Early Life Cohort Feasibility Study

Non-questionnaire measures, and additional informant interview topics

Alongside the first draft questionnaire for the primary informant, we are also consulting on a draft specification for non-questionnaire measures to be included in the Early Life Cohort Feasibility Study, and on the topics selected for the additional informant interview. More specifically, we are consulting on:

- The core measures to be implemented within the time and funding envelope already available, which includes direct assessments of the child and of parent-child interaction, placement of an app, and biosamples.

- Our approach to record linkages.

- The topic outline for the additional informant questionnaire (with the full questionnaire to be developed in Autumn 2021).

- The additional measures we propose to apply to ESRC for, for potential additional funding.

Please provide your comments and suggestions via the following consultation form.

Important note: it has yet to be determined by the funder whether the target age of the infant at first interview in the feasibility study will be at 6 months or 9 months (with interviews in practice taking place at a window of ages around this). We have specified measures here that would be taken at 9 months. Some of these (as indicated below) would need to be re-designed if the 6 month protocol is adopted instead.

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1. Core measures to be included within time and funding already available

The feasibility study will include measures comprising:

- Placement and use of the Babysteps app designed to measure and record infant development including parent-infant interaction video. (Section 1.1)
- Direct developmental assessments of the infant, which we refer to as neuroscience-informed measures (on an independent sub-sample of 500 issued families). (Section 1.2)
- Bio-samples (on an independent sub-sample of 500 issued families). (Section 1.3)

One of the main aims of the feasibility study will be to test the implementation of the these measures, particularly those that have not been carried out at scale before in this context, including key data quality parameters in relation to interviewer training and monitoring, protocol fidelity and data completeness and quality.

Note the rationale for sub-sampling, where applicable, is both for reasons of cost and practicalities, but also to potentially enable measurement of the impact of including these additional measures on the recruitment rate

1.1 BabySteps smartphone app – placement and recording of parent-infant interaction

Smartphone-based data capture offers the possibility of measuring developmental trajectories and family processes at much higher temporal resolution than through standard questionnaires. We plan to utilise an innovative smartphone app 'BabySteps', designed by the University of Iowa for studying early child development.

All primary informants will be asked to download a smartphone app, called BabySteps, during the household visit and record a video of them playing with the cohort child. The structure of the play video will be decided upon by the study team prior to the commencement of the fieldwork contract, but is likely to include an episode of face-to-face social play between parent and child, an episode of play with toys, and an episode in which the parent shows the child a picture book. Each episode will last 2 minutes, with an overall budgeted 10 minutes of interview time.

After the visit, the primary informant will be encouraged to complete a number of other activities via the app, which would include audio recordings of linguistic interactions, logging of key developmental milestones, the recording of additional videos of the child's behaviour at home, and ecological momentary assessment-based assessments of parent mood states (EMA), infant sleep patterns, and the child's daily activities.

Respondents without their own Smartphone will not be eligible for the Babysteps app tasks, as the study will not provide devices to those that do not own them.

1.2 Neuroscience-informed measures

For a sub-sample of 500 issued families, the primary informant interview will also contain an additional 15 minutes of measures, comprising of two elements:

1.2.1 Direct assessment of infant critical developmental functions

We will undertake direct assessment of infant critical developmental functions such as habituation/learning, gaze following, turn-taking and imitation, via video-recording to record looking behaviour. The exercise will likely comprise five short tasks in total. Three of these will be computer-based tasks, and two behavioural tests.

For the computer-based tasks, the infant will sit in front of a wide portable screen on their parent's lap and be presented with different visual stimuli side by side towards the edges of the screen; the infant's gaze shifts will be recorded using a webcam attached to the screen and linked to a laptop computer. The three short tests will involve the viewing of stimuli designed to test the infant's habituation rate, attention and social information processing.

The behavioural tests will consist of 2-3 short interactions with the interviewer. In one test, the interviewer assesses the child's gaze-following ability by sequentially turning to objects placed to the left, right and behind the infant, pointing and saying the child's name. In a second, the child is introduced to several new and interesting toys, to observe the child's looking at, and communication with the interviewer, which allows us to assess the child's 'joint attention skills'. The specific tasks used will depend on decisions that are yet to be taken regarding the age of assessment (e.g. 6 versus 9 months), because these tasks must be age-appropriate.

1.2.2 Use of wearable actimetry sensor

The infant would wear an actimetry sensor during the visit, including during the BabySteps parent-child interaction video, which measures blood oxygen levels and heart rate as well as activity. Where practicable, this sensor will be fitted as early as possible during the visit and worn by the infant throughout the visit. It is particularly important that the sensor is worn during the BabySteps parent-child interaction video, and the direct assessments of infant development.

An enhanced neuro-measures protocol is under consideration and development, should additional funding be secured. This would likely involve an extension of the time allowed for neuro-measures for the same sub-sample of cases. (Section 4.1)

1.3 Biosample collection

A sub sample of 500 issued families will be invited to participate in the collection of bio-samples. Biosample collection is to take place during the household visit, including with Own Household Fathers (see additional informants, further below).

In the core protocol we will collect whole saliva samples from the biological parents of the infant, and buccal swabs from infants. It is likely that only additional informants who are biological parents of the cohort child will be eligible for the saliva sample

collection. The time allocation for this is 10 minutes for the primary informant (for them and their child) and 5 minutes for the additional informant.

The primary purpose of this collection is to assess the feasibility of collecting buccal and saliva samples from infants and parents as part of the feasibility study protocol, and to test levels and patterns of consent to provide bio-samples, including among sub-groups. In the main study, the opportunity to fully genotype the cohort and natural parents before subsequent attrition takes place would create a world-unique data resource, bringing strong methodological benefits.

