 or overview\$1)).ab,ti.
- 24 Retrospective Studies/
- 25 Prospective Studies/
- 26 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
- 27 fluoridation/
- 28 exp Fluorides/ or fluorid*.mp.
- 29 Fluoride Poisoning/ or Fluorosis, Dental/ or fluorosis.mp.
- 30 27 or 28 or 29
- 31 26 and 30
- 32 neurobehavioral.mp. or Neurobehavioral Manifestations/
- 33 Prenatal Exposure Delayed Effects/ or neurobehavioural.mp.
- 34 Intelligence/ or intelligence or "executive function"
- 35 iq.mp.
- 36 exp Neurodevelopmental Disorders/ or neurodevelop*.mp. or exp Intellectual Disability/
- 37 neurocognitive.mp. or exp Neurocognitive Disorders/
- 38 exp Neurotoxicity Syndromes/ or neurotoxic*.mp.
- 39 exp Cognition Disorders/ or Cognition/ or Cognitive Dysfunction/ or cognit*.mp.
- 40 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
- 41 31 and 40
- 42 limit 41 to yr="2014 -Current"

Medline = 84

Embase = 119

Cochrane = 33

Scopus=91

Total after removal of duplicates and false drops = 43

Appendix 8: Referenced articles in NHNZ pleading

The following articles have been cited by NHNZ in their submission on community water fluoridation. The reviewers have identified and considered all references cited by NHNZ. Many of the references are out of scope, as they were published prior to the OPMCSA 2021 update.

McDonagh, M. S., et al. (2000). "Systematic review of water fluoridation." BMJ 321(7265): 855-859.

Iheozor-Ejiofor, Z., et al. (2015). "Water fluoridation for the prevention of dental caries." Cochrane Database of Systematic Reviews(6).

Age 5 and Year 8 oral health data from the Community Oral Health Service. Ministry of Health.

<https://www.health.govt.nz/nz-health-statistics/health-statistics-and-data-sets/oral-health-data-and-stats/age-5-and-year-8-oral-health-data-community-oral-health-service>

Schluter P.J and Lee M. "Water fluoridation and ethnic inequities in dental caries profiles of New Zealand children aged 5 and 12-13 years: analysis of national cross-sectional registry databases for the decade 2004-2013" BMC Oral Health 2016 Feb 18;16:21.

"Draft NTP Monograph on the State of the Science Concerning Fluoride Exposure and neurodevelopmental and Cognitive health Effects: A systematic Review 2022."

Bashash et al. 2017; "Prenatal Fluoride exposure and cognitive outcomes in children at 4 and 6-12 years of age in Mexico." Environ Health Perspect 125(9): 1-12.

Green et al. 2019; Association between maternal fluoride exposure during pregnancy and IQ scores in offspring in Canada, JAMA Pediatr. E1-E9.

Till et al. 2020: Fluoride exposure from infant formula and child IQ in a Canadian birth cohort, Environ Int 134: 105315.

Broadbent JM, Thomson WM, Moffitt TE, Poulton R. 2015. Community water fluoridation and intelligence response. Am J Public Health. 105:3-4.

Guth S et al. Toxicity of fluoride: critical evaluation of evidence for human developmental neurotoxicity in epidemiological studies, animal experiments and in vitro analyses. Archives of Toxicology (2020) 94: 13 7 5-1415

Hirzy, J.H., et al., Developmental Neurotoxicity of Fluoride: A Quantitative Risk Analysis Toward Establishing a Safe Dose for Children. Fluoride, 2016. 49(4): p. 379-400 DOI:10.5772/intechopen.70852.

Grandjean, P., Developmental fluoride neurotoxicity: an updated review. Environ Health, 2019. 18(1): p. 110 DOI:10.1186/s12940-019-0551-x.

Childsmile: The Scottish Childsmile programme is a national toothbrushing programme in schools and preschools in Scotland. <https://www.childsmile.nhs.scot/professionals/childsmile-toothbrushing/>

Appendix 9: Additional Study

An additional study assessing neurodevelopmental outcomes was published after the completion of the evidence brief. (Malin et al., 2024)

This was a study of 229 mother-child pairs drawn from 1065 predominantly Hispanic women and their children from the MADRES (Maternal and Developmental Risks from Environmental and Social Stressors) cohort. A single maternal urinary fluoride (MUF) level was measured in the third trimester and the Preschool Child Behavior Checklist (CBCL) was completed by the mothers when their child was about 36 months old. An association between MUF and a composite borderline clinical and clinical score (60-63 and >63, respectively) was found with a 0.68mg/l higher MUF associated with 1.8 times the odds of Total Problems T score being in borderline or clinical range (OR=1.83; 95%CI: 1.17 to 2.86; p=0.008).

There are several concerns regarding the validity of this finding including residual confounding, the uncertain clinical significance of a combining borderline and clinical range scores together, and the validity of a single MUF level (spot sample) as an approximation of chronic fluoride exposure. There are also concerns regarding the applicability of a specific population cohort to the population of Aotearoa New Zealand and community water fluoridation. Taking all these factors into account, the findings of this study do not alter the conclusions of this review or that undertaken in 2014 and 2021.

16 September 2024

Jason Varuhas

Crown Law Office

Wellington

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 DFTF 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 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

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.

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Community water fluoridation: Additional information on recent publications

The purpose of this document

This document has been prepared to supplement the existing 2024 evidence brief completed by the Ministry of Health | Manatū Hauora. It addresses information regarding community water fluoridation (CWF) published since the evidence brief was completed. The developments include;

- The final publication of the US National Toxicology Program Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition: A Systematic Review [1], published in August 2024 (the NTP report).
- The Cochrane review of the evidence related to the prevention of dental decay by community water fluoridation, published in October 2024. [2]
- Issues raised from the October 2024 ruling from the US District Court for the Northern District of California relating to CWF in the US. [3]

Overall conclusion

These recent developments do not alter the conclusions reached regarding the health benefits and safety aspects of CWF in New Zealand.

There is clear and convincing evidence of the effectiveness of CWF to reduce the incidence and severity of dental caries. The evidence remains robust even in the presence of fluoridated oral health products.

There is a possible association between concentrations of fluoride in drinking water above the upper limit used for CWF and mild neurodevelopmental delay. However, there is no evidence of causation and no demonstrated pathophysiological mechanism. The studies reporting an association between neurodevelopmental harm and fluoride are heavily biased by reliance on a small number of datasets which have been mined for negative associations between fluoride and health. Therefore, at the current time there is no evidence that CWF causes neurodevelopmental delay.

Overview of the Ministry of Health’s 2024 CWF evidence brief

A systematic review of the safety and effectiveness of CWF for the prevention of dental caries was undertaken by the Ministry of Health in 2024 (the 2024 MoH Review). The review supplemented information already available from the 2014 and 2021 reviews of CWF undertaken by the Royal Society of New Zealand [4] and the Office of the Prime Minister’s Chief Science Advisor (OPMCSA) [5]. The protocol of the 2024 MoH Review is fully explained in the document and follows accepted best practice. The inclusion and exclusion criteria for the 2024 MoH Review are also discussed below. In addition, the 2024 MoH Review was externally peer reviewed and considered by the reviewers to be of a high standard.

The 2024 MoH Review was undertaken as a systematic review to ensure that the best quality evidence was used to inform the Director-General of Health’s Bill of Rights analysis. The primary advantage of a systematic review is that individual studies are identified for quality and relevance and then amalgamated and placed in context. The context in this case being the safety and effectiveness of CWF. A systematic review avoids the issues associated with recency bias,¹ and the attribution of disproportionate weight to individual studies which correspond to a particular predetermined position.

All relevant publications regarding the risks and benefits of CWF were identified through a thorough search of the literature which was conducted by a qualified and experienced research librarian alongside the authors of the 2024 MoH Review. The time-period of the search was extended backwards to ensure all publications published since the OPMCSA 2021 report were identified.

Monitoring of the evidence regarding CWF and related issues of fluoride in drinking water is an ongoing function of the Ministry of Health. A monthly review of all relevant literature regarding fluoride in drinking water is undertaken by the Ministry of Health. The majority of articles identified by the monthly search are not relevant to CWF but provide important context for the authors of the 2024 MoH Review and others within the Ministry of Health who monitor evidence pertaining to fluoride in drinking water.

Rationale for inclusion/exclusion criteria in the evidence brief

Collating published studies from systematic reviews and regularly supplementing this information with newly published data from original studies using robust search criteria provides an effective mechanism for ensuring inclusion of relevant studies. In addition, the use of systematic reviews is a robust approach to identifying and synthesising a body of evidence, that is, it looks at the overall evidence, identifies sources of potential bias and draws conclusions about that body of evidence as a whole. In this situation, it is very unlikely, at least in the context of such a large, established body of evidence, that a single study would alter the overall conclusions, although we always approach new evidence with an open mind, judging each publication on its merits.

¹ Recency bias occurs when undue weight is given to the most recent publication.

The initial search was undertaken to identify systematic reviews of the benefits and risks of CWF published between January 2019 and April 2024. The aim was to identify new evidence since the publication of the OPMSCA 2021 report on the risks and benefits of CWF. The search period was extended to 2019 to ensure all relevant material was identified. Published individual studies were also searched for, to ensure that we identified all relevant evidence published since 2021. Individual studies already included in the systematic reviews identified were excluded to avoid double counting.

Publications were excluded if they had not been peer-reviewed. Therefore, editorials, letters, opinion pieces and review articles which did not use a systematic methodology (that is, narrative reviews) were not incorporated into the 2024 MoH Review. Studies which were referenced in the OPMCSA report were excluded from the evidence brief as they already informed the existing evidence base. Non-English language publications were also excluded. These inclusion and exclusion criteria were to ensure that only the most relevant, applicable and appropriate studies were included in our evidence brief.

Scientific protocol requires that for an intervention study to be valid, it must compare groups of people who are clearly defined by their exposure to the intervention. Therefore, to assess the risks and benefits of CWF, a treatment group, who receive CWF, must be compared to a group of people who received little or no fluoride in their drinking water. In the 2024 MoH Review, weight was given to studies comparing CWF with sources of drinking water containing fluoride levels well below that used in CWF. This was to ensure that the study presents an accurate reflection of the effects of CWF in a New Zealand context.

