

Attachment 5 – INTEMANN

COCHRANE 2015 - OPENING WITH COMMENTARY

Introductory Comment to analysis of Cochrane 2015:

Both sides of the fluoridation debate have nominated the Cochrane Review 2015 as supporting their case. By way of demonstration of what Cochrane actually says, the following is the unedited first six pages of the Review, and under each of Cochrane's statements are my comments in italics.

From actually reading the highly regarded Cochrane Review, there seems no reasonable conclusion than that:

After 70 years of fluoridation there remains a distinct LACK of any reliable evidence to support the idea that water fluoridation is of any significant dental benefit. Fluoridation is a failed experiment that should no longer be endorsed.

THE COCHRANE REVIEW 2015, referred to below as 'Cochrane'.

Title: "Water fluoridation for the prevention of dental caries"

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<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010856.pub2/full>

My comment: Cochrane is well known as being pro-fluoridation, in the sense that the researchers start assuming fluoridation is dentally effective.

Background

Dental caries is a major public health problem in most industrialised countries, affecting 60% to 90% of school children. Community water fluoridation was initiated in the USA in 1945 and is currently practised in about 25 countries around the world; health authorities consider it to be a key strategy for preventing dental caries. Given the continued interest in this topic from health professionals, policy makers and the public, it is important to update and maintain a systematic review that reflects contemporary evidence.

My comment: Agreed, except it is a half-truth. The more complete truth is that vastly most of the 25 countries recognised by Cochrane actually fluoridate only a small percentage of their population, usually < 10%.

*More accurately, only eight (8) countries still fluoridate the majority of their population, listed here from highest to lowest % fluoridation:
Singapore, Brunei, Australia, Malaysia, Republic of Ireland, USA, Chile, NZ.
Source: British Fluoridation Society. (Israel was highly fluoridated, but stopped all fluoridation in 2014).*

Most countries that earlier started fluoridation have since stopped for various reasons. not the least being the failure of fluoridation proponents to back their claims with evidence. Fluoridation is not a successful leading intervention.

Objectives

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.

Search methods

We searched the following electronic databases: 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). We searched the US National Institutes of Health Trials Registry (ClinicalTrials.gov) and the World Health Organization's WHO International Clinical Trials Registry Platform for ongoing trials. There were no restrictions on language of publication or publication status in the searches of the electronic databases.

My comment: Good, Cochrane is a meta-analysis of many studies globally, and there were no language limitations applied.

Selection criteria

For caries data, we 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. For the assessment of fluorosis, we included any type of study design, with concurrent control, that compared populations exposed to different water fluoride concentrations. We included populations of all ages that received fluoridated water (naturally or artificially fluoridated) or non-fluoridated water.

My comment: Good, but note that only one Australian study was accepted as qualifying for consideration in Cochrane's meta-analysis, and it was deemed by Cochrane to be a weak study. That is amazing in a negative sense, in that Australia – being among the most intensive fluoridating countries globally – has historically failed to produce quality research. If someone says that such-and-such an Australian study successfully demonstrates the effectiveness of fluoridation, know that the study is probably not of sufficient quality to over-turn or cast doubt on Cochrane's findings.

In their 1991 fluoridation report, Australia's National health and Medical Research Council (NHMRC) recognised the significant need for Australia - as a predominant fluoridating nation - to step up and lead with quality fluoridation research.

However, no such result eventuated, and Australia continues to produce small unreliable single studies, weakly controlled, without a plan for continuous improvement or independent review.

Data collection and analysis

We used an adaptation of the Cochrane 'Risk of bias' tool to assess risk of bias in the included studies.

We included the following caries indices in the analyses: decayed, missing and filled teeth (dmft (deciduous dentition) and DMFT (permanent dentition)), and proportion caries free in both dentitions. For dmft and DMFT analyses we calculated the difference in mean change scores between the fluoridated and control groups. For the proportion caries free we calculated the difference in the proportion caries free between the fluoridated and control groups.

For fluorosis data we calculated the log odds and presented them as probabilities for interpretation.

