Editorial

The Cochrane review of water fluoridation; a commentary

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The recently published systematic review of water fluoridation by the Cochrane Oral Health Group (Iheozor-Ejiofor et al., 2015) concludes that "the initiation of water fluoridation results in a 35% reduction in dmft and a 26% reduction in DMFT compared to the median control group value" and that "there were also increases in the percentage of caries-free children of 15% in deciduous dentition and 14% in permanent dentition" - oral health improvements which led the COHG authors to the view that "fluoridation is effective at reducing caries levels in children". Looking at broadly the same literature, the York Report (McDonagh et al., 2000) made similar findings and concluded that the evidence was of "moderate quality" and that "the best available evidence suggests that fluoridation of drinking water supplies does reduce caries prevalence". The Australian National Health and Medical Research Council (2007) concluded that "the existing body of evidence strongly suggests that water fluoridation is beneficial at reducing dental caries". In two American reviews the authors concluded that there is "strong evidence that community water fluoridation is effective in reducing the cumulative experience of dental caries within communities" (Truman et al., 2002) and that there was "strong evidence of effectiveness in reducing dental caries across populations" (Community Preventive Services Task Force, 2013).

All five systematic reviews between 2000 and 2015 reached the conclusion that fluoridation reduces dental caries in children. Three of them called the evidence 'strong'. Mc-Donagh *et al.* called it 'moderate'. The Cochrane authors talk of 'limited confidence' in the size of the effect estimates and say that if they had applied (which they did not) the GRADE criteria ordinarily used in Cochrane systematic reviews for assessing the quality of clinical studies, they would have been forced to categorise the fluoridation studies as 'low quality' which, they acknowledged, may be 'too judgemental'.

Cochrane methodology over the years has been developed primarily to evaluate the results of randomised clinical trials for new drugs and clinical interventions for use with individuals, not public health initiatives targeted at populations. The Cochrane review of water fluoridation adopted this approach, leading the authors to reject all cross-sectional studies and to set inclusion criteria that excluded a large number of useful studies conducted over the past 25 years. In this Editorial I shall try to:

- clarify some of the differences in approach in the above-mentioned reviews;
- provide examples of good practice in some observational fluoridation studies;

- consider the Cochrane Group's claim that "there is no evidence in relation to socio-economic status nor on the effect of water fluoridation on adults"; and,
- consider further the impact of water fluoridation against the widespread use of other fluorides such as toothpaste and the implications for future systematic reviews.

The Cochrane Methods Handbook notes that the most reliable evidence is drawn from randomised clinical trials where each individual participant has an equal or known chance of being allocated to test or control. Indeed, all of the cited reviews accept this contention. However, some also question the practicality of such a requirement where a community rather than individuals form the test group (Iheozor-Ejiofor *et al.*, 2015.)

Two of the issues identified by McDonagh et al. (2000) and the Cochrane Group are confounding and blinding. Confounders are factors, other than water fluoridation, that might potentially influence the outcome of the study. Randomisation in clinical trials seeks to address this potential problem but, as noted (Iheozor-Ejiofor, 2015; McDonagh et al., 2000), this is not practicable in water fluoridation studies. However, the inclusion criteria for both reviews required baseline pre-fluoridation caries data for test and control communities. The comparability of the two communities in relation to dental caries is thus assured. The issue, then, is whether confounding factors affect the two communities differently during the course of the study, leading in each case to a lower level of caries in the fluoridated community. While this is a plausible scenario in a few studies because of, for example, shifts in the socio-economic mix of one of the populations, it seems increasingly unlikely when considering around twenty studies. As one of the principal investigators for the York report, Jos Kleijnen, subsequently explained: "On the issue of the beneficial effect of public water fluoridation the review (McDonagh et al., 2000) reassures you that the health authority was correct in judging that the fluoridation of public water prevents caries" (Khan et al., 2003). The second issue identified by both McDonagh et al. (2000) and Iheeozor-Ejiofor et al. (2015) was concerned with blinding and the possibility of examiner bias. Again, when the community is the target, this is logistically difficult to resolve but not impossible. Two approaches have been used; radiographs read blindly by an independent examiner (Backer Dirks et al., 1961) or by bussing all the children to a third common examination site (Hardwick et al., 1982). Both of these studies provided convincing evidence of the efficacy of water fluoridation.

The Cochrane Group also argues that there is neither

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Conflict of Interest: MAL was formerly chair of the British Fluoridation Society, a member of the advisory panel for the York systematic review and a member of the Medical Research Council (2002) Expert Group

evidence of the effectiveness in adults nor of the impact on socio-economic differences in dental caries. Other reviews clearly differ. McDonagh et al. (2000) for example note that "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, but not using the per-cent caries free measure". Griffin et al. (2007) reviewed nine studies on adults and indicated that water fluoridation reduced caries by around 27%. One of these studies was conducted in North Wales by Derek Thomas, a Consultant in Dental Public Health, and his statistical colleague, Kassab, from the University of Bangor (Thomas and Kassab, 1992). Thomas examined 649 women aged 16-35, all inpatients staying in St David's maternity hospital. The women came from the island of Anglesey (fluoridated) and from mainland North Wales (non-fluoridated) - areas separated by a narrow stretch (300 to 800 metres) of water and joined by road and rail bridges. The women were examined blind to their residential origin. Thomas and Kassab showed a 30% lower level of DMFT in the fluoridated group. While it is reasonable to recognise the limitations of such a study, to dismiss it completely seems harsh.

What then about the effectiveness of community water fluoridation in the modern environment where fluoride toothpaste use is widespread? Rugg-Gunn and Do (2012) reviewed studies published between 1990 and 2010. Most, if not all, were cross-sectional studies in which potential confounders are clearly an important issue. They found: 59 studies from 10 countries; a modal 30-59% lower dmft in fluoridated areas; and, a modal 40-49% lower DMFT. They also examined in detail eight studies in which unadjusted and data further adjusted for confounders were presented. They noted "*no great change in the percentage caries reduction after adjustment compared with before adjustment*".

If we are to understand more fully the impact of water fluoridation on socio-economic differences and adult dental health and, indeed, the effectiveness of water fluoridation in the modern environment, we will for the foreseeable future depend upon cross-sectional observational studies. Rugg-Gunn and Do (2012) provide useful insights into how the quality of these studies can be improved. We should also welcome the recent longitudinal study by Blinkhorn *et al.* (2015) and emphasise that any new fluoridation schemes in the UK, indeed worldwide, should include a similarly rigorous evaluation. Meanwhile dental public health should join the wider public health debate about appropriate methods for reviewing public health interventions (Anglemyer *et al.*, 2014; Black, 1996; Petticrew, 2015; Rychetnik *et al.*, 2002; Shepperd *et al.*, 2009; Victora *et al.*, 2004).

Whilst seeking the best available studies within their respective fields, systematic reviews of public health studies need a different approach from reviews of clinical studies. The Cochrane Collaboration itself has guidelines (Armstrong and Waters, 2007) that may assist in such a differentiation but were not used on this occasion. Future reviews of water fluoridation should be designed in ways that will ensure a broader and more sensitive approach to capturing the totality of the relevant contemporary evidence.

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