The Impact and Economic Evaluation of A Better Start

EVALUATION PROTOCOL

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The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable UK guidelines.

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2. **INTRODUCTION**

2.1 Background Information

There is strong evidence that the first few years of life build the foundations for future health and wellbeing and that taking a preventative approach together with systems changes in local agencies, can improve the life chances of babies and children. However, these interventions have yet to be tested at scale. The Big Lottery Fund has invested £215M in funding A Better Start (ABS) in order to improve understanding about effective early childhood intervention in five competitively selected areas across England: Bradford, (led by Bradford Trident); Blackpool (led by the National Society for the Prevention of Cruelty to Children - NSPCC); Lambeth (led by National Children's Bureau - NCB); Nottingham (led by Nottingham City Care), and; Southend-On-Sea (led by the Pre-School Learning Alliance). These geographical areas have a high level of need in terms of deprivation, and child health.

Big Lottery Fund aims to use the learning from this investment to promote a shift in public policy, public funding and agency culture away from remedial services to greater investment in prevention in pregnancy and the first few years of life. Each area will deliver science- and evidence-based preventative programmes, policies and services, with a focus on the most disadvantaged families. Investment will take place in antenatal and postnatal support programmes that set out to achieve one or more of the following: (i) improve a child's social and emotional development – preventing harm before it happens (including abuse and neglect, perinatal mental health problems and domestic violence) as well as encouraging parenting practices that promote attachment; (ii) improve their language development by encouraging parents to talk, read and sing to, and particularly to praise – their babies and toddlers, and by ensuring local childcare services emphasise language development; and (iii) improve their nutrition and reduce obesity by encouraging breast-feeding and promoting good nutritional practices. The evidence suggests that these three areas can have a significant impact on long-term life chances and outcomes.

Each area will also address systems change across all children and families' agencies. The systems changes should deliver less bureaucratic, more joined-up services; services that are prevention-focused; that are needs- and demand-led; that work for a whole family; and that get it right for families first time.

Big Lottery Fund has invested in the Warwick Consortium, led by the University of Warwick, to conduct a 10-year study designed to evaluate the impact of ABS across these five selected intervention areas, compared with matched comparison sites.

In addition to the impact evaluation, Warwick Consortium are also undertaking an implementation evaluation involving the collection of process data from the participating sites, and a learning and dissemination work-stream to ensure that the lessons in terms of what works, for whom, and why, are identified and widely disseminated.

2.2 Warwick Consortium: The Team

Warwick Consortium is led by Professor Jane Barlow, and comprises a team that includes both substantive and methodological expertise, and that will enable it to successfully evaluate and disseminate the learning from ABS. Jointly, it has a strong track record in conducting multi-strand evaluations of complex programmes, and in combining the methodologies required for this including: longitudinal surveys, impact analysis using survey and administrative data, randomised controlled trials (RCTs), cost-effectiveness measurement, qualitative interviews, and analysis. The team includes field leaders in terms of socio-emotional development (Jane Barlow), nutrition (Professor Carolyn Summerbell) and early years education (Professor Kathy Sylva). There is also academic expertise in biometric measurement (Professor Vivette Glover), childbirth and the perinatal period (Professor Debra Bick), implementation research (Professor Geoff Lindsay) economic evaluation (Professor Stavros Petrou), and longitudinal evaluation and analysis (Professor Alastair Leyland).

The core team (responsible to the day-to-day running of the evaluation) includes the Universities of Warwick and Oxford, along with Ipsos MORI (evaluation fieldwork), Bryson Purdon Social Research (BPSR) (analysis) and ECORYS UK (learning and dissemination).

The evaluation is project-managed by Virginia Woolgar, based at the University of Oxford.

3. RATIONALE FOR A BETTER START

Big Lottery Fund's decision to invest in preventative early intervention is both important and timely. There is a strong growing body of evidence supporting the need for preventative early intervention, particularly during pregnancy and the first three years of life. Below is a summary of the evidence regarding the factors that are associated with good or compromised outcomes in terms of nutrition, socio-emotional development and educational achievement (including language and speech) during the first three years of life. This research has informed the design of the evaluation, including the proposed choice of outcomes to be measured, and the time points at which these are assessed.

Briefly stated (providing selected references only):

3.1 Poverty

Despite improvements in absolute levels of poverty and universal access to education and healthcare, poverty continues to be a significant predictor of compromised functioning in terms of nutritional and psychological wellbeing and educational outcomes (Marmot 2008). However, the research shows that the effects of poverty on these outcomes are almost entirely mediated by parental care, which provides considerable opportunity for remediation and interventions.

3.2 Early Years Developmental and Biological Factors

Research increasingly supports the view that the origins of much adult disease lie in the 'developmental and biological disruptions occurring during the early years of life' (Shonkoff, Boyce, McEwen, 2009), and more specifically as a result of the 'biological embedding of adversities during sensitive developmental periods' (p.2009). This research suggests that the brain plays a central role in this process because it 'interprets and regulates behavioural, neuroendocrine, autonomic and immunological responses to adverse events, serves as a target of acute and chronic psychosocial and physical stress, and changes both structurally and functionally as a result of significant adversity'. For example, children's exposure to the type of 'toxic stress' (i.e. recurrent physical and/or emotional abuse, chronic neglect, parental substance misuse and domestic violence, severe mental health problems) that is more common in families living in poverty, also leads to changed brain architecture and reduced thresholds for stress, that continue throughout the life course, increasing the risk of stress-related disease and cognitive impairment.

The two key sensitive periods are pregnancy and the first three years of life because pre- and post-natal stress cause alterations in the function of the hypothalamic-pituitary-adrenal axis, which makes the hormone cortisol, leading to increased production (Glover, O'Connor & O'Donnell, 2010). This underlies some of the alterations in foetal and child brain neurodevelopment following early exposure to stress, and may also be one of the mediators of an altered epigenetic profile (see below).

3.3 Genotypes

Recent research on differential susceptibility has found that children's genotypes interact with their caregiving environment to influence the impact of early caregiving. For example, gene x environment studies show that children with a short 5-HTTLPR allele have very unfavourable outcomes when parenting is compromised, but that these children also have significantly better outcomes than usual when parenting is better than average (Kochanska et al., 2011).

3.4 Epigenetic Mechanisms

There is now good evidence that early experience is associated with altered long-term outcomes, at least in part, by epigenetic mechanisms. These epigenetic (or on top of genetic) changes are functionally relevant modifications to the genome that do not involve a change in nucleotide sequence. They involve the addition of extra chemicals, such as methyl groups to the DNA, that alter whether, or how much, a specific gene is expressed or turned on or off. Such epigenetic changes can persist through the life of an individual and even be passed to the grandchild generation. Several studies have now shown that altered fetal experience in utero, due for example to pregnancy-specific anxiety (Hompes et al., 2013) or to maternal stress caused by interpersonal violence (Radtke et al., 2011) cause epigenetic changes in the child. Postnatal experience can also cause long-lasting epigenetic changes (McGowan et al., 2009). Epigenetic changes are therefore the most promising biological markers both for the effects of early

experience and the possible effects of intervention, and a recent study has found that the Nurse Family Partnership (Olds, 2008) is associated with an altered epigenetic profile in the adult children, compared with the matched cohorts (O'Donnell and Meaney, personal communication).

3.5 Attachment

Attachment appears to be one of the key mechanisms by which children regulate their emotional states, particularly when they are stressed (e.g. Sroufe, 2005). There is now incontrovertible evidence showing that securely attached children experience a range of improved outcomes, and that insecure and particularly disorganised attachment, are both associated with less optimal functioning. Disadvantaged children have considerably higher rates of both insecure and disorganised attachment.

4. OBJECTIVES

4.1 Evaluation Objectives

The overall aim of this research evaluation is to provide robust evidence about the impact and cost-effectiveness of the Big Lottery Fund ABS Programme, focusing predominantly on pregnancy and the first three years of life, identifying what interventions work, for whom, and under what circumstances.

The survey tools have been designed using a range of validated and standardised measures across three domains: socio-emotional health; nutrition; speech, language and learning.

The impact and economic evaluation will assess short- (birth – 3 years), and medium- (4-5 years) outcomes in each of the three key outcome domains. It will also measure parental outcomes that are strong predictors of infant/child functioning.

The impact and economic evaluation of ABS will address the following research questions:

I. How effective is ABS in improving children's socio-emotional functioning; nutrition; and language?
II. How cost-effective is ABS?

The evaluation of the ABS programme will also provide answers to the following questions:

III. How quickly do we find improvements in outcomes, and how sustainable are these over time?
IV. How does this compare with families in other areas not supported by Big Lottery Fund's investment?
V. Is the programme investment worthwhile?
VI. How much does it cost to run the programme, including the initial set-up, and over time?
VII. How cost-effective are different approaches in terms of the outcomes achieved?

4.2 Hypotheses

The study has been designed to address the following hypotheses:

1. A Better Start will have an impact on children's socio-emotional functioning, their nutritional status, and their language development at 3 and 7 years of age;
2. The impact of the programme will be mediated by change in parental functioning including their mental health and parenting practices;
3. A range of process factors including the level of service provision and the integrity with which such services are delivered will mediate the success of the programme.

5. DESIGN AND METHODOLOGY

5.1 Study Design and Timescale

Central to the Impact evaluation is a longitudinal study based on a series of surveys of parents and children in both intervention and matched comparison areas. It will begin in 2015, firstly with the piloting of questionnaires over a 3-month period across two of the intervention areas (Lambeth and Southend), prior to the collection of baseline data from families of 1, 2 and 3-year-olds across all intervention and comparison sites. This will generate data on all proposed parent and child outcomes (up to when the children are aged 3) prior to the implementation of *A Better Start* in the five sites. Before running the main longitudinal study, the Consortium will run a small pilot in all intervention areas and five comparison areas, to test its recruitment and early data collection methods. This will take place in 2016.

The cohort study will begin in 2019 and end in 2026. All elements of the study will be replicated in matched comparison areas to generate counterfactual estimates. During its life cycle, the study will use a wide-range of data collection methods (listed in Table 1) to track families from mid-pregnancy until the children are aged 5 years. The primary data collection methods will be face-to-face interviews undertaken by trained and experienced Ipsos MORI field researchers, either in families' homes or other place of their choice - e.g. Children's Centres – (up to age 3), followed by parental online and/or postal surveys, and in-school teacher assessments when children are 5-years of age.

The study has been designed to generate a significant amount of evidence, key elements of which are:

- Data from within programme areas will be used to measure and quantify short-, medium- and longer-term outcomes for the families who are being targeted by the interventions, and to establish how these evolve over time, from pre-programme to late programme;
- Data from within comparison areas will generate estimates of the counterfactual outcomes for matched parents and children who are not receiving the interventions, but are receiving standard services;
- For both intervention and comparison areas, the implementation data about how parents use and experience services, will generate an understanding about how any intervention impacts have been achieved;
- For both intervention areas and selected comparison areas (e.g. the closest matched comparison area per intervention area), early years services data will generate an understanding about systems change within early years provision and help us determine whether any changes detected over time are due to ABS or occur for another reason;
- Administrative data on child and family outcomes in the five ABS areas against those in other similar matched areas, will provide estimates of the impact of the programmes across the whole of the eligible population, to test whether the work of the five areas has area-wide impacts;
- Data on costs and services from the five areas will be combined with our findings on the impact of the programme, which will permit us to measure the cost-effectiveness of the programme, both overall and for each site.

The data collection within intervention and comparison areas comprises two components:

1. Cross-sectional, baseline surveys of parents of 1, 2 and 3 year-olds in the first year of the programme (2016/17), which will provide baseline data on outcomes for current parents and children in all our areas prior to the implementation of A Better Start. Baseline surveys will be conducted in both intervention and matched comparison areas, allowing us to (a) check that the intervention and comparison areas are the same prior to the start of the programme; and (b) to allow us to measure changes in outcomes over time in both the intervention and comparison areas.
2. A large cohort study, starting recruitment in 2019, which will generate data on impact. Families will be tracked until the children are 5-years of age. In addition to parent and teacher-report data, we will collect additional data for a sub-sample of families, using measures that will provide valuable information, but which are too costly to collect and/or process across the entire sample.

