

Critique of the review of 'Water fluoridation for the prevention of dental caries' published by the Cochrane Collaboration in 2015

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IN BRIEF

- Discusses critically a recently published review of the effectiveness of water fluoridation.
- Highlights the lost opportunity to evaluate the vast majority of recent studies on water fluoridation to answer the research questions.
- Suggests modern and appropriate methods for systematic evaluation of the effectiveness of water fluoridation.

The Cochrane Review on water fluoridation for the prevention of dental caries was published in 2015 and attracted considerable interest and comment, especially in countries with extensive water fluoridation programmes. The Review had two objectives: (i) to evaluate the effects of water fluoridation (artificial or natural) on the prevention of dental caries, and (ii) to evaluate the effects of water fluoridation (artificial or natural) on dental fluorosis. The authors concluded, *inter alia*, that there was very little contemporary evidence, meeting the Review's inclusion criteria, that evaluated the effectiveness of water fluoridation for the prevention of dental caries. The purpose of this critique is to examine the conduct of the above Review, and to put it into context in the wider body of evidence regarding the effectiveness of water fluoridation. While the overall conclusion that water fluoridation is effective in caries prevention agrees with previous reviews, many important public health questions could not be answered by the Review because of the restrictive criteria used to judge adequacy of study design and risk of bias. The potential benefits of using wider criteria in order to achieve a fuller understanding of the effectiveness of water fluoridation are discussed.

INTRODUCTION

The Cochrane Review¹ on water fluoridation for the prevention of dental caries was published in 2015 (referred to in this article as the Cochrane Review) and attracted considerable interest and comment, especially in countries with extensive community water fluoridation programmes. The Cochrane Review had two stated objectives: (i) to evaluate the effects of

water fluoridation (artificial or natural) on the prevention of dental caries, and (ii) to evaluate the effects of water fluoridation (artificial or natural) on dental fluorosis. The authors concluded that the initiation of water fluoridation results in reductions in caries which translate into a 35% reduction in primary teeth and a 26% reduction in permanent teeth, with an increase of 15% in the percentage of children free of decay experience in primary teeth and an increase of 14% in the percentage of children free of decay experience in permanent teeth. However, they found that there was very little recent or contemporary evidence, meeting the Cochrane Review's inclusion criteria, that has evaluated the effectiveness of water fluoridation for the prevention of dental caries. They said that around 70% of the studies they reviewed pre-dated the introduction of fluoride-containing toothpaste in the mid to late 1970s. They also reported that there is insufficient evidence to determine whether water fluoridation results in a change in disparities in caries levels across socio-economic status (SES) groups (although this was not a stated review objective). The authors did not identify any evidence, meeting the Review's inclusion criteria, to determine the effectiveness of water

fluoridation for preventing caries in adults; they argued that there was insufficient information to determine the effect on caries levels of stopping water fluoridation programmes; and that there was a significant association between dental fluorosis and fluoride level in water supplies up to 5 mg/L.

The stated intention of the Cochrane Review was to update the systematic review on the same topic by the NHS Centre for Reviews and Dissemination, York University, published in 2000 (conventionally known as the York Review).² However, the Cochrane Review had only two of the five original objectives of the York Review. The study protocol for the Cochrane Review published in 2013³ stated 'The effectiveness of fluoridated water (artificially or naturally) is well documented (McDonagh 2000; NHMRC 2007; Truman 2002) and alternative fluoride sources such as toothpastes and varnishes have also been proven to be effective (Marinho 2013; Walsh 2010)'. The protocol also stated: 'Given the continued interest in this [water fluoridation] topic, from both health professionals, policy makers and the public, it is important to update and maintain a systematic review of the available evidence.'

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The purpose of this critique is to examine the methods and assumptions used in the 2015 Cochrane Review and to put the Review into context in the wider body of evidence regarding the effectiveness of water fluoridation. While the overall conclusion that water fluoridation is effective in caries prevention is consistent with previous reviews, many important public health questions could not be answered by the Cochrane Review because of the restrictive inclusion criteria used to judge adequacy of study design and risk of bias. The potential benefits of using wider criteria in order to achieve a fuller understanding of the effectiveness of water fluoridation are discussed.

THE NATURE OF WATER FLUORIDATION PROGRAMMES

Water fluoridation is an intervention to benefit public health at the population level, involving adjusting the fluoride concentration in public water supplies for total geographical communities. As a population intervention it differs from measures to benefit health aimed at individuals. For individual clinical interventions, decisions to treat are based on knowledge of the proven efficacy and effectiveness of the drug or other technology as demonstrated in randomised controlled trials (RCTs) and on the clinical judgement of the prescriber based on his or her knowledge of the individual patient being treated. With public health interventions things are different. There will only sometimes be RCTs demonstrating efficacy and effectiveness. There are frequently no such trials because the highly complex practical, ethical and financial factors involved mean that RCTs are not feasible. Consequently, when determining whether a public health intervention is cost effective, evidence has to be drawn from a wide variety of other scientific methods and research designs including cross-sectional ones and process evaluations.^{4,5} In the case of water fluoridation, this may involve, for example, an assessment that would indicate how well the preparatory and operational stages of a programme of water fluoridation have fared. In many cases it is simply impossible to make recommendations for public health interventions and policy if reliance is only placed on RCTs. Further, with public health interventions, the issue is not about individual patient benefit but whether the population as a whole will benefit. So, for example, reducing population level salt intake by changing the composition of processed foods has the effect of reducing population levels of hypertension with correspondingly fewer strokes. Not all individuals benefit equally from public health interventions and some people will still suffer strokes, but the population as a whole benefits because there are fewer strokes overall. Water

