Community Dental Health (2020) **37,** 1–6
Received 25 March 2020; Accepted 3 May 2020

doi:10.1922/CDH_000682020Goodwin06

Recruitment and Consent in an observational study

Michaela Goodwin,[1] William Whittaker,[2] Tanya Walsh,[1] Richard Emsley,[3] Matthew Sutton,[2] Martin Tickle,[1] Michael Kelly[4] and Iain Pretty[1]

[1]University of Manchester, School of Dentistry, UK; [2]University of Manchester, Population Health, Health Services Research & Primary Care, UK; [3]King's College London, Psychiatry, Psychology & Neuroscience, UK; [4]University of Cambridge, Public Health, UK

Objective: The study sought to explore the consent rate and associated potential bias across a cohort in a large longitudinal population based study. ***Research design***: Data were taken from a study designed to examine the effects of the reintroduction of community water fluoridation on children's oral health over a five-year period. Children were recruited from a fluoridated and non-fluoridated area in Cumbria, referred to as Group 1 and Group 2. ***Results***: Data were available for 3138 individuals. The consent rate was 12.91 percentage points lower in Group 2 than Group 1 (95% CI -16.27 to -9.56, $p<0.001$). The population in Group 2 was more deprived (higher Index of Multiple Deprivation (IMD)) than Group 1 before consent was taken. Consent was not associated with deprivation in either group. ***Conclusion***: The cohort appeared to be unaffected by IMD-related non-consent. However there was a difference in consent rate between the two groups. With the population in Group 1 being more deprived than Group 2, it will be important to incorporate these differences into the analysis at the end of this longitudinal study.

Keywords: *Public health, consent, bias, deprivation, water fluoridation*

Introduction

Non-consent in research is an important issue that can result in bias affecting the validity of results. Consent bias (also known as authorisation/volunteer bias) occurs when the group consenting to participate differs from non-consenters (Junghans and Jones, 2007). Bias can also occur if consent is different between the control and intervention groups involved. These biases can impact on a study by creating a group that is not representative of the population being studied. A poor consent rate or consenting only a specific demographic can skew the study before any data are collected. Failure to recruit either those who would benefit most from an intervention or give vital insight into a research area, such as older or socio economically deprived individuals, could lead to an over or under estimation of the prevalence of a disease or condition (Hewison and Haines, 2006). It could also distort the association of risk factors and health outcomes or fail to capture the range of views and impacts regarding a health issue.

A variety of methods can be used to address or reduce consent bias. These include using opt out rather than active consent or utilising data about non consenters to ascertain weights and imputation techniques to adjust for these biases (Junghans and Jones, 2007). Opt out is not always possible or appropriate in research. Several methods can be employed to obtain consent in opt in approaches. These include face-to-face consent or consent through postal response. Face-to-face consent is often preferred, as direct discussion with research volunteers improves their understanding of what is involved in participating (Flory and Emanuel, 2004). Face-to-face consent can also be supplemented by the use of multimedia, audio/visual illustrations. When face-to-face consent is not possible postal consent can be quick and cost effective, but does raise other issues relating to informed consent, especially for those with lower literacy or whose first language is not the one used in information sheets or consent forms (Aliyu and Mahmud, 2016). Potential differences in consent following this process are particularly important where randomisation is not being used, for example in instances of natural experiments or observational studies (Craig *et al.*, 2012, 2017). It is important to establish if differences observed are due to socio-demographic differences in the population or due to selection bias. Various large scale birth cohort studies have used either postal or face to face consent. A Norwegian birth cohort study recruiting participants via postal invitation, which included a consent form and questionnaire achieved a participation rate of 42.7% (64,136 out of 150,309 potential participants) (Magnus *et al.*, 2006). A recent birth cohort study carried out in Sydney, Australia approached most parents face to face at postnatal wards and achieved a consent rate of 57% (1866 out of 3262). However a proportion of potential participants were missed and were therefore approached through postal consent, which produced a 20% consent rate (Woolfenden *et al.*, 2016). A systematic review looking at informed consent and selection bias in observational studies showed differences between participants and non participants and noted its potential impact on the validity of the results from such research (Kho, 2009).

