

Attachment 1 - Intemann

NHMRC Recommendations for health safety studies: as quoted from two fluoridation reports by Australia's *National Health and Medical Research Council* (NHMRC), namely:

1. "The Effectiveness of Water Fluoridation", NHMRC, March 1991
2. "Review of Water Fluoridation and Fluoride Intake from Discretionary Fluoride Supplements", NHMRC, 1999

Copies sourced from NSW Health, circa 2004.

The boxed text below is an added summary of the relevant recommendation.

1. "The Effectiveness of Water Fluoridation", NHMRC, March 1991.

Health Study Recommendations

B. Review of evidence (p 14)

9. "However, there have been no systematic epidemiological studies of skeletal fluorosis in fluoridated and non-fluoridated areas ... the Working Group recognises that the deposition of fluoride in bone provides a reason for monitoring the future bone cancer rates in human populations in relation to their fluoride exposure."

→ The incidence of bone cancer should be monitored in relation to fluoride exposure.

D. Recommendations (p 18)

3. "That proposals be developed to: develop monitoring mechanisms to document total fluoride intakes by adults with a view to estimating levels of deposition in bone, bearing in mind that water fluoridation at around 1 ppm appears, on present evidence, to be the main single source of fluoride intake in adults."

→ There should be careful and systematic analysis of fluoride accumulation in bone.

6. Considerations of possible toxicity and of safety margins

6.1 Introduction (p 78-79)

"It is important to consider safety margins in relation to more than the 'average exposure', since individuals may vary substantially in the total external dose of exposure that they receive and in their biological susceptibility to that exposure. With respect to daily ingestion of fluoride, a 10- to 20-fold variation has been estimate between adult individuals. A safety factor of 10 is normally assumed to provide protection for high-risk groups. Any other major uncertainties must be compensated for by increasing this safety factor.

"The human and animal databases on fluoride toxicology are extensive. Therefore, despite the uncertainties inherent in the approach described above, some aspects of fluoride toxicity in man may be evaluated with a degree of confidence usually not available with other food-borne or environmental chemicals."

→ Existing human and animal fluoride toxicological studies should be mined, and a safety factor of at least 10x adopted to provide protection for high-risk groups.

6.4 Skeletal fluorosis (p 84)

“Approximately 50 per cent of ingested fluoride is excreted by the kidneys (if they are healthy) and almost all of the remainder is deposited in the skeleton. Although this skeletal deposition is not permanent (being subject to dynamic equilibrium between intake and excretion) the net effect is a tendency for fluoride to cumulate in bones with increasing age (Murray, 1986).”

“It also seems that fluorosis is more likely in populations which are malnourished (Srikantia, 1985). Theoretically, people with impaired renal function are at greater risk of developing skeletal fluorosis and two US cases of skeletal fluorosis are recorded in patients who had been exposed to water fluoride levels of 1.7 and 2.6 ppm, Juncos and Donadio (1972).”

“The advent of fluoridated toothpastes in Australia has almost certainly increased fluoride deposition in the bones of some Australians. It would not be surprising if there were some undetected cases of skeletal fluorosis in the Australian population in individuals with pathological thirst disorders and/or impaired renal function. However, the matter has not been systematically examined. This matter should be the subject of careful and systematic review.”

→ There should be careful and systematic analysis of fluoride accumulation in bone, skeletal fluorosis, and any relationship with impaired renal function.

6.6 Carcinogenicity (p 89)

“The current NHMRC Working Group also concurs with the Knox Report which noted in its conclusions: "It is desirable, nevertheless, that cancer rates should continue to be examined in fluoridated areas; even though there is no reason to anticipate that fluoridation will influence cancer rates, such surveillance should, out of prudence, be a routine." (Knox, 1985).”

→ There should be routine surveillance of cancer rates in fluoridated areas.

8. Future monitoring and research in Australia

8.1 Introduction (p 105-106)

“It has been a surprise to members of the Working Group to discover that, on the one hand, Australian and New Zealand critics of fluoridation have been at the forefront of the international debate on this public health measure while, on the other hand, the profluoridation argument has relied extensively on overseas studies and data. Australia has, more than most countries, invested heavily in fluoridation as a public health measure (and this has achieved beneficial results), but it has contributed less to the fundamental body of knowledge which is, and will continue to be, essential if water fluoridation is to continue as a national and regional preventive strategy.”

“It is a matter for concern that the Working Group cannot point to a single ongoing Australian study which monitors adequately the impact and possible adverse consequences of this policy, and that in its pursuit of the terms of reference, the Working Group has had to rely on: indirect analyses of very inadequate datasets, collected not for the monitoring of this policy but for other purposes; a limited number of Australian studies; and upon overseas investigations of these matters. The Working Group's recommendations and conclusions are the consequence of its attempts to arrive at the best possible assessment of the likely risks and benefits of continuing fluoridation at the present level, or of adopting alternative policies. Those recommendations and conclusions must be qualified by emphasising the current dearth of an adequate evaluative Australian database.

