

# Investigation of bias related to non-return of consent for a dental epidemiological survey of caries among five-year-olds

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Estimates of caries levels derived from an epidemiological survey of five-year-olds in England were lower than expected. This survey used, for the first time, a consent method which involved parents providing positive, written consent for their child to be included in the survey. This contrasted to the previous method when negative consent was used. **Aim:** To interrogate the dataset to try and establish the reasons for the lower than expected estimates and explore the effect of non-return of parental consent, including the role of deprivation. **Basic research design:** Statistical analysis of an existing dataset and a sub-set of this dataset. **Main outcome measures:** Estimates of caries prevalence and severity in groups and sub-groups of a population-based, random sample of five-year-olds. **Results:** Hypotheses relating to possible changes in the process of data collection and analysis were rejected as reasons for the apparent reduction in disease estimates, as was the impact of oral and general health improvement programmes. Analysis of higher non-return levels on differences between past and current estimates and analysis of the associations between caries estimates, non-consent and summed deprivation measures based on home postcodes showed some relationships between these variables but could not identify a simple relationship. **Conclusion:** There is a more complex relationship between non-return of consent and disease levels than can be explained by deprivation alone.

**Key words:** dental epidemiology, consent bias, socio-demographic indices

## Introduction

Nationally coordinated epidemiological surveys of oral health among child cohorts in the UK have been run using standards set by the British Association for the Study of Community Dentistry (BASCD) for sampling, examination, measurement and reporting since 1987 (Pine *et al.*, 1997; Pitts *et al.*, 1997). These standards previously included using a negative consent method whereby parents were informed of forthcoming examinations taking place in schools and given the opportunity to withdraw their children if they wished to do so (Pine *et al.*, 1997). In May 2006 the Department of Health for England sent out directions that the method of consent should change such that positive, written consent from parents of young children must be sought (Department of Health, 2007).

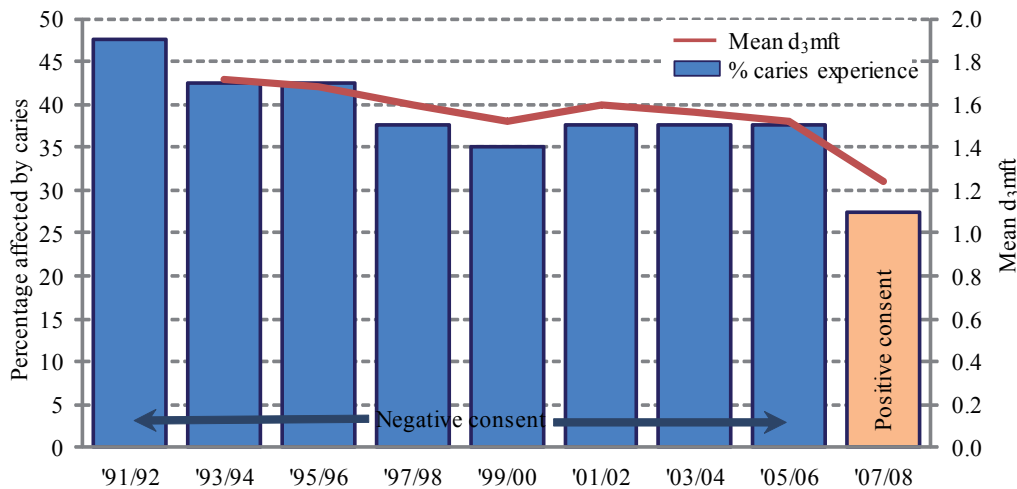
This requirement was fully implemented in the 2007/08 survey of five-year-olds, with parents being sent information about the purpose and nature of the survey. Consent forms accompanied these letters for completion by parents and return to the school. Second letters were sent to parents who had not responded to the first.

Analysis of the data showed that both the severity and the prevalence of caries among this cohort appeared to have reduced significantly (Davies *et al.*, 2011).

