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Predictive tool for estimating the potential effect of water fluoridation on dental caries

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Objective To provide a tool for public health planners to estimate the potential improvement in dental caries in children that might be expected in a region if its water supply were to be fluoridated. ***Basic Research Design*** Recent BASCD (British Association for the Study of Community Dentistry) dental epidemiological data for caries in 5- and 11-year-old children in English primary care trusts in fluoridated and non-fluoridated areas were analysed to estimate absolute and relative improvement in dmft/DMFT and caries-free measures observed in England. Where data were sufficient for testing significance this analysis included the effect of different levels of deprivation. ***Results*** A table of observed improvements was produced, together with an example of how that table can be used as a tool for estimating the expected improvement in caries in any specific region of England. Observed absolute improvements and 95% confidence intervals were: for 5-year-olds reduction in mean dmft 0.56 (0.38, 0.74) for IMD 12, 0.73 (0.60, 0.85) for IMD 20, and 0.94 (0.76, 1.12) for IMD 30, with 12% (9%, 14%) more children free of caries; for 11-year-olds reduction in mean DMFT 0.12 (0.04, 0.20) for IMD 12, 0.19 (0.13, 0.26) for IMD 20, 0.29 (0.18, 0.40) and for IMD 30, with 8% (5%, 11%) more children free from caries. ***Conclusions*** The BASCD data taken together with a deprivation measure are capable of yielding an age-specific, 'intention to treat' model of water fluoridation that can be used to estimate the potential effect on caries levels of a notional new fluoridation scheme in an English region.

Key words: Caries prediction, dental caries, deprivation, predictive tool, water fluoridation.

Introduction

In the United Kingdom (UK), despite improvements in the permanent dentition, dental caries remains a significant public health problem (Peterson, 2003). Decay experience in the primary dentition of 5-year-olds has not changed for 20 years (Pitts *et al.*, 2005). Inequalities in dental disease prevalence and severity persist, with more caries experienced by children, especially younger children, in lower socio-economic groups (Steele and Lader, 2004). Many studies have demonstrated the close association between deprivation and dental caries, no matter how deprivation is measured (Locker, 2000). The disease has a significant impact on the quality of life of children and their families (Milsom *et al.*, 2002) and makes a significant contribution to the costs of UK National Health Service (NHS) dental services.

Dental caries is most effectively prevented and controlled at population level through public health interventions such as water fluoridation. Water fluoridation has been described as the most cost-effective means of improving dental caries levels (Horowitz, 1996) and evidence suggests that it has an effect over and above that of fluoridated toothpaste (McDonagh *et al.*, 2000), the most common source of population exposure to fluoride salts. With enactment by Parliament of the Water Act (2003), water fluoridation is now an option for local health authorities in England to consider. Therefore, a tool to predict the expected benefits of water fluoridation on dental caries in populations with known baseline disease levels would be useful for public health planners.

The authoritative York systematic review of water fluoridation (McDonagh *et al.*, 2000) concluded that it resulted, approximately, in an additional 15% of children having no evidence of tooth decay with an average of 2.3 fewer teeth affected. These estimates of effectiveness might be considered as a predictive tool for the effect of water fluoridation, but suffer serious shortcomings for that purpose. These medians were obtained using different ages of children, aggregating data on primary and permanent dentition, and combining studies from disparate regions of the world. This is acceptable for a rough estimate of the effect of fluoridation on caries in a population, but will conceal any variations with age or between primary and permanent teeth. More significantly, these estimates (or any other estimates which are simple constants) logically cannot apply to very different populations, and certainly where mean dmft is less than 2.3 or where 85% of children are caries-free (CF). It might, therefore, be reasonable to expect that a more satisfactory tool would show a variation in improvement related to the baseline caries measures.

