# School-based epidemiological surveys and the impact of positive consent requirements

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**IN BRIEF**

- This paper expands on concerns expressed by an earlier opinion piece on the impact of new consent requirements on dental epidemiological surveys.
- It discusses the importance of survey data in the evidence-based commissioning of dental services and the targetting of oral health promotion.
- It reports the impact of positive consent on the validity of survey findings and implications for uses of the data.

A requirement to obtain positive consent for participants in school-based dental epidemiological surveys was introduced in 2006.[1-3] Concern has been expressed about the impact of the changes on the validity of results as the need to obtain positive consent is likely to reduce the numbers participating.[4] An additional concern is that the new requirement may also lead to samples that are biased, resulting in them being unrepresentative of the population from which they are drawn. This paper aims to discuss the implications of the changes on the quality of future school-based dental epidemiological surveys, and whether they threaten the validity of survey findings at a time when such information is critical in informing the local commissioning of dental services.

## Introduction and background

In the UK, two major groups of epidemiological surveys are undertaken of child dental health. Decennial surveys have been undertaken since 1973 in England and Wales and in the whole of the UK since 1983. These surveys have collected data on a range of cohorts, with the 2003 survey restricted to children aged 5, 8, 12 and 15 years. The second group is those co-ordinated by the British Association for the Study of Community Dentistry (BASCD). These local surveys have been undertaken since 1985, surveying the caries experience of 5-year-olds every other year and older children in the intervening years.

Both groups of surveys strive for high levels of methodological rigour. They provide standardised definitions of diseases surveyed, examiners are trained and calibrated and there are clear guidelines on sampling to ensure those participating are representative of the population from which they are drawn.[5-9] The findings of both are now published online and the BASCD surveys are also published each spring in the journal *Community Dental Health*. Taken together they provide valuable information of the distribution of dental diseases and conditions (particularly caries) and also their trends over time.

The surveys' findings have a wide range of applications. For example, they provide the opportunity to make international comparisons of dental health in children. They have also confirmed the fall in caries experience over the past three decades since the introduction of fluoride toothpaste. At a national and regional level the information on the distribution of caries has been critical when researching and arguing for public health measures such as water fluoridation,[10,11] and will be fundamental when considering the need for new fluoridation schemes.[12] Locally, survey data have been used to identify areas for targeting oral health promotion measures; an approach endorsed by the Department of Health for England.[13] Data from subsequent surveys would also contribute to the evaluation of these programmes. Information on treatment experienced by children has informed the ongoing debate on the restoration of primary teeth.[14,15] Finally, as information on health needs is essential to inform commissioning,[16] survey data will contribute to the evidence-based local commissioning of dental services by Primary Care Organisations (PCOs) in England, Wales and Northern Ireland.

## Changes to the consent requirement

Before 2006 the BASCD coordinated school-based dental epidemiological surveys were undertaken using so-called negative consent as outlined in national guidance.[17] Under these arrangements, parents/guardians were informed that the survey was taking place and given the option to decline their child's involvement - a child would be examined unless such notification was received or if the child refused to be examined. New guidance has superseded this; those administering surveys

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are now required to obtain positive consent from parents/guardians for their child's participation.[1–3] This ordinarily involves sending a consent form home, invariably with the child, for a parent/guardian to sign and to return to the school. A child will only be included in a survey if positive notification is received. However, the requirement is dependent on the age of the child – children of 10/11 years (ie year 6) and older are deemed as competent as long as the process and the purpose of the survey are explained and the child is informed that they can decline involvement if they wish.[1]