***My comment:** Good, but note that Cochrane looked at data from decades ago to the present. Historically, decay statistics (like in school dental surveys) have been measured in dmft and DMFT, where the count is of **whole teeth** only, regardless how extensive or minimal the decay of the tooth.*

*More recently, the measure is more accurately of **tooth surfaces** – dmfs and DMFS. The Cochrane results should be interpreted in that light.*

Fluoridation studies on the other hand rarely report in terms of actual teeth, usually only reporting % reduction, so a merely 'relative' statistic.

It is a reflection, I think, of Cochrane's intention to be objective, that they have in one place – their Main results - reported on actual teeth decayed (not just statistical %).

Main results

A total of 155 studies met the inclusion criteria; 107 studies provided sufficient data for quantitative synthesis.

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 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.

***My comment:** Here Cochrane remarkably reports on actual teeth decayed, shown above in **bold** (my emphasis). It reports that fluoridation appears to deliver an average saving of 1.81 teeth or cavities per 6-year old child, and 1.16 teeth or cavities per 12-year-old).*

That's a declining benefit over time, and also needs to be balanced against any costs or dental disbenefit (such as dental fluorosis).

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.

My comment: Agreed. The world-wide available data is insufficient to show that fluoridation helps the socio-economically disadvantaged. Fluoridation cannot rightly be said to 'help the poor' and fluoridation proponents should cease with any such claim because there is no sound data to support it.

There is insufficient information to determine the effect of stopping water fluoridation programmes on caries levels.

My comment: Agreed. The globally available data is insufficient to show whether or not decay rates are affected by stopping fluoridation. Fluoridation proponents should cease making claims to the contrary.

No studies that aimed to determine the effectiveness of water fluoridation for preventing caries in adults met the review's inclusion criteria.

My comment: Agreed. The globally available data is insufficient to show whether fluoridation is dentally beneficial for adults. Fluoridation proponents should cease claiming that it does benefit adults.

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.

My comment: Agreed. At a fluoridation level of 0.7 mgF/L, Cochrane found that 12% of people will have fluorosis of aesthetic concern. Australian conditions are somewhat different in that here we have (1) lower fluoride in baby formula than most places, but (2) a higher fluoridation level at 1 mgF/L.

Let's say those two factors balance out. It would then be true to say that fluoridation is associated with a dental cost in the form of at least 10% of people suffering dental harm of aesthetic concern. That is an actual cost to those affected and should be taken into account in deciding whether or not to support fluoridation.

Authors' conclusions

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.

***My comment:** Agreed. The quality of fluoridation science is weak and the quality of evidence is poor. Fluoridation science is nowhere near 'settled', except in the sense it is basically void of quality evidence. The available fluoridation dental evidence is mostly old and does not reflect current conditions, in particular the greater use of toothbrushing and topical fluorides especially toothpaste. It is entirely possible that fluoridation itself now has no benefit over and above the topical use of fluorides. Fluoridation has no strong science or data on its side. Fluoridation could be just an outdated myth.*

Plain language summary

Water fluoridation to prevent tooth decay

Background

Tooth decay is a worldwide problem affecting most adults and children. Untreated decay may cause pain and lead to teeth having to be removed. In many parts of the world, tooth decay is decreasing. Children from poorer backgrounds still tend to have greater levels of decay.

***My comment:** Agreed in part. Tooth decay is widespread, and can be a significant problem for the individual and society. However, decay rates have been declining in many parts of the world over the past several decades, in fluoridated and unfluoridated countries. Most countries never commenced fluoridation, and of those that did start many ceased the practice long ago, so fluoridation cannot be the cause of the historic decline. Only eight countries still water fluoridate to any great extent*

Fluoride is a mineral that prevents tooth decay. It occurs naturally in water at varying levels. Fluoride can also be added to the water with the aim of preventing tooth decay. Fluoride is present in most toothpastes and available in mouthrinses, varnishes and gels.

***My comment:** Agreed, but only in the sense that topically applied fluoride does appear to help prevent decay. Consumed fluoride is another thing, and Cochrane reports no compelling evidence that fluoride in drinking water is a significant factor in decay reduction.*

Also, the vast majority of natural surface waters contain very little fluoride, for example locally it approximates 0.05 mgF/L.