5.1.1 Potential Additional Data Collection

During both the recruitment pilot and the baseline study, ethical approval permits the team to request consent to hold mothers' contact details for 12 months after the initial interview. This allows the field team to make contact with them again should further research prove valuable.

It is made clear in both the pilot and baseline studies that providing consent for re-contact at this stage does not lead to any obligation or expectation that mothers will take part in any future study, or that any further contact will necessarily take place.

5.1.2 Areas and Timelines

During the baseline survey (2016/17) and cohort study (January 2019 - 2026), data will be collected from:

- 5 intervention areas
  - **Blackpool** (wards: Brunswick; Talbot; Claremont; Bloomfield; Clifton; Park; Victoria);
  - **Bradford** (wards: Bradford Moor; Little Horton; Bowling & Barkerend);
  - **Lambeth** (wards: Stockwell; Tulse Hill; Vassall; Coldharbour);
  - **Nottingham** (wards: Arboretum; St Anne's; Bulwell; Aspley);
  - **Southend** (wards: Milton; West Shoebury; Westborough; Shoeburyness; Victoria; Kursaal)
- 13 comparison areas (3 per programme area):

  BLACKPOOL COMPARATORS
  - **Barnsley** (wards: North East; Stairfoot; Dearne South; Worsbrough; Monk Bretton; St Helens; Dearne North)
  - **Stoke-on-Trent** (wards: Joiner's Square; Burslem Central; Blurton West & Newstead; Meir South; Hollybush & Longton West; Meir North; Bentilee & Ubberley**)**
  - **Plymouth** (wards: Moor View; Efford & Lipson; St Duseaux; Ham; Devonport; St Peter & the Waterfront; Honicknowle)
- **BRADFORD COMPARATORS**
  - **Coventry** (wards: Binley & Willenhall; Foleshill; Longford)
  - **Derby** (wards: Sinfin; Normanton; Arboretum)
- **LAMBETH COMPARATORS**
  - **Islington** (wards: Junction; Tollington; Hillrise; Holloway
  - **Hackney** (wards: Cazenove; Lordship; Queensbridge; Stoke Newington Central)
  - **Hammersmith and Fulham** (wards: Askew; Shepherd's Bush Green; College Park & Old Oak; Wormholt & White City)
- **NOTTINGHAM COMPARATORS**
  - **Hull** (wards: Bransholme East; Ings; Newington; Pickering)
  - **Southampton** (wards: Bevois; Coxford; Redbridge; Bitterne)
  - **Birmingham** (wards: Billesley; Kings Norton; Bartley Green; Springfield)
- **SOUTHEND COMPARATORS**
  - **Sefton** (wards: Cambridge; Duke's; Ford; Kew; Netherton & Orrell; Norwood)
  - **Portsmouth** (wards: Hilsea; Fratton; Cosham; Nelson; Paulsgrove; Charles Dickens)

Table 1 provides both an overview of data collection methods at each study time-point, and of the timeline for both the baseline and cohort studies.

Table 1. Summary of main evaluation timeline, data collection methods and time-points

Year	Stage involved	Mother / main carer	(Brief resident) Partner Q'aire	Additional assessments
BASELINE DATA COLLECTION				
2016/17	Baseline	Face-to-face interview of families with children of ages 1,2 & 3	x	x
2016/17	PILOT PARTICPANT IDENTIFICATION & RECRUITMENT METHODOLOGY			
	26-36 weeks' pregnant	Face-to-face interview	✓	x

	Baby aged 2-months	Short online or postal survey	x	x
	Baby aged 4-months[1]	Short telephone interview or online survey	x	x
COHORT STUDY				
2019/20	26-36 weeks' pregnant	Face-to-face interview	✓	x
2019/20	At birth		x	Hair Sample from mother (to measure cortisol)
2019/20	Baby in first week of life		x	Cheek (Buccal) Swab (for epigenetic purposes)
2019/20	Baby aged 4-months	Short telephone interview or online online survey	x	x
2020/21	Child aged 1	Face-to-face interview at home	✓	CARE Index (video clip of child playing to assess parent-child interaction)
2021/22	Child aged 2	Face-to-face interview at home	✓	From the child: both hair sample (cortisol) and a cheek swab (to measure epigenetic changes)
2022/23	Child aged 3	Face-to-face interview at home	✓	
2024/25	Child aged 5	Postal or online survey Schools Data	x	video-recorded MCAST measure of child attachment – carried out in school by trained researcher

5.2 Questionnaires

Questionnaires have been designed to include validated and adapted measures, and bespoke questions to assess primary and secondary child and parental outcomes. Survey time-points include the following: 26-36 weeks antenatal; 4-months postnatal; ages 1, 2, 3 and 5.

The main types of data will be collected as follows:

5.2.1 ABS Programme Services data: pathways and connectivity

To understand the degree to which systems change may have occurred within programmes, there is a requirement to understand the early years system and how it operates in each area at the beginning and throughout the lifetime of the ABS programmes. The evaluation must also be able to compare with areas that have not had the benefit of the ABS programme, to provide an understanding whether any changes detected are due to ABS or have occurred for another reason. This will involve undertaking a mapping exercise of antenatal and early years services in the five ABS areas and five of the (most closely matched) comparison areas.

The research team will contact relevant lead professionals in a range of antenatal and early years services, such as midwifery, health visiting and Children's Centres, to collect some simple data on the structure of services in this area. This information may be collected via a short questionnaire, a telephone interview or a face-to-face interview, depending on the type of information we are requesting.

5.2.2 Parent-Report Data

The survey questionnaires will comprise a number of demographic questions, and standardised and validated self-report questionnaires to assess a range of aspects of parental and child wellbeing including self-report measures of mental health; substance use; and domestic violence.

[1] Schedule permitting, i.e. where local R&D approval has not been issued as quickly as expected, it may only be possible to follow-up participants in these areas to the 26-36 weeks' gestation or 2-month postnatal time-point, rather than to 4-months postnatal as originally intended.

5.2.3 Teacher-Report Data

Teachers will be invited to complete teacher report versions of measures of children's social and emotional functioning (e.g. Strengths and Difficulties Questionnaire) at 5 years.

5.2.4 Child-Report Data

Children will take part in a number of assessments of their language at different ages using a range of standardised measures (e.g. Bayley Scales at 12 months; British Ability Scales at 3 years); a measure of their attachment at 5-years in which they are invited to complete the Manchester Child Attachment Story Task in school; a measure of their self-esteem and feelings about school (All About Me Questionnaire).

5.2.5 Objective Data

We will in addition collect the following objective measures of outcome:
Non-invasive biometric measures include the following:

- Mother's hair sample to assess cortisol levels at or around the time of birth - subsample
- Baby buccal (cheek) swab to assess epigenetics at or around the time of birth and again at age 2 - subsample
- Child hair sample and buccal swab at 2 years – subsample.

Other objective non-biological measures include the following:

- Height and weight – full sample at all time points post-delivery
- 3-minute videotape recording of parent-infant interaction at 12 months (CARE Index) – subsample only
- Home learning environment at 3 years – full sample
- Manchester Child Attachment Story Task (MCAST) measure of attachment at 5 years – subsample only

5.2.6 Administrative Data

There will be several points in the study where we ask participants to consent to their data being linked to other existing health, education and social care data:

- When participants sign up for the study they are asked for their consent to give permission to use the birth records of their child. This will provide information about the weight of the baby, type of delivery and gestation period of the pregnancy;
- Participants will also be asked at this time if they will consent to the evaluation team receiving identifiable service use data from the ABS intervention sites lead organisations (e.g. nature and extent of participation in service interventions such as Family Nurse Partnership, Bumps for Babies etc.). A data sharing agreement will exist between the evaluation team and each of the service providers;
- After the first interview when the woman is 26-36 weeks' pregnant she will be asked for permission to use her NHS number to link to her Hospital Episode Statistics records. This will provide information on hospital inpatient, outpatient and day case admissions throughout the period of follow-up;
- After the first interview, when the woman is 26-36 weeks' pregnant, she will also be asked for her permission to access her child's ASQ3 data. This is an Ages and Stages Questionnaire – a child development rating scale, which will be collected from 2015 onwards as part of a child's assessment at the age of 2 years. The ASQ3 is being collected as a Public Health Outcome indicator and Local Authorities will report the data to a central point before it is published, most likely by CHIMAT.
- When the child reaches three years old the mother will be asked as part of the face-to-face interview if we can link her child's information to their school records using the National Pupil Database. If she agrees, we shall ask the name of the school in the 5 year olds' postal questionnaire
- Administrative data on the educational progress of cohort children will be gathered at ages 5 and 6 years from the Pupil Level Annual Schools Census or PLASC. At the time of writing, this would include:
    - The phonics test administered in schools at age 6
    - Early Years Foundation Stage Profile (EYFSP) results at age 5, although these are now due to be withdrawn. If equivalent tests are reinstated then these data will be used instead. If they are not, alternative reliable standardised tests will need to be used.

In this event, an amendment to the ethics application would be submitted with full details, once known.

5.3 Evaluation Participants

5.3.1 Inclusion Criteria

The evaluation will include participants who meet the following criteria:

- Pregnant women aged 16 or over, who reside in the evaluation intervention and comparison area wards (identifiable by postcode).

5.3.2 Exclusion Criteria

The following individuals will be excluded from the study:

- Women who are not pregnant
- Pregnant females who reside within the evaluation intervention or comparison wards, but are aged less than 16 years
- Pregnant women who have been involved in the pilot study or in the cohort study, with a previous child
- Pregnant women who do not reside in the evaluation intervention or comparison area wards
- Pregnant women who reside in one of the evaluation area wards, but are suffering from severe mental illness (e.g. psychosis)
- Women who know they are moving away from an evaluation area within the first 6 months of the beginning of the study

5.4 Recruitment and Informed Consent

5.4.1 Baseline Recruitment

In addition to the main longitudinal cohort study the evaluation will collect baseline data from each of the participating sites prior to the introduction of ABS. This will involve administering the 1; 2 and 3-year face-to-face survey with a sample of parents of 1; 2 and 3 year old children at one time-point only. These families will not be involved in the main cohort study, and their data will be used to provide an indication of the level of parent and child wellbeing in the sites prior to implementation of A Better Start. This will provide the evaluation with a set of baseline measures for children aged 1, 2 and 3 years.

A short piloting of baseline questionnaires will take place prior to the main baseline survey. Parents will be identified using a commercial sampling frame called Emma's Diary and, based on results, this sampling frame will most likely be used to identify parents eligible to take part in the main baseline survey.

Emma's Diary is the largest pre-natal database in the UK and collects c. 650,000 records each year. It has been used as a sampling frame for other studies, including research into pregnancy discrimination at work for the Equal Opportunities Commission[2] and in an evaluation conducted by evaluation partners Bryson Purdon Social Research for the NSPCC[3]. However, in order to ascertain whether this sampling frame will provide appropriate coverage and response rates for this evaluation, a review of the viability of using Emma's Diary for the main baseline survey will be undertaken following the pilot, and recommendations made for further discussion by the Consortium.

Emma's Diary is a communication platform for mothers-to-be, new parents and healthcare professionals. In association with the Royal College of General Practitioners, Emma's Diary offers a programme of targeted communications, providing advice and health information. It produces a pregnancy guide, which is distributed to women through GP surgeries, generally on their first visit to the doctor/midwife regarding their pregnancy. This guide also contains information on how women can register with Emma's Diary in order to receive gift packs of free baby products. Parents who

[2] http://www.maternityaction.org.uk/wp/wp-content/uploads/2013/09/eocpregnancydiscrimwomensurvey.pdf

[3] http://www.nspcc.org.uk/globalassets/documents/evaluation-of-services/evaluation-preventing-non-accidental-head-injuries-nahi-programme-impact.pdf

sign up to Emma's Diary give their consent for other organisations to contact them by post, telephone, SMS or email about selected products, services and research.