Regular caries surveys of five-year-olds in England reveal a slight decline in caries severity and prevalence from 1991 to 2005/06, then an apparently far steeper drop in 2007/08 (Figure 1) (Davies *et al.*, 2011; Pitts *et al.*, 2007). In England the mean  $d_3mft$  for was 1.47 in 2005/06, and 1.11 in 2007/08, representing an apparent

reduction of 24.4%. The proportion of children with caries experience in 2005/06 was 38% and in 2007/08, 31%: a reduction of 7 percentage points and 18.4% in the overall proportion affected. This large apparent reduction could be explained by a real improvement in oral health, a calculation error, a change in examination or measurement criteria or a change in the sample, perhaps as a result of the change in consent requirements. Each of these possibilities has been investigated and reported here.

No single oral health improvement programme implemented in England would have been capable of reducing disease levels in the region of 24.4% in mean severity, or 18.4% in prevalence. The reduction in prevalence of caries experience is higher than could be predicted for implementation of a water fluoridation scheme (Foster *et al.*, 2009), therefore suspicion must be raised about the apparent scale of change. These differences exceed those shown in Scotland where a wide-reaching, high-intensity programme has been running for some time (Davies *et al.*, 2011). No such country-wide interventions have taken place in England during the years preceding the 2007/08 survey. The national 'Brushing for Life' programme provided free fluoride toothpaste for young children in some Primary Care Trusts (PCTs) (Blinkhorn, 2008), yet the apparent reduction in mean  $d_3mft$  appears to affect all. A reduction in the number of brands of children's toothpaste containing low levels of fluoride occurred from mid-2008, following the publication of Delivering Better Oral Health (Department of Health and BASCD, 2009) and children in the survey under scrutiny had been examined prior to this.



**Figure 1.** Mean caries severity ( $d_3mft$ ) and prevalence ( $d_3mft > 0$ ) for five-year-old children in England, 1991 to 2007/08 using BASCD criteria

There has, however, been a political focus to take children out of poverty and considerable activity to support families, for example via the Sure Start initiative. If there was other hard evidence of improvements in health, social or educational outcomes for this cohort it is conceivable that there has been a real, sudden and recent reduction in disease levels. In the absence of these it can only be concluded that real improvements in oral health, if they exist at all in this cohort, cannot explain the large change in caries levels reported in this survey.

Consideration should be given to whether there was a calculation error in all surveys carried out since 1987, or an error in the calculation of the mean  $d_3mft$  for the 2007/08 survey. The calculation of  $d_3mft$  scores is a feature of the Dental SurveyPlus 2 (DSP2) program, used for data collection and analysis, and is inaccessible to change. The DSP2 program has been used for at least four previous surveys and the earlier version of Dental SurveyPlus 2 program was used in the years prior to this. During this time caries levels among five-year-olds have remained comparable. In addition, checking of the components of the  $d_3mft$  index reveals a reduction in all three parts, not just the composite score. On this basis the possibility of calculation error must be disregarded.

The same criteria for initial sampling, examination, caries measurement, recording and reporting have been used since 1987 (Pine *et al.*, 1997; Pitts *et al.*, 1997). The same diagnostic standards have been used and examiners are trained and calibrated on them, using the same gold standard throughout. The same conventions have been applied and made clearer using a national protocol. The initial sampling of schools has been conducted in the same way for all past surveys, so the consideration that the process, other than the change in the method of gaining consent, has caused a change in reported disease levels must be rejected.

The hypothesis is that consent bias, caused by the new requirement that all sampled children must have positive, written consent provided by their parents to be included in the examination, has resulted in a non-representative sample. The view is that parents of children with higher

levels of disease were less likely to provide consent for their inclusion in the survey. Research on postal questionnaire studies has shown that non-responders can have higher caries levels (Tickle *et al.*, 2003). This may have been linked to lifestyle factors that led to higher levels of disease, or parental knowledge that their children had decay and a desire to conceal this. Caries levels of non-responders in this survey are unknown, but socio-economic status could be assigned as home postcodes of responders and non-responders were known.