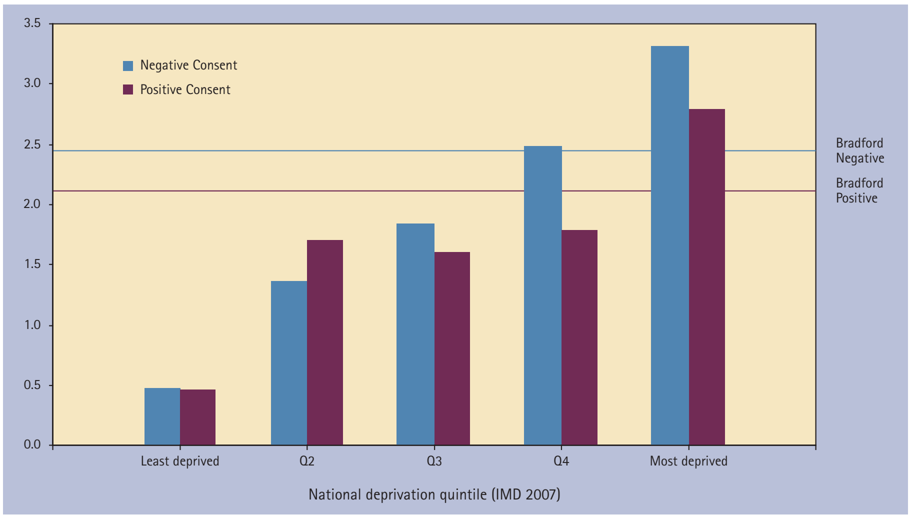

**Fig. 1 Dental decay experience (dmft) of 5-year-old children examined under positive and negative consent for all children and by deprivation quintile in Bradford and Airedale tPCT**

**Table 1 Dental caries experience (dmft) and mean difference with 95% confidence intervals (95% CI) of 5-year-old children examined under positive and negative consent by deprivation quintile in Bradford and Airedale tPCT**

| IMD Quintile | Mean dmft (n) and difference [95% CI] | | | |
|---|---|---|---|---|
| | Negative | Positive | Difference | All children |
| 1 | 0.47 (279) | 0.46 (52) | 0.01 [-0.27, 0.29] | 0.47 (331) |
| 2 | 1.37 (338) | 1.69 (26) | -0.33 [-1.34, 0.68] | 1.39 (364) |
| 3 | 1.83 (454) | 1.59 (138) | 0.24 [-0.26, 0.74] | 1.78 (592) |
| 4 | 2.48 (494) | 1.78 (170) | 0.71 [0.21, 1.2] * | 2.30 (664) |
| 5 | 3.30 (1371) | 2.79 (336) | 0.52 [0.11, 0.92] * | 3.20 (1707) |
| All children | 2.44 (2936) | 2.11 (722) | 0.33 [0.08, 0.58] * | 2.38 (3658) |

*Two-tailed t-test on difference between means (p <0.01)

## The impact of changes to the consent requirement

White and co-workers[4] argued cogently that the introduction of positive consent would not only add to difficulties in achieving acceptable response rates in surveys, but would also increase administrative costs. They cited the adverse effects of positive consent on participation in a study undertaken in Somerset.[18–20] Recent guidance states that where the overall consent rate falls below 25%, consideration should be given to abandoning the survey.[9]

An additional concern is that positive consent may also lead to response bias if some sections of the community are more likely to provide positive consent than others. This would result in study samples that are unrepresentative of the population from which they are drawn. Although synthetic estimates of disease levels can be calculated in such circumstances, the impact of positive consent on response bias is currently unquantifiable. Therefore any synthetic estimation must be interpreted with caution.[21]

The new guidance on consent in England[1] was introduced during the 2005/06 national BASCD coordinated survey of 5-year-olds. Consequently, some schools were surveyed using negative consent and others with positive. This provided the opportunity to test whether positive consent resulted in biased samples. Schools in Bradford and Airedale Teaching Primary Care Trust (tPCT) were identified as being surveyed following a positive or negative consent process and randomly allocated to examiners and scheduled randomly in the survey programme. Owing to the timing of the publication of the guidance, most schools were surveyed under negative consent (Table 1). Data from both groups of schools were analysed with regard to caries experience and socio-economic deprivation, using the decayed missing and filled teeth index (dmft) and the Index of Multiple Deprivation (IMD)[22] for participants' postcodes of residence.

