

# Effect of fluoridated water on invasive NHS dental treatments for adults: the LOTUS retrospective cohort study and economic evaluation

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## Scientific summary

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# Scientific summary

## Background

There is a lack of contemporary evidence on the effectiveness and cost effectiveness of water fluoridation in populations who are also using fluoride toothpastes and have significantly lower levels of decay than when most of the research on water fluoridation was carried out. In their 2002 review of water fluoridation, the UK Medical Research Council identified several priority areas for future research, in particular:

- the effect of water fluoridation on the dental health of adults
- the effects of fluoridation on health and well-being beyond the usual measures of decayed, missing or filled teeth
- the economic impacts of water fluoridation
- how the effects of water fluoridation vary with social class.

Conducting research on the effects of water fluoridation in adults involves significant methodological challenges. This has resulted in a paucity of evidence and recommendations for research that have not been addressed in 20 years. The present study has been designed to contribute to the evidence base in a pragmatic and cost-efficient way, using routinely collected NHS dental claims data.

During our initial public engagement work, patients and the public told us that preventing dental treatment, particularly 'the drill' or 'injection', was a key impact that they would hope water fluoridation would produce. Other impacts were not losing teeth to extraction and avoiding costly dental charges. This feedback is reflected in our choice of primary and secondary outcome measures.

## Aim

To pragmatically assess the clinical and cost effectiveness of water fluoridation for preventing dental treatment and improving oral health.

## Primary objective

- Impact of water fluoridation on NHS invasive dental treatments (fillings, extractions).

## Secondary objectives

- Impact on oral health [number of teeth and caries experience, missing and filled teeth (DMFT)].
- Impact on social inequalities.
- Cost effectiveness and return on investment (ROI).

## Study inclusion criteria

1. Adults and adolescents aged 12 years and over who had attended an NHS dental practice in England within the last 10 years. Adolescents were included in the study cohort because they are likely to have all of their permanent, adult teeth.

2. Patient confirmed as a unique individual using the combination of NHS Business Service Authority (BSA) identifier (initial, surname, gender, date of birth) and NHS number.

## Study exclusion criteria

1. Individuals who did not have at least two episodes of dental attendance within the 10-year observation period.

The reason for this was to provide at least two data points on location of residence (to assign fluoridation exposure).

## Cohort setting

The study population data set was supplied by NHS BSA, which processes payment claims for NHS for dentists. The NHS BSA data retention period is 10 years.

National Health Service primary dental care is delivered in a range of settings and types of services, including:

- general dental practices (high street practices)
- prison dental services
- community dental services (special care referral service, which treats patients with additional needs, including medical conditions, disabilities, homelessness or drug use)
- domiciliary settings (home visits for housebound patients)
- urgent/out-of-hours services for patients without a regular dentist
- specialised referral-only services such as sedation or oral surgery.

Data on care delivered in all of the above services are collected by NHS BSA.

## Selection of the study population

Selection of the study population was carried out on 21 October 2020, by NHS BSA. Individual dental treatment claim entries for England and Wales were screened for linkage and selection by NHS BSA in the following order:

Identifiable data:

1. Withdrawn or 'no information' claims (FP17s) were dropped.
2. Claims with no 1 : 1 match between NHS number and NHS BSA ID were dropped.
3. Claims containing only orthodontic care were dropped.
4. Patients whose NHS number was on 'NHS national data opt-out list' were dropped.

Anonymised data:

5. Patients who had attended only once were dropped.
6. Patients aged under 12 years were dropped.
7. Patients whose first recorded address was not in England were dropped.
8. Patients whose first course of treatment was prior to 22 November 2010 were dropped.

The study population data set, securely transferred to the University of Manchester, included anonymised data on 17,855,239 unique individuals.

## Exposure assignment

Water fluoride sample data (mg F/l) were obtained from water suppliers in England under the Environmental Information Regulations (2004) and converted from water supply zones to lower super output areas (LSOAs) using mapping in statistical software 'R'. This resulted in a record of annual mean water fluoride concentrations by LSOA for every year between 2010 and 2020.

Individuals within the study population data set were then assigned an individual water fluoride exposure (mg F/l) by combining their residential history (recorded in the NHS BSA dental claims data set) with the annual concentration of fluoride in the drinking water of the LSOAs they lived in between 2010 and 2020.

Individuals exposed to drinking water with a grand mean fluoride concentration  $\geq 0.7$  mg F/l between 2010 and 2020 were assigned to the 'optimally fluoridated' group, and those with a grand mean of  $< 0.7$  mg F/l were assigned to the 'sub/non-optimally fluoridated' group.