Correspondence to: Dr Michaela Goodwin, University of Manchester, School of Dentistry, UK. E-mail: michaela.goodwin@manchester.ac.uk

If there is differential consent between intervention and control groups resulting in a different distribution of potential effect modifiers, data about consenters and non-consenters can be used to ascertain weights so that imputation techniques can be employed to adjust for these biases. Weighting can also be important when oversampling of certain demographics occurs in order for results to be generalizable at the end of analysis (U S Bureau of Labor Statistics, 1997; Zhang *et al*., 2013).

This paper reports findings regarding consent and non-consent taken primarily face-to-face from a non randomised, observational study designed to examine the effects of the reintroduction of community water fluoridation on young children's oral and general health. Due to the nature of the intervention (water fluoridation) both full blinding to the groups and randomisation were not possible, therefore the issue of bias is especially important to consider.

Aim

This study describes the recruitment methods carried out in a hospital for a non randomised, observational study. It sought to explore differences in Index of Multiple Deprivation (IMD) and other important characteristics potentially affecting the primary outcome of the study between the control (Group 1) and intervention group (Group 2). We have not named the areas for the groups as the study is still in progress, with members of the team blinded to groups.

We sought to test the following hypotheses:

1. That the control and intervention group populations did not differ significantly before consent took place
2. That consent did not differ between control and intervention groups
3. That consent did not differ by gender and/or IMD
4. That any relationship between IMD, gender and consent was similar between groups

The findings of this study will inform whether there may be counfounding bias caused by consenting issues and/or demographics in the control and intervention groups that would need to be accounted for in future analyses of the study.

Methods

The data have been taken from a prospective, comparative investigation of the effects of the reintroduction of water fluoridation on young children's oral and general health. A census approach will compare oral health of those living in the fluoridated and non-fluoridated areas. The sample consists of those who were conceived after the reintroduction of fluoride in Cumbria.

Eligible participants were children born in one of two designated hospitals, one based in a fluoridated population and another in control population (in a non fluoridated areas), from 1st September 2014 to 31st August 2015.

Participants were recruited primarily at their 20-week scan appointment; those who were missed at this point were approached after delivery at the maternity clinic, if they were also missed at this point they were invited to participate through a letter home (Figure 1). Parents of all children who were born at the two hospitals within Cumbria were given the opportunity to participate on behalf of their child. Anonymised data on Index of Multiple Deprivation (IMD) and gender of consenters and non-consenters were provided by the hospitals involved. IMD deciles were assigned based on the mother's postcode and gives a relative measure of overall deprivation for small areas in England, UK (Ministry of Housing Communities & Local Government, 2015).

Analysis

Deprivation and age between Group 1 and Group 2

The first set of analysis tested for difference in IMD of all those eligible to participate, between the control and intervention group via linear probability models (Ordinary Least Squares regressions) of group against gender and IMD decile. This was to establish if the groups were already different before recruitment.

Linear probability models were preferred over a general chi-square tests of association due to the additional ability to identify how the distribution of IMD varied

