



Early Life Cohort Feasibility Study

Report on findings from August 2021 second questionnaire and non-questionnaire consultation



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Introduction

This document summarises the results of a consultation exercise that took place in August 2021, on the first draft of the scientific protocol for the Early Life Cohort Feasibility Study. This formed the second stage of a wider academic/ data user consultation exercise. The results from the first stage – a consultative conference held in June 2021 - are described in a separate document [here](#).

At this second stage of the academic/ data user consultation in August 2021, the Early Life Cohort Feasibility Study consulted on different parts of its scientific protocol. We asked for consultation feedback on:

- 1) Questionnaires
 - a. Primary Informant questionnaire first draft
The target length of the interview was 60 minutes including record linkage consents. The proposed child age at interview was yet to be determined but it was suggested that it would be in the range of 6-9 months. Consultees were informed the intended mode of data collection was face-to-face, with both CAPI and CASI components. The draft questionnaire provided to consultees was nearly 10 minutes over length.
 - b. Topic outline for an additional informant questionnaire
- 2) Non-questionnaire measures
 - a. Core measures to which were envisaged to be implemented within the time and funding envelope already available, which included direct assessments of the child and of parent-child interactions, placement of an app, and biosamples.
 - b. Record linkage approach.
 - c. Additional measures (enhancements) which would be proposed to ESRC for additional funding.

We received feedback from 39 consultees on our questionnaire content, and 14 consultees on our non-questionnaire measure proposals. This document outlines a summary of comments received and subsequent changes made to these areas of the scientific protocol since August 2021.

Questionnaires

Approach to primary and additional informant questionnaires

At consultation, we asked for feedback on the draft of the 60-minute primary informant (PI) questionnaire, and the proposed topics for inclusion in the 30-minute additional informant (AI) questionnaire:

- 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

Some consultees had specific suggestions for topics that should be included in the AI questionnaire (parenting beliefs, life events, parent-infant bonding, service use, working arrangements, employment history, level of contact with child/engagement with parenting, substance use, couple relationship, effect of child's crying and sleep on parent wellbeing). In general, consultees commented that they would like the two questionnaires to be inclusive of all family types, not assuming nuclear family sets ups or that the mother is necessarily the individual providing most care.

Absorbing these consultation comments, we revised our approach by categorising our question topics into three levels: household, parent/carer, and child. We also revised our approach by defining three types of interviews: Primary Informant, Own-Household Father, and Additional Informants (partners of PIs or OHFs). The respondent will then be directed to specific parts of the overall questionnaire depending on the interview type category they fall into: Household-level questions would be asked once per household (PI and/or OHF), parent/carer questions would be asked of each parent, and child questions would be asked for each cohort child (if there are multiple births).

This approach is inclusive, since it ensures we collect detailed information on all parents, regardless of which parent does which interview, and that as much similar information as possible is collected across different parental questionnaires. The approach also ensures that the AI or OHF interviews would be suitably engaging for fathers, as they will typically take these questionnaires. Such an approach is also more inclusive to which parent is selected to take the primary informant questionnaire: should the PI be the father then questions specific to the birth mother will be asked in the AI questionnaire and vice versa.

A map of which respondent answers which question is in Table 1: Questionnaires overview July 2022. (N.B. that the module topics are not presented in order of administration)

Table 1: Questionnaires overview July 2022

MODULE TYPE AND INFORMANT	Topics	Estimated Timing (min)	PI	OHF	AI
Household	Family Interview (Household Information)	15	X	X	
	Housing, incl. address history, languages				
	Household income, benefits, debts, wealth				
	Contact information				
	Interviewer Observations				
Parent/Carer: Background	Basic details	6	X	X	X
	Employment				
	Pay				
	Parental leave				
	Education				
	Ethnicity				
	Religion				
Parent/Carer: CASI	Parent-infant bonding	13	X	X	X
	Social support, Life Satisfaction and Loneliness				
	Couple relationship				
	Mental and Physical Health				
	Substance use				
	Life events				
	Disadvantage indicators				
Parent/Carer: Primary Informant	Information on parents who are not full-time residents and/or not partner of PI	8	X		
	Partner information: employment, pay, parental leave, education, ethnicity and general health				
	Childcare and childcare support				
	Service use				
Child: Primary informant	Baby ethnicity	7	X		
	Fertility treatments				
	Birth and delivery				
	Child anthropometrics				
	Child health (including diet, sleep, screen use and crying) and development				
Child	Early care activities	5	X	X	X
	Child temperament				
Parent/Carer: Mother	Pregnancy	1	X	X	X
Parent/Carer: Father	Engagement in childcare	0.5		X	X
Record Linkage	Data linkage consents	5	X	X	X
TOTAL			60	40	30

Topic areas

1) Household grid/information

The household grid/information module at consultation was primarily informed by the structure of the household section of the SEED wave 1 survey. The module included basic demographic information on the informant and child, a relationship grid between members of the household, basic demographics on members of the household, information on the relationship between the informant and their partner (length of relationship, cohabitation), how often the child sees their other parent if they are not present in the household, and whether the child has any other residences. We also planned an address history since pregnancy, though this was not written at the time.

