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ORIGINAL ARTICLE

Economic evaluation of a water fluoridation scheme in Cumbria, UK

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Abstract

Objectives: The addition of fluoride to community drinking water supplies has been a long-standing public health intervention to improve dental health. However, the evidence of cost-effectiveness in the UK currently lacks a contemporary focus, being limited to a period with higher incidence of caries. A water fluoridation scheme in West Cumbria, United Kingdom, provided a unique opportunity to study the contemporary impact of water fluoridation. This study evaluates the cost-effectiveness of water fluoridation over a 5–6 years follow-up period in two distinct cohorts: children exposed to water fluoridation in utero and those exposed from the age of 5.

Methods: Cost-effectiveness was summarized employing incremental cost-effectiveness ratios (ICER, cost per quality adjusted life year (QALY) gained). Costs included those from the National Health Service (NHS) and local authority perspective, encompassing capital and running costs of water fluoridation, as well as NHS dental activity. The measure of health benefit was the QALY, with utility determined using the Child Health Utility 9-Dimension questionnaire. To account for uncertainty, estimates of net cost and outcomes were bootstrapped (10 000 bootstraps) to generate cost-effectiveness acceptability curves and sensitivity analysis performed with alternative specifications.

Results: There were 306 participants in the birth cohort (189 and 117 in the non-fluoridated and fluoridated groups, respectively) and 271 in the older school cohort (159 and 112, respectively). In both cohorts, there was evidence of small gains in QALYs for the fluoridated group compared to the non-fluoridated group and reductions in NHS dental service cost that exceeded the cost of fluoridation. For both cohorts and across all sensitivity analyses, there were high probabilities (>62%) of water fluoridation being cost-effective with a willingness to pay threshold of £20 000 per QALY.

Conclusions: This analysis provides current economic evidence that water fluoridation is likely to be cost-effective. The findings contribute valuable contemporary evidence in support of the economic viability of water fluoridation scheme.

KEYWORDS
child, cost savings, England, fluoridation, fluorides, schools

1 | INTRODUCTION

Oral diseases are the most common non-communicable diseases worldwide, even though they are largely preventable.[1] According to the Global Burden of Disease Study 2019, oral diseases affect about 3.5 billion people worldwide, with dental caries being the most common condition. Almost 2 billion people suffer from permanent tooth caries, while 520 million children suffer from primary tooth caries.[2] Caries in particular can result in health and economic burdens, causing pain, sepsis and affecting quality of life.[3]

Dental decay is still one of the most common diseases affecting children in the United Kingdom (UK), but there has been evidence of a decline in disease in recent years. In comparison with the 2003 survey, the 2012 national oral health survey found that obvious decay experience prevalence in 5-year-olds reduced from 41% to 31% in England, 52% to 41% in Wales and 61% to 40% in Northern Ireland (data for Scotland were not reported).[4,5]

Community water fluoridation, the addition of fluoride to community drinking water supplies, has been a long-standing public health intervention aiming to improve dental health.[6,7] It was introduced in areas of the UK during the 1960s and 1970s against a background of high population prevalence of dental decay. Alongside this, has been the widespread use of fluoride toothpastes since the mid-1970s. The prevalence and severity of decay have fallen dramatically, though the causal link between this and water fluoridation has been questioned by several reviews that queried the scientific rigour of early water fluoridation studies.[8–10]

A recent scoping review found water fluoridation is a cost-effective strategy when it is compared with non-fluoridated water, independent of the perspective, time horizon or discount rate applied.[11] However, the review highlighted weaknesses in the evidence base in particular three were identified. The lack of cost-utility analyses (with outcomes measured in clinical or monetary terms rather than on health-related quality of life) making comparisons with other initiatives difficult; the limitations of existing studies in terms of geographic coverage (only two UK studies were identified) in terms of identification of adverse events; and in the need to account for declining incidence in caries over time. The two UK-based studies[12,13] are limited by the same criticisms identified by the systematic reviews on water fluoridation effectiveness—the studies were conducted at a time before widespread use of fluoride toothpaste and the significant fall that has been seen in dental caries prevalence in the UK. Health economic evaluation of water fluoridation is important because of its high profile and because the costs to the NHS of treating tooth decay are very significant. The NHS in England spends about £3.4 billion per year net on dental services; the value of the private market is estimated at £2.3 billion per year.[14] Patient charges roughly make up a quarter of the total primary care NHS budget. Much of the NHS dental budget is consumed by the detection and treatment of dental caries. With falling population levels of caries and increasing costs of NHS dental services, a health economic evaluation is now an imperative for any contemporary investigation of water fluoridation.

In West Cumbria (Cornhow and Ennerdale), a water fluoridation scheme established in the 1960s had been offline for several years due to a need to refurbish the fluoride dosing plant. The refurbishment totally replaced the fluoride plant and equipment. Fluoridation resumed in West Cumbria in 2013, which provided a unique opportunity to study the contemporary impact of water fluoridation. This study aims to perform an economic evaluation of the impacts of the introduction of water fluoridation in West Cumbria. Cost-effectiveness analysis (CEA) is performed over a 5-year follow-up in two separate cohorts: children exposed to water fluoridation in utero and those exposed from the age of 5. Effectiveness is measured using health-related quality of life and costs from an NHS and local authority perspective. The study provides an empirical evaluation of the cost-effectiveness of water fluoridation in a UK context that addresses the issues of a need for contemporary evidence, the need for health-related quality of life assessments of cost-effectiveness, the need for a comparative assessment of effectiveness and the incorporation of adverse treatments in the analyses. This study is a part of the CATFISH project (Cumbrian Assessment of Teeth a Fluoride Intervention Study for Health) that aimed to provide robust evidence of the effects and costs of a 'reintroduced' water fluoridation scheme on the oral health of young children.[15]

