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Effect of second mailing for consent on child dental survey results

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Introduction: Written parental consent of young children has been required for dental surveys in Wales since 2006. The 2007/08 survey produced much lower caries scores than previous surveys, believed to be associated with low participation of children with caries experience. ***Objective:*** To test the null hypothesis that decay variables from a second mailing of parental consent are no different from those generated from a first mailing. ***Methods:*** Cross-sectional caries (d_3mft) survey of children aged 5-6 during 2011/12. Survey criteria complied with British Association for the Study of Community Dentistry guidance. Comparison of dental epidemiological variables generated from data collected via first and second mailing for consent. ***Results:*** The aggregate d_3mft for all 7,734 children examined was 1.6. The mean d_3mft for the first mailing was 1.5 (6,678 children) compared with a d_3mft of 2.2 (1,056 children) for the second mailing. Equivalent data for d_3mft(d_3mft>0) and %d_3mft>0 were: d_3mft(d_3mft>0) 3.8 first mailing compared with d_3mft(d_3mft>0) 4.1 second mailing; and *%d_3mft>0* 39.5% first mailing compared with %d_3mft>0 54.1% second mailing. Mean d_3mft and %d_3mft>0 showed statistically significant differences. ***Conclusions:*** Null hypothesis is rejected for d_3mft and %d_3mft>0. The findings suggest non-responders to the first mailing do have higher prevalence of decay than responders. To facilitate comparisons of reported decay levels, future surveys using mailed forms for consent purposes should include at least two mailings and report the number of mailings used to facilitate comparisons of reported decay levels.

Key words: *epidemiology, child, dental caries, bias (epidemiology), research design, data collection*

Introduction

Consent processes impact on reported disease levels when individuals (or in the case of young children, their parents) are asked to consent to participate in a survey including a clinical examination. Changes to advice issued by legal advisors to government departments in England and Wales in 2006 on consent for dental surveys have had different impacts for older and younger children. For surveys of children aged 11 and over each child is now provided with information and given the opportunity to consent individually. Work undertaken in Wales on 14- and then 12-year-old children prior to 2006 demonstrated that this approach had little impact on participation rates in the surveys which were typically over 90% (Monaghan and Morgan 2009; Morgan and Monaghan 2010).

The situation is different for younger children. Until 2006, NHS dental surveys of school year 1 (aged 5-6) across the UK examined children unless parents had formally refused participation after a notification letter was sent home (i.e. opt-out). In 2006 for England and Wales this requirement to opt-out was changed to formal written consent (i.e. opt-in) following new legal advice provided to government health departments (Department of Health, 2006; Welsh Assembly Government, 2006). Large scale surveys of dental health are usually undertaken in school settings and most rely upon written communication with parents to provide them with an opportunity to consent or refuse. In the area of health and healthcare use of positive consent for observational studies (Al-Shahi *et al.,* 2005) and use of postal questionnaires can both be associated with non-response bias (Hoeymans *et al.,* 1998; O'Neill *et al.,* 1995). Thus new consent arrangements requiring parents to positively respond to a letter and consent, clearly had potential to introduce non-response bias.

The impact of this change in approach to consent was a sudden and large reduction in both participation rates in the 2007/08 survey and in reported caries incidence in the parts of the UK where the new consent arrangements were required (Davies *et al.,* 2011, Dyer *et al.,* 2008) and has continued to have impact (Monaghan *et al*., 2014, Davies *et al*., 2014). There was sufficient evidence to suggest the hypothesis that parents of children with caries experience were less likely to opt-in to the surveys (Monaghan *et al.,* 2011). In the absence of detailed understanding of the bias introduced it was not possible to reweight results to generate data for 2007/08 directly comparable to 2005/06 data. It was concluded that there was sufficient bias present to invalidate cross border comparison of findings from England and Wales with those from Scotland who still used an opt-out approach (Davies *et al.,* 2011; Monaghan *et al.,* 2011).

The consent process for these surveys relies upon responses to letters, sometimes accompanied by a supplementary questionnaire, sent to the home address. It is known that non-responders to postal questionnaires frequently differ from responders (Hill *et al.,* 1997) and measures such as repeat mailings are recommended (Tickle *et al.,* 2003). Given this knowledge it was decided to design the consent process for the dental survey of school year 1 children (aged 5-6) in Wales to explore whether there was a difference in the caries

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experience of responders to a first and second mailing of the consent form.

For this study the null hypothesis to be tested is that decay variables collected as a result of the second mailing of parental consent are no different from those generated following the first mailing.

Methods

A cross-sectional oral survey of children aged 5-6 (UK school year 1) was undertaken in state-funded schools in Wales between October 2011 and March 2012. The sampling and survey criteria complied with British Association for the Study of Community Dentistry guidance (Pine *et al.,* 1997a; b). The Welsh benchmark examiner attended the UK training event and was calibrated against the UK benchmark. Then 18 examiners in Wales attended a local training event and successfully calibrated.