Topic One: US National Toxicology Program Monograph

The US National Toxicology Program (NTP) published the final version of its Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition: A Systematic Review in August 2024. [1] The initial NTP literature review covered the period up to May 2020 and all of the relevant information in the initial literature review was covered in the report from the OPMCSA in 2021. [5] The final NTP report included a supplement to the draft versions to include studies on neurodevelopmental delay published from May 2020 to October 2023. This period of time matches the period of time covered by the 2024 MoH Review and all relevant studies included in the NTP supplement are included in the 2024 MoH Review.

The NTP review was designed to evaluate total fluoride exposure from all sources and was not designed to evaluate the health effects of fluoridated drinking water alone. However, it is important to note that there were **“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.”** [bold is our emphasis]

In the main body of the NTP review document, an analysis of 19 studies² reporting the impact of fluoride exposure during pregnancy on IQ in the child was undertaken. In the supplement, an analysis of 12³ studies was undertaken. The main NTP document assessed the 19 studies as being of high quality. However, only three were prospective cohort studies,⁴ which seriously limits the ability to infer any causality and is inconsistent with the GRADE levels of evidence which would rate randomised trials initially as being high quality and retrospective observational studies (which formed the majority of studies) initially as low-quality evidence⁵. The 19 studies were carried out in countries with high naturally occurring water fluoride levels (i.e., they were not carried out in places with CWF) and with very different methodologies. The range of study designs and high levels of naturally occurring fluoride seriously limits the generalisability and applicability to CWF in places like New Zealand and the USA.

Of the 12 studies identified in the supplement, seven were cross-sectional and assessed outcomes in children. These studies were not included in the 2024 MoH Review as they were not studies of CWF. Five were prospective cohort studies of maternal fluoride exposure. [6-10] All of these, except one, [9] were identified in the 2024 MoH Review.

² From 72 studies identified.

³ From 28 studies identified.

⁴ A prospective study design enables the development of a high-quality study methodology, as opposed to using data collected for routine clinical purposes or other studies. This approach decreases the risk of both confounders and bias and improves the quality of the study and the reliability of the result.

⁵ <https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/#:~:text=GRADE%20has%20four%20levels%20of,data%20starts%20at%20low%20quality.>

Of the five prospective cohort studies, the study by Dewey [6] was included in the 2024 MoH Review, although major deficiencies in the methodology were identified and discussed in the 2024 MoH Review.

Of the other four cohort studies, one was excluded due to not meeting the outcome criteria [10] and two were found to be included in 2 and 3 of the systematic reviews in the 2024 MoH Review. [7, 8]

The final cohort study was not identified by the search strategy of the 2024 MoH Review. However, having evaluated the study, it would have been excluded because it did not meet the exposure criteria i.e., it used spot maternal urinary fluoride concentration as a measure of exposure. [9]

For completeness we discuss the four studies further here.

The study by Farmus [7] includes the MIREC data which is the same population as Green [11] and Till [12] and the results are included in three of the systematic reviews assessed in the 2024 MoH Review. The study also uses maternal spot urine measurements to assess long term maternal fluoride exposure. As discussed below, spot maternal urine assessment is an unsuitable measurement of fetal fluoride exposure.

The two studies by Goodman [8, 9] were excluded. One study, which is based on the ELEMENT dataset, is not an assessment of CWF and uses maternal spot urine tests to assess fluoride exposure. [8] The results of this study are also included in two of the systematic reviews assessed in the 2024 MoH Review. The second study is based on the MIREC dataset (which is discussed below) and was designed to assess whether there is an interaction between maternal urinary fluoride concentration, maternal urinary iodine concentration and IQ in children. [9]

The study by Grandjean reports results from the Odense Child Cohort, in which no association between maternal urinary fluoride and IQ in the children was identified. [10] This data was also combined with data from two previously reported studies derived from the MIREC and ELEMENT datasets to produce a benchmark dose analysis, which is not relevant to CWF as it includes information from non-CWF studies. It was excluded from the 2024 MoH Review because the outcome (benchmark dose analysis) did not meet the inclusion criteria and used maternal urinary fluoride concentration as a measure of long-term fluoride exposure and fetal fluoride exposure (benchmark dose studies and maternal urinary fluoride concentrations are discussed further below).

The NTP report concludes that “**higher levels of fluoride exposure, such as drinking water containing more than 1.5 milligrams of fluoride per litre, are associated with lower IQ in children. More studies are needed to fully understand the potential for lower fluoride exposure to affect children’s IQ.**” [bold is our emphasis]

The NTP review authors’ expressly state that “This Monograph and Addendum do not address whether the sole exposure to fluoride added to drinking water in some countries (i.e., fluoridation, at 0.7 mg/L in the United States and Canada) is associated with a measurable effect on IQ.” Further, the NTP review authors state that “This Monograph and

Addendum do not assess benefits of the use of fluorides in oral health or provide a risk/benefit analysis.”

To summarise, the NTP review indicates that there may be an **association** between exposure to high fluoride levels ($>1.5 \text{ mg/l}$) in drinking water with lower IQ in children. This level is greater than that used for CWF in New Zealand. In evaluating the review, it is important to also note that there is no biological mechanism of harm identified, no supporting evidence of harm from animal models and no evidence of causality. There has been substantial criticism of the methodology adopted including inconsistent application of risk of bias criteria, inadequate statistical rigour and selective reporting of non-significant study results. [13-18]

Methodological issues in NTP studies

Including studies that use maternal urinary fluoride levels as a measure of exposure

A group of authors have, in an attempt to avoid the difficulties inherent in estimating long-term fluoride exposure from cross-sectional studies⁶, published several articles derived from a single dataset, which was designed to test for the impact of known environmental neurotoxins, such as lead, to perform a secondary analysis for the effects of fluoride in pregnancy. [7, 10-12, 19] It is this group of articles which have formed the basis of most of the evidence suggesting an association between CWF and neurodevelopmental delay. The data set, called MIREC, used single maternal urine sample (a spot urine sample) during each trimester of pregnancy to measure the concentration of known neurotoxins. However, while this approach may be reasonable for some compounds such as lead in which a spot urine sample can reflect long-term exposure, a spot urine sample only measures the consumption of fluoride over the previous few hours and does not assess long-term exposure to fluoride. For example, a woman who had recently consumed fluoridated water or brushed their teeth with fluoride toothpaste would have an elevated level of fluoride in their spot sample.

Therefore, studies that used urinary fluoride levels were excluded from the 2024 MoH Review as spot samples are not considered to be a valid measure of chronic exposure due to their high variability over the day and from day-to-day. A detailed discussion of the underlying flaws of using the MIREC data is presented in a review by Guichon et al. [20] The key points are that: spot urine samples are unable to determine long-term fluoride exposure; the correlation between maternal urine levels and maternal blood levels are poor or absent [21]; the relationship between maternal serum fluoride levels and fetal fluoride levels is variable [22]; and the metabolism within the different compartments of the fetal circulation⁷ has not been determined. [23]

⁶ A cross-sectional study uses a single time frame to compare two groups with (purportedly) different exposure to an intervention.

⁷ The three relevant compartments are fetal, placental and amniotic.

The application of GRADE criteria

There are also concerns about the application of the GRADE⁸ approach to rating the quality of the body of evidence within the NTP review. The review authors do not start with assessing the study design for rating the quality of evidence (randomised trials start as 'high' and observational studies start as 'moderate') as required using this approach⁹ but rather start with key features of study design.¹⁰ Considering the number of cross-sectional studies, studies with high risk of bias, lack of adjustment for confounders, and the number of non-significant results, it is not clear why the confidence in the conclusions of the body of evidence has not been downgraded from 'moderate' to 'low' or even 'very low'.

The assessment of neurodevelopmental delay

The MIREC data includes IQ measurements which were undertaken in each of the cities participating in the research. Measuring IQ is known to be difficult, even when using recognised testing methods. The MIREC study used different examiners in each city, which is a clear source of bias. In addition, the level of competence of the examiners is not explained, and importantly, there is no difference in the IQ of the total cohort of children in cities with or without CWF, which varied by 4-8 IQ points in the cities irrespective of the fluoridation status. Therefore, an observed difference of a 4 IQ point difference in the sample of mother-child dyads who lived in cities with or without CWF¹¹ is based on inadequate measurements of the relevant variable (fetal fluoride exposure) and is of doubtful clinical significance because of major concerns regarding the assessment of the outcome (IQ) which is less than the baseline variability in IQ reported between the cities.

In summary, 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 community water fluoridation.

⁸ Grading of Recommendations, Assessment, Development and Evaluation [Link](#)

⁹ 5.1 Factors determining the quality of evidence

<https://gdt.gradepro.org/app/handbook/handbook.html#h.trgki08omk7z>

¹⁰ Figure 1. Page 18 of the NTP review.

¹¹ The analysis of IQ related to fluoride exposure was only a subset of the total number of children who were tested for IQ.

Topic Two: 2024 Cochrane Review

Overview

Two Cochrane reviews [2, 24] have been undertaken to determine if CWF is better than water without added fluoride at:

- reducing the number of teeth, or tooth surfaces, with signs of decay.
- increasing the number of people who have no tooth decay.

The latest Cochrane review was published in October 2024, and updated a 2015 Cochrane review on CWF.

The Cochrane review remains a good source of evidence in relation to the efficacy of CWF. The review only included prospective studies with a concurrent control, comparing at least two populations, one receiving fluoridated water and the other non-fluoridated water, with at least two points in time evaluated. Groups had to be comparable in terms of the concentration of fluoride in drinking water prior to the introduction of CWF¹². The purpose of the study design was to obtain a measure of change in caries experience in the fluoridated community from before implementation of fluoridation to sometime afterwards, and to compare this change with any change in the control (or reference) community over the same time period. Considering that the majority of studies were undertaken prior to 1975, during a period of time when fluoridated toothpaste was not widely available, the results of the Cochrane review are robust, good-quality evidence that CWF decreases the incidence of caries experience and tooth decay.

Due to the inclusion criteria, the 2015 Cochrane review was unable to demonstrate a statistically significant improvement in dental caries as only two publications published since 1975 fulfilled the criteria.