An enhanced bio-measure protocol is under consideration and development, should additional funding be secured. This would likely involve an extension of the time allowed for bio-measures for the same sub-sample of cases. (Section 4.4)

2. Data linkage consents and linkage strategy

Linkage to administrative records will be an important part of the feasibility study. The scientific value of such linkages derives from the rich information they add for both substantive and methodological research. A first draft of the record linkage strategy for the feasibility study can be found here.

Data linkage consents will be included in primary informant and additional informant interviews, with the aim to link to administrative records of these informants and infants.

Consents will be collected to enable linkage to:

- Health records (for mothers, fathers and infants), including: pregnancy and birth, primary care, inpatient admissions, outpatient appointments, A&E attendances, critical care; child records (neonatal records, newborn screening, child measurement, health and development, data congenital anomaly and rare diseases); vital events records including deaths; and prescribing and vaccination data.
- Education records (for mothers and fathers) held by DfE and devolved administrations
- Economic records circumstances held by DWP and HMRC.

Our approach to consent – in particular, whether this will be via explicit, or implicit informed consent, is currently under consideration including through public dialogue research.

We do not aim to collect consent for linkage to sibling administrative data at this stage, but this would be considered for a future stage of the study.

3. Additional informant interviews

We use the term primary informant to refer to the respondent who will be asked to complete a longer interview and thus be the primary provider of information to the study. We use the term additional informant to refer to respondents who will be asked to complete a shorter interview and thus be an additional provider of information to the study.

In most families, the primary informant will be the child's birth mother, and most often there will be only one eligible additional informant and this will be the child's birth father. All own-Household Fathers (OHFs) who live in a different household to the cohort child will be eligible for an additional informant interview. In a small proportion of families, there will be a second person eligible for an additional informant interview, where there is a step-parent figure residing in the same household as the cohort child. We may also consider conducting step-parent additional informant interviews with partners of OHFs, where the infant spends a significant amount of time in the OHF household.

Our design will be sensitive to different family formations, including interviewing both parents in same-sex couple households, foster and adoptive parents (including kinship care by other family-members such as grandparents).

Additional informants will be asked to complete a 30-minute interview.

The additional informant interview will likely be a subset of the questions asked of the primary informant, though additional questions will also be included. At this stage, we welcome comments and suggestions on the following prioritized topics:

- Living arrangements and children
- Occupation
- Education
- Personal income
- Ethnicity
- General Health
- Social support
- Couple relationship satisfaction
- Mental health
- Play and childcare activities
- Work life balance

The interview will also include the collection of record linkage consents, and bio-samples. Placement of Babysteps app with additional informants including OHFs would be subject to further funding.

4. Proposed enhancement bids to be submitted to ESRC

Many of the suggestions made by consultees for novel measurement will not be possible within the core funded time limits and budget. ESRC has given us the opportunity to apply for additional funding for priority measures which support the objectives of the feasibility study, and will be looking for evidence from the consultation that these proposals are supported. A number of areas which we see as being a priority from the point of view of consultees in our first round of consultation, and also promising scientifically from our own appraisal include:

4.1 Developmental neuroscience measures:

The core protocol includes capacity to measure some core developmental competencies using structured tasks recorded on video, including gaze following, turn-taking, joint attention and imitation and habituation, social information processing and sustained/focal attention using looking tasks and observed behaviour in a subgroup of 500 participants. We would propose to include more sophisticated methods from neuroscience within this same subgroup, including using mobile EEG for measuring brain function (e.g., resting state connectivity measures and event-related potentials), and eye tracking to obtain richer and more ecologically valid data on infant learning and information processing. These yield extremely rich and potentially scientifically very valuable information that would serve as a repository for discovery science in the future. Not only are they of immediate potential benefit, but such rich sources of data allow novel uses to be capitalised on in the future, as new techniques become available (e.g., in signal processing or AI-based pattern recognition). They are also comparatively costly, and require careful testing to ensure fieldworkers can deliver them to a suitably high standard.

4.2 Passive wearable devices for capturing the early linguistic environment

The core protocol includes some questionnaire items and interviewer observations to capture facets of the early linguistic environment. We propose placement of LENA devices with a subgroup of families in order to directly record linguistic interactions and automatically segmented speech sounds (both produced by the baby and directed at the baby) to compute a range of informative indices, such as quantity of infant directed speech, turn-taking and contingency metrics. Such measures have proven to be quite predictive of later language development, but few studies thus far have used this methodology in large-scale representative studies.

4.3 Infant-child interactions

In our core protocol, we have proposed to record a brief 5-minute play interaction between the primary carer and the baby. Such direct observations of parent-infant interaction were strongly supported by the consultation, and their scientific value is well-established. We have also included a budget to passively record infant movement and heart rate for a sub-sample of participants for the duration of the visit, and this will

allow us to examine associations between infant heart rate and parent-infant interactions, as well as the above mentioned cognitive developmental tasks. An additional request for funding could enable placement of the BabySteps app and recording of father-infant interactions and of triadic interactions between infant and both parents.

4.4 Biologically-enhanced protocol

Our core protocol includes saliva collection from parents and cheek swabs from the infant for genotyping. There was considerable interest among consultees for a more biologically in-depth study or substudy. Key examples raised in the consultation included a wider array of biological samples (e.g., hair, nails, faecal and urine samples) and biological processes (e.g., microbiome, inflammation). There was also interest in having a boosted twin sample to support behavioural genetic analysis to support and broaden the genomics work (e.g., within-family analyses, controlling for family level stratification). Other somewhat complex biologically or biomedically oriented measures that were suggested included rigorous tests of the baby's vision and body composition.