Water fluoridation: reviewing the evidence

Aim

- Overview of the Cochrane systematic review on water fluoridation
  - Justification for inclusion/exclusion criteria
  - Use of GRADE in determining the overall quality of evidence
  - Interpretation of the findings

Systematic review process

Develop PICO

↓

Locate studies

↓

Abstract data from studies

↓

Assess the risk of bias in the studies

↓

Synthesise the data for each outcome

↓

Assess heterogeneity and publication bias

↓

Assess the quality of the evidence and draw conclusions
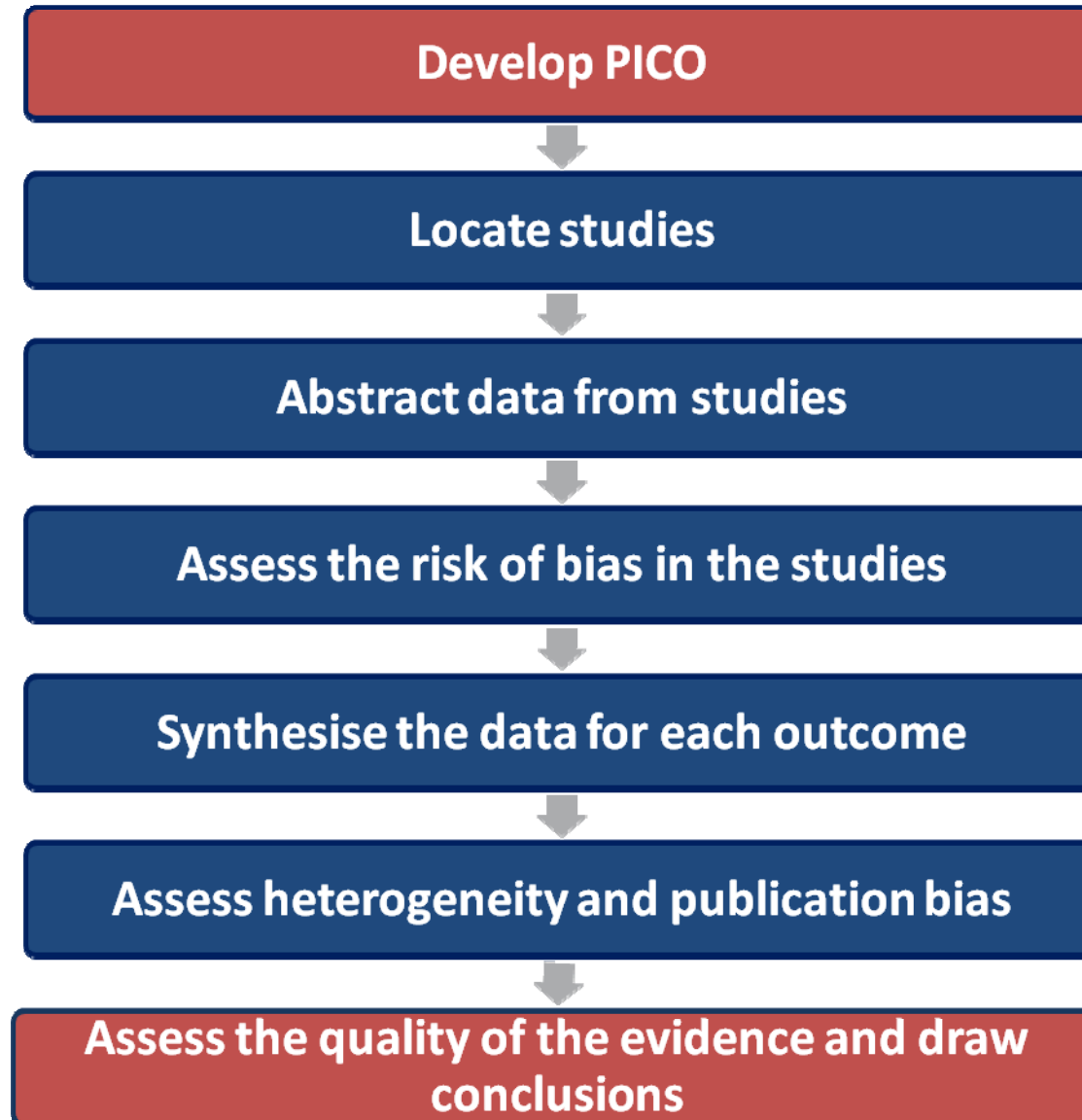
Objectives

- To evaluate the effects of fluoridated water (artificial or natural) on the prevention of dental caries

- To evaluate the effects of fluoridated water (artificial or natural) on dental fluorosis

Population, Intervention, Outcomes

P   All ages receiving fluoridated water (naturally or artificially) and populations receiving   non-fluoridated water

I   CARIES - A change in the level of fluoride in the water supply of at least one of the study areas within three years of the baseline survey

FLUOROSIS - Fluoride at any concentration present in drinking water

O   Dental caries
Dental fluorosis
Harms – not a comprehensive review

Types of studies

Dental caries

• Prospective studies with a concurrent control

• Comparing at least two populations, one receiving fluoridated water and the other non-fluoridated water

• At least two points in time evaluated

• Groups had to be comparable in terms of fluoridated water at baseline.