“The fact that substantial (but possibly lesser) improvements in dental public health are being achieved in other countries through the application of discretionary fluorides, and without the necessity for mass supplementation through water supplies, makes it particularly important that the NHMRC establish an effective monitoring and research programme in relation to its water fluoridation policy. This programme must extend beyond the dental public health domain, and should include a consideration of the broad impact of fluoride supplementation on human health and ecology. The opportunity offered by the differential timing and variable use of water fluoridation in different Australian cities should be used to design studies which will inform the debate not only here but overseas.

“Accordingly, the Working Group proposes to the NHMRC that it should take immediate steps to rectify this. Serious deficiency, and that it should take the lead in commissioning or inviting expressions of interest to study the following aspects of the question.”

- ➔ Water fluoridation must be accompanied by active research. Australia – as a major fluoridating nation – should be a leader in monitoring and research across all aspects: water fluoridation and its dental alternatives, and also fluoride’s effect on human health more generally.
- ➔ Use should be made of differential fluoridation status in different parts of Australia, to make comparisons of effects.

8.3 Total fluoride intake and public health (p 107)

“There are no Australian reports which permits the Working Group to precisely estimate, with confidence, the current intake of fluoride which various aged individuals are ingesting, nor the differential amount of fluoride which is being stored in Australian skeletons, in fluoridated and unfluoridated areas. Australia is reliant on overseas studies for assumption that these amounts are likely to be small enough to present no risk to long term health.

“The evidence arising from the NTP studies which have led the NHMRC Committee on Toxicity to classify fluoride as an "equivocal" carcinogen in high dosage in rats makes it imperative that public health recommendations in the future be based on accurate knowledge of the total fluoride intake of Australians. Accordingly, the Working Group believes that proposals to monitor this load should be developed for various indicator populations within Australia and that these studies should take account of the range of deliberative and involuntary intakes which are occurring in both normal and susceptible individuals, in both fluoridated and unfluoridated areas.”

- ➔ There must be accurate knowledge and monitoring of fluoride intake from all sources and of fluoride storage in bone, in various indicator and susceptible populations and for the range of fluoride intake.

8.4 Monitoring for toxicity (p. 108)

“Dental fluorosis is a sensitive indicator of storage of fluoride in teeth during the developmental stages of tooth formation, but does not indicate the amount of fluoride which is being incorporated into bone throughout adult life. The Working Group has no evidence that this latter amount is rising to troublesome levels, but neither has the issue been studied in any systematic way. If skeletal fluorosis is occurring at all in Australians, it is likely to be slight, and will most likely occur in those who drink large amounts of fluoridated water, or whose renal function is impaired. Studies of bone fluoride collected at autopsy in selected individuals could provide needed reassurance that the current policy is not resulting in hazardous levels of bone accumulation.

“The Working Group remains unconvinced by very limited published reports in the overseas literature, and sporadic claims by Australian individuals, of a significant problem with allergy or hypersensitivity to fluoride in the water supply. It is desirable to explore in a rigorous fashion whether the vague constellation of symptoms which are claimed to result from ingestion of fluoridated water can be shown to be reproducibly developed in these "susceptible" individuals. These claims are being made with sufficient frequency to justify well-designed studies which can properly control for subject and observer bias.

“Community concerns at the possibility that fluoride might, in certain circumstances, act as a carcinogen have surfaced repeatedly and have been heightened by the "equivocal" findings in the NTP rodent studies discussed elsewhere in this report. Fluoride intake of some degree is universal, and discretionary intakes of added fluoride are very widespread in the Australian population. During the conduct of any future epidemiologic studies, it will be very difficult to determine the levels of fluoride to which cancer sufferers and selected controls have been exposed, but systematic efforts to determine this are highly desirable.

“These issues also deserve the attention of a multidisciplinary group, backed by sufficient funds to initiate rigorous studies which can contribute information to the international knowledge base on these matters.”

- 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.
- The potential for fluoride hypersensitivity should be rigorously examined.
- Ways should be found to study the relationship between degree of individual fluoride exposure and the incidence of cancer, using a multi-disciplinary approach.

8.5 Costs and benefits of different approaches to caries protection (p 109)

“The final judgement about the value of a fluoridation program cannot be made exclusively in economic terms. However, a comprehensive review of the economic consequences of maintaining fluoridation is required and the Working Group believes that an updated approach using more conservative assumptions about the level of protection which water fluoridation now provides, should be attempted, as an adjunct to decision-making on this matter.”

