OPTIONS FOR THE DESIGN OF THE 2012 BIRTH COHORT STUDY

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Authorship

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CONTENTS

EXECUTIVE SUMMARY

1. As part of the £28.5M investment in the UK birth cohort studies, ESRC in collaboration with MRC wishes to establish a new birth cohort study in 2012. The design of the study will be developed from recommendations in the Longview report to ESRC, 'Scientific Case for a New Cohort Study' (SCNCS) and based on a much larger sample than that of previous studies - 50,000. The funding available for the study over 5 years is between £21M and £23M. ESRC commissioned Longview to consider the advantages and disadvantages of different design options for the new study, to consider the role of the new study in the cohort studies series as a whole and as a major international comparative resource and to set out broad costings for the different design options. The work was carried out by the original team (with one change) that conducted the SCNCS scoping study. Consultations were undertaken with UK and overseas experts on technical matters concerning the survey and to canvas their views on the SCNCS proposals.

2. The report first reviews the scientific case for the new cohort study and the recommendations concerning its design and coverage and establishes principles that should inform the new design. The major sample design options are then considered followed by data collection requirements over the first 5 years of the cohort's life, Continuity and comparability issues are then considered and finally costs and options. .

Sample design

3. Two major design options are examined: a large national probability sample (n= 50,000 achieved cases) of pregnancies registered over a specified period, as opposed to a smaller national probability sample (n = 20,000 achieved cases), accompanied by a number of area studies each based on all pregnancies registered in the area over a specified period (n=5,000 achieved cases). The latter design meets the scientific requirement of large scale representative population sampling for continuity in the birth cohort study series and the need for highly clustered data for specialised investigations and studies encompassing ecological depth.

4. Management of the programme would be in the form of a "hub" and "nodes" model, comprising a central team responsible for the national probability sample (NPS) survey and the programme as a whole led by a Principal investigator (P) for the whole programme and area teams, each with a PI responsible for the local study. 80% of the data collected would be common to the NPS survey and the area surveys. The other 20% specified by the area teams would reflect their specialised area of scientific interest. The core data would be specified jointly between the core and the area teams, with ultimate responsibility lying with the national PI.

5. The national team would have a budget for commissioning a national agency to conduct the NPS survey, The local teams would have their own budgets to meet staff costs and the cost of the local area survey conducted by the same agency. Local interviewers would be recruited with the help of the local area study team. A database for the NPS and area study surveys would be managed centrally and shared with the area teams. Capacity building would be supported through the assignment of PhD students to the teams. Other specialised data would be collected in accordance with proposals for which support would be sought outside the core budget. A major effort would be made to promote the programme across the widest range of scientific disciplines to raise interest in running the area studies.

Data collection

6. The team is convinced of the strong case, following the ALSPAC model, of recruiting the sample including fathers during the mother's pregnancy rather than at the baby's birth. This is because of the growing scientific interest in the shaping influences on development from the earliest stages of life. Up to 4 data collections: pre natal, birth (largely through medical records), 4-6 months, 2-3 years. Surveys would be conducted through home visits by specially trained interviewers. At birth, data collection would include collection of a sample of cord blood. A sample of the mother's blood would be taken and stored at the ante natal visit. The types of data collected in each survey are specified under the headings of socio-economic and cultural environment, psycho social environment, cognitive development, health and behaviour, biomarkers health, child development, biomarkers and environmental toxicity.

Continuity and comparability

7. The new study meets the requirement of continuity with the birth cohort studies while meeting new scientific demands. Evidence collected from comparable overseas studies starting in much the same period as the new British study point to considerable potential for the study's use as an international resource for comparative research.

Costs

8. Cost components comprise: NPS core team, area teams, NPS survey data collection, biomedical measurement (maternal and cord blood), area study data collection. A number of options are costed based on different sample sizes, different combinations of NPS and area studies and different numbers of surveys. It is concluded that the option producing the best scientific returns will comprise an NPS survey of 20,000 achieved cases in combination with 3 area studies based on 5,000 achieved cases at a cost of £26M. This exceeds the budget by £3M and would require supplementation. Two areas studies would just stay within budget at £23M but at much scientific cost. To stay within budget under either of these options would also mean transferring the

2-3 years infancy survey into the next phase of funding, i.e. restricting the programme budget to support for data collection pre-natally, at birth and post-natally at 4-6 months. Subject to success in gaining supplementary funding at both national and local level, additional area studies could be included, specialised research projects funded and the infancy survey restored.

9. £1M from the main budget should be available for teams to bid for their specialised area study work. £2M should be protected for the piloting work essential to the study.

10. All data should be made easily accessible to the research community in the shortest possible time frame. Once the data collected in each survey has been reported, the data edited and derived variables constructed the new resource should be promoted as available for general research use.

1. INTRODUCTION

(a) Background

1.1. Funding has now been approved at £28.5M for a major investment in the UK birth cohort studies as longitudinal research resources. This will be used by the ESRC and MRC to support jointly a new infrastructure to improve accessibility of data and encourage cross cohort analysis and harmonisation of survey design. The expanded research resource will include a new birth cohort study scheduled for 2012, the design for which will be developed from recommendations in the Longview report of the scoping study conducted for ESRC, *Scientific Case for a New Cohort Study (SCNCS)*.

1.2 The new birth cohort is intended to be much larger than in previous studies, embracing up to 50,000 individuals and operating within a budget over the first 5 years of between £21M - £23M. The possibility of co-funding will expand this budget further, especially to expand the range of early bio-medical measurement ('biomarkers'), which is a prominent feature of the SCNCS recommendations and strongly endorsed by the Funding Councils.

1.3 The Birth Cohorts Facility (BCF) Development Group has been established – first meeting 19th January 2009 - to draw up a specification for the new cohort study as the basis for commissioning a PI and research team to design and implement the new study, with the team in place by Autumn 2009. As a starting point for the work of the Development Group ESRC has commissioned Longview (through the University of Warwick) to re-visit the original recommendations of the SCNCS report[1] .The report is to be directed at:

1. Presenting an analysis of the main advantages and disadvantages of the selected options for the various types of research (social, economic, behavioural and medical) associated with the new birth cohort.

2. Considering the long-run comparability of each design for a new birth cohort with existing birth cohorts (notably the 1946 (NSHD), 1958 (NCDS), 1970 (BCS70) 1992 Avon Longitudinal Study of Parents and Children (ALSPAC) and the 2000 Millennium Cohort (MCS).

3. Taking into account the extent to which each design option will provide scope for the future development of a major international comparative resource, based upon similar studies in the US, France and Germany. This will involve consultations with individuals and/or

[1] http://www.longviewuk.com/pages/documents/FINALREPORTSCNCS16.10.07.doc and Appendices

research teams in the US (National Children's Study), ELFE in France and the new German study, National Educational Panel Study (NEPS).

4. Providing broad costings for the various options drawing on recent cost estimates associated with similar studies elsewhere in the UK.

1.4 Accordingly, the team that carried out the SCNCS scoping study was reconvened to carry out the new work[2]. In the limited time available (under two months, including the Christmas period) the collection of evidence was restricted. Three team meetings were held to agree strategy, schedule the work and review drafts. Cohort study experts were consulted for technical advice and reactions to what we were proposing. Meetings were held with Heather Joshi and colleagues at the Centre for Longitudinal Studies, Institute of Education, and with George Davey Smith and colleagues from the ALSPAC Team in the University of Bristol. Individual contacts were also made with Jean Golding, University of Bristol, Carol Dezateux, Institute of Child Health, members of the NSHD team at University College, Nick Buck and Heather Laurie of the "Understanding Society" team, University of Essex, Jay Belsky, Birkbeck College, Tom O'Connor, University of Rochester, Alison MacFarlane, City University.

1.5 The team was also requested to investigate specifically the comparative potential of the new study in relation to three parallel overseas studies: the US National Children's Study begun in 'vanguard' form in 2007, the new French birth cohort study (ELFE) due to begin field work in 2010 and the National Education Panel Study (NEPS) in Germany, which includes a birth cohort study due to begin in 2012. Team member, Bob Michael, had extensive knowledge of NCS, through involvement at the design stage and wrote papers for the project on its history and progress. He also supplied information about the US 'Fragile Families' Study based in 22 US cities, which has parallels with our design option 2. Highly productive meetings were also held with Henri Leridon and colleagues, (ELFE), and Peter Blossfeld and colleagues (NEPS).

