HEALTH EFFECTS OF WATER FLUORIDATION

TECHNICAL REPORT

NHMRC CLINICAL TRIALS CENTRE

THE UNIVERSITY OF SYDNEY

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The NHMRC Clinical Trials Centre (CTC) is a not-for-profit, academic research organisation that coordinates and conducts investigator-initiated trials, involving researchers from Australia and internationally. The CTC upholds a core commitment to integrity and transparency in clinical trials research, including publication of our research independent of funder influence. The National Health and Medical Research Council (NHMRC) provided initial funding to establish the CTC and we participate in competitive grant processes (NHMRC's and others) to secure funding for our continuing research activities, which includes tenders for government projects such as systematic reviews and technical writing of health and medical information.

A team within the NHMRC which is separate from the grants management area of NHMRC is responsible for developing evidence-based clinical and public health guidelines and advice. It is this section of NHMRC that advertised for tenders from panellists of the NHMRC Health Evidence Panel to undertake this evaluation. The CTC participated in a transparent panel procurement process to win this contract to evaluate the evidence as documented in this report.

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OBJECTIVES OF THE EVIDENCE REVIEW

RATIONALE FOR THE REVIEW

Controversy around water fluoridation in Australia is sometimes elicited due to concerns focussed on ethical issues or possible harmful effects of fluoride. On 20 June 2013, attendees of an expert meeting on water fluoridation advised that NHMRC's 2007 Review (NHMRC 2007) should be updated and broadened to accommodate any new evidence on the health effects of water fluoridation published since 2006. Following this advice, at its meeting on 21 June 2013, the Council of NHMRC reaffirmed NHMRC's 2007 public statement and recommended that NHMRC update the body of evidence to include more recent studies and assess their relevance in the Australian context.

The rationale for this evidence evaluation is to update the evidence on the health effects of water fluoridation from NHMRC's 2007 Review (NHMRC 2007) to assist the NHMRC to provide evidence based guidance on the benefits and harms of water fluoridation.

HISTORY OF THE REVIEW

This review was initially commissioned as a systematic review of the health effects of water fluoridation, excluding dental effects paired with a critical appraisal of the Cochrane Review (Iheozor-Ejiofor et al 2015) on the dental effects of fluoride. It was anticipated that the Cochrane Review would provide the necessary data for the assessment of the dental effects of water fluoridation.

The Cochrane Review adopted similar criteria to the "York" review (McDonagh et al 2000) for the inclusion of studies. In both reviews, only prospective studies with a concurrent negative control, with at least two points in time evaluated and a change in fluoridation in the experimental arm were included. 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.

Therefore supplementary data was requested and a second review was commissioned to examine the effects of water fluoridation on dental caries. This review was undertaken in two parts; an overview of existing systematic reviews (including the Cochrane review) and a systematic review of recent primary studies. However, the existing Cochrane review was considered sufficient for the assessment of the effects of water fluoridation on dental fluorosis as the inclusion criteria were broader and so it likely did capture the contemporary evidence. No further searches or data extraction were undertaken for this outcome.

REVIEW ACTIVITIES

As set out in the research protocols, the review of the evidence for the health effects of water fluoridation includes the following activities:

1. To undertake a systematic review to identify and evaluate evidence on the dental effects of water fluoridation, which consists of:
    a. An overview of existing systematic reviews.
    b. A systematic review of recent primary studies.
2. To undertake a systematic review to identify and evaluate evidence on other possible health effects of water fluoridation.

RESEARCH QUESTIONS

The research questions for the systematic reviews were developed using the PICOS (Population, Intervention, Comparator, Outcome, Study type) method and approved by the Fluoride Reference Group. The research questions are:

1. What is the effect of water fluoridation (community water fluoridation between 0.4-1.5ppm) compared to a non-fluoridated water supply (defined as <0.4ppm,) on dental caries?
2. What are the health effects (excluding dental caries and dental fluorosis) of water fluoridation (community water fluoridation or naturally occurring) compared to a non-fluoridated water supply (defined as <0.4ppm) or fluoridation at a different level?

The PICOS criteria for the research questions, as specified in the research protocols are outlined in Table 1, Table 2 and Table 3.

Table 1 PICOS criteria for the evaluation of the dental effects of water fluoridation, overview of reviews

Criterion	Description
Population	Populations of all ages Subgroup analysis: Life stage: infants (ages 0-4), children (ages 5-11), adolescents (ages 12-17), adults (ages 18-64) and later adulthood age (ages 65+) People with special needs: including low income and social disadvantage Rural and remote communities
Intervention/Exposure	Drinking water with a fluoride level within current Australian levels (0.4ppm-1.5ppm)
Comparator	Non-fluoridated drinking water (<0.4ppm)
Outcome	Dental caries
Study type	Reviews of primary studies. To be included in this overview a review must include a systematic search that attempts to identify all relevant primary studies.

Abbreviations: ppm = parts per million

Table 2 PICOS criteria for the evaluation of the dental effects of water fluoridation, systematic review of primary studies

Criterion	Description
Population	Populations of all ages Subgroup analysis: Life stage: infants (ages 0-4), children (ages 5-11), adolescents (ages 12-17), adults (ages 18-64) and later adulthood age (ages 65+) People with special needs: including low income and social disadvantage Rural and remote communities
Intervention/Exposure	Drinking water with a fluoride level within current Australian levels (0.4ppm-1.5ppm)
Comparator	Non-fluoridated drinking water (<0.4ppm)
Outcome	Dental caries
Study type	Any comparative study that was not included in the reviews identified in the Overview of Reviews

Abbreviations: ppm = parts per million

Table 3 PICOS criteria for the evaluation of the health effects of water fluoridation

Criterion	Description
Population	Populations of all ages Subgroup analysis: • Life stage: infants (ages 0-4), children (ages 5-11), adolescents (ages 12-17), adults (ages 18-64) and later adulthood age (ages 65+) • People with special needs: including low income and social disadvantage • Rural and remote communities
Intervention/Exposure	Fluoride at any concentration present in drinking water
Comparator	1. Non fluoridated drinking water (<0.4ppm); or 2. Drinking water with a different concentration of fluoride.
Outcome	Any reported health effects (excluding dental caries and dental fluorosis) including: • Neuro-cognitive disorders • Dementia • Neuro-developmental disorders • All cancers (malignant neoplasms) other than bone cancer • Cancers of the bone, and specifically osteosarcoma • Congenital abnormalities • Skeletal effects • Mortality • Renal effects • Thyroid dysfunction • Any other adverse effects
Study type	Any comparative study design

Abbreviations: ppm = parts per million

LITERATURE SEARCH FOR DENTAL CARIES: OVERVIEW OF REVIEWS

ELECTRONIC DATABASE SEARCHES

All searches of electronic databases were performed on the 12th of November, 2015. The databases searched were:

- EMBASE.com (includes EMBASE and MEDLINE)
- PreMedline (via Ovid)
- PsycInfo (via Ovid)
- Global Health (via Ovid)
- EBM (Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effects, NHS Economic Evaluation Database, and Health Technology Assessment)

For each database, a systematic search strategy was developed to identify all relevant reviews of primary studies on the effect of water fluoridation on dental caries. Search strategies were designed using index terms and text words based on key elements of the research question and PICOS criteria (see Table 1). An additional study design (systematic review) filter was applied, adapted from the filter published by the NHMRC (1999). These search strategies were specified in the research protocol and no changes were made to the strategies prior to their implementation.

To identify reviews of primary studies on the effects of water fluoridation on dental caries, databases were searched from 1st October 2006 onwards, updating the search from the NHMRC (2007) review with a two-month overlap. If the database did not allow restriction by month of publication, then the search was conducted from 2006 onwards. The results of the database searches are presented in Table 4, Table 5, Table 6, Table 7 and Table 8. In total, 100 citations were retrieved from the database searches.

Table 4 Search performed using EMBASE.com

No	Terms	Citations
1	'fluoridation'/exp OR 'fluoridation'	6,548
2	fluorid*:ab,ti OR fluorin*:ab,ti OR flurin*:ab,ti OR flurid*:ab,ti	62,052
3	#1 OR #2	63,308
4	'water supply'/exp	30,787
5	water*:ab,ti	719,647
6	#4 OR #5	725,868
7	#3 AND #6	10,691
8	#7 AND ([systematic review]/lim OR [meta analysis]/lim)	22
9	'meta analysis.pt'	0
10	'meta anal'	8
11	metaanal	3
12	(quantitativ* AND review) OR (quantitative AND overview)	58,843
13	(systematic AND review) OR (systematic AND overview)	177,386
14	(methodologic* AND review) OR (methodologic* AND overview)	36,797
15	#9 OR #10 OR #11 OR #12 OR #13 OR #14	248,017
16	#7 AND #15	59

No	Terms	Citations
17	#8 OR #16	67
18	#17 AND [humans]/lim	62
19	#18 AND [1-10-2006]/sd	37

Table 5 Search performed using Psychinfo via Ovid

No	Terms	Citations
1	(fluorid$ or fluorin$ or flurin$ or flurid$).mp.	357
2	water$.mp.	34,078
3	1 and 2	76
4	limit 3 to human	52
5	limit 4 to yr="2006 -Current"	33

Table 6 Search performed using EBM Reviews (Cochrane Database of Systematic Reviews, Health Technology Assessment, NHS Economic Evaluation Database, ACP Journal Club, Database of Abstracts of Reviews of Effects) via Ovid

No	Terms	Citations
1	exp Fluoridation/	12
2	(fluorid$ or fluorin$ or flurin$ or flurid$).ti.	108
3	(fluorid$ or fluorin$ or flurin$ or flurid$).ab.	44
4	1 or 2 or 3	130
5	exp Water Supply/	28
6	water$.ti.	105
7	water$.ab.	138
8	5 or 6 or 7	226
9	4 and 8	26
10	limit 9 to yr="2006 -Current"	19

Table 7 Search performed using preMEDLINE via Ovid

No	Terms	Citations
1	(fluorid$ or fluorin$ or flurin$ or flurid$).mp.	9,072
2	water$.mp.	90,763
3	1 and 2	1,280
4	editorial.pt.	21,801
5	Letter.pt.	29,265
6	comment.pt.	43,692
7	4 or 5 or 6	83,979
8	3 not 7	1,258
9	((quantitativ* and review) or (quantitative and overview)).mp.	3,306
10	((systematic and review) or (systematic and overview)).mp.	115,857
11	((methodologic* and review) or (methodologic* and overview)).mp.	3,193
12	9 or 10 or 11	19,778
13	8 and 12	5
14	limit 13 to ("in data review" or in process or medline or oldmedline)	3

No	Terms	Citations
15	limit 14 to yr="2006 -Current"	3

Table 8 Search performed using Global Health via Ovid

No	Terms	Citations
1	exp Fluoridation/	453
2	(fluorid$ or fluorin$ or flurin$ or flurid$).ti.	3,014
3	(fluorid$ or fluorin$ or flurin$ or flurid$).ab.	5,517
4	1 or 2 or 3	5,922
5	exp Water Supply/	5,793
6	water$.ti.	34,294
7	water$.ab.	150,870
8	5 or 6 or 7	154,529
9	((quantitativ* and review) or (quantitative and overview)).af.	3,137
10	((systematic and review) or (systematic and overview)).af.	17,302
11	((methodologic* and review) or (methodologic* and overview)).af.	3,345
12	9 or 10 or 11	21,038
13	"man".od.	1,441,904
14	4 and 8 and 12 and 13	13
15	limit 14 to yr="2006 -Current"	8

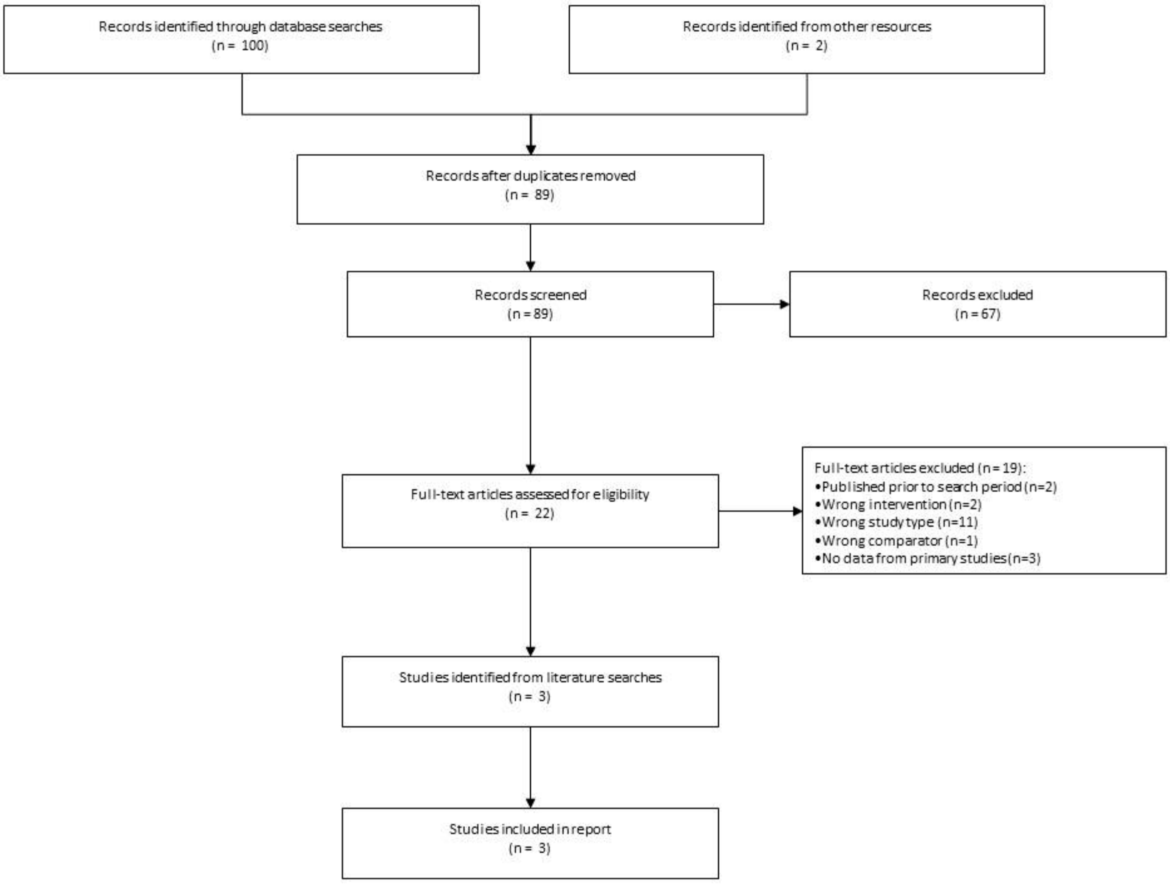
SEARCHING OF OTHER RESOURCES

As described in the research protocol, searches of additional relevant resources were conducted. General internet searches were conducted to identify relevant reports, guidelines and health technology assessments concerning water fluoride levels. The reference lists of all included reviews identified in the literature search were checked for additional studies. The searching of other resources identified two additional relevant studies that had not been identified in the database searches.

REVIEW OF CITATIONS

All citations retrieved from the searches of electronic databases and other resources were downloaded into Reference Manager Software. The 102 records were checked for duplicate citations. A total of 13 duplicate citations were removed, leaving 89 citations eligible for review. A summary of the citation review process is presented in Figure 3 and the stages of the review process are described in detail below. All citation review activities were carried out independently by two reviewers. Disagreements between the reviewers were resolved by discussion.

Figure 1 Summary of review of citations, overview of reviews



Review of titles and abstracts

All citations were initially reviewed by consideration of their title and abstract. In this stage studies were excluded based on the PICOS criteria specified in the research protocol. The criteria used to exclude irrelevant studies are presented in Table 9.

Table 9 Inclusion criteria used in the review of citations

Criterion	Explanation
Population	A study of human participants
Intervention	Fluoride in drinking water within current Australian levels (0.4 ppm 1.5 ppm)
Comparator	Non-fluoridated drinking water (<0.4 ppm)
Outcome	Dental caries
Study type	A review of primary studies. To be included in this overview a review must include a systematic search that attempts to identify all relevant primary studies.
Publication date	Published after 1st October 2006

Abbreviations: ppm = parts per million

Application of the criteria resulted in the exclusion of 67 citations. For the remaining 22 citations, the full text of the publication was retrieved for further review.

Review of full text

The 22 studies were assessed using the full text of the publication. See Figure 1 for a summary of the review process. Two studies had been published prior to the specified start date of 1st October, 2006 and were excluded.

The remaining studies were assessed against the exclusion criteria used in the review of titles and abstracts, leading to the exclusion of 17 studies as described below:

- Intervention: 2 studies were excluded because they did not assess fluoride in drinking water within current Australian levels (0.4ppm 1.5ppm).
- Study type: 12 studies were excluded due to being the wrong study type. Of these, 6 were economic evaluations, 5 did not use systematic methods to identify primary studies and one included non-comparative studies only.

A further three studies were excluded because they did not report any data for their included primary studies.

STUDIES INCLUDED FROM THE LITERATURE SEARCH

The literature search resulted in the inclusion of three studies. The citations for these studies are listed in Table 33 on page 56.

LITERATURE SEARCH FOR DENTAL CARIES: SYSTEMATIC REVIEW OF RECENT PRIMARY STUDIES

ELECTRONIC DATABASE SEARCHES

All searches of electronic databases were performed on the 17th of November, 2015. The databases searched were:

- EMBASE.com (includes EMBASE and MEDLINE)
- PreMedline (via Ovid)
- PsycInfo (via Ovid)
- Global Health (via Ovid)
- EBM (Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effects, NHS Economic Evaluation Database, and Health Technology Assessment)

For each database, a systematic search strategy was developed to identify all relevant primary studies on the effect of water fluoridation on dental caries. Search strategies were designed using index terms and text words based on key elements of the research question and PICOS criteria (see Table 2).

To identify primary studies on the effects of water fluoridation on dental caries, databases were searched from 1st October 2006 onwards, updating the search from the NHMRC (2007) review with a two-month overlap. If the database did not allow restriction by month of publication, then the search was conducted from 2006 onwards. The results of the database searches are presented in Table 10, Table 11, Table 12, Table 13, Table 14 and Table 15. In total, 1568 citations were retrieved from the database searches.

Table 10 Search performed using EMBASE.com

No	Terms	Citations
1	exp Fluoridation/ or Fluoridation.af.	12,670
2	(fluorid* or fluorin* or flurin* or flurid*).ab,ti.	108,197
3	1 or 2	110,626
4	exp water supply/	60,521
5	"water*".ab,ti.	1,227,954
6	4 or 5	1,239,969
7	3 and 6	18,515
8	exp dental caries/	82,443
9	'tooth deminerali?ation'.af.	1,966
10	'dmf index'.af.	8,892
11	(dmft or dmfs or dft or dfs).af.	61,510
12	((tooth or teeth or dent*) and (caries or carious or decay or deminerali* or cavit*)).af.	156,187
13	caries.af.	98,098
14	8 or 9 or 10 or 11 or 12 or 13	213,473
15	7 and 14	5,070
16	limit 15 to yr="2006 -Current"	1,298
17	limit 16 to human	1,059

Table 11 Search performed using Psychinfo via Ovid

No	Terms	Citations
1	(fluorid$ or fluorin$ or flurin$ or flurid$).mp.	357
2	water$.mp.	34105
3	1 and 2	76
4	limit 3 to human	52
5	limit 4 to yr="2006 -Current"	33

Table 12 Search performed using All EBM via Ovid

No	Terms	Citations
1	exp Fluoridation/	43
2	(fluorid$ or fluorin$ or flurin$ or flurid$).ti.	2,303
3	(fluorid$ or fluorin$ or flurin$ or flurid$).ab.	2,071
4	1 or 2 or 3	3,318
5	exp Water Supply/	146
6	water$.ti.	2,587
7	water$.ab.	11,819
8	5 or 6 or 7	12,601
9	exp dental caries/	1,542
10	caries.af.	3,582
11	'tooth demineral?ation'.af.	321
12	(dmft or dmfs or dft or dfs).af.	1,773
13	((tooth or teeth or dent*) and (caries or carious or decay or demineral* or cavit*)).af.	5,271
14	9 or 10 or 11 or 12 or 13	7,085
15	4 and 8 and 14	141
16	limit 15 to yr="2006 -Current" [Limit not valid in DARE; records were retained]	56

Table 13 Search performed using All EBM via Ovid

No	Terms	Citations
1	(fluorid$ or fluorin$ or flurin$ or flurid$).af.	9,107
2	water$.af.	98,074
3	1 and 2	1,307
4	Caries.af.	2,796
5	3 and 4	92
6	limit 5 to yr="2006 -Current"	83

Table 14 Search performed using preMEDLINE via Ovid

No	Terms	Citations
1	(fluorid$ or fluorin$ or flurin$ or flurid$).af.	9,107
2	water$.af.	98,074
3	1 and 2	1,307
4	Caries.af.	2,796
5	3 and 4	92
6	limit 5 to yr="2006 -Current"	83

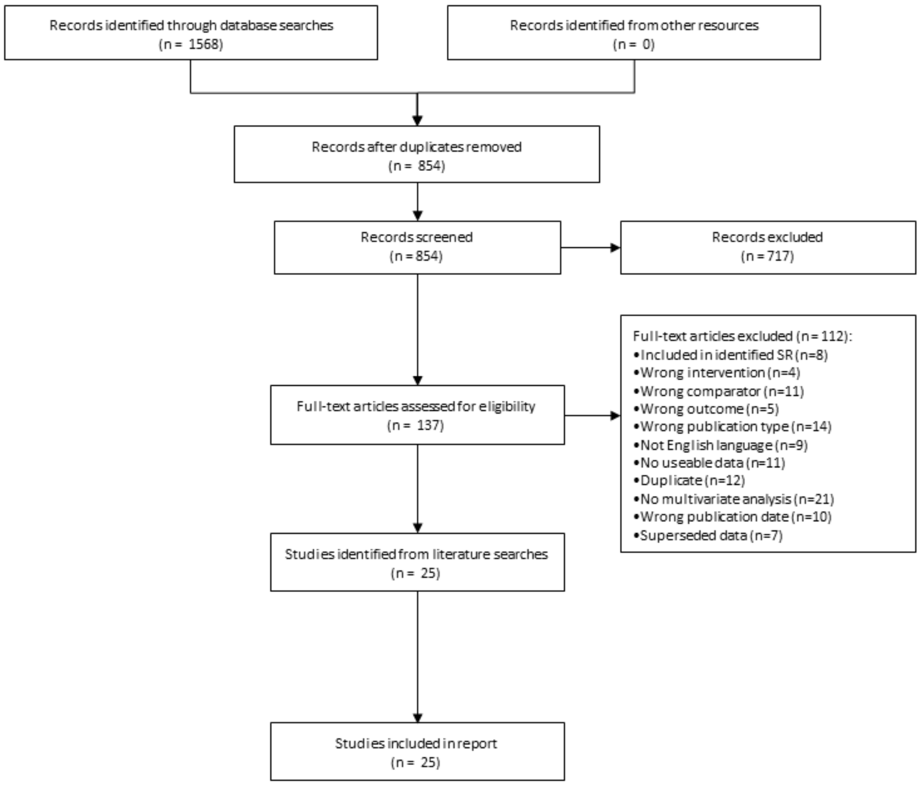
Table 15 Search performed using Global Health via Ovid

No	Terms	Citations
1	exp Fluoridation/	875
2	(fluorid$ or fluorin$ or flurin$ or flurid$).af.	9745
3	1 or 2	9745
4	exp Water Supply/	9609
5	water$.af.	256455
6	4 or 5	256455
7	3 and 6	4492
8	exp dental caries/	8280
9	caries.af.	9563
10	'tooth demineral?ation'.af.	13
11	(dmft or dmfs or dft or dfs).af.	1665
12	((tooth or teeth or dent*) and (caries or carious or decay or demineral* or cavit*)).af.	11637
13	8 or 9 or 10 or 11 or 12	12431
14	7 and 13	1216
15	limit 14 to yr="2006 -Current"	337

REVIEW OF CITATIONS

All citations retrieved from the searches of electronic databases and other resources were downloaded into Reference Manager software. The 1568 records were checked for duplicate citations. A total of 714 duplicate citations were removed, leaving 854 citations eligible for review. A summary of the citation review process is presented in Figure 2 and the stages of the review process are described in detail below. All citation review activities were carried out independently by two reviewers. Disagreements between the reviewers were resolved by discussion.

Figure 2 Summary of review of citations, systematic review of recent primary studies



Review of titles and abstracts

All citations were initially reviewed by consideration of their title and abstract. In this stage studies were excluded based on the PICOS criteria specified in the research protocol. The criteria used to exclude irrelevant studies are presented in Table 16.

Table 16 Inclusion criteria used in the review of citations

Criterion	Explanation
Population	A study of human participants
Intervention	Fluoride in drinking water
Comparator	Compares: Fluoride within current Australian levels (0.4 ppm–1.5 ppm) vs. unfluoridated water (<0.4 ppm)
Outcome	Dental caries
Study type	A comparative study design
Publication type	Published after 1st October 2006 Not included in the reviews identified in the overview of reviews

Abbreviations: ppm = parts per million

Application of the criteria resulted in the exclusion of 717 citations. For the remaining 137 citations, the full text of the publication was retrieved for further review.

Review of full text
The 137 studies were assessed using the full text of the publication. Eight studies had been published prior to the specified start date of 1st October, 2006 and two were re-publications of studies originally published prior to this start date and were excluded.

The remaining studies were assessed against the exclusion criteria used in the review of titles and abstracts, leading to the exclusion of 102 studies as described below:

- Intervention: 3 studies were excluded because they did not assess fluoride in drinking water within current Australian levels (0.4ppm-1.5ppm) and 1 other study the intervention was not water fluoridation.
- Comparator: 11 studies were excluded because the comparator was not <0.4 ppm fluoride
- Publication type: 14 studies were excluded due to being the wrong study type. Of these, 5 were narrative reviews, 3 were commentaries, 4 were conference abstracts or proceedings, 1 was an interview and 1 was a letter.
- Included in identified systematic review: 8 studies were excluded as they had been included in a systematic review already identified
- Wrong outcome: 2 studies were excluded due to not measuring dental caries and 3 studies due to not measuring dental caries with a valid measure.
- Duplicate: 12 studies were identified as duplicates
- Not in English: 9 studies were excluded as they were not published in English
- No multivariate analysis: 21 studies were excluded because they did not conduct a multivariate analysis including known confounders
- No useable data: 11 studies were excluded for not having any useable data
- Superseded data: 7 studies were excluded because a more recent study had been identified using the same survey data.

STUDIES INCLUDED FROM THE LITERATURE SEARCH

The literature search resulted in the inclusion of 25 studies. The citations for these studies are listed in Table 34 on page 56.

LITERATURE SEARCH FOR OTHER HEALTH EFFECTS

ELECTRONIC DATABASE SEARCHES

All searches of electronic databases were performed on the 14th of October, 2014. The databases searched were:

- EMBASE.com (includes EMBASE and MEDLINE)
- PreMedline (via Ovid)
- PsycInfo (via Ovid)
- Global Health (via Ovid)
- All EBM (Includes the Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, Health Technology Assessment and Cochrane Methodology Register)

For each database, a systematic search strategy was developed to identify all relevant published evidence on the health effects of water fluoridation by using index terms and text words based on key elements of the research question and PICOS criteria (see Table 3). These search strategies were specified in the research protocol and no changes were made to the strategies prior to their implementation.

To identify primary studies of the health effects of water fluoridation, all databases were searched from 1st October, 2006 onwards, updating the search from the NHMRC (2007) review with a two month overlap. If the database did not allow restriction by month of publication, then the search was conducted from 2006 onwards. The results of the database searches are presented in Table 17, Table 18, Table 19, Table 20 and Table 21. In total, 2,166 citations were retrieved from the database searches.

Table 17 Search performed using EMBASE.com

No	Terms	Citations
1	'fluoridation'/exp OR 'fluoridation'	6,394
2	fluorid*:ab,ti OR fluorin*:ab,ti OR flurin*:ab,ti OR flurid*:ab,ti	58,750
3	#1 OR #2	59,975
4	'water supply'/exp	28,515
5	Water*:ab,ti	664,218
6	#4 OR #5	670,086
7	#3 AND #6	10,048
8	#7 AND [humans]/lim	4,058
9	#8 NOT ([conference abstract]/lim OR [editorial]/lim OR [letter]/lim OR [note]/lim)	3,787
10	#9 AND [1-10-2006]/sd	1,113

Table 18 Search performed using Psychinfo via Ovid

No	Terms	Citations
1	(fluorid$ or fluorin$ or flurin$ or flurid$).mp.	314
2	water$.mp.	31,491
3	1 and 2	64
4	limit 3 to human	43
5	limit 4 to yr="2006 -Current"	24

Table 19 Search performed using All EBM via Ovid

No	Terms	Citations
1	exp Fluoridation/	42
2	(fluorid$ or fluorin$ or flurin$ or flurid$).ti.	2,219
3	(fluorid$ or fluorin$ or flurin$ or flurid$).ab.	2,006
4	1 or 2 or 3	3,188
5	exp Water Supply/	146
6	water$.ti.	2,359
7	water$.ab.	10,657
8	5 or 6 or 7	11,409
9	4 and 8	301
10	limit 9 to yr="2006 -Current"	120

Table 20 Search performed using preMEDLINE via Ovid

No	Terms	Citations
1	(fluorid$ or fluorin$ or flurin$ or flurid$).mp.	7,922
2	water$.mp.	79,761
3	1 and 2	1,090
4	editorial.pt.	18,710
5	Letter.pt.	30,168
6	comment.pt.	47,054
7	4 or 5 or 6	82,201
8	3 not 7	1,070
9	limit 8 to ("in data review" or in process or medline or oldmedline)	281
10	limit 9 to yr="2006 -Current"	277

Table 21 Search performed using Global Health via Ovid

No	Terms	Citations
1	exp Fluoridation/	854
2	(fluorid$ or fluorin$ or flurin$ or flurid$).ti.	4,853
3	(fluorid$ or fluorin$ or flurin$ or flurid$).ab.	7,402
4	1 or 2 or 3	8,835
5	exp Water Supply/	8,856
6	water$.ti.	40,602
7	water$.ab.	197,942
8	5 or 6 or 7	204,391
9	"man".od.	1,631,278
10	4 and 8 and 9	2,063
11	limit 10 to yr="2006 -Current"	632

SEARCHING OF OTHER RESOURCES

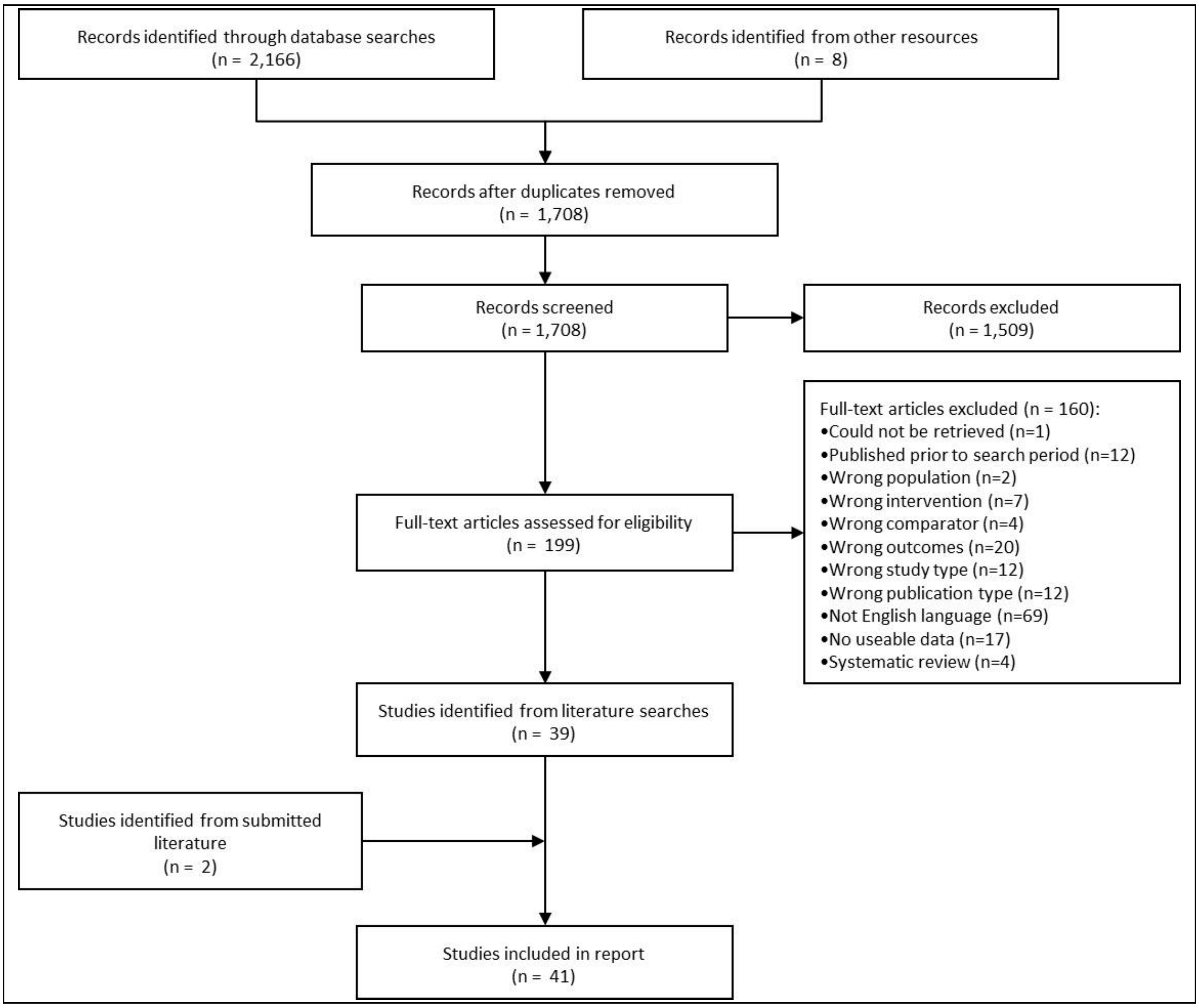
As described in the research protocol, searches of additional relevant resources were conducted. Searches of Australian resources included the Trove database of the National Library of Australia, the NHMRC website, State and Federal health department websites, and State and Federal environment and water authority websites. Searches of international resources included searches of the websites of health and water authorities in the United Kingdom, United States of America, Ireland, New Zealand and the European Union. General internet searches were conducted to identify guidelines and health technology assessments concerning water fluoride levels. The website of the Fluoride Action Network was also searched for relevant published studies.

The reference lists of all studies included in the report and all relevant systematic reviews identified in the literature search were checked for additional studies. The research protocol stated that a separate search of the journal Fluoride would be conducted; however, this search was not necessary as the Journal fluoride was indexed by Embase.com at the time of the database searches. The searching of other resources identified eight additional relevant studies that had not been identified in the database searches.

REVIEW OF CITATIONS

All citations retrieved from the searches of electronic databases and other resources were downloaded into Reference Manager software. The 2,174 records were checked for duplicate citations. A total of 466 duplicate citations were removed, leaving 1,708 citations eligible for review. A summary of the citation review process is presented in Figure 3 and the stages of the review process are described in detail below. All citation review activities were carried out independently by two reviewers. Disagreements between the reviewers were resolved by discussion.

Figure 3 Summary of review of citations



Review of titles and abstracts

All citations were initially reviewed by consideration of their title and abstract. In this stage studies were excluded based on the PICOS criteria specified in the research protocol. The criteria used to exclude irrelevant studies are presented in Table 22.

Table 22 Inclusion criteria used in the review of citations

Criterion	Explanation
Population	A study of human participants
Intervention	Fluoride in drinking water
Comparator	Compares either: Fluoride at a given concentration vs. unfluoridated water Fluoride at a given concentration vs. fluoride at different concentration
Outcome	Report on health effects other than dental caries and dental fluorosis
Study type	A comparative study design
Publication type	Published after 1st October 2006

Application of the criteria resulted in the exclusion of 1,509 citations. For the remaining 199 citations, the full text of the publication was retrieved for further review.

Review of full text
The 199 studies were assessed using the full text of the publication. See Figure 3 for a summary of the review process. For one study (Sharma et al 2010) the full text of the publication could not be retrieved and the study was excluded. A further 12 studies had been published prior to the specified start date of 1st October, 2006 and were excluded.

The remaining studies were assessed against the exclusion criteria used in the review of titles and abstracts (see Table 22), leading to the exclusion of 56 studies as described below:

- Population: 2 studies were excluded as they were geological studies that did not assess the health of individuals.
- Intervention: 7 studies were excluded because they did not assess only water fluoride as the intervention.
- Comparator: 4 studies were excluded as they did not report a comparison of different water fluoride levels.
- Outcomes: 20 studies were excluded because they did not report on the specified outcomes. Of these, two studies reported only on dental caries and dental fluorosis, two studies did not report on any health outcomes, nine studies reported on surrogate outcomes only, two studies reported the use of Community Periodontal Index only, and five studies reported on skeletal fluorosis but did not report on the grade of fluorosis.
- Study type: 12 studies were excluded because the selection methods used in these studies confounded the assessment of the study outcomes. These studies purported to compare subjects from areas with differing water fluoride levels, but actually compared people with fluorosis in one region to those without fluorosis in another region. In all studies the subjects from the “high” fluoride area were only included if they had dental fluorosis and subjects in the “low” fluoride area were only included if they had no dental fluorosis. Consequently, the subjects in the “high” and “low” fluoride groups were actually not representative of all the people living in that area and exposed to that level of fluoride. As a result of this flawed design, it was impossible to assess the independent effect of water fluoride levels on the study outcomes. The findings of these studies were considered irretrievably confounded and the studies were excluded with the approval of the NHMRC and the Fluoride Reference Group.
- Publication type: 11 studies were excluded due to being commentaries, guidelines, interviews and narrative reviews. One additional study was excluded because the study was only partially translated.

The Fluoride Reference Group advised that studies assessing periodontal disease using only the Community Periodontal Index should be excluded. The Community Periodontal Index is a screening measure for periodontal disease involving the recording of a summary measure for sextants of the mouth and the assigning of the worst score from those sextants to the whole mouth. In its original form it described periodontal status along a continuum from superficial gingival inflammation, calculus and periodontal pocket formation, implying progression of the disease along that continuum, which has been severely criticized. While it has been used in 'pathfinder surveys' it is not used in rigorous oral epidemiological surveys, or detailed periodontal research.

Rigorous oral epidemiological studies of periodontal disease involve the recording of multiple observations on each tooth of gingival recession and periodontal pocket depth, and the calculation of Clinical Attachment Loss. These observations are then tested against case definitions of periodontal disease. The three common periodontal case definitions are the

American Association of Periodontology and the U.S Centres for Disease Control and Prevention; the US National Centre for Health Statistics; and, the European Federation of Periodontology.

A total of 69 studies were excluded due to being published in a language other than English. Of these, 68 were published in Chinese and one was published in Korean.

Of the remaining studies, 17 were excluded as they did not report any outcome data that could be used in the current review. Four studies did not report the water fluoride levels for the populations compared in the study, twelve studies did not report outcomes by water fluoride level, and one study was a before and after study that only reported outcome data from after the intervention was implemented.

Systematic reviews

The literature search identified four relevant systematic reviews (Choi et al. 2012, Ludlow et al. 2007, Ortega Garcia et al. 2006 and Parnell et al. 2009). As set out in the research protocol, these were not eligible for inclusion in the current review, but were considered sources for eligible primary studies. The list of included studies from each of the systematic reviews was checked against the citations identified in the literature search. This checking did not identify any additional studies that met the criteria for inclusion in the current review. For a description of the contents of these systematic reviews please see the evidence evaluation report.

STUDIES INCLUDED FROM THE LITERATURE SEARCH

The literature search resulted in the inclusion of 39 studies. A further 2 studies were included from the literature received following the public call for evidence. In total, 41 studies were included in the current review. The citations for these studies are listed in Table 35, on page 56.

LITERATURE RECEIVED FROM PUBLIC CONSULTATION

PUBLIC CALL FOR EVIDENCE

The Australian community was invited to submit published studies to be evaluated as part of the systematic review on the health effects of water fluoridation from 23 July until 22 August 2014. Literature that met the scope of the systematic review was provided to the evidence review team at the University of Sydney. These studies were evaluated the same way as those identified using the systematic searches for the review.

Studies in the scope of the systematic review
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 includes 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); and
- A study which reports outcomes relevant for human health.

Studies outside the scope of the systematic review
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 University of Sydney team. Studies were not evaluated in the systematic review if they focus 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.

- 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 University of Sydney team completed the systematic review.

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

- Studies published before 1 October 2006 are outside the scope for this review as they were considered in NHMRC's 2007 Systematic Review of the Efficacy and Safety of Fluoridation; and

- Studies based on a type of evidence that is not appropriate to the systematic to the systematic review, e.g. personal story, medical record, raw data, narrative review, case series or case report.

REVIEW OF RECEIVED CITATIONS

A total of 379 citations were received by the NHMRC. These were reviewed for eligibility and 183 citations were deemed out of scope. A total of 193 studies were deemed in scope and these included in vitro studies and in vivo studies in both animals and humans. Of these, the 99 studies conducted in humans were considered potentially eligible for inclusion in the review and these were passed to the University of Sydney team for further assessment.

The University of Sydney used the following assessment process for the citations:

1. The citation was checked against the results of the literature search.
2. If the citations had been identified in the literature search this was noted and no further action was taken.
3. Citations that had not been identified in the literature search were reviewed in full text using the same criteria described for the review of full text articles from the literature search.
4. For studies that were not eligible, their status was noted together with the reason for exclusion.
5. Studies that were assessed as eligible for inclusion were added to the studies included in the review.

Of the 99 potentially eligible studies, 62 had been identified in the literature search and were not considered further. The remaining 37 studies were assessed for eligibility and 35 were not eligible for inclusion. The remaining two studies were considered eligible for inclusion in the review and were added to the list of included studies. Both of the eligible studies were published in journals that were not indexed by Medline or Embase, which is the reason they were not identified through the literature search. The results of the review of the received citations are presented in Table 23 below.

Table 23: Review of citations received from the public call for evidence

ID	Authors	Title	Publication date	Identified in search	Eligible for inclusion	Comment
1.01	Czajka M.	Systemic effects of fluoridation	2012	Yes	NA	None
2.01	Grandjean & Landrigan	Neurobehavioural effects of developmental toxicity	2014	No	No	Publication type – narrative review
2.02	Peckham & Awofeso	Water Fluoridation: A Critical Review of the Physiological Effects of Ingested Fluoride as a Public Health Intervention	2014	Yes	NA	None
6.01	Ludlow et al.	Effects of fluoridation of community water supplies for people with chronic kidney disease	2007	Yes	NA	None
6.03	Xiong et al.	Dose–effect relationship between drinking water fluoride levels and damage to liver and kidney functions in children	2007	Yes	NA	None
7.05	Spittle	Fluoride Fatigue	2008	No	No	Publication type – narrative review
7.28c	Choubisa	Fluoride in Drinking Water and its Toxicosis in Tribals of Rajasthan, India	2012	No	No	Outcomes - skeletal fluorosis not graded
7.30	Agalakova & Gusev	Molecular Mechanisms of Cytotoxicity and Apoptosis Induced by Inorganic Fluoride	2011	No	No	Population – in vitro studies (narrative review)
7.32	National Research Council of the National Academies: Committee on Fluoride in Drinking Water	Fluoride in drinking water: A Scientific Review of EPA's Standards	2006	Yes	NA	Identified in grey literature search
8.07	Chandrajith et al.	Dose-dependent Na and Ca in fluoride-rich drinking water - Another major cause of chronic renal failure in tropical arid regions	2011	No	No	Population - study investigates fluoride levels in villages - no assessment of people
8.11	Vazquez-Alvarado et al.	Genotoxic damage in oral epithelial cells induced by fluoride in drinking-water on students of Tula de Allende, Hidalgo, Mexico	2012	No	No	Outcomes – surrogate outcomes
8.14	Grandjean & Landrigan	Developmental neurotoxicity of industrial chemicals	Dec-06	No	No	Publication type – narrative review
8.17	Choi et al.	Developmental fluoride neurotoxicity: a systematic review and meta-analysis	2012	Yes	NA	

ID	Authors	Title	Publication date	Identified in search	Eligible for inclusion	Comment
8.19	Varol et al.	Aortic elasticity is impaired in patients with endemic fluorosis	2010	No	No	Study type - confounded study
8.20	World Health Organization	Endocrine Disrupting Chemicals	2012	No	No	Publication type – narrative review
8.37	Irmak et al.	Fluoride toxicity and new-onset diabetes in Finland	2014	No	No	Publication type – narrative review
8.38	Chiba et al.	Effect of fluoride intake on carbohydrate metabolism, glucose tolerance, and insulin signaling.	2012	No	No	Publication type – narrative review
8.53	Liu et al.	Assessment of relationship on excess fluoride intake from drinking water and carotid atherosclerosis development in adults in fluoride endemic areas, China	2014	Yes	NA	None
8.56	Adali et al.	Impaired heart rate recovery in patients with endemic fluorosis	2013	No	No	Study type - confounded study
8.64	Varol et al.	Impact of chronic fluorosis on left ventricular diastolic and global functions	2010	No	No	Study type - confounded study
8.71	Tamer et al.	Osteosclerosis due to endemic fluorosis	2007	Yes	NA	None
8.80	Rao et al.	Morphometry of buccal mucosal cells in fluorosis–a new paradigm	2011	No	No	Study type - confounded study
8.92	Pawar et al.	Cytogenetic analysis of human lymphocytes of fluorosis-affected men from the endemic fluorosis region in Nalgonda district of Andhra Pradesh, India	2014	Yes	NA	None
9.08	Chandrajith et al.	Chronic kidney diseases of uncertain etiology (CKDue) in Sri Lanka: geographic distribution and environmental implications	2011	Yes	NA	None
9.15	National Kidney Foundation	Fluoride Intake in Chronic Kidney Disease	2008	Yes	NA	Identified in grey literature search
9.39	Bandara et al.	Chronic renal failure among farm families in cascade irrigation systems in Sri Lanka associated with elevated dietary cadmium levels in rice and freshwater fish (Tilapia)	2008	Yes	NA	None
9.54	Singh et al.	A comparative study of fluoride ingestion levels, serum thyroid hormone & TSH level derangements, dental fluorosis status among school children from endemic and non-endemic fluorosis areas	2014	Yes	NA	None
9.55	Meng et al.	Assessment of iodine status in children, adults, pregnant women and lactating women in iodine-replete areas of China	2013	Yes	NA	None

ID	Authors	Title	Publication date	Identified in search	Eligible for inclusion	Comment
9.57	Yasmin et al.	Effect of excess fluoride ingestion on human thyroid function in Gaya region, Bihar, India	2013	No	No	Study type - confounded study
9.61	Kutlucan et al.	The investigation of effects of fluorosis on thyroid volume in school-age children	2013	Yes	NA	Identified in grey literature search
9.63	Shashi & Singla	Clinical and biochemical profile of deiodinase enzymes and thyroid function hormones in patients of fluorosis	2013	No	No	Study type - confounded study
9.66	Zhang	Studies of relationships between the polymorphism of COMT gene and plasma proteomic profiling and children's intelligence in high fluoride areas	2012	Yes	NA	Identified in grey literature search
9.67	Hosur et al.	Study of thyroid hormones free triiodothyronine (FT3), free thyroxine (FT4) and thyroid stimulating hormone (TSH) in subjects with dental fluorosis	2012	No	No	Study type - confounded study
9.69	Koroglu et al.	Serum parathyroid hormone levels in chronic endemic fluorosis	2011	Yes	NA	None
9.73	Isaac et al.	Prevalence and manifestations of waterborn fluorosis among schoolchildren in Kaiwara village of India: a preliminary study	2009	Yes	NA	None
9.75	Wang et al.	Fluoride-induced thyroid dysfunction in rats: roles of dietary protein and calcium level	2009	No	No	Study type – animal study
9.77	Xiang et al.	Fluoride and thyroid function in children in two villages in China	2009	No	Yes	Journal is not indexed by the databases included in the literature search
9.79	Wang et al.	Effects of protein and calcium supplementation on bone metabolism and thyroid function in protein and calcium deficient rabbits exposed to fluoride	2008	No	No	Study type – animal study
9.82	Gupta et al.	Changes in serum seromucoid following compensatory hyperparathyroidism: A sequel to chronic fluoride ingestion	2008	Yes	NA	None
10.01	Broadbent et al.	Community Water Fluoridation and Intelligence: Prospective Study in New Zealand	2014	Yes	NA	Identified in grey literature search
10.02	Public Health England	Water fluoridation: health monitoring report for England 2014	2014	Yes	NA	None
10.04	Levy et al.	Effects of Life-long Fluoride Intake on Bone Measures of Adolescents: A Prospective Cohort Study	2014	Yes	NA	None

ID	Authors	Title	Publication date	Identified in search	Eligible for inclusion	Comment
10.06	Chachra et al.	The Long-term Effects of Water Fluoridation on the Human Skeleton	2010	Yes	NA	None
10.07	European Commission Scientific Committee on Health and Environmental Risks	Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water	2010	No	No	Publication type – narrative review
10.09	Nasman et al.	Estimated Drinking Water Fluoride Exposure and Risk of Hip Fracture	2013	Yes	NA	None
12.03	Balmer et al.	The prevalence of molar incisor hypomineralisation in Northern England and its relationship to socioeconomic status and water fluoridation	2012	Yes	NA	None
12.04	Comber et al.	Drinking water fluoridation and osteosarcoma incidence on the island of Ireland	2011	Yes	NA	None
12.07	Blakey et al.	Is fluoride a risk factor for bone cancer? Small area analysis of osteosarcoma and Ewing sarcoma diagnosed among 0–49-year-olds in Great Britain, 1980–2005	2014	Yes	NA	None
12.09	Jolaoso et al.	Does fluoride in drinking water delay tooth eruption?	2014	Yes	NA	None
13.02	Ozsvath	Fluoride and environmental health: a review	2009	Yes	NA	None
17.01	Ranjan & Yasmin	Health problems in fluoride endemic areas of Gaya District	2012	No	No	Same study cohort as included study by Ranjan 2012 ID 238 This publication does not contain any additional usable data for health outcomes reported by water fluoride level
17.07	Yasmin et al.	Haematological changes in fluorotic adults and children in fluoride endemic regions of Gaya district, Bihar, India	2014	No	No	Study type - confounded study
17.10	Amini et al.	Drinking water fluoride and blood pressure: an environmental study	2011	Yes	NA	None
17.11	Ersoy et al.	Effect of endemic fluorosis on hematological parameters	2010	No	No	Study type - confounded study
17.12	Susheela et al.	Effective interventional approach to control anaemia in pregnant women	2010	No	No	Intervention – dietary counselling and fluoride consumption counselling

ID	Authors	Title	Publication date	Identified in search	Eligible for inclusion	Comment
17.15	Susheela et al.	Early diagnosis and complete recovery from fluorosis through practice of interventions	2014	No	No	Intervention – dietary counselling
17.18	Saifullah et al.	Spirometry changes due to prolonged exposure to high level of fluoride in drinking water	2013	No	No	Conference abstract
17.19	Varol & Varol	Water-borne fluoride and primary hypertension	2013	No	No	Narrative review
19.01	House of Representatives Standing Committee on Health and Ageing	Bridging the Dental Gap: Report on the inquiry into adult dental services	2013	No	No	Publication type – report of Government inquiry
19.02	Australian Research Centre for Population Oral Health	Outcome of fluoride consensus workshop 2012 to review Fluoride Guidelines from 2005	2012	No	No	Publication type – guidelines without specific systematic review
19.05	Foley	Fluoride and osteosarcoma: A bone of contention	2014	No	No	Publication type – narrative review
19.07	Kidney Health Australia	2011 Review of Kidney Health Australia Fluoride Position Statement	2011	No	No	Publication type – Systematic review No additional studies eligible for inclusion
20.02	National Fluoride Information Service	Community Water Fluoridation and Osteosarcoma – Evidence from Cancer Registries	2013	Yes	NA	Identified in grey literature search
20.03	National Fluoride Information Service	Fluoride Neurotoxicity: Review of evidence from drinking water studies	2011	Yes	NA	Identified in grey literature search
20.04	National Fluoride Information Service	A review of recent literature on potential effects of CWF programmes on neurological development and IQ attainment	2013	Yes	NA	Identified in grey literature search
20.06	National Fluoride Information Service	Review of Scientific Papers Relating to Water Fluoridation published between January 2000 and July 2010	2011	Yes	NA	Identified in grey literature search
20.07	National Fluoride Information Service	Review of Scientific Papers Relating to Water Fluoridation published between January and November 2010	2011	Yes	NA	Identified in grey literature search
20.08	National Fluoride Information Service	Review of Scientific Papers Relating to Water Fluoridation published between December 2010 and August 2011	2012	Yes	NA	Identified in grey literature search

ID	Authors	Title	Publication date	Identified in search	Eligible for inclusion	Comment
20.09	National Fluoride Information Service	Review of Scientific Papers Relating to Water Fluoridation published between September 2011 and January 2012	2013	Yes	NA	Identified in grey literature search
20.10	National Fluoride Information Service	Review of Scientific Papers Relating to Water Fluoridation published between February and July 2012	2013	Yes	NA	Identified in grey literature search
20.11	National Fluoride Information Service	Review of Scientific Papers Relating to Water Fluoridation published between August and December 2012	2013	Yes	NA	Identified in grey literature search
20.12	National Fluoride Information Service	Review of Scientific Papers Relating to Water Fluoridation published between January and June 2013	2014	Yes	NA	Identified in grey literature search
21.01	National Cancer Institute	Fluoridated Water Fact Sheet	2012	No	No	Publication type – narrative review
21.02	Irish Dental Association	Fluoridation in Ireland - The dental profession looks back over 50 years	2012	Yes	NA	Relevant individual articles within this supplement were identified in the literature search.
21.03	US EPA	Fluoride: Dose-Response Analysis For Non-cancer Effects	2008	Yes	NA	Identified in grey literature search
21.04	The Irish Expert Body on Fluorides and Health	Position Statement from the Irish Expert Body on Fluorides and Health regarding Water Fluoridation in the Republic of Ireland	2012	Yes	NA	Identified in grey literature search
21.06	Parnell et al.	Water Fluoridation	2009	Yes	NA	None
21.07	Tiemann	Fluoride in Drinking Water: A Review of Fluoridation and Regulation Issues	2011	Yes	NA	Identified in grey literature search
22.03	Armfield	When public action undermines public health: a critical examination of antifluoridationist literature	2007	No	No	Publication type – narrative review of antifluoridation studies
23.06	Buzalaf et al.	Biomarkers of Fluoride in Children Exposed to Different Sources of Systemic Fluoride	2011	Yes	NA	None
23.07	Buzalaf et al.	Validation of Fingernail Fluoride Concentration as a Predictor of Risk for Dental Fluorosis	2012	Yes	NA	None
23.08	Chen et al.	Change of urinary fluoride and bone metabolism indicators in the endemic fluorosis areas of southern china after supplying low fluoride public water	2013	Yes	NA	None

ID	Authors	Title	Publication date	Identified in search	Eligible for inclusion	Comment
23.11	Ding et al.	The relationships between low levels of urine fluoride on children's intelligence, dental fluorosis in endemic fluorosis areas in Hulunbuir, Inner Mongolia, China	2011	Yes	NA	None
24.02	Majumdar	Health impact of supplying safe drinking water containing fluoride below permissible level on fluorosis patients in a fluoride-endemic rural area of West Bengal	2011	Yes	NA	None
24.06	Newbrun	What we know and do not know about fluoride	2010	Yes	NA	None
31.013	Singh et al.	Acetylcholinesterase activity in fluorosis adversely affects mental well-being: an experimental study in rural Rajasthan	2014	No	No	Outcomes – surrogate outcomes
31.017	Karimzade et al.	Investigation of intelligence quotient in 9-12 year-old children exposed to high- and low-drinking water fluoride in West Azerbaijan province, Iran	2014	Yes	NA	None
31.035	Pratap et al.	A correlation between serum vitamin, acetylcholinesterase activity and IQ in children with excessive endemic fluoride exposure in Rajasthan, India	2013	No	Yes	Journal is not indexed by the databases included in the literature search Note: author name is printed incorrectly, first author is V.P. Singh
31.043	Trivedi et al.	Assessment of groundwater quality with special reference to fluoride and its impact on IQ of schoolchildren in six villages of the Mundra Region, Kachchh, Gujarat, India	2012	Yes	NA	None
31.044	Seraj et al.	Effect of high water fluoride concentration on the intellectual development of children in Makoo/Iran	2012	Yes	NA	Identified in grey literature search
31.045	Saxena et al.	Effect of fluoride exposure on the intelligence of school children in Madhya Pradesh, India	2012	Yes	NA	None
31.060	Shivaprakash et al.	Relation between dental fluorosis and intelligence quotient in school children of Bagalkot district	2011	Yes	NA	None
31.066	Poureslami et al.	Intelligence quotient of 7 to 9 year-old children from an area with high fluoride in drinking water	2011	No	No	Duplicate publication of data from included study by Poureslami 2011
31.086	Sharma et al.	Prevalence of neurological manifestations in a human population exposed to fluoride in drinking water	2009	Yes	NA	None

ID	Authors	Title	Publication date	Identified in search	Eligible for inclusion	Comment
31.114	Fan et al.	The effect of high fluoride exposure on the level of intelligence in children	2007	Yes	NA	Identified in grey literature search
31.115	Coplan et al.	Confirmation of and explanations for elevated blood lead and other disorders in children exposed to water disinfection and fluoridation chemicals	2007	Yes	NA	None
31.117	Trivedi et al.	Effect of high fluoride water on intelligence of school children in India	2007	Yes	NA	None
31.118	Wang et al.	Arsenic and fluoride exposure in drinking water: children's IQ and growth in Shanyin County, Shanxi Province, China	2007	Yes	NA	None
31.120	Rocha-Amador et al.	Decreased intelligence in children and exposure to fluoride and arsenic in drinking water	2007	Yes	NA	None

Abbreviations: NA = not applicable

EVIDENCE COLLECTION

CLASSIFICATION OF THE EVIDENCE

The NHMRC Evidence Hierarchy was used to assess the level of evidence for each included study. The type of outcome being assessed affects the type of study design that can be used. The assessment of harms is often best assessed using observational studies, particularly when rare outcomes or outcomes which require prolonged exposure are sought. Therefore, the level of evidence of included studies was assessed using the aetiology question hierarchy. Ecological studies are not normally included in the levels of evidence for aetiology research questions. For the purposes of this review ecological studies were classed as Level IV evidence. The study designs included for each level of evidence are shown in Table 24.

Table 24 NHMRC evidence hierarchy: designations of 'levels of evidence' for intervention and aetiology research questions

Level	Intervention [a]	Aetiology [b]
I [c]	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A prospective cohort study
III-1	A pseudorandomised controlled trial	All or none [d]
III-2	A comparative study with concurrent controls: • Non-randomised experimental trial [e] • Cohort study • Case-control study • Interrupted time series with a control group	A retrospective cohort study
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study [f] • Interrupted time series without a parallel control group	A case-control study
IV	Case series with either post-test or pre-test/post-test outcomes	A cross-sectional study or case series

a. Definitions of these study designs are provided on pages 7-8 How to use the evidence: assessment and application of scientific evidence (NHMRC 2000b).
b. If it is possible and/or ethical to determine a causal relationship using experimental evidence, then the 'Intervention' hierarchy of evidence should be utilised. If it is only possible and/or ethical to determine a causal relationship using observational evidence (i.e. cannot allocate groups to a potential harmful exposure, such as nuclear radiation), then the 'Aetiology' hierarchy of evidence should be utilised.
c. A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence.
d. All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of small pox after large-scale vaccination.
e. This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (i.e. utilise A vs B and B vs C, to determine A vs C with statistical adjustment for B).
f. Comparing single arm studies i.e. case series from two studies. This would also include unadjusted indirect comparisons (i.e. utilise A vs B and B vs C, to determine A vs C but where there is no statistical adjustment for B).

QUALITY ASSESSMENT

Methods

The quality and risk of bias for each individual study was assessed by two independent reviewers. Any disagreements were resolved through discussion. The method used to assess quality and risk of bias was based on study type. The assessment methods for each study type are presented below.

Systematic review

The methodological quality of systematic reviews was assessed using the AMSTAR instrument (available at AMSTAR Tool). All items are answered with either 'yes', 'no', 'can't answer' or 'not applicable'. An answer of 'yes' is scored as one point and all other answers score zero points. The assessment was performed independently by two reviewers, with any disagreements being resolved through discussion. A copy of the AMSTAR instrument is presented below.

Table 25 AMSTAR quality assessment instrument

Item	Question	Answer	Comment
1	Was an 'a priori' design provided? [a]		
2	Was there duplicate study selection and data extraction? [b]		
3	Was a comprehensive literature search performed? [c]		
4	Was the status of publication (i.e. grey literature) used as an inclusion criterion? [d]		
5	Was a list of studies (included and excluded) provided? [e]		
6	Were the characteristics of the included studies provided? [f]		
7	Was the scientific quality of the included studies assessed and documented? [g]		
8	Was the scientific quality of the included studies used appropriately in formulating conclusions? [h]		
9	Were the methods used to combine the findings of studies appropriate? [i]		
10	Was the likelihood of publication bias assessed? [j]		
11	Was the conflict of interest stated? [k]		

Abbreviations: CA = can't answer; N = no; NA = not applicable; Y = yes

a. The research question and inclusion criteria should be established before the conduct of the review. Note: Need to refer to a protocol, ethics approval, or pre-determined/a priori published research objectives to score a "yes."
b. There should be at least two independent data extractors and a consensus procedure for disagreements should be in place. Note: 2 people do study selection, 2 people do data extraction, consensus process or one person checks the other's work.
c. At least two electronic sources should be searched. The report must include years and databases used (e.g., Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found. Note: If at least 2 sources + one supplementary strategy used, select "yes" (Cochrane register/Central counts as 2 sources; a grey literature search counts as supplementary).
d. The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc. Note: If review indicates that there was a search for "grey literature" or "unpublished literature," indicate "yes." SINGLE database, dissertations, conference proceedings, and trial registries are all considered grey for this purpose. If searching a source that contains both grey and non-grey, must specify that they were searching for grey/unpublished lit.
e. A list of included and excluded studies should be provided. Note: Acceptable if the excluded studies are referenced. If there is an electronic link to the list but the link is dead, select "no."
f. In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analysed e.g., age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported. Note: Acceptable if not in table format as long as they are described as above.
g. 'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant. Note: Can include use of a quality scoring tool or checklist, e.g., Jadad scale, risk of bias, sensitivity analysis, etc., or a description of quality items, with some kind of result for EACH study ("low" or "high" is fine, as long as it is clear which studies scored "low" and which scored "high"; a summary score/range for all studies is not acceptable).
h. The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations. Note: Might say something such as "the results should be interpreted with caution due to poor quality of included studies." Cannot score "yes" for this question if scored "no" for question 7.
i. For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e., Chi-squared test for homogeneity, I2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e., is it sensible to combine?).Note: Indicate "yes" if they mention or describe heterogeneity, i.e., if they explain that they cannot pool because of heterogeneity/variability between interventions.
j. An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test, Hedges-Olken). Note: If no test values or funnel plot included, score "no". Score "yes" if mentions that publication bias could not be assessed because there were fewer than 10 included studies.

k. Potential sources of support should be clearly acknowledged in both the systematic review and the included studies. Note: To get a "yes," must indicate source of funding or support for the systematic review AND for each of the included studies.

Cohort studies and case-control studies

The quality of identified cohort or case-control studies was assessed using the cohort and case-control checklists developed by the Scottish Intercollegiate Guidelines Network (SIGN) (available from SIGN checklists). Both checklists include an assessment of the internal validity of the study, with consideration of the selection of subjects; the assessment of exposure and outcomes; the potential for confounding; and the statistical analysis used. The checklists also include an overall assessment of the study, which is classified as:

- High quality: Majority of the criteria were met with little or no risk of bias. The results are unlikely to be changed by further research.
- Acceptable: Most of the criteria were met. There were some flaws in the study with an associated risk of bias. The conclusions may change in light of further studies.
- Low quality: Either most of the criteria were not met, or there were significant flaws relating to key aspects of the study design. The conclusions are likely to change in light of further studies.

Examples of the two instruments are presented in Table 26 and Table 27.

Table 26 SIGN cohort study checklist

-	Section 1: Internal validity	-
1.1	The study addresses an appropriate and clearly focused question.[1]	
-	Selection of subjects	-
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.[2]	
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.[3]	
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.[4]	
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.[5]	
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.[6]	
-	Assessment	-
1.7	The outcomes are clearly defined.[7]	
1.8	The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable.[8]	
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.[9]	
1.10	The method of assessment of exposure is reliable.[10]	
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.[11]	
1.12	Exposure level or prognostic factor is assessed more than once.[12]	
-	Confounding	-
1.13	The main potential confounders are identified and taken into account in the design and analysis.[13]	
-	Statistical Analysis	-
1.14	Have confidence intervals been provided?[14]	
-	Section 2: Overall assessment of the study	-
2.1	How well was the study done to minimise the risk of bias or confounding?[15]	
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	
2.3	Are the results of this study directly applicable to the patient group targeted in this guideline?	
2.4	**Notes.** Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	

Abbreviations: CA = can't answer; N = no; NA = not applicable; Y = yes

[1] Unless a clear and well defined question is specified in the report of the review, it will be difficult to assess how well it has met its objectives or how relevant it is to the question you are trying to answer on the basis of the conclusions.

[2] This relates to selection bias. It is important that the two groups selected for comparison are as similar as possible in all characteristics except for their exposure status, or the presence of specific prognostic factors or prognostic markers relevant to the study in question.

[3] This relates to selection bias. The participation rate is defined as the number of study participants divided by the number of eligible subjects, and should be calculated separately for each branch of the study. A large difference in participation rate between the two arms of the study indicates that a significant degree of selection bias may be present, and the study results should be treated with considerable caution.

[4] If some of the eligible subjects, particularly those in the unexposed group, already have the outcome at the start of the trial the final result will be subject to performance bias. A well conducted study will attempt to estimate the likelihood of this occurring, and take it into account in the analysis through the use of sensitivity studies or other methods.

[5] This question relates to the risk of attrition bias. The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but in observational studies conducted over a lengthy period of time a higher drop-out rate is to be expected. A decision on whether to downgrade or reject a study because of a high drop-out rate is a matter of judgement based on the reasons why people dropped out, and whether drop-out rates were comparable in the exposed and unexposed groups. Reporting of efforts to follow up participants that dropped out may be regarded as an indicator of a well conducted study.

[6] For valid study results, it is essential that the study participants are truly representative of the source population. It is always possible that participants who dropped out of the study will differ in some significant way from those who remained part of the study throughout. A well conducted study will attempt to identify any such differences between full and partial participants in both the exposed and unexposed groups. This relates to the risk of attrition bias. Any unexplained differences should lead to the study results being treated with caution.

[7] This relates to the risk of detection bias. Once enrolled in the study, participants should be followed until specified end points or outcomes are reached. In a study of the effect of exercise on the death rates from heart disease in middle aged men, for example, participants might be followed up until death, or until reaching a predefined age. If outcomes and the criteria used for measuring them are not clearly defined, the study should be rejected.

[8] This relates to the risk of detection bias. If the assessor is blinded to which participants received the exposure, and which did not, the prospects of unbiased results are significantly increased. Studies in which this is done should be rated more highly than those where it is not done, or not done adequately.

[9] This relates to the risk of detection bias. Blinding is not possible in many cohort studies. In order to assess the extent of any bias that may be present, it may be helpful to compare process measures used on the participant groups - e.g. frequency of observations, who carried out the observations, the degree of detail and completeness of observations. If these process measures are comparable between the groups, the results may be regarded with more confidence.

[10] This relates to the risk of detection bias. A well conducted study should indicate how the degree of exposure or presence of prognostic factors or markers was assessed. Whatever measures are used must be sufficient to establish clearly that participants have or have not received the exposure under investigation and the extent of such exposure, or that they do or do not possess a particular prognostic marker or factor. Clearly described, reliable measures should increase the confidence in the quality of the study

[11] This relates to the risk of detection bias. The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

[12] This relates to the risk of detection bias. Confidence in data quality should be increased if exposure level is measured more than once in the course of the study. Independent assessment by more than one investigator is preferable.

[13] Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The possible presence of confounding factors is one of the principal reasons why observational studies are not more highly rated as a source of evidence. The report of the study should indicate which potential confounders have been considered, and how they have been assessed or allowed for in the analysis. Clinical judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be. A study that does not address the possibility of confounding should be rejected.

[14] Confidence limits are the preferred method for indicating the precision of statistical results, and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with extreme caution.

[15] Rate the overall methodological quality of the study, using the following as a guide: High quality: Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. Acceptable: Most criteria met. Some flaws in the study with an associated risk of bias, Conclusions may change in the light of further studies. Low quality: Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies. Please note that a retrospective study (i.e. a database or chart study) cannot be rated higher than acceptable.

Table 27 SIGN case-control study checklist

-	Section 1: Internal validity	-
1.1	The study addresses an appropriate and clearly focused question.[1]	
-	Selection of subjects	-
1.2	The cases and controls are taken from comparable populations.[2]	
1.3	The same exclusion criteria are used for both cases and controls.[3]	
1.4	What percentage of each group (cases and controls) participated in the study?[4]	Cases: Controls:
1.5	Comparison is made between participants and non-participants to establish their similarities or differences.[5]	
1.6	Cases are clearly defined and differentiated from controls.[6]	
1.7	It is clearly established that controls are non-cases.[7]	
-	Assessment	-
1.8	Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment.[8]	
1.9	Exposure status is measured in a standard, valid and reliable way.[9]	
-	Confounding	-
1.10	The main potential confounders are identified and taken into account in the design and analysis.[10]	
-	Statistical Analysis	-
1.11	Confidence intervals are provided.[11]	
-	Section 2: Overall assessment of the study	-
2.1	How well was the study done to minimise the risk of bias or confounding?1[2]	
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	
2.4	Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	-

Abbreviations: CA = can't answer; N = no; NA = not applicable; Y = yes

[1] Unless a clear and well defined question is specified in the report of the review, it will be difficult to assess how well it has met its objectives or how relevant it is to the question you are trying to answer on the basis of the conclusions.