- There should be a comprehensive analysis of the economic consequences of fluoridation, using different assumptions of the dental effectiveness of fluoridation.

9. Conclusions and recommendations

9.1 Historical background and general summary (p 109-110)

“There have been two long-standing public concerns over the addition of fluoride to drinking water. One concern is that fluoride at raised levels of intake may have adverse effects upon health. The other is that water fluoridation encroaches upon civil liberties, since it entails an involuntary exposure.”

“Considerations of effectiveness, cost-effectiveness and population coverage all continue to favour water fluoridation as the preferred primary source of supplementary fluoride. However, the fact that fluoride in drinking water constitutes an involuntary exposure necessitates a particular requirement for public health policy on this matter to be both up-to-date and prudent.

“While, on the available evidence, there is no justification for lowering the fluoride concentration in drinking water, public health prudence requires that this option be kept in mind in the course of future public health surveillance and evaluation. Whereas avoidance of excessive individual exposure in young childhood is best approached by controlling the intake of discretionary fluoride, avoidance of excessive exposure of the community to lifetime cumulation of fluoride would, if required, be best approached by reducing the concentration of fluoride in drinking water.”

- ➔ Water fluoridation is a convenient method to deliver supplementary fluoride, but involves involuntary (compelled) exposure. Therefore it is essential that policy be informed by the best available evidence.
- ➔ Policy-makers must always remain open to the option of lowering the fluoride concentration in drinking water to reduce fluoride intake, especially for adults based on lifetime consumption. (See also p 104)

9.2 Major conclusions (p 110-112)

“The major conclusions from the above review are:

4. “The recent equivocal evidence of increased risk of bone neoplasms in one species of experimental animals exposed to very high doses of fluoride indicates a need for a raised and ongoing attentiveness to these (and any other) possibilities of adverse effects in human populations experiencing lifelong exposure to fluoride supplementation.”

7. “If, in the light of future health surveillance, there were any future need for a community-wide reduction in long-term exposure to fluoride in adults, this would be best achieved by reduction in the concentration of fluoride in drinking water.”

- ➔ There should be more attention to the possibility of adverse health effects over a lifetime of fluoride exposure. The best way to reduce long-term exposure would be to lower the concentration of fluoride in drinking water.

9.3 Recommendations (p 112)

“develop monitoring mechanisms to document total fluoride intakes by adults with a view to estimating levels of deposition in bone, bearing in mind that water fluoridation at around 1 ppm appears, on present evidence, to be the main single source of fluoride intake in adults.”

- ➔ In designing fluoride intake monitoring, recognise that water fluoridation appears to be the main single source of fluoride intake. (That may seem obvious, but NHMRC fluoridation reviews have not expressed consistent statements on this topic).

Conclusion – 1991 Review recommendations

It is clear that the 1991 reviewers intended that NHMRC should adopt a pro-active approach to the investigation of potential or even possible adverse health effects from fluoride consumption, and a significant number of specific recommendations for action were made.

None of those recommendations appear ever to have been actioned

2. “Review of Water Fluoridation and Fluoride Intake from Discretionary Fluoride Supplements”, NHMRC, 1999

Health Study Recommendations

Extracts from the 1999 review:

Chapter 2 (p. 3), notes that infants under six months should receive no supplementary fluoride even if local water is not artificially fluoridated.

In Chapter 8 (p. 9) it is recommended that no supplementary fluoride should be given to children under 3 years, even if they live in an unfluoridated area.

The reasoning behind those changes are cited at Chapter 6, page 2):

“Recommendations from professional bodies regarding fluoride intake:

“In 1986, the American Academy of Paediatrics stated that for optimal dental health benefits the total daily intake of fluoride should be 0.05-0.07 mg fluoride per kg bodyweight.”

→ Care should be taken to minimise fluoride intake by infants and young children.

Chapter 6, page 17, recommends that “infant formula is reconstituted with low-fluoride water in a fluoridated area. This may add to the cost of feeding if distilled or mineral water has to be purchased.”

→ Consideration should be given to the need to make-up infant formula using non-fluoridated water.

Chapter 5, page 2 reports that “8. Some evidence exists that tooth eruption is delayed in fluoridated areas. It has been suggested that a proper comparison of caries rates should involve children one year older in fluoridated areas than in non-fluoridated areas.”

→ Caution should be applied in interpreting dental outcomes.

Chapter 4, page 9 reports that “Fluoride is largely excreted via the kidneys. Patients with renal failure have plasma levels three times higher than normal individuals from the same region. The effect of such high plasma levels on bone merits investigation,”

The Chapter 4 Summary reports that:

“A wide range of plasma concentrations have been observed which may indicate inter-individual differences in fluoride pharmacokinetics.

