Author's response to reviews

Title: Protocol of the Baseline Assessment for the Environments for Healthy Living (EHL) Wales Cohort Study

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Author's response to reviews: see over
Dear editors

Reviewer: Vincent Jaddoe

Thank you very much for the opportunity to address the comments of the reviewers. Please find our amendments outlined below.

1. Give some ideas about new ideas and approaches to similar studies (ALSPAC, MOBA, DBC, SWS, Generation R). What does this study add to all the existing cohorts?

(Pages 7-9). In terms of its design, EHL has many similarities with other prenatally-recruited birth cohort studies, including the Avon Longitudinal Study of Parents and Children (ALSPAC), the Generation R study, the Danish National Birth Cohort study, and the Norwegian Mother and Child Cohort Study (MoBa) [26-29]. These similarities also extend to its collection of umbilical cord blood, which will provide an important resource for immediate and future epidemiological studies. However, due to issues of feasibility, we will not collect biological samples from mothers during pregnancy or DNA from the offspring, as has been done elsewhere (e.g. [30]). Finally, and in agreement with other birth cohort studies (e.g. [26, 27]), we plan to develop a randomly-selected ‘focus cohort’ with which we can pursue more time-consuming data collection methods, including parental interviews and other air quality sampling techniques such as dust sampling. Related to this, formal collaboration with other birth cohort studies is currently a high priority.
Despite its similarities in design, EHL also departs from other birth cohort studies in some important respects. Our study focuses on research gaps which were identified at the two-day workshop held at the Wellcome Trust in 2008 to improve the research potential of existing longitudinal data. These gaps include objective, measured data as opposed to subjective data (e.g. accelerometer records of physical activity as opposed to questionnaire assessment), and measurements in pregnancy as opposed to postnatal baseline measures. Related to this, a major strength of this study is its use of home visits with study participants. These visits occur during the participant’s pregnancy and enable objective measurements to be taken of the housing, neighbourhood, and parental/intrauterine environments. In this way, exposure information is collected by the researcher(s) in person, rather than by more remote methods such as telephone interviews as has been done in the Danish National Birth Cohort study [28]. As all home visits will occur during the gestational period, no mothers will be recruited to the study after the birth of their baby, which contrasts with the Generation R study [27]. Further, participants will not be requested to attend dedicated research centres for the purposes of the study, as they are elsewhere [27], thereby reducing the participant burden which may bias recruitment in birth cohort studies and risk substantial loss to follow-up [31]. In addition, this study responds to