

Substantiating material for statements made by Fluoride Free Australia Inc. in the “Yes case” for the Port Macquarie-Hastings fluoridation community poll

5. NHMRC’s exclusion of many toxicity studies

Entrenched policy: Australia’s National Health and Medical Research Council (NHMRC) has endorsed fluoridation since 1953, **but their reviews have excluded many toxicity studies** and they have never financed even their own recommended health safety studies.

NHMRC’s reviews have excluded many toxicity studies

Background

In 1950, only five years into a planned ten-year trial, fluoridation commenced in earnest in the US town of Grand Rapids. The US Public Health Service enthusiastically endorsed fluoridation despite the planned trials not complete and despite various warnings of the potential damage to health from the fluorides.

Meanwhile in Australia, in 1953, Beaconsfield, Tasmania became the first town to fluoridate – despite no safety studies having been conducted or even planned. By 1974, still without any safety studies and with growing evidence that fluoridation was not effective in reducing tooth decay, every capital city in Australia except Brisbane was fluoridated.

Even before the 1950s, there had been strong interest in fluoride’s adverse effects on health from breathing industrial fumes. But from the early 1990s, there was growing interest in the potential for harm from consumption of fluoride from any source, including fluoridated water.

Growing evidence of harms ignored

The body of evidence of potential harm from fluoride consumption has continued growing since the 1990s. More details are available [here](#) and [here](#) and see our article [here](#).

At the same time, NHMRC has however:

- admitted abandoning in 2002 all its planned health safety studies due to insufficient resources,
- admitted never having funded any projects to investigate potential adverse health effects from fluoride or fluoridation, and
- excluded from their fluoridation reviews most of the globally published research evidence, on what we argue below are spurious grounds, that effectively prevent NHMRC from considering fluoride’s true **toxicity**.

The first two points are discussed [here](#).

The following section discusses the third point.

Toxicity

Toxicity is determined by:

1. Analysing the measured health effects from some substance at varying doses or exposures;
2. Correlating the findings to establish a dose-response curve;
3. Establishing a No Observable Adverse Effect Level;
4. To that Level, applying a safety factor of at least 10x dilution to account for differences in individuals, so as to arrive at a presumed safe dose.

Toxicology succeeds in providing guidance to protect health by being comprehensive; by admitting evidence from a wide range of sources – in vitro, animal, human – and a wide range of doses, so as to arrive at a finding of safety in which we can have confidence.

In its dealings with fluoridation, NHMRC throws out that principle of toxicology, by applying severely limiting restrictions on the type of studies it admits.

To be accepted in NHMRC fluoridation reviews, studies must:

- Be published in English – thereby excluding studies originating in non-English speaking countries where fluoride science is often more advanced;
- Consider humans only, with no animal studies accepted - despite such studies being an essential component in evaluating the toxicological “weight of evidence”;
- Consider fluoride exposure only from fluoride in drinking water – thereby ignoring the importance of total fluoride from all sources, such as toothpaste, foods and beverages;
- Consider water with fluoride concentration no greater than 1.5 mg/L, on the grounds that it is inapplicable to Australian conditions with 1mgF/L in water – thereby ignoring that some Australians drink 2, 3 or 4 times more water than others, and it’s the ‘dose’ that makes the poison, not the concentration in water.

NHMRC rather appears to be studiously disinterested in toxicology and the real toxicity of fluoride. Its fluoridation reviews are literally a ‘study of fluoridation’, totally dismissing the bigger and far more important issue of actual effects of fluoride ingestion on human health.

If NHMRC truly wanted to determine a toxicological ‘safe’ dose for fluoride, it would admit any relevant good quality study, whether from China, or on rats, or involving toothpaste, or higher water concentrations. It would admit single studies and more complex meta-analyses of multiple studies. It would ensure sufficient resources to fund its own recommended safety studies.

As long as NHMRC declines to step outside of ‘fluoridation’ to study ‘fluoride’ itself, it can never be in a position to advise the nation on the safety or not of fluoridation, and its recommendations should be ignored.

Following are just some examples of relevant and potentially very useful studies and information that NHMRC has excluded or ignored.

