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Evaluating the evidence on water
fluoridation and human health in Australia
2014-2017: Administrative Report

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Introduction

The National Health and Medical Research Council (NHMRC) continually reviews scientific research on water fluoridation to ensure its advice is based on the best available and most relevant evidence for the Australian context. This Administrative Report documents the development processes used by NHMRC to develop its 2016-2017 resources on water fluoridation and human health. These include:

- Health Effects of Water Fluoridation: Evidence Evaluation Report (Evidence Evaluation Report)¹
- Health Effects of Water Fluoridation: Technical Report (Technical Report)²
- Information Paper - Water fluoridation: dental and other human health outcomes (Information Paper)³
- Evidence Commentary Report
- NHMRC Public Statement 2017: Water fluoridation and human health in Australia (2017 Public Statement)⁴
- Water fluoridation and human health in Australia: Questions and Answers (Q&As)⁵

1. Background

1.1. 2006-2007

In 2006, NHMRC undertook a systematic review of the evidence for the efficacy and safety of fluoride interventions. This review considered possible benefits and harms of different sources of fluoride that could be used to deliver fluoride to the Australian community including drinking water, milk, salt and topical fluoride treatments. The resulting report, titled *A Systematic Review of the Efficacy and Safety of Fluoridation* (2007 Systematic Review) was published in 2007.⁶

Based on the findings of this review, NHMRC issued the *NHMRC Public Statement: The Efficacy and Safety of Fluoridation* (2007 Public Statement).⁷ This recommended that water be fluoridated in the target range of 0.6 to 1.1 milligrams per litre (mg/L), depending on climate, to balance reduction of dental caries (tooth decay) and occurrence of dental fluorosis (mottling of teeth). It also stated that fluoridation of drinking water is an effective way to ensure people across the community are exposed to fluoride and can benefit from its preventative role in tooth decay, regardless of age, gender or socio-economic status.

1.2. 2012-2013

At its meeting in November 2012, the Council of NHMRC (Council) advised that NHMRC consider options for investigating new evidence on the health effects of fluoridation. In response, on 20 June 2013 NHMRC hosted a meeting of experts and state and territory government health representatives to consider NHMRC's advice on water fluoridation. The main outcome of this meeting was to ask NHMRC to update its 2007 Systematic Review, subject to the availability of funding.

Following this meeting, Council reaffirmed its position on the 2007 Public Statement (allow continuation of government advice) and recommended that NHMRC update the body of evidence to include more recent studies and assess their relevance in the Australian context.

2. Governance of the Evaluation

2.1. Fluoride Reference Group (FRG)

2.1.1. Appointment Process

The FRG was a working committee established by a delegate of the NHMRC Chief Executive Officer (CEO), under section 39 of the *National Health and Medical Research Council Act 1992* (NHMRC Act).

The committee was selected to ensure appropriate expertise in the key areas of science and review methodology, in order to undertake an evidence based assessment. The committee comprised highly-regarded experts in the fields of public health, oral health, epidemiology, child health, toxicology, cancer, bone biology, neurodevelopment, Aboriginal and Torres Strait Islander health, water management and health ethics. The FRG was not established on the basis of pro or anti fluoridation views. A consumer representative joined the FRG, nominated by Consumer Health Forum of Australia.

2.1.2. Terms of Reference

The FRG was appointed to:

- Guide the development of an evaluation of the evidence on the health effects of water fluoridation, focusing on studies published since 2006
- Consider the outcomes of this evaluation, and use these findings to:
 - Inform the development of an evidence evaluation report that synthesises the evidence and identifies critical gaps in the current evidence base
 - Guide the identification of key issues to be considered by the Council and CEO of NHMRC as the Office of NHMRC translated the evidence review into an information paper on the artificial fluoridation of drinking water
- Consider comments received during consultation on the draft Information Paper.

2.1.3. Declarations of Interest Process

Members of NHMRC committees provide high quality, expert and independent advice that allows NHMRC to fulfil its functions under the NHMRC Act. Members are appointed for their expertise and experience across a diverse range of professions and fields. Appointments are also made with consideration of balancing the benefit of having persons with expertise against the risks of their interests biasing a process.

Appointees to committees of NHMRC are required to disclose their interests consistent with section 42A of the NHMRC Act and section 29 of the *Public Governance, Performance and Accountability Act 2013*. Prior to appointment decisions being made, NHMRC asked each prospective member of the FRG to disclose their interests to NHMRC in writing.

Prospective members were specifically asked to identify, to the best of their ability, interests including:

- Employment by an entity having commercial or other interests in fluoride or fluoridation
- Financial interests or relationships including ownership, board membership, honoraria, consultancies, or research funding related to fluoride or fluoridation
- Publications, speeches or expert testimony regarding fluoride or fluoridation
- Involvement in the development of guidelines, standards, education material or fact sheets related to fluoride or fluoridation
- Affiliations or associations with any organisation having an interest either for or against fluoridation

Under the *Public Governance, Performance and Accountability Act 2013*, members had a responsibility to declare any interests to the whole committee and members had a joint responsibility to decide on the management of any perceived or real conflict. No unmanageable conflicts were identified by the FRG or NHMRC and there were no instances in the development process where members of the Working Committee determined that a disclosed interest warranted a member being absent from a discussion or decision.

Throughout the project, members were reminded of their obligation to consider any interest that may have arisen since the last meeting or with any particular agenda items. All disclosures and determinations about interests were recorded in the minutes of the FRG meetings. Members' relevant expertise and a summary of their disclosed interests were accessible on the NHMRC website throughout the duration of the project (**Appendix A**).

2.1.4. Membership

Appointments to the FRG were effective from 31 May 2014 to 30 May 2017. The Members were:

- Emeritus Professor Judith Whitworth AC FTSE (Chair) — Emeritus Professor, John Curtin School of Medical Research, Australian National University
- Professor Vicki Anderson — Director, Clinical Sciences Research, Murdoch Children's Research Institute; Director, Psychology, Royal Children's Hospital; Professorial Fellow, School of Psychological Sciences, University of Melbourne
- Doctor Meenakshi Arora — Lecturer in Environmental Engineering, Melbourne School of Engineering, University of Melbourne
- Associate Professor Stephen Corbett — Director, Centre for Population Health, Western Sydney Local Health District; Conjoint Associate Professor, School of Public Health, University of Sydney and Western Clinical School, Westmead
- Professor Dallas English — Professor of Epidemiology and Biostatistics, Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, University of Melbourne; Research Fellow, Cancer Epidemiology Centre, Cancer Council Victoria
- Professor Matthew Gillespie — Professor, Faculty of Medicine, Nursing and Health Sciences, Monash University
- Associate Professor Sharon Goldfeld — Paediatrician, Centre for Community Child Health, Royal Children's Hospital; Co-Group Leader, Policy Equity and Translation, Murdoch Children's Research Institute; Professor, Department of Paediatrics, Faculty of Medicine Dentistry and Health Sciences, University of Melbourne
- Professor Alison Jones — Executive Dean, Faculty of Science, Medicine and Health, University of Wollongong Clinical Toxicologist, Blacktown Hospital

- Associate Professor Frederic Leusch — Associate Professor and Head of Discipline, Soil Water and Energy, School of Environment, Griffith University
- Professor Mike Morgan^a — Head of School, Melbourne Dental School, University of Melbourne (until 25 June 2016)
- Adjunct Professor Kaye Roberts-Thomson — School of Dentistry, University of Adelaide
- Professor Wendy Rogers — Professor of Clinical Ethics, Department of Clinical Medicine and Department of Philosophy, Macquarie University
- Emeritus Professor A. John Spencer — Professor of Social and Preventive Dentistry, School of Dentistry, University of Adelaide
- Professor Frederick Wright — Associate Director and Clinical Professor, Centre for Research and Education on Ageing, Concord Clinical School, University of Sydney and Concord General and Repatriation Hospital
- Ms Debra Petrys (Consumer Nominee) — Member, Consumers Health Forum Australia.

2.1.5. FRG Meetings

The FRG met on 26 June and 7 August 2014 to advise on the scope of the evidence evaluation.