Based on feedback from consultees, we considerably expanded the questions we asked about parents who do not live full time in the child's household (other parent's demographics, whether child stays overnight with that parent, whether that parent stays overnight in PI's household). To aid this, we also adapted the household grid to be inclusive of part-time residents. We also updated all questions about sex and gender in the grid to align with the approach taken in Next Steps Age 32 Sweep: we will be asking about the PI's sex and gender, but only gender for all other members of the household over age 11, and only sex for the cohort child. Lastly, we updated the relationships in our household grid to be more accurate and sensitive to modern day living arrangements (e.g. removing the use 'natural' to refer to biological/birth relationships, and updating step relatives to also include a parent's partner and their family, in case they are not classified as 'step').

One consultee suggested we ask about custody arrangements between separated parents. Due to space constraints, we deprioritised asking about this at the first wave given that we have detailed information about household composition and the nature of the relationship between parents in the current draft.

Other changes that we have made to this topic area independent of consultation comments include:

- 1) Clarifying the exact parental relationship to the cohort member if the PI is not a birth/biological parent (devised by the children of the 2020s survey)
- 2) Not asking any questions about non-resident partners, who are not the child's parent, owing to space constraints
- 3) Dropped length of cohabitation with resident partner and whether ever lived with child's other parent and for how long owing to space constraints
- 4) Dropped questions about child's other residences (besides with other parent) owing to space constraints, and that at age 6 months the child is unlikely to spend considerable amounts of time not living with at least one parent.

2) Background (employment, education, ethnicity)

This module at consultation included questions on PI's housing tenure (as in *MCS wave 7*), parents' economic activity and employment (*combination of questions from Next Steps Age 32 sweep and COSMO wave 1*), employment history since pregnancy (*not written*), working arrangements (*CLS covid surveys*) parental leave of both parents (*combination of questions from MCS wave 7 and the Maternity and Paternity Rights Survey*), parents' education (*BCS70*), parents' and child's ethnicities (*Census 2021*), PI's country of birth (*MCS waves 1 and 6*), languages spoken at home (*Next Steps 32*) and religion (*Census 2021*).

Following feedback from consultees we significantly revised the section on parental leave to better reflect a diversity of leave options for different types of parent, and not only ask about

statutory maternity and paternity leave. We also revised our education questions to be more appropriate for all UK nations, expanded our country of birth question to also ask which UK nation respondent was born in, and ask about what year the respondent first came to the UK to live.

One consultee requested we ask more about work flexibility, shift work and agency work in the questionnaire. We agreed and developed these questions drawing from the Labour Force Survey, but we were unfortunately unable to fit the questions in under questionnaire time constraints. One consultee requested we look at career breaks and we decided this could be incorporated via an employment history module. Again, regrettably this had to be deprioritised during cuts decisions in favour of having a pregnancy and address history instead. Some consultees requested a broader focus on the employment module to capture pandemic-related impact on work. We deprioritised looking at this in the questionnaire given we will be fielding the survey in 2023, and our priority is to test questions for a main stage survey, which will occur even later. Another consultee asked if we could explore intentions to return to work after parental leave, but we could not include this under current space constraints. Finally, one consultee requested a question about whether leave for parenting was taken at the same time for the two parents, but this was deprioritised in favour of including more inclusive questions on parenting leave.

Other modifications made to this section independent of the consultation include:

- 1) Questions dropped on housing type and availability of outdoor space, given this can be added via geo-linkage.
- 2) Updating the employment questions to align with SOC2020 and NS-SEC employment coding requirements.
- 3) Clarifying employment response coding for if a parent is currently on any kind of leave.
- 4) Questions added to account for the dropping of the employment history (to make sure when last job ended is included).
- 5) Dropped questions relating to paid and unpaid overtime because of space constraints, leaving one question on usual hours worked.
- 6) Questions dropped relating to working conditions and flexible working opportunities.
- 7) Dropped questions on amount of paid and unpaid parental leave because of space constraints, instead choosing to expand the parental leave section to ask about a variety of leave types/stopping work around the child's birth.

