LIFE STUDY | Understanding lives – now and for the future

Birth Component Pilot: Opt-in fieldwork

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Forward

Life Study, a new and multidisciplinary birth cohort for the UK, was developed by the Life Study scientific leadership team together with experts from a wide range of disciplines drawn from the biomedical, clinical and social science research communities who formed part of a wider affiliated scientific network. It was designed to reflect the key research themes of the study, capitalise on the unique opportunities afforded, and to enable a wide range of research questions and policy issues relevant to children to be explored.

The design of Life Study incorporated two integrated yet methodologically distinct components – the recruitment of pregnant women to the study in the second trimester of their pregnancy via hospital-based centres (the pregnancy component) and a national probability sample of babies at the corrected postnatal age of six months, identified from linked NHS/birth registration records held by the UK national statistical authorities (the birth component).

To progress the birth component, the research team at UCL tendered for fieldwork assistance. Ipsos MORI won this competitive tendering process and were duly appointed to undertake work associated with a pilot study for the birth component survey, collecting information from the mothers and fathers of babies, selected from birth registration records in England, Wales and Scotland to participate voluntarily in the study. Ipsos MORI worked closely with the Life Study team from the date of their appointment in December 2014 until December 2015.

Three reports from Ipsos MORI form part of the preparatory work undertaken for the Life Study birth component. This report focuses on the design of the sample and the collaboration with the statistical authorities in this process of drawing a sample of mothers for participation in the pilot. Other reports describe the face-to-face fieldwork for the pilot[1], including interviewer briefing procedures, and qualitative work with lone mothers, exploring options for contacting non-resident fathers[2].

The pilot study and associated activities demonstrate emphatically that an 'opt-in' approach, whereby mothers are invited by the statistical authorities to participate before their names and addresses are released to the researchers, is no longer an option. The identification of an appropriate legal gateway for an 'opt-out' approach (the option to refuse to participate when approached by researchers) is now of paramount importance.

A second important feature of the pilot was that it tested a process through which birth registration records could be selected and linked to the equivalent NHS record, utilising information on prematurity to ensure interviews with mothers could take place when the

[1] http://discovery.ucl.ac.uk/1485697/
[2] http://discovery.ucl.ac.uk/1485696/

child was at the same developmental age. But it is not just the sampling procedures that underpin the value of this work. A new technique for the integration of a database management system used for the construction of questionnaires with the scripting of questionnaires for use by interviewers, proved the accuracy and efficiency of this approach to the design and management of questionnaires. An experimental design to the contact made with potential participants showed how a more engaging design can enhance participation. The qualitative work reveals how important it is to gain the confidence of lone mothers when attempting to engage non-resident fathers with the study.

The Life Study Scientific Steering Committee (members listed below) is responsible for the birth component, having approved its final design and piloting.

Professor Peter Brocklehurst
Professor Simon Burgess
Professor Carol Dezateux
Professor Peter Elias
Professor Paul Elliott
Professor Alan Emond
Professor Hilary Graham
Professor Frank Kelly
Professor Kathleen Kiernan
Professor David Leon
Professor Diane Reay
Professor Anna Vignoles (chair)

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Peter Elias

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The Nuffield Foundation is an endowed charitable trust that aims to improve social well-being in the widest sense. It funds research and innovation in education and social policy and also works to build capacity in education, science and social science research. The Nuffield Foundation has funded this project, but the views expressed are those of the authors and not necessarily those of the Foundation. More information is available at www.nuffieldfoundation.org.

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Life Study: Birth Component

Pilot: Opt-in fieldwork

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1 Acknowledgements

This work was supported by the Economic and Social Research Council [Grant numbers ES/J007501/1, ES/L002507/1, ES/L002353/1, ES/L012871/1, ES/N007549/1] and the Nuffield Foundation.

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2 Introduction

2.1 Background

A baby's development is shaped by many influences, from the most immediate ones such as his/her parents, wider family and home environment; to the local environment, schools and services; as well as more distant influences such as government policies.

The overall aim of Life Study was to understand how the family, social and physical environment in very early life influences child development, health and well-being in the children being born in the UK today.

Life Study intended to follow the physical, social and emotional development, health and well-being of up to 80,000 UK babies and their families, with three quarters of this number to be followed from pregnancy onwards. Collecting information at different time points in a child's early life would allow researchers to identify important pathways to health and well-being and to explore the timing and sequence of different events and experiences early in life. As well as mothers, Life Study also involved fathers or other partners, recognising their important role in a child's development and later life.

Funding for the part of Life Study described in this report (the Birth Component) was provided through the UK Government Department of Business Innovation and Skills (BIS) Large Facilities Capital Fund (LFCF), with additional contributions from the Economic and Social Research Council (ESRC), Medical Research Council (MRC) and University College London (UCL). Funding for the work with resident and non-resident fathers and partners was provided by the Nuffield Foundation.

In July 2015 the ESRC and the MRC agreed that the research councils' funding for Life Study would be discontinued from early 2016 due to the serious challenges encountered in recruiting participants. This decision was announced publicly on 22 October 2015. The work described in this report was already underway prior to this decision and progressed to completion in November 2015.

Life Study had an integrated design comprising two samples of the population – one recruited in pregnancy, referred to as the Pregnancy Component, and the other recruited after birth, referred to as the Birth Component. Following a tendering competition managed by UCL, in December 2014 Ipsos MORI was appointed as the fieldwork contractor to deliver the first two waves of the Birth Component.

The overall design of the Birth Component was that a nationally representative sample of c. 20,000 children living throughout the UK would be recruited into Life Study via birth registration records, with mothers and fathers/partners interviewed when the sampled baby was six months old (six-month interview) and mothers interviewed again when the sampled baby was one year old (12-month interview). The intention was to follow babies throughout their lives with future waves of Life Study being commissioned at a later date.

2.2 The pilot

During the tendering process Ipsos MORI proposed a large-scale pilot of the six-month and 12-month waves of the Birth Component before the main stage was commissioned. Aside from the general desirability of extensive piloting before beginning a large-scale cohort study, there was uncertainty about the viability of the new sampling frame and opt-in approach Life Study proposed to use for the Birth Component.

The Child Benefit Register, which is held and maintained by Her Majesty's Revenue and Customs (HMRC), used to be the default sampling frame to obtain samples that involved children and young people in the

UK. Indeed it was the sampling frame used for the UK's most recent cohort study – the Millennium Cohort Study.

On 7 January 2013, the rules for claiming tax benefit changed. It is no longer possible to derive financial benefit[1] from receipt of Child Benefit where a child has one or more parents whose adjusted net income is over £60,000 per year. Further, it is not possible to gain the full financial benefit from receipt of Child Benefit where a child has one or more parents whose adjusted net income is between £50,000 and £60,000 per year (whose Child Benefit is clawed back at a rate of £1 in every £100). The government estimated about 15 per cent of families that were previously eligible would be affected by these changes with about 11 per cent losing benefit completely.

The impact of this is that babies born to parents with higher net incomes will be under-represented on the Child Benefit Register. This means that any sample for a cohort study based on Child Benefit records would be biased away from these higher-income households.

In January 2013, the Life Study team was given Section 251 approval[2] to recruit participants using the services of the Medical Research Information Service (MRIS) at the Health and Social Care Information Centre.

UCL's specification required the Birth Component to use birth registration records as the sampling frame. These records hold information on the age, address, name and occupation and country of birth of the mother (and the father for married couples and those are not married but who co-register the birth). In England and Wales, they also include linked information provided when registering the baby to obtain the NHS number (including birth weight, gestational age and ethnicity of the mother). UCL entered into discussions with the three Statistical Authorities – the Office for National Statistics (ONS), National Records of Scotland (NRS), and the Northern Ireland Statistics and Research Agency (NISRA). The ONS and NRS agreed to take part in the pilot; NISRA indicated that they could not participate in a pilot study prior to July 2015. They also indicated they would only have capacity to undertake an opt-in process over a two-month timeframe, not a four-month timeframe as we envisaged. As a result, NISRA did not take part in the pilot.

The pilot and associated development work was planned to take place over the following timeframe:

- Opt-in fieldwork for the first month's sample run: April to May 2015
- Opt-in fieldwork for the second month's sample run: May to June 2015
- Development of pilot fieldwork documents: April to May 2015
- Scripting of Dimensions interviewing programme: April to July 2015
- Processing of opt-in data: July 2015
- Pilot fieldwork: August to September 2015

[1] Higher income parents may still claim for Child Benefit; however, they will make no net financial gain from doing so.
[2] Section 60 of the Health and Social Care Act 2001 as re-enacted by Section 251 of the NHS Act 2006 allows the Secretary of State for Health to make regulations to set aside the common law duty of confidentiality for defined medical purposes. The Regulations that enable this power are called the Health Service (Control of Patient Information) Regulations 2002.The Health Research Authority took on responsibility for Section 251 in April 2013, establishing the Confidentiality Advisory Group (CAG) function.

2.3 The opt-in approach

By law all births in England, Wales and Northern Ireland must be registered within 42 days of the child being born. In England and Wales, the General Register Office, which is part of Her Majesty's Passport Office, is responsible for collating birth registrations and it shares birth registration information with the ONS on the basis that it is not disclosed to anyone in an identifiable format without the individual's specific permission. In Scotland, all births must be registered within 21 days of the child being born by a Registrar of Births, Deaths and Marriages. NRS are responsible for collating birth registrations.