On 27 and 28 July 2015 the FRG met to critically appraise the first parts of the evidence evaluation. At this meeting the FRG also advised on the scope of the Information Paper in light of the findings from the evidence evaluation. The FRG started the process of synthesising the evaluation to develop evidence statements for each dental or other human health outcome, and an overall conclusion regarding water fluoridation as a public health intervention, using the *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) approach.^b These deliberations continued during a series of teleconferences held in November and December 2015 and through the provision of out-of-session comments. A further face-to-face meeting was held on 15 March 2016 and a teleconference on 4 April 2016. The Evidence Evaluation Report and Technical Report were finalised on 24 August 2016, following the FRG 18 May 2016 meeting and subsequent out-of-session comments, where members appraised the supplementary review and discussed feedback from independent methodological review on the completed evidence evaluation.

The FRG advised on drafts of the Information Paper at its 4 April, 18 May and 9 August 2016 meetings, including consideration of feedback from the jurisdictional health departments. Public consultation on the draft Information Paper occurred from 14 September to 13 October 2016. On 29 and 30 November 2016, the FRG met to consider public consultation submissions and advise on any revisions required. The group also advised on the need for any updates to the 2007 Public Statement and on the draft Q&As.

The final meeting of the FRG was held on 23 March 2017 via teleconference. At this meeting, members considered additional comments received from the jurisdictional health departments as well as feedback from independent expert review on the draft Information Paper, and advised on required revisions.

All discussions of the FRG were robust and open, and decision-making was consensus-based. Minutes from all meetings and teleconferences were recorded by NHMRC's Project Team.

^a Resigned on 25 July 2016 due to other work commitments

^b For more information on the GRADE approach refer to <http://www.gradeworkinggroup.org> and the GRADE Handbook (<http://grade.pro.org>)

2.2. NHMRC Project Team

The project was managed by the Public Health team of the Evidence, Advice and Governance Branch.

2.3. Australian Government Department of Health and Jurisdictional Health Departments

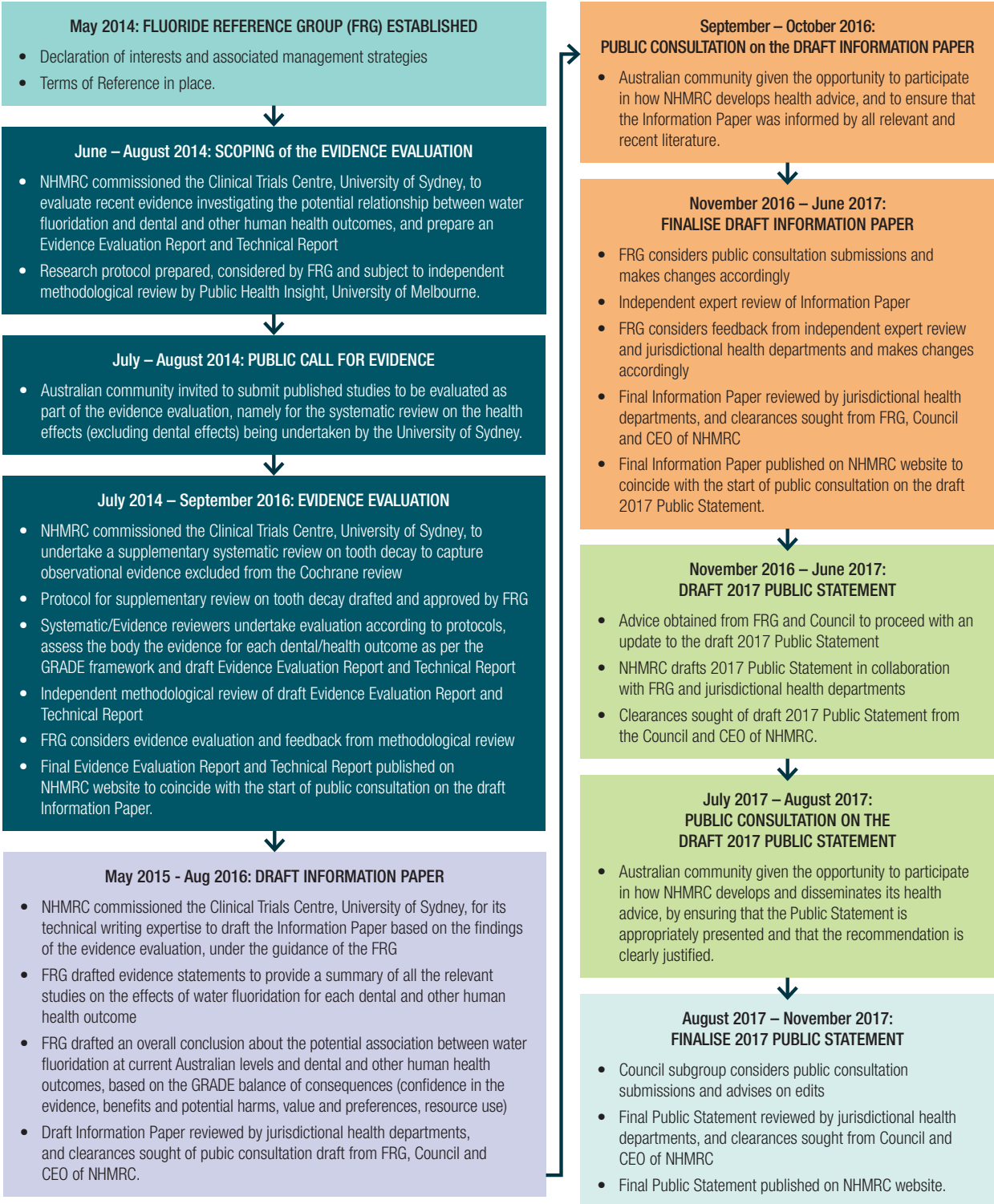
This project was funded by NHMRC, with contributions from most jurisdiction health departments and the Australian Government Department of Health.

NHMRC consulted with these bodies throughout the development of its 2016-2017 resources on water fluoridation and human health.

3. Overview of the Evaluation

An overview of the steps involved in developing NHMRC’s 2016-2017 resources on water fluoridation and human health is provided at [Figure 1](#). More detail on the development process of each of these resources is provided in later sections of this report.

Figure 1: Process for developing NHMRC’s 2016-2017 resources on water fluoridation and human health



4. Independent and Contracted Services

4.1. Evidence Reviewers: Evidence Evaluation Report and Technical Report

The Clinical Trials Centre, University of Sydney, undertook the evaluation of the evidence and prepared the Evidence Evaluation Report and Technical Report.

4.2. Independent Methodological Reviewers of the Evidence Evaluation Report and Technical Report

Public Health Insight, University of Melbourne, conducted independent expert methodological review of the evidence evaluation in two stages: Research Protocol in July 2014 and Evidence Evaluation Report in May 2016.

4.3. Technical Writers: Information Paper

The Clinical Trials Centre, University of Sydney, prepared the Information Paper (under a separately tendered contract to the evidence evaluation).

4.4. Independent Expert Reviewers of Information Paper

In 2017, the draft Information Paper was independently reviewed, focussing on the content and the GRADE methodology. The reviewers and their expertise included:

- Mr John Frangos (DABT, FACTRA) — expertise in toxicology
- Ms Tarah Hagen (ToxConsult Pty Ltd) — expertise in toxicology
- Emeritus Professor Stephen Leeder (University of Sydney) and Dr Angela Beaton (Waikato Institute of Technology) — expertise in evidence-based review/translation methods
- Professor Tracy Merlin (University of Adelaide) — expertise in public health and evidence-based review/translation methods
- Professor Eric Reynolds (University of Melbourne) — expertise in dental/oral health

5. Products or steps of the Evaluation

5.1. 2016 NHMRC Evidence Evaluation (2014-2016)

5.1.1. The independent evidence review team

The Clinical Trials Centre, University of Sydney, was commissioned by NHMRC in June 2014 to evaluate recent evidence investigating the potential relationship between water fluoridation and dental and other human health outcomes. A team from the Clinical Trials Centre was engaged for its expertise in systematic review methodology from NHMRC's Health Evidence Panel, following a competitive tender process. The evidence review team completed a declaration of interest process before being appointed by NHMRC and no conflicts of interest were identified.

The independent evaluation was undertaken in accordance with a research protocol that was approved by the NHMRC Project Team, based on advice from the FRG at its 26 June and 7 August 2014 meetings, before the evidence evaluation started. The research protocol outlined the scope, clinical questions, and methodology of the evidence review.