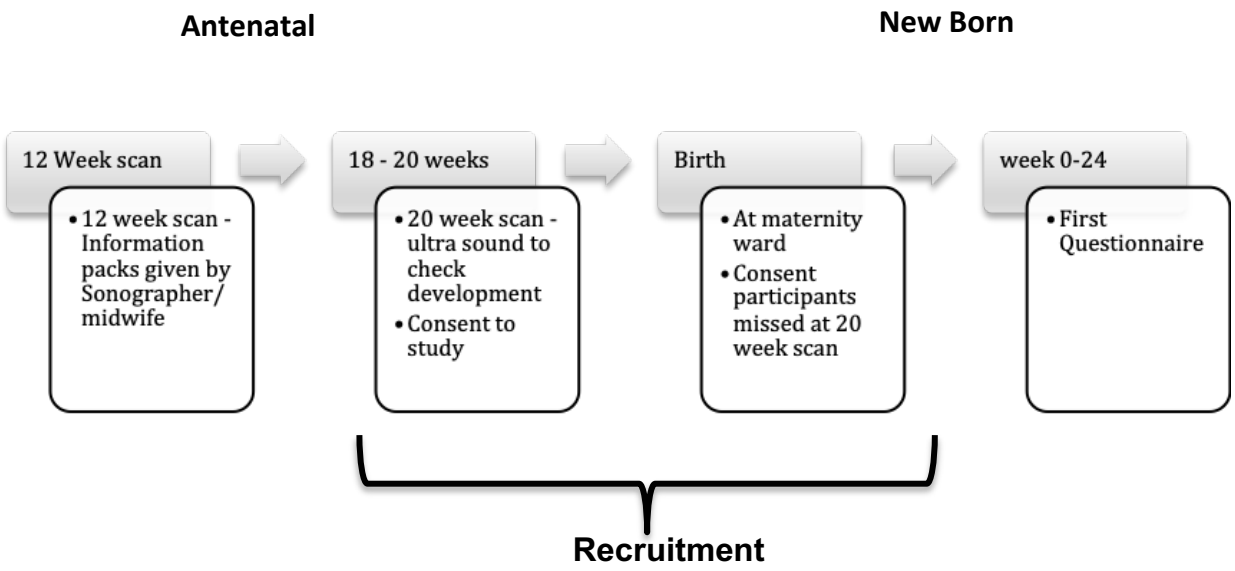

Figure 1. *Recruitment period for birth cohort*

between the two groups (for example, whether the difference was focussed on a particular decile such as the least or most deprived).

Consent between Group 1 and Group 2

The second set of analyses tested for differences in consent between groups via linear probability models of consent. This was used to determine if any consent bias was introduced which could impact on the results.

Consent by gender, IMD and group

The third set tested whether consent differed by gender and IMD and whether this relationship differed between the two groups to understand whether this may bias later trial evaluations of effectiveness. We estimate linear probability models of consent against age and IMD for i) both groups combined (Group 1 and Group 2), ii) Group 1 only, and iii) Group 2 only.

To test whether the relationship between gender, IMD and consent differed by group we produced a second linear probability model for consent with gender and IMD interacting with the group dummy as supplementary analyses. Any significant interaction terms would imply consent in one group may be biased beyond population-level differences in gender and/or IMD.

Statistical significance level was set at the conventional 5% for all analyses. Statistical analysis was performed using STATA (StataCorp, 2015). This originating study has been reviewed and approved by an NHS ethics committee (14/EE/0108) and NIHR. All participants provide written informed consent before enrolling in the study.

Results

A total of 3,138 parent-child dyads were approached for recruitment, this comprised 1,849 in Group 1 and 1,289 in Group 2 (Data available in Appendix at https://www.researchgate.net/publication/342550355_Appendix_A_-Table_A1_A2_and_A3). Omitting those ineligible (159 dyads, 5.07% for example those who lived outside of the Cumbria area or were about to move), not approached (40, 1.27%), and those withdrawn/removed (67, 2.14% for example those who had moved out of the area since consenting) gave a final sample of 2,872 dyads. There were 49 missing gender data (13 in Group 1, 36 in Group 2), and 28 missing IMD scores (19 in Group 1 and 9 in Group 2). The final sample with complete data on consent, IMD and gender for the birth cohort analyses was 2,796 comprised of 1,634 (58%) in Group 1 and 1,162 (42%) in Group 2. A 71% consent rate (2,035 dyads) was achieved between September 2014 and August 2015.

Gender and IMD by group

Data were examined to determine if there were any differences between the groups for all those eligible to take part. Table 1 gives the distributions of gender and IMD within each group.

Table 2 gives the estimates from an OLS regression of group against gender and IMD dummies. The estimates are interpreted as the percentage point difference for the dummy versus the base category. For example, the estimate for the male dummy of -0.0267 is interpreted as the percentage of males in Group 2 was 2.67 percentage points lower than in Group 1.

There was no significant difference in the percentage of males within each group (-2.67 percentage point difference, 95%CI -6.24 to 0.90) (Table 2). IMD deciles 2, 4, and 5 were relatively less concentrated in Group 2, whereas IMD decile 10 was borderline more concentrated in Group 2, which could imply Group 2 was relatively more deprived than Group 1, before consent was taken.