In many surveys that use Child Benefit Records, an "opt-out" approach is used. This is usually carried out by post and is an opportunity for parents to remove themselves from the sample. Effectively, it is in lieu of seeking permission from parents for their details to be passed to a fieldwork contractor. UCL sought Approved Researcher status under the Statistics and Registration Act 2007. However, the ONS informed UCL that, in their view, for Data Protection reasons an invitation letter could be sent to mothers only on an "opt-in" basis. Accordingly an opt-in approach was developed for the Life Study Birth Component. An opt-in approach is where potential respondents are notified a study is taking place, and have to give consent for their contact details to be passed to a fieldwork contractor, before they can be approached.

Opt-out approaches have been used successfully for previous cohort studies such as the Millennium Cohort Study; using an opt-in approach was therefore a departure from the usual design and hence a pilot was required to test its feasibility fully.

2.4 Objectives of the pilot

The primary objective of the Birth Component pilot was to achieve a minimum of 400 interviews with mothers of babies born in two months, and to test response rates and all survey processes. This report covers the sampling and opt-in approach of the pilot; a further, separate report looks at fieldwork and other issues. The objectives relating to sampling and the opt-in approach were as follows:

- Ensuring the processes for sampling (requiring information to pass between Ipsos MORI and the Statistical Authorities) worked in a timely way.
- Ensuring that the Statistical Authorities could draw the sample as required, and checking whether they could make use of expected date of delivery rather than actual date of birth in drawing the sample.
- Checking whether the Statistical Authorities were able to make use of Health and Social Care Information Centre address tracing and updating prior to the initial mailout for each sampled month.
- Ensuring that the Statistical Authorities were able to manage the process effectively including dealing with the overlapping months and the full reminder regime.
- Ensuring that the Statistical Authorities could manage to deal with the experiment with two different opt-in approaches (use of different materials, but same reminder regime – initial mailout and two reminders).
- Assessment of response to opt-in for each approach and whether the six-week opt-in period was effective (too long or too short).
- Assessment of the information provided by those opting-in and of how good this information was.

- Ensuring Ipsos MORI could process the response materials returned to them in an effective and timely manner.

3 Sampling

3.1 Population definition

The agreed approach for the Birth Component was that the Statistical Authorities would sample babies from birth registration records and recruit mothers via the opt-in approach. Subsequently Ipsos MORI interviewers would attempt to interview those mothers that opted-in, along with (where applicable) resident partners or non-resident fathers.

To be eligible for the pilot a mother had to:

- Be aged 16+ at date of birth of the selected baby and be its biological mother.
- Be living in private residential accommodation.
- Have legal responsibility for the selected baby.
- Not be living on the Isles of Scilly or (in Scotland) north of the Caledonian Canal or on the islands.

To be eligible for the pilot a resident partner had to:

- Be aged 16+ at date of birth of the selected baby.
- Be living with the mother.

Many cohort studies to date have included interviews with fathers who live with their children, but it is rare for studies to include non-resident fathers, and UCL were interested in including non-resident fathers in Life Study. Data from the first round of the Millennium Cohort Study, where mothers were interviewed when their baby was nine months old, suggests that around 15 per cent of the mothers were not living with the father of their baby at that point. Most of the non-resident fathers were in contact with the mother and baby (58% saw their baby three times a week or more, and only 3% never saw their baby). Therefore, non-resident fathers appear to be playing an important role in the life of the mother and the baby and consequently they were deemed of scientific interest.

The funding for this part of Life Study was provided by the Nuffield Foundation. The inclusion of non-resident fathers meant an adjustment to the sampling design was needed. This adjustment affected the timeframe set out in section 3.2, by adding an additional two months to the opt-in fieldwork. UCL and Ipsos MORI agreed that mothers who opted-in from the first two sample runs would be issued for face-to-face fieldwork during August and September 2015 (as originally envisaged), but that opting-in lone mothers only from the final two sample runs would be issued to interviewers for fieldwork in October and November 2015.

To be eligible for the pilot a non-resident father had to:

- Be the biological father of the selected baby.
- Be aged 16+ at date of birth of the selected baby.
- Be living at a different address from the mother.

3.2 Construction of pilot areas

The pilot sample was selected in a purposive manner (that is, not to be nationally representative), designed to generate sufficient sample sizes over the proposed four months of pilot sampling. It was intended that the sample for the first two months would be used for piloting the procedures for interviewing mothers, resident partners and non-resident fathers; the final two months would be used for piloting the procedures for the non-resident fathers (although we would need to interview lone mothers to establish the identity of the non-resident fathers).

Ipsos MORI agreed with UCL that the target number of interviews for the pilot would be 480 mothers (400 mothers in the first two months; 80 in the final two months), 220 partners (first two months only) and 80 non-resident fathers (across all four months). Construction of the pilot areas was undertaken by Ipsos MORI.

In constructing the pilot areas, Ipsos MORI assumed a 33 per cent opt-in response rate. There was considerable uncertainty about what the response rate would be. We had assumed that it might be possible to achieve a 50 per cent response rate for the opt-in approach based on the Infant Feeding Survey experience, and then decided to lower that significantly as a contingency. We assumed a 50 per cent face-to-face response rate among those mothers who opted-in (or a composite response rate of around 17%). This implied we would need to sample 1,200 babies per month and invite their mothers to opt-in to the survey. To maximise the number of non-resident fathers interviewed, it was agreed to sample 1,600 babies per month, with the intention that this might enable us to over-sample lone mothers to issue to interviewers.

The three Statistical Authorities (the ONS, NRS and NISRA) supplied Ipsos MORI with counts of live births for each postcode sector for the years 2011 to 2013. The mean of the number of births over the three years was calculated for each postcode sector and divided by twelve to give the approximate number of births that we could expect in any month.

The construction of the pilot areas was informed by two considerations:

- We needed to ensure that the interviewers were provided with fieldwork assignments of a viable size. We decided to aim for a target number of 25 mothers in total over the two months to allocate to each interviewer for the pilot. This implied we needed to construct 32 pilot areas for interviewers to work in.

- We did not know what the opt-in response rate would be, nor the response rate during face-to-face fieldwork among those mothers who did opt-in[3].

The birth counts were aggregated to postal district counts and this was used to identify a longlist of 151 postal districts that had a sufficient number of births to include in the pilot. The minimum number of births over the two months in any of the pilot areas had to be 100 (i.e. about 50 per month). This longlist consisted of 95 postal districts in England, 45 in Scotland and 11 in Wales.

[3] The best evidence of opt-in response rates available to us was the Infant Feeding Survey in 2010. This was not ideal, as the Infant Feeding Survey enjoyed three advantages that Life Study could not: a) a sponsor – the NHS – that was bound to resonate with new mothers more than UCL b) it was not a cohort study, and could be presented as a study involving the initial questionnaire and one follow-up contact, not as a long-term commitment c) it had a strong focus – infant feeding – which is extremely salient for new mothers, whereas Life Study covered a very wide range of topic areas. On the other hand, the Infant Feeding Survey had a much longer opt-in instrument (40 pages) than we proposed to use for the Birth Component.

3.3 Selection of pilot areas

Using the longlist of 151 postal districts, we identified interviewers that were potentially able to work in these areas during the pilot fieldwork period. The potential pilot areas were built up around the home addresses of the interviewers to save on travel costs. From those potential areas, we selected 32 pilot areas that gave a good geographical spread (22 in England and five in each of Wales and Scotland).

3.4 Selection of babies

Ipsos MORI provided the ONS and NRS with the list of 32 pilot areas to be used in the pilot.

In England and Wales, it was agreed that, where babies were born more than one month prematurely, the sampling reference date needed to be based on the expected delivery date rather than the actual date of birth. The reason for this was to facilitate the study of the impact of developmental age on child development.

In Scotland, NRS indicated that this procedure would not be possible in the pilot, but hoped to be able to implement it at the main stage. Accordingly, in Scotland the sampling reference date was actual date of birth.

For each monthly sample run, all babies registered as living in the selected pilot areas were selected for inclusion in the pilot, in accordance with the procedure outlined above.

3.5 Managing the process with the Statistical Authorities

The role of the Statistical Authorities in the pilot was to draw the sample of babies on our behalf, and administer the opt-in approach. To facilitate this Ipsos MORI drew up a detailed sampling note which clearly set out the agreed procedures including deadlines. At the request of UCL, Ipsos MORI liaised closely with the Statistical Authorities throughout the sampling and opt-in approach.

The Statistical Authorities gave us an assurance that birth registration records would be up-to-date two months after the last date in the birth month. For example, for babies born in January of any given year, the ONS would expect to possess up-to-date records by the end of March, and thus be able to undertake sampling in the following month.

Once records were available, the Statistical Authorities identified all eligible births registered in the selected pilot areas for each sampling run. They then provided Ipsos MORI with counts of births in the selected pilot areas for that sampling run. Ipsos MORI checked the actual counts of births against the expected numbers to identify any potential problems.

Once the counts for each monthly sample were signed off by Ipsos MORI, the ONS and NRS allocated each sampled baby a serial number, according to a specification provided by Ipsos MORI. This was used to monitor returned questionnaires and administer the reminder process.

Mothers of sampled babies were randomly allocated a two-page or eight-page recruitment questionnaire, depending on whether the serial number of the sampled baby was an odd or even number. If the serial number was an even number, then the mother was sent a two-page questionnaire. If the serial number was an odd number, then the mother was sent an eight-page questionnaire.

The Statistical Authorities screened the sample against death records they held, so that selected babies (and, in Scotland, mothers) who were known to have passed away were removed from the sample prior to the opt-in mailings.