• For the purposes of this review, 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.

Caries – initiation of CWF

McDonagh	Community Guide	COCHRANE
Adriasola 1959	Adriasola 1959	Adriasola 1959
Alvarez-Ubilia 1959	Alvarez-Ubilia 1959	
Arnold 1956	Arnold 1956	Arnold 1956
Ast 1951	Ast 1951	Ast 1951
Backer-Dirks 1961	Backer-Dirks 1961	Backer-Dirks 1961
Beal 1971	Beal 1971	Beal 1971
Beal 1981	Beal 1981	Beal 1981
		Blinkhorn (unpublished)
Blayney 1960	Blayney 1960	
Brown 1965	Brown 1965	Brown 1965
DHSS England 1969	DHSS England 1969	DHSS England 1969
DHSS Scotland 1969	DHSS Scotland 1969	DHSS Scotland 1969
DHSS Wales 1969	DHSS Wales 1969	DHSS Wales 1969
Gray 1999	Gray 2001	Gray 2001
Guo 1984	Guo 1984	Guo 1984
Hardwick 1982	Hardwick 1982	Hardwick 1982
Kunzel 1997	Kunzel 1997	Kunzel 1997
Kunzel 1997	Kunzel 1997	
Loh 1996	Loh 1996	Loh 1996
Pot 1974	Pot 1974	Pot 1974
		Tessier 1987

Caries – discontinuation of CWF

McDonagh	Community Guide	COCHRANE
Attwood 1988	Attwood 1988	
DHSS 1969	DHSS 1969	
Hobbs	Hobbs	
Kalsbeek 1993	Kalsbeek 1993	
Kunzel 1997	Kunzel 1997	
Maupome 2000	Maupome 2001	Maupome 2001
Seppa 1998	Seppa 1998	
Wragg 1992	Wragg 1992	

Caries – disparities

McDonagh	Community Guide	COCHRANE
Beal 1971	Beal 1971	Beal 1971
Bradnock 1984	Bradnock 1984	
Carmichael 1980	Carmichael 1980	
Carmichael 1989	Carmichael 1989	
DHSS, 1969	DHSS, 1969	
Evans 1996	Evans 1996	
Gray 2000	Gray 2000	Gray 2001
Holdcroft 1999	Holdcroft 1999	Holdcroft 1999
Jones 1997	Jones, 1997	
Jones 2000	Jones 2000	
Murray 1984	Murray 1984	
Murray 1991	Murray 1991	
	Peres 2006	
Provart 1995	Provart 1995	
Riley 1999	Riley 1999	
Rugg-Gunn 1977	Rugg-Gunn 1977	
	Whelton 2004	
	Whelton 2006	

- Water fluoridation **has been effective** at reducing caries in children in the past

- There is **uncertainty around the size of effect** of water fluoridation in populations today

- **Insufficient evidence** to determine the effect of water fluoridation on:
  - **disparities in caries** levels across socio-economic status
  - **caries levels in adults**

- **Insufficient evidence** to determine the effect of **removing water fluoridation programmes** from areas where they already exist

- **Speculation regarding harms** associated with higher levels of fluoride in water (e.g. cancer, lowered intelligence, endocrine dysfunction). Previous reviews suggest there is **insufficient evidence to draw conclusions about them**

Initiation of water fluoridation

Outcome	Measure	McDonagh 2000	Community Guide	Cochrane
Caries	Change in % caries free children (deciduous dentition)	Median 14.6%, IQI: 5.1% to 22.1% (range: -5.0% to 64%)	Median of 25.1%, IQI: 20.35% to 30.45% (range: 19.8% to 31.6%)	15% (95% CI 11% to 19%)
	Change in % caries free children (permanent dentition)			14% (95% CI 5% to 23%)
	Change in dmft (mean difference)	Median 2.25 teeth, IQI: 1.28 to 3.63 teeth (range: - 0.5 to 4.4)		1.81 (95% CI 1.31 to 2.31
	Change in DMFT(mean difference)			1.16 (95% CI 0.72 to 1.61

Outcome	Measure	McDonagh 2000	Community Guide	Cochrane
Disparities in Caries	dmft/DMFT	Inconsistent evidence "Evidence is of insufficient quality to allow confident statements about whether there is an impact on social inequalities"**	-	Insufficient evidence
	% caries reduction	-	Inconsistent evidence	Insufficient evidence
Fluorosis	Proportion of fluorosed at 0.7 ppm	42 (95% CI: 34 to 51)	38 (95% CI: 28 to 48)	40 (95% CI: 35 to 44)

some evidence that water fluoridation reduces the inequalities in dental health across social classes in 5 **and 12 year-olds, using the dmft/DMFT measure.