If young children swallow too much fluoride while their permanent teeth are forming, there is a risk of marks developing on those teeth. This is called 'dental fluorosis'. Most fluorosis is very mild, with faint white lines or streaks visible only to dentists under good lighting in the clinic. More noticeable fluorosis, which is less common, may cause people concern about how their teeth look.

***My comment:** Agreed, over-consumption of fluoride in growing children can result in teeth affected by dental fluorosis. Cochrane reports elsewhere that around 12% of children in fluoridated areas develop fluorosis that is easily noticeable and of aesthetic concern. (And a few % are even more severely affected). That is not an insignificant side effect, and should not be glossed over in assessing the costs and supposed benefits of fluoridation.*

Review question

We carried out this review to evaluate the effects of fluoride in water (added fluoride or naturally occurring) on the prevention of tooth decay and markings on teeth (dental fluorosis).

***My comment:** Agreed, except to say it is disingenuous to describe dental fluorosis as 'markings'. Fluorosis isn't just a surface effect, but affects the tooth's inner material structure, making it more prone to brittleness and breaking, as well as being unsightly.*

Study characteristics

We reviewed 20 studies on the effects of fluoridated water on tooth decay and 135 studies on dental fluorosis. The evidence is up to date at 19 February 2015.

***My comment:** Noted. From the 70 years of fluoridation, Cochrane could identify only 20 fluoridation dental studies sufficiently well designed and conducted to deliver reasonably confident conclusions. That is hardly a winning endorsement of fluoridation benefits or 'the science' that supposedly backs fluoridation.*

Nineteen studies assessed the effects of starting a water fluoridation scheme. They compared tooth decay in two communities around the time fluoridation started in one of them. After several years, a second survey was done to see what difference it made. Around 70% of these studies were conducted before 1975. Other, more recent studies comparing fluoridated and non-fluoridated communities have been conducted. We excluded them from our review because they did not carry out initial surveys of tooth decay levels around the time fluoridation started so were unable to evaluate changes in those levels since then. We reviewed one study that compared tooth decay in two fluoridated areas before fluoridation was stopped in one area. Again, after several years, a second survey was done to see what difference it made.

My comment: *Noted. Cochrane only accepted studies that were designed to be able to assess the dental impact of 'fluoridation' versus 'no fluoridation' over time. Australia has produced only one such study, and Cochrane deemed it to be weak in quality.*

The 'hype' that still surrounds the early fluoridation trials and studies appears to be just hype. Most of those early trials were abandoned before intended completion; later found to be error-prone, or too poorly designed to deliver reliable conclusions.

Around 73% of dental fluorosis studies were conducted in places with naturally occurring – not added – fluoride in their water. Some had levels of up to 5 parts per million (ppm).

My comment: *Noted. The statement reveals how little dental fluorosis research has been conducted by artificially fluoridating countries.*

Key results

Our review found that water fluoridation is effective at reducing levels of tooth decay among children. The introduction of water fluoridation resulted in children having 35% fewer decayed, missing and filled baby teeth and 26% fewer decayed, missing and filled permanent teeth. We also found that fluoridation led to a 15% increase in children with no decay in their baby teeth and a 14% increase in children with no decay in their permanent teeth. These results are based predominantly on old studies and may not be applicable today.

Within the 'before and after' studies we were looking for, we did not find any on the benefits of fluoridated water for adults.

We found insufficient information about the effects of stopping water fluoridation.

We found insufficient information to determine whether fluoridation reduces differences in tooth decay levels between children from poorer and more affluent backgrounds.

Overall, the results of the studies reviewed suggest that, where the fluoride level in water is 0.7 ppm, there is a chance of around 12% of people having dental fluorosis that may cause concern about how their teeth look.

My comment: *Noted, and that this section repeats the same findings in its 'Main Results', discussed above, albeit here reporting percentages decay reduction only, without mentioning decay reductions in terms of actual teeth.*

Quality of the evidence

We assessed each study for the quality of the methods used and how thoroughly the results were reported. We had concerns about the methods used, or the reporting of the results, in the vast majority (97%) of the studies. For example, many did not take full account of all the factors that could affect children's risk of tooth decay or dental fluorosis. There was also substantial variation between the results of the studies, many of which took place before the introduction of fluoride toothpaste. This makes it difficult to be confident of the size of the effects of water fluoridation on tooth decay or the numbers of people likely to have dental fluorosis at different levels of fluoride in the water.