3) Income, disadvantage, and environment

The consultation version of this module included questions on:

- PI's pay (*MCS waves 7 and 8*)
- Partner's take home pay (*MCS 7*)
- Income sources including from employment and benefits (*MCS wave 8 and Next Steps 32*)
- Household income (*COSMO wave 1*)
- Debts including mortgage amount (*MCS6*)
- How well managing financially (*MCS1-8; COSMO1; NS32*)
- Assets and wealth (*MCS6*)
- Housing conditions (*Next Steps 32*)
- Disadvantage indicators (*Food Standards Agency's Food and You Survey for food poverty; Smith et al. 2013 paediatrics survey for financial insecurity; Osborn index of deprivation*)

- Grandparents' socio-economic status at 14 (*Life Study adaptation of Goldthorpe's class schema*)
- Interviewer observations of the home (*Home Observation for Measurement of the Environment scale (Caldwell & Bradley, 1984), as used in MCS2*) and neighbourhood (*MCS wave 2 and Crime Survey for England and Wales*).

Based on consultation comments that some response lists were out of date in this module, we gained further feedback from colleagues at the Department for Work and Pensions who coordinate the Family Resources Survey to update our list of income sources/benefits to be appropriate for all UK nations (e.g. Universal Credit does not exist in Northern Ireland). The lists of assets was also updated in line with the versions being used in currently fielded CLS surveys.

There was interest from consultees to probe further about financial support from ex-partners for children and financial support from grandparents: subsequently the ELC income module was generally aligned with the income module for the MCS wave 8, which included a question about whether the respondent receives child maintenance payments/financial support from an ex-partner and financial support from family members.

Consultees also raised that the grandparent's SES questions were not inclusive for those who did not live with a father and mother at 14. We therefore adapted the questions using the current formulation in the Labour Force Survey, which only asks about the main earner of the parent's household at age 14, rather than their mother and father. Regrettably under space constraints, this measure has been deprioritised as it can be reliably asked in other waves, as one consultee suggested.

Regarding household observations, two consultees requested more information on how chaotic and calm the household was, one requested a question about whether the TV was on during the interview, and one requested a measure of books in the household. The latter was not added because it did not appear in any versions of home interviewer observation scales, however two items were added to address the amount of chaos/interference with the interview from the DISCORD scale (Descriptive In-Home Survey of Chaos—Observer Reported, (Whitesell et al., 2015, Journal of Family Psychology)).

There were a few consultee suggestions which we did not include in this module. This included pandemic-related impact on finances and debt as we have deprioritised COVID-19 questions throughout the questionnaire; the impact of National Insurance increase on finances as this would need to be modelled rather than asked directly; information on amount of rent paid which would not be useful in the absence of space to ask about housing costs in full (e.g. to generate a measure of after housing costs income) ; more questions relating to neighbourhood as these can be gained through geo-linkage; and more questions on deprivation which were not possible under space constraints.

Separately from the consultation suggestions, the following changes were made to this topic area:

- 1) The pay and income questions were aligned with the module being used in wave 8 of MCS
- 2) We will not be asking as detailed questions on benefits as in MCS wave 8, however we will be probing further on family related benefits specifically as this will be of importance to our sample
- 3) Questions were added on the baby box/bundle schemes in Wales and Scotland so that there is policy relevant information for these countries

- 4) All interviewer reported neighbourhood observations were dropped as this information will be gained via geo-linkage
- 5) The deprivation questions were streamlined down to three items based on children of the 2020s pilot data (problems in the home (from COSMO1), cutting/skipping meals (from Food Standards Agency 'Food and You' Surveys) and inability to afford essential baby items (from Smith et al. 2013 paediatrics).

4) Pregnancy, birth and child anthropometrics

At consultation, this module included questions about any fertility treatments used by the parents (*based on MCS1 questions*), type of delivery and when the birth occurred (*Life Study and GUS wave 1*), and questions relating to the baby's length, weight and head circumference currently and at birth (*MCS1*).

Following feedback from consultation, the module was adapted so that questions about the child's conception and birth could answered by any PI, regardless of whether they were the child's birth mother. We also adapted the focus on fertility treatments to be specifically about trying for the cohort child, rather than any treatments used historically.

We received interest from several respondents on extending the questions asked around the pregnancy/birth of the cohort member: intentionality of the pregnancy, time to conception, contraceptive use, miscarriages, the birth order of the child and any obstetric complications. In response to this, we have included a new 'pregnancy history' set of questions for the primary informant, where they will report on their number of live births (to help establish birth order) as well as more information about the birth mother's health during pregnancy and after delivery. Questions on time to conception were developed based on questions from MCS1 and Next Steps 32, but these had to be deprioritised under space constraints.