2 | METHODS

The study design was peer reviewed, and the study protocol was published in 2016. Liverpool Central NHS ethics committee (for the older school cohort) and Cambridge South NHS ethics committee (for the birth cohort) provided a favourable ethical opinion (REC reference 13/NW/0494 and 14/EE/0108, respectively). A prospective longitudinal cohort design was employed with two distinct populations, a birth cohort and an older school cohort.[15] In the birth cohort, children were recruited at birth between September 2014 and August 2015. A census approach was taken to recruitment based on births in two hospital sites: West Cumberland Hospital (Whitehaven) and Cumberland Infirmary (Carlisle). These children had a 'full effect' of water fluoridation as they received both systemic water fluoridation (from in utero), where fluoride has been incorporated into the enamel as it develops; and topical exposure to fluoride from drinking water which acts once a tooth has erupted by creating an environment at the tooth surface which favours remineralization. Children had a dental examination at 3

TABLE 1 Water fluoridation cost per capita (£).

Year	Cost	Cost per capita	Cost per capita (0–12 years)
Capital cost	1643889.60	9.88	73.78
2014	32543.13	0.20	1.46
2015	100598.55	0.60	4.52
2016	44322.15	0.27	1.99
2017	76009.36	0.46	3.41
2018	105172.75	0.63	4.72
2019	87565.21	0.53	3.93
	446211.16	2.69	20.03
EAC	392245.46	2.36	17.61
Total (present value)	2090100.75	12.56	93.81
Total (EAC)	2353472.78	14.14	105.63

Note: 166 461 (all ages), 22 280 (0–12), The populations relate to fluoridated areas (Copeland and Allerdale), no water fluoridation costs are attributed to non-fluoridated areas (Carlisle, Barrow-in Furness, South Lakeland, and Eden). We assumed children residing in specific postcode areas had exposure to fluoridated water.

Abbreviation: EAC, Equivalent Annualized Cost.

and 5 years of age, and questionnaire data were collected throughout their participation in the study.

The older school cohort comprised children recruited in their first year of school from September 2013. Children were invited to participate from primary schools in Cumbria. These children had predominantly topical exposure to water fluoridation where the preventative effect would come from creating an environment which would encourage remineralization of enamel and inhibit bacterial metabolism. This group enabled comparison of effects 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. In the birth cohort, 2035 children were consented into the study. In the older school cohort, there were 1662 children in the study.

2.1 | Economic analyses

CEA took an NHS and local authority perspective. The primary measure for the economic analysis was the incremental cost-effectiveness ratio (ICER). The ICER was estimated as the net cost divided by the net quality adjusted life year (QALY) estimates obtained from regression analyses comparing costs and benefits in the fluoridated group to the non-fluoridated group.

2.2 | Cost measures

The cost to the local authority of water fluoridation (both capital and running cost) were obtained by requests to the water company and local authority. In addition, the costs of dental treatments (both routine and emergency) to the NHS were included.

Cost was presented in UK sterling (£) 2014, costs beyond 2014 were discounted from Year 2 at a discount rate of 3.5% in line with National Institute for Health and Clinical Excellence (NICE) guidance for technology appraisal.[16]

The cost of water fluoridation was allocated in two ways: First, the cost was distributed across the entire population residing in areas with fluoridation, and second, the cost of water fluoridation was distributed evenly across the population aged 0–12 years in areas with fluoridation. The latter approach is a stronger assumption that fluoridation is targeted to children only. Population data were sourced from Office for National Statistics (ONS).[17] Capital costs were transformed into an equivalent annual cost with a discount factor of 3.5% and a period of 6 years (a conservative approach that assumes the capital only lasts for 6 years). While operational beyond the study period, the conservative assumption was made that all capital expenditure covered a 6-year duration, representing the longest follow-up period across both cohorts. The costs for capital expenditure used in the setup of the fluoridation plant amounted to £1 643 890 to the local authority. This was a single capital work programme covering both Ennerdale and Cornhow schemes. Whereas local authority total reported running costs were £493102.72 (total discounted running cost: £446211.16). In years 2014 and 2016, the local authority paid a proportion of the final running cost with the remaining covered by United Utilities. Water fluoridation cost per capita are provided in Table 1. Variation in costs occurred due to flooding at points of 2016 disrupting fluoridation in one plant for a period of the year and intermittent fluoridation in the initial year of setup.

Costs for service use were captured by data from the NHS Business Service Authority (BSA) on dental activity per child, and from hospital activity records obtained through North Cumbria Integrated Care Foundation Trust. The NHS BSA Dental Services remunerates dentists based on FP17 claims submitted and provides dental statistics and key information to national, regional and local NHS organizations. NHS BSA data contain information on Units of Dental Activity (UDA) attributed to a child for a course of treatment. The NHS commissioning and reimbursement of services is based on UDAs and not per-item (e.g., a Band 1 covers 1 UDA but involves activity including examinations and scale and polish, the same UDAs are applied if a child received only an examination or an examination and scale and polish). Each child could have multiple courses of treatment over the 5-year period. The unit cost applied to a UDA varies depending on the dental practice providing the service.* There were no co-payments by the children's parents or guardians.