The evidence evaluation aimed to build on evidence identified in previous reviews, namely by McDonagh et al. in 2000⁸ and NHMRC in 2007⁷, so was limited to evidence published between 2006 and 2015. It included the following activities:

1. A comprehensive evaluation of the dental effects of water fluoridation, which consisted of:
 - a) an overview of systematic reviews (overview) on the effects of water fluoridation on tooth decay
 - b) a supplementary systematic review of recent primary studies on the effects of water fluoridation on tooth decay not identified in the reviews included in the overview
 - c) a critical appraisal of Ihezor-Ejiofor et al. 2015 review on tooth decay and dental fluorosis (commonly known as the 2015 Cochrane review).⁹
2. A systematic review of other possible health effects of water fluoridation.

The results and methods of this review are detailed respectively in the Evidence Evaluation Report and Technical Report. This includes the research questions using the PICOS approach (population, intervention, comparator, outcomes and setting), the search strategy, methods used to select, appraise and summarise the evidence, results, and evidence statements.

The Evidence Evaluation Report and Technical Report were published on the NHMRC website on 14 September 2016, to coincide with the start of public consultation on the draft Information Paper.

5.1.2. Public Call for Evidence (23 July - 22 August 2014)

Prior to the evidence evaluation commencing, the Australian community was invited to submit published studies to be evaluated as part of the systematic review on the health effects (excluding dental effects) of water fluoridation. Literature that met the scope of the systematic review was provided to the Clinical Trials Centre evidence review team. They evaluated studies identified by the community in the same way that they evaluated studies found using their own systematic searches (see [Figure 2](#)).

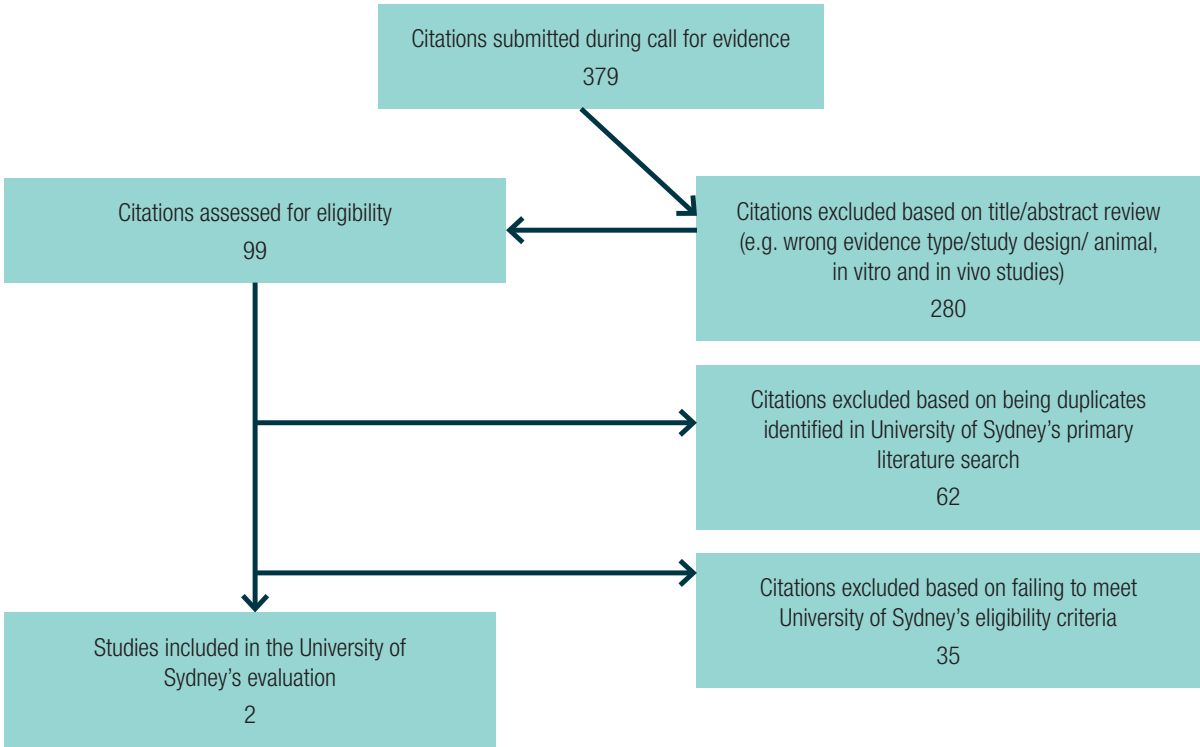
Studies in scope for the call for evidence

NHMRC was transparent in stating which studies were in and outside scope via the NHMRC public consultation website at <https://consultations.nhmrc.gov.au>.

To be accepted by NHMRC, published studies were required to be all of the following:

- Published after 1 October 2006
- An examination of fluoridated drinking water, not other fluoride interventions (e.g. fluoridated milk, salt, bottled water or topical fluoride applications such as toothpaste, varnish, gel or mouth rinse)
- Publicly available in English
- Available in full text
- A study or systematic review that included a group exposed to drinking water that contains fluoride and a comparison group exposed to drinking water with a lower concentration of fluoride or non-fluoridated water (defined as having a concentration of fluoride less than 0.4 mg/L)
- A study which reported outcomes relevant for human health.

Figure 2: Process for selecting literature submitted during the 2014 public call for evidence to allow inclusion in the formal systematic review of the health effects of water fluoridation



Studies outside the scope of the call for evidence

Whilst of interest to the community, the following topics were considered by NHMRC in other ways and so were outside the scope of the systematic review undertaken by the Clinical Trials Centre. Studies were not evaluated in the systematic review if they focused *exclusively* on the following topics:

Dental caries and dental fluorosis

Studies on the effects of water fluoridation on dental caries (tooth decay) and dental fluorosis (mottling of the teeth) were simultaneously investigated by the Cochrane Collaboration, an international not-for-profit organisation which conducts systematic reviews of the effects of health care.^c

Chemicals used to fluoridate drinking water

The chemicals used to fluoridate drinking water will be considered by the NHMRC Water Quality Advisory Committee in their ongoing review of the *Australian Drinking Water Guidelines*. This is a separate project.

Ethics of water fluoridation

The systematic review is concerned only with the health effects of water fluoridation. Ethical issues associated with water fluoridation were considered by the Australian Health Ethics Committee once the Clinical Trials Centre team completed the systematic review.

Studies that were not considered in the systematic review at any stage included:

- Studies published before 1 October 2006 as they were considered in NHMRC's 2007 Systematic Review
- Studies based on a type of evidence that is not appropriate to the systematic review, e.g. personal story, medical record, raw data, narrative review, case series or case report.

Where permission was granted by submitters, submissions have been published on the NHMRC website at <https://consultations.nhmrc.gov.au> on 30-31 March 2015.

5.1.3. Supplementary systematic review of recent primary studies on the effects of water fluoridation on tooth decay

The systematic review of primary studies on tooth decay was a supplementary activity. Originally, NHMRC anticipated that the 2015 Cochrane review would provide the necessary data for the assessment of the dental effects of water fluoridation.

At its 27 - 28 July 2015 meeting, the FRG discussed and critically appraised the 2015 Cochrane review. Members queried whether a further evidence evaluation could be carried out to capture the contemporary evidence from observational studies that were excluded from the 2015 Cochrane review. FRG members considered that such a supplementary review was needed to inform their recommendations, as it would likely strengthen the findings of the Cochrane review and be of greater relevance to the Australian context.

^c At the time of the call for evidence, it was anticipated that the 2015 Cochrane review would provide the necessary data for the assessment of the dental effects of water fluoridation, so the University of Sydney was not commissioned to undertake a systematic review of the dental effects. This decision was later changed as per 'Supplementary Systematic Review of recent primary studies on the effects of water fluoridation on tooth decay' section

For tooth decay outcomes, the 2015 Cochrane review only included prospective studies with a concurrent negative control, with at least two points in time evaluated and a change in fluoridation in the experimental arm. Few contemporary studies met these inclusion criteria, and therefore the review was unable to assess the role of community water fluoridation in a contemporary setting. Furthermore, the study designs included are unable to assess the effects of water fluoridation on adults due to the long follow up time which would be required in order to approach lifetime exposure.

At the 27 - 28 July 2015 FRG meeting, it was agreed that the NHMRC Fluoridation Project Team would work with the already contracted evidence reviewers (Clinical Trials Centre) to scope the parameters and feasibility of a supplementary systematic review to capture observational evidence on tooth decay excluded from the Cochrane review. This supplementary review did not seek to identify additional studies on dental fluorosis, as for this outcome the 2015 Cochrane review was considered sufficient given it had broader inclusion criteria. As such, no further searches or data extraction were undertaken for this outcome.