fluoridation is not a clinical intervention done to an individual. It is a population level intervention and should be judged as such.⁶⁻¹⁵

Therefore, measurement of the impact of water fluoridation is not like a clinical intervention for the following reasons. First, the context in which water is fluoridated is complex:^{16,17} its introduction and maintenance requires legislation, installation and maintenance of equipment, technical training of water treatment plant operators, development and adherence to procedures and processes, and continuity of supply and regular monitoring. Second, its impact is more than just change in 'dmft/DMFT' scores. The effectiveness of water fluoridation can potentially be seen in reductions in caries incidence (both coronal and root caries), as well as reductions in edentulousness, dental pain, dental abscesses, prescription of antibiotics, and dental treatment for children under general anaesthetics and admissions to hospital. It reduces costs to the individual and community, and helps to improve people's quality of life. While the 'percentage caries-free' and 'mean dmft/DMFT' in the community as a whole are useful statistics, there is also a need to assess the impact of water fluoridation in those with the highest caries experience, since this group presents the biggest challenge in dental public health and dental practice.

The cause-and-effect relationship between water fluoridation and caries prevention is confounded by the unequal distribution of disease risk and preventive behaviours in society, in particular, variations in use of other sources of fluoride, mainly from toothpaste, and diet, particularly sugar consumption. In many societies, these are closely linked to SES, and evaluation should also measure and control for these explanatory factors and interactions. Water fluoridation should be evaluated using contemporary methods which are appropriate for evaluating public health interventions with such complexities, and systematic reviews should take this into account.

Many of the early evaluations of the effectiveness of water fluoridation were repeated cross-sectional studies in both the community about to implement water fluoridation and also in a control (or reference) community receiving drinking water with an unadjusted, low fluoride concentration. Evaluations took place before fluoridation began (baseline) to determine comparability between the two communities, and after a suitable number of years (very often five years). This design is known as a non-randomised, concurrent-control, before-and-after study. These early studies, conducted in the 1940s, 50s, 60s and 70s,

showed clearly that fluoridation of drinking water was effective at reducing the burden of dental caries, and many health authorities followed national policy by introducing water fluoridation on the basis of these studies. Over time, in many countries, coverage of the population with water fluoridation schemes was almost complete, at least to the limits of public health requirements and technical feasibility. In such jurisdictions, the priority for health authorities was to monitor the continued effectiveness of existing schemes. Most recent evaluations of water fluoridation have been of this type, using the most appropriate design, which is a single cross-sectional survey of fluoridated and non-fluoridated groups with control for confounding factors. One of the critical problems with the 2015 Cochrane Review is that these data have been excluded from the Review. This important point will be discussed further below.

Surveillance and evaluation of water fluoridation programmes are routinely carried out on behalf of the administration overseeing the programme, be it a local authority or a Government agency. Publication in academic journals is not the goal of such agencies. Systematic reviews should recognise this reality and ensure that such evaluations are identified and reviewed. Similarly, in such cases where the evaluation is published, reviewers should determine whether the evaluation is more comprehensively described in a full report written for administrators/managers of the fluoridation programme. While this 'grey literature' was sought in the York Review, there is no record that this was done in the 2015 Cochrane Review.

CRITERIA FOR INCLUDING STUDIES AND QUALITY ASSESSMENT

Requirement for 'at least two points in time'

The Cochrane Review states: 'For caries data, we included only prospective studies with a concurrent control, comparing at least two populations, one receiving fluoridated water and the other non-fluoridated water, with at least two points in time evaluated. Groups had to be comparable in terms of fluoridated water at baseline.' The purpose of this requirement appears to be to obtain a measure of change in caries experience in the fluoridated community from before implementation of fluoridation to sometime afterwards, and to compare this change with any change in the control (or reference) community over the same time period. This is similar to a method used to evaluate the effectiveness of self-administered fluoride