2024 Cochrane Update

The 2024 Cochrane review concluded that:

- studies conducted after 1975 showed that adding fluoride to water may lead to slightly less tooth decay in children's baby teeth. There was uncertainty about whether adding fluoride to water reduced tooth decay in children's permanent teeth or decay on the surfaces of permanent teeth.
- adding fluoride to water may slightly increase the number of children who have no tooth decay in either their baby teeth or permanent teeth. However, these results also included the possibility of little or no difference in tooth decay.
- studies conducted in 1975 or earlier showed a clear and important effect on prevention of tooth decay in children. However, due to the increased availability of fluoride in toothpaste since 1975, it is unlikely that we will see this effect across all populations today.

¹² With a single study of before and after cessation of CWF.

There were very few additional studies identified in the 2024 update that conformed to the selection criteria, which remained the same as the 2015 inclusion criteria. Because of the lack of available studies, sensitivity analyses were undertaken, including seeing if the removal of studies deemed to be at critical risk of bias and which required imputation of standard deviation¹³ changed the effect estimate to any major degree. [2]

To fully understand the conclusions of the 2024 review, it is necessary to understand that the Cochrane review reported 12 outcomes related to dental caries as described in Appendix 1. All of the measures used to identify dental caries were associated with an improvement in oral health with CWF. For measures of DMFT/dmft, a positive effect size indicates a greater decrease in the number of decayed, missing or filled teeth for individuals exposed to the intervention (CWF) compared to those not exposed to CWF. For changes in the proportion of caries free individuals, a negative number indicates a greater number of individuals exposed to CWF remain caries free compared to those not exposed.

Not all of the improvements were statistically significant at the conventionally accepted 95% confidence interval.¹⁴ For this reason the authors were cautious about their conclusions despite all indices being consistent with a beneficial effect of CWF.

Therefore, the restrictive requirements for inclusion of studies into the 2015 and 2024 Cochrane review of CWF which was undertaken to ensure that only studies of a particular design (with an innate low risk of bias) were included in the analysis has again resulted in insufficient information being available to provide a clear answer to the effectiveness of CWF. It does not imply that CWF is ineffective in a modern setting, only that few studies using the required study design have been performed.

Although the Cochrane review provides good quality evidence, there are many other studies with a range of designs which have found strong associations between CWF and improvements in oral health and very few studies which do not support the benefits of CWF. While individually these studies may provide lower quality evidence on the basis of their design, they constitute a large body of evidence that CWF remains effective in the modern environment. A detailed analysis of the evidence supporting the efficacy of CWF in the modern era is provided in the peer-reviewed 2024 MoH Review, which builds upon the previous reviews in 2014 and 2021 by the Royal Society and OPMCSA.

¹³ These statistical processes are used to assess the effect of including low quality studies and studies that need imputation.

¹⁴ A 95% confidence interval implies that the relevant statistic, in this case the difference in oral health between CWF and non-CWF areas, is 95% likely to be correct.

Topic Three: US District Court for the Northern District of California Overview

On 24 September 2024 the US District Court for the Northern District of California released a ruling relating to community water fluoridation. [3] The Court was considering, under the Toxic Substances Control Act, whether the evidence suggests that fluoridation of drinking water at levels typical in the United States “poses an unreasonable risk of injury to health.”

The Court found that fluoridation of water at 0.7 milligrams per litre – the level presently considered “optimal” in the United States – poses an unreasonable risk of reduced IQ in children. The Court noted that this finding does not conclude with certainty that fluoridated water is injurious to public health, rather there is an unreasonable risk of such injury.

The Court ruled that the U.S. Environmental Protection Agency (EPA) must take regulatory action in response to the ruling. While the EPA is required to take action, the ruling did not prescribe what that response should be. The Court did not direct the cessation of fluoridation of public drinking water supplies or direct fluoridation at a particular level.

The issues considered from that ruling include (i) a discussion of benchmark studies; (ii) the issue of safety margins for chemicals in water; and (iii) “additive effects”. (Issues relating to the NTP monograph, which was also considered in the US judgment, have already been discussed above).

Comment

Benchmark Dose studies

Attempts have been made to calculate a benchmark dose¹⁵ (BMD) [25] for fluoride toxicity in humans. [26] Such studies were relied on in the reasoning of the September US Court judgment.

The BMD approach involves determining a critical effect (e.g., IQ) and the benchmark response (this is a predetermined change in the response rate which, by default, is either a decrease in IQ of 5% or 10%). Once these parameters have been determined, different mathematical models are applied to fit the dose-response data to estimate the BMD. The dose response data are derived from published studies looking at fluoride and IQ.

Based on the available data, there are some legitimate concerns about whether it is appropriate to attempt to calculate a BMD and the validity and accuracy of the BMDs that have been calculated. The validity of the results of the BMD studies depends on the quality and applicability of the study (or studies) from which the input data is derived. There are several reasons why the BMDs calculated [10, 27] may be problematic:

¹⁵ A benchmark dose (BMD) is a dose or concentration that produces a predetermined change in the response rate of an adverse effect. This predetermined change in response is called the benchmark response (BMR).

- The quality and selection of the input data i.e., it is unclear why some studies were selected e.g., Bashash, Thomas [28], Goodman, Bashash [8], Green, Lanphear [11] and others were not e.g., Broadbent, Thomson [29]
- There are limitations such as a small sample size and lack of control of other neurotoxins e.g., Green, Lanphear [11]
- The high variability of the IQ data used (see Fig 3A from Green, Lanphear [11])
- There is considerable debate about any dose-response curve especially at low exposure of fluoride (see dose-repose curves from Veneri, Vinceti [30] in the 2024 MoH Review)
- Animal and in vitro studies have not been considered.
- Assessment of exposure: as noted above, maternal urinary/blood fluoride levels, are not a reliable measure of chronic exposure.
- Assessment of outcome: measuring IQ in a standardised, reliable way in younger children is challenging; it should ideally be assessed by the same person, in the same way and using a valid instrument – this is not often undertaken.

In summary, the BMD is a model which is derived from original research. Therefore, the relevance of the model is dependent on the accuracy of the original data. Insufficient consideration of possible confounders, reliance on a small number of studies, concerns about both exposure and outcome measurement, and rejection of studies that show no effect on IQ, brings considerable doubt as to the appropriateness of conducting at BMD analysis and of the accuracy and robustness of the BMD results.

Safety margins

Regarding safety margins for fluoride, the current recommended level of fluoride in CWF is based on the risk of severe dental fluorosis, which is a proven complication of ingesting high concentrations of fluoride and for which there is a considerable safety margin. Currently, there is no evidence of a causal relationship between fluoride and neurodevelopmental delay, nor is there a proven mechanism by which this could occur. Therefore, the issue of a margin of error in the context of CWF does not arise.

Additive effects – Dietary sources of fluoride in NZ

New Zealand has low levels of naturally occurring fluoride in its environment which results in a low level of fluoride in water. [31] The major sources of fluoride in New Zealand are from CWF and fluoridated dental products such as fluoridated toothpaste. [32-36] (Appendix 2). A review of the amount of fluoride ingested for different population groups has been undertaken and discussed in the 2021 review of CWF by the OPMCSA. Recent data is also available from unpublished theses. [37, 38]

In New Zealand, where CWF is implemented, fluoride is added to water to a concentration of about 0.7 mg/L. Studies of actual levels indicate that few samples are over the recommended level of 1.0 mg/L and very few over the Maximum Allowable Value (MAV) of 1.5 mg/L. When this does occur, it is usually for a very short period of time. [31]

Regarding fluoride intake in children, fluoride concentrations in breast milk are substantially lower than that observed in maternal plasma and are relatively insensitive to changes in the fluoride concentration of drinking water. Therefore, exclusively breastfed children receive little fluoride in their diet. [39] Fluoride concentrations in infant formula in Australia and New Zealand are low. For babies who are bottle fed, the recommended volume of formula (as recommended by the Ministry of Health) for infants from birth to six months of age is 700ml per day of total fluid, which would result in ingestion of less than 0.5 mg/day of fluoride and is well within the recommended guidelines. [40]

The Australian and New Zealand governments jointly set nutrient reference values for a range of nutrients. [41] These values include recommended adequate intake and upper limit values for fluoride intake, which vary based on age and gender. The evidence above demonstrates that the total fluoride intake from all dietary sources remains below the recommended adequate intake for all age groups and that the risks of long-term overdosage from additive effects in any age range is minimal.

Appendix 1: Studies published after 1975 reporting dental caries associated with CWF from the 2024 Cochrane review

| Group | Analysis | No. of studies | No of participants | Statistical Method | Effect size |
|--------------|--|-----------------------|---------------------------|---------------------------|-----------------------------|
| 1.1.1 | Change in the number of decayed, missing or filled primary teeth (dmft) | 2 | 2908 | Mean Difference (95% CI) | 0.24 [-0.03, 0.52] |
| 1.2.1 | Change in the number of decayed, missing or filled permanent teeth (DMFT) | 4 | 2856 | Mean Difference (95% CI) | 0.27 [-0.11, 0.66] |
| 1.3.1 | Change in the number of decayed, missing or filled permanent surfaces (DMFS) | 1 | 343 | Mean Difference (95% CI) | 2.46 [1.11 – 3.81] |
| 1.4.1 | Change in the proportion of caries free participants (primary teeth) | 2 | 2908 | Mean Difference (95% CI) | -0.04 [-0.09, 0.01] |
| 1.5.1 | Change in the proportion of caries free participants (permanent teeth) | 2 | 2348 | Mean Difference (95% CI) | -0.03 [-0.07, 0.01] |
| 1.6.1 | Sensitivity analysis - all included studies: change in the number of decayed, missing or filled primary teeth (dmft) | 3 | 6622 | Mean Difference (95% CI) | 1.08 [-0.53, 2.70] |
| 1.7.1 | Sensitivity analysis - all included studies: change in the number of decayed, missing or filled permanent teeth (DMFT) | 6 | 12906 | Mean Difference (95% CI) | 0.53 [0.00, 1.06] |
| 1.8.1 | Sensitivity analysis - all included studies: change in the proportion of caries free participants (primary teeth) | 4 | 9608 | Mean Difference (95% CI) | -0.10 [-0.19, -0.01] |
| 1.9.1 | Sensitivity analysis - all included studies: change in the proportion of caries free participants (permanent teeth) | 3 | 10502 | Mean Difference (95% CI) | -0.12 [-0.33, 0.09] |
| 1.10.1 | Sensitivity analysis - change in analytical approach: change in the number of decayed, missing or filled primary teeth (dmft) | 2 | 2825 | Mean Difference (95% CI) | 0.28 [0.12, 0.43] |
| 1.11.1 | Sensitivity analysis - excluding studies with imputed standard deviations: change in the number of decayed, missing or filled primary teeth (dmft) | 2 | 2908 | Mean Difference (95% CI) | 0.24 [-0.03, 0.52] |
| 1.12.1 | Sensitivity analysis - excluding studies with imputed standard deviations: change in the number of decayed, missing or filled permanent teeth (DMFT) | 2 | 1535 | Mean Difference (95% CI) | 0.53 [-0.45, 1.51] |

The analyses in red indicate a statistically significant benefit observed in cohorts living in locations with CWF. Other indices indicate CWF is beneficial, but confidence intervals include a zero-mean difference, so are not statistically significant at the 95% confidence level.