This paper aims to explore the effect of non-return of parental consent for inclusion in dental surveys on the resulting estimates of caries prevalence and severity and the factors associated with this, including deprivation.

## Method

Caries prevalence surveys of child cohorts have used BASCD standards and processes for many years across the UK. In England these surveys are undertaken within the National Health Service Dental Epidemiology Programme (NHS DEP). They were usually undertaken by all PCTs in England with Community Dental Services providing the fieldwork. Cohorts for scrutiny are agreed by a national network and central training and calibration is provided by BASCD and then cascaded to PCT fieldwork teams in each region by regional coordinators and trainers. Each PCT fieldwork team randomly samples schools according to a standard method and then contacts each sampled school. Schools provide class lists with dates of birth and these are used to identify children whose age would make them eligible to be sampled on a specified examination day. Since 2007, positive, written consent has been sought from the parents or carers of all sampled children. First, request letters are sent to the children's homes and, where no response is received a second request is made. Only children for whom parents or carers have provided positive, written consent are examined, but basic details of all the sampled children are collected.

Once each PCT has completed the examinations the anonymised data are checked, cleaned, sorted and saved using the DSP2 program according to national guidance. Regional Coordinators then upload datasets from each PCT in their region to The Dental Observatory which checks and collates summarised data into a single database for England. Home postcodes are used to assign deprivation scores (Index of Multiple Deprivation, IMD, Communities and Local Government, 2008) and PCT and local authority codes for each case. These data are then analysed to produce a series of measures for each PCT and local authority which are reported on the North West Public Health Observatory website and in other publications.

For the 2007/08 survey further analysis was conducted to assess the impact, direction and magnitude of possible consent bias. If the reduced caries levels are related to consent return levels it would be expected that PCTs with low response levels would have greater suppression of reported disease estimates than PCTs with high response levels. This was tested for one SHA where the differences in mean  $d_3mft$  for each of 12 PCTs between the 2005/06 survey (negative consent) and 2007/08 (positive consent) could be calculated then compared to the PCT's positive consent return levels for the 2007/08 survey. The strength of association was measured using Pearson's correlation coefficient.

The relationships between caries, deprivation and non-consent rates were investigated using summary measures for all PCTs in England. The IMD score was used to classify households into quintiles, from most to least deprived. To investigate further the social factors that are linked with provision of written consent, analyses were also carried out using another index of social grouping: People and Places (Beacon Dodsworth, 2011). This system classifies households using Census data and a range of other measures. The classifications are nominal with a general hierarchy. It is more descriptive

of household type than IMD alone and may assist with identification of communities of particular types which could be predicted to have lower consent return levels.

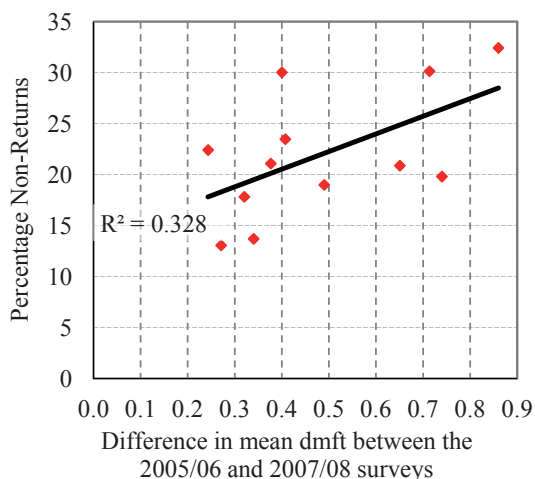
Data were weighted to match the proportions of the actual population, using both IMD and People and Places groupings to investigate the feasibility and utility of using these methods to adjust or 'correct' the data and improve the accuracy of the population estimates.