**the data for the effects in children of other ages did not show an effect (or disparities increased)

Quality of the evidence

McDonagh

•no formal overall assessment

•based on validity of individual studies/volume of evidence

CDC – Community Guide

•published criteria for assessing the strength of a body of evidence (Briss et al, 2000)

Cochrane

• GRADE – published criteria for systematic reviewers/guideline developers for assessing quality of a body of evidence

Evidence of Effectiveness	Execution of study (good or fair)	Suitability Of Design	Number of Studies	Consistent	Effect Size
STRONG	Good	Greatest	≥ 2	Yes	Meaningful
	Good	Greatest or Moderate	≥ 5	Yes	Meaningful
	Good /Fair	Greatest	≥ 5	Yes	Meaningful
	Meet criteria for SUFFICIENT but not STRONG body of evidence				LARGE
SUFFICIENT	Good	Greatest	1	NA	Meaningful
	Good /Fair	Greatest or Moderate	≥ 3	Yes	Meaningful
	Good /Fair	Greatest Moderate Least	≥ 5	Yes	Meaningful
Expert Opinion	Varies	Varies	Varies	Varies	Meaningful
INSUFFICIENT	Inadequate designs or execution		Too Few	No	Small

The categories are not mutually exclusive; a body of evidence meeting criteria for more than one of these should be categorized in the highest possible category.

Adapted from Briss et al 2000

GRADE

http://www.guidelinedevelopment.org

Determinants of the quality of the body of evidence

- – Risk of bias

- – Inconsistency *(or heterogeneity)*

- – Indirectness *(PICO and applicability)*

- – Imprecision
  (number of events and confidence intervals)

- – Publication bias

Reaching a decision with GRADE

Quality of Evidence can vary from:

HIGH	$\oplus\oplus\oplus\oplus$	
MODERATE	$\oplus\oplus\oplus\bigcirc$	**Confidence**
LOW	$\oplus\oplus\bigcirc\bigcirc$	
VERY LOW	$\oplus\bigcirc\bigcirc\bigcirc$	

Outcomes

Initiation of water fluoridation compared with low/non-fluoridated water for the prevention of dental caries						
Patient or population: people of all ages Settings: community setting Intervention: initiation of water fluoridation Comparison: low/non-fluoridated water						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk in area with low/non-fluoridated water	Risk in area with initiation of water fluoridation				
Caries in deciduous teeth (dmft)[1] Scale from: 0 to 20 (lower = better) Follow-up: range from 3-12 years						

Caries in deciduous teeth (dmft)