Appendix 2: Studies of dietary fluoride in NZ¹⁶

| Author, country, year | Population group | Study method (<i>Dietary, biochemical, clinical, analysis</i>) | Fluoride intake males | Fluoride intake females | Main fluoride sources |
|--|-------------------|--|---|---|---|
| Chowdhury N. Brown R. Shepherd M. NZ, 1990 (46) | n = 60 11-13 m | Method: Comparison of F (0.8-0.9 mg/L) and NF (0.09-0.1 mg/L) regions. Dietary: 3-day duplicate method. Analysis: ion-specific electrode. | Dietary intake only (mean ± SD, mg/day): F area = 0.26 ± 0.13 ↓ NF area = 0.08 ± 0.05 ↓ Intake from diet, toothpaste and tablets (mean ± SD, mg/day): F area = 0.31 ± 0.23 ↓ NF area = 0.20 ± 0.17 ↓ | | Water Infant formula Soy-milk formulae Fluoridated toothpastes and tablets |
| Chowdhury N. Drummond B. Smillie A. NZ, 1996 (40) | n = 66 3-4 y | Method: Longitudinal study comparing F (0.9-1.0 mg/L) and NF (0.2-0.3 mg/L) regions. Dietary: 3 separate duplicate diets. Biochemical: ingestion of toothpaste and supplements. Analysis: ion-specific electrode. | Dietary intake only (mean ± SD, mg/day): F area = 0.36 ± 0.17 ↓ NF area = 0.15 ± 0.06 ↓ Intake from diet, toothpaste and supplements (mean ± SD, mg/day): F area = 0.68 ± 0.27 ↓ NF area = 0.49 ± 0.25 ↓ | | Water Toothpaste (especially in the NF areas) |
| Cressey P. Gaw S. Love J. NZ, 2010 (10) | 14-18 y | Method: Estimated dietary fluoride intake based on NF water supply (0.1 mg/L), and F water supply (1.0 mg/L). Dietary: simulated diets or using national 24-hour dietary recall surveys. | Mean estimated dietary intake (mg/day): F area = 1.89 ↓ NF area = 0.86 ↓ Mean estimated intake from toothpaste = 0.20 mg/day | Mean estimated dietary intake (mg/day): F area = 1.68 ↓ NF area = 0.73 ↓ Mean estimated intake from toothpaste = 0.20 mg/day | Water Bread Tea Carbonated beverages |
| NZ Total Diet Study (Ministry of Primary Industries) NZ, 2016 (6) | 11-14 y | Method: National study sampling 132 foods predominantly representing the most commonly consumed foods. Dietary: 57% of sample analysed for fluoride, including water. | Range of intake = 0.20-0.70 mg/day ↓ 25% of AI (2.0mg)/day 5% of UL (10.0mg)/day | Range of intake = 0.20-0.60 mg/day ↓ 20% of AI (2.0mg)/day 4% of UL (10.0mg)/day | Water Tea |
| The Fluoride in Schoolchildren Study (FLOSS) NZ, 2018 (39) | n = 64 9-11 y | Method: Cross-sectional study comparing F and NF regions. Dietary: 24hr weighed diet records. Clinical: 24hr urine samples. Analysis: deionised water samples collected to calculate fluoride ingested from toothpaste. | Dietary intake only (mg/day) F area = 0.73 ± 0.37 ↓ NF area = 0.29 ± 0.28 ↓ Intake from diet and toothpaste (mg/day): F = 1.55 ± 0.95 ↓ NF = 1.04 ± 0.85 ↓ | | Water Toothpaste (52-67% total fluoride intake) |

F = area with fluoridated water; NF = area with non-fluoridated water; m = months; y = years; AI = adequate intake; UL = Upper Level; SD = standard deviation;

↓ = Mean is below MOH adequate intake recommendations for selected age group; ↑ = Mean is above MOH adequate intake recommendations for selected age group

Additional research

Dietary fluoride in older children and adolescents has been calculated using robust methodologies. The studies both demonstrate that CWF did not result in dietary intakes above the upper acceptable limit in these groups. These results are consistent with evidence from previous studies outlined in the OPMCSA evidence review.

Table 2. Total fluoride intake in subsets of NZ population

| Age | Adequate intake mg/day | Upper limit mg/day | Intake CWF Breast mg/day (SD) [38] | Intake CWF-Bottle mg/day |
|-------------------------|---------------------------|-----------------------|---------------------------------------|-----------------------------|
| 9-13 years [38] | 2.0 | 10.0 | 1.04 (0.87) [38] | 1.55 (0.96) |
| 14-18 years female [37] | 3.0 | 10.0 | 0.56 (0.32) [37] | 2.37 (1.04) |
| 14-18 years male [37] | 3.0 | 10.0 | 0.50 (0.21) ⁴ | 1.63 (0.66) |

¹⁶ Source: Shahin, A. (2021). The fluoride intake from diet, water and toothpaste of New Zealand adolescents. University of Otago.

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Office of the Mayor

4 December 2024

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Dear Dr Sarfati

Fluoridation Directive

Thank you for your letter dated 3 December 2024 with details of your reconsideration of the direction in light of the assessment under the Bill of Rights Act 1990. We acknowledge that you have continued the directive to fluoridate the Bream Bay and Whangārei drinking water supplies by 28 March 2025.

Steps to comply with directive

Since receipt of the original directive dated 27 July 2022 and subsequent extension of time, Whangarei District Council (Council) has been taking the following steps to comply with the directive to commence fluoridation in Whangarei:

- In October 2023 a contract to install fluoridation equipment was awarded by Council. At the same time Council also agreed to accept funding from the Ministry of Health for the full cost of constructing the fluoridation infrastructure at the first four plants.
- Ahuroa, Ruddells, Ruakaka and Whau Valley Water treatment plants are ready to be dry commissioned before Christmas with full commissioning able to start in late February 2025 and be fully operational by 28 March 2025.
- Construction of the Poroti Water Treatment plant has been delayed and Council has kept the Ministry fully updated of progress and is taking all practicable steps to have the plant commissioned as soon as possible. Council has also applied for funding (\$1.5 million) to complete the work at Poroti which will require the installation of fluoridation equipment separately (instead of in conjunction with the Poroti water treatment plant upgrade as originally planned). Council has yet to hear back from the MoH about this funding.

Community and Elected Member concerns

While Council has been taking all practicable steps to implement fluoridation within the deadlines specified by the Ministry, as you will have been informed, at the 28 November 2024 Whangarei District Council meeting, Elected Members adopted a Notice of Motion (attached). Councillors passed the attached resolution (7 to 6) not to add fluoride to Council's water supply. A staff report (attached) preceded this Notice of Motion advising Elected Members of the potential risks of not complying with the Directive.

Moving forward

As outlined above, Council has worked closely with the Ministry to complete the installation of equipment required for fluoridation and staff will continue to do so.

We would like to meet to discuss the concerns of our residents and elected members, and what possible outcomes and solution can be provided for Whangārei.

Yours faithfully,



Vince Cocurullo

Mayor of Whangārei



Simon Weston

CE Whangarei District Council

Resolution of Whangarei District Council 28 November 2024

That the Council:

1. Resolves to not add fluoride to the Whangarei District's water supplies as required by the directive from the Ministry of Health (MOH);
2. This decision is based on recent court rulings and research that question the effectiveness, safety and legality of fluoridation; and
3. That the Mayor and the Chief Executive write to the Ministry of Health, the Minister of Health and the coalition government advising them of this decision.

6.2 Notice of Motion re Fluoridation – Cr Gavin Benney

Meeting: Whangarei District Council
Date of meeting: 28 November 2024
Reporting officer: Simon Weston (Chief Executive)

1 Purpose / Te Kaupapa

To consider a Notice of Motion received from Councillor Gavin Benney.

2 Recommendations / Whakataunga

That the Council:

1. Resolves to NOT fluoridate the Whangarei District's water supplies as required by the directive from the Ministry of Health (MOH);
2. This decision is based on recent court rulings and research that question the effectiveness, safety and legality of fluoridation;
3. That the Mayor and the Chief Executive write to the Ministry of Health, the Minister of Health and the coalition government advising them of this decision.

3 Background / Horopaki

The Chief Executive received a Notice of Motion, within the timeframe specified in Standing Orders, from Councillor Benney for inclusion in the agenda for the 28 November 2024 Council meeting.

A staff report relating to this Notice of Motion has been included in the agenda.

4 Discussion / Whakawhiti kōrero

Cr Benney proposes to move the following motion:

That the Council:

1. *Resolves to NOT fluoridate the Whangarei District's water supplies as required by the directive from the Ministry of Health (MOH);*
2. *This decision is based on recent court rulings and research that question the effectiveness, safety and legality of fluoridation;*

3. *That the Mayor and the Chief Executive write to the Ministry of Health, the Minister of Health and the coalition government advising them of this decision.*

Cr Benney's signed Notice of Motion and background information is appended as Attachment 1.

5 Significance and engagement / Te Hira me te Arawhiti

The decisions or matters of this Agenda do not trigger the significance criteria outlined in Council's Significance and Engagement Policy, and the public will be informed via agenda publication on the website or Council News.