## Results

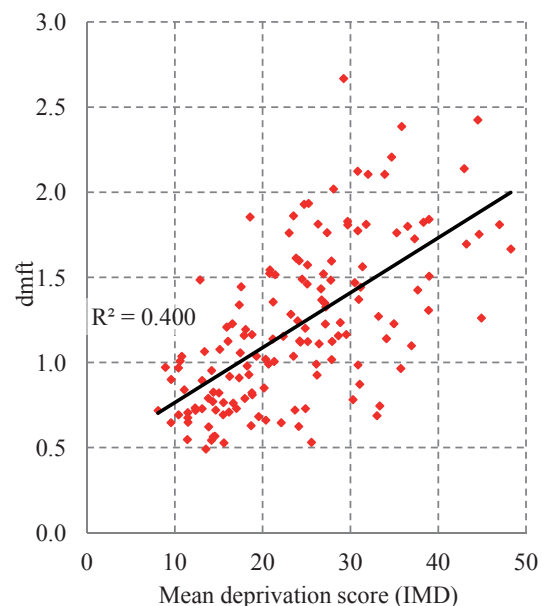
Positive consent was received for 71% of the children sampled in the 2007/08 survey, 5% of parents returned consent forms refusing consent and, for 23% of sampled children no form was returned after two requests. This resulted in 139,727 children examined and included in the final analysis, representing 67% of those sampled and 25% of this age group attending mainstream state schools. This total is 36% lower than the previous survey of five-year-olds when 216,873 children, 42% of the total population of this age group and 87% of those sampled, were examined (Pitts *et al.*, 2007).

The proportion of sampled children who were consented and examined varied between and within Strategic Health Authority (SHA) regions; in London SHA 58% of sampled children were examined while in South Central SHA 75% were examined. Within South West SHA only 24.3% of sampled children were examined in Bournemouth and Poole PCT while 88.6% were examined in Dorset PCT (Davies *et al.*, 2011).

Figure 2 shows the association between the proportion of children within each of 12 PCTs for whom no consent was returned and the difference in mean caries levels between the previous and current surveys. Pearson's correlation coefficient for this association was 0.572 ( $p=0.047$ ), with the range of non-return levels being 14% to 32% and the range of differences in mean severity levels being 0.25 to 0.86  $d_3mft$ .



**Figure 2.** Difference in mean  $d_3mft$  between 2005/06 and 2007/08 survey results for PCTs, by consent return level, North West Region only



**Figure 3.** Mean  $d_3mft$  and mean deprivation scores for five-year-olds by PCT, England 2007/08

Figure 3 shows the relationship between mean PCT  $d_3mft$  values and mean deprivation score of PCTs. The graph shows a significant correlation between caries and deprivation ( $r=0.632$ ,  $p<0.001$ ) This shows the positive association between the two measures and the  $R^2$  value of 0.400 shows that this deprivation score explains 40% of the variation in PCT caries levels.

Figure 4 shows the association between the mean IMD scores and the proportion of non-consenters within each PCT area. This shows that as PCT mean deprivation levels worsen the proportion of non-consenters increases ( $r=0.436$ ,  $p<0.001$ ), although this association is not as strong as that between caries and deprivation, with the IMD explaining 19% of the variation in PCT consent levels. There is considerable scatter above and below the line indicating the relationship.

Figure 5 shows the association between the mean  $d_3mft$  values and the proportion of non-consenters within each PCT area. The graph shows that the mean  $d_3mft$  values slightly increase as non-consent rates increase ( $r=0.25$   $p<0.001$ ). Again, the strength of association is not strong, explaining only 6%, and there is a wide degree of scatter.

The adjustments to the data using IMD and People and Places made very little difference to the estimates. The overall estimate of  $d_3mft$  for England, without adjusting for deprivation, was 1.11. Adjusting using IMD quintiles and People and Places both gave an estimate of 1.14. At individual PCT level, the median adjustment made to the raw value using the IMD analysis was 0.003 (range -0.63 to 0.29), and using the People and Places analysis was -0.002 (range -0.83 to 0.35).