On 24 September 2015 the Clinical Trials Centre was commissioned to undertake the supplementary systematic review on tooth decay. This review was undertaken in two parts; an overview of existing systematic reviews (including the 2015 Cochrane review) and a systematic review of recent primary studies.

The Clinical Trials Centre prepared another research protocol that outlined the scope, clinical questions and methodology for this additional part of the evidence review. Feedback on and approval of the protocol were sought from the FRG at their 5 November 2015 meeting (held via teleconference) before the review began.

5.1.4. Independent Methodological Review

Public Health Insight, University of Melbourne, was contracted in July 2014 to assess the methodological quality of the Clinical Trials Centre's evidence evaluation, to ensure that the review followed the systematic and rigorous approach documented in the review protocol. The methodological reviewers were appropriately qualified in systematic review processes and methodology. The University of Melbourne successfully tendered to complete this activity through a competitive tender process using the NHMRC Health Evidence Panel. The methodological review team completed a declaration of interest process before being appointed by NHMRC and no conflicts of interest were identified.

Public Health Insight completed an independent methodological appraisal of the draft Research Protocol to provide NHMRC with assurance of the proposed methodology for the evidence evaluation. The methodologists comments were provided to the Clinical Trials Centre who revised the protocol accordingly, based on advice of the FRG at its meeting of 7 August 2014, prior to the evaluation of the evidence commencing.

Once the evidence evaluation was complete, Public Health Insight appraised the methodological quality of the Evidence Evaluation Report and Technical Report, including whether the rigorous approach prescribed in the review protocol had been adhered to, and whether the interpretation and reporting of the evidence were transparent and thorough.

The methodologists determined that the evidence evaluation used appropriate methods and aligned with the protocol, appropriately noting any changes to the planned approach. It was suggested that key issues to be addressed were to:

- ensure clear signposting throughout to improve readability and distinguish between the various components of the evaluation
- include the research questions and PICOS tables as per protocols
- reassess some studies to ensure the accuracy of the quality rating
- comment on diagnostic levels of tooth decay
- provide further justification of some methodological approaches including presentation of outcomes.

The FRG discussed the feedback from methodological review at its 18 May 2016 meeting and were satisfied with the methodologist's appraisal. In subsequent drafts of its reports, the Clinical Trials Centre addressed the issues raised to further clarify its procedures and processes.

5.1.5. Governance and Stakeholder Involvement

The draft Evidence Evaluation Report and Technical Report were discussed at a meeting of the FRG held on 27 and 28 July 2015, with the content and evidence statements on the numerous health and dental outcomes refined using a consensus approach over a series of meetings/teleconferences held from then until 18 May 2016.

The Evidence Evaluation Report was provided to Council on 14 July 2016. The CEO subsequently agreed to publically release the Evidence Evaluation Report and Technical Report on the NHMRC website, to coincide with the start of public consultation on the draft Information Paper on 14 September 2016.

5.2. Evidence Commentary Report

The Evidence Commentary Report documents the FRG's discussion, appraisal and translation of the Evidence Evaluation Report, including key issues in interpreting the evidence to the Australian context.

The Evidence Commentary Report also documents the FRG's application of the GRADE^d approach to develop the Evidence Statements and reach the overall conclusion. The Evidence Statements represent the association of water fluoridation with individual reported health and dental outcomes. The overall conclusion summarises the impact of water fluoridation as a public health intervention.

To develop an overall conclusion regarding water fluoridation as a public health intervention, the FRG took into account the Evidence Statements on each of the health and dental outcomes described in the Evidence Evaluation Report, as well as considering other factors that are collectively referred to as the 'balance of consequences' in the GRADE process. These include:

- the quality of and confidence in the evidence
- the balance of benefits versus harms
- values and preferences
- resource implications
- equity

^d For more information on the GRADE approach, refer to the GRADE handbook, accessible from <http://www.gradepro.org>

- acceptability of the intervention to stakeholders
- feasibility.

This report was completed by the Clinical Trials Centre as part of its separate Technical Writing contract with NHMRC, and was a required deliverable in preparation for drafting the Information Paper. The Clinical Trials Centre successfully tendered to complete this activity through a competitive process using the NHMRC Health Evidence Panel.

Drafting of the Evidence Commentary Report commenced at a two day meeting of the FRG that was convened on 27 and 28 July 2015. The FRG's deliberations in assessing the evidence continued over teleconferences held in November and December 2015 and through the provision of out-of-session comments. A further face-to-face meeting was held on 15 March 2016 and a teleconference on 4 April 2016.

In response to feedback from independent expert review of the draft Information Paper (see below), the Evidence Commentary Report was revised between March and May 2017 to ensure the FRG's application of GRADE was transparent and that a consistent approach had been applied to all evidence statements.

5.3. Information Paper (2015-2017)

5.3.1. Developing the Information Paper

In January 2015 NHMRC commissioned Technical Writers to draft an Information Paper, under the guidance of the FRG. The Clinical Trials Centre successfully tendered to complete this activity through a competitive process (and one separate to the evidence evaluation), using the NHMRC Health Evidence Panel.

The Information Paper summarises the findings of the 2016 NHMRC Evidence Evaluation (including evidence captured in the in the 2000 McDonagh review and NHMRC's 2007 Systematic Review) and assesses how relevant these findings are for Australia.

The Information Paper also considers:

- additional evidence on the relationship between water fluoridation and inequalities in tooth decay
- additional evidence on the relationship between water fluoridation and hospital visits for the treatment of tooth decay
- additional evidence on the perceptions of dental fluorosis in Australia
- the resource use and cost effectiveness of water fluoridation
- the ethics of water fluoridation
- relevant evidence put forward during public consultation on the draft Information Paper.

The additional evidence was provided by FRG members, jurisdictional health departments and via public consultation.

A draft Information Paper was available for public consultation from 14 September to 13 October 2016.

The final Information Paper was issued by the CEO of NHMRC on 4 July 2017.

5.3.2. Ethical considerations

The Information Paper addresses the ethics of water fluoridation and factors considered by the FRG in determining the 'balance of consequences'. The key ethical concern is that water fluoridation may be viewed as forced medication, which affects individual choice. The FRG also considered the likely values and preferences of the community, the effects of water fluoridation on disadvantaged Australians, the costs of tooth decay versus water fluoridation and the costs and other burdens to individuals and the health system if water fluoridation ceased. These considerations are summarised in the Ethical considerations section of the Information Paper,³ and were considered by the FRG (predominantly at its meetings of 27-28 July 2015, 15 March and 4 April 2016), and the Australian Health Ethics Committee on 10 June 2016.

5.3.3. Public Consultation (14 September - 13 October 2016)

On 14 July 2016 Council considered the draft Information Paper, prior to it being released by the CEO for public consultation.

The public consultation process allowed members of the public to make submissions about the document, comment on the evidence-based approach that was undertaken and provide any relevant additional evidence for consideration. To be considered, evidence had to meet specified inclusion criteria (as per the advertised scope below).

The public consultation process was conducted in accordance with Section 13 of the NHMRC Act. The public consultation was advertised on the NHMRC consultation website^e and via NHMRC's regular email newsletters. Invitations were also emailed to a large number of key stakeholders including government departments, professional bodies and individuals who had contacted NHMRC regarding NHMRC's fluoride work.

In total, 30 complete submissions and 923 references were received from a variety of stakeholders including 20 individuals and 10 organisations (four from state government health or water supply departments, and six from non-government organisations). Twenty-four submissions were from Australia, three were from the United States, and one each from Canada, New Zealand and the United Kingdom. This feedback informed revisions to the draft Information Paper, as advised by the FRG.

Where permission was granted by submitters, submissions were published on the NHMRC website at <https://consultations.nhmrc.gov.au> on 4 July 2017.

Studies in scope for public consultation on the draft Information Paper

NHMRC was transparent in stating which studies were in and outside scope via the NHMRC public consultation website.^f

To be accepted by NHMRC, published studies on the dental or other human health effects of water fluoridation were required to be all of the following:

- published after 1 October 2006*
- based on scientific research (i.e. data that has been systematically collected and analysed)*
- relevant to water fluoridation and human health*
- publicly available and published in English*
- report one or more dental or other human health outcomes
- compared at least two groups with exposure to different levels of fluoride in drinking water

e <https://consultations.nhmrc.gov.au>

f While NHMRC could have disregarded any submission that did not meet the scope/address the questions, FRG was prudent in considering all submissions received in full.