The report

1.6 The purpose of the report is to inform the decisions of the Development Group on the specification for commissioning the 2012 Birth Cohort Study and its scientific leadership. As a first step towards meeting this requirement, this paper supplies first a resume of the SCNC report's main recommendations, then sets out the options under two main headings Research Design, Biomarker and Developmental Measurement and briefly considers the potential role of the study as an International Research Resource. Costing of competing designs and of the options within a preferred design, follow.

[2] Carli Lessof of NatCen replaced Susan Purdon of NatCen

(b) Scientific case

1.7 The case for extending the series of previous studies starting in 1946 through investment in a new one to start in 2012 resides in the major challenges that are likely to face Britain and the world more generally in the coming era. These include:

- child development in rapidly changing contexts, including the physical and social environment
- changing demography, including the ageing population
- globalisation, including global forces associated with the transformation of economies, brought about by technological change
- migration, including increasing population heterogeneity and the growth of large minority populations in some host countries, such as Britain
- rising inequalities and risks of social exclusion associated with gender, ethnicity, age and disability

1.8 The scientific programme that follows embraces the range of factors that impact on a child's development from conception onwards on outcomes in the different life domains, including most prominently:

- cognitive development and education
- physical health and development
- emotional and behavioural well-being

1.9 The over-arching theoretical framework to inform the programme is broadly described as the *life course perspective*, which conceptualises development in terms of pathways comprising transitions in the different (interacting) domains of life at different levels (family, community and society) and at different stages (infancy, childhood, adolescence, adulthood, old age) and the effects changing societies and different cultures have on these. Also, of central importance to understanding these life course processes are their biological foundations including the interplay between genetic endowment and the physical and social environment. Notably, in some respects the overall scientific purpose to which the new study will be directed is broader than that of new cohort studies that are being established in other countries e.g. Perinatal Epidemiology (Nordic countries); Child Health and Physical Environment (US National Children's Study/ELFE); Education and Competence (Germany) – though all share some common measurement.

1.10 Important extensions to the British programme include:

- cross-cohort comparisons to establish the effects of secular change on life course processes for cohorts born at different times, in which measurement continuity from previous studies is at a premium
- intergenerational studies, involving data collection from cohort members' children to assess the transfer of economic, human, social, cultural, psychological and biological resources across the generations
- cross-national studies to assess the effects of systemic and cultural differences on life course processes. Cross-national comparability of data also offers the opportunity of data pooling, which is of particular importance in the large datasets needed for the investigation of gene-environment interaction.

1.11 The programme will also be greatly enhanced by methodological development. By 2012 advances in the collection and storage of biomedical samples and in laboratory processing, which have been made in recent years, are likely to be extended further. Expanded facilities for clinic-based, as well as home-based, assessment will also open up for the new study the opportunity to use the most advanced and sophisticated measurement, together with new techniques for data collection. 'Adaptive interviewing', which takes the traditional structured interview to new levels of conversational analysis, will be supported further by web based technology and the use of such resources as digital video recorders, enhancing opportunities for more efficient collection of a wider range of data than has been possible in the past. Linkage to administrative records will also be much easier and faster than has been possible previously, reducing respondent burden and with the quality of such data for research purposes also likely to be much improved. Expansion of digitalised storage and retrieval will further improve data accessibility and enhance research use

1.12 The value of such technical advances with the prospect of enhanced data quality needs however to be set against some of the growing challenges confronted by survey research such as concerns about data protection and declining response rates. This makes the case for developing strategies to build confidence and enthusiasm for participating in the study, while minimising respondent burden particularly for the traditionally more difficult individuals to recruit such as fathers. Comprehensive development work and piloting has a major role to play in developing optimum means of maximising response in any given survey and minimising attrition from the study as a whole and needs to be a core part of the programme. The *Understanding Society* 'Innovation Panel' supplies a valuable model in this respect. Strong infrastructure for ensuring continuities of policy and practice with respect to cohort member liaison and support is another important feature of an effective longitudinal study and needs to be in place for the new cohort study.

(c) Context in terms of the earlier studies

1.13. The principle of maintaining continuity in the birth cohort studies series (1946, 1958, 1970, 1992, 2000) demands special attention in the consideration of research design. The history of the cohort studies has been that of a changing design strategy influenced initially by an urgent policy need for evidence (e.g. on infant mortality, Plowden committee on primary education). More recently research design has been more strategic, driven by scientific concerns with critical periods in life when development is most rapid. Nevertheless all the studies have collected core data including demographic, socio-economic indicators and cognitive, behavioural and biological developmental measures taken in more than one survey.

1.14 The time series thus created enables continuities and discontinuities in life course processes and their outcomes to be charted across changing societal and physical environmental contexts. Thus each new study needs both to adapt to the future while maintaining consistency with the past. The core requirement, and hence foundation, of the whole programme is the construction of life histories prospectively on a large scale and over an extended period ranging back to the earliest stage of life. This is the key principle, which the SCNS report argued was paramount for the new study.

(d) Survey design

1.15 The scientific programme to which the new study is directed thus embraces both continuity of the existing series and the development of new features of design and coverage, to reflect new scientific demands. Expansion of the sample from what were initially 5,000 (1946 cohort study) births in a single week up to 16-20,000 cases, in each new national birth cohort that followed (1958, 1970, 2000) is recognition of the need to embrace relatively small population sub-groups in sufficient numbers for robust analysis. Such groups include twins, people with disabilities and particular ethnic minorities. Large samples are also needed for the study of genetic influences.

1.16 A more recent scientific requirement is to support the examination of different local ecologies in which development, from conception onwards, takes place. In the case of the most recent (2000) study, MCS, this was achieved by selecting all births over a 12 month period in over 400 UK electoral wards with ‘over-sampling’ to expand the sample in disadvantaged areas with high ethnic minority concentrations and in Scotland, Wales and Northern Ireland. The US National Children’s Study, takes the principle further in a nationally representative sample comprising over 100,000 babies, in 105 geographically defined sites. Finally one of the studies, ALSPAC beginning in 1992-3, and now recognised as part of the cohort study series, concentrated data collection in one UK area thus being able to exploit to the full the local social and institutional context in which child development took place. ALSPAC is also unique among the studies in the richness of data collection, undertaking three monthly postal monitoring for the first 7 years of the study

and annual clinic-based assessments for one tenth of the sample. At age 16, the team is seeking to engage all participating cohort members in clinical assessment using the Wellcome Trust Clinical Research Facility established in the University of Bristol for this purpose.

1.17 The SCNCS report considered ways of combining the best features of these different designs, formulating three major options:

1. A national probability sample with large number (several hundred) small clusters
2. A national probability sample with a small number (15-25) of larger clusters
3. A national probability sample in parallel with five to six large area clusters of the ALSPAC kind sharing common data (80%)

1.18 By default a fourth option is the original birth cohort study design based on a census of births in a single week in a given year. But because this design eliminates study of the effects of seasonality on developmental processes, it was not considered further by the SCNCS team. Though no firm conclusion was reached, Option 3 tended to be favoured as meeting the largest number of scientific objectives to which the new study will be directed.

(e) Principles

1.19 In developing the design for the new study, and identifying options within it, a number of generic principles are put forward:

1. Simplicity of data structure – to maximise scientific use by researchers representing a diversity of scientific interests and disciplines

2. Single overall PI - i.e. core team leader with ultimate responsibility for all decisions concerning the national programme

3. Early documentation - production of a report on each new survey, including a preliminary analysis of the data, fully cleaned and edited and a specification of key derived variables to precede data release

4. Access – to be as easy as possible for *bona fide* researchers on the condition that all investigators using the data report back outcomes of use including scientific publications

5. Capacity – training function to build the capacity needed to design, manage and analyse, a survey of this size and complexity as part of the series of which it forms a part

6. Maximum use of administrative data sources - to enhance the coverage of the main study and help reduce respondent burden including quality appraisal of the data to be used

7. Harmonisation - to ensure measurement comparability between the new study, the earlier studies in the series, the UKLHS, and other UK and overseas longitudinal studies

8. Governance and management - to ensure that the programme has overall coherence and robustness and achieves its timetables, while supporting both national and area-specific scientific investigations

9. Research ethics mechanism - to ensure measurement burden is minimised, data collection procedures are minimally intrusive and carry low risk, duty of care is observed, and confidentiality of all data is assured

10. Panel maintenance facility - to ensure that attrition from the study is minimised

(f) Cost constraints

1.20 In accordance with these principles sample design option (3) was specified as comprising up to 60,000 achieved cases, divided broadly between a sample of 20,000 in a National Probability sample (NPS) for the 'core study' accompanied by five or six area studies, comprising clusters of up to 5,000 to 6,000 in each area. No overall cost was attributed in the report to this design, though it was noted that the cost of the development phase alone of the US National Children's Study was $50M. Clearly how far the proposed design can be realised in full will be subject to the total budget available, which, as we show in section 5, is at present substantially below what would be needed. The options considered later therefore take the financial constraint into account, in trying to identify what is feasible and what could be achieved with supplementary funding to build the budget further.