Overall the process of sampling went relatively smoothly. Some flexibility was required on the part of all parties to ensure the sampling process and checking did not cause any delay to the opt-in mailings, but this was managed without great difficulty.

3.6 The issued sample

Table 3.1 shows the number of babies selected by month, showing expected births against actual numbers.

Response is discussed in detail in Chapter 4. It was apparent from an early stage that the response rate to the opt-in approach was very disappointing. Ipsos MORI prepared a paper analysing the progress of the Birth Component in detail (see Appendix 1) and, among other things, recommended cancelling the final sample run and carrying out a more limited pilot, while attempts were made to access other sampling frames which would result in a viable data collection method for the Birth Component. At a meeting on 8 July 2015, UCL agreed with Ipsos MORI's proposal to cancel the final sample run and Ipsos MORI informed the Statistical Authorities accordingly.

Table 3.1: Number of babies selected by country and sample run

Overall	**Total**	**England**	**Wales**	**Scotland**
	n	n	n	n
Planned	**4800**	3300	750	750
Actual	**4778**	3307	771	700
Babies from first sample run	**n**	n	n	n
Planned	**1600**	1100	250	250
Actual	**1644**	1136	271	237
Babies from second sample run	**n**	n	n	n
Planned	**1600**	1100	250	250
Actual	**1489**	1050	235	204
Babies from third sample run	**n**	n	n	n
Planned	**1600**	1100	250	250
Actual	**1645**	1121	265	259

At that meeting it was decided to issue mothers opting-in from six of the 32 pilot areas only for baseline survey fieldwork, as it looked at that stage as if we would have insufficient numbers of mothers opting-in from the other pilot areas.

4 Developing the opt-in fieldwork approach

4.1 The opt-in instruments

Prior to the Birth Component being commissioned UCL had developed an opt-in instrument, along with a survey leaflet.

This opt-in instrument took the form of a reply paid card, which asked mothers of the sampled babies if they wished to find out more about Life Study. It also asked them for the name, date of birth and gender of the sampled baby, as well as whether they were living with someone as a couple (intended to help us identify potential babies with a non-resident father). Finally, mothers were asked to fill in their contact details, along with the best time and day for an interviewer to call.

As this approach was untried, and as the Infant Feeding Survey 2010 had successfully used a questionnaire as the opt-in instrument, Ipsos MORI proposed that an experiment was carried out during the opt-in approach, whereby selected babies were randomly allocated to the reply paid card approach or the questionnaire approach. A description of the development of the questionnaire approach and copies of the documents used are contained in Appendix 2.

4.2 Delivering the opt-in fieldwork approach

Ipsos MORI were responsible for developing the opt-in approach. The mothers of selected babies were sent an invitation pack to opt-in to Life Study comprising:

- A covering letter.
- A two-page or eight-page questionnaire.
- A leaflet explaining what Life Study was about.
- A reply paid envelope.

Those returning the questionnaire and not explicitly stating they wanted no further contact were deemed to have "opted-in" to Life Study. We send two reminder mailings to non-responders. The packs were identical except the wording of each reminder was different to the other letters.

The covering letters were developed by Ipsos MORI. The literature on survey methods recommends strongly that reminder letters are different to the initial letter – appealing to different response propensities, and taking a new approach – with the aim of getting different people to respond to the reminder stage[4]. We therefore adopted this approach for the Birth Component. The covering letters used the logo of the appropriate Statistical Authority as well as the Life Study logo, and were signed by the Principal Investigator of Life Study, Professor Carol Dezateux. Although procedures were in place to try and ensure mothers whose baby had passed away were not invited to opt-in to Life Study (see Chapter 2), we recognised it was inevitable that the lag in updating records did not eliminate this possibility. A suitable sentence was included in the covering letter to apologise for any distress we may have inadvertently caused.

Ipsos MORI decided to substitute the reply paid card with a two-page questionnaire. We did so because it made the printing process much easier and also because we were concerned that a reply paid card

[4] Dillman, D.A., Smyth, J.D. & Christian, L.M. (2014). Internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method, 4th Edition. John Wiley & Sons Inc.

was less confidential than a questionnaire placed in a reply paid envelope, which could negatively affect response.

The leaflet had been designed and approved by UCL prior to the commissioning of the Birth Component. Ipsos MORI were afforded the opportunity to make comments on the text and a small number of changes were made. Two versions of the leaflets were produced to reflect the fact there are different Statistical Authorities covering England and Wales and Scotland.

Life Study was undertaken within an *Ethics and Information Governance Framework* developed by UCL. Section 7.1 of the Framework states that:

The core scientific protocol and operational procedures of the Life Study resource, as well as proposed uses of it, will have approval from appropriate ethics committees in accordance with guidance from relevant bodies (such as the Health Research Authority) and with relevant provisions (such as the Research Governance Frameworks of England, Wales, and Scotland; Governance Arrangements for Research Ethics Committees; and Standard Operating Procedures for Research Ethics Committees in the United Kingdom).

Accordingly, all survey documents were submitted to and approved by the NHS London – City and East Research Ethics Committee (REC reference 12/LO/1492).

4.3 Working with the Statistical Authorities

The administration of the opt-in approach depended on the co-operation of the ONS and NRS.

The process developed for administering the opt-in approach depended largely on two factors:

- The requirement that the identity of the sampled mothers should not be disclosed to Ipsos MORI unless they consented.
- The printing capabilities of the Statistical Authorities.

The ONS administered the opt-in approach in England and Wales. They have an in-house printing capability and agreed to undertake the printing of all stationery except business reply envelopes and the survey leaflet. This was because the trifold survey leaflet, designed by UCL, comprised three conjoined A5 panels that when laid flat measured 17.48 inches in length and 8.27 inches wide (larger than A4 paper size). As most survey leaflets are printed on A4, Ipsos MORI asked one of their approved printing suppliers to print the survey leaflets and business reply envelopes, because the ONS lacked the necessary equipment to do so. Survey leaflets and business reply envelopes were delivered to the ONS in stages on request. The ONS then carried out the remaining printing, fulfilment and despatch.

NRS administered the opt-in approach in Scotland. While they had the in-house capacity for sampling, they did not have any in-house printing capacity. Accordingly, Ipsos MORI asked one of our approved printing suppliers to print and fulfil the survey packs, ensuring that the serial numbers of sampled babies were printed on the covering letters so they were visible inside the outer window envelopes. When the packs arrived at NRS, staff at NRS printed off labels containing the name and address of the sampled baby's mother and affixed them over the window of the envelopes. NRS then despatched the survey packs.

The dates of each mailing are set out in the following tables:

Table 4.1: Opt-in fieldwork dates (England and Wales)

Sample run		First sample run	Second sample run	Third sample run
Invitation	Planned	w/c 20 April 2015	w/c 18 May 2015	w/c 15 June 2015
	Actual	10 June 2015	17 June 2015	20 July 2015
First reminder	Planned	w/c 11 May 2015	w/c 8 June 2015	w/c 6 July 2015
	Actual	20 July 2015	11 August 2015	21 August 2015
Second reminder	Planned	w/c 25 May 2015	w/c 22 June 2015	w/c 20 July 2015
	Actual	21 August 2015	2 September 2015	11 September 2015

Table 4.2: Opt-in fieldwork dates (Scotland)

Sample run		First sample run	Second sample run	Third sample run
Invitation	Planned	w/c 20 April 2015	w/c 18 May 2015	w/c 15 June 2015
	Actual	26 May 2015	3 June 2015	22 June 2015
First reminder	Planned	w/c 11 May 2015	w/c 8 June 2015	w/c 6 July 2015
	Actual	23 June 2015	27 June 2015	17 July 2015
Second reminder	Planned	w/c 25 May 2015	w/c 22 June 2015	w/c 20 July 2015
	Actual	9 July 2015	17 July 2015	28 August 2015

The cut-off date for opt-in fieldwork was 2 October 2015.

Tables 4.1 and 4.2 show that the opt-in approach experienced significant delays. This has a potentially important implication. The design is based on the baseline survey interviews being conducted with mothers of the sampled babies when the babies are between five and seven months old (aged approximately between 22 and 30 weeks). Babies develop rapidly in the early months of life and consequently it is important to have as little variation as possible in the age of the babies at time of interview, to ensure the data about the babies are robust. A two-month interviewing window was deemed necessary so that interviewers had sufficient time to complete their assignment and achieve high response rates. It was acknowledged that it was important that the number of interviews conducted with mothers when the selected baby had a corrected postnatal age greater than seven months should be minimised.

There were several causes of the delay. We did not receive REC approval of the opt-in documents until 6 May 2015 and given the time lags in printing and despatch, inevitably this meant that the invitation mailings would have been sent out one month late in any event. This would not have been a problem at the main stage as long as sufficient time was built in for REC approval of survey documents. Had this

delay not occurred it is reasonable to assume that the mean age of the babies would have been around 25 weeks (rather than the ideal of 22 weeks) at the start of fieldwork.

There were a number of other factors which caused delays:

- There were capacity issues with the Statistical Authorities. This in itself was unsurprising as the task was a new one to them, and given the nature of the pilot study, they did not have the opportunity to undertake longer-term planning and capacity building as they could have done for the main stage.

- The leaflet, because it was not printed on a standard paper size, required more time for printing, compared with using the standard survey leaflet size of A4. This caused an additional delay at the start of the fieldwork process and in hindsight, it might have been sensible to ask UCL to redesign the leaflet from the outset.