[2] Study participants may be selected from the target population (all individuals to which the results of the study could be applied), the source population (a defined subset of the target population from which participants are selected), or from a pool of eligible subjects (a clearly defined and counted group selected from the source population. If the study does not include clear definitions of the source population it should be rejected.

[3] All selection and exclusion criteria should be applied equally to cases and controls. Failure to do so may introduce a significant degree of bias into the results of the study.

[4] Differences between the eligible population and the participants are important, as they may influence the validity of the study. A participation rate can be calculated by dividing the number of study participants by the number of eligible subjects. It is more useful if calculated separately for cases and controls. If the participation rate is low, or there is a large difference between the two groups, the study results may well be invalid due to differences between participants and non-participants. In these circumstances, the study should be downgraded, and rejected if the differences are very large.

[5] Even if participation rates are comparable and acceptable, it is still possible that the participants selected to act as cases or controls may differ from other members of the source population in some significant way. A well conducted case-control study will look at samples of the non-participants among the source population to ensure that the participants are a truly representative sample.

[6] The method of selection of cases is of critical importance to the validity of the study. Investigators have to be certain that cases are truly cases, but must balance this with the need to ensure that the cases admitted into the study are representative of the eligible population. The issues involved in case selection are complex, and should ideally be evaluated by someone with a good understanding of the design of case-control studies. If the study does not comment on how cases were selected, it is probably safest to reject it as a source of evidence.

[7] Just as it is important to be sure that cases are true cases, it is important to be sure that controls do not have the outcome under investigation. Control subjects should be chosen so that information on exposure status can be obtained or assessed in a similar way to that used for the selection of cases. If the methods of control selection are not described, the study should be rejected. If different methods of selection are used for cases and controls the study should be evaluated by someone with a good understanding of the design of case-control studies.

[8] If there is a possibility that case ascertainment can be influenced by knowledge of exposure status, assessment of any association is likely to be biased. A well conducted study should take this into account in the design of the study.

[9] The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

[10] Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The possible presence of confounding factors is one of the principal reasons why observational studies are not more highly rated as a source of evidence. The study should indicate which potential confounders have been considered, and how they have been allowed for in the analysis. Clinical judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected. A study that does not address the possibility of confounding should be rejected.

[11] Confidence limits are the preferred method for indicating the precision of statistical results, and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with extreme caution.

[12] Rate the overall methodological quality of the study, using the following as a guide: High quality: Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. Acceptable: Most criteria met. Some flaws in the study with an associated risk of bias, Conclusions may change in the light of further studies. Low quality: Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.

Cross sectional studies and ecological studies

The research protocol for the review did not specify a quality assessment instrument for cross sectional studies and ecological studies. In the absence of validated instruments specific to cross sectional studies and ecological studies, the NHMRC approved the use of a generic instrument produced by NICE for the assessment of quantitative studies reporting correlations and associations (available from NICE checklists). Studies were also classified as high quality, acceptable quality or low quality, to be consistent with the assessments generated with the SIGN checklists. An example of the NICE instrument for quality assessment of quantitative studies reporting correlations and associations is presented in Table 28.

Table 28 NICE ecological and cross-sectional study checklist

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described? • Was the country (e.g. developed or non-developed, type of health care system), setting (primary schools, community centres etc.), location (urban, rural), population demographics etc adequately described?	++ + − NR NA	
1.2 Is the eligible population or area representative of the source population or area? • Was the recruitment of individuals, clusters or areas well defined (e.g. advertisement, birth register)? • Was the eligible population representative of the source? Were important groups underrepresented?	++ + − NR NA	
1.3 Do the selected participants or areas represent the eligible population or area? • Was the method of selection of participants from the eligible population well described? • What % of selected individuals or clusters agreed to participate? Were there any sources of bias? • Were the inclusion or exclusion criteria explicit and appropriate?	++ + − NR NA	

Issue	Rating	Comment
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised? • How was selection bias minimised?	++ + − NR NA	
2.2 Was the selection of explanatory variables based on a sound theoretical basis? • How sound was the theoretical basis for selecting the explanatory variables?	++ + − NR NA	
2.3 Was the contamination acceptably low? • Did any in the comparison group receive the exposure? • If so, was it sufficient to cause important bias?	++ + − NR NA	
2.4 How well were likely confounding factors identified and controlled? • Were there likely to be other confounding factors not considered or appropriately adjusted for? • Was this sufficient to cause important bias?	++ + − NR NA	
2.5 Is the setting applicable to the Australia? • Did the setting differ significantly from Australia?	++ + − NR NA	
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable? • Were outcome measures subjective or objective (e.g. biochemically validated nicotine levels ++ vs self-reported smoking −)? • How reliable were outcome measures (e.g. inter- or intra-rater reliability scores)? • Was there any indication that measures had been validated (e.g. validated against a gold standard measure or assessed for content validity)?	++ + − NR NA	
3.2 Were the outcome measurements complete? • Were all or most of the study participants who met the defined study outcome definitions likely to have been identified?	++ + − NR NA	
3.3 Were all the important outcomes assessed? • Were all the important benefits and harms assessed? • Was it possible to determine the overall balance of benefits and harms of the intervention versus comparison?	++ + − NR NA	
3.4 Was there a similar follow-up time in exposure and comparison groups? • If groups are followed for different lengths of time, then more events are likely to occur in the group followed-up for longer distorting the comparison. • Analyses can be adjusted to allow for differences in length of follow-up (e.g. using person-years).	++ + − NR NA	
3.5 Was follow-up time meaningful? • Was follow-up long enough to assess long-term benefits and harms? • Was it too long, e.g. participants lost to follow-up?	++ + − NR NA	

Issue	Rating	Comment
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)? • A power of 0.8 (i.e. it is likely to see an effect of a given size if one exists, 80% of the time) is the conventionally accepted standard. • Is a power calculation presented? If not, what is the expected effect size? Is the sample size adequate?	++ + − NR NA	
4.2 Were multiple explanatory variables considered in the analyses? • Were there sufficient explanatory variables considered in the analysis?	++ + − NR NA	
4.3 Were the analytical methods appropriate? • Were important differences in follow-up time and likely confounders adjusted for?	++ + − NR NA	
4.6 Was the precision of association given or calculable? Is the association meaningful? • Were confidence intervals or p values for effect estimates given or possible to calculate? • Were CIs wide or were they sufficiently precise to aid decision-making? If precision is lacking, is this because the study is under-powered?	++ + − NR NA	
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)? • How well did the study minimise sources of bias (i.e. adjusting for potential confounders)? • Were there significant flaws in the study design?	++ + −	
5.2 Are the findings generalisable to the source population (i.e. externally valid)? • Are there sufficient details given about the study to determine if the findings are generalisable to the source population? • Consider: participants, interventions and comparisons, outcomes, resource and policy implications.	++ + −	
Overall quality rating		

Abbreviations: NA = not applicable; NR = not reported

DATA EXTRACTION

Data were extracted from individual studies using a standardised data extraction form designed specifically for these reviews. Data extraction was performed by one reviewer and checked by a second reviewer. Any discrepancies were resolved by discussion or consultation with a third reviewer. Missing data from individual studies was not sought. Samples of the data extraction forms are presented in Table 29 and Table 30. Where necessary, the form was adapted to best present the results of individual studies.

Table 29 Data extraction template for systematic reviews

General information	Study ID	
	Title	
	Country of origin	
	Source of funding	
	Possible conflicts of interest (for study authors or translators)	
AMSTAR Rating		
Characteristics of review and included primary studies	Aim/objectives of study	
	Study design	
	Search Methods	
	Selection Criteria	
	Level of evidence (lowest identified)	
	Study types identified	
	Quality of Evidence evaluated	
	Exposure duration	
	Source population description	
	Inclusion criteria	
	Exclusion criteria	
Participant characteristics	Interventions	
	Comparators	
	Subgroups reported	
Results: [outcome]	Definition (with units) Method of measurement	
	No. of studies and participants analysed	
	No. of studies and participants excluded or missing (with reasons)	
	Statistical method of analysis	
	Results	
Authors' conclusion		
Correspondence if required		
Reviewer's notes		

Table 30 Data extraction template for primary studies

General information	Study ID			
	Date form completed			
	Country of origin Source of funding Possible conflicts of interest			
Study characteristics	Aim/objectives of study			
	Study design			
	Level of evidence			
	Study location			
	Study duration			
	Exposure duration			
	Source population description			
	Inclusion/exclusion criteria			
	Recruitment procedures			
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled			
	Age			
	Male			
	Other characteristics			
	Subgroups reported			
Exposure and setting	Description of exposure and control			
	Setting			
Results: Outcome	Definition Method of measurement			
	No. of participants analysed			
	No. of participants excluded or missing			
	Imputation of missing data			
	Statistical method of analysis			
	Participant category	Intervention	Comparator	Effect estimate
	All participants			
	Females			
	Males			
Authors' conclusion				
Correspondence if required				
Reviewer's notes				

ASSESSMENT OF THE EVIDENCE

PRESENTATION OF THE RESULTS

The results from the included studies were discussed by outcome. For outcomes other than dental outcomes, the evidence has been presented based on the applicability of the included studies. Study applicability was based on how similar the water fluoride levels reported within each study were to those experienced in Australia:

1. High applicability studies – unfluoridated water (<0.4 ppm fluoride) vs. water with up to 1.5 ppm fluoride
2. Partial applicability studies – unfluoridated water (<0.4 ppm fluoride) vs. water with > 1.5 ppm fluoride; and water with 0.4-1.5 ppm fluoride vs. water with > 1.5 ppm fluoride
3. Limited applicability studies – studies in which all groups compared had water fluoride levels > 1.5 ppm

Where studies reported mean water fluoride levels that value was used to judge applicability. Where studies only reported a range for water fluoride the mid-point of the range was used to judge applicability.

The discussion for each outcome includes a description of:

- The number of studies identified that reported the outcome
- The quality of the studies, as assessed using the appropriate tool
- A summary of the results from all studies.

In addition to the discussion, results have been presented in table form. The results tables include information on the study population, intervention, comparator and effect estimates. Where available, the results were to be stratified by study type and by the following populations:

- Participant age: infants (ages 0-4), children (ages 5-11), adolescents (ages 12-17), adults (ages 18-64) and later adulthood age (ages 65+)
- High needs groups: Aboriginal and Torres Strait Islander peoples, and culturally and linguistically diverse communities
- High risk groups: Pregnant women, the frail elderly and children in non-fluoridated areas, rural and remote
- Special needs groups: People with mental illness; chronic physical conditions (e.g. diabetes, cardiovascular disease, chronic kidney disease); intellectual or physical difficulties; substance abuse; and victims of torture and trauma.

Based on initial scoping undertaken during development of the research protocol, it was not anticipated that sufficient evidence would be identified for any individual outcome that would warrant a pooled analysis. The systematic review did not identify any outcomes with sufficient quantity and quality of evidence to justify a pooled analysis and so no such analyses were performed.

OUTCOME DEFINITION AND PRIORITISATION

The Fluoride Reference Group provided definitions of the outcomes and outcome measures to be included in the review. The outcomes to be included are presented in Table 31.

Table 31 Outcomes from the systematic review to be included in the evidence evaluation

Outcome	Definition of outcome	Examples of diseases under this outcome	Outcome measures	Rationale for selecting this outcome
Dental caries	Chronic and progressive disease of the mineralised and soft tissues of the teeth.	NA	Any measure of dental caries including: Change in the number of decayed, missing and filled deciduous and permanent surfaces and teeth (dmfs/DMFS and dmft/DMFT). Incidence of dental caries. Percentage of caries-free children.	Fluoride impedes the demineralisation of tooth enamel and enhances its remineralisation. The progression of cavitation depends on the balance of the demineralisation and remineralisation processes.
Dental fluorosis	Hypomineralisation of the dental enamel. It can appear on the teeth as white flecks, brown staining or pitting of the enamel and in severe cases could cause aesthetic concern.	NA	Any measure of dental fluorosis including: Percentage of fluorosed children. Dean's Fluorosis Index. TSIF (Tooth Surface Index of Fluorosis). TFI (Thylstrup and Fejerskov index). Modified DDE (Developmental Defects of Enamel).	While the teeth are still forming, chronic ingestion of high concentrations of fluoride can cause hypomineralisation of the dental enamel.
Neuro-cognitive disorders	Disturbances in the mental process related to thinking, reasoning, and judgment.[1]	Delirium Alzheimer disease[2]	Any method of measuring this outcome will be included and reported as stated by the authors of each systematic review or study.	Fluoride exposure may cause molecular, cellular, and anatomical changes in the nervous system, and could affect brain function.[3]
Dementia	The impairment of brain function, involving memory, thinking and concentration.[4]		Any method of measuring this outcome will be included and reported as stated by the authors of each systematic review or study. *Note: When commenting on these outcome measures, the University of Sydney is to review the Dementia Outcomes Measurement Suite at Dementia assessment , for which Professor Henry Brodaty contributed to the deliberations of the Expert Measurement Group.*	Dementia has been distinguished from other neurocognitive disorders, because of its vascular causes and that as it is a progressive disease, accumulation or long term exposure to fluoride may need consideration.

[1] MESH term for 'cognitive disorders'.
[2] MESH term for 'Delirium, Dementia, Amnestic, Cognitive Disorders'.
[3] National Research Council Committee on Fluoride in Drinking Water 2006. *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*.
[4] Cayton, H., N. Graham, and J. Warner, Dementia: Alzheimer's and other dementias - the 'at your fingertips' guide. 2002.

Outcome	Definition of outcome	Examples of diseases under this outcome	Outcome measures	Rationale for selecting this outcome
Neuro-developmental disorders	Disorders of brain function that affect emotion, learning, and memory.[5]	Intellectual disability Communication disorders Autism spectrum disorder Attention-deficit/hyperactivity disorder Specific learning disorders Motor disorders[6]	Any method of measuring this outcome will be included and reported as stated by the authors of each systematic review or study.	Fluoride crosses the placenta. If fluoride reaches the developing foetus and is incorporated into its tissues, it could disturb the development of an embryo or foetus. High concentrations of fluoride exposure may also alter reproductive hormones.[5]
All cancers (malignant neoplasms) other than bone cancer	A range of diseases in which some of the body's cells become defective, begin to multiply out of control, can invade and damage the area around them, and can also spread to other parts of the body to cause further damage.[7]	Site specific cancers, e.g. lung, bladder cancer	Any measure of: Incidence; or Mortality	Fluoride could be genotoxic in humans, inducing mutations and chromosome aberrations in cells.
Cancers of the bone, and specifically osteosarcoma	Cancer that forms in cells of the bone.	Osteosarcoma Chondrosarcoma Ewing sarcoma	Any measure of: Incidence; or Mortality	Bone is the most plausible site for cancer associated with fluoride because of its deposition into bone and its mitogenic effects on bone cells in culture.[8] Fluoride can have a mitogenic effect on osteoblasts which could provide a mechanism by which fluoride could increase the risk for osteosarcoma.[9]

[5] American Psychological Association. April 2012. Research Forum. *The importance of differential diagnosis in neurodevelopmental disorders: Implications for IDEIA*.
[6] DSM-5 Table of Contents - American Psychiatric Association.
[7] Australian Institute of Health and Welfare and Australasian Association of Cancer Registries 2012. *Cancer in Australia: an overview, 2012*. Cancer series no. 74. Cat. no. CAN 70. Canberra: AIHW.
[8] National Research Council Committee on Fluoride in Drinking Water, 2006.Fluoride in Drinking Water: A Scientific Review of EPA's Standards.

Outcome	Definition of outcome	Examples of diseases under this outcome	Outcome measures	Rationale for selecting this outcome
Congenital abnormalities	Structural or functional abnormalities present at birth that can cause physical disability, intellectual and developmental disability, and other health problems.[10]	Congenital malformation (e.g. cleft lip or palate, heart defects, limb defects) Functional, or developmental abnormalities (e.g. behavioural disorders, speech or language difficulties, congenital hypothyroidism, congenital hyperthyroidism) Chromosomal disorders (e.g. Trisomy 21, Prader-Willi syndrome, Fragile X syndrome)[11]	Any method of measuring this outcome will be included and reported as stated by the authors of each systematic review or study.	Fluoride crosses the placenta. If fluoride reaches the developing foetus and is incorporated into its tissues, it could disturb the development of an embryo or foetus.[9] High concentrations of fluoride exposure may also alter reproductive hormones.[11]
Skeletal effects (other than bone cancers)	Diseases of or relating to a skeleton.	Bone fracture Skeletal fluorosis Osteosclerosis	Any method of measuring skeletal effects will be included – positive and negative, as reported by the authors of each systematic review or study. The exception being skeletal fluorosis where outcome measures will be restricted to stage II and stage III of the disease.	Fluoride is readily incorporated into the crystalline structure of bone and accumulates over time.[11] Within the bone, fluoride ions can replace hydroxyl ions in the hydroxyapatite lattice with possible implications for its mechanical properties. Elevation of the fluoride concentration in plasma directly increases osteoblastic differentiation. A number of bone disorders could also be affected by these mechanisms.[12] Under certain conditions fluoride may weaken bone and increase the risk of fractures.[12]
All-cause mortality	All deaths reported in a given population.[13]	NA	Any method of measuring this outcome will be included and reported as stated by the authors of each systematic review or study.	Should fluoride be linked to mortality, the impact of this outcome would be very high.

[10] National Institute of health.Birth Defects: Condition Information.
[11] National Research Council Committee on Fluoride in Drinking Water, 2006.Fluoride in Drinking Water: A Scientific Review of EPA's Standards.
[12] Medical Research Council working group report. 2002. Water fluoridation and health.
[13] MESH term for 'mortality'.

Outcome	Definition of outcome	Examples of diseases under this outcome	Outcome measures	Rationale for selecting this outcome
Renal effects	Pathological processes of the kidney or its component tissues.	NA	Any method of measuring this outcome will be included and reported as stated by the authors of each systematic review or study.	Renal excretion is the major route of elimination for inorganic fluoride from the body. As a result, kidney cells are exposed to relatively high fluoride concentrations, making the kidney a potential site for acute fluoride toxicity.[14]
Thyroid dysfunction	Pathological processes involving the thyroid gland[15].	Acquired hypothyroidism Acquired hyperthyroidism Goitre Thyroiditis Graves disease Thyrotoxicosis[16]	Any method of measuring this outcome will be included and reported as stated by the authors of each systematic review or study.	Fluoride exposure may affect thyroid function or the activity of the thyroid hormones.[17]
Any other adverse event	An adverse outcome that occurs during or after the use of the intervention but is not necessarily caused by it.[18]	NA	Any method of measuring this outcome will be included and reported as stated by the authors of each systematic review or study.	NA

GRADE specifies three categories of outcomes according to their importance for decision making; critical, important but not critical and of limited importance. Classification of importance of the outcomes was performed by the Fluoride Reference Group prior to the start of review activities and is provided below.

Table 32 Classification of importance of the outcomes

Outcome	Rate importance of outcome
Dental caries	Critical for decision making
Dental fluorosis	Critical for decision making
Neuro-cognitive disorders	Important, but not critical
Dementia	Important, but not critical
Neuro-developmental disorders	Important, but not critical
Cancers of the bone, and specifically osteosarcoma	Important, but not critical
Congenital abnormalities	Important, but not critical
All cancers (malignant neoplasms) other than bone cancer	Important, but not critical
Skeletal effects (other than bone cancers)	Important, but not critical
All-cause mortality	Important, but not critical

[14] National Research Council, Subcommittee on Health Effects of Ingested Fluoride. 1993. Health Effects of Ingested Fluoride.
[15] MESH term for 'thyroid disease'.
[16] Examples from MESH tree for thyroid disorder and ICD10 Disorders of thyroid gland (E00-E07)
[17] National Research Council Committee on Fluoride in Drinking Water, 2006.Fluoride in Drinking Water: A Scientific Review of EPA's Standards.
[18] The Cochrane Collaboration glossary.

Outcome	Rate importance of outcome
Renal effects	Important, but not critical
Thyroid dysfunction	Important, but not critical
Any other adverse event	Important, but not critical

GRADE ASSESSMENT

The evidence for each outcome was assessed using the GRADE system for rating the quality of evidence (Guyatt et al 2011) with some modification for the assessment of a public health intervention (Harder et al 2015). The GRADE assessment was performed by one reviewer and checked by a second reviewer. Any discrepancies were resolved by discussion or consultation with a third reviewer.

Under the GRADE system, the overall quality of the evidence for an outcome is categorised as high, moderate, low or very low depending on the study design. On the advice of the NHMRC, and with the approval of the Fluoride Reference Group, this review has adopted the GRADE categorisation suggested by Harder et al (2015), in which non-randomized designs which are less prone to bias are categorised in the GRADE system as being of moderate quality. For this review, all Level II, Level III-1 and Level III-2 studies were initially categorised as moderate quality and all Level III-3 and Level IV studies were initially graded as low quality.

The quality of the evidence was decreased if any of the following conditions were met:

- Serious or very serious limitation to study quality
- Important inconsistency
- Some or major uncertainty about directness
- Imprecise or sparse data
- High probability of reporting bias

The quality of the evidence was increased if the evidence had not been downgraded and if any of the following conditions are met:

- Strong or very strong evidence of association based on consistent evidence from two or more observational studies, with no plausible confounders
- Very strong evidence of association based on direct evidence with no major threats to validity
- Evidence of a dose-response gradient
- All plausible confounders would have reduced the effect

The review also allowed the possibility for upgrading the evidence if the effects observed were consistent across study designs, as suggested by Harder et al (2015). For this review, this was applied if consistent results were observed across different levels of evidence.

The reasoning behind any increase or decrease in the rating of evidence was recorded in the footnotes to the GRADE assessment tables. The full GRADE evidence profiles were included in the discussion of each outcome. The Summary of Findings tables for all outcomes were included in the discussion section of the Evidence Evaluation report.

The GRADE system for assessing evidence was not originally designed to consider evidence for public health interventions. Consequently, for public health interventions like water fluoridation, where evidence of efficacy comes from observational studies, much of the evidence will ultimately be rated as ‘low’ or ‘very low’ quality. Due to concerns that the potential pejorative connotations of these descriptors may result in the evidence being disregarded and/or misinterpreted, the Fluoride

Reference Group decided to omit the descriptors and describe the evidence in terms of the confidence in the reported results.

DEVELOPMENT OF EVIDENCE STATEMENTS

Evidence statements on the health effects of water fluoridation for each outcome were developed by the Fluoride Reference Group. The NHMRC also conducted a quality assurance process to ensure that evidence was summarised consistently across all of the identified outcomes.

Each evidence statement includes a summary of any evidence identified in the previous NHMRC review and the evidence identified in the current review. The evidence statements for each outcome are presented following the GRADE assessment and take into account the extent and strength of the clinical evidence from the studies identified through the systematic review.

FULL LIST OF INCLUDED STUDIES

Table 33 List of included studies from overview of reviews of dental caries

Study ID	Citation
Iheozor-Ejiofor 2015	Iheozor-Ejiofor, Z, Worthington, HV et al 2015. Water fluoridation for the prevention of dental caries, The Cochrane database of systematic reviews.
Griffin 2007	Griffin, SO, Regnier, E et al 2007. Effectiveness of fluoride in preventing caries in adults, Journal of Dental Research, 86 (5), 410-415.
Rugg-Gunn and Do 2012	Rugg-Gunn, AJ and Do, L 2012. Effectiveness of water fluoridation in caries prevention, Community Dentistry and Oral Epidemiology, 40, 55-64.

Table 34 List of studies from the review of primary studies of dental caries

Study ID	Citation
Armfield 2013	Armfield, JMS 2013. Water fluoridation and the association of sugar-sweetened beverage consumption and dental caries in Australian children, American journal of public health, 103 (3), 494-500.
Blinkhorn 2015	Blinkhorn, AS, Blinkhorn, AS et al 2015. A 4-year assessment of a new water-fluoridation scheme in New South Wales, Australia, International dental journal, 65 (3), 156-163.
Broffitt 2013	Broffitt, BL 2013. Factors associated with surface-level caries incidence in children aged 9 to 13: The Iowa Fluoride Study, Journal of public health dentistry, 73 (4), 304-310.
CDC 2011	Centers for Disease Control and Prevention (CDC) 2011. Dental caries in rural Alaska Native children--Alaska, 2008, MMWR, Morbidity and mortality weekly report. 60 (37), 1275-1278.
Chankanka 2011	Chankanka, OC 2011. Longitudinal associations between children's dental caries and risk factors, Journal of public health dentistry, 71 (4), 289-300.
Crocombe 2015	Crocombe LA, Brennan DS et al 2015. The effect of lifetime fluoridation exposure on dental caries experience of younger rural adults, Australian dental journal, 60 (1), 30-37.
da Silva 2015	da Silva JV, Machado FC et al 2015. Social Inequalities and the Oral health in Brazilian Capitals, Ciencia & Saude Coletiva, 20 (8), 2539-2548.
Do 2015	Do LG, Ha DH et al 2015. Factors attributable for the prevalence of dental caries in Queensland children, Community Dentistry & Oral Epidemiology, 43 (5), 397-405.
Do and Do 2015	Do, L and Do, L 2015. Contemporary multilevel analysis of the effectiveness of water fluoridation in Australia, Australian & New Zealand Journal of Public Health, 39 (1), 44-50.
Do and Spencer 2011	Do, LG and Spencer, AJ 2011. Oral health status of Vietnamese children: findings from the National Oral Health Survey of Vietnam 1999, Asia-Pacific journal of public health / Asia-Pacific Academic Consortium for Public Health, 23 (2), 217-227.
Do 2014	Do, LGM 2014. Dental caries and fluorosis experience of 8-12-year-old children by early-life exposure to fluoride, Community dentistry and oral epidemiology, 42 (6), 553-562.
Do 2007	Do, LGS 2007. Risk-benefit balance in the use of fluoride among young children, Journal of Dental Research, 86 (8), 723-728.
Freire 2013	Freire, MCR 2013. [Individual and contextual determinants of dental caries in Brazilian 12-year-olds in 2010], Revista de saude publica, 47 Suppl 3 (pp 40-49), Dec.
Haysom 2015	Haysom, L, I 2015. Oral health and risk factors for dental disease of Australian young people in custody, Journal of Paediatrics and Child Health, 51 (5), 545-551.

Kamppi 2013	Kamppi, AT 2013. Geographical distribution of dental caries prevalence and associated factors in young adults in Finland, Caries research, 47 (4), 346-354.
Lalloo 2015	Lalloo, R 2015. Does fluoride in the water close the dental caries gap between Indigenous and non-Indigenous children?, Australian dental journal, 60 (3), 390-396.
Lee 2015	Lee, HJ and Han, DH 2015 Exploring the determinants of secular decreases in dental caries among Korean children. Community Dentistry & Oral Epidemiology 43(4), 357-365. 2015.
MacHiulskiene 2009	MacHiulskiene, VB, V 2009. Prevalence and extent of dental caries, dental fluorosis, and developmental enamel defects in Lithuanian teenage populations with different fluoride exposures, European Journal of Oral Sciences, 117 (2), 154-160.
McGrady 2012	McGrady, MGE 2012. The association between social deprivation and the prevalence and severity of dental caries and fluorosis in populations with and without water fluoridation, BMC public health, 12 (pp 1122), 2012.
McLaren 2012	McLaren, LE 2012. Drinking water fluoridation and oral health inequities in Canadian children, Canadian journal of public health = Revue canadienne de sante publique, 103 (7 Suppl 1), eS49-eS56. Included
Postma 2008	Postma TC, Ayo-Yusuf OA et al 2008. Socio-demographic correlates of early childhood caries prevalence and severity in a developing country--South Africa, International dental journal, 58 (2), 91-97.
Skinner 2014	Skinner, J et al 2014. Factors associated with dental caries experience and oral health status among New South Wales adolescents, Australian & New Zealand Journal of Public Health, 38 (5), 485-489
Slade 2013	Slade, GDS 2013. Effects of fluoridated drinking water on dental caries in Australian adults, Journal of Dental Research, 92 (4), 376-382.
Wang 2012	Wang, XW 2012. Genetic and environmental factors associated with dental caries in children: The Iowa Fluoride Study, Caries research, 46 (3), 177-184.
Zander 2013	Zander, A et al 2013. Risk factors for dental caries in small rural and regional Australian communities, Rural & Remote Health, 13 (3), 2492.

Table 35 List of included studies from review of other health effects

Study ID	Citation
Amini 2011	Amini, H, Taghavi Shahri, SM et al 2011. Drinking water fluoride and blood pressure? An environmental study, Biological Trace Element Research, 144 (1-3), 157-163.
Barbato 2009	Barbato, PR and Peres, MA 2009. Tooth loss and associated factors in adolescents: a Brazilian population-based oral health survey, Revista de Saude Publica, 43 (1), 13-25.
Blakey 2014	Blakey, K, Feltbower, RG et al 2014. Is fluoride a risk factor for bone cancer? Small area analysis of osteosarcoma and Ewing sarcoma diagnosed among 0-49-year-olds in Great Britain, 1980-2005, International Journal of Epidemiology, 43 (1), 224-234.
Broadbent 2014	Broadbent, JM, Thomson, WM et al 2014. Community Water Fluoridation and Intelligence: Prospective Study in New Zealand, American journal of public health, 105 (1), 72-76.
Burke 2010	Burke, FM, Whelton, H et al 2010. Fluoridation and tooth wear in Irish adults, Community Dentistry and Oral Epidemiology, 38 (5), 415-421.
Chandrajith 2011	Chandrajith, R, Nanayakkara, S et al 2011. Chronic kidney diseases of uncertain etiology (CKDue) in Sri Lanka: Geographic distribution and environmental implications, Environmental Geochemistry and Health, 33 (3), 267-278.
Choi 2015	Choi, AL, Zhang, Y et al 2015. Association of lifetime exposure to fluoride and cognitive functions in Chinese children: A pilot study, Neurotoxicology and Teratology, 47, 96-101.

Study ID	Citation
Comber 2011	Comber, H, Deady, S et al 2011. Drinking water fluoridation and osteosarcoma incidence on the island of Ireland, Cancer Causes and Control, 22 (6), 919-924.
Diouf 2012	Diouf, M, Cisse, D et al 2012. Pregnant women living in areas of endemic fluorosis in Senegal and low birthweight newborns: Case-control study, Revue d'Epidemiologie et de Sante Publique, 60 (2), 103-108.
Eswar 2011	Eswar, P, Nagesh, L et al 2011. Intelligence quotients of 12-14 year old school children in a high and a low fluoride village in India, Fluoride, 44 (3), 168-172.
Fan 2007	Fan, Z, Dai, H et al 2007. The Effect of High Fluoride Exposure on the Level of Intelligence in Children, The Environment and Health Journal, 24 (10), 802-803.
Huang 2013	Huang, C-Q 2013. X-rays changes of forearm and shank of residents from areas with different fluoride contents in drinking water in Jilin province, Chinese Journal of Endemiology, 32 (2), 208-212.
Hussain 2010	Hussain, J, Hussain, I et al 2010. Fluoride and health hazards: Community perception in a fluorotic area of central Rajasthan (India): An arid environment, Environmental Monitoring and Assessment, 162 (1-4), 1-14.
Jolaoso 2014	Jolaoso, IA, Kumar, J et al 2014. Does fluoride in drinking water delay tooth eruption?, Journal of Public Health Dentistry, 74 (3), 241-247.
Karimzade 2014	Karimzade, S, Aghaei, M et al 2014. Investigation of intelligence quotient in 9-12-year-old children exposed to high- and low-drinking water fluoride in West Azerbaijan Province, Iran, Fluoride, 47 (1), 9-14.
Kharb 2012	Kharb, S, Sandhu, R et al 2012. Fluoride levels and osteosarcoma, South Asian Journal of Cancer, 1 (2), 76-77.
Koltermann 2011	Koltermann, AP, Giordani, JMA et al 2011. The association between individual and contextual factors and functional dentition status among adults in Rio Grande do Sul State, Brazil: A multilevel study, Cadernos de Saude Publica, 27 (1), 173-182.
Kutlucan 2013	Kutlucan, A, Koroglu, BK et al 2013. The investigation of effects of fluorosis on thyroid volume in school-age children, Med Glas Ljek komore Zenicko-doboj kantona, 10 (1), 93-98.
Levy 2012	Levy, M and Leclerc, B-S 2012. Fluoride in drinking water and osteosarcoma incidence rates in the continental United States among children and adolescents, Cancer Epidemiology, 36 (2), e83-e88.
Liu 2014	Liu, H, Gao, Y et al 2014. Assessment of relationship on excess fluoride intake from drinking water and carotid atherosclerosis development in adults in fluoride endemic areas, China, International Journal of Hygiene and Environmental Health, 217 (2-3), 413-420.
Namkaew 2012	Namkaew, M and Wiwatanadate, P 2012. Association of fluoride in water for consumption and chronic pain of body parts in residents of San Kamphaeng district, Chiang Mai, Thailand, Tropical Medicine and International Health, 17 (9), 1171-1176.
Nasman 2013	Nasman, P, Ekstrand, J et al 2013. Estimated drinking water fluoride exposure and risk of hip fracture: A cohort study, Journal of Dental Research, 92 (11), 1029-1034.
NFIS 2013	National Fluoride Information Service 2013, Community Water Fluoridation and Osteosarcoma - Evidence from Cancer Registries. New Zealand Ministry of Health.
Neidell 2010	Neidell, M, Herzog, K et al 2010. The association between community water fluoridation and adult tooth loss, American journal of public health, 100 (10), 1980-1985.
Ostovar 2013	Ostovar, A, Dobaradaran, S et al 2013. Correlation between Fluoride Level in Drinking Water and the Prevalence of Hypertension: an Ecological Correlation Study, The International Journal of Occupational and Environmental Medicine, 4 (4), 216-217.
PHE 2014	Public Health England 2014, Water fluoridation: health monitoring report for England 2014. London.
Ranjan 2012	Ranjan, S and Yasmin, S 2012. Assessment of groundwater quality in Gaya region with respect to fluoride, Journal of Ecophysiology and Occupational Health, 12 (3-4), 21-25.
Rocha-Amador 2007	Rocha-Amador, D, Navarro, ME et al 2007. Decreased intelligence in children and exposure to fluoride and arsenic in drinking water, Cadernos de Saude Publica, 23 (Suppl. 4), S579-S587.
Saxena 2012	Saxena, S, Sahay, A et al 2012. Effect of fluoride exposure on the intelligence of school children in Madhya Pradesh, India, Journal of Neurosciences in Rural Practice, 3 (2), 144-149.
Schwartz 2014	Schwartz, GG 2014. Eye cancer incidence in U.S. States and access to fluoridated water, Cancer Epidemiology Biomarkers and Prevention, 23 (9), 1707-1711.

Study ID	Citation
Seraj 2012	Seraj, B, Shahrabi, M et al 2012. Effect of High Water Fluoride Concentration on the Intellectual Development of Children in Makoo/Iran, Journal of Dentistry of Tehran University of Medical Sciences, 9 (3), 221-229.
Sharma 2009a	Sharma, JD, Jain, P et al 2009. Gastric discomforts from fluoride in drinking water in Sanganer Tehsil, Rajasthan, India, Fluoride, 42 (4), 286-291.
Sharma 2009b	Sharma, JD, Sohu, D et al 2009. Prevalence of neurological manifestations in a human population exposed to fluoride in drinking water, Fluoride, 42 (2), 127-132.
Singh 2014	Singh, N, Verma, KG et al 2014. A comparative study of fluoride ingestion levels, serum thyroid hormone & TSH level derangements, dental fluorosis status among school children from endemic and non-endemic fluorosis areas, SpringerPlus, 3 (7).
Singh 2013	Singh, VP, Singh, CD et al 2013. A correlation between Serum Vitamin, Acetylcholinesterase Activity and IQ in Children with Excessive Endemic Fluoride exposure in Rajasthan, India, International Research Journal of Medical Sciences, 1 (3), 12-16.
Srikanth 2008	Srikanth, R, Chandra, TR et al 2008. Endemic fluorosis in five villages of the Palamau District, Jharkhand, India, Fluoride, 41 (3), 206-211.
Sun 2013	Sun, L, Gao, Y et al 2013. An assessment of the relationship between excess fluoride intake from drinking water and essential hypertension in adults residing in fluoride endemic areas, Science of the Total Environment, 443, 864-869.
Topuz 2006	Topuz, O, Akkaya, N et al 2006. Bone resorption marker and ultrasound measurements in adults residing in an endemic fluorosis area of Turkey, Fluoride; 2006, 39 (2), 138-144.
Trivedi 2012	Trivedi, MH, Sangai, NP et al 2012. Assessment of groundwater quality with special reference to fluoride and its impact on IQ of schoolchildren in six villages of the Mundra region, Kachchh, Gujarat, India, Fluoride, 45 (4), 377-383.
Trivedi 2007	Trivedi, MH, Verma, RJ et al 2007. Effect of high fluoride water on intelligence of school children in India, Fluoride, 40 (3), 178-183.
Wang 2007	Wang, S-X, Wang, Z-H et al 2007. Arsenic and fluoride expose in drinking water: Children's IQ and growth in Shanyin Country, Shanxi Province, China, Environmental Health Perspectives, 115 (4), 643-647.
Xiang 2009	Xiang, Q, Chen, L et al 2009. Fluoride and thyroid function in children in two villages in China, Journal of Toxicology and Environmental Health Sciences, 1 (3), 54-59.

COMPLETED QUALITY ASSESSMENT AND DATA EXTRACTION FOR THE INCLUDED REVIEWS

GRIFFIN ET AL. (2007)

Quality assessment

Item	Question	Answer	Comment
1	Was an 'a priori' design provided?	No	Not reported
2	Was there duplicate study selection and data extraction?	Yes	Two reviewers independently reviewed the abstract and title of each record and completed the data extraction form
3	Was a comprehensive literature search performed?	Yes	MEDLINE, EMBASE & CENTRAL searched. Search strings reported. FDA, American Dental Association and manufacturers of fluoride products contacted for unpublished clinical studies
4	Was the status of publication (i.e. grey literature) used as an inclusion criterion?	Yes	FDA, American Dental Association and manufacturers of fluoride products contacted for unpublished clinical studies.

Item	Question	Answer	Comment
5	Was a list of studies (included and excluded) provided?	Yes	Both included with reasons for exclusion
6	Were the characteristics of the included studies provided?	Yes	Methods, participants, intervention, outcomes and additional information supplied in tables
7	Was the scientific quality of the included studies assessed and documented?	No	Not reported
8	Was the scientific quality of the included studies used appropriately in formulating conclusions?	No	Not reported
9	Were the methods used to combine the findings of studies appropriate?	Yes	Random-effects model. Heterogeneity tested.
10	Was the likelihood of publication bias assessed?	No	Not reported
11	Was the conflict of interest stated?	No	Funding reported for systematic review only.

Data extraction

General information	Study ID	33
	Title	Effectiveness of fluoride in preventing caries in adults
	Country of origin	USA
	Source of funding	Division of Oral health, Centers for Disease Control and Prevention; Defense Resources management institute; Naval Postgraduate School; National science Foundation
	Possible conflicts of interest (for study authors or translators)	NR
AMSTAR Rating		6/10
Characteristics of review and included primary studies	Aim/objectives of study	To examine the effectiveness of self- and professionally applied fluoride and water fluoridation among adults
	Study design	Systematic review
	Search Methods	Searched MEDLINE (1966 to 2004), EMBASE (1988 to 2004) and CENTRAL. References from retrieved articles searched. American Dental Association, FDA, and manufacturers of topical fluoride products contacted for unpublished trials.
	Selection Criteria	Published in English, lasted ≥1 yr, examined association between fluoride and caries in intact human teeth in study population that included adults. For water fluoridation: cross-sectional studies were included if participants lived most of their lives in fluoridated/non-fluoridated communities, or they estimated the effect of exposure to water fluoridation controlling for potential confounding factors. Studies excluded if mean age of population <20 yrs, did not have concurrent control group, or had insufficient information to extrapolate the benefit of fluoride to all 28 teeth and to calculate a standard error.
	Level of evidence (lowest identified)	IV
	Study types identified	For water fluoridation: ecological cross-sectional and prospective cohort
	Quality of Evidence evaluated	No
	Exposure duration	'Most of lifetime'
	Source population description	Populations ≥20 years living in various states in the USA, Australia, Sweden, Great Britain, & Canada
	Inclusion criteria	NR
	Exclusion criteria	NR
Participant characteristics	Interventions	Fluoridated drinking water
	Comparators	Non-fluoridated drinking water
	Subgroups reported	NR
Results: dental	Definition (with units)	DMFT/S (decayed, missing,& filled permanent teeth or surfaces) or DFT/S

caries	Method of measurement	(decayed & filled permanent teeth or surfaces) NR
	No. of studies and participants analysed	N=9 studies with 7853 participants (1 already included in the Cochrane review and 3 in Rugg-Gunn (2012))
	No. of studies and participants excluded or missing (with reasons)	NR
	Statistical method of analysis	1. Fisher's inverse chi-squared method to see if combined p-values were statistically significant 2. Relative risk calculated for each water fluoridation cross-sectional study 3. Absolute difference in annual caries increment
	Results (See Table below for individual study results)	1. Water fluoridation, all adults, coronal caries (N=9 studies; n=7,853 participants) p<0.001 2. Summary RR=0.654 (95%CI: 0.490-0.874) [N=7 studies; n=5,409 participants] Prevented fraction of 34.6% (95%CI: 12.6%-51.0%) Heterogeneity present. See Appendix figure 2 below. When restricted to studies published after 1979 [N=5 studies; n=2530 participants] the prevented fraction was 27.2% (95%CI: 19.4%-34.3%). "Heterogeneity was not an issue." 3. See figure 1 and 2 below (no numerical data reported)
Authors' conclusion	"These findings suggest that fluoride prevents caries among adults of all ages."	
Correspondence if required	None	
Reviewer's notes	Only results for water fluoridation were extracted. It should be noted that Burt et al (1986)/Ekland et al (1987) compare high-fluoride water content (3.5 ppm) with 'optimal-fluoride' content (0.7 ppm); Murray et al (1971) is set in a naturally fluoridated community of levels between 1.5-2.0 ppm; and the fluoride level in Stamm et al (1990) is 1.6 ppm.	

IHEOZOR-EJIOFOR ET AL. (2015)

Quality assessment

Item	Question	Answer	Comment
1	Was an 'a priori' design provided?	Yes	Protocol published 9 December 2013 on Cochrane website – research question and inclusion criteria included
2	Was there duplicate study selection and data extraction?	Yes	2 review authors independently screened titles and extracted data with disagreements resolved by discussion or 3rd review author consulted
3	Was a comprehensive literature search performed?	Yes	7 databases searched (dates reported) + trial registries, reference lists of identified trials and review articles were looked at for relevant articles; search strategies provided
4	Was the status of publication (i.e. grey literature) used as an inclusion criterion?	Yes	Searched regardless of publication language or status; Considered inclusion of prospective studies with concurrent control (dental caries), and any study design (dental fluorosis).
5	Was a list of studies (included and excluded) provided?	Yes	List of included and excluded studies (including reason for exclusion) provided
6	Were the characteristics of the included studies provided?	Yes	Characteristics (i.e. methods, participants, interventions, outcomes, funding) of all included studies provided
7	Was the scientific quality of the included studies assessed and documented?	Yes	All studies assessed for risk of bias using Cochrane 'Risk of Bias' assessment tool adapted for non-randomised studies (domains: sampling, confounding, blinding of outcome assessment, incomplete outcome data, incomplete reporting, other bias)

8	Was the scientific quality of the included studies used appropriately in formulating conclusions?	Yes	e.g. "Our confidence in the size of the effect … is limited due to the high risk of bias, …"
9	Were the methods used to combine the findings of studies appropriate?	Yes	Heterogeneity tested using I^2 statistic; random effects model used which is appropriate with substantial statistical heterogeneity
10	Was the likelihood of publication bias assessed?	Yes	Stipulated in the protocol that this would be assessed if the meta-analyses had more than 10 included studies – two outcomes had 10 studies, and one other nine
11	Was the conflict of interest stated?	Yes	Internal sources of support: The Cochrane Oral Health Group, which is supported by the Manchester Academic Health Sciences Centre (MAHSC) and the NIHR Manchester Biomedical Research Centre, The University of Manchester, UK. Also mentions external sources.*

Abbreviations: UK = United Kingdom

* Caries: Six (of 19) studies were funded by research grants from research organisations, health authorities and government organisations etc. while the other studies did not state their funding sources. Fluorosis: Forty-four studies were supported by research grants from government organisations and health authorities, non-governmental organisations, research organisations, universities or a combination of these sources etc. Sources of support were not explicitly stated in 86 studies.

Data extraction

General information	Study ID	90
	Title	Water fluoridation for the prevention of dental caries
	Country of origin	UK; Canada
	Source of funding	The University of Manchester, UK. Manchester Academic Health Sciences Centre, UK. National Institute for Health Research (NIHR), UK. Cochrane Oral Health Group Global Alliance, UK.
	Possible conflicts of interest (for study authors or translators)	"Authors on this review have also been involved in the evaluation of the evidence using different methodology for the CDC Task Force Recommendation on Water Fluoridation."
AMSTAR Rating		11/11
Characteristics of review and included primary studies	Aim/objectives of study	To evaluate the effects of water fluoridation (artificial or natural) on the prevention of dental caries. To evaluate the effects of water fluoridation (artificial or natural) on dental fluorosis.
	Study design	Systematic review
	Search Methods	Searched: The Cochrane Oral Health Group's Trials Register (to 19 February 2015); The Cochrane Central Register of Controlled Trials (CENTRAL; Issue 1, 2015); MEDLINE via OVID (1946 to 19 February 2015); EMBASE via OVID (1980 to 19 February 2015); Proquest (to 19 February 2015); Web of Science Conference Proceedings (1990 to 19 February 2015); ZETOC Conference Proceedings (1993 to 19 February 2015). Searched ClinicalTrials.gov and the World Health Organization's International Clinical Trials Registry Platform for ongoing trials to 19 February 2015. No restrictions on language of publication or publication status in the searches of the electronic databases.
	Selection Criteria	Caries data: Included only prospective studies with a concurrent control that compared at least two populations - one receiving fluoridated water and the other non-fluoridated water - with outcome(s) evaluated at least two points in time. Fluorosis data: Included any type of study design, with concurrent control, that compared populations exposed to different water fluoride concentrations. Included populations of all ages that received fluoridated water (naturally or artificially fluoridated) or non-fluoridated water.

General information	Study ID	90
	Level of evidence (lowest identified)	IV
	Study types identified	Prospective observational studies (cross-sectional / ecological; controlled before-and-after; interrupted time series; prospective cohort)
	Quality of Evidence evaluated	Yes
	Exposure duration	Unclear, but assume lifetime exposure. Note that all studies were in children.
	Source population description	Populations living in North and Central America (USA, Canada, Mexico, Cuba, Antigua), South America (Chile, Argentina, Brazil, Venezuela), Europe (Germany, England, Holland, Ireland, Greece, Netherlands, Finland, Iceland, Portugal, Hungary, Italy, Switzerland, Scotland, Wales, Estonia, Lithuania, Sweden, Serbia, Poland, Denmark), Asia (China, India, Indonesia, Taiwan, Sri Lanka, Turkey, Saudi Arabia, Singapore, Malaysia, Thailand, Iran, Japan), Africa (Tanzania, Namibia, Sudan, Ghana, South Africa, Uganda, Ethiopia), and Australasia (Australia, New Zealand)
	Inclusion criteria	Populations of all ages. Outcomes looking at any measure of dental caries, specific measures of dental fluorosis, or any adverse effects.
	Exclusion criteria	Reported. Inappropriate study design was the main reason for exclusion.
Participant characteristics	Interventions	Fluoridated drinking water
	Comparators	Non-fluoridated drinking water. The reviewers determined that “water with a fluoride concentration of 0.4 parts per million (ppm) or less (arbitrary cut-off defined a priori) was classified as non-fluoridated.”
	Subgroups reported	“Subgroup analyses according to whether data were collected prior to the widespread use of fluoride toothpaste, or after: we used a cut-off of 1975 for this purpose. We made the decision to undertake subgroup analyses by date of study conduct post hoc, following peer review comments.” There were no studies included on adults, so all results are in children.
Results: dental caries	Definition (with units) Method of measurement	Dental caries: dmft (decayed missing and filled deciduous teeth), DMFT (decayed missing and filled permanent teeth), DMFS (decayed missing and filled surfaces in permanent teeth), and proportion of caries-free children (deciduous and permanent dentition). Disparities in caries: decayed, extracted and filled deciduous teeth, dmft, and percentage of caries-free children. Dental fluorosis: Dean’s index, TFI, TSIF, DDE, other indices, specific enamel defects, or did not state the index used at all. Studies using mean value or Community Fluorosis Index (CFI)) were not used for analysis.
	No. of studies and participants analysed	19 studies on caries. Of these, there were: • 9 studies with 44,268 participants provided data on dmft, • 10 studies with 78,764 participants provided data on DMFT, • 1 study reported on 343 participants on DMFS, • 10 studies with 39,966 participants reported on the proportion of caries-free children for deciduous dentition, • 8 studies with 53,538 participants reported on proportion of caries-free children for permanent dentition.
	No. of studies and participants excluded or missing (with reasons)	112 studies were excluded. Reasons included: (1) absence of data from two time points for one or both study groups, (2) unsuitable control group, and (3) absence of concurrent control group.
	Statistical method of analysis	For dmft and DMFT analyses the difference in mean change scores between the fluoridated and control groups was calculated. For the proportion caries free the difference in the proportion caries free between the fluoridated and control groups was calculated. For fluorosis data the log odds was calculated and presented as probabilities for interpretation. For the forest plots, a random effects model using inverse variance was done, with the standard calculations for heterogeneity done as well.
	Results	“The results from the caries severity data indicate that the initiation of water fluoridation results in reductions in dmft of 1.81 (95%CI 1.31 to 2.31; 9

General information	Study ID	90
		studies at high risk of bias, 44,268 participants) and in DMFT of 1.16 (95% CI 0.72 to 1.61; 10 studies at high risk of bias, 78,764 participants). This translates to a 35% reduction in dmft and a 26% reduction in DMFT compared to the median control group mean values. There were also increases in the percentage of caries free children of 15% (95% CI 11% to 19%; 10 studies, 39,966 participants) in deciduous dentition and 14% (95% CI 5% to 23%; 8 studies, 53,538 participants) in permanent dentition. The majority of studies (71%) were conducted prior to 1975 and the widespread introduction of the use of fluoride toothpaste." "There is insufficient information to determine whether initiation of a water fluoridation programme results in a change in disparities in caries across socioeconomic status (SES) levels." "There is insufficient information to determine the effect of stopping water fluoridation programmes on caries levels." "No studies that aimed to determine the effectiveness of water fluoridation for preventing caries in adults met the review's inclusion criteria." "With regard to dental fluorosis, we estimated that for a fluoride level of 0.7 ppm the percentage of participants with fluorosis of aesthetic concern was approximately 12% (95% CI 8% to 17%; 40 studies, 59,630 participants). This increases to 40% (95% CI 35% to 44%) when considering fluorosis of any level (detected under highly controlled, clinical conditions; 90 studies, 180,530 participants). Over 97% of the studies were at high risk of bias and there was substantial between-study variation."
Authors' conclusion	"There is very little contemporary evidence, meeting the review's inclusion criteria, that has evaluated the effectiveness of water fluoridation for the prevention of caries." "The available data come predominantly from studies conducted prior to 1975, and indicate that water fluoridation is effective at reducing caries levels in both deciduous and permanent dentition in children. Our confidence in the size of the effect estimates is limited by the observational nature of the study designs, the high risk of bias within the studies and, importantly, the applicability of the evidence to current lifestyles. The decision to implement a water fluoridation programme relies upon an understanding of the population's oral health behaviour (e.g. use of fluoride toothpaste), the availability and uptake of other caries prevention strategies, their diet and consumption of tap water and the movement/migration of the population. There is insufficient evidence to determine whether water fluoridation results in a change in disparities in caries levels across SES. We did not identify any evidence, meeting the review's inclusion criteria, to determine the effectiveness of water fluoridation for preventing caries in adults." "There is insufficient information to determine the effect on caries levels of stopping water fluoridation programmes." "There is a significant association between dental fluorosis (of aesthetic concern or all levels of dental fluorosis) and fluoride level. The evidence is limited due to high risk of bias within the studies and substantial between-study variation."	
Correspondence if required	Anne-Marie Glenny, Cochrane Oral Health Group, School of Dentistry, The University of Manchester, Coupland 3 Building, Oxford Road, Manchester, M13 9PL, UK. Email: a.glenny@manchester.ac.uk.	
Reviewer's notes	The inclusion criteria were very restrictive. This excluded a lot of contemporary evidence, particularly Australian evidence. Expert advisors mentioned that the fluorosis measures were not entirely reflective of current practice and fluorosis of aesthetic concern was questionable, and this may be in part due to a majority of the evidence found being published pre-1975. Public perceptions and dental practices may have changed since these studies were done. Also water fluoride levels were very high compared with Australian level.	

RUGG-GUNN AND DO (2012)

Quality assessment

Item	Question	Answer	Comment
1	Was an 'a priori' design provided?	No	Not reported
2	Was there duplicate study selection and data extraction?	No	Not reported
3	Was a comprehensive literature search performed?	No	"Professional Internet search" conducted but no details provided
4	Was the status of publication (i.e. grey literature) used as an inclusion criterion?	Yes	Included government reports
5	Was a list of studies (included and excluded) provided?	No	Only list of included studies provided.
6	Were the characteristics of the included studies provided?	Yes	Study type, number subjects, country & community, year when fluoridation began, non-F caries index, and % caries reduction
7	Was the scientific quality of the included studies assessed and documented?	No	Not reported
8	Was the scientific quality of the included studies used appropriately in formulating conclusions?	No	Conclusions focussed on differences between pre- and post-1990 results using previous publication of pre-1990 studies
9	Were the methods used to combine the findings of studies appropriate?	No	Results reported in table and graphs showing differences in results between pre-1990 and post-1990 studies.
10	Was the likelihood of publication bias assessed?	No	
11	Was the conflict of interest stated?	No	Author of review stated there was no conflict of interest. Source of funding of review and included studies not reported.

Data extraction

General information	Study ID	93
	Title	Effectiveness of water fluoridation in caries prevention.
	Country of origin	Australia / UK
	Source of funding	NR
	Possible conflicts of interest	None declared by authors.
AMSTAR Rating		2/10
Characteristics of review and included primary studies	Aim/objectives of study	To review the effectiveness of adjusted fluoridation of public water supplies in the prevention of dental caries, with emphasis on studies published since 1990 and to discuss aspects of their design and reporting compared to studies published prior to 1990.
	Study design	Review
	Search Methods	"…included a professional Internet literature search, back-tracking from references given in publications, hand-searching of each issue of four relevant journals and corresponding with colleagues in countries with water fluoridation." No other details reported.
	Selection Criteria	Studies published between 1990 and 2010; intentional fluoride adjustment "to the optimum"; continuous fluoridation; outcomes of dmf (decayed, missing or filled deciduous teeth) or DMF (decayed, missing or filled permanent teeth) for fluoridated and non-fluoridated communities; published in a scientific journal or government report. Naturally occurring fluoride in drinking water excluded.
	Level of evidence (lowest identified)	IV
	Study types identified	Ecological cross-sectional and before & after studies
	Quality of Evidence evaluated	No
	Exposure duration	Assumed lifetime exposure
	Source population description	Populations living in USA, Canada, Argentina, Brazil, UK, Ireland, Israel,

General information	Study ID	93
		Korea, Australia, and NZ
	Inclusion criteria	NR
	Exclusion criteria	NR
Participant characteristics	Interventions	Fluoridated drinking water
	Comparators	Non-fluoridated drinking water
	Subgroups reported	Various age groups of adults and regions. See Table of results for details.
Results: dental caries	Definition (with units) Method of measurement	dmft/s (decayed, missing & filled deciduous teeth or surfaces) or DMFT/S (decayed, missing & filled permanent teeth or surfaces) NR
	No. of studies and participants analysed	N=58 studies included Participant numbers NR (8 already included in the Cochrane review)
	No. of studies and participants excluded or missing (with reasons)	NR
	Statistical method of analysis	NR
	Results	see Table 36 below
Authors' conclusion	"Fewer studies have been published recently. More of these have investigated effect at the multi-community, state, or even national level. The dmf/DMF index remains the most widely used measure of effects. %CR [percentage caries reduction] was lower in recent studies, and the 'halo' effect was discussed frequently. Nevertheless, reductions were still substantial. Statistical control for confounding factors are now routine, although the effect on per cent reductions tended to be small."	
Correspondence if required	Author contacted about search methods but no clarification possible.	
Reviewer's notes	This was mainly focussed on the differences between pre- and post-1990 studies. 59 studies reported to be identified however one study included results from 6 primary studies therefore actually 58 primary studies identified. Spencer et al (2008) was not included in the results table by the systematic review authors.	

Table 36 Summary of results from primary studies in Rugg-Gunn (2012)

Author year	Age of subjects	Index	Mean dmft in non-fluoride group	% Caries reduction	Study type
Armfield 2010	5–10	dmft	2.33	29	X adj
Booth et al 1992[1]	3	dmft	0.74	59	X
Brown et al 1990	8	dmft	3.5	31	X
Chin et al 2007	5	dft	4.12	34	X
Cortes et al 1996	6–12	dmft	2.1	29	X adj
Cypriano et al 2003[1]	5	dmft	5.5	49	X
Dini et al 1998	5–6	dmft	5.3	51	X
Evans et al 2009	5	dmft	0.88	30	H
Foster et al 2009	5	dmft	1.58	46	X adj
Evans et al 2009	6	dmft	1.96	68	H
Jones et al 1997	5	dmft	1.9	44	X adj
Kanagaratnam et al 2009[1]	9	dmft	2.42	31	X adj
Kang et al 2005	6	dft	4.13	59	H
O'Mullane et al 1996[2]	5	dmft	2.1	52	X
O'Mullane et al 1996[2]	5	dmft	1.8	33	X
Riley et al 1999	5	dmft	1.8	52	X adj
Saliba et al 2008	5	dmft	3.36	31	X
Whelton et al 2004[1]	5	dmft	1.7	41	X adj
Whelton et al 2006[1]	5	dmft	1.8	44	X adj
Zadik et al 1992 / Kelman 1996	5	dmft	3.89	55	X
Tickle et al 2003	5	dmft	1.43	29	X adj

Abbreviations: dmft = number of decayed, missing & filled deciduous teeth; dft = number of decayed & filled deciduous teeth; X = cross-sectional study; H = historical (before-&-after) study; adj = results adjusted for confounders in multivariate analysis

[1] Included in Iheozor-Ejiofor et al (2015) Cochrane review but not included in meta-analysis

[2] Different Health Board regions

COMPLETED QUALITY ASSESSMENT AND DATA EXTRACTION FORMS FOR THE INCLUDED PRIMARY STUDIES – DENTAL CARIES

ARMFIELD ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	School children aged 5-16 years attending school dental service in 4 states (SA, Vic, Tas, QLD) of Australia between 2002-2005
1.2 Is the eligible population or area representative of the source population or area?	++	Within each state, children stratified by living in fluoridated or non-fluoridated region and whether they lived in a metropolitan or non-metropolitan area. Within each stratum, school dental service clinics were selected proportionally to size of clinic. Children selected randomly by date of birth.
1.3 Do the selected participants or areas represent the eligible population or area?	+	Response rate to questionnaire was 67.4%. In addition another 1,684 (6%) were not included due to no being able to match questionnaire data to an examination. To adjust for possible bias resulting from the nonresponse rate, post-stratification weighting using census data was carried out.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Percentage lifetime exposure to fluoridated water (calculated using a database on the fluoride level in public water for each Australian postal code and from information provided by the parents on the child's residential history and drinking water source at each residence)
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Confounders assessed included age, gender, household income, parental education, remoteness, tooth brushing frequency, & sugar-sweetened beverage consumption. Included in analysis.
2.5 Is the setting applicable to the Australia?	++	Set in Australia
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	"…a level of standardization was attempted through the use of instruction manuals and training.
3.2 Were the outcome measurements complete?	+	Totals for variables vary from 16,508 to 15,240
3.3 Were all the important outcomes assessed?	++	dmft/DMFT
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Included in analysis were age, gender, household income, parental education, remoteness, tooth

		brushing frequency, & sugar-sweetened beverage consumption.
4.3 Were the analytical methods appropriate?	++	General linear modelling
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Some risk of selection bias due to not being able to include about 40% of the participants' data. However, to adjust for possible bias resulting from the nonresponse rate, post-stratification weighting using census was carried out.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Set in four states in Australia
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	210
	Date form completed	17/12/2015
	Country of origin Source of funding Possible conflicts of interest	Australia This research was supported by the National Health and Medical Research Council (project grant no. 207806). NR
Study characteristics	Aim/objectives of study	To examine the demographic and socioeconomic differences in the consumption of sugar-sweetened beverages (SSBs), its association with dental caries in children, and whether exposure to water fluoridation modifies this association.
	Study design	Ecological
	Level of evidence	IV
	Study location	Australia
	Study duration	NA
	Exposure duration	NA
	Source population description	Children aged 5-16 years enrolled in Australian school dental services in 2002 to 2005
	Inclusion/exclusion criteria	NR
	Recruitment procedures	Cross-sectional baseline data was used from a longitudinal cohort study. Multisite baseline data were collected between 2002 and 2005 using a stratified random sampling of children from 4 Australian states: South Australia, Victoria, Tasmania, and Queensland. Within each state, children were stratified by metropolitan or nonmetropolitan residence and by whether they lived in a fluoridated or non-fluoridated region. Within each of the defined strata, we selected School Dental Service clinics according to probability proportional to size using the clinic's average annual client throughput. Children were sampled when attending their routine School Dental Service examination and randomly selected using their date of birth.
Participant characteristics		Whole study
	No. of participants enrolled	16,857
	Age (range)	5-16 years
	Gender	8,471 male 8,037 female
	Household income	7,078 ≥AU$ 40,000 5,976 AU$ 40,001-80,000 2,186 >AU$ 80,000
	Parental education	9,506 High school 6,635 Some university
	Remoteness	10,429 Major city

		3,467 Inner regional 2,402 Outer regional to very remote	
	Tooth brushing	4,660 ≤once daily 11,010 ≥twice daily	
	Fluoridated water exposure	7,285 0-50% lifetime 8,916 >50% lifetime	
Exposure and setting		Intervention	
	Description of exposure and control (including level of fluoride)	Percentage lifetime exposure to fluoridated water (calculated using a database on the fluoride level in public water for each Australian postal code and from information provided by the parents on the child's residential history and drinking water source at each residence)	
	Setting (including social context)	School-based study	
Results: dmft/DMFT	Definition (with units) Method of measurement	Decayed, missing, & filled deciduous/permanent teeth (dmft/DMFT) Dental examination	
	No. of participants analysed	16,508 (various totals for each characteristic – see full paper for details)	
	No. of participants excluded or missing (with reasons)	NR	
	Imputation of missing data		
	Statistical method of analysis	General linear model	
	Participant category (If results are stratified: e.g. by age, special populations etc.)	**β estimate* (95%CI)**	p-value
	aged 5-10 years dmft	-0.66 (-0.77, -0.54)	p<0.001
	aged 11-16 years DMFT	-0.10 (-0.20, 0.00)	p<0.05
	*0-50% lifetime exposure was the reference; adjusted for age, gender, household income, parental education, remoteness, tooth brushing frequency, & sugar-sweetened beverage consumption		
Authors' conclusion	These results underscore the importance of considering SSB consumption as a major risk indicator for dental caries. The results also reconfirm the continued benefits of community water fluoridation in preventing caries and support the idea that exposure to fluoridated water confers additional benefits in helping to reduce the impact of dental disease.		
Correspondence if required	None		
Reviewer's notes	β estimates for other variables not extracted Statistically significant interaction between fluoride exposure and sugar-sweetened beverage consumption for both deciduous and permanent teeth (more apparent in permanent dentition).		

BLINKHORN ET AL (2015)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Children aged 5-7 years attending State or Catholic schools in Gosford city, Wyong, Ballina, & Byron Shires.
1.2 Is the eligible population or area representative of the source population or area?	+	Schools were randomly selected until individual school roles added up to 900 per area. NB: 4 schools in Ballina/Byron Shires refused to participate
1.3 Do the selected participants or areas represent the eligible population or area?	+	Those children in the appropriate classes with positive consent to participate (from parents/guardians) were invited to participate. Response rates (range): fluoridated 73.6 - 79.0% newly fluoridated 80.1 – 81.9% unfluoridated 55.3 – 65.7%

		Participants from unfluoridated areas may not represent eligible population. However, to adjust for possible bias resulting from the nonresponse rate, post-stratification weighting using census-derived population estimates
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Based on area fluoridation status. Characteristics of participants for baseline year (2008) similar. Participants from unfluoridated areas may not represent eligible population.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Age, gender, Indigenous status, cardholder status, maternal country of birth, education achievement of parents, tooth brushing behaviour, & sugary drink consumption measured and controlled for in multivariate analysis.
2.5 Is the setting applicable to the Australia?	++	Study conducted in four areas in NSW
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Two dentists & 4 therapists were trained & calibrated to use the same diagnostic system. Same team employed for each year. Intraclass correlations (ICC) ranged from 0.79 to 0.91 in 2008, from 0.69 to 0.93 in 2010 and from 0.76 to 0.90 in 2012.
3.2 Were the outcome measurements complete?	NR	
3.3 Were all the important outcomes assessed?	++	Yes – dmft, % caries free, significant caries index
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	Four years
3.5 Was follow-up time meaningful?	++	Four years
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	++	A sample-size calculation suggested that 500 children were required from each site to detect a difference in the mean decayed, missing and filled teeth (dmft) index for primary teeth in 5-year-old children of 0.3 with a power of 0.8 at a significance level of 0.05.
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Multivariate analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	95%CI reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Participants from unfluoridated areas may not be representative due to high non-response rate (34-45%). However it is unlikely to have overestimated the effect as the newly fluoridated area in 2008 had similar findings. All other methods unlikely to introduce high risk of bias.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Set in NSW, Australia.

Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	1148		
	Date form completed	8/12/15		
	Country of origin Source of funding Possible conflicts of interest	Australia Centre for Oral Health Strategy, New South Wales Health, the Australian Dental Association (New South Wales Branch) and Northern Sydney and Central Coast Local Health Service. "The authors declare they have no competing interests."		
Study characteristics	Aim/objectives of study	To monitor the changes in dental caries prevalence of 5- to 7-year-old children living in a fluoridated area, a newly fluoridated area and in an area without water fluoridation, in NSW, Australia.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Australia		
	Study duration	NA		
	Exposure duration	Lifetime		
	Source population description	Children 5-7 years old attending school who were residents of four communities – one fluoridated for 40 years, one newly fluoridated, & two unfluoridated		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	Children were drawn from Catholic and State Schools in the three areas. Schools were randomly selected from a master list until the individual school rolls for primary school children, 5- to 7 years of age, added up to around 900, to allow for a non-response of around 35%.		
Participant characteristics		Fluoridated	Newly fluoridated	Unfluoridated
	No. of participants enrolled / examined: • 2008 • 2010 • 2012	 1065 / 825 1054 / 833 1102 / 811	 932 / 781 1047 / 857 1040 / 844	 945 / 523 927 / 594 932 / 612
	Age (years; mean): • 2008 • 2010 • 2012	 6.1 5.9 5.7	 6.0 5.5 5.5	 6.3 5.6 5.6
	Gender (% male): • 2008 • 2010 • 2012	 50.8 53.2 50.2	 48.7 49.3 51.7	 50.3 52.7 51.1
	Other characteristics (e.g. ethnicity, illness, social class)	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Fluoridated (Wyong Shire)	Newly fluoridated (Gosford city)	Unfluoridated (Ballina & Byron Shires)
	Description of exposure and control (including level of fluoride)	Water fluoridation (for over 40 years)	Water fluoridation (initiated 2008)	Non-fluoridated water supply
	Setting (including social context)	School-based study. Population in Wyong Shire were slightly younger than Gosford, had a lower median household income and lower Index of Relative Socio-economic Advantage and Disadvantage. Most of the un-fluoridated communities were smaller than Gosford and Wyong and more rural. Authors reported that "[i]nevitably there will be some social differences."		
Results: dmft	Definition (with units) Method of measurement	Decayed, missing or filled primary teeth (dmft) Clinical examination		

	No. of participants analysed: • 2008 • 2010 • 2012	825 833 811	781 857 844	523 594 612
	No. of participants excluded or missing (with reasons): • 2008 • 2010 • 2012	240 (not examined) 221 (not examined) 291 (not examined)	151 (not examined) 190 (not examined) 196 (not examined)	422 (not examined) 333 (not examined) 320 (not examined)
	Imputation of missing data	NR		
	Statistical method of analysis	Multivariate analysis of incidence rate ratio (IRR) adjusted for age, gender, Indigenous status, cardholder status, maternal country of birth, education achievement of parents, tooth brushing behaviour, & sugary drink consumption		
	Participant category	IRR (95%CI)		
		2008	2010	2012
	Fluoridated	1.00	1.00	1.00
	Newly fluoridated	1.47 (1.20–1.80)	1.41 (1.10–1.80)	1.11 (0.85–1.45)
	Unfluoridated	2.06 (1.48–2.85)	2.81 (2.16–3.64)	2.23 (1.66–2.98)
Results: decayed teeth	Definition (with units) Method of measurement	Decayed primary teeth (dt) Clinical examination		
	No. of participants analysed: • 2008 • 2010 • 2012	825 833 811	781 857 844	523 594 612
	No. of participants excluded or missing (with reasons): • 2008 • 2010 • 2012	240 (not examined) 221 (not examined) 291 (not examined)	151 (not examined) 190 (not examined) 196 (not examined)	422 (not examined) 333 (not examined) 320 (not examined)
	Imputation of missing data	NR		
	Statistical method of analysis	Multivariate analysis of incidence rate ratio (IRR) adjusted for age, gender, Indigenous status, cardholder status, maternal country of birth, education achievement of parents, tooth brushing behaviour, & sugary drink consumption		
	Participant category	IRR (95%CI)		
		2008	2010	2012
	Fluoridated	1.00	1.00	1.00
	Newly fluoridated	1.64 (1.33–2.03)	1.19 (0.92–1.53)	1.15 (0.87–1.52)
	Unfluoridated	2.29 (1.64–3.21)	2.40 (1.83–3.14)	2.29 (1.68–3.11)
Results: caries experience	Definition (with units) Method of measurement	Caries experience = % with decayed, missing or filled primary teeth (dmft >0) Clinical examination		
	No. of participants analysed: • 2008 • 2010 • 2012	825 833 811	781 857 844	523 594 612
	No. of participants excluded or missing (with reasons): • 2008 • 2010 • 2012	240 (not examined) 221 (not examined) 291 (not examined)	151 (not examined) 190 (not examined) 196 (not examined)	422 (not examined) 333 (not examined) 320 (not examined)
	Imputation of missing data	NR		
	Statistical method of analysis	Multivariate analysis of odds ratio (OR) adjusted for age, gender, Indigenous status, cardholder status, maternal country of birth, education achievement of parents, tooth brushing behaviour, & sugary drink consumption		
	Participant category	OR (95%CI)		

		2008	2010	2012
	Fluoridated	1.00	1.00	1.00
	Newly fluoridated	1.72 (1.37–2.16)	1.26 (0.97–1.61)	1.22 (0.95–1.57)
	Unfluoridated	2.93 (2.01–4.27)	2.40 (1.84–3.15)	1.96 (1.49–2.57)
Authors' conclusion	"Fluoridation of public water supplies in Gosford ['newly fluoridated'] and Wyong ['fluoridated'] offers young children better dental health than those children who do not have access to this public health measure [Ballina & Byron Shires]."			
Correspondence if required	None			
Reviewer's notes	Results for serious caries index not extracted (no multivariate analysis)			

BROFFITT ET AL. (2013); WANG ET AL. (2012); CHANKANKA ET AL. (2011)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Infants born in Iowa 1992-5
1.2 Is the eligible population or area representative of the source population or area?	+	Participants of the Iowa Fluoride Study (an ongoing longitudinal study of oral health habits, fluoride exposures, beverages intake, & dental outcomes) Subjects recruited at birth (1992-5) among postpartum units at 8 Iowa hospitals and aged 18-21 years in 2013. "Approximately 50 percent of those invited to participate elected to do so. Overall, 1385 mothers participated in some portion of the IFS, and approximately 580 children continue to be followed at 20 to 23 years of age." From: Iowa Fluoride study accessed 14.12.15
1.3 Do the selected participants or areas represent the eligible population or area?	+	Broffitt et al. (2013): Those who participated in the mixed dentition (9 years) and permanent dentition (13 years) examinations Wang et al. (2012): Selection procedure NR Chankanka et al. (2011): Those who participated in all 3 examinations (approx. 5, 9, & 13 years) and had ≥2 dietary diaries (3-5 & 6-8 years) and ≥2 questionnaires (during 11-13 years)
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Broffitt et al (2013): Water fluoride level in home tap water (mean level 0.82 ppm; range 0.03-5.41 ppm; median 0.97 ppm) Wang et al. (2012): Fluoride intake from water (considering intake amounts & the composite fluoride concentration from all major water sources used by children) Chankanka et al. (2011): Composite water fluoride (ppm) determined at all time points as weighted averages of main sources of water (i.e. home/school, bottled/filtered/tap water) at each time point
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Known confounders measured
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified	++	Known confounders assessed and controlled for in

and controlled?		analysis
2.5 Is the setting applicable to the Australia?	+	Similar healthcare and socioeconomic factors likely
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Broffitt et al (2013): Weighted kappa 0.55 (surface level scoring); 0.66 (permanent dentition) Wang et al. (2012): Chankanka et al. (2011):
3.2 Were the outcome measurements complete?	NR	
3.3 Were all the important outcomes assessed?	++	
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Yes
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Broffitt et al. (2013): confidence intervals reported Wang et al. (2012): NR Chankanka et al. (2011): NR
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Unclear how representative the participants of the Iowa Fluoride Study are of the eligible population (50% agreed to participate). Relatively select group i.e. high SES.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Unclear how generalisable
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	105 / 232 / 269
	Date form completed	9/12/15
	Country of origin Source of funding Possible conflicts of interest	USA NIH grants, Biosciences Advantage program, & Wright-Bush-Shreves Endowed Professorship for Wang (2012. Not reported for Broffitt (2013) or Chankanka (2011) NR
Study characteristics	Aim/objectives of the studies	Broffitt (2013): To assess caries incidence and risk factors for young adolescents. Wang (2012): To assess genetic and environmental determinants of primary tooth caries in the Iowa Fluoride Study cohort. Chankanka (2011): To assess the longitudinal associations between caries outcomes and modifiable risk factors.
	Study design	Cohort
	Level of evidence	III-2
	Study location	USA
	Study duration	Ongoing longitudinal study (participant recruitment 1992-1995)

	Exposure duration	Lifetime		
	Source population description	The Iowa Fluoride Study participants		
	Inclusion/exclusion criteria	Broffitt (2013): Participants in the Iowa Fluoride Study who participated in both the mixed (~9 years) & permanent dentition (~13 years) included. Those with inadequate responses for water fluoride levels, tooth-brushing frequency or beverage intake estimates were excluded. Wang et al. (2012): Participants in the Iowa Fluoride Study were included. Chankanka et al. (2011): Participants in the Iowa Fluoride Study who had all 3 dental examinations of the primary, mixed, & permanent dentition + ≥2 abstracted dietary diaries during ages 3-5 & 6-8 years + ≥2 questionnaires during age 11-13 years period were included.		
	Recruitment procedures	The Iowa Fluoride Study recruited mothers and newborns from 8 Iowa hospital postpartum units from 1992-1995 and has been collecting fluoride, dietary, and other related information associated with dental fluorosis and caries since children were 1.5 months old.		
Participant characteristics		Broffitt et al. (2013)	Wang et al. (2012)	Chankanka et al. (2011)
	No. of participants enrolled	523	575	156
	Age	Range: 9-13 years	Mean: 5.2 ± 0.4 years	Mean age (years) of dentition examinations: -primary 5.15±0.38 -mixed 9.17±0.76 -permanent 13.20±0.35
	Gender	NR	300 girls 275 boys	45% female
	Caries	Age 9 $D_{2+}F>0$ 22% Age 9 D_1 (surface level) 6%	See Figure 1 in full paper	
	Other characteristics	96% non-Hispanic white 49% mothers with 4-yr college degree 82% family income ≥$40,000 in 2007 67% fluoridated home tap water Brushed teeth 1.5 times per day on average Other characteristics – see full paper	95% from Caucasian families 2% African American 3% from other ethnic groups	37.8% high & 34.4% middle SES
Exposure and setting		Intervention		
	Description of exposure and control	Broffitt et al (2013): Water fluoride level in home tap water (mean level 0.82 ppm; range 0.03-5.41 ppm; median 0.97 ppm) Wang et al. (2012): Fluoride intake from water (considering intake amounts & the composite fluoride concentration from all major water sources used by children)		

		Chankanka et al. (2011): Composite water fluoride (ppm) determined at all time points as weighted averages of main sources of water (i.e. home/school, bottled/filtered/tap water) at each time point		
	Setting (including social context)	Community-based study		
Results: Broffitt et al. (2013)	Definition (with units) Method of measurement	1st molar occlusal caries incidence from age 9 to 13 years (defined as progression to cavitated lesion [D_{2+}] or filled [$D_{2+}F$]) Clinical examination		
	No. of participants analysed	443		
	No. of participants excluded or missing (with reasons)	80 excluded (inadequate responses for water fluoride levels, tooth brushing frequency or beverage intake)		
	Imputation of missing data	NR		
	Statistical method of analysis	Mixed effects logistic regression		
	Participant category	Variable	Odds ratio* (95%CI)	p-value
	All participants	Home tap water fluoride level (ppm)	0.32 (0.10 – 1.02)	0.056
		Low income * water fluoride interaction	0.13 (0.02 – 0.79)	0.03
	*Odds ratio adjusted for $D_{2+}FS>0$ at 9 years (vs. none), D_1 score at 9 years (vs. none), brushing frequency (AUC, age 9-13), D_1 * brushing frequency interaction, low income, & low income * fluoride level interaction			
Results: Wang et al. (2012)	Definition (with units) Method of measurement	Tooth surfaces with frank cavitated or filled caries experience (d_2fs total) Pit and fissure surfaces with caries experience (d_2fs pit/fissure) Caries experience of all other tooth surfaces (d_2fs smooth surface) Clinical examination		
	No. of participants analysed	575		
	No. of participants excluded or missing (with reasons)	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Linear & logistic regression of the following factors: age, gender, tooth-brushing frequencies & fluoride intake from water NB: "–" represents negative association (protective) between covariates and caries phenotype		
	Participant category	Caries score (primary dentition)	Fluoride intake (p-value from linear / logistic regression)	
	All participants	d_2fs total	– (0.002 / 0.02)	
		d_2fs pit/fissure	– (0.003 / 0.008)	
		d_2fs smooth surface	– (0.003 / 0.002)	
Results: Chankanka et al. (2011)	Definition (with units) Method of measurement	New non-cavitated caries (transitions from sound to non-cavitated lesions) New cavitated caries (transitions from sound/non-cavitated caries to cavitated caries or filled lesions)		
	No. of participants analysed	156		
	No. of participants excluded or missing (with reasons)	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Negative binomial generalised linear mixed models (GLMM) NB: water fluoride not carried over into multivariate analysis		
	Participant category	Outcome	**β estimate**	P value
	All participants	New non-cavitated caries	–0.28	0.34
		New cavitated caries	–0.18	0.57
Authors' conclusion	Broffitt (2013): When assessing age 9 to 13 caries incidence on 1st molar occlusal surfaces, prior caries experience was an important risk indicator. More frequent tooth brushing with fluoridated dentifrice was effective at protecting sound surfaces from new caries, and higher home tap water fluoride levels were also protective, but significantly more so for low-income families.			

	Wang (2012): Frequent tooth brush[ing] and higher fluoride intake from water were both found in our study to act as protective factors against caries. Chankanka (2011): Greater tooth brushing frequency was significantly associated with fewer new non-cavitated caries, while gender, exam variable [3 dental examinations were carried out at different ages], and composite water fluoride level were not significantly associated with new non-cavitated caries. Gender, SES, tooth brushing frequency, and composite water fluoride level were not significantly associated with new cavitated caries.
Correspondence if required	None
Reviewer's notes	Broffitt et al. (2013): Low income * water fluoride interaction was included above as results show benefit for low income population. The authors note that the results may not be generalisable to other tooth surfaces or other teeth; nor to the general population of the US Chankanka (2011): Results presented were the univariate analyses only. Fluoride was not carried over to the multivariate analysis as the univariate results were not statistically significant

CENTERS FOR DISEASE CONTROL AND PREVENTION (2011)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	+	The area in Alaska is vaguely described.
1.2 Is the eligible population or area representative of the source population or area?	+	Only 5 villages are used in the analysis out of a possible 52.
1.3 Do the selected participants or areas represent the eligible population or area?	NR	Baseline demographics of the selected participants not reported.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Exposure to water fluoridation based on water supply. Villages were chosen based on size, water fluoridation status, and willingness of village residents and village schools to participate. Two villages with fluoridated water and three villages without fluoridated water were selected.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	+	An age-adjusted bivariate analysis was performed to assess risk factors for dental caries (dft >0 and DMFT >0). Risk factors included sociodemographic factors (e.g., sex), children's behaviours (e.g., tooth brushing, dental floss use, and soda pop consumption), parents' behaviours (e.g., tooth brushing), access to care, and water fluoridation status.
2.5 Is the setting applicable to the Australia?	+	A rural indigenous population in a developed country with a healthcare system not similar to Australia
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	No descriptive statistics reported

3.2 Were the outcome measurements complete?	+	No descriptive statistics reported
3.3 Were all the important outcomes assessed?	++	The number of decayed primary teeth (dt), decayed and filled primary teeth (dft), decayed permanent teeth (DT), and decayed, missing, and filled permanent teeth (DMFT) were determined for each participant.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	+	Analyses for soda consumption and frequency of teeth brushing
4.3 Were the analytical methods appropriate?	+	Adjusted odds ratio reported
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	Statistical significance reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Convenience sampling used
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Only 5 villages sampled
Overall quality rating	Low	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	288		
	Date form completed	17/12/2015		
	Country of origin Source of funding Possible conflicts of interest (for study authors or translators)	USA NR NR		
Study characteristics	Aim/objectives of study	To identify the impact of water fluoridation on dental caries in rural Alaskan native children		
	Study design	Cross-sectional		
	Level of evidence	IV		
	Study location	Alaska		
	Study duration	October/November 2008		
	Exposure duration	Lifetime		
	Source population description	Children (4-15) in 5 from 52 villages within a remove Alaskan region		
	Inclusion/exclusion criteria	All children aged 4-15 living in the 5 villages.		
	Recruitment procedures	Villages were chosen based on size, water fluoridation status, and willingness of village residents and village schools to participate. Two villages with fluoridated water and three villages without fluoridated water were selected		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	348	NR	NR
	Age (median)	9	NR	NR
	Gender (males)	52%	NR	NR
Exposure and setting		Intervention		Comparator
	Description of exposure and control (including level of fluoride)	Lifetime fluoride exposure		No fluoride exposure
	Setting (including social	Rural Alaska		Rural Alaska

	context)			
Results: outcome (repeat for each outcome)	Definition (with units) Method of measurement	dft, DMFT		
	No. of participants analysed	348		
	No. of participants excluded or missing (with reasons)	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Prevalence (having one or more tooth affected) and severity (mean dt, dft, DT, and DMFT) were determined by age group (4–5, 6–8, 9–11, and 12–15 years), sex, and village fluoridation status. An age-adjusted bivariate analysis was performed to assess risk factors for dental caries (dft >0 and DMFT >0). Risk factors included sociodemographic factors (e.g., sex), children's behaviours (e.g., tooth brushing, dental floss use, and soda pop consumption), parents' behaviours (e.g., tooth brushing), access to care, and water fluoridation status. Backward selection of risk factors that reached a significance level of p≤0.25, on age-adjusted bivariate analysis, were used to conduct multivariate logistic regression. Multivariate models were age- and sex-adjusted. In addition, dental caries severity for the region was compared with estimates for same-aged U.S. children from the National Health and Nutrition Examination Survey from 1999–2004		
	Participant category	Children from fluoridated villages	Children from non-fluoridated villages	Effect estimate (AOR; 95% CI)
	dft Age Group: 4-5	67%	100%	3.5 (2.8-4.3) p<0.001
	dft Age Group: 6-8	73%	97%	
	dft Age Group: 9-11	68%	71%	
	dft Age Group: 12-15	0%	0%	
	DMFT Age Group: 4-5	0%	0%	1.7 (1.4-2.1) p<0.001
	DMFT Age Group: 6-8	31%	57%	
	DMFT Age Group: 9-11	65%	86%	
	DMFT Age Group: 12-15	91%	91%	
Authors' conclusion	In this investigation, Alaska Native (AN) children, including children from fluoridated communities, had much higher dental caries prevalence and severity than same-aged U.S. children. Thus, additional risk factors (e.g., diet), some of which might not have been captured in this investigation, contributed to higher levels of disease. The investigation suggests that fluoridating village water systems likely would decrease the prevalence and severity of dental caries among AN children in the region who live in villages without fluoridated water. Collaborations between the villages and state and federal agencies to implement preventive interventions should be encouraged.			
Correspondence if required	None required			
Reviewer's notes				

CROCOMBE ET AL. (2015); SLADE ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Total Australian population
1.2 Is the eligible population or area representative of the source population or area?	+	Adults aged 15 years and older from all 8 states and territories. Needed to have a telephone and be dentate. This may have caused an underrepresentation of some subgroups e.g. Indigenous people. Crocombe et al. (2015) was a subset of this population i.e. people aged 15-46 years living in non-capital city areas (defined as 'rural').

1.3 Do the selected participants or areas represent the eligible population or area?	++	Stratified, clustered, random sample.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Exposure to fluoridated water assessed using Australian Research centre for Population Oral Health records (registers fluoride levels for 99.4% of the Australian population). % Lifetime exposure to fluoride of 1 ppm in drinking water assessed by questionnaire of time spent in locations. Recall bias could be present.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	+	Likely, as participants were asked about time spent living at residences.
2.4 How well were likely confounding factors identified and controlled?	++	Age, gender, region (capital vs. non-capital), country of birth, dental visit reasons, toothbrushing frequency, F supplement use, education, & annual income all recorded. Multivariate analysis. Smoking, diabetes, mouthrinsing, sugar-free gum use, FTE dentists per head, time between dental visits, avoided/delayed due to cost & interdental cleaning also included in Crocombe et al. (2015)
2.5 Is the setting applicable to the Australia?	++	Study conducted in Australia
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	30 dentist-examiners trained in study procedures conducted examinations. Intra-class-correlation coefficient of reliability was 0.85 at the tooth level & 0.98 at the person-level among examiners.
3.2 Were the outcome measurements complete?	+	31% (1,726 of 5,505 examined participants) either did not return questionnaire or reported <50% residential history.
3.3 Were all the important outcomes assessed?	++	Yes - DMFT & DFS
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	++	"The target sample size was calculated to address different survey aims, namely, 80% power with 5% type-I error in detecting reductions of 10% in age-group specific mean DMFT since the 1987-1988 national survey."
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Multivariate analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	95%CI reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Good selection methods. 31% did not have complete enough data set however sensitivity analysis showed results were consistent for missing data. May be some underrepresentation of Indigenous people &

		people without access to landline.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Set in Australia
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	581 / 202	
	Date form completed	7/12/15	
	Country of origin Source of funding Possible conflicts of interest	Australia NHMRC, Australian Government Department of Health & Ageing, Australian Institute of Health & Welfare, Colgate Oral Care, Australian Dental Association, and the US Centers for Disease Control & Prevention "The authors declared no potential conflicts of interest with respect to the authorship and/or publication of this article." –Slade et al. (2013)	
Study characteristics	Aim/objectives of study	To confirm whether the level of lifetime fluoridation exposure is associated with lower dental caries experience in adults ≥15 years (Slade et al. 2013) and adults 15–46 years (Crocombe et al. 2015)	
	Study design	Ecological	
	Level of evidence	IV	
	Study location	Non-capital city Australia	
	Study duration	NA	
	Exposure duration	Lifetime	
	Source population description	Participants of the National Survey of Oral Health 2004-6 (NHSOH)	
	Inclusion/exclusion criteria	Crocombe et al. (2015): Those born between 1960 & 1990 (aged 15-45 years) were included. Those residing in a state capital city and who were edentulous were excluded. Slade et al. (2013): analysed data from the 2004-2006 Australian National Survey of Adult Oral Health which examined 5,505 people (aged ≥15 years) selected randomly from all areas of Australia. Telephone interviews of potential participants established eligibility and collected sociodemographic and dental care information. Those with natural teeth were asked to have a dental examination.	
	Recruitment procedures	NHSOH 2004-6: Clustered stratified random sample of persons aged 15 years or more	
Participant characteristics		Crocombe et al. (2015)	Slade et al. (2013)
	No. of participants enrolled	466	3,779
	Age	Range: 15 to 45 years old 28.2 % aged 15-25 years 29.2% aged 25-35 years 42.5% aged 35-45 years	Range: 15+ years old 246 aged 15-24 years 416 aged 25-34 years 765 aged 35-44 years 792 aged 45-54 years 842 aged 55-64 years 718 aged 65+ years
	Gender	49.8% female	2,321 female 1458 male
	Country of birth	91.1% born in Australia	2,929 Australia 457 NZ, UK 393 Other
	Household income	19.2% <$30,000 per annum 35.4% $30-<$60,000 45.4% $60,000+	1,537 <$40,000 annual income 1,185 $40-<80,000 841 ≥$80,000 216 NR
	Education	46.7% no post-secondary education 24.1% Degree/Teacher/Nurse 29.1% Trade/Diploma/Certificate	1,272 Year 12 or less 1,044 Some college/diploma 1,463 University degree

	Dental habits	52.1% brushed teeth ≥2x daily 61.1% mouthrinse ≥daily 64.9% no chewing gum last week 14.3% interdental cleaning ≥daily 41.3% interdental cleaning <daily 44.4% interdental cleaning not regularly	1,447 brushed teeth <2x daily 2,304 brushed teeth ≥2x daily 28 brushing NR 226 use F supplement 1,109 did not use F supplement 174 F supplement NR 2,270 F supplement not asked
	Region of state	466 non-capital city	2,443 capital city 1,336 remainder of state
	Years of birth	466 in 1960-1990	1,509 in 1960-1990 2,270 before 1960
	Dental care	22.6% eligible to public dental care 3.3% resident where 50+ FTE dentists/100,000 20.1% a lot trouble paying $100 dental bill 43.8% visit dentist ≥annually 51.7% visit dentist for check-up rather than problem 34.9% delayed dental care due to cost	2,186 visit dentist for check-up 1,593 visit dentist for problem
	Diabetes	2.9%	NR
	Smoking	17.0% present 21.6% past smoker 61.4% never	NR
Exposure and setting		Crocombe et al. (2015)	Slade et al. (2013)
	Description of exposure and control (including level of fluoride)	*Intervention:* ≥50% lifetime fluoride exposure *Comparator:* <50% lifetime fluoride exposure	% lifetime fluoride exposure • <25% • 25% to <50% • 50% to <75% • ≥75 %
	Setting (including social context)	Non-metropolitan residence in Australia	All regions Australia
Results for Crocombe et al. (2015)	Definition (with units) Method of measurement	Number of decayed missing & filled teeth (DMFT), Decayed teeth (D), Missing teeth (M), Filled teeth (F) Clinical examination	
	No. of participants analysed	466	
	No. of participants excluded or missing (with reasons)	NR	
	Imputation of missing data	NR	
	Statistical method of analysis	Multivariate regression analysis	
	Participant category	Regression coefficient estimate	p-value
	DMFT	–2.45	<0.01
	Decayed teeth	0.10	0.65
	Missing teeth	–0.03	0.92
	Filled teeth	–2.52	<0.01
Results for Slade et al. (2013)	Definition (with units) Method of measurement	Number of decayed missing & filled teeth (DMFT), DFS (Decayed & filled surfaces) Clinical examination	
	No. of participants analysed	3,779	
	No. of participants excluded or missing (with reasons)	NR	
	Imputation of missing data	Missing residential data for ≤50% of years investigated, fluoridation exposure for the missing years was assumed to be their average fluoride exposure. If missing >50%, fluoridation exposure was treated as missing. In the sensitivity analysis 0 ppm fluoride was assigned to missing years in participants with ≤50% of years with missing data.	

		Hot-deck multiple imputation used to investigate bias due to missing data in another sensitivity analysis.			
	Statistical method of analysis	Multivariate regression analysis (adjusted for age, region of state, gender, country of birth, reason for dental visits, tooth brushing frequency, use of fluoride supplements, annual income, & highest level of education)			
	Participant category (ref <25% of lifetime)	DMFT		DFS	
		1960-1990 cohort β (95% CI)	Pre-1960 cohort β (95% CI)	1960-1990 cohort β (95% CI)	Pre-1960 cohort β (95% CI)
	≥ 75% of lifetime	-1.14 (-2.09, -0.19)	-2.58 (-4.05, -1.11)	-3.44 (-5.28, -1.60)	-11.10 (-15.47, -6.72)
	50 to < 75% of lifetime	0.27 (-0.87, 1.40)	0.09 (-0.61, 0.79)	0.18 (-2.19, 2.56)	-1.88 (-4.78, 1.02)
	25 to < 50% of lifetime	0.75 (-0.73, 2.23)	-0.47 (-1.22, 0.28)	2.23 (-1.32, 5.77)	-2.72 (-6.01, 0.56)
Authors' conclusion	Slade et al. (2013): In this cross-sectional examination survey of a nationally representative sample of Australian adults, greater lifetime exposure to water fluoridation was associated with lower levels of caries experience. Crocombe et al. (2015): The higher level of lifetime fluoridation exposure was associated with substantially lower caries experience in younger rural adults, largely due to a lower number of filled teeth.				
Correspondence if required	None				
Reviewer's notes	Only results for missing teeth in Crocombe el at. (2015) has been used in the evidence review as Slade et al. (2013) has the complete data set				

DA SILVA ET AL. (2015); FREIRE ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Population of Brazil
1.2 Is the eligible population or area representative of the source population or area?	++	Probabilistic cluster sampling was used in the Brazilian Oral Health Study 2010, with 2 stages in the 26 State capitals, and Federal District, and 3 stages in municipalities in the interior of the 5 regions of Brazil.
1.3 Do the selected participants or areas represent the eligible population or area?	+	Selected age groups from the Brazilian Oral Health Study 2010
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Fluoridated water supply in town/city based on National Basic Sanitation survey 2008 (level NR)
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	+	Age, income, gender, residences connected to water supply assessed and included in analysis
2.5 Is the setting applicable to the Australia?	+	Partially. Likely differences in socioecono0mic and healthcare systems.

Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	dmft/DMFT but no inter- or intra-rater reliability assessments reported
3.2 Were the outcome measurements complete?	NR	
3.3 Were all the important outcomes assessed?	+	
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	
4.3 Were the analytical methods appropriate?	++	
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Participants likely to be representative of source population.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	May not be entirely generalisable to Australian context
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	1149; 95; 97	
	Date form completed	8/01/16	
	Country of origin Source of funding Possible conflicts of interest	Brazil NR NR	
Study characteristics	Aim/objectives of study	Da Silva et al. (2015): To evaluate the relationship of socioeconomic conditions and national public policy of fluoridation of the water supply, oral health conditions of the population of 12 years in the Brazilian capital. Freire et al. (2013): To estimate the prevalence and severity of dental caries in Brazilian children and the association with individual and contextual factors.	
	Study design	Ecological	
	Level of evidence	IV	
	Study location	Brazil	
	Study duration	NA	
	Exposure duration	NA	
	Source population description	Participants of the Brazilian Oral Health Study 2010: This household-based survey was conducted by the Brazilian Ministry of Health in 177 cities in the whole country, including the 27 state capitals. About 38,000 people divided into five age groups (5, 12, 15–19, 35–44 and 65–74 years-old) were interviewed and examined in their homes by trained and calibrated dentists, all workers of the Brazilian public health system. (Roncalli et al 2014)	
	Inclusion/exclusion criteria	NR	
	Recruitment procedures	Da Silva et al. (2015): Those participants aged 12 years from the Brazilian Oral Health Study 2010. Freire et al. (2013): Those participants aged 12 years from the Brazilian Oral Health Study 2010.	
Participant		Da Silva et al. (2015)	Freire et al. (2013)

characteristics	No. of participants enrolled	NR	7,247
	Age	12 years	12 years
	Gender	NR	3,645 female 3,602 male
	Skin colour	NR	2,868 white 706 black 3,470 brown 142 yellow 61 Indigenous
	Household income	NR	748 >R$2,500 1,069 R$1,501-2,500 3,663 R$501-1,500 1,378 ≤R$500
	Dental measures (mean)	DMFT 12 years 2.06 Caries-free 44.00 Missing teeth 0.12	DMFT 2.04 caries prevalence 56.0% severe caries prevalence 22.2%
Exposure and setting		Intervention	
	Description of exposure and control	Fluoridated water supply in town/city based on National Basic Sanitation survey 2008 (level NR)	
	Setting (including social context)	National household survey	
Results: outcome (repeat for each outcome)	Definition (with units) Method of measurement	Decayed, missing, filled deciduous/permanent teeth (dmft/DMFT) Untreated dental caries (d/D >0) Severe dental caries (dmft/DMFT ≥4) Oral examination	
	No. of participants analysed	Da Silva et al. (2015): NR Freire et al. (2013): 7,247 (1.1% not examined)	
	No. of participants excluded or missing (with reasons)	as above	
	Imputation of missing data	NR	
	Statistical method of analysis	Da Silva et al. (2015): Multiple linear regression Freire et al. (2013):Poisson multiple regression	
Da Silva et al. (2015)	Participant category	Estimate from multiple linear regression* (95%CI)	
DMFT 12 years	All participants	-0.613 (-1.030, -0.196) ; p-value 0.006	
Mean missing teeth	All participants	-0.330 (-0.602, -0.058) ; p-value 0.019	
Caries-free	All participants	6.750 (-1.131, 14.631) ; p-value 0.09	
	*adjusted for sociosantitary condition & economic deprivation		
Freire et al. (2013)	Participant category	PR§ (95%CI)	
Prevalence dental caries	All participants	0.90 (0.83 – 0.97)	
Severe attack of dental caries	All participants	0.78 (0.68 – 0.90)	
	§PR=prevalence ratio; adjusted for gender, skin colour, household income, residences connected to water supply, & median income municipality.		
Authors' conclusion	Da Silva et al. (2015): Water fluoridation is associated with a reduction in mean DMFT and missing teeth (even when taking into account social and economic factors) Freire et al. (2013): "…universal access to fluoridated drinking water should continue to be one of the priorities of national oral health care strategies."		
Correspondence if required	None		
Reviewer's notes	Information about recruitment for Brazilian Oral Health Study 2010 from: Roncalli, AG, Tsakos, G et al 2014. Social determinants of dental treatment needs in Brazilian adults, BMC Public Health, 14 (1), 1-11.		

DO & SPENCER (2007)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Participants of the Child Oral Health Study 2002-2004
1.2 Is the eligible population or area representative of the source population or area?	++	Participants of the Child Oral Health Study 2002-2004 in South Australia attending the School Dental service
1.3 Do the selected participants or areas represent the eligible population or area?	+	Selected by year of birth 1989-1994 Data re-weighted to adjust for different sampling ratios and age and gender distribution.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	% lifetime exposure to fluoridated water up to age 3 years Data collected by questionnaire – recall bias may be present
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Confounders were age in months at 6-year examination, gender, birth cohort, fluoride supplements, infant formula, household income, age toothpaste use started, brushing frequency, amount toothpaste used, after brushing routine, eating/licking toothpaste habit, & parental education Adjusted for in logistic regression
2.5 Is the setting applicable to the Australia?	++	Set in South Australia
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Caries prevalence (dmfs molars and canines) Likely to be reliable
3.2 Were the outcome measurements complete?	+	Unclear - 72% of participants data used in regression analysis (480/667)
3.3 Were all the important outcomes assessed?	++	Yes – caries and fluorosis
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	As above
4.3 Were the analytical methods appropriate?	++	Logistic regression
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals given
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Some aspects unclear due to not being reported
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Set in South Australia

Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	471		
	Date form completed	8/01/16		
	Country of origin Source of funding Possible conflicts of interest	Australia The study was supported by the University of Adelaide, by a National Health and Medical Research Council Project Grant, by an Australian Dental Research Foundation grant, and by the South Australian Dental Service. NR		
Study characteristics	Aim/objectives of study	To evaluate the balance of benefit and risk of several fluoride exposures among South Australian children.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	South Australia		
	Study duration	NA		
	Exposure duration	NA		
	Source population description	The study was nested in a large-scale population-based study, the Child Oral Health Study (COHS), conducted in 2002–04 among South Australian children attending the School Dental Service (SDS).		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	Selected by year of birth [Do, LG and Spencer, AJ 2007. Decline in the prevalence of dental fluorosis among South Australian children, Community Dentistry and Oral Epidemiology, 35 (4), 282-291.]		
Participant characteristics		Whole study		
	No. of participants enrolled	667		
	Age (range)	8-13 at time of study		
	Gender	349 boys 328 girls		
	Caries prevalence	32.3%		
	Mean dmfs (SD)	1.57 (3.3)		
	Fluorosis prevalence	11.3%		
Exposure and setting		Intervention		
	Description of exposure and control	% lifetime exposure to fluoridated water from birth to 3 years age		
	Setting	School-based study		
Results: prevalence of caries at age 6 years	Definition Method of measurement	Proportion of participants with number of decayed, missing & filled deciduous molars & canines > 0 recorded at 6 years old (%dmft>0) Clinical examination		
	No. of participants analysed	480		
	No. of participants excluded or missing (with reasons)	187 (no reasons given)		
	Imputation of missing data	No		
	Statistical method of analysis	Logistic regression		
	Participant category	Exposure (% lifetime exposure to fluoridated water)	Odds ratio* (95%CI)	p-value
	All participants	>50% lifetime	0.4 (0.2-0.7)	p<0.05
		> 0-50% lifetime	0.5 (0.3-0.9)	p<0.05
		0% lifetime	1	-
	Participant category	Exposure	Population prevented fraction†	Potential change§
	All participants	Birth to 3 years age	34.3 (5.7 – 50.9)	111
	*adjusted for age in months at 6-year examination, gender, birth cohort, fluoride supplements, infant formula, household income, age toothpaste use started, brushing frequency, amount toothpaste used, after brushing routine, eating/licking toothpaste habit, & parental education † Proportion of cases prevented by exposure			

	§ Number of cases per 1000 children with deciduous caries at age 6 yrs prevented by the exposure, given the population prevalence of 32.3%
Authors' conclusion	Exposure to fluoridated water was negatively associated with caries
Correspondence if required	None
Reviewer's notes	Results for fluorosis not extracted

DO ET AL. (2011)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Children & young people living in Vietnam.
1.2 Is the eligible population or area representative of the source population or area?	++	14 provinces & cities were randomly selected with the probability proportional to population size to represent 62 provinces of the whole country. Provinces were stratified into urban and rural (where appropriate) and 2 districts were selected for each stratum in a province. Schools were selected as sampling clusters within each district based on their population size.
1.3 Do the selected participants or areas represent the eligible population or area?	++	Children were randomly recruited from selected schools based on their date of birth and age group. Four age groups were defined: 6 to 8, 9 to 11, 12 to 14, and 15 to 17 years. Some 14 subjects of each age group were selected in each cluster making the total targeted sample of 3,139 children.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	NR	Unclear. Exposure determined by fluoride level in drinking water. How level was determined was not reported.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes – all variables associated with caries prevalence.
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	+	Parental questionnaire used for detailing children's socioeconomic status (SES), oral hygiene habits, and dental care utilization. Risk of recall bias. Confounders controlled for during linear regression.
2.5 Is the setting applicable to the Australia?	-	Set in developing country without intentional water fluoridation. Small numbers of participants exposed to fluoride level applicable to Australian context.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	DMFS/dmfs measured by clinical examination by trained and calibrated dental examiners.
3.2 Were the outcome measurements complete?	++	
3.3 Were all the important outcomes assessed?	++	Caries experience and dental fluorosis.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	

Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	
4.3 Were the analytical methods appropriate?	++	Linear regression models
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	Standard error reported
Section 5: Summary	**-**	**-**
5.1 Are the study results internally valid (i.e. unbiased)?	+	Unclear risk of selection bias. Some risk of recall bias. Participants likely to be representative.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Study set in a developing country. Naturally occurring fluoride in drinking water. Very few participants exposed to fluoride levels applicable to Australian context.
Overall quality rating	Low	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	293
	Date form completed	14/12/15
	Country of origin Source of funding Possible conflicts of interest	Vietnam Supported by the University of Adelaide, Australian Agency for International Development, & the Ministry of Health of Vietnam. NR
Study characteristics	Aim/objectives of study	To describe the oral health status, to analyse its socioeconomic distribution, and to evaluate change over time in the oral health of Vietnamese children.
	Study design	Ecological
	Level of evidence	IV
	Study location	Vietnam
	Study duration	NA
	Exposure duration	Assumed lifetime
	Source population description	Children & young people aged 6-17 years attending school in Vietnam
	Inclusion/exclusion criteria	NR
	Recruitment procedures	14 provinces & cities were randomly selected with the probability proportional to population size to represent 62 provinces of the whole country. Provinces were stratified into urban and rural (where appropriate) and 2 districts were selected for each stratum in a province. Schools were selected as sampling clusters within each district based on their population size. Children were randomly recruited from selected schools based on their date of birth and age group. Four age groups were defined: 6 to 8, 9 to 11, 12 to 14, and 15 to 17 years. Some 14 subjects of each age group were selected in each cluster making the total targeted sample of 3,139 children.
Participant characteristics		Whole study
	No. of participants enrolled	2,748
	Age (range)	6-17 years
	Gender	1,339 male 1,409 female
	Location (2762)	Urban 1,588 Rural 1,174
	Parental education (2705)	Primary or lower 506 Secondary school 1,606 Tertiary or vocational 593
	Income (×1000 VND/month) (2666)	≤400 1,089 >400 and ≤800 962

		>800 615	
	Age group (years) (2762)	6-8 years 705 9-11 years 692 12-14 years 695 15-17 years 670	
	Natural fluoride in water (ppm) (2515)	<0.3 ppm 2,026 0.3-0.5 ppm 319 >0.5 ppm 170	
Exposure and setting		Intervention	
	Description of exposure and control (including level of fluoride)	Naturally occurring fluoride in water (actual level fluoride NR) NB: participants allocated into three groups: <0.3 ppm; 0.3-0.5 ppm; >0.5 ppm	
	Setting (including social context)	School-based study	
Results: deciduous caries (dmfs)	Definition (with units) Method of measurement	Decayed, missing & filled deciduous teeth surfaces Clinical examination	
	No. of participants analysed	1,351 (children aged 6-11 years)	
	No. of participants excluded or missing (with reasons)	NR	
	Imputation of missing data	NR	
	Statistical method of analysis	Linear regression model (adjusted for age, gender, age tooth-brushing started, age toothpaste use started, brushing frequency, household income, dental visit, residential status, parental education, & area)	
	Participant category	**Unstandardised β (SD)**	p-value
	Participants aged 6-11 years	–2.99 (1.12)	0.008
Results: permanent caries (DMFS)	Definition (with units) Method of measurement	Decayed, missing & filled permanent teeth surfaces Clinical examination	
	No. of participants analysed	2,762 (all children)	
	No. of participants excluded or missing (with reasons)	NR	
	Imputation of missing data	NR	
	Statistical method of analysis	Linear regression model (adjusted for age, gender, age tooth-brushing started, age toothpaste use started, brushing frequency, household income, dental visit, residential status, parental education, & area)	
	Participant category	**Unstandardised β (SE)**	p-value
	All participants	–0.34 (0.35)	0.330
Authors' conclusion	The level of fluoride naturally occurring in drinking water was found to be associated with protection against caries in the deciduous dentition. The effect of fluoride on the permanent dentition was less pronounced, partly owing to relatively lower caries experience in permanent teeth. However, only 7% of the population was exposed to fluoride from drinking water at a level that confers dental benefit.		
Correspondence if required	None		
Reviewer's notes	Only data for fluoride exposure extracted		

DO ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	All children aged 5-12 year attending schools in New South Wales.
1.2 Is the eligible population or area representative of the source population or area?	++	Random selection of schools from each NSW health service region then, a stratified random sample of

		children aged 5-12 years from each school based on age and gender distribution.
1.3 Do the selected participants or areas represent the eligible population or area?	++	Data from NSW Child Dental Health Survey (CDHS) 2007 as above. Only children aged 8-12 years were used for this report.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Percentage of lifetime exposure to fluoridated water in the first 3 years of life. Calculation based on locations of residence and time spent there. Locations were linked to Australian public water supplies' fluoride levels. Parents estimated child's proportion of public water usage as part of all water consumption for each period of residency listed.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Age, gender, household income, parental education, & supplementary fluoride use measured and controlled for in regression analysis.
2.5 Is the setting applicable to the Australia?	++	Study conducted in NSW, Australia.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Calibrated dental examiners & recorders collected the outcome data. Inter-examiner reliability kappa 0.83 to 0.99
3.2 Were the outcome measurements complete?	+	Some variables had missing data e.g. &% for water fluoride exposure
3.3 Were all the important outcomes assessed?	++	Yes – dental fluorosis, % with caries, and mean dmfs/DMFS
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Regression analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	95%CI reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Good selection methods. Recall bias should be considered.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Set in Australia but in only one state
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	24
	Date form completed	3/12/15

	Country of origin Source of funding Possible conflicts of interest	Australia Centre for Oral Health Strategy, NSW Health, Research Foundation & University of Adelaide Scholl of Dentistry, & NHMRC Career Development Fellowship. NR			
Study characteristics	Aim/objectives of study	To evaluate associations of different levels of exposure to fluoride in early childhood with dental caries and dental fluorosis experience in school children.			
	Study design	Ecological			
	Level of evidence	IV			
	Study location	NSW, Australia			
	Study duration	NA			
	Exposure duration	Various (0-100% exposure from birth to 3 years)			
	Source population description	Participants of the NSW Child Dental Health Survey 2007 (NSW CDHS)			
	Inclusion/exclusion criteria	NA			
	Recruitment procedures	For the NSW CDSH: Random selection of schools from each NSW health service region then, a stratified random sample of children aged 5-12 years from each school based on age and gender distribution. Only children aged 8-12 years were used for this report.			
Participant characteristics		Whole study (NB: data weighted to represent population estimates; some variables have missing data)			
	No. of participants enrolled	2,611 (76% of children aged 8-12 years)			
	Age (state mean/median/range)	8-12 years			
	Gender	51.2% male (n=1319)			
	% lifetime exposure to F in water (birth to 3 yrs)	1498 (64.0%) 100% lifetime 557 (21.3%) >0-99% lifetime 386 (14.6%) 0% lifetime			
	Household income	548 (22.2%) ≤40,000 AUD 810 (32.7%) >40-80,000 AUD 642 (25.7%) >80-120,000 AUD 437 (19.4%) >120,000 AUD			
	Parental education	624 (24.1%) Low 1490 (57.4%) Medium 472 (18.5%) High			
	Dietary F supplement use	2419 (94.2%) Never used 186 (5.8%) Ever used			
Exposure and setting		Intervention		Comparator	
	Description of exposure and control (including level of fluoride)	Lifetime exposure to fluoride in water (from birth to 3 years)† • 100% • 0-99%		0% lifetime exposure to fluoride in water (from birth to 3 years) †	
		† Calculated by summing time at residence during age period x public water fluoride level x % public water use / age x 100			
	Setting (including social context)	School-based study in NSW			
Results: dmfs	Definition (with units) Method of measurement	Decayed, missing & filled primary teeth Clinical examination			
	No. of participants analysed	1,406			
	No. of participants excluded or missing (with reasons)	NR			
	Imputation of missing data	NR			
	Statistical method of analysis	Multivariate regression analysis adjusting for household income, parental education, dietary F supplement use, age & gender (NB: Poisson distribution for caries prevalence & negative binomial distribution for dmfs)			
	Participant category (all aged 8-10 years)	Caries prevalence (%)	PR (95%CI)	Mean dmfs	RR (95%CI)

	100% Lifetime exposure	32.6	0.83 (0.70–0.99)	2.38	0.65 (0.54–0.78)
	0-99% Lifetime exposure	31.5	0.81 (0.65–1.01)	2.30	0.66 (0.53–0.82)
	0% Lifetime exposure	39.0	Ref	3.82	Ref
		PR = prevalence ratio; RR = rate ratio			
Results: DMFS	Definition (with units) Method of measurement	Decayed, missing & filled permanent teeth Clinical examination			
	No. of participants analysed	2,611			
	No. of participants excluded or missing (with reasons)	NR			
	Imputation of missing data	NR			
	Statistical method of analysis	Multivariate regression analysis adjusting for household income, parental education, dietary F supplement use, age & gender (NB: Poisson distribution for caries prevalence & negative binomial distribution for dmfs)			
	Participant category (all aged 8-12 years)	Caries prevalence (%)	PR (95%CI)	Mean DMFS	RR (95%CI)
	100% Lifetime exposure	22.6	0.84 (0.67–1.07)	0.59	0.76 (0.62–0.94)
	0-99% Lifetime exposure	22.6	0.81 (0.62–1.06)	0.63	0.84 (0.66–1.07)
	0% Lifetime exposure	28.0	Ref	0.91	Ref
		PR = prevalence ratio; RR = rate ratio			
Authors' conclusion	There were significant associations of dental caries and fluorosis experience with sources of early childhood fluoride exposure among children aged 8–12 years in New South Wales. Exposure to fluoridated water during the first 3 years of life was associated with better oral health of school-age children.				
Correspondence if required	None				
Reviewer's notes	Only caries data extracted				

DO ET AL. (2015); DO & SPENCER (2015)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	School attendees aged 5-14 years in Queensland, Australia
1.2 Is the eligible population or area representative of the source population or area?	+	Queensland schools selected with probability proportional to size of enrolment. Schools which refused to participate were replaced by another within same socioeconomic strata.
1.3 Do the selected participants or areas represent the eligible population or area?	++	Children aged 5-14 years randomly selected from participating schools
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Fluoride exposure assessed by location – supplied with fluoridated water or not.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Confounders measured using questionnaire including SES, oral health behaviours/practices, and use of dental services. Multivariable multilevel models controlled for confounders
2.5 Is the setting applicable to the Australia?	++	Set in Queensland

Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Intra-class correlation coefficient for dental caries assessment 0.8 – 0.9 Trained examiners
3.2 Were the outcome measurements complete?	++	Yes
3.3 Were all the important outcomes assessed?	++	Dental caries
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	
4.3 Were the analytical methods appropriate?	++	Different methods used in each study but appear to be appropriate
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Selection methods adequate. Unclear whether schools participating were representative. Fluoride exposure assessed by location. Good data collection and analysis.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	School-based study set in Queensland, Australia
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	1157; 1174
	Date form completed	16/12/15
	Country of origin Source of funding Possible conflicts of interest	Australia This study was supported by a research grant from the Queensland Government. In-kind support by the Queensland Area Health Services, the Office of Chief Dental Officer, the examination teams & ARCPOH staff. Loc Do is supported by NHMRC CDF#1025045. The authors declare that there is no conflict of interest related to this study
Study characteristics	Aim/objectives of study	Do et al. (2015): To investigate contextual and compositional factors associated with the prevalence of dental caries in children and to estimate the population impact of those factors. Do & Spencer (2015): The purpose of this study was to establish the baseline comparisons of caries experience in areas of Queensland that implemented fluoridation between 2009 and 2011 and the existing positive fluoridated comparison area of Townsville. A further aim was to estimate levels of child caries experience of Queensland children who will reach a full lifetime in newly fluoridated areas over the next decade and a half.
	Study design	Ecological
	Level of evidence	IV
	Study location	Queensland, Australia
	Study duration	NA
	Exposure duration	Assumed lifetime
	Source population description	5-14 year old school children in Queensland
	Inclusion/exclusion criteria	NR

	Recruitment procedures	Stratified two-stage sample design: Schools from the public, catholic and independent educational sectors were stratified into four socioeconomic bands on the basis of their postcodes, Socioeconomic Index for Areas (SEIFA) score and selected with a probability proportional to size of enrolment. School principals were approached to gain their school's participation. Schools that declined to participate were replaced, where possible, by another school from within the same stratum. Children aged 5–14 years were randomly selected from each participating school.	
Participant characteristics		Primary dentition (5-8 year olds)	Permanent dentition (9-14 year olds)
	No. of participants enrolled	2214	3186
	Age, n; mean (SE)	2214 6.5 (0.03)	3186 11.5 (0.10)
	Sex, n; w% (SE)	Male 1107 51.2 (1.3) Female 1107 48.8 (1.3)	1618 51.5 (1.5) 1568 48.5 (1.5)
	Indigenous status, n; w% (SE)	Indigenous 135 5.2 (1.0) Nonindigenous 2079 94.8 (1.0)	175 4.9 (0.8) 3011 95.1 (0.8)
	Household income, n; w% (SE)	Low 657 33.1 (2.2) Medium 1026 45.9 (1.7) High 417 21.0 (1.6)	1013 36.8 (1.6) 1379 42.7 (1.3) 633 20.5 (1.4)
	Parental education, n; w% (SE)	School only 589 26.7 (1.9) Vocational 449 20.8 (1.4) University 1111 52.5 (2.2)	898 28.8 (1.4) 640 20.0 (1.0) 1544 51.2 (1.8)
	Brushing frequency, n; w% (SE)	<2 times/day 603 26.9 (1.5) 2+ times/day 1576 73.4 (1.5)	854 27.0 (1.2) 2270 73.0 (1.2)
	Use F supplements, n; w% (SE)	Ever used 233 14.4 (1.1) Never used 1973 85.6 (1.1)	475 18.0 (1.0) 2697 82.0 (1.0)
	Age first used F toothpaste, n; w% (SE)	Before or at 18 months 1337 60.7 (1.6) 19–30 months 522 23.2 (1.1) After 30 months 355 16.1 (1.5)	1773 56.7 (1.2) 793 23.9 (1.0) 620 19.4 (1.1)
	Sugary drinks	0–1 drinks/day 1398 64.0 (1.7) 2–3 drinks/day 586 24.9 (1.2) 4+ drinks/day 230 11.0 (1.2)	1733 56.7 (1.2) 793 23.8 (0.9) 620 19.4 (1.1)
	School type	Public 1533 66.5 (4.7) Independent 442 19.2 (4.4) Catholic 239 14.4 (3.8)	2085 64.8 (4.2) 680 19.1 (3.4) 420 16.0 (3.7)
	Fluoridation status	Fluoridated 769 5.2 (0.7) Non-fluoridated 1445 94.8 (0.7)	918 5.3 (0.6) 2268 94.7 (0.6)
Exposure and setting		Intervention	Comparator
	Description of exposure and control	Water fluoridation (Townsville)	Non-fluoridated water (all other areas)
	Setting (including social context)	School-based study	
Results: Prevalence of dental caries/mean dmfs/DMFS	Definition (with units) Method of measurement	Do et al. (2015): Prevalence of caries defined as %DMFS>0 or %dmfs>0 Do & Spencer (2015): Mean number of decayed, missing & filled deciduous/permanent surfaces (dmfs/DMFS) Oral examination	
	No. of participants analysed	NR	
	No. of participants excluded or missing (with reasons)	NR	
	Imputation of missing data	NR	
	Statistical method of analysis	Data were weighted to adjust for carrying probabilities of selection Do et al. (2015): Complementary log-log regression Do & Spencer (2015): Nonlinear estimation was used in the models with the distributional assumption for dmfs/DMFS scores as negative binomial because of skewness of these count variables.	

Do et al. (2015)	Participant category	Caries prevalence (%; 95%CI)	Full model* PR (95%CI)	PAF (%)	N
	Children aged 5-8 years	Fluoridated area: 36.9% (58.7–67.4)	Reference	-	-
		Non-fluoridated area: 47.7% (44.3–51.1)	1.29 (1.11 – 1.50)	21%	99
	Children aged 9-14 years	Fluoridated area: 29.4% (26.1–32.9)	Reference	-	-
		Non-fluoridated area: 39.3% (36.4–42.3)	1.49 (1.01 – 2.21)	31%	120
	*fluoridated areas were the reference; adjusted for age, gender, and all individual, school, & area-level factors PR = prevalence ratio; PAF = population attributable fraction; N = number of cases for every 1000 population to be prevented should the exposure (lack of water fluoridation) be eliminated given the prevalence of 47.1% [5-8 year olds] or 38.8% [9-14 year olds]				
Do & Spencer (2015)	Participant category	Mean dmfs (95%CI)	Full model* RR (95%CI)		
	Children aged 5-8 years	Fluoridated area: 2.75 (2.16–3.34)	0.61 (0.44 – 0.82)		
		Non-fluoridated area: 4.31 (3.79–4.84)	Reference		
	Participant category	Mean DMFS (95%CI)	Full model* RR (95%CI)		
	Children aged 9-14 years	Fluoridated area: 0.82 (0.65–0.99)	0.63 (0.47 – 0.85)		
		Non-fluoridated area: 1.51 (1.31–1.71)	Reference		
	*non-fluoridated areas were the reference; adjusted for age, gender and all individual, school, & area-level factors RR = rate ratio				
Authors' conclusion	Do et al. (2015): A multitude of factors had significant population impact on the prevalence of dental caries in children. Water fluoridation has a significant population impact on dental caries experience in this child population. Do & Spencer (2015): Comparison of caries experience of children at the time of the extension of water fluoridation supported the rationale for this population health measure.				
Correspondence if required	None				
Reviewer's notes	Both studies appear to be using the same data				

HAYSOM ET AL. (2015)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	All young people in custody in NSW
1.2 Is the eligible population or area representative of the source population or area?	++	All young people in custody in 8 juvenile justice centres & one high-security juvenile correctional centre between August and October 2009 were eligible for participation.
1.3 Do the selected participants or areas represent the eligible population or area?	+	On study day or unavailable (15.5%); refused consent (4.6%)

Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Fluoridation of water supply of usual residence obtained from NSW Centre for Oral Health Strategy
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	+	Assessed by questionnaire & location of usual residence. Recall bias possible.
2.5 Is the setting applicable to the Australia?	++	
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Clinical examination. No inter- or intra-rater reliability assessed.
3.2 Were the outcome measurements complete?	+	18.6% had incomplete dental examination
3.3 Were all the important outcomes assessed?	++	DMFT, periodontal disease, plaque
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	
4.3 Were the analytical methods appropriate?	++	Multivariate logistic regression (adjusted odds ratios) & negative binomial regression analyses (incident rate ratios)
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Unclear how representative the participant population is with only 65% of eligible population participating/with full data
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Set in Australian juvenile centres
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	26
	Date form completed	11/01/16
	Country of origin Source of funding Possible conflicts of interest	Australia This study was funded and staffed by Juvenile Justice, Justice and Forensic Mental Health Network and the Centre for Aboriginal Health (NSW Ministry of Health). NR
Study characteristics	Aim/objectives of study	To describe the prevalence and risk factors for markers of poor oral health in Aboriginal and non-Aboriginal young people in custody in Australia.
	Study design	Ecological
	Level of evidence	IV
	Study location	Australia
	Study duration	NA

	Exposure duration	NA	
	Source population description	All young people in custody in 8 juvenile justice centres & one high-security juvenile correctional centre	
	Inclusion/exclusion criteria	Those with precedent work or court commitments not invited to participate	
	Recruitment procedures	All young people who were in custody between August and October 2009 were eligible for participation.	
Participant characteristics		Whole study	
	No. of participants enrolled	361 consented	
	Age (mean)	17.1 years (of those with complete dental exam n=294)	
	Gender	268 men 26 women	
	Fluoridation	240 fluoridated 35 non-fluoridated	
	Indigenous status	136 Aboriginal 158 non-Aboriginal	
	NB: see paper for full details		
Exposure and setting		Intervention	
	Description of exposure and control	Water fluoridation (fluoridation status of reticulated water supply obtained from NSW Centre for Oral Health Strategy)	
	Setting	Prison-based study	
Results: caries / DMFT	Definition (with units) Method of measurement	Decayed, missing & filled permanent teeth Clinical examination	
	No. of participants analysed	294	
	No. of participants excluded or missing (with reasons)	67 (incomplete dental examination)	
	Imputation of missing data	NR	
	Statistical method of analysis	Multivariate logistic regression (adjusted odds ratios) & negative binomial regression analyses (incident rate ratios)	
	Participant category	Caries experience OR* (95%CI)	p-value
	All participants	3.35 (1.16 – 9.66)	0.03
	Participant category	DMFT IRR* (95%CI)	p-value
	All participants	1.77(1.11 – 2.83)	0.02
	* fluoridated areas were the reference; adjusted for aboriginality, age group, gender, history out-of-home care, socioeconomic disadvantage, remoteness, time incarcerated, snacks >2x weekly, preferred sweetened drinks, tooth brushing frequency, toothache/problem with teeth/gums, self-reported status of teeth, dental service previous year, & location dental provider previous year. OR = odds ratio IRR = incidence rate ratio 95%CI = 95% confidence interval		
Authors' conclusion	Young people entering NSW custody have some of the worst oral health in Australia, with those from geographically remote areas without water fluoridation being at highest risk.		
Correspondence if required	None		
Reviewer's notes	None		

KAMPPI ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Male military recruits in 24 garrisons in Finland
1.2 Is the eligible population or area representative of the source population or area?	+	Four garrisons excluded because of outsourced dental service.
1.3 Do the selected participants or areas represent the eligible population or area?	+	All conscripts in 15 garrisons and every 5th conscript in alphabetical order in the five largest garrisons were

		included in the study.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Data for fluoride levels accessed from the Geological Survey of Finland. Mean values calculated from combined values of streams, springs, dug and drilled wells in each municipality as reported in 2000.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Place of residence and speaking Swedish and/or Finnish reflect SES which affects caries prevalence
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	+	Place of residence and language spoken included in analysis.
2.5 Is the setting applicable to the Australia?	+	Similar socioeconomic and healthcare systems. Some fluoride levels above that used in Australian setting.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	All dentists in Defence Force were examiners plus one dentist conscript, and two external researchers. Inter-rater agreement ICC=0.73 & 0.71. Intra-rater agreement ICC=0.72
3.2 Were the outcome measurements complete?	++	
3.3 Were all the important outcomes assessed?	++	DMFT/DT
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Confounders as above
4.3 Were the analytical methods appropriate?	++	Generalised linear mixed models
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Sample of male conscripts in Finland – unclear how representative of all male conscripts. Limited confounders assessed
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Likely to be generalisable to Australian setting
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	124
	Date form completed	12/01/16
	Country of origin	Finland
	Source of funding	"The following organizations supported the study with a grant: Colgate Gaba in collaboration with the Finnish Dental Society Apollonia to V.A., the Society of the Finnish Female Dentists to both T.T. and V.A., and the Finnish Association for Dentists in Public Health to T.T."
	Possible conflicts of interest	"None of the researchers have any interests which might harm the

		objectivity of this study in any way.”	
Study characteristics	Aim/objectives of study	To investigate whether regional differences in caries prevalence among young healthy males still exist in Finland and to study the possible risk caused by place of residence-associated factors for caries prevalence analysing the role of fluoride level in the drinking water, main language in the municipality, location of residence on the urban-rural axis, and dentist density for the possible caries risk.	
	Study design	Ecological	
	Level of evidence	IV	
	Study location	Finland	
	Study duration	NA	
	Exposure duration	NA	
	Source population description	Male conscripts born 1990-2 in the Finnish Defence Force Jan-Jul 2011 from 20 garrisons	
	Inclusion/exclusion criteria	NR	
	Recruitment procedures	All conscripts in 15 garrisons and every 5th conscript in alphabetical order in the five largest garrisons were included in the study.	
Participant characteristics		Whole study	
	No. of participants enrolled	13,564	
	Age (range)	19-21 years	
	Gender	All male	
	Mean DMFT / DT	4.11 / 1.4	
	% DMFT / DT = 0	21.3% / 54.9%	
Exposure and setting		Intervention	
	Description of exposure and control	Mean values calculated from combined values of streams, springs, dug and drilled wells in each municipality as reported in 2000. Categorised into three groups: 0.0-0.3ppm; >0.3-0.8ppm; >0.8ppm	
	Setting	Military-based study	
Results: cariological treatment need	Definition (with units) Method of measurement	Cariological treatment need (Decayed permanent teeth [DT] >0) Clinical examination	
	No. of participants analysed	13,564	
	No. of participants excluded or missing (with reasons)	162 (missing zip codes) 98 (missing fluoride data)	
	Imputation of missing data	NR	
	Statistical method of analysis	Generalised linear mixed model with logit link	
	Participant category	Fluoride level	OR* (95%CI)
	All participants	0.0 – 0.3 ppm	reference
		>0.3 – 0.8 ppm	0.80 (0.72 – 0.88)
		>0.8 ppm	0.79 (0.69 – 0.92)
	* OR = odds ratio; Adjusted for urban/rural residence & language spoken		
Authors' conclusion	In conclusion, regional/geographical differences in caries prevalence among healthy young males still exist in Finland. The residence-related protective factors for caries risk are Swedish spoken as the main language (indicating higher socio-economic status), high fluoride content in water, and living in urban areas (indicating higher educational status). No association between dentist density and caries prevalence could be established.		
Correspondence if required	None		
Reviewer's notes	Results from one model reported – other model included province of residence rather than urban/rural as a variable. NB >0.8 vs. 0.0-0.3ppm not statistically significant OR=0.86 (0.73 – 1.02)		

LALLOO ET AL. (2015)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	All children attending school dental service in Queensland, South Australia, Western Australia, Tasmania, Northern Territory, Australian Capital Territory
1.2 Is the eligible population or area representative of the source population or area?	++	Random selection of children attending school dental service (SDS). Weighted at regional level to account for different sampling fractions implemented to select children. Data also weighted to adjust for different recall intervals for children.
1.3 Do the selected participants or areas represent the eligible population or area?	++	Data from Child Dental Health Survey (CDHS) 2010 as above.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Post code of children's residence (all states/territories except WA) or clinic (WA). Fluoride concentration in water supply was matched to the postcode. NB: Parts of Qld only fluoridated since 2008 were considered non-fluoridated. Assumption that children didn't move during their lifetime. Indigenous status collected routinely at SDS by self-report.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	-	Age and gender controlled for in regression analysis. Results stratified by Indigenous status. Important confounders like sugar consumption, use of fluoride toothpaste and SES not included.
2.5 Is the setting applicable to the Australia?	++	Study conducted in Australia. NSW & VIC not included
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	No reliability testing
3.2 Were the outcome measurements complete?	+	5.4% of records with missing data on Indigenous status and fluoridation were removed.
3.3 Were all the important outcomes assessed?	++	Yes – % caries-free and no untreated decay
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Regression analysis

4.6 Was the precision of association given or calculable? Is the association meaningful?	++	95%CI reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Good selection methods. Assumption that children did not move from fluoridated to non-fluoridated areas or vice versa. Indigenous children may move locations more. Poor capture of confounding factors.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Set in Australia but excluded VIC and NSW
Overall quality rating	Low	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	1158			
	Date form completed	02/12/15			
	Country of origin Source of funding Possible conflicts of interest	Australia Australian Institute of Health and Welfare NR			
Study characteristics	Aim/objectives of study	To assess whether access to fluoride in the water closed the gap in dental caries between Indigenous and non-Indigenous children.			
	Study design	Ecological			
	Level of evidence	IV			
	Study location	Queensland, South Australia, Western Australia, Tasmania, Northern Territory, Australian Capital Territory			
	Study duration	NA			
	Exposure duration	Approximately 10 years			
	Source population description	Participants of the Child Dental Health Survey (CDHS) 2010			
	Inclusion/exclusion criteria	NA			
	Recruitment procedures	For the CDHS: Random sample of children attending the school dental service (SDS) by selecting those examined during 2010 who were born on specific days of the month.			
Participant characteristics		Whole study	Indigenous	Non-Indigenous	
	No. of participants enrolled	97,809	6.7%	93.3%	
	Age (mean/range)	10.1 (10.0-10.2)	10.1 (9.8-10.3)	10.1 (10.0-10.2)	
	Gender	51% female	55.4%	50.6%	
	Mean dmft	2.33	3.84*	2.22*	
	Mean DMFT	1.14	2.00*	1.08*	
	At least one fissure sealant	23.1%	20.1%	23.3	
	Fluoridated water (≥0.5 ppm) prior to 2008	78.3%	57.9%*	79.7%*	
		* non-overlapping 95%CI			
Exposure and setting		Intervention	Comparator		
	Description of exposure and control	Fluoride level in water supply ≥0.5 ppm	Fluoride level in water supply <0.3 ppm		
	Setting	School-based study. Children attending SDS.			
Results: % caries-free	Definition (with units) Method of measurement	dmft / DMFT = 0 (decayed, missing & filled deciduous or permanent teeth) Clinical examination			
	No. of participants analysed	97,809			
	No. of participants excluded or missing (with reasons)	NA			
	Imputation of missing data	NA			
	Statistical method of analysis	Logistic regression analysis adjusting for age and gender			
	Participant category	dmft = 0 % (95%CI)	dmft = 0 Adjusted OR (95%CI)	DMFT = 0 % (95%CI)	DMFT = 0 Adjusted OR (95%CI)

	Indigenous (<0.3 ppm)	22.9 (20.2–25.9)	Reference	44.3 (40.2–48.6)	Reference
	Indigenous (≥0.5 ppm)	27.3 (23.7–31.2)	1.27 (0.98 – 1.63)	50.3 (45.1–55.4)	1.30 (1.01 – 1.68)
	Non-Indigenous (<0.3 ppm	36.3 (35.3–37.3)	1.93 (1.63 – 2.29)	53.8 (52.6–55.1)	1.60 (1.32 – 1.95)
	Non-Indigenous (≥0.5 ppm))	52.5 (51.0–54.0)	3.78 (3.17 – 4.50)	70.7 (69.3–72.0)	3.72 (3.04 – 4.56)
Results: no untreated decay	Definition (with units) Method of measurement	d / D = 0 (decayed deciduous or permanent teeth) Clinical examination			
	No. of participants analysed	97,809			
	No. of participants excluded or missing (with reasons)	NA			
	Imputation of missing data	NA			
	Statistical method of analysis	Logistic regression analysis adjusting for age and gender			
	Participant category	d = 0 % (95%CI)	d = 0 Adjusted OR (95%CI)	D =0 % (95%CI)	D =0 Adjusted OR (95%CI)
	Indigenous (<0.3 ppm)	33.8 (30.7–37.1)	Reference	58.1 (53.4–62.6)	Reference
	Indigenous (≥0.5 ppm)	48.6 (44.5–52.7)	1.87 (1.51 – 2.33)	71.6 (67.0–75.8)	1.89 (1.37 – 2.59)
	Non-Indigenous (<0.3 ppm)	48.6 (47.5–49.7)	1.86 (1.60 – 2.16)	65.1 (63.8–66.4)	1.39 (1.14 – 1.69)
	Non-Indigenous (≥0.5 ppm)	71.3 (70.0–72.6)	4.92 (4.21 – 5.75)	85.2 (84.0–86.3)	4.61 (3.73 – 5.70)
Authors' conclusion	Water fluoridation is effective in reducing dental caries, but does not appear to close the gap between non-Indigenous children and Indigenous children.				
Correspondence if required	None required				
Reviewer's notes					

LEE & HAN (2015)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	In the 2003 survey which was made up of 60 survey districts, a classroom for all school grades was randomly selected, and every fifth student was examined. The 2006 and 2010 surveys were the same as that of the 2003 survey except for the number of survey districts and number of participants. The number of districts changed to 150 in the 2006 survey, and every fifth student was examined.
1.2 Is the eligible population or area representative of the source population or area?	++	Random selection of children within 60 districts. Adjusted for gender and rural/urban.
1.3 Do the selected participants or areas represent the eligible population or area?	++	Data were from the Korea National Oral Health Surveys (KNOHS)
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Information was collected with a stratified cluster sampling procedure.
2.2 Was the selection of explanatory variables based on	++	Yes

a sound theoretical basis?		
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	+	Gender and rural/urban controlled in regression analysis. Results stratified by age.
2.5 Is the setting applicable to the Australia?	+	Study conducted in developed country with similar fluoride levels to Australia.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	An examiner was acceptable to conduct the survey when inter-examiner variability for untreated dental caries and caries experience was acceptable and good agreement for untreated dental caries and caries experience with the chief investigator was achieved (κ ≥ 0.7).
3.2 Were the outcome measurements complete?	++	
3.3 Were all the important outcomes assessed?	++	Untreated dental caries and caries experienced
3.4 Was there a similar follow-up time in exposure and comparison groups?	N/A	
3.5 Was follow-up time meaningful?	N/A	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Regression analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	95%CI reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Good selection criteria attempting to cover the population in question.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Study conducted in developed country with similar fluoride levels to Australia.
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	1155
	Date form completed	15/12/2015
	Country of origin Source of funding Possible conflicts of interest	South Korea NR None of the authors have a conflict of interest in relation to this study.
Study characteristics	Aim/objectives of study	To trace the secular changes in childhood dental caries and two major dental public health programs including water fluoridation and dental sealants from 2003 to 2010 using nationally representative Korean data and to examine the potential contributions of trends in childhood dental caries.
	Study design	Ecological
	Level of evidence	IV
	Study location	South Korea
	Study duration	NR
	Exposure duration	Lifetime
	Source population description	Korea National Oral Health Surveys (KNOHS): 2003, 2006, 2010
	Inclusion/exclusion criteria	Children aged 8, 10, and 12