agents at an individual-level (such as fluoride-containing toothpastes) and, commonly, these trials last for three years so that three year caries incidence and increments in intervention and reference groups may be compared. However, trials follow the same individuals, whereas the studies included in the Cochrane Review almost always follow the same communities. The authors of the Cochrane Review infer that, in a non-randomised trial, recording caries experience in both communities before commencement of water fluoridation and finding similar caries experience in the two communities before water fluoridation, the communities would remain similar over time. This is surprising, since the Cochrane Review inclusion criterion stipulates that the baseline examination should be within three years of implementation of water fluoridation: an acknowledgement that the communities may, mainly through population change, lose comparability after three years. While this assumption of similarity may be reasonable over a short period, it becomes less tenable as the period between baseline and final examinations increases. This comes *ad extremis* in the Cochrane Review, in identifying the effect in adults. Thus, for an evaluation of the possible benefits for 50-year-olds, baseline information on the caries experience of people of this age would be required in the community to be fluoridated and in a comparable reference community, as well as information to be collected 50 years later on the caries experience of people from the same age group in the same communities which have continued to remain fluoridated or non-fluoridated for the whole of that very long period. Such requirements are unfeasibly stringent given the potential for community demographic characteristics to change over time, and render 50 year historical comparability of intervention and reference communities meaningless for present-day comparisons.

Even in shorter-term studies (for example, the evaluation of the health of 5-year-olds after five years of water fluoridation), the requirement for baseline and follow-up caries experience data in both the intervention and reference communities, as well as recording of possible confounding factors, could be questioned. As already mentioned, most evaluations of water fluoridation over the past 15 to 20 years have involved surveillance of existing water fluoridation programmes. The most appropriate study design for this purpose is a single cross-sectional study with controls and does not require examination 'at two time points'. Besides the obvious advantage in a greater number of opportunities for study, including a greater

number of populations served, the value of this approach in estimating the impact of an intervention has increased with the improvement of study design and data collection, the mainstreaming of powerful and fast computing and the application of new more sophisticated statistical methods. Cross-sectional studies can now address many of the methodological weaknesses which compromised their value in the past. The main concern is controlling for confounding factors and quantifying the amount of the difference between or among groups that is due to the intervention of interest.

Requirement for a positive reference community when evaluating the effect of cessation of water fluoridation

Fluoridation of water has been stopped in a number of communities worldwide and the effect on caries experience in these communities has been reported. The authors of the Cochrane Review introduced a new requirement for including such evaluations into their analysis. They required the existence of a positive (fluoridated) reference community during the period of time from cessation of water fluoridation to the evaluation – for example, five years after cessation – with information on caries experience in both communities before cessation and after cessation. Reasons for cessation of water fluoridation vary but often it is due to regional or national policy. Thus, all fluoridation programmes in the region would cease, ruling out the possibility of a comparable positive reference community. Examples of this occurred in Scotland; the effects of cessation of water fluoridation in both Wick and Stranraer were evaluated, but not against positive reference communities since national policy ensured none existed. The authors of the Cochrane Review did not accept the concept of a negative reference community, although it had previously been accepted by the authors of the York Review. While the difference in caries experience between the previously fluoridated community and the positive control community at follow-up examination would be a measure of disbenefit, since this is in practice difficult if not impossible to obtain, change in caries experience in a non-fluoridated reference community between baseline and follow-up examination is a measure of change in background caries experience, allowing an estimate of decline in benefit in the previously fluoridated community. This approach was accepted in the York Review which examined data on the effect of cessation of water fluoridation in 22 analyses (eight studies). In 14 of these, 'stopping water

fluoridation led to an increase in caries in the previously fluoridated area compared to the never-fluoridated area.' The Cochrane Review analysed just one of these studies.

A systematic review sometimes involves a trade-off between methodological excellence and purity, and meaningful and useful data for policy makers, the public and politicians. Evidence, even that produced by the most pristine methods, never speaks for itself or tells you exactly what to do; it always requires interpretation.¹⁷ If methodological excellence blinds us to the power of data, imperfect though it may be, about which we can make an assessment and a judgement, this may be a serious deficiency. We believe that has happened in the 2015 Cochrane Review.

Exclusion of modern methods of surveillance of water fluoridation programmes

In many countries with water fluoridation programmes, surveillance of existing schemes is a public health priority and mandated in legislation. For example, the 'Health (Fluoridation of Water Supplies) Act, 1960', Government of Ireland,¹⁸ which permitted fluoridation of water in Ireland, requires 'the Minister [for Health] to arrange from time to time for such surveys as appear to him to be desirable to be made as respects the health [...] of persons [...] in the functional area of a health authority.' Such surveillance¹⁹ has also been recommended in other countries including Australia, New Zealand, the USA, Canada, Israel and England.^{20,21} In all of these countries, scientifically robust evaluations have been made and published, recording the continued effectiveness of water fluoridation. These are cross-sectional studies, which have compared the caries experience of people, of various ages, with a history of exposure, partial exposure, or no exposure to water fluoridation. Multivariable analyses have controlled for possible confounding factors, allowing an unbiased estimate to be made of the strength of association of water fluoridation with dental caries.²² However, because of their lack of 'baseline' data, these studies were excluded from the Cochrane Review.