## Propensity score matching

Individuals in the optimally fluoridated group were matched to individuals in the sub/non-optimally fluoridated group using propensity scores. The baseline characteristics used to create the propensity scores were selected using subject matter knowledge and theory to include all hypothesised confounders and important outcome predictors. To inform the selection of these variables, causal assumptions were made explicit using directed acyclic graphs.

Baseline characteristics for propensity score estimation and matching were based on data recorded at the patient's first course of treatment:

- sex
- age
- ethnicity
- deprivation decile
- NHS exemption status
- rural-urban classification
- number of units of dental activities (UDAs) commissioned per person with the patient's local authority of residence
- dental practice contract type
- dental practice deprivation decile.

Propensity scores were estimated using logistic regression, and matching was carried out using three specifications of nearest neighbour matching (one-to-one, variable ratio and variable ratio with a 0.25 calliper). The resulting matched data set which best met our pre-specified criteria regarding overall sample size, balance on baseline characteristics and ability to estimate the average treatment effect in the treated group was taken forwards for further analysis.

## Analysis of health effects

The effect of optimal water fluoridation on primary and secondary clinical outcomes was estimated using negative binomial regression models, including matching weights and using cluster-robust standard errors. Incidence rate ratios (IRRs) and 95% confidence intervals (CIs) were calculated for the mean number of invasive dental treatments received, the mean number of DMFTs and the mean number of missing teeth by fluoridation group. To determine whether there was a differential effect of water

fluoridation according to deprivation, we included patient deprivation decile [Index of Multiple Deprivation (IMD) 2015] as an interaction term.

## 'Clinical' relevance of primary outcome

We engaged with 54 public and professional stakeholders from across the UK through 3 online workshops to explore views on what might be considered a relevant/practically significant effect of optimal water fluoridation on our primary outcome. We identified a wide range of views and some suggestions that dentists felt smaller reductions were meaningful, compared to non-dentists, but most contributors felt a reduction of at least one invasive NHS dental treatment per person over 10 years would be needed to be considered meaningful (a 16% relative reduction in the workshop scenario).

## Health economic evaluation

The health economic evaluation involved a cost-effectiveness and a ROI analysis. The time horizon was 2010–20, and the perspective was public sector payors [NHS, Public Health England (PHE) and local authorities]. Operating and capital costs of water fluoridation for England were supplied by PHE for the financial years 2013–9, with mean annual costs used for 2010–2. All costs are reported in 2020 prices.

National Health Service dental care utilisation and patient charges were contained within the study population data set provided by NHS BSA, and an average UDA price for England supplied by NHS BSA [under the Freedom of Information Act (2000)] was used to calculate NHS costs.

Differences in costs between patients from optimally fluoridated and sub/non-optimally fluoridated groups were estimated using a generalised linear model (GLM) with a log-link and a gamma distribution to account for right-skewed cost data.

Cost effectiveness was based on the primary study outcome, assessed as the additional cost per avoided episode of invasive dental treatment [incremental cost-effectiveness ratio (ICER)]. We also calculated total NHS dental charges paid by patients in the optimally fluoridated and sub/non-optimally fluoridated groups.

Water fluoridation cannot be provided on an individual basis, therefore per-patient cost effectiveness and ROI estimates were extrapolated from our sample to the estimated population of regular users of NHS dental services using a range of scenarios.

## Results

The study population data set (the full cohort) supplied by NHS BSA included records relating to 17,855,239 unique individuals. After propensity score matching (using nearest neighbour, one-to-three variable ratio), the matched cohort contained data on 6,370,280 individuals: 4,777,710 in the sub/non-optimally fluoridated group and 1,592,570 in the optimally fluoridated group.

## Primary objective

The rate of invasive dental treatments in the optimally fluoridated group was 3% lower than that of the sub/non-optimally fluoridated group (IRR 0.969, 95% CI 0.967 to 0.971). There was a predicted mean difference of 0.173 fewer invasive dental treatments per person (95% CI 0.185 to 0.161) in the optimally

fluoridated group compared to the sub/non-optimally fluoridated group. During our stakeholder engagement work, only 4 of 54 contributors considered this magnitude of reduction to be meaningful.

## Secondary objectives

### *Oral health*

Mean DMFT in the optimally fluoridated group was 2% lower than in the sub/non-optimally fluoridated group (IRR 0.984, 95% CI 0.983 to 0.985). There was a predicted mean difference of 0.212 fewer DMFTs (95% CI 0.229 fewer to 0.194 fewer) in the optimally fluoridated group compared to the sub/non-optimally fluoridated group.