Findings from the 2005/06 (opt-out) and 2007/08 (opt-in, single mailing) were used to inform the power calculation for this research. It was estimated that the non-responder mean d_3mft was 0.5-1.0 higher than the single mailing findings from 2007/08. Using β of 0.9 and α of 0.05 with a mean d_3mft in 2007/08 of 1.98 and a variance of 3.90 the sample size required for the second mailing was estimated at 640. This was considered achievable at all Wales level given that the sample would include approximately 11,000 children.

The sampling frame for the main survey was designed to sample 250 children from the smallest Unitary Authority in Wales, Merthyr Tydfil (population 58,000). Similar proportions of the school year population were drawn from other Unitary Authorities (local government geographies in Wales). Schools were stratified into smaller and larger schools and then randomly selected. All children in school year 1 in smaller schools were invited to participate and a randomly selected 50% of children in the larger schools. Some 11,461 children were invited to participate, and 7,734 children in 616 schools were examined. Primary schools in Wales are generally small hence an average of 12 children per school. Given the number of schools involved we believe the impacts of clustering on these findings at the all Wales level will be minimal.

Examinations were conducted in the school setting using a light generating 4,000 lux at 1 metre. The threshold for diagnosis of caries was visual sign of caries into dentine (d_3mft) in the deciduous dentition (Pitts and Fyffe, 1988). Missing deciduous incisors were presumed naturally exfoliated. Details of the survey protocol are available online (Monaghan, 2011).

The consent forms were sent to the home address of the child with an addressed and postage paid return envelope. The forms were on white paper for the first mailing and coloured paper for the second mailing. Data, including the response to first or second mailing for consent, was collected locally using Dental SurveyPlus 2 software, and forwarded to the Welsh Oral Health Information Unit. Within the Unit the data were imported into SPSS for data cleaning and analysis. Analysis included comparison of dental caries variables generated from data collected from the first and second mailing of the consent forms. Descriptive statistics (including means and 95% confidence intervals) for caries indices for first and second mailings were calculated and used to highlight statistically significant differences.

Results

A total of 11,461 children were sampled for the survey, and of these 7,734 were examined (67.5%) of whom 6,678 were examined following receipt of a first mailing consent form and 1,056 in response to a second mailing consent form. Analysis of a subset of the response return data showed that 7.5% of those sampled had returned a form giving consent but the children were then absent on the day of examination. Summary survey data can be accessed via the Welsh Oral Health Information Unit website: www.cardiff.ac.uk/dentl/research/themes/applied-clinicalresearch/epidemiology/oralhealth.

The mean d_3mft for the first mailing was 1.5 (95%CI: 1.4,1.6) compared with a d_3mft of 2.2 (95%CI 2.0,2.5) for the second mailing (Table 1). This finding suggests that, on average, the children of parents who did not respond to a first mailing were more likely to have decay experience.

The two factors which contribute to mean decay experience of a population include the prevalence of decay among the population and the mean decay experience of those with at least one tooth affected by decay. Therefore it is worth exploring which of these factors contributed to higher decay levels among second mailing consented children.

The proportion of children with decay ($\%d_3mft>0$) among responders to the first consent form was 39.5% (95%CI 38.4%,40.7%) compared with 54.1% (95%CI 51.1%,57.2%) for the second mailing (Table 1). A much larger proportion of children with decay are found among those who consented to the second mailing. The mean number of decayed teeth per child with at least one decayed tooth (d_3mft ($d_3mft>0$)) was similar for

Table 1. Mean d_3mft, $\%d_3mft>0$ and $d_3mft(d_3mft>0)$ with associated 95% confidence intervals for 1st and 2nd mail shots and combined result

	d_3mft		$\%d_3mft>0$		$d_3mft(d_3mft>0)$	
	mean	*95%CI*	$\%d_3mft>0$	*95%CI*	*mean*	*95%CI*
1st mail shot	1.5	1.4, 1.6	39.5	38.4, 40.7	3.8	3.7, 3.9
2nd mail shot	2.2	2.0, 2.5	54.1	51.1, 57.2	4.1	3.8, 4.4
Combined	1.6	1.5, 1.7	41.4	40.3, 42.5	3.8	3.7, 4.0

the first and second mailing at 3.8 and 4.1 respectively (Table 1). This difference is not statistically significant, thus the main contributor to the increased mean d_3mft responding to the second mailing was the proportion of children with decay.

The data which is published in Wales to report decay levels will be based upon the aggregate results from the two mailings to allow comparison with 2 mailing data collected in England. The fact that 1,056 replied to the second mailing compared with 6,678 for the first mailing means that the reported decay indices for all children examined are closer to the mean values for those examined with consent obtained from the first mailing. The mean d_3mft for all 7,734 children examined as a part of the survey was 1.6 (95%CI 1.5,1.7). The proportion of children with decay was 41.4%.