The process for sample selection and recruitment will be as follows:

1. Ipsos MORI field team will send an advance mailing to selected mothers registered with Emma's Diary for the purpose of piloting of the baseline questionnaires. The standard invitation letter will explain the nature and aims of the study and why mothers are being invited to take part. The letter will also explain that a study researcher will contact them shortly in person to discuss the study further, and to ask if they wish to take part.
2. Along with the advance mailing, the potential respondents will also be provided with:
   - A full information sheet about the study. This information sheet will state clearly to potential respondents that they have been contacted due to giving permission when registering with Emma's Diary.
   - An opt-out form and return pre-paid envelope so the potential respondent can tick a box to indicate they wish to opt-out, rather than having to call or email and/or feeling that they have to provide any explanation.
3. In order to provide reasonable time to opt-out, Ipsos MORI will give potential respondents a minimum of 2 weeks before making contact to invite them to take part in the baseline pilot survey (which involves a face-to-face interview);
4. The subsequent contact from Ipsos MORI to the potential respondent to discuss the study will be made face-to-face, rather than by telephone. Interviewers will gently check that the child is living at home and well, and will be better placed by being there in person to deal with any sensitive situations in an appropriate way.
5. If at that time the respondent agrees, the researcher will make a time to visit, obtain written informed consent and conduct the interview[4].

The same procedures will be followed for the main baseline survey.

Ipsos MORI has a strong track record in surveys with families, which means that its interviewers are very experienced in engaging and working considerately with this type of audience. All interviewers working on this study will attend a briefing day specifically about this survey before they start work, and this will include a section about how to handle a situation where they are communicating with a family who have lost their baby or have major problems.

It should be noted that the sample provider, Emma's Diary, run their data through the Baby Mailing Preference Service (MPS) on a weekly basis. The Baby MPS is a free service that can be signed up to in order to reduce number of baby-related mailings received. This service is particularly aimed at families who have experienced the sad circumstances of the death of a baby.

Interviewers are accompanied by an experienced supervisor when starting work on a new project, and received on-going telephone support throughout the study duration

Before starting work in an area, interviewers are advised to check-in at the local police station to show their ID cards and advise local police they will be working in the area for a specified period of time.

5.4.2 Main Cohort Study Recruitment

Participant Identification and Providing Permission to be Contacted

Participants eligible to take part in the evaluation will be identifiable by their postcode by a member of their relevant local NHS Trust maternity team at the time of booking (at approximately 9-12 weeks' gestation). A Participant Information Sheet (PIS), containing all information about the evaluation (in a potential respondent's native language where possible), will be given to her in person or posted out to her at this time, along with standard antenatal information.

Working within the existing systems and processes of individual participating Trust maternity (or Health Visiting) teams and the available resources within each, eligible pregnant women will subsequently be asked by a member of their maternity and/or research team (for instance, this may be a midwife, research midwife, researcher, Clinical Trials Assistant (CTA) or Healthcare Assistant (HCA) or any other trained team member) if they have received and read the evaluation

[4] Additional permission will be sought to ***retain*** participants' contact details should the research team wish to re-contact them regarding any future follow-up research (refer to Section ***5.1.1 Potential Additional Data Collection***).

information. The team member will provide the information again if it has been misplaced or has not been received, and will take a few minutes to run through the PIS and answer any questions the potential respondent may have. Subsequently, if the potential respondent is happy to provide signed permission for her contact details (preferably name, address, telephone number and/or email) to be passed on to the Ipsos MORI research team, she and the team member will complete the form together and sign it. This is then either uploaded and transferred securely electronically (encrypted) to Ipsos MORI, or by using the pre-paid addressed envelopes provided. A copy of the signed permission to be contacted form is maintained within the potential respondent's notes.

Once received, Ipsos MORI will cross-check that the postcode matches to one of the intervention wards or matched comparison wards of interest and that the woman is therefore eligible for inclusion. Ipsos will email the evaluation Project Manager at the University of Warwick and Oxford a password protected file of any ineligible participants in order that she can send them a letter acknowledging their commitment to take part and thanking them for their time. Thus, the evaluation Project Manager will also have access to some Personal Data (see Section 9 for details of data management and security).

Ipsos MORI will check with the designated named individual at each Trust (see Section 5.4.5) that the woman is still pregnant prior to contacting her. This process will be repeated during the main longitudinal evaluation starting January 2019 prior to contacting any woman at or around the time of birth who has been randomly selected to provide a biological sample.

Only if permission is granted, an Ipsos MORI researcher will contact the woman - by writing or telephone and/or in person – to discuss the evaluation and answer questions, and ask if she is still happy to take part in the study; if so, a first face-to-face appointment will be scheduled to take place when the woman is approximately 26 - 36 weeks pregnant. This interview may occur at a time and place convenient to her. If she does not feel comfortable about the meeting taking place in her home, she may request to meet at a friend or family member's, or in a local Children's Centre etc. Informed consent is taken by the Ipsos MORI researcher prior to conducting the interview and a copy of the consent form is retained by Ipsos MORI, a copy retained by the respondent. A third copy is sent securely (encrypted) by Ipsos MORI to the respondent's maternity contact.

The relevant NHS Trust will receive one accrual for each pregnant women who provides informe3d consent and takes part in the antenatal interview. The Trust will also receive an additional accrual for each neonate (but not the mother) who provides a buccal (cheek) swab (see section 5.4.6.1)

Please note that completing a *Permission to be Contacted* Form to be passed on to Ipsos MORI is *not* informed consent, and is therefore *not* a commitment to take part in the study. When she is later contacted by Ipsos MORI, the potential respondent is completely at liberty to refuse to take part in the study and, even if she agrees, provides her consent and takes part in the antenatal survey, she can withdraw at any time over the life of the study.

5.4.3 Post-Recruitment Participant Exclusions and Withdrawals

Post-Recruitment Exclusions

As a result of the fact that the evaluation is focusing on specific intervention areas and comparing these with the outcomes of families receiving standard services in comparison areas, families will be excluded from the evaluation post-recruitment if:

- They do not go on to have a live birth
- They move away from the evaluation intervention or comparison areas after the evaluation has begun
- They move into the evaluation intervention and comparison areas after the evaluation has begun
- Their participating child is taken into care, but only where informed consent from the appropriate authority for the child to continue in the evaluation cannot be obtained

Post-Recruitment Withdrawals

Families may withdraw from the evaluation as they wish, at any time. Sample sizes have been designed to take into account attrition rates over the evaluation period. Withdrawal from the study will not affect the participant's entitlement to intervention services in any way.

5.4.4 Recruitment for the School-based Data Collection

Schools will be recruited via Head Teachers within both the intervention and comparison areas (and will also be sent a letter by their local authority requesting support for the research). For the age 5 data collection points, they will be sent a pack of standardised survey materials, including the teacher questionnaires,) and parental consent forms. Guidance on completion will be provided at each time-point by a University of Oxford researcher by telephone.

5.4.5 Piloting of the Recruitment Process

Beginning in early 2016, a small pilot study will be undertaken across each of the five ABS programme areas, and one comparison area for each of these areas – 10 areas in total - to test the methodology for recruitment and optimal response rates for the first two postnatal survey completion options. Families will be followed up until the 4-month postnatal time-point only, schedule permitting[5].

All of the procedures being used in the main cohort study will apply, but parents will be informed that they are taking part in a pilot study, prior to the commencement of the main study. This will also provide the research team with the opportunity to pilot the data collection procedures.

The team has discussed concerns regarding potential late foetal loss when consent for contact details may be taken and passed on to Ipsos MORI, and; the 26-36 weeks antenatal Participant Informed Consent being taken and first interview conducted by Ipsos MORI. In order to avoid causing further undue distress by unknowingly contacting a woman who may have suffered a late foetal loss, the evaluation team has discussed with NHS Trust midwifery teams, implementing the following process:

- Approximately 1 week prior to the 26-36 weeks antenatal fieldwork starting, using a previously arranged named single contact, Ipsos MORI will email each NHS Trust maternity unit a password-protected sample file of the names and addresses of potential participants identified by the midwives at that Trust, and who agreed to pass on their contact details. Each individual within this sample will be allocated a unique reference number;
- The key maternity contact at each unit will be asked cross-check these details against his or her *'no-longer pregnant database'* (administered by all maternity units), and to respond to Ipsos MORI by email within c. 5-7 working days, sending the *reference numbers only* of women they *do not* wish Ipsos MORI to contact. The maternity unit key contact *does not* have to divulge any personal or confidential information; however, the Consent for Contact Details and Study Consent Forms relating to both pilot study and main evaluation, have now been amended to include an additional clause giving the potential respondent a choice about whether she may permit her midwife or other healthcare professional known to her contact the study team should she no longer wish/be unable to be involved due to '*medical reasons'*.
- If Ipsos MORI *does not* receive any response, *all* women within that sample will be contacted;
- If Ipsos MORI *is* notified of any women who should not be contacted, the field team will be informed immediately and these individuals *will not* be sent an advance mailing.

Trusts will also undertake their own screening on a routine basis as per their own standard protocols, and will inform Ipsos MORI in between times should they become aware of a woman who should no longer be contacted. Unfortunately, after a mother and baby are discharged from the Trust alive and well, there is no further screening mechanism that can be implemented after this time.

5.4.6 Informed Consent

Written and confirmed consent to take part in the evaluation will be sought at the time of, but prior to, conducting the first 26-36 weeks' antenatal face-to-face interview.

- Informed Consent will be sought as follows:
- From the ***mother only*** to take part in either the pilot of recruitment methodology or the main evaluation;
- Additionally, from the ***resident*** partner/father, should he wish to complete the existing short partner questionnaires scheduled to be completed at 26-36 weeks' pregnancy and again when the child reaches ages 1, 2 and 3 years[6].

[5] Where local R&D approval has not been issued as quickly as expected, it may only be possible to follow-up participants in these areas to the 26-36 week gestation or 2-month postnatal time-point, rather than to 4-months postnatal as originally intended.

[6] If a mother (assuming the role of primary carer) and the partner disagree about taking part in the study or this causes any conflict, the mother will in no way be persuaded to participate.

- Additionally, for permission to retain the details of ***the mother*** to ***re-contact*** her about any future follow-up research (refer to Section ***5.1.1 Potential Additional Data Collection***);
- ***Verbally*** for continued participation in the evaluation at each face-face interview (when child is aged 1, 2 and 3 years).

Consent can be withdrawn at any time.

Informed Consent for Sub-Samples

Additional written informed consent will be sought for the randomly selected biometric sub-sampling procedures at birth (i.e. consent will be taken by a GCP-trained member of the NHS maternity/health visiting unit at or around the time of birth (up to 4 weeks after the birth), to take a hair sample from the mother and a buccal (cheek) swab from the baby).

Accruals will be provided to the Trust for both the mother providing informed consent and taking part in the antenatal survey (but not again by agreeing to provide a hair sample at birth - see section 5.4.2). However, her baby can be counted as one additional accrual by the Trust by providing a cheek swab at birth.

Separate verbal consent will be sought for the Ipsos MORI researcher to take a sub-sample from these same families when the child is aged 2 years (hair sample and a cheek swab from the child), and from the same or other randomly selected families at age 1 (CARE index) and by the University of Oxford researcher, who will take a sub-sample of the Manchester Child Attachment Story Task (MCAST) in school when the same or other children are aged 5-years. The mother may refuse to give consent for any of the sub-sampling procedures at any time even if she has previously consented, or to complete all of the questionnaires; this does not affect the right of she and her child to remain in the study.