Some consultee requests that could not be accommodated under space constraints included the exact time of delivery and whether the parents were pre-term or low birthweight themselves. We also did not prioritise asking whether a birth partner was allowed to accompany the birth mother due to COVID-19 rules, as this will not be relevant at time of fielding the survey.

Other modifications to this section include:

- 1) Dropping questions about the type of delivery because of space constraints, allowing time for questions on fertility treatments.
- 2) Dropping all questions about baby anthropometrics apart from baby's birthweight. This was informed by children of the 2020's pilot data where there was a very high number of don't know responses to these questions.

5) Child temperament

The child temperament scale included in the consultation document was the Carey Revised Infant Temperament Questionnaire, which was used in the first wave of the Millennium Cohort Study.

One consultee suggested that we update the measure to the Infant Behaviour Questionnaire (IBQ), which is considered a less outdated measure than the Carey. The shortest version of the IBQ contains 37 items, which was too long under questionnaire space constraints. Study co-principal investigator Prof. Pasco Fearon and the children of the 2020s study team therefore conducted a factor analysis of the IBQ measure to shorten the number of items down

to 14, making the scale usable under space constraints, and this will be used instead of the Carey.

6) Early care, home learning and service use

The version of this module at consultation contained a measure about how often the parent did certain activities with their child (*ALSPAC*), a set of questions about division of household and childcare tasks between the PI and their partner (from *GUS wave 1*), questions about parenting beliefs (*MCS wave 1*), childcare providers (adapted from *SEED wave 1*), grandparental support with childcare (from *GUS wave 1 and MCS wave 1*) and service use including health, community and internet based services (*devised by the Children of the 2020s survey, through consultation with the Department of Education and inspired by the EU Client Services Receipt Inventory*).

We addressed consultee concerns that the childcare questions were unclear when it came to the child's other parent: we included instruction that care provided by the other parent was not 'childcare', and engagement with parenting by the non-primary caregiver will be asked about separately in the additional informant interview. Consultees also raised that the grandparental care questions did not specify which grandparents were taking care of the child. We decided that this should be left open to accommodate different familial circumstances, but added a probe whether care is provided by the respondent's own parents, or other grandparents. Four consultees also requested these 'type of support received from grandparents' questions be extended to care from other relatives and alloparents, but there is not enough space to do this for all potential carers. One consultee also requested more information on child activities, which has been partially addressed through a more comprehensive list of which child-related community services the family uses.

One consultee asked whether a measure of 'technoference', when parents are distracted from care by their technology, could be included. We explored some questions written by experts on this topic but were not satisfied at their validity for inclusion. Three consultees requested more extensive questions on parenting beliefs and aspirations, however this could not be prioritised due to space constraints and can be asked at a later stage. One consultee requested questions on child discipline which we did not include because the child is too young at 6 months to intentionally misbehave, and the parenting stress index captures some element of how parents react to challenging parenting situations. One consultee also asked for a question about whether childcare providers wore facemasks as this may affect children's speech and social development. We consulted with experts in this area who confirmed that mask wearing has been rare in council provided childcare and other settings since the start of the pandemic, so we did not prioritise a question on this. We also did not include questions on how childcare services were disrupted by COVID-19, as requested by two consultees, given that we have deprioritised covid questions throughout the questionnaire.

Other changes we have made to this topic area include:

- 1) Cutting division of labour questions as we decided extent of engagement with parenting/child activities (reported separately by the PI and AI) was of greater interest under space constraints than perceptions of division of labour between the parents. This was based on a greater number of publications on this topic from *MCS wave 1* which included both engagement and division questions.
- 2) Updating the list of childcare providers to be more age appropriate for 6-month-olds
- 3) Adding a question to distinguish which relatives provide care for the child
- 4) Questions dropped relating to use of family centres/hubs and use of internet services, based on limited information gained on these topics in the children of the 2020s pilot

and differing priorities in ELC compared to children of the 2020s which is Department for Education funded.

- 5) Service use questions were revised in line with amendments made by the children of the 2020s team after holding a service use workshop with experts and the Department for Education. The questions were refined to focus on 1) health care providers relevant to the mother and baby and 2) community-based services for the mother and baby.

7) Parent-infant bonding

The bonding scale in the consultation questionnaire draft was 12 items used in the ALSPAC Pregnancy, Birth and Infancy sweep.

Two consultees suggested in the early care module to have more on parental over-reactivity to the stresses of parenting. One consultee also raised that we should consider the Maternal Postnatal Attachment Scale and the Parenting Stress Subscale, the latter having been used by Growing up in Ireland for both mothers and fathers.