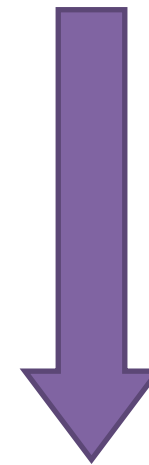# Assumed risk

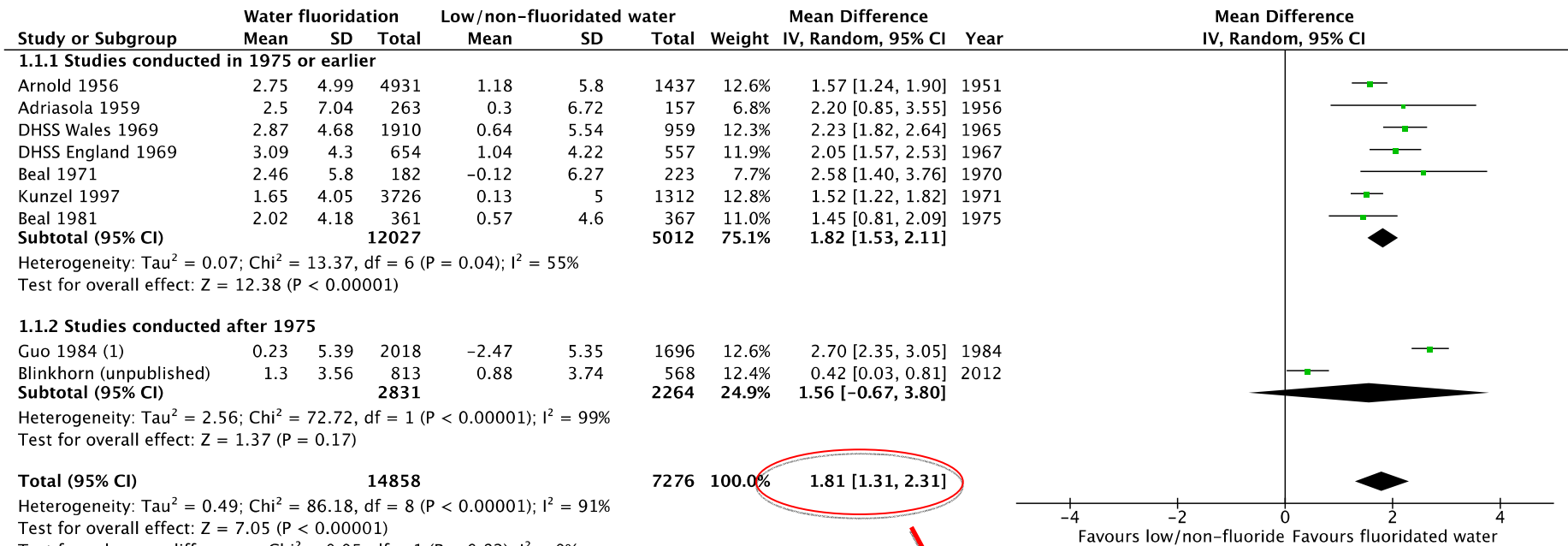| Initiation of water fluoridation compared with low/non-fluoridated water for the prevention of dental caries						
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Caries in deciduous teeth (dmft)[1] Scale from: 0 to 20 (lower = better) Follow-up: range from 3-12 years	The mean dmft at follow-up in the low/non-fluoridated areas ranged from 1.21 to 7.8 (median 5.1)					

The mean dmft at follow-up in the low/non-fluoridated areas ranged from 1.21 to 7.8 (median 5.1)

Corresponding risk

Study or Subgroup	Water fluoridation			Low/non–fluoridated water			Weight	Mean Difference IV, Random, 95% CI	Year	Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total				
1.1.1 Studies conducted in 1975 or earlier										
Arnold 1956	2.75	4.99	4931	1.18	5.8	1437	12.6%	1.57 [1.24, 1.90]	1951	
Adriasola 1959	2.5	7.04	263	0.3	6.72	157	6.8%	2.20 [0.85, 3.55]	1956	
DHSS Wales 1969	2.87	4.68	1910	0.64	5.54	959	12.3%	2.23 [1.82, 2.64]	1965	
DHSS England 1969	3.09	4.3	654	1.04	4.22	557	11.9%	2.05 [1.57, 2.53]	1967	
Beal 1971	2.46	5.8	182	−0.12	6.27	223	7.7%	2.58 [1.40, 3.76]	1970	
Kunzel 1997	1.65	4.05	3726	0.13	5	1312	12.8%	1.52 [1.22, 1.82]	1971	
Beal 1981	2.02	4.18	361	0.57	4.6	367	11.0%	1.45 [0.81, 2.09]	1975	
Subtotal (95% CI)			12027			5012	75.1%	1.82 [1.53, 2.11]		

Heterogeneity: Tau² = 0.07; Chi² = 13.37, df = 6 (P = 0.04); I² = 55%
Test for overall effect: Z = 12.38 (P < 0.00001)

1.1.2 Studies conducted after 1975										
Guo 1984 (1)	0.23	5.39	2018	−2.47	5.35	1696	12.6%	2.70 [2.35, 3.05]	1984	
Blinkhorn (unpublished)	1.3	3.56	813	0.88	3.74	568	12.4%	0.42 [0.03, 0.81]	2012	
Subtotal (95% CI)			2831			2264	24.9%	1.56 [−0.67, 3.80]		

Heterogeneity: Tau² = 2.56; Chi² = 72.72, df = 1 (P < 0.00001); I² = 99%
Test for overall effect: Z = 1.37 (P = 0.17)

Total (95% CI)			14858			7276	100.0%	1.81 [1.31, 2.31]		

Heterogeneity: Tau² = 0.49; Chi² = 86.18, df = 8 (P < 0.00001); I² = 91%
Test for overall effect: Z = 7.05 (P < 0.00001)
Test for subgroup differences: Chi² = 0.05, df = 1 (P = 0.82), I² = 0%

Footnotes
(1) Guo 1984 commenced in 1971; possibility of fluoridated toothpaste being introduced during study period

−4   −2   0   2   4
Favours low/non–fluoride   Favours fluoridated water

MD 1.81 (95%CI 1.31, 2.31)

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Corresponding risk

Initiation of water fluoridation compared with low/non-fluoridated water for the prevention of dental caries