Informed Consent for the School-based Data Collection

Parents will be asked at the age 3 interviews for details of the school likely to be attended by their child, and for consent for the research team to contact the school. Parents who do not know the child's intended school at age 3 will be asked for consent to be re-contacted at age 4 in order to obtain this information. Consent for data collection at age 5 will also be obtained at this time (i.e. at age 3 where parents know the school, at age 4 when they do not). However, since this will represent the last point of direct contact with parents, parental consent for data collection at age 6 will be obtained via teachers in the schools at the time of the age 5 teacher survey.

The evaluation has been designed to predominately follow the progress and outcomes of the child. If a child taking part in the evaluation were subsequently removed from the care of the mother, or the mother dies etc., then informed consent would be sought from the child's primary carer or guardian to continue in the evaluation.

5.5 Sample Size

5.5.1 Baseline Surveys

A total of 899 interviews will take place across all ABS programme areas and 802 across all fifteen comparison areas, with a breakdown as follows (c.1701 in total):
Parents of children aged 1, 2 and 3 years:

- Programme areas: 378 children aged 1; 313 children aged 2; 208 children aged 3
- Comparison areas: 225 children aged 1; 361children aged 2; 216 children aged 3

5.5.2 Main Cohort Evaluation Surveys

The primary research question will be addressed using a longitudinal cohort study in which a target of 2,885 pregnant women across the five intervention and fifteen matched comparison areas will be recruited to the study. Further detail is provided in Table 2.

Table 2. Cohort Survey Sample Sizes

Survey Time Point	ABS (Programme) Areas	Comparison (Matched Control) Areas
26-36 weeks' antenatal	1715	1170
Child Aged 1 Year	1200	825
Child Aged 2 Years	1060	720
Child Aged 3 Years	815	555

5.5.3 Sample Size Justification

The sample size for the cohort study has been set with the primary aim, after attrition, of generating 815 interviews with parents of three year olds in programme areas and 555 in comparison areas. The 'headline' estimates of impact will be based on difference-in-differences estimates. That is, change since baseline for children of the same age group in ABS areas, minus change since baseline in comparison areas. For outcomes at age 1, for instance, this will be based on the four sets of data within the second row of the table (i.e. 500; 270; 1200; 825). Samples of this size will enable detection of effect sizes of 0.25 standard deviations (with 80% power). For binary outcomes, this equates to being able to detect an impact of around 12 percentage points (i.e. if 12% of children in ABS areas have a better outcome at age 1 as a direct result of the programme, a difference-in-difference estimate should be observed that is significantly different to zero).
At Age 2 the cohort sample sizes will have been subject to attrition, and the detectable effect size at age 2 will be just over 0.25; and with further attrition at Age 3, the detectable effect size will be 0.26.

In practice, it is hoped that no real differences in the baseline outcomes for ABS and comparison areas will be observed. If baseline differences can be ruled out, then the evaluation can focus on comparing the ABS and comparison cohort samples. This will greatly improve the statistical power. For example, at age 1, if only the two cohort samples of 1200 and 825 were compared, effect sizes of 0.13 standard deviations could be detected.

5.5.4 Recruitment Pilot Sample

A total of 300 interviews are planned, with 150 interviews starting at 28-weeks antenatal, running until 4-months postnatal across all five programme intervention areas, and 150 across five of the fifteen comparison areas. The five pilot comparison areas are: **Stoke-on-Trent**; **Derby**; **Hammersmith and Fulham**; **Birmingham**, and; **East Kent** (matched target wards within each area are listed on page 13).

Sample sizes for the pilot study are sufficient to test whether the recruitment process is working as planned. There will be no formal statistical analysis of the difference in survey outcomes between these two pilot samples so a power calculation is not appropriate here. (In fact, the evaluation does not expect to observe any large statistical differences between the two groups because the mothers will be recruited before any major impacts of ABS are expected).

5.5.5 Sub-sample Sizes

The evaluation has been costed to collect the main outcomes on the whole sample. However, a number of objective measures have been built in, which are more costly to administer and process; therefore these have been built into the study using a sub-sample design, with large enough power but minimising cost. The sub-sample sizes are listed in Table 3. Each of the subsample outcomes has been powered to detect change in the region of 0.25 standard deviations.

Table 3. Sub-sample Sizes (I = Intervention Area and C = Comparison Area)

	Hair		Buccal		CARE Index		Story Stem	
	I	**C**	**I**	**C**	**I**	**C**	**I**	**C**
Birth	100	100	100	100	-	-	-	-
Age 1	-	-	-	-	300	105		
Age 2	100	100	100	100	-	-	-	-
Age 3	-	-	-	-	-	-	375	375

Sub-sample Size Justification

The sample sizes for the embedded studies of hair strands, buccal swabs, care index and story stem measures are based on effect sizes found in other similar studies. A sample of 100 hair samples at birth in both the intervention and comparison group will allow for an effect size of 0.4 to be detected with 80% power. Similarly, at age 2. Combining the birth and age 2 sample will allow for a detectable effect size of 0.28. Samples of 90 per group (both at birth and age 2) for buccal swabs will allow for similar effect sizes. (O'Donnell et al., (personal communication) have shown the long-term effects of the Nurse Family Partnership on genome-wide variation in DNA methylation in

whole blood samples from participants at 27 years of age (n=89), with a component accounting for 7.10% of the variance in DNA methylation, representing an effect size of d=0.39.)

The care index sample of 300 in the intervention group and 105 in the comparison group allows for a detectable effect size of 0.32. And sample of 375 in both groups for the story stem measures allows for a detectable effect size of 0.2. The Olds research (Olds et al., 2004; Robinson et al., 2000) is most similar in design to the current study and has therefore been used as a basis for this sample size calculation. That research involved an RCT of a nurse home-visiting intervention during the first 2 years of the child's life. Analysis compared outcomes for children of nurse-visited mothers with children of mothers receiving free transport for parental care appointments plus developmental screening and referral services for the child. When tested close to their 6th birthday, nurse-visited children born to mothers with low levels of psychological resources expressed less aggression and incoherence in response to story stems with effect sizes of 0.24 and 0.35 respectively (Olds et al., 2004).

5.6 Comparison Areas Selection

The evaluation will select and recruit three matched comparison areas per ABS intervention area. Given that not all the potential comparison sites approached will agree to take part, a total of ten comparison areas per ABS area have been identified, with three 'preferred' areas and a reserve list of seven others.

The National Foundation for Educational Research (NFER) 'Children's Services Statistical Neighbour Benchmarking Tool' was used to do this. This tool was designed so that Local Authorities (LAs) could compare themselves with other 'similar' LAs on their progress on Every Child Matters (ECM) outcomes.

The evaluation design has set out to achieve a set of comparison areas per ABS LA that are currently very similar to the ABS area in terms of any indicators that are:

a) Publically available; and
b) Are likely to be highly correlated with the outcomes being measured in the evaluation surveys

Led by statistical expertise, the evaluation team agreed that the most relevant indicators to use were:

- Percentage of babies of low birth weight;
- Prevalence of maternal smoking;
- Prevalence of breast feeding;
- Percentage obesity at age 5;
- Percentage with good level of development at EYFS;
- Percentage of pupils achieving 5+ GCSEs;
- Percentage of children in care.

The NFER model provides ten statistical neighbours per LA. So, for instance, Blackpool's ten are:

- Torbay
- Tameside
- Redcar & Cleveland
- Plymouth
- Hartlepool
- North East Lincolnshire
- Barnsley
- Isle of Wight
- Doncaster
- Stoke-on-Trent

The variables used by NFER to generate the neighbours include a combination of relative deprivation, economic profile, urban/rural, and ethnicity.

The ten LAs that NFER identify are in priority order. For example, the closest match to Blackpool is Torbay. This means that in principle the evaluation could simply use the first three NFER LAs per ABS LA as its comparison areas. However, we plan to make use of all ten and reprioritise them so that they are more closely aligned with ABS outcomes.

In order to identify which of the ten NFER areas are the best matches to the ABS area across these seven indicators, an overall 'distance score' was created between the ABS and each of the potential comparison areas (with the distance score being based on a Euclidean distance metric, and using standardised scores per indicator). The three areas at shortest distance to the ABS area are the three that have been selected in the first instance, and the matching of programme wards with comparison wards is currently ongoing.

We will also aim to establish in all areas prioritised as comparison sites, whether there is any evidence of early years' initiatives that might make it unsuitable as a comparison area for ABS.

5.7 Data Collection Instruments

5.7.1 Evaluation Outcome Measures

The impact and economic evaluation will assess short- (birth – 3 years) and medium- (4-5 years) outcomes in each of three key outcome domains (e.g. social and emotional development; speech and language; nutrition). It will also measure parental outcomes that are strong predictors of infant/child functioning. This will be undertaken using a range of bespoke and universal (i.e. standardised and validated) instruments.

The outcomes framework involves the collection of the following types of data:

- **Demographics and other matching data**
- **Individual trajectories (short-, medium- and long-term)**
  - Parental outcomes
  - Child outcomes
- **Service-use:** detailed data that will enable understanding of how any programme impacts have been achieved, and that will inform the economic evaluation
- **Population level data**: gathered using sources such as Chimat or LAIT for each to complement the data on the families receiving the intervention and that will assess area-level impact.

Parental outcomes will include measures of: health and mental health; relationships with the child; parental functioning; and parental context (e.g. social support).

Child outcomes will include measures of: nutrition and health; socio-emotional development; and language, cognitive and school outcomes.

Additional sub-sample data will be collected using a number of measures (e.g. buccal swabs to assess epigenetic changes, video-taped coding of parent-child interaction, story-stem exercise to measure attachment, and observations of the home learning environment).

5.7.2 Primary Outcome Measures

Since this is a long-term formative evaluation, a number of key primary outcome measures have been carefully selected for parents and children within each of the domains of socio-emotional, nutrition, and language and cognitive development.

The key outcomes being measured are as follows:

Nutrition

a) Method of feeding will be assessed in pregnancy and the first year using bespoke questions.
b) Weight/length/height will be assessed using standard data at birth and following school entry; and using routine techniques (i.e. scales) at all time-points.
c) Patterns of food intake will be assessed using the Children's dietary questionnaire (CDQ) at 3 and 5 years.
d) Feeding practices will be assessed using the Comprehensive Feeding practices Questionnaire (CFPQ) at 3 and 5 years.

Socio-Emotional Functioning

a) At 12 months, socio-emotional functioning will be assessed using the **Brief Infant Toddler Social Emotional Assessment Scale (BITSEA)**.
b) Mother-infant interaction will be assessed in a sub-sample of children using the **CARE Index** coding of videotaped interaction.
c) An objective measure of stress will also be undertaken by measuring cortisol levels in a subsample only using small hair samples from mother at birth and the child at 2 years;

d) At 2, 3 and 5 years, social competence will be assessed using the **Adaptive Social Behaviour Inventory (ASBI)**.
e) At 5 years, behavioural development will be assessed using the **Strengths and Difficulties Questionnaire (SDQ).** At ages 5 ~~7~~, parents and teachers will complete the ASBI and SDQ.
f) Self-Esteem will be assessed using a brief child-report instrument - the **Piers-Harris Self-Concept Scale.**
g) Attachment will be assessed in a subsample only at 3 years using the **Story Stem Attachment Dolls House.**

Speech, Language and Learning

a) At 12 months, motor, language and cognitive development will be assessed in a sub-sample of children using the Bayley Scales (BSID-II MDI)
b) At 2 years, vocabulary knowledge will be assessed using the parental-report Sure Start Language Measure (SSLM) across the whole sample
c) At 3 years, expressive vocabulary and comprehension (understanding of spoken language) will be assessed using the BAS III
d) At age 5, the Early Years Foundation Stage Profile (EYFSP) will provide a teacher assessment of children's development and readiness for school in a range of areas (physical, personal social and emotional, communication and language, literacy, maths, understanding of the world expressive arts and design)
e) At age 6, a measure of children's phonics decoding skills will be provided by the Year 1 phonics test

5.7.3 Key Validated Measures

EQ-5D-5L

Overall health and parental psychological functioning will be measured at 26-36 weeks' antenatal, 4-months postnatal, and again at ages-1, 2 and 3, in part through the use of the EQ-5D-5L – a standardised instrument providing a measure of health outcome. Applicable to a wide range of health conditions, the EQ-5D-5L questionnaire provides a simple descriptive profile and a single index value for health status. It is cognitively simple, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire.