Through our own research, it appeared that the ALSPAC bonding measure had not been used widely in existing literature, but the MCS wave 1 bonding questions had. Further, it appeared there is no one highly respected or validated scale of parental bonding according to existing systematic reviews and meta-analyses. As a result, we changed the parental bonding measures: we dropped the ALSPAC measure, and instead used the scale devised for the Millennium Cohort Survey wave 1, so that comparisons could be made between the cohorts by researchers. Second, we included the Parenting Stress Subscale as used in Growing up in Ireland. The validation of the measure for both mothers and fathers met a study aim that questionnaire content should engage, and be relevant to, fathers. The index also incorporates a measure of parental over-reactivity which meets the request of consultees.

8) Parental Health

Parental health questions in the consultation draft included:

- General self-rated health, longstanding illness and experiencing pain (*SEED wave 1, MCS wave 1, GUS wave 1, NESS*)
- Treatment for anxiety and depression (*SEED wave 1, MCS wave 1, GUS wave 1, NESS*)
- Height and weight (*MCS1*)
- Covid, long covid, covid vaccination, whether furloughed because of covid (*CLS covid surveys*)
- Problems accessing health care services (*CLS covid surveys*)

Consultees raised that the measure of longstanding illness was no longer the standardised GSS/ONS measure. We changed the question to the standardised version and included the standardised follow-up item on how much impact their illness had on day-to-day activities. We therefore dropped the question about pain interfering with daily life as this was not part of the standardised set.

One consultee requested that familial health be asked about, which we were not able to address under space constraints. One consultee also requested that partner's treatment for anxiety and depression be asked about, which we did not include as it will be asked in the AI interview and is sensitive.

The following changes were also made independent of the consultation comments:

- 1) Parental height and weight questions were cut as this can be collected at later waves

- 2) All COVID-19 related questions were cut given that under space constraints we need to prioritise testing questions for the main stage survey
- 3) Problems accessing services has also been cut under current space constraints, instead prioritising the question on which health care providers and community services have been used (see early care).

9) Life events, discrimination and abuse

The Life Events module seen at consultation was taken from the ALSPAC list of events and threatening experiences (Brugha et al., 1985) and the CLS COVID-19 surveys. We had adapted the response options to ask whether the event had occurred since pregnancy, since birth, both, or never, in order to better pinpoint the potential effect of the life event on the cohort child. We also included two items on discrimination from the CLS COVID-19 surveys (racial and other types), and three questions relating to violence from a partner.

We incorporated several consultee comments into revisions of the life events question text: we combined the partnership dissolution questions into one to save space (not distinguishing whether it was a legal divorce), we revised the question text about 'problems with the police' to 'trouble with' to clarify this did not include instances where they were the victim/a witness, and we included homelessness into the item about housing difficulties. Two consultees also suggested we adapt the response options for the discrimination questions to continue asking whether this happened during and/or after pregnancy, which we included.

Three consultees raised concerns about how the intimate partner violence questions would be asked (i.e. to those with a current partner? An ex-partner?) and as a result we modified the questions to the formulation in BCS70 which encompasses violence from any partner. Two consultees also requested questions that captured emotional coercion as well as violence, which the BCS70 questions include. Due to space constraints, and the highly sensitive nature of these questions for a first wave survey, all these questions on intimate partner violence and emotional coercion were ultimately cut.

Consultee suggestions we did not incorporate included distinguishing whether the respondent was a perpetrator of crime as it is sensitive and very complicated to report on, and probing about what kind of discrimination they received. We decided to leave the question open to any kind of abuse, especially given the intimate partner violence questions have been cut.

10) Social Support

The social support scales in the consultation draft included the 6-item Brief form of the Perceived Social Support Questionnaire (*F-SozU K-6*), and the 4-item Social Provisions Scale (as used in the *CLS COVID-19 surveys*).

One consultee requested that more questions about social support during the pandemic be included, but these were not developed as lockdown restrictions will be too long ago when the survey is fielded. Another consultee requested to focus specifically on support in the first few months of life, which we did not add given the life events module focuses on stressors in the early months of life, and that the questionnaire will be fielded at age 6 months which is earlier than the originally planned 9-months. Some consultees commented they would like more support questions specifically about the PI's partner, but we did not develop these further as the couple relationship questions address this. Lastly one consultee requested a question be included on objective social isolation (household size/composition, network size, frequency of contact with network), which is conceptually distinct from perceived social support and loneliness (asked about in the mental health section). We explored the possibility of including a question on frequency of contact with friends and family (not parents which is already asked

in the questionnaire) from BCS70, however there was not space under current timing constraints.