Skeletal fluorosis

In 1991, the US Department of Health and Human Services estimated that adults living in communities water fluoridated at 1mgF/L routinely ingest between 1.6 and 6.6 mg of fluoride per day. That same rate of ingestion applies to fluoridated Australians, and overlaps the dose that modern research indicates can cause **arthritic symptoms and the early stages of skeletal fluorosis**. A recent example is the Swedish study, ([Helte et al 2021](#)), published in April 2021, which found at least 50 per cent higher rates of hip bone fractures in post-menopausal women who consumed drinking

water containing up to 1mg/L of fluoride. This large, high-quality study involved a cohort of more than 4,000 older Swedish women and extended for 13 years – from 2004 to 2017.

In its 1991 fluoridation review, NHMRC acknowledged the need for safety studies and made numerous recommendations, including concerning bone:

- The incidence of bone cancer should be monitored in relation to fluoride exposure;
- There should be careful and systematic analysis of fluoride accumulation in bone, skeletal fluorosis, and any relationship with impaired renal function;
- There should be bone fluoride analysis on autopsy of individuals selected so as to assess fluoride accumulation over a lifetime, e.g. individuals with renal impairment or high volume water consumers.

As noted above, none of those studies were undertaken

In its later 1999 fluoridation review, NHMRC reported:

“Since 1991 there have been 16 studies of water fluoridation and its effects on bone either BMD or fracture incidence. The pivotal cohort study of fluoridated water exposure and fractures or BMD demonstrated a trend for a decreased risk of hip fracture in France for water fluoride levels from 0.11ppm to 0.7ppm and an increase at 1ppm (Jacquim-Gadda, 1998.)”

Again, NHMRC took no precautionary action from this warning, issuing no cautions but continued to deem fluoridation ‘safe’ despite having also cancelled all its own planned health safety studies.

Today the **total weight of evidence** – from animal studies, clinical studies, and epidemiological studies - shows overwhelmingly that fluoride [accumulates in our bones](#), making them [more brittle and prone to fracture](#), and that a lifetime exposure to fluoride will contribute to [higher rates of hip fracture](#) in the elderly.

Failing to have considered such studies, NHMRC still declares fluoridation safe.

Osteosarcoma

There has been long-standing concern about the possibility that fluoride could be associated with osteosarcoma (bone cancer). A detailed timeline of this research can be found [here](#).

The fluoride/osteosarcoma connection is biologically plausible: 1) Bone is the principal site of fluoride accumulation, particularly during the growth spurts of childhood; 2) Fluoride is a mutagen when present at sufficient concentrations, and 3) Fluoride stimulates the proliferation of bone-forming cells (osteoblasts), which may “increase the risk for some of the dividing cells to become malignant.” (NRC 2006).

Several human epidemiological studies found an association between fluoride in drinking water and the occurrence of osteosarcoma in young males. (Cohn 1992; Hoover 1991). Similarly, the National Toxicology Program’s (NTP 1990) cancer bioassay found that fluoride-treated male rats had a dose-dependent increase in osteosarcoma. (Bucher 1991).

In 2001, a Harvard researcher Elise Bassin conducted an age-specific analysis of a national case-control study (Douglass 1995) that had reported no association between lifelong exposure to fluoridated water and osteosarcoma. Bassin’s age-specific analysis found that **boys** consuming fluoridated water at ages 6 to 8 years (the mid childhood growth spurt) had a statistically significant and “remarkably robust” risk of developing osteosarcoma during their teenage years (Bassin 2001).

Initially published as a PhD dissertation at Harvard, the study was later published in 2006 in *Cancer Causes & Control*. The evidence of the Bassin analysis has never been refuted.

Although highly relevant and plausible, NHMRC declined to recognise the Bassin analysis of evidence in either its 2006 or 2017 fluoridation reviews. That action smacks of criminal negligence with regard to any child who suffers osteosarcoma consequent to being fluoridated during a critical growth stage. Where is NHMRC's sense of responsibility to protect the national community?