State-Trait Anxiety Inventory

Parental psychological functioning will also be assessed using the 6-item State-Trait Anxiety Inventory (STAI), an instrument that quantifies adult anxiety. The STAI is used to simplify the separation between state anxiety and trait anxiety, feelings of anxiety and depression, and the short version uses a 6-question response, which is very quick and simple for the respondent to complete. The questionnaire is split into the S-Anxiety T-Anxiety scales. The questions are answered on the basis of a 1-4 scale, with the focused areas including worry, tension, apprehension and nervousness. Respondents will be asked to complete the 6-item STAI as part of the 26-36 weeks' antenatal and 4-months postnatal, questionnaires.

Pregnancy Related Anxiety Questionnaire

A growing body of research suggests that elevated anxiety during pregnancy is a specific predictor of negative mental health outcomes for women and children. The Pregnancy Related Anxiety Questionnaire (PRAQ-R) assesses three subscales of anxiety that are specific to pregnancy; fear of giving birth, fear of bearing a disabled child, and pregnancy-related concerns about one's appearance. It is used in this evaluation at the 26-36 weeks' antenatal time point.

Maternal Antenatal Attachment Scale

The developing relationship between the mother and the foetus will be measured using the Maternal Antenatal Attachment Scale (MAAS). It consists of 19 items divided over two subscales: "Quality of Attachment (QA)" (11 items) and "Intensity of Preoccupation (IP)" (8 items). The subscale QA measures the quality of the mother's affective experience towards the unborn child (such as feelings of closeness and tenderness versus feelings of detachment and distance or irritation). The second subscale IP assesses the strength of feelings toward the unborn child and the amount of time thinking or dreaming about and talking to the foetus. All items are scored on 5-point Likert scales. The minimum score for the Global Attachment (i.e., Total) MAAS (GA) score is 19 and the maximum score is 95. The scores of the subscale QA range between 11 and 55 and

those of the subscale IP vary between 8 and 40. On both subscales and the GA, higher scores reflect a positive quality of attachment and a high preoccupation with the unborn child.

Mother-to-Infant Bonding Scale

The Mother-to-Infant Bonding Scale (MIBS) will assess the feelings of the mother towards her new baby at the 2-month postnatal time point. Some mothers find it hard to relate to their new baby, and such failure may have long-term effects on the child. The MIBS is a simple 8-item self-rating tool and is acceptable for use with mothers and provides significant correlations with their early mood.

Mothers Object Relations Scale

Assessment of maternal perceptions of infant warmth and invasion towards the mother, and identification of any potential attachment difficulties, will be assessed using the 14 item self-score Mothers Object Relations scale (MORS), designed to provide information about the mother's views of her baby. The MORS is commonly used as a screening tool to ensure that mothers are not suffering from clinically significant levels of either anxiety or depression. During the evaluation, it will be included at the 4-months postnatal time point.

Edinburgh Postnatal Depression Scale

Symptoms of emotional distress and depression in the mother during the postnatal period will be assessed using the STAI and the Edinburgh Postnatal Depression Scale (EPDS) at the 4-months postnatal time point. The EPDS is a 10 item self-report measure and a score of 10-30 indicates varying degrees of emotional distress and depression, with a score of 30 being the most severe. The measure includes one question about suicidal thoughts. If a respondent answers yes to this question, the researcher will be alerted to make further enquiry about the nature of any thoughts of self-harm in order for the level of risk to be determined and appropriate referrals made where indicated to ensure the safety of the mother and baby.

Primary Care Post Traumatic Stress Disorder Screen

The Primary Care Post Traumatic Stress Disorder (PC-PTSD) is a 4-item screen that was designed for use in primary care and other medical settings. The screen includes an introductory sentence to cue respondents to traumatic events. The authors suggest that in most circumstances the results of the PC-PTSD should be considered "positive" if a patient answers "yes" to any 3 items. Those screening positive should then be assessed with a structured interview for PTSD. The screen does not include a list of potentially traumatic events. Respondents in the evaluation will be asked to complete the screen as part of the 4-months postnatal survey to assess the occurrence of any recent traumatic events, including, but not limited to, the birth of their baby.

Brief Infant and Toddler Socio-emotional Adjustment Scale

Infant social and emotional adjustment will be assessed using the Brief Infant and Toddler Socio-emotional Adjustment Scale (BITSEA), which comprises a 42-item parent-report measure of infant and toddler (that is, 1- to 3-year-old children) social and emotional adjustment. It comprises two subscales – competence and problems measured using a three-point Likert scale. A higher score for the competence subscale and a lower score for the problems subscale indicate better adjustment. It also discriminates children with clinically significant problems from matched subjects.

Sure Start Language Measure

The Sure Start Language Measure (SSLM) is a parental report measure of early language development. It measures English vocabulary knowledge (the original assessment was based on a list of 100 words) alongside a measure of parental concern about language and other cognitive and social development. The most recent version of the SSLM will be used for this study. It comprises a reduced list of 50 words and four questions about parental concerns (Harris, Law and Roy, 2005), which the authors concluded is easier and quicker to use and addresses differences seen when using the 100-word format between children of different language. A higher score indicates more advanced language development.

Strengths and Difficulties Questionnaire

The Strengths and Difficulties Questionnaire (SDQ) is a brief behavioural screening questionnaire for use with children aged from 3 to 16 years. The SDQ includes 25 items on psychological attributes, measured using a 3-point Likert scale (not true, somewhat true, certainly true). Separate versions exist for parents and for teachers/educators, who are asked the extent to which each

descriptor (e.g. considerate of other people's feelings) is true for the child in question. For older children (11+) there is also a self-completion version. The items are organised into 5 scales, each with 5 items: emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems (totals of these 4 scales added to generate a total difficulties score out of 20) and pro-social behaviour. A higher score denotes more difficulties on the four 'problem' subscales.

British Ability Scales (II)

The British Ability Scales (II) battery is an educational psychology tool that provides a reliable standardised measure of children's cognitive and linguistic functioning, and has been adapted for use by survey interviewers. The evaluation will use two subscales of the BAS assessments - 'naming vocabulary' and 'picture similarity', the first being a measure of vocabulary and the second being a measure of non-verbal reasoning ability. Scores are age adjusted.

Adaptive Social Behaviour Inventory

The Adaptive Social Behaviour Inventory (ASBI) is an instrument based on 30 questions, developed to assess multiple dimensions of social competence in young children, using parents or educators as raters. For this research, we propose using the 5 factors identified in the EPPE research: compliance, pro-social, confidence, anti-social and anxiety (Sammons et al, 1999: EPPE Technical Paper 2). A higher score denotes more problems (antisocial and anxiety) or more strengths (compliance, pro-social, confidence).

5.7.4 Bespoke Questions and Adapted Measures

Toddler Home Learning Environment Index and HOME Short Form

Evidence suggests that parental involvement in early learning has a greater impact in children's wellbeing and achievement than any other factor, such as family income, parental education or school environment. The evaluation will use selections from the Toddler Home Learning Environment (HLE) index and HOME short form (SF), used in previous longitudinal studies, at ages 1, 2 and 3, to assess the home learning environment of the child. The questions focus on educationally orientated activities such as reading to the child, playing and learning activities with letters, numbers and shapes, painting and drawing and visiting the library. A higher score denotes a more supportive home learning environment.

Nutrition

The nutrition-related questions in the evaluation from 4-months postnatal up to age-5 comprise selected questions from the Child Dietary Questionnaire (CDQ), and relate to planned feeding (breast or bottle), breastfeeding, weaning age and types of foods, food supplements and dietary habits. For older children (specifically ages 5), additional questions are asked about fruit and vegetables consumption, sugar-sweetened beverages and water – three of the stronger determinants of excess weight gain in young children (as assessed from previous cohort studies). Height and weight will be measured at specific time points and mapped (for age and sex) on to standard centile charts used in the UK to assess child growth. This will give an indicator of whether a baby is under-height (stunted), underweight or overweight.

Domestic Violence

Questions about domestic abuse are included in the surveys when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. Respondents are asked whether they have been subject to, or used violence against their partner/ex-partner, since finding out they were pregnant, then subsequently within the last 6-months, and what type of violence this entailed (if any). These questions were adapted from Ipsos MORI/ Home Office: Violence against women and girls: teen sexual coercion, violence and rape: TRA Campaign Tracking adapted from Troubled Families evaluation.

Early Trauma/Abuse

A question about whether early trauma or abuse was happening in the home when the respondent was growing up is asked at the 26-36-weeks' survey point. This question was adapted from Troubled Families evaluation.

Alcohol

Questions about alcohol are included in the surveys when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. They ask respondents whether they have drunk alcohol within the past four weeks of being interviewed. The questions were adapted from the Millennium Cohort Study (MCS1) questionnaire http://www.cls.ioe.ac.uk/page.aspx?&sitesectionid=860&sitesectiontitle=Questionnaire

Substance Misuse

Questions about substance misuse are included in the surveys when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. They ask respondents whether they have taken street drugs within the past four weeks of being interviewed. The questions were adapted and updated from the 2006 Offending, Crime and Justice Survey (NatCen & BMRB) and Ipsos MORI Health Behaviour in School-Aged Children (HBSC) Study.

Smoking

Questions about smoking are included in the surveys when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. They ask respondents whether they have smoked tobacco products within the past four weeks of being interviewed. The questions were adapted from the Millennium Cohort Study (MCS1) questionnaire http://www.cls.ioe.ac.uk/page.aspx?&sitesectionid=860&sitesectiontitle=Questionnaire

Resource-Use

Questions about the use of hospital services, community health and social services and legal services will be asked when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. These particular questions have been adapted from the validated Client Services Receipt Inventory originally developed by the Personal Social Services Research Unit, University of Kent.

Education/Work Record

Questions about the formal education and work status of the respondent and their partner (if applicable) are included in the surveys when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. The questions are from ONS (taken from the Troubled Families evaluation).The questionnaire to be used at the age year survey point also includes a question about the current work status of the respondent and their partner (if applicable).

Ethnicity/Religion

Questions about the ethnicity of the respondent and her partner/the biological father of the child, as well as whether the respondent is religious, are asked when the respondent is 26-36 weeks' pregnant. They are derived from the ONS (taken from Troubled Families evaluation).

Tenure

Questions about the respondent's housing provision are included in the surveys when the respondent is 26-36 weeks' pregnant and the children are aged 1, 2, and 3 years. They are derived from the following existing surveys: Millennium Cohort Study, Troubled Families evaluation and Avon Longitudinal Study of Parents and Children (ALSPAC).

Household Income

Questions about household income and how well the respondent is managing financially are included in the surveys when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. The questions are from ONS (taken from Troubled Families evaluation), NESS (adapted) and Family and Children Study (FACS).

Social Support

These bespoke questions are loosely modelled on the Social Support Questionnaire (SSQ). The SSQ is a 27-item questionnaire designed to measure perceptions of social support and satisfaction with that social support. Part 1 asks participants to list all the people that fit the description of the question, and Part 2 asks participants to indicate how satisfied they are, in general, with these people.