Table 1. Distribution of gender and IMD within each group

	Combined areas n = 2796 %	*Group 1 n = 1634 %*	*Group 2 n = 1162 %*
Gender			
Female	48.32	47.25	49.83
Male	51.68	52.75	50.17
IMD decile			
Least deprived	2.00	1.84	2.24
2	5.19	6.12	3.87
3	5.79	4.53	7.57
4	9.98	13.28	5.34
5	10.48	12.42	7.75
6	11.19	11.51	10.76
7	14.02	13.16	15.23
8	15.49	17.01	13.34
9	13.23	11.44	15.75
Most deprived	12.63	8.69	18.16

Table 2. Linear probability estimates of group status by gender and IMD decile^

	Estimate	95% CI
Gender		
Female (base)		
Male	-0.027	-0.062 to 0.009
IMD decile		
Least deprived (base)		
2	-0.155*	-0.303 to -0.006
3	0.079	-0.067 to 0.225
4	-0.242**	-0.380 to -0.104
5	-0.158*	-0.296 to -0.021
6	-0.066	-0.203 to 0.071
7	-0.013	-0.148 to 0.122
8	-0.107	-0.241 to 0.027
9	0.031	-0.105 to 0.170
Most deprived	0.133	-0.003 to 0.268
Constant	0.479	0.351 to 0.606
N	2,796	
R-Squared	0.051	

*p < 0.05, **p < 0.01, ***p < 0.0001
(^Ordinary Least Squares regression of a binary group variable against gender and IMD decile variables).

Consent by group

Consent was 13 percentage points lower in Group 2 than Group 1 (95% CI = -16.27 to -9.56, Table 3).

Table 4 presents the estimates from an OLS regression of consent against group, gender, and IMD decile, for three models: i) the total sample (Group 1 and Group 2), ii) Group 1 alone, and iii) Group 2 alone. In the total sample model consent was 12.10 percentage points lower in Group 2 (95% CI: -15.33 to -8.66). No IMD decile relationship with consent was found for either the total sample or within each Group. There was slight evidence of Group 2 having a higher consent rate for males compared to females (p=0.031). Table A2 (Data available in Appendix at https://www.researchgate.net/publication/342708074_Appendix_A_-Table_A1_A2_and_A3) gives the consent rate across group, gender and IMD decile. The overall consent rate was 71.75%.

Consent rates were similar across groups for gender and IMD decile with all group interactions insignificant at the conventional 5% level of significance (Data available in Appendix at https://www.researchgate.net/publication/342708074_Appendix_A_-Table_A1_A2_and_A3).

Table 3. Consent vs. no consent for those in Group 1 and 2 with valid IMD)

	Combined areas n = 2,796 %	*Group 1 n = 1634 %*	*Group 2 n = 1162 %*	*Difference %*
Consent breakdown				
Consent	71.75	77.11	64.20	-12.91 [-16.27, -9.56] p=0.001
No Consent	28.25	22.89	35.80	
Break down of non-consent				
Declined	12.95	11.14	15.49	
No response	15.31	11.75	20.31	

(^ difference estimated by OLS regression of consent against a group dummy).

Table 4. Linear probability model estimates for consent against group, gender and IMD decile

	Total sample		*Group 1*		*Group 2*	
	Estimate	*95% CI*	*Estimate*	*95% CI*	*Estimate*	*95% CI*
Group						
Group 1 (base)						
Group 2	-0.121***	-0.155, -0.087				
Gender						
Female (base)						
Male	0.024	-0.009, 0.057	-0.002	-0.043, 0.039	0.061*	0.006, 0.116
IMD decile						
Least deprived (base)						
2	-0.030	-0.167, 0.107	-0.083	-0.255, 0.088	0.059	-0.172, 0.290
3	0.013	-0.123, 0.148	0.018	-0.160, 0.196	0.015	-0.194, 0.225
4	0.006	-0.122, 0.134	-0.036	-0.197, 0.124	0.084	-0.135, 0.303
5	-0.045	-0.172, 0.083	-0.085	-0.246, 0.077	0.014	-0.195, 0.222
6	-0.009	-0.136, 0.118	-0.046	-0.208, 0.116	0.040	-0.162, 0.243
7	-0.019	-0.144, 0.106	-0.043	-0.203, 0.118	0.009	-0.188, 0.206
8	-0.067	-0.191, 0.057	-0.089	-0.247, 0.070	-0.047	-0.246, 0.152
9	-0.033	-0.158, 0.092	-0.042	-0.204, 0.120	-0.024	-0.220, 0.173
Most deprived	-0.116	-0.241, 0.010	-0.136	-0.302, 0.029	-0.092	-0.287, 0.104
Constant	0.794***	0.674, 0.913	0.835***	0.682, 0.987	0.623***	0.437, 0.810
N	2,796		1,634		1,162	
R-Squared	0.0276		0.0072		0.0144	

*p < 0.05, **p < 0.01, ***p < 0.0001
(^Ordinary Least Squares regression of a binary consent variable against group, gender and IMD decile variables.)