- not have exclusively selected participants only on the basis of reported health effects (e.g. case reports).

To be accepted by NHMRC other supporting material/additional evidence relevant to making decisions of water fluoridation in the Australian context were required to meet the criteria indicated above with an asterisk (*).

Studies outside the scope of public consultation on the draft Information Paper

- Studies that have already been considered in the 2016 NHMRC evidence evaluation, as documented in the Evidence Evaluation Report and Technical Report
- Evidence already provided in the 5.1.2. Public Call for Evidence (23 July - 22 August 2014)
- Personal opinions, medical records, raw data, animal studies, narrative reviews and editorials.

The FRG met on 29-30 November 2016 to consider all submissions and the references that met the criteria for consideration.^g Where necessary, the Information Paper was revised accordingly.

More information and/or consideration and/or clarity were requested on:

- the effect of dental fluorosis on the structural integrity of teeth and whether it is a sign that other parts of the body may be affected
- the chemicals used to fluoridate drinking water and whether they are toxic/waste products
- the FRG and NHMRC's declarations of interest and potential biases in favour of water fluoridation
- how the evidence was interpreted, especially in regards to cognitive or intelligence deficits, kidney damage and thyroid problems
- the appropriateness of the inclusion and exclusion criteria, particularly to the exclusion of in-vitro and animal studies
- the mechanism of actions of fluoride in drinking water in preventing tooth decay
- whether water fluoridation is mass medication and requires informed individual consent.

Council gave regard to these submissions and the advice of the FRG at its 16 March 2017 session.

The citations received were assessed against specified inclusion criteria (as per the advertised scope of public consultation below) and considered by the FRG. The key reasons for being excluded were: being published prior to 1 October 2006, being the wrong sort of study (e.g. a narrative review, animal study or non-scientific) and/or the studies having already been considered in the 2016 Evidence Evaluation Report.

A total of eight references are included in the Information Paper (see **Appendix B**). Their inclusion was based on the FRG's assessment that the evidence was relevant to Australia and was important for decision making.

5.3.4. Independent Expert Review (February - March 2017)

After comments from public consultation were incorporated, the draft Information Paper was reviewed by six independent expert reviewers (see 4. Independent and Contracted Services). The expert reviewers were required to declare any potential interests as per the process outlined for FRG members.

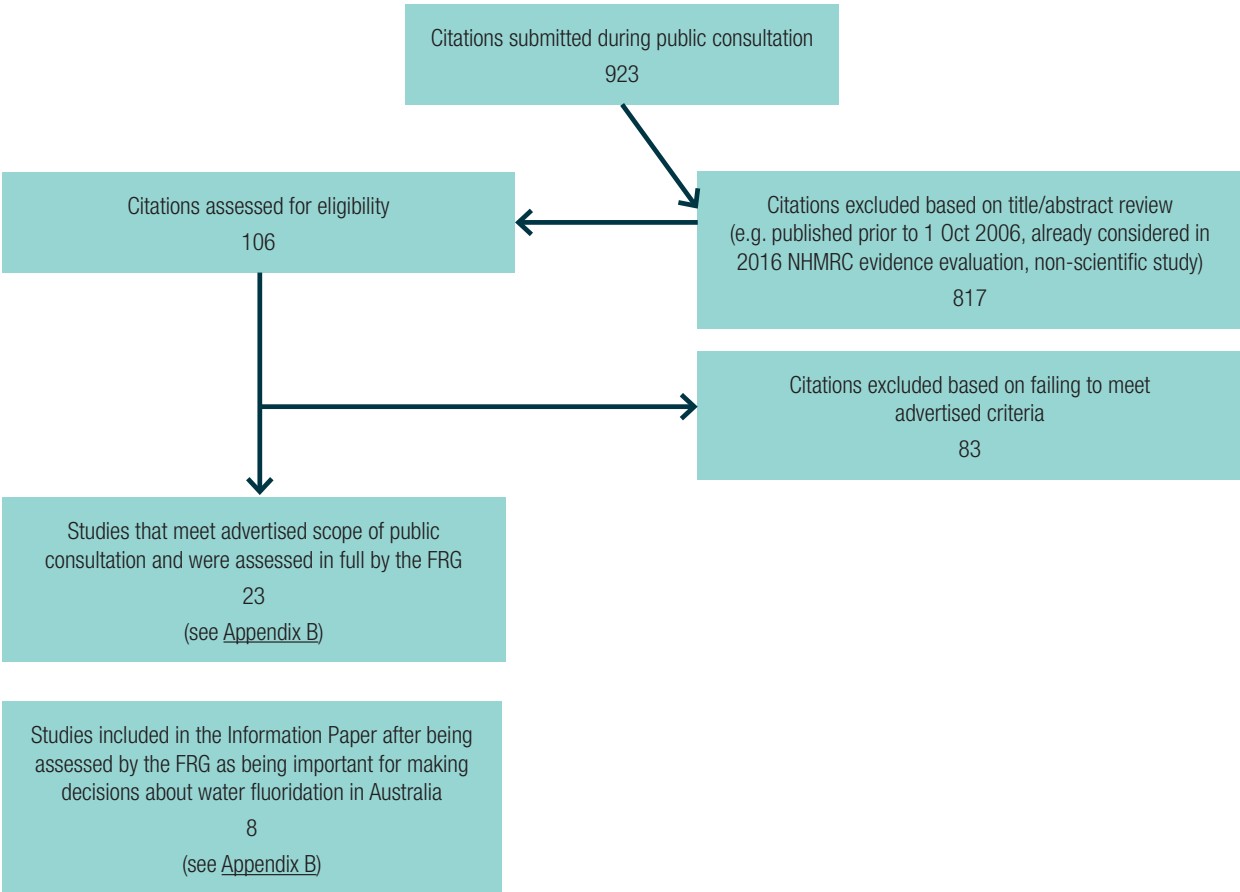
Expert reviewers were asked to check that the FRG had appropriately interpreted the evidence, applied GRADE and considered comments from public consultation. The expert reviewers were also asked to comment on the appropriateness of the Information Paper for the target audiences and to provide any extra evidence that they thought should have been considered. Five expert review reports were received (one report was co-authored by two reviewers).

^g While NHMRC could have disregarded any submissions that did not meet the scope/address the questions, FRG was prudent in considering all submissions received in full.

Key positive feedback was that:

- the draft Information Paper is generally readable and useful for the target audiences
- procedures followed by NHMRC to develop the Information Paper are comprehensive and scientifically robust
- FRG’s concerns/criticisms of the 2015 Cochrane review are appropriate
- most of the Evidence Statements show an appropriate translation of the evidence
- FRG’s application of GRADE to develop an overall conclusion is extensive, robust and of a high standard, and modifying it for public health was justified
- FRG has appropriately taken into account and responded to comments received during public consultation
- no evidence seems to have been missed
- the FRG’s inclusion of extra information (i.e. evidence that was not included in NHMRC’s 2016 evidence evaluation) under ‘Additional Considerations’ is appropriate and adds insight into the importance of water fluoridation.

Figure 3: Process for selecting literature submitted during the 2016 public consultation for consideration in the Information Paper



More information and/or consideration and/or clarity were requested on:

- improving the readability of some sections of the draft Information Paper, particularly the Plain Language Summary, to ensure it is suitable for community members with less than a tertiary level of education
- reviewing the conclusion that community water fluoridation at current Australian levels does not cause *any* health problems as it insinuate that all potential health effects have been examined and there was sufficient evidence to make definitive conclusions regarding each one
- checking some Evidence Statements to ensure a consistent approach was taken throughout, especially for the categories of 'the evidence shows no association' and 'insufficient evidence to reach a conclusion'
- making the methods for developing the Evidence Statements more transparent, including information on how evidence from the 2000 McDonagh review, 2007 NHMRC review and NHMRC's 2016 evidence evaluation were 'weighted'
- providing a more detailed evidence to decision/recommendation framework (if NHMRC makes a recommendation), showing each element of the GRADE 'balance of consequences' and justifying the strength of the recommendation
- the 23 citations that met the advertised scope of public consultation and the eight included in the Information Paper.