The lengthy administration time required for the SSQ made it impractical to include the measure in full. As the consortium were unable to identify a set of questions from elsewhere that would serve a similar purpose it was decided to develop bespoke questions specifically for this survey. These bespoke questions are based on metrics measured in the SSQ, but using a standard satisfaction scale to identify participants' level of satisfaction with having people for support in each area at a general level.

These questions are included in the surveys when the children are aged 1, 2, and 3 years.

Disabilities, Care and Social Worker Involvement

Questions about whether the child, his/her parent/s or sibling/s have any learning difficulties, long-term illnesses or disabilities and any social worker involvement with the family are included in the surveys when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. They were taken from the Troubled Families evaluation and Millennium Cohort Study (MCS1) Questionnaire.
(http://www.cls.ioe.ac.uk/page.aspx?&sitesectionid=860&sitesectiontitle=Questionnaire)

Biological father

Questions about the respondent's relationship with the biological father of the study child and the father's relationship with the child are included in the surveys when the respondent is 26-36 weeks' pregnant and when the children are aged 1, 2, and 3 years. They were adapted from the Millennium Cohort Study (MCS1) Questionnaire.
http://www.cls.ioe.ac.uk/page.aspx?&sitesectionid=860&sitesectiontitle=Questionnaire

Grandparent involvement

Questions about how often the child sees his/her grandparents and whether they help out in different ways are included in the surveys when the children are aged 1, 2, and 3 years. They were adapted from the Millennium Cohort Study (MCS1).

Childcare

Questions about which childcare arrangements the respondent uses for the study child are included when the children are aged 1, 2, and 3 years. Questions about whether the child qualifies or uses the free early years' entitlement are included at age 2 and 3 years. These are all bespoke questions.

Data-linking permission and NHS number

We will collect data from the health and social care records of the respondent and the study child using their NHS numbers. Respondents will be asked if they consent to linking their survey answers to the health and social care records of themselves and their child. This will include accessing the child's ASQ3 data – an Ages and Stages Questionnaire undertaken as part of an overall development assessment of the child at the age of 2 years.

5.7.5 School-based Data Collection Measures

At age 5 data will be collected from parents using a postal (or online) questionnaire administered by Ipsos MORI, rather than using face-to-face techniques.

The measures to be used are:

- Social, emotional and behavioural adjustment will be measured using the **Social Behaviour Questionnaire (age 5),** to be completed by the child's teacher. This is an adapted version of the Strengths and Difficulties Questionnaire (SDQ), which includes selected questions from the Adaptive Social Behaviour Inventory (ASBI). See Section 3.2.1 for description of the SDQ and ASBI. The Social Behaviour Questionnaire was developed for, and validated by, the Effective Provision of Pre-School Education (EPPE) research team.

The University of Oxford will also gather administrative data from national assessments at two time-points:

- The Age 6 Phonics Check: The phonics screening check is a short, simple assessment to make sure that all pupils have learned phonic decoding to an appropriate standard by the age of 6. All year 1 pupils in maintained schools, academies and free schools must complete the check.

5.8 Sub-sample Protocols

Verbal consent will be taken at each time-point for each biological sub-sample. Even if a parent has consented to a previous sample, he or she can refuse consent at any time, and is under no obligation to provide a further sample. Under no circumstances will a parent be pressured into providing a sample where he or she does not wish to, and can remain in the study without providing any or further samples.

5.8.1 Hair Sample

Hair samples are being used in the evaluation to provide an indicator of stress by measuring cortisol levels from the mother at birth and the child aged 2 years. A trained hospital midwife will take a sub-sample of hair from the mother at birth, while the trained and experienced field researcher/interviewer will take a hair sample from the child at age 2 years. If the child does not have enough hair at either of these time-points, a sample will not be requested.

Hair strands (total diameter of approximately 3mm and total sample size of 10-50mg) will be taken from the middle of the back of the head and cut (not pulled out) with clean sterile scissors as close to the scalp as possible. It is important that the hair follicle itself is not included. The sample will then be placed in a sterile container with the scalp (root) end at the bottom.

Research and/or Community Midwifes and Ipsos MORI will store hair samples at room temperature in a safe and secure area before mailing, in sealed envelopes and in batches, to the to the Evaluation Project Manager at the University of Warwick Medical School, where these samples will be stored before being couriered securely in batches, to the laboratory overseas for analysis. A Material Transfer Agreement will be put in place between the University of Warwick and all NHS Trusts involved in the evaluation, and with Ipsos MORI, as well as the laboratory overseas. The samples will be analysed in the lab of Dr Clemens Kirschbaum in Germany, who leads a well-established automated laboratory for this type of analysis.

5.8.2 Buccal Swab

Buccal swabs are being used in the evaluation to provide epigenetic information from the baby at birth and at age-2. A trained hospital or community midwife will take a buccal (cheek) swab - from the baby at birth or in the first few weeks of life, and the trained and experienced field researcher / interviewer will take another sample again when the child is 2 years of age. A special foam tip collection swab (Epicentre catch-all collection swab) will be used. This swab comprises a long, foam bud on a plastic stick that has been specially designed for use with infants and children. The long length of the stick allows one end to be held while the other end is in the infant's mouth, eliminating any choking hazard. The foam will be gently wiped five times down the child's inner cheek. The swab will be replaced in its special Epicentre collection tube. If for any reason the infant becomes distressed, the collection will be abandoned.

Immediately after taking the Buccal Swab, Research and/or Community Midwifes (at birth) and Ipsos MORI Researchers (at 2 years) will mail Buccal Swabs to the Evaluation Project Manager at the University of Warwick Medical School, where these samples will be stored in the laboratory at -20°C before being couriered securely in batches, to the laboratory overseas for analysis. A Material Transfer Agreement will be put in place between the University of Warwick and all NHS Trusts involved in the evaluation, and with Ipsos MORI, as well as the laboratory overseas. The genome-wide epigenetic profiles will be measured and analysed by Kieran O'Donnell in the Montreal laboratory of Professor Michael Meaney, the acknowledged world leader in this type of research.

5.8.3 CARE Index

The CARE-Index will be used when the child is aged 1 and it has been extensively validated as a measure of parent-toddler interaction. It measures three aspects of maternal behaviour (sensitivity, covert and overt hostility, and unresponsiveness) and four aspects of a toddler's behaviour (cooperativeness, compulsive compliance, difficultness and passivity). Scores range from 0 to 14, higher scores indicating better sensitivity and/or co-operation and so on, and the scores for each are interdependent such that a high score for maternal sensitivity is related to a low score for hostility and unresponsiveness. Similarly a high score for infant co-cooperativeness is related to a low score for difficultness, passivity or compulsive compliance.

The CARE-Index has been shown to discriminate abusing, neglecting, problematic and adequate dyads. A trained and experienced Ipsos MORI field researcher and interviewer will request permission from a sub-sample of participants to take a video clip of them interacting with their child

as they would normally, for a period of 3 minutes. This video clip will be stored securely prior to being viewed only by coders who have been specially trained and certified reliable using the CARE-Index. After coding, each clip will be destroyed.

5.8.4 The Manchester Child Attachment Story Task (MCAST)

The MCAST is a structured doll play methodology designed to assess young children's internal mental representations of attachment relationships with a specific caregiver. It is suitable for children aged 4-8.5 years. Using doll-play, children complete a series of attachment-related stories initiated by the researcher. The dolls represent the caregiver and the child. When compared with some other established 'story stem' measures, the MCAST is structured with a standardised script although semi-structured aspects do allow for some flexibility and adaptation for that particular child and for a more natural and engaging storytelling process.

The MCAST takes 15-30 minutes to administer and will be conducted in-school by a fully trained and experienced University of Oxford (Department of Education) field researcher. The researcher will request permission from a sub-sample of participants to undertake the MCAST with their child. The exercise will be videoed and transcribed. The video clips will be stored securely and in anonymous format prior to being viewed by the coders. Trained coders employed by the University of Oxford, Department of Education will carry out the MCAST coding. The videos will be transferred to the University Oxford using a secure password protected method.

5.9 Economic Evaluation

The economic consequences of compromised outcomes in early childhood are likely to be felt across several formal sectors, including the health, social, education and voluntary sectors, as well as informal sectors. The economic evaluation will therefore focus on the following major components of costs: NHS primary and secondary care, local authority care, educational support, support from voluntary groups or other agencies, and costs borne by families and informal sectors. Intervention costs will reflect the costs necessary to implement A Better Start, including the development and training of accredited providers, the cost of delivering the programme, participant monitoring activities, and any follow-up/management.

Two economic evaluations will be undertaken: (i) a within cohort study economic evaluation will compare individual-level costs and outcomes using propensity score techniques described previously to construct the programme and comparison groups, and (ii) a decision analytic cost-effectiveness model will be used to estimate the expected incremental cost per unit change in primary outcomes for ABS in comparison to usual care. For both analyses, the economic assessment method will, as far as possible, adhere to the methodological recommendations of the NICE Reference Case (2008). The primary perspective adopted in both analyses will be that of society as a whole. However, the potential impact of adopting a NHS and personal social services perspective will also be explored in separate sensitivity analyses (NICE, 2008).

5.9.1 Within Cohort Study Analysis

The within cohort study analysis will compare the costs and outcomes between *A Better Start* programme and comparison group at the end of follow up. In addition to the resource impacts associated with the delivery of A Better Start programme, broader resource utilisation will be captured through two principal sources: (i) participant questionnaires, adapted from the Client Services Receipt Inventory, administered at each follow-up point; and (ii) data from routine data collection systems. Unit costs for relevant resource inputs will largely be derived from local and national sources and estimated in line with best practice. Primary research using established accounting methods may also be required to estimate unit costs. Costs will be standardised to current prices where possible. One way of presenting the results of this economic evaluation is through the use of cost-consequences analysis, which will provide a profile of both the incremental costs and incremental consequences of A Better Start programme across relevant sectors and domains. In addition, we plan to undertake a cost-effectiveness analysis on the basis of the primary outcome measures selected for the cohort studies. Results will be presented using incremental cost-effectiveness ratios and cost-effectiveness acceptability curves generated via non-parametric bootstrapping. This accommodates sampling (or stochastic) uncertainty and varying levels of willingness to pay for reductions in the primary outcomes of interest. Additionally, net benefit statistics will be estimated. A series of sensitivity analyses will explore the effects of

uncertainty surrounding key parameters on the incremental cost-effectiveness ratios. Discounting of costs and consequences to present values will follow national methodological guidance.

5.9.2 Decision Analytic Cost-effectiveness Analysis

The decision analytic cost-effectiveness analysis model will use a lifetime time horizon to capture the full impact of any differences in the primary outcomes on the long-term cost-effectiveness of A Better Start programme. The methods for estimating parameter inputs will be the same as for the within cohort study analysis, although evidence from external secondary sources (drawn for targeted literature searches) may also be required. Probabilistic sensitivity analyses will be undertaken using Monte Carlo simulation techniques. The outputs reported from this analysis will be the same as for the within cohort study analysis.

6. DATA MANAGEMENT

6.1 Data Security

Data security will be guaranteed by the lead organization for this tender (University of Warwick) and will comply with Department of Health (DH) /Department for Education (DfE) requirements, including the Data Protection Act. It will also comply with the University of Warwick policies, which are available as follows:
http://www2.warwick.ac.uk/services/gov/legalservices/whentouse/dataprotection

The University of Warwick has drawn up a Data Processing, Sharing and Transfer Agreement for the evaluation of ABS that must be signed and adhered to by all partners within the Warwick Consortium. A copy of this agreement is available on request.

For these purposes, Big Lottery Fund is the data Controller and the University of Warwick as the contractor university, is the Data Processor. The programme will be set up to ensure that all constituent members of the Management Team and extended research team are aware of and act in compliance with the data security requirements as per contract. Data security will cover data collected by the research team or commissioned researchers in addition to the data made available by the individual sites.