Patient or population: people of all ages
Settings: community setting
Intervention: initiation of water fluoridation
Comparison: low/non-fluoridated water

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk in area with low/non-fluoridated water	Risk in area with initiation of water fluoridation				
Caries in deciduous teeth (dmft)[1] Scale from: 0 to 20 (lower = better) Follow-up: range from 3-12 years	The mean dmft at follow-up in the low/non-fluoridated areas ranged from 1.21 to 7.8 (median 5.1)	The mean dmft in the areas with water fluoridation was 1.81 lower (1.31 lower to 2.31 lower)				

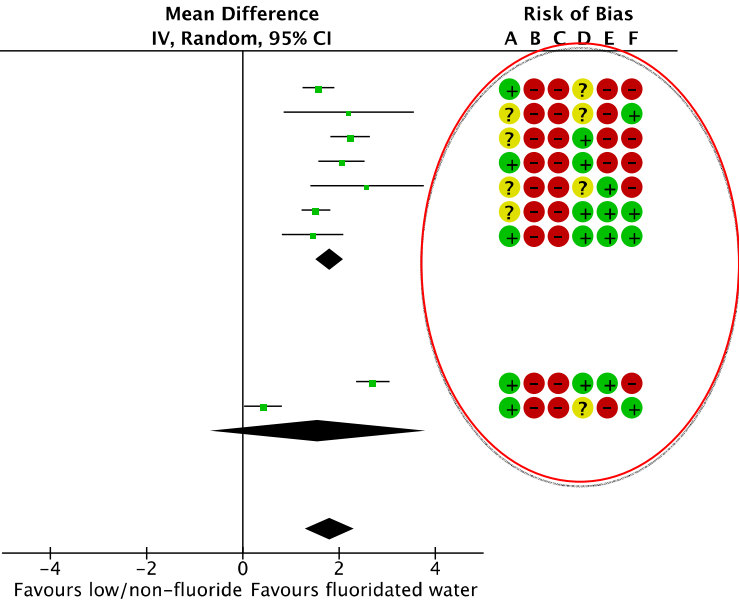The mean dmft in the areas with water fluoridation was 1.81 lower (1.31 lower to 2.31 lower)

Number of studies

Initiation of water fluoridation compared with low/non-fluoridated water for the prevention of dental caries						
Patient or population: people of all ages **Settings: community setting** **Intervention: initiation of water fluoridation** **Comparison: low/non-fluoridated water**						
Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**No of participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
	Risk in area with low/non-fluoridated water	**Risk in area with initiation of water fluoridation**				
Caries in deciduous teeth (dmft)[1] Scale from: 0 to 20 (lower = better) Follow-up: range from 3-12 years	The mean dmft at follow-up in the low/non-fluoridated areas ranged from 1.21 to 7.8 (median 5.1)	The mean dmft in the areas with water fluoridation was 1.81 lower (1.31 lower to 2.31 lower)		44,268[2] (9 observational studies)		

44,268 participants
(9 observational studies)

Risk of bias

Study or Subgroup	Water fluoridation Mean	SD	Total	Low/non-fluoridated water Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Year
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Study or Subgroup	Water fluoridation Mean	SD	Total	Low/non-fluoridated water Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Year
1.1.2 Studies conducted after 1975									
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Footnotes
(1) Guo 1984 commenced in 1971; possibility of fluoridated toothpaste being introduced during study period

Favours low/non-fluoride   Favours fluoridated water

Risk of bias legend
(**A**) Sampling
(**B**) Confounding
(**C**) Blinding of outcome assessment (detection bias)
(**D**) Incomplete outcome data (attrition bias)
(**E**) Selective reporting (reporting bias)
(**F**) Other bias

