Evaluation of water fluoridation scheme in Cumbria: the CATFISH prospective longitudinal cohort study

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Scientific summary

CATFISH study

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Scientific summary

Background

The addition of fluoride to community drinking water supplies has been a long-standing public health intervention to improve dental health and was introduced in the UK during the 1960/70s against a background of high population prevalence of dental decay. Following widespread use of fluoride toothpastes in the mid-1970s, the prevalence and severity of decay have dramatically fallen, leading to questions regarding the cost-effectiveness of water fluoridation (WF) in contemporary populations. These questions were raised by a number of systematic reviews that queried the scientific rigour of early WF studies.

Water fluoridation is also a highly contentious issue, with both pro fluoridationists and anti-fluoridationists arguing vociferously for their point of view, and in often heated and politically charged debates. There have been no new WF schemes in the UK since the late 1970s and some schemes have been withdrawn. Less than 10% of the UK population receive fluoridated water, a figure that often surprises both lay and professional groups.

Against this background, there is a need to redress two major elements of the fluoride scientific debate:

1. the impact of low caries levels in the UK population and the segmentation of the disease into the most disadvantaged groups
2. the identified weaknesses of early works.

The prolonged interruption of fluoride dosing at two schemes established in the late 60s/early 70s in Cumbria, Cornhow and Ennerdale, followed by the resumption of dosing, offered a unique opportunity to undertake an assessment of what was, from a biological perspective, a new scheme. This met an important requirement of the Medical Research Council criteria for a high-quality study and, hence, the CATFISH (Cumbrian Assessment of Teeth a Fluoride Intervention Study for Health) study was undertaken.

Aims and objectives

The CATFISH study aimed to:

- assess the impact of WF on oral health (dental caries) in two separate cohorts of children exposed to WF in utero and from 5 years old over a 5-year follow-up period
- assess whether or not fluoridating water is a cost-effective strategy in these cohorts
- determine if WF reduced health inequalities in these cohorts.

Our objectives were to:

- recruit children into two cohorts, that is, a birth cohort and a cohort of children entering their first year of primary school (i.e. aged 5 years)
- assess children's dental health by clinical examination at set intervals
- use the Index of Multiple Deprivation (IMD) as a measure of deprivation in our assessment of the impact of WF on health inequalities
- assess the cost-effectiveness of WF using a formal health economic evaluation

- measure potential effect modifiers that may explain any differences in the groups using questionnaire data
- meet the requirements of a high-quality evaluation by considering the weaknesses identified in previous WF studies
- account for bias due to lack of blinding in clinical examinations by supplementing this with remote photographic scoring.

Methods

A prospective longitudinal cohort design was employed with two distinct populations.

Birth cohort

From September 2014 to September 2015, children were recruited at birth. These children had a 'full effect' of WF, as they received both systemic exposure to WF (from in utero), resulting in incorporation of fluoride into the enamel as it develops, and topical exposure to WF in the form of exposure to fluoride in drinking water, which acts once a tooth has erupted by creating an environment at the tooth surface that favours remineralisation. Children had a dental examination at 3 and 5 years of age, and questionnaire data were collected throughout their participation in the study. A census approach was taken to recruitment based on births in two hospital sites [i.e. West Cumberland Hospital (Whitehaven, UK) and Cumberland Infirmary (Carlisle, UK)].

Older school cohort

Children were recruited in their first year of school, from September 2013. These children had predominantly topical exposure to WF and, therefore, the preventative effect would come from creating an environment that would encourage remineralisation of enamel and inhibit bacterial metabolism. This group enabled comparison of effect size with children who have systemic and topical exposure as the cohorts age. Children had a dental examination at 5, 7 and 11 years of age, and questionnaire data were collected throughout their participation in the study. Children in primary schools in Cumbria were invited to participate.

Intervention/control

Control participants lived in the east of Cumbria, whereas the intervention group lived in the west of Cumbria, receiving drinking water from either Ennerdale or Cornhow water treatment plants. The intervention was implemented by United Utilities (Warrington, UK) who were responsible for regulating the dose at 1 part per million (ppm) fluoride in the drinking water. The control was defined as children receiving drinking water from treatment plants where fluoride had not been added.

A sample size calculation was conducted before the study began, based on previous research. The proportions of 0.47 of 'non-exposed' children developing caries and of 0.37 of 'exposed' children developing caries were used to detect a risk difference of 0.1 (risk ratio 0.8) at a significance level of 0.05 and with 90% power, resulting in a total sample size of 1044 children.