Jones *et al.* (1997) and Riley *et al.* (1999), using regression techniques, demonstrated that the effect of water fluoridation in reducing caries was significantly related to socioeconomic status with the relatively greater benefit accruing to the lower socioeconomic (SES) strata of a child population, i.e., those with the higher experience of the disease. Whilst many factors are known to modify the effect of fluoridation – population movement, halo effects, consistency in delivery of the agent, for example – SES of the target population is probably the most sali-

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ent as well as being the most readily measurable. For this reason it was determined that SES of the notional target population must be included in any predictor of the effect of fluoridation.

The aim of this observational, cross-sectional, ecological study was to estimate the potential effect of water fluoridation in English primary care trusts (PCTs) on improvement in caries experience and percentage of children who have no experience of caries for various levels of SES, using national dental epidemiological survey data.

Methods

Data sources

Data from the NHS national programme of dental epidemiological surveys co-ordinated by the British Association for the Study of Community Dentistry (BASCD) of 5-year-old children in 2003-4 and 11-year-old children in 2004-5 in England were used as source data (Pitts *et al.*, 2005, 2006). In these nationwide surveys caries prevalence and experience are recorded at the clinically important cavitation level (so called 'obvious' caries). The surveys were conducted in state schools in each PCT using a prescribed sampling procedure (Pine *et al.*, 1997) and involved the collection of data by trained and calibrated examiners under standardised conditions (Mitropoulos, 1992). The populations of schoolchildren sampled were from schools within those areas and the majority were likely to have been resident within the PCT's geographical boundaries. Data collected from different areas of the country are therefore directly comparable. PCT level Index of Multiple Deprivation (IMD) scores (Office of the Deputy Prime Minister, 2004) were obtained from the Eastern Region Public Health Observatory (ERPHO) for the PCTs as configured in the BASCD dental surveys (based on PCT boundaries as they existed on 31 December 2002).

Data on the percentage of the population of each PCT with access to fluoridated water were taken from the British Fluoridation Society (2006) report. Where at least half the population of a PCT had access to fluoridated water, the PCT catchment area was classified as fluoridated (F PCT). Non-F PCTs were classified as those where under half had such access or the PCT was recorded as having a 'natural variable low level' or 'natural variable' level of fluoride. Data for 5-year-olds were abstracted from 267 PCTs with identified IMD values which comprised 34 F PCTs and 233 non-F PCTs. Data for 11-year-olds comprised 246 PCTs with identified IMD values consisting of 33 F PCTs and 213 non-F PCTs.

Statistical analysis

Scatter plots with regression lines were generated to show the relationship between both IMD and water fluoridation status and mean dmft for 5-year-olds. The association between these data was investigated by regression analysis using STATA statistics data analysis package. Fluoride status, IMD and the interaction between them were fitted to predict mean dmft. A quadratic term in IMD was also included in the model (IMD^2) to test whether the association between IMD and dmft (IMD^2) was linear, together with its interaction with fluoride status. The interaction terms were removed from the model if they were not statistically significant. Age was also included in the model as a potential confounder. Since the variance of dmft increased with IMD, two approaches were used to improve the reliability of the estimates:

- Robust standard errors were used to allow for the heteroskedasticity
- The analysis was repeated using log dmft as the outcome variable (since this did not show heteroskedasticity.)

Each observation was weighted by the size of the sample to improve the efficiency of the estimates. Q-Q plots were used to assess the normality of the residuals from the regression models. These procedures were repeated for caries experience of 11-year-olds.

A similar procedure was followed using the proportion of children who were caries-free (CF) as the outcome variable. In this case, the weights applied to each sample were

$$n / (p (1 - p))$$

where n is the sample size and p the prevalence of CF in that PCT, to allow for the effects of both the sample size and the prevalence of caries-free on the precision of each estimate.

The absolute difference in CF between non-F and F PCTs was investigated. Again these procedures were repeated for 11-year-olds.