Mean dmft are presented for children surveyed under positive and negative consent and arranged in quintiles of deprivation. Those surveyed under positive consent had lower caries experience and differences tended to be greater in the more socio-economically deprived (Table 1 and Fig. 1). Differences in mean dmft were significantly different in the two most deprived quintiles (p <0.01). When comparing all children, those surveyed under positive consent had on average 13.5% less caries experience than those surveyed under negative consent (mean dmft 2.11 v 2.44, p <0.01).

## Discussion

These data suggest that positive consent requirements may have compromised the validity of the findings of the dental survey in Bradford and Airedale and the effects were more marked in groups where dental caries is most prevalent. The impact in more affluent social groups is unclear due to the low numbers of participants in such groups surveyed under positive consent (Table 1). Bradford has a population with a high proportion of minority ethnic groups, particularly of Pakistani origin. Children of Pakistani descent can have higher levels of caries experience in primary teeth[23,24] and problems of gaining consent for treatment in this group have been reported.[25] It may be that positive consent requirements have unintentionally reduced the numbers of such children in the survey due to cultural and language barriers. Further research into these factors would be beneficial.

Care should be taken when generalising these findings to the rest of the UK, as the sample is unlikely to be representative of the nation as a whole. Nonetheless, they raise questions about the findings of the 2005/06 BASCD survey of 5-year-olds and those of the 2007/08 survey of the same age group completed recently. There are also ramifications for the forthcoming national survey. It is probable that caries experience will be underestimated and particularly in areas of high socio-economic deprivation and certain minority ethnic groups. This will not only compromise the surveillance of disease, but also influence any oral health needs assessments undertaken, the evidenced-based commissioning of local dental services and the effective targeting of health promotion campaigns. For example, a number of PCTs in England are considering the need for fluoridation and Strategic Health Authorities will need to consult about its implementation. In addition, PCTs that have fluoridation schemes are required to survey caries levels as part of monitoring requirements. In both, the validity of survey findings and their comparability over time are critical.

Significantly, recent Department of Health of England guidance for childhood obesity surveillance instructs PCTs to measure all reception year children (aged 4-5 years) and year 6 children (aged 10-11 years) effectively under negative consent arrangements.[26] We support this approach to ensure the validity of the findings. Moreover, given the impact of the consent changes in the dental survey reported here, it is questionable whether obesity surveillance should be introduced if positive consent was required. While a discussion of the importance of consent and the maintenance of autonomy is beyond this article, arguably the risk of harm to children in obesity surveillance (eg stigmatism and bullying)[26] is greater that any potential harm that could be caused during a dental survey; although dental examinations inevitably involve some minor physical contact, they are relatively non-invasive as they only involve visual examination.

Pragmatic approaches to the problem of consent have been discussed by the Department of Education and Skills for England[4] and the Department of Health, Social Services and Public Safety in Northern Ireland.[2] These included obtaining consent from parents/guardians for children's participation in health surveys at school entry but with the option to withdraw consent at any time. However, in England it was concluded that PCTs should make local arrangements rather than establish a national approach.[4] In contrast, the Scottish National Dental Inspection Programme[27] continues under negative consent in line with the Education (Scotland) Act 1980.

## Conclusion

The introduction of positive consent may have compromised the findings of the 2005/06 BASCD coordinated survey of 5-year-olds in Bradford and Airedale and may have had similar effects elsewhere in the UK. This raises questions about the 2007/08 survey completed recently, future surveys conducted under such arrangements and whether retrospective comparisons with earlier data can be made. Problems associated with obtaining positive consent are being recorded as part of the 2007/08 survey.[9] Given the approach adopted for obesity surveillance, if significant problems are reported it would seem reasonable to permit negative consent for dental surveys. At the very least, a formal large-scale study should be undertaken to test whether positive consent biases samples.

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