- The printers were late in delivering the leaflets for the first ONS' reminder mailings for the first two sample runs.

- The requirement that the identity of the sampled mothers should not be disclosed to Ipsos MORI unless they consented meant additional co-ordination and steps in the process. For example in Scotland once our printers had finished their task we had to despatch the mailing to National Records of Scotland, not the respondents, which inevitably added days to the process. Further, this tended to cause delays at both the invitation and reminder stages.

- We also became aware of potential problems resulting from a re-direction of mail necessary because of Ipsos MORI's office move at the start of July 2015. We did make representations to Royal Mail but were forced to hold up mailings for over one week in late July and early August, in the hope that any missing mail would be delivered to us and to avoid irritating mothers who had already responded.

5 Opt-in response

The opt-in response rate, broken down by country and sample run, is shown in Table 5.1. Overall 18.9 per cent of mothers invited to opt-in returned a questionnaire. A very small proportion refused directly to Ipsos MORI (0.2%) and 2.2 per cent had gone away. It is important to note that not all responding agreed to participate in Life Study because the two-page opt-in instrument enabled respondents to refuse further participation (see below).

Overall, the opt-in response rate did not fluctuate significantly by sample run. The selected pilot areas were not designed to produce a nationally representative sample, and so country comparisons should be made with caution. The opt-in response rate did significantly differ by country, with response being highest in England (19.6%) and lowest in Wales (16.2%).

Table 5.1: Opt-in response rates by country and sample run

Overall	**Total**		**England**		**Wales**		**Scotland**	
	n	**%**	n	%	n	%	n	%
Questionnaires issued	**4778**		3307		771		700	
Gone away	**103**	**2.2%**	74	2.2%	14	1.8%	15	2.1%
Refused	**9**	**0.2%**	5	0.2%	1	0.1%	3	0.4%
Questionnaires received	**904**	**18.9%**	647	19.6%	125	16.2%	132	18.9%
No response	**3762**	**78.7%**	2581	78.0%	631	81.8%	550	78.6%
First sample run								
	n	**%**	n	%	n	%	n	%
Questionnaires issued	**1644**		1136		271		237	
Gone away	**34**	**2.1%**	23	2.0%	3	1.1%	8	3.4%
Refused	**5**	**0.3%**	4	0.4%	0	0.0%	1	0.4%
Questionnaires received	**302**	**18.4%**	213	18.8%	42	15.5%	47	19.8%
No response	**1303**	**79.3%**	896	78.9%	226	83.4%	181	76.4%
Second sample run								
	n	**%**	n	%	n	%	n	%
Questionnaires issued	**1489**		1050		235		204	
Gone away	**31**	**2.1%**	24	2.3%	6	2.6%	1	0.5%
Refused	**3**	**0.2%**	1	0.1%	0	0.0%	2	1.0%
Questionnaires received	**290**	**19.5%**	212	20.2%	37	15.7%	41	20.1%
No response	**1165**	**78.2%**	813	77.4%	192	81.7%	160	78.4%
Third sample run								
	n	**%**	n	%	n	%	n	%
Questionnaires issued	**1645**		1121		265		259	
Gone away	**38**	**2.3%**	27	2.4%	5	1.9%	6	2.3%
Refused	**1**	**0.1%**	0	0.0%	1	0.4%	0	0.0%
Questionnaires received	**312**	**19.0%**	222	19.8%	46	17.4%	44	17.0%
No response	**1294**	**78.7%**	872	77.8%	213	80.4%	209	80.7%

These opt-in response rates are undoubtedly very disappointing. They imply that the composite response rate (i.e. after taking into account the face-to-face pilot interviewing) to the baseline wave of the Birth Component is unlikely to be higher than 15 per cent and might be lower. The response rate is the one single measure that is available across all surveys and is used as an indicator of a survey's quality. One can debate how appropriate that might be, but a total composite response rate of about 10 to 20 per cent would generally be considered to be exceptionally low, and the results from the survey data susceptible to unacceptably large biases, making it unwise or impossible generalise from any findings to the population as a whole, as has been done on all previous UK birth cohort studies.

Table 5.2 shows the opt-in response rate by experimental condition. Overall, the eight-page instrument achieved an opt-in response rate of 20.2 per cent and the two-page instrument 17.6 per cent. It is clear that whatever opt-in instrument used, the opt-in response rate is very disappointing.

Table 5.2: Opt-in response rates by experimental condition

Overall	**Total**		**8 page**		**2 page**	
	n	**%**	n	**%**	n	**%**
Questionnaires issued	**4778**		2410		2368	
Gone away	**103**	**2.2%**	50	2.1%	53	2.2%
Refused	**9**	**0.2%**	6	0.2%	3	0.1%
Questionnaires received	**904**	**18.9%**	488	20.2%	416	17.6%
No response	**3762**	**78.7%**	1866	77.4%	1896	80.1%
First sample run						
	n	**%**	n	%	n	%
Questionnaires issued	**1644**		825		819	
Gone away	**34**	**2.1%**	19	2.3%	15	1.8%
Refused	**5**	**0.3%**	2	0.2%	3	0.4%
Questionnaires received	**302**	**18.4%**	162	19.6%	140	17.1%
No response	**1303**	**79.3%**	642	77.8%	661	80.7%
Second sample run						
	n	**%**	n	%	n	%
Questionnaires issued	**1489**		755		734	
Gone away	**31**	**2.1%**	15	2.0%	16	2.2%
Refused	**3**	**0.2%**	3	0.4%	0	0.0%
Questionnaires received	**290**	**19.5%**	158	20.9%	132	18.0%
No response	**1165**	**78.2%**	579	76.7%	586	79.8%
Third sample run						
	n	**%**	n	%	n	%
Questionnaires issued	**1645**		830		815	
Gone away	**38**	**2.3%**	16	1.9%	22	2.7%
Refused	**1**	**0.1%**	1	0.1%	0	0.0%
Questionnaires received	**312**	**19.0%**	168	20.2%	144	17.7%
No response	**1294**	**78.7%**	645	77.7%	649	79.6%

The comparison in Table 5.2 is flattering to the two-page instrument. This is because the two-page instrument contained a question asking mothers if they wanted further information. Mothers could tick either "YES, I want more information", or "NO, please do not contact me again". Those who ticked "NO, please do not contact me again" were not counted as having opted-in to Life Study, even if they filled their name or contact details on the instrument. Thus a fair comparison is to compare opt-in participation rates, that is having excluded those saying their baby was no longer with them (on the eight-page instrument) or "NO, please do not contact me again" on the two-page instrument.

Table 5.3 shows the results of this analysis of the opt-in participation rate to the experiment. This shows that the participation rate to the opt-in process was 16.6 per cent overall. The eight-page instrument did perform significantly better, achieving a participation rate of 20.2 per cent, compared to 12.9 per cent for the two-page instrument.

Table 5.3: Opt-in participation rates by experimental condition

Overall	**Total**		8 page		2 page	
	n	**%**	n	**%**	n	**%**
Questionnaires issued	**4778**		2410		2368	
Gone away	**103**	**2.2%**	50	2.1%	53	2.2%
Refused	**9**	**0.2%**	6	0.2%	3	0.1%
Questionnaires received	**904**	**18.9%**	488	20.2%	416	17.6%
No response	**3762**	**78.7%**	1866	77.4%	1896	80.1%
Of which:						
My baby is no longer with me	**2**	**0.0%**	2	0.1%	N/A	N/A
NO, please do not contact me again	**111**	**2.3%**	N/A	N/A	111	4.7%
Participating	**791**	**16.6%**	486	20.2%	305	12.9%

The opt-in instruments were paper self-completion questionnaires. When they were returned to Ipsos MORI the contact details provided on the instruments were entered into a database so they could be used as the sample file for the baseline survey, administered by interviewers face-to-face. Table 5.4 shows the prevalence of contact details provided (of those opting-in).

Over nine in 10 mothers opting-in provided the minimum information required for us to approach them for the face-to-face baseline survey (the baby's full name, their own full name, and their address). There was no significant difference by experimental condition in terms of the provision of the minimum contact details required to administer the face-to-face baseline survey.

If one defines net participation as those opt-in *and* providing useable contact details, then the net opt-in participation rate was 15.4 per cent (735 valid responses). The net opt-in participation rate was 18.7 per cent among those receiving the eight-page instrument (450 valid responses) and 12.0 per cent among those receiving the two-page instrument (285 valid responses).

Table 5.4: Prevalence of contact details provided by experimental condition

Contact details	**Total**		8 page		2 page	
	n	**%**	n	%	n	%
Mothers opting-in	**791**		486		305	
% giving baby's full name	**773**	**97.7%**	472	97.1%	301	98.7%
% giving own full name	**767**	**97.0%**	468	96.3%	299	98.0%
% giving at least one email address	**742**	**93.8%**	450	92.6%	292	95.7%
% giving at least one telephone number	**688**	**87.0%**	403	82.9%	285	93.4%
% giving an address	**753**	**95.2%**	463	95.3%	290	95.1%
% giving baby's full name/own full name/address	**735**	**92.9%**	450	92.6%	285	93.4%

Tables 5.5 and 5.6 show the opt-in response rates by mailing stage for England and Wales and Scotland.