General anaesthetic data included the number of general anaesthetics provided; the unit cost applied here was £935 sourced as the unit cost for multiple extraction of teeth as a day case within hospital taken from NHS national cost collection data.

2.3 | Outcome measures

Utility values were obtained from the Child Health Utility 9-Dimension (CHU9D) questionnaire. The CHU9D is a generic health-related quality of life measure and validated to be used for children aged 7–17.[18–21] Unlike other generic quality of life measures, CHU9D was developed with young children from its inception. To identify the dimensions, in-depth interviews with young individuals with different chronic and acute health conditions were used with the aim of exploring how their health affects their life.[22–24] The CHU9D contains nine dimensions (worried, sad, pain, tired, annoyed, schoolwork, sleep, daily routine and activities), each with five levels. Children (or proxies for younger children aged 5–7) self-complete the questionnaire with questions placed in the context of how the child is today/last night.

In the birth cohort, the absence of a baseline CHU9D utility measure necessitated the assumption that the utility value (1: perfect health) remains consistent across both fluoridated and non-fluoridated groups. At follow-up, parents/carer completed the CHU9D for the child at age 5. While CHU9D was originally created and validated to be used for children aged 7–11 years old, a proxy version for children aged 5–7 years old has also been created and has been trialled. Early results indicate a proxy reported (parent) CHU9D is appropriate.[25]

For the older school cohort, parents/carer completed the questionnaire at age 5 and children self-completed the questionnaire at their final clinical assessment (age 11).

The CHU9D responses were transformed to utility measures using preference weights obtained from a sample of 300 adults in the UK[21]; then, QALYs were estimated as

$$\text{QALY} = \sum_{i=1}^{n} \left[\left[\left(U_{i,t=1} + U_{i,t=2} \right) / 2 \right] \times \left(d_{i,t=2} - d_{i,t=1} \right) \right]$$

where U = utility value, i = individual, d = day of assessment, and t = assessment point (1 = baseline, 2 = final). QALYs were discounted from Year 2 at a discount rate of 3.5% in line with NICE guidance for technology appraisal.[16]

2.4 | Statistical analyses

The CHU9D data, QALYs, service use and cost were summarized with descriptive statistics (provided in Appendix S1). Regression analyses were used to estimate incremental (net) cost and QALYs. Age, gender, deprivation quintile of child's residence, follow-up duration (years) and CHU9D utility measure at baseline were included as covariates for the analysis to estimate net cost and QALYs.

Gender and age were included to reflect the fact that health and utility typically vary across gender and decline with age. Deprivation quintiles included due to the variation in deprivation observed between fluoridated and non-fluoridated areas in the study. The CHU9D utility measure at baseline was included as an overall measure of health and health need. As there is no baseline CHU9D utility measure for the birth cohort, no adjustment of baseline was possible for this cohort in the regression analysis.

To account for uncertainty in the parameter estimates, the estimates of net cost and outcomes from the regression were bootstrapped to simulate 10 000 pairs of net cost and net outcomes. These simulated pairs of net cost and net outcomes were used to generate cost-effectiveness acceptability curve (CEAC), as recommended by NICE for health technology appraisals.[26] The simulated net QALY values from the bootstrap simulation were assigned a monetary value using a range of maximum willingness to pay values from £1 to £30 000 to gain one QALY. This was based on the range of willingness to pay thresholds (WTPT) historically implied by NICE decisions.[27] The figure £20 000 was chosen as this is the standard threshold used to determine whether interventions are acceptable to the NHS.

An incremental net monetary benefit (INMB) statistics of water fluoridation for each pair of simulated net cost and net outcome for each WTPT is estimated as

$$\text{Incremental Net Monetary Benefit} = (\text{net QALYs gained} * \text{Amount willing to pay to gain one QALY}) - \text{net cost}$$

For a range of WTPT, a CEAC is presented which plots the proportion of bootstrapped simulations where the incremental net monetary benefit of water fluoridation is greater than zero for each WTPT.[28–31] The intervention is considered cost-effective where the

*Dental practices are given a UDA target which is the volume of UDAs the practice is commissioned to provide on behalf of the NHS. Each practice also has a UDA value which is the actual amount the dental practice is paid. Dividing the value by the target provides a unit cost per UDA. Each course of treatment is allocated a UDA volume (Band 1: 1 UDA; Band 2: 3 UDA; Band 3: 12 UDA; and Urgent: 1.5 UDA).

proportion of bootstrapped simulations with a positive incremental net monetary benefit measure exceed 50%.

2.5 | Missing data

The approach suggested by Faria et al (2014) for identifying the missing data mechanism was followed.[32] First, the proportions of missing cost and QALY data were reported to observe whether there were differential rates across fluoridated and non-fluoridated groups. Second, logistic regressions of missing cost and QALY indicators were performed with a fluoridation group indicator, baseline covariates and baseline QALY as explanatory variables.

If rates of missing data are similar and no baseline covariate or fluoridation indicator are significant predictors of missing data, then the assumed missing data mechanism is missing completely at random (MCAR) and complete case analysis (CCA) is the preferred model specification. If rates of missing data are similar and baseline covariates are significant predictors of missing data, then the assumed missing data mechanism is covariate-dependent missing completely at random (CD-MCAR) and the CCA is the preferred model specification. If rates of missing data are similar and baseline QALY are significant predictors of missing data, then the assumed missing data mechanism is missing at random (MAR), and imputation of missing data is the preferred methodological approach.[33]

MAR was approached by multiple imputation. Imputation was performed by fluoridation group with all baseline variables (age, gender, Index of Multiple Deprivation (IMD) quintile), cost (fluoridation cost, dental cost and general anaesthetic cost) and CHU9D domains included in the imputation model.