2. SAMPLE DESIGN OPTIONS

2.1 The specification of the sample design is governed by the demands of the scientific programme, which identifies two features:

- Large national probability sample
- Area studies based on clusters

The Options, as broadly specified, are appraised in terms of strengths and weaknesses in meeting programme requirements.

(a) Population definition

2.2 The first task is to specify the population from which the sample or samples are to be drawn and identify a sampling frame from which to select them. In a birth cohort study a critical decision links population definition to time of first data collection:

- prior to pregnancy (e.g. US National Children's Study)
- during pregnancy (e.g. ALSPAC)
- at birth (NSHD, NCDS, BCS70)
- some time after birth (MCS).

2.3 The SCNCS report argued that the best scientific returns were to be gained from starting the study in pregnancy to encompass the effects of:

a) Inter-uterine environment on fetal development
b) Toxicity of physical environment
c) Psychological and physical health of mother
d) Mother's heath related behaviour and lifestyle, e.g. smoking, drinking and drugs
e) Family structure
f) Parent attributes
g) IVF

2.4 There is also the practical value of a prenatal visit in offering one of the best opportunities for recruitment to the study, especially the typically hard to reach fathers.

2.5. The first population of interest (population A) is therefore a population of pregnancies, which is defined by all those who could possibly be born within a given time period (population A) - and also possibly within a given area. The second population is those who are actually born in this time period (population B). This implies that the collection of registrations have to span a longer period than the period defining B. To study events that occur before birth (e.g. abortion, miscarriage etc.) population A is the relevant one. For the study of birth and subsequent events population B is relevant.

(b) Sample design options

2.6 The next task is to revisit the advantages and disadvantages of each of the major design options identified in the SCNCS report:

Option 1: ***An achieved probability sample of 50,000 of the whole population to provide information for national estimates and comparability with previous cohorts.***

This is close to the US NCS and the UK MCS but we note that while it will involve clustering this will be for design efficiency reasons rather than because information that derives from the clustering is seen as important scientifically. Its advantages are as follows:

1. It will generate a very large nationally representative, Equal Probability of Selection Method (EPSEM) sample, with large enough numbers for studies of small groups, such as ethnic minorities.
2. It could be centrally coordinated with an accessible database, common protocols and documentation that would maintain consistency over time.
3. The team would be relatively large and could contain within it a range of specialists in sampling, documentation, data management and data analysis as well as subject specialists.
4. It could provide a more consistent approach to data collection, training of interviewers and measurers.
5. It would provide a straightforward comparison with earlier cohorts and some international studies.

Disadvantages are as follows:

1. It could not easily reflect contextual information, especially in relation to local institutions and services and other interactional settings including those with peers such as play groups and so on.
2. What clustering there existed at the start that did enable contextual information, for example on area characteristics, would dissipate over time so that any advantage would become less.

Option 2:
An achieved probability sample of some 20-25 clusters, with 2000 – 3000 in each cluster, augmented with a large national sample selected in similar fashion to previous cohorts

This is intermediate between options 1 and 3. We shall not consider it in detail since it would seem to suffer the same ‘disintegration’ problem as option 1 without the clusters being large enough to carry out their own substantial analyses.

Option 3: ***An achieved probability sample selected as in option 1 but of size about 20,000*****, with another 30,000 spread across areas.**

This is a quite new design that puts together a nationally representative sample with a small number of large area studies (clusters). The advantages are as follows:

1. The national representative sample will be large enough to make proper comparisons with previous cohorts.
2. The area studies will have their own teams, thus involving a larger number of scientists. Each team could have a special research interest and be funded to run the area study on the basis of the research proposal(s) they put forward
3. A common (core) set of measures (80%) will be collected on the national sample and each cluster. These will include socio-economic, demographic, developmental (including biological) and educational data. These data will enable linking across clusters providing data strength.
4. Additional data (20%) will be collected uniquely in each cluster to reflect researchers' interests, geographical and compositional differences e.g. ethnic minorities. A case for this will need to be made in each cluster bid: note that the central team may also bid for one cluster.
5. The team administering a cluster need not be located in the same geographical area as the cluster but an attempt should be made to have at least one cluster in each UK country and to include urban and rural areas.
6. The clusters, while having some disintegration, will retain enough local data, as evidenced by ALSPAC, to carry out sensitive contextual analyses.
7. The existence of several clusters is intended to encourage replication of findings across different contexts

The disadvantages are:

1. Unless included in a specification of cluster requirements, certain small population groups that could have been studied in option 1 may not be represented in sufficient numbers in the national sample and not sampled sufficiently within any cluster.
2. It will be more difficult to ensure a common protocol for the core measures.
3. Coordination generally can be difficult in a 'hub' and 'nodes' model with distributed responsibilities as evidenced from the US-NCS
4. Specialist expertise, for example in data analysis, may not be as well represented as in option 1, although a pooling and interchange of expertise should be possible.

2.7 We propose to consider option 3 in more detail for the following reasons:

a) Given that it is proposed to have an achieved sample size of approximately 50,000 so that the national sample (size 20,000 in option 3) is comparable to previous cohorts, the risk of losing comparability over time is minimal.
b) Environmental, contextual and interactional factors are becoming of increasing interest to social and health researchers and this option is an attempt to recognise that.
c) Having more than one research team, with differing perspectives , will encourage a diversity of approaches and questions and this is seen as an important strength.
d) Area teams will be encouraged to establish local links and thus be able to bid for matching local funds for their work.

(c) Staffing

Core team

2.8 We assume that the core team will require a full-time principle investigator (PI) for the whole period, senior and junior research staff, IT and admin support and clerical staff and a survey manager. Other expenditure will include travel to interviewer briefings, software and consumables.

Area teams

2.9 Area teams will be a trimmed down version of the core team with the same (part FTE) core staffing, including a PI, senior and junior research staff and admin, IT and clerical support, but reduced survey operations responsibility and related functions such as travel.

(d) Organisation

2.10 A crucial feature of this mixed design is where responsibility for decision making lies and deciding what is core and what is area-specific. Although we do not wish to make very hard and fixed recommendations about this, a working distribution is suggested at 80% of the data collected across the NPS and the areas and 20% area-specific, the content of which would be determined largely by the area team. The area teams themselves would be part of a system comprising a ‘hub’ team with responsibility for the NPS survey and the core data throughout the project, and ‘node’ teams with responsibility for each of the separate area studies. The PI for each node would join with the others to form the overall Management Committee for the project, including the overall PI located in the hub. This Committee would be the ultimate decision making body for the whole programme, but following the experience of the US-NCS in the case of dispute the overall PI would have the final say.

2.11 Data collection would be carried out by a national agency commissioned centrally by the NPS team for the NPS survey and locally by the area teams. Because of insufficient interviewers likely to be available in each local area, local health professionals would be recruited including active and retired health visitors and nurses who would be recruited with the help of the local team and trained by the national agency to the highest standards of survey data collection. This field force is likely to remain fairly stable over time and will therefore provide the same kind of resource for the subsequent surveys.

2.12 The first survey would arise through GP registration, leading to ante natal clinic visits where recruitment to the survey would take place by inviting the mother to supply some data on the spot and to participate further in the study through accepting a home visit from an interviewer. ALSPAC experience suggests that a visit from a health professional representing a local scientific research team is likely to enhance response and encourage loyalty to the survey as a whole.