Table 5.5: Opt-in response rates by mailing stage (England and Wales)

Sample run		First sample run	Second sample run	Third sample run	Total
Invitation	Questionnaires received	146	137	135	418
	% of overall	57%	55%	50%	54%
First reminder	Questionnaires received	69	53	75	197
	% of overall	27%	21%	28%	26%
Second reminder	Questionnaires received	40	59	58	157
	% of overall	16%	24%	22%	20%
Total	Questionnaires received	255	249	268	772

Table 5.6: Opt-in response rates by mailing stage (Scotland)

Sample run		First sample run	Second sample run	Third sample run	Total
Invitation	Questionnaires received	27	18	23	68
	% of overall	57%	44%	52%	52%
First reminder	Questionnaires received	5	17	13	35
	% of overall	11%	41%	30%	27%
Second reminder	Questionnaires received	15	6	8	29
	% of overall	32%	15%	18%	22%
Total	Questionnaires received	47	41	44	132

As is normally the case in postal surveys, the invitation mailing was the most successful, accounting for just over half the responses received. The first reminder was marginally more successful than the second reminder, again in line with the normal experience.

Table 5.7 shows the sample profile by experimental condition. Only a very small number of demographic questions were asked on the opt-in instruments and so the potential for analysis is limited.

Table 5.7: Sample profile by experimental condition

Overall	**Total**		8 page		2 page	
	n	**%**	n	**%**	n	**%**
Mothers opting-in and giving baby's full name/own full name/address	**735**		450		285	
Median age (in middle of sample run)	**32**		32		N/A	
Single baby	**704**	**96%**	437	**97%**	267	**94%**
Twins	**21**	**3%**	10	**2%**	11	**4%**
Triplets	**3**	*	0	**0%**	3	**1%**
Missing information	**7**	**1%**	3	**1%**	4	**1%**
Baby boy	**364**	**50%**	228	**51%**	136	**48%**
Baby girl	**346**	**47%**	216	**48%**	130	**46%**
Missing information	**25**	**3%**	6	**1%**	19	**7%**
Living as a couple	**648**	**88%**	396	**88%**	252	**88%**
Not living as a couple	**62**	**8%**	42	**9%**	20	**7%**
Missing information	**25**	**3%**	12	**3%**	13	**5%**

* denotes a percentage greater than zero but less than 0.5 per cent.

The mean age of the mothers opting in to Life Study was 31.4 years (note mothers' age was collected on the eight-page instrument only). For comparison, according to the latest ONS figures, in 2013 the standardised average (mean) age of all mothers giving birth in England and Wales was 30.0 years[5]. The proportion of mothers saying they were not living with someone was lower (8%) than anticipated (15%). This means that the interviewers administering the baseline surveys are likely to identify many fewer non-resident fathers than we hoped.

The sampling instructions for the ONS specified that:

For babies that are more than one month premature, the sampling reference date needs to be based on the expected delivery date (EDD) rather than the date of birth: those babies will be allocated to the sampling month based on their EDD.

We wanted to establish whether these sampling instructions had been implemented successfully by looking at the evidence from the opt-in data. As the opt-in data were collected using paper self-completion questionnaires there is potential for outliers to be generated by respondents making mistakes, and also the possibility of transcription errors resulting from unclear handwriting.

All given dates of birth that were before 31 December 2013 or after 30 June 2015 were considered to be unreliable data and were excluded from the analysis. We then computed the difference in days between each baby's expected and actual date of birth. The prevalence of babies born at a

[5] *Live Births in England and Wales by Characteristics of Mother 1, 2013* (available at http://www.ons.gov.uk/ons/rel/vsob1/characteristics-of-Mother-1--england-and-wales/2013/stb-characteristics-of-mother-1--2013.html#tab-Timing-of-Childbearing).

gestational age of under 28 weeks is extremely low and these cases were identified with a view to deciding whether these should be considered outliers. Manual inspection of these data suggested these cases should also be considered unreliable and not included in the analysis.

This left 200 babies in the opt-in data who were born prematurely and the data for whom we considered reliable. The distribution of these are shown in Table 5.8 below:

Table 5.8: Sample profile by experimental condition

	Total	
	n	%
1 to 7 days premature	92	46%
8 to 14 days premature	56	28%
15 to 21 days premature	32	16%
22 to 28 days premature	12	6%
More than 28 days premature	8	4%
More than 31 days premature	6	3%

There were six babies in the opt-in data where data appear reliable and they were born more than 31 days prematurely. All were registered in England and Wales after birth and were thus sampled by the ONS. We manually examined these records, and were satisfied the sampling had been carried out correctly. There were two cases where the sampling appeared wrong. Here the babies had expected dates of delivery right at the end of the preceding month, so we do not see this as particularly problematic. We would need to investigate further with the ONS why these cases were sampled in the wrong sampling month, but assume this is an artefact of a cut-off the ONS employed, rather than error.

We also examined the actual dates of birth of babies in the Scottish sample. For data that we consider reliable all given dates of birth were in the correct sample run.

Table 5.9 shows the age of the 146 sampled babies in the six pilot areas on the first day of face-to-face baseline survey fieldwork (8 September 2015). The mothers of eight other sampled babies were issued to interviewers but we did not have information about the age of the sampled baby.

The mean age of the babies in the six pilot areas was 29.5 weeks against an ideal of 22 weeks (to achieve an even spread of interviews, where most interviews were conducted near 26 weeks). As fieldwork was scheduled to last eight weeks, this meant that at pilot, the postnatal age of a significant number of the babies was greater than seven months.

Table 5.9: Age of sampled babies in weeks in six pilot areas on the first day of face-to-face fieldwork (8 September 2015)

Age of sampled babies in weeks	First sample run	Second sample run	Third sample run	Total
23			23.8%	6.8%
24			14.3%	4.1%
25			26.2%	7.5%
26			26.2%	7.5%
27		13.3%	7.1%	6.2%
28		24.4%		7.5%
29		26.7%		8.2%
30		22.2%		6.8%
31	8.5%	13.3%		7.5%
32	22.0%		2.4%	9.6%
33	23.7%			9.6%
34	33.9%			13.7%
35	11.9%			4.8%
Base	*59*	*45*	*42*	*146*

6 Conclusions/recommendations

We now give our conclusions, and recommendations where appropriate, against each of the objectives of the pilot which are relevant to the sampling processes and opt-in approach. Later we make further comments about the implications of this opt-in approach for the future of birth cohort studies in the UK.

6.1 Review of pilot objectives

Ensuring the processes for sampling (requiring information to pass between Ipsos MORI and the Statistical Authorities) worked in a timely way

Our experience of working with the Statistical Authorities on the sampling went smoothly. Some flexibility was required on the part of all parties to ensure the sampling processes and checking did not delay the opt-in mailings, and this was managed without great difficulty.

Ensuring that the Statistical Authorities could draw the sample as required, and checking whether they could make use of expected rather than actual date of birth in drawing the sample

The numbers of expected births and the number of actual births sampled were very similar. The evidence from the opt-in data presented at the end of Chapter 4 suggests that the Statistical Authorities were able to draw the sample as required. The ONS appeared able to use expected rather than actual date of birth. NRS were unable to use this sampling method in the pilot and NISRA did not take part at all. Further investigation would be necessary to establish whether NRS and NISRA would be able to use the expected rather than actual date of birth.

Checking whether the Statistical Authorities were able to make use of Health & Social Care Information Centre address tracing and updating prior to the initial mailout for each sampled month

We asked the ONS whether they were able to make use of Health and Social Care Information Centre address tracing and updating prior to the initial mailout for each sampled month. The ONS informed us that due to recent changes the Health and Social Care Information Centre required the setting up of data access agreements so their data could be used for screening and posting purposes. The ONS were advised this would not be agreed and signed off prior to the pilot so the intention was the ONS would do this work in time for the main stage. The proportion of returns where the named mother had gone away was low – under three per cent – suggesting the quality of the address data on birth registration records is high.

Ensuring that the Statistical Authorities were able to manage the process effectively including dealing with the overlapping months, and the full reminder regime

We describe in Chapter 3 a number of problems which made this process challenging for the Statistical Authorities. We believe that the Statistical Authorities would need much greater capacity, and more extensive piloting to work through the project management difficulties, before we would be assured that the process would be effectively managed. Nonetheless, we should stress that the problems encountered by the Statistical Authorities were not the cause of the low opt-in response rates.

Ensuring that the Statistical Authorities could manage to deal with the experiment with two different opt-in approaches (use of different materials, but same reminder regime – initial mail out and two reminders)

The Statistical Authorities managed the experiment effectively and the evidence we have gives us no concerns in this regard.

Assessment of response to opt-in for each approach and whether the six week opt-in period was effective (too long or too short)

In Chapter 4 we set out the opt-in response rates, with our conclusion that they are very disappointing and not high enough to support statistical inference to an underlying population. We do not believe the low opt-in response rates are a function of the fieldwork period which was if anything too prolonged. The difficulties presented by the opt-in approach (particularly around printing process) means that a six-week opt-in period is too short, and at least nine weeks would be required. This would not however deliver higher opt-in response rates.

Assessment of the information provided by those opting in and how good this information was

The quality of the information provided by those opting-in appeared good. The level of item non-response was low the proportion providing sufficient contact details was very high.

Ensuring Ipsos MORI could process the materials sent by those opting in effectively and in a timely manner

In the event this was not tested as the procedures which would be needed in the main stage were not used (we issued all the opt-in sample we received in six pilot areas in one batch).

6.2 The implications for the future of Birth Cohort Studies in the UK

There are two questions pertinent to the future of Birth Cohort Studies in the UK, which we now attempt to answer, before making a recommendation. Is an opt-in approach to fieldwork (using birth registration records as a sampling frame) a viable practical proposition? Further, and most importantly, does it provide a sound basis for a birth cohort study?