The imputed cost and QALYs and domains of resource (cost) and CHU9D domains were compared to the CCA cost and QALYs to assess whether the imputation appears to be valid. To obtain incremental cost and QALY estimates, seemingly unrelated regression models of the imputed datasets were estimated. Where the missing data mechanism was inferred as MCAR, sensitivity analyses explored the impact on assuming MAR.

2.6 | Sensitivity analysis

Sensitivity analyses were performed to investigate the effect of changing the methods used on estimates of whether water fluoridation was cost-effective. This included re-running the analysis for: assuming the missing data mechanism is that of missing at random; attributing cost of fluoridation to the population aged 0 to 12 years old; and a cost-effectiveness analysis using two alternative clinical measures as outcomes—volume of decayed missing filled teeth (dmft) avoided and no presence of decay (with willingness to pay thresholds of £1000 and £20 000 applied to highlight sensitivity).

3 | RESULTS

3.1 | Sample and missing data mechanism

In the birth cohort, 2035 children were consented into the study, 1444 had an examination at school, 3 of these had no identifier to link to the questionnaire data giving a sample of 1441 children in the study. In total, 514 completed the questionnaire at 5 years (927 did not). Two had no valid deprivation quintile score (1 with questionnaire data and 1 with no questionnaire data) giving 513 and 926 with data on deprivation who did and did not have questionnaire data, respectively.

Of the 513 children who completed the questionnaire, 8 had no follow-up dates (7 due to non-provision of birth date and 1 due to non-provision of questionnaire completion date) and 1 had a follow-up date of zero, which was deemed a coding error. In the final birth cohort sample of 504 children, 47 of these had incomplete data across 1 or more domains of the CHU9D giving a final sample of 457 with complete CHU9D data (31.8% of 1439 children).

General anaesthetic activity and costs data were complete in the sample, but 165 children had no NHS BSA data activity and costs, resulting in a complete cost sample of 339 children (67.3% of 504 children). Children with no dental activity were included in the missing NHS BSA data, as were data where the NHS BSA was unable to match respondents in the sample to NHS BSA data. According to the 2013 Child Dental Health Survey, only 6% of children aged 5 had never visited a dentist,[34] which suggests that most of missing data are the result of an inability to match respondents rather than actual zero activity; we therefore assume the data are missing rather than zero.

The rates of missing data in total and by fluoridation group are provided in Appendix S2. Complete data are similar across the groups, providing some support towards the missing data mechanism being that of MCAR.

In the older school cohort, 1662 children consented in the study with 1192 having an assessment at 11 years. Nineteen of the 1192 had missing data at follow-up, 5 because follow-up was greater than 7 years (a clear coding issue), and 14 because of incomplete follow-up or baseline assessment dates. Among 1173 with complete follow-up dates, 9 had no age recorded and a further 19 no deprivation recorded, this gave a sample of 1145 children. In total, 392 had CHU9D data at baseline (2 incomplete) and 388 at follow-up (4 incomplete). In total, 388 children had complete CHU9D data at both timepoints (33.9%). This gives a sample of 390 children in the older school cohort with complete baseline CHU9D.

Inference on the missing data mechanism was made on the sample of 390 children with baseline data. Four respondents had incomplete data across one or more domains of the CHU9D at follow-up giving a sample of 386 with complete CHU9D data (99.0%). General anaesthetic activity and costs data were complete for all respondents, but 116 had no NHS BSA data activity and costs, resulting in a complete

TABLE 2 CHU9D utility values at each assessment, length of the follow-up, QALY and discounted QALY for birth and older school cohorts.

Birth Cohort			
	Non-fluoridated ($n=189$)	**Fluoridated ($n=117$)**	**Difference**
	Mean (s.d.), (95% CI)	**Mean (s.d.), (95% CI)**	**Difference (95% CI)**
CHU9D Utility values; Age 5 questionnaire	0.928 (0.068), (0.918; 0.938)	0.932 (0.063), (0.920; 0.943)	0.004 (−0.012; 0.019)
Follow-up duration (years)	4.9 (0.4), (4.8; 4.9)	4.81(0.3), (4.8; 4.9)	−0.1 (−0.1; 0.0)
QALY	4.70 (0.41), (4.64; 4.76)	4.65 (0.38), (4.58; 4.72)	−0.05 (−0.14; 0.05)
Discounted QALY	4.35 (0.35), (4.30; 4.40)	4.31 (0.32), (4.25; 4.37)	−0.04 (−0.12; 0.04)
Older School Cohort			
	Non-fluoridated ($n=159$)	**Fluoridated ($n=112$)**	**Difference**
CHU9D Utility values: Age 5 (Baseline)	0.938 (0.063), (0.929; 0.948)	0.929 (0.063), (0.918; 0.941)	−0.009 (−0.024; 0.006)
CHU9D Utility values: Age 11 (Final Assessment)	0.892 (0.081), (0.879; 0.904)	0.896 (0.085), (0.880; 0.912)	0.005 (−0.015; 0.025)
Follow-up duration (years)	5.8 (0.2), (5.8; 5.9)	5.9 (0.2), (5.9; 6.0)	0.1 (0.1; 0.2)
QALY	5.34 (0.37), (5.28; 5.39)	5.42 (0.38), (5.35; 5.5)	0.08 (−0.01; 0.18)
Discounted QALY	4.86 (0.33), (4.81; 4.91)	4.93 (0.33), (4.87; 4.99)	0.07 (−0.02; 0.14)

Abbreviations: CHU9D, Child Health Utility 9-Dimensions; CI, Confidence Interval; QALY, Quality Adjusted Life Year; s.d., Standard Deviation.