Risk of bias

a) **No concerns, or any concerns are negligible (do not downgrade)**

b) **Serious concerns (downgrade 1 level)**

c) **Very serious concerns (downgrade 2 levels)**

Inconsistency (heterogeneity)
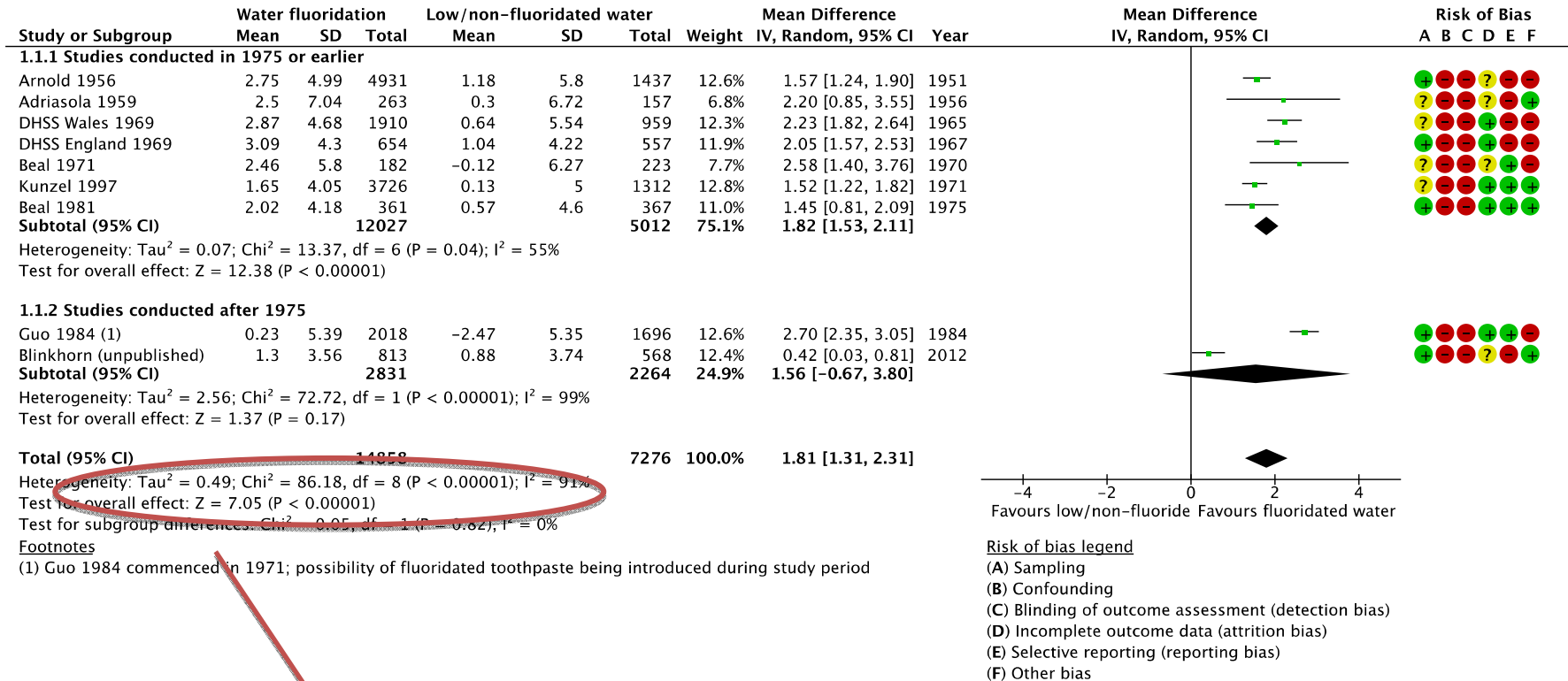
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Inconsistency

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c) Very serious inconsistency (downgrade 2 levels)

Indirectness

- \> 70% of the evidence from 1975 or earlier
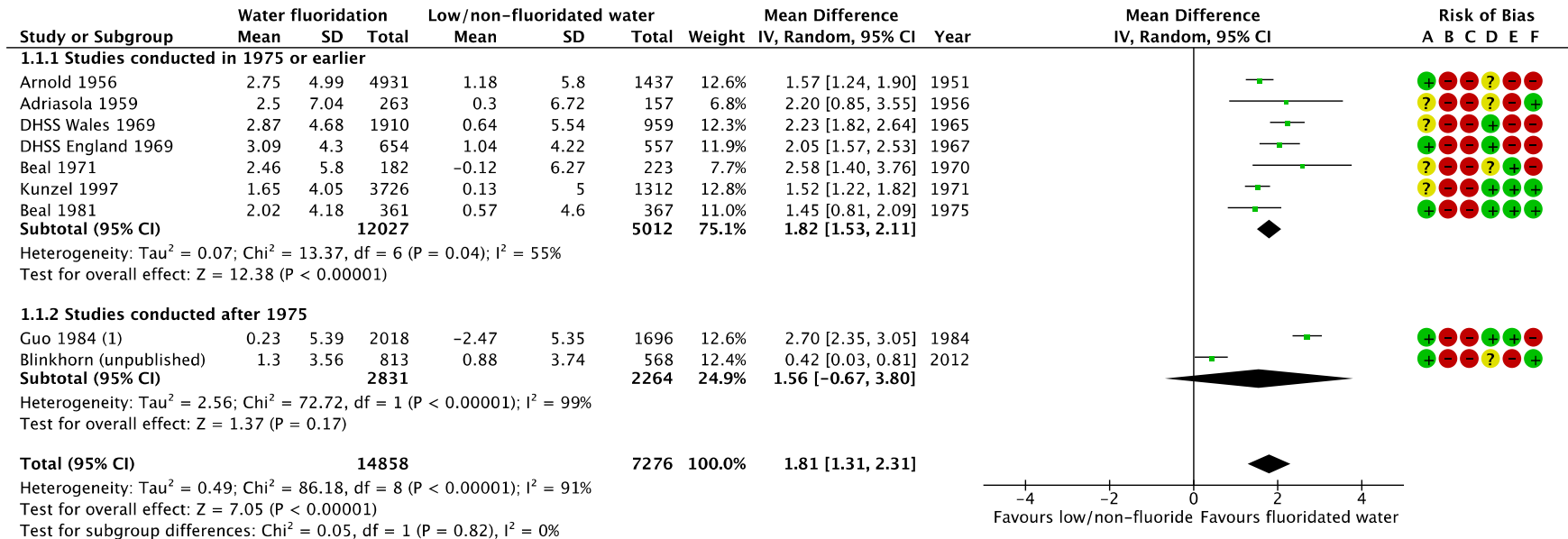- No studies on adults with regard to caries