2.13 It is assumed that core data including up to 20% specified for local purposes by the area teams would be funded from the budget for the whole programme. The area teams would themselves raise funding to support additional specialised data collection, specific to their own area of interest. Each area might focus, for example on a particular aspect of development or capitalise on the geographical proximity of sample members within the multi level design. Consideration should be given to allocating up to £IM from the budget to support this work which the teams would bid for.

2.14 The teams would be selected on the basis of balance between geographical diversity and the scientific challenges that their proposal was attempting to meet. Beyond these parameters there would be open competition for each area study as well as the programme as a whole through the hub team.

(e) Sample size

2.13 Our recommended sample averaging 20,000 achieved cases (registered pregnancies) in the NPS study and 5,000 achieved cases in each area reflects a trade-off between statistical precision of estimates and the number of estimates available to compare across areas for replication purposes. The recommendation also reflects a number of considerations arising from the reviews of cohort studies and consultations undertaken in the work done for the SCNCS report

1 The new birth cohort study is not focused on the study of any particular scientific outcome or hypothesis in a single research programme but multiple outcomes, hypotheses and programmes - each of which would demand a different sample size to achieve a specified level of statistical power- .within a broad framework of “important scientific questions” (para 4.14).

2 An NPS sample of 20,000 maintains continuity with the 1958, 1970 and 2000 studies and therefore offers the same level of statistical power as these studies.

3 Area studies' samples averaging 5,000 approximate that of the 1946 cohort study, are feasible to collect in a specified period, and because of the loyalty factor', are likely to experience relatively low levels of attrition.

4 For area studies requiring much higher numbers than 5000 as in gene-gene and gene-environment interaction, pooling across areas and with the NPS sample can be used to boost numbers to the required levels.

2.14 We believe the 5000 area sample size is adequate to meet scientific purposes, though a boost to 6000 would provide insurance to meet contingencies such as higher than anticipated attrition rates, albeit at a cost to other parts of the programme.

(f) Data collection over time

2.15 We think that there is some merit in the suggestion to collect data from individuals at different sets of ages. The detailed decision on this can be postponed to the piloting stage. However, it may well be that some of the area studies will wish to collect data at different ages and this is perfectly acceptable so long as there is an agreed set of ages where all the sample members have data collected, even though the data collection may be spread over a period of, say, a year, similar to the MCS.

(g) Piloting

2.16 The piloting stage should start as early as possible in 2010. Initially it will encompass the national study only, but piloting for the areas will also need to start in 2010 depending on the start dates for these studies, which could be up to 1 year after the national study. Piloting would be directed at developing and testing all features of the survey from recruitment through local liaison and data gathering to instrumentation and data collection. Ideally the work should start sufficiently early in the programme to allow one follow-up before the beginning of main field work. Some valuable work on recruitment, for example, could precede the establishment of the research teams and begin almost immediately.

(h) Timetable

2.17 A timetable showing all stages of the survey is shown below. The five year programme begins in 2010 with design and piloting and ends in 2014 with the infancy survey.

Timetable	Activity
2009	Pre-piloting recruitment, scoping of admin data, data linkage, scoping of local services, promoting the study Core team appointed
2010	Development of sample design and measurement specification Longitudinal pilot first survey Area study teams appointed
2011	Longitudinal pilot second survey and pilot write up Design specification for antenatal and post natal surveys
2012	Ante natal recruitment First antenatal survey
2013	Birth records collection Antenatal survey data prep and report First post natal data collection (4-6 months)
2014	Post natal survey (4-6 months) report Infancy survey design
2015	Infancy survey

(i) Data base and analysis

2.18 A central database comprising all core and core-funded area-specific data will be constructed and managed by the core team with full on-line accessibility for the local teams. Because of the design complexity, as well as the need to compensate for attrition and missing data, a high level of data analysis sophistication will be necessary both for the teams themselves, especially the area teams, but also for secondary users. Once the studies are underway effort should be devoted to enhancing this capacity and some of the funds should be reserved for this purpose. Partly this will involve training, and partly it will involve the selection or development of suitable software.

(j) Generating interest

2.19 Once a first tender document has been issued there should be a systematic attempt to generate interest in the study. A group should be established to disseminate knowledge about the programme, bring interested researchers together, extend interest to new research groups and disciplines and generate ideas for useful work. Without such advocacy there will be a danger that not enough interest will be generated, especially among those

currently not active in cohort study research; opportunities should be provided to involve new groups. In particular a series of meetings/conferences could be arranged where researchers from studies around the world could attend to stimulate discussion Eucconet organised by the ELFE team is currently being established to serve this purpose and would supply good vehicle for this.

3. DATA COLLECTION

a) Introduction

3.1 The principal aim of the data collection is to provide a resource for study of the processes of individual development, and the social, economic, environmental and genetic influences on those processes, and for comparisons with findings from the earlier large birth cohort studies. The initial focus on the early years needs to be seen in the context of a long term study spanning the whole life course in which some of the most important returns in terms of health, and life chances will not be realised until well into adulthood. The scope and value of the later work will be critically dependent on the planning of the first stage of the study.

3.2 It is now understood, as we argued in *SCNCS*, that behavioural, cognitive and physical development are integrated, complex and interactive processes which are strongly influenced by the social, economic, and physical environment (including nutrition), by exposure to maternal psychological stress, and by the child's genetic endowment. These processes begin at the earliest time in life, and at that stage the physical aspect is the most accessible to measurement. Although measurement of the cognitive and behavioural processes can only begin after birth, important aspects of the development of cognitive and behavioural capacity need to be measured before birth, in terms of growth and exposures to influences on growth that come from the social and family environment and from genetic sources.

3.3 The large sample required to study the genetic and environmental influences and the smaller population sub-groups groups is, in research design terms, not entirely compatible with the requirement to measure behavioural, cognitive and physical development in sufficient detail. That is the design challenge. We addressed that in sampling terms, by providing a large base from which to collect core data on all sample members, and also for the geographically based area samples which are necessary for the collection of the more detailed data for use in more specialised investigations

3.4 We have considered the core data collection in terms of both the national probability sample and the area samples. Our principle has been to outline some key topic areas that we consider essential exemplified, where possible, by measurement methods currently available.

3.5 We consider that ideally 4 collections of core data from the whole sample are needed by age 3 years. It seems clear, however, from the estimates to be considered in section 5 that the budget would be unable to support such a programme for a sample of 50,000. Nevertheless we think there is value in showing what will be needed, and if not fundable in this first stage of the study, then in the next one. Our recommendation is that the first core measurements should be made in the antenatal period, the second at the birth, the third at age 6 months and the fourth at 30 months. The first part of

this chapter outlines why we consider these the optimum times for data collections in the major topic areas. Then we consider how best to operationalise the data collection proposals and options.

(b) Measurement domains

(i) Core measures of the family socio-economic and cultural environment

3.6 Information on the socio-economic environment, to be collected on those recruited either to the national probability sample or to an area sample, should include not only indicators of economic circumstances and parental and grand-parental occupations and education, but also baseline markers of the family culture and aspirations (in terms for example of pro-social behaviour) in which the child will develop habits of response, temperament and behaviour that will strongly influence later learning and health related habits.

Before birth

3.7 Pre-pregnancy information should be collected on the mother's and father's dates of birth, NHS numbers, marital history, education, training, occupation and income, use of social services, and receipt of benefits, and on the educational level and main occupations of their parents. Information should also be collected about current marital status, occupation, income and housing of the mother, and her use of social services and benefits, as well as indicators of the parents' interests, concerns, and aspirations, and plans for the baby. Information about the neighbourhood should be collected by record linkage with administrative data. There may be advantages in linking with the Department of Work and Pensions register of pregnancies.

The ideal option is to collect personal information at home interviews; that would increase the likelihood of obtaining first-hand information from fathers.

The simpler option, if this cannot be undertaken, is to use self-completion postal questionnaires; there is a great deal of experience with self-completion postal questionnaires on these topics though there is always uncertainty about their reliability for some purposes and poor literacy can be an inhibiting factor.

At birth

3.8 It would not be feasible to collect socio-economic data at the time of birth if, as will be suggested, most information is taken from clinical records**.**

Between birth and age 3 years

3.9 At any of the data collections during infancy it is important to collect basic socio-economic information on partnership/marital status, occupation, income

and housing, receipt of social services and benefits, and to use record linkage to collect neighbourhood and if possible also benefits and social services data. It will also be important to collect information on the parents' interests, concerns, and aspirations for themselves and the child.