TABLE 3 Cost of services used and total cost of water fluoridation and health and social care, £'s UK, 2014, unadjusted for baseline covariates.

	Birth Cohort			**Older School Cohort**		
	Non-fluoridated ($n=189$)	**Fluoridated ($n=117$)**		**Non-fluoridated ($n=159$)**	**Fluoridated ($n=112$)**	
Type of service	**Mean (s.d.)**	**Mean (s.d.)**	**Difference (95% CI)**	**Mean (s.d.)**	**Mean (s.d.)**	**Difference (95% CI)**
Dental activity	136.94 (71.03)	101.27 (54.64)	−35.67 (−50.77; −20.56)	432.73 (191.61)	360.00 (200.20)	−72.73 (−120.14; −£25.32)
Emergency hospital activity (dental)	24.88 (137.97)	20.99 (130.64)	−3.89 (−35.19; 27.41)	102.20 (287.34)	87.76 (267.55)	−14.45 (−82.29; 53.40)
Total (EAC)	0 (0.00)	14.14 (0.00)	14.14	0 (0.00)	14.14 (0.00)	14.14
Total costs of water fluoridation and health and social care						
	Mean (s.d.), (95% CI)	**Mean (s.d.), (95% CI)**	**Difference (95% CI)**	**Mean (s.d.), (95% CI)**	**Mean (s.d.), (95% CI)**	**Difference (95% CI)**
Baseline to follow-up assessment	161.82 (155.86), (139.45; 184.18)	136.41 (147.74), (109.35; 163.46)	−25.41 (−30.78; 9.96)	534.93 (342.79), (481.24; 588.62)	461.89 (340.05), (398.22; 525.57)	−73.03 (−156.01; 9.95)

Abbreviations: EAC, Equivalent Annualized Cost (capital and running costs); s.d., Standard Deviation.

cost sample of 274 children (70.3%). Complete data are similar across the groups, providing some support towards the missing data mechanism being that of MCAR. Appendix S3 provides the estimates from logistic regressions of missing data against baseline covariates, outcomes and a fluoridation group indicator. No baseline variable was associated with missing data on either costs or QALYs (including baseline CHU9D); this supports the missing data mechanism of MCAR. As such, our preferred model specification for the older school cohort is that of CCA. MAR is explored as sensitivity analyses.

3.2 | CHU9D health status, utility and QALYs

There were no clear differences between the fluoridated and non-fluoridated groups at baseline or follow-up in older school cohort and at follow-up in birth cohort. Although there appeared to be little evidence of differences in QALYs between the two groups (Table 2), the responses to the individual domains of the CHU9D are presented in Appendix S4 for those with complete CHU9D cost data (the CCA sample) for both birth and older cohort.

TABLE 4 Primary analysis of the cost-effectiveness of water fluoridation (£), bootstrapped data.

Statistic	Birth Cohort	Older School Cohort
Cost difference (95% CI) £'s, 2014	−£21.55 (−£55.61; £15.40)	−£64.01 (−£150.11; £20.13)
QALY difference (95% CI)	0.01 (−0.02; 0.04)	0.01 (−0.04; 0.06)
Incremental cost/QALY gained	Water fluoridation dominates	Water fluoridation dominates
Incremental net monetary benefit (95 percentile) WTPT = 20 000	£246 (−£416; £905)	£255 (−£779; £1250)
Probability water fluoridation cost-effective if WTPT = 20 000	77%	68%

Abbreviations: CI, Confidence Interval; QALY, Quality Adjusted Life Year; WTPT, Willingness to Pay Threshold.

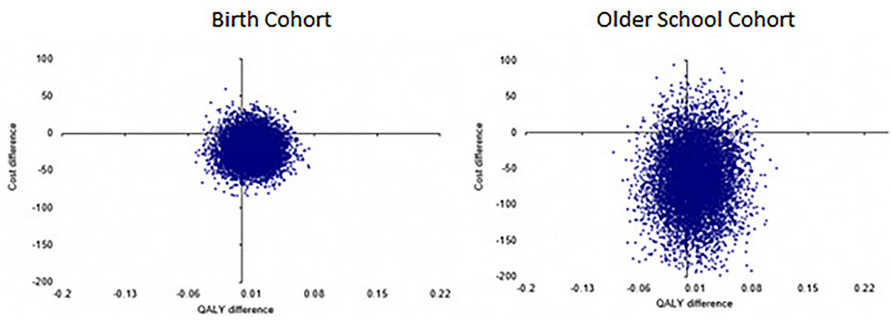

FIGURE 1 Cost effectiveness plane of net cost and QALYs, primary analysis.