## Discussion

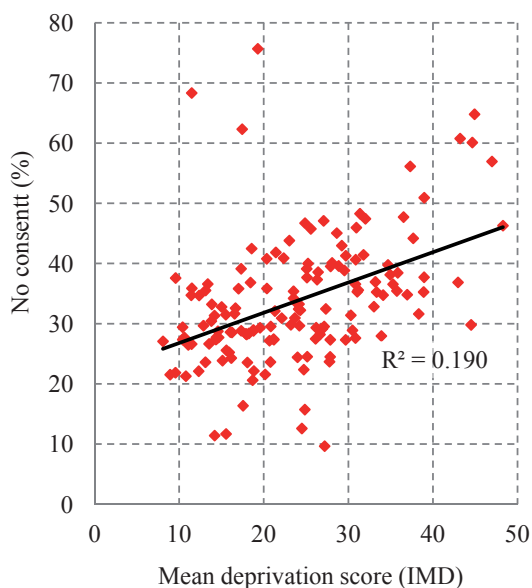
The NHS DEP survey programme provides a valuable source of information which is used by service planners, researchers, health improvement practitioners within health organisations, local and central government. A

change which reduces the value of the data merits investigation as far as possible and the analyses described above summarise the methods that have been undertaken to do this.

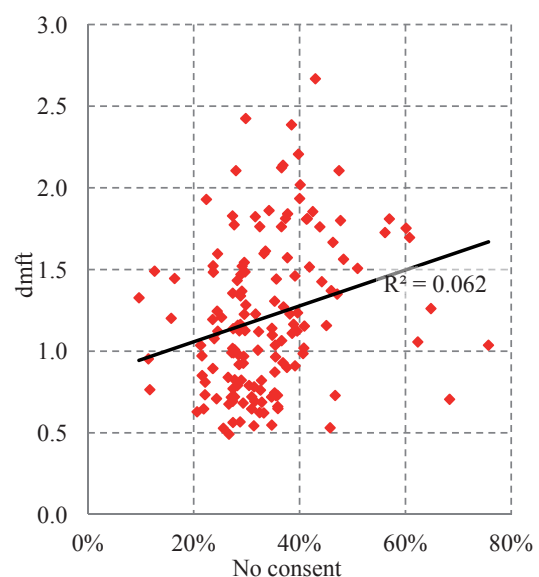
Deeper analyses of the data arising from the first survey in England using a different method of consent revealed an apparent change in the data but were not able to clearly identify any factors biasing the results.

Re-examination of the application of measurement criteria and of the methods of calculation of the  $d_3mft$  index and its components showed that a consistent approach has been used over many years of these surveys and no change had occurred for the 2007/08 survey. If there had been a change in examination method or diagnostic criteria or coding this could have explained a change in resulting caries severity or prevalence levels that would have affected the whole sample. If this had been the case then the impact could probably have been predicted, measured and adjusted for. However, this was not the case. Indeed, the long term consistency has allowed the observation of a reduced level of disease to take place and reasons for it to be investigated.

It should be noted that a lack of consent only rarely came about as a result of parents sending back a form which indicated that they did not want their child to be included. Rather, the majority of non-consenters simply did not return their forms, (23% of children did not return a form). There are a number of possible reasons for this; some parents may have had difficulty understanding the form or replying to it because of reduced literacy skills; some parents may not have looked in school bags so the forms were not seen; some forms may not have been completed or returned because of a lack of motivation, or interest or organisation. Another possibility is that parents who knew their children had poor oral health might have wanted to conceal this fact and therefore did not return the form, thereby withholding consent.



**Figure 4.** Non-consent levels and IMD deprivation scores by PCTs among five-year-olds, England, 2007/08



**Figure 5.** Relationship between mean  $d_3mft$  and proportions of five-year-olds for whom no positive consent was received in PCTs, England, 2007/08



It would have been very useful to have information about features of responders and non-responders. However the only information available about non-consenters was home postcodes, and the key piece of information about their levels of disease cannot be known. Maximum use was made of home postcodes to group responders and non-responders according to two types of socio-demographic indices. These showed the associations between deprivation and caries severity and between deprivation and consent return levels but could not be used to show the link between actual disease levels and consent returns.