Results

Fig. 1 shows the scatter plots and regression lines for the mean dmft and IMD for F and non-F PCTs for 5-year-olds, with the regression equation coefficients given in Table 1. The regression models were restricted to PCTs with IMD less than 45, since above this value the data were sparse and there were some highly influential points. dmft was lower in the F PCTs, with the difference between F and non-F PCTs being greater at higher levels of IMD. Fig. 1 indicates that the predicted values, and hence expected effect of fluoridation, from both the dmft and log-dmft models were very similar.

Since the absolute difference between F and non-F PCTs depends on the IMD of the PCT, and a confidence interval for the effect at a particular value of IMD cannot be calculated from the regression equation alone, the calculations have been performed at representative values of 12, 20 and 30: see Table 2. In the first group of data columns in Table 2, the absolute difference in caries experience between non-F and F PCTs for different IMD values for 5 and 11-year-olds is shown. Absolute difference is defined here as the subtraction of the predicted value of dmft/DMFT in the non-F PCTs from the predicted value at the same level of IMD in the F PCTs. The 95% CIs for the absolute differences in mean dmft/DMFT between F and non-F PCTs suggested that these were unlikely to have occurred by chance. The improvement (reduction) in dmft/DMFT was greater in more deprived areas, where dmft/DMFT was higher initially.

The relative difference can be calculated directly from Table 1 (the predicted dmft/DMFT in the F PCTs

Table 1. Coefficients from regression equations.

Decimal places	variable	5-year-olds dmft raw data	5-year-olds dmft log transformed	5-year-olds % caries-free raw data	5-year-olds % caries-free log transformed
3	F-status	-0.306 (-0.623 to 0.011)	-0.622 (-0.730 to -0.515)	12.47 (9.773 to 15.176)	0.207 (0.161 to 0.253)
4	F-status * IMD	-0.0211 (-0.0349 to -0.0072)			
4	IMD	0.0960 (0.0637 to 0.1283)	0.0646 (0.0440 to 0.0852)	-1.704 (-2.2820 to -1.1260)	-0.0283 (-0.0387 to -0.0180)
5	IMD^2	-0.00117 (-0.00188 to -0.00046)	-0.00082 (-0.00126 to -0.00038)	0.0221 (0.00913 to 0.03498)	0.000365 (0.00014 to 0.00060)

		11-year-olds DMFT raw data	11-year-olds DMFT log transformed	11-year-olds % caries-free raw data	11-year-olds % caries-free log transformed
3	F-status	-0.050 (-0.239 to 0.139)	-0.400 (-0.526 to -0.273)	7.706 (4.610 to 10.802)	0.116 (0.0692 to 0.1621)
4	F-status * IMD	-0.0082 (-0.0169 - 0.0005)			
4	IMD	0.0321 (0.0109 to 0.0533)	0.0568 (0.0258 to 0.0877)	-1.2530 (-2.0200 to -0.4850)	-0.0177 (-0.0292 to -0.0062)
5	IMD^2	-0.00039 (-0.000900 to 0.000122)	-0.00080 (-0.00151 to -0.00009)	0.01700 (-0.00114 to 0.03515)	0.00023 (-4.26e-05 to 5.05e-04)

A quadratic term in IMD was also included in the model (IMD^2) to test whether the association between IMD and dmft was linear.