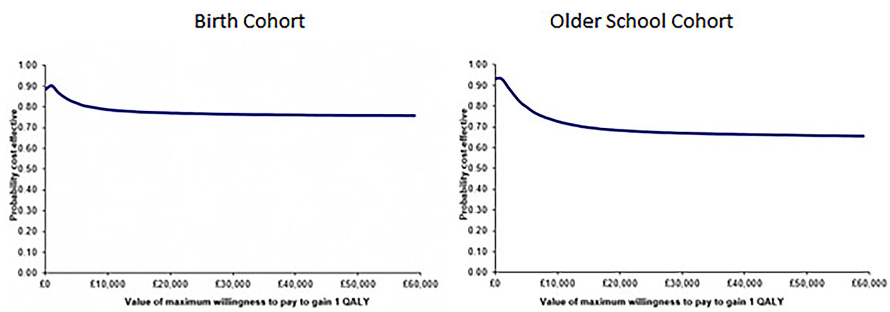

FIGURE 2 Cost-effectiveness acceptability curve.

3.3 | Service use and cost

Most treatments were for Band 1 with low activity for other courses of treatment, urgent care and general anaesthetic over the period. The average volume of treatments per band and general anaesthetics per child are presented in Appendix S5 for children with complete cost data, irrespective of whether CHU9D data are complete. Overall, primary and community dental services were the highest cost component (Table 3). Complete QALYs, cost and clinical data by fluoridation group are provided in Appendix S6.

3.4 | Cost-effectiveness

Table 4 reports the bootstrap simulations of cost and QALY differences as well as the results of the cost-effectiveness acceptability analysis. In both the birth and older school cohorts, there were evidence of small positive gains in QALYs for the fluoridated group compared to the non-fluoridated group and reductions in NHS dental service cost associated with water fluoridation that exceeded the cost of fluoridation. Figure 1 provides the distribution of the 10 000 simulated cost and QALY differences. The simulations for QALY differences fall both across negative and positive differences, in line with the inference of a lack of statistical significance. Similarly, the simulated costs fall both across positive and negative differences. However, taking both distributions into account the mass of simulations lies in the southeast quadrant implying a greater probability of being cost-effective (both increasing QALYs and reducing costs).

The CEAC for both cohorts are provided in Figure 2. This plots the proportion of simulations lying below a WTPT threshold. As the threshold increases the slope of the threshold line becomes steeper, meaning interventions with negative QALYs would be less likely to have simulations fall below the threshold. In both cohorts, there are simulated costs and QALYs lying in the northwest and southwest quadrants this means the CEAC drops with a greater WTPT. To see this consider increasing the threshold until it is almost perpendicular to the y-axis (an extremely high WTPT), here the proportion of simulations falling below the threshold would reflect the simulations

TABLE 5 Sensitivity analysis.

Statistic	Birth Cohort: Imputed data	Birth Cohort: Fluoridation costs attributed to children aged 0–12 years
Cost difference (95% CI) £'s, 2014	−£20.70 (−£48.80; £9.71)	£69.94 (£35.88; £106.89)
QALY difference (95% CI)	0.02 (−0.00; 0.04)	0.01 (−0.02; 0.04)
Incremental cost/QALY gained	Water fluoridation dominates	£6245
Incremental net monetary benefit (95 percentile) WTPT = £20000	£433 (−£40; £921)	£154 (−£507; £813)
Probability water fluoridation cost-effective if WTPT = £20000	96%	68%
Statistic	**Older School Cohort**	
Cost difference (95% CI) £'s, 2014	−£66.91 (−£148.90; £15.36)	£27.95 (−£57.90; £114.40)
QALY difference (95% CI)	0.02 (−0.03; 0.06)	0.01 (−0.04; 0.06)
Incremental cost/QALY gained	Water fluoridation dominates	£2973
Incremental net monetary benefit (95 percentile) WTPT = £20000	£369 (£452; £1132)	£160 (−£878; £1134)
Probability water fluoridation cost-effective if WTPT = £20000	81%	62%

Abbreviations: CI, Confidence Interval; QALY, Quality Adjusted Life Year; WTPT, Willingness to Pay Threshold.

lying in the northeast and southeast quadrants. In a simulation with a WTPT of £20000, the probability of water fluoridation being cost-effective was approximately 77% and 68% in birth and older school cohorts, respectively.

3.5 | Sensitivity analysis

In the older school cohort, multiple imputation had a minimal impact on QALYs but increased the cost difference slightly and the opposite was true in the birth Cohort (Table 5, multiply imputed costs and QALYs are provided in Appendices S6 and S7. This increased the probability of fluoridation being cost-effective at a willingness to pay per QALY threshold of £20000 (from 77% to 96%) in birth and older school cohorts (from 68% to 81%).

Allocating the capital and running costs of fluoridation only to children increased the costs so that the negative net cost identified in the primary analysis was overturned. The probability that water fluoridation was cost-effective at a willingness to pay per QALY threshold of £20000 was reduced (from 0.77% to 68%) in the birth cohort and marginally impacted (from 68% to 62%) in the older school cohort.

For the clinical outcomes analyses the sample concerned those with valid age and deprivation scores (1422 and 1114 for the birth and older school cohorts, respectively), there were complete data on the clinical measures with missing data arising solely from the cost of dental treatment (Appendix S2). Missing data were greater than for the QALY analyses for both cohorts. The analyses of missing data suggested MCAR and MAR were appropriate missing data mechanisms for the birth and older school cohorts, respectively (Appendices S8 and S9). The analyses for the older school cohort therefore adopted an imputation approach.

The results of cost-effectiveness estimates where the clinical outcomes were the measures of effectiveness show similar results to the primary (QALY) analysis (Table 6), with either outcome having better oral health in the fluoridated group (0.13 fewer decayed, missing and filled teeth (95% CI: −0.06; 0.32) and 2.04 percentage points more likely to have no decay (−0.02; 0.06)), and lower cost, again, supporting a conclusion that water fluoridation was likely to be cost-effective.