Requirements for recording confounding factors

Avoiding and minimising methodological bias in analytical epidemiology is important and it is generally accepted that research studies have to demonstrate that bias has been considered and controlled for as far as reasonably possible. However, for studies to be rated as having a 'low' risk of bias, the Cochrane Review required that information

on four possible confounding factors be recorded and included in analyses: 'sugar consumption/dietary habits, SES, ethnicity, and use of other fluoride sources.' The Cochrane Review gave no justification for requiring all four of these requirements. While there is good evidence that all four influence caries development, there is also good evidence that dietary habits and home use of fluoride products are strongly related to SES in many communities.^{23,24} It may, therefore, be unnecessary to record diet and use of fluoride products if SES is recorded, and the requirement to record many potential confounders needs to be considered carefully, especially as dietary habits are notoriously difficult to record and quantify. Ethnic differences are relevant in some communities only. It should be noted in Table 2 of Rugg-Gunn and Do²⁵ that the percent caries reductions recorded both before and after adjustment for confounding factors by multivariable analyses were very similar in seven out of the eight studies identified in that review. Thus the insistence on the requirement to include the above four confounding factors may be misguided. While in many countries, low income and limited education are positively associated with caries development, this is not so in some countries.²⁶ Potential confounding factors should be decided at a local level, with justification of their relevance.

Design of study

The Cochrane Review maintained that the RCT would be the best design for evaluating the effectiveness of water fluoridation, while simultaneously acknowledging its impracticability in this instance. Although RCTs are the method of choice for evaluating the effectiveness of medicines and some clinical interventions, literature published during the past 20 years has indicated that they are inappropriate for evaluating public health preventive programmes and other complex interventions.⁶⁻¹⁵ Using water fluoridation as an example, it is not possible to randomly assign individuals to fluoridated and non-fluoridated water supplies. RCTs may have high internal validity, but they also may have poor external validity. As Petticrew¹⁵ pointed out, public health science has moved on from saying 'what works' to exploring 'what happens'. There is a stark contrast in approach when the Cochrane Review on water fluoridation is compared with the recent World Health Organization (WHO) systematic review of dietary sugars and dental caries.^{27,28} National nutrition guidelines and water fluoridation are both public health issues. While the former (Cochrane) review's requirements for study

design were very restrictive, the latter (WHO) included studies with a variety of designs: of the 55 studies eligible for inclusion, three were intervention, eight cohort, 20 population, and 24 cross-sectional.^{27,28} Both the Cochrane Review¹ and the WHO review²⁸ used the GRADE method for assessing the quality of evidence.

The role of cross-sectional studies with concurrent controls to monitor the differential in caries between long fluoridated and negative reference sites should have been explored for its potential to address the research question of the continued effectiveness of water fluoridation in an environment of other fluoride sources. The issue of the length of follow-up required, especially among adults, should have prompted consideration of cohort studies, whether true prospective studies built around differing exposure to water fluoridation or historical cohort studies which can be derived from cross-sectional comparisons. Ecological studies can also be in the mix due to the population-level implementation of water fluoridation, leading to the possible use of multilevel modelling in analysis. Instead, the Cochrane Review has attempted to answer all the supplementary research questions through evidence from non-randomised, concurrent and negatively controlled before-and after-studies. This, it could be argued, led to what is termed 'an empty review'. The Cochrane Review's conclusion that 'there is very little contemporary evidence that has evaluated the effectiveness of water fluoridation for the prevention of caries' is self-fulfilling due to its omission of contemporary studies designed for surveillance of public health programmes.

DENTAL FLUOROSIS

The Cochrane Review has a second stated objective of evaluating the effect of water fluoridation (artificial or natural) on dental fluorosis. This basically repeats an evaluation of the dose-response relationship between fluoride in water supplies and dental fluorosis that Dean and others documented in the 1930s and 1940s.²⁹ This objective explains the inclusion of natural fluoride concentrations well above those used in adjusted water fluoridation programmes. It is also a repeat of the analyses presented in the York Review.

Research about fluoride in drinking water was initially focused on dental fluorosis. Subsequent dose-response research by Dean and others gave an equal consideration to fluorosis and dental caries. The premise behind adjustment of water supplies to around 1 mgF/L was that fluorosis at that concentration was of no public health consequence. While fluorosis was present, it was

of both low prevalence and severity. It was considered to be of such limited severity that it was frequently not discernible by the public and, if discernible, was of minor consequence in relation to the disease, discomfort and distress that was associated with caries. Hence the early water fluoridation trials and the replications though the 1950s to 1970s did not place as much emphasis on fluorosis as an outcome as caries. Reporting tended to confirm the expected low prevalence of any fluorosis, and its low severity – mostly questionable and very mild with few cases of mild fluorosis. This was to be contrasted with the presence of fluorosis at an even lower prevalence and severity distribution in non-fluoridated areas.