	Recruitment procedures	In the 2003 survey which was made up of 60 survey districts, a classroom for all school grades was randomly selected, and every fifth student was examined. The 2006 and 2010 surveys were the same as that of the 2003 survey except for the number of survey districts and number of participants. The number of districts changed to 150 in the 2006 survey, and every fifth student was examined. In the 2010 survey, 6-, 8-, 10-, 12-, and 15-year-old children from 200 districts were selected, a classroom for each school age was randomly selected, and all the students in the classroom were examined.		
Participant characteristics	Age 8 years	2003	2006	2010
	No. of participants enrolled	599	875	5,732
	Age (state mean/median/range)	8	8	8
	Gender	NR	NR	NR
	Other characteristics (e.g. ethnicity, illness, social class)	NR	NR	NR
	Untreated caries, n (%)	133 (22.2)	92 (10.8)	456 (7.6)
	Caries experience, n (%)	259 (43.2)	267 (30.3)	1591 (27.2)
	DMFT, mean	1.03	0.67	0.57
	Sealant, n (%)	206 (34.4)	338 (39.4)	3025 (52.9)
	Water fluoridation, n (%)	80 (13.4)	48 (5.0)	482 (8.5)
	Rural residents, n (%)	90 (15.0)	86 (13.0)	840 (13.3)
	Age 10 years	2003	2006	2010
	No. of participants enrolled	600	888	5,760
	Age (state mean/median/range)	10	10	10
	Gender	NR	NR	NR
	Other characteristics (e.g. ethnicity, illness, social class)	NR	NR	NR
	Untreated caries, n (%)	204 (34.0)	125 (14.2)	715 (11.4)
	Caries experience, n (%)	369 (61.5)	397 (44.4)	2664 (46.2)
	DMFT, mean	1.89	1.18	1.16
	Sealant, n (%)	183 (30.5)	355 (41.6)	2970 (50.9)
	Water fluoridation, n (%)	80 (13.3)	48 (5.0)	483 (8.6)
	Rural residents, n (%)	90 (15.0)	88 (13.1)	856 (12.3)
	Age 12 years	2003	2006	2010
	No. of participants enrolled	597	1,755	6,253
	Age (state mean/median/range)	12	12	12
	Gender	NR	NR	NR
	Other characteristics (e.g. ethnicity, illness, social class)	NR	NR	NR
	Untreated caries, n (%)	297 (49.7)	399 (23.7)	1306 (19.8)
	Caries experience, n (%)	453 (75.9)	1068 (61.1)	3811 (60.5)
	DMFT, mean	3.25	2.17	2.08
	Sealant, n (%)	148 (24.8)	580 (34.0)	3083 (48.9)
	Water fluoridation, n (%)	70 (11.7)	96 (5.0)	393 (7.0)
	Rural residents, n (%)	90 (15.1)	159 (13.8)	792 (10.8)
Exposure and setting		Intervention	Comparator	
	Description of exposure and control (including level of fluoride)	The definition of water-fluoridated community was the community which was provided fluoridated tap water more than 3 years at the survey.	The definition of water-fluoridated community was the community which was provided fluoridated tap water more than 3 years at the survey.	
	Setting (including social context)	School-based study	School-based study	
Results: untreated dental caries	Definition (with units) Method of measurement	The prevalence of untreated dental caries was defined as the existence of untreated dental caries (yes versus no)		

	No. of participants analysed	23,059		
	No. of participants excluded or missing (with reasons)	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Logistic regression was used to test the association of water fluoridation with dental caries in each survey year controlling for gender and urban/rural area. The contributions of water fluoridation to the time trends in the prevalence of dental caries was adjusted for each of those with water fluoridation in the baseline regression models and examining the changes in the adjusted odds ratios (ORs) for each survey year. The model adjusted for gender and urban/rural area was the baseline model in this analysis. The roles of water fluoridation were evaluated with the percentage (%) excess odd explained, which can be calculated as $[(OR_{baseline} - OR_{baseline + water fluoridation}) / OR_{baseline} - 1)]$ in this study. This percentage excess odd explained represents the degree to which water fluoridation explains the trends for the dental caries.		
	Participant category	2003	2006	2010
	8 years (OR; 95% CI)	0.89 (0.50–1.59)	0.58 (0.18–1.92)	0.71 (0.48–1.04)
	10 years (OR; 95% CI)	0.79 (0.47–1.33)	0.72 (0.28–1.85)	1.14 (0.87–1.49)
	12 years (OR; 95% CI)	0.40 (0.23–0.69)	1.21 (0.74–1.97)	0.67 (0.50–0.89)
Results: caries experience	Definition (with units) Method of measurement	The prevalence of caries experience was defined as the existence of caries experience (yes versus no)		
	No. of participants analysed	23,059		
	No. of participants excluded or missing (with reasons)	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Logistic regression was used to test the association of water fluoridation with dental caries in each survey year controlling for gender and urban/rural area. The contributions of water fluoridation to the time trends in the prevalence of dental caries was adjusted for each of those with water fluoridation in the baseline regression models and examining the changes in the adjusted odds ratios (ORs) for each survey year. The model adjusted for gender and urban/rural area was the baseline model in this analysis. The roles of water fluoridation were evaluated with the percentage (%) excess odd explained, which can be calculated as $[(OR_{baseline} - OR_{baseline + water fluoridation}) / OR_{baseline} - 1)]$ in this study. This percentage excess odds explained represents the degree to which water fluoridation explains the trends for the dental caries.		
	Participant category	2003	2006	2010
	8 years (OR; 95% CI)	1.30 (0.81–2.11)	1.41 (0.47–4.25)	0.80 (0.57–1.14)
	10 years (OR; 95% CI)	0.92 (0.57–1.50)	1.18 (0.64–2.20)	1.04 (0.70–1.54)
	12 years (OR; 95% CI)	0.74 (0.42–1.30)	0.87 (0.44–1.74)	0.92 (0.69–1.22)
Authors' conclusion	Collectively, among Korean children 8–12 years of age, childhood dental caries substantially decreased from 2003 to 2010. These remarkable decreases were found among all age and gender groups. However, the decreases were not explained by concomitant secular changes in dental sealant and water fluoridation. The likely causes for these secular trends remain to be determined.			
Correspondence if required	None required			
Reviewer's notes	None			

MCGRADY ET AL. (2012)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	11-13 year olds attending schools in Manchester & Newcastle, UK

1.2 Is the eligible population or area representative of the source population or area?	+	Lifetime resident 11-13 year olds attending selected schools in Manchester & Newcastle. Which schools or number of schools asked to participate & actually participating NR.
1.3 Do the selected participants or areas represent the eligible population or area?	+	Unclear – around 50% of eligible population participated in study.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Fluoridation of water supply
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Deprivation, diet, use of toothpaste, rinsing behaviour all affect caries prevalence
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	+	Deprivation assessed by postcode. Age at examination was the only other confounder included in the regression model.
2.5 Is the setting applicable to the Australia?	++	Similar socioeconomic and healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	One examiner blind to residence status. No reliability testing.
3.2 Were the outcome measurements complete?	++	
3.3 Were all the important outcomes assessed?	+	Dental fluorosis also assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	+	Only age at examination and deprivation included in analysis.
4.3 Were the analytical methods appropriate?	++	Logistic regression
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Participants likely to be highly selected and may not represent source population. Oral hygiene practices not included in regression analysis. Likely overestimated effect estimate.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Very likely to be generalisable to Australian context
Overall quality rating	Low	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	76
	Date form completed	11/01/16
	Country of origin Source of funding	UK IAP is funded by a Clinician Scientist Award from the National Institute for Health Research (UK). The Colgate Palmolive Dental Health Unit is funded by an unrestricted grant from Colgate Palmolive. This study was funded by the Clinician Science Award with support from The Colgate Palmolive

	Possible conflicts of interest	Dental Health Unit. None of the authors are aware of any competing interests in the production of this manuscript.		
Study characteristics	Aim/objectives of study	To determine the association between social deprivation and the prevalence of caries (including caries lesions restricted to enamel) and enamel fluorosis (on the maxillary central incisors) in areas served by either fluoridated or non-fluoridated drinking water.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	UK		
	Study duration	NA		
	Exposure duration	Lifetime		
	Source population description	Students attending school aged 11-13 years in Manchester and Newcastle. UK		
	Inclusion/exclusion criteria	Students not lifetime residents of either city or who did not have both maxillary central incisors were excluded. Not reported but subject flow chart shows subjects excluded because they "Failed to meet criteria: Ortho N=13 F sup N=1 Denture N=1"		
	Recruitment procedures	Schools were selected based upon the percentage free school meals entitlement (%FSME) to provide a spectrum of socio-economic backgrounds and their willingness to participate.		
Participant characteristics		Whole study	Intervention (Newcastle)	Comparator (Manchester)
	No. of participants enrolled	1,783	910	873
	Age (mean)	12.44	12.56	12.32
	Gender	56% male	54% male	57% male
	Mean Index of Multiple Deprivation (IMD)	36.11	35.11	37.04
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Water fluoridation (1ppm)	Non-fluoridated	
	Setting	School-based study		
Results: caries into dentine / caries white spot lesion	Definition (with units) Method of measurement	Caries into dentine (D_{4-6}MFT) Caries at white spot level (D_{1-6}MFT) Clinical examination		
	No. of participants analysed	1,783		
	No. of participants excluded or missing (with reasons)	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Logistic regression		
	Participant category	Caries into dentine OR* (95%CI)	*p*-value	
	All participants	1.840 (1.500 – 2.258)	<0.001	
	Participant category	Caries white spot lesion OR* (95%CI)	*p*-value	
	All participants	2.11 (1.622 – 2.680)	<0.001	
	* Newcastle (intervention) is the reference; OR = odds ratio; 95%CI = 95% confidence interval; Adjusted for age at examination & IMD (Index of Multiple Deprivation) score			
Results: difference in D4-6MFT between degrees of deprivation	Participant category	Mean D4-6MFT		
	Quintile deprivation (based on IMD score)	Newcastle (fluoridated)	Manchester (non-fluoridated)	
	1	0.38	0.45	
	2	0.47	0.84	
	3	0.62	1.07	
	4	0.87	1.37	
	5	0.99	1.52	
Authors'	Water fluoridation appears to reduce the social class gradient between deprivation and caries experience			

conclusion	when considering caries into dentine. However, this was associated with an increased risk of developing mild fluorosis.
Correspondence if required	None
Reviewer's notes	Fluorosis data not extracted

MCLAREN & EMERY (2012)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Participants of the Canadian Health Measures Study (CHMS)
1.2 Is the eligible population or area representative of the source population or area?	++	A probability sampling strategy was used, incorporating aspects of stratification and cluster sampling. Specifically, a list of 257 potential data collection sites was created, based on Statistics Canada's Labour Force Survey area frame. From the 257 sites, 15 were selected, stratified by region, proportional to the Canadian population. Within each site, approximately 350 respondents were sampled, stratified by age group (five age groups: 6-11, 12-19, 20-39, 40-59, 60-79).
1.3 Do the selected participants or areas represent the eligible population or area?	++	Of individuals selected for the survey, the response rate for the household interview was 88.3%, of whom 84.9% further agreed to undergo the clinic examination. We focused on children aged 6 to 11 years old.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	According to information from various sources, each site as fluoridated, not fluoridated or mixed. The not-fluoridated and mixed sites were combined. Therefore selection bias very likely.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Socioeconomic variables and oral habits all affect caries prevalence
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Identified by questionnaire. Controlled for in analyses.
2.5 Is the setting applicable to the Australia?	++	Similar healthcare and socioeconomic characteristics
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Most likely – examined by Canadian Forces dentist. No inter- or intra-rater reliability testing.
3.2 Were the outcome measurements complete?	++	
3.3 Were all the important outcomes assessed?	++	dmft/DMFT
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	

4.2 Were multiple explanatory variables considered in the analyses?	++	
4.3 Were the analytical methods appropriate?	++	Ordinary least squares regression adjusted for covariates
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	The comparator group will include participants exposed to fluoridation. This would under-estimate the effect estimate. Participants as a whole probably representative of Canadian population.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Very likely generalisable to Australian setting
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	154		
	Date form completed	12/01/16		
	Country of origin Source of funding Possible conflicts of interest	Canada NR NR		
	Aim/objectives of study	To examine the association between exposure to drinking water fluoridation and oral health inequities among Canadian children.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Canada		
	Study duration	NA		
	Exposure duration	NA		
	Source population description	Canadian Health Measures Survey (CHMS): cross-sectional survey during 2007-9 of individuals aged 6-79 years living in privately occupied dwellings across all provinces and territories.		
	Inclusion/exclusion criteria	Excluded from CHMS: persons living on Indian Reserves or Crown lands, residents of institutions, full-time members of the Canadian Forces and residents of certain remote regions.		
	Recruitment procedures	Probability sampling strategy: 15 sites from 257 were selected, stratified by region, proportional to the Canadian population; within each site, approximately 350 respondents were sampled, stratified by age group (five age groups: 6-11, 12-19, 20-39, 40-59, 60-79); this study focused on children aged 6 to 11 years old.		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	1,081	389	628
	Age (range)	6-11 years	6-11 years	6-11 years
	Gender male (n, %) female	512 (50.4) 505 (49.6)	196 (50.3) 193 (49.7)	317 (50.4) 311 (49.6)
	dmftDMFT, mean	2.42 (SD 3.1)	2.2 (SD 3.0)	2.6 (SD 3.2)
	dmftDMFT, score 0 (n, %) 1-2 3+	443 (43.6) 219 (21.6) 354 (34.8)	186 (47.9) 83 (21.4) 119 (30.7)	255 (40.6) 136 (21.7) 237 (37.7)
	Highest household education High school grad. Certif./diploma Bachelor's degree >Bachelor's degree	 179 (17.6) 449 (44.2) 267 (26.3) 122 (12)	 66 (16.9) 177 (45.4) 98 (25.1) 49 (12.6)	 113 (18) 272 (43.3) 170 (27.1) 73 (11.6)
	Income adequacy Low	267 (26.3)	94 (24.3)	174 (27.7)

	Middle	267 (26.3)	117 (30.2)	148 (23.5)
	High	483 (47.5)	177 (45.5)	307 (48.9)
	Owns home No	258 (25.4)	113 (29.2)	143 (22.7)
	Yes	759 (74.6)	276 (70.8)	485 (77.3)
	Dental insurance No	198 (19.5)	76 (19.5)	123 (19.5)
	Yes	819 (80.5)	313 (80.5)	505 (80.5)
	Born in Canada No	77 (7.6)	27 (7.1)	50 (8.0)
	Yes	940 (92.4)	362 (93.0)	578 (92.0)
	Lived in home at least 2 years No	168 (16.5)	64 (16.5)	104 (16.5)
	Yes	849 (83.5)	325 (83.5)	524 (83.5)
	Usually drinks tap water No	430 (42.2)	283 (45.1)	149 (38.2)
	Yes	587 (57.8)	345 (54.9)	240 (61.8)
	Source of tap water Municipal system	861 (84.7)	114 (18.1)	44 (11.3)
	Other	156 (15.3)	514 (81.9)	345 (88.7)
Exposure and setting		Intervention	Comparator	
	Description of exposure and control (including level of fluoride)	Fluoridated areas according to information from “various sources”	Non-fluoridated areas and ‘mixed’ sites (mixed sites are supplied by both fluoridated and unfluoridated water)	
	Setting (including social context)	Population-based study		
Results: dmft/DMFT	Definition Method of measurement	Number of decayed, missing & filled permanent or deciduous teeth (DMFT/dmft) Clinical exam		
	No. of participants analysed	1,017		
	No. of participants excluded or missing (with reasons)	64 (incomplete data)		
	Imputation of missing data	NR		
	Statistical method of analysis	Ordinary least squares regression		
	Participant category	Coefficient (95%CI)	p-value	
	All participants	-1.6 (-3.4 to 0.12)*	<0.10	
		-0.49 (-1.0 to 0.03)†	<0.10	
	*dmft/DMFT regressed on fluoridation status, SES variables, & fluoridation x SES interaction terms, adjusted for covariates † dmft/DMFT regressed on fluoridation status & SES variables, adjusted for covariates			
Authors’ conclusion	Among children aged 6 to 11 in the CHMS, we detected an inverse association between community drinking water fluoridation status and oral health outcomes, such that fluoridation was associated with fewer decayed, missing and filled teeth.			
Correspondence if required	None			
Reviewer’s notes	None			

POSTMA ET AL. (2008)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	+	The source population is described in a separate publication
1.2 Is the eligible population or area representative of the source population or area?	++	The NCOHS used a two-staged cluster sampling method, weighted to produce a representative sample of South African children.
1.3 Do the selected participants or areas represent the eligible population or area?	++	

Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Two-staged cluster sampling method
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	+	socio-demographic factors, sugar expenditure/consumption, and rural/urban controlled in regression analysis.
2.5 Is the setting applicable to the Australia?	+	Study conducted in developing country with similar environmental factors to Australia.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	An examiner was acceptable to conduct the survey when inter-examiner variability for untreated dental caries and caries experience was acceptable and good agreement for untreated dental caries and caries experience with the chief investigator was achieved ($\kappa \geq 0.7$).
3.2 Were the outcome measurements complete?	++	
3.3 Were all the important outcomes assessed?	++	Severity of dental caries
3.4 Was there a similar follow-up time in exposure and comparison groups?	N/A	
3.5 Was follow-up time meaningful?	N/A	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Multiple logistic regression analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	95%CI reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Good selection criteria attempting to cover the population in question.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Study conducted in developing country with similar environmental factors to Australia.
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	951
	Date form completed	15/12/2015
	Country of origin Source of funding Possible conflicts of interest	South Africa Department of Health, South Africa NR
Study characteristics	Aim/objectives of study	To describe early childhood caries (ECC) severity in South Africa and examine the association between ECC (prevalence and severity) and socio-demographic factors, controlling for water fluoride levels and sugar consumption by means of area-based measures obtained from alternative sources.

	Study design	Ecological			
	Level of evidence	IV			
	Study location	South Africa			
	Study duration	NR			
	Exposure duration	Lifetime			
	Source population description	1999/2002 South African National Children's Oral Health Survey (NCOHS)			
	Inclusion/exclusion criteria	NR (previously reported)			
	Recruitment procedures	NCOHS used a two-staged cluster sampling method, weighted to produce a representative sample of South African children. The sample was stratified by geographical location, and participating schools were randomly selected within the various districts. The locality of the school was indicated as urban, peri-urban, or rural. The peri-urban and rural groups were grouped into one category, namely non-urban, during subsequent analyses.			
Participant characteristics		No caries	Isolated caries	Severe caries	Very severe caries
	No. of participants enrolled	2644	1336	1605	237
	Age (mean (months); SD)	60.53 (6.78)	62.02 (6.42)	60.91 (6.66)	62.77 (6.20)
	Gender - males, %	45.05%	20.68%	30.33%	3.94%
	Gender - females, %	46.15%	23.11%	27.19%	3.54%
	Locality - Urban	40.34%	22.78%	32.31%	4.55%
	Locality - Non-urban	51.13%	21.11%	24.92%	2.84%
	Ethnicity - Black	47.74%	21.58%	27.32%	3.36%
	Ethnicity - Coloured	23.18%	25.08%	45.48%	6.26%
	Ethnicity – Asian	47.09%	20.22%	29.64%	3.05%
	Ethnicity – White	61.19%	20.36%	15.43%	3.02%
	Income – High	48.83%	22.98%	24.95%	3.24%
	Income – Middle	41.25%	23.80%	31.45%	3.50%
	Income – Unemployed	49.43%	18.14%	28.86%	3.57%
	Fluoride - <0.1ppm	25.85%	18.84%	28.41%	26.89%
	Fluoride – 0.1-0.29pmm	34.38%	17.47%	19.79%	28.36%
	Fluoride - ≥0.3ppm	40.58%	16.46%	12.94%	30.03%
Exposure and setting		Intervention		Comparator	
	Description of exposure and control (including level of fluoride)	Based on the South African fluoride supplement dosage schedule, previously reported data regarding the fluoride content in public drinking water supplies were used to categorise the fluoride in drinking water. The school address served as matching reference and in cases where fluoride values were unavailable, the water fluoride content of the closest neighbouring town was used.			
	Setting (including social context)	School-based study			
Results: Isolated, severe, or very severe early childhood caries	Definition (with units) Method of measurement	Isolated: caries in one or two molars and/or incisors Severe: labio-lingual caries on the maxillary incisors, where the molars are either affected, or not Very severe: caries involving virtually all the teeth, including the mandibular incisors Adapted Wyne classification using dmft score. Dental examination			
	No. of participants analysed	5,822			
	No. of participants excluded or missing (with reasons)	NR			
	Imputation of missing data	NR			
	Statistical method of analysis	Multiple logistic regression analyses* were used to illustrate the independent association between ECC and the socio-demographic factors, sugar expenditure/consumption and fluoride content in drinking water. ECC served			

			as the outcome measure in three separate multiple logistical regression models. The level of statistical significance was set at 5%. *adjusted for age, gender, locality, ethnicity & income			
	Participant category	Comparisons	Fluoride level in public drinking water supply			
			<0.10 ppm	0.10-0.29 ppm	0.30-0.6 ppm	>0.6 ppm
	All participants	No caries compared with ECC	Reference	OR=0.80 (0.64-0.99)	OR=0.62 (0.44-0.87)	OR=0.40 (0.25-0.63)
	All participants	'Isolated' caries compared with the severe forms of ECC	Reference	OR=0.91 (0.73-1.14)	OR=0.71 (0.48-1.04)	OR=0.71 (0.25-2.03)
	All participants	'Isolated' and 'severe' ECC compared with 'very severe' ECC	Reference	OR=1.00 (0.64-1.55)	OR=1.01 (0.55-1.87)	OR=0.57 (0.14-2.38)
Authors' conclusion	ECC should be considered a serious public health problem in South Africa, especially among the socially disadvantaged groups. Although water fluoridation may help to reduce the prevalence of ECC, a greater reduction in the more severe forms of ECC (which is the more predominant form of ECC in the studied population) would only be achieved through an integrated Primary Oral Health Care approach that includes not only oral health promotional interventions, but also interventions that address underlying social determinants. This will include interventions directed at improving the living standards of the population, particularly the most disadvantaged groups.					
Correspondence if required	None required					
Reviewer's notes	None					

PUBLIC HEALTH ENGLAND (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Total population of England
1.2 Is the eligible population or area representative of the source population or area?	++	Eligible population fully represents the source population
1.3 Do the selected participants or areas represent the eligible population or area?	++	Sample fully represents the eligible population
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Standardised geographical areas of similar average population & households mapped to Drinking Water Directorate data on intentional fluoridation areas. Naturally fluoridated areas excluded.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Table of condition, indicator, and rationale for inclusion reported.
2.3 Was the contamination acceptably low?	+	Unclear -depends on how great and in what direction groups within the population move between exposed and non-exposed areas.
2.4 How well were likely confounding factors identified and controlled?	++	Data on age, gender, deprivation, and ethnicity taken from census data. Adjusted incidence rate ratios calculated.
2.5 Is the setting applicable to the Australia?	++	Yes – fluoride levels similar and can also assume some sociocultural similarities.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Most likely – all data sourced from various national databases. No reliability testing.
3.2 Were the outcome measurements complete?	++	Most likely as most outcomes would be required to be reported to the various databases e.g. cancer, deaths. Perhaps only kidney stones may be under-counted as information only from emergency admission.
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	All identical within each outcome
3.5 Was follow-up time meaningful?	+	Follow-up times varied between 3 to 15 years. Longest was for osteosarcoma which took into account lag period of at least 10 years after introduction of the majority of the fluoridation.
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	++	Large sample size
4.2 Were multiple explanatory variables considered in the analyses?	+	Yes, multivariate analyses conducted
4.3 Were the analytical methods appropriate?	+	All analyses appear to be appropriate
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported for all analyses, p-values reported for some analyses.

Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Comprehensive nationwide data from governmental sources (Hospital Episode Statistics, Office of National Statistics, English Cancer Registration Service, Drinking Water Directorate etc.) which was analysed appropriately.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Similar fluoride levels and sociodemographic characteristics to Australia
Overall quality rating	Acceptable	Analyses well controlled for confounding factors. Use of national registries allows for very large sample size. NB: retrospective study cannot be rated higher than 'acceptable'

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	1283		
	Date form completed	20/02/15		
	Country of origin Source of funding Possible conflicts of interest	United Kingdom Department of Health, UK NR		
Study characteristics	Aim/objectives of study	To monitor the effect of water fluoridation schemes on the health of people living in the areas covered.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	England		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Total population of England		
	Inclusion/exclusion criteria	Exclusion criteria: Lower super output areas (LSOAs*) located in water quality zones (WQZs) classified as naturally fluoridated Ages 25 to 49 years excluded from osteosarcoma analysis *these are standardised geographic areas with an average of roughly 1,500 residents and 650 households		
	Recruitment procedures	Data extracted from various sources – see individual outcome tables below for details		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	Various – see individual outcome tables below for details		
	Age	NR	NR	NR
	Gender	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Areas (LTLAs) with community water fluoridation	Areas (LTLAs) without community water fluoridation	
		Exposure to fluoridated water was estimated at the lower tier local authority (LTLA) level for caries experience. LTLAs are administrative districts and are made up of lower super output areas (LSOAs) which are standardised areas used for 10 yearly census data. Water quality zones (WQZs) from the Drinking Water Inspectorate were mapped onto each 2001 LSOA and assigned a fluoridation status – yes/no; LSOAs located in WQZs with natural fluoride levels up to 1ppm were given a separate classification. LTLAs were considered fluoridated if >50% of their constituent LSOAs were within a fluoridated WQZ.		

		LTLAs can be aggregated into a smaller number of upper-tier local authorities (UTLAs) were relevant (as for hospital admissions for dental caries below)		
	Setting	Population-based study with unit of exposure at an area level.		
Results: mean d3mft/ D3MFT	Definition (with units) Method of measurement	Experience of decay expressed in terms of the mean number of decayed, missing, & filled deciduous/permanent teeth (d3mft/D3MFT) Data from the National Dental Epidemiology Programme surveys of 5-year olds (2012) & 12-year olds (2009) involving visual examination of school children for missing teeth, filled teeth, & teeth with obvious decay into dentine (denoted by the '3' in d3mft/D3MFT)		
	No. of participants analysed	NR		
	No. of participants excluded or missing (with reasons)	Mean d3mft data missing from 0% of fluoridated & 5.5% of non-fluoridated areas (*p*=0.38 Fisher's exact test) Mean D3MFT data missing from 12% of fluoridated & 7.9% of non-fluoridated areas (*p*=0.50 Fisher's exact test)		
	Imputation of missing data	NR		
	Statistical method of analysis	Weighted linear regression		
	Participant category	Intervention weighted mean (95%CI)	Comparator weighted mean (95%CI)	Effect estimate Difference (95% CI)
• mean d3mft	All 5-year olds	0.81 (0.71,0.90)	1.01 (0.95,1.07)	–0.20 (–0.36, –0.04); *p*<0.001
	All 5-year olds (adjusted for deprivation & ethnicity)	-	-	–0.37 (–0.48, –0.27); *p*<0.001
	Four least deprived quintiles	-	-	–0.16 (–0.32, –0.01); *p*=0.04
	Most deprived quintile	-	-	–0.51 (–0.75, –0.27); *p*<0.001
• mean D3MFT	All 12-year olds	0.65 (0.61,0.69)	0.76 (0.72,0.79)	–0.10 (–0.20, –0.01); *p*<0.001
	All 12-year olds (adjusted for deprivation & ethnicity)		-	–0.19 (–0.27, –0.11); *p*<0.001
	Four least deprived quintiles			–0.07 (–0.17, 0.04) ; *p*=0.21
	Most deprived quintile			–0.25 (–0.44, –0.07); *p*<0.01
Results: Prevalence of any d3mft/ D3MFT	Definition (with units) Method of measurement	Experience of decay expressed in terms of % of children with decayed, missing, & filled deciduous/permanent teeth any (d3mft/D3MFT >0) Data from the National Dental Epidemiology Programme surveys of 5-year olds (2012) & 12-year olds (2009) involving visual examination of school children for missing teeth, filled teeth, & teeth with obvious decay into dentine (denoted by the '3' in d3mft/D3MFT)		
	No. of participants analysed	NR		
	No. of participants excluded or missing (with reasons)	Mean d3mft data missing from 0% of fluoridated & 5.5% of non-fluoridated areas (*p*=0.38 Fisher's exact test) Mean D3MFT data missing from 12% of fluoridated & 7.9% of non-fluoridated areas (*p*=0.50 Fisher's exact test)		
	Imputation of missing data	NR		
	Statistical method of analysis	Generalised linear models (binomial distribution)		
	Participant category	Intervention weighted prevalence (%) (95%CI)	Comparator weighted prevalence (%) (95%CI)	Effect estimate % difference in odds of prevalence (%) (95% CI)
• prevalence of any d3mft	All 5-year olds (crude difference)	26 (24,28)	29 (28,30)	–15 (–29, 2.5)
	All 5-year olds (adjusted for deprivation & ethnicity)	-	-	–28 (–35, –21); *p*<0.001
	Four least deprived quintiles	-	-	–17(–28, –3.9); p[<]0.01
	Most deprived quintile	-	-	–32 (–42, –19); *p*<0.001
• prevalence of	All 12-year olds (crude difference)	31 (30,33)	34 (33,35)	–11 (–20, –0.1); p=0.03

any D3MFT	All 12-year olds (adjusted for deprivation & ethnicity)	-	-	–21 (–29, –12); *p*<0.001
	Four least deprived quintiles	-	-	–9 (–21, 5); *p*=0.21
	Most deprived quintile	-	-	–26 (–40, –8); *p*<0.01
Results: Rate of hospital admissions for dental caries ages 1-4 years	Definition (with units) Method of measurement	Experience of decay expressed in terms of % of children with decayed, missing, & filled deciduous/permanent teeth any (d3mft/D3MFT >0) Data from the Annual Report of the Chief Medical Officers 2012 of hospital admission rate for dental caries in children aged 1-4 years per 1000,000 children aged 1-4 years by upper-tier local authority (UTLA) for the period 2009-2012.		
	No. of participants analysed	NR		
	No. of participants excluded or missing (with reasons)	No indicator data for 2/15 (13%) of fluoridated areas compared to 15/136 (11%) in non-fluoridated areas (p=0.68 Fisher's exact test).		
	Imputation of missing data	NR		
	Statistical method of analysis	Negative binomial models		
	Participant category	Intervention crude rate per 100,000 pyar (median; range; SD)	Comparator crude rate per 100,000 pyar (median; range; SD)	Effect estimate Difference in rate (%) (95% CI)
	All 1-4 year olds (crude difference)	221 (42; 13-773; 257)	400 (370; 7-1550; 311)	–45 (–68, –6); *p*=0.03
	All 1-4 year olds (adjusted for deprivation)	-	-	–55 (–73, –27); *p*=0.001
	Four least deprived quintiles	-	-	–27(–62, 39); *p*=0.34
	Most deprived quintile	-	-	–76 (–89, –45); *p*=0.001
Authors' conclusion	This monitoring report provides evidence of lower dental caries rates in children living in fluoridated compared to non-fluoridated areas. Similarly, infant dental admission rates were substantially lower. Although this was an exploratory analysis, the findings were consistent with a greater effect – that is a greater reduction in caries – in the most deprived communities with a 32% reduction at age five years and a 26% reduction at age 12 years compared to the combined four least deprived quintiles.			
Correspondence if required	None			
Reviewer's notes	Mean d3mft/D3MFT are weighted for population size of local authorities			

SKINNER ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	All 14-15 year olds living in NSW, Australia
1.2 Is the eligible population or area representative of the source population or area?	++	All 14-15 year olds attending metropolitan & non-metropolitan secondary schools under the jurisdiction of the NSW Department of Education and Training, the Catholic Education Commission and Independent Schools. Home schooled & teenagers not attending school not included.
1.3 Do the selected participants or areas represent the eligible population or area?	++	Random sample of 14-15 year olds attending metropolitan & non-metropolitan secondary schools under the jurisdiction of the NSW Department of

		Education and Training, the Catholic Education Commission and Independent Schools.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Assessment method NR. Assumption that participants had same access over their lifetime. Weighting of proportions.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Yes
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Most confounding factors measured by questionnaire. Data weighted to ensure estimates reflect actual population of 14-15 year olds in NSW. Multivariate analysis controlled for confounders.
2.5 Is the setting applicable to the Australia?	++	Set in NSW, Australia
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	19 calibrated examiners performed 1,269 examinations in 84 schools. Inter- & intra-rater reliability NR.
3.2 Were the outcome measurements complete?	+	Yes
3.3 Were all the important outcomes assessed?	++	Decayed, missing & filled teeth.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Logistic regression (for dichotomous caries outcomes i.e. any caries & severe caries); Negative binomial regression for DMFT counts
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals provided
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Good selection methods. Unclear how exposure status was assessed. Good measurement and analysis of confounders.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Highly applicable.
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	1196
	Date form completed	16/12/15
	Country of origin Source of funding Possible conflicts of interest	Australia NR NR
Study	Aim/objectives of study	To investigate the potential social and behavioural risk factors influencing

characteristics		the oral health of teenagers aged 14 and 15 years living in New South Wales, Australia.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	NSW, Australia		
	Study duration	NA		
	Exposure duration	Assumed lifetime		
	Source population description	Secondary students aged 14 and 15 years attending schools in NSW under the jurisdiction of the NSW Department of Education and Training, the Catholic Education Commission and Independent Schools.		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	Random sample of year 9 secondary students aged 14 and 15 years.		
Participant characteristics		Whole study		
	No. of participants enrolled	1,199		
	Age (range)	14-15 years		
	Gender	566 male 633 female		
	Mean DMFT	1.15		
	Simple prevalence (% with DMFT > 0)	44.4%		
	Severe caries (% with DMFT > 3)	10.6%		
	Annual family income ($60,000 or less)	42.4%		
	Mothers Education Level Completed University/College	33.0%		
	Tooth brushing Frequency Twice per day or more	56.8%		
	Immediate Treatment Need	5.6%		
	No Toothache in the Last 12 Months	61.8%		
	Sealants (% with at least 1)	28.4%		
	Dental utilisation in the past year (% yes)	63.7%		
	Fluoridated water (% yes)	87.0%		
	Fluoridated toothpaste (% yes)	89.4%		
	NB: above proportions are weighted to reflect to ensure estimates reflected Estimated Resident population of 14-15 year olds in NSW from which participants were selected. Sampling weights were calculated as probabilities of selection, accounting for differential response rates by Local Health District, age, & gender.			
	Subgroups reported	above variables stratified by gender		
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Fluoridated water (level NR)	Non-fluoridated water (level NR)	
	Setting	School-based study		
Results: Caries experience (DMFT / DMFT>0 / Severe caries)	Definition (with units) Method of measurement	Caries experience defined as decayed, missed & filled permanent teeth (DMFT); any dental caries (DMFT>0); severe caries (DMFT>3)		
	No. of participants analysed	1,199		
	No. of participants excluded or missing (with reasons)	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Logistic regression (for dichotomous caries outcomes i.e. any caries & severe caries); Negative binomial regression for DMFT counts		
	Participant category	DMFT	DMFT>0	Severe caries
	All participants	RR* = 0.58 (0.44-0.75); *p*<0.001	OR* = 0.59 (0.37-0.94); *p*<0.01	OR* = 0.60 (0.36-1.01); *p*-value NR

		*adjusted for all risk factors (i.e. income, mother's education level, sugary drink consumption, dental visit last year, tooth-brushing frequency), age, & gender
Authors' conclusion	The oral health of 14- and 15-year-olds in NSW is influenced by social and dietary factors as well as access to fluoridated water supplies. The protective factors included brushing teeth twice or more per day and access to fluoridated water, while high sugary drink consumption and coming from a low income family were related to increased dental caries experience. There was also a strong relationship between self-rated oral health status with DMFT and with caries experience.	
Correspondence if required	None	
Reviewer's notes	Only multivariate results for fluoride extracted	

ZANDER (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	The source population was not in Aboriginal communities but taken from schools with at least 20% Aboriginal students
1.2 Is the eligible population or area representative of the source population or area?	+	The source population is representative of communities with a large proportion of Aboriginal people. The source population is not representative of an Aboriginal population.
1.3 Do the selected participants or areas represent the eligible population or area?	++	Response rate from eligible population was response rate 72%.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	A sensitivity analysis was used to adjust the results by patients who had migrated into or out of non-fluoridated areas.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Concession card status, age and brushing frequency, gender, water fluoridation, Aboriginal status and parental education were controlled for confounding
2.5 Is the setting applicable to the Australia?	++	Study conducted in NSW
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Most likely. Standard procedures used. ICC=0.97
3.2 Were the outcome measurements complete?	++	It appears that outcome measures for all participants are included.
3.3 Were all the important outcomes assessed?	++	Concession card status, age and brushing frequency, gender, water fluoridation, Aboriginal status and parental education were controlled for confounding
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	
3.5 Was follow-up time meaningful?	NA	

Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	+	A larger sample size would be needed to reduce the type I error
4.2 Were multiple explanatory variables considered in the analyses?	++	
4.3 Were the analytical methods appropriate?	++	Logistic regression and sensitivity analyses used to adjust for confounding factors
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Odds ratios, confidence intervals and p values reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Good internal validity.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	The results were generalisable to communities in Australia which have large proportion of Aboriginals.
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	650		
	Date form completed	16/12/2015		
	Country of origin Source of funding Possible conflicts of interest (for study authors or translators)	Australia NSW Ministry of Health Research was conducted while at the NSW Centre for Oral Health Strategy. The Program is offered in partnership with the University of New South Wales.		
Study characteristics	Aim/objectives of study	To gather contemporary oral health data from small rural or regional Australian communities, and investigate caries risk factors in these communities.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Three recognised Aboriginal communities located on the coast south of Sydney (Wreck Bay, La Perouse and Wallaga Lake)		
	Study duration	October/November 2011		
	Exposure duration	Lifetime		
	Source population description	Children attending schools, preschools & day care centres near three Aboriginal communities in NSW		
	Inclusion/exclusion criteria	A complete list of schools, preschools and day-care centres near the communities was prepared. The following inclusion criteria were applied to select schools and preschools for the study: • situated within a 30 km radius of the Aboriginal community of interest or attended by the majority of children in that community • at least 20% Aboriginal enrolment • enrols children aged 3-12 years. On the basis of these criteria, 11 schools and preschools were selected for the study, and all agreed to participate. While it is not possible to know the exact child population within 30 km of the Aboriginal communities of interest, a total of four schools did not meet the selection criteria for level of Aboriginal enrolment and were thus not surveyed. Six of the 11 surveyed schools were in non-fluoridated areas and five were in the fluoridated area.		
	Recruitment procedures	All 602 children aged 3-12 years who attended these schools were eligible to participate in the study, and each received informed consent material and a questionnaire to be completed by a parent or carer. Participation in the study required informed parental consent.		
Participant characteristics		Whole study	Fluoridated	Non-Fluoridated
	No. of participants enrolled	434	255	179

	Age (mean)	7.7	NR	NR
	Gender (males)	235 (54%)	137 (54%)	98 (55%)
	Age – 3-4	NR	57 (22%)	26 (15%)
	Age – 5-6	NR	59 (23%)	50 (28%)
	Age –7-8	NR	51 (20%)	36 (20%)
	Age –9-10	NR	53 (21%)	33 (18%)
	Age –11-12	NR	35 (14%)	34 (19%)
	Aboriginal	NR	67 (26%)	71 (40%)
Exposure and setting		Fluoridated	Non-Fluoridated	
	Description of exposure and control (including level of fluoride)	Residing in a community (La Perouse) which has access to fluoridated water	Residing in a community (Wreck Bay and Wallaga Lake) which does not have access to fluoridated water	
	Setting (including social context)	Communities with a proportion of Aboriginal members	Communities with a proportion of Aboriginal members	
Results: dmft/DMFT	Definition (with units) Method of measurement	Caries experience was determined using two measures: the deciduous and permanent decayed, missing and filled teeth (dmft/DMFT) score, and the proportion of children who were caries-free. The dmft/DMFT was calculated for each child by adding all teeth with one or more carious lesions (either currently carious or filled, implying previous caries).		
	No. of participants analysed	434		
	No. of participants excluded or missing (with reasons)	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Logistic regression was used to determine independent predictors for caries (Yes/No) as the dependent variable. Potential independent predictors of caries were determined a priori, and included water fluoridation, Aboriginal status, age, gender, concession card status (Y/N), parent education level (completed school/did not complete school) and tooth-brushing frequency (≤ 1/day, ≥ 2/day). Initially logistic regression models tested for associations between individual predictors and caries experience. All predictors with a p-value <0.25 were then entered into a single logistic regression model and the backwards selection method was used to derive the final model. Effect modification was examined in two sets of sensitivity analyses of fluoridation status and toothbrushing/Aboriginal status. A p-value of less than 0.05 was considered statistically significant.		
	Participant category	Intervention	Comparator	Effect estimate (OR; 95% CI)
	Fluoridation (all participants)	NR	NR	1.06 (0.67-1.67)
	Fluoridation (excluded children who have lived in both fluoridated and non-fluoridated communities)	NR	NR	0.81 (0.46-1.43)
	Fluoridation (only children who have lived in both fluoridated and non-fluoridated communities)	NR	NR	1.01 (0.59-1.71)
Authors' conclusion	The rural/remote children in this study had worse oral health than either state or national average in both the 5-6 year old and 11-12 year age groups. Socioeconomic status, tooth-brushing and Aboriginal statuses were significantly associated with caries in these communities. To close the substantial gap in oral health outcomes between rural and metropolitan residents, approaches that target rural areas, Aboriginal people and those from low socioeconomic backgrounds are needed.			
Correspondence if required	None required			
Reviewer's notes	Fluoridation status did not reach significance at the 5% level			

COMPLETED QUALITY ASSESSMENT AND DATA EXTRACTION FORMS FOR THE INCLUDED PRIMARY STUDIES – OTHER HEALTH EFFECTS

AMINI ET AL. (2011)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Population of Iran
1.2 Is the eligible population or area representative of the source population or area?	-	Sparse details about reports of the Ministry of Health of Iran
1.3 Do the selected participants or areas represent the eligible population or area?	NR	-
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	Previous monitoring study of fluoride in the ground water resources of Iran performed in 2008
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	-	No theoretical basis for the hypothesis
2.3 Was the contamination acceptably low?	NA	No intervention / comparator groups
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Hypertension derived from provincial report, caries-free index from Ministry of Health of Iran report
3.2 Were the outcome measurements complete?	NR	Unclear whether all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	No intervention / comparator groups
3.5 Was follow-up time meaningful?	NA	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	+	Simple regression analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	p-values reported for regression analyses
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Unclear quality of analyses. Simple regression analysis. No identification or controlling for confounding factors.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Fluoride levels range from 0.23 to 1.86 ppm. Dissimilar health care system.
Overall quality rating	Low	Unclear participant recruitment methods. Poor statistical analyses.

Abbreviations: NA = not applicable; NR = not reported

Data extraction

General information	Study ID	Amini et al. (2011)		
	Date form completed	02/02/15		
	Country of origin Source of funding Possible conflicts of interest	Iran NR NR		
Study characteristics	Aim/objectives of study	To examine the relationship between fluoride in ground water resources and the blood pressure of Iranian population in an ecological study		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Iran		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Population of Iran		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	Participants identified from reports from the Ministry of Health of Iran		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	NR	NR	NR
	Age	NR	NR	NR
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting	Description of exposure and control	Population exposed to fluoride concentration in ground water resources. Mean concentrations derived from a previous Iranian monitoring of fluoride study performed in 2008 and published in 2010. Fluoride concentrations ranged from 0.23 to 1.86 ppm.		
	Setting	Population-based study. Participants identified from Iranian Ministry of Health reports.		
Results: Hypertension	Definition Method of measurement	Mean prevalence of hypertension (blood pressure ≥140/90 mm Hg) Derived from the provincial report of non-communicable disease risk factor surveillance of the Islamic Republic of Iran, published in 2007.		
	No. of participants analysed	NR		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Simple regression analysis Significance test (*r* - not described)		
	Participant category	Intervention	Comparator	Effect estimate *r*
	All participants	NR	NR	0.495 p=0.005
	Females	NR	NR	0.36 p=0.048
	Males	NR	NR	0.48 p=0.007
Results: Systolic blood pressure	Definition Method of measurement	Mean systolic blood pressure (mmHg) Published (2004) index of Iranian children (both primary dentition and permanent teeth)		
	No. of participants analysed	NR		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Simple regression analysis		
	Participant category	Intervention	Comparator	Effect estimate *r*
	Female	NR	NR	0.352 p=0.057
	Male	NR	NR	0.431 p=0.018
Results: Diastolic blood pressure	Definition Method of measurement	Mean diastolic blood pressure (mm Hg) Derived from the provincial report of non-communicable disease risk factor surveillance of the Islamic Republic of Iran, published in 2007.		

	No. of participants analysed	NR		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Simple regression analysis Significance test (*r* - not described)		
	Participant category	Intervention	Comparator	Effect estimate *r*
	Females	NR	NR	0.273 p=0.144
	Males	NR	NR	0.151 p=0.417
Authors' conclusion	It can be declared that with the increase of fluoride levels in ground water resources, the hypertension prevalence statistically increases, especially in males.			
Correspondence if required	None required			
Reviewer's notes	Correlation between fluoride levels and 6 & 9 year olds caries-free rates was measured to 'validate' the fluoride levels.			

Abbreviations: NR = not reported

BARBATO ET AL. (2009)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Participants of the Brazilian Oral Health Survey 2002-2003 . (Brazilians aged 18 months to 74 years old)
1.2 Is the eligible population or area representative of the source population or area?	++	All 15-19 year olds in randomly selected locations. Numbers not reported. Multistage cluster sampling used to select individuals.
1.3 Do the selected participants or areas represent the eligible population or area?	+	All data for 15 to 19 year old participants in the Brazilian Oral Health Survey 2003 data (n=16,833). 85% response rate (n=19,910 asked to participate)
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Based on geographic location i.e. whether water supply is fluoridated or not
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Tooth loss due to caries experience
2.3 Was the contamination acceptably low?	NR	-
2.4 How well were likely confounding factors identified and controlled?	++	Age, gender, skin colour, location, per capita income, education gap, type of dental service all measured and controlled for in analysis. Other sources of fluoride not measured e.g. toothpaste.
2.5 Is the setting applicable to the Australia?	+	Unclear – level of fluoride not reported; unknown how similar dental/health services are
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Examiners all trained to follow WHO criteria. Description of setting of examination given and examiners were blind to associations being tested. Tooth loss measurement probably reliable but no inter- or intra-rater reliability scores reported.
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	+	Did not count number of decayed or filled teeth. Other information collected included dental crown & periodontal conditions, occlusal disorders, dental fluorosis, & need for dental prostheses.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-

3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	++	Socioeconomic & demographic factors
4.3 Were the analytical methods appropriate?	+	Poisson regression and Wald test
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	p-values and precise confidence intervals reported.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Other fluoride sources, such as toothpaste, were not measured.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Cluster sampling used to promote generalisability
Overall quality rating	Acceptable	Good participant recruitment and sampling. Appropriate analyses.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Barbato et al. (2009)		
	Date form completed	16/02/15		
	Country of origin Source of funding Possible conflicts of interest	Brazil NR NR		
Study characteristics	Aim/objectives of study	To estimate the prevalence of tooth loss among Brazilian adolescents aged 15 to 19 and to describe factors associated.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Brazil		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Participants of the Brazilian Oral Health Survey 2002-2003		
	Inclusion/exclusion criteria	Inclusion: 15 to 19 year olds		
	Recruitment procedures	Cluster sampling of 250 cities in Brazil and then random sampling of individuals from those populations. Those individuals invited to participate.		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	16,833	7,529	9,304
	Age (range)	15 - 19 years	15 - 19 years	15 - 19 years
	Male	42%	NR	NR
	Skin colour	Asian 501 White 7,071 Lighter-skinned black 7,369 Dark-skinned black 1,686 Indigenous169	NR	NR
	Per capita income	≥R$ 200.00 n=3,373 R$ 10 0.00-199.99 n=4,195 R$ 66.68-99.99 n=2,102 R$ 34.30-66.67 n=3,783 ≤R$ 34.29 n=3,380	NR	NR
	Education gap	No 7,024 Yes 9,522	NR	NR
	Type of dental service	Private 3,611 Contracted 1,129 Public 9,242	NR	NR
	Subgroups reported	NR	NR	NR

Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Fluoridated water supply, fluoride concentration NR	Non-fluoridated water supply, fluoride concentration NR	
	Setting	Community-based study. Outcomes based on secondary data obtained from the 2003 Brazilian Oral Health Survey.		
Results: Prevalence ratio of missing teeth	Definition Method of measurement	Missing teeth per subject Sum of codes 4 (missing teeth due to dental caries) and 5 (missing teeth due to other causes) for crown diagnosis for every 32 dental spaces examined per subject Oral examination performed at participant's household under natural light using the WHO community periodontal index ballpoint probe, a flat mirror and wooden tongue spatulas		
	No. of participants analysed	16,833		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NA		
	Statistical method of analysis	Poisson regression, Wald test Models adjusted for type of service, education gap, income, age, skin colour, gender, & locality		
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect estimate Prevalence ratio* (95%CI)
	Overall (unadjusted)	2,272/7,529 (30.2%)	4,281/9,304 (46.0%)	1.52 (1.46, 1.59) *p*<0.01
	Overall (adjusted)	NR	NR	1.40 (1.34, 1.46) *p*<0.01
	South (unadjusted)	NR	NR	1.23 (1.07, 1.41) *p*=0.003
	South (adjusted) NB: skin colour & service type not included as p>0.25 in bivariate analysis	NR	NR	1.15 (1.00, 1.06) *p*=0.049
	Southeast (unadjusted)	NR	NR	1.08 (0.96, 1.21) *p*=0.211
	Southeast (adjusted) NB: service type not included as p>0.25 in bivariate analysis	NR	NR	0.97 (0.86, 1.09) *p*=0.598
	Central-West (unadjusted)	NR	NR	1.11 (0.99, 1.25) *p*=0.081
	Central-West (adjusted) NB: income not included as p>0.25 in bivariate analysis	NR	NR	1.06 (0.93, 1.19) *p*=0.304
	North (unadjusted)	NR	NR	0.92 (0.83, 1.03) *p*=0.134
	North (adjusted) NB: skin colour & service type not included as p>0.25 in bivariate analysis	NR	NR	0.93 (0.83, 1.04) *p*=0.202
	Northeast (unadjusted)	NR	NR	1.66 (1.48, 1.86) *p*<0.01
	Northeast (adjusted)	NR	NR	1.63 (1.45, 1.84) *p*<0.01
	* NB: intervention group is the reference group			
Authors' conclusion	Adolescents living in localities with non-fluoridated water supply were 40% more likely to have tooth loss compared with those living in areas with fluoridated water supply.			
Correspondence if required	None required			
Reviewer's notes	Authors report that the database they sourced their data from may have some errors of reporting. Tooth loss was found to be associated (after adjustment for confounders) with rural location, being female, non-white & non-dark-skinned black, increasing age, income >R$199.99, education gap, & use of private dental services.			

Abbreviations: NA = not applicable; NR = not reported; R$ = Brazilian Real; WHO = World Health Organization

BLAKEY ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Population of Great Britain
1.2 Is the eligible population or area representative of the source population or area?	NA	
1.3 Do the selected participants or areas represent the eligible population or area?	++	Population data derived from small area unit census data (England & Wales) & postcode sectors (Scotland). Study population limited to 0-49 year olds reduces confounding other-cause Ewing or osteosarcoma.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Fluoride level for water supply zones most likely very accurate & is continuously monitored. Assignment of fluoride level to census small area units required linking using postcode distributions & weighting averages.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Fluoride is deposited in bone.
2.3 Was the contamination acceptably low?	NA	No intervention / comparator groups.
2.4 How well were likely confounding factors identified and controlled?	++	Multiple models used in sensitivity analysis. Population restriction to 0-49 years limits confounding from Paget's disease & post-radiotherapy osteosarcoma/Ewing sarcoma
2.5 Is the setting applicable to the Australia?	+	Average level of F assigned to each small area unit in the study ranged from 0.00-1.27 ppm, which map onto the recommended F levels in Australia (between 0.6-1.1 ppm). NB: monitoring data suggests that 33% of artificially fluoridated water supply zones were <0.7 ppm.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Outcome data obtained from cancer registries.
3.2 Were the outcome measurements complete?	++	Likely that all cases identified.
3.3 Were all the important outcomes assessed?	++	Yes.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	No intervention / comparator groups.
3.5 Was follow-up time meaningful?	NA	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Multiple models used in sensitivity analysis.
4.3 Were the analytical methods appropriate?	++	Negative binomial regression
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	90% confidence intervals provided for RR. p-values provided for sensitivity analyses.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Good data collection. Confounding factors taken into account. Sensitivity analysis done. Unclear how much bias, if any, introduced with data linkage.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Similar levels of fluoride as Australia in addition to healthcare system
Overall quality rating	Acceptable	Conclusions may change in light of further studies.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Blakey et al. (2014)
	Date form completed	27/01/15
	Country of origin Source of funding Possible conflicts of interest	United Kingdom Bone Cancer Research Trust (BCRT) [grant reference number: BCRT/08/08], North of England Children's Cancer Research (NECCR) Fund, the National Institute for Health Research (NIHR) and Children with Cancer UK. "None declared"
Study characteristics	Aim/objectives of study	To examine whether increased risk of primary bone cancer (osteosarcoma, Ewing sarcoma) was associated with living in areas with higher concentrations of fluoride in drinking water.
	Study design	Ecological
	Level of evidence	IV
	Study location	Great Britain (England, Scotland and Wales)
	Study duration	NR
	Exposure duration	NR
	Source population description	Total population of Great Britain
	Inclusion/exclusion criteria	Included cases of osteosarcoma and Ewing sarcoma, diagnosed at ages 0-49, in England, Scotland and Wales between1980-2005.
	Recruitment procedures	NA
Participant characteristics		Whole study
	No. of participants enrolled	Population of Great Britain (derived from national census data & adjusted to be compatible with 2001 census boundaries)
	Age (range)	0 - 49 years
	Male	NR
	Other characteristics	Adjustment for deprivation (Townsend score -see notes)
	Subgroups reported	0-14 years, 15-29 years, 30-49 years at diagnosis.
Exposure and setting		Whole study
	Description of exposure and control	Mean drinking water fluoride concentration Routine fluoride monitoring data sampled between 2004 & 2006 were obtained from Scottish Water and the Drinking Water Inspectorate (England, Wales). Mean fluoride level ranged from 0.00-1.27 ppm.
	Setting	Population-based study. Small Area Units (SAUs) were used in analysis: census wards in England and Wales (0-49 years population range: 297-29,300, median: 3090), postcode sectors in Scotland (0-49 years population range: 23-15,916, median: 3201)
Results: Osteosarcoma	Definition Method of measurement	Cases of osteosarcoma Case data extracted from 10 regional cancer registries in Great Britain. Cases for 0-14 year olds cross-checked against National Registry of Childhood Tumours. Cases were grouped using ICD-0-3 classification.
	No. of participants analysed	2,566 cases
	No. of participants excluded or missing	NR
	Imputation of missing data	NR
	Statistical method of analysis	Negative binomial regression (examined the relationship between incidence rates and level of fluoride in drinking water at small area level). Regression was adjusted for age-group, gender, the interaction age-group*gender, the Townsend score & the interaction Townsend score*female.
	Participant category	Association between osteosarcoma risk and fluoride in drinking water (RR per one ppm increase in the level of F)
	All participants	Crude incidence: 2.59 per 1,000,000 (2,566 / 992,213) NB: from McNally et al (2012) RR: 1.001 (90% CI: 0.871-1.151)
Results: Ewing sarcoma	Definition Method of measurement	Cases of Ewing sarcoma Case data extracted from 10 regional cancer registries in Great Britain.

		Cases for 0-14 year olds cross-checked against National Registry of Childhood Tumours. Cases were grouped using ICD-0-3 classification.
	No. of participants analysed	1,650 cases
	No. of participants excluded or missing	NR
	Imputation of missing data	NR
	Statistical method of analysis	Negative binomial regression (examined the relationship between incidence rates and level of fluoride in drinking water at small area level). Regression adjusted for age-group, gender, the interaction age-group*gender, Scotland, East Midlands, population density, & non-car ownership.
	Participant category	Association between osteosarcoma risk and fluoride in drinking water (RR per one ppm increase in the level of F)
	All participants	Crude incidence: 1.66 per 1,000,000 (1,650 / 992,213) NB: from McNally et al (2012) RR: 0.929 (90% CI: 0.773-1.115)
Authors' conclusion	Key Messages • There was no evidence of an association between fluoride in drinking water and osteosarcoma or Ewing sarcoma before or after adjustment for small area level deprivation. • 33% of artificially fluoridated water supply zones in Great Britain were found to be supplying water that was below 0.7 parts per million of fluoride, the lower limit of the optimal level for dental health benefit. • There was no evidence that those who lived in an artificially fluoridated area of Great Britain were at increased risk of osteosarcoma or Ewing sarcoma. • There was no evidence that those living in an area of Great Britain with naturally occurring fluoride within the optimal level for dental health benefit were at increased risk of osteosarcoma or Ewing sarcoma.	
Correspondence if required	None required	
Reviewer's notes	To adjust for deprivation, a time-series of indicators (Townsend index comprises unemployment, non-car ownership, non-home ownership, & household overcrowding) was obtained from each census during the study period and geographically converted to be compatible with 2001 SAUs.	

Abbreviations: NR = not reported; RR = relative risk; SAU = Small Area Units

BROADBENT ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	All births between April 1, 1972 and March 31, 1973 in Dunedin, New Zealand
1.2 Is the eligible population or area representative of the source population or area?	++	91% of eligible births included in the cohort
1.3 Do the selected participants or areas represent the eligible population or area?	++	High inclusion rate (91%) Cohort families represent the full range of socioeconomics statuses in the general population of New Zealand's South Island
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Residency in an area with or without community water fluoridation. No discussion regarding patient migration.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Research attempting to disprove the unfounded link between fluoride and neurological development
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Socioeconomic status, birth weight and breastfeeding controlled for in childhood analysis. In addition, educational achievements controlled for in adulthood analysis.
2.5 Is the setting applicable to the Australia?	++	Highly applicable, similar water fluoridation levels (up to 0.85 ppm) and similar health care system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Wechsler Adult Intelligence Scale administered by trained psychometrists
3.2 Were the outcome measurements complete?	+	IQ assessments for some individuals missing at some waves however individuals tended to return to the study at a later wave.
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	At minimum, 5 years
3.5 Was follow-up time meaningful?	++	Exposure long enough to observe hypothesised effects, very long follow-up (38 years)
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	No power calculation. Nearly 1,000 IQ scores included in analysis however approximately only 10% of these were from the control arm
4.2 Were multiple explanatory variables considered in the analyses?	++	Models adjusted for relevant confounding factors
4.3 Were the analytical methods appropriate?	++	Adjusted general linear models
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	p-values and 95% CIs reported for model parameter estimates
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Good statistical analyses, adequate data collection methods
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Good participant recruitment, more balanced numbers in study arms would have improved the study
Overall quality rating	High	Adjustment for confounders performed to a high standard

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Broadbent et al. (2014)		
	Date form completed	23/02/15		
	Country of origin Source of funding Possible conflicts of interest	New Zealand US National Institute of Dental and Craniofacial Research Grant, UK Medical Research Council Grant, US National Institute on Aging Grant, Health Research Council of New Zealand Programme Grant NR		
Study characteristics	Aim/objectives of study	To test the hypothesis that spending childhood in an area with community water fluoridation is associated with lower IQ in childhood and adulthood		
	Study design	Prospective cohort		
	Level of evidence	II		
	Study location	Dunedin, New Zealand		
	Study duration	1972 - 2012		
	Exposure duration	A minimum of 5 years (n=922), or 3 (n=103) where data for 5 years were unavailable, up to 38 years		
	Source population description	Complete birth cohort of consecutive births in Dunedin, New Zealand		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	Recruitment from the Dunedin Multidisciplinary Health and Development Study		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	1,037 (91% of eligible births)	NR	NR
	Age (range)	0 - 38 years	NR	NR
	Male	52%	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Residency in an area with community water fluoridation (0.85 ppm) to age 5 (or 3 where age 5 years were unavailable)	Residency in an area without community water fluoridation (0.0-0.3 ppm) to age 5 (or 3 where age 5 years were unavailable)	
	Setting	Population-based study. Longitudinal investigation of a general population sample of those born in one city in New Zealand. 38-years of prospective follow-up with 95.4% retention of the original cohort.		
Results: IQ	Definition Method of measurement	IQ standardised to population norms (mean = 100; SD = 15) Wechsler Intelligence Scale for Children-Revised at ages 7, 9, 11 & 13 Wechsler Adult Intelligence Scale-Fourth Edition at age 38 Administered by train psychometrists blinded to previous IQ data and community water fluoridation status		
	No. of participants analysed	992 for childhood (standardised average of 4 childhood assessments) 942 for adulthood		
	No. of participants excluded or missing	Number NR Reasons idiosyncratic rather than systematic		
	Imputation of missing data	NR		
	Statistical method of analysis	General linear models fitted using the built-in *glm* function of Stata Adjusted for sex, socioeconomic status in childhood, low birth weight, and breastfeeding		
	Participant category	Intervention mean ± SD	Comparator mean ± SD	Effect estimate b (95% CI)
	Age 7 to 13 years	100.0 ± 13.5	99.8 ± 13.0	0.15 (-2.83, 3.14) *p*=0.92
	Age 38 years	100.2 ± 14.2	98.1 ± 13.5	2.20 (-1.04, 5.44) *p*=0.184
Authors' conclusion	The findings do not support the assertion that fluoride exposure in the context of community water fluoridation can affect neurologic development or IQ			
Correspondence if	None required			

required	
Reviewer's notes	Analyses of the use of fluoride toothpaste/tablets also performed. IQ component scores also reported.

BURKE ET AL. (2010)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Adults (aged ≥ 16 years) in Republic of Ireland
1.2 Is the eligible population or area representative of the source population or area?	++	Participants identified from Irish electoral lists
1.3 Do the selected participants or areas represent the eligible population or area?	++	The sample profile was compared to census data, and the distribution of disadvantage and household size was found to be representative of the national population
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Stratified random sampling based on age, gender and level of deprivation
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	+	Unclear. Number of years of exposure to fluoridated water in the current home taken into account but no mention of exposure prior to current home.
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	++	Similar public water fluoridation intervention, similar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Modified Smith and Knight tooth wear index administered by teams of community dentists and dental nurses. Examiners were trained on subjects and models and reproducibility was measured on models because of the low prevalence of wear on subjects available for training and calibration exercises
3.2 Were the outcome measurements complete?	-	Results for 32 participants not reported.
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	Either lifetime exposure (16-24 year olds) or at least 35 years exposure for the older age groups
3.5 Was follow-up time meaningful?	++	Exposure was long enough to observe hypothesised effects
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	+	Chi-squared test for distribution of tooth wear absent
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	p-value only reported for ANOVA analysis
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Sample was representative of national population. No adjustment for confounding factors.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Similar to Australian population. Intentional water fluoridation
Overall quality rating	Acceptable	Good participant selection and outcome measurement. Calculation of fluoride exposure unclear.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Burke et al. (2010)			
	Date form completed	23/01/15			
	Country of origin Source of funding Possible conflicts of interest	Ireland NR NR			
Study characteristics	Aim/objectives of study	To determine the prevalence of tooth wear in Ireland and its relationship to water fluoridation			
	Study design	Cross-sectional			
	Level of evidence	IV			
	Study location	Ireland			
	Study duration	2000 to 2002			
	Exposure duration	Range from 0 to 38 years			
	Source population description	Adults (16 years and older) in Ireland identified from electoral lists			
	Inclusion/exclusion criteria	NR			
	Recruitment procedures	Stratified random sample. Stratifying factors were age, gender and level of deprivation of residents (possession of a medical card used as a surrogate for disadvantaged)			
Participant characteristics		Whole study	Full fluoridation	Part fluoridation	No fluoridation
	No. of participants enrolled	2,556	1047	920	557
	Age	NR	NR	NR	NR
	Male	42.3%	NR	NR	NR
	Other characteristics	NR	NR	NR	NR
	Subgroups reported	NR	NR	NR	NR
Exposure and setting	Description of exposure and control	Fluoridation history was traced using details and history of the source of participants' water supplies recorded on the consent form. Participants were placed in one of three exposure categories: Full (either a lifetime or at least 35 years of exposure), Part (some exposure) and None (no exposure to fluoride at any residence). Fluoride concentration was in the range 0.8 – 1.0 ppm since 1964 then reduced to 0.6 to 0.8 ppm in 1970.			
	Setting	Population-based study. Recruitment performed from Irish electoral lists			
Results: Tooth wear	Definition Method of measurement	Index: 0 = No Wear, 1 = Mild, 2 = Moderate, 3 = Severe The index used was a modification of the tooth wear index developed by Smith and Knight. A numeric score was allocated to each surface of the upper anterior teeth and the worst surface of the lower anterior teeth. For each of the six upper anterior teeth, the score of the most severely affect surface was taken for each tooth. The mean score per scored tooth was then calculated for each subject.			
	No. of participants analysed	2,556			
	No. of participants excluded or missing	32			
	Imputation of missing data	NR			
	Statistical method of analysis	ANOVA			
	Participant category	Full fluoridation	Part fluoridation	No fluoridation	ANOVA
	Age 16-24	N = 603 Mild: 33.9% Moderate: 3.3% Severe: 0.4%	N = 264 Mild: 40.8% Moderate: 0.7% Severe: 0.0%	N = 314 Mild: 33.4% Moderate: 2.5% Severe: 0.0%	NR
	Age 35-44	N = 292 Mild: 71.3% Moderate: 10.5% Severe: 0.7%	N = 483 Mild: 60.1% Moderate: 9.2% Severe: 1.0%	N = 171 Mild: 60.4% Moderate: 16.3% Severe: 3.5%	NR
	Age 65+	N = 152 Mild: 51.2% Moderate: 31.5% Severe: 10.3%	N = 173 Mild: 54.2% Moderate: 36.3% Severe: 2.5%	N = 72 Mild: 62.4% Moderate: 19.3% Severe: 11.6%	NR

	All participants	NR	NR	NR	F = 5.32 *P*=0.0049
Authors' conclusion	No significant relationship was found between fluoridation and tooth wear				
Corresponden ce if required	None required				
Reviewer's notes	None				

Abbreviations: ANOVA = analysis of variance; NR = not reported

CHANDRAJITH ET AL. (2011)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	+	Adults in 4 regions in Sri Lanka's dry zone.
1.2 Is the eligible population or area representative of the source population or area?	NR	-
1.3 Do the selected participants or areas represent the eligible population or area?	NR	-
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	Fluoride level in drinking water measured. Unclear how representative participants are.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	-
2.3 Was the contamination acceptably low?	NR	-
2.4 How well were likely confounding factors identified and controlled?	NR	-
2.5 Is the setting applicable to the Australia?	-	Dissimilar health systems
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	-	Prevalence of CKD from population studies (not cited) with proteinuria as an indicator.
3.2 Were the outcome measurements complete?	NR	-
3.3 Were all the important outcomes assessed?	+	Prevalence of hypertension and diabetes also reported.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	-	Student's t-test but only reported result is for comparing fluoride ("The mean values of fluoride are not significantly different (p>0.005) [sic] among the three [there were four] studied regions.")
4.6 Was the precision of association given or calculable? Is the association meaningful?	NR	-
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Descriptive study. Unclear participant selection or representativeness. Very poorly reported with errors.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Dissimilar health system and sociodemographic characteristics to Australia.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

<table>
<tr><td rowspan="3">General information</td><td>Study ID</td><td colspan="12">Chandrajith et al. (2011)</td></tr>
<tr><td>Date form completed</td><td colspan="12">24/02/15</td></tr>
<tr><td>Country of origin
Source of funding

Possible conflicts of interest</td><td colspan="12">Sri Lanka
Japanese team supported by Japan Society for the Promotion of Science (Grant Nos. 21406018 and 17109007), Special Coordination Funds for Promoting Science and Technology (No.1300001), Japan Science and Technology Agency and Ministry of Health, Labor and Welfare of Japan (No. H21-food-003) and a grant from the Ministry of Education, Science, Sports and Culture of Japan (No. 18018022).
Funding agents had no role in study design, data collection & analysis, decision to publish or preparation of manuscript.</td></tr>
<tr><td rowspan="9">Study characteristics</td><td>Aim/objectives of study</td><td colspan="12">To investigate the role of possible geo-environmental factors, particularly the content of fluoride & some trace metals in drinking water consumed by people in regions in Sri Lanka affected by endemic chronic kidney disease of uncertain aetiology (CKDue).</td></tr>
<tr><td>Study design</td><td colspan="12">Ecological</td></tr>
<tr><td>Level of evidence</td><td colspan="12">IV</td></tr>
<tr><td>Study location</td><td colspan="12">Sri Lanka</td></tr>
<tr><td>Study duration</td><td colspan="12">NR</td></tr>
<tr><td>Exposure duration</td><td colspan="12">NR</td></tr>
<tr><td>Source population description</td><td colspan="12">Adults (>18 years) with CKD in four regions (Medawachciya, Nikawewa, Huruluwewa & Giradurukotte) of the north central of Sri Lanka.</td></tr>
<tr><td>Inclusion/exclusion criteria</td><td colspan="12">NR</td></tr>
<tr><td>Recruitment procedures</td><td colspan="12">NR</td></tr>
<tr><td rowspan="6">Participant characteristics</td><td></td><td colspan="3">Whole study</td><td colspan="3">Medawachciya</td><td colspan="3">Huruluwewa</td><td colspan="3">Giradurukotte</td></tr>
<tr><td>No. of participants enrolled</td><td colspan="3">5,685</td><td colspan="3">4,107</td><td colspan="3">233</td><td colspan="3">1,345</td></tr>
<tr><td>Age</td><td colspan="3">>18 years</td><td colspan="3">>18 years</td><td colspan="3">>18 years</td><td colspan="3">>18 years</td></tr>
<tr><td>Male</td><td colspan="3">NR</td><td colspan="3">NR</td><td colspan="3">NR</td><td colspan="3">NR</td></tr>
<tr><td>Prevalence CKD in adults and children</td><td colspan="3">NR</td><td colspan="3">5%</td><td colspan="3">0.2%</td><td colspan="3">4.0%</td></tr>
<tr><td>Subgroups reported</td><td colspan="3">NR</td><td colspan="3">NR</td><td colspan="3">NR</td><td colspan="3">NR</td></tr>
<tr><td rowspan="3">Exposure and setting</td><td></td><td colspan="4">Medawachciya</td><td colspan="4">Huruluwewa</td><td colspan="4">Giradurukotte</td></tr>
<tr><td>Description of exposure and control</td><td colspan="4">Exposed to naturally occurring fluoride in groundwater (mean 1.02 ppm, range 0.52 – 4.90)</td><td colspan="4">Exposed to naturally occurring fluoride in groundwater (mean 1.03 ppm, range NR – 1.68)</td><td colspan="4">Exposed to naturally occurring fluoride in groundwater (mean 0.74 ppm, range NR – 2.14)</td></tr>
<tr><td>Setting</td><td colspan="12">Community-based study. Recruited based on residency in pre-selected villages.</td></tr>
<tr><td rowspan="8">Results: CKD</td><td>Definition
Method of measurement</td><td colspan="12">Prevalence of chronic kidney disease
NR</td></tr>
<tr><td>No. of participants analysed</td><td colspan="12">5,685</td></tr>
<tr><td>No. of participants excluded or missing</td><td colspan="12">NR</td></tr>
<tr><td>Imputation of missing data</td><td colspan="12">NR</td></tr>
<tr><td>Statistical method of analysis</td><td colspan="12">NR</td></tr>
<tr><td>Participant category</td><td colspan="3">Medawachciya
n/N (%)</td><td colspan="3">Huruluwewa
n/N (%)</td><td colspan="3">Giradurukotte
n/N (%)</td><td colspan="3">Effect estimate</td></tr>
<tr><td>All participants</td><td colspan="3">NR/4,107 (3.7%)</td><td colspan="3">NR/233 (3.2%)</td><td colspan="3">NR/1,345 (3.9%)</td><td colspan="3">NR</td></tr>
<tr><td colspan="13"></td></tr>
<tr><td rowspan="3">Results: CKDue</td><td>Definition

Method of measurement</td><td colspan="12">Prevalence of chronic kidney disease of unknown aetiology based on population studies
Proteinuria used as indicator</td></tr>
<tr><td>No. of participants analysed</td><td colspan="12">5,685</td></tr>
<tr><td>No. of participants excluded</td><td colspan="12">NR</td></tr>
</table>

	or missing				
	Imputation of missing data	NR			
	Statistical method of analysis	NR			
	Participant category	Medawachciya n/N (%)	Huruluwewa n/N (%)	Giradurukotte n/N (%)	Effect estimate
	All participants	NR/4,107 (84%)	NR/233 (0%)	NR/1,345 (96%)	NR
Authors' conclusion	No single geochemical or biogeochemical parameter could be clearly and directly related to the aetiology of CKD on the basis of the elements determined during this study.				
Correspondence if required	None required				
Reviewer's notes	Mean fluoride level for Giradurukotte region reported as 0.63mg/L in text & 0.74mg/L in table. CDK prevalence in adults >18 years & overall population transposed in text. Results for other regions not extracted as they have not reported *both* fluoride level & CKD prevalence. Prevalence of CKDue reported as being based on population-based studies. Other trace metals where tested for including: cadmium, lead, aluminium, nickel, copper, zinc, arsenic, & uranium The results for diabetes and hypertension were not able to be extracted due to incomplete data.				