4 | DISCUSSION

The study aimed to conduct an economic evaluation of water fluoridation in two cohorts of children, children exposed to water fluoridation in utero and those exposed from the age of 5. The findings demonstrated that the probability of being cost-effective at a willingness to pay of £20000 per QALY was approximately 77% and 68% in birth and older school cohorts, respectively. Sensitivity analyses included imputation of missing data, where cost of water fluoridation was apportioned to only those children aged 0 to 12, and use of alternative clinical outcome measures, volume of dmft avoided and presence of no decay. The sensitivity analyses provided a consistent picture with water fluoridation being likely to be cost-effective.

The current study's strengths are in its ability to address the shortcomings noted in earlier research. The CATFISH study has provided the first contemporary evaluation of the (re)-introduction of a water fluoridation scheme in England since the publication

TABLE 6 Sensitivity analysis with alternative outcomes.

Statistic	Birth Cohort Alternative outcome measure: volume dmft avoided	Alternative outcome measure: no decay
Cost difference (95% CI) £'s, 2014	−£19.73 (−£41.20; £2.36)	−£19.73 (−£41.20; £2.36)
Outcome difference (95% CI)	0.13 (−0.06; 0.32)	0.02 (−0.02; 0.06)
Incremental cost/dmft/no decay gained	Water fluoridation dominates	Water fluoridation dominates
Incremental net monetary benefit (95 percentile) WTPT = £1000	£146 (−£49; £347)	£40 (−£6; £87)
Probability water fluoridation cost-effective if WTPT = £1000	93%	95%
Incremental net monetary benefit (95 percentile) WTPT = £1000	£2544 (−£1312; £6539)	£428 (−£427; £1247)
Probability water fluoridation cost-effective if WTPT = £20000	90%	84%
Statistic	**Older School Cohort***	
Cost difference (95% CI) £'s, 2014	−£60.34 (−£107.26; −£12.38)	−£60.34 (−£107.26; −£12.38)
Outcome difference (95% CI)	0.11 (0.02; 0.21)	0.04 (−0.01; 0.09)
Incremental cost/dmft/no decay gained	Water fluoridation dominates	Water fluoridation dominates
Incremental net monetary benefit (95 percentile) WTPT = £1000	£173 (£71; £280)	£101 (£35; £167)
Probability water fluoridation cost-effective if WTPT = £1000	100%	100%
Incremental net monetary benefit (95 percentile) WTPT = £20000	£2308 (£514; £4072)	£896 (−£35; £1842)
Probability water fluoridation cost-effective if WTPT = £20000	99%	97%

Abbreviations: CI, Confidence Interval, WTPT, Willingness to Pay Threshold.
*Imputed data.

of the York and MRC systematic reviews of the effectiveness of water fluoridation over 20 years ago. The study sought to directly address study weaknesses identified in those systematic reviews and in the subsequent Cochrane Systematic Review.[8–10,15] A recent scoping review identified several weaknesses in the body of evidence, including the lack of cost-utility analysis, the measurement of outcomes in terms of clinical or monetary outcomes rather than health-related quality of life and insufficient geographic coverage.[11] The UK-based studies were conducted prior to the widespread use of fluoride toothpaste and the notable decline in the occurrence of dental cavities in the UK.[12,13] The study addresses gaps by analysing the impacts of water fluoridation on health-related quality of life, enabling cost-utility analyses, and over a more recent time period.

While this study has strengths, there are also limitations to acknowledge. First, the use of generic health-related quality of life measures for a dental intervention may not be the most appropriate outcome measure when considering cost-effectiveness due to the potential for this to be insensitive to changes in oral health. In the last two decades, the appropriateness of relating health-related quality of life to oral health has been largely endorsed, with the development and validation of site-specific oral health-related quality of life (OHRQoL) measures for adults and children, such as the Oral Health Impact Profile (OHIP)[35] and the Child Perceptions Questionnaire (CPQ)[36] for children. However, the CHU9D shows potential as an outcome measure when compared to the CPQ in children attending a dental examination in New Zealand.[37] In addition, the chosen approach was taken to meet NICE conventions and to assist in comparisons to other public health interventions not limited to dental health. Further research could broaden the approaches taken here to include more relevant metrics such as cost per tooth saved or cost of keeping a child caries free.

Second, the long-term impacts of water fluoridation need to be examined.

Third, the primary analysis in the health economics analyses is the CCA (complete case analysis). This is rarely sufficient in trials.[32] However, there are certain features of this study that help explain why MCAR is an appropriate missing data mechanism. First, there was only one follow-up time point in the data for the collection of both child health utility and cost data. Second, missing cost data were the result of a third party (the NHS), and not due to reporting of children or patients, the rates of missing NHS data were similar across fluoridation groups and did not appear to be associated with baseline covariates or outcomes.

Fourth, missing child health utility in the birth cohort was mitigated due to the assumption of equal health at baseline, and for the older school cohort by providing the questionnaire at the time of the follow-up examinations. Sensitivity analyses where the missing data mechanism was assumed to be MAR helps support the MCAR approach, with minimal impact on the cost-effectiveness inference for both the birth and older school cohorts.