Feedback from independent expert review informed further revisions to the draft Information Paper, as advised by the FRG.

5.3.5. Governance and Stakeholder Involvement

Prior to public consultation, the draft Information Paper went to Council on 14 July 2016. Council recommended to the CEO that the draft Information Paper be released for public consultation, pending further consultation with jurisdictional health departments, which occurred throughout July and August 2016.

The final Information Paper was considered by Council out of session in May 2017 for recommendation to the CEO for issuing. The CEO accepted the Council's advice and issued the Information Paper on 4 July 2017.

5.4. Public Statement (2017)

The 2017 Public Statement updates and replaces NHMRC's 2007 Public Statement to reflect the recent evidence reviewed by NHMRC. Unlike the Evidence Evaluation Report and Information Paper, it contains NHMRC's recommendation on community water fluoridation, and a range within which NHMRC supports states and territories fluoridating their drinking water supplies.

The 2017 Public Statement was drafted by NHMRC with input from the FRG and jurisdictional health departments from February to May 2017. A draft was available for public consultation from 4 July to 3 August 2017.

Twenty eight submissions were received from a variety of stakeholders including 14 individuals and 14 organisations (three from state government health departments and 11 from non-government organisations). This feedback informed revisions to the draft Public Statement, as advised by a small subgroup of Council.

Where permission was granted by submitters, submissions were published on the NHMRC website at <https://consultations.nhmrc.gov.au>.

The final Public Statement was considered by the Council on 12 October 2017 for recommendation to the CEO for issuing. The CEO accepted the Council's advice and agreed to issue the Public Statement.

5.5. Questions and Answers resource (2017)

To foster consistent messages on water fluoridation and human health between the various states and territories, and support the release of the 2017 Public Statement, NHMRC worked with the jurisdictional health departments throughout 2017 to develop a national set of Questions and Answers. These were considered by Council on 12 October 2017, prior to seeking a recommendation to the CEO that they be publically released. The Questions and Answers contain answers to commonly asked questions about water fluoridation and its use in Australia.

Appendix A: Fluoride Reference Group Disclosure of Interests

Members' relevant expertise and a summary of their disclosed interests were accessible on the NHMRC website throughout the duration of the project. These details are provided below and were current for the FRG's term of appointment from 31 May 2014 to 30 May 2017.

Emeritus Professor Judith Whitworth AC FTSE (Chair)

Emeritus Professor, John Curtin School of Medical Research, Australian National University

Relevant experience:

- Former Director and Howard Florey Professor of Medical Research, John Curtin School of Medical Research, Australian National University
- Previously Chief Medical Officer of the Commonwealth and Chair of the World Health Organization's Global Advisory Committee on Health Research
- Research interests include hypertension, systems physiology, public policy, preventive medicine, public health and health services

Summary of disclosed interests:

- Chairs an advisory committee for the Australian and New Zealand Clinical Trials Registry
- Member of the Board of Therapeutic Innovation Australia

Professor Vicki Anderson

Director, Clinical Sciences Research, Murdoch Children's Research Institute

Director, Psychology, Royal Children's Hospital

Professorial Fellow, School of Psychological Sciences, University of Melbourne

Relevant experience:

- Paediatric neuropsychologist whose research focuses on disorders of childhood that impact on the central nervous system
- Member of the Australian Health Ethics Committee, a Principal Committee of NHMRC, in the 2012-15 triennium

Summary of disclosed interests:

- No interests disclosed

Doctor Meenakshi Arora

Lecturer in Environmental Engineering, Melbourne School of Engineering, University of Melbourne

Relevant experience:

- Environmental engineer with research expertise in urban water management and water quality
- Contributed to the development of a de-fluoridation plant to provide safe drinking water to communities in rural India which are exposed to high levels of naturally occurring fluoride

Summary of disclosed interests:

- Has published studies regarding fluoride in water and its possible effects on human health
- Appointed as Guest Editor for a special issue “The Health Effects of Water Fluoridation” in the International Journal of Environmental Research and Public Health in 2016

Associate Professor Stephen Corbett

Director, Centre for Population Health, Western Sydney Local Health District
Conjoint Associate Professor, School of Public Health, University of Sydney and Western Clinical School, Westmead

Relevant experience:

- Public and environmental health physician
- Research interests include environmental health risk assessment and management, regulatory policy and practice, chronic disease prevention, air and water quality and health, environmental lead contamination and remediation, bioaerosols, food borne illness and Aboriginal health

Summary of disclosed interests:

- Member of the Australian Faculty of Public Health Medicine
- Former non-executive Board Member, Sydney Catchment Authority
- Current non-executive Board Member, Food Standards Australia and New Zealand
- Co-authored a 1993 paper on fluoride and health in NSW

Professor Dallas English

Professor of Epidemiology and Biostatistics, Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, University of Melbourne

Research Fellow, Cancer Epidemiology Centre, Cancer Council Victoria

Relevant experience:

- Epidemiologist specialising in cancer epidemiology and cancer screening
- Senior Principal Research Fellow, Cancer Council Victoria

Summary of disclosed interests:

- No interests disclosed

Professor Matthew Gillespie

Professor, Faculty of Medicine, Nursing and Health Sciences, Monash University

Relevant experience:

- Cell biologist with research expertise in bone cell biology and bone cancers
- Former Director and Head of Bone, Joint and Cancer, Prince Henry’s Institute
- Past President, Australian and New Zealand Bone and Mineral Society

Summary of disclosed interests:

- Member of NHMRC Audit Committee

Associate Professor Sharon Goldfeld

Paediatrician, Centre for Community Child Health, Royal Children's Hospital
Co-Group Leader, Policy Equity and Translation, Murdoch Children's Research Institute

Professor, Department of Paediatrics, Faculty of Medicine Dentistry and Health Sciences, University of Melbourne

Relevant experience:

- Paediatrician and public health physician
- Research interests include child health and development, equity and intervention studies
- Senior Medical Advisor to the Victorian Department of Education and Early Childhood Development

Summary of disclosed interests:

- Co-authored an oral health position statement for the Royal Australasian College of Physicians and spoke at the launch of the position statement

Professor Alison Jones

Executive Dean, Faculty of Science, Medicine and Health, University of Wollongong
Clinical Toxicologist, Blacktown Hospital

Relevant experience:

- Clinical toxicologist
- Research expertise includes public health, poisons, risk assessment and preventive medicine

Summary of disclosed interests:

- Member of the Board for the Australian Strategic Policy Institute and for Medical Deans Australia and New Zealand
- Received fees for providing advice to Coroners NSW and the Australian Medical Council
- Has held NHMRC research grants
- Is contracted to provide NSW Health with toxicology advice, including advice on fluoride. The money from this contract goes into a University of Wollongong research fund which provides research costs and educational travel costs for staff and students for the School of Medicine, including Professor Jones. Professor Jones authorises expenditure on those funds, except where she is a beneficiary, which is then reviewed and signed by the Senior Deputy Vice Chancellor
- Assisted the NSW Chief Health Officer with education initiatives about the benefit/ risk of water fluoridation in 2013, and the Ballina/ Byron Bay open meeting in 2014
- Appointed to The Fluoridation of Public Water Supplies Advisory Committee for NSW, which provides advice on water fluoridation to the NSW Government

Associate Professor Frederic Leusch

Associate Professor and Head of Discipline, Soil Water and Energy, School of Environment, Griffith University

Relevant experience:

- Environmental toxicologist
- Research expertise includes biotechnology, endocrine disruption and health risk assessment of alternate water sources (purified recycled water, managed aquifer recharge, storm water)
- Former Program Leader for Water Quality and Diagnostics at the Smart Water Research Centre, Griffith University

Summary of disclosed interests:

- Received consultancy fees from the water industry for work unrelated to fluoride
- Has held grants from the water industry for work unrelated to fluoride
- Teaches students about water quality issues at Griffith University
- Chair of the NHMRC Water Quality Advisory Committee
- Appointed to the Project Review Team of Water Research Australia
- Has been the Associate Editor on environmental toxicology for Chemosphere since 2014

Professor Mike Morgan^h

Head of School, Melbourne Dental School, University of Melbourne

Relevant experience:

- Master's degree and a PhD in the area of dental public health and epidemiology
- Research expertise includes the causes and prevention of oral disease, oral health informatics and clinical trials of dental caries preventive agents

Summary of disclosed interests:

- Involved in the Australian Research Centre for Population Oral Health School of Dentistry Workshop on the Use of Fluorides in Australia 2012
- Lectures on Population Oral Health at the University of Melbourne
- Member of the Victorian Department of Health Fluoride Reference Group
- Involved with the Public Health Association Australia
- Board member of VicHealth
- A Director on the Australian Dental Council

Adjunct Professor Kaye Roberts-Thomson

School of Dentistry, University of Adelaide

Relevant experience:

- Oral health epidemiologist
- Research expertise includes public health interventions, Aboriginal health, health promotion, inequality in oral health and access to dental care

Summary of disclosed interests:

- Has published studies and reports, and spoken publically about fluoridated water and its effects on oral health
- Involved in the development of pamphlets and information sheets on fluorides and dental decay, co-funded by the University of Adelaide and Colgate Oral Care
- NHMRC grants for research regarding the effects of fluoride and fluoridated water on oral health
- Former Director of the Dental Practice Education and Research Unit, Australian Research Centre for Population Oral Health. The Dental Practice Education and Research Unit is a joint venture between the University of Adelaide and Colgate Oral Care
- Co-Chair of the Australian chapter of the Alliance for a Cavity-Free Future which is a group of experts promoting caries prevention and management for all age groups. While the alliance receives some sponsorship from the Colgate Oral care, she receives no remuneration for this position

^h Resigned on 25 July 2016 due to other work commitments.

Professor Wendy Rogers

Professor of Clinical Ethics, Department of Clinical Medicine and Department of Philosophy, Macquarie University

Relevant experience:

- Bioethicist with expertise in public health ethics, the ethics of evidence-based health care, vulnerable populations, justice in research and conflicts of interest
- Member of the Australian Health Ethics Committee, a Principal Committee of NHMRC, in the 2012-15 triennium

Summary of disclosed interests:

- No interests disclosed

Emeritus Professor A. John Spencer

Professor of Social and Preventive Dentistry, School of Dentistry, University of Adelaide

Relevant experience:

- Former Professor of Social and Preventive Dentistry and the Founding Director of the Australian Research Centre for Population Oral Health, University of Adelaide
- Research expertise includes dental public health and dental services, dental caries and fluorosis, oral health and quality of life and oral epidemiology

Summary of disclosed interests:

- Deputy Chair of the National Advisory Council on Dental Health 2011-2012
- Editorship of the journal Community Dentistry and Oral Epidemiology
- Co-led the Australian Research Centre for Population Oral Health 2005 Workshop on the use of fluorides in Australia
- Presented at the Australian Research Centre for Population Oral Health 2012 Fluoride Consensus Workshop and co-developed the subsequent publication on the Outcome of the Fluoride Consensus Workshop 2012 to review the Fluoride Guidelines from 2005 published in the Australian Dental Association News Bulletin 2013
- Gave lectures on Water Fluoridation to students at the University of Adelaide
- Examined PhD theses related to fluorides, caries and fluorosis
- Held an unpaid advisory role contributing to the update of the Federation Dentaire Internationale Policy Statement on Promoting Oral Health through Water Fluoridation
- Expert Witness on water fluoridation in the Land and Environment Court of NSW cases of Rous Water and Euorobodalla Shire Council
- Member and received consulting fees from the Nutritional Reference Values Fluoride Expert Working Group 2013-2014 for revision of the Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes
- Received lecture honorariums and travel costs from the New Zealand Dental Association for continuing professional education lectures on water fluoridation, and honorarium for paper and presentation at International Association for Dental Research 2017 symposium on Guidelines for fluoride intake
- Consulting, National Oral Health Project, Primary Health Care Organization, Qatar
- Received the Burrow Award for caries prevention involving the use of fluorides in 2012 from the International Association for Dental Research

- Received the Distinguished Scientist Award from the Behavioural, Epidemiologic and Health Services Research Group in 2013 from the International Association for Dental Research
- Has held a research grant from Queensland Health and multiple NHMRC grants for research regarding fluoridation and dental services. Some of these research projects have received support from Colgate Oral Care in the form of oral care gift packs for participants in oral examinations
- Has published studies and co-authored reports related to water fluoridation and fluorides
- Has been associated with the Australian Research Centre for Population Oral Health, Dental Practice Education Research Unit that promotes prevention in dental practice with the institutional support of Colgate Oral Care
- Associated with the Australian Dental Association

Professor Frederick Wright

Associate Director and Clinical Professor, Centre for Research and Education on Ageing, Concord Clinical School, University of Sydney and Concord General and Repatriation Hospital

Relevant experience:

- Research expertise in health promotion, geriatric dentistry, and ageing and dental service utilisation
- Former Chair of the National Oral Health Promotion Advisory Committee and a former Chief Dental Officer for the NSW Government

Summary of disclosed interests:

- Has published studies related to water fluoridation/fluorides and dental health.
- Presented a lecture series on Dental Public Health to students at Charles Sturt University and other universities.
- Provided expert testimony to the Land and Environment Court of NSW during the proceedings of *Oshlack v Rous Water, Ballina Shire Council, Lismore, 2011 – 2012.*
- Has been involved in the development of guidelines and other materials for NSW Health as Chief Dental Officer from 2005 – 2012.
- Is associated with the Australian Dental Association, the Public Health Association of Australia, the International Association for Dental Research, and the Royal Australasian College of Dental Surgeons.

Ms Debra Petrys (Consumer Nominee)

Member, Consumers Health Forum Australia

Relevant experience:

- Nominated by the Consumers Health Forum Australia as a Member suitable to provide a consumer perspective to the Fluoride Reference Group
- Worked in public health for many years
- Former General Manager of National Programs for the Council on the Ageing

Summary of disclosed interests:

- No interests disclosed

Appendix B: Studies that Met the Advertised Scope for Public Consultation on the draft Information Paper and FRG's Assessment

Citation	FRG advice	FRG decision to include/ exclude from the Information Paper
1 Barnett-Rose R. Compulsory water fluoridation: Justifiable public health benefit or human experimental research without informed consent? Wm & Mary Envtl L & Pol'y Rev, 2014; 39: 201	Not a scientific study – rather it is a narrative that explores various legal issues, not necessarily ethics, about water fluoridation.	Exclude
2 Bin G, Liu H, Zhao C, Zhou G, Ding X, Zhang N, et al. Refractive errors in northern China between the residents with drinking water containing excessive fluorine and normal drinking water. Biol Trace Elem Res. 2016; 173(2): 259-67.	NHMRC's 2016 Evidence Evaluation did not find any outcomes regarding refractive errors. This study also concluded that the refractive errors did not result from ingestion of mild to excessive amounts of fluoride in the drinking water, so adds no value.	Exclude
3 Cornwell DA, McTigue NE and Hayes S. State of the science: community water fluoridation. Colorado: Water Research Foundation, 2015.	Recent review of the benefits and harms of water fluoridation in US.	Include
4 Crouchley K and Trevithick R. Dental health outcomes of children residing in fluoridated and non-fluoridated areas of Western Australia. Western Australia: Department of Health, 2016.	Relates to prevalence of dental caries in children associated with access to fluoridated water.	Include
5 de Almeida ME, Teixeira AK, Alencar CH, Paiva SM, and Abreu MH. Agreement between parents and adolescents on dental fluorosis: a population-based study. Braz Oral Res, 2013; 27(2): 91-6.	Based in Brazil so lacks relevance and not applicable to perceptions of dental fluorosis in Australia.	Exclude
6 de Castilho LS, e Ferreira EF, and Perini E. Perceptions of adolescents and young people regarding endemic dental fluorosis in a rural area of Brazil: psychosocial suffering. Health Soc Care Community, 2009;17(6): 557-63.	Based in Brazil so lacks relevance and not applicable to perceptions of dental fluorosis in Australia.	Exclude
7 Fluegge K. Community water fluoridation predicts increase in age adjusted incidence and prevalence of diabetes in 22 states from 2005 and 2010. J Water Health, 2016; 14(5): 864-77.	Water fluoridation levels above those used in Australia. Diabetes was not an outcome found in NHMRC's 2016 Evidence Evaluation. Study very difficult to understand.	Exclude