Is an opt-in approach to fieldwork (using birth registration records as a sampling frame) a viable practical proposition?

A desirable aspect of the design of the Birth Component would be to spread the sample of babies over a full calendar year (indeed the Birth Component envisaged a sample of babies would be drawn monthly over four years). By doing so the sample is not as susceptible to data being conditioned by the time of year the sample was drawn, as occurred on the 1946, 1958 and 1970 birth cohort studies, all of which sampled babies born in one particular week.

The requirement to spread the sample of babies over at least one full calendar year, and potentially more, means that a high level of commitment, capacity and project management skill is necessary to ensure the sampling is carried out in a robust manner, and that the implementation of the opt-in mailings and processing of data are timely.

By adopting a design using birth registration records as a sampling frame this introduces two problems making a challenging task particularly difficult: a) the involvement of three Statistical Authorities (for a UK-wide study) and b) additional printing and project management processes necessary because of the requirement that the identity of mothers cannot be disclosed to the fieldwork contractor without their consent.

In the pilot, it was apparent that the capacity of the Statistical Authorities varied considerably. The ONS were best equipped to take part in Life Study. They carried out the sampling processes in a satisfactory manner and could carry out most of the printing tasks required. Unfortunately, they could not undertake all the printing themselves and they would have needed to add additional capacity to have been

confident of meeting the regular mailing deadlines over a 48-month period. NRS were able to carry out the sampling in a satisfactory manner, but could not undertake the printing and as a result this made the implementation of the opt-in approach slower than it would be otherwise. More worrying was NISRA's lack of capacity meaning they could not take part in the pilot at all.

Undoubtedly, there is potential to improve project management processes significantly, but the requirement to draw monthly samples across three Statistical Authorities, and for each Statistical Authority to liaise closely with a fieldwork contractor to implement an opt-in approach involving three mailings which must occur in a timely manner, means the Birth Component would always be at considerable risk of experiencing problems. These problems would carry with them two major risks to data quality:

a. There would be a risk of error in the sampling in one or more months

b. There would be a risk of variation of the age of babies at the time of the six-month interview which could compromise data quality at the baseline survey.

Had Child Benefit records been available the first problem (co-ordination with three Statistical Authorities, each with differing capacities) would have been eliminated; and the second problem would have been much more manageable because the fieldwork contractor would have complete control over the mailing process.

For these reasons we would not consider an opt-in approach to fieldwork (using birth registration records as a sampling frame) a viable practical proposition unless the Statistical Authorities had much greater capacity, and without more extensive piloting to work through the project management difficulties.

Does using an opt-in approach provide a sound basis for a birth cohort study?

It is well known that opt-in approaches tend to result in lower response rates than use of opt-out approaches, and have also been shown to bias samples towards populations with fewer "problems" or lower levels of material disadvantage[6]. A key concern was whether the opt-in approach could be made to work for the Birth Component of Life Study.

As discussed in Chapter 4, the opt-in response rates observed were very disappointing. For practical purposes the response rate for the opt-in approach must be those mothers opting-in and providing useable contact details (meaning they could be interviewed for the baseline survey). The overall net opt-in response rate was 15.4 per cent, rising to 18.7 per cent when an eight-page opt-in instrument was used.

Could the opt-in approach be improved? As discussed in Chapter 2, the most successful opt-in approach that we know of, used in the Infant Feeding Survey in 2010, had three advantages that the Birth Component did not enjoy:

- A sponsor – the NHS – that was bound to resonate with new mothers more than UCL.
- It was not a cohort study, and could be presented as a study involving the initial questionnaire and one follow-up contact[7], not as a long-term commitment.

[6] Junghans, C., Feder, G., Hemingway, H., Timmis, A. and Jones, M. (2005) Recruiting patients to medical research: double blind randomised trial of opt-in versus opt-out strategies. *British Medical Journal*, 331,940.

[7] Note that in fact there were two follow-up contacts. In the survey leaflet which accompanied the initial invitation to Stage 1, potential respondents were told, "we would like to find out how you are feeding your baby as he or she gets older, IFF Research hope to contact you again in a few months time".

- It had a strong focus – infant feeding – which is extremely salient for new mothers, whereas Life Study covered a very wide range of topic areas.

On the other hand the Infant Feeding Survey had a much longer opt-in instrument, because it also aimed to collect a great deal of data as well as permission to follow-up mothers at a later date. Our experience in the pilot suggests the very significant advantages the Infant Feeding Survey enjoyed above outweighed the disadvantage of the longer instrument length.

Given the very low opt-in response rate observed in the pilot, which cannot be blamed on a short fieldwork period, we do not think what might be termed "tinkering" amendments to the opt-in approach would solve the problem of low opt-in response rates.

A radical re-design that might aim to use the advantages enjoyed by the Infant Feeding Survey is possible but without very extensive experimental work, we cannot be confident that this would improve the opt-in response rates to a level (50% of more) that might make the composite response rate to the baseline survey of the Birth Component credible.

Could non-response weighting be a panacea? Non-response weighting is often used to ameliorate the effects of bias in survey samples. As birth registration records might allow for some useful data linkage to NHS records, it may well be possible to use more sophisticated weighting strategies for the Birth Component than are normally used for either the baseline of longitudinal studies or cross-sectional studies. However, with a low composite response rate it is highly unlikely that a weighting strategy could be devised, even using data linkage, that could eliminate the very probable non-response bias for many of the large number of variables in the Birth Component data. The most effective approach for reducing bias in a survey is to increase the likelihood of participation. Relying on weighting is not a credible option. If a study achieves a very low composite response rate, then however sophisticated the weighting, it will not reassure stakeholders of the accuracy of the estimates.

For the reasons given above we conclude that, even if it were proven to be a viable practical proposition, using an opt-in approach does not provide a sound basis for a birth cohort study.

Recommendation for the future

The unintended consequence of the government's decision to revoke universal entitlement to Child Benefit has been to remove a viable sampling frame for birth cohort studies without leaving an obvious substitute in its place. Birth registration records appear attractive because of their coverage, but this study has shown that using them as a sampling frame creates data collection problems which appear insurmountable.

Plainly Ipsos MORI has a vested interest in the continuation of birth cohort studies as a potential fieldwork contractor. We believe that these studies are rightly world renowned, that there is a very strong public interest that they should continue on a sound methodological footing, and that most others in the social research and policy-making communities would agree.

At a meeting with Ipsos MORI on 8 July 2015 UCL had undertaken to explore potential alternatives and over the summer of 2015 a good deal of work was undertaken to secure access on an "opt-out" basis to the database which holds the NHS numbers of the population (the Personal Demographics Service) and generates the numbers for all new births. Had access to this database been achieved, then a viable alternative to using Child Benefit records would have become available, and potentially the future of UK birth cohort studies would have been secure. Unfortunately, it was not possible to bring this work to a conclusion.

We believe that the experience of the pilot outlined in this report underlines the urgency with which the search for an alternative sampling frame for birth cohort studies should be undertaken. This ought to be one of the social research community's highest priorities. If this is not done, then it seems there may be no further credible birth cohort studies undertaken in the UK.

Appendix 1

The text of a memorandum from Ipsos MORI to UCL entitled "Life Study Birth Component – Problems with the opt-in process and their consequences", dated 2 July 2015, is set out below:

You will be aware from my regular reports since 12 June that the response rate to the opt-in process for the Birth Component has been extremely disappointing. This memo I hope can serve as a background paper for our meeting at ICH at 3.30pm on 7 July.

In it, we describe why the current opt-in process will not be a feasible approach for the Birth Component. We recommend a radical re-design to the opt-in approach, in tandem with an exploration of an opt-out approach using a different sampling frame. We also make recommendations for work to be carried out in the interim while a viable design for the Birth Component is developed, in particular carrying out a much more limited face-to-face pilot in August/September.

The current situation

Our current best estimate is that the final response rate to the opt-in process will be no higher than 15 per cent. This is far lower than the 33 per cent allowed for...It seems certain that we will not achieve the planned 1,056 opt-in returns from the [first] and [second] sample runs, which would have enabled us to sub-sample 800 mothers for the face-to-face pilot at 6 months (biasing the sample towards those not living with a partner), and ultimately to issue 400 mothers for the web/CATI pilot at 12 months. In fact we are very unlikely to get anywhere near those numbers. As a small proportion of mothers returning a questionnaire may not include their address, or will ask for no further contact (perhaps 10% of all those submitting a return), the response rate, taking this into account, will probably finish at around 13 - 14 per cent…

Problem

The disappointing opt-in process compromises several of the agreed objectives of the Birth Component Pilot. However, this is not the main issue.

A low response rate to the opt-in process, of the order of 13 - 14 per cent, means that the net response rate (i.e. after taking into account the face-to-face pilot) to the baseline wave of the Birth Component is unlikely to be higher than 10 per cent and might be lower. The response rate is the one single measure that is available across all surveys and is used as an indicator of a survey's quality. One can argue how appropriate that might be, but the reality is that a response rate of about 10 to 20 per cent would be considered by the funders or wider research community to be exceptionally low. We believe they would view the results from the survey data as likely to be subject to unacceptably large biases, making it impossible for them to justify generalising from any findings to the population as a whole, as has been done on all previous UK birth cohort studies. This, in our view, will mean the Birth Component data will carry no credibility with the funders or wider research community.