- Fluoride is largely excreted via the kidneys. Patients with renal failure have plasma levels three times higher than normal individuals from the same region. The effect of such high plasma levels on bone merits investigation.”

Chapter 5, page 2 reports that “9. Unless these confounding factors are determined accurately it is not possible to take them into account in statistical analysis.”

→ Renal insufficiency appears to be accompanied by low fluoride clearance, and should be monitored for occurrence and effects.

Chapter 5, page 72 reports: “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.)”

→ Attention should be paid to the effect of fluoride consumption on bone strength.

Chapter 8, page 1 reports:

“2. The prevalence of fluorosis in the 1990s is much higher than it was in the prefluoridation era. In Australia, a number of studies have examined the prevalence and severity of fluorosis. The reported prevalence of fluorosis in fluoridated areas is 40% for 12 year-olds in Perth, 56.8% for 10-16+ year-olds in South Australia and a Dean’s Index of 0.26 for 12 year-olds in Melbourne. Figures for non-fluoridated areas include 33% for Bunbury, 29.3% for 10-16+ year-olds in South Australia and the Melbourne report does not include a non-fluoridated comparison area.”

Chapter 7, page 16 states that: “The public perception of fluoridation as a health benefit may be endangered if the prevalence of fluorosis continues to increase at its current rate.”

→ The incidence of dental fluorosis due to fluoridation is rising, and is cause for concern.

Conclusion on 1999 Review

All attention in the 1999 review is on how to control fluoride intake from discretionary sources, completely ignoring the recommendation of the 1991 NHMRC review that a reduction in fluoride concentration in water should be considered if fluoride intake is to be reduced. The need to reduce fluoride intake is shown by the rising incidence of dental fluorosis, for which the easiest fix would be to lower the fluoride concentration of water fluoridation.

Many of the health recommendations of the 1991 review appear to have been ignored in the 1999 report. Allegations of fraud were made shortly after, arising from the failure of NHMRC to deliver on its commitment in 1991 and then in 1999, to undertake specific health safety studies, most urgently concerning fluoride’s effects on kidney function, but also regarding other matters and organs.

The reason for NHMRC’s failure to undertake planned health safety studies is identified in a letter from NHMRC to NSW Health, dated 24 February 2005, which states as follows.

“In 1998, HAC [Health Administration Commission], commissioned a review of fluoride use in Australia. It had been intended that this review would update NHMRC advice on the topic. However, in December 2002, it became apparent that the review was deficient in a number of areas including consideration of fluoride intakes in different age groups, sources of fluoride, and fluoride and oral health. HAC recognised that there were insufficient resources available to complete the additional work required to finalise the report. Consequently HAC agree it was necessary to discontinue this work and has no plans to recommence at this stage.”

Comment: That letter is provided as [Attachment 2](#).

Fluoridation continues apace in Australia, with NHMRC continuing to promote fluoridation safety despite never – in the 70 years of fluoridation – conducting any of even their own recommended health safety studies. That is a demonstrable failure in bureaucratic duty of care, and warrants an end to fluoridation post haste.

The situation is confirmed in a letter from NHMRC to PMHC, 29 April 2016 which states:

“NHMRC awarded funding to a project investigating the risk and long term impact of dental fluorosis as a result of exposure to fluoride. Apart from this research, there have been no projects funded by NHMRC prior to or after 2000 that investigated potential negative effects from fluoride or fluoridation.”

Comment: That letter is provided as [Attachment 3](#).

Despite the many 1991 NHMRC recommendations, sometimes for “urgent” and “imperative” health safety actions, NHMRC has no intention of funding any such investigations into potential negative effects. Fluoridation is a policy running blind.

Despite the lack of any safety studies being done, NHMRC declares on page 2 of the 2016 letter that:

“In the ADWG (Australian Drinking Water Guidelines), safety factors have been applied in order to take into account the uncertainty when extrapolating from animal studies to humans, or to account for variation between humans when only small human studies are available. The information used to set the guideline value for fluoride in drinking water comes directly from human studies and therefore the use of safety factors was not considered necessary.”

Comment: One is prompted to wonder if NHMRC is deliberately misleading the reader, or is just absent any corporate memory regarding the weakness of its own information base, specifically its lack of having funded a single human health safety study or ever assessed the health effects of fluoridation over a lifetime.

The Australian nation is being put at risk by NHMRC’s failure of duty of care to the health of the nation.

[Attachment 4](#) outlines NHMRC’s further inadequacies with regard to its 2007 and 2016 fluoridation reviews, where important, available and highly relevant studies showing adverse health effects from fluoride consumption through fluoridation were excluded or dismissed from serious consideration.