Osteosarcoma references:

- Bassin EB. (2001). *Association Between Fluoride in Drinking Water During Growth and Development and the Incidence of Osteosarcoma for Children and Adolescents*. Doctoral Thesis, Harvard School of Dental Medicine. [[See study](#)]
- Bassin EB, Wypij D, Davis RB, Mittleman MA. (2006). [Age-specific Fluoride Exposure in Drinking Water and Osteosarcoma \(United States\)](#). *Cancer Causes and Control* 17: 421-8.
- Bucher J.R., Heitmanck M.R., Toft J., Persing R.L. Eustis S.L. Haseman J.K. (1991). [Results and conclusions of the National Toxicology Program's rodent carcinogenicity studies with sodium fluoride](#). *International Journal of Cancer* 48(5):733-7.
- Cohn P.D. (1992). [A Brief Report On The Association Of Drinking Water Fluoridation And The Incidence of Osteosarcoma Among Young Males](#). New Jersey Department of Health and Environmental Health Services.
- Hoover R.N., Devesa S.S., Cantor K.P., Lubin J.H., Fraumeni J.F. (1991). [Time trends for bone and joint cancers and osteosarcomas in the Surveillance, Epidemiology and End Results \(SEER\) Program](#). [National Cancer Institute](#). In: Appendix E and Appendix F of, Review of Fluoride: Benefits and Risks Report of the Ad Hoc Committee on Fluoride of the Committee to Coordinate Environmental Health and Related Programs US Public Health Service.
- McGuire S.M., Douglass C.W., Joshi A., Hunter D., DaSilva J. (1995). [Fluoride exposure and osteosarcoma](#). [Abstract] *Journal of Dental Research* 74:98.
- National Research Council (2006). *Fluoride in Drinking Water: A scientific Review of EPA's Standards*; National Research Council (NRC) 2006 of the National Academy of Sciences.
- National Toxicology Program [NTP] (1990). [Toxicology and Carcinogenesis Studies of Sodium Fluoride in F344/N Rats and B6C3f1 Mice](#). Technical report Series No. 393. NIH Publ. No 91-2848. National Institute of Environmental Health Sciences, Research Triangle Park, N.C.

NRC Review (2006)

In 2006, the US National Research Centre (NRC) published a comprehensive 3-year-long review of fluoride science, conducted by a panel of 12 scientists and health professionals. The NRC 2006 review identified concerns about damage to teeth and bone, and a range of other health effects associated with fluoride exposure, including damage to the brain, disruption of the endocrine system (thyroid gland, pineal gland, and glucose metabolism), and bone cancer.

NRC (2006) emphasised the need for detailed long-term biomonitoring, in various areas including the brain and endocrine system, especially the thyroid. The report importantly recommended the use of better methods to measure fluoride body burden (by analysis of fluoride in blood and urine), and not continue relying on purely epidemiological estimates of fluoride intake from community fluoridation.

Despite representing a treasure-trove of toxicologically important research into fluoride's health effects, NRC 2006 was excluded from NHMRC's 2007 fluoridation review on the grounds it was:

- "Not a clinical study" – which is true. The NRC 2006 review is a meta-analysis of many studies relevant to 'fluoride in water', and by rights should have been considered in the 2007 NHMRC review, due to the wealth of many clinical studies it offered on fluoride toxicity;
- Limited to the consideration of fluoride concentrations of 2 to 4mg/L, thus not relevant given Australia's fluoride concentration range of 0.6 to 1.1mg/L.

The latter ground is false on two counts. Firstly, many NRC (2006) studies **did** consider lower fluoride concentrations, involving rates of fluoride intake that could easily be exceeded in individuals under Australian conditions. Secondly, toxicity is derived from studies at various doses or concentrations, which would make **all** the NRC 2006 studies potentially useful, had NHMRC been interested in fluoride toxicity.

NHMRC's 2007 fluoridation review

NHMRC has proudly reported that its 2007 fluoridation review examined 5,500 studies (8 August 2013 ABC *Catalyst*). However the final report only assessed 77 studies, the remainder having been excluded as not relevant to Australian conditions, despite being relevant to fluoride ingestion thus toxicity.

The 'culling' of studies is normal process in any 'systematic review'. What is objectionable is the notion that fluoridation can be deemed safe despite specifically excluding studies on fluoride consumption from all sources and in any dose. Importantly, NRC (2006) and Bassin (2006), already mentioned, could both have provided important, toxicologically relevant findings had they not been dismissed on spurious grounds.

The NHMRC 2017 fluoridation review excluded many individual studies that, had they been accepted, could have transformed NHMRC's judgement regarding fluoride and health.