However, the introduction of other sources of fluoride through fluoride supplements (tablets and drops) and fluoridated toothpaste altered the relationship of near maximal prevention of caries and acceptable levels of fluorosis. Fluorosis became a concern. Through the 1980s, there were reports of higher-than-expected prevalence and severity of fluorosis, especially in (but not restricted to) fluoridated areas. Initially, the focus was on fluoride supplement regimens, resulting in recommended doses being revised downwards before those regimens were phased out as a public health measure in many countries. This was followed by a recognition that fluoridated toothpaste was ingested, especially by young children. Research on dental fluorosis increasingly focused on trends in prevalence and severity, and explored risk indicators/factors and the attributable risk for fluorosis. In the Cochrane Review, the effect of water fluoridation on the prevalence of fluorosis should have been isolated from the confounding effect of other fluorides. The Cochrane Review's analysis of fluorosis studies is silent on the possible contribution of other fluorides, such as fluoridated toothpaste, which risks leaving readers with the impression that all dental fluorosis arises from fluoride in water supplies. Research since 2000 has indicated that a greater proportion of dental fluorosis risk is due to the use (and therefore swallowing) of fluoride-containing toothpastes than to optimally fluoridated water.^{30,31}

The subject of the Cochrane Review was 'water fluoridation', rather than fluoride in drinking water. In community water fluoridation programmes, the recommended fluoride concentration is usually in the range 0.5 to 1.0 mgF/L. This target concentration is decided after the climatic temperature and background fluoride exposure have been taken into account – for example, the recommended concentration is 0.5 mgF/L in Singapore and 1.0 mgF/L in Newcastle upon

Tyne. Two principles stem from this: first, that it is unnecessary to consider dental fluorosis in communities with fluoride concentrations more than that used in water fluoridation programmes (that is 1.0 mgF/L); second, that comparisons should be made between dental fluorosis levels in the fluoridated community and the reference (non-fluoridated) community. The difference between these levels is the statistic of interest – the fluorosis risk due to water fluoridation. This comparison between intervention and reference communities was the method used for evaluating caries prevention in the Cochrane Review but, for an unexplained reason, not for the evaluation of dental fluorosis. For communities with lower fluoride concentrations (such as 0.5 mgF/L), their fluorosis levels should be compared with those in the corresponding reference (non-fluoridated) community. This would overcome the anomaly in the Cochrane Review of, in effect, comparing fluorosis levels recorded in cooler, better nourished populations (such as Newcastle upon Tyne) with those in hot, less-well-nourished populations (such as India, Saudi Arabia and Namibia). Undernutrition is a recognised risk factor for dental enamel defects^{32,33} and the severity recorded is substantially different in areas of the world with different levels of development. The rationale for including data from communities with water fluoride concentrations higher than those recommended is unclear, and it is not applicable to the evaluation of water fluoridation where fluoride concentrations are controlled and maintained within acceptable limits. The highly restrictive approach taken by the Cochrane Review in examining the effect of community water fluoridation on dental caries seems to have been abandoned for dental fluorosis. The reason for this difference is unclear.

The Cochrane Review presented information on the prevalence of dental fluorosis in two ways – (i) any level of fluorosis, and (ii) fluorosis of aesthetic concern. The reason for presenting information for any level of dental fluorosis is unclear, especially since some of the indices used were not specific for dental fluorosis and recorded the full range of developmental defects of enamel; for these there are many causes of the altered enamel other than fluoride.³⁴ An example of this is the DDE index, although most reports of studies where the DDE index has been used have provided data on the three types of enamel defect separately, allowing some comparison with indices of enamel fluorosis.³⁵ In addition, it is now recognised that the lower grades of dental fluorosis are not detrimental to appearance. Research shows that communities rate questionable and very

mild fluorosis as of better appearance and higher self-rated oral health than no fluorosis, with some reports stating that moderate fluorosis is judged as no different to teeth without any fluorosis.^{36–38} This indicates that if a threshold exists for fluorosis of aesthetic concern, it may be higher than that proposed in the 1990s, which was equivalent to mild fluorosis. The possible explanation for this shift is that enamel opacities classed as mild fluorosis are a whitening of teeth, a characteristic that has become socially desirable, as evidenced by the demand for tooth whitening products and procedures. There is recent evidence that the severity of diffuse enamel opacities reduces with further maturation during adolescence.³⁹

THE 2015 COCHRANE REVIEW WITHIN THE CONTEXT OF THE TOTALITY OF INFORMATION ON WATER FLUORIDATION FOR THE PREVENTION OF DENTAL CARIES

It should be emphasised, first, that the Cochrane Review states ‘that water fluoridation is effective at reducing caries levels in both deciduous [primary] and permanent dentition in children.’ In this, it agrees with all other authoritative reviews.^{2,40–47} The findings and conclusions of the Cochrane Review are at odds, though, with the literature on the effectiveness of water fluoridation in respect of: its effectiveness in adults; its effectiveness in reducing social disparities in oral health; and the effect of cessation of water fluoridation. On these, the Cochrane Review said that there was insufficient evidence; it did not say that water fluoridation was ineffective in these regards. It is a fundamental premise of interpreting evidence from trials that the absence of evidence, or the existence of poor-quality evidence, should not be confused with, or taken to imply, an absence of effect. There is a risk that the Cochrane Review will be inadvertently, or deliberately, misinterpreted in this way.