The ideal option at data collections during infancy is for information on these topics to be collected at interview.

The simpler option is to use postal questionnaires.

(ii) Core measures of the psychosocial environment

3.10 The family and caregiving environments constitute the main proximal sources of influence on children's development in infancy and early childhood. In addition, maternal lifestyle factors (smoking, drinking etc), along with mothers' exposure to stress, are now increasingly recognized as having key impacts on the prenatal (intrauterine) environment, affecting not only children's pre-and post-natal physical development, but also their behaviour and cognition.

Before the birth

3.11 Antenatal measures of the mother's lifestyle factors in pregnancy, along with her experience of anxiety, stress and depression (and of the sources such problems, in terms of exposure to adverse life events), are essential. It is also essential to collect information on the quality of relationships between parents (discord, support etc), the availability of other sources of family and social support, and the attitudes of the mother and her partner to the pregnancy. Initial measures of the parents' general health and personality characteristics could also be made at this point.

At birth

3.12 Although there are arguments for collecting information on the stresses associated with the birth, it is not practical to consider doing so in the context of a large-scale study.

Between birth and age 3 years

3.13. Post-natal assessments should include repeated measures of parents' mental and physical health and stress exposure, along with data on patterns of child care (including the extent and nature of non-maternal care, both formal and informal). Parenting, and the quality of parent-child relationships, should be central to the assessments at each post-natal contact. In infancy, such assessments should focus on sensitivity and attunement to the infant's needs, parental warmth, affection/rejection, and parent-child attachment. In the toddler years additional assessments are needed to cover behaviour management and disciplinary strategies, and approaches to conflict

management and problem solving. At each point, measures should also include age-appropriate indicators of activities with the child and approaches to cognitive stimulation. The quality of the parents' relationship (including, where appropriate, relationships with non-resident biological parents and with new partners) should continue to be assessed at all post-natal assessments. Information should also be collected on family social networks and sources of instrumental, social and emotional support outside the family.

(iii) Core measures of the child's cognitive development, temperament and behaviour

Between birth and age 3 years

3.14 It would be highly desirable to assess temperament (generally regarded as a constitutional feature showing important genetic influence, which shows links with later cognitive performance as well as with behaviour), as early as possible after the immediate post-natal period, and before the effects of parenting and other aspects of the child's early experience begin to have their effects. This early assessment of temperament (by maternal/caregiver report), would thus best be done at age 4 - 6 months.

3.15 Later measures of temperament and emotional/behavioural adjustment could be made at the same time as initial measures of cognitive development. The timing of this second assessment requires careful consideration: current expert advice suggests, for example, that cognitive assessments at age 2 years (a point of major developmental change) show less strong associations with both prior developmental measures and later outcomes than those made at age 30 months or older.

3.16 MCS included direct assessments of cognitive development at age 3, successfully administered by survey interviewers; if feasible, measures of this kind have clear advantages over maternal reports, though these too are valuable. Parent/caregiver-report measures of emotional/behavioural development are widely available for pre-schoolers. Ideally these would be complemented by independent assessments of behaviour (including patterns of mother/child interaction), to ensure that continuities with assessments at later ages are not heavily influenced by rater effects. Studies of sub-samples (either area-based, or across the full cohort), could be used to achieve this intensity of record.

(iv) Core biomarker measures

3.17 Two purposes of biomarker measures should be distinguished. First are those that indicate development (physical, cognitive and so on) and second are those concerned with health. We distinguish those categories here, and further distinguish measures of health as they affect or indicate growth and development from those that are of scientific value for studies of health. The aim here is to outline information essential for understanding the processes of

development, and to describe options for data collection that could be either expanded to become more detailed studies of health or returned to for future more detailed health studies. The health aspects should include the use of linkage to NHS e-records in general practice and in hospital.

Before birth

3.18The biomarker data should include pre-pregnancy data (on shape and size and health related habits and infectious illness experience), elements of the mother's physical health in pregnancy that particularly affect the child's development (infectious illness, blood pressure, diet, exercise, smoking, drug and alcohol habits), the estimated date of conception, data on the father's shape and size and health and health related habits currently and before the pregnancy, and a biological sample (sputum or blood) from which to derive DNA.

3.19 In addition, richer data could be added, for example on the mother's exposure to toxicity, her diet and experience of infectious illness (using a blood sample, or blood samples taken at each antenatal visit, and/or samples of blood, hair and nails), and the ultrasound scans made at each antenatal visit could be digitised and stored in order to measure the baby's prenatal growth.

The ideal option is to collect data at each antenatal visit by short-self-completion questionnaire (to fathers as well as mothers where possible), abstraction from and/or linkage to clinical notes, blood and sputum sampling (including one paternal sputum sample), and saving ultrasound scans. In addition a postal questionnaire would be sent in.

The simpler option is abstraction/linkage to clinic records, a postal questionnaire, and sputum samples to be returned by post.

At birth

3.20 Measures of the baby's shape and size and the length of gestation provide a basic summary of physical development before birth. Details of the delivery and the baby's health in the first moments of life are essential because they are known to be associated with infant mental and physical development.

This data collection has to be as simple as possible, given the clinical circumstances.

The ideal option is to collect a sample of cord blood (for the baby's DNA and indicators of maternal toxic exposures), and the placenta for preparation as a pathological specimen, and to ask staff to take extra measurements of the baby. Information should be taken from clinical records, through record linkage.

The simpler option is to collect information entirely using record linkage clinical records.

From birth to age 3 years

3.21 Measures of physical development in early infancy should include length/height, weight and shape, in order to show the growth trajectory, and measures of motor, sensory and respiratory development, and attainment of bladder and bowel control. The growth trajectory is an essential indicator of development because it is known to be sensitive to physical and emotional exposures: these include infant feeding and diet and exercise, and mother's stress and smoking, each of which must also be measured. Health and its care should be monitored through record linkage.

The ideal option is to have 2 data collections, one at about 4-6 months and the other at age 2 years or later. Data collection at 6 months reduces recall time during this early period of rapid development, and at 2 years or later some important aspects of biological function (e.g. respiratory function) can be measured. However such measurement would need to be part of an area study.

The simpler options are (a) to have a postal questionnaire data collection at age 6 months. That would have the disadvantage of relying on the mother's recall for some important information. Many babies are seen by health visitors at clinics as well as by general practitioners during the first year of life, and so clinic record abstracted data could be obtained. Again this would be most easily managed in an area study.

(v) Core measures of environmental toxicity

3.22 These measures are concerned with the physical environment and not with the environment in terms of individual behaviour of the parents and child, such as diet and parental smoking. In this respect there is relatively little experience in British large birth cohort studies, although there are quite a number of smaller studies, mostly concerned with respiratory health and development. The new US large birth cohort study is concentrating, particularly in the early years, on environmental measures of atmospheric and chemical pollutants in the home and outside, and much could be learned for their experience. In ELFE there is also interest in the naturally occurring pollutants in the water supply and radiation. This is a topic on which new hypotheses are being rapidly developed, as new chemicals are introduced into everyday life, and so expert advice on the state of the science should be taken before planning any data collection. In Britain some information, for example on water quality, fluoride additives, proximity to polluting industry, traffic and power lines, can be collected from administrative data sources.

3.23 Measures of the home environment can be made on samples of the water supply, using records of methods of heating and cooking, samples of

house dust, and by using simple methods (such as cards that record atmospheric pollutants) to collect data on the mother's exposure to pollutants. Blood samples from the mother can also be used for these purposes.

3.24 Because of the short time available to us to explore this topic, and given the absence of British expertise in the birth cohort studies and the very early stages of development of this kind of work in the US and the French birth cohort studies, we have not recommended inclusion of this topic in the core data collection. It might usefully be pursued through one or more area studies.

(c) Operationalising the core data collection

3.25 Collection of core data in as much detail as possible should be undertaken with all sample members, including those in the national probability sample and those in the area samples. Initial identification and recruitment of sample members at first antenatal visits would offer a valuable opportunity to 'sell' the concept and identity of the study if clinic staff were well briefed, and were themselves identified with the study. It also increases the likelihood of obtaining information directly from fathers.