Discussion

In 1993, Prendergast *et al.,* undertook a dental survey using negative (opt-out) consent and a postal questionnaire to parents. They were able to consider the caries experience of responders and non-responders to the questionnaire. On the basis of finding higher disease experience (prevalence of caries and mean caries per child) among children of non-responding parents they predicted that use of positive parental consent would be biased and underestimate true caries levels. Others predicted this again in 2007 when new consent arrangements were notified (White *et al.,* 2007).

The null hypothesis being tested in this research is that decay variables collected as a result of the second mailing of parental consent are no different from those generated following the first mailing. While mean numbers of decayed teeth per child with decay ($d_3mft(d_3mft>0)$) were similar (not rejecting the null hypothesis for this variable) the prevalence of decay experience was much higher among second mailing responders, rejecting the null hypothesis for this indicator and contributing to statistically significant raised mean d_3mft scores also.

The results in this paper reflect that there is a degree of bias in the examination findings in response to positive consent forms sent through the post. While the mean number of decayed teeth per child with decay experience (d_3mft ($d_3mft>0$)) are similar across the first and second mailing responders, a much larger proportion of those who consented following the second mailing had decay experience. This finding is consistent with the hypothesis proposed previously that parents of children with decay are less likely to respond with positive consent to participate in these surveys (Monaghan *et al.,* 2011). That paper by Monaghan *et al.,* also illustrated that the fall in participation and associated caries indices were consistent across all quintiles of deprivation. Therefore the analyses here are focussed solely on caries indices among first and second mailing responders.

The difference between these aggregated first and second mailing results and the levels of disease resulting from the first mailing only are small, an increase of 0.1 on d_3mft score and 2% on prevalence of caries, and not statistically significant. Reflection on the results prior to the change in consent approach and the analyses in this paper, suggest it is likely that the true decay levels of the school year 1 population are higher than population means currently reported, reflecting the contribution of the caries experience of those not examined. Ideally we need some data on the true caries rate of non-responders (Tickle *et al.*, 2003). In the absence of data on the true caries rate amongst those who did not participate following two mailings of consent forms it is unclear to what degree the indices of caries experience reflect the true caries experience of the whole school year 1 population. Techniques to maximise response rates are only of partial assistance (Glenny *et al*., 2013). The collection and separate analysis of responses to a second mailing of consent forms provide an opportunity for insight into the likely disease levels among non-participants. If we assume that the caries experience of non-responders matched that of those examined following a second mailing of consent forms then the mean d_3mft would be 1.8 (compared with 1.6 d_3mft from combined 1st and 2nd mailing) and the $\%d_3mft>0$ would be 45.7% (compared with 41.4% from combined mailing).

Consideration could be given to a third mailing of a consent form. This could explore whether those examined following a third mailing demonstrate similar decay experience to those examined after the second mailing. However the addition of another wait for a response and third mailing would add to practical difficulties (e.g. the burden on co-operating schools). It is probable that the response to a third mailing would be lower still than the response to the second mailing. There is no certainty that the number of third mailing responders generated from a survey of a school year in Wales examining approximately 11,000 pupils would be large enough to affect results to a statistically significant degree.

It is clear that the requirement for positive parental consent for caries surveys of younger children in Wales since 2006 do underestimate the true caries levels. The findings here have wider implications.

Although the addition of a second mailing did not make a statistically significant difference to reported caries indices (comparing first mailing results with combined mailing results) there is merit in undertaking a second mailing. In addition to the potential to raise the overall response rate a second mailing offers the opportunity to look for differences in disease experience of responders to first and subsequent mailings. Such analyses can assist in understanding whether and to what degree the overall results of a survey are likely to over- or under-estimate the true disease picture and could be used to inform any estimates of caries levels which correct for non-response bias (Locker, 2000). Interestingly, in contrast with postal questionnaire surveys of adults regarding specific chronic conditions which typically produce slightly high estimations of disease prevalence (Al-Shahi *et al.,* 2005; Hill *et al.,* 1997; Hoeymans *et al.,* 1998, O'Neill *et al.,* 1995), this study showed under-estimation of caries. In the absence of data on the true caries experience of non-responders we can only speculate on the magnitude of the bias. On the basis of this and previous studies this bias seems to be moderately large. The findings from this study including the extrapolated estimates noted earlier in this discussion will be taken into the UK survey programme decision making process to inform future reporting.

A variety of locally chosen colours of paper were used in this survey to identify responses to the second mailing. We do not believe that the use of coloured paper for the second mailing explains the difference in caries reported above.

For surveys, particularly school based dental surveys, where consent is obtained by use of mailed letters at least two mailings of such paperwork is advisable, and published data should indicate the number of mailings used to seek consent.

Conclusions

The null hypothesis is rejected for prevalence of decay but not for severity of decay among those with decay experience. Responses to the second mailing suggest that non-responders to the first mailing do have higher prevalence of decay. Future surveys using mailed forms for consent purposes should include at least two mailings and report the number of mailings used to facilitate comparisons of reported decay levels. Analyses of disease experience among responders to each mailing should be undertaken to inform the direction and potential magnitude of any over- or under-estimation of disease experience (Locker, 2000).

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