The earliest study of the effect of fluoridated water on the dental health of adults was reported in the USA in 1943.⁴⁸ Since then, many studies have reported lower caries experience in adults who have lived in fluoridated communities than adults who have lived in communities with low concentrations of fluoride in drinking water. In 2007, Griffin and co-workers, working for the US Centers for Disease Control and Prevention (CDC), published a systematic review⁴⁹ on the effectiveness of fluoride in preventing caries in adults. For the nine studies which satisfied the inclusion criteria, water fluoridation significantly reduced caries experience ($p < 0.001$). For the five studies published after 1979, the prevented fraction was 27%. Since the publication of

that systematic review, several publications have supported its conclusions.^{50–53}

As mentioned earlier, the use of water fluoridation to reduce dental health inequalities was not a stated objective of the Cochrane Review, so it is unsurprising that the narrow inclusion criteria fail to identify any reports. In contrast, the York Review stated: ‘There appears to be some evidence that water fluoridation reduces the inequalities in dental health across social classes in five and 12-year-olds using the dmft/DMFT measure. This effect was not seen in the proportion of caries-free children among five-year-olds.’ A recent analysis of national data in England²⁰ concluded that caries prevalence and experience were lower in communities receiving fluoridated water than in communities receiving water low in fluoride, and suggested that ‘the effect is greater within the most deprived communities.’

The impact of cessation of water fluoridation was considered above. It was noted that the York Review concluded: ‘The best available evidence from studies following withdrawal of water fluoridation indicates that caries prevalence increases, approaching the level of the low fluoride group. Again, however, the studies were of moderate quality (level B) and limited quantity.’ The Australian National Health and Medical Research Council (NHMRC) 2007 review⁴³ concurred with the conclusions of the York Review, stating: ‘[the York Review] also suggest that cessation of fluoridation resulting in a narrowing of the difference in caries prevalence between the fluoridated and non-fluoridated populations. Only one additional relevant original study was identified in the current review and this did not change the conclusion of the existing systematic review.’

Public health policy and decisions in public health should be grounded in the totality of the evidence with appropriate consideration of the quality of that evidence, its context, relevance, applicability and cost. There is no doubt that there is a considerable amount of evidence indicating that water fluoridation is effective in caries prevention. This evidence considers not only oral health-related outcome measures such as dmft/DMFT scores, but also dental abscesses, toothache and admission to hospital for general anaesthetics.^{54–56} It was listed by the US CDC as one of ten most important public health initiatives during the twentieth century.⁵⁷ The Cochrane Review used methods which were very restrictive: the American Academy of Pediatrics commented that the Cochrane Review of community water fluoridation had excluded 97% of the evidence.⁵⁸ Those considering this Cochrane Review or embarking on a further review of water fluoridation should bear this in mind.

Declarations of interest

AJRG was a member of the MRC (UK) working group on water fluoridation and health and is a trustee of The Borrow Foundation. AJS is a member of the Australian Government Department of Health, Nutritional Reference Values Fluoride Expert Working Group and the National Health and Medical Research Council Fluoride Reference Group. HPW is Principal Investigator of the FACCT study funded by the Irish Health Research Board and is an evaluation of the impact of changes in the policy on children's oral health in Ireland. She is an independent advisor to the British Fluoridation Society. CJ is a member of the British Fluoridation Society, the Cochrane Oral Health Group and commented on the Cochrane review protocol. JFB is vice-chairman, British Fluoridation Society. PC is a communications adviser to the National Alliance for Equity in Dental Health and the British Fluoridation Society. PVC is Chief Dental Officer for Canada. JJ is President, American Fluoridation Society. MPK is co-investigator on the CATFISH study of a water fluoridation scheme in Cumbria. MAL was a member of the Advisory Panel for the York Review, a member of the MRC Expert Group and formerly Chair of the British Fluoridation Society. JMcG is manager, Fluoridation Activities, American Dental Association. DO'M is a member of the Irish Expert Body on Fluorides and Health. PPS is the President, Ontario Association of Public Health Dentistry. WMT was a member of the panel which produced the Royal Society of New Zealand report on community water fluoridation. SMW works for The Borrow Foundation. SPZ is Chief Dental Officer with Israeli Ministry of Health. The other authors declare no interests.