3.26 Area samples have been found, in the extensive ALSPAC study experience, to be a great advantage for collection of not only core data, but also for more focussed data collection. Area samples would also make collaboration between the study and staff in health, social and education services much easier, and much more likely to be fruitful in terms of data collection both through individual contacts and through records. The area surveys also offer opportunities to give the study a local identity, through media profiling. There would be a distinct long-term advantage in locating area samples within reach of clinical research facilities, such as those provided by the Wellcome Trust.

3.27 Money must be ear-marked for study promotion, particularly for maintaining the kinds of contacts with mothers that keep them identified with the study, such as birthday cards to the child and a study web site that shows and explains findings.

Before birth

3.28 The best option is to begin to collect core data on all sample mothers at their first antenatal clinic visit, using that opportunity to take a blood sample (for DNA extraction) additional to those routinely taken, to abstract data from records on the health of the mother and fetus. Then an interviewer administered home interview would follow, at which the data outlined above would be collected.

3.29 Supplementary funding could be sought to increase the intensity of this data collection from all sample mothers in terms, for example, of greater record abstraction, digitising and saving ultrasound scans, and taking

additional blood samples at later antenatal visits. This might apply particularly in the area based studies.

At birth

3.30 At the birth of all babies born to sample mothers and delivered by NHS (and hopefully also private) health care staff, clinic staff would be asked to take a cord blood sample for the study, and clinical record data would be abstracted later, wherever possible by electronic means.

In early infancy

3.31 The first data collection in infancy, at age 4-6 months, should take the form of a home interview, carried out by an interviewer trained to take anthropometric measurements and to make simple assessments of sensory and motor development of the baby. The first visit would provide good quality data about the baby's early growth and development, nutrition, temperament and attention, and data on the mother's experience of postnatal depression, without a long period of recall.

3.32 Linkage to medical records could, in addition, provide important information on the baby's health, and health care.

(d) Opportunities for more detailed data collections

3.33 The large area samples will provide the opportunity for more detailed studies of neighbourhood and local effects, and more detailed measurement of individuals, because data collection costs will be lower (less travelling), and because they offer greater likelihood of individuals travelling to clinics or other centres where such measures can be most effectively taken (as in ALSPAC and the 1946 study). They also offer good opportunities for setting up such studies, through local knowledge of facilities, and the opportunity to develop and maintain good relations with education and health care practitioners, as well as with sample members. The latter offer a source of recruitment of interviewers to undertake locally the core data collection.

3.36 As noted previously, the more detailed kinds of studies are not included in the budgets considered here, and would be funded by separate grant applications to appropriate sources.

3.37 An essential management task is implied, in that the overall PI and the Management Committee will have to have control over the development of additional studies, because of the risk of over-exposure of sample members to data collection exercises, and the risk of distorting the core study's identity in the minds of the participants.

4. CONTINUITIES AND COMPARABILITIES

a) Research Design

4.1 The two cardinal principles that inform the design options considered in chapter 3 are (a) continuity of each new study as part of a series and (b) adaptability to meet new scientific demands. Although the features of the samples used through the series of the 1946, 1958, 1970, 1992 and 2000 studies have changed over time, together with the timing of data collection, especially in the early years, they share the common feature of supplying estimates relating to the population through different stages of the life course. These estimates extend beyond the prevalence of attributes at different ages and stages of life, compared across cohorts, to modelling the processes reflecting interaction between human agency, the individual's biological characteristics, and the social and physical environment, through which their life course is constructed. Thus over time the value of the studies for comparative purposes increases as the developmental patterns emerge, or fail to emerge, in the same form and at the same ages, in successive cohorts.

4.2 We have no doubt that the continuity of the birth cohort study series should remain a central feature of the new study. We were also concerned to address in the SCNCS report the possible gaps in the data record and consequent reduced potential for analysis to meet the latest scientific demands. One clear priority is the need for larger samples than have been used in the past. Studies of, for example, gene-environment interaction require much larger scale data than is typically available in the previous studies – hence the massive scale of the US NCS and the 500,000 strong UK Biobank.

4.3 The other requirement is the need to study in much finer detail the interactional settings in which development takes place. To what extent are exposures to different settings in nursery schools, through primary and secondary education, the teenage peer group, the work place and the community, key sources of influence in shaping development and the life course? Where you live and who you know can make a substantial difference to who you become. The family, of course, provides the first of these interactional settings and continues its significance, especially in the early years of life, and continuing through the teens and adulthood. In later years roles and the dependencies that go with them reverse, as increasingly the members of the previous generation who are now grandparents become dependent on their own children to look after them.

4.4 Both types of design are realised in different analytic approaches, with time series analysis addressing continuity and discontinuity across cohorts by replicating and testing models through successive cohorts across historical time. The more recent developments, as exemplified by ALSPAC, in what is proposed for the new study, draw into the statistical analysis the different features of the environment at a number of levels; community, work place,

school, and family, in a multi-level framework.

4.5 But statistical methods are not the only analytic approach available. Area study has the added attraction of enabling much more intensive case studies of individuals and groups identified within the statistical framework, using social biographical and ethnographic methods.

4.6 The advantage of the design we have proposed is that these two distinctive features, time series continuity and local ecology, offer opportunities for much enhancement of the scientific programme. Moreover, providing equal probability sampling of pregnancies is used in the national study, by means of appropriate weighting and imputation methods the national and area study clusters can be used in combination as representative of the national population. Thus a sample that includes a 20,000 national probability sample component and a set of six area studies based on probability samples, each 5,000 in size, can be converted to a single national sample of 50,000 for the study of relatively rare groups and gene-environment interaction. The principle can be extended further to overseas samples as we consider later.

b) Data collection

4.7 The principle of continuity is realised further in the timing and content of data collection. Figure 4.1 shows sample ages at data collections and means of data collection in the earlier large birth cohort studies in Britain.

FIGURE 4.1 DATA COLLECTIONS THAT INCLUDED ALL SAMPLE MEMBERS IN THE EXISTING LARGE-SCALE BRITISH BIRTH COHORT STUDIES UP TO AGE 7 YEARS (SAMPLE SIZE AT STUDY ONSET)

Ages at data collections	1946 cohort NSHD (N=5,362)	1958 cohort NCDS (N=17,773)	1970 cohort BCS70 (N=16,135)	1992 cohort ALSPAC (N=14,541)	2000-1 cohort MCS (N=18,819)
Month 4 of pregnancy				**P&C**	
Month 5 of pregnancy				**P**	
Month 6 of pregnancy				**P**	
Month 8 of pregnancy				**P**	
Birth	**C&M**	**C&M**	**C&M**	**C&M**	
4 weeks				**P**	
8 weeks				**P**	
6 months				**P**	
8 months				**P**	
9 months					**I&C**
15 months				**P**	
18 months				**P**	
21 months				**P**	
2 years	**H&HV**			**P**	
30 months				**P**	
33 months				**P**	
3 years					**I&C**
38 months				**P**	
42 months				**P**	
47 months				**P**	
4 years	**H&HV**				
54 months					
57 months					
5 Years			**H,HV&C**		**I&C**
61 months				**P**	
65 months				**P**	
69 months				**P**	
6 years	**H,HV&ME**				
73 months				**P**	
77 months				**P**	
81 months				**P**	
7 years	**H,HV,ME&T**	**H,HV,ME&T**			**I&C**

C=Clinic records. H=Home visit. HV=Health visitors collected data. I=Interviewers collected data. M=Midwives collected data. ME=Medical examination for the study. P=Postal questionnaires. T=Teachers collected data.

4.8 The table reveals relative rarity of data collection the early years in some of the studies compared, with for example ALSPAC, and more convergence later on. However ALSPAC's developmental monitoring every three months up to the age of 4 was by post, whereas NSHD used heath visitors collecting the data during a home visit at two year intervals. This diversity of approaches reflects both overall funding constraints and the different scientific foci and policy priorities to which the studies' funding was directed.

4.9 The earlier birth cohort studies were concerned in their research into early life, with both the building of scientific knowledge and policy. The first study provided a baseline measure of survival, health, growth and development in early life, and of the roles played by the children's families and by the care services in those processes. That information was used to reveal great socio-economic and geographic disparities in the health of mothers and babies. The three following studies were designed specifically to measure progress in reducing those disparities, and their findings greatly influenced health and social policy. Although the two most recent studies have investigated maternal health and the early life health and development of their babies in other ways, they have been equally concerned to address the question of whether the disparities shown in the earlier studies were being reduced.