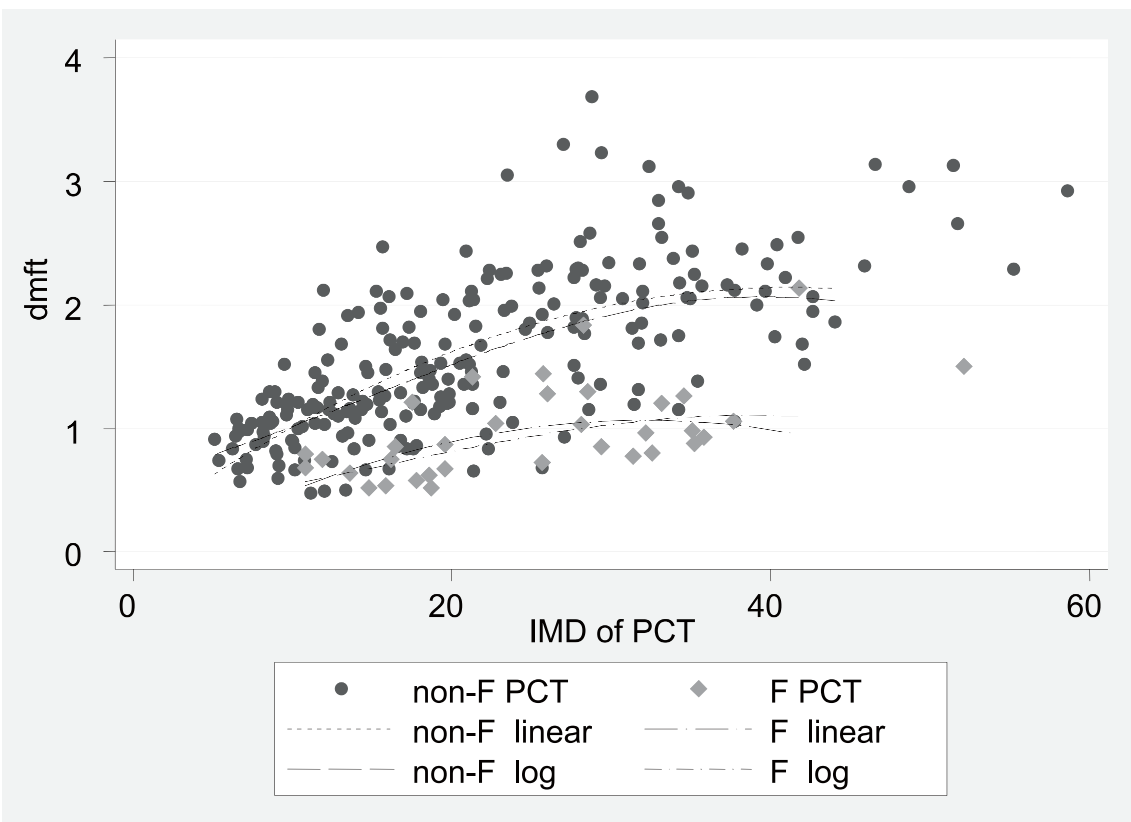

Figure 1. *Scatter plot and regression lines for dmft in 5-year-olds in F and non-F PCTs*

is e^{β} times the predicted dmft/DMFT in the non-F PCTS, where β is the coefficient from the regression model). Fig. 1 shows that the two models produced very similar predicted values: if the relative reduction from the log-transformed model were converted to an absolute reduction (which would depend on IMD), it would be similar to that given in Table 2.

Fig. 2 shows the scatter plot and regression lines for percentage CF for 5-year-olds and IMD for F and non-F PCTs. The interaction between IMD and fluoridation status was not significant for 5- and 11-year-olds so this term was omitted from the regression model when the association between CF and fluoridation status was investigated. The overall (absolute) improvement in the

Table 2. A tool for estimating improvement in dental caries due to water fluoridation

		absolute improvement		*relative improvement*		*values over all non-F PCTs*	
	IMD	*dmft/DMFT change*	*95% CI*	*change*	*95% CI*	*mean caries value*	*range of caries values*
dmft (5-yr-olds)	12	-0.56	-0.74 to -0.38				
	20	-0.73	-0.85 to -0.60	-46%	-52% to -40%	1.58	0.47 to 3.69
	30	-0.94	-1.12 to -0.76				
caries-free (5-yr-olds)		12%	9% to 14%			60%	30% to 83%
DMFT (11-yr-olds)	12	-0.12	-0.20 to -0.04				
	20	-0.19	-0.26 to -0.13	-33%	-41% to -24%	0.67	0.19 to 1.32
	30	-0.29	-0.40 to -0.18				
caries-free (11–yr-olds)		8%	5% to 11 %			68%	46% to 88%