1. Iheozor-Ejiofor Z, Worthington H V, Walsh T *et al*. Water fluoridation for the prevention of dental caries. Cochrane database of Systematic Reviews 2015, Issue 6. Art. No.: CD010856. DOI: 10.1002/14:651858.CD010856.pub2.
2. McDonagh M, Whiting P, Bradley M *et al*. A systematic review of public water fluoridation. York: University of York, NHS Centre for Reviews and Dissemination, 2000.
3. Iheozor-Ejiofor Z, O'Malley LA, Glenny A M *et al*. Water fluoridation for the prevention of dental caries. Cochrane Database of Systematic Reviews 2013, Issue 12. Art. No.: CD010956. DOI: 10.1002/14: 651858.CD010856.
4. National Institute for Health and Care Excellence (NICE). *Methods for the development of NICE public health guidance*. 3rd ed. London: NICE, 2012. Available online at <http://www.nice.org.uk/article/pmg4/chapter/1%20Introduction> (accessed August 2015).
5. National Institute for Health and Care Excellence (NICE). *Developing NICE guidelines: the manual*. London: NICE, 2014. Available online at <https://www.nice.org.uk/article/pmg20/chapter/1%20Introduction%20and%20Overview> (accessed August 2015).
6. Rychetnik L, Frommer M, Hawe P, Shiell A. Criteria for evaluating evidence on public health interventions. *J Epidemiol Community Health* 2002; **56**: 119–127.
7. Victora C G, Habicht J-P, Bryce J. Evidence-based public health: moving beyond randomized trials. *Am J Publ Health* 2004; **94**: 400–405.
8. Jackson N, Waters E. Criteria for the systematic review of health promotion and public health interventions. *Health Promot Int* 2005; **20**: 367–374.
9. Waters E, Doyle J, Jackson N, Howes F, Brunton G, Oakley A. Evaluating the effectiveness of public health interventions: the role and activities of the Cochrane Collaboration. *J Epidemiol Community Health* 2006; **60**: 285–289.
10. Armstrong R, Waters E, Jackson N *et al*. *Guidelines for systematic reviews of health promotion and public health interventions*. Version 2. Melbourne University: Australia, 2007.
11. Doyle J, Armstrong R, Waters E. Issues raised in systematic reviews of complex multisectoral and community based interventions. *J Public Health* 2008; **30**: 213–215.
12. Bamba C. Real world reviews: a beginner's guide to undertaking systematic reviews of public health policy. *J Epidemiol Community Health* 2011; **65**: 14–19.
13. Rehfuess E A, Akl E A. Current experience with applying the GRADE approach to public health interventions: an empirical study. *BMC Public Health* 2013; **13**: 9.
14. Anglemeyer A, Horvath H T, Bero L. Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials (review). Cochrane database of Systematic Reviews 2014, Issue 4, Art. No. MR000034.
15. Petticrew M. Time to rethink the systematic review catechism? Moving from 'what works' to 'what happens'. *Syst Rev* 2015; **4**: 36.
16. Kelly M P, Morgan A, Ellis S, Younger T, Huntley J, Swann C. Evidence based public health: a review of the experience of the National Institute of Health and Clinical Excellence (NICE) of developing public health guidance in England. *Soc Sci Med* 2010; **71**: 1056–1062.
17. Kelly M P, Moore T A. The judgement process in Evidence Based Medicine and Health Technology Assessment. *Soc Theory Health* 2012; **10**: 1–19.
18. Government of Ireland. Health (Fluoridation of water supplies) Act, 1960. Dublin: Irish Statute Book Produced by the Office of the Attorney General, 1960. Information available online at <http://www.irishstatutebook.ie/eli/1960/act/46/enacted/en/html> (accessed March 2016)
19. Whelton H, O'Mullane D. Monitoring the effectiveness of water fluoridation in the Republic of Ireland. *J Ir Dent Assoc* 2012; **58(Suppl 3)**: S6–S8.
20. Public Health England. Water fluoridation: health monitoring report for England 2014. Available online at <https://www.gov.uk/government/publications/water-fluoridation-health-monitoring-report-for-england-2014> (accessed August 2015).
21. Young N, Newton J, Morris J *et al*. Community water fluoridation and health outcomes in England: a cross-sectional study. *Community Dent Oral Epidemiol* 2015; **43**: 550–559.
22. Do L, Spencer A J. Contemporary multilevel analysis of the effectiveness of water fluoridation in Australia. *Aust NZ J Public Health* 2015; **39**: 44–50.
23. Public Health England. *National diet and nutrition survey: results from years 1–4 (combined) of the rolling programme (2008/2009 – 2011/12)*. London: Public Health England, 2014.
24. Health and Social Care Information Centre. *Children's dental health survey, England, Wales and Northern Ireland, 2013*. London: HSCIC, 2015.
25. Rugg-Gunn A J, Do L. Effectiveness of water fluoridation in caries prevention. *Community Dent Oral Epidemiol* 2012; **40 (Suppl. 2)**: 55–64.
26. Al-Hosani E, Rugg-Gunn A. Combination of low parental educational attainment and high parental income related to high caries experience in pre-school children in Abu Dhabi. *Community Dent Oral Epidemiol* 1998; **26**: 31–36.
27. Moynihan P J, Kelly S A M. Effect on caries of restricting sugars intake: systematic review to inform WHO guidelines. *J Dent Res* 2014; **93**: 8–18.