In particular, we will employ appropriate organisational, operational and technological processes and procedures to keep all data safe from unauthorised use or access, loss, destruction, theft or disclosure. The organisational, operational and technological processes and procedures adopted will comply with the requirements of ISO/IEC 27001 as appropriate to the services being provided to Big Lottery Fund. In all cases we will be advised and guided by the University of Warwick's Research Support Services and Data Security Officer. We will at all times comply with the Data Protection Act 1998 and comply with its requirements (e.g. all laptops have full disk encryption and all USB sticks are fully encrypted).

Data security includes the storage and protection of data from loss (e.g. appropriate back up of data on the relevant organization network and password protection). For example, data will be backed up securely and normally only be kept on a password protected networked computer. Data will not be kept on any laptop or other removable drive or device unless there is appropriate encryption and password protection, and the use of the device or laptop is necessary for the research. Laptops will have full disk encryption using either a CESG (Communications Electronic Security Group) CAPS approved product or alternatively a product that complies with the FIPS 140-2 Standard. USB devices used for transferring the Department's Data will be encrypted to the FIPS 140-2 Standard. Transmission of data between members of the team and DfE will be via encrypted and password protected files with passwords sent separately.

All the paper records (e.g. interview transcripts will be coded and hence anonymous), with codings kept separate from the written records. All material will be kept securely within locked filing cabinets. Destruction of confidential paper records will be by shredder and electronic files by the procedures advised at that time by the University'.

6.1.1 Data Confidentiality

An 'opt-in' method to the evaluation is being employed, such that at the time of potential participant identification, the participant must give consent for their name, telephone number and/or email address (only) to be passed on to Ipsos MORI in order to be contacted. For those individuals who do not provide consent, their contact details will remain confidential and will not be passed to Ipsos MORI. In these circumstances, no further action will be taken. At no time in this identification process will anyone other than the midwife and the patient have access to the patient's details, medical information or otherwise.

On recruitment of participants to the study, each individual will be allocated a unique number (i.e. the data will linked-anonymised). Ipsos MORI will keep all personal identifiers and only an anonymised dataset will be transferred securely to other members of the consortium.

The cohort survey data, and linked administrative data, will be collected by Ipsos MORI but primarily analysed by Drs Caroline Bryson and Susan Purdon of Bryson Purdon Social Research LLP (BPSR).

Non-identifiable data only that is generated from the study will be stored securely, in a format that can be analysed (i.e. SPSS files), in accordance with Data Protection procedures, by Big Lottery Fund as Data Controller for the study. This includes coded non-identifiable data files generated from the additional CARE-Index and Story-stem subsamples. All films will be deleted from the video camera as soon as they are downloaded on to a disc to be coded. Once coded, these discs will be securely and professionally shredded by the Universities of Warwick (CARE index) and Oxford (Story-stem).

Samples of hair and buccal swabs will be kept by the relevant laboratories and will not be used for any further research purposes without the further consent being sought from the participating families. Data confidentiality will be secured using unique number coding, thus samples will be non-identifiable.

6.2 Data Analysis

The baseline and cohort studies are complex and cover a very large range of outcomes, over multiple data collection points. The longitudinal cohorts will generate a steady stream of rich and complex data the analysis of which is to be planned in detail before each analysis stage. A balance will need to be struck between exploring the data in depth, so that the data contribute as much as possible to our understanding of the nature and size of programme effects, and contributes to the evaluation in a formative way, but without any risk of 'fishing' for positive results. We plan to manage this as follows:

At the start of each analysis phase, and before any data analysis has started, the team will generate a detailed analysis plan. This will cover:

1. The outcomes to be included in the analysis, including how they are to be coded;
2. The datasets to compare (e.g. whether the analysis will compare newly created datasets with earlier ones from the evaluation (including the baseline), or whether the comparison will be cross-sectional programme v comparison);
3. Whether there are to be any sub-groups analyses;
4. How 'explanatory' variables are to be used;
5. How the analysis will be done (such as when, and how, propensity score matching will be used, regression analysis, and so on);
6. How to present the results (i.e. tables, graphs etc.)

The decisions on the analysis plan each time will partly be driven by programme theory (that is, what changes might we expect to observe, given the logic of the programme). But there will also be new hypotheses to be tested, these being generated by other strands of the evaluation (such as any suggestions from the implementation study that the programme is looking to be particularly successful for some groups of parents and less so for others).

Over and above this planned analysis, we will include some exploratory analysis at each phase – such as running impact estimates for a range of sub-groups over and above the sub-groups for which theory suggests that differences should arise. This analysis will be kept separate from the main analysis, and reported on as separate. The intention is to use the data to identify any potential anomalies in impacts that can then be fed back into the implementation study for testing.

As data build up from the longitudinal study we will start to create multiple datasets that can then be analysed in multiple ways. Much of the analysis will be child-age-specific and will use the data cross-sectionally. For instance, when looking at the impact of the programme by age 3, comparisons will be made across six independent samples: baseline, cohort 1, and cohort 2, in both programme and comparison areas. The sorts of questions this will answer will be whether change since baseline in age 3 outcomes has been greater in programme areas than in comparison areas. Other analyses will make more direct use of the longitudinal nature of the two cohorts: such as 'have children in programme areas followed different trajectories over their early years than children in comparison areas'. Or, 'to what degree can outcomes at age 3 be explained by earlier experiences of the parent and child'.

We envisage that most of our analysis of impact will be based on comparisons between programme and comparison area groups that have been balanced on confounding variables using propensity score matching. That is, each time the comparison area data is used to generate an estimate of the counterfactual, differences between the background characteristics of the two groups (programme and comparison) will be established using regression modelling (either probit or logistic regression)

and a ‘propensity’ to be in the programme group estimated. The two groups will then be matched on this propensity score. This will ensure a reasonably close match in the two groups on the full range of background characteristics. If there is evidence of biasing non-response effects in the cohorts over time then weighting of the data to try and remove any such bias will be considered. All statistical tests and standard errors will be calculated taking into account the matching, non-response weights, and between-comparison-area effects.

7. EVALUATION ORGANISATION AND MANAGEMENT

7.1 Monitoring and Quality Assurance

As the lead organisation for this evaluation, the University of Warwick will provide the guarantee of Quality Assurance. Warwick has extensive infrastructure provision, and is currently managing over £43 million in health research income. Warwick's well-resourced infrastructure can provide the necessary financial, legal, corporate and business relations expertise, to ensure that in the contract work is managed with a high level of proficiency.

7.1.1 Quantitative Survey and Impact Evaluation Design

- We have ensured our team has appropriate expertise in terms of all aspects of the conduct of the study. We are using sampling frames that are as up-to-date as possible, and will assess and report on any deficiencies and their impact on study estimates.
- Our experience and expertise enable us to use high quality instruments to meet the research objectives of the study.
- Our experience and expertise in designing evaluation studies will ensure that the proposed work is as free from bias as possible and that are of adequate statistical power. Any implicit risk of bias or error will be fully acknowledged and reported.

7.1.2 Research Governance

The proposed research will be conducted in accordance with the Research Governance framework and the University of Warwick framework: http://www2.warwick.ac.uk/services/ris/research_integrity

a) In addition to ethical approval being granted for this evaluation, all R&D leads in NHS Trusts and other relevant bodies (e.g. CRN) will be informed about the research, including all professionals caring for the study participants.
b) Research protocols have been established to address both the safety of study participants and the researchers undertaking the surveys.
c) When the results of the evaluation have been established the findings will be disseminated to all of the study participants in a format that is accessible (most likely through the study website www.youandyourchild.co.uk and by letter).
d) All research interviewers employed on the study will have been granted Disclosure and Barring Service (DSB) approval (previously known as CRB).

7.1.3 Analysis and Reporting

Substantive reports will be written to be accurate, accessible and relevant, with final approval for all reports being guaranteed by the Chief Investigator.

7.2 Management Structure

The quality of the research will be ensured via the following management structure:

- **An Evaluation Management Group**, consisting of all members of the Consortium, which meets monthly.
- **An Evaluation Steering Committee** with an externally appointed Independent Chair (Emeritus Professor Heather Joshi, University College London Institute of Education), which meets 2-3 times per annum. Other members include key leads within the Consortium, Big Lottery Fund, Department for Education and members of the Advisory Group. The role of the Steering Group is to:
  - Monitor, supervise and advise on the progress and conduct of the A Better Start Evaluation towards its interim and overall objectives, and to advise on participant safety and scientific credibility;
  - Review at regular intervals relevant new information from other sources;
  - Consider the recommendations of the Overall Management Group, the Advisory Board and/or Big Lottery Fund as sponsor;
  - Ensure Big Lottery Fund are well informed via CI reporting, on the progress of the study;
  - Advise Big Lottery Fund on publicity and presentation on all aspects of the evaluation.
- **An independent external Advisory Group**, advising on a variety of issues relating to evaluation design and conduct (Professor Jeanne Brooks Gunn, University of Columbia), developmentally sensitive interviewing and factors affecting children's adjustment (Professor

Michael Lamb, University of Cambridge) and policy (Jean Gross CBE). This advisory group meets 2-3 times per annum and on an ad-hoc basis as required.

Additional procedures will also be followed:

- The project is managed by an evaluation Senior Project Manager (Virginia Woolgar) based at the University of Warwick.
- In addition to the Chief Investigator, Professor of Public Health in the Early Years, Jane Barlow, University of Warwick, the following leads have been appointed within the Consortium:
  - Deputy Chief Investigator Professor Geoff Lindsay, University of Warwick
  - Professor of Evidence Based Midwifery, Debra Bick, Kings College London – Lead for Recruitment Design and Implementation
  - Ms Sarah Knibbs, Research Director, Social Research Institute Ipsos MORI – Lead for Data Collection
  - Professor of Health Economy, Stavros Petrou – Lead for Economic Impact
  - Professor of Nutrition, Carolyn Summerbell, Durham University – Lead for Nutrition
  - Emeritus Professor of Perinatal Psychobiology, Vivette Glover, Imperial College London – Lead for Biometric Subsampling Design and Implementation
  - Professor of Education, Kathy Sylva, University of Oxford – Lead for Educational Impact Design and Implementation
  - Professor of Statistics and Public Health, Alastair Leyland, University of Glasgow and Dr Susan Purdon, Bryson Purdon Social Research – Lead for Impact Analyses
  - Dr Laurie Day, Director, ECORYS – Lead for Impact Learning and Dissemination
- Clear lines of responsibility have been set to ensure quality standards are upheld, to time and to budget.
- All key tasks have been assigned to one or other collaborating partners and progress on tasks will be monitored throughout the life of the project.
- A timetable has been set with the funder that will be adhered to with appropriate milestones to be achieved through the course of the project.
- The Project Manager reports to the funder on an ad-hoc, bi-monthly and annual basis and early warnings are highlighted of any unavoidable delays.
- An up-to-date risk register is maintained, with strategies for minimising risk and risk mitigation.

8. PATIENT AND PUBLIC INVOLVEMENT (PPI)

Parent and public representatives have been involved within the majority of the five successful ABS awarded areas – either in an ad-hoc capacity, but predominantly through specific independent Public Involvement Groups (such as Blackpool Community Voice for A Better Start), and have contributed towards the direction and design of these successful programmes.

Warwick Consortium has made use of these existing groups in terms of PPI; we have also worked with ABS area programme staff to identify public participants for involvement in consultation where no official groups existed. Consultation to date has included meeting with large groups of PPI representatives from Blackpool, Bradford, Lambeth and Southend-on-Sea during the latter half of 2014, in order to inform the content and design of the evaluation's Participant Information Leaflet, to discuss and address any concerns about the evaluation, and to gain insight into any issues that may arise regarding recruitment within these areas, and how these could be dealt with to optimise future recruitment and retainment to the study.