Clinical examinations were undertaken by trained and calibrated dental examiners, using caries into dentine as the threshold for diagnosis. In addition, clinical intraoral photographs were taken and remotely scored by an additional examiner without knowledge of the fluoridation status of the participant. The primary outcome was the proportion of children who had the presence or absence of clinical evidence of caries into dentine in their primary teeth (birth cohort) and permanent teeth (older school cohort). In addition, we collected data from the NHS Business Services Authority relating to dental activity and the number of dental extractions undertaken with dental general anaesthetic (DGA) in hospitals for each cohort. Relative deprivation was measured using the IMD (from 2010) and participants' postcodes. We also recorded eruption times of primary teeth to determine if this could influence caries outcomes.

Questionnaire data concerning a range of potential behaviours and practices that could affect the outcome, for example weaning, diet, toothbrushing and other fluoride sources, were collected directly from both parents and older children.

Statistical analysis for the primary outcome was performed using generalised linear models with fixed effects for group for the unadjusted effect estimate and, additionally, area deprivation quintile, age and sex for the adjusted effect estimate. We calculated the mean number of decayed, missing and filled teeth (in primary teeth in the birth cohort and in permanent teeth in the older school cohort), with an assumption of caries as the underlying cause, to compare the caries increment in each group. This was assessed using a negative binomial regression, including area deprivation quintile, age and sex as covariates and number of erupted teeth as an offset. Analysis of DGA data also utilised generalised linear models, with fixed effects for group for the unadjusted effect estimate, and area, deprivation quintile and sex for the adjusted effect estimate. Secondary outcomes (e.g. behaviours that could affect dental health) were analysed using generalised estimating equations to allow for repeated measures within participants. Health disparities were investigated in both cohorts by comparing decayed, missing or filled teeth (primary) (dmft) and decayed, missing or filled teeth (permanent) (DMFT) across exposed and non-exposed groups by quintile of deprivation. Generalised linear models with the appropriate link function and including an exposure by deprivation interaction term were undertaken to determine the effects at different levels of deprivation.

Cost-effectiveness analyses took an NHS and local authority perspective. Costs included the capital and running costs of WF, and NHS dental activity. The measure of health benefit was quality-adjusted life-years (QALYs). QALYs gained from baseline to end of follow-up were estimated as the number of days multiplied by utility scores for health-related quality of life. The utility values were estimated from the Child Health Utility 9-Dimensions questionnaire. Cost-effectiveness was summarised using incremental cost-effectiveness ratios (i.e. cost per QALY gained).

Estimates of net costs and outcomes were bootstrapped (i.e. a form of random sampling with replacement) (10,000 bootstraps) to generate cost-effectiveness acceptability curves that provided the probability of cost-effectiveness for a range of thresholds for willingness to pay for a QALY. Sensitivity analyses included alternative specifications where missing data were imputed, where costs of WF were apportioned to only children aged 0–12 years and for the clinical outcome measures of presence of no decay and mean number of decayed, missing and filled teeth avoided.

Results

Recruitment number and loss to follow-up

In the birth cohort, 2035 participants consented out of a potential 3138 infants born in Cumbria. The final clinical examination involved 1444 participants. Questionnaire response varied throughout the study. A total of 516 parents completed the questionnaire in the final round of questionnaires.

In the older school cohort, 1662 participants consented out of a potential 3077 children invited to participate. The final clinical examination involved 1192 participants and 1185 children completed the final child questionnaire.

Primary outcome

In the birth cohort, 17.4% of children in the intervention group had decayed, missing or filled teeth, compared with 21.4% of children in the control group [unadjusted odds ratio (OR) 0.77, 95% confidence interval (CI) 0.59 to 1.01]. However, there was evidence of a significant association between fluoridation and the presence of decay when important confounders [i.e. deprivation (reference IMD quintile 1), age and sex (reference male)] were adjusted for (adjusted OR 0.74, 95% CI 0.56 to 0.98).

For the older school cohort, although a similar difference was seen, with 19.1% of children in the intervention group and 21.9% of children in the control group having decayed, missing or filled teeth, the estimated effect was smaller in the older school cohort and there was insufficient evidence of an effect, with an unadjusted OR of 0.84 (95% CI 0.64 to 1.12) and an OR adjusted for deprivation (reference IMD quintile 1), age, dmft at baseline and sex (reference male) of 0.80 (95% CI 0.58 to 1.09).