6 Attachments / Ngā Tāpiritanga

Attachment 1: Cr Benney's signed Notice of Motion and background information

To the Chief Executive

Under the Whangarei District Council's Standing Orders (Adopted 15th December 2022) – Clause 27.1, page 56.

It is my intention to move the following Notice of Motion at the Whangarei District Council's meeting on 28th November 2024.

NOTICE OF MOTION

1. That Whangarei District Council (WDC) resolves to NOT fluoridate the Whangarei District's water supplies as required by the directive from the Ministry of Health (MOH);
2. This decision is based on recent court rulings and research that question the effectiveness, safety and legality of fluoridation;
3. That the Mayor and Chief Executive write to the Ministry of Health (MOH), the Minister of Health and the coalition government advising them of this decision.


Signed on 21 October 2024

Cr Gavin Benney
Hikurangi-Coastal Ward Councillor
Whangarei District Council

NOTICE OF MOTION

1. That Whangarei District Council (WDC) resolves to NOT fluoridate the districts water supplies as required by the directive from the Ministry of Health
2. The decision is based on recent court rulings and research that question the effectiveness, safety and legality of fluoridation
3. That the Mayor and Chief Executive write to the Ministry of Health (MOH), the Minister of Health and the coalition government advising them of this decision.

Background/Further information (Compiled by Councillor Gavin Benney)

DIRECTIVE

- In 2022 the then Director General of Health (DGoH) Ashley Bloomfield directed 14 councils to fluoridate their water supplies.
- In November 2023 that directive was found by the High Court to be unlawful in that it did not adequately consider the Bill of Rights Act
- That decision has been appealed by the MOH
- the appeal is still before the courts and is unlikely to be heard until late 2025
- despite the High Court finding the directive unlawful, the current Director General of Health has directed the 14 councils to proceed with fluoridation
- In June 2024 the High Court ruled the directives still to be valid citing legal counsel for the DGoH as there being no evidence the DGoH would take an enforcement approach, but rather is concentrating on an educative approach.

RECENT RESEARCH AND COURT DECISIONS

- In September 2024 a United States Federal Court issued a ruling that "fluoridation poses an unreasonable risk to human health"
- Numerous recent studies in the USA and Canada found fluoridation causes damage to the developing brains of children
- (As stated above) In November 2023 the NZ High Court found the directive to be unlawful

FLUORIDE

- Fluoride used in our water supply is an industrial waste product from the fertiliser industry.
- It is unprocessed hazardous waste
- Fluoride is a chemical compound and is not a natural product
- Fluoride is a neurotoxin
- All science agrees that Fluoride is dangerous to peoples health, the issue that causes disagreement is the level of fluoride required
- Most scientists agree that children should not ingest fluoride
- New Zealand councils fluoridate their water supplies between 0.7 and 1 milligrams per litre (mg/l)
- many studies now find that 0.7 mg/l poses an unreasonable risk of injury
- It is widely accepted that pregnant women should not ingest fluoride.

HOW EFFECTIVE IS FLUORIDE IN OUR WATER SUPPLY?

- The Cochrane Collaboration, that the DGH relied on for making the directive has now been updated and has found there is very little evidence and, in fact, there may be no benefit.
- The two major studies prior to Cochrane (LOTUS 2024 and CATFISH 2022) were funded by the UK Government and they both found basically the same as Cochrane, that there was very little evidence the fluoridation reduced dental decay.
- Tooth paste manufacturers who use fluoride are required to display 'Do Not Swallow' on their tubes
- Only a tiny percentage of a fluoridated water supply is drinking water (between 1 and 3%)

-The vast majority of the fluoridated water supply is used for all other household requirements i.e. cooking, showering, bathing, washing clothes etc

-This means that your clothes, skin, food and stomach will be subject to contact with a neurotoxin for no reason.

-If the Whangarei water supply is fluoridated this will reach only around 60% of the population

-It is argued that the remaining 40% of the population on private water supply is the most 'at risk' group

POLITICAL SITUATION

-In 2021 the then Labour Government passed a bill taking the power to fluoridate or not off local councils and given directly to the Director General of Health

-Dr Shane Reti (now Minister of Health) was opposed to that bill and introduced a supplementary order for local health authorities to be involved in decision making

-this was lost

-In October 2024 coalition government partner NZ First passed a remit that the fluoridation of water supplies should go back to local government.

-It has been reported numerous times that the DGoH has advised that there is no intention to fine local councils who do not obey the directive

-In 2018 the NZ Supreme Court ruled that fluoridation is compulsory mass medication that engages section 11 of the Bill of Rights, our right to refuse medical treatment. No other substance is put into our water supply for medicinal purposes.

-In the past couple of years the government has spent tens of millions of dollars installing equipment for fluoridation

-The yearly cost to councils is unknown but is at least \$100,000 annually.

WHAT COUNTRIES FLUORIDATE THEIR WATER?

- Fluoridation has been banned in all of continental Europe
- Only 4% of the world's population drink fluoridated water
- Only 8 countries have more than 50% fluoridation
- The US Environmental Protection Agency is now legally obliged to "reduce or remove the risk posed by fluoridation". This could, and probably will be, the end of fluoridation in the USA.
- Only 3 countries in the world have mandatory fluoridation

ARE THERE OTHER OPTIONS?

- A targeted program in schools aimed at educating and teaching children (similar to the Childsmile model used effectively in Scotland)
- Sugar tax on products that cause tooth decay
- Education on dental health

All the above alternatives are cheaper and much more effective in fighting tooth decay

BILL OF RIGHTS ACT

- Section 11 of the BOR states that everyone has the right to refuse medical treatment. As stated above, the NZ Supreme Court ruled that fluoridation does engage this section. What was not agreed either way, was if fluoridation also engages section 5 making it a "justifiable limitation". This is why the DGoH has been ordered by the High Court to undertake a Bill of Rights analysis to show why she thinks it is justified. It has now been one year since she was ordered and there has still been no analysis,

HEALTH ACT

- Section 23 states that "it shall be the duty of every local authority to improve, promote and protect public health within its district
- Section 23(c) states that "if satisfied that any nuisance, or any condition likely to be injurious to health or offensive, exists in the district, to cause all proper steps to be taken to secure the abatement of the nuisance or the removal of the condition"

6.1 Notice of Motion – Background Information

Meeting: Whangarei District Council

Date of meeting: 28 November 2024

Reporting officer: Andrew Venmore – Manager Water Services, Rebecca Vertongen – Legal Counsel

1 Purpose / Te Kaupapa

To provide background information on the Directive from the Director-General of Health to fluoridate and to provide context of legal obligations and risks in relation to the Notice of Motion regarding fluoridation.

2 Recommendation/s / Whakataunga

That the Council:

1. Notes the information contained in this report about the Directions relating the fluoridation of Whangārei's water supply and legal advice relevant to the notice of motion.
2. Notes the legal advice on the legal risks which include the potential for:
 - Prosecution;
 - Intervention by the Minister of Local Government;
 - The Ministry of Health directly intervening to implement the directive;
 - The Ministry of Health seeking a court order for implementation; and
 - The risk of personal liability for Elected Members.
3. Notes that the Ministry of Health has indicated that their Bill of Rights review is in its final stages and they hope it will be completed by the end of the year.
4. Notes that staff will keep Elected Members informed of any new or updated information as it becomes available.

3 Background / Horopaki

In July 2022 the Director-General of Health issued a directive for WDC, along with 13 other Councils, to fluoridate water supplied from five water treatment plants in Whangarei and Bream Bay. The timeframe for this directive to be implemented was June 2024 for Whau Valley, July 2024 for Ruddells, September 2024 for Ahuroa and Ruakaka Water Supplies and June 2026 for Poroti Water Supply.

In October 2023 a contract to install fluoridation equipment was awarded. At the same time Council also agreed to accept funding from the Ministry of Health totaling \$4,557,856.88 (excl GST), being the full cost of constructing the fluoridation infrastructure at the first four plants. At Poroti the fluoride equipment was to be installed as part of the plant upgrade project in 2026. The operational cost of fluoridation will have to be met by Council.

In April, Council agreed to request an extension from the Director-General of Health. A response was received from the Director-General on 7th June 2024 approving the extension until 28 March 2025. This means that fluoride will need to be added to the water at the four treatment plants from the last week of February 2025. The final site, Poroti, has been directed to fluoridate by July 2026. Staff have made a funding application to the Ministry of Health to cover the costs of constructing fluoride dosing facilities at Poroti.

4 Discussion / Whakawhiti kōrero

4.1 Other Councils

Of the 13 other Councils that have been directed to Fluoride their water supplies, 7 have started fluoridation at all or some of the directed sites. Two other Councils are due to commence fluoridation before the end of the year. The remaining Councils have completion dates in 2025.

4.2 Legal Assessment - Executive Summary

- The decision of whether or not to fluoridate a water supply, is **not** currently a power or function of Local Authorities.
- The government, in amending the Health Act 1956, has made the decision regarding whether or not to begin fluoridation of a water supply a power and function of the Director-General Health.
- Local authorities retain no lawful discretion whether to comply with a Direction.
- The declaration taken by Elected Members at the start of the term requires them to perform the functions imposed by the Local Government Act and any other Act, including the Health Act 1956.
- The Courts have held (as recently as July 2024) that there is no justifiable reason for a local authority to refuse to implement the Director-General of Health's directive.

4.2.1 Legal Background

On 10th November 2023 the High Court issued its judgement finding the Director-General had made an error of law by not explicitly considering the New Zealand Bill of Rights Act 1990 in making the decision. However, the High Court did not quash the directives, nor did it find that fluoridation of water supplies was unlawful, and the original direction remained in force. A second hearing was held on 2nd February 2024 to consider the appropriate relief. The judge decided that the directions remain in place but directed the Director-General of Health to assess each direction in terms of the Bill of Rights Act.

The Ministry of Health have indicated that the Bill of Rights review is nearing completion and they hope that it will be completed by the end of the year. A further appeal is being heard in June 2025. The Courts have stated that "*There is no basis in Radich J's decision, or any other authority to which I have been referred, for the proposition it was unlawful for the Council to comply with a valid Direction simply because it is being reconsidered due to an error of law.*"

4.2.2 Changes to Health Act 1956 removed Council decision making on fluoridation

In 2021 the government passed legislation transferring the control of water fluoridation from local authorities to the Director-General of Health. The Bill had unanimous support from parliament in its third and final reading in November 2021. The stated intention of the Bill was to introduce consistent decision making in relation to fluoride. It also recognized the significant costs that Council's had incurred in litigation defending decision to fluoridate.