Abbreviations: CKD = chronic kidney disease; CKDue = chronic kidney disease of unknown aetiology; NR = not reported

CHOI ET AL. (2015)

Quality Assessment

Issue	Rating	Comment
Section 1: Population		
1.1 Is the source population or source area well described?	++	First-grade children, aged 6 to 8 years in Mainning County in southern Cichuan, rural China
1.2 Is the eligible population or area representative of the source population or area?	-	Children recruited from one school only, no discussion about generalisability of children from that school
1.3 Do the selected participants or areas represent the eligible population or area?	+	Neither method of selection or proportion agreeing to participate described. Only exclusion criteria reported.
Section 2: Method of selection of exposure (or comparison) group		
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Method of selection not reported. Don't know if all children or a subset from the single school participated. Well-water fluoride levels tested & recorded by Mianning County Center for Disease Control (CDC) – some seasonal changes but fluoride concentrations same over years.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Some suggestion in past studies of fluoride affecting IQ but not strong evidence and mechanism speculative.
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	++	Nutrition (weight & height), age, iron deficiency, parental education & income level Review of CDC records found that other contaminants, including lead & arsenic, in water to be very low
2.5 Is the setting applicable to the Australia?	–	Unlikely as levels of fluoride in study not often seen in Australia (range from 1 to 4 ppm)
Section 3: Outcomes		
3.1 Were the outcome measures and procedures reliable?	++	After translation and training, examinations were conducted by trained public health researchers and scored by a neuropsychologist. Tests were considered culture-independent, reflected a range of functional domains, & had been found to be useful in other non-English speaking rural populations.
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	+	The neuropsychological tests only test visual memory and learning, manual dexterity, fine motor skills, and copying.
3.4 Was there a similar follow-up time in	++	Lifetime exposure

exposure and comparison groups?		
3.5 Was follow-up time meaningful?	++	Exposure was long enough to observe hypothesised effects
Section 4: Analyses		
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	-	Unlikely, only 51 subjects. Power calculation NR – pilot study.
4.2 Were multiple explanatory variables considered in the analyses?	++	Beta coefficient adjusted for age, gender, parity, illness <3yrs old, household income, carer's age & education.
4.3 Were the analytical methods appropriate?	++	Regression analysis with confounder adjustment
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	95% confidence intervals given.
Section 5: Summary		
5.1 Are the study results internally valid (i.e. unbiased)?	+	Assumption that well-water fluoride concentration represents total fluoride exposure over lifetime. Good confounder adjustment.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	May be generalisable to other Chinese rural villages with comparable drinking water fluoride content. Representativeness of the children from the one school was not assessed.
Overall quality rating	Acceptable	Participant recruitment satisfactory. Good statistical analyses.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	2135
	Date form completed	Choi et al. (2015)
	Country of origin Source of funding Possible conflicts of interest	China/US/Denmark Internal institutional funds NR
Study characteristics	Aim/objectives of study	To assess the feasibility and validity of exposure assessment and neurobehavioural testing of a population of school children in rural China in order to test the hypothesis that increased fluoride exposure is related to impairments in neurobehavioural development.
	Study design	Ecological
	Level of evidence	IV
	Study location	Sunshui Village, Mianning County, Sichuan Provence, China
	Study duration	NR
	Exposure duration	Lifetime
	Source population description	First-grade children, aged 6-8 years who were students at the primary school in Sunshui Village, Mianning County, Sichuan province, China
	Inclusion/exclusion criteria	Inclusion: Families remaining at the same residence since conception Exclusion: children who did not speak Chinese, who were not students at the primary school in Sunshui Village in Mianning County, or who had a chronic or acute disease that might affect neurobehavioural function tests.
	Recruitment procedures	NR
Participant characteristics		Whole study
	No. of participants enrolled	51
	Age (mean ± SD)	7.1 years ± 0.6
	Male	47.1%
	Other characteristics	Mean birth weight, present weight & height, systolic & diastolic BP, haemoglobin, haematocrit, parity, number in household, household income, and characteristics of parent/guardian (age, relationship to child, education level, occupation) Did not report with respect to fluoride exposure
	Subgroups reported	Boys/Girls

Exposure and setting	Description of exposure and control	Fluoride concentrations in residence-specific water source (measured by the Mianning County Center for Disease Control) of the mothers' residence during pregnancy and onwards. Mean water fluoride concentration = 2.20 ppm (range 1.0 to 4.07) Two other proxies for water fluoride concentration were measured: morning urine fluoride concentration, and degree of dental fluorosis in each child.
	Setting	Community-based study. Children from one school in rural community in China
Results: various neuropsychological tests	Definition Method of measurement	Five neuropsychological tests: Three subsets of the Wide Range Assessment of Memory and Learning (WRAML), two subsets of the Wechsler Intelligence Scale for Children-Revised (WISC-IV), the drawing subtest of the Wide Range Assessment of Visual Motor Ability (WRAVMA), the finger tapping task, and the grooved pegboard test. They test aspects of memory & learning, copying & fine motor ability, and manual dexterity.
	No. of participants analysed	51
	No. of participants excluded or missing	0
	Imputation of missing data	NA
	Statistical method of analysis	Multiple regression analysis (adjusted for child's gender, age, parity, illness <3yrs old, household income, carer's age & education)
	Participant category	Effect estimate beta (95% CI)
	WRAML Finger Windows Visual Learning total Visual Learning delay Visual Learning difference Design Memory	 1.46 (-3.81, 6.74) 0.92 (-9.30, 11.1) 0.53 (-4.30, 5.35) -0.44 (-3.52, 2.65) 4.81 (-5.90, 15.5)
	WISC-IV Squareroot block design Digit span Forward Backward Total	 1.10 (-0.94, 3.14) -0.95 (-4.44, 2.53) -0.44 (-3.37, 2.50) -1.39 (-6.76, 3.98)
	WRAVMA Drawing	1.02 (-3.19, 5.24)
	Finger tapping Preferred hand Non-preferred hand	 1.23 (-7.01, 9.46) 5.03 (-2.17, 12.2)
	Grooved pegboard Log10 dominant hand Log10 non-dominant	 0.07 (-0.11, 0.25) -0.02 (-0.18, 0.14)
Authors' conclusion	"This pilot study in a community with stable lifetime fluoride exposures supports the notion that fluoride in drinking water may produce developmental neurotoxicity..." This conclusion is based on the finding of a statistically significant decrease in backward/total digit span in the moderate/severe fluorosis group compared to the normal/questionable fluorosis group.	
Correspondence if required	None required	
Reviewer's notes	There was no significant correlation found between fluoride water concentration and any of the neuropsychological test scores as seen in the results above. Correlation between dental fluorosis, fluoride concentration in urine, and neuropsychological test scores was also investigated but as the exposure of interest is drinking water fluoride concentration, this data was	

	not extracted.

Abbreviations: NR = not reported; WISC-IV = Wechsler Intelligence Scale for Children-Revised; WRAML = Wide Range Assessment of Memory and Learning; WRAVMA = Wide Range Assessment of Visual Motor Ability

COMBER ET AL. (2010)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Total population of Northern Ireland and the Republic of Ireland
1.2 Is the eligible population or area representative of the source population or area?	NA	-
1.3 Do the selected participants or areas represent the eligible population or area?	++	Participants identified through national cancer registries. All osteosarcoma patients included in the analysis
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Fluoridation categories assigned by urban vs. rural electoral divisions in the Republic of Ireland.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	NR	No discussion regarding participant migration or length of residency at current residence
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	++	Similar public water fluoridation intervention, and similar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Use of ICD morphologies in the national registries
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	-	Authors discuss weak power as limitation of the study
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	+	Simple comparison of rates, no Chi-squared test for distribution of osteosarcoma patients by age
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Standardised rate ratios and 95% CIs reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	No adjustment for confounding factors or examination of baseline characteristics. Inconclusive findings.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Similar public water fluoridation intervention, and similar healthcare system to Australia
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Comber et al. (2010)
	Date form completed	29/01/15
	Country of origin	Ireland

	Source of funding Possible conflicts of interest	Northern Ireland Cancer Registry is funded by the Public Health Agency for Northern Ireland NR		
Study characteristics	Aim/objectives of study	To establish if differences in the incidence of osteosarcoma in Northern Ireland (NI) and the Republic of Ireland (RoI) could be related to their different drinking water fluoridation policies		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Northern Ireland and the Republic of Ireland		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Populations of Northern Ireland & the Republic of Ireland		
	Inclusion/exclusion criteria	None		
	Recruitment procedures	Cases of osteosarcoma were identified from the Northern Ireland Cancer Registry and the National Cancer Registry of Ireland for the 13-year period 1994-2006 using ICD-O3 'osteosarcoma' morphologies.		
Participant characteristics		Whole study	Fluoridated	Non-fluoridated
	No. of participants enrolled	183 osteosarcoma cases in a population of 5,531,835	92 osteosarcoma cases in a population of 2,588,482	91 osteosarcoma cases in a population of 2,943,353
	Age	All ages	All ages	All ages
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	Gender Age-groups	Gender Age-groups	Gender Age-groups
Exposure and setting		Fluoridated		Non-fluoridated
	Description of exposure and control	Participants in the Republic of Ireland were divided into electoral divisions. Each electoral division was assigned to either an 'urban' or 'rural' category based on population density, and the 'urban' electoral divisions were considered fluoridated.		All participants from Northern Ireland and the 'rural' electoral divisions of the Republic of Ireland were assigned to the non-fluoridated category.
	Setting	Population-based study. Cases were identified from the Northern Ireland Cancer Registry and the National Cancer Registry of Ireland.		
Results: Osteosarcoma	Definition Method of measurement	Age-standardised incidence rate ratio of osteosarcoma (SIRR) Identified from national registries using ICD-03 morphology codes from M-9180/3 to M-9195/3		
	No. of participants analysed	183 cases of osteosarcoma from a total population of 5,531,835		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Comparison of age-standardised rates		
	Participant category	RoI fluoridated Age-standardised incidence rates per 100,000 per year (95%CI)	RoI non-fluoridated Age-standardised incidence rates per 100,000 per year (95%CI)	Standardised incidence rate ratio (95% CI)
	Females: 0 – 24 years	0.27 (0.23–0.32)	0.36 (0.28–0.43)	0.77 (0.58 – 1.02)
	Females: all ages	0.21 (0.14–0.28)	0.20 (0.10–0.29)	1.05 (0.59 – 1.87)
	Males: 0 – 24 years	0.52 (0.46–0.58)	0.50 (0.41–0.58)	1.04 (0.85 – 1.28)
	Males: all ages	0.32 (0.23–0.41)	0.29 (0.18–0.40)	1.11 (0.70 – 1.76)
	Total: 0 – 24 years	0.40 (0.36–0.43)	0.43 (0.37–0.48)	0.92 (0.78 – 1.09)
	Total: all ages	0.26 (0.21–0.32)	0.25 (0.17–0.32)	1.07 (0.75 – 1.54)
	Participant category	RoI fluoridated	NI	SIRR (95% CI)
	Females: 0 – 24 years	0.27 (0.23–0.32)	0.19 (0.14–0.24)	1.43 (1.07 – 1.90)

	Females: all ages	0.21 (0.14–0.28)	0.12 (0.06–0.19)	1.68 (0.94 – 2.98)
	Males: 0 – 24 years	0.52 (0.46–0.58)	0.53 (0.45–0.61)	0.97 (0.80 – 1.17)
	Males: all ages	0.32 (0.23–0.41)	0.29 (0.19–0.40)	1.09 (0.70 – 1.68)
	Total: 0 – 24 years	0.40 (0.36–0.43)	0.37 (0.32–0.41)	1.08 (0.92 – 1.27)
	Total: all ages	0.26 (0.21–0.32)	0.21 (0.15–0.27)	1.27 (0.90 – 1.80)
	Participant category	RoI fluoridated	All non-fluoridated	SIRR (95% CI)
	Females: 0 – 24 years	0.27 (0.23–0.32)	0.26 (0.22–0.30)	1.05 (0.83 – 1.33)
	Females: all ages	0.21 (0.14–0.28)	0.16 (0.10–0.21)	1.34 (0.83 – 2.17)
	Males: 0 – 24 years	0.52 (0.46–0.58)	0.52 (0.46–0.57)	1.00 (0.85 – 1.17)
	Males: all ages	0.32 (0.23–0.41)	0.29 (0.22–0.37)	1.09 (0.75 – 1.59)
	Total: 0 – 24 years	0.40 (0.36–0.43)	0.39 (0.36–0.43)	1.01 (0.88 – 1.15)
	Total: all ages	0.26 (0.21–0.32)	0.22 (0.18–0.27)	1.17 (0.87 – 1.58)
	Participant category	RoI non-fluoridated	NI	SIRR (95% CI)
	Females: 0 – 24 years	0.36 (0.28–0.43)	0.19 (0.14–0.24)	1.86 (1.33 – 2.62)
	Females: all ages	0.20 (0.10–0.29)	0.12 (0.06–0.19)	1.60 (0.77 – 3.33)
	Males: 0 – 24 years	0.50 (0.41–0.58)	0.53 (0.45–0.61)	0.93 (0.74 – 1.16)
	Males: all ages	0.29 (0.18–0.40)	0.29 (0.19–0.40)	0.98 (0.59 – 1.64)
	Total: 0 – 24 years	0.43 (0.37–0.48)	0.37 (0.32–0.41)	1.17 (0.97 – 1.41)
	Total: all ages	0.25 (0.17–0.32)	0.21 (0.15–0.27)	1.19 (0.78 – 1.80)
Authors' conclusion	If fluoride in drinking water does indeed constitute an excess risk for osteosarcoma, the effect in Ireland is too small for detection using current epidemiological methods			
Correspondence if required	None required			
Reviewer's notes	Results stratified by gender & other age ranges (25-49 years; 50-74 years; & 75+ years) not extracted			

Abbreviations: NR= not reported; NI = Northern Ireland; RoI = Republic of Ireland; SIRR = Standardised incidence rate ratio

DIOUF ET AL. (2011)

Quality Assessment

-	Section 1: Internal validity	-
1.1	The study addresses an appropriate and clearly focused question.	Y
-	Selection of subjects	-
1.2	The cases and controls are taken from comparable populations.	Y
1.3	The same exclusion criteria are used for both cases and controls.	Y
1.4	What percentage of each group (cases and controls) participated in the study?	CA
1.5	Comparison is made between participants and non-participants to establish their similarities or differences.	Y
1.6	Cases are clearly defined and differentiated from controls.	Y
1.7	It is clearly established that controls are non-cases.	Y
-	Assessment	-
1.8	Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment.	N
1.9	Exposure status is measured in a standard, valid and reliable way.	N
-	Confounding	-
1.10	The main potential confounders are identified and taken into account in the design and analysis.	Y
-	Statistical analysis	-
1.11	Confidence intervals are provided.	Y
-	Section 2: Overall assessment of the study	-
2.1	How well was the study done to minimise the risk of bias or confounding?	Acceptable
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	Low
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	Low

2.4	Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	Support for the hypothesis that within an endemic area, dental fluorosis in pregnant women is associated with a risk of giving birth to a low birth weight infant. Main area of concern is the studies weak methods for capturing participants' exposure to fluoride. Overall quality assessment: Low

Abbreviations: CA = can't answer; N = no; NA = not applicable; Y = yes

Data Extraction

General information	Study ID	Diouf et al. (2011)		
	Date form completed	23/02/15		
	Country of origin Source of funding Possible conflicts of interest	Senegal NR Authors declare that they have no conflicts of interest		
Study characteristics	Aim/objectives of study	To consider a potential link between dental fluorosis, fluoridated water intake by mothers and birth weight among infants		
	Study design	Case-control		
	Level of evidence	III-3		
	Study location	Diourbel region, Senegal		
	Study duration	February to May 2010		
	Exposure duration	NR		
	Source population description	Mothers giving birth at the Heinrich Lubcke Hospital in Diourbel. Cases are mothers with newborns whose weight <2.5 kg, controls are mothers of newborns whose weight ≥2.5 kg.		
	Inclusion/exclusion criteria	Inclusion: mothers with a pre-natal Medical Attendance Record Exclusion: mothers with a gynaecologic infection during pregnancy, who gave birth to a stillborn baby, who gave birth to twins, who gave birth at home or whose health condition prevents a clinical oral examination		
	Recruitment procedures	Successive recruitment in order of arrival		
Participant characteristics		Whole study	Cases	Controls
	No. of participants enrolled	324	108	216
	Age (mean)	NR	27 years	27.68 years *p*=0.34
	Male	0%	0%	0%
	BMI	NR	21.66	22.98 *p*=0.22
	Anaemia (%)	NR	24.1	9.3 *p*<0.01
	Diabetes (%)	NR	6.5	3.7 *p*=0.26
	Hypertension (%)	NR	23.1	11.6 *p*<0.01
	Malaria (%)	NR	17.6	10.2 *p*=0.06
Exposure status	Description of outcome status	Participants stratified by whether they consume drill, well or mineral water with fluoride concentrations of 4.7, 0.009 and 0.0 ppm respectively.		
	Setting	Hospital-based study. All newborn and parturient mothers giving birth at the Heinrich Lubcke Hospital were eligible.		
Results: Low birth weight	Definition Method of measurement	Participants with newborns weighing <2.5 kg Baby scale (2008 Kern MBE 10K10 v1.0)		
	No. of participants analysed	324		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Multivariate regression analysis		
	Participant category	Cases n/N (%)	Controls n/N (%)	Effect estimate Score ratio (95% CI)
	Mineral water	11/108 (10.2%)	13/216 (13.9%)	1

	Well water	30/108 (27.8%)	92/216 (42.6%)	0.89 (0.39 – 1.98) p=0.77
	Drilling water	67/108 (62%)	94/219 (43.5%)	1.94 (0.91 – 4.15) p=0.07
	Multivariate analysis	0.88 (0.5 – 2.51) well vs. mineral water		
		1.99 (1.3 – 3.67) drill vs. mineral water p=0.04		
Authors' conclusion	The results support the hypothesis that within an endemic area, dental fluorosis in pregnant women is associated with a risk of giving birth to a low weight infant.			
Correspondence if required	None required			
Reviewer's notes	Study focused on dental fluorosis scores rather than source of water and its fluoride concentration			

Abbreviations: BMI = body mass index; NR = not reported

ESWAR ET AL. (2011)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Schoolchildren (12 to 14 years) in the Davangere district, Karnataka, India.
1.2 Is the eligible population or area representative of the source population or area?	-	Villages selected based on fluoride concentration. No participant identification details.
1.3 Do the selected participants or areas represent the eligible population or area?	-	No discussion regarding representativeness. Method of selection: convenience sampling. Inclusion criteria broad.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Exposure groups based on fluoride concentrations in the groundwater, measured by fluoride ion selective electrode.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies. Unclear what the possible mechanism might be.
2.3 Was the contamination acceptably low?	NR	No discussion regarding participant migration between villages
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system. Level of fluoride higher than in Australian water supply.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Raven's Progressive Matrices test, no reliability details
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	
3.5 Was follow-up time meaningful?	NR	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	++	'Z' test and Chi-squared test
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Test statistics (Z/χ2) and p-values reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	No adjustment for confounding factors. High risk of selection bias due to convenience sampling and broad inclusion criteria.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Very unlikely to be generalisable to Australian context.

Overall quality rating	Low	Representativeness of the small sample unclear. Basic statistical analyses only.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Eswar et al. (2011)		
	Date form completed	04/02/15		
	Country of origin Source of funding Possible conflicts of interest	India NR NR		
Study characteristics	Aim/objectives of study	To compare the IQ scores of 12-14 year old schoolchildren living in a high fluoride village with the IQ scores of similar group of children in a low fluoride village in the Davangere district, Karnataka, India		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Davangere district, Karnataka, India		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Schoolchildren (aged 12-14 years) in Ajjihalli and Holesirigere		
	Inclusion/exclusion criteria	Inclusion criteria: Continuous residents of the village since birth and drinking water from the same public water supply Exclusion criteria: History of trauma or injury to the head, congenital or acquired neurological disorders, psychological disorders, absent on the day of survey		
	Recruitment procedures	Convenience sampling, one school from each village selected		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	133	68	65
	Age (range)	12 - 14 years	12 - 14 years	12 - 14 years
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Exposure to drinking water with naturally occurring 2.45 ppm fluoride	Exposure to drinking water with naturally occurring 0.29 ppm fluoride	
	Setting	School-based study. Participants recruited from one high school in Ajjihalli (high fluoride) and one in Holesirigere (low fluoride)		
Results: IQ	Definition Method of measurement	Intelligent Quotient Raven's Standard Progressive Matrices test		
	No. of participants analysed	133		
	No. of participants excluded or	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Chi-squared test and 'Z' test		
	Participant category	Intervention Mean ± SD n/N (%)	Comparator Mean ± SD n/N (%)	Effect estimate
	All children	88.8 ± 15.3	86.3 ± 12.8	Z = 1.03 *p*=0.30
	Children with IQ ≥ 90	25/68 (36.8%)	24/65 (52.3%)	χ^2 = 3.25 *p*=0.06
Authors' conclusion	Fluoride level in drinking water was not significantly associated with IQ level of 12-14 year old schoolchildren in a high and a low fluoride village of the Davangere district, Karnataka, India.			
Correspondence if required	None required			
Reviewer's notes	None			

Abbreviations: NA = not applicable; NR = not reported

FAN ET AL. (2007)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Schoolchildren (aged 7 to 15 years) in Pucheng county, China
1.2 Is the eligible population or area representative of the source population or area?	+	9 groups from one village in Pucheng county. Individual participant recruitment not described.
1.3 Do the selected participants or areas represent the eligible population or area?	+	Children 'randomly' selected but method not described, nor were the schools they attended. Inclusion/exclusion criteria & proportion agreeing to participate NR.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Children selected from areas identified as having low- or high-fluoride water. Representativeness not assessed
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Previous research in high fluoride water areas suggesting effect on IQ cited.
2.3 Was the contamination acceptably low?	+	Unclear. Average urine sample fluoride levels lower in low-fluoride group but not significantly different from those in high-fluoride group.
2.4 How well were likely confounding factors identified and controlled?	–	Poorly. Assumption that factors like cuisine, economy, living environment, education all similar but none were measured.
2.5 Is the setting applicable to the Australia?	–	Unlikely. Fluoride levels in high-fluoride water much higher than in Australia. Other sources of fluoride possible in China e.g. brick tea, coal burning fires.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	IQ test valid but no description of procedure or inter- or intra-rater reliability.
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	No power calculation
4.2 Were multiple explanatory variables considered in the analyses?	-	No
4.3 Were the analytical methods appropriate?	++	Correlation coefficient, Student's t-test, and chi-squared tests.
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Test statistics and p-values reported for all analyses
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	–	No confounding factors measured. Simple analysis of differences of outcomes.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	–	Unclear whether sample was representative.
Overall quality rating	Low	Recruitment details NR, only unadjusted analyses

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Fan et al. (2007)
	Date form completed	18/02/15
	Country of origin Source of funding Possible conflicts of interest	China NR NR for author

		Translated by *FoxTranslate* courtesy of Fluoride Action Network		
Study characteristics	Aim/objectives of study	Investigate the effect of high fluoride exposure on the level of intelligence in children.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	One village in Pucheng county, Saahxi province, China		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	School children aged 7 to 14 years old from primary schools in Pucheng county, Shaanxi, China		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	Children selected randomly. No other information.		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	79	42	37
	Age (range)	7 - 14 years	7 - 14 years	7 - 14 years
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Drinking water with fluoride concentration of 3.15 ppm. No water improvement schemes put in place in their locations.	Low-fluoride water supply of 1.03 ppm. Water improvement schemes initiated between 1988 & 1992.	
	Setting	The entire village reported to be similar in respect to cuisine, income sources, living environment, culture/education, agricultural goods etc. No chemical factories in area. No measures or data reported.		
Results: IQ	Definition Method of measurement	IQ score Chinese Combined Raven's Test image book (CRT-C2) for testing with CRT-C2 intelligence module to calculate score		
	No. of participants analysed	79		
	No. of participants excluded or missing	None		
	Imputation of missing data	NA		
	Statistical method of analysis	Chi squared test Student's t-test		
	Participant category	Intervention mean ±SD n/N (%)	Comparator mean ±SD n/N (%)	Effect estimate
	Mean IQ score ±SD	96.11 ± 12.00	98.41 ± 14.75	t=0.76 p>0.05
	IQ score ≥130	0/42 (0%)	1/37 (2.7%)	χ^2=2.24 p>0.05
	IQ score 120-129	0/42 (0%)	2/37 (5.4%)	
	IQ score 110-119	4/42 (9.5%)	5/37 (13.5%)	
	IQ score 90-109	28/42 (66.7%)	18/37 (48.0%)	
	IQ score 80-89	7/42 (16.7%)	8/37 (21.6%)	
	IQ score 70-79	2/42 (4.8%)	2/37 (5.4%)	
	IQ score ≤69	1/42 (2.3%)	1/37 (2.7%)	
Authors' conclusion	Exposure to high levels of fluoride is likely to cause a certain level of harm to a child's level of intelligence.			
Correspondence if required	None required			
Reviewer's notes	The village is in a region severely impacted by dental fluorosis. Of nine groups in the village, 4 were switched to low-fluoride water; the other 5 were not. No other information given. Investigators also measured the fluoride concentration in the children's urine as well as the degree of dental fluorosis present and calculated statistical significance of the difference between high- and low-fluoride groups.			

Abbreviations: NA = not applicable; NR = not reported

HUANG ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Residents (16 to 60 years) of selected villages of Jilin Province
1.2 Is the eligible population or area representative of the source population or area?	NR	No participant identification or representativeness details
1.3 Do the selected participants or areas represent the eligible population or area?	NR	No method of selection reported. No indication how representative groups are or whether they are comparable.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Based on fluoride concentration in village groundwater as measured by an ion selective electrode.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	High fluoride consumption can cause skeletal fluorosis.
2.3 Was the contamination acceptably low?	+	Only residents who had lived in the village for at least 10 years were eligible
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system, groundwater fluoridation rather than public water supply fluoridation
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	NR	No outcome capture method details
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	+	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	At least 10 years for both groups
3.5 Was follow-up time meaningful?	+	Exposure was likely to be long enough to observe hypothesised effects
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	++	Chi-squared test
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	$\chi 2$ and p-values only reported when significant
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	No adjustment for confounding factors. High risk of selection bias due to unclear participant recruitment method and no information of degree of representativeness.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Levels of fluoride much higher than Australian context. Differing health care system and socioeconomic characteristics.
Overall quality rating	Low	Poor participant recruitment details, basic statistical analyses

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Huang et al. (2013)
	Date form completed	12/02/15
	Country of origin Source of funding Possible conflicts of interest	China NR NR
Study	Aim/objectives of study	To understand the characteristics of forearm and crus x-rays of residents

characteristics		from areas with varying concentrations of fluoride in their drinking water, providing evidence for diagnosis of osteofluorosis.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Jilin Province, China		
	Study duration	NR		
	Exposure duration	At least 10 years		
	Source population description	Residents (16 to 60 years) of 15 villages from Qianan and Non Counties of Jilin Province, China		
	Inclusion/exclusion criteria	Villages with at least 50 years of history, complete records of drinking water fluoride levels for that period with a variation of no more than 0.3 ppm in well fluoride concentration, residents with no habit of drinking tea, low population mobility, no major difference with respect to ethnicity, the natural environment, level of economic development, means of work, lifetime, no industrial or coal-burning fluoride pollution, no other sources of fluoride, and no low-fluoride drinking water alternatives		
	Recruitment procedures	NR – subjects divided in to 5 age groups		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	675	485	190
	Age (range)	16 - 60 years	16 - 60 years	16 - 60 years
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Exposed to 1.5 – 7.0 ppm fluoride in groundwater	Exposed to 0.5 – 1.0 ppm fluoride in groundwater	
	Setting	Population-based study. Participants recruited from villages in Jilin Province China.		
Results: Articular degeneration	Definition Method of measurement	NR X-ray		
	No. of participants analysed	675		
	No. of participants excluded or missing (with reasons)	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Chi-squared test		
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect estimate
	All patients	153/485 (33.6%)	41/190 (21.6%)	*p*<0.05
Results: Osteoporosis	Definition Method of measurement	NR X-ray		
	No. of participants analysed	675		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Chi-squared test		
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect estimate
	All patients	30/485 (6.2%)	13/190 (6.8%)	Non-significant
Authors' conclusion	The detection rate for articular degeneration is clearly higher in the high fluoride group than the low fluoride group, indicated that the articular degeneration present is not limited to the natural changes that would normally be seen in the population, but rather that the excess intake of fluoride increasing the opportunity for damage.			
Correspondence if required	None			
Reviewer's notes	Other bone analyses reported but not extracted			

Abbreviations: NA = not applicable; NR = not reported

HUSSAIN ET AL. (2010)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Adults (aged >21 years) in the central part of Rajasthan
1.2 Is the eligible population or area representative of the source population or area?	-	General and house-to-house survey, unclear if all eligible participants/houses or just a sample were surveyed.
1.3 Do the selected participants or areas represent the eligible population or area?	NR	No reporting of selection method of participants
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Groups selected based on fluoride concentrations.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Skeletal fluorosis is a known adverse effect of high fluoride consumption.
2.3 Was the contamination acceptably low?	NR	No discussion regarding patient migration between villages
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Very high fluoride concentration in groundwater, dissimilar healthcare system.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Survey, reliability details NR
3.2 Were the outcome measurements complete?	-	Unclear
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	
3.5 Was follow-up time meaningful?	NR	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	-	No statistical analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	-	No statistical analysis
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Sample selection details are poor – high risk of selection bias. No statistical analysis.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Fluoride levels much higher than in Australian context. Differing socioeconomic and health system characteristics.
Overall quality rating	Low	

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Hussain et al. (2010)
	Date form completed	11/02/15
	Country of origin Source of funding Possible conflicts of interest	India Council of Scientific and Industrial Research, New Delhi NR
Study characteristics	Aim/objectives of study	To investigate the quality of drinking water with special reference to the concentration of fluoride in most rural habitations of Central Rajasthan, India and to study the cases of fluorosis in the villages having more than 5.0 ppm fluoride.

	Study design	Ecological			
	Level of evidence	IV			
	Study location	Central Rajasthan, India			
	Study duration	2003 to 2006			
	Exposure duration	NR			
	Source population description	Households of villages in the central part of Rajasthan			
	Inclusion/exclusion criteria	Unclear. House-to-house survey in villages where fluoride concentration was above 5.0 ppm. Also a general survey conducted.			
	Recruitment procedures	NR			
Participant characteristics		Whole study	Fluoride. <4 ppm	Fluoride. 4-6 ppm	Fluoride. >6 ppm
	No. of participants enrolled	1,998	482	981	535
	Age	NR	NR	NR	NR
	Male	NR	NR	NR	NR
	Other characteristics	NR	NR	NR	NR
	Subgroups reported	NR	NR	NR	NR
Exposure and setting	Description of exposure and control	Exposure to naturally occurring fluoride in the groundwater. For extraction, villages grouped by fluoride concentration: <4 ppm, 4-6 ppm or >6 ppm.			
	Setting	Population-based study. Participants recruited from villages with high levels of naturally occurring fluoride.			
Results: Grade II skeletal fluorosis	Definition Method of measurement	Generalised bone and joint pain, stiffness and rigidity of dorso-lumbar spine and restricted movements at spine and joints. House-to-house survey			
	No. of participants analysed	1,998			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	None			
	Participant category	Fluoride. <4 ppm	Fluoride. 4-6 ppm	Fluoride. >6 ppm	Effect estimate
	All patients	81/482 (16.8%)	197/981 (20.1%)	93/535 (17.4%)	NR
Results: Grade III skeletal fluorosis	Definition Method of measurement	Symptoms of grade II with deformities of spine and limbs, knock knees, crippled or bedridden state, kyphosis, invalidism, genu-varum and genu-valgum. House-to-house survey			
	No. of participants analysed	1,998			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	None			
	Participant category	Fluoride. <4 ppm	Fluoride. 4-6 ppm	Fluoride. >6 ppm	Effect estimate
	All patients	0/482 (0.0%)	9/981 (0.9%)	3/535 (0.6%)	NR
Authors' conclusion	Prevalence and severity of skeletal fluorosis were found to be increased with increasing fluoride concentration.				
Correspondence if required	None				
Reviewer's notes	Results for dental fluorosis not extracted				

Abbreviations: NA = not applicable; NR = not reported

JOLAOSO ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	+	School children in the US aged 4-22 years.

1.2 Is the eligible population or area representative of the source population or area?	++	Data from 1986-1987 National Survey of Oral Health in US of school children aged 4-22 years (n=40,693) was used for this study. They were selected using a complex, stratified multistage probability sampling technique.
1.3 Do the selected participants or areas represent the eligible population or area?	++	Children aged 5-17 years with a history of a single continuous residence were selected from the 1986-1987 US National Survey of Oral Health.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Based on school drinking water fluoride level. Schools with water fluoride levels >1.2 ppm excluded. Unclear how school water reflects home water fluoride levels.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Those taking fluoride tablets and/or drops were excluded. Measurement of fluoridated toothpaste exposure and deprivation/SES not included
2.3 Was the contamination acceptably low?	NR	Fluoride levels in home water may be different
2.4 How well were likely confounding factors identified and controlled?	+	Age, gender, ethnicity, metropolitan status and school region controlled for in analysis
2.5 Is the setting applicable to the Australia?	++	Socioeconomic and health system similarities. Also fluoride levels similar to Australia
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Oral examination of permanent teeth. Teeth missing for orthodontic or non-disease reasons were excluded.
3.2 Were the outcome measurements complete?	++	Yes
3.3 Were all the important outcomes assessed?	+	Caries attack rate also measured
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	
3.5 Was follow-up time meaningful?	NR	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	No power analysis conducted
4.2 Were multiple explanatory variables considered in the analyses?	+	Caries attack rate also measured. Age, gender, ethnicity, metropolitan status, and school region included.
4.3 Were the analytical methods appropriate?		Generalised linear regression
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	No confidence intervals reported. P-values reported.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Representative sample. Exposure based on a population measure. Outcome measurement and analysis adequate.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Similar socioeconomic and healthcare systems. Comparable fluoride levels.
Overall quality rating	Acceptable	

NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Jolaoso et al. (2014)
	Date form completed	11/08/15
	Country of origin	USA
	Source of funding	HRSA Maternal and Child Health Services Block Grant, HRSA Residency Training in Dental Public Health Grant, and CDC Oral Disease Prevention Program
	Possible conflicts of	"Financial Disclosure: none"

<table>
<tr><td></td><td>interest</td><td colspan="4"></td></tr>
<tr><td rowspan="10">Study characteristics</td><td>Aim/objectives of study</td><td colspan="4">To assess if the reduction in DMFS (decayed, missing, and filled surfaces) associated with optimally fluoridated water observed in national surveys would remain after accounting for differences in the number of erupted teeth.</td></tr>
<tr><td>Study design</td><td colspan="4">Ecological</td></tr>
<tr><td>Level of evidence</td><td colspan="4">IV</td></tr>
<tr><td>Study location</td><td colspan="4">USA</td></tr>
<tr><td>Study duration</td><td colspan="4">NR</td></tr>
<tr><td>Exposure duration</td><td colspan="4">NR</td></tr>
<tr><td>Source population description</td><td colspan="4">Data from the 1986-1987 National Survey of Oral Health in US Schoolchildren was used.</td></tr>
<tr><td>Inclusion/exclusion criteria</td><td colspan="4">Analysis restricted to children aged 5-17 years with a history of a single continuous residence. Children who were receiving fluoride tablets and/or drops, or whose school water fluoride was >1.2 ppm were excluded</td></tr>
<tr><td>Recruitment procedures</td><td colspan="4">Data from the 1986-1987 National Survey of Oral Health in US Schoolchildren was used. The survey used a complex, stratified, multistage probability sample to measure the prevalence of dental caries and dental fluorosis.</td></tr>
<tr><td></td><td></td><td colspan="4"></td></tr>
<tr><td rowspan="6">Participant characteristics</td><td></td><td>Whole study</td><td>“Fluoride deficient water” (<0.3 ppm)</td><td>“Suboptimal water fluoride level” (0.3-<0.7 ppm)</td><td>“Optimal water fluoride level” (0.7-1.2 ppm)</td></tr>
<tr><td>No. of participants enrolled</td><td>13,348</td><td>NR</td><td>NR</td><td>NR</td></tr>
<tr><td>Age</td><td>5-17 years</td><td>NR</td><td>NR</td><td>NR</td></tr>
<tr><td>Male</td><td>NR</td><td>NR</td><td>NR</td><td>NR</td></tr>
<tr><td>Other characteristics</td><td>NR</td><td>NR</td><td>NR</td><td>NR</td></tr>
<tr><td>Subgroups reported</td><td>NR</td><td>NR</td><td>NR</td><td>NR</td></tr>
<tr><td rowspan="2">Exposure and setting</td><td>Description of exposure and control</td><td colspan="4">Fluoride level in drinking water from each surveyed school’s water supply. Participants categorised into those exposed to <0.3 ppm, 0.3-<0.7 ppm, and 0.7-1.2 ppm fluoride in the schools’ drinking water.</td></tr>
<tr><td>Setting</td><td colspan="4">Population-based study. Participants identified the 1986-1987 National Survey of Oral Health in US Schoolchildren.</td></tr>
<tr><td rowspan="8">Results: Erupted permanent teeth</td><td>Definition

Method of measurement</td><td colspan="4">Mean number of erupted permanent teeth (sound, decayed, missing because of caries, and filled). NB: teeth missing for orthodontic or non-disease reasons were excluded
Clinical examination by trained dentists</td></tr>
<tr><td>No. of participants analysed</td><td colspan="4">13,348</td></tr>
<tr><td>No. of participants excluded or missing</td><td colspan="4">NR</td></tr>
<tr><td>Imputation of missing data</td><td colspan="4">NR</td></tr>
<tr><td>Statistical method of analysis</td><td colspan="4">Generalised linear regression analysis (adjusted for age, gender, race/ethnicity, metropolitan status, and school region)</td></tr>
<tr><td>Participant category</td><td>“Fluoride deficient water” (<0.3 ppm)</td><td colspan="2">“Suboptimal water fluoride level” (0.3-<0.7 ppm)</td><td>“Optimal water fluoride level” (0.7-1.2 ppm)</td></tr>
<tr><td>All participants (SE)</td><td>19.03 (0.07)</td><td colspan="2">18.96 (0.09)</td><td>18.89 (0.07)</td></tr>
<tr><td></td><td colspan="4">p=0.12</td></tr>
<tr><td rowspan="3">Results: Erupted permanent first molar in 7 year olds</td><td>Definition

Method of measurement</td><td colspan="4">Mean number of erupted permanent first molar in 7 year olds (sound, decayed, missing because of caries, and filled first molars). NB: teeth missing for orthodontic or non-disease reasons were excluded
Clinical examination by trained dentists</td></tr>
<tr><td>No. of participants analysed</td><td colspan="4">1,193</td></tr>
<tr><td>No. of participants</td><td colspan="4">NR</td></tr>
</table>

	excluded or missing			
	Imputation of missing data	NR		
	Statistical method of analysis	Generalised linear regression analysis (adjusted for gender, race/ethnicity, metropolitan status, and school region)		
	Participant category	"Fluoride deficient water" (<0.3 ppm)	"Suboptimal water fluoride level" (0.3-<0.7 ppm)	"Optimal water fluoride level" (0.7-1.2 ppm)
	All participants (SE)	3.82 (0.06)	3.67 (0.09)	3.92 (0.06)
		Pairwise comparison of 'suboptimal' vs. 'optimal level' statistically significant (p<0.01); other comparisons not significantly different		
Results: Caries attack rate	Definition Method of measurement	Total number of decayed, missing due to caries, and filled surfaces divided by the total number of erupted surfaces (units: number of surfaces attached per 1,000 surfaces at risk). NB: all missing teeth due to caries were assumed to have had all surfaces affected by caries. Clinical examination by trained dentists		
	No. of participants analysed	13,348		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Generalised linear regression analysis (adjusted for age, gender, race/ethnicity, metropolitan status, and school region)		
	Participant category	"Fluoride deficient water" (<0.3 ppm)	"Suboptimal water fluoride level" (0.3-<0.7 ppm)	"Optimal water fluoride level" (0.7-1.2 ppm)
	Permanent teeth per 1,000 surfaces at risk (SE)	34.21 (0.89)	31.03 (1.21)	28.52 (0.87)
		p<0.001		
	1st molar per 1,000 surfaces at risk (SE)	92.78 (2.33)	81.18 (3.19)	72.68 (2.30)
		p<0.001		
Authors' conclusion	Exposure to optimal fluoride in drinking water did not delay the eruption of permanent teeth			
Correspondence if required	None			
Reviewer's notes	Only data for erupted permanent teeth and erupted permanent first molar in 7 year olds reported in evidence review. Statistically significant differences in adjusted mean number of erupted permanent teeth were observed with respect to age (p<0.0001), gender (p<0.0001), and ethnicity (p<0.0001) NB: all pair-wise comparisons of ethnicity statistically significant (all p<0.01), except for Hispanic vs. Others (p>0.05) Statistically significant differences in adjusted mean number of erupted 1st molar teeth in 7 year olds were observed for gender (p<0.01) and ethnicity (p=0.01) NB: pair-wise comparisons of White vs. all other ethnicities statistically significant (all p<0.05); other pairwise comparisons by ethnicity not significant Other variables associated with caries attack rate include age, region, ethnicity, and gender (p<0.05): younger age, male gender, white ethnicity were independently associated with lower caries attack rate. Children living in the southwest region also showed lower caries attack rate.			

NR = not reported

KARIMZADE ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well	-	Country and location described. Health system unclear.

described?		Population demographics unclear.
1.2 Is the eligible population or area representative of the source population or area?	+	Participants were selected by random sampling methods, but no further details provided. Both study groups are said to be from areas with similar characteristics (educationally, economically, socially, culturally and generally) but no details provided.
1.3 Do the selected participants or areas represent the eligible population or area?	-	Participants limited to 9-12 year old male children. Participants selected by random sampling. Not clear what proportion of approached agreed to participate. Inclusion/exclusion criteria not provided.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Not clear how long study participants were resident in areas of study. Participants selected by random sampling but unclear how many agreed to participate.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Cite human and animal studies which are said to show that exposure to high levels of F in the water may decrease IQ scores.
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	-	The 2 areas are said to be similar in general demographic and geographic characteristics, but no details provided. Iodine levels & other potential confounders were not measured.
2.5 Is the setting applicable to the Australia?	-	Study looked at areas with high F (3.94 ppm) and low F (0.25ppm). Neither of these overlaps Australia's recommended F levels (0.6-1.1 ppm).
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Iranian version of the Cattell test was chosen to measure IQ (RB Cattell, scale 2-A, for children age 8-13). Unclear if test has been validated. Questionnaires were completed by children after receiving instructions from a teacher and an examiner.
3.2 Were the outcome measurements complete?	NR	Unclear if most or all study participants meeting inclusion criteria were identified. Inclusion criteria NR.
3.3 Were all the important outcomes assessed?	++	The outcome of interest was IQ score; the study assessed IQ scores.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	Sample sizes and powering issues not discussed.
4.2 Were multiple explanatory variables considered in the analyses?	NR	Only data on the relationship between F concentration and IQ scores provided in the article.
4.3 Were the analytical methods appropriate?	-	Article states that questionnaires were used to measure potential confounders (educational, economic, social, cultural, general demographic factors) but no details or analyses provided. Follow up NR.
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	Mean, SD and 95% CI reported for IQ scores by high/ low F level.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Many aspects not reported and/or unclear.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Probably not. Study sample limited to 9-12 year old male children; duration of exposure unclear.
Overall quality rating	Low	Many criteria above not reported on; flaws in numerous aspects of study design.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID36	Karimzade et al. (2014)		
	Date form completed	30/01/15		
	Country of origin Source of funding Possible conflicts of interest	Iran NR NR		
Study characteristics	Aim/objectives of study	To investigate the relationship between fluoride in drinking water and children's intelligence quotient (IQ).		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	West, Azerbaijan, Iran		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Male children (9 to 12 years) residing in the villages of Poldashi and Piranshahr, West Azerbaijan, Iran.		
	Inclusion/exclusion criteria	Exclusion: children with mental retardation, neurological disorders, and congenital or acquired diseases of the nervous system.		
	Recruitment procedures	Participants in both groups (high-F and low-F) were selected by random sampling methods. No further details provided.		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	39	19	20
	Age (mean)	NR	10.47 years	10.89 years
	Male	100%	100%	100%
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Water samples collected from drinking water supplies in Poldashi (wells and springs) with mean fluoride concentration of 3.94 ppm.	Water samples collected from drinking water supplies in Piranshahr (wells and springs) with mean fluoride concentration of 0.25 ppm.	
	Setting	Unclear.		
Results: IQ	Definition Method of measurement	Intelligence Quotient Iranian version of the Cattell IQ test (RB Cattell, scale 2-A, for children age 8-13). Test included 46 questions. Questionnaires were completed by children after receiving instructions from a teacher and an examiner. IQ scores were classified into 7 categories: <70 retarded/low; 70-79 borderline/below average; 80-89 dull normal/low average; 90-109 normal/average; 110-119 bright normal/high average; 120-129 superior/good; >129 very superior/excellent.		
	No. of participants analysed	39		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Unpaired t-test and Chi-squared test		
	Participant category	Intervention (high F) mean ± SD	Comparator (low F) mean ± SD	Effect estimate
	All participants	81.21 ± 16.17	104.25 ± 20.73	p=0.0004
	IQ scores by category:			
	<70 to 89	13/19 (68%)	4/20 (20%)	p=0.0067
	90 to 109	4/19 (21%)	7/20 (35%)	p=0.0067
	110 to >129	2/19 (10.5%)	9/20 (45%)	p=0.0067
Authors' conclusion	The study found that children residing in a region with a high drinking water F level had lower IQs compared to children living in a low drinking water F region (p<0.001). The differences could not be attributed to confounding educational, economic, social, cultural, and general demographic factors.			

Correspondence if required	Not required
Reviewer's notes	The article reports IQ scores by 7 categories, however, significance testing is done on amalgamated categories (IQ <70 to 89, i.e. retarded, borderline, and dull normal categories; IQ 90-109 i.e. normal category; IQ 110-129+ i.e. bright normal, superior and very superior categories). The amalgamated categories are therefore reported here. The study suggests that the differences could not be attributed to confounders; however, it is not clear how this was established, as no analysis was provided.

Abbreviations: NA = not applicable; NR = not reported

KHARB ET AL. (2012)

Quality Assessment

-	Section 1: Internal validity	-
1.1	The study addresses an appropriate and clearly focused question.	Y
-	Selection of subjects	-
1.2	The cases and controls are taken from comparable populations.	N
1.3	The same exclusion criteria are used for both cases and controls.	N
1.4	What percentage of each group (cases and controls) participated in the study?	Cases: 100% Controls: 100%
1.5	Comparison is made between participants and non-participants to establish their similarities or differences.	N
1.6	Cases are clearly defined and differentiated from controls.	CA
1.7	It is clearly established that controls are non-cases.	CA
-	Assessment	-
1.8	Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment.	N
1.9	Exposure status is measured in a standard, valid and reliable way.	N
-	Confounding	-
1.10	The main potential confounders are identified and taken into account in the design and analysis.	N
-	Statistical analysis	-
1.11	Confidence intervals are provided.	N
-	Section 2: Overall assessment of the study	-
2.1	How well was the study done to minimise the risk of bias or confounding?	Poor quality
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	No
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	No
2.4	Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	Drinking water fluoride levels were significantly higher in patients with osteosarcoma as compared to controls. Very poor quality study. Cannot assess whether cases and controls are comparable. Recruitment procedures NR. Small numbers, and lack of control for confounders make study at a very high risk of bias

Abbreviations: CA = can't answer; N = no; NA = not applicable; Y = yes

Data Extraction

General information	Study ID	Kharb et al. (2012)		
	Date form completed	14/01/15		
	Country of origin Source of funding Possible conflicts of interest	India NR None declared		
Study characteristics	Aim/objectives of study	To analyse serum and drinking water fluoride in osteosarcoma patients		
	Study design	Case-control		
	Level of evidence	III-3		
	Study location	India		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	10 patients with osteosarcoma (cases) and 10 healthy volunteers (controls)		
	Inclusion/exclusion criteria	Patients with osteosarcoma and healthy volunteers – no matching of controls to cases reported		
	Recruitment procedures	NR		
Participant characteristics		Whole study	Cases	Controls
	No. of participants enrolled	20	10	10
	Age	NR	NR	NR
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Outcome status	Description of outcome status	Assessment of osteosarcoma status not reported		
	Setting	NR		
Results: Water fluoride	Definition Method of measurement	Fluoride levels (ppm) Cases and controls provided samples of water from their current residence. Fluoride levels estimated by ion selective electrode.		
	No. of participants analysed	20		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		
	Participant category	Cases (mean ± SD)	Controls (mean ± SD)	Effect estimate
	All patients	1.30 ± 0.76	0.48 ± 0.24	$p<0.001$
Authors' conclusion	Drinking water fluoride levels were significantly higher in patients with osteosarcoma as compared to controls.			
Correspondence if required	None required			
Reviewer's notes	Serum fluoride levels also measured and analysed. Also significantly higher in patients with osteosarcoma ($p<0.05$)			

Abbreviations: NA = not applicable; NR = not reported

KOLTERMANN ET AL. (2011)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Adults (aged 35 – 44 years) in the State of Rio Grande do Sul, Brazil
1.2 Is the eligible population or area representative of the source population or area?	++	Participants identified from State Health Department cross-sectional population-based study
1.3 Do the selected participants or areas represent the eligible population or area?	++	Stratified sample of municipalities by population size and region of the State
Section 2: Method of selection of	-	-

exposure (or comparison) group		
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Exposure time to water fluoridation taken from national oral health survey.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Fluoride exposure improves functional dentition through reduction in dental caries.
2.3 Was the contamination acceptably low?	NR	Unclear whether participants may have moved between water supplies.
2.4 How well were likely confounding factors identified and controlled?	++	Odds ratios adjusted for contextual and individual variables
2.5 Is the setting applicable to the Australia?	+	No information regarding fluoride concentrations in fluoridated areas but relates to intentional fluoridation of public water supply.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Dentists were trained and calibrated to conduct the clinical examination, and structured interviews were held with the participants
3.2 Were the outcome measurements complete?	+	218 (2.1%) functional dentition records absent, participants excluded
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	++	A range variables explored in a multivariate analysis
4.3 Were the analytical methods appropriate?	++	Chi-squared test for the bivariate analysis and multilevel logistic regression
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	95% confidence intervals reported for adjusted odds ratios
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Good recruitment and adjustment for confounding factors. Large study population.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Relates to intentional fluoridation of the public water supply.
Overall quality rating	Acceptable	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Koltermann et al. (2011)
	Date form completed	29/01/15
	Country of origin Source of funding Possible conflicts of interest	Brazil NR NR
Study characteristics	Aim/objectives of study	To investigate the association between individual and contextual factors in the functional dentition of adults in the State of Rio Grande do Sul, Brazil
	Study design	Ecological
	Level of evidence	IV
	Study location	State of Rio Grande do Sul, Brazil
	Study duration	2000 to 2002
	Exposure duration	NR
	Source population description	Adults (35 – 44 years) living in the State of Rio Grande do Sul
	Inclusion/exclusion criteria	NR
	Recruitment procedures	Data were collected from clinical examinations and structured interviews based on a cross-sectional population-based study conducted by the Rio Grande do Sul State Health Department in 2003

Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	10,625	NR	NR
	Age (range)	35 – 44 years	NR	NR
	Male	36.9%	NR	NR
	Ethnicity	5.3% black 5.9% brown 6.9% other 82.0% white	NR	NR
	Family income (in Reais)	24.6% ≤279.00 50.7% 280.00-800.00 24.7% ≥801.00	NR	NR
	Schooling (years)	29.9% ≤4 44.3% 5-8 25.8% ≥9	NR	NR
Exposure and setting	Description of exposure and control	Time since exposure to fluoridation of public water supply in the place of residence came from the national oral health survey. Fluoride concentration exposure details not reported.		
	Setting	Population-based study, participants identified from State Health Department cross-sectional study		
Results: Functional dentition	Definition Method of measurement	≥20 teeth present Assessed by trained dentists calibrated to conduct the clinical examinations		
	No. of participants analysed	10,407		
	No. of participants excluded or missing	218 participants excluded because they lacked information on functional dentition		
	Imputation of missing data	None		
	Statistical method of analysis	Multilevel logistic regression adjusted for contextual, individual demographic and individual health-system variables.		
	Participant category	Intervention	Comparator	Adj OR (95% CI)
	All participants	≥10 years fluoridation (N = 4,125)	≤5 years fluoridation (N = 5,519)	1.78 (1.32 – 2.40) *p*<0.01
	All participants	5-9 years fluoridation (N = 763)	≤5 years fluoridation (N = 5,519)	1.88 (1.20 – 2.95) *p*<0.01
Authors' conclusion	Individuals living in urban areas and in municipalities with better socioeconomic standards and a longer history of fluoridation in the public water supply showed high functional dentition rates			
Correspondence if required	None required			
Reviewer's notes	None			

Abbreviations: NR = not reported

KUTLUCAN ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Children aged 10 to 15 years living in Yenice, Dere, & Anadolu quarters in Isparta, Turkey.
1.2 Is the eligible population or area representative of the source population or area?	+	School-based recruitment was carried out. Unclear if important groups underrepresented.
1.3 Do the selected participants or areas represent the eligible population or area?	NR	Not reported. Study participants determined on the basis of data from a previous study in the area.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	Groups selected from areas with known high/normal concentration of F in water. Sampling method NR. F concentration in reservoir (high concentration areas) and tap (low concentration area) water provided, but process of sampling NR.
2.2 Was the selection of explanatory variables	++	Previous, small human studies showing association between F

based on a sound theoretical basis?		levels and thyroid pathologies.
2.3 Was the contamination acceptably low?	NR	
2.4 How well were likely confounding factors identified and controlled?	-	Confounding factors not controlled for.
2.5 Is the setting applicable to the Australia?	-	Fluoride levels higher than seen in Australian context.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Process of measuring height and weight (components of BSA) and calculating BSA described. Process for measuring TTV and calculating echobody index described.
3.2 Were the outcome measurements complete?	NR	Results for all participants reported
3.3 Were all the important outcomes assessed?	+	Thyroid hormone levels not measured.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	
3.5 Was follow-up time meaningful?	NR	
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	Sample sizes and powering issues not discussed.
4.2 Were multiple explanatory variables considered in the analyses?	-	Some consideration of iodine level in the urine. No adjusted/multivariate analysis.
4.3 Were the analytical methods appropriate?	+	Student's t-test
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	*p*-values provided but no test statistics
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Selection bias highly likely. No adjustment for confounders. Too many aspects not reported.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Fluoride levels higher than used in Australia. Health system likely to be different.
Overall quality rating	Low	Many criteria above not reported on; flaws in many aspects of study design.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Kutlucan et al. (2013)		
	Date form completed	16/01/15		
	Country of origin Source of funding Possible conflicts of interest	Turkey "No specific funding was received for this study" NR		
Study characteristics	Aim/objectives of study	To compare urine iodine, fluoride, and measure thyroid volumes in 10-15 year old children.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Isparta, Turkey		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Schoolchildren (10 to 15 years) living in the quarters of Yenice, Dere and Anadolu in Isparta, Turkey		
	Inclusion/exclusion criteria	Inclusion criteria: NR. Exclusion criteria: previous medical history of thyroidal disease, detection of nodule on USG, signs of thyroiditis.		
	Recruitment procedures	Intervention and control groups were determined from data in a study conducted by a Local Health Directorate of Isparta in 2001.		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	559	261	298
	Age (mean ± SD)	NR	12.00 ± 1.50 years	11.87 ± 1.37 years
	Male	48.3%	46.7%	49.7%
	Weight (mean ±SD)	NR	38.33 ± 10.17 kg	43.67 ± 12.67 kg

				p<0.001
	Height (mean ±SD)	NR	144.77 ± 10.16 cm	147.58 ± 11.49 cm p=0.002
	Body surface area (mean ±SD)	NR	1.23 ± 0.20 m^2	1.34 ± 0.23 m^2 p<0.001
	BMI (mean ±SD)	NR	17.99 ± 3.09 kg/m^2	19.82 ± 3.71 kg/m^2 p<0.001
	Urinary iodine concentration (mean ±SD)	NR	93.12 ± 38.51 μg/L	98.41 ± 33.40 μg/L p=0.083
	Subgroups reported	10-11 years old; 12-13 years old; 14-15 years old (NB: total numbers in this analysis different from 'all participants' analysis – see notes below)		
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Fluoride levels in samples from 18 major water reservoirs in Yenice and Dere quarters. Mean water fluoride concentration = 4.6 ppm (Dere) & 2.8 ppm (Yenice)	Fluoride level in tap water in Anadolu quarter. Mean fluoride concentration = 0.19 ppm p<0.001	
	Setting	School-based study. Participants were identified from a previous study conducted in the area.		
Results: Total thyroid volume (TTV)	Definition Method of measurement	TTV = sum of volume of both lobes (ml) Lobe volume = π/6 x transverse x sagittal x antero-posterior lengths Ultrasound measurement of above dimension with neck hyperextended when patient supine.		
	No. of participants analysed	559		
	No. of participants excluded or missing	NA		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		
	Participant category	Intervention mean ± SD	Comparator mean ± SD	Effect estimate
	All participants	8.60 ± 3.11 ml	8.73 ± 2.75 ml	p=0.624
Results: Echobody index	Definition Method of measurement	Echobody index =total thyroid volume / body surface area (ml/m^2). Total thyroid volume as above Body surface area = (weight x 4) +7 / (weight + 90)		
	No. of participants analysed	559		
	No. of participants excluded or missing	NA		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		
	Participant category	Intervention mean ± SD	Comparator mean ± SD	Effect estimate
	All participants	6.94 ± 2.14 ml/m^2	6.48 ± 1.53 ml/m^2	p=0.003
	10-11 years old	7.08 ± 2.15 ml/m^2	6.85 ± 2.17 ml/m^2	p=0.424*
	12-13 years old	6.27 ± 1.48 ml/m^2	6.25 ± 1.35 ml/m^2	p=0.910*
	14-15 years old	7.40 ± 1.73 ml/m^2	6.54 ± 1.52 ml/m^2	p=0.011*
Authors' conclusion	A relation between fluoride concentration and thyroid gland with ultrasonographic examination was firstly evaluated, and it was concluded that fluoride affected thyroid gland although it was weakly significant. After puberty, echobody index in subjects with fluorosis was markedly high. Based on our results, we thought that fluorosis increases thyroid volume in children with fluorosis after puberty.			
Correspondence if required	None required			

Reviewer's notes	*when stratified by age, the total numbers of subjects (n=261; 298 respectively) is much smaller than the numbers for 'all participants' analysis (n=261; 298 respectively); no explanation given The two groups differed significantly in weight, height, body surface area & body mass index. Moreover, when stratified by age, the groups differed significantly in weight, height & body mass index.

Abbreviations: NA = not applicable; NR = not reported

LEVY ET AL. (2012)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Children (aged 5 – 19 years) in continental U.S.
1.2 Is the eligible population or area representative of the source population or area?	+	Participants identified through a public health information system. Some data missing from database but vast majority is present.
1.3 Do the selected participants or areas represent the eligible population or area?	++	No eligible children excluded from the sample
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	States categorised into two exposure groups based on proportion of population receiving community water fluoridation. No attempt to address the movement of children between states
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	NR	No discussion about participant movement between states with potentially different fluoridation policies
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	++	Similar public water fluoridation intervention. Similar healthcare system.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Osteosarcoma incidence derived from CDC database
3.2 Were the outcome measurements complete?	NR	Participant numbers not discussed
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	++	Poisson regression models
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Risk ratios, 95% confidence intervals and p-values reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Sample appears to be representative of national population, despite data missing from the database for some states over some time periods. No adjustment for confounding factors or assessment of participant movement between states.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Similar fluoride levels and health system.
Overall quality rating	Acceptable	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Levy et al. (2012)		
	Date form completed	30/01/15		
	Country of origin Source of funding Possible conflicts of interest	U.S. NR Declaration that they do not have any potential conflict of interests		
Study characteristics	Aim/objectives of study	To explore the hypotheses that the percentage of the population on public water systems receiving fluoridated water correlates with sex, age and state-specific rates of osteosarcoma incidence in continental U.S. and that young males are more at risk to osteosarcoma than females		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	U.S.		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Children in continental U.S.		
	Inclusion/exclusion criteria	Data from Hawaii was expressly excluded.		
	Recruitment procedures	Identification of participants from the U.S. Cancer Statistics available through the Centre for Disease Control and Prevention Wonder public health information system. NB: Incidence data missing for District of Columbia, 1999–2006; Maryland 2000–2001, 2004–2005; Mississippi 1999–2002; South Dakota 1999–2000; Tennessee 1999–2003; Virginia 1999–2002; and Wisconsin 1999–2006.		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	NR	NR	NR
	Age (range)	5 – 19 years	5 – 19 years	5 – 19 years
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting	Description of exposure and control	Continental U.S. states were dichotomised according to the percentage of the population receiving community water fluoridation: 'low' states were those where 30% or less of the population received fluoridated water between 1992 and 2006, 'high' states were those in which 85% or more of the population met the same criteria. State community water fluoridation (CWF) status from 1992–2006 was sourced from the National Oral Health Surveillance System, CDC.		
	Setting	Population-based study.		
Results: Osteosarcoma incidence rate	Definition Method of measurement	Number of new osteosarcoma cancer occurring during a year, expressed as the number of cancers per 100,000 population at risk. Cumulative incidence data of osteosarcoma was obtained for 1999-2006 from CDC national public health information system.		
	No. of participants analysed	NR		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Incidence rates compared between groups using Poisson regression models stratified by age, sex and community water fluoridation status		
	Participant category	High CWF states rate/1,000,000 (95%CI)	Low CWF states rate/1,000,000 (95%CI)	Risk ratio (95% CI)
	Males, aged 5 - 9	3.0 (2.3–3.9)	3.1 (2.2–4.1)	0.99 (0.67 – 1.45) *p*=0.95
	Males, aged 10 – 14	7.8 (6.7–9.1)	8.2 (6.8–9.8)	0.96 (0.76 – 1.21) *p*=0.70
	Males, aged 15 – 19	11.6 (10.2–13.1)	11.5 (9.8–13.4)	1.01 (0.83 – 1.23) *p*=0.93
	Females, aged 5 - 9	3.1 (2.4–4.0)	2.9 (2.1–4.0)	1.05 (0.71 – 1.65) *p*=0.81
	Females, aged 10 – 14	8.4 (7.2–9.7)	9.9 (8.3–11.7)	0.85 (0.68 – 1.06) *p*=0.15
	Females, aged 15 – 19	6.3 (5.3–7.5)	5.9 (4.6–7.3)	1.08 (0.82 – 1.43) *p*=0.60
Authors'	The findings are consistent with the hypothesis that community water fluoridation has no influence on the			

conclusion	development of osteosarcoma for either sex or age group during childhood or adolescence.
Correspondence if required	None required
Reviewer's notes	Additional analysis performed using data from the surveillance, epidemiology and end results (SEER) public-access database of the National Cancer Institute to test the hypothesis that young males are more at risk to osteosarcoma than females. The results of the analysis also provided no evidence that young males are at greater risk than females of the same age group to osteosarcoma from fluoride in drinking water.

Abbreviations: NR = not reported

LIU ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Adults (>40 years) residing in eight villages in Zhaozhou County in the Heilongjiang Province
1.2 Is the eligible population or area representative of the source population or area?	++	Participants identified after investigating basic information for all residents living in selected villages
1.3 Do the selected participants or areas represent the eligible population or area?	+	Exclusion for many pre-existing conditions where atherosclerosis is likely to be found e.g. stroke, coronary artery disease & diabetes, may introduce bias as not clear what group these individuals were in.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Study groups based on water fluoride in their drinking water
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies only.
2.3 Was the contamination acceptably low?	+	Participants had to be living at the same address for at least 10 years.
2.4 How well were likely confounding factors identified and controlled?	++	Attempt to control for confounding factors by restriction e.g. those with diabetes excluded. Other confounding factors measured e.g. smoking, BMI, blood pressure, blood lipids, and adjusted for in multivariate analysis
2.5 Is the setting applicable to the Australia?	-	Fluoride levels exceed that found in Australia. Dissimilar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Carotid ultrasound examinations. Description of procedure. Used published intima-media thickness cut-off for subclinical atherosclerosis.
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	At least 10 years
3.5 Was follow-up time meaningful?	+	Unclear if exposure was long enough to observe hypothesised effects
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	
4.2 Were multiple explanatory variables considered in the analyses?	++	Multivariable logistic regression performed
4.3 Were the analytical methods appropriate?	++	Chi-squared test and multivariable logistic regression
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	p-values reported for all analyses. Additionally, adjusted ORs and 95% CIs reported for multivariable logistic regression analysis.

Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Unclear on the representativeness of the study sample. People with coronary artery disease & stroke excluded.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Fluoride levels of comparator groups all above Australian concentrations.
Overall quality rating	Acceptable	High quality statistical analyses

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Liu et al. (2014)				
	Date form completed	20/01/15				
	Country of origin Source of funding Possible conflicts of interest	China National Natural Science Foundation of China and Heilongjiang Provincial Health Bureau Subject of China NR				
Study characteristics	Aim/objectives of study	Assess the dose-response association with various levels of chronic fluoride exposure in the atherosclerosis development and the possible role of fluoride in the progression of atherosclerosis in adults who live in the drinking water fluoride endemic areas.				
	Study design	Cross-sectional				
	Level of evidence	IV				
	Study location	China				
	Study duration	NR				
	Exposure duration	At least 10 years				
	Source population description	Adults (>40 years) residing in eight villages in Zhaozhou County in the Heilongjiang Province. Water supplies in these study villages were from shallow wells and tube wells equipped with hand pumps with high fluoride concentrations.				
	Inclusion/exclusion criteria	Living at the same address for at least 10 years. Excluded for a past history of diabetes, coronary heart disease, stroke, kidney disease, liver disease, respiratory disease, emaciation, or long-term use of drugs.				
	Recruitment procedures	Selection based on basic demographic information				
Participant characteristics		Whole study	Normal fluoride level	Mild fluoride level	Moderate fluoride level	Heavy fluoride level
	No. of participants enrolled	585	186	180	155	64
	Age (mean ± SD)	NR	54.3 ± 8.4	54.8 ± 8.4	56.0 ±9.7	56.9 ±10.2
	Male	43.4%	41.9%	46.7%	40.6%	45.3%
	BMI (mean ± SD)	NR	24.5 ± 3.4	24.7 ± 4.4	24.0 ± 4.3	24.3 ± 3.5
	Subgroups reported	NR	NR	NR	NR	NR
Exposure and setting		Normal	Mild	Moderate	Heavy	
	Description of exposure and control	≤1.20 ppm fluoride in their well drinking water	1.21 – 2.00 ppm fluoride in their well drinking water	2.01 – 3.00 ppm fluoride in their well drinking water	≥3.01 ppm fluoride in their well drinking water	
	Setting	Community based study. Adults grouped by fluoride level as measured by ion selective electrode. Cut-off points chosen according to the national monitoring program of drinking-water-borne endemic fluorosis.				
Results: Intima pathological changes	Definition Method of measurement	Intima-media thickness of carotid artery between 1.0mm and 1.5mm Measured by carotid ultrasound examination using B-mode ultrasonography scanning and a high-frequency imaging probe.				
	No. of participants analysed	585				
	No. of participants excluded or missing	0				
	Imputation of missing data	NA				
	Statistical method of analysis	Chi-squared test				
	Participant category	Intervention	Comparator	Effect estimate		

		n/n (%)	n/n (%)	χ2
	All participants	Mild: 29/180 (16.1%)	Normal: 15/186 (8.1%)	NR *p*=0.009
	All participants	Moderate: 23/155 (14.8%)	Normal: 15/186 (8.1%)	NR *p*=0.013
	All participants	Heavy: 8/64 (12.5%)	Normal: 15/186 (8.1%)	NR *p*=0.018
	All participants	Moderate: 23/155 (14.8%)	Mild: 29/180 (16.1%)	NR *p*=0.979
	All participants	Heavy: 8/64 (12.5%)	Mild: 29/180 (16.1%)	NR *p*=0.705
	All participants	Heavy: 8/64 (12.5%)	Moderate: 23/155 (14.8%)	NR *p*=0.697
Results: Carotid plaque	Definition Method of measurement	Intima-media thickness of carotid artery over 1.5mm Measured by carotid ultrasound examination using B-mode ultrasonography scanning and a high-frequency imaging probe.		
	No. of participants analysed	585		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Chi-squared test		
	Participant category	Intervention n/n (%)	Comparator n/n (%)	Effect estimate χ2
	All participants	Mild: 20/180 (11.1%)	Normal: 15/186 (8.1%)	NR *p*=0.009
	All participants	Moderate: 19/155 (12.3%)	Normal: 15/186 (8.1%)	NR *p*=0.013
	All participants	Heavy: 11/64 (17.2%)	Normal: 15/186 (8.1%)	NR *p*=0.018
	All participants	Moderate: 19/155 (12.3%)	Mild: 20/180 (11.1%)	NR *p*=0.979
	All participants	Heavy: 11/64 (17.2%)	Mild: 20/180 (11.1%)	NR *p*=0.705
	All participants	Heavy: 11/64 (17.2%)	Moderate: 19/155 (12.3%)	NR *p*=0.697
Results: Atherosclerosis	Definition Method of measurement	Participants with intima pathological changes or carotid plaque See above		
	No. of participants analysed	585		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Chi-squared test Multivariable logistic regression OR[a]: adjusted for sex and age OR[b]: adjusted for sex, age, systolic & diastolic blood pressure, total cholesterol, & high density lipoprotein-cholesterol		
	Participant category	Intervention n/n (%)	Comparator n/n (%)	Effect estimate χ2 OR (95% CI)
	All participants	Mild: 49/180 (27.2%)	Normal: 30/186 (16.1%)	χ2=NR *p*=0.009 OR[a]=1.91 (1.12 – 3.27) *p*<0.05 OR[b]=1.93 (1.11 – 3.35) *p*<0.05
	All participants	Moderate: 42/155 (27.1%)	Normal: 30/186 (16.1%)	χ2=NR *p*=0.013 OR[a]=1.89 (1.08 – 3.29) *p*<0.05 OR[b]=2.02 (1.13 – 3.60) *p*<0.05
	All participants	Heavy: 19/64 (29.7%)	Normal: 30/186 (16.1%)	χ2=NR *p*=0.018 OR[a]=2.11 (1.05 – 4.23) *p*<0.05 OR[b]=2.33 (1.12 – 4.82) *p*<0.05
	All participants	Moderate: 42/155 (27.1%)	Mild: 49/180 (27.2%)	χ2=NR *p*=0.979
	All participants	Heavy: 19/64 (29.7%)	Mild: 49/180 (27.2%)	χ2=NR *p*=0.705
	All participants	Heavy:	Moderate: 42/155	χ2=NR *p*=0.697

		19/64 (29.7%)	(27.1%)	
Authors' conclusion	A significant correlation between excess drinking water fluoride exposure and prevalence of carotid artery atherosclerosis in adults living in fluoride endemic areas was found.			
Correspondence if required	None required			
Reviewer's notes	None			

Abbreviations: NA = not applicable; NR = not reported

NAMKAEW ET AL. (2012)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Adults (>50 years) residing in San-Kamphaeng district, Chiang Mai, Thailand.
1.2 Is the eligible population or area representative of the source population or area?	+	Participants recruited from two sub-districts in Thailand, one with levels of fluoride of ≥0.7 mg/l, the other <0.7mg/l. Number of samples calculated proportionally to the total population of each village in the sub-districts by quota sampling Recruitment method not described
1.3 Do the selected participants or areas represent the eligible population or area?	+	Method of selection not described. Exclusion for a few pain confounding conditions only. Inclusion restricted to subjects ≥50 years. All individuals agreed to participate.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Reported that the groups had similar geographic, proportion of water sources, occupation and race characteristics but no measurement of said factors. Selection based on water samples taken from the individuals' possible sources of drinking water.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Evidence for hypothesis drawn from other published studies. High fluoride levels can cause skeletal fluorosis.
2.3 Was the contamination acceptably low?	++	No participant movement between sub-districts for at least 30 years
2.4 How well were likely confounding factors identified and controlled?	-	Family history of body pain and previous injury including in regression analyses. However other causes of pain not included.
2.5 Is the setting applicable to the Australia?	-	Naturally occurring fluoride in a country with a healthcare system dissimilar to Australia
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	Patient survey. Pain assessed using the Thai version of the 11-point Likert scale. Results aggregated into two groups: with/without pain. Intra-rater reliability for the pain evaluation tested with Cohen's kappa (0.932). Discussion of excluding known causes of chronic pain from medical records in limitations section but no information about how that was done or the method's accuracy.
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	+	No skeletal or other outcomes assessed by examination or x-ray
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	Inclusion criterion of living in the same sub-district for more than 30 years and never migrated to other places
3.5 Was follow-up time meaningful?	++	30 years exposure should have been long enough to observe hypothesised effects
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	Fluoride levels, family history, previous injury, location. No other diseases e.g. rheumatoid arthritis

4.3 Were the analytical methods appropriate?	+	Binary logistic regression to assess the association between average daily fluoride dose and body pain Chi-squared test for prevalence of body pain absent
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Adjusted OR and 95% CI reported for regression analysis.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	High risk of confounding and measurement bias. No assessment of the representativeness of the study sample. Other causes of chronic pain not considered.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Only applies to individuals 50 years old and older. Fluoride water levels not applicable to Australian context
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Namkaew et al. (2012)		
	Date form completed	21/01/15		
	Country of origin Source of funding Possible conflicts of interest	Thailand NR NR		
Study characteristics	Aim/objectives of study	To explore the relationship between level of exposure to fluoride-contaminated water and chronic pain in San Kamphaeng district, Chiang Mai, Thailand		
	Study design	Cross-sectional		
	Level of evidence	IV		
	Study location	Chiang Mai, Thailand		
	Study duration	January to March 2011		
	Exposure duration	At least 30 years		
	Source population description	Residents of Pookha or On-tai sub district of San Kamphaeng district, Chiang Mai, Thailand		
	Inclusion/exclusion criteria	Inclusion: 50 years or over, having lived in Pookha or On-tai sub-district for more than 30 years, never migrated to other places and able to communicate and understand the survey questions Exclusion: congenital abnormality, neurological disease, cancer with neuropathic pain and use of artificial aids for limbs		
	Recruitment procedures	Quota sampling		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	534	NR	NR
	Age (mean ± SD, range)	62 ± 9.1 years, 50 - 80	NR	NR
	Male	48.1%	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Exposure to drinking water where fluoride ≥0.7 ppm	Exposure to drinking water where fluoride was <0.7 ppm	
	Setting	Community based study. Intervention and comparator based on two geographical sites with differing levels of naturally occurring fluoride in drinking water.		
Results: Body pain	Definition Method of measurement	Presence of ‘Pain’ Assessed using the Thai version of the 11-point Likert scale. Pain classified into four levels (0-3) with 0 being no pain and 3 being severe pain. ‘Pain’ consisted of levels 1 to 3.		
	No. of participants analysed	534		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Binary logistic regression with model selection using a forward stepwise		

		technique Average daily fluoride dose as an independent variable dichotomised to ≤0.2 mg/kg/day and >0.2 mg/kg/day Odds ratio adjusted for family history of pain and history of injury to lower body		
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect estimate Adj. OR (95% CI)
	Lower back	191/274 (69.7%)	157/260 (60.4%)	1.58 (1.10 – 2.28)
	Knee	164/274 (59.9%)	157/260 (60.4%)	NR
	Leg	101/274 (36.9%)	97/260 (37.3%)	NR
Authors' conclusion	Chronic pain, especially lower back pain, is associated with average daily fluoride dose and location (high/low fluoride area).			
Correspondence if required	None required			
Reviewer's notes	It is important to note that the results apply to those 50 years and over with chronic lower back pain of no known origin. Dose-response was also assessed. Binary logistic regression analysis reported to show that low back pain was associated with an increased odds of a higher average daily fluoride dose (ADFD): adjusted OR=5.12 (95%CI: 1.59 – 16.98). Leg and knee pain were not associated with ADFD.			

Abbreviations: NA = not applicable; NR = not reported

NÄSMAN ET AL. (2013)

Quality Assessment

-	Section 1: Internal Validity	-
1.1	The study addresses an appropriate and clearly focused question.	Y
-	Selection of Subjects	-
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Y
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	NA
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	Y
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.	NA
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	NA
-	Assessment	-
1.7	The outcomes are clearly defined.	Y
1.8	The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable.	NA
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	NA
1.10	The method of assessment of exposure is reliable.	CA
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	NA
1.12	Exposure level or prognostic factor is assessed more than once.	N
-	Confounding	-
1.13	The main potential confounders are identified and taken into account in the design and analysis.	Y
-	Statistical Analysis	-
1.14	Have confidence intervals been provided?	Y
-	Section 2: Overall Assessment of the Study	-
2.1	How well was the study done to minimise the risk of bias or confounding?	Acceptable
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	Acceptable
2.3	Are the results of this study directly applicable to the patient group targeted in this guideline?	Acceptable

2.4	Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	No association between chronic fluoride exposure and the occurrence of hip fractures

Abbreviations: CA = can't answer; N = no; NA = not applicable; Y = yes

Data Extraction

General information	Study ID	Näsman et al. (2013)				
	Date form completed	14/01/2015				
	Country of origin Source of funding Possible conflicts of interest	Sweden Foundation Swedish Patent Revenue Fund grant Declaration of no potential conflicts of interest provided				
Study characteristics	Aim/objectives of study	To investigate possible adverse health effects from drinking water fluoride exposure on bone tissue				
	Study design	Retrospective cohort				
	Level of evidence	III-2				
	Study location	Sweden				
	Study duration	From registry inception (1964) to 31st December 2006				
	Exposure duration	Lifetime				
	Source population description	Individuals born between 1900-1919, alive and living in their municipality of birth at the time of start of follow-up				
	Inclusion/exclusion criteria	Exclusion for hip fracture before start of follow-up				
	Recruitment procedures	Identification in the Swedish Register of Population				
Participant characteristics		Whole study	Very low	Low	Medium	High
	No. of participants enrolled	473,277	250,222	134,554	54,312	13,736
	Age (median at study entry)	62.8 years	NR	NR	NR	NR
	Male	53.2%	52.0%	54.1%	55.2%	54.5%
	Median duration follow-up	16.7 years	NR	NR	NR	NR
	Number of hip fractures	60,773	NR	NR	NR	NR
	Number of 1st low-trauma hip fractures	50,923	NR	NR	NR	NR
	Median age 1st fracture	80.0	NR	NR	NR	NR
	Subgroups reported	NR	NR	NR	NR	NR
Exposure and setting	Description of exposure and control	Fluoride exposure was limited to the exposure from community water supplies. Four average lifetime exposure categories: very low (<0.3 ppm), low (0.3 - 0.69 ppm), medium (0.7 – 1.49 ppm) and high (≥1.5 ppm).				
	Setting	Community-based study. Average lifetime fluoride exposure estimated for each patient. Data from parish records matched to fluoride measurements in community water supplies. Fluoride measurements made yearly from 1960 to 1968 and every 5 years thereafter.				
Results: Hip fracture	Definition Method of measurement	Hip fracture as a failure event. Determined until December 31, 2006 from the Swedish National In-Patient Register and the Swedish Cause of Death Register by ICD code (ICD- 7 to -9 diagnoses starting with 820 and ICD-10 diagnoses S72.0-S72.2)				
	No. of participants analysed	473,277				
	No. of participants excluded or missing	Missing exposure data for 20,453 participants at one or more fluoride assessment time points.				
	Imputation of missing data	NR				
	Statistical method of analysis	Cox proportion hazards model adjusted for gender, age group, county of residence, calendar group				
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect Estimate HR (95% CI)		
	All participants	Low NR/134,554 (NR)	Very low NR/250,222 (NR)	0.97 (0.94 – 0.99)		
	All participants	Medium	Very low	0.97 (0.94 – 1.00)		

		NR/54,312 (NR)	NR/250,222 (NR)	
	All participants	High NR/13,736 (NR)	Very low NR/250,222 (NR)	0.98 (0.93 – 1.04)
Results: First low-trauma hip fractures	Definition Method of measurement	Low-trauma osteoporotic hip fracture as a failure event. Determined until December 31, 2006 from the Swedish National In-Patient Register and the Swedish Cause of Death Register by ICD code		
	No. of participants analysed	473,277		
	No. of participants excluded or missing	Missing exposure data for 20,453 participants at one or more fluoride assessment time points.		
	Imputation of missing data	NR		
	Statistical method of analysis	Cox proportion hazards model adjusted for gender, age group, county of residence, calendar group		
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect Estimate HR (95% CI)
	All patients	Low NR/134,554 (NR)	Very low NR/250,222 (NR)	0.95 (0.93 – 0.98)
	All patients	Medium NR/54,312 (NR)	Very low NR/250,222 (NR)	0.97 (0.93 – 1.00)
	All patients	High NR/13,736 (NR)	Very low NR/250,222 (NR)	1.00 (0.94 – 1.06)
Authors' conclusion	The authors found no association between chronic fluoride exposure and the occurrence of hip fracture. The risk estimates did not change in analyses restricted to only low-trauma osteoporotic hip fractures.			
Correspondence if required	None required			
Reviewer's notes	High energy trauma fractures were not included in any of the analyses.			

Abbreviations: NA = not applicable; NR = not reported

NATIONAL FLUORIDE INFORMATION SERVICE (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	New Zealand population
1.2 Is the eligible population or area representative of the source population or area?	NA	-
1.3 Do the selected participants or areas represent the eligible population or area?	NA	-
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Cases were allocated to exposure group if census area unit (recorded with diagnosis, age, & sex in Registry) had community water fluoridation. How that was determined not reported but likely to be accurate.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Fluoride is deposited in bone.
2.3 Was the contamination acceptably low?	NR	-
2.4 How well were likely confounding factors identified and controlled?	-	No other factors except sex & age recorded. Results were stratified by age and sex.
2.5 Is the setting applicable to the Australia?	++	Water fluoridation at similar levels and comparable health systems, and 'Western' world demographics.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Very likely as a legislative requirement to report cases of osteosarcoma to Registry. Also diagnosis requires histological confirmation.
3.2 Were the outcome measurements complete?	++	All cases have to be reported.

3.3 Were all the important outcomes assessed?	NA	Only interested in osteosarcoma.
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	Incident cases over a nine year period.
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	-	Only incidence over nine years reported. No analysis of the statistical significance of the difference between incidence rates.
4.6 Was the precision of association given or calculable? Is the association meaningful?	-	Only incidence calculated with no measure of precision.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	–	Only crude incidence rates and no analysis of the significance or controlling for confounding.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Likely to be generalisable to Australian context.
Overall quality rating	Low	No statistical analyses. Crude rates only.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	NFIS (2013)
	Date form completed	19/02/15
	Country of origin Source of funding Possible conflicts of interest	New Zealand New Zealand Ministry of Health NR
Study characteristics	Aim/objectives of study	Explore the possible association between community water fluoridation (CWF) and an increased risk of osteosarcoma
	Study design	Ecological
	Level of evidence	IV
	Study location	New Zealand
	Study duration	Uses data from NZ Cancer registry from 2000-2008
	Exposure duration	NR
	Source population description	Total population of New Zealand
	Inclusion/exclusion criteria	NA
	Recruitment procedures	All cases of osteosarcoma recorded in NZ Cancer Registry for the years 2000-2008. As it is compulsory that all pathology laboratories report on all cancers (other than non-melanoma skin cancers) and all new osteosarcoma cases require laboratory diagnosis, then all cases of osteosarcoma are recorded in the registry.
Participant characteristics		Whole study
	No. of participants enrolled	Total NZ population (number NR)
	Age (range)	0 - 65+ years
	Male	NR
	Other characteristics	NR
	Subgroups reported	NR
Exposure and setting	Description of exposure and control	Census area unit (recorded in the NZ cancer registry) of where a case lived at time of diagnosis determined exposure to community water fluoridation (CWF) or not
	Setting	Population-based study. Total population of New Zealand eligible with cases recruited from national cancer registry
Results: incidence of osteosarcoma	Definition Method of measurement	Incidence of osteosarcoma (per 1,000,000 people per year) Rates for each gender & age group were calculated using 2006 census estimates.

	No. of participants analysed		Total population of New Zealand	
	No. of participants excluded or missing		NR	
	Imputation of missing data		NA	
	Statistical method of analysis		None	
	Participant category		Community water fluoridation Incidence (n)	No Community water fluoridation Incidence (n)
	0-9 years	All	1.7 (5)	2.7 (6)
		Male	1.3 (2)	4.3 (5)
		Female	2.1 (3)	0.9 (1)
	10-19 years	All	10.4 (33)	11.1 (27)
		Male	10.6 (17)	12.7 (16)
		Female	10.2 (16)	9.3 (11)
	20-39 years	All	1.7 (11)	2.3 (9)
		Male	2.6 (8)	3.6 (7)
		Female	0.9 (3)	1.0 (2)
	40-64 years	All	2.5 (16)	0.9 (5)
		Male	2.3 (7)	1.8 (5)
		Female	2.8 (9)	0.0 (0)
	65+ years	All	1.7 (4)	4.8 (11)
		Male	4.0 (4)	6.6 (7)
		Female	0.0 (0)	3.2 (4)
Authors' conclusion	These rates indicate that there is no difference in the rates of osteosarcoma cases between areas with community water fluoridation and areas without community water fluoridation for both sexes.			
Correspondence if required	None required			
Reviewer's notes	Average cases per year also reported			

Abbreviations: NA = not applicable; NR = not reported

NEIDELL ET AL. (2010)

Quality Assessment

-	Section 1: Internal Validity	-
1.1	The study addresses an appropriate and clearly focused question.	Y
-	Selection of subjects	-
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Y
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	NR
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	NA
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.	NA
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	NA
-	Assessment	-
1.7	The outcomes are clearly defined.	Y
1.8	The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable.	NA
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	NA
1.10	The method of assessment of exposure is reliable.	Y
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	N
1.12	Exposure level or prognostic factor is assessed more than once.	N
-	Confounding	-
1.13	The main potential confounders are identified and taken into account in the design and	Y

	analysis.	
-	Statistical Analysis	-
1.14	Have confidence intervals been provided?	Y
-	Section 2: Overall Assessment of the Study	-
2.1	How well was the study done to minimise the risk of bias or confounding?	Acceptable
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	Acceptable
2.3	Are the results of this study directly applicable to the patient group targeted in this guideline?	Acceptable
2.4	Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	The study suggests that the benefits of community water fluoridation may be larger than previously believed.

Abbreviations: CA = can't answer; N = no; NA = not applicable; Y = yes

Data Extraction

General information	Study ID	Neidell et al. (2010)		
	Date form completed	14/01/2015		
	Country of origin Source of funding Possible conflicts of interest	U.S. Not clear – one author received a fellowship from the College of Dental Medicine NR		
Study characteristics	Aim/objectives of study	To estimate the association between community water fluoridation exposure at various stages of life and adult tooth loss		
	Study design	Retrospective cohort		
	Level of evidence	III-2		
	Study location	U.S.		
	Study duration	1995-1999		
	Exposure duration	Lifetime		
	Source population description	Individuals born between 1950-1969 living in the communities described in the 1992 Water Fluoridation Census		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	Identification in the BRFSS annual survey		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	92,701 tooth loss category observations	NA	NA
	Age	NR	NA	NA
	Male	NR	NA	NA
	Ethnicity	89.4% white	NA	NA
	Education	6.3% < high school degree 58.0% high school degree 35.7% college degree	NA	NA
Exposure and setting	Description of exposure and control	Water fluoridation status was assigned to participants using county-level community water fluoride values based on the 1992 Water Fluoridation Census complied by the CDC. Community water fluoride values applied to each county from the date fluoridation commenced. Fluoridation measured 3 times: current, 20 years ago, and at birth. Current fluoridation used data from the last year of the county fluoridation values. Fluoridation 20 years ago used values from 20 years before the Behavioral Risk Factor Surveillance System (BRFSS) survey. Fluoridation at birth used current county data from the year of the birth of the BRFSS respondent.		
	Setting	Community based study. Tooth loss observations matched to community water fluoride values. Participant's fluoride exposure within each county assumed to be equal and the proportion of the population served by each county's water system assumed to be fixed over time.		

Results: Tooth loss	Definition Method of measurement	Tooth loss (as a categorical variable) Categories (as defined in the BRFSS): 1: no tooth loss 2: 5 teeth or fewer 3: 6 teeth or more but not all 4: all teeth		
	No. of participants analysed	92,701 tooth loss category observations		
	No. of participants excluded or missing	NA		
	Imputation of missing data	NA		
	Statistical method of analysis	Interval regression with tooth loss as a dependent categorical variable		
	Participant category	Current CWF Coeff (SE)	CWF 20y ago Coeff (SE)	CWF at birth Coeff (SE)
	All participants	0.061 (0.123)	-0.083 (0.123)	-0.255 (0.066) $p<0.01$
	White	0.013 (0.114)	-0.007 (0.119)	-0.186 (0.075) $p<0.05$
	Black	0.118 (0.349)	-0.556 (0.341)	-0.372 (0.179) $p<0.05$
	<High-school degree	-0.113 (0.611)	-0.216 (0.584)	-0.609 (0.404)
	High-school degree	0.079 (0.151)	-0.052 (0.155)	-0.389 (0.086) $p<0.01$
	College degree	0.048 (0.107)	-0.073 (0.113)	-0.057 (0.060)
Authors' conclusion	Our results indicate that CWF levels in the county of residence at the time of the respondent's birth are significantly related to tooth loss but current CWF levels are not. In addition, the impact of CWF exposure is larger for individuals of lower socioeconomic status. The benefits of community water fluoridation may be larger than previously believed. Community water fluoridation may impart a lasting improvement in ethnic and economic disparities in oral health.			
Correspondence if required	Not required			
Reviewer's notes	Authors report alternative regression models. Alternative models modify the dependent variable from tooth loss category to imputed tooth loss, include current fluoridation only and/or use interval regression versus linear regression. The results abstracted here were deemed the most appropriate. All models exhibit similar results and conclusions.			

Abbreviations: NA = not applicable; NR = not reported

OSTOVAR ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	+	Villages from one Iranian province.
1.2 Is the eligible population or area representative of the source population or area?	+	All residents of 91 villages in Bushehr province, Iran. Recruitment method not described.
1.3 Do the selected participants or areas represent the eligible population or area?	NA	Whole population selected.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Fluoride concentration in drinking water of each village.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	-	Based on two poor quality ecological studies and unknown theoretical plausibility.
2.3 Was the contamination acceptably low?	NA	No intervention / comparator groups
2.4 How well were likely confounding factors identified and controlled?	-	No information collected.
2.5 Is the setting applicable to the Australia?	+	Fluoride concentrations are similar to Australia, however health system, cultural, economic, & lifestyle differences lessen applicability.
Section 3: Outcomes	-	-

3.1 Were the outcome measures and procedures reliable?	+	Number of people in each village and number with hypertension recorded in provincial health centre surveillance system. Not known how accurate this database is.
3.2 Were the outcome measurements complete?	NR	-
3.3 Were all the important outcomes assessed?	NR	-
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	No intervention / comparator groups
3.5 Was follow-up time meaningful?	NA	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	No power calculation.
4.2 Were multiple explanatory variables considered in the analyses?	-	No
4.3 Were the analytical methods appropriate?	+	Simple linear regression.
4.6 Was the precision of association given or calculable? Is the association meaningful?	-	p-value reported for Spearman's rho; unlikely to be meaningful – correlation only
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Not very strong correlation with unlikely direction of effect (prevalence of hypertension drops with increasing fluoride); multiple confounders not measured; very poor reporting of measurement of outcomes; cross-sectional
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Perhaps generalisable to Australian context
Overall quality rating	Low	No participant recruitment details, weak statistical analysis

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Ostovar et al. (2013)
	Date form completed	29/01/15
	Country of origin Source of funding Possible conflicts of interest	Iran NR None declared
Study characteristics	Aim/objectives of study	To examine the relationship between fluoride level of drinking water with the prevalence of hypertension.
	Study design	Ecological
	Level of evidence	IV
	Study location	Bushehr province, Iran
	Study duration	NR
	Exposure duration	NR
	Source population description	People living in 91 villages in Bushehr province, Iran.
	Inclusion/exclusion criteria	NR
	Recruitment procedures	NR
Participant characteristics		Whole study
	No. of participants enrolled	160,150
	Age	NR
	Male	50.4%
	Other characteristics	NR
	Subgroups reported	NR
Exposure and setting	Description of exposure and control	Fluoride concentration in the drinking water in each village was tested using the SPADNS method. Median (interquartile range) fluoride concentration = 0.8 (0.9) ppm Range (extrapolated from graph): 0.2 – 2.2 ppm
	Setting	Community study of all inhabitants of 91 villages in one province in Iran. Reported as being "almost similar in terms of cultural issues." Population of villages ranged from 21 to 12097.
Results: prevalence	Definition	Prevalence (%) = number patients with hypertension/total population (all

of hypertension in village	Method of measurement	ages) in each village. Range: 0.3% to 30.3% Information extracted from the provincial health centre surveillance system.
	No. of participants analysed	160,150 people from 91 villages
	No. of participants excluded or missing	NR
	Imputation of missing data	NR
	Statistical method of analysis	Weighted least squares linear regression analysis.
	Participant category	**Estimate of correlation**
	Overall	y = 1.435 – 0.416x Spearman's rho = -0.578, p<0.001
Authors' conclusion	There was a negative correlation between fluoride level in water and the risk of hypertension.	
Correspondence if required	None required.	
Reviewer's notes	Graph of prevalence of hypertension (±SEM) vs. fluoride concentration in paper.	

Abbreviations: NA = not applicable; NR = not reported

PUBLIC HEALTH ENGLAND (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Total population of England
1.2 Is the eligible population or area representative of the source population or area?	++	Eligible population fully represents the source population
1.3 Do the selected participants or areas represent the eligible population or area?	++	Sample fully represents the eligible population
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Standardised geographical areas of similar average population & households mapped to Drinking Water Directorate data on intentional fluoridation areas. Naturally fluoridated areas excluded.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Table of condition, indicator, and rationale for inclusion reported.
2.3 Was the contamination acceptably low?	+	Unclear -depends on how great and in what direction groups within the population move between exposed and non-exposed areas.
2.4 How well were likely confounding factors identified and controlled?	++	Data on age, gender, deprivation, and ethnicity taken from census data. Adjusted incidence rate ratios calculated.
2.5 Is the setting applicable to the Australia?	++	Yes – fluoride levels similar and can also assume some sociocultural similarities.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Most likely – all data sourced from various national databases
3.2 Were the outcome measurements complete?	++	Most likely as most outcomes would be required to be reported to the various databases e.g. cancer, deaths. Perhaps only kidney stones may be under-counted as information only from emergency admission.
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	All identical within each outcome
3.5 Was follow-up time meaningful?	+	Follow-up times varied between 3 to 15 years. Longest was for osteosarcoma which took into account lag period of at least 10

		years after introduction of the majority of the fluoridation.
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	++	Large sample size
4.2 Were multiple explanatory variables considered in the analyses?	+	Yes, multivariate analyses conducted
4.3 Were the analytical methods appropriate?	+	All analyses appear to be appropriate
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	Confidence intervals reported for all analyses, p-values reported for some analyses.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Comprehensive nationwide data from governmental sources (Hospital Episode Statistics, Office of National Statistics, English Cancer Registration Service, Drinking Water Directorate etc.) which was analysed appropriately.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	++	Similar fluoride levels and sociodemographic characteristics to Australia
Overall quality rating	Acceptable	Analyses well controlled for confounding factors. Use of national registries allows for very large sample size.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	PHE (2014)		
	Date form completed	20/02/15		
	Country of origin Source of funding Possible conflicts of interest	United Kingdom Department of Health, UK NR		
Study characteristics	Aim/objectives of study	To monitor the effect of water fluoridation schemes on the health of people living in the areas covered.		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	England		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Total population of England		
	Inclusion/exclusion criteria	Exclusion criteria: Lower super output areas (LSOAs*) located in water quality zones (WQZs) classified as naturally fluoridated Ages 25 to 49 years excluded from osteosarcoma analysis *these are standardised geographic areas with an average of roughly 1,500 residents and 650 households		
	Recruitment procedures	Data extracted from various sources – see individual outcome tables below for details		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	Various – see individual outcome tables below for details		
	Age	NR	NR	NR
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Areas (LSOAs) with community water fluoridation	Areas (LSOAs) without community water fluoridation	
		Water quality zones (WQZs) from the Drinking Water Inspectorate were mapped onto each 2001 LSOA and assigned a fluoridation status – yes/no; LSOAs located in WQZs with natural fluoride levels up to 1ppm were given a separate classification.		

	Setting	Population-based study with unit of exposure at an area level.		
Results: Hip fractures	Definition Method of measurement	Number of hip fracture in-patient consultant episodes (per 100,000 person-years at risk (pyar)) Hospital Episode Statistics: admissions between Apr 2007 – Mar 2013; coded as S72.0; S72.1; S72.2; 1st or 2nd diagnosis; emergency admission Office of National Statistics: population age, gender, & ethnicity proportions		
	No. of participants analysed	312,856,448		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Ecological analysis at area level for crude rates Adjusted rate calculated by constructing multivariate models using a reverse step-wise procedure		
	Participant category	Intervention n/N; crude rate per 100,000 pyar	Comparator n/N; crude rate per 100,000 pyar	Effect estimate Incidence rate ratio (%) (95% CI)
	All patients (crude rate)	45,219/37,971,918; 119	303,848/274,884,530; 111	7.2 (4.9, 9.6); *p*<0.001
	All patients (adjusted for age, gender, deprivation)	-	-	0.9 (-0.8, 2.6); *p*=0.29; (32,424 cases with adjustment data available)
	All patients (adjusted for age, gender, deprivation, ethnicity)	-	-	0.7 (-1.0, 2.4); *p*=0.42; (31,619 cases with adjustment data available)
Results: Kidney stones	Definition Method of measurement	Number of kidney stone in-patient consultant episodes (per 100,000 person-years at risk (pyar)) Hospital Episode Statistics: admissions between Apr 2007 – Mar 2013; coded as N20.0; N20.1; N20.2; N20.9; 1st or 2nd diagnosis; emergency admission Office of National Statistics: population age, gender, & ethnicity proportions		
	No. of participants analysed	312,856,448		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Ecological analysis at area level for crude rates Adjusted rate calculated by constructing multivariate models using a reverse step-wise procedure		
	Participant category	Intervention n/N; crude rate per 100,000 pyar	Comparator n/N; crude rate per 100,000 pyar	Effect estimate Incidence rate ratio (%) (95% CI)
	All patients (crude rate)	18,579/37,971,918; 48.9	141,963/274,884,530; 51.6	-5.3 (-7.1, -3.5); p<0.001
	All patients (adjusted for age, gender, deprivation)	-	-	-8.4 (-10,-6.7); p<0.001; (32,424 cases with adjustment data available)
	All patients (adjusted for age, gender, deprivation, ethnicity)	-	-	-7.9 (-9.6, -6.2); p<0.001; (31,619 cases with adjustment data available)
Results: All-cause mortality	Definition Method of measurement	Mortality for Jan 2009 to Jan 2012 (per 1000,000 person-years at risk(pyar)) Office of National Statistics: deaths, and population age, gender, & ethnicity proportions		
	No. of participants analysed	208,570,962		

	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Ecological analysis at area level for crude rates Adjusted rate calculated by constructing multivariate models using a reverse step-wise procedure		
	Participant category	Intervention n/N; crude rate per 100,000 pyar	Comparator n/N; crude rate per 100,000 pyar	Effect estimate Incidence rate ratio (%) (95% CI)
	All patients (crude rate)	233,922/25,314,612; 924	1,602,206/183,256,350; 874	5.2 (3.4, 7.0); *p*<0.001
	All patients (adjusted for age, gender, deprivation)	-	-	-1.4 (-2.6, -0.3); *p*=0.02; (32,424 cases with adjustment data available)
	All patients (adjusted for age, gender, deprivation, ethnicity)	-	-	-1.3 (-2.5, -0.1); *p*=0.04; (31,619 cases with adjustment data available)
Results: Down's syndrome	Definition Method of measurement	Cases of Down's syndrome for 2009 – 2012 inclusive (per 10,000 live births) National Down Syndrome Cytogenetic Register: number of confirmed cases of Down's including live births, still births, late miscarriages, & terminations of pregnancy with fetal anomaly Office of National Statistics: live births by individual year of maternal age by area		
	No. of participants analysed	2,727,300		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Poisson regression model		
	Participant category	Intervention n/N; prevalence per 10,000 live births (95% CI)	Comparator n/N; prevalence per 10,000 live births (95%CI)	Effect estimate Incidence rate ratio (%) (95% CI)
	All patients (crude rate)	658/303,818; 21.7 (20.0, 23.4)	5,961/2,423,482; 24.6 (24.0, 25.2)	-12 (-19, -4); *p*<0.01
	All patients (adjusted for maternal age)	-	-	2 (-6, 10); *p*=0.68
Results: Bladder cancer	Definition Method of measurement	All primary invasive bladder cancer recorded in cancer registries with date of diagnosis between 2000 & 2010 inclusive; ICD-10 code C67 National Cancer Registration Service: cases of primary bladder cancer Office of National Statistics: population age, gender, & ethnicity proportions		
	No. of participants analysed	555,127,448		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Ecological analysis at area level for crude rates Direct standardisation to the European standard population structure Univariate and multivariate models to calculate adjusted rate ratio		
	Participant category	Intervention n/N; age standardised rate per 100,000 pyar (95% CI)	Comparator n/N; age standardised rate per 100,000 pyar (95% CI)	Effect estimate Incidence rate ratio (%) (95% CI)
	All patients (crude rate)	11,327/67,978,298; 12.4 (12.2, 12.6)	84,780/487,149,150; 13.0 (12.9, 13.1)	-4.4 (-6.7,-2.1); *p*<0.001

	All patients (adjusted for age, gender, deprivation)	-	-	-8.6 (-11, -6.7); *p*<0.001
	All patients (adjusted for age, gender, deprivation, ethnicity)	-	-	-8.0 (-9.9, -6.0); *p*<0.001
Results: Osteosarcoma	Definition Method of measurement	All cases of osteosarcoma in England recorded in cancer registries with date of diagnosis between 1995 & 2010; ICD codes 9180 to 9195, suffix 3 National Cancer Registration Service Office of National Statistics for population age, gender, & ethnicity proportions		
	No. of participants analysed	248,234,551		
	No. of participants excluded or missing	NR (NB: Ages 25 to 49 years excluded)		
	Imputation of missing data	NR		
	Statistical method of analysis	Ecological analysis at area level for crude rates Direct standardisation to the European standard population structure Univariate and multivariate models to calculate adjusted rate ratio		
	Participant category	Intervention n/N; age standardised rate per 100,000 pyar (95% CI)	Comparator n/N; age standardised rate per 100,000 pyar (95% CI)	Effect estimate Incidence rate ratio (%) (95% CI)
	<25 years (crude rate)	148/31,313,151; 0.45 (0.38, 0.52)	949/216,921,400; 0.42 (0.40, 0.45)	8.0 (-9.3, 29); *p*=0.39
	<25 years (adjusted for age, gender, deprivation)	-	-	6.6 (-11, 27); *p*=0.48
	<25 years (adjusted for age, gender, deprivation, ethnicity)	-	-	8.2 (-9.3, 29); *p*=0.38
	<25 years – male (crude rate)	92/15,981,438; 0.55 (0.45, 0.68)	540 /110,831,320; 0.47 (0.43, 0.51)	18 (-5.4, 48); *p*=0.14
	<25 years - male (adjusted for age, gender, deprivation)	-	-	16 (-11, 27); *p*=0.20
	<25 years - male (adjusted for age, gender, deprivation, ethnicity)	-	-	17 (-7.1, 46); *p*=0.19
	<25 years – female (crude rate)	56/15,331,713; 0.35 (0.26, 0.46)	409/106,090,080; 0.37 (0.34, 0.41)	-5.3 (-29, 26); *p*=0.70
	<25 years - female (adjusted for age, gender, deprivation)	-	-	-4.7 (-28, 27); *p*=0.74
	<25 years - female (adjusted for age, gender, deprivation, ethnicity)	-	-	-2.5 (-27, 30); *p*=0.86
	≥50 years (crude rate)	73/33,080,465; 0.20 (0.15, 0.25)	587/232,282,090; 0.23 (0.21, 0.25)	-12 (-31, 13); *p*=0.32
	≥50 years (adjusted for age, gender, deprivation)	-	-	-10 (-30, 15); *p*=0.38
	≥50 years	-	-	-15 (-34, 9.6); *p*=0.21

	(adjusted for age, gender, deprivation, ethnicity)			
Results: All cancer	Definition Method of measurement	All cases of cancers in England (excluding non-melanoma skin cancer) recorded in cancer registries with date of diagnosis between 2007 & 2010; ICD codes C00 to C97, excluding C44 National Cancer Registration Service Office of National Statistics for population age, gender, & ethnicity proportions		
	No. of participants analysed	208,770,962		
	No. of participants excluded or missing	NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Ecological analysis at area level for crude rates Direct standardisation to the European standard population structure Univariate and multivariate models to calculate adjusted rate ratio		
	Participant category	Intervention n/N; age standardised rate per 100,000 pyar (95% CI)	Comparator n/N; age standardised rate per 100,000 pyar (95% CI)	Effect estimate Incidence rate ratio (95% CI)
	All patients (crude rate)	131,288 /25,314,612; 402 (399, 404)	921,583/183,256,350; 396 (395, 397)	2.7 (1.4, 4.0); *p*<0.001
	All patients (adjusted for age, gender, deprivation)	-	-	-1.1 (-1.9, -0.3); *p*<0.01
	All patients (adjusted for age, gender, deprivation, ethnicity)	-	-	-0.4 (-1.2, 0.4); *p*=0.29
Authors' conclusion	Hip fractures: There was no evidence of a difference in the rate of hip fractures between fluoridated and non-fluoridated areas. Kidney stones: There was evidence that the rate of kidney stones was lower in fluoridated areas than non-fluoridated areas. All-cause mortality: While there was some evidence that the rate of deaths from all recorded causes was lower in fluoridated areas than non-fluoridated areas, the size of the effect was small. Down's syndrome: There was no evidence of a difference in the rate of Down's syndrome in fluoridated and non-fluoridated areas. Bladder cancer: There was evidence that the rate of bladder cancer was lower in fluoridated areas than non-fluoridated areas. Osteosarcoma among under 25-year olds: There was no evidence of a difference in the rate of osteosarcoma between fluoridated and non-fluoridated areas. Osteosarcoma among people aged 50 and over: There was no evidence of a difference in the rate of osteosarcoma between fluoridated and non-fluoridated areas. All cancer: There was no evidence of a difference in the rate for all types of cancer between fluoridated and non-fluoridated areas.			
Correspondence if required	None required			
Reviewer's notes	This was also published in the Community Dentistry and Oral Epidemiology journal in 2015 (Young et al 2015). This report also considers levels of dental caries and dental fluorosis in fluoridated and non-fluoridated areas.			

Abbreviations: NR = not reported

RANJAN & YASMIN (2012)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well	+	Undefined children and adults in villages of the Gaya district,

described?		Bahir, India
1.2 Is the eligible population or area representative of the source population or area?	NR	-
1.3 Do the selected participants or areas represent the eligible population or area?	NR	-
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Exposure groups based on fluoride concentrations in the groundwater
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	NR	No discussion of patient migration
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	-	Poorly described questionnaire
3.2 Were the outcome measurements complete?	++	Results reported for all participants
3.3 Were all the important outcomes assessed?	-	Baseline characteristics not captured
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	-	No analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	-	No precision of association given
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	No participant details. Weak outcome capture methods. No statistical analysis
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Dissimilar healthcare system & demographic factors.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Ranjan et al. (2012)
	Date form completed	06/02/15
	Country of origin Source of funding Possible conflicts of interest	India University Grants Commission (India) NR
Study characteristics	Aim/objectives of study	To report on the groundwater quality of certain regions of Gaya district, with special emphasis on fluoride contamination and its impact on human health
	Study design	Ecological
	Level of evidence	IV
	Study location	Bihar, India
	Study duration	NR
	Exposure duration	NR
	Source population description	Inhabitants of 31 villages of Bodh Gaya, Manpir, Wazirganj, Belaganj, Amas and Bankebazar blocks in Gaya district of Bihar in India
	Inclusion/exclusion criteria	NR

	Recruitment procedures	NR			
Participant characteristics		Whole study	<0.4 ppm	0.4 – 1.5 ppm	**≥1.5 ppm**
	No. of participants enrolled	2,732	418	1,664	650
	Age	NR	NR	NR	NR
	Male	NR	NR	NR	NR
	Other characteristics	NR	NR	NR	NR
	Subgroups reported	NR	NR	NR	NR
Exposure and setting	Description of exposure and control	Exposed to naturally occurring fluoride in village groundwater. Villages categorised by fluoride level into <0.4 ppm, 0.4 - 1.5 ppm and ≥1.5 ppm. Results pooled within each category.			
	Setting	Population-based study			
Results: Joint pain	Definition Method of measurement	NR Health survey			
	No. of participants analysed	2,732			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	None			
	Participant category	<0.4 ppm n/N (%)	0.4 – 1.5 ppm n/N (%)	**≥1.5 ppm** n/N (%)	Effect estimate
	Adult males	18/174 (10.3%)	23/684 (3.4%)	141/272 (51.8%)	NR
	Adult females	44/165 (26.7%)	183/685 (26.7%)	151/264 (57.2%)	NR
	Children	0/79 (0.0%)	0/295 (0.0%)	61/114 (53.5%)	NR
	All	62/418 (14.8%)	206/1664 (12.4%)	353/650 (54.3%)	NR
Results: Gastrointestinal problems	Definition Method of measurement	NR Health survey			
	No. of participants analysed	2,732			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	None			
	Participant category	<0.4 ppm n/N (%)	0.4 – 1.5 ppm n/N (%)	**≥1.5 ppm** n/N (%)	Effect estimate
	Adult males	32/174 (18.4%)	165/684 (24.1%)	110/272 (40.4%)	NR
	Adult females	28/165 (17.0%)	165/685 (24.1%)	110/264 (41.7%)	NR
	Children	38/79 (48.1%)	57/295 (19.3%)	58/114 (50.9%)	NR
	All	98/418 (23.4%)	387/1664 (23.3%)	278/650 (42.8%)	NR
Results: Headache	Definition Method of measurement	NR Health survey			
	No. of participants analysed	2,732			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	None			
	Participant category	<0.4 ppm n/N (%)	0.4 – 1.5 ppm n/N (%)	**≥1.5 ppm** n/N (%)	Effect estimate
	Adult males	10/174 (5.7%)	71/684 (10.4%)	72/272 (26.5%)	NR
	Adult females	21/165 (12.7%)	99/685 (14.5%)	72/264 (27.3%)	NR
	Children	7/79 (8.9%)	7/295 (2.4%)	18/114 (15.8%)	NR
	All	38/418 (9.1%)	177/1664 (10.6)	162/650 (24.9%)	NR
Results: Insomnia	Definition Method of measurement	NR Health survey			
	No. of participants analysed	2,732			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			

	Statistical method of analysis	None			
	Participant category	<0.4 ppm n/N (%)	0.4 – 1.5 ppm n/N (%)	**≥1.5 ppm** n/N (%)	Effect estimate
	Adult males	0/174 (0.0%)	28/684 (4.1%)	38/272 (14.0%)	NR
	Adult females	8/165 (4.8%)	59/169 (8.6%)	36/264 (13.6%)	NR
	Children	0/79 (0.0%)	0/295 (0.0%)	0/114 (0.0%)	NR
		8/418 (1.9%)	87/1664 (5.2%)	74/650 (11.4%)	NR
Authors' conclusion	None relating to health effects of fluoride				
Correspondence if required	None required				
Reviewer's notes	There are a number of errors of addition in Table 3 of the article reporting the health effects of fluoride. The values presented here for the number of participants has been independently calculated.				

Abbreviations: NA = not applicable; NR = not reported

ROCHA-AMADOR ET AL. (2007)

Quality Assessment

Issue	Rating	Comment
Section 1: population	-	-
1.1 Is the source population or source area well described?	++	Children (aged 6-10 years old) attending grades 1-3 in public schools in three rural areas
1.2 Is the eligible population or area representative of the source population or area?	++	All children were screened for eligibility, the three selected communities were similar in general demographic characteristics
1.3 Do the selected participants or areas represent the eligible population or area?	++	Random selection of eligible children with 85% response rate. No significant difference in age, gender proportion, or time of residence was observed between study participants and non-participants. Inclusion criteria reported.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	++	Tap water and bottled water (where available) samples were collected in polyethylene bottles at each child's home the same day of biological monitoring and fluoride level was measured.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	++	Lifetime village residents
2.4 How well were likely confounding factors identified and controlled?	+	Some confounding factors adjusted for in regression analysis
2.5 Is the setting applicable to the Australia?	-	Very high fluoride levels, healthcare system dissimilar to Australia's
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Intelligence assessed using the Wechsler Intelligence Scale for Children Revised Mexican Version by a trained neuropsychologist masked to participants fluoride levels
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	All included children had lived in the area since birth
3.5 Was follow-up time meaningful?	++	Lifetime exposure was long enough to observe hypothesised effects
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	++	Urinary and water fluoride and arsenic
4.3 Were the analytical methods appropriate?	++	Multivariable regression analysis

4.6 Was the precision of association given or calculable? Is the association meaningful?	+	p-values reported for significant variables in multivariable analysis. Magnitude of effect unclear from the reporting of regression coefficients on the logarithm scale.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	++	Analyses adjusted well for confounding factors, selection bias appears to be low.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Fluoride levels much higher than in the Australian context. Sociocultural differences very likely.
Overall quality rating	Acceptable	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Rocha-Amador et al. (2007)			
	Date form completed	23/01/2015			
	Country of origin Source of funding Possible conflicts of interest	Mexico Consejo Nacional de Ciencia y Tecnología NR			
Study characteristics	Aim/objectives of study	To explore the association between exposure to fluoride and arsenic in drinking water and intelligence in children			
	Study design	Cross-sectional			
	Level of evidence	IV			
	Study location	Mexico			
	Study duration	NR			
	Exposure duration	Lifetime			
	Source population description	All children attending grades 1-3 in public schools in three rural areas in Mexico (n=480)			
	Inclusion/exclusion criteria	6-10 years old who had lived in the same area since birth			
	Recruitment procedures	Random selection of all eligible children, as determined by in-person interviews			
Participant characteristics		Whole study	Low	Medium	High
	No. of participants enrolled	132	52	20	60
	Age (mean ± SD)	NR	8.3 ± 1.1 years	7.7 ± 1.0 years	8.3 ± 1.1 years
	Male	NR	54%	50%	48%
	SES	NR	7.0 ± 1.3	6.3 ± 0.9	5.9 ± 1.4
	Water arsenic (mean ± SD)	NR	5.8 ± 1.3 µg/L	169 ± 0.9 µg/L	194 ± 1.3 µg/L
	Subgroups reported	NR	NR	NR	NR
Exposure and setting		Low	Medium	High	
	Description of exposure and control	Exposure to naturally occurring fluoride level in Moctezuma (mean ± SD: 0.8 ± 1.4 ppm)	Exposure to naturally occurring fluoride level in Salitral (mean ± SD: 5.3 ± 0.9 ppm)	Exposure to naturally occurring fluoride level in 5 de Febrero (mean ± SD: 9.4 ± 0.9 ppm)	
	Setting	School-based study. Participants from grades 1-3 in public schools in three rural areas.			
Results: Performance IQ	Definition Method of measurement	Intelligent Quotient Assessed using the Wechsler Intelligence Scale for Children Revised Mexican Version			
	No. of participants analysed	132			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	Multivariable regression model adjusted for Pb blood, mother's education, socioeconomic status, height-for-age z-score and transferrin saturation			
	Participant category	Intervention Log Coefficient on F	Comparator	Effect estimate	
	All participants	-6.7	NA	*p*<0.001	
Results: Verbal IQ	Definition	Intelligent Quotient			

	Method of measurement	Assessed using the Wechsler Intelligence Scale for Children Revised Mexican Version		
	No. of participants analysed	132		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Multivariable regression model adjusted for Pb blood, mother's education, socioeconomic status, height-for-age z-score and transferrin saturation		
	Participant category	Intervention Log Coefficient on F	Comparator	Effect estimate
	All participants	-11.2	NA	*p*<0.001
Results: Full IQ	Definition Method of measurement	Intelligent Quotient Assessed using the Wechsler Intelligence Scale for Children Revised Mexican Version		
	No. of participants analysed	132		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Multivariable regression model adjusted for Pb blood, mother's education, socioeconomic status, height-for-age z-score and transferrin saturation		
	Participant category	Intervention Log Coefficient on F	Comparator	Effect estimate
	All participants	-10.2	NA	*p*<0.001
Authors' conclusion	The data from this research support the conclusion that fluoride and arsenic in drinking water have a potential neurotoxic effect in children.			
Correspondence if required	None required			
Reviewer's notes	Results for arsenic not extracted			

Abbreviations: NA = not applicable; NR = not reported

SAXENA ET AL. (2012)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	School children (aged 12 years) in Madhya Pradesh state, India
1.2 Is the eligible population or area representative of the source population or area?	+	Participants identified through government schools and were in the fifth or sixth grade
1.3 Do the selected participants or areas represent the eligible population or area?	+	The selected villages were reported to be similar in population and general demographic characteristics but no objective data. Proportion of children refusing to participate not reported.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Participants were selected by stratified cluster sampling of areas, according to fluoride concentration in the groundwater. Other sources of fluoride not considered.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	++	Lifetime village residents
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Comparable fluoride concentrations in one group but others much higher. Dissimilar healthcare system.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures	-	Intelligence measured using Raven's Standard Progressive

reliable?		Matrices however no mention of reliability. Validity of conversion of Raven's score to "IQ grade" not reported
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	+	Children were excluded if they were not lifelong residents of the area or had a change in water supply since birth. Recall bias possible.
3.5 Was follow-up time meaningful?	++	Exposure was long enough to observe hypothesised effects
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	+	Sample size calculation was performed based on the results of a pilot study but not reported
4.2 Were multiple explanatory variables considered in the analyses?	+	Regressions of intelligence grade on urinary and water fluoride however no adjustment for potentially confounding factors
4.3 Were the analytical methods appropriate?	+	Chi-squared test for distributions of baseline characteristics. ANOVA for intelligence grades, levels of fluoride, lead and arsenic Simple linear regressions with intelligence grade as dependent variable.
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	Test statistics and associated p-values reported for all analyses. Unclear if association meaningful.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	High risk of measurement bias. No adjustment for confounding factors. Unclear if the sample population is representative of the source population.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Comparison fluoride levels above that seen in Australia. Sociocultural factors are very different too.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Saxena et al. (2012)				
	Date form completed	22/01/15				
	Country of origin Source of funding Possible conflicts of interest	India NR NR				
Study characteristics	Aim/objectives of study	To assess the relationship between exposure to different drinking water fluoride levels and children's intelligence in Madhya Pradesh state, India				
	Study design	Cross-sectional				
	Level of evidence	IV				
	Study location	Madhya Pradesh state, India				
	Study duration	NR				
	Exposure duration	Lifetime (12 years)				
	Source population description	12-year old school children from either villages in Karera Block, Shivpuri district or Parvaliya village, Bhopal district in Madhya Pradesh state, India				
	Inclusion/exclusion criteria	Exclusion for not being lifelong residents of that area, having a change in water source since birth, or a history of congenital or acquired neurological disease and/or head injury				
	Recruitment procedures	Stratified cluster sampling of areas according to the fluoride concentration in the groundwater based on the geological survey report of the Government of India				
Participant characteristics		Whole study	<1.5 ppm	1.5–3.0 ppm	3.1–4.5 ppm	>4.5 ppm
	No. of participants enrolled	170	50	39	43	38
	Age	12 years	12 years	12 years	12 years	12 years
	Male	NR	54.0%	51.3%	48.8%	52.6%
	Socioeconomic status (mean ± SD)	NR	2.28 ± 0.70	2.31 ± 0.73	2.35 ± 0.69	2.39 ± 0.68

	Education of head of family (mean ± SD)	NR	7.14 ± 4.13 years	7.31 ± 3.95 years	7.40 ± 4.30 years	6.71 ± 3.12 years
	Height/age (mean ± SD)	NR	2.26 ± 0.88	2.41 ± 0.82	2.35 ± 0.92	2.24 ± 0.85
	Weight/height (mean ± SD)	NR	2.30 ± 0.86	2.08 ± 0.84	2.35 ± 0.87	2.32 ± 0.90
	Subgroups reported	NR	NR	NR	NR	NR
Exposure and setting	Description of exposure and control	Exposure to natural levels of fluoride present in drinking water. Participants categorised by fluoride level into 4 groups. Fluoride levels analysed by a fluoride ion selective electrode.				
	Setting	School-based study. Selected children were from government schools and were in the fifth or sixth grade.				
Results: Intelligence grade	Definition Method of measurement	Mean intelligence grade (higher grade = lower IQ) IQ measured using the Raven's Standard Progressive Matrices. IQ scores converted to grades: I: intellectually superior (score ≥ 95th percentile) II: definitely above average (75th percentile ≤ score < 95th percentile) III: intellectually average (25th percentile ≤ score < 75th percentile) IV: definitely below average (5th percentile ≤ score < 25th percentile) V: intellectually impaired (score ≤ 5th percentile)				
	No. of participants analysed	170				
	No. of participants excluded or missing	0				
	Imputation of missing data	NA				
	Statistical method of analysis	ANOVA Linear regression with intelligence grade as the dependent variable				
	Participant category	<1.5 ppm mean	1.5–3.0 ppm mean	3.1–4.5 ppm mean	>4.5 ppm mean	Effect estimate
	All participants	3.16	3.85	4.23	4.45	$p < 0.001$ both tests
	Simple linear regression	R=0.534, R2=0.286, ANOVA=67.14, $p < 0.001$				
	Stepwise multiple linear regression	The only significant independent variable was urinary fluoride (R=0.542; R2=0.294; ANOVA 69.944; $p < 0.001$)				
Authors' conclusion	The data supports the conclusion that children exposed to fluoride are at risk for impaired intelligence development.					
Correspondence if required	None required					
Reviewer's notes	The validity of converting the scores for the Raven's test into "intelligence grade" and then using an ANOVA to compare the average scores is unclear. Simple linear regression with intelligence grade as the dependent variable and water fluoride concentration as the independent variable					

Abbreviations: ANOVA = analysis of variance; NA = not applicable; NR = not reported

SCHWARTZ ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Data from North American Association of Central Cancer Registries (all ages, from 2006-2010).
1.2 Is the eligible population or area representative of the source population or area?	NA	-
1.3 Do the selected participants or areas represent the eligible population or area?	+	Study population was limited to non-Hispanic whites only. Data from 6 states was not available. Washington DC met exclusion criteria (cases <10).
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison)	++	Used data on fluoridation from the CDC (model reported to be

group. How was selection bias minimised?		validated).
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Based on plausible hypothesis
2.3 Was the contamination acceptably low?	NA	No intervention / comparator groups.
2.4 How well were likely confounding factors identified and controlled?	++	Also looks at correlation between incidence rates and: latitude, longitude, population density, ophthalmologist density.
2.5 Is the setting applicable to the Australia?	+	Unclear what the fluoridation levels were in the study (NR) but setting somewhat similar to Australian.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Outcome data obtained from North American Association of Central Cancer Registries.
3.2 Were the outcome measurements complete?	++	Likely that all cases identified.
3.3 Were all the important outcomes assessed?	++	Yes
3.4 Was there a similar follow-up time in exposure and comparison groups?	NA	No intervention / comparator groups
3.5 Was follow-up time meaningful?	NA	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NA	Sample sizes and powering issues not discussed, however, this is explicitly identified as a hypothesis generating study.
4.2 Were multiple explanatory variables considered in the analyses?	++	Yes
4.3 Were the analytical methods appropriate?	++	Yes
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	Only a range of age-adjusted incidence rates reported (lowest and highest values; CIs provided). Individual state data not reported (except in a figure).
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Good data collection. Appropriate analysis with exploration of potential confounders. Sensitivity analysis done.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	+	Likely generalisable to Australian context. Study limited to non-Hispanic whites only.
Overall quality rating	Acceptable	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Schwartz et al. (2014)
	Date form completed	28/01/15
	Country of origin Source of funding Possible conflicts of interest	United States NR “No potential conflicts of interest were disclosed”
Study characteristics	Aim/objectives of study	To generate insight into the aetiology of uveal melanoma by correlating eye cancer incidence rates in U.S. states with geographic and demographic features (including availability of fluoridated water).
	Study design	Ecological
	Level of evidence	IV
	Study location	United States
	Study duration	NR
	Exposure duration	NR
	Source population description	Data on population density as obtained from 2010 US Census.
	Inclusion/exclusion criteria	Included data on non-Hispanic whites only; data on incidence among African Americans and Hispanic were not included. Rates based on <10 cases were censored.
	Recruitment procedures	NA
Participant characteristics		Whole study
	No. of participants enrolled	NR (residents of 44/50 states were included)
	Age	“all ages”

	Male	NR
	Other characteristics	Included data for non-Hispanic whites only.
	Subgroups reported	NA
Exposure and setting	Description of exposure	Proportion of population receiving fluoridated water (%) Fluoridation data was obtained from the Centres for Disease Control and Prevention (CDC); CDC tracks the number of persons receiving fluoridated water using a validated data system maintained in cooperation with the Association of State and Territorial Dental Directors.
	Setting	Population-based study.
Results: Eye cancer	Definition Method of measurement	Age-adjusted incidence of eye cancer (n/100,00) Eye cancer rate used as a surrogate for uveal melanoma rate (90% of adult eye cancers are melanomas & majority involve the uveal tract). Data on eye and orbit cancers (by state, 2006-10, all ages) was obtained from North American Association of Central Cancer Registries. Age-adjusted to the 2000 US standard population.
	No. of participants analysed	NR (data from 44 of 50 states)
	No. of participants excluded or missing	NR (data from Washington, DC was censored due to small rates; n=9)
	Imputation of missing data	NA
	Statistical method of analysis	Multivariable linear regression.
	Participant category	Outcome: correlation between age adjusted incidence rates of eye cancer and risk factor
	Percentage receiving fluoridated water	r=0.38, p=0.01
	Percentage receiving fluoridated water, model including latitude	r=0.45, p=0.002
	Age adjusted incidence rates for eye cancer	Range only reported: From 0.29/100,000 (95% CI: 0.15-0.51; based on 13 cases) in South Dakota, to 1.23/100,000 (95% CI: 1.10-1.43; based on 242 cases) in Oregon
Authors' conclusion	In this hypothesis-generating study, we observed that eye cancer incidence rates in U.S. states are inversely correlated with the availability of fluoridated water. If confirmed by analytic studies, this finding may be a productive clue to the enigmatic aetiology of uveal melanoma.	
Correspondence if required	Not required.	
Reviewer's notes	Consider pulling out the scatter plot of all states' incidence rates of eye cancer and proportion of the population with access to fluoridated water (figure 1, page 1709)	

Abbreviations: NA = not applicable; NR = not reported

SERAJ ET AL. (2012)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Makoo region, Iran.
1.2 Is the eligible population or area representative of the source population or area?	+	6 to 11 year old children from five villages in Makoo region. Method for participant recruitment not reported. Study included children from areas that were reported to be similar in the demographic and geographic characteristics, SES status and occupations.
1.3 Do the selected participants or areas represent the eligible population or area?	NR	Method of selection NR. Numbers excluded NR
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison)	++	Group allocation based on mean fluoride levels in drinking water

group. How was selection bias minimised?		sources from previous 12 years. Fluoride levels reported to be in line with those measured during study. Participants were lifelong residents in the villages under study, with mothers having lived in the area during their pregnancies.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	++	Cite previous studies looking at effect of fluoride on neurological development.
2.3 Was the contamination acceptably low?	NR	-
2.4 How well were likely confounding factors identified and controlled?	+	Confounders identified (educational levels, age & gender) and found not to influence IQ score & not included in analysis. Iodine & lead levels measured in water. Reported verification that households received iodine enriched salts for cooking/eating purposes. The 5 selected areas are reported to be similar in general demographic and geographic characteristics, with comparable SES status and similar occupations.
2.5 Is the setting applicable to the Australia?	-	Intervention groups' level of fluoride much higher than that in Australia. Health system very likely to be different.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	-	IQ measured using Raven's test, administered in a school classroom, under the supervision of a psychologist, a teacher, and an assistant in a blinded manner. Unclear what IQ score ranges were used for Stanford-Binet, and the categories used in the article (e.g. "superior," "above average," etc.) do not match those in Stanford-Binet.
3.2 Were the outcome measurements complete?	NR	-
3.3 Were all the important outcomes assessed?	++	The outcome of interest was IQ score; the study assessed IQ scores.
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	Lifelong residents & mothers were resident during pregnancy.
3.5 Was follow-up time meaningful?	++	Likely to see an effect over 6-11 years
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	Sample sizes and powering issues not discussed.
4.2 Were multiple explanatory variables considered in the analyses?	++	Analysed relationship between IQ score and: child's age, gender, child's educational level, parent's educational level (both mother and father), fluorosis intensity, water fluoride content.
4.3 Were the analytical methods appropriate?	+	Confounders considered; follow-up time NR.
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	Mean and SD reported; p-values reported for group level outcomes but not by Stanford-Binet category.
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Recruitment & representativeness of participants unclear. Reasonable analysis.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Fluoride exposures much higher to that seen in Australia. Health system & sociodemographic characteristics very likely dissimilar.
Overall quality rating	Low	Selection bias likely. Not applicable to Australian context.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Seraj et al. (2012)
	Date form completed	22/01/15
	Country of origin Source of funding Possible conflicts of interest	Iran NR NR
Study characteristics	Aim/objectives of study	To investigate the effect of different levels of fluoride in drinking water on the intelligence quotient (IQ) of children living in five rural areas in Makoo, Iran.
	Study design	Ecological

	Level of evidence	IV			
	Study location	Makoo, Iran			
	Study duration	NR			
	Exposure duration	All participants were lifelong residents in the villages under study, with mothers having lived in the area during their pregnancies.			
	Source population description	Children 6-11 years old were selected from 5 villages in Makoo (Iran): Babur, Panjarlu, Dizaj, Small Donalau, Large Donalau, and classified into 3 groups based on F content of their water supply (high, medium, normal). Normal: 0.5-1 ppm; Medium: 3.1 ± 0.9ppm; High: 5.2 ± 1.1ppm.			
	Inclusion/exclusion criteria	Inclusion NR. Exclusion: history of genetic disease, systemic disorders or brain trauma in the family.			
	Recruitment procedures	NR			
Participant characteristics		Whole study	High fluoride level	Medium fluoride level	Normal fluoride level
	No. of participants enrolled	239	96	106	91
	Age (range)	6-11 years	NR	NR	NR
	Male	59.4%	NR	NR	NR
	Other characteristics	Not provided, but article states that the 5 selected areas were similar in their general demographic and geographic characteristics, with inhabitants having a comparable socioeconomic status and similar occupations.			
	Subgroups reported	NR	NR	NR	NR
Exposure and setting		Intervention		Comparator	
	Description of exposure and control	Determined by mean fluoride level in water from the 5 villages measured by local health clinics during the previous 12 years Fluoride levels were: normal: 0.5-1 ppm; medium: 3.1 ± 0.9 ppm, high: 5.2 ± 1.1 ppm.			
	Setting	Community-based study. Method for participant identification and recruitment not reported.			
Results: IQ	Definition Method of measurement	Intelligent Quotient Raven's Colour Progressive Matrices			
	No. of participants analysed	293			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	ANOVA post-hoc test and Kruscal-Wallis.			
	Participant category	High fluoride mean ± SD	Medium fluoride mean ± SD	Normal fluoride mean ± SD	Effect estimate
	All participants	88.58 ± 16.01	89.03 ± 12.99	97.77 ± 18.91	*p*=0.001 (medium & high vs. normal) *p*=0.995 (high vs. medium)
	IQ scores by Stanford-Binet classification***: Superior	0/96 (0%)	0/106 (0%)	4/91 (4.4%)	NR
	Above Average	2/96 (2.1%)	6/106 (5.7%)	17/91 (18.7%)	NR
	Normal or average	61/96 (63.5%)	58/106 (54.7%)	47/91 (51.6%)	NR
	Dullness and lower IQ	33/96 (34.4%)	42/106 (39.6%)	23/91 (25.3%)	NR
Authors' conclusion	The IQ scores of children living in areas with above the standard water fluoride levels were lower compared to children living in normal fluoride level regions. The proportion of children with above the normal intelligence in the group with the standard level of fluoride in their drinking water was greater than those with medium and				

	high fluoride content. Age, gender, child's and parent's educational level had no significant impact on the IQ scores.
Correspondence if required	Not required.
Reviewer's notes	***Stanford-Binet classification of IQ scores cited in the article's body: genius 164+; very superior 148-164; superior 132-148; above average 116-132; average 84-116; dullness 68-84; borderline 52-68; mental deficiency <58. These labels do not quite match the categories used in article's Table 3 (reproduced above); it is not clear what IQ score ranges were actually used for each category in Table 3. It is also worth noting that the Stanford-Binet classification that is cited as a reference in the article, and the classification actually used in the article, do not match in terms of categories or score ranges.

Abbreviations: NA = not applicable; NR = not reported

SHARMA ET AL. (2009A)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Children (6 to 18 years) and adults in villages of Sanganear Tehsil, India
1.2 Is the eligible population or area representative of the source population or area?	-	No participant identification details
1.3 Do the selected participants or areas represent the eligible population or area?	-	No discussion regarding representativeness
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Exposure groups based on fluoride concentrations in the groundwater, measurement details absent. High risk of selection bias.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	NR	No discussion about movement of participants between villages
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	-	Poorly described questionnaire
3.2 Were the outcome measurements complete?	NR	-
3.3 Were all the important outcomes assessed?	-	Baseline characteristics not captured
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	-	No statistical analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	NA	-
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	High risk of selection bias: representativeness of the sample unclear, baseline characteristics NR. Weak outcome capture methods. No confounding factors measured.

5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Different healthcare systems. Significantly different to Australian society.
Overall quality rating	Low	High risk of selection bias. No statistical analysis.