In addition to these consultation considerations, we also dropped the Social Provisions Scale because of tight trade off considerations, and that there would still be one scale on perceived social support (the Brief form of the Perceived Social Support Questionnaire).

11) Couple Relationship

The scales included in the consultation draft were the 4-item Couple Satisfaction Index (CSI-4) and the 7-item Golombok-Rust Inventory of Marital State (GRIMS), which has been used in MCS and the Life Study.

One consultee requested a co-parenting measure be added to the module, as challenges in cooperation can have an impact on child upbringing and the parental relationship. As a result, we included a co-parenting disagreement question from GUS wave 1, which we adapted to be asked both in relation to the child's other parent and the PI's partner, should those be different people.

Four consultees raised concerns about whether this module would only be asked for resident partners. In theory, the questions could be asked for resident, part-time resident and non-resident partners. However, under space constraints, identifying a non-resident partner who is not the child's parent was deprioritised in the household grid, so the module will only be asked in relation to either a resident/part-time resident partner or a non-resident parent partner.

One consultee requested the Quality of Marriage Index should be included because the questions relate to cooperation and support from partners who are the child's other parent. We did not include the scale as some of the questions did not read well for non-resident parent partners, and the scale is currently used predominantly for cohabiting and married couples in the existing literature. We prioritised other relationship quality measures, and co-parenting items instead.

Two consultees requested more items on relationship conflict such as the Understanding Society parental conflict indicators, or the Conflict Tactics Scale short form. We explored the possibility of including more questions on parental conflict, such as frequency of arguments, but these were deprioritised given the sensitivity of the questions and that conflict is encompassed in the existing scales.

One consultee requested a question for reason for relationship breakdown with the child's other parent, if they had been in a relationship but were now no longer together. We included a question on this from Next Steps 32, but it had to be cut under timing constraints.

Separately to consultation feedback, we also removed the GRIMS scale under timing constraints. This decision was informed by a very high correlation in MCS wave 1 data between the 'happiness' measure from CSI-4 and both individual and summed GRIMS items, and that the happiness items and GRIMS items all loaded strongly onto one factor in a factor analysis, with the happiness item bring the most additional information of all the items. The happiness measure was also predictive of both parent-child bonding and mental health measures in MCS wave 1, with GRIMS items not moderating these findings indicating again that it brings little additional information.

12) Parental Mental Health and Loneliness

The mental health scales included in the consultation draft were the short form 2-item PHQ and 2-item GAD (*PHQ-4*) and the Kessler-6 inventory. There were also two questions on self-

harm (*MCS wave 7 and COSMO wave 1*) and four ONS advised questions on loneliness (*taken from ELSA (UCLA Loneliness Scale) and Community Life Survey*).

Consultees responded positively to the inclusion of these mental health scales, though one thought that only one scale was needed. One consultee asked for more items on postnatal depression such as the Edinburgh post-natal depression score. We consulted with other experts, and decided not to include this item as it will be highly correlated to the PHQ/GAD at 6 months old. Furthermore, the questions asking about when health professionals were consulted and treatment taken for anxiety and depression (see parental health) will be indicative of postnatal depression.

Another consultee requested an item on parental stress and coping, such as the coping health inventory for parents. Subsequently the parenting stress index has been added to the questionnaire (see bonding), but coping was not included as there will be a high degree of overlap with other measures in the questionnaire such as the stress index, support questions and couple relationship.

Aside from these consultation considerations, we cut the questions relating to self-harm as they are sensitive for a first wave questionnaire. We also condensed the 4 loneliness questions down to the single loneliness item recommended by the ONS to save on space. We then added one question on perceived life satisfaction and a question about how trusting the respondent is to align ELC with the other CLS cohort surveys, but only kept the former (life satisfaction) under tight timing constraints.

13) Alcohol, Smoking and Substance Use

The draft consultation questions on substance use included:

- Current drinking frequency and average units (GUS wave 1)
- Current heavy drinking frequency (GUS wave 1)
- Drinking frequency during pregnancy (GUS wave1)
- Smoking at all during pregnancy (GUS wave 1)
- Current smoking amount (GUS wave 1)
- Smoking around baby (Life Study)
- Electronic cigarette use in pregnancy (devised)
- Use of smokeless tobacco and shisha (Life Study)
- Use of illicit drugs ever, in last 12 months, use with dependency in last 12 months, consulting a professional about use (GUS wave 1)

One consultee suggested revising the module so that drinking/smoking in pregnancy was asked first before current use, and also whether better detail could be asked about how smoking/drinking behaviour changed during pregnancy (changing amount, when the change occurred and whether alternative products used). We significantly revised this module after consultation to better encapsulate smoking/drinking during pregnancy. We first ask about usual drinking/smoking prior to pregnancy, then amount drank/smoke in each trimester if they did it at all, followed by current drinking/smoking. We then expanded the e-cigarette questions with the help of experts, building off questions from the US PATH study, about current e-cigarette use and use in pregnancy.