The requirements under the Health Act 1956 have been set out in previous agenda items but in summary:

- The Director-General of health may direct a local authority to add or not to add fluoride to drinking water supplied through its local authority supply (section 116E(1)).
- A local authority that receives a direction under section 116E must comply with that direction (section 116I(1)).

Since the legislation changed, the role of local authorities and the validity of the directions issued have been tested through the Courts. A summary of that litigation is included in Appendix 1. There is no instance where the Court held that Council has any remaining discretion to choose whether or not comply with a Direction.

4.2.3 Declaration taken by Councillors

At the 13 November 2024 briefing, Councillors asked for clarification on the role of the oath/declaration taken by Elected Members at the beginning of their term, with the role of Elected Members in relation to fluoridation.

Pursuant to Clause 14, Schedule 7 of the Local Government Act 2002, Whangārei District Council's Elected Members made the following declaration on 2 November 2022:

I, [name of Elected Member] declare that I will faithfully and impartially, and according to the best of my skill and judgment, execute and perform, in the best interests of Whangārei District, the powers, authorities, and duties vested in, or imposed upon, me as a member of the Whangārei District Council by virtue of the Local Government Act 2002, the Local Government Official Information and Meetings Act 1987, or any other Act.

The declaration imposes in a broad sense a duty of civic responsibility, diligence and competence in carrying out the functions of the particular body. The duties outlined are complemented by the code of conduct which all Councils are required to have (clause 15, Schedule 7 of Local Government Act 2002). The code sets out the understandings and expectations adopted by the local authority regarding the manner in which members may conduct themselves while acting in their capacity as members.

In wording of the declaration and the Code of Conduct includes a duty to uphold the law or to perform those functions imposed upon an Elected Member by any other Act.

There is no latitude or leeway within the declaration or the Code of Conduct which allows for an Elected Member to wilfully (as opposed to accidentally) disregard the law or a lawful instruction, even if they do not agree with that law or instruction.

4.2.4 Potential Legal Implications of Notice of Motion

If Council accepts the Notice of Motion and resolves not to fluoridate the district's water supplies as required by the Directive from the Director-General of Health, the following are legal risks:

Prosecution

Failure to follow a direction to fluoridate the water supply is a strict liability offence. This means that is not necessary to prove that WDC intended to commit the offence.

The Ministry has indicated in the recent hearing for *New Health New Zealand Incorporated v Director-General of Health [2024] NZHC 1717* that they would pursue an educational approach in the first instance:

[8] Mr Varuhas, for the respondents, opposed the application on the basis that it is at odds with my previous decisions, that the first respondent is actively complying with the orders that have been made, that the first respondent's directions remain valid in the meantime and that there is no indication that the Director-General would take enforcement action in relation to the directions. ...

[11] Mr Varuhas put it on the basis that at this stage the Director-General is taking an educative approach. Any decision on enforcement action would need to be informed by the Solicitor-General's guidelines. In the event that enforcement action was threatened, then the most appropriate course would be for any council affected to seek interim orders.

Before filing the charging document – the Ministry would have to be confident that they could satisfy the threshold for prosecution under the Solicitor General Guidelines (and any internal prosecution policy they have) which requires satisfaction of two requirements:

1. Evidence which can be adduced in court which is sufficient to provide a reasonable prospect of conviction – the Evidential Test; and
2. Prosecution is required in the public interest – the Public Interest Test.

If a resolution is passed to the effect of Council not following the Directive, the evidential test would be clearly satisfied. If Whangārei District Council is the only (or first) Council to refuse to follow the directive, there is the possibility that the public interest test could be satisfied in such proceedings having a deterrent value for other local authorities who have or may be issued Directions.

Minister of Local Government Intervention

A refusal by members of a local authority to perform and exercise lawful functions, could be the basis for a ministerial intervention. The intervention powers of the Minister of Local Government hinge on when there is a “problem” in relation to a local authority. Section 256 of the Local Government Act 2002 defines a problem as including:

- (a)(ii) a significant or persistent failure by the local authority to perform 1 or more of its functions or duties under any enactment.

If the Minister considers that failure to follow a direction of the Director-General of Health is a problem, there are various levels of ministerial intervention available under the Local Government Act including the appointment of a Crown Review Team (section 258), Crown Observer (section 258B), Crown Manager (section 258D) or Commission (section 258F) commissioner to assist or direct Council to address the problem or to perform the functions of Council.

Other Ministry of Health legal actions

There are other legal options available to the Ministry which may be more likely to achieve their goals relating to the fluoridation of Whangārei's water supply than prosecution (unless it is considered that the deterrent value of initiating a prosecution is of higher importance to them):

- Intervene directly to implement the directive: Where the local authority ... fails to exercise any power or perform any duty under this Act, the Director General may himself or herself exercise the power or perform the duty (section 123(2)) or get employees or contractors to do so (section 123(3)).
- Apply for a writ of mandamus to compel a local authority to perform any duty that the local authority has failed to perform under the act (section 123A Health Act 1956).

Each of these would involve the legal costs of Council responding to claims and potentially responsibility for the costs of the Ministry in bringing the proceedings.

Personal liability for Elected Members

As outlined in the briefing agenda for 13 November 2024, Elected Members are usually protected from personal liability under the Local Government Act 2002 and indemnified for any action taken in good faith and carrying out the powers and responsibilities of the Council (section 43 LGA 2002).

However, this indemnity does not apply, and Elected Members may be liable (jointly and separately) for losses incurred by the Council, where a decision of the governing body has resulted in:

- Unlawfully spent money; and
- Unlawfully incurred a liability.

Costs incurred from refusing to follow an order from the Director-General of Health could fall within this exemption to the indemnification provisions. The provisions have been considered to impose an obligation on a member who is aware of an issue to take an active part, a failure to vote or silence on the vote may be taken as assent. Liability would only be incurred by those Elected Members who voted in favour of the decision that resulted in the unlawful act (and those who abstain).

Members are only liable for these types of losses if the Auditor-General issues a report on the loss to the Minister of Local Government. An elected member will have a defence (and will not be liable) if they can prove the act (or failure to act) that resulted in the loss occurred:

- without their knowledge;
- with their knowledge but against their protests made at or before the time when the loss occurred;
- contrary to the manner in which they voted on the issue at a meeting; or
- in circumstances where they acted in good faith and relied on reports, information, or professional / expert advice given by a council staff member or a professional adviser or expert on matters that the elected members reasonably believed were within the person's competency

4.2.5 Conclusion

The decision whether or not to fluoridate is not a power or function of local government. The exact consequence of failing to follow the Directive is unknown because there are a number of different options available to the Ministry of Health and the government. This item outlines the legal risks of non compliance.

5 Significance and engagement / Te Hira me te Arawhiti

The decisions or matters of this Agenda do not trigger the significance criteria outlined in Council's Significance and Engagement Policy, and the public will be informed via agenda publication on the website.

6 Attachments / Ngā Tāpiritanga

Appendix 1: Summary of cases relating to Fluoridation since the legislation was changed

Appendix 1: Summary of cases relating to Fluoridation since the legislation was changed.

| Type of application and date | Case reference | Outcome of case |
|---|--|--|
| Costs award 2 July 2024 | Fluoride Action Network (NZ) Inc v Hastings District Council [2024] NZHC 1781 | <p>Consideration of costs to be awarded after Fluoride Action Network's unsuccessful application for interim injunction</p> <p>Justice Lahood: "<i>The proceeding was effectively another vehicle for groups that oppose fluoridation to challenge the Director-General's directions to local authorities to fluoridate their water supplies and to challenge the fluoridation of water in New Zealand more generally ... issues relating to justification of water fluoridation have already been raised and dismissed by the courts at all levels. In addition, Parliament has explicitly endorsed water fluoridation as a public health measure.</i>"</p> <p>Outcome: Fluoride Action Network ordered to pay costs of \$41,000 against to Hastings District Council.</p> |
| Interim injunction application 16 May 2024 | Fluoride Action Network (NZ) Inc v Hastings District Council [2024] NZHC 1313 | <p>Application for urgent injunction by Fluoride Action Network to halt the introduction of fluoride to urban water supply of Hastings.</p> <p>Summary of decision by Justice Lahood:</p> <p><i>In summary, I consider the application for judicial review should be dismissed because:</i></p> <p>(a) It was not unlawful for the Council to comply with a valid Direction simply because it is being reconsidered due to an error of law. The legal effect of Radich J's decision is that acting upon the Direction is not presumptively unlawful.</p> <p>(b) Neither <u>s 6 of the New Zealand Bill of Rights Act 1990</u> (Bill of Rights), or the principle of legality, require the legislation to be interpreted in a way that gives the Council a discretion whether to comply with the Direction.</p> <p>(c) There is ample evidence to provide a rational basis for both the Council's decision not to seek an extension of the deadline to comply with the Direction, and for the Director-General to not offer one.</p> |

| | | |
|---|---|---|
| | | <p><i>There is no basis in Radich J's decision, or any other authority to which I have been referred, for the proposition it was unlawful for the Council to comply with a valid Direction simply because it is being reconsidered due to an error of law.</i></p> <p>Outcome: No interim injunction granted.</p> |
| Application Interim orders seeking recall of decision 26 June 2024 | New Health New Zealand Incorporated v Director-General of Health [2024] NZHC 1717 | <p>New Health sought interim order preventing further action regarding to directions, amended to be a recall of the February 2024 decision.</p> <p>Justice Radich:</p> <p>At the conclusion of this morning's teleconference, I said that I would not be making the interim declarations sought. The starting point is that, in [33] of my 16 February 2024 decision, having considered the position, I concluded that it was not appropriate in this case for an interim order to be made. The applicant seeks, through the recall application, to have that conclusion altered. That application is yet to be considered but at this stage I do not see a basis to make such a material change to the decision on relief.</p> <p>... there has been no indication that the Director-General would take enforcement action and the Director-General has not taken any such action. Mr Varuhas put it on the basis that at this stage the Director-General is taking an educative approach. Any decision on enforcement action would need to be informed by the Solicitor-General's guidelines.</p> <p>Outcome: New Health application unsuccessful</p> |
| Relief hearing 16 February 2024 | New Health New Zealand Incorporated v Director-General of Health [2024] NZHC 196 | <p>Parties were unable to agree on relief. Hearing considering relief – i.e. whether the directions should be quashed or not.</p> <p>Justice Radich:</p> <p><i>However, I am not satisfied that the appropriate remedy is to quash the decisions. As I said in the first decision, regard needs to be had to such factors as the potential for significant prejudice to public administration, prejudice to third parties and events subsequent. It is apparent from evidence filed that funding is being provided to local authorities for the capital</i></p> |