Fifth, while costs and outcome data are presented at 2014 values, it is recognized that parameters within cost-effectiveness studies go out of date so decision-makers need to be aware that if a study was repeated today there may be differences in costs and health outcomes.[38]

Sixth, the current work only considers the *benefits* of water fluoridation and has not considered the only broadly accepted *risk* of water fluoridation, fluorosis. This is due to the birth cohort examinations concluding at 5 years of age, whereas fluorosis examinations are typically conduction around 12 years of age when the anterior permanent teeth are erupted. Given the high levels of caries free individuals in the population, it is essential that an assessment of fluorosis is undertaken to enable the very modest benefits seen in this study to be placed into context, again providing policy makers with all the information required to inform decision-making.

Seventh, UDA, the measure of dental treatment, reflects a grouping of treatments. It was not possible to identify whether there were differences in preventative activity occurring between dentists in the fluoridated or non-fluoridated groups. However, the guidance for dentists was universal across the two areas: 'Fluoride varnish is one of the best options for increasing the availability of topical fluoride regardless of the levels of fluoride in any water supply' [footnote 14].[39]

Finally, missing data related to dental treatment were assumed to reflect issues with NHS reporting rather than reflecting non-use. The 2013 Child Health Survey found only 6% of 5-year-olds and 1% of 8-year-olds had never been to the dentist (0% by age 12).[40] Non-use is thus likely to explain only a fraction of the missing data. It is possible children attended a private dentist though this was not identifiable in the data.

A recent scoping review concluded that the evidence suggests water fluoridation was likely to be cost-effective, with this finding being consistent over a range of economic evaluation approaches and geographies.[11] The current study also demonstrates that water fluoridation is likely to be a cost-effective strategy, though the impacts on quality of life are negligible in the cohorts studied with cost-effectiveness largely being driven by relative lower costs. The finding of reduced caries in the analyses of clinical outcomes is in line with previous studies.

The study provides several insights into the costs and practicalities of water fluoridation for policymakers. The decision over who should fund water fluoridation may be informed by the findings from this study which indicate that the capital and running costs associated with water fluoridation constitute only a minor proportion of cost of dental care. At £14.14 per capita, this amount is 36% and 16% of the cost reduction of NHS dental services for the birth and school cohorts, respectively, and reduced dental costs more than offset the cost of water fluoridation. Restricting the study perspective exclusively to the NHS would only reinforce the dominance found for water fluoridation.

In the years 2014 and 2016, a third party covered a portion of the running costs. The exact proportion remains unknown, but assuming that the total running costs for these years equalled that of 2015 (£100598.55), the resulting increase in per capita costs would be approximately £0.73 and £5.59 for all ages and individuals aged 0–12, respectively.

While the study finds that water fluoridation is likely to be cost-effective, in the analyses of QALYs the probabilities range from 62% to 92%, policymakers need to consider this range, alternatively phrased, there is an 8–38% likelihood that water fluoridation is not cost-effective. Where decision-making criteria are based on clinical outcomes, the study suggests a greater likelihood of cost-effectiveness, ranging from (84–99) %.

There are a number of unanswered questions that future research could explore. Future research should develop a decision-analytic model, to determine the cost-effectiveness of fluoridation over a longer time horizon. This should incorporate data from the current NIHR funded programme, LOTUS, evaluating the impact of fluoridation in adults; as well as expert knowledge elicitation methods in areas where there is data paucity.[41]

The approach to apportioning water fluoridation cost in this study has been conservative, with an assumption of a capital life of 6 years, which is likely to overstate the cost for the water fluoridation group. Additional sensitivity analyses could explore allocating a longer lifetime for capital, though this would only increase the probability of cost-effectiveness by decreasing costs for children in the fluoridated group.

While this within-study evaluation finds evidence that water fluoridation is likely to be cost-effective, the study does not inform potential impacts on the adult population, nor does it incorporate potential adverse effects such as fluorosis. Evaluations of the impacts of water fluoridation of adults and the lifetime effect of water fluoridation are needed. There is the potential that water fluoridation has the potential to benefit adults as they retain their teeth into older age. Further research is required to complete health economic modelling beyond the ages observed in the cohorts.

The impacts of water fluoridation on inequalities were highlighted as a need for further research in the MRC Working Party Report, Water Fluoridation and Health.[9] The small samples in the analyses restrict the potential to explore sub-group analyses, particularly around deprivation. Under a larger sample, this would be an informative approach for a future study to explore.

5 | CONCLUSION

This analysis provides economic evidence that the intervention is likely to be cost-effective for children with probabilities greater than

62%. The study equips policymakers with contemporary evidence and the use of health-related quality of life outcome measures facilitate comparative assessments with other interventions using generic measures of health as outcome measures. However, the potential for water fluoridation to reduce inequalities in health and oral health needs exploring, and the long-term effects of water fluoridation beyond childhood need to be better understood, particularly in relation to potential impacts of fluorosis.

AUTHOR CONTRIBUTIONS

All authors made substantial contributions to conception and design, or acquisition of data, analysis and interpretation of data, all were involved in the drafting of the manuscript or revising it critically for important intellectual content, and all authors approved the final version to be published.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests.

DATA AVAILABILITY STATEMENT

The CATFISH study investigators are committed to furthering research by sharing where possible participant data. However, we are unable to share data for this project given participants were informed the only people to have access to the information are the scientists involved in the study. Therefore, we are unable to provide access to data within a repository given ethics approval, consent and information provided to participants. We cannot share third party data from NHS Business Service Authority (NHS BSA) for legal and ethical reasons. Interested parties can request data from NHS BSA but would need to seek appropriate permission and consent.

CONSENT FOR PUBLICATION

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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