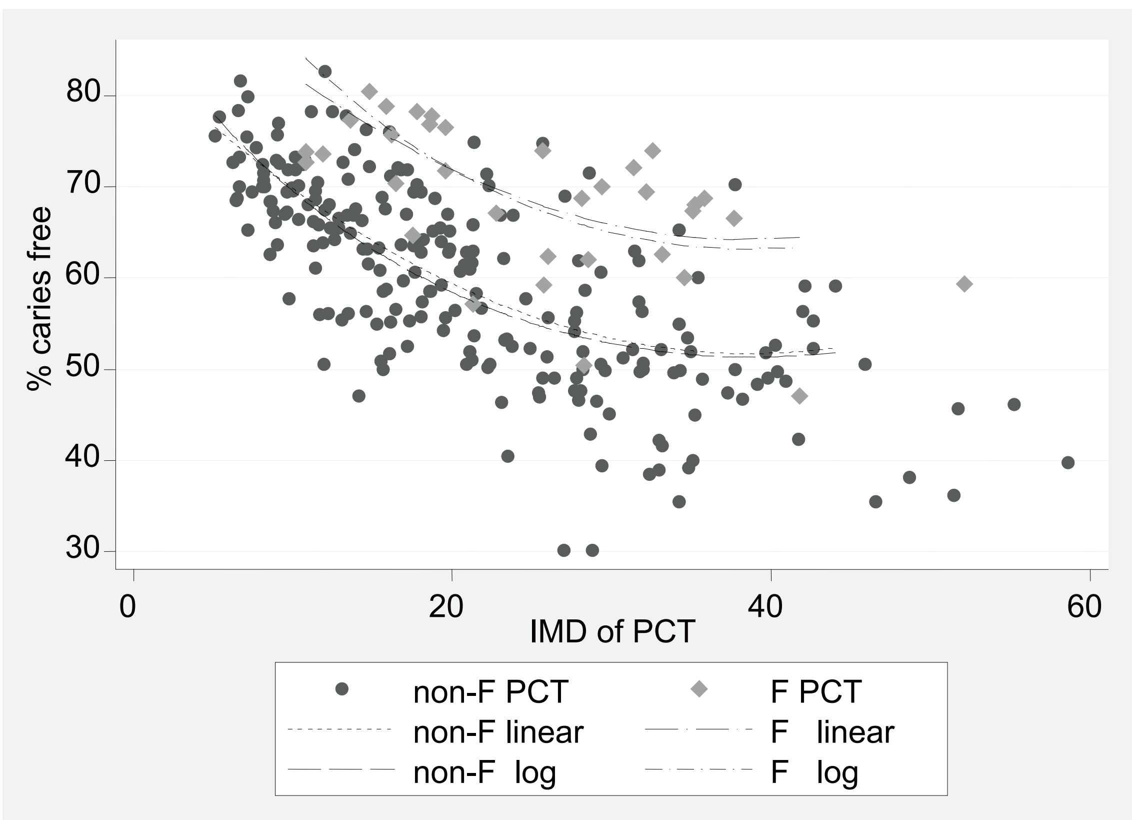

Figure 2. *Scatter plot and regression lines for caries-free in 5-year-olds in F and non-F PCTs*

percentage of CF children between non-F and F PCTs is given in the first group of data columns in Table 2.

The final data columns in Table 2 give the mean and range of values of the various caries measures over all the non-F PCTs: this represents the levels of caries in today's child population in England without the benefit of water fluoridation.

Discussion

The very extensive data set, covering all PCTs in England with identified IMD values and involving measurement of over 150,000 5-year-old and around 100,000 11-year-old children permitted an empirical study of the potential effect of water fluoridation on dental caries. The purpose was pragmatic as a piece of health services research intended for health service planners and designed to produce 'intention to treat' estimates of the expected effect of fluoridation on dental caries. It was not designed to demonstrate the effect of water fluoridation *per se*. Evidence of cause and effect cannot be deduced from an ecological study.