| | | |
|--|---|---|
| | | <p><i>works to which the directions relate. Practical relief needs to be given to require the substantive rights assessment to be undertaken by the Director-General, but without at this stage in the process setting the decision aside.</i></p> <p>Outcome: Director-General to review rights assessment but directions still in effect.</p> |
| Application for judicial review of Director General directions to 14 Councils 10 November 2023 | New Health New Zealand Incorporated v Director-General of Health [2023] NZHC 3183 | <p>Application for judicial review by New Health New Zealand Incorporated on basis that Director-General of Health had not considered Bill of Rights.</p> <p>Outcome: yes, the Director-General was required to turn his mind to whether the directions given to the 14 local authorities under s 116E of the Health Act were in each case a reasonable limit on the right to refuse medical treatment, he needed to be satisfied that they were and, if satisfied, he needed to say why that was so. No relief granted at this hearing.</p> <p>Outcome: Parties sent away to see if can agree on relief outcome.</p> |
| Application for interim injunction 16 September 2022 | New Health New Zealand Inc V Wellington Water Ltd [2022] NZHC 2389 | <p>Application for interim injunction by New Health New Zealand Inc to stop Wellington turning fluoridation back on after a technical fault had led them to stopping fluoridation for a time.</p> <p>Justice Cooke: <i>I accept that the applicant can technically say it has a position to preserve under s 15. But substantively Wellington water supplies have been fluoridated since the 1960s, and the argument that the operational failures mean that interim relief is now appropriate pending the substantive challenge is at best opportunistic, and also somewhat artificial given that full fluoridation has largely been restored. The applicant has already engaged in very extensive litigation contending that fluoridation of drinking water supplies is unjustified, and that litigation has failed in the High Court, the Court of Appeal, and the Supreme Court. Its views have been heard and already dismissed at all levels. In any event there is now legislation that prevents local authorities from discontinuing fluoridation. Notwithstanding the arguments advanced by the applicant it seems to me that this legislation likely applies.</i></p> <p>Outcome: Application for interim injunction refused.</p> |



6 December 2024

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Office of the Mayor
 Whangarei District Council

By email: mayor@wdc.govt.nz
Simon.Weston@wdc.govt.nz

Dear Mayor Cocurullo and Mr Weston

Whangarei fluoridation direction

I am writing in response to your letter dated 4 December 2024 regarding my direction to fluoridate the Whangārei and Bream Bay supplies (the supplies). The direction was issued under section 116E of the Health Act 1956 and creates a mandatory legal obligation on the Whangarei District Council (the Council) to fluoridate the supplies to the required level by 28 March 2025. This legal requirement applies despite any Council motion to the contrary and has been upheld by a number of recent judicial decisions. The Ministry of Health (the Ministry) consulted the Council before the direction was put in place, and again more recently as part of the Bill of Rights consideration process.

As advised in previous correspondence, it is an offence under section 116J of the Health Act 1956 for a local authority to contravene or permit the contravention of a direction. The penalty for such a contravention upon conviction is a fine of up to \$200,000 and a further fine not exceeding \$10,000 for every day or part of a day during which the offence continues.

I expect councils to comply with their directions. The Ministry will consider whether to take enforcement action where there is evidence of non-compliance with directions by a council, particularly where there is deliberate or continuing non-compliance. In addition to the other options set out in the legal advice provided to the Council by the Council's legal advisor, the Ministry will also consider whether to seek contractual remedies in light of the significant funding support provided to the council to enable fluoridation.

I have considered all matters that council members have cited in relation to the motion. The Ministry has carried out a thorough review of the scientific evidence relating to community water fluoridation, and this is available on the Ministry's website. The evidence review concluded that fluoride is safe and effective at the levels used in New Zealand. The evidence (including the evidence published since 2021) indicates ongoing clear benefits from community water fluoridation including when alternative forms of fluoride (such as fluoride toothpaste) are also available.

I strongly encourage elected members to heed the advice provided to them by their officials regarding the risks of the proposed course of action. In addition to risking significant penalties, a large body of evidence shows that failure to fluoridate increases avoidable harm for community members.

The purpose of local government includes to “promote the social, economic, environmental, and cultural well-being of communities in the present and for the future”¹. Community water fluoridation will decrease the incidence and severity of dental caries, particularly amongst children, with significant benefits for the health and well-being of your community now and in the future.

I look forward to the Council’s cooperation and commencement of fluoridation by the due date.

Yours sincerely



Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora

¹ section 10(1)(b), Local Government Act 2002

4.2 Northland Emergency Services Trust Lease Update

| | |
|---------------------------|--|
| Meeting: | Extraordinary Whangarei District Council |
| Date of meeting: | 18 December 2024 |
| Reporting officer: | Tony Collins – Manager District Development Dominic Kula – General Manager Planning and Development |
| | |

1 Purpose / Te Kaupapa

To update Council on operational matters relating to the proposed relocation of the Northland Emergency Services Trust (NEST) to Whangarei District Airport.

2 Recommendations / Whakataunga

That Council:

1. Notes the forthcoming completion of lease discussions, with a lease for the proposed new facility / standalone agreement being almost ready for consideration under delegation to the Chief Executive.
2. Notes that any lease for the blue hangar will be considered under delegation to the Chief Executive alongside the lease for the new facility and standalone agreement.

3 Background / Horopaki

On 11 November 2021, Council resolved in an Extraordinary Council Meeting to support in principle relocation of NEST to Onerahi Airport. The decision included a resolution to re-establish the Airport Noise Management Committee.

The potential relocation of NEST was an early point of focus for the Committee upon its re-establishment in 2022, culminating in recommendations of the Airport Noise Management Committee being adopted by Council in September 2022. Around that time Council received judicial review proceedings relating to its in principle decisions, with lease discussions largely being put on hold while those were worked through. The High Court found in favour of Council in late 2023, with settlement discussions concluding in December 2023.

Lease discussions with NEST progressed over the course of this year. Over that time staff have worked through the operational impacts of NEST's potential relocation with formal updates being provided to the Airport Noise Management Committee in April and December 2024.

This report is to provide Elected Members with an update following the 05 December 2024 Airport Noise Management Committee meeting.

4 Discussion / Whakawhitit kōrero

In mid-2023 Council renewed NEST's lease at Kensington for a further total of three years meaning they have until mid-2026 to vacate Kensington. The implications of this are NEST has approximately 18 months to establish a new operational base. In order to progress consenting and construction processes NEST require secure tenure for the proposed development.

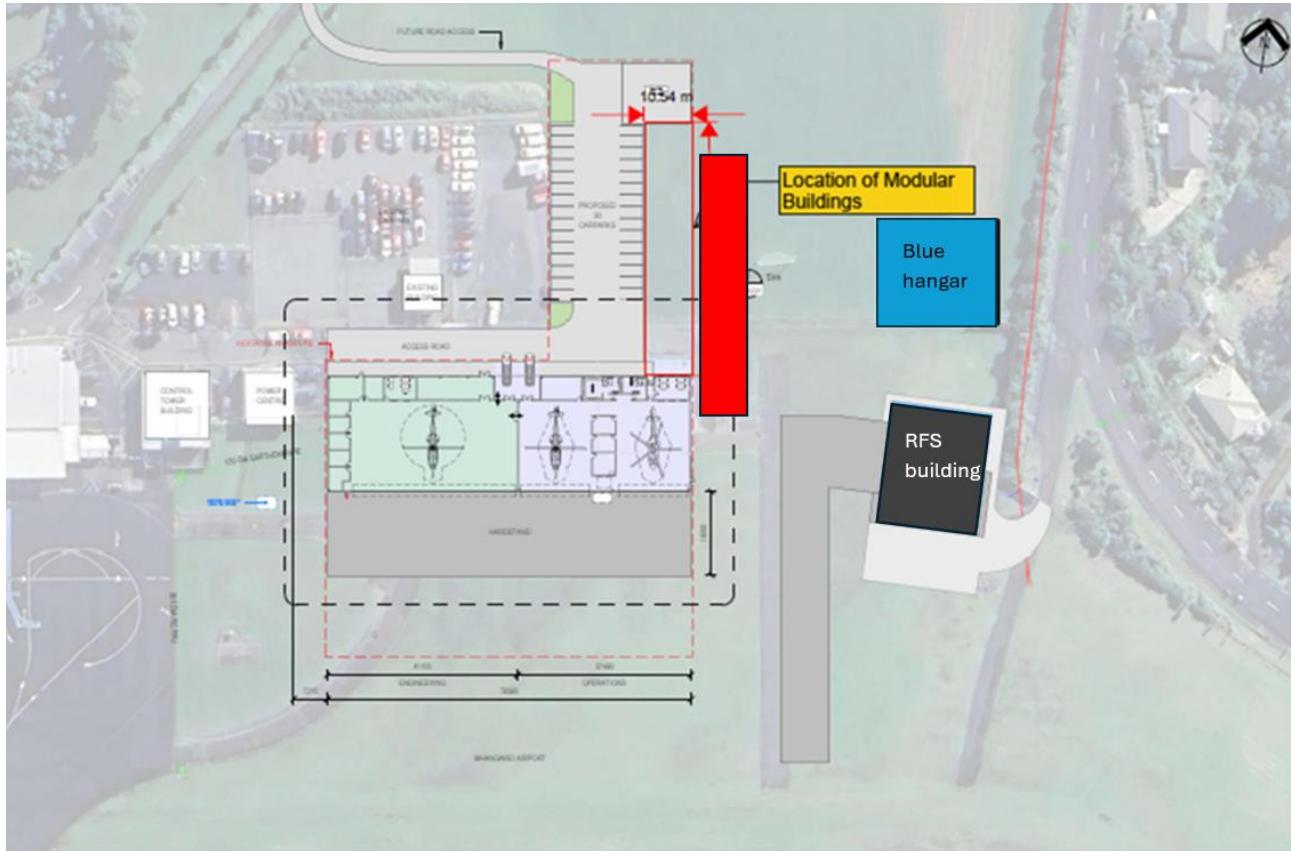
4.1 Leases (new facility and blue hangar)

Lease discussions have involved working with NEST and airport management to ensure that the proposed location for any lease is consistent with matters previously traversed with the Council and the Airport Noise Management Committee and is positioned so as to not negatively impact on the airport's wider operational requirements.