4.10 Each of the studies was continued in order to undertake similar research with respect to education. The baseline study showed the influences of schools and families, as well as the earlier processes of development, on both cognitive function and its change during the school years, and on educational attainment. Again great socio-economic and geographic inequalities were revealed, and the following studies showed the progress made in reducing them. In consequence, their findings fundamentally influenced educational and social policy.

4.11 The challenge for each of the studies has been to develop a design that can inform policy and progress scientific knowledge, with the best and most up-to-date methods of measurement that can be used with very large samples, and to provide results that can be compared with those from the earlier studies. The challenge remains the same for the new study.

4.12 The earlier large-scale birth cohort studies have been important in revealing the inter-relationship of psychological and physical aspects of child development, and the effects of the social, economic, and psychological environment on the processes of development. Those influences begin at the earliest moments of antenatal life, and many begin before then.

4.13 Although there has been some dispute in the past about the cohort studies' scientific focus, it is now clear, as we argued in the *SCNCS* report, that in order to understand the processes of development it is necessary to measure, on the one hand, cognitive, behavioural, temperamental and physical aspects, and on the other, the social and physical environmental and

genetic influences related to them. It can be argued that the earlier studies concentrated on health in the early years for policy reasons, because of the stubbornly high and socially and geographically skewed contemporary peri-natal and infant mortality rates. At later ages those studies concentrated on cognitive development and educational performance, also for policy reasons. This new birth cohort study must also be attentive to current policy questions, for example those concerned with anti-social and pro-social behaviour, with family and social cohesion, with obesity, and with the foundations of life-long well-being, health and the processes of ageing. In that sense it will provide a valuable kind of continuity.

4.14 Disputes about the scientific focus of the studies have also been concerned with the extent to which these kinds of studies have to be, on one hand restrained from becoming studies of everything (with consequent risk of using measurements that are too simplified to be valuable), and on the other, studies that are too narrowly focussed. Another distinction resides in the principle of collecting as much information as possible as compared with collecting only data for which a specific use is already planned. It is worth careful consideration of these questions as the study design develops. At this early design stage, as the Workshop on 'Developing infrastructure for research across the biomedical and social sciences' recommends, the focus should be on the important scientific questions that the study should address rather than specific hypotheses for testing.

4.15 The new study will necessarily also differ from the earlier investigations because of developments in methods of measurement and in knowledge in all the disciplines concerned. Nevertheless comparisons of findings in the British studies will be important, and so the continuity should include comparability where possible, and should also include comparability with the most recent large studies, such as *Born in Bradford* (www.borninbradford.nhs.org.uk).

(c) Comparability with large birth cohort studies in other countries

4.16 Some large birth cohort studies in other countries have been deliberately modelled on the British studies (e.g. the North Finnish birth cohort studies); others have been developed in response to scientific developments (e.g. the Danish and Norwegian pregnancy cohort studies are concerned particularly with genetic influences on development and health) as well as with policy concerns (e.g. the US National Children's Study's and the French ELFE study's concerns with the impact of atmospheric environmental elements on development), or to a combination of both (e.g. the Rotterdam Generation R study is 'designed to identify early environmental and genetic causes of normal and abnormal growth, development and health from fetal life until young adulthood' www.generationr.nl).

4.17 As part of the brief for the study we were asked to investigate specifically three examples of new cohort studies that were likely to be starting from birth in a comparable time period to the new cohort British study. These were the

US National Children's Study (NCS); the German National Education Panel Study (NEPS); and the new French birth cohort study (ELFE). These differ from each other substantially with respect to the focus of interest, reflecting the different scientific programmes to which they are primarily directed. We have also learned much from them in formulating the design presented here.

4.18 Thus the US National Children's Study, one of the largest of its kind, comprises 100,000 babies tracked from conception in 105 geographical locations across the USA selected as a probability sample. PIs are located in a number of 'research sites' (currently over 60) for a number of areas, with an overall Director in the National Institute for Child Health and Development (NICHD) in Washington DC. The core data collection is coordinated centrally by the USA's largest survey organisation, Westat, also located in Washington DC. The main focus in the NCS study is child health and a particular interest is to understand the effects of toxicity in the physical environment in different places on development, pre and post birth, up to age 25 years. The French study, ELFE, similarly gives a strong emphasis to child health and environmental quality, but also more explicitly pursues programmes in the socio-economic domain, education and psychology.

4.19 Of the three studies we investigated, ELFE, in terms of coverage, comes closest to the new British study. But rather than make the first contact with the mother during pregnancy ELFE begins instead with specified dates in the year when babies are born, all of whom will become members of the sample. ELFE's problem currently is to get a firm government commitment to the main data collection due to begin in 2010. Although major pilots have been undertaken and funding is available for the preparatory work needed in 2009, there is yet to be confirmation of the 2010 first data collection.

4.20 The German National Educational Panel Study (NEPS), began with a different focus again: the development of competence through the life course, starting with experience of kindergarten and moving on through the elementary and secondary school years through to university and the work place. This is a very well endowed study with 70M Euros allocated to the work. There was no intention initially to include a follow-up component from birth in the programme, but under pressure from sponsors it has been agreed that the cohort born in 2012, rather than being identified through entry to kindergarten, would actually begin at birth. The broader programme in which the study is embedded, together with the new cohort study itself, offers considerable opportunities for specialist comparative studies on educational careers and the development of competence of the kind which an Area team might wish to take up.

4.21 Again rather paralleling the difference between cohorts started at different historical time points, there is enough common measurement between the UK and overseas studies to make some useful comparative analyses. This makes the case, which we argued strongly in the SCNCS report that opportunities need to be taken from the very earliest stage of the

development of a new cohort studies for harmonisation of measurement and focus, so that comparative analyses can be undertaken. Such analyses will of course be looking for systemic effects on life course processes, not in any 'league table' sense, but to elucidate this element of person-environment interaction. In addition where common measurements are shared across studies and biomarkers such as DNA are collected, rather than the strategy of replicating findings from one study to another, data can be aggregated to produce the very large samples that are needed for some of the more refined gene-environment analyses. Finally there is a view that in certain research areas such as environmental toxicity in the US National Children's study, research coverage is so comprehensive that there is little need for further investigation elsewhere. In this case the added value of collaboration is seen as lying in the complementarity of pooled knowledge rather than in the expansion of the research resource through data pooling.

5. COSTS

5.1 The previous chapters have set out the design options for each of the components of the scientific programme: sample design, data collection. In this chapter we pursue the issue of costs, starting with the core elements of costs identified through consultations with cohort studies experts and then combining these in terms of a number of costed options, which the budget of £21M to £23M over five years might be able to support, with or without enhancement. These are then prioritised against the budget available.

5.2 The key cost components are:

a) NPS data collections conducted by a national agency before birth, at 4-6 months, at age 2-3 years (Birth data will be collected from medical records).
b) Area study data collections as in (a)
c) Clinic-based biomedical measurement, including use of equipment and sample storage. (Costs of analysis of biological samples are not included).
d) Core team staff with responsibility for the survey based on the national probability sample and the overall management of the programme;
e) Area studies teams' staff with responsibility for the local clinic-based data collection and the local data collection in the core study.

5.3 Additional components of the programme that need to be costed separately comprise:

a) two years of piloting
b) fund to support area studies specialist investigations
c) fund to support PhD Students affiliated to the teams

5.4 Sources of this information were: (a) The National Centre for Social Research (NatCen); (b) the Centre for Longitudinal Studies team, (c) The ALPSAC team including the chair of the "Born in Bradford" Advisory Committee. Each drew on their most recent cohort study costing experience. Thus fieldwork costing for the national probability sample drew on comparable work done by NatCen for the Millennium Cohort Study updated to the present time. The area studies costs were based on ALSPAC's estimates of recent and current surveys, including the current clinic-based assessment of the whole participating sample at age 16.

(a) **Core data collection costs**

5.5 Table 5.1 shows the scheduling of data collection across the five years of the programme and the type of contact with the family involved as cost components.