Non-response weighting is often used to ameliorate the effects of bias in survey samples. As Birth Records might allow for some useful data linkage, it may well be possible to use more sophisticated weighting strategies for the Birth Component than are normally used for either the baseline of longitudinal studies or cross-sectional studies. However, with a low response rate it is highly unlikely that a weighting strategy could be devised, even using data linkage, that could eliminate the very probable non-response bias for many of the large number of variables in the Birth Component data. The most effective approach for reducing bias in a survey is to increase the likelihood of participation. Relying on weighting is not a

credible option. If a study achieves a very low response rate, then however sophisticated the weighting, it will not reassure stakeholders of the accuracy of the estimates…

Thus the purpose of the meeting, on 7 July, in our view, should be:

1. To identify steps we might take to develop a viable design for the Birth Component.
2. To decide what, in the interim, we should do to maximise the value of the Birth Component work undertaken so far.

…

Steps to develop a viable design for the Birth Component

As the opt-in process has been very disappointing so far, we believe that the only real options facing us are:

1. A radical re-design of the opt-in process.
2. Attempting to use an opt-out process with the same or another sampling frame.

In our view we can and should pursue both of these options concurrently.

A radical re-design of the opt-in process

The most successful opt-in process that we know of, used in the Infant Feeding Survey in 2010, had three advantages that the Birth Component does not enjoy:

1. It had a sponsor – the NHS - that was bound to resonate with new mothers. Unfortunately University College London cannot hope to enjoy the same association with potential respondents.
2. It was not a cohort study, and could be presented as a study involving the initial questionnaire and one follow-up contact, not as a long-term commitment.
3. It had a strong focus – infant feeding – which is extremely salient for new mothers, and did not carry the possible perception of a lack of focus which Life Study, with its understandable desire to cover a wide range of topic areas, might suffer from.

On the other hand the Infant Feeding Survey had a much longer opt-in instrument (40 pages) than the Birth Component (2 and 8 pages depending on experimental condition). However, it appears the very significant advantages listed above outweighed the longer instrument length.

We have ruled out what might be termed "tinkering" amendments to the opt-in process, as we do not see how they could possibly raise the response rate by the large amount necessary. The design needs to be radically re-thought to increase the response rate to an acceptable level.

We propose a radical re-design that might aim to use the advantages enjoyed by the Infant Feeding Survey by doing the following:

1. Exploring the idea of co-sponsorship with either the NHS or a Government Department (Department of Health or Department for Education).
2. Altering the procedures so that respondents to the opt-in process are told that there will be one further face-to-face visit only. At this face-to-face visit we propose the interviewer introduces the nature of the birth cohort study to them, taking advantage of the rapport built up by the interviewer and the proven ability of face-to-face interviewers to deliver high response rates.
3. Change the purported focus of the study to make it stronger, focusing on issues of obvious importance to mothers. Further, the linked nature of the study (apparent on the survey website)

means some respondents have perceived they are being recruited to the Pregnancy Component (we know this because of calls to the helpline). Therefore we would strongly recommend giving the Birth Component a separate brand and website.

We understand developing this package would take some time, and we cannot predict whether or not a radically re-designed opt-in process would work. But without a radical re-design of this kind, we do not see any prospect of the opt-in approach working, to enable a credible Birth Component.

We are aware that there are ethical implications to what we say at b) above. However, it is not ethical to carry out a study with the current protocols when a change in procedures would produce a much improved study. We also feel the Birth Component is not comparable to the Pregnancy Component where tissue samples are taken, or analogous to agreeing to be subject to a medical procedure. These understandably demand very different protocols which are not appropriate for a survey.

At the *Understanding Society* baseline respondents were not informed the study would be longitudinal until the first interviewer visit; even at that point the interviewer had discretion as to the extent to which they set out its longitudinal nature. *Understanding Society* did not use an opt-in process, but still needed to take such steps to maximise the response rate at the recruitment stage.

At the Millennium Cohort Study baseline respondents were sent a leaflet informing them it was a cohort study prior to the face-to-face interviewer visit. However the information provided in the leaflet was not as detailed as that we are providing at the opt-in stage, and the Millennium Cohort Study used an opt-out approach, and this did not suffer from the manifest weaknesses of an opt-in approach.

We submit that an approach whereby at the face-to-face visit respondents are told for the first time the Birth Component is a longitudinal study is ethical, and allows participants to decide whether or not to continue with the study on the basis of a discussion with an interview and with the opportunity of taking part in an interview to gain a better understanding of what participation involves. In other words they are likely to be making a much more informed choice than they are in the opt-in process.

Attempting to use an opt-out process with the same or another sampling frame

The experience of previous birth cohort studies, other longitudinal studies and cross-sectional studies is that a face-to-face methodology using named sample is a viable approach and delivers high response rates, if an "opt-out" method[8] is used i.e. where respondents do not have to make an effort to volunteer themselves for the study (as in the Birth Component).

We understand that ONS have already confirmed to you that for legal reasons it is not possible for them to administer an opt-out process and then pass on details to us. However, if there is any doubt or ambiguity about the responses you have had from ONS, we would strongly recommend further follow-ups and if necessary taking legal advice on Data Protection law, as, aside from the access issues, Birth Records are an excellent sampling frame.

There is no reason to think an opt-in process using an alternative sampling frame to Birth Records would be any more successful than what we have seen so far. Thus the alternative is to explore using an alternative sampling frame to Birth Records, which allows an *opt-out process*. In our view there are two possible options: MIDAS and Child Benefit Records.

[8] An opt-out procedure is usually carried out by post and is an opportunity for parents to remove themselves from the sample – effectively, it is in lieu of seeking permission from parents for their details to be passed onto the survey organisation. Once parents have opted not to take part in the survey, they cannot be contacted again.

Below is a summary of what we know about each database and our recommendations. At Annex 1 is further information about each database.

The Medical Research Information Service Integrated Database & Administration System (MIDAS)

The Health and Social Care Information Centre (HSCIC) maintains a database called the Medical Research Information Service Integrated Database & Administration System (MIDAS). MIDAS has almost complete coverage of the population, up-to-date contact information[9] and also includes a range of variables that would be useful for selecting the sample (including age). ONS believe it contains information on "virtually everyone in England and Wales". There appears to be an equivalent database in Scotland[10] but we do not if the same is true for Northern Ireland.

In theory MIDAS would be an excellent sampling frame for the Birth Component. However, to the best of our knowledge it has never been used as a sampling frame for a quantitative survey, not even for those run for the HSCIC itself. We have used it successfully for a pilot study for a large health and well-being survey among 15-year-olds in England. In our view despite the potentially lengthy and costly process that might have to be undertaken to achieve access, this is well worth exploring.

There have been difficulties recently with accessing health data via HSCIC, in the wake of the care.data problems. However, we believe these problems are now less acute, and HSCIC is currently exploring the use of MIDAS for a survey looking at child and adolescent mental health. It is therefore possible that in the near future there will be a precedent set for making use of MIDAS for health-related surveys, and further, that HSCIC's difficulties will be over.

We are aware that it will take some time to obtain access to MIDAS, and, further, the sampling work for the main stage would likely be many months away. It is also likely that some sponsorship would be needed from a Government Department such as the Department of Health.

The Child Benefit (CB) Register

The Child Benefit (CB) Register, which is held and maintained by Her Majesty's Revenue and Customs (HMRC), used to be the default sampling frame to obtain samples that involved children and young people in the United Kingdom. Indeed it was the sampling frame used for the Millennium Cohort Study.

Since 7 January 2013, the rules for claiming tax benefit changed. It is no longer possible to derive financial benefit[11] from receipt of Child Benefit where a child has one or more parents whose adjusted net income is over £60,000 per year. Further, it is not possible to gain the full financial benefit from receipt of Child Benefit where a child has one or more parents whose adjusted net income is between £50,000 and £60,000 per year (whose Child Benefit is clawed back at a rate of £1 in every £100). The Government estimates about 15 per cent of families that were previously eligible would be affected by these changes with about 11 per cent losing benefit completely.

The impact of this is that babies born to parents with higher net incomes will be under-represented on the Child Benefit Register. This means that any sample for the Birth Component based on CB records will be biased away from these higher-income households. However, it is important to note that the degree of

[9] We do not know how frequently it is updated with new births. Babies are issued with NHS numbers soon after birth but we would need to do some work to establish how quickly.
[10] The equivalent database in Scotland is the Community Health Index (CHI) database (http://www.informationgovernance.scot.nhs.uk) which is a database of everyone who is registered with a GP Practice in Scotland. The database contains demographic information and has been used as a sampling frame for the Scottish Health and Care Experience Survey 2013/14 Patient Experience survey (http://www.gov.scot/Publications/2015/03/8892/1).
[11] Higher income parents may still claim for Child Benefit; however, they will make no net financial gain from doing so.

bias thereby created will be far less of a problem for the credibility of the Birth Component than the bias created by 90 per cent or more of the baseline sample not taking part.

Information can only be released from CB records in certain circumstances:

1. A legal (or information sharing) gateway[12] needs to be in place (through a secondary organisation that already has a legal gateway).
2. HMRC also need to demonstrate that there is a benefit to them before a case can be made to pass over information from the CB records.

The Child Benefit Register would be a worse sampling frame than MIDAS for the Birth Component, but has the advantage in that it has been used as a sample frame for many studies. In our view despite the potentially lengthy process that might have to be undertaken to achieve access, this is well worth exploring at the same time as the MIDAS option is explored.

Engaging the wider research community

We fully appreciate the many implications of what we are proposing: the process of obtaining access to alternative sampling frames will take considerable time, and has uncertain prospects of success.