Secondary outcomes

Mean dmft count in the birth cohort was 0.49 in the intervention group and 0.69 in the control group. For the older school cohort, the mean DMFT count was 0.32 in the intervention group and 0.40 in the control group. For the adjusted analysis, the incidence rate ratio (IRR) for the birth cohort dmft rate was 0.61 (95% CI 0.44 to 0.86) in the intervention group compared with the control, and for the older school cohort the IRR DMFT rate was 0.69 (95% CI 0.52 to 0.93). Both the birth and older school cohorts represent statistically significant lower rates of decay in the intervention groups after adjusting for confounders.

The remainder of our secondary outcomes, including, for example, number of DGAs for dental extractions, self-reported health outcomes and eruption timing (in the birth cohort only), demonstrated no significant differences between the intervention and control groups.

There is a clear social gradient in caries experience, with more deprived areas having lower proportions of caries-free children and children with higher mean dmft/DMFT scores. There was no significant difference in the performance of WF on caries experience across deprivation quintiles (according to analysis where an interaction term was added to the model).

Cost-effectiveness

In both the birth cohort and older school cohort there was evidence that WF resulted in small positive gains in QALYs, as well as reductions in NHS dental service costs associated with WF that exceeded the costs of fluoridation. For both cohorts, WF was likely to be cost-effective at a willingness-to-pay threshold of £20,000 per QALY (probabilities > 0.62). The figure of £20,000 was chosen as this is the standard threshold used to determine whether or not interventions constitute good value for money for the NHS.

Water fluoridation represented a small proportion of total NHS dental and WF costs, at £14.14 per capita (£105.63 when apportioned to each child aged 0 to 12). NHS dental services cost over 10 times this amount for the birth cohort and over three times this amount for the older school cohort.

Conclusions

The impact of WF in the birth cohort, although statistically significant once adjusted for important confounders, is much smaller than previous studies have reported. The intervention was cost-effective in this group; however, the clinical and public health significance of the modest reduction in caries status needs to be compared with the effect of other dental health preventative measures. Although a similar clinical difference was seen for children in the older school cohort, who had topical exposure, there was insufficient evidence of an effect; however, the intervention was still cost-effective for this group. Although this may suggest that WF acts either mainly via the systemic route or in combination with topical effects, the follow-up period for the permanent teeth was short and may not have provided sufficient time for caries to develop to produce a measurable difference between groups. In both cohorts, we could find no strong evidence that WF reduces dental health inequalities. Caries prevalence was lower than expected (≈ 20% in both cohorts at the end of the study period) but was in line with other national surveys, with the 2019 oral health survey of 5-year-olds indicating that, on average, 23.4% of children in England had experience of dental decay and 24.2% of children across areas examined in Cumbria had a dmft greater than zero. This prevalence demonstrates that the decline in caries continues and prevalence levels should be considered when deciding on population versus targeted prevention strategies.

Further research

This study examined the potential benefits of community WF, that is, a reduction in dental caries; however, it has not considered the potential risks. Most authorities believe that dental fluorosis is the only proven side effect of the consumption of water that has been fluoridated to the target 1 part per million. We were not able to assess the impact of fluorosis on the birth cohort, as children in this cohort were not old enough to demonstrate the presence of fluorotic lesions on permanent teeth at the end of the follow-up period, and, as a systemic artefact, fluorosis could not be assessed in the older school cohort. To complete the picture of balanced risk and benefit, the birth cohort should be assessed for fluorosis when they are 11 years old.

The study has suggested a modest oral health benefit in the birth cohort; however, our clinical findings are restricted to the primary dentition only and, therefore, it is important to determine if benefits are seen as the permanent dentition erupts (i.e. do children in the birth cohort carry the benefit as they get older?).

The use of a population-wide intervention for a disease that is concentrated in identifiable groups of individuals against a picture of falling disease prevalence has been challenged, and the results of this study confirm that most children are caries free, irrespective of their WF status. Consideration should be given to evaluation of targeted approaches to caries reduction that could be compared with the results of the current work as a contemporary evaluation of water fluoride effectiveness in a UK population.

Study registration

This study is registered as Integrated Research Application System 131824 and 149278.

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