Table 5.1 Data collection schedule - core and area studies

Data collection Stage	Method
GP registration of pregnancy	
Ante natal Clinic	Recruitment of mother to the study Take blood sample
Prenatal	Survey interview 60 minutes mother 20 minutes father
Birth	Hospital records Take cord blood sample
Post natal (4-6 months)	Survey interview 60 minutes mother 20 minutes father 15 minutes observation or child measurement
Infancy (2-3 years)	60 minutes mother 20 minutes father 30 minutes assessment

5.6 The 'method' translates directly into data collection costs at each stage of the programme and for the programme as whole. These are shown for different achieved sample sizes together with the core team costs and clinic (bio-medical measurement) costs in table 5.2 below. A 10% sample reduction is assumed from the prenatal to first post-natal survey reflecting mainly pregnancies not resulting in live births. Between the two post natal surveys the further 10% reduction is assumed reflecting likely sample attrition.

Table 5.2 NPS core data collection costs

NPS sample size	Pre natal (Home visit- survey Interview £M	Birth (Midwife) (medical records and biomedical samples) £M	Post natal – 4-6 months (Home visit - survey interview, developmental mile stones, red book) £M	2-3 years (Home visit – survey interview, developmental measurement) £M	Core team £M	Total (rounded) £M
n=20,000	4	1.6	4.5	5.3	4.7	20
n=25,000	4.8	2.0	5.4	6.4	4.7	23
n=30,000	5.6	2.4	6.3	7.4	4.7	26
n=50,000	8.5	4.3	9.8	11.3	4.7	39

Note: The first row in the table includes fixed and variables costs roughly split 25% fixed, 75% variable

The cost of the NPS data collection based on an initial achieved sample of 20,000 mothers with four data collections works out at £20M pounds, which runs close to the cost of the total budget available £21-23M. The cost for an achieved sample of 50,000 mothers, as originally specified, comes to £39M.

(b) Area core data collection costs

5.6 Table 5.3 shows the costs of data collection for different numbers of area studies each of which is based on the initial achieved sample of 5,000 mothers.

Table 5.3 Area Study core data collection costs

Area studies	Pre natal (Home visit- survey Interview £M	Birth (Midwife) (medical records and biomedical samples) £M	Post natal – 4-6 months (Home visit - survey interview, developmental mile stones , red book) £M	2-3 years (Home visit – survey interview, developmental measurement) £M	Area team £M	Total (rounded) £M
None	0	0	0	0	0	0
One	0.8**	0.4	0.9**	1.1**	1.8	5
Two	1.6**	0.8	1.8**	2.2**	3.6	10
Three	2.4	1.2	2.7	3.3	5.4	15
Four	3.2	1.6	3.6	4.4	7.2	20
Five	4.0	2.0	4.5	5.5	9.0	25
Six	4.8**	2.4	5.4**	6.6**	10.8	30

This shows the cost of one area study at £5M, which would stretch the budget even for combination with an NPS at the minimum realistic size, 20,000, beyond its current limit

(c) Combined design

5.7 Table 5.4 shows the cost of combining the NPS survey at 20,000 with different numbers of area studies.

Table 5.4 Combined design data collection costs

Type of study	Pre natal (Home visit- survey Interview £M	Birth (Midwife) (medical records and biomedical samples) £M	Post natal – 4-6 months (Home visit - survey interview, developmental mile stones , red book) £M	2-3 years (Home visit – survey interview, developmental measurement) £M	Team Costs £M	Total (rounded) £M
NPS n=20,000	4	1.6	4.5	5.3	4.7	20.
One area	4.8	2,0	5.4	6.4	6.5	25.
Two areas	5.6	2.4	6.3	7.5	8.3	30.
Three areas	6.4	2.8	7.2	8.6	10.2	35
Four areas	7.2	3.2	8.1	8.7	11.9	40
Five areas	8.0	3.6	9.0	10.8	13.7	45
Six areas	8.8	4.0	9.9	11.9	15.5	50

The figures identify a substantial budget shortfall for all but the most modest version of the ideal plan. The present budget (£21-23 million) would support a programme comprising four data collections, but no area studies. The survey costs for one area study, in which core data collection is carried out by the national agency, pushes the costs up to £25 million, two area studies to £30 million and 6 area studies to £50 million.

(d) Savings

5.8 Clearly to meet the requirements of the programme savings have to be found by considering different options. Options to consider are:

1. Reducing the overall sample size from 50,000 to 20,000, i.e. no area

studies
2. Removing one of the three data collections: pre-natal visit, post natal visit at 4-6 months; age 2-3 years visit
3. Suspending all biomarker data collection until supplementary funding is assured, targeted specifically at this purpose, e.g. Wellcome Foundation.
4. Using telephone or postal methods for home-based interviewing

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5.9 A number of assumptions need to be addressed in reviewing these options:

1. The savings to be gained from a given survey by reducing sample numbers give only marginal savings because of the survey setup costs, which represent 25% of the survey costs. NatCen estimates show the marginal cost of an additional 10,000 interviews at £1.6million against the cost of the initial 20,000 survey which including the setup cost, works out at £4million. Area study survey costs with field work conducted by the national agency are priced at the same rate as for the national survey. However if interviewers were all recruited locally it is likely there would be savings because of the reduce travel costs

2. Core costs cover all core clinic-based data collection, and core survey data costs if collected by local teams, rather than the national agency.

3. Core team and area teams' costs are relatively fixed across the period of the programme, with data collections repeated at frequent intervals, so there is no easy way in which cost reductions can be made reflecting fluctuations in the survey operations themselves, i.e. the full team needs to be in place for most if not all of the period once piloting begins.

4. Clinic based biomedical measurement, including use of equipment and sample storage, is identified as a separate core cost from other data collection in accordance with the options given in chapter 3. Processing of biomedical data is not included. All other data collection on parents or children is included in the estimates of core survey costs.

5.10 Each option for reducing costs is now considered:

1. Removing one of the three data collections: pre-natal viit, post natal visit at 4-6 months; age 2-3 years visit

Of the three possibilities here our preference is for postponing the third (age 2-3) survey. This would not only permit a much wider range of standardized measurement, but would move the survey into the next phase of the

programme for which new funding will be sought, possibly attracting the interest of government departments such as Education with a special interest in the preschool period: ***savings= £11.9M***

2. Suspending all biomarker data collection until supplementary funding is assured, targeted specifically at this purpose

This would offer medical funders such as Wellcome the opportunities for a major stake in the study: ***savings= £4.00M***

3. Reducing the total achieved sample size from 50,000 to 20,000

This would exclude the area studies from the programme. To restore them would mean drawing additional funding into the study from e.g. Local Authority and Health Services in funding a cohort study to serve local as well as scientific purposes c.f. “Born in Bradford”, “Newham Panel Study”. Interest has already been shown in the possibility of such an area study in the GLA. If 50% of funding was raised from local sources – ***savings = £5 million per area study***

4. Using telephone and postal data collection methods

These options could reduce the cost of data collection considerably
The problem with them is the constraint placed on time and coverage (telephone) and the potentially damaging effects on data reliability and response (postal) - ***savings would be £2M for telephone and £2.7M postal for the first survey, i.e. across all three in the order of £6M for telephone and £8M for postal***

(d) Conclusions

5.11 Ruling out the last option the costs of different options in our order of priority are:

1. NPS 20,000, fourth survey postponed, 3 area studies = £26M
2. NPS 20,000, fourth survey postponed, 2 area studies = £23M
3. NPS 20,000, fourth survey included, 1 area study = £25M
4. NPS 50,000, fourth survey postponed, no area study = £28M

5.12 We conclude that option 1 offers the optimum means of meeting the scientific aims of the programme. However the budget would need supplementation of in the order of £3million from national or local sources to pay for it, or further savings would need to be found by, for example, replacing the first postnatal home visit interview by a telephone interview or postal contact. (For the reasons given above we believe that both these options would significantly reduce the quality of the study and should be ruled out.)

5.13 Reducing the area studies to two (option 2) brings the cost down to

£23M which is just within the budget but weakens the programme scientifically. Retaining the fourth survey, even with only one area study (option 3), requires £25M, which is still above budget. It would also eliminate the key replication function from the programme. If the whole study reverted to the traditional model of the single NPS survey expanded to 50,000 as discussed in section 2 (option 4) the cost would be £28M, the highest cost of all, and the main innovative features of the programme would be lost.

5.13 Under all options means would still need to be found to meet additional cost elements including longitudinal piloting (£2M) and a budget for area studies specialised investigations (£1M) – the second of which might be sought from the research budget in ESRC. The PhD studentships might similarly be eligible for support from ESRC's training budget.