It could be argued that such an approach fails to provide validity of effectiveness since there is no randomisation of subjects to fluoridated and non-fluoridated areas and inadequate control of confounding factors that are recognised determinants for dental caries; instead the randomised controlled trial (RCT) would be the design of choice. However a RCT would be inappropriate and impracticable for investigating a public health strategy such as water fluoridation. Therefore, other approaches using non-randomised studies such as observational, cross-sectional studies should not be denigrated but viewed as the best available evidence (Downer, 2007). Indeed, Glasziou (2004) has noted that much of clinical and public health knowledge comes from observational research. There is an increasing recognition of the role of non-randomised studies for the assessment of effectiveness, when RCTs simply do not exist and are not possible to conduct (Deeks et *al.,* 2003).

Confounding factors and effect modifiers have, as far as possible within the limitations of the data sources, been taken into account, notably the important effects of age, dentition, social class and location. The data lack controls for, or measurements of, confounding factors such as migration, and other known (or unknown) variables that might have an effect on dental caries, e.g. access to dental treatment, sugar consumption, use of fluoride toothpaste and other fluoride products, and which also differ between the F and non-F PCTs. The observed differences may reflect this confounding in addition to the true effect of fluoridation.

Some of the sources of confounding in the data we can be confident will tend to underestimate the effect of fluoridation. The percentage of the population in a PCT with access to fluoridated water cited in the British Fluoridation Society (2006) report is a customarily used reference for these data, albeit an approximation. The report does not include the fluoride concentration in the water supplies. The assumption has been made that the concentrations in water supplies in the areas of PCTs that are listed as fluoridated are all similar, between the permitted range of 0.7 to 1.2 mg/l of fluoride. If areas with lower concentrations were included, then this study will under-estimate the effect of fluoridation. Moreover, non-F PCTs will contain natural fluoride in the drinking water, albeit at a sub-optimal concentration to have a measurable therapeutic dental benefit. This would contribute similarly to reducing the differential effect of fluoridation between fluoridated and non-fluoridated PCTs. These factors would tend to produce an underestimate for the effect of water fluoridation. Further, categorisation of fluoride from a continuous variable to fluoridated and non-fluoridated categories can lead to bias and this bias is likely to be towards the null. Further, this bias will depend on whether there is a dose-response effect of fluoride on dental health. However, if there is a threshold effect, and we categorise at the threshold, the effect size need not be biased.

A number of PCTs are partially fluoridated. There is no information about whether the children measured were drawn proportionally from fluoridated and non-fluoridated areas within PCTs. The effect of designating a PCT fluoridated which has 50% or more of its population with access to fluoridated water is again to reduce the estimates of effect and the statistical significance.

Table 3. An example of the use of the tool

Example PCT has IMD 40, 5-year-olds have mean dmft 1.75, CF 53%, and 11-year-olds have mean DMFT 1.05, CF 52%.

Absolute improvements in dmft/DMFT increase consistently with IMD for IMD 12, 20, 30; there is no reason to expect this to reverse. Therefore we can take IMD 30 (the nearest below 40 in the table) and expect an improvement no worse than will be predicted for the reduced IMD.

For 5-year-olds:

- estimate 1 (by absolute improvement): dmft 1.75 should improve by 0.94 to dmft 0.81
- estimate 2 (by relative improvement): dmft 1.75 should improve by 46% to dmft 0.95

Take the poorer improvement: we would expect dmft to improve to less than 0.95

Improvement in CF at age 5 should be from 53% to 65%

Similarly DMFT at age 11 should improve from 1.05 to 0.76 or 0.70 – i.e. to less than 0.76

Improvement in CF for 11-year-olds should improve from 52% to 60%

The dental survey data do not take any account of the period of residency in F and non-F PCTs. There will have been natural migration between F and non-F areas. Again this is likely to have caused under-estimation of the effect of fluoridation since, in the UK, more than 90% of the population reside in non-fluoride areas while incomers from elsewhere - apart, notably, from migrants from the Republic of Ireland - are also more likely to have come from a fluoride deficient locality than one with an optimum fluoride level in the water supplies.