Discussion

Consent is the first hurdle of any human research project and few studies are expected to achieve 100% consent. Non-consent can become an issue if either the consent is so low the sample size cannot be reached, resulting in a loss of power to detect an assumed effect size, or if there is a systematic skew in the type of people consenting, with certain groups under represented. In this research, two groups were consented, one in an area receiving an intervention and one in an area that did not. Therefore it is important to establish that there were no differences between these two groups before they could be consented.

As data were available on IMD and gender for everyone eligible to take part, this information was analysed to determine if there were differences between recruitment sites before consent. Whilst Group 2 could be viewed as somewhat more deprived (Table 1), there was no significant association found between consent by IMD decile in general, or by group (Data available in Appendix A). This suggests our analyses is unlikely to be biased due to non-consent related to deprivation.

There were no differences in the gender composition between the two groups (Table 1). Gender did not appear to be associated with consent in general or by group (Data available in Appendix A). Our analyses are unlikely to be biased due to non-consent related to gender.

Given those who could be recruited to Group 1 were significantly less deprived than Group 2. This means the groups were systematically different before consent could take place and this would need to be accounted for in future analysis. This is important as the current longitudinal study will examine the proportion of children who are caries free in each group, which can be associated with the level of deprivation.

It is also interesting to note that the difference in consent appears to be mainly made up of those who did not respond, rather than those who declined to take part. Twelve percent of those eligible to be in Group 1 did not respond, which was overall less deprived, while 21% did not respond in Group 2. This could indicate that the difference in consent was not necessarily due to individuals not wanting to be part of the study but simply not signing up. This has been seen in similar health studies with those accepting to take part in the study being more affluent, but when looking at decliners and non responders, there was almost no differences in the levels of decliners but there were a higher prorpotion of non responders who were deprived vs those who were affluent (Foster *et al.*, 2015).

The results also show a difference in the level of consent between the two groups (intervention and control), indicating the chance of consenting were higher in Group 1 than Group 2 (Table 4). It could be argued that as consent is associated with socio-economic status/deprivation (Spence *et al.*, 2015) this could be why the group from a more deprived area showed a lower consent rate. However the results suggested that the difference in consent between the two groups at each IMD decile was not significantly different. This indicates those in Group 2, no matter the level of deprivation, were slightly less likely to consent than Group 1.

Non consent bias has been observed throughout a variety of research projects with various methods used to reduce this disparity (Nakash *et al.*, 2006; Sakshaug *et al.*, 2012). It may be averted by using an opt-out approach (Junghans and Jones, 2007). However this was not possible for this study, given the nature of the research. Some information, for example IMD, can be available for non-consenters, allowing the data to be weighted so that samples can be comparable with the general population.

Conclusions

This study considers two sources of bias caused by non-random sampling. First, systematic differences in population characteristics at baseline and second, the resulting study samples arising from self-selection. The implication for this longitudinal study (and for others evaluating similar interventions where randomisation is not possible) is to take this into account and adjust for these differences in the analysis. Non-representativeness caused by non-consent can be accounted for using weighting approaches to obtain representation. For example, *inverse probability weights* (Horvitz and Thompson, 1952) i.e. 1/(probability that unit is selected). Non-response can be accounted for using the probability of selection, such as logistic regression (sometimes called propensity weighting). Weighting can also adjust for an auxiliary variable (e.g. deprivation) affected by significant consent bias to enable more accurate inference of the variation in outcome (Bethlehem, 2009). However, as consent was unrelated to deprivation or gender there is no justification for adopting such weighting approaches in this study.