Indirectness

a) Yes, totally or reasonably well (do not downgrade)

b) Serious indirectness (downgrade 1 level)

c) Very serious indirectness (downgrade 2 levels)

Imprecision

Study or Subgroup	Water fluoridation Mean	SD	Total	Low/non–fluoridated water Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Year	Risk of Bias A B C D E F
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Kunzel 1997	1.65	4.05	3726	0.13	5	1312	12.8%	1.52 [1.22, 1.82]	1971	? − − + + +
Beal 1981	2.02	4.18	361	0.57	4.6	367	11.0%	1.45 [0.81, 2.09]	1975	+ − − + + +
Subtotal (95% CI)			12027			5012	75.1%	1.82 [1.53, 2.11]		

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Favours low/non–fluoride   Favours fluoridated water

Footnotes
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Risk of bias legend
(A) Sampling
(B) Confounding
(C) Blinding of outcome assessment (detection bias)
(D) Incomplete outcome data (attrition bias)
(E) Selective reporting (reporting bias)
(F) Other bias

Imprecision

a) No imprecision, or any imprecision is negligible (do not downgrade)

b) Serious imprecision (downgrade 1 level)

c) Very serious imprecision (downgrade 2 levels)

Publication bias

Is publication bias likely?

Publication bias

a) Not likely/undetected (do not downgrade)

b) Strongly suspected (downgrade 1 level)

Magnitude of effect

a) No, not particularly large (do not upgrade)

b) Large effect (upgrade 1 level)

c) Very large effect (upgrade 2 levels)

GRADE

Quality of Evidence varies from:

HIGH	⊕⊕⊕⊕
MODERATE	⊕⊕⊕◯
LOW	⊕⊕◯◯
VERY LOW	⊕◯◯◯

↓ **Confidence**

GRADE

Quality of Evidence varies from:

HIGH	⊕⊕⊕⊕	
MODERATE	⊕⊕⊕◯	
LOW	⊕⊕◯◯	**Confidence** ↓
VERY LOW	⊕◯◯◯	

Initiation of water fluoridation compared with low/non-fluoridated water for the prevention of dental caries

Patient or population: people of all ages
Settings: community setting
Intervention: initiation of water fluoridation
Comparison: low/non-fluoridated water

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk in area with low/non-fluoridated water	Risk in area with initiation of water fluoridation				
Caries in deciduous teeth (dmft)[1] Scale from: 0 to 20 (lower = better) Follow-up: range from 3-12 years	The mean dmft at follow-up in the low/non-fluoridated areas ranged from 1.21 to 7.8 (median 5.1)	The mean dmft in the areas with water fluoridation was 1.81 lower (1.31 lower to 2.31 lower)		44,268[2] (9 observational studies)	⊕⊕⊖⊖[3,4,5,6]	

⊕⊕⊖⊖

"Low quality"

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Terminology

- much debate around the appropriateness of GRADE when applied to public health interventions

- terminology of 'low quality' for evidence may appear too judgmental

- reworded in terms of 'confidence'

⊕⊕⊕⊕ We are very confident that the true effect lies close to that of the estimate of the effect. Further research is very unlikely to change the estimate of effect.

⊕⊕⊕ ⊖ We are moderately confident in the effect estimate. Further research may change the estimate.

⊕⊕⊖⊖ Our confidence in the effect estimate is limited. Further research is likely to change the estimate.

⊕⊖⊖⊖ We are very uncertain about the estimate.