However, maintaining the current Birth Component design or tinkering with it in our view is not an option for the reasons already given. We now know that it is not possible to use an opt-in process using Birth Records to deliver a successful birth cohort study. This puts the future of birth cohort studies in the UK at risk, putting an end to a long tradition. This is therefore an issue not just for Life Study but for the whole research community. We believe that it is possible and vital to leverage support from the wider research community, at a high level, to help gain access to either MIDAS or CB records, or to allow an opt-out process using Birth Records. Success would secure the future of UK birth cohort studies.

What, in the interim, we should do to maximise the value of the Birth Component work undertaken so far.

We propose the following course of action:

1. Cancel the currently scheduled briefings.
2. Cancel the [fourth] sample run opt-in process (an immediate decision is needed at the 7 July meeting for timetable reasons).
3. Conduct a limited pilot in the (likely) small number of sampling points where 25 mothers have opted-in and provided contact details.

We now consider each of these in turn.

Cancel the currently scheduled briefings

[We] assume[d] we would achieve the planned 1,056 opt-in returns from the [first] and [second] sample runs, enabling us to sub-sample 800 mothers for the face-to-face pilot at 6 months (biasing towards those not in living with a partner), and ultimately to issue 400 mothers for the web/CATI fieldwork at 12 months. Further, [we] assume[d] 25 mothers will opt-in, provide sufficient contact details and be issued to face-to-face interviewers in each of 32 sampling points across Great Britain.

I attach at Annex 2 the agreed objectives of the Birth Component Pilot…As we see it, currently the following objectives for interviewer fieldwork and feedback from interviewers and participants cannot be

[12] http://www.hmrc.gov.uk/manuals/nmwmanual/NMWM16070.htm

satisfactorily achieved due to a lack of opt-in returns (the same is of course true for the web/CATI pilot at 12 months):

- Assess training of interviewers and whether this is effective in equipping them to do what is required.
- Assess response to study in the field.
- Gain feedback on how the interview works within an in home setting and highlight any issues that cause problems.
- Assess response among partners and how the partner interview works in practice.
- Gauge length of interview (both main and partner).
- Check questionnaire is working as it should (routing makes sense etc.).
- Assess number of visits required for full response.
- Assess the length of the fieldwork period and whether this is sufficient to allow for full call backs and chasing.
- Assess the level of movers, and how effective tracing attempts are.
- Obtain feedback from (some) participants to assess their views on taking part, their levels of engagement and their ideas for any improvements or changes.
- Gain feedback from interviewers on the fieldwork processes and the interview, and whether there are suggested improvements and changes.

…

Therefore we propose that we cancel the currently scheduled briefings, pending a re-design of the opt-in process.

Cancel the [fourth] sample run opt-in process

In the original timetable the [third] sample run, which was commissioned to boost the number of non-resident fathers we might interview at the face-to-face pilot at 6 months and the web/CATI pilot at 12 months, occurred…well before we were aware of the poor response to the opt-in process.

As we now know the response rate for the opt-in process will be far lower than we need to achieve the limited number of interviews with non-resident fathers…no useful purpose is served by implementing the [fourth] sample run. We propose we inform the Statistical Authorities that we do not intend to carry out this opt-in process (National Records of Scotland have already carried out the [fourth] sample run).

Costs have clearly been incurred for the [third] sample run and opt-in process, and given that we could use any returns in a limited pilot (discussed below), we propose to continue with this opt-in process to its conclusion…

Conduct a limited pilot in the (likely) small number of sampling points where 25 mothers have opted-in and provided contact details

A great deal of work has already gone into the scripting of the Birth Component and we feel given its complexity there is great merit in conducting a limited pilot to gather valuable feedback about how the script is working, identifying problems, and checking our systems are functioning as they should. This will enable us to ensure any subsequent pilot and the main stage go more smoothly than they might have done otherwise.

However, we propose that we:

- Delay the issuing of sample…to maximise the number of sampling points we might issue (reflecting the delays we have experienced in the opt-in process); and
- Carry out a revised briefing programme once the likely sampling points are known. This would probably involve meetings rather than formal briefings, held around the country with interviewers working on the limited pilot.

Summary of recommended actions

We are aware that having to reconsider the approach to the Birth Component is far from ideal, and introduces many challenges. However, it is important to recognise that without a radical change of course, the Birth Component will not succeed. We do not say this lightly; our concern is to ensure that we address the problems directly. I hope I have at least outlined some strategies which have a chance of turning the Birth Component into a viable study, and, most importantly, mapping a way towards continuing the UK's proud tradition of cohort studies. I thought it might be helpful to summarise our recommendations.

1. Radically re-design and pilot the opt-in process. This is likely to take at least six months.
2. In parallel with recommendation 1, explore the possibility of accessing MIDAS and the Child Benefit Register, for use with an "opt-out" process. This is likely to take many months.

Thus by the middle of 2016, and hopefully much earlier, we would know what the best design option is for the Birth Component. In the meantime we would:

1. Cancel the currently scheduled briefings.
2. Cancel the [fourth] sample run opt-in process (a decision is needed at the meeting for timetable reasons).
3. Conduct a limited pilot in the (likely) small number of sampling points where 25 mothers have opted-in and provided contact details.
4. Develop the web/CATI methodology and carry out the scripting tasks.

We are ready to assist you in this as far as we can, and to help bring in additional partners if required.

Appendix 2

By asking for some actual information from the mothers in a questionnaire, we hoped to appeal to the altruism that survey organisations generally rely on. The potential problem with a reply paid card is that it does not appeal to altruism, as mothers are invited to request further information only. We recommended an experiment to test both approaches.

An eight-page questionnaire was developed by Ipsos MORI in close collaboration with UCL. Originally UCL wished to use the "Ages and Stages" (ASQ) self-completion instrument[13], as this was felt appropriate to engage mothers with the study. As a result of a number of potential problems including copyright issues, the nature of the language used on the instrument and difficulty contacting the publisher, it was decided the eight-page questionnaire should comprise as its core two instruments which had been validated in other studies: the Brief Infant Sleep Questionnaire (BISQ) and the Baby Eating Behaviour Questionnaire (BEBQ). At the end of the questionnaire mothers were informed we wished to contact them again to take part in Life Study, and were asked to fill in their contact details.

The two-page reply paid form and the eight-page questionnaire mainly differed in that the latter used the BISQ and BEBQ while the former did not. In other respects efforts were made to keep the instruments as similar as possible.

[13] The ASQ-3 questionnaire was developed by academics at the University of Oregon and some others. For further information, please see http://agesandstages.com/products-services/asq3.

Appendix 3

The text of the sampling instructions sent to ONS and NRS is set out below:

This specification gives details of the stages of the sampling that will be carried out by ONS in order to obtain the pilot sample for the Life Study. The pilot sample will be selected over two months for babies born in [first month] and [second month] 2015 (that were not more than one month premature), or for babies that were more than one month premature, babies with expected delivery dates in [first month] and [second month] 2015. For the sake of brevity, we will refer to these as [first month] and [second month] 2015 babies.

Please note that the Life Study team has applied for funding to also interview non-resident fathers. If that bid is successful, then the pilot sampling stage will be extended to include [third month] and [fourth month] 2015 babies. For the purposes of this specification, we will assume that the pilot sample period is for two months, but please note that it is likely that it will be extended to cover four months.

Deadlines that require actions from Ipsos MORI are highlighted in this specification in green, and those that are required from ONS are highlighted in yellow.

(A) Sampling Births

ONS has already supplied Ipsos MORI with aggregated counts of births for each postcode sector for the previous three years. These were used to select the points (groups of postcode sectors) in which the pilot sample will be selected. These postcode sectors have been sent to ONS.

The sample of [first month] 2015 babies will be all babies in the postcode sectors that were:

- born in [first month] 2015 and were **not** born more than one month premature; and
- born more than one month premature and would have been expected to be born in [first month] 2015 based on their expected delivery date (EDD). For these babies their actual birth date will be in or before [month before first month].

Note that any babies born before 24 weeks are not eligible for the study and should be removed from the sample.

In addition, for multiple births in which one of the babies died, all the surviving babies should also be removed from the sample.

ONS will extract these babies from the birth records database in the selected postcode sectors and send Ipsos MORI aggregated counts at the postcode sector level of the number of [first month] babies so that they can be checked. These counts will be sent by ONS before...These will be checked and signed off by Ipsos MORI before...

This process will be repeated for the [second month] babies as well in the same set of postcode sectors. The counts of [second month] babies will be sent by ONS before...These will be checked and signed off by Ipsos MORI before...

(B) The *Opt In* Process

ONS will need to start the *opt in* process for the [first month] babies in the selected postcode sectors on…and for the [second month] babies in the selected postcode sectors on...ONS will need to identify multiple births so that each parent is only included once in the *opt in* procedure.

The ID codes for the pilot sample points were included in the list of selected points supplied by Ipsos MORI. Note that the codes are different for the two months of the pilot sample (and will be different for [third month] and [fourth month] babies as well if these are months included). If ID codes for the pilot areas are 7 digits long. ONS will need to produce 9 digit ID codes for each case by adding two digits to the end counting up from 01 to the total number of births in that point for that month.

As part of an experiment, two sets of *opt in* materials are to be sent out. Alternate cases within each point will be allocated to the two experimental groups as follows: cases with an odd serial number will be allocated to experimental group A and cases with an even number allocated to experimental group B.

We will send more details of the *opt-in* process in a separate note.

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