One consultee queried how these questions would be answered if the PI was not the birth mother, this has been addressed by having these questions included in both the PI and AI interviews. Another consultee suggested we use AUDIT questions about substance use, which we did not follow in order to harmonise with MCS wave 1 for comparison. Another

consultee asked if we could ask a question about problematic drinking, but we were not able to include under space constraints.

Other changes made to this section independent of the consultation included cutting questions relating to smokeless tobacco/shisha given a low population prevalence, and reducing the illicit substance use questions to only one question on use ever. This was because these questions are highly sensitive for a first wave study.

14) Child health and development

The child health and development topic areas at consultation included questions on:

- Child's general health (*GUS wave 1, Life Study*)
- Visits to A&E (*SEED wave 1, Life Study*)
- Chronic health problems (*SEED wave 1*)
- Hospitalisations (*SEED wave 1*)
- Developmental concerns (*SEED wave 1*)
- Child's diet – breastfeeding, other milk and solids (*MCS wave 1*)
- Child's sleep (*MCS wave 1*, the Sleep Habits Questionnaire Revised (Seifer et al., 1996) and the Brief Infant Sleep Questionnaire)
- How parent's sleep is affected (*MCS wave 1*)
- Child screen use (*SEED wave 1*)
- Child's crying (*Born in Bradford wave 1 and MCS wave 1*)
- Developmental Milestones (*Growing up in Scotland wave 1*)
- CDI words and gestures form

Two consultees requested whether the child's vaccinations and parent vaccine hesitancy could be asked, given that these will not be reliably available through record linkage. We therefore included a single question from the Life Study about whether the child's immunisations were up to date, as we did not have space for the more extensive set of questions used in MCS wave 1. We also improved our question about visits to A&E after a consultee raised that the wording from SEED only related to accidents/injuries rather than any potential reason, and we updated the example of a 'solid food' in the feeding questions to a more current example than that used in MCS wave 1.

Consultees had some additional suggestions for this topic area which we did not include because the child was too young at 6 months. These included a measure of child attachment and the child's social development.

A question on exclusive breastfeeding was requested by two consultees but we did not include this as it can be inferred from when different milks/foods introduced. A consultee also requested a question on intention to breastfeed and if they stopped, why they stopped. We considered asking a question about main reason the respondent stopped breastfeeding but were not able to include this under space constraints.

Two consultees asked for more information about crying: whether there was a colic diagnosis and how easy the child was to console. We did not prioritise the former as colic can be implied from the existing questions about crying, and consoling is addressed to an extent in the child temperament questions.

One consultee also asked if we could differentiate between weekday and term time sleep to understand level of disturbance better, but we did not have space for this additional detail.

On child development, one consultee requested we ask about the age at which a skill was first acquired, which we did not include this because of difficulties with retrospective reporting.

Another consultee asked whether we would consider using the ages and stages questionnaire. We cross-checked the developmental items included in our draft with the ASQ for 6 months and the CREDI 6 months measures, and concluded they were appropriate for the age group and overlapped with these scales. We therefore did not use either ASQ or CREDI as they were much longer than the set of developmental milestones in GUS wave 1. One consultee also asked if a question could be included on parental understanding of child development to aid policy programmes, but there was insufficient space to explore this. Finally, one consultee requested a question asking whether the child was born with a medical condition/disability, which we deprioritised in favour of knowing about any conditions the child had.

Other modifications made to questions in this topic area included:

- 1) Dropping all communication and language questions, as the child will be too young at 6 months
- 2) A question about child's sleep location was dropped in favour of more questions about the child's sleeping behaviour
- 3) Dropping the questions about developmental concerns, given objective developmental milestones questions will also be asked

Non-questionnaire measures and enhancements

At consultation, we consulted on including the following measures alongside the questionnaires:

1) **BabySteps app placement and recording of parent-infant interaction**

Babysteps is a smartphone app designed by the University of Iowa to study early child development. We originally proposed to use this app within the feasibility study to measure developmental trajectories and family process at a much higher temporal resolution than through standard questionnaires. The app would be placed during the primary informant in-home visit, and a video recorded of the parent playing with the cohort child for around 2 minutes. The PI would then 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.