28. WHO. *Guideline: Sugars intake for adults and children*. Geneva: World Health Organization, 2015.
29. Murray J J, Rugg-Gunn A J, Jenkins G N. *Fluorides in caries prevention*. 3rd ed. Oxford: Butterworth-Heinemann, 1991.
30. Do L G, Spencer A J. Oral health-related quality of life of children by dental caries and fluorosis experience. *J Publ Health Dent* 2007; **67**: 132–139.
31. Pendrys D G. Risk of enamel fluorosis in nonfluoridated and optimally fluoridated populations: considerations for the dental professional. *J Am Dent Assoc* 2000; **131**: 746–755.
32. Rugg-Gunn A J, Al-Mohammadi S M, Butler T J. Effects of fluoride level in drinking water, nutritional status, and socio-economic status on the prevalence of developmental defects of dental enamel in permanent teeth in Saudi 14-year-old boys. *Caries Res* 1997; **31**: 259–267.
33. Rugg-Gunn A J, Al-Mohammadi S M, Butler T J. Malnutrition and developmental defects of enamel in 2- to 6-year-old Saudi boys. *Caries Res* 1998; **32**: 181–192.
34. Rugg-Gunn A J. *Nutrition and dental health*. Oxford: Oxford University Press, 1993.
35. Mohamed A R, Thomson W M, Mackay T D. An epidemiological comparison of Dean's index and the Developmental Defects of Enamel (DDE) index. *J Public Health Dent* 2010; **70**: 344–347.
36. Do L G, Spencer A J. Risk-benefit balance in the use of fluoride among young children. *J Dent Res* 2007; **86**: 723–728.
37. Chankanka O, Levy S M, Warren J J, Chalmers J M. A literature review of aesthetic perceptions of dental fluorosis and relationships with psychosocial aspects/oral health related quality of life. *Community Dent Oral Epidemiol* 2010; **38**: 97–109.
38. Onorriobe U, Rozier R G, Cantrell J, King R S. Effects of enamel fluorosis and dental caries on quality of life. *J Dent Res* 2014; **93**: 972–979.
39. Do L G, Ha D H, Spencer A J. Natural history and long-term impact of dental fluorosis: a prospective cohort study. *Med J Aust* 2016; **204**: 25.
40. Royal College of Physicians. *Fluoride, teeth and health*. London: Royal College of Physicians, 1976.
41. MRC. Water fluoridation and health. *Working group report*. London: Medical Research Council, 2002.
42. NHMRC. *The effectiveness of water fluoridation*. Canberra: Australian Government Publishing Service, 1991.
43. NHMRC. *A systematic review of the efficacy and safety of fluoridation*. Canberra: Australian Government, 2007.
44. Community Preventive Services Task Force. *Preventing dental caries; community water fluoridation*. Atlanta: Guide to community preventive services, 2013.
45. Royal Society of New Zealand. Health effects of water fluoridation; a review of the scientific evidence. Wellington: Royal Society of New Zealand, 2014.
46. WHO. Fluorides and oral health. *WHO Technical Report Series 846*. Geneva: World Health Organization, 1994.
47. WHO. World Health Assembly. *Oral Health: action plan for promotion and integrated disease prevention*. WHA60.17. Geneva: World Health Organization, 2007.
48. Deatherage C F. Fluoride domestic waters and dental caries experience in 2026 white Illinois selective service men. *J Dent Res* 1943; **22**: 129–137.
49. Griffin S O, Regnier E, Griffin P M, Huntley V. Effectiveness of fluoride in preventing caries in adults. *J Dent Res* 2007; **86**: 410–415.
50. Mahoney G, Slade G D, Kitchener S, Barnett A. Lifetime fluoridation exposure and dental caries experience in a military population. *Community Dent Oral Epidemiol* 2008; **36**: 485–492.
51. Hopcraft M S, Yapp K E, Mahoney G, Morgan M V. Dental caries experience in young Australian army recruits 2008. *Aust Dent J* 2009; **54**: 316–322.
52. Slade G D, Sanders A E, Do L, Roberts-Thompson K, Spencer A J. Effects of fluoridated drinking water on dental caries in Australian adults. *J Dent Res* 2013; **92**: 376–382.
53. Crocombe LA, Brennan D S, Slade G D, Stewart J F, Spencer A J. The effect of lifetime fluoridation exposure on dental experience of younger rural adults. *Aust Dent J* 2015; **60**: 30–37.
54. Slack-Smith L, Colvin L, Leonard H, Kilpatrick N, Bower C, Brearley Messer L. Factors associated with dental admissions for children aged under 5 years in Western Australia. *Arch Dis Child* 2009; **94**: 517–523.
55. Elmer T B, Langford J W, Morris A J. An alternative marker for the effectiveness of water fluoridation: hospital extraction rates for dental decay, a two-region study. *Br Dent J* 2014; **216**: E10.
56. Klivitsky A, Tasher D, Stein M, Gavron E, Somekh E. Hospitalizations for dental infections: optimally versus nonoptimally fluoridated areas in Israel. *J Am Dent Assoc* 2015; **146**: 179–183.
57. CDC. Ten great public health achievements – United States, 1900–1999. *MMWR Morb Mortal Wkly Rep* 1999; **48**: 241–243.
58. American Academy of Pediatrics. *The Cochrane review of community water fluoridation. Campaign for dental health*. 2015. Available online at <http://ilikemyteeth.org/the-cochrane-review-of-community-water-fluoridation/> (accessed January 2016).