The evaluation tem will continue to consult with these user groups throughout the lifetime of the study to obtain advice, provide an opportunity for them to raise concerns, and to obtain their input to the research. Two parent representatives will also sit on the Steering Committee, which meets 2-3 times per year, and is chaired independently by Professor Heather Joshi, UCL Institute of Education, and involves other independent expert members (for example Professor Jeanne Brooks-Gunn, University of Columbia, Jean Gross CBE, Professor Michael Lamb, University of Cambridge, Mr Steve Hamilton and Mr Julian Ward, Department of Education).

9. ETHICAL CONSIDERATIONS

This study raises a number of ethical issues in addition to the routine issues relating to consent, anonymity and data storage etc.

9.1 Collection of Biological Non-invasive Data

In addition to collection of routine parent-report data using standardised questionnaires that will be administered as part of surveys, the evaluation plans to utilise some biological but non-invasive objective outcome measures, some of which will be taken from the whole sample, and some from a randomly selected sub-sample.

Non-invasive biometric measures include the following:

- Maternal hair sample to asses cortisol levels - subsample
- Baby buccal (cheek) swab to assess epigenetics at or around the time of birth - subsample
- Child hair sample and buccal swab at 2 years – subsample
- Other objective non-biological measures include the following:
- Height and weight – full sample at all time points post-delivery
- 3-minute videotape recording of parent-infant interaction at 12 months – subsample only
- Story-stem measures of attachment at 3 years – subsample only
- Home learning environment at 3 years – full sample

Participants will be verbally consented for all of the above at each face-to-face stage of the process (i.e. they will not be requested to consent to these particular aspects of data collection at the outset of the study). Parents are under no obligation to consent to provide a sample even if they have done so before, and will remain in the study regardless of this decision, if they wish to do so.

9.2 Payment for Participation

At each face-to-face interview (28 weeks pregnancy; ages 1, 2 and 3 years) and for completion of the 4-months postnatal survey, participants will be offered a £10 Love2Shop voucher as recognition of the time that they have contributed; no separate payment is offered for any of the above objective data measurements or for completion of the 4-months postnatal resource-use questionnaire (except for the piloting of recruitment); or at age 5 years. Participants will be informed about this financial compensation at the outset of the study.

9.3. Sampling Frame

The baseline surveys, which are cross-sectional surveys of three age groups (age 1, 2 and 3), will require a different sampling approach to that being used for the purpose of the main cohort study. The preferred method is to sample via Emma's Diary, which has been used as a sampling frame for other studies, including research into pregnancy discrimination at work for the Equal Opportunities Commission[7] and in an evaluation conducted by evaluation partners Bryson Purdon Social Research for the NSPCC[8]. In the event that it is permitted, Emma's Diary will be used to identify parents living in one of the study areas who have a child aged 1-3 years. The proposed process of recruiting respondents to the baseline survey is outlined in Section 5.4.1.

9.4 Identification of Families in Need of Support

The data collection will involve survey questionnaires comprising a range of standardised and validated questions asking about a range of aspects of parental wellbeing including mental health; substance use and experience of domestic violence. This may result in the identification of families who have additional support needs. We will routinely provide all families with an information sheet listing core local helplines and services. Trained researchers will also provide emotional support at the time of the interview and encouragement to contact their GP or health

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7 http://www.maternityaction.org.uk/wp/wp-content/uploads/2013/09/eocpregnancydiscrimwomensurvey.pdf

8 http://www.nspcc.org.uk/globalassets/documents/evaluation-of-services/evaluation-preventing-non-accidental-head-injuries-nahi-programme-impact.pdf

visitor where appropriate. In the event that we identify a child who may be at risk of harm, the relevant social services will be informed.

9.5 Inclusion of participants who have English language difficulties

In order to capture the experiences and attitudes of as many different ethnic groups as possible, we propose to use the following processes to try and include those who would not be able to complete an interview in English.

For the longitudinal cohort surveys, we will translate the participant-facing materials (including consent forms, invitation letters and information leaflets) into the most prevalent languages spoken in the fieldwork areas and these will be available for participants on request. As midwives and other health professionals are identifying and recruiting the sample for the cohort surveys, they will be well placed to identify any English language difficulties at the time of recruitment so that the survey information can be given in the most appropriate language.

The sample for the baseline surveys is generated differently from the cohort surveys – from a commercial sampling frame via Emma's Diary, the largest pre-natal database in the UK – and we do not propose to translate participant-facing materials for the baseline. The sample is generated from pregnant women or mothers who sign up to Emma's Diary via one of their communication platforms, such as their website or pregnancy guide. As all of Emma's Diary communications are in English only, we have assumed that anyone signing up is proficient enough in English to be able to understand survey materials in English.

However, we will try and conduct interviews in languages other than English if necessary in both the main baseline and cohort surveys. If an interviewer identifies a participant who is willing to take part in the survey but is unable to do so in English, Ipsos MORI will attempt to use an appropriate bilingual interviewer to conduct the interview in the participant's preferred language.

As it would not be appropriate to give the CAPI machine to participants who have English language difficulties to do the self-completion section of the interview themselves, interviewers will be asked to administer the questions in this section to participants in all non-English interviews. Therefore, all interviews that are conducted in a language other than English will be entirely interviewer-administered. As the questions in the self-completion section are more sensitive and it may become obvious that it is not appropriate for the interviewer to continue asking them, a code will be added to each question that will allow the interviewer to skip the remainder of the self-completion section if necessary. In addition, and as with all the questions asked in the interview, participants are allowed to refuse any that they do not wish to answer.

As it is so important that questions from non-adapted validated measures are asked in exactly the same way and consistently across all interviews, independent translations of these sections will be made onto paper for interviewers to read out at the appropriate points within the interview. Responses will be entered by the interviewer into the (English) CAPI script. This includes any non-adapted validated measures included in the self-completion section, so the interviewer will need to read the questions and answers (where appropriate) from the translated paper version in these instances.

This means that translations onto paper would be made for the following sections in face-to-face interviews across the baseline and cohort surveys:

Cohort Pilot		Main Baseline		Main Cohort	
26-36 week questionnaire		**Age 1, 2, 3 questionnaire***		**26-36 week questionnaire**	**Age 1, 2, 3 questionnaire***
1.	**Edinburgh Postnatal Depression Scale (EPDS)**	1.	Adaptive Social Behaviour Inventory (ASBI)	1. Edinburgh Postnatal Depression Scale (EPDS)	1. Adaptive Social Behaviour Inventory (ASBI)
2.	**EQ-5D-5L (health outcomes)**	2.	Brief Infant Toddler Social Emotional Assessment (BITSEA)	2. EQ-5D-5L (health outcomes)	2. Brief Infant Toddler Social Emotional Assessment (BITSEA)
3.	**Maternal Antenatal Attachment Scale (MAAS)**			3. Maternal Antenatal	

4. Pregnancy Related Anxiety Questionnaire (PRAQ) **5. State-Trait Anxiety Inventory (STAI).**	3. Edinburgh Postnatal Depression Scale (EPDS) 4. EQ-5D-5L (health outcomes) 5. Strengths and Difficulties Questionnaire (SDQ)		Attachment Scale (MAAS) 4. Pregnancy Related Anxiety Questionnaire (PRAQ) 5. State-Trait Anxiety Inventory (STAI).		3. Edinburgh Postnatal Depression Scale (EPDS) 4. EQ-5D-5L (health outcomes) 5. Strengths and Difficulties Questionnaire (SDQ)

**Although the Sure Start Language Measure (SSLM) and British Ability Scales are included in the baseline and cohort Age 1, 2, 3 questionnaires without adaptation, they are not included in the paper translation list above because translation is not appropriate as both are tests of English vocabulary.*

At survey time-points which involve collecting data via methods other than face-to-face interviews (e.g. online), participants will be able to request to complete the survey in a different language via a translated paper questionnaire.

9.6 Potential Risks to Participants

Participation in the study is not associated with any known risks. All research protocols have been developed with a view to promoting and protecting participant welfare including their dignity, rights, safety and wellbeing. A study Steering Group and an Expert Advisory Group will be regularly convened to ensure that the welfare of participants is paramount. The Advisory Group comprises individuals with appropriate specialist skills in terms of adult mental health and child protection. The advice of this group will be sought as regards all issues relating to the wellbeing of the study participants.

The survey questionnaires will ask parents about a range of topics, some of which they may find upsetting. For example, we will be asking parents about their mental health, whether they use substances, whether anyone is hurting them (e.g. domestic violence). It is also acknowledged that in identifying participants to contribute to the baseline data collection, extreme care and sensitivity must be exercised to avoid causing further distress to parents who may: a) have suffered a miscarriage, stillbirth, neonatal or later child death; b) have a child experiencing serious health problems; c) have had their child taken into the care of family or social services. Please refer to Sections 5.4.1 and 5.4.5 for further details of the sensitive process investigators will follow in relation to the both the baseline sampling process, and pilot study/main evaluation identification and recruitment, respectively.

- The following steps have been taken to minimise risk to the participants:
- The sensitive aspects of the survey questionnaire will be undertaken using self-completion methods, which should minimise embarrassment if a participant doesn't wish to disclose sensitive information to the researchers[9].
- If a participant does not want to answer particular question they can skip to the next set of questions
- The interviewers will routinely give all participants an information leaflets with relevant helpline numbers for the participant to refer to if they feel they need to talk to someone else about any of the issues discussed in the interview
- In the event that the interviewer becomes aware of any risks to the safety of a child in the home, the relevant social services department will be informed. Participants will be made aware in the information sheet that all information that they provide will be confidential unless there are concerns about the safety of the child under which circumstances the information may be shared under the terms of the Children Act 1989.

[9] However, using self-completion methods will not be possible for interviews conducted in languages other than English as the interviewing script will be in English only – please refer to Section 9.5 for more details of the processes we will follow in the case of a non-English interview.

- In the event that the interviewer is made aware of any substance use by the participant or, risk of domestic violence, the interviewee will be provided with relevant information about accessing support.

9.7 Potential Risks to Researchers

The researchers will be visiting the homes of unknown women living in disadvantaged wards. There may be a small risk of them being exposed to violence on the part of the women or her partner.

Trained, experienced Ipsos MORI field interviewers, who have additionally attended briefing sessions on this particular project, will conduct the survey research. Wherever possible interviewers work in local areas where they have a good sense of what the area is like and what the potential risks to their safety might be, although sometimes interviewers will have to travel into areas they are not familiar with.

Interviewers will follow the Ipsos MORI safety protocol at all times. These include the following:

Interviewers will follow our Ipsos MORI's safety protocols at all times. Thus, interviewers are advised as follows:

- Not wear expensive jewellery or clothes, but to think about the area in which they are working, and how best to fit in and avoid causing any offence
- Travel light, and lock bags away in the boot before setting off for interviews in order that others don't view any valuables
- Carry any shoulder bag on a short strap with the clasp facing inwards
- Carry a phone card or a mobile phone (but not on view)
- Make a family member, friend or colleague aware of their destination and what time to expect them back. If plans change, the interviewer should contact this person or persons
- Notify the police that they are working in the area
- Relinquish their laptop or other possessions if threatened for these items
- As a visitor in a participant's home, to respect the cultural norms of the home they are entering
- Say who they are, why they are there and hand their ID to the respondent so that they it can be checked thoroughly by the interviewee
- Ensure they are able to keep calm in situations and assess whether it would be best to leave the interviewee home or not
- If they feel at risk at any time, interviewers should close down the interview and leave as quickly as they can
- If they become involved in an incident, interviewers should report it to the police and then report it to their Region Manager

10. DISSEMINATION AND PUBLICATION

The evaluation and learning for A Better Start is also being delivered by the Warwick Consortium - specifically by partner, Ecorys UK. A programme of activities will be delivered to ensure outcomes and learning from this vital programme evaluation are promoted and shared amongst interested stakeholders. This will include capacity building for local partnerships to implement a learning strategy, a series of national conferences, workshops and policy round table sessions and bespoke website and communications activities, as well as academic publications. A final evaluation report will also be prepared.

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