Another potential confounding factor is that the subjects' places of residence may not coincide with their schools' postcode areas (the IMD index uses postcodes). However, an analysis of data from the census BASCD epidemiological survey of the dental health of 5-6-year-olds conducted in 2005/6 (Pitts *et al*., 2007) in the city of Bristol, indicated that of the 77% of children with verifiable postcodes, two-thirds lived in the same ward as the school they attended. For those who lived in a district outside the postcode of the school, it is unlikely, on the whole, that this neighbouring postal district would receive a different water supply from that of the school.

However, the effect of fluoridation may also be overestimated due to confounding by unmeasured variables: for example, if sugar consumption tended to be higher in non-F PCTs at a given level of IMD. A more likely source of overestimation is measurement imprecision in measuring deprivation: if our measure of deprivation is imperfect, it is likely to underestimate the strength of the association between IMD and the outcomes, and hence adjusting for it will not remove all the association, giving rise to 'residual confounding'.

Despite the acknowledged shortcomings in the data, it is suggested that the estimates provided can give more dependable and useful data for predicting potential reductions in dental caries that would result from fluoridating a population's water supply than can the results of the York systematic review (McDonagh *et al*., 2000). The absolute reduction of teeth affected by dental decay is less than the estimates from the latter review. This reflects the general improvement in child oral health compared with the oral health of populations used in the York review. The absolute improvement in the percentage of the child population not affected by caries is also less than the York estimate, particularly for 11-year-olds. The results from the current study would allow public health planners to estimate the benefits on caries of water fluoridation for modern populations. A worked example is given in Table 3. It should be noted that whenever two estimates are available, it has been taken as the lower of the absolute and the relative effect. Therefore, the findings are conservative: the effect of fluoridation may well be greater than that estimated.

Further analysis could enable power calculations of required sample sizes needed to reject null hypotheses that water fluoridation has no effect. Moreover, for example, in a prospective cohort study of any projected new fluoridation scheme (Downer and Blinkhorn, 2007) carried out according to the recommendations of the York review (McDonagh *et al*., 2000) such analysis might enable estimations of the required sample size to be made within each stratum of SES of the notional child target population.

The absolute estimated effect of water fluoridation on caries experience varies with deprivation, therefore also with baseline caries experience, with the largest effect in PCTs with the highest IMD values and poorest dental health. This differential effect of water fluoridation provides evidence that it does reduce inequalities in dental health across social classes. Although there was a higher proportion of children who were free of caries in F PCTs compared with non-F PCTs, a greater benefit was not demonstrated in PCTs with the highest IMD values. This is in line with the findings from the York review.

There are important considerations for generalisation to other countries. This could be a problematic exercise given their economic and cultural differences from the UK. The UK has a compulsory ten-yearly census, producing high quality small area measures of deprivation. In addition, the UK has well co-ordinated national dental epidemiological surveys giving a large, reliable data set for population studies of caries (Downer *et al.*, 2005). The development of the predictive tool is also dependent on the availability of the deprivation measure being mapped to the same area used in the dental surveys. This may not be reproducible in countries where the database is not so well established, or where the majority of the population is covered by water fluoridation, as the effect of water fluoridation will not be locally discrete.

The predictions of this tool need to be compared, when data become available, with empirical measurements. Consideration should now be given to introducing new water fluoridation schemes for populations with high material and social deprivation and undertaking high quality evaluations of their effect. The model described is capable of producing useful estimates of the potential benefit of new fluoridation schemes in terms of reduced dental disease.

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