Consultees were overall very supportive of this idea and the possibility of gathering rich observational data. Additional suggestions included a video recording of how the parent carries their child, as an often-missed element of parent-child interaction, and including video interactions between the child, their mother and their father. The latter has been included in the enhancements proposal (see infant-parent interaction videos). Consultees with concerns raised that the app may be disengaging for parents who are less confident about their parenting, and that there may be accessibility issues as the app relies on smartphone ownership and data to operate it. Consultees also raised that reminders and incentives would be key to encourage use of the app.

2) **Direct assessment of infant critical developmental functions**

On an issued sub-sample of 500 families, we proposed to undertake direct assessment of infant critical developmental functions such as habituation/learning, gaze following, turn-taking and imitation, via videorecording to record looking behaviour. The exercise would comprise five short tasks in total. Three of these would be computer-based tasks (testing the infant's habituation rate, attention and social information processing), and two behavioural tests (to test gaze tracking and 'joint attention skills').

Consultees commented this was an exciting innovation, and that it was essential to include these objective assessments to complement the subjective parent-made assessments in the questionnaire.

3) **Wearable actimetry sensor**

In the same issued sub-sample, the infant would wear an actimetry sensor during the visit, which measures blood oxygen levels and heart rate as well as activity. The sensor would be worn during the BabySteps parent-child interaction video, and the direct assessments of infant development.

One consultee commented they will be interested to see the acceptability among parents of use of these devices on young children.

4) **Saliva samples from parents and buccal swabs from infants**

On a separate issued sub-sample of 500 families, we proposed bio-samples will be collected from the infant (buccal swab) and their biological parents (saliva sample), including own-household fathers. The aim 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 general, consultees were positive about this proposed data collection, with three commenting that they would prefer a larger sample size in order to ensure suitable ethnic diversity in the sample and so that the data could be used in a GWAS meta-analyses. Two consultees raised the need for very clear engagement materials about the purpose and confidentiality of this data collection, and one consultee raised that their may be ethical implications about only collecting samples from biological parents.

In addition to these core measures, we also consulted on four proposed novel measures to be included in an enhancements additional funding proposal to the ESRC. These were:

5) Developmental neuroscience measures – EEG

In the subsample involved in the assessments of infant core developmental competencies, we proposed 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.

Consultees were positive about the inclusion of this measure, though one raised concern about how intrusive the EEG device would be for infants.

6) LENA devices to capture linguistic environment

We proposed the 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.

Consultees thought this data collection would be useful and excellent for collecting rich in-home data.

7) Infant-parent interaction videos

In addition to the video interaction recorded between the PI and their child on BabySteps, we suggested testing viability of recording interaction between the child and both their parents, individually and together.

There was strong support for this among consultees, with comments that it would be very novel and enable rich information capture. There was one concern that the use of a smartphone app could exclude some study members.

8) Biologically enhanced protocol

In addition to the saliva samples, we proposed collecting some additional bio-

samples such as hair, nails, faeces and urine. Measurement of the infant's body composition and vision were also suggested.

Formal assessment of infant visual function was strongly supported by one consultee, and there was some support for additional bio-sample collection. Consultees did raise concerns that the faecal/urine samples may be difficult to collect and overly invasive. Hair and nail samples were felt to be useful, but may also be difficult to collect as a relatively large sample of infant hair would need to be collected. One additional suggestion was to collect finger-prick blood samples from parents for biomarker generation.

On the basis of these consultation contributions, we submitted an application to ESRC to enable ELC to undertake a set of small-scale field testing of a range of measures. These will test the potential for trained fieldwork agency staff to collect specialised objective measurements across a range of domains, including:

- Neuroscience (including a looking-time task, eye-tracking, and mobile EEG, together with the use of an actimetry device)
- Measurements of the early language environment (through placement in the home of the LENA device)
- Biosampling (testing the feasibility of collecting and assaying hair samples from babies)
- Anthropometry (including weight, length, head circumference and adiposity).

In order to include these field tests within the overall ELC-FS budget envelope, a decision has been taken not to include Baby Steps app in the protocol for the ELC-FS because it is being tested in the Children of the 2020s study, and also to include the direct assessment of infant critical developmental functions, and actimetry device as part of the small scale field tests, rather than issuing it to 500 subsample of feasibility study participants as we had originally envisioned.

Record linkages

At consultation, the following record linkage consents were proposed:

1. 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.
2. Education records (for mothers and fathers) held by DfE and devolved administrations
3. Economic records circumstances held by DWP and HMRC

Two consultees suggested social service/social care record linkage should be gained, one suggested pre-school health assessment data, early year records from nurseries.

Our current record linkage strategy is still being developed and further information about how these suggestions were taken into account will be provided in due course.