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Sharma et al. (2009a)			
	Date form completed	03/02/15			
	Country of origin Source of funding Possible conflicts of interest	India NR NR			
Study characteristics	Aim/objectives of study	To evaluate gastrointestinal effects of fluoride in drinking water on children and adults residing in village areas of Sanganer Tehsil, Rajasthan, India			
	Study design	Ecological			
	Level of evidence	IV			
	Study location	Rajasthan, India			
	Study duration	NR			
	Exposure duration	NR			
	Source population description	Children (6 to 18 years) and adults of villages of Sanganer Tehsil			
	Inclusion/exclusion criteria	NR			
	Recruitment procedures	Ten villages were selected from each fluoride group for the study			
Participant characteristics		Whole Study	Low F	Medium F	High F
	No. of participants enrolled	1,135 children 1,475 adults	360 children 458 adults	375 children 489 adults	400 children 528 adults
	Age	NR	NR	NR	NR
	Male	50.5% children 49.5% adults	49.2% children 49.3% adults	51.4% children 49.3% adults	50.8% children 49.8% adults
	Other characteristics	NR	NR	NR	NR
	Subgroups reported	NR	NR	NR	NR
Exposure and setting	Description of exposure and control	Villages of Sanganer Tehsil were divided into three groups based on the fluoride concentration in the groundwater: High F (>1.5 ppm), Medium F (1.0-1.5 ppm) and Low F (<1.0 ppm)			
	Setting	Community-based study. At least 10 villages in Sanganer Tehsil from each fluoride group were included in the study.			
Results: Gastrointestinal discomfort	Definition Method of measurement	Presence of stomach ache, bloated feeling, nausea, diarrhoea or constipation Determined by a human health survey with a questionnaire. Sum of any gastrointestinal discomforts. Participants reporting more than one discomfort may be double counted.			
	No. of participants analysed	1,135 children 1,475 adults			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	None			
	Participant category	Low F n/N (%)	Medium F n/N (%)	High F n/N (%)	Effect estimate
	Children – Total	0/360 (0.0%)	0/375 (0.0%)	68/400 (17.0%)	NA
	Children – Female	0/183 (0.0%)	0/182 (0.0%)	31/197 (15.7%)	NA
	Children – Male	0/177 (0.0%)	0/193 (0.0%)	37/203 (18.2%)	NA
	Adults – Total	110/458 (24.0%)	155/489 (31.7%)	469/528 (88.8%)	NA

	Adults – Female	46/232 (19.8%)	77/248 (31.0%)	231/265 (87.2%)	NA
	Adults – Male	64/226 (28.3%)	78/241 (32.4%)	238/263 (90.5%)	NA
Authors' conclusion	The maximum number of cases of gastric discomfort were observed in the high fluoride areas, which may therefore be correlated with high fluoride concentrations in the groundwater used for drinking and cooking as well as poor nutrition among the inhabitants.				
Correspondence if required	None required				
Reviewer's notes	Only individual gastric discomforts reported, summed for extraction				

Abbreviations: NA = not applicable; NR = not reported

SHARMA ET AL. (2009B)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Children (6 to 18 years) and adults in villages of Sanganear Tehsil, India
1.2 Is the eligible population or area representative of the source population or area?	-	Recruitment not defined. No participant identification details
1.3 Do the selected participants or areas represent the eligible population or area?	-	No discussion regarding representativeness
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Exposure groups based on fluoride concentrations in the groundwater, measurement details absent. Not able to determine that groups were similar for all aspects except fluoride water level.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	NR	No discussion regarding participant migration
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	-	Poorly described questionnaire
3.2 Were the outcome measurements complete?	NR	-
3.3 Were all the important outcomes assessed?	-	Baseline characteristics not captured
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	No discussion about movement of participants between villages
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	-	No statistical analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	NA	-
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	High risk of selection bias. Representativeness of the sample unclear, baseline characteristics NR. Weak outcome capture methods. No statistical analysis.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Different healthcare systems. Significantly different to Australian society.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Sharma et al. (2009b)			
	Date form completed	06/02/15			
	Country of origin Source of funding Possible conflicts of interest	India NR NR			
Study characteristics	Aim/objectives of study	To investigate the effect of high fluoride in drinking water on neurobehavioural patterns of human population in villages of a fluoride endemic area			
	Study design	Ecological			
	Level of evidence	IV			
	Study location	Rajasthan, India			
	Study duration	NR			
	Exposure duration	NR			
	Source population description	Children (6 to 18 years) and adults of villages of Sanganer Tehsil			
	Inclusion/exclusion criteria	NR			
	Recruitment procedures	Ten villages were selected from each fluoride group for the study			
Participant characteristics		Whole study	Low F	Medium F	High F
	No. of participants enrolled	1,145 children 1,556 adults	372 children 513 adults	355 children 477 adults	418 children 566 adults
	Age	NR	NR	NR	NR
	Male	50.6% children 51.0% adults	50.0% children 50.5% adults	50.7% children 50.7% adults	51.0% children 51.6% adults
	Other characteristics	NR	NR	NR	NR
	Subgroups reported	NR	NR	NR	NR
Exposure and setting	Description of exposure and control	Villages of Sanganer Tehsil were divided into three groups based on the fluoride concentration in the groundwater: High F (>1.5 ppm), Medium F (1.0 - 1.5 ppm) and Low F (<1.0 ppm)			
	Setting	Community-based study. 10 villages in Sanganer Tehsil from each fluoride group were included in the study.			
Results: Headache	Definition Method of measurement	Presence of headache Determined by a human health survey with a questionnaire.			
	No. of participants analysed	1,145 children 1,556 adults			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	None			
	Participant category	Low F n/N (%)	Medium F n/N (%)	High F n/N (%)	Effect estimate
	Children	0/372 (0.0%)	0/355 (0.0%)	47/418 (11.2%)	NA
	Adults	8/513 (1.6%)	12/477 (2.5%)	179/566 (31.6%)	NA
Results: Insomnia	Definition Method of measurement	Presence of insomnia Determined by a human health survey with a questionnaire.			
	No. of participants analysed	1,145 children 1,556 adults			
	No. of participants excluded or missing	0			
	Imputation of missing data	NA			
	Statistical method of analysis	None			
	Participant category	Low F n/N (%)	Medium F n/N (%)	High F n/N (%)	Effect estimate
	Children	0/372 (0.0%)	0/355 (0.0%)	47/418 (11.2%)	NA

	Adults	6/513 (1.2%)	7/477 (1.5%)	151/566 (26.7%)	NA
Authors' conclusion	Fluoride may cause various neurological manifestations, including headache and insomnia, among subjects residing in endemic areas that may be due, at least in part, to the adverse action of fluoride on the brain and various organs such as the kidney controlled by the brain through various hormones				
Correspondence if required	None required				
Reviewer's notes	The study also reported on lethargy, polyuria and polydipsia. These were not extracted as are not specific health effects.				

Abbreviations: NA = not applicable; NR = not reported

SINGH ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Schoolchildren (9 to 14 years) from Dausa and Jaipur, Rajasthan, India
1.2 Is the eligible population or area representative of the source population or area?	NR	Recruitment procedures NR
1.3 Do the selected participants or areas represent the eligible population or area?	-	Method of selection NR. Only male children included.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	High risk of selection bias even though the two groups were matched for age and sex. No reporting of comparison of subject and control group characteristics.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies only
2.3 Was the contamination acceptably low?	NR	No discussion regarding participant migration
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	High naturally occurring fluoride in groundwater. Dissimilar healthcare system.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	IQ measured by Raven's test, no discussion of reliability
3.2 Were the outcome measurements complete?	-	Missing results for 3 in subject group. No reporting of control group numbers.
3.3 Were all the important outcomes assessed?	+	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	-	No statistical analysis of differences between IQ scores
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	p-values reported for Mann-Whitney U-tests when performed (baseline characteristics only)
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Poor assessment of the comparability of the study groups, no adjustment for confounding factors, no statistical analysis.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Only generalisable to the male source population. Unlikely to be generalisable to Australian population
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Singh et al. (2013)		
	Date form completed	19/01/15		
	Country of origin Source of funding Possible conflicts of interest	India NR NR		
Study characteristics	Aim/objectives of study	Assess the correlation between serum vitamin, acetylcholinesterase (AChE) activity and IQ in children with excessive endemic fluoride exposure.		
	Study design	Cross-sectional		
	Level of evidence	IV		
	Study location	Rajasthan, India		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Male schoolchildren (9 to 14 years) from the high fluoride region (Dausa) with similar living conditions, parental literacy, socioeconomic status and health history. Age and sex matched controls selected from a relatively low fluoride region (Jaipur).		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	NR		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	NR	73	NR
	Age (mean)	NR	12.3 years	12.2 years
	Male	100%	100%	100%
	BMI (mean)	NR	23.2	22.9
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Exposure to natural fluoride in Dausa where fluoride content in water is more than 2.0 ppm (mean ± SD: 6.8 ± 1.6)	Exposure to natural fluoride in Jaipur where fluoride content is less than 1.5 ppm (mean ± SD: 1.0 ± 0.2)	
	Setting	Community-based study. Children exposed to the measured levels of naturally occurring fluoride in their home drinking water. Water from each child's home was sampled and fluoride content analysed using ion selective electrode.		
Results: IQ	Definition Method of measurement	IQ score Raven's Test		
	No. of participants analysed	142		
	No. of participants excluded or missing	3 – reasons NR		
	Imputation of missing data	NR		
	Statistical method of analysis	None		
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect estimate
	IQ score: >130	0/70 (0%)	0/72 (0%)	NA
	IQ score: 120-129	1/70 (1.4%)	2/72 (2.8%)	NA
	IQ score: 110-119	2/70 (2.8%)	5/72 (6.9%)	NA
	IQ score: 90-109	21/70 (29.2%)	34/72 (47.2%)	NA
	IQ score: 80-89	25/70 (34.7%)	22/72 (30.6%)	NA
	IQ score: 70-79	16/70 (22.2%)	7/72 (9.7%)	NA
	IQ score: <69	5/70 (6.9%)	2/72 (2.8%)	NA
Authors' conclusion	Excessive fluoride delineates the neuronal impairment which was evident by reduced IQ scores and serum AChE activity.			
Correspondence if required	None required			
Reviewer's notes	No assessment of difference between IQ distributions, only male participants included. AChE results not			

	extracted.

Abbreviations: NA = not applicable; NR = not reported

SINGH ET AL. (2014)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Schoolchildren (8 to 15 years) in Udaipur district, India
1.2 Is the eligible population or area representative of the source population or area?	-	No participant identification details
1.3 Do the selected participants or areas represent the eligible population or area?	-	No discussion regarding representativeness
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	High risk of selection bias: no method described; participants in control group were "of the same age range and socioeconomic status, residing in the non-endemic area, without exhibiting dental fluorosis". Investigators also selected half of intervention group from areas with F up to 2.6ppm and the other with F up to 5.1ppm.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	NR	No discussion regarding participant migration
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system. Levels of fluoride in intervention group much higher than seen in Australia.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Serum samples of children were investigated to assess FT4, FT3, and TSH hormone levels using Immuno Chemiluminiscence Microparticle Assay with the Bayer Centaur Anutoanalyzer
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	+	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	Other factors that may affect thyroid function not considered
4.3 Were the analytical methods appropriate?	+	Student's t-test. No multivariate analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	p-values reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	Groups not comparable. High risk of selection bias. No adjustment for confounding factors.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Fluoride levels in intervention group much higher than in Australia. Very different sociodemographic characteristics.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Singh et al. (2014)

	Date form completed	10/02/15		
	Country of origin Source of funding Possible conflicts of interest	India NR The authors declare that they have no competing interests		
Study characteristics	Aim/objectives of study	To determine the fluoride status and compare it with the free T4, free T3, and thyroid stimulating hormone levels of children with and without dental fluorosis living in an endemic fluorosis area		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Rajasthan, India		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Schoolchildren (8 to 15 years) residing in villages of the Udaipur district of Rajasthan. The intervention group was taken from the following endemic fluorosis villages: Slumber, Sarada, Kalutada, Devgaun and Kejad. Controls were taken from Sardarpura.		
	Inclusion/exclusion criteria	Specific sampling of 30 children with and 30 without dental fluorosis for the intervention group		
	Recruitment procedures	NR		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	70	60	10
	Age (range)	8 -15 years	8 -15 years	8 -15 years
	Male	NR	NR	NR
	Free Triiodothyronine (FT_3) (range)	1.1 – 4.57 pg/mL	1.1 – 4.57 pg/mL	1.90 – 4.13 pg/mL
	Free Thyroxine (FT_4) (range)	0.8 – 1.98 ng/dL	0.8 – 1.98 ng/dL	0.87 – 1.67 ng/dL
	Thyroid Stimulating Hormone (TSH) (range)	0.96 – 10.99 µIU/m	1.41 – 10.99 µIU/m	0.96 – 3.54 µIU/m
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Half of the group exposed to drinking water with up to 2.6 ppm fluoride, remaining half exposed to up to 5.1 ppm fluoride. Mean water fluoride concentration was 2.7 ppm (range: 1.6 – 5.5).	Drinking water fluoride concentration <1.0 ppm. Mean water fluoride concentration was 1.0 ppm (range: 0.98 – 1).	
	Setting	School-based study. Participants recruited from five villages with endemic fluorosis and one non endemic village.		
Results: FT_3 hormone levels	Definition Method of measurement	Free Triiodothyronine (pg/mL) Immuno Chemiluminiscence Microparticle Assay with the Bayer Centaur Autoanalyzer		
	No. of participants analysed	70		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		
	Participant category	Intervention mean ± SD	Comparator mean ± SD	Effect estimate t
	All participants	3.06 ± 1.10	2.50 ± 0.71	1.59 *p*=0.117
Results: FT_4 hormone levels	Definition Method of measurement	Free Thyroxine (ng/dL) Immuno Chemiluminiscence Microparticle Assay with the Bayer Centaur Autoanalyzer		
	No. of participants analysed	70		
	No. of participants excluded or missing (with reasons)	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		

	Participant category	Intervention mean ± SD	Comparator mean ± SD	Effect estimate t
	All participants	1.20 ± 0.22	1.18 ± 0.22	0.26 *p*=0.796
Results: TSH levels	Definition Method of measurement	Thyroid Stimulating Hormone (µIU/mL) Immuno Chemiluminiscence Microparticle Assay with the Bayer Centaur Autoanalyzer		
	No. of participants analysed	70		
	No. of participants excluded or missing (with reasons)	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		
	Participant category	Intervention mean ± SD	Comparator mean ± SD	Effect Estimate t
	All participants	3.71 ± 1.94	2.50 ± 0.75	1.94 *p*=0.057
Results: Delayed eruption	Definition Method of measurement	No. of children with delayed tooth eruption NR		
	No. of participants analysed	70		
	No. of participants excluded or missing (with reasons)	0		
	Imputation of missing data	NA		
	Statistical method of analysis	None		
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect Estimate
	All participants	32/60 (53.3%)	0/10 (0.0%)	NA
Authors' conclusion	Improvement in the health of children would likely be achieved in management strategies incorporate emerging knowledge to address fluoride toxicity in the individuals, even if residing in non-endemic fluoride areas			
Correspondence if required	None required			
Reviewer's notes	Intervention group is pooled from the participants with and without dental fluorosis (groups 1A and1B) in the high fluoride villages			

Abbreviations: NA = not applicable; NR = not reported

SRIKANTH ET AL. (2008)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Children (< 18 years) and adults in five villages of the Palamau district of Jharkhand, India
1.2 Is the eligible population or area representative of the source population or area?	-	Method to select villages not reported. No participant identification details
1.3 Do the selected participants or areas represent the eligible population or area?	-	Method to select participants not reported. Proportion agreeing to participate not reported. No discussion regarding representativeness
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	Exposure groups based on fluoride concentrations in the groundwater. High risk of selection bias.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies
2.3 Was the contamination acceptably low?	NR	No discussion regarding participant migration
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Naturally occurring fluoride at levels often much higher than in Australia. Dissimilar healthcare system.

Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	-	Poorly described questionnaire
3.2 Were the outcome measurements complete?	NR	-
3.3 Were all the important outcomes assessed?	+	Skeletal fluorosis in adults and dental fluorosis in children.
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	-	No statistical analysis
4.6 Was the precision of association given or calculable? Is the association meaningful?	NA	-
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	No selection methods described. Representativeness of the sample unclear. Baseline characteristics NR Weak outcome capture methods. No statistical analysis.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Levels of fluoride mostly higher than in Australia. Dissimilar healthcare system. Dissimilar sociocultural characteristics.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Srikanth et al. (2008)					
	Date form completed	10/02/15					
	Country of origin Source of funding Possible conflicts of interest	India NR NR					
Study characteristics	Aim/objectives of study	To determine the extent of fluorosis in five selected villages in Palamau where groundwater is the major source of drinking water					
	Study design	Ecological					
	Level of evidence	IV					
	Study location	Palamau, India					
	Study duration	NR					
	Exposure duration	NR					
	Source population description	Children (<18 years) and adults from five villages of Ganke, Mukhiya Tola, Satyari Tola, Chukru, and Bakhari in the Palamau district of Jharkhand, India					
	Inclusion/exclusion criteria	NR					
	Recruitment procedures	Out of 10 fluoride-affected villages, five were selected based on the severity of symptoms of endemic fluorosis					
Participant characteristics		Whole study	Ganke	Satyari	Mukhiya	Bakhari	Chukru
	No. of participants enrolled	345 children 818 adults	45 children 85 adults	41 children 103 adults	52 children 115 adults	88 children 238 adults	119 children 277 adults
	Age	NR	NR	NR	NR	NR	NR
	Male	51.3% adults	NR	NR	NR	NR	NR
	Other characteristics	NR	NR	NR	NR	NR	NR
	Subgroups reported	NR	NR	NR	NR	NR	NR
Exposure and	Description of exposure and	Exposed to naturally occurring fluoride in groundwater. Across all five					

setting	control	villages the range of fluoride concentrations was 1.51 to 4.39 ppm.		
	Setting	Population-based study. Participants recruited from pre-selected villages.		
Results: Moderate skeletal fluorosis	Definition Method of measurement	NR Health survey		
	No. of participants analysed	818 (adults only)		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	None		
	Participant category	Intervention n/n (%)	Comparator n/n (%)	Effect estimate
	Ganke residents	4/85 (4.7%)	NA	NA
	Satyari residents	7/103 (6.8%)	NA	NA
	Mukhiya residents	17/115 (14.8%)	NA	NA
	Bakhari residents	20/238 (8.4%)	NA	NA
	Chukru residents	14/277 (5.1%)	NA	NA
	All participants	62/818 (7.6%)	NA	NA
Results: Severe skeletal fluorosis	Definition Method of measurement	NR Health survey		
	No. of participants analysed	818 (adults only)		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	None		
	Participant category	Intervention n/n (%)	Comparator n/n (%)	Effect estimate
	Ganke residents	1/85 (1.2%)	NA	NA
	Satyari residents	4/103 (3.9%)	NA	NA
	Mukhiya residents	1/115 (0.9%)	NA	NA
	Bakhari residents	3/238 (1.3%)	NA	NA
	Chukru residents	2/277 (0.7%)	NA	NA
	All participants	11/818 (1.3%)	NA	NA
Authors' conclusion	A level of 2.5 ppm fluoride was found to be a critical threshold for manifestations of crippling skeletal fluorosis. Household defluoridation along with improved nutrition rich in calcium is recommended for amelioration of fluorosis in these villages.			
Correspondence if required	None required			
Reviewer's notes	None			

Abbreviations: NA = not applicable; NR = not reported

SUN ET AL. (2013)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Adults (40 to 75 years) from eight villages in Zhaozhou County in the Heilongjiang Province.
1.2 Is the eligible population or area representative of the source population or area?	+	Participants identified after investigating basic information for all residents living in selected villages. Unclear how representative they are of the source population.
1.3 Do the selected participants or areas represent the eligible population or area?	+	Method of selection from eligible population not described. Exclusion for many pre-existing conditions either causing or associated with hypertension. 40% (331/818) of the eligible population were excluded.
Section 2: Method of selection of exposure (or comparison) group	-	-

2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Study groups based on water fluoride in their drinking water. Other sources of fluoride not measured e.g. tea, coal.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	-	Any association between hypertension is speculative at best.
2.3 Was the contamination acceptably low?	NR	-
2.4 How well were likely confounding factors identified and controlled?	+	Controlled for confounding by excluding people with non-essential hypertension and measures other known confounding factors e.g. obesity, smoking, alcohol, age
2.5 Is the setting applicable to the Australia?	-	Fluoride levels exceed that found in Australia. Dissimilar healthcare system and sociocultural factors e.g. diet
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Blood pressure measured three times in the morning using a mercury sphygmomanometer
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	At least 10 years.
3.5 Was follow-up time meaningful?	+	Exposure was probably long enough to observe hypothesised effects
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	++	Multivariable logistic regression performed
4.3 Were the analytical methods appropriate?	++	Chi-squared test and multivariable logistic regression
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	p-values reported for chi-squared test. 95% CI reported for multivariable logistic regression. Effect estimate was imprecise (95%CI 1.4 to 5.9)
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Unclear on the representativeness of the study sample. Other sources of fluoride not considered e.g. tea, coal burning. Good statistical analyses.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Level of fluoride associated in this study with essential hypertension was much greater than that seen in Australia. Other sociodemographic characteristics dissimilar.
Overall quality rating	Acceptable	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Sun et al. (2013)
	Date form completed	20/01/15
	Country of origin Source of funding Possible conflicts of interest	China National Natural Science Foundation of China Authors declare that they have no competing financial interests
Study characteristics	Aim/objectives of study	To identify the relationship between excess fluoride intake from drinking water and the prevalence of essential hypertension in adults who reside in fluoride endemic areas
	Study design	Cross-sectional
	Level of evidence	IV
	Study location	Zhaozhou County, China
	Study duration	NR
	Exposure duration	At least 10 years
	Source population description	Adults (40 to 75 years) from eight villages in Zhaozhou County in the Heilongjiang Province. Water supplies in these study villages were from shallow wells and tube wells equipped with hand pumps with high fluoride concentrations.

	Inclusion/exclusion criteria	Living at the same address for at least 10 years who drank the water from tube wells or small wells for more than 10 years. Excluded for a past history of diabetes, high blood glucose, coronary heart disease, stroke, carotid atherosclerosis, secondary hypertension, kidney disease, liver disease, respiratory disease, emaciation, long-term use of drugs or family history of hypertension.				
	Recruitment procedures	Selection based on basic demographic information				
Participant characteristics		Whole study	Normal fluoride level	Mild fluoride level	Moderate fluoride level	High fluoride level
	No. of participants enrolled	487	129	163	130	65
	Age (range)	40–75 years	40–75 years	40–75 years	40–75 years	40–75 years
	Male	40.9%	40.3%	42.9%	39.2%	45.3%
	Other characteristics	See notes	See notes	See notes	See notes	See notes
	Subgroups reported	NR	NR	NR	NR	NR
Exposure and setting		Normal	Mild	Moderate	High	
	Description of exposure and control	≤1.20 ppm fluoride in well drinking water	1.21–2.00 ppm fluoride in well drinking water	2.01–3.00 ppm fluoride in well drinking water	≥3.01 ppm fluoride in well drinking water	
	Setting	Community-based study. Adults grouped by fluoride level as measured by ion selective electrode. Cut-off points chosen according to the national monitoring program of drinking-water-borne endemic fluorosis.				
Results: Hypertension	Definition	Sum of participants with any of the three types of hypertension: isolated systolic hypertension (SBP≥140mm Hg & DBP<90mm Hg), isolated diastolic hypertension (DBP≥90mm Hg & SBP<140mm Hg), or systolic-diastolic hypertension (SBP≥140mm Hg & DBP≥90mm Hg).				
	Method of measurement	Participant blood pressure was measured three times in the morning using a mercury sphygmomanometer.				
	No. of participants analysed	487				
	No. of participants excluded or missing	None				
	Imputation of missing data	NA				
	Statistical method of analysis	Chi-squared test Multivariable logistic regression (ORs adjusted for sex, age, smoking, alcohol consumption, BMI & endothelin-1)				
	Participant category	Intervention n/N (%)	Comparator n/N (%)	Effect estimate χ^2 Adj. OR (95% CI)		
	All participants	Mild 40/163 (24.5%)	Normal 26/129 (20.2%)	NR, *p*=0.401 1.02 (0.56 – 1.86)		
	All participants	Moderate 42/130 (32.3%)	Normal 26/129 (20.2%)	NR, *p*=0.018 1.73 (0.94 – 3.19)		
	All participants	High 32/65 (49.2%)	Normal 26/129 (20.2%)	NR, *p*<0.001 2.84 (1.38 – 5.83)		
	All participants	Moderate 42/130 (32.3%)	Mild 40/163 (24.5%)	NR, *p* = 0.151 NA		
	All participants	High 32/65 (49.2%)	Mild 40/163 (24.5%)	NR, *p* < 0.001 NA		
	All participants	High 32/65 (49.2%)	Moderate 42/130 (32.3%)	NR, *p* = 0.028 NA		
Authors' conclusion	This research suggested a significant relationship between excess fluoride from drinking water and essential hypertension in adults living in fluoride endemic areas, although the underlying mechanisms were somewhat unclear.					
Correspondence if required	None required					
Reviewer's notes	BMI (kg/m²), smoking, & alcohol consumption recorded – not significant differences between groups					

Abbreviations: NA = not applicable; NR = not reported

TRIVEDI ET AL. (2007)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Schoolchildren (12 to 13 years) from Chandlodia and Sachana
1.2 Is the eligible population or area representative of the source population or area?	-	No participant identification details
1.3 Do the selected participants or areas represent the eligible population or area?	+	Recruited from the only school in each village
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	High risk of selection bias. No indication how comparable the two groups are Nutritional and socioeconomic status of both areas is very similar and good, but slightly lower in Sachana. No details reported.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies only
2.3 Was the contamination acceptably low?	++	Lifelong village residents
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to measure or control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	No description of how questionnaire administered. Tailored questionnaire with 97% reliability rate. Blinding not reported.
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	+	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	++	Lifetime exposure
3.5 Was follow-up time meaningful?	++	Exposure long enough to observe hypothesised effects
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	++	Student's t-test
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	p-values reported. No confidence intervals
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	No adjustment for confounding factors. No comparison of baseline characteristics. Insufficient details to assess comparability of two groups.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Very unlikely to be generalisable to Australia setting due to higher fluoride level and considerable sociodemographic differences.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Trivedi et al. (2007)
	Date form completed	09/02/15
	Country of origin Source of funding Possible conflicts of interest	India NR NR

Study characteristics	Aim/objectives of study	To examine the fluoride exposure of two groups of schoolchildren and its impact on their IQ		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	Gujurat district, India		
	Study duration	NR		
	Exposure duration	Lifetime		
	Source population description	Schoolchildren (12 to 13 years) residing in the low fluoride area of Chandlodia, Ahmedabad and the high fluoride area of Sachana, in the Sanand district of Gujarat		
	Inclusion/exclusion criteria	Life-long residents of their respective locations		
	Recruitment procedures	NR		
Participant characteristics		**Whole study**	**Intervention**	**Comparator**
	No. of participants enrolled	190	89	101
	Age (range)	12 - 13 years	12 - 13 years	12 - 13 years
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		**Intervention**	**Comparator**	
	Description of exposure and control	Exposed to natural occurring fluoride present in the groundwater of Sachana (mean fluoride 5.55 ppm)	Exposed to natural occurring fluoride present in the groundwater of Chandlodia (mean fluoride 2.01 ppm)	
	Setting	School-based study. Participants recruited out of the 6th and 7th standards.		
Results: IQ	Definition Method of measurement	Intelligence Quotient A questionnaire prepared by Prof. Shah and standardised on the Gujarati population with 97% reliability rate in relation to the Stanford-Binet Intelligence Scale.		
	No. of participants analysed	190		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		
	Participant category	**Intervention** mean ± SE	**Comparator** mean ± SE	**Effect estimate**
	All participants	91.72 ± 1.13	104.44 ± 1.23	p<0.001
	Females	94.15 ± 1.35	103.87 ± 2.21	p<0.01
	Males	90.24 ± 1.58	108.80 ±1.47	p<0.001
Authors' conclusion	The study indicated that the mean IQ level of students exposed to high fluoride drinking water was significantly lower than that of the students exposed to a lower fluoride level in drinking water.			
Correspondence if required	None required			
Reviewer's notes	None			

Abbreviations: NA = not applicable; NR = not reported

TRIVEDI ET AL. (2012)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Schoolchildren (12 to 13 years) from six villages of the Mundra region, Kachchh, Gujurat
1.2 Is the eligible population or area representative of the source population or area?	-	No participant identification details
1.3 Do the selected participants or areas represent the eligible population or area?	-	'Representative samples of children' mentioned but not well described

Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	-	High risk of selection bias. No indication how comparable the two groups are. Exposure groups based on fluoride concentrations in the groundwater of each village.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies only
2.3 Was the contamination acceptably low?	NR	No discussion regarding participant migration
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to measure or control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Dissimilar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	+	No description of how questionnaire administered. Tailored questionnaire with 97% reliability rate. Blinding not reported.
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	+	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	+	Student's t-test only
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	p-values reported to be <0.05 for all analyses
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	-	No adjustment for confounding factors. Insufficient details regarding representativeness of the sample
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Very unlikely to be generalisable to Australia setting due to higher fluoride level and considerable sociodemographic differences.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Trivedi et al. (2012)
	Date form completed	06/02/15
	Country of origin Source of funding Possible conflicts of interest	India Gujarat Council of Science and Technology, Gandhinagar NR
Study characteristics	Aim/objectives of study	To assess the groundwater quality in a semi-arid region of Kachchh with special reference to fluoride contamination as one part of the study. As a second part of the investigation, the impact of fluoride on IQ of schoolchildren with the same socio-economic status in the Mundra region of Kachchh, Gujarat, was also included.
	Study design	Ecological
	Level of evidence	IV
	Study location	India
	Study duration	NR
	Exposure duration	NR
	Source population description	Schoolchildren (12 to 13 years) were selected from six villages: Baroi, Chhasara, Gundala, Mundra, Pragpar, and Zarpara in the semi-arid Mundra region of Kachchh, Gujurat
	Inclusion/exclusion criteria	Attendance at school over 80%

	Recruitment procedures	NR		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	84	34	50
	Age (range)	12 – 13 years	12 – 13 years	12 – 13 years
	Male	NR	NR	NR
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Exposed to natural occurring fluoride present in the groundwater of Chhasra, Mundra, and Gundala villages (mean fluoride 2.3 ppm).	Exposed to natural occurring fluoride present in the groundwater of Baroi, Zarpara and Pragpar villages (mean fluoride 0.84 ppm).	
	Setting	School-based study. Participants recruited out of the 6th and 7th standards.		
Results: IQ	Definition Method of measurement	Intelligence quotient A questionnaire prepared by Prof. Shah and standardised on the Gujarati population with 97% reliability rate in relation to the Stanford-Binet Intelligence Scale.		
	No. of participants analysed	84		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		
	Participant category	Intervention mean ± SE	Comparator mean ± SE	Effect estimate
	Females	90.18 ± 3.32	94.37 ± 2.98	$p<0.05$
	Males	94.88 ± 2.96	99.97 ± 2.10	$p<0.05$
	All participants	92.53 ± 3.13	97.79 ± 2.54	$p<0.05$
Authors' conclusion	Because of high fluoride concentrations in the groundwater, children have greater exposure to fluoride that may lead to low IQ as compared to the nearby villages with low fluoride in their groundwater.			
Correspondence if required	None required			
Reviewer's notes	None			

Abbreviations: NA = not applicable; NR = not reported

WANG ET AL. (2007)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Schoolchildren (8 to 12 years) from three villages in Gucheng township and three villages in Heshengbao township
1.2 Is the eligible population or area representative of the source population or area?	+	Arranged meetings through local health clinics, village leaders, & teachers from the children's schools. Implication that all schoolchildren were invited to participate.
1.3 Do the selected participants or areas represent the eligible population or area?	+	80% and 75% of children in the Gucheng and Heshengbao villages agreed to participate in the study respectively. Method of selection not described. No explicit inclusion or exclusion criteria.
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	+	Aimed to reduce sampling bias by selecting a large number of individuals. Reported that all groups lived in rural areas with similar geographic and cultural conditions and a comparable level of socioeconomic development.
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies only
2.3 Was the contamination acceptably low?	NR	No discussion regarding participant migration

2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Naturally occurring fluoride at very high levels (e.g. 7-9 ppm). Dissimilar healthcare system, diet, and sociodemographic parameters.
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Combined Raven's Test – The Rural in China method, administered by a team of trained personnel with medical backgrounds.
3.2 Were the outcome measurements complete?	++	Results for all participants reported
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	NR	-
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	+	Paired q-test, Chi-squared test and Student's t-test
4.6 Was the precision of association given or calculable? Is the association meaningful?	+	Highlighted where p-values were <0.05 or <0.01
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	No adjustment for confounding factors. Sample was a very large proportion of the eligible population.
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Not generalisable to Australian context.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Wang et al. (2007)		
	Date form completed	09/02/15		
	Country of origin Source of funding Possible conflicts of interest	China Shanxi Natural Science Foundation grant 20031093 The authors declare they have no competing financial interests		
Study characteristics	Aim/objectives of study	To investigate the effects of arsenic and fluoride exposure on children's intelligence and growth		
	Study design	Ecological		
	Level of evidence	IV		
	Study location	China		
	Study duration	NR		
	Exposure duration	NR		
	Source population description	Schoolchildren (8 to 12 years) from three high fluoride villages in Gucheng township and three control villages in nearby Heshengbao township		
	Inclusion/exclusion criteria	NR		
	Recruitment procedures	NR		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	376	180	196
	Age (mean ± SD)	NR	9.9 ±1.4	9.9 ±1.5
	Male	54.3%	51.1%	57.1%
	Other characteristics	see notes	see notes	see notes
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Exposure to naturally occurring fluoride in groundwater in three	Exposure to naturally occurring fluoride in groundwater in three	

		villages in Gucheng township (mean fluoride concentration from 21 samples = 8.3 ± 1.9 ppm)	villages in Heshengbao township (mean fluoride concentration from 11 samples = 0.5 ± 0.2 ppm)	
	Setting	Community-based study. Average fluoride content in drinking water in the village was used as the basis to form the study groups.		
Results: IQ	Definition Method of measurement	Intelligence quotient Combined Raven's Test – The Rural in China method		
	No. of participants analysed	376		
	No. of participants excluded or missing	0		
	Imputation of missing data	NA		
	Statistical method of analysis	Student's t-test		
	Participant category	Intervention mean ± SD	Comparator mean ± SD	Effect estimate
	All participants	100.5 ± 15.8	104.8 ± 14.7	$p<0.05$
Authors' conclusion	This study indicates that exposure to fluoride in drinking water is associated with neurotoxic effects in children.			
Correspondence if required	None required			
Reviewer's notes	Average income, parents' education, & exposure time reported for each group but not extracted (no statistically significant differences). Height, weight, chest circumference, lung capacity outcomes also reported but not extracted. Children in the control group were taller than those in the high fluoride group ($p<0.05$).			

Abbreviations: NA = not applicable; NR = not reported

XIANG ET AL. (2009)

Quality Assessment

Issue	Rating	Comment
Section 1: Population	-	-
1.1 Is the source population or source area well described?	++	Children (8 to 13 years) in Wamiao and Xinhuai villages
1.2 Is the eligible population or area representative of the source population or area?	NR	Participant identification details not discussed
1.3 Do the selected participants or areas represent the eligible population or area?	NR	No discussion regarding representativeness
Section 2: Method of selection of exposure (or comparison) group	-	-
2.1 Selection of exposure (and comparison) group. How was selection bias minimised?	NR	No sampling details
2.2 Was the selection of explanatory variables based on a sound theoretical basis?	+	Evidence for hypothesis drawn from other published studies only
2.3 Was the contamination acceptably low?	NR	No discussion regarding participants migration
2.4 How well were likely confounding factors identified and controlled?	-	No attempt to control for confounding factors
2.5 Is the setting applicable to the Australia?	-	Fluoride range very high. Dissimilar healthcare system
Section 3: Outcomes	-	-
3.1 Were the outcome measures and procedures reliable?	++	Measurements made using standard scientific instruments
3.2 Were the outcome measurements complete?	+	Results for all participants not reported. Per protocol analysis.
3.3 Were all the important outcomes assessed?	++	All relevant outcomes assessed
3.4 Was there a similar follow-up time in exposure and comparison groups?	NR	-
3.5 Was follow-up time meaningful?	NR	-
Section 4: Analyses	-	-
4.1 Was the study sufficiently powered to detect	NR	-

an intervention effect (if one exists)?		
4.2 Were multiple explanatory variables considered in the analyses?	-	No multivariate analysis
4.3 Were the analytical methods appropriate?	++	Student's t-test and Pearson's correlation coefficient
4.6 Was the precision of association given or calculable? Is the association meaningful?	++	t values, coefficients and p-values reported
Section 5: Summary	-	-
5.1 Are the study results internally valid (i.e. unbiased)?	+	Poor assessment of the comparability of the study groups. No assessment of how well the study population is representative of the source population
5.2 Are the findings generalisable to the source population (i.e. externally valid)?	-	Not generalisable to Australian population.
Overall quality rating	Low	-

Abbreviations: NA = not applicable; NR = not reported

Data Extraction

General information	Study ID	Xiang et al. (2009)		
	Date form completed	16/01/15		
	Country of origin Source of funding Possible conflicts of interest	China Jiangsu Province Association for Endemic Disease Control and Prevention NR		
Study characteristics	Aim/objectives of study	Assess the association between fluoride intake and thyroid function in children.		
	Study design	Cross-sectional		
	Level of evidence	IV		
	Study location	Wamaio and Xinhuai, China		
	Study duration	February to June 2003		
	Exposure duration	NR		
	Source population description	Children living in Wamiao village (severe endemic fluorosis area) and Xinhuai (non-endemic fluorosis area)		
	Inclusion/exclusion criteria	Children aged 8-13 years old from Wamaio or Xinhuai village		
	Recruitment procedures	NR		
Participant characteristics		Whole study	Intervention	Comparator
	No. of participants enrolled	170	82	88
	Age (mean ± SD)	NR	11.0 ± 1.4 years	10.8 ± 1.7 years
	Male	57.6%	56.0%	59.1%
	Other characteristics	NR	NR	NR
	Subgroups reported	NR	NR	NR
Exposure and setting		Intervention	Comparator	
	Description of exposure and control	Exposure to natural fluoride levels in Wamiao village Mean fluoride level = 2.36 ± 0.70 (range 0.62 – 4.00 ppm)	Exposure to natural fluoride levels in Xinhuai village Mean fluoride level = 0.36 ± 0.10 (0.23 – 0.77 ppm)	
	Setting	Community-based study. Children recruited from pre-selected villages.		
Results: TT3	Definition Method of measurement	Total triiodothyronine (ng/mL) in serum Measured with the Test Kit from Hainan Huamei Medicine Co. Ltd, manufactured by BioCheck, Inc.		
	No. of participants analysed	130		
	No. of participants excluded or missing	40 – reasons NR		
	Imputation of missing data	NR		
	Statistical method of analysis	Student's t-test for between village differences and Pearson's correlation coefficient for within village correlation		
	Participant category	Intervention	Comparator	Effect estimate

		mean ± SD (N) Pearson's coefficient	mean ± SD (N) Pearson's coefficient	t
	All participants	1.47 ± 0.28 (62) 0.087 *p*=0.502	1.47 ± 0.33 (68) 0.108 *p*=0.381	0.855 *p*=0.394
Results: TT4	Definition Method of measurement	Total thyroxine (µg/dL) in serum Measured with the Test Kit from Hainan Huamei Medicine Co. Ltd, manufactured by BioCheck, Inc.		
	No. of participants analysed	119		
	No. of participants excluded or missing	51 – reasons not reported		
	Imputation of missing data	NR		
	Statistical method of analysis	Student's t-test for between village differences and Pearson's correlation coefficient for within village correlation		
	Participant category	Intervention mean ± SD (N) Pearson's coefficient	Comparator mean ± SD (N) Pearson's coefficient	Effect estimate t
	All participants	9.67 ± 1.76 (58) 0.057 *p*=0.672	9.22 ± 2.54 (61) -0.167 *p*=0.198	1.111 *p*=0.269
Results: TSH	Definition Method of measurement	Thyroid-stimulating hormone (µIU/mL) in serum Measured with the Test Kit from Hainan Huamei Medicine Co. Ltd, manufactured by BioCheck, Inc.		
	No. of participants analysed	129		
	No. of participants excluded or missing	41 – reasons not reported		
	Imputation of missing data	NR		
	Statistical method of analysis	Student's t-test for between village differences and Pearson's correlation coefficient for within village correlation		
	Participant category	Intervention mean ± SD (N) Pearson's coefficient	Comparator mean ± SD (N) Pearson's coefficient	Effect estimate t
	All participants	3.88 ± 2.15 (62) 0.023 *p*=0.858	2.54 ± 2.07 (67) -0.112 *p*=0.381	3.604 *p*<0.001
Authors' conclusion	TT3 and TT4 concentrations in children's serum in the two villages did not exhibit a significant difference. TSH concentration in Wamiao village was significantly higher than that in Xinhuai village. The authors conclude that high fluoride exposure can cause functional abnormalities of the thyroid.			
Correspondence if required	None required			
Reviewer's notes	Relationship between fluoride and dental fluorosis also examined but not extracted			

Abbreviations: NR = not reported

STUDIES EXCLUDED FROM THE REVIEW OF DENTAL CARIES

OVERVIEW OF REVIEWS

Studies excluded after full text review

Below is the list of studies excluded following full text review. The reason for exclusion is noted at the end of each citation.

Bader, JD, Rozier, G et al 2015. Dental caries prevention: the physician's role in child oral health (Structured abstract), *Health Technology Assessment* Database, 2015 Issue 3. Wrong intervention: not water fluoride 0.4-1.5ppm

Carey, CM 2014. Focus on fluorides: update on the use of fluoride for the prevention of dental caries, *The journal of evidence-based dental practice*, 14, 95-102. Wrong study type: not a systematic search of primary studies

Centre for Reviews and Dissemination 2012. A model to determine the economic viability of water fluoridation (Provisional abstract), *NHS Economic Evaluation Database (NHSEED)*, 2015 Issue 2. Wrong study type: economic evaluation

Centre for Reviews and Dissemination 2012. A retrospective view on the viability of water fluoridation in South Africa to prevent dental caries (Provisional abstract), *NHS Economic Evaluation Database (NHSEED)*, 2015 Issue 2. Wrong study type: economic evaluation

Centre for Reviews and Dissemination 2015. A systematic review of public water fluoridation (Structured abstract), *Database of Abstracts of Reviews of Effects*2. Publication date: published prior to 1 October 2006

Centre for Reviews and Dissemination 2012. Cost-effectiveness of extending the coverage of water supply fluoridation for the prevention of dental caries in Australia (Provisional abstract), *NHS Economic Evaluation Database (NHSEED)*, 2015 Issue 2. Wrong study type: economic evaluation

Centre for Reviews and Dissemination 2010. Drinking water fluoridation in South East Queensland: a cost-effectiveness evaluation (Provisional abstract), *NHS Economic Evaluation Database (NHSEED)*, 2015 Issue 2. Wrong study type: economic evaluation

Centre for Reviews and Dissemination 2013. The economic value of Quebec's water fluoridation program (Provisional abstract), *NHS Economic Evaluation Database (NHSEED)*, 2015 Issue 2. Wrong study type: economic evaluation

Centre for Reviews and Dissemination 2010. The impact of changing dental needs on cost savings from fluoridation (Provisional abstract), *NHS Economic Evaluation Database (NHSEED),* 2015 Issue 2. Wrong study type: economic evaluation

Da Cunha, LF and Tomita, NE 2006. Dental fluorosis in Brazil: A systematic review from 1993 to 2004, *Cadernos de Saude Publica*, 22 (9), 1809-1816. Publication date: published prior to 1 October 2006

Frazão, P, Peres, MA et al 2011. Drinking water quality and fluoride concentration, *Revista de Saude Publica*, 45 (5), 964-973. Wrong study type: not a systematic search of primary studies

Health Canada 2008, *Findings and Recommendations of the Fluoride Expert Panel (January 2007).* No data from primary studies

Jones, J 2015, *Fluoride Effectiveness in Prevention of Dental Caries in High Caries Risk Adults .* AHRQ. Wrong study type: not a systematic search of primary studies

Marino, RJ, Khan, AR et al 2013. Systematic review of publications on economic evaluations of caries prevention programs, *Caries Research*, 47 (4), 265-272. Wrong study type: not a systematic search of primary studies

Moyer, VA 2014. Prevention of dental caries in children from birth through age 5 years: US preventive services task force recommendation statement, *Pediatrics*, 133 (6), 1102-1111. Wrong intervention: individual fluoride supplementation

Murphy, G and Cunningham, J 2015. Fluoridated water for cavity prevention: a review of the clinical-effectiveness, cost-effectiveness, and guidelines (Structured abstract), *Health Technology Assessment Database,* 2015 Issue 3. No data from primary studies

Pizzo, G, Piscopo, MR et al 2007. Community water fluoridation and caries prevention: A critical review, *Clinical Oral Investigations*, 11 (3), 189-193. Wrong study type: not a systematic search of primary studies

Satur, JG, Gussy, MG et al 2010. Review of the evidence for oral health promotion effectiveness, *Health Education Journal*, 69 (3), 257-266. No data from primary studies

Studies excluded after title and abstract review

Below is the list of studies excluded following the review of titles and abstracts. The reason for exclusion is noted at the end of each citation.

Armfield, JM, Spencer, JA et al 2013. Water fluoridation and the association of sugar-sweetened beverage consumption and dental caries in Australian children, *American Journal of Public Health*, 103 (3), 494-500. Wrong study type: not a systematic review of primary studies

Awofeso, N 2012. Ethics of artificial water fluoridation in Australia, *Public Health Ethics*, 5 (2), 161-172. Wrong outcome: not dental caries

Berg, J, Gerweck, C et al 2011. Evidence-based clinical recommendations regarding fluoride intake from reconstituted infant formula and enamel fluorosis: A report of the American Dental Association Council on Scientific Affairs, *Journal of the American Dental Association*, 142 (1), 79-87. Wrong outcome: not dental caries

Binns, C and Low, WY 2014. Oral public health in the Asia-Pacific region, *Asia-Pacific Journal of Public Health*, 26 (3), 224-225. Wrong study type: not a systematic review of primary studies

Bottenberg, P, Van Melckebeke, L et al 2008. Knowledge of Flemish paediatricians about children's oral health-Results of a survey, *Acta Paediatrica*, 97 (7), 959-963. Wrong intervention: not water fluoride 0.4-1.5ppm

Bourgoin, A 2014. The use of the Internet for alternative views on health, *Dissertation Abstracts International Section A: Humanities and Social Sciences*, 74, 10-A(E). Wrong intervention: not water fluoride 0.4-1.5ppm

Broadbent, JM, Thomson, WM et al 2015. Broadbent et al. Respond, *American Journal of Public Health*, 105 (4), e3-e4. Wrong study type: not a systematic review of primary studies

Broughton, JR, Person, M et al 2014. Ukaipðniho: the place of nurturing for oral health, *The New Zealand dental journal*, 110 (1), 18-23. Wrong study type: not a systematic review of primary studies

Brumback, RA 2012. Review of The case against fluoride: How hazardous waste ended up in our drinking water and the bad science and powerful politics that keep it there, *Journal of Evidence-Based Complementary & Alternative Medicine*, 17 (2), 140-141. Wrong study type: not a systematic review of primary studies

Cagetti, MG, Campus, G et al 2013. A systematic review on fluoridated food in caries prevention, *Acta odontologica Scandinavica*, 71 (3-4), 381-387. Duplicate

Cagetti, MG, Campus, G et al 2013. A systematic review on fluoridated food in caries prevention, *Acta odontologica Scandinavica*, 71 (3/4), 381-387. Duplicate

Cagetti, MG, Campus, G et al 2013. A systematic review on fluoridated food in caries prevention, *Acta odontologica Scandinavica*, 71 (3-4), 381-387. Wrong intervention: not water fluoride 0.4-1.5ppm

Centre for Reviews and Dissemination 2015. Association of Down's syndrome and water fluoride level: a systematic review of the evidence (Structured abstract), *Database of Abstracts of Reviews of Effects*. Publication date

Centre for Reviews and Dissemination 2015. Water fluoridation, bone mass and fracture: a quantitative overview of the literature (Structured abstract), *Database of Abstracts of Reviews of Effects*. Publication date

Centre for Reviews and Dissemination 2015. Water fluoridation, osteoporosis, fractures: recent developments (Structured abstract), *Database of Abstracts of Reviews of Effects*. Publication date

Chapple, ILC, Van der Weijden, F et al 2015. Primary prevention of periodontitis: managing gingivitis, *Journal of clinical periodontology*, 42 Suppl 16, S71-S76. Wrong intervention: not water fluoride 0.4-1.5ppm

Choi, AL, Sun, G et al 2012. Developmental fluoride neurotoxicity: a systematic review and meta-analysis, *Environmental Health Perspectives*, 120 (10), 1362-1368. Duplicate

Choi, AL, Sun, G et al 2012. Developmental fluoride neurotoxicity: A systematic review and meta-analysis, *Environmental Health Perspectives*, 120 (10), 1362-1368. Wrong outcome: not dental caries

Choi, AL, Sun, G et al 2012. Meta-analysis of 27 studies of fluoride neurotoxicity in children, *Epidemiology*, 23 (5), S25. Wrong outcome: not dental caries

Choi, AL, Zhang, Y et al 2015. Association of lifetime exposure to fluoride and cognitive functions in Chinese children: A pilot study, *Neurotoxicology and Teratology*, 47, 96-101. Duplicate

Choi, AL, Zhang, Y et al 2015. Association of lifetime exposure to fluoride and cognitive functions in Chinese children: A pilot study, *Neurotoxicology and Teratology*, 47, 96-101. Wrong outcome: not dental caries

Chong, YL, Clarkson, JE et al 2014, *Slow-release fluoride devices for the control of dental decay.* Art No.: CD005101. Wrong intervention: not water fluoride 0.4-1.5ppm

Cunha, LF and Tomita, NE 2006. Dental fluorosis in Brazil: a systematic review from 1993 to 2004, *Cadernos de Saude Publica*, 22 (9), 1809-1816. Duplicate

Do, LG, Spencer, AJ et al 2011. Oral health status of Vietnamese children: Findings from the National Oral Health Survey of Vietnam 1999, *Asia-Pacific Journal of Public Health*, 23 (2), 217-227. Wrong study type: not a systematic review of primary studies

Ephraim, E, Chukwunweike, B et al 2013. Prevalence of dental fluorosis: a case study of the government secondary school, Ogbia, Bayelsa State, Nigeria, *Continental Journal of Medical Research*, 7 (2), 1-8. Wrong outcome: not dental caries

Frisardi, V, Solfrizzi, V et al 2010. Aluminum in the diet and Alzheimer's disease: From current epidemiology to possible disease-modifying treatment, *Journal of Alzheimer's Disease*, 20 (1), 17-30. Wrong intervention: not water fluoride 0.4-1.5ppm

Gelinas, J and Allukian, MJ 2014. Neurodevelopmental toxicity: Still more questions than answers, *The Lancet Neurology*, 13 (7), 647-648. Wrong study type: not a systematic review of primary studies

Gillespie, G, Marinho, CV et al 2007, *Salt fluoridation for preventing dental caries.* Art. No.: CD006846. Wrong intervention: not water fluoride 0.4-1.5ppm

Grandjean, P and Choi, AL 2015. Community water fluoridation and intelligence, *American Journal of Public Health*, 105 (4), e3. Wrong study type: not a systematic review of primary studies

Ha, DH, Crocombe, LA et al 2014. Clinical oral health of Australia's rural children in a sample attending school dental services, *The Australian Journal of Rural Health*, 22 (6), 316-322. Wrong study type: not a systematic review of primary studies

Harding, MA and O'Mullane, DM 2013. Water fluoridation and oral health, *Acta medica academica*, 42 (2), 131-139. Wrong study type: not a systematic review of primary studies

Haysom, L, Indig, D et al 2015. Oral health and risk factors for dental disease of Australian young people in custody, *Journal of Paediatrics and Child Health*, 51 (5), 545-551. Wrong study type: not a systematic review of primary studies

Hoftyzer, MK 2013. Narrative, ethos, and artificial fluoridation: The 'storying' of a public health policy, *Dissertation Abstracts International Section A: Humanities and Social Sciences*, 74 (5-A(E)), No-Specified. Wrong study type: not a systematic review of primary studies

Horowitz, AM, Kleinman, DV et al 2013. What Maryland adults with young children know and do about preventing dental caries, *American Journal of Public Health*, 103 (6), e69-e76. Wrong study type: not a systematic review of primary studies

Horowitz, AM, Kleinman, DV et al 2015. Perspectives of Maryland adults regarding caries prevention, *American Journal of Public Health*, 105 (5), e58-e64. Wrong study type: not a systematic review of primary studies

Huber, AC and Mosler, HJ 2013. Determining the differential preferences of users of two fluoride-free water options in rural Ethiopia, *Journal of Public Health*, 21 (2), 183-192. Wrong study type: not a systematic review of primary studies

Huber, AC, Bhend, S et al 2012. Determinants of exclusive consumption of fluoride-free water: A cross-sectional household study in rural Ethiopia, *Journal of Public Health*, 20 (3), 269-278. Wrong study type: not a systematic review of primary studies

Huber, AC, Tobias, R et al 2014. Evidence-based tailoring of behavior-change campaigns: Increasing fluoride-free water consumption in rural Ethiopia with persuasion, *Applied Psychology: Health and Well-Being*, 6 (1), 96-118. Wrong study type: not a systematic review of primary studies

Huerta-Saenz, L, Irigoyen, M et al 2012. Tap or bottled water: Drinking preferences among urban minority children and adolescents, *Journal of Community Health: The Publication for Health Promotion and Disease Prevention*, 37 (1), 54-58. Wrong study type: not a systematic review of primary studies

Hujoel, PP, Zina, GL et al 2009. Infant formula and enamel fluorosis A systematic review, *Journal of the American Dental Association*, 140 (7), 841-854. Wrong outcome: not dental caries

Iheozor-Ejiofor, Z, Worthington, HV et al Water fluoridation for the prevention of dental caries. Duplicate

Ijaz, S, Marinho, CV et al 2010, *Professionally applied fluoride paint-on solutions for the control of dental caries in children and adolescents.* Art. No.: CD008364. Wrong intervention: not water fluoride 0.4-1.5ppm

Jeon, S 2013. Bayesian data mining techniques in public health and biomedical applications, *Dissertation Abstracts International: Section B: The Sciences and Engineering*, 74 (4-B(E)), No-Specified. Wrong intervention: not water fluoride 0.4-1.5ppm

Keeling, J 2013. Development of systematic knowledge management for public health: A public health law ontology, *Dissertation Abstracts International: Section B: The Sciences and Engineering*, 73 (9-B(E)), No-Specified. Wrong intervention: not water fluoride 0.4-1.5ppm

Khishfe, R 2012. Relationship between nature of science understandings and argumentation skills: A role for counterargument and contextual factors, *Journal of Research in Science Teaching* , 49 (4), 489-514. Wrong intervention: not water fluoride 0.4-1.5ppm

Kisely, S, Quek, LH et al 2011. Advanced dental disease in people with severe mental illness: Systematic review and meta-analysis, *The British Journal of Psychiatry*, 199 (3), 187-193. Duplicate

Kumar, S 2012. Water fluoridation, dental fluorosis, bone fluorosis, and skeletal fluorosis among persons in the Hojai sub-division, Nagaon District, Assam, India: A quantitative overview, *Fluoride*, 45 (3), 180-181. Wrong study type: not a systematic review of primary studies

MacDonald, LH 2010. Microbiological and plant-driven redox systems in groundwater and links between water, health, and policy, *Dissertation Abstracts International: Section B: The Sciences and Engineering*, 71 (6-B), 3870. Wrong population: not human

Machoy-Mokrzynska, A and Machoy, Z 2006. Current trends in fluorine research, *Annales Academiae Medicae Stetinensis*, 52 Suppl 1, 73-77. Wrong outcome: not dental caries

Marinho, VC, Higgins, JP et al 2003. Topical fluoride (toothpastes, mouthrinses, gels or varnishes) for preventing dental caries in children and adolescents, *Cochrane database of systematic reviews (Online)*4), CD002782. Wrong intervention: not water fluoride 0.4-1.5ppm

Marino, RJ, Khan, AR et al 2013. Systematic review of publications on economic evaluations of caries prevention programs, *Caries Research*, 47 (4), 265-272. Duplicate

Marya, CM, Ashokkumar, BR et al 2014. Exposure to high-fluoride drinking water and risk of dental caries and dental fluorosis in Haryana, India, *Asia-Pacific Journal of Public Health*, 26 (3), 295-303. Wrong study type: not a systematic review of primary studies

Merrick, J and Feldberg, I 2013. A pain in my tooth, *Journal of Pain Management*, 6 (4), 267-269. Wrong study type: not a systematic review of primary studies

Neumann, AS, Lee, KJ et al 2011. Impact of an oral health intervention on pre-school children <3 years of age in a rural setting in Australia, *Journal of Paediatrics and Child Health*, 47 (6), 367-372. Wrong intervention: not water fluoride 0.4-1.5ppm

NHS Centre for Reviews and Dissemination 2015. A systematic review of public water fluoridation (Structured abstract), *Health Technology Assessment Database,* 2015 Issue 3. Duplicate

Ortega GarcÃ-a, JA, FerrÃ-s, IT et al 2006. Environmental neurotoxins (IV). Tobacco, alcohol, solvents, fluoride, food additives: Adverse effects on the fetal and postnatal nervous system. Preventive measures, *Acta Pediatrica Espanola*, 64 (10), 493-502. Wrong outcome: not dental caries

Parnell, C, Whelton, H et al 2009. Water fluoridation, *European archives of paediatric dentistry : official journal of the European Academy of Paediatric Dentistry*, 10 (3), 141-148. Wrong study type: not a systematic review of primary studies

Pessan, JP, Toumba, KJ et al 2011. Topical use of fluorides for caries control, *Monographs in Oral Science*, 22, 115-132. Wrong intervention: not water fluoride 0.4-1.5ppm

Petersen, PE and Phantumvanit, P 2012. Perspectives in the effective use of fluoride in Asia, *Journal of Dental Research*, 91 (2), 119-121. Wrong study type: not a systematic review of primary studies

Postma, J, Butterfield, PW et al 2011. Rural children's exposure to well water contaminants: Implications in light of the American Academy of Pediatrics' recent policy statement, *Journal of the American Academy of Nurse Practitioners*, 23 (5), 258-265. Wrong study type: not a systematic review of primary studies

Qu, J and Fan, M 2010. The current state of water quality and technology development for water pollution control in China, *Critical Reviews in Environmental Science and Technology*, 40 (6), 519-560. Wrong study type: not a systematic review of primary studies

Rosenblatt, A, Stamford, TC et al 2009. Silver diamine fluoride: a caries "silver-fluoride bullet", *Journal of Dental Research*, 88 (2), 116-125. Wrong intervention: not water fluoride 0.4-1.5ppm

Rosenblatt, A, Stamford, TCM et al 2009. Silver diamine fluoride: a caries "silver-fluoride bullet", *Journal of Dental Research*, 88 (2), 116-125. Duplicate

Rugg-Gunn, A and BÃ¡nÃ³czy, J 2013. Fluoride toothpastes and fluoride mouthrinses for home use, *Acta medica academica*, 42 (2), 168-178. Wrong intervention: not water fluoride 0.4-1.5ppm

Rugg-Gunn, A and Banoczy, J 2013. Fluoride toothpastes and fluoride mouthrinses for home use, *Acta medica academica*, 42 (2), 168-178. Duplicate

Shader, RI 2014. A blueberry cocktail helps with memory loss: Too good to be true?, *Journal of Clinical Psychopharmacology*, 34 (4), 421-422. Wrong study type: not a systematic review of primary studies

Simon, MJK, Beil, FT et al 2014. High fluoride and low calcium levels in drinking water is associated with low bone mass, reduced bone quality and fragility fractures in sheep, *Osteoporosis International*, 25 (7), 1891-1903. Wrong population: not human

Skillman, SM, Doescher, MP et al 2010. The challenge to delivering oral health services in rural America, *Journal of Public Health Dentistry*, 70 (s1), S49-S57. Duplicate

Skillman, SM, Doescher, MP et al 2010. The challenge to delivering oral health services in rural America, *Journal of Public Health Dentistry*, 70 (SUPPL. 1), S49-S57. Wrong study type: not a systematic review of primary studies

Slack-Smith, L, Colvin, L et al 2013. Dental admissions in children under two years - A total-population investigation, *Child: Care, Health and Development*, 39 (2), 253-259. Wrong study type: not a systematic review of primary studies

Slomka, P, Berman, DS et al 2014. The role of PET quantification in cardiovascular imaging, *Clinical and Translational Imaging*, 2 (4), 343-358. Wrong intervention: not water fluoride 0.4-1.5ppm

Tabatabaei-Moghaddam, H, Sano, Y et al 2014. A case study in creating oral health messages for rural low-income families: A comparison to the cultural appropriateness framework, *Health Promotion Practice*, 15 (5), 646-653. Wrong intervention: not water fluoride 0.4-1.5ppm

Tubert-Jeannin, S, Auclair, C et al 2011. Fluoride supplements (tablets, drops, lozenges or chewing gums) for preventing dental caries in children, *Cochrane database of systematic reviews (Online)*, 12, CD007592. Wrong intervention: not water fluoride 0.4-1.5ppm

TubertJeannin, S, Auclair, C et al 2011. Fluoride supplements (tablets, drops, lozenges or chewing gums) for preventing dental caries in children, *Cochrane Oral Health Group*. Duplicate

Wanigasuriya, K 2014. Update on uncertain etiology of chronic kidney disease in Sri Lanka's north-central dry zone, *MEDICC Review*, 16 (2), 61-65. Wrong outcome: not dental caries

Yengopal, V, Chikte, UM et al 2010. Salt fluoridation: a meta-analysis of its efficacy for caries prevention, *SADJ : journal of the South African Dental Association = tydskrif van die Suid-Afrikaanse Tandheelkundige Vereniging*, 65 (2), 60-67. Wrong intervention: not water fluoride 0.4-1.5ppm

Yeung, CA 2008. A systematic review of the efficacy and safety of fluoridation, *Evidence-based dentistry*, 9 (2), 39-43. Wrong study type: summary of NHMRC 2007 review

Yeung, CA, Chong, LY et al 2015. Fluoridated milk for preventing dental caries, *The Cochrane database of systematic reviews*, 9, CD003876. Wrong intervention: not water fluoride 0.4-1.5ppm

Yin, X-H, Huang, G-L et al 2015. Exposure to fluoride in drinking water and hip fracture risk: A meta-analysis of observational studies, *PLoS ONE*, 10 (5),Wrong outcome: not dental caries

Yocum, E. 2012, 'A community's experience with environmental health research at the fernald feed production plant', In: Wing, S. (eds), *Tortured Science: Health Studies, Ethics and Nuclear Weapons in the United States.* Baywood Publishing Co, 53-67. Wrong study type: not a systematic review of primary studies

SYSTEMATIC REVIEW OF PRIMARY STUDIES

Studies excluded after full text review

Below is the list of studies excluded following full text review. The reason for exclusion is noted at the end of each citation.