List of Abbreviations:

IMD – Index of Multiple Deprivation
NPEU – National Perinatal Epidemiology Unit
OLS – Ordinary Least Squares

Declarations

Ethics Approval

This study has been reviewed and approved by an NHS ethics committee (14/EE/0108 – Birth cohort and 13/NW/0494 – School Cohort) and NIHR. All participants provide written informed consent prior to enrolling in the study.

Consent for Publication

Not applicable

Conflict of interests

The authors declare that they have conflict of interest.

Funding

This project was funded by the National Institute for Health Research Public Health Research (NIHR PHR) Programme (Project number 12/3000/40). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR PHR Programme or the Department of Health and Social care.

Acknowledgments

We would like to thank North Cumbria University Hospital for their work on recruitment for the Birth Cohort.

Availability of Data

The datasets generated and/or analysed during the current study are not publicly available at the moment as the overall study (on water fluoridation) will not be completed until 2021.

References

Aliyu, G. and Mahmud, S. M. (2016); Postal recruitment and consent obtainment from index cases of narcolepsy. *BMC Medical Ethics* **17**, 6.

Bethlehem, J. (2009): Applied Survey Methods. Hoboken, NJ, USA: John Wiley & Sons, Inc.

Flory, J. and Emanuel, E. (2004): Interventions to Improve Research Participants' Understanding in Informed Consent for Research. *Journal of the American Medical Association* **292**, 1593-601

Foster, A., Horspool, K.A., Edwards, L., Thomas, C.L., Salisbury, C. and Montgomery, A.A. (2015): Who does not participate in telehealth trials and why? A cross-sectional survey. *Trials*, *BioMed Central* **16**, 258.

Hewison, J. and Haines, A. (2006): Overcoming barriers to recruitment in health research. *BMJ (Clinical research)* **333**, 300–2.

Horvitz, D. G. and Thompson, D. J. (1952): A Generalization of Sampling Without Replacement From a Finite Universe, *Journal of the American Statistical Association* **47**, 663–685.

Junghans, C. and Jones, M. (2007): Consent bias in research: how to avoid it. *Heart* **93**,1024–5.

Kho, M. E. (2009): Written informed consent and selection bias in observational studies using medical records: systematic review. *British Medical Journal* **338,** b866–b866

Magnus, P., Irgens, L.M., Haug, K., Nystad, W., Skjaerven, R. and Stoltenberg C. (2006): Cohort profile: The Norwegian Mother and Child Cohort Study. *International Journal of Epidemiology* **35,** 1146–1150

Ministry of Housing Communities & Local Government (2015): English indices of deprivation 2015, Statistical Release. Available at: https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015 (Accessed: 30 April 2019).

Nakash, R. A., Hutton, J. L., Jørstad-Stein, E. C., Gates, S. and Lamb, S. E. (2006): Maximising response to postal questionnaires--a systematic review of randomised trials in health research. *BMC Medical Research Methodology* **6**, 5.

Sakshaug, J. W., Couper, M. P., Ofstedal, M. B. and Weir, D. R. (2012): Linking Survey and Administrative Records: Mechanisms of Consent. *Sociological Methods & Research* **41**, 535–569.

Spence, S., White, M., Adamson, A.J. and Matthews, J.N.S. (2015): Does the use of passive or active consent affect consent or completion rates, or dietary data quality? Repeat cross-sectional survey among school children aged 11-12 years. . *British Medical Journal* **5**, 6457–6457.

StataCorp (2015) 'Stata Statistical Software: Release 15'. College Station, TX: StataCorp LLC.

U S Bureau of Labor Statistics (1997) National Longitudinal Survey of Youth. Available at: https://www.nlsinfo.org/content/cohorts/nlsy97/using-and-understanding-the-data/sample-weights-design-effects (Accessed: 31 August 2016).

Woolfenden, S., Eapen, V., Axelsson, E., Hendry, A., Jalaludin, B. and Dissanayake, C. (2016): Who is our cohort: recruitment, representativeness, baseline risk and retention in the "Watch Me Grow" study? *BMC Pediatrics*, **16**, 46.

Zhang, L. C., Thomsen, I. and Kleven, Ø. (2013): On the Use of Auxiliary and Paradata for Dealing With Non-sampling Errors in Household Surveys. *International Statistical Review* **81,** 270–288.