Citation	FRG advice	FRG decision to include/exclude from the Information Paper
8 Gleber-Netto FO, Diniz IM, Mudado FA, Fraga MG and Vargas AM. Assessment of aesthetic perception of mild and moderate dental fluorosis levels among students from the Federal University of Minas Gerais-UFMG, Brazil. <i>Oral Health Prev Dent</i> , 2011; 9(4): 339-45.	Based in Brazil so lacks relevance and not applicable to perceptions of dental fluorosis in Australia.	Exclude
9 Hart R, Feelemyer J, Gray C, Lodise T, Patel N, Wymer S, McNutt LA. Relationship between municipal water fluoridation and preterm birth in Upstate New York. Abstract presented at American Public Health Association November 7-9, 2009.	Conference abstract is over five years old, and no published paper has resulted. Preterm birth was not an outcome detected in NHMRC's 2016 Evidence Evaluation.	Exclude
10 Jaguar Consulting on behalf of the Department of Health and Human Services. Impact analysis: Expanding water fluoridation in Victoria. Unpublished, 2016.		Include
11 Kavand G, Broffitt B, Levy SM and Warren JJ. Comparison of dental aesthetic perceptions of young adolescents and their parents. <i>J Public Health Dent</i> . 2012; 72(2):164-71.	Lacks relevance and not applicable to perceptions of dental fluorosis in Australia. Not just about fluorosis, but the shape of teeth.	Exclude
12 Malin AJ and Till C. Exposure to fluoridated water and attention deficit hyperactivity disorder prevalence among children and adolescents in the United States: an ecological association. <i>Environ Health</i> , 2015; 14: 17.	Does not control for confounding factors (e.g. did not take account of socioeconomic status (SES) other sources of fluoride exposure, exposure to other contaminants etc.) It assumes SES, exposure to fluoride and diagnosis of ADHD are the same across a population. It lacks a plausible hypothesis and the outcomes are largely a result of a trawling exercise. Refers to overseas countries with high to very high levels of fluoride. ADHD was not an outcome revealed in NHMRC 2016 Evidence Evaluation.	Exclude
13 McLaren L, McNeil DA, Potestio M, Patterson S, Thawer S, Faris P et al. Equity in children's dental caries before and after cessation of community water fluoridation: differential impact by dental insurance status and geographic material deprivation. <i>Int J Equity Health</i> , 2016; 15: 24.	Unclear presentation of results. Has methodological limitations, and while its methodology will not be formally assessed, it is likely to have a high risk of bias. Could add value to the inequalities section.	Include
14 Moore D and Poynton M. Review of the benefits and costs of water fluoridation in New Zealand. Report prepared for the Ministry of Health, 2015.	New Zealand study with relevance to Australia.	Include
15 Peckham S, Lowery D and Spencer S. Are fluoride levels in drinking water associated with hypothyroidism prevalence in England? A large observational study of GP practice data and fluoride levels in drinking water. <i>J Epidemiol Community Health</i> , 2015; 69(7): 619-24.	Published after the cut off for the 2016 NHMRC Evidence Evaluation. Has several methodological limitations.	Include

Citation	FRG advice	FRG decision to include/ exclude from the Information Paper
16 Peres MA, Peres KG, Barbato PR and Hofelmann DA. Access to fluoridated water and adult dental caries: A natural experiment. J Dent Res, 2016; 95(8): 868-74.	Good longitudinal analysis. Contributes to the scant information about tooth decay in adults and water fluoridation. Published after the cut-off for the formal evidence evaluation, so its methodology will not be formally assessed. It is a prospective cohort study that is likely to be of moderate quality.	Include
17 Rocha Amador D, et al. Evaluation of thyroid hormones (TSH and T4) in pregnant women exposed to fluoride (F-) in drinking water. Abstract of Presentation at 27th Conference of the International Society for Environmental Epidemiology Publish. August 30 - September 3, 2015.	Water fluoridation levels in this study were much higher than Australia and there is insufficient data to draw any conclusions.	Exclude
18 Sachdeva S, Ahmed J and Singh B. Thyroid dysfunction associated with excess fluoride intakes: scope for primary prevention. Thyroid Research and Practice, 2016; 13(3): 119-25.	Does not compare areas with two levels of fluoride.	Exclude
19 Schulter 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; 16: 21.	Could add value to the inequality discussion in the Information Paper.	Include
20 Sebastian S.T and Sunitha S. A cross-sectional study to assess the intelligence quotient (IQ) of school going children aged 10-12 years in villages of Mysore district, India with different fluoride levels. J Indian Soc Pedod Prev Dent, 2015; 33(4): 307–11.	Does not correct for confounding factors. This means a low confidence in the results.	Exclude
21 Sudhir KM, Chandu GN, Prashant GM and Subba Reddy VV. Effect of fluoride exposure on intelligence quotient (IQ) among 13-15 year old school children of known endemic area of fluorosis, Nalgonda District, Andhra Pradesh. Journal of the Indian Association of Public Health Dentistry, 2009 (13): 88-94.	In general, studies that come from India and China have not been comparable as the levels of fluoride are normally much higher; however this study shows levels that are more applicable to Australian levels. It included four different levels of water fluoridation. Although the study has more applicable levels, the study is flawed as it does not correct for confounding factors. This means a low confidence in the results.	Exclude
22 Tellez M, Santamaria RM, Gomez J, and Martignon S. Dental fluorosis, dental caries, and quality of life factors among schoolchildren in a Colombian fluorotic area. Community Dent Health, 2012; 29(1): 95-9.	Based in Colombia, where dental fluorosis is moderate or severe and there are cultural differences. Lacks relevance and not applicable to perceptions of dental fluorosis in Australia. Study does not consider confounders such as straightness of teeth.	Exclude
23 Zhang S, Zhang X, Liu H, Qu W, Guan Z, Zeng Q et al. Modifying effect of COMT gene polymorphism and a predictive role for proteomics analysis in children's intelligence in endemic fluorosis area in Tianjin, China. Toxicol Sci, 2015; 144(2): 238–45.	Based on urine and serum measures. Does not correct for confounding factors and the analysis of water fluoridation is uncontrolled. This means a low confidence in the results.	Exclude

References

- 1 Jack B, Ayson M, Lewis S, Irving A, Agresta B, Ko H, et al. Health effects of water fluoridation: Evidence evaluation report. Report to the National Health and Medical Research Council (NHMRC). Canberra: NHMRC; 2016. <https://www.nhmrc.gov.au/files_nhmrc/file/your_health/fluoridation/20160824_evidence_report_final_1.pdf>
- 2 Jack B, Ayson M, Lewis S, Irving A, Agresta B, Ko H, et al. Health effects of water fluoridation: Technical report. Report to the National Health and Medical Research Council (NHMRC). Canberra: NHMRC; 2016. <https://www.nhmrc.gov.au/files_nhmrc/file/your_health/fluoridation/20160824_technical_report_final_0.pdf>
- 3 National Health and Medical Research Council. Information Paper - Water fluoridation: dental and other human health outcomes. Report prepared by the Clinical Trials Centre at University of Sydney. Canberra: NHMRC; 2017. <<https://www.nhmrc.gov.au/health-topics/health-effects-water-fluoridation>>
- 4 National Health and Medical Research Council. NHMRC Public Statement 2017: Water fluoridation and human health in Australia. <<https://www.nhmrc.gov.au/health-topics/health-effects-water-fluoridation>>
- 5 National Health and Medical Research Council. Water fluoridation and human health in Australia: Questions and Answers. <<https://www.nhmrc.gov.au/health-topics/health-effects-water-fluoridation>>
- 6 National Health and Medical Research Council. A systematic review of the efficacy and safety of fluoridation. Canberra: NHMRC; 2007. <http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/eh41_1.pdf>
- 7 National Health and Medical Research Council. NHMRC public statement: The efficacy and safety of fluoridation 2007. Canberra: NHMRC; 2007. <https://www.nhmrc.gov.au/files_nhmrc/publications/attachments/eh41_statement_efficacy_safety_fluoride.pdf>
- 8 McDonagh, M and Whiting, P et al. A Systematic Review of Public Water Fluoridation. University of York: NHS Centre for Reviews and Dissemination, 2000. <<http://www.nhs.uk/Conditions/Fluoride/Documents/crdreport18.pdf>>
- 9 Iheozor-Ejiofor, Z and Worthington, HV et al. Water fluoridation for the prevention of dental caries. University of York: The Cochrane Database of Systematic Reviews, 2015. <http://www.cochrane.org/CD010856/ORAL_water-fluoridation-prevent-tooth-decay>