My comment: Noted. The quality of the evidence assessed was poor, whether in design and/or reporting, and failed to produce repeatable or reliable results. The evidence base for fluoridation is poor, and the science is definitely not settled except as regards its poor quality.

Authors' conclusions

Implications for practice

There is very little contemporary evidence, meeting the review's inclusion criteria, evaluating the effectiveness of water fluoridation for the prevention of caries.

The data come predominantly from studies conducted prior to 1975, and indicate that water fluoridation is effective at reducing caries levels in both the 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 behaviours (e.g. use of fluoride toothpaste), the availability and uptake of other caries-prevention strategies, 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 socioeconomic status. There are no studies that met the review's inclusion criteria, from which to determine the effectiveness of water fluoridation for preventing caries in adults.

There is insufficient information to determine the effect of stopping water fluoridation programmes on caries levels.

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.

The studies that have examined dental fluorosis as an outcome are generally more recent than those that have examined caries and, consequently, may be influenced by other sources of fluoride. These additional sources are seldom reported.

My comment: Noted. This section basically repeats conclusions already stated above.

Implications for research

More contemporary studies, evaluating the effectiveness of water fluoridation for the prevention of caries, are needed. These studies should include a concurrent control with comparable caries levels at baseline. Caries data should therefore be measured at least two time points (i.e baseline and follow-up).

Since all the included studies examined the effectiveness of water fluoridation in children, research on effectiveness among adults is needed.

Standardised diagnostic criteria and reporting techniques for caries and dental fluorosis would improve comparability of results across studies.

More research is also needed to understand the contribution of fluoride from sources other than water; the consumption of tap water within a population; the effect of water fluoridation over and above other caries preventive measures, namely dental sealants and fluoride varnishes; the impact of water fluoridation on disparities in oral health; and adverse effects associated with fluoridated water (particularly in areas with naturally high levels of fluoride).

***My comment:** The poor quality of the studies and the need for better designed studies is noted. However, those observations and recommendations are unfortunately not new and have been reported many times elsewhere, just for instance the significant York fluoridation review 2000.*

There appears to have been no effort by proponents of fluoridation to step up and deliver quality science to back their case. After 70 years, it is past time for waiting and fluoridation should be stopped due to (1) lack of evidence to support its claims of dental benefit and (2) the growing evidence of potential harms to human health from fluoride consumption and fluoridation.

MY CONCLUDING COMMENT – *The above presents just the first six pages of the Cochrane Review, which nevertheless accurately represent Cochrane’s core findings.*

Cochrane’s central finding is the LACK of reliable evidence supporting any clear dental benefit from fluoridation for any age or sector, plus the significant negative dental effect of dental fluorosis.

The Cochrane group has been held to be pre-eminent in the field of meta-analysis, so their findings should be respected. In essence in 2015 Cochrane fluoridation review ‘proved’ that, starting from fluoridation’s beginnings, there has been no real effort invested in demonstrating fluoridation’s dental benefit if any. Fluoridation’s supposedly outstanding dental benefit looks strongly like a myth.

Perhaps more importantly, the other side of the issue concerns general health, apart from teeth. There is now rapidly growing evidence globally, associating fluoride consumption with the potential for various adverse health effects, and supported by explanatory biological mechanisms.

For 70 years NHMRC has said fluoridation is unconditionally safe to health. Yet the Minutes of their first meeting on fluoridation in 1953 show that NHMRC was aware from the start that fluoride consumption represents an already-known risk to health, such that it resolved then that if fluoridation were to be started then safety studies (such as the measure of daily fluoride intake) must also be conducted.

Despite that early knowledge, NHMRC has itself admitted in writing to Port Macquarie-Hastings Council that it has never funded a single project to investigate potential adverse health effects (Attachment 3, page 1, 3rd paragraph).

Fluoridation is demonstrably a failure in duty of care, not dentally effective, a known probable risk to general health, and should be stopped forthwith.