Xiang et al

Of particular note is Xiang et al, 2003; "Effects of fluoride in drinking water on children's intelligence". (Fluoride, vol 36, no. 2, pp. 84 – 94), which compared the IQ of two villages:

- Low fluoride village – average fluoride in well water = 0.36ppm (range 0.18 – 0.76ppm)
- High fluoride village – average fluoride in well water = 2.5ppm (range 0.57 – 4.5ppm)

This study was obviously highly relevant to Australian rates of fluoridation at 1 mgF/L, and by rights should have been considered by NHMRC. It was however excluded on the grounds of "wrong intervention", and lacking a low or optimal fluoride group. Both those reasons seem indefensible: Xiang et al studied the effects of water fluoridation, as per NHMRC's criteria, and considered both a low and a high fluoride concentration.

The Xiang study also controlled – as it should - for important confounders including lead, arsenic and iodine intake.

It found a drop of 5 – 10 IQ points across the whole range of ages in the high fluoride village, compared to the low fluoride village, with a clear dose-response. Moreover, the critical concentration above which adverse effects demonstrated was in the range 0.75 and 1.5 ppm – which includes the concentration at which Australia fluoridates, and leaves no margin of error for safety in the Australian situation.

That important information should have been considered by NHMRC, but intentionally was not, being deemed "excluded" (NHMRC 2016, p. 423).

NHMRC's 2017 fluoridation review

In 2014 NHMRC selected 1 October 2006 as the earliest publication date for studies to be included in the next NHMRC review, effectively preventing any opportunity to reconsider the 2006 NRC review, the Bassin 2006 Osteosarcoma study, and Xiang (2003) (all discussed above).

NHMRC's 2017 review once again adopted a selection process designed to look only at studies that mirrored the Australian 1 mgF/L fluoridation regimen, excluding very many studies that would have been recognised had meaningful toxicological criteria been applied.

- 1,708 peer-reviewed and 66 non-peer-reviewed articles were initially identified – a total of 1,774.
- Based on abstracts alone, the number was reduced to 199, but only 39 articles reaching the final report.
- 379 public submissions were received, many nominating relevant toxicity studies, but only TWO papers were admitted into the final report.
- In total, from an initial 2,153 studies identified, only 41 were included in the final report.

The 2017 review:

- Only referenced 15 of at least 50 IQ studies that were available as of July 2017, and relevant to fluoride neurotoxicity;
- Did not mention the highly significant Harvard meta-analysis (Choi, 2012) involving 27 fluoride toxicity studies – 26 of which showed an average 7-point IQ loss associated with fluoride consumption, with a notable dose-response relationship. The authors specifically reported the consistent correlation between increased fluoride levels and reduced IQ, and the lack of any confounding variables that could explain the relationship. . . Despite this clear outcome, the 27 Choi studies were excluded by NHMRC;
- Failed even to mention a significant study by Malin and Till (2015) associating fluoridation with ADHD, despite that study having been brought specifically to NHMRC's attention in 2016, and it fulfilling all relevant criteria for inclusion (Malin AJ, Till C. Exposure to fluoridated water and attention deficit hyperactivity disorder prevalence among children and adolescents in the United States: an ecological association. *Environ Health*, 2015; 14: 17).

It was **truly astounding** that NHMRC's 2017 review also gave the New Zealand Broadbent (2014) study a high-quality rating and low risk of bias, despite the study's failure to account for confounding factors in fluoride intake and the presence of other water chemicals. NHMRC then presumed to use this **single** Broadbent (2014) study to justify a finding of "no association between water fluoridation at current Australian levels and the cognitive function of children or adults."

Conclusion - if you don't look you won't find

NHMRC is only able to continue in its defence of the safety of fluoridation by:

- ignoring its own earlier recommendations for safety studies to be conducted;
- avoiding conducting studies of total fluoride intake and adverse health effects, and
- excluding from its reviews suitable toxicological studies that would, if included, be able to demonstrate whether fluoride has adverse effects on health or can be safe at some level of consumption.

This is an extremely serious situation, involving a failure of duty of care and betrayal of the people's trust in the NHMRC to deliver the best possible **health advice** to the nation.

Fluoride Free Australia will defend its statements on this matter in court if necessary.

We are confident that if and when the facts surrounding NHMRC's dealings with the fluoride science are ever brought to formal audit, Australian's will compare it to the junk science that propped up the promotion and defence of tobacco, asbestos and sugar.