Each of the analyses carried out to investigate the relationships between consent, deprivation and disease levels contributed to some understanding of the situation. The analysis that looked into a form of 'dose response' showed that for the 12 PCTs involved the reduction in disease levels between the 2005/2006 results and those for 2007/08 was largest where consent return levels were lowest. As consent return levels reduced so the measured effect of disease level 'suppression' increased. Clearly response levels were having some impact and bias was a definite outcome. This might have been predicted with the assumption that consent forms were less likely to be returned from more deprived households where caries levels might have been expected to be higher. In this way only children with lower levels of disease would have been examined. However this association only explained half of the effect so it likely that another factor, other than a direct link between consent return levels and resulting caries levels, must be involved.

Analysis of the 2007/08 data also showed that caries levels were associated with deprivation, but deprivation alone cannot predict caries levels. It is likely that this is not a direct relationship of cause and effect. The scientific understanding of the cause of caries explains that lifestyle factors such as higher frequency intake of sugar or low frequency exposure to fluoride cause caries to occur and progress, not deprivation itself. Such factors may be more prevalent in more deprived households, but they are not restricted to them so caries can also occur among children living in families which are not classified by their postcode as 'deprived'.

This investigation also found an association between deprivation and provision of positive consent such that in PCTs with higher levels of deprivation non-response levels were higher. However this relationship was not as strong as might be predicted. Within each PCT different norms of behaviour are likely to exist, regardless of deprivation as measured from postcodes, such that the return of forms to school may be more actively undertaken in some areas than others. A recent trial of methods to incentivise consent returns and anecdotal evidence suggests that the influence of the school policy and culture, and the activity of the secretariat, are significant and may be more influential on consent form returns than deprivation or any other factors (Glenny *et al.*, 2013).

Whilst the relationship between consent and caries levels cannot be explained by these postcode-based deprivation measures which are generated at Lower Super Output Area level and used as averages for each PCT, it may be the case that more sensitive measures of deprivation at individual level may explain more of the relationship.

These associations were further investigated by linking non-consent return levels of each PCT and the caries severity measured among those who had consented. This showed that there was a relationship whereby disease severity increased as levels of non-consent increased. This suggested that in areas where families were least likely to return a form to school, disease levels in other children living there were higher than in PCTs where consent return levels were good.

None of these associations were strong enough to allow for modelling or for a correction factor to be employed to weight the data to allow for under-representation of children that were missing because of lack of consent. It is clear that factors other than deprivation are associated with caries and with response or non-response to a request for consent.

Whilst there is a clear association between deprivation, however it is measured, and both the return of positive consent letters and levels of caries it is not possible to measure the magnitude of the effect, nor explain it clearly. The absence of information about non-consenters is a major barrier to doing this. Attempts to weight the information to allow for biased samples due to non-consent based on socio-demographic variables were unsuccessful as there were relatively small proportions of children who live in the more deprived groups. It can be hypothesised that the bias of consent return is associated with factors which are related to lifestyles linked with higher levels of caries, over and above those described by deprivation alone.

Very similar findings and conclusions were drawn from analyses of a survey in Wales which had been similarly affected by a requirement to have positive, written consent from a parent (Monaghan *et al.*, 2011). The authors concluded that caries status could be more important than deprivation as a factor affecting provision of consent. Following this work it has been suggested that an indication of the method of obtaining consent should be shown alongside survey results.

## Conclusions

There is a more complex relationship between consent and disease levels than can be explained by deprivation alone. It would appear that those parents whose children have higher levels of disease are the least likely to have provided positive, written consent and this is not restricted to the most deprived groups. The magnitude of the effects of this hypothesis cannot currently be measured so the current data cannot be used for comparison with past surveys data. In the absence of information about the caries levels of non-responders it is not possible to apply a correction factor to the data.

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