The plan below shows the latest iteration of the intended new facility. The red outlined area indicates the location of the proposed building. This will sit perpendicular to the aircraft hangars and handstand area required for the rescue helicopters. NEST are looking at modular construction in order to enable relocation in the event that a new airport becomes operational within the term of the lease.

The black box to the lower right is the new Rescue Fire Service building currently under construction and the blue box indicates approximately where the existing blue hangar currently owned by NEST is to be relocated. NEST is seeking a separate lease for the relocated blue hangar.

It is proposed that the relocated blue hangar be used to house the larger AW169 helicopter during the transition to Onerahi/construction of their new facility, following which it will be used for storage and the housing their new flight simulator (a larger simulator than the version currently housed in buildings at the airport)



It is proposed that this be at commercial rates and staff are exploring conditions on any lease limiting noise generating activities once the transition to the main hangar is complete. The proposed relocated blue hangar is currently owned by NEST with the underlying land being leased by them at commercial rates from the Airport. It is currently located in the approximate location of the purple box.

4.2 Northern Rescue Helicopters

For the sake of clarity, while Council decisions and negotiation have been with NEST, it should be noted that NEST is one of two Trusts - the other being Auckland Rescue Helicopter Trust - that sit under a parent company Northern Rescue Helicopters Limited. NEST have indicated that the operation of these trusts is currently in the process of being consolidated, and that in the near future all operations (and branding) will be through Northern Rescue Helicopters. As such any agreements will either be with Northern Rescue Helicopters, or will provide for transfer to that entity.

4.3 Stand-alone Agreement

Any Airport tenants or users are already required to comply with relevant legislation, Council policies, the District Plan and other operational requirements of the Airport. While taking this into account and based on various undertakings given as part of community engagement, judicial proceedings and Airport Noise Management Committee meetings, it is intended that the lease for both the new operations base and the proposed relocated blue hangar will be accompanied by a standalone agreement between Council and NEST. The agreement will encompass commitments that have been made by NEST to reduce noise and take into account matters raised by the community during the engagement undertaken since the time the matter of their relocation to Onerahi was first raised. A draft stand-alone agreement has been developed and is currently each parties' solicitors before being finalised.

While still in draft form/subject to change the key points of note are that NEST will:

- a. Undertake its activities taking into account concerns of neighbouring residents;
- b. To reduce noise effects wherever reasonably possible;
- c. Not undertake flight training activities at Whangarei Airport (refer below for further discussion);
- d. Have and comply with its own Fly Neighbourly Program, engaging with the ANMC in reviewing the programme;
- e. When reviewing future options for replacement aircraft will consider aircraft with lower noise emissions;
- f. Will develop an authorisation procedure for late night ground runs, when required for emergency situations.
- g. Comply with its noise abatement procedures whenever possible;
- h. Comply with any Airport Noise Management Plan including any requirements or specifications within that plan providing for maintenance and testing whenever possible.
- i. Comply with all statutory, regulatory and other governmental controls regulating its activities and in particular governing noise.
- j. Engage in good faith with Council and the Airport Noise Management Committee.

Further to this it is made clear that any agreement would need to be consistent/comply with relevant legislation and Council policies, including the District Plan and designations. It is also proposed to limit the number of aircraft in the lease and/or standalone agreement to three, with two in normal operation, making any change to the number subject to approval of the Lessor.

4.4 Training

While specified training would not occur at the Airport when NEST relocate to that location, flights will still be required to transit to and from any offsite flight training locations, and NEST have highlighted a need to practise simulated aircraft malfunctions on departure or arrival (if the exercise has no impact on the standard flight path and time taken to arrive or depart), and the potential for in flight instrument approaches (again, assuming these do not overfly). NEST will have updated its fleet to AW169 helicopters by the time of any relocation (hence the need for a larger simulator) and has confirmed that all other training outside of simulator training is still intended to be undertaken away from the airport.

4.5 Maintenance

Alongside this NEST have clarified heavy maintenance for requirements across Northern Rescue Helicopters fleet of five AW169s. As the AW169 helicopters require fewer major checks they are subject to in less ground runs than currently occur at Kensington with the s76. NEST have estimated ground running required for AW169's post heavy maintenance is as follows:

- *Each aircraft requires on average 1.5 checks per year, total = 7.5 checks per year.*
- *Ground run time post maintenance, average 30 minutes, total = 3.75 hours per year.*

While it would be for NEST to demonstrate compliance with the relevant rules for engine testing, we have sought feedback on this from Marshal Day. If NEST are unable to comply then they would need to obtain any necessary resource consents, as per previous resolutions of Council and the draft terms of proposed agreements.

4.6 Financial/budget considerations and options

The information contained within this report and the action being sought result in no financial impacts. This is predominantly an informational update following previous decisions of Council.

In supporting in principle the potential relocation of NEST to Onerahi in September 2022 Council considered the following options:

1. Support continued operation at Kensington, taking into account constraints at that site/suitability going forward and community views and preferences.
2. Support relocation to the Airport, taking into account the suitability of that site and community views and preferences.
3. Not support the operation of NEST at either site, leaving it to NEST to find an alternative.

While it was highlighted that a potential fourth option could be for Council to take an active role in finding an alternative site for NEST, it was noted that is no requirement for Council to do so (NEST is a standalone charitable trust), and that NEST had already considered multiple sites before landing on the Airport as their preferred location.

Since that time it has become clear that continued operation from Kensington is not tenable. As such the options are broadly to either continue to support relocation to the airport, or to require NEST to find an alternative site (acknowledging feedback previously provided to Council by NEST site selection). However, given the advanced stage of negotiations, and the lead time for site selection, design, consenting and construction, NEST would not likely be able to find and relocate to an alternative site within the within the remaining term of their Kensington lease.

In terms of the blue hangar specifically, noting that the hangar is currently owned by NEST, the options are broadly to relocate the hangar and lease to NEST, or not. The advantage of relocating and leasing the hangar is that it will provide for a training simulator associated with the new AW169 helicopters to be located at the airport, supporting the commitment of NEST to remove physical training. Feedback from NEST is that they will keep the separate/current sub-lease elsewhere on the airport for their existing (smaller) simulator, with that building not being large enough to house the new simulator. The potential disadvantage is the risk of noise being generated from a hangar that is closer to the airport boundary. However, and as indicated above, NEST are proposing that the blue hangar be used for storage and to house a simulator. To further mitigate this risk staff exploring conditions in any lease that limit noise generating activities within the blue hangar once NEST's transition to the new facility is complete (as indicated above there will be a helicopter housed there during the transition, and until the new facility is operational).

4.7 Next Steps

The leases and standalone agreement are all but complete. We are now working through final feedback from each parties' legal representatives, and are looking at a number of small inclusions where appropriate. It is noted that the Chief Executive has delegation to approve leases at the Airport without a resolution of Council.

However, given the interest in the NEST relocation, and the feedback and recommendations of the Airport Noise Management Committee in September 2022, Council has previously considered this matter and provided specific delegation to the Chief Executive to authorise both a lease and standalone agreement. The consideration of these under delegation is now imminent, with NEST requiring an approved lease prior to tendering and commencing works early next year.

This update has been formally brought to Council following consideration by the Airport Noise Management Committee in order to ensure Council has full visibility prior to executing

these agreements, with it being noted that any lease for the blue hangar will also be considered under existing delegation to the Chief Executive at the same time.

5 Significance and engagement / Te Hira me te Arawhiti

While the potential for public interest in the move has been identified in previous papers this paper is predominantly an update. The decisions in the paper do not trigger two or more of the criteria in Council's Significance and Engagement Policy, and the public will be informed via Agenda publication on the website.

Those most affected by and interested in the potential relocation of NEST's flight operations to the Airport (NEST itself, the Airport and residents of Onerahi living close to the Airport) have representation on the Airport Noise Management Committee. The December update to the Committee enabled the views of those parties to be heard / reflected prior to a formal update being provided to Council.

RESOLUTION TO EXCLUDE THE PUBLIC

That the public be excluded from the following parts of proceedings of this meeting.

The general subject of each matter to be considered while the public is excluded, the reason for passing this resolution in relation to each matter, and the specific grounds under Section 48(1) of the Local Government Official Information and Meetings Act 1987 for the passing of this resolution are as follows:

| | |
|----|--|
| 1. | The making available of information would be likely to unreasonably prejudice the commercial position of persons who are the subject of the information. {Section 7(2)(c)} |
| 2. | To enable the council (the committee) to carry on without prejudice or disadvantage commercial negotiations. {(Section 7(2)(i))}. |
| 3. | To protect the privacy of natural persons. {Section 7(2)(a)}. |
| 4. | Publicity prior to successful prosecution of the individuals named would be contrary to the laws of natural justice and may constitute contempt of court. {Section 48(1)(b)}. |
| 5. | To protect information which is the subject to an obligation of confidence, the publication of such information would be likely to prejudice the supply of information from the same source and it is in the public interest that such information should continue to be supplied. {Section 7(2)(c)(i)}. |
| 6. | In order to maintain legal professional privilege. {Section 2(g)}. |
| 7. | To enable the council to carry on without prejudice or disadvantage, negotiations {Section 7(2)(i)}. |

Resolution to allow members of the public to remain

If the council/committee wishes members of the public to remain during discussion of confidential items the following additional recommendation will need to be passed:

Move/Second

"That _____ be permitted to remain at this meeting, after the public has been excluded, because of his/her/their knowledge of Item _____.

This knowledge, which will be of assistance in relation to the matter to be discussed, is relevant to that matter because _____.

Note:

Every resolution to exclude the public shall be put at a time when the meeting is open to the public.