Aldosari, A.M.A. 2010. Associations among dental caries experience, fluorosis, and fluoride exposure from drinking water sources in Saudi Arabia. *Journal of public health dentistry*, 70, (3) 220-226 Notes: Comparator: not <0.4ppm fluoride in multivariate analysis

Antunes, J.L.F. 2006. Individual and contextual determinants of dental treatment needs of children with primary dentition in Brazil. (Saude bucal coletiva.) [Portuguese]. *Ciencia & saude coletiva*, 11, (1) 79-87 Notes: Publication date: published prior to 1 October 2006

Antunes, J.L.F. 2006. Multilevel assessment of determinants of dental caries experience in Brazil. *Community dentistry and oral epidemiology*, 34, (2) 146-152 Notes: Publication date: published prior to 1 October 2006

Ardenghi, T.M. 2013. Inequalities in untreated dental caries prevalence in preschool children in Brazil. (Special issue.) [Portuguese English]. *Revista de saude publica*, 47, (Supl. 3) 129-137 Notes: Duplicate

Ardenghi, TMP 2013. [Inequalities in untreated dental caries prevalence in preschool children in Brazil], *Revista de saude publica*, 47 Suppl 3 (pp 129-137), Dec. Notes: Outcome: prevalence of untreated decays – an indication of access to dental care

Armfield, J.M. 2008. The benefits of water fluoridation across areas of differing socio-economic status. *Australian dental journal*, 53, (2) 180-183 Notes: No multivariate analysis

Armfield, J.M. 2010. Community effectiveness of public water fluoridation in reducing children's dental disease. *Public Health Reports*, 125, (5) 655-664 Notes: Rugg-Gunn and Do 2012

Arnold, J. 2006. Effect of fluoridated public water supplies on dental caries prevalence. 1956. *Bulletin of the World Health Organization*, 84, (9) 761-764 Notes: Publication date: republication of an article from 1956

Arora, A.E. 2010. Dental caries in children: a comparison of one non-fluoridated and two fluoridated communities in NSW. *New South Wales public health bulletin*, 21, (11-12) 257-262 Notes: No multivariate analysis

Awofeso, N.K. 2013. Water, sanitation, and public health. *Journal of Environmental and Public Health*, 2013 , 2013. Article Number, 641749 Notes: Publication type: narrative review

Bae, K.H.H. 2011. A comparison of dental caries status in cities with or without fluoridation. *Epidemiology*, Conference, (var.pagings) January Notes: Duplicate

Bailie, R.S.S. 2009. Association of natural fluoride in community water supplies with dental health of children in remote Indigenous communities - Implications for policy. *Australian and New Zealand journal of public health*, 33, (3) 205-211 Notes: Superseded data

Bao, L., Bao, L., Li, Y., & Zhang, Y. 2007. [Dental caries and fluorosis among 12-year-old children with different fluoride exposure in Heilongjiang province]. [Chinese]. *Shanghai Kou Qiang Yi Xue/Shanghai Journal of Stomatology*, 16, (6) 574-577
Notes: Duplicate

Bao, L.L. 2007. Dental caries and fluorosis among 12-year-old children with different fluoride exposure in Heilongjiang province. *Shanghai kou qiang yi xue = Shanghai journal of stomatology*, 16, (6) 574-577 Notes: Language: Chinese

Bastos, J.L. 2009. Color/race inequalities in oral health among Brazilian adolescents. *Revista Brasileira de Epidemiologia*, 12, (3) 313-324 Notes: No useable data: results not reported by water fluoride level

Berndt, C.M. 2010. Fluorosis, caries and oral hygiene in schoolchildren on the Ombili Foundation in Namibia. *Oral health & preventive dentistry*, 8, (3) 269-275 Notes: No multivariate analysis

Blinkhorn, A.S. 2008. Can we reduce dental inequalities in children? *International Journal of Health Promotion and Education*, 46, (3) 113 Notes: Publication type: conference proceeding

Blinkhorn, A.S., Blinkhorn, A.S., Byun, R., Johnson, G., Metha, P., Kay, M., & Lewis, P. 2015. The Dental Health of primary school children living in fluoridated, pre-fluoridated and non-fluoridated communities in New South Wales, Australia. *BMC oral health*, 15, 9 Notes: Superseded data

Bruvo, M.E. 2008. Optimal drinking water composition for caries control in populations. *Journal of Dental Research*, 87, (4) 340-343 Notes: No useable data: no statistical analysis of caries by water fluoride

Celeste, R.K., Celeste, R.K., Nadanovsky, P., & De Leon, A.P. 2007. [Association between preventive care provided in public dental services and caries prevalence]. [Portuguese]. *Revista de saude publica*, 41, (5) 830-838 Notes: Duplicate

Celeste, R.K.N. 2007. Association between preventive care provided in public dental services and caries prevalence. *Revista de saude publica*, 41, (5) 830-838 Notes: Language: Portuguese

Celeste, R.K.N. 2010. How much of the income inequality effect can be explained by public policy? Evidence from oral health in Brazil. *Health Policy*, 97, (2-3) 250-258 Notes: Superseded data

Cheng, K.K.C. 2007. Adding fluoride to water supplies. *British Medical Journal*, 335, (7622) 699-702 Notes: Publication type: narrative review

Cho, H.-J.L. 2014. Association of dental caries with socioeconomic status in relation to different water fluoridation levels. *Community dentistry and oral epidemiology*, 42, (6) 536-542 Notes: No useable data: no statistical analysis of caries by water fluoride

Cho, H-JJ 2014. Systemic effect of water fluoridation on dental caries prevalence, *Community dentistry and oral epidemiology*, 42 (4), 341-348 Notes: Intervention: not fluoride level 0.4-1.5ppm

Connett, P. & Connett, P. 2006. Water fluoridation--a public health hazard. *International Journal of Occupational & Environmental Health*, 12, (1) 88-91 Notes: Publication date: published prior to 1 October 2006

Cook, S.L.M. 2008. Dental caries experience and association to risk indicators of remote rural populations. *International Journal of Paediatric Dentistry*, 18, (4) 275-283 Notes: Intervention: not water fluoride 0.4-1.5ppm

de Campos Mello TR, Antunes JL, Waldman EA., de Campos Mello, T.R., Antunes, J.L.F., & Waldman, E.A. 2008. [Prevalence of untreated caries in deciduous teeth in urban and rural areas in the state of Sao Paulo, Brazil]. [Portuguese]. *Pan American Journal of Public Health*, 23, (2) 78-84 Notes: Duplicate

De Campos Mello, T.R.A. 2008. Prevalence of untreated caries in deciduous teeth in urban and rural areas in the state of Sao Paulo, Brazil. *Revista Panamericana de Salud Publica/Pan American Journal of Public Health*, 23, (2) 78-84 Notes: Language: Portuguese

de Carvalho RB, Medeiros UV, dos Santos KT, Pacheco Filho AC., de Carvalho, R.B., Medeiros, U.V.d., dos Santos, K.T., & Pacheco Filho, A.C. 2011. [Influence of different concentrations of fluoride in the water on epidemiologic indicators of oral health/disease]. [Portuguese]. *Ciencia & saude coletiva*, 16, (8) 3509-3518 Notes: Duplicate

de Carvalho, R.B. 2011. Influence of different concentrations of fluoride in the water on epidemiologic indicators of oral health/disease. *Ciencia e Saude Coletiva*, 16, (8) 3509-3518 Notes: Language: Portuguese

Do, L.G.L. 2012. Association between infant formula feeding and dental fluorosis and caries in Australian children. *Journal of public health dentistry*, 72, (2) 112-121 Notes: No useable data: no statistical analysis of caries by water fluoride

Ekstrand, K.R.C. 2010. Factors associated with inter-municipality differences in dental caries experience among Danish adolescents. An ecological study. *Community dentistry and oral epidemiology*, 38, (1) 29-42 Notes: No multivariate analysis

Evans, R.W.H. 2009. Water fluoridation in the Blue Mountains reduces risk of tooth decay. *Australian dental journal*, 54, (4) 368-373 Notes: Rugg-Gunn and Do 2012

Franzolin, S.O.G. 2010. Epidemiology of fluorosis and dental caries according to different types of water supplies. *Ciencia & saude coletiva*, 15 Suppl 1, (pp 1841-1847) Jun Notes: No multivariate analysis

Freire, M.d. 2013. Individual and contextual determinants of dental caries in Brazilian 12-year-olds in 2010. (Special issue.) [Portuguese English]. *Revista de saude publica*, 47, (Supl. 3) 40-49 Notes: Duplicate

Freitas, C.H.S. 2013. [Methodological discussion about prevalence of the dental fluorosis on dental health surveys]. *Revista de saude publica*, 47 Suppl 3, (pp 138-147) Dec Notes: Outcome: not dental caries

Freitas, C.H.S. 2013. Methodological discussion about prevalence of the dental fluorosis on dental health surveys. (Special issue.) [Portuguese English]. *Revista de saude publica*, 47, (Supl. 3) 138-147 Notes: Duplicate

Frias AC, Antunes JL, Junqueira SR, Narvai PC., Frias, A.C., Antunes, J.L.F., Junqueira, S.R., & Narvai, P.C. 2007. [Individual and contextual determinants of the prevalence of untreated caries in Brazil]. [Portuguese]. *Pan American Journal of Public Health*, 22, (4) 279-285 Notes: Duplicate

Frias, A.C.A. 2007. Individual and contextual determinants of the prevalence of untreated caries in Brazil. *Revista Panamericana de Salud Publica/Pan American Journal of Public Health*, 22, (4) 279-285 Notes: Language: Portuguese

Frias, A.C.N. 2006. Cost of fluoridating the public water supply: A study case in the city of Sao Paulo, Brazil, 1985-2003. *Cadernos de saude publica*, 22, (6) 1237-1246 Notes: Publication date: published prior to 1 October 2006

Gabardo MC, da Silva WJ, Moyses ST, Moyses SJ., Gabardo, M.C.L., da Silva, W.J., Moyses, S.T., & Moyses, S.J. 2008. Water fluoridation as a marker for sociodental inequalities. *Community Dentistry & Oral Epidemiology*, 36, (2) 103-107 Notes: No useable data: results not reported by water fluoride level

Goncalves MM, Leles CR, Freire Mdo, Goncalves, M.M., Leles, C.R., & Freire, M.d.C.M. 2013. Associations between Caries among Children and Household Sugar Procurement, Exposure to Fluoridated Water and Socioeconomic Indicators in the Brazilian Capital Cities. *International Journal of Dentistry*, 2013, 492790 Notes: No useable data: no statistical analysis of caries by water fluoride alone

Ha, D.H., Crocombe, L., & Ha, D.H.d.h.e.a. 2014. Clinical oral health of Australia's rural children in a sample attending school dental services. [References]. *The Australian Journal of Rural Health*, .22, (6) Notes: Superseded data

Han, D.H.K. 2011. A comparison of dental caries status in cities with or without water fluoridation. *Epidemiology*, Conference, (var.pagings) January Notes: Publication type: conference abstract

Hardcastle, L.R.B. 2015. Fluoridating Army community water systems in the US Army Public Health Command Region-West Area of Responsibility. *U.S.Army Medical Department journal.* (pp 38-48) 01 Notes: Publication type: narrative review

Hashizume, L.N.M. 2013. Effect of the widespread use of fluorides on the occurrence of hidden caries in children. *International Journal of Paediatric Dentistry*, 23, (1) 72-76 Notes: No multivariate analysis

Hopcraft, M.S.M. 2006. Pattern of dental caries experience on tooth surfaces in an adult population. *Community dentistry and oral epidemiology*, 34, (3) 174-183 Notes: Publication date: published prior to 1 October 2006

Hopcraft, M.S.Y. 2009. Dental caries experience in young Australian Army recruits 2008. *Australian dental journal*, 54, (4) 316-322 Notes: Rugg-Gunn and Do 2012

Iida, H.K. 2009. The association between enamel fluorosis and dental caries in U.S. schoolchildren. *Journal of the American Dental Association*, 140, (7) 855-862 Notes: No useable data: no statistical analysis of caries by water fluoride

Johnson, N.W.L. 2014. Effectiveness of water fluoridation in caries reduction in a remote Indigenous community in Far North Queensland. *Australian dental journal*, 59, (3) 366-371 Notes: No multivariate analysis

Kanagaratnam S.Schluter 2009. Enamel defects and dental caries in 9-year-old children living in fluoridated and nonfluoridated areas of Auckland, New Zealand. *Community dentistry and oral epidemiology*, 37, (3) 250-259 Notes: Rugg-Gunn and Do 2012

Khazaei, M. 2013. Dental caries prevalence among schoolchildren in urban and rural areas of Qom province, central part of Iran. *Middle East Journal of Scientific Research*, 18, (5) 584-591 Notes: No multivariate analysis

Khazaei, M.M. 2012. Fluoride concentration in drinking water supplies in QOM, Iran, and DMFT index of 12-year-old students. *Fluoride*, Conference, (var.pagings) 153-September Notes: Publication type: conference abstract

Kirkeskov, L et al 2010. The association between fluoride in drinking water and dental caries in Danish children. Linking data from health registers, environmental registers and administrative registers, *Community Dentistry & Oral Epidemiology*, 38 (3), 206-212. Notes: Outcome: use of %dmfs≥2 which is not true caries prevalence

Koh, R. & Koh, R. 2015. Effects of water fluoridation on caries experience in the primary dentition in a high caries risk community in Queensland, Australia. *Caries research*, 49, (2) 184-191 Notes: No multivariate analysis

Kotecha, P.V.P. 2012. Prevalence of dental fluorosis & dental caries in association with high levels of drinking water fluoride content in a district of Gujarat, India. *Indian Journal of Medical Research*, 135, (6) 873-877 Notes: Comparator: not <0.4ppm fluoride

Kouzmina, E. 2009. Oral health status of 12-year-old children in Russia. *Pravention und Gesundheitsforderung*, 4, (2) 131-134 Notes: Comparator: not <0.4ppm fluoride

Lauris, J.R.P. 2012. Decline in dental caries among 12-year-old children in Brazil, 1980-2005. *International dental journal*, 62, (6) 308-314 Notes: Superseded data

Leake, J et al 2008. Severe dental caries, impacts and determinants among children 2-6 years of age in Inuvik Region, Northwest Territories, Canada, *Journal (Canadian Dental Association)*, 74 (6), 519-Aug Notes: Outcome: incorrect definition of severe early childhood caries

Lennona, M.A. 2006. One in a million: The first community trial of water fluoridation. *Bulletin of the World Health Organization*, 84, (9) 759-760 Notes: Publication date: published prior to 1 October 2006

MacHiulskiene, V.B., V 2009. Prevalence and extent of dental caries, dental fluorosis, and developmental enamel defects in Lithuanian teenage populations with different fluoride exposures. *European Journal of Oral Sciences*, 117, (2) 154-160 Notes: No multivariate analysis

Mahoney, G.S. 2008. Lifetime fluoridation exposure and dental caries experience in a military population. *Community dentistry and oral epidemiology*, 36, (6) 485-492 Notes: Rugg-Gunn and Do 2012

Mapengo, M.A.M. 2010. Dental caries in adolescents from public schools in Maputo, Mozambique. *International dental journal*, 60, (4) 273-281 Notes: Intervention: not water fluoride 0.4-1.5ppm

Marya, C.M.A. 2014. Exposure to high-fluoride drinking water and risk of dental caries and dental fluorosis in Haryana, India. *Asia-Pacific journal of public health / Asia-Pacific Academic Consortium for Public Health*, 26, (3) 295-303 Notes: Comparator: not <0.4ppm fluoride

Marya, C.M.D. 2010. Relationship of dental caries at different concentrations of fluoride in endemic areas: an epidemiological study. *The Journal of clinical pediatric dentistry*, 35, (1) 41-45 Notes: Comparator: not <0.4ppm fluoride

Mascarenhas, A.K., Mascarenhas, A.K., & Mashabi, S. 2008. High fluoride concentration in drinking water may increase the prevalence and severity of dental fluorosis, and decrease occurrence of caries. *The Journal of Evidence based Dental Practice*, 8, (1) 15-16 Notes: Publication type: commentary

Mascarenhas, A.K., Mascarenhas, A.K., & Scott, T. 2008. Does exposure to fluoridated water during the crown completion and maturation phases of permanent first molars decrease pit and fissure caries? *The Journal of Evidence based Dental Practice*, 8, (1) 17-18 Notes: Publication type: commentary

McLaren, L. 2014. The impact of removing fluoridation from municipal water supplies in Canada: a tale of two cities. *Journal (Canadian Dental Association)*, 80, (pp e30) 2014 Notes: Publication type: interview

Meyer-Lueckel, H.B. 2007. Prevalence of caries and fluorosis in adolescents in Iran. *Quintessence International*, 38, (6) 459-465 Notes: No multivariate analysis

Meyer-Lueckel, H.P. 2006. Caries and fluorosis in 6- and 9-year-old children residing in three communities in Iran. *Community dentistry and oral epidemiology*, 34, (1) 63-70 Notes: Publication date: published prior to 1 October 2006

Montero, M., Montero, M., Rojas-Sanchez, F., Socorro, M., Torres, J., & Acevedo, A.M. 2007. [Dental caries and fluorosis in children consuming water with different fluoride concentrations in Maiquetia, Vargas State, Venezuela]. [Spanish]. *Investigacion Clinica*, 48, (1) 5-19 Notes: Duplicate

Montero, M.R.-S. 2007. Dental caries and fluorosis in children consuming water with different fluoride concentrations in Maiquetia, Vargas State, Venezuela. *Investigacion Clinica*, 48, (1) 5-19 Notes: Language: Spanish

Mullen, J.M. 2012. Caries status in 16 year-olds with varying exposure to water fluoridation in Ireland. *Community dental health*, 29, (4) 293-296 Notes: No multivariate analysis

Nahum, L.H. & Nahum, L.H. 2015. Mutual Medical Dental Problems: Fluoridation of Water Supply. 1965. *Connecticut Medicine*, 79, (3) 177-179 Notes: Publication date: republished article from 1965

Narvai, P.C.F. 2006. Dental caries in Brazil: Decline, polarization, inequality and social exclusion. *Revista Panamericana de Salud Publica/Pan American Journal of Public Health*, 19, (6) 385-393 Notes: Publication date: published prior to 1 October 2006

Nascimento S.Frazao 2013. [Dental health in Brazilian adults between 1986 and 2010]. *Revista de saude publica*, 47 Suppl 3, (pp 69-77) Dec Notes: Intervention: not water fluoridation

Nascimento, S.D. & Frazao 2013. Dental health in Brazilian adults between 1986 and 2010. (Special issue.) [Portuguese English]. *Revista de saude publica*, 47, (Supl. 3) 69-77 Notes: Duplicate

Nohno, K.S. 2006. Fluoride intake from food and liquid in Japanese children living in two areas with different fluoride concentrations in the water supply. *Caries research*, 40, (6) 487-493 Notes: No multivariate analysis

Peres, M.A.A. 2006. Is water fluoridation effective in reducing inequalities in dental caries distribution in developing countries? Recent findings from Brazil. *Sozial- und Praventivmedizin*, 51, (5) 302-310 Notes: Superseded data

Punitha, V.C.S. 2014. Prevalence of dental fluorosis in a non-endemic district of Tamil Nadu, India. *Biosciences Biotechnology Research Asia*, 11, (1) 159-163 Notes: No useable data: results not reported by water fluoride level

Rahmani, A.R. 2010. Child dental caries in relation to fluoride and some inorganic constituents in drinking water in Arsanjan, Iran. *Fluoride*, 43, (3) 179-186 Notes: No multivariate analysis

Rahmani, A.R. 2010. Drinking water fluoride and child dental caries in Noorabademamasani, Iran. *Fluoride*, 43, (3) 187-193 Notes: No multivariate analysis

Ramezani, G., Ramezani, G., Valaie, N., & Rakhshan, V. 2015. The effect of water fluoride concentration on dental caries and fluorosis in five Iran provinces: A multi-center two-phase study. *Dental Research Journal*, 12, (1) 31-37 Notes: Comparator: not <0.4ppm fluoride

Ranjan S.Yasmin 2012. Assessment of groundwater quality in Gaya region with respect to fluoride. *Journal of Ecophysiology and Occupational Health*, 12, (3-4) 21-25 Notes: No multivariate analysis

Rihs, L.B. 2009. Dental caries and tooth loss in adults in a Brazilian southeastern state. *Journal of Applied Oral Science*, 17, (5) 392-396 Notes: No multivariate analysis

Rihs, L.B.D. 2008. Root caries in areas with and without fluoridated water at the southeast region of Sao Paulo State, Brazil. *Journal of Applied Oral Science*, 16, (1) 70-74 Notes: No multivariate analysis

Saliba NA, Moimaz SA, Casotti CA, Pagliari AV., Saliba, N.A., & Moimaz, S. 2008. Dental caries of lifetime residents in Baixo Guandu, Brazil, fluoridated since 1953--a brief communication. *Journal of public health dentistry*, 68, (2) 119-121 Notes: Rugg-Gunn and Do 2012

Shaffer, J.R.P. 2013. Demographic, socioeconomic, and behavioral factors affecting patterns of tooth decay in the permanent dentition: Principal components and factor analyses. *Community dentistry and oral epidemiology*, 41, (4) 364-373 Notes: No useable data: no statistical analysis of total caries by water fluoride

Shanthi, M. & Shanthi, M. 2014. Relationship Between Drinking Water Fluoride Levels, Dental Fluorosis, Dental Caries and Associated Risk Factors in 9-12 Years Old School Children of Nelakondapally Mandal of Khammam District, Andhra Pradesh, India: A Cross-sectional Survey. *Journal of International Oral Health*, 6, (3) 106-110 Notes: Comparator: not <0.4ppm fluoride

Shekar, C.C. 2012. Prevalence of dental caries and dental fluorosis among 12 and 15 years old school children in relation to fluoride concentration in drinking water in an endemic fluoride belt of Andhra Pradesh. *Indian journal of public health*, 56, (2) 122-128 Notes: Comparator: not <0.4ppm fluoride

Singh, KA, Spencer, AJ et al 2007. Effects of water fluoride exposure at crown completion and maturation on caries of permanent first molars, Caries Research, 41 (1), 34-42. Unusable data

Singh, K.A. 2015. Water Fluoridation Has a Pre-eruptive Effect in Preventing Caries in Children. The journal of evidence-based dental practice, 15, (2) 64-65 Notes: Publication type: commentary

Skinner, J. 2012. Use of GIS to allocate water fluoridation status in the NSW Teen Dental Survey 2010. *Australian and New Zealand journal of public health*, 36, (4) 393
Notes: Publication type: letter

Skinner, J.J. 2013. Dental caries in 14- and 15-year-olds in New South Wales, Australia. *BMC public health*, 13, (pp 1060) 2013 Notes: No multivariate analysis

Sohu, D. 2007. Groundwater quality of villages of Sanganer Tehsil: focus on fluoride and fluorosis. *Journal of Ecotoxicology & Environmental Monitoring*, 17, (3) 227-233 Notes: Comparator: not <0.4ppm fluoride

Spencer, A.J.A. 2008. Exposure to water fluoridation and caries increment. *Community dental health*, 25, (1) 12-22 Notes: Rugg-Gunn and Do 2012

Spencer, A.J.B. 2010. The Strong Teeth Study; Background, rationale and feasibility of fluoridating remote Indigenous communities. *International dental journal*, 60, (3 SUPPL. 2) 250-256 Notes: No multivariate analysis

Steinmeyer, R. 2011. [Influence of natural fluoride concentration in drinking water on dental health of first class pupils in an area with enhanced fluoride content at the beginning of the 21st century]. *Gesundheitswesen (Bundesverband der Arzte des Offentlichen Gesundheitsdienstes (Germany))*, 73, (8-9) 483-490 Notes: Language: German

Sukhabogi, J. & Sukhabogi, J. 2014. Dental Fluorosis and Dental Caries Prevalence among 12 and 15-Year-Old School Children in Nalgonda District, Andhra Pradesh, India. *Annals of Medical & Health Sciences Research*, 4, (Suppl 3) S245-S252 Notes: Comparator: not <0.4ppm fluoride

Sukhabogi, J.R.P. 2013. Prevalence of dental caries and dental fluorosis among 12 and15 year-old school children in an endemic fluoride area of Nalgonda district, Andhra Pradesh, India. *Annals of Tropical Medicine and Public Health*, 6, (4) 422-429 Notes: Comparator: not <0.4ppm fluoride

Sullivan, O. 2015. Water fluoridation, dentition status and bone health of older people in Ireland. *Community dentistry and oral epidemiology*, 43, (1) 58-67 Notes: Outcome: not dental caries

Tiano, A.V.P. 2009. Dental caries prevalence in children up to 36 months of age attending daycare centers in municipalities with different water fluoride content. *Journal of Applied Oral Science*, 17, (1) 39-44 Notes: No multivariate analysis

Tocque, K. 2015. Inequalities in dental health: an ecological analysis of the interaction between the effects of water fluoridation and social deprivation on tooth decay in children living in England. *Journal of Public Health and Epidemiology*, 7, (7) 206-216 Notes: Superseded data

Uceda PR, Sanzone LA, Phillips CL, Roberts MW., & Uceda, P.R. 2013. Fluoride Exposure, Caregiver Education, and Decayed, Missing, Filled Teeth (dmft) in 2-5 year-old English or Spanish Speaking Children. *The open dentistry journal*, 7, 175-180 Notes: No useable data: results not reported by water fluoride level

Veiga, N.A. 2013. Prevalence of dental caries and fluorosis among a sample of adolescents living in a fluoridated and a non-fluoridated water region. *European Journal of Epidemiology*, Conference, (var.pagings) S226 Notes: Publication type: conference abstract

Vitoria, I., Vitoria, I., Maraver, F., & Almerich-Silla, J.M. 2014. [Fluoride content in tap water in Spain and prevention of dental caries]. [Spanish]. *Gaceta Sanitaria*, 28, (3) 255-256 Notes: Language: Spanish

Whelton, H.C. 2006. Dental caries and enamel fluorosis among the fluoridated population in the Republic of Ireland and non-fluoridated population in Northern Ireland in 2002. *Community dental health*, 23, (1) 37-43 Notes: Rugg-Gunn and Do 2012

Whelton, H.O. 2012. Monitoring the effectiveness of water fluoridation in the Republic of Ireland. *Journal of the Irish Dental Association*, 58, (3 Suppl) S6-S8 Notes: Publication type: narrative review

White, B.A.G. 2014. Preventing dental caries through community water fluoridation. *North Carolina medical journal*, 75, (6) 430-431 Notes: Publication type: narrative review

Yang, C.-C.L. 2013. Relationship between urinary fluoride level, incidences of dental fluorosis and caries of children in fluorosis areas after change of water sources. *Chinese Journal of Endemiology*, 32, (6) 673-676 Notes: Language: Chinese

Young, N., Young, N., Newton, J., Morris, J., Morris, J., Langford, J., Iloya, J., Edwards, D., Makhani, S., & Verne, J. 2015. Community water fluoridation and health outcomes in England: a cross-sectional study. *Community Dentistry & Oral Epidemiology*, 43, (6) 550-559 Notes: Duplicate: Published paper of Public Health England (2014) report

Studies excluded after title and abstract review

Below is the list of studies excluded following the review of titles and abstracts. The reason for exclusion is noted at the end of each citation.

2012. 30th Conference of the International Society for Fluoride Research, Advances in Fluoride Research. *Fluoride*, Conference, (var.pagings) - September Study type

2009. Fluoride to be added to Southampton's water supply. *British Dental Journal*, 206, (5) 244 Study type

2009. For the dental patient: fluoride: nature's tooth decay fighter. *Journal of the American Dental Association (1939)*, 140, (1) 126 Study type

2014. Patient's page. Water fluoride. *Journal - Oklahoma Dental Association*, 105, (2) 8 Study type

2013. Scientific opinion on dietary reference values for fluoride. *EFSA Journal*, 11, (8) 3332 Study type

2013. Special Issue: Epidemiology and prevention of dental caries. (Special Issue: Epidemiology and prevention of dental caries.). *Acta medica academica*, 42, (2) 105-247 Study type

2014. Special Issue: Oral health. (Special Issue: Oral health.). *Asia-Pacific Journal of Public Health*, 26, (3) 224-327 Study type

Abdellah, A.M. 2014. Assessment of drinking water quality in Grand Khartoum City, Khartoum State, Sudan. *Journal of Atoms and Molecules*, 4, (1) 645-655 Population

Abdullah, A.Z.S. 2006. The effect of copper on demineralization of dental enamel. *Journal of Dental Research*, 85, (11) 1011-1015 Intervention/Exposure

Abdulmonem, A. 2013. Does vitamin E protect against sodium fluoride toxicity on the cerebellar cortex of albino rats? *Middle East Journal of Scientific Research*, 16, (7) 1019-1026 Population

Abell, S. 2008. Fluoride supplementation. *Clinical Pediatrics*, 47, (1) 91-92 Intervention/Exposure

Aghdasi, H. 2014. A survey of relationship between drinking water fluoride concentration and DMFT index in guidance school students: a case study Piranshahr and Poldasht, West Azarbayjan. [Persian]. *Urmia Medical Journal*, 25, (3) 199-207 Comparator

Aguiar, T.R.P. 2012. Influence of the curing mode on fluoride ion release of self-adhesive resin luting cements in water or during pH-cycling regimen. *Operative Dentistry*, 37, (1) 63-70 Population

Ahmed, N.A.M. 2007. Dental caries prevalence and risk factors among 12-year old schoolchildren from Baghdad, Iraq: A post-war survey. *International dental journal*, 57, (1) 36-44 Intervention/Exposure

Ajayi, D.M.D. 2008. The fluoride content of drinking water and caries experience in 15-19 year old school children in Ibadan, Nigeria. *African journal of medicine and medical sciences*, 37, (1) 15-19 Intervention/Exposure

Akers, H.F. 2008. Collaboration, vision and reality: Water fluoridation in New Zealand (1952-1968). *New Zealand Dental Journal*, 104, (4) 127-133 Study type

Akhilesh, J. 2009. An assessment of fluoride concentrations in different districts of Madhya Pradesh, India. *International Journal of Chemical Sciences*, 7, (1) 147-154 Population

Akpata, E.S.B. 2014. Fluoride intake from fluids and urinary fluoride excretion by young children in Kuwait: a non-fluoridated community. *Community dentistry and oral epidemiology*, 42, (3) 224-233 Outcome

Al-Bloushi, N.S.T. 2012. High resolution mapping of reticulated water fluoride in Western Australia: Opportunities to improve oral health. *Australian dental journal*, 57, (4) 504-510 Population

Al-Harbi, M.S. 2014. Ameliorative effect of selenium and curcumin on sodium fluoride induced hepatotoxicity and oxidative stress in male mice. *Journal of Chemical and Pharmaceutical Research*, 6, (4) 984-998 Population

Al-Harbi, M.S. 2014. Immunotoxic effect of sodium fluoride and the mitigating effect of selenium and curcumin in male mice. *Biosciences, Biotechnology Research Asia*, 11, (1) 27-33 Population

Al-Mulla, A.K. 2010. Combination of high-fluoride toothpaste and no post-brushing water rinsing on enamel demineralization using an in-situ caries model with orthodontic bands. *Acta odontologica Scandinavica* , 68, (6) 323-328 Intervention/Exposure

Al Zraikat, H.P. 2011. The incorporation of casein phosphopeptide-amorphous calcium phosphate into a glass ionomer cement. *Dental materials : official publication of the Academy of Dental Materials*, 27, (3) 235-243 Population

Alavi, A.-A.A. 2006. The prevalence of dental caries in 5-18-year-old insulin-dependent diabetics of Fars Province, southern Iran. *Archives of Iranian Medicine*, 9, (3) 254-260 Intervention/Exposure

Albertsson, K.W., V 2010. Awareness of toothbrushing and dentifrice habits in regularly dental care receiving adults. *Swedish Dental Journal*, 34, (2) 71-78 Intervention/Exposure

Alessandri, B.G. & Alessandri Bonetti, G. 2014. The effect of zinc-carbonate hydroxyapatite versus fluoride on enamel surfaces after interproximal reduction. *Scanning*, 36, (3) 356-361 Population

Algarni, A.A., Algarni, A.A., Lippert, F., & Hara, A.T. 2015. Efficacy of stannous, fluoride and their combination in dentin erosion prevention in vitro. *Pesquisa Odontologica Brasileira = Brazilian Oral Research*, 29, 2015., Population

Alhawij, H., Alhawij, H., Lippert, F., & Martinez-Mier, E.A. 2015. Relative fluoride response of caries lesions created in fluorotic and sound teeth studied under remineralizing conditions. *Journal of dentistry*, 43, (1) 103-109 Population

Almerich-Silla, J.M.M. 2008. Caries and dental fluorosis in a western Saharan population of refugee children. *European Journal of Oral Sciences*, 116, (6) 512-517 Intervention/Exposure

Alves RX, Fernandes GF, Razzolini MT, Frazao, Alves, R.X., Fernandes, G.F., Razzolini, M.T.P., Frazao, P., Marques, R.A.d.A., & Narvai, P.C. 2012. [Evolution in access to fluoridated water in Sao Paulo State, Brazil, from the 1950s to the early 21st century]. [Portuguese]. *Cadernos de saude publica*, 28 Suppl, s69-s80 Study type

Alves, R.X.F. 2012. Evolution in access to fluoridated water in Sao Paulo state, Brazil, from the 1950s to the early 21st century. *Cadernos de saude publica*, 28, (SUPPL) 69-80 Study type

Amanlou, M., Amanlou, M., Hosseinpour, M., Azizian, H., Khoshayand, M.R., Navabpoor, M., & Souri, E. 2010. Determination of fluoride in the bottled drinking waters in Iran. *Iranian Journal of Pharmaceutical Research*, 9, (1) 37-42 Population

Ambarkova, V.G. 2011. The effect of fluoridated dentifrice formulations on enamel remineralisation and microhardness after in Vitro demineralization. *Acta Stomatologica Croatica*, 45, (3) 159-165 Intervention/Exposure

American Academy of Pediatrics, Committee on Native American Child Health, Canadian Paediatric Society, First Nations, Inuit and Métis Committee. 2011. Early childhood caries in indigenous communities. [Review]. *Pediatrics*, 127, (6) 1190-1198 Study type

Anderson, L.M. 2012. The importance of substate surveillance in detection of geographic oral health inequalities in a small state. *Journal of public health management and practice : JPHMP*, 18, (5) 461-468 Intervention/Exposure

Antunes, J.L.F. 2010. Dental health policies in Brazil and their impact on health inequalities. *Revista de saude publica*, 44, (2) 360-365 Study type

Arbind, K. 2013. Ultrastructural histocytopathology of spleen of rat (Rattus norvegicus) induced by fluoride toxicity. *South Asian Journal of Experimental Biology*, 3, (4) 183-187 Population

Arjun, T.N. 2015. Efficacy of herbal dentifrice in the reduction of dental caries compared against commercially available fluoride containing dentifrice: an experimental trial. *World Journal of Pharmacy and Pharmaceutical Sciences (WJPPS)*, 4, (4) 800-807 Intervention/Exposure

Armfield, J.M. & Armfield, J.M. 2006. The extent of water fluoridation coverage in Australia. *Australian & New Zealand Journal of Public Health*, 30, (6) 581-582 Study type

Armfield, J.M. & Armfield, J.M. 2007. When public action undermines public health: a critical examination of antifluoridationist literature. *Australia & New Zealand Health Policy*, 4, 25 Study type

Armfield, J.M.A. 2010. Risk perception and water fluoridation support and opposition in Australia. *Journal of public health dentistry*, 70, (1) 58-66 Outcome

Armfield, J.M.S. 2007. Community effectiveness of fissure sealants and the effect of fluoridated water consumption. *Community dental health*, 24, (1) 4-11 Intervention/Exposure

Arora, A.E. 2010. Parental support for water fluoridation in Lithgow, New South Wales. *Australian dental journal*, 55, (4) 417-422 Outcome

Arthi, V. 2013. Oral health literacy of parents of pre-schoolers in New Zealand. *Journal of Theory and Practice of Dental Public Health*, 1, (4) 20-29 Outcome

Arthur RA, Martins VB, de Oliveira CL, Leitune VC, Collares FM, Magalhaes AC, Maltz, Arthur, R.A., Martins, V.B., de Oliveira, C.L., Leitune, V.C.B., Collares, F.M., Magalhaes, A.C., & Maltz, M. 2015. Effect of over-the-counter fluoridated products regimens on root caries inhibition. *Archives of Oral Biology*, 60, (10) 1588-1594 Intervention/Exposure

Arunakul, M.T. 2011. Efficacy of xylitol and fluoride mouthrinses on salivary mutans streptococci. *Asian Pacific Journal of Tropical Biomedicine*, 1, (6) 488-490 Intervention/Exposure

Ashkenazi, M., Ashkenazi, M., Bidoosi, M., & Levin, L. 2014. Effect of Preventive Oral Hygiene Measures on the Development of New Carious lesions. *Oral health & preventive dentistry*, 12, (1) 61-69 Intervention/Exposure

Ashkenazi, M.B. 2012. Factors associated with reduced compliance of children to dental preventive measures. *Odontology*, 100, (2) 241-248 Intervention/Exposure

Ashkenazi, M.C. 2007. Self-reported compliance with preventive measures among regularly attending pediatric patients. *Journal of dental education*, 71, (2) 287-295 Intervention/Exposure

Austin, R.S.R. 2010. The effect of increasing sodium fluoride concentrations on erosion and attrition of enamel and dentine in vitro. *Journal of dentistry*, 38, (10) 782-787 Population

Awofeso, N. 2012. Ethics of artificial water fluoridation in Australia. *Public Health Ethics*, 5, (2) 161-172 Study type

Awofeso, N. 2014. Water fluoridation: a critical review of the physiological effects of ingested fluoride as a public health intervention. *TheScientificWorldJournal*, 2014, (pp 293019) 2014 Study type

Aylward, L.L.H. 2015. Biomonitoring Equivalents for interpretation of urinary fluoride. *Regulatory Toxicology and Pharmacology*, 72, (1) 158-167 Outcome

Ayo-Yusuf, O.A.A. 2007. Socio-economic inequities in dental caries experience of 12-year-old South Africans: policy implications for prevention. *SADJ : journal of the South African Dental Association = tydskrif van die Suid-Afrikaanse Tandheelkundige Vereniging*, 62, (1) 6-11 Intervention/Exposure

Ayoob S.Gupta 2006. Fluoride in drinking water: A review on the status and stress effects. *Critical Reviews in Environmental Science and Technology*, 36, (6) 433-487 Study type

Bagramian, R.A.G. 2009. The global increase in dental caries. A pending public health crisis. *American journal of dentistry*, 22, (1) 3-8 Study type

Bailey, W. 2008. Populations receiving optimally fluoridated public drinking water - United States, 1992-2006. *Morbidity and Mortality Weekly Report*, 57, (27) 737-741 Outcome

Bakarcic, D.J. 2014. Guidelines for teeth fluoridation with respect to fluoride concentration in Primorje-Gorski Kotar County. *Paediatria Croatica*, 58, (1) 25-30 Population

Bal IS, Dennison PJ, Evans RW., Bal, I.S., & Dennison, P. 2015. Dental fluorosis in the Blue Mountains and Hawkesbury, New South Wales, Australia: policy implications. *Journal of Investigative & Clinical Dentistry*, 6, (1) 45-52 Outcome

Balan, H. 2012. Fluoride--the danger that we must avoid. *Romanian journal of internal medicine = Revue roumaine de medecine interne*, 50, (1) 61-69 Study type

Baldwin of Bewdley 2007. Fluoridation: Addressing the arguments. *BMJ (Clinical research ed*,). 335, (7625) 841 Study type

Bali, P., Bali, P., Prabhakar, A.R., & Basappa, N. 2015. An Invitro Comparative Evaluation of Compressive Strength and Antibacterial Activity of Conventional GIC and Hydroxyapatite Reinforced GIC in Different Storage Media. *Journal of Clinical and Diagnostic Research JCDR*, 9, (7) ZC51-ZC55 Intervention/Exposure

Banoczy, J.R.-G. 2013. Milk fluoridation for the prevention of dental caries. *Acta medica academica*, 42, (2) 156-167 Intervention/Exposure

Bansal, R.B. 2015. A comparative evaluation of the amount of fluoride release and re-release after recharging from aesthetic restorative materials: An in vitro study. *Journal of Clinical and Diagnostic Research*, 9, (8) ZC11-ZC14 Population

Barker, J.C. & Barker, J.C. 2008. An ethnographic study of Latino preschool children's oral health in rural California: Intersections among family, community, provider and regulatory sectors. *BMC oral health* , 8, 8 Outcome

Baskaradoss, J.C. 2008. Prevalence of dental fluorosis and associated risk factors in 11-15 year old school children of Kanyakumari District, Tamilnadu, India: A cross sectional survey. *Indian Journal of Dental Research*, 19, (4) 297-303 Outcome

Bayrak S, Tunc ES, Aksoy, Bayrak, S., Tunc, E.S., Aksoy, A., Ertas, E., Guvenc, D., & Ozer, S. 2010. Fluoride release and recharge from different materials used as fissure sealants. *European journal of dentistry*, 4, (3) 245-250 Intervention/Exposure

Beltran-Aguilar, E.D.B. 2010. Prevalence and severity of dental fluorosis in the United States, 1999-2004. *NCHS data brief* (53) 1-8 Outcome

Beltran-Aguilar, E.D.B. 2015. Water intake by outdoor temperature among children aged 1-10 years: Implications for community water fluoridation in the U.S. *Public Health Reports*, 130, (4) 362-371 Outcome

Bengharez, Z.F. 2012. Evaluation of fluoride bottled water and its incidence in fluoride endemic and non endemic areas. *e-SPEN Journal*, 7, (1) e41-e45 Population

Bergamo, E.T.B. 2015. Fluoride concentrations in the water of Maringa, Brazil, considering the benefit/risk balance of caries and fluorosis. *Brazilian oral research*, 29, (1) 47 Population

Betancourt-Lineares, A., Betancourt-Lineares, A., Irigoyen-Camacho, M.E., Mejia-Gonzalez, A., Zepeda-Zapeda, M., & Sanchez-Perez, L. 2013. [Dental fluorosis prevalence in Mexican localities of 27 states and the D.F.: six years after the publication of the Salt Fluoridation Mexican Official Regulation]. [Spanish]. *Revista de Investigacion Clinica*, 65, (3) 237-247 Outcome

Bhargava, A.S.K. 2013. Relation between water and salivary fluoride levels among children residing in communities having different naturally occuring water fluoride levels in Andhra Pradesh, India. *Biology and Medicine*, 5, 65-68 Comparator

Binns, C., & Low, W.-Y. 2014. Oral public health in the Asia-Pacific region. [References]. *Asia-Pacific Journal of Public Health*, .26, (3) Study type

Blakey, K.F. 2014. Is fluoride a risk factor for bone cancer? Small area analysis of osteosarcoma and Ewing sarcoma diagnosed among 0-49-year-olds in Great Britain, 1980-2005. *International Journal of Epidemiology*, 43, (1) 224-234 Outcome

Blinkhorn, A.B. 2009. Is there a role for triclosan/copolymer toothpaste in the management of periodontal disease? *British Dental Journal*, 207, (3) 117-125 Study type

Bonow, M.L.M. 2013. Efficacy of 1.23% APF gel applications on incipient carious lesions: A doubleblind randomized clinical trial. *Brazilian oral research*, 27, (3) 279-285 Intervention/Exposure

Borinskii IuN, Rumiantsev VA, Borinskaia EIu, Beliaev VV., & Borinskii, I.N. 2009. [Fluoride content in potable water and drinks. Connection with dental caries prevention and dental fluorosis]. [Russian]. *Stomatologiia*, 88, (5) 59-63 Population

Borinskii, I.N.R. 2009. Fluoride content in potable water and drinks. Connection with dental caries prevention and dental fluorosis. *Stomatologiia*, 88, (5) 59-63 Population

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Wold, S.J.B. 2008. Going the extra mile: beyond health teaching to political involvement. *Nursing forum*, 43, (4) 171-176 Study type

Wong S.Abelson 2011. Policy statement - Early childhood caries in indigenous communities. *Pediatrics*, 127, (6) 1190-1198 Study type

Wong, H.M. & Wong, H.M. 2006. Association between developmental defects of enamel and different concentrations of fluoride in the public water supply. *Caries research*, 40, (6) 481-486 Outcome

Woods, N.W. 2009. Factors influencing the need for dental care amongst the elderly in the Republic of Ireland. *Community dental health*, 26, (4) 244-249 Outcome

Woodward, S.M. 2009. The implementation of community based programmes. *Milk fluoridation for the prevention of dental caries* 107-126 Intervention/Exposure

Wu, I.I.M. 2006. The dental knowledge and attitudes of medical practitioners and caregivers of pre-school children in Macau. *Hong Kong Journal of Paediatrics*, 11, (2) 133-139+161 Intervention/Exposure

Xia, Y.L. 2013. Prevalence of dental caries in Shantou City Guangdong Province fluorosis areas after water improvement. *Chinese Journal of Endemiology*, 32, (3) 309-311 Comparator

Xu HH, Weir MD, Sun, & Xu, H.H.K. 2010. Strong nanocomposites with Ca, PO(4), and F release for caries inhibition. [Review] [84 refs]. *Journal of Dental Research*, 89, (1) 19-28 Intervention/Exposure

Xu, H.H.K. 2010. Strong nanocomposites with Ca, PO4, and F release for caries inhibition. *Journal of Dental Research*, 89, (1) 19-28 Population

Xu, P., Xu, P., Deng, M., Zhou, X., Li, J., Cheng, L., & Xu, X. 2014. [Effect of arginine dentifrice on remineralization of initial enamel carious lesions]. [Chinese]. *Hua Xi Kou Qiang Yi Xue Za Zhi*, 32, (1) 32-35 Population

Xu, P.D. 2014. Effect of arginine dentifrice on remineralization of initial enamel carious lesions. *Hua xi kou qiang yi xue za zhi = Huaxi kouqiang yixue zazhi = West China journal of stomatology*, 32, (1) 32-35 Population

Yamashita, J.M. 2013. Role of arginine and fluoride in the prevention of eroded enamel: an in vitro model. *Australian dental journal*, 58, (4) 478-482 Population

Yang, Q.-L.C. 2013. Occlusion of dentinal tubules using tricalcium silicate. *Chinese Journal of Tissue Engineering Research*, 17, (38) 6740-6746 Population

Yeung CA, Chong LY, Glenny AM., & Yeung, C.A. 2015. Fluoridated milk for preventing dental caries. [Review][Update of Cochrane Database Syst Rev. 2005;(3):CD003876; PMID: 16034911]. *Cochrane Database of Systematic Reviews*, 9, CD003876 Intervention/Exposure

Yeung, A.C. 2015. Fluoridated milk for preventing dental caries. *Cochrane Database of Systematic Reviews*, 9, 2015., Intervention/Exposure

Yeung, C.A. 2008. A systematic review of the efficacy and safety of fluoridation. *Evidence-based dentistry*, 9, (2) 39-43 Study type

Yeung, C.A. & Yeung, C.A. 2011. Efficacy of salt fluoridation. *Evidence-based dentistry*, 12, (1) 17-18 Intervention/Exposure

Yeung, C.A. & Yeung, C.A. 2007. Fluoride prevents caries among adults of all ages. *Evidence-based dentistry*, 8, (3) 72-73 Study type

Yeung, C.A. & Yeung, C.A. 2014. Water fluoridation could save NHS millions every year. *BMJ*, 348, g2855 Study type

Yimcharoen, V.R. 2011. The effect of casein phosphopeptide toothpaste versus fluoride toothpaste on remineralization of primary teeth enamel. *Southeast Asian Journal of Tropical Medicine and Public Health* , 42, (4) 1032-1040 Population

Yousefii, Z.H. 2013. Fluoride level in drinking water supplies of Gonbad-e Qabus, 2008-2012. *Journal of Mazandaran University of Medical Sciences*, 23, (101) 48-53 Population

Yuan, H.L. 2014. Esthetic comparison of white-spot lesion treatment modalities using spectrometry and fluorescence. *The Angle orthodontist*, 84, (2) 343-349 Population

Zalizniak, I. & Zalizniak, I. 2013. Ion release and physical properties of CPP-ACP modified GIC in acid solutions. *Journal of dentistry*, 41, (5) 449-454 Population

Zandim, D.L., Zandim, D.L., Tschoppe, P., & Sampaio, J.E. 2011. Effect of saliva substitutes in combination with fluorides on remineralization of subsurface dentin lesions. *Supportive Care in Cancer*, 19, (8) 1143-1149 Population

Zhang LingLin, Xue Jing, Li JiYao, Zou Ling, Hao YuQing, Zhou XueDong, & Li Wei 2009. Effects of Galla chinensis on inhibition of demineralization of regular bovine enamel or enamel disposed of organic matrix. *Archives of Oral Biology*, 54, (9) 817-822 Population

Zhang YiLong, Ma Rong, & Li ZhengHong 2014. Human health risk assessment of groundwater in Hetao Plain (Inner Mongolia Autonomous Region, China). *Environmental Monitoring and Assessment*, 186, (8) 4669-4684 Population

Zhang, X., Zhang, X., Li, Y., Sun, X., Kishen, A., Deng, X., Yang, X., Wang, H., Cong, C., Wang, Y., & Wu, M. 2014. Biomimetic remineralization of demineralized enamel with nano-complexes of phosphorylated chitosan and amorphous calcium phosphate. *Journal of Materials Science-Materials in Medicine*, 25, (12) 2619-2628 Population

Zhang, Y., Zhang, Y., Liu, L., Cheng, R., & Lu, Z. 2008. [Difference between dental caries and oral health behavior of family in primary dentition]. [Chinese]. *Hua Xi Kou Qiang Yi Xue Za Zhi*, 26, (1) 67-69 Intervention/Exposure

Zhang, Y.L. 2008. Difference between dental caries and oral health behavior of family in primary dentition. *Hua xi kou qiang yi xue za zhi = Huaxi kouqiang yixue zazhi = West China journal of stomatology*, 26, (1) 67-69 Intervention/Exposure

Zhang, Y.S. 2012. Dentin hypersensitivity in an endemic fluorosis rural area of China. *Fluoride*, Conference, (var.pagings) 215-216 Outcome

Zhi QH, Lo EC, Kwok AC., & Zhi, Q.H. 2013. An in vitro study of silver and fluoride ions on remineralization of demineralized enamel and dentine. *Australian dental journal*, 58, (1) 50-56 Population

Zhong QiZhi, Zhou ZhenBang, & Shi XiangJun 2011. Investigation on knowledge, attitude and behavior of oral health among dental clinics patients in a community hospital. [Chinese]. *Occupation and Health*, 27, (12) 1391-1393 Outcome

Zhou, C.-H.S., X 2008. Quantitative microradiographic analysis of remineralization of enamel lesions promoted by casein phosphopeptide amorphous calcium phosphate and fluoride. *Journal of Jilin University Medicine Edition*, 34, (6) 1022-1026 Population

Zhou, Q., Zhou, Q., Liu, J., Zhang, C., Zhang, S., & Li, Y. 2011. [Epidemiology survey of dental caries and fluorosis of children in Kunming city]. [Chinese]. *Hua Xi Kou Qiang Yi Xue Za Zhi*, 29, (5) 514-516 Comparator

Zhou, Q.L. 2011. Epidemiology survey of dental caries and fluorosis of children in Kunming city. *Hua xi kou qiang yi xue za zhi = Huaxi kouqiang yixue zazhi = West China journal of stomatology*, 29, (5) 514-516 Intervention/Exposure

Zhu, B., Zhu, B., Li, J.-Y., & Zhou, X.-D. 2007. [Effect of Galla Chinesis on the demineralization of dental root tissue in pH cycling model]. [Chinese]. *Zhongguo Zhong Yao Za Zhi/Zhongguo Zhongyao Zazhi/China Journal of Chinese Materia Medica*, 32, (6) 529-531 Intervention/Exposure

Zhu, B.L. 2007. Effect of Galla Chinesis on the demineralization of dental root tissue in pH cycling model. *Zhongguo Zhongyao Zazhi*, 32, (6) 529-531 Population

Zohoori, F.V.D. 2012. Fluoridated toothpaste: Usage and ingestion of fluoride by 4- to 6-yr-old children in England. *European Journal of Oral Sciences*, 120, (5) 415-421 Intervention/Exposure

Zohoori, F.V.O. 2012. Comparison of estimated daily dietary fluoride intake by food diary and duplicate-plate collection methods. *Proceedings of the Nutrition Society*, Conference, (var.pagings) 2012 Outcome

Zohoori, F.V.W. 2013. Fractional urinary fluoride excretion of 6-7-year-old children attending schools in low-fluoride and naturally fluoridated areas in the UK. *British Journal of Nutrition*, 109, (10) 1903-1909 Outcome

Zusman, S.P. 2012. Water fluoridation in Israel: ethical and legal aspects. (Ethics in public health.). *Public Health Reviews*, 34, (1) unpaginated Study type

STUDIES EXCLUDED FROM THE REVIEW OF OTHER HEALTH EFFECTS

SYSTEMATIC REVIEW OF PRIMARY STUDIES

Studies excluded after full text review

Below is the list of studies excluded following full text review. The reason for exclusion is noted at the end of each citation.

Arvind, BA, Isaac, A et al 2012. Prevalence and severity of dental fluorosis and genu valgum among school children in rural field practice area of a medical college, *Asian Pacific Journal of Tropical Disease*, 2 (6), 465-469. No useable data - outcomes not reported by water fluoride level

Ba, Y, Zhu, J-Y et al 2010. Serum calciotropic hormone levels, and dental fluorisis in children exposed to different concentrations of fluoride and iodine in drinking water, *Chinese Medical Journal*, 123 (6), 675-679. Outcomes - surrogate outcomes

Bashir, MT, Ali, SB et al 2013. Health effects associated with fluoridated water sources - a review of central Asia, *Asian Journal of Water, Environment and Pollution*, 10 (3), 29-37. Publication type - narrative review

Bassin, EB, Wypij, D et al 2006. Age-specific fluoride exposure in drinking water and osteosarcoma (United States), *Cancer Causes & Control*, 17 (4), 421-428. Date - in NHMRC 2007 review

Bhardwaj, M and Shashi, A 2013. Dose effect relationship between high fluoride intake and biomarkers of lipid metabolism in endemic fluorosis, *Biomedicine and Preventive Nutrition*, 3 (2), 121-127. Study type - confounded study

Bhardwaj, M and Aggarwal, S 2013. Evaluation of biochemical interaction and correlation between high fluoride ingestion and protein metabolism, *Biomedicine and Preventive Nutrition*, 3 (2), 129-137. Study type - confounded study

Bhardwaj, M and Shashi, A 2012. Meta-analysis of electrolyte imbalance in human fluorosis, *Biomedicine and Preventive Nutrition*, 2 (4), 294-302. Study type - confounded study

Bramlett, MD, Soobader, M-J et al 2010. Assessing a multilevel model of young children's oral health with national survey data, *Community Dentistry and Oral Epidemiology*, 38 (4), 287-298. Outcomes - no health outcomes

Cao, Y, Xie, Y et al 2009. Prevalence of fluorosis associated with drinking water in Dali county, Shaanxi, 2008. [Chinese], *Disease Surveillance*, 24 (9), 722-723. Language Chinese

Carton, RJ 2006. Review of the 2006 United States National Research Council report: Fluoride in drinking water, *Fluoride*, 39 (3), 163-172. Publication type - commentary

Centre for Reviews and Dissemination 2014. *A systematic review of public water fluoridation (Structured abstract).* Date - refers to 2000 York review

Centre for Reviews and Dissemination 2014. *Association of Down's syndrome and water fluoride level: a systematic review of the evidence (Structured abstract).* Date - refers to a 2001 publication of the same title

Centre for Reviews and Dissemination 2014. *Water fluoridation, bone mass and fracture: a quantitative overview of the literature (Structured abstract).* Date - refers to a 1999 publication

Centre for Reviews and Dissemination 2014. *Water fluoridation, osteoporosis, fractures: recent developments (Structured abstract).* Date - refers to a 2001 publication of the same title

Chachra, D, Limeback, H et al 2010. The long-term effects of water fluoridation on the human skeleton, *Journal of Dental Research*, 89 (11), 1219-1223. Outcomes - surrogate outcomes

Chahal, A, Bala, M et al 2014. Comparative evaluation of serum fluoride levels in patients with and without chronic abdominal pain, *Clinica Chimica Acta*, 429, 140-142. Comparator - water fluoride only measured in cases

Chandra Shekar, BR, Suma, S et al 2013. Malocclusion status among 15 years old adolescents in relation to fluoride concentration and area of residence, Indian Journal of Dental Research, 24 (1), 1-7. Outcomes – surrogate outcomes

Chen, D, Meng, F et al 2014. A typical investigation of thyroid nodules in adults of Juye county of Shandong province. [Chinese], *Chinese Journal of Control of Endemic Diseases*, 29 (1), 5-8. Language Chinese

Chen, H, Yan, M et al 2012. Spatial distribution and temporal variation of high fluoride contents in groundwater and prevalence of fluorosis in humans in Yuanmou County, Southwest China, *Journal of Hazardous Materials*, 235-236, 201-209. Outcomes - skeletal fluorosis not graded

Chen, J, Xiao, B-Z et al 2009. Analysis of environmental fluoride of the coal-burning endemic fluorosis areas in Chongqing, *Chinese Journal of Endemiology*, 28 (5), 541-544. Language Chinese

Chen, P, Wei, S-Y et al 2011. Endemic fluorosis in Huangyuan county Qinghai province in 2009: An analysis of surveillance results, *Chinese Journal of Endemiology*, 30 (3), 303-305. Language Chinese

Chen, P-Z, Yun, Z-J et al 2009. Analysis on surveillance outcome of endemic fluorosis in Shandong Province from 1992 to 2006, *Chinese Journal of Endemiology*, 28 (5), 537-540. Language Chinese

Chen, P-Z, Yun, Z-J et al 2006. Epidemiologic studies of endemic fluorosis in Jiaxiang. A county in Shandong province, *Chinese Journal of Endemiology*, 25 (5), 537-540. Language Chinese

Chen, P-Z, Yun, Z-J et al 2012. Epidemiological investigation and analysis of water-related endemic fluorosis in the south area of Shandong province in 2009, *Chinese Journal of Endemiology*, 31 (5), 566-570. Language Chinese

Chen, P-Z, Yun, Z-J et al 2010. Investigation on the prevention and control of endemic fluorosis in the southwestern area of Shandong province in 2007, *Chinese Journal of Endemiology*, 29 (2), 186-189. Language Chinese

Chen, P, Yun, Z et al 2010. Endemic fluorosis in the north area of Shandong province. [Chinese], *Chinese Preventive Medicine*, 11 (4), 332-335. Language Chinese

Chen, S, Li, B et al 2013. Change of urinary fluoride and bone metabolism indicators in the endemic fluorosis areas of southern China after supplying low fluoride public water, *BMC public health*, 13 (156. No useable data - before and after study of fluoride reduction, but no data from "before"

Chen, Y, Han, F et al 2008. Research on the intellectual development of children in high fluoride areas, *Fluoride*, 41 (2), 120-124. Date - translation of paper from 1991

Cheng, G and Cui, X 2010. Epidemiological survey on endemic fluorosis in Dongying city, Shandong province. [Chinese], *Chinese Preventive Medicine*, 11 (3), 274-276. Language Chinese

Choi, AL, Sun, G et al 2012. Developmental fluoride neurotoxicity: A systematic review and meta-analysis, *Environmental Health Perspectives*, 120 (10), 1362-1368. Systematic review

Choubisa, SL, Choubisa, L et al 2007. Fluorosis in subjects belonging to different ethnic groups of Rajasthan (India), *Journal of Communicable Diseases*, 39 (3), 171-177. No useable data - outcomes not reported by water fluoride level

Choubisa, SL, Choubisa, L et al 2010. Osteo-dental fluorosis in relation to age and sex in tribal districts of Rajasthan, India, *Journal of Environmental Science and Engineering*, 52 (3), 199-204. Outcomes - skeletal fluorosis not graded

Dai, H-X, Zeng, P et al 2013. Analysis of a survey results of patients with suspected high iodine goiter in Liuji Town Fuping County of Shaanxi Province, *Chinese Journal of Endemiology*, 32 (4), 408-411. Language Chinese

Ding, S-R, Lu, Q et al 2011. Endemic fluorosis in guide county of Qinghai province in 2008: An analysis of surveillance results, *Chinese Journal of Endemiology*, 30 (3), 306-308. Language Chinese

Ding, Y, YanhuiGao et al 2011. The relationships between low levels of urine fluoride on children's intelligence, dental fluorosis in endemic fluorosis areas in Hulunbuir, Inner Mongolia, China, *Journal of Hazardous Materials*, 186 (2-3), 1942-1946. No useable data - outcomes not reported by water fluoride level

Elmer, TB, Langford, JW et al 2014. An alternative marker for the effectiveness of water fluoridation: hospital extraction rates for dental decay, a two-region study, *British Dental Journal*, 216 (5), E10. Intervention - deprivation rating, not specifically water fluoride

Fan, Z-X, Li, Y et al 2011. Drinking-water type of fluorosis in Shaanxi province in 2009: An analysis of surveillance results, *Chinese Journal of Endemiology*, 30 (3), 294-297. Language Chinese

Gao, J, Qin, Z et al 2014. Analysis of water quality relationship with the incidence of gastrointestinal disease in Huai'an. [Chinese], *Journal of Food Safety and Quality*, 5 (4), 1246-1249. Language Chinese

Gao, P and Yu, Y 2008. Analysis of prevalent features of human brucellosis in 1997-2007 in Anyang City. [Chinese], *China Tropical Medicine*, 8 (7), 1203-1204. Language Chinese

Goudu, AS and Naidu, MD 2013. Effect of fluoride on oxidative stress and biochemical markers of bone turnover in postmenopausal women, *Fluoride*, 46 (4), 208-211. Outcomes - surrogate outcomes

Gupta, SK, Gupta, RC et al 2008. Changes in serum seromucoid following compensatory hyperparathyroidism: A sequel to chronic fluoride ingestion, *Indian Journal of Clinical Biochemistry*, 23 (2), 176-180. Outcomes - surrogate outcomes

Hao, P, Ma, X et al 2010. [Effect of fluoride on human hypothalamus-hypophysis-testis axis hormones], *Wei sheng yan jiu = Journal of hygiene research*, 39 (1), 53-55. Language Chinese

He, F-Z, Guo, M et al 2011. Surveillance analysis of drinking water borne fluorosis in Tibet autonomous region in 2009, *Chinese Journal of Endemiology*, 30 (2), 194-196. Language Chinese

He, M-X and Zhang, C-N 2010. Investigation of children's intelligence quotient and dental fluorosis in drinking water-type of endemic fluorosis area in Pucheng county Shaanxi province before and after drinking water change, *Chinese Journal of Endemiology*, 29 (5), 547-548. Language Chinese

Hong, F, Cao, Y et al 2008. Research on the effects of fluoride on child intellectual development under different environmental conditions, *Fluoride*, 41 (2), 156-160. Date - translation of paper from 2001

Hou, C-C, Han, S-Q et al 2010. Investigation on the prevalent condition of adult osteofluorosis in the endemic fluorosis areas of Tianjin in 2008, *Chinese Journal of Endemiology*, 29 (3), 322-324. Language Chinese

Hu, L-A, Wang, Y et al 2012. Surveillance analysis of drinking water-born endemic fluorosis in 2009 in Xuchang city, Henan province, *Chinese Journal of Endemiology*, 31 (3), 318-320. Language Chinese

Huang, C-Q, Chen, Z et al 2009. Diagnosis on endemic skeletal fluorosis: Clinical vs. X-rays examination, *Chinese Journal of Endemiology*, 28 (2), 194-196. Language Chinese

Huang, C-Q, Wang, C-H et al 2009. Outcome analysis of surveillance on endemic fluorosis during thr period of 1991 to 2006 in Jilin Province, *Chinese Journal of Endemiology*, 28 (4), 424-428. Language Chinese

Huang, J-N, Zhou, X-Y et al 2009. Study on the dose-response relationships between the drinking water and bone mineral density, and serum osteocalcin, *Chinese Journal of Endemiology*, 28 (2), 150-153. Language Chinese

Isaac, A, Silvia, WDCR et al 2009. Prevalence and manifestations of water-born fluorosis among schoolchildren in Kaiwara village of India: A preliminary study, *Asian Biomedicine*, 3 (5), 563-566. No useable data - outcomes not reported by water fluoride level

Jaganmohan, P, Narayana Rao, SVL et al 2010. Biochemical and haematological investigations on fluorosis threaten patients at Nellore district, Andhra Pradesh, India, *World Journal of Medical Sciences*, 5 (3), 54-58. No useable data - fluoride level for controls not specified

Jaganmohan, P, Narayana Rao, SVL et al 2010. Prevalence of high fluoride concentration in drinking water in Nellore District, A.p., India: A biochemical study to develop the relation to renal failures, *World Journal of Medical Sciences*, 5 (2), 45-48. No useable data - fluoride level for controls not specified

Jarvis, HG, Heslop, P et al 2013. Prevalence and aetiology of juvenile skeletal fluorosis in the south-west of the Hai district, Tanzania - a community-based prevalence and case-control study, *Tropical Medicine and International Health*, 18 (2), 222-229. Outcomes - skeletal fluorosis not graded

Jia, L-H, Ma, J et al 2013. Analysis of an investigational result of drinking-water-borne endemic fluorosis in Hebei Province in 2010, *Chinese Journal of Endemiology*, 32 (6), 659-661. Language Chinese

Jia, L-H, Ma, J et al 2011. The investigation of drinking-water-borne endemic fluorosis in Hebei province in 2009, *Chinese Journal of Endemiology*, 30 (2), 184-187. Language Chinese

Johnson, J 2014. Water fluoridation, *Today's FDA : official monthly journal of the Florida Dental Association*, 26 (5), 32-33. Publication type - narrative review

Kirzioglu, Z, Altun, AC et al 2011. Saliva characteristics of children with dental fluorosis and the effect of high fluoride water on the saliva, *Fluoride*, 44 (4), 227-231. Outcomes - surrogate outcomes

Koroglu, BK, Ersoy, IH et al 2011. Serum parathyroid hormone levels in chronic endemic fluorosis, *Biological Trace Element Research*, 143 (1), 79-86. Study type - confounded study

Kotoky, P, Barooah, PK et al 2008. Fluoride and endemic fluorosis in the Karbianglong district, Assam, India, *Fluoride*, 41 (1), 72-75. Population - study investigates fluoride levels in villages - no assessment of people

Kumar, S, Sharma, J et al 2009. Fluoride - An adjunctive therapeutic agent for periodontal disease? Evidence from a cross-sectional study, Medicina Oral, Patologia Oral y Cirugia Bucal, 14 (10), e547-e553. Outcomes – use of Community Periodontal Index

Kumar, T and Takalkar, A 2010. Study of the effects of drinking water naturally contaminated with fluorides on the health of children, *Biomedical Research*, 21 (4), 423-427. No useable data - outcomes not reported by water fluoride level

Levy, SM, Eichenberger-Gilmore, J et al 2009. Associations of fluoride intake with children's bone measures at age 11, *Community Dentistry and Oral Epidemiology*, 37 (5), 416-426. Intervention - total fluoride, not water fluoride

Levy, SM, Warren, JJ et al 2014. Effects of life-long fluoride intake on bone measures of adolescents: A prospective cohort study, *Journal of Dental Research*, 93 (4), 353-359. Intervention - total fluoride, not water fluoride

Li, G, Hou, X et al 2011. Surveillance analysis on endemic fluorosis in Weinan in 2008. [Chinese], *Modern Preventive Medicine*, 38 (7), 1211-1213. Language Chinese

Li, J, Yao, L et al 2008. Effects of high fluoride level on neonatal neurobehavioral development, *Fluoride*, 41 (2), 165-170. Date - translation of paper from 2004

Li, S and Zhou, J 2013. Investigation on prevalent condition of dental fluorosis and skeletal fluorosis after water-improvement projects in the endemic fluorosis areas of Qingtongxia City. [Chinese], *Modern Preventive Medicine*, 40 (13), 2543-2546. Language Chinese

Liang, Y, Wang, S-P et al 2010. Study on relationship between drinking water endemic fluorosis and urine fluorine in Linyi county, Shanxi province, *Chinese Journal of Endemiology*, 29 (2), 193-195. Language Chinese

Liao, M, Liu, J et al 2008. Outcome analysis of endemic fluorosis control in Guangxi in 2006, *Chinese Journal of Endemiology*, 27 (3), 300-302. Language Chinese

Liu, J-Y, Liu, H et al 2010. Survey of adult carotid atherosclerosis in water-related endemic fluorosis areas in Heilongjiang province in 2008, *Chinese Journal of Endemiology*, 29 (6), 634-636. Language Chinese

Liu, S, Lu, Y et al 2008. Report on the intellectual ability of children living in high-fluoride water areas, *Fluoride*, 41 (2), 144-147. Date - translation of paper from 2000

Liu, X-L, Bai, G-L et al 2010. Investigation and analysis on endemic fluorosis associated with drinking water in Shaanxi in 2008, *Chinese Journal of Endemiology*, 29 (2), 171-175. Language Chinese

Liu, Y, Yu, B et al 2013. Investigation of drinking water-born endemic fluorosis in Henan province in 2010. [Chinese], *Modern Preventive Medicine*, 40 (15), 2776-2779. Language Chinese

Lu, T, He, G et al 2010. Epidemiological investigation on endemic fluorosis of drinking water type in Xinxiang City from 2008 to 2009. [Chinese], *Endemic Diseases Bulletin / Di Fang Bing Tong Bao*, 25 (6), 13-15. Language Chinese

Ludlow, M, Luxton, G et al 2007. Effects of fluoridation of community water supplies for people with chronic kidney disease, *Nephrology Dialysis Transplantation*, 22 (10), 2763-2767. Systematic review

Macek, MD, Matte, TD et al 2006. Blood lead concentrations in children and method of water fluoridation in the United States, 1988-1994, *Environmental Health Perspectives*, 114 (1), 130-134. Intervention - method of fluoridation

Majumdar, KK 2011. Health impact of supplying safe drinking water containing fluoride below permissible level on flourosis patients in a fluoride-endemic rural area of West Bengal, *Indian journal of public health*, 55 (4), 303-308. No useable data - specific fluoride levels not reported

Manimaran, G, Nellaiappan, S et al 2013. Groundwater induced fluorosis and rickets health hazards at Melaseithalai, Tuticorin District of Tamilnadu, *Online International Interdisciplinary Research Journal*, 3 (5), 145-151. No useable data - average water fluoride values not reported

McLaren, L 2014. The impact of removing fluoridation from municipal water supplies in Canada: a tale of two cities, *Journal (Canadian Dental Association)*, 80, e30. Publication type – interview

Megalamanegowdru, J, Ankola, AV et al 2012. Periodontal health status among permanent residents of low, optimum and high fluoride areas in Kolar District, India, Oral health & preventive dentistry, 10 (2), 175-183. Outcomes - use of Community Periodontal Index

Nagarajappa, R, Pujara, P et al 2013. Comparative assessment of intelligence quotient among children living in high and low fluoride areas of Kutch, India - a pilot study, *Iranian Journal of Public Health*, 42 (8), 813-818. Study type - confounded study

Nayak, B, Roy, MM et al 2009. Health effects of groundwater fluoride contamination, *Clinical Toxicology*, 47 (4), 292-295. No useable data - outcomes not reported by water fluoride level

NHS Centre for Reviews and Dissemination 2014. A systematic review of public water fluoridation (Structured abstract), *Health Technology Assessment Database*3). Date - refers to 2000 York review

Nirgude, AS, Saiprasad, GS et al 2010. An epidemiological study on fluorosis in an urban slum area of Nalgonda, Andhra Pradesh, India, *Indian journal of public health*, 54 (4), 194-196. Comparator - not comparing fluoride levels

Niu, Z-H and Zhao, J-L 2012. Analysis of monitoring data of drinking-water borne endemic fluorosis in Xinzhou of Shanxi province in 2010, *Chinese Journal of Endemiology*, 31 (3), 321-324. Language Chinese

Noble, A, Amerasinghe, P et al 2014. Review of literature on chronic kidney disease of unknown etiology (CKDu) in Sri Lanka, *IWMI Working Paper*, 158. Publication type - narrative review

Opydo-Szymaczek, J and Borysewicz-Lewicka, M 2007. Transplacental passage of fluoride in pregnant Polish women assessed on the basis of fluoride concentrations in maternal and cord blood plasma, *Fluoride*, 40 (1), 46-50. Intervention - not water fluoride

Ortega Garcia, JA, Ferris, IT et al 2006. Environmental neurotoxins (IV). Tobacco, alcohol, solvents, fluoride, food additives: Adverse effects on the fetal and postnatal nervous system. Preventive measures, *Acta Pediatrica Espanola*, 64 (10), 493-502. Systematic review

Pandey, A 2010. Prevalence of fluorosis in an endemic village in central India, *Tropical Doctor*, 40 (4), 217-219. No useable data - outcomes not reported by water fluoride level

Park, EY, Hwang, SS et al 2008. Effects of long-term fluoride in drinking water on risks of hip fracture of the elderly: an ecologic study based on database of hospitalization episodes, *Journal of preventive medicine and public health = Yebang Ç"ihakhoe chi*, 41 (3), 147-152. Language Korean

Parnell, C, Whelton, H et al 2009. Water fluoridation, *European archives of paediatric dentistry : official journal of the European Academy of Paediatric Dentistry*, 10 (3), 141-148. Systematic review

Pawar, AC, Naik, SJK et al 2014. Cytogenetic analysis of human lymphocytes of fluorosis-affected men from the endemic fluorosis region in Nalgonda district of Andhra Pradesh, India, *Fluoride*, 47 (1), 78-84. Study type - confounded study

Peckham, S and Awofeso, N 2014. Water fluoridation: A critical review of the physiological effects of ingested fluoride as a public health intervention, *The Scientific World Journal*, 2014. Publication type - narrative review

Poureslami, HR, Horri, A et al 2011. A comparative study of the IQ of children age 7-9 in a high and a low fluoride water city in Iran, *Fluoride*, 44 (3), 163-167. Study type - confounded study

Prystupa, J 2011. Fluorine - A current literature review. An NRC and ATSDR based review of safety standards for exposure to fluorine and fluorides, *Toxicology Mechanisms and Methods*, 21 (2), 103-170. Publication type - narrative review

Qin, L, Huo, S et al 2008. Using the raven's standard progressive matrices to determine the effects of the level of fluoride in drinking water on the intellectual ability of school-age children, *Fluoride*, 41 (2), 115-119. Date - translation of paper from 1990

Ravula, S, Harinarayan, CV et al 2012. Effect of fluoride on reactive oxygen species and bone metabolism in postmenopausal women, *Fluoride*, 45 (2), 108-115. Outcomes - surrogate outcomes

Rawlani, S, Rawlani, S et al 2010. Assessment of skeletal and non-skeletal fluorosis in endemic fluoridated areas of Vidharbha Region, India: a survey, *Indian Journal of Community Medicine*, 35 (2), 298-301. Comparator - not comparing fluoride levels

Rihs, LB, da Silva, DD et al 2009. Dental caries and tooth loss in adults in a Brazilian southeastern state, *Journal of Applied Oral Science*, 17 (5), 392-396. Outcomes - caries

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Studies excluded after title and abstract review

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Abd El Naser, YG, Kamel, AF et al 2013. Thyroid volumes and iodine status in Egyptian South Sinai schoolchildren, *Archives of Medical Science*, 9 (3), 548-554. Intervention

Abdullah, AZ, Stafford, SM et al 2006. The effect of copper on demineralization of dental enamel, *Journal of Dental Research*, 85 (11), 1011-1015. Intervention

Abrams, B, Diwu, Z et al 2009. 3-Carboxy-6-chloro-7-hydroxycoumarin: A highly fluorescent, water-soluble violet-excitable dye for cell analysis, *Analytical Biochemistry*, 386 (2), 262-269. Population

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Adelario, AK, Vilas-Novas, LF et al 2010. Accuracy of the simplified Thylstrup & Fejerskov index in rural communities with endemic fluorosis, *International Journal of Environmental Research and Public Health*, 7 (3), 927-937. Intervention

Afolabi, OK, Oyewo, EB et al 2013. Oxidative indices correlate with dyslipidemia and pro-inflammatory cytokine levels in fluoride-exposed rats, *Arhiv za Higijenu Rada i Toksikologiju*, 64 (4), 521-529. Population

Aghdasi, H, Borujeni, FG et al 2014. A survey of relationship between drinking water fluoride concentration and DMFT index in guidance school students: a case study Piranshahr and Poldasht, West Azarbayjan. [Persian], *Urmia Medical Journal*, 25 (3), 199-207. Outcomes

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Ahmed, NAM, Astrom, AN et al 2007. Dental caries prevalence and risk factors among 12-year old schoolchildren from Baghdad, Iraq: A post-war survey, *International dental journal*, 57 (1), 36-44. Outcomes

Ahn, S-J, Lee, S-J et al 2011. Effects of different fluoride recharging protocols on fluoride ion release from various orthodontic adhesives, *Journal of Dentistry*, 39 (3), 196-201. Population

Ahoyo, TA, Fatombi, KJ et al 2011. Impact of water quality and environmental sanitation on the health of schoolchildren in a suburban area of Benin: Findings in the Savalou-Bante and Dassa-Glazoue sanitary districts, *Medecine Tropicale*, 71 (3), 281-285. Comparator

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Ajayi, DM, Denloye, OO et al 2008. The fluoride content of drinking water and caries experience in 15-19 year old school children in Ibadan, Nigeria, *African journal of medicine and medical sciences*, 37 (1), 15-19. Outcomes

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Almeida, BS, Cardoso, VE et al 2007. Fluoride ingestion from toothpaste and diet in 1- to 3-year-old Brazilian children, *Community Dentistry and Oral Epidemiology*, 35 (1), 53-63. Intervention

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Armfield, JM 2010. Community effectiveness of public water fluoridation in reducing children's dental disease, *Public Health Reports*, 125 (5), 655-664. Outcomes

Armfield, JM and Akers, HF 2011. Community water fluoridation support and opposition in Australia, *Community Dental Health*, 28 (1), 40-46. Intervention

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Armfield, JM 2008. The benefits of water fluoridation across areas of differing socio-economic status, *Australian Dental Journal*, 53 (2), 180-183. Outcomes

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Arora, A and Evans, RW 2010. Dental caries in children: a comparison of one non-fluoridated and two fluoridated communities in NSW, *New South Wales public health bulletin*, 21 (11-12), 257-262. Outcomes

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