Initiation of water fluoridation compared with low/non-fluoridated water for the prevention of dental caries

Patient or population: people of all ages
Settings: community setting
Intervention: initiation of water fluoridation
Comparison: low/non-fluoridated water

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Caries in deciduous teeth (dmft)[1] Scale from: 0 to 20 (lower = better) Follow-up: range from 3-12 years	The mean dmft at follow-up in the low/non-fluoridated areas ranged from 1.21 to 7.8 (median 5.1)	The mean dmft in the areas with water fluoridation was 1.81 lower (1.31 lower to 2.31 lower)		44,268[2] (9 observational studies)	⊕⊕⊝⊝[3,4,5,6]	This indicates a reduction in dmft of 35% in the water fluoridation groups over and above that for the control groups We have limited confidence in the size of this effect due to the high risk of bias within the studies and the lack of contemporary evidence

This indicates a reduction in dmft of 35% in the water fluoridation groups over and above that for the control groups
We have limited confidence in the size of this effect due to the high risk of bias within the studies and the lack of contemporary evidence

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Patient or population: people of all ages
Settings: community setting
Intervention: initiation of water fluoridation
Comparison: low/non-fluoridated water

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk in area with low/non-fluoridated water	Risk in area with initiation of water fluoridation				
Caries in deciduous teeth (dmft)[1] Scale from: 0 to 20 (lower = better) Follow-up: range from 3-12 years	The mean dmft at follow-up in the low/non-fluoridated areas ranged from 1.21 to 7.8 (median 5.1)	The mean dmft in the areas with water fluoridation was 1.81 lower (1.31 lower to 2.31 lower)		44,268[2] (9 observational studies)	⊕⊕⊖⊖[3,4,5,6]	This indicates a reduction in dmft of 35% in the water fluoridation groups over and above that for the control groups We have limited confidence in the size of this effect due to the high risk of bias within the studies and the lack of contemporary evidence

Footnotes

1. dmft - decayed, missing and filled deciduous teeth
2. Total number of participants measured. Analysis undertaken on average number of participants measured at baseline and follow-up for each study
3. Studies at high risk of bias; quality of the evidence downgraded
4. Substantial heterogeneity present, however, given that the direction of effect was the same in all but on of the studies/outcomes we did not downgrade due to heterogeneity
5. Indirectness of evidence due to lack of contemporary evidence; quality of the evidence downgraded. 71% of the studies conducted prior 1975; the use of fluoridated toothpaste, the availability of other caries prevention strategies, diet and tap water consumption are all likely to have changed in the populations in which the studies were conducted. No studies on the effect of water fluoridation in adults met the inclusion criteria
6. Very large effect size; quality of the evidence upgraded twice

Evidence of Effectiveness	Execution of study (good or fair)	Suitability Of Design	Number of Studies	Consistent	Effect Size
STRONG	Good	Greatest	≥ 2	Yes	Meaningful
	Good	Greatest or Moderate	≥ 5	Yes	Meaningful
	Good /Fair	Greatest	≥ 5	Yes	Meaningful
	Meet criteria for SUFFICIENT but not STRONG body of evidence				LARGE
SUFFICIENT	Good	Greatest	1	NA	Meaningful
	Good /Fair	Greatest or Moderate	≥ 3	Yes	Meaningful
	Good /Fair	Greatest Moderate Least	≥ 5	Yes	Meaningful
Expert Opinion	Varies	Varies	Varies	Varies	Meaningful
INSUFFICIENT	Inadequate designs or execution		Too Few	No	Small

The categories are not mutually exclusive; a body of evidence meeting criteria for more than one of these should be categorized in the highest possible category.

Adapted from Briss et al 2000

Cochrane review too restrictive?

- **Cross-sectional and other study designs**

Rugg-Gunn & Do 2012

- – Comprehensive search published 1990-2010
- – 59 studies
- – Three types of study design included:
  - Historical (retrospective or self-) control
  - Cross-sectional – unadjusted
  - Cross-sectional - adjusted for confounding factors
- – % caries reduction lower in recent studies

Water fluoridation
Health monitoring report for England 2014

Mean D3MFT

- Non-F   0.71 (95% CI 0.68 to 0.75)
- F   0.63 (95% CI 0.58 to 0.68)

11% difference (0.08 D3MFT)

Cochrane review: 26% difference

"strong evidence that mean D3MFT was lower in fluoridated compared to non-fluoridated areas"

Potential impact of including cross-sectional studies

- Likely to see smaller overall effect size
- GRADE recommendation would remain the same, or be reduced (low/very low quality)

"This indicates a reduction in dmft of 35% in the water fluoridation groups over and above that for the control groups. We have limited confidence in the size of this effect"

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"This indicates a reduction in dmft of ??% in the water fluoridation groups over and above that for the control groups. We have limited confidence in the size of this effect"

- Acknowledge difference between systematic reviews and

- Clarity of gra evidence/bo

- Remain tran

- Maintain op

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