We found no significant difference in the mean number of missing teeth between the optimally fluoridated group and the sub/non-optimally fluoridated group (IRR 1.001, 95% CI 0.999 to 1.003). The negative binomial model predicted a mean difference of 0.006 more missing teeth in the fluoridated group, but the 95% CI includes the possibility of no effect (95% CI 0.008 fewer to 0.021 more).

### *Effect of water fluoridation on social inequalities*

In all deciles, the predicted number of invasive treatments was lower in the optimally fluoridated group than the sub/non-optimally fluoridated group, but the size of the reductions was very small. The largest predicted reduction of 0.337 fewer invasive dental treatments per person (95% CI 0.371 fewer to 0.302 fewer) was in the most deprived decile (IMD 1), a relative reduction of 5.3%.

The relationship between patient deprivation and DMFT was unclear and did not demonstrate a social inequality gradient in the expected direction. Therefore, we are unable to conclude whether water fluoridation reduced social inequalities in DMFT. Small differences were evident in each decile, but the direction of effect was not consistent.

Small differences in the number of missing teeth per person in the optimally fluoridated and sub/non-optimally fluoridated groups were evident in each decile of deprivation, but the direction of effect was not consistent.

Overall, we could find no compelling evidence that water fluoridation reduced socioeconomic disparities in oral health in adult and adolescent users of NHS dental services.

## Health economic results

### *Water fluoridation costs*

Total expenditure on water fluoridation between 2010 and 2019 was estimated to be £46,791,388. The cost of optimal water fluoridation per person over 10 years was estimated to be £10.30. No new water fluoridation programmes were commissioned between 2010 and 2020; therefore, our cost estimates for water fluoridation do not include setup costs, which are highly site-specific and can be significant.

### *National Health Service dental treatment and patient charges*

In the GLM, the marginal effects estimate revealed a saving in NHS treatment costs for optimally fluoridated patients over the study period of £22.26 per person (95% CI £21.43 to £23.09). This represents a relative reduction in costs to the NHS of 5.5% per person between 2010 and 2020. Patients in the optimally fluoridated group paid £7.64 less (2%) in total NHS dental charges than patients in the non-optimally fluoridated group between 2010 and 2020.

### Population-level cost effectiveness and return on investment

Water fluoridation is a whole-population intervention, which cannot be implemented on a per-person basis. In terms of cost effectiveness and ROI, it is important to consider the potential size of the population to whom our within-sample (per person) findings may apply.

In the scenario thought to be most likely by our steering committee (that 62.9% of the population aged 12 years can be expected to use NHS dental services at least twice in 10 years), we estimate that:

- The cost to avoid one invasive dental treatment (the ICER) was £94.55.
- The predicted ROI for water fluoridation in England between November 2010 and October 2020 was estimated to be £16,884,595 (a 36% return on the investment).

### Conclusions

Receipt of optimal water fluoridation between 2010 and 2020 resulted in very small health effects which may not be meaningful for individuals, and we could find no evidence that water fluoridation reduced social inequalities in dental health. Slightly lower dental service utilisation produced a positive ROI during the period of observation, but it must be remembered that the cost estimates for water fluoridation did not include the initial set-up of the programmes. Where new capital investment in water fluoridation is required, the estimated project costs should be evaluated against the estimated savings contained within this report and the projected lifespan of the infrastructure. Whether the case for water fluoridation programmes can be based solely on a predicted ROI rather than meaningful health improvements may need to be considered by stakeholders.

### Recommendations for research

- 1 NHS primary care dental data are a potentially valuable resource for research, surveillance and epidemiology. Consideration should be given as to how to develop this resource further. Suggestions include: commissioning enhanced data collection through a network of dental providers (similar to medical G.P. Clinical Practice Research Datalink network); mandatory use of NHS numbers, recording the reason for treatment (caries, periodontal disease, trauma, repair of old restoration); steps to increase the completeness of patient ethnicity data and validation of the DMFT data.
- 2 Routinely collected water quality monitoring data should be made publicly available. A central, annually updated database of water fluoride concentrations (mg F/l) at a small area level is required to support future research and monitoring of water fluoridation.
- 3 To broaden the evidence base for triangulation, the effect of water fluoridation on the dental health of adults should be investigated in any future national dental epidemiology surveys.
- 4 To determine if the estimated cost to avoid one invasive dental treatment (the ICER) represents good value for money, further work is required to identify a threshold level for 'good value' for this outcome.

### Trial registrations

This trial is registered as ISRCTN96479279, CAG: 20/CAG/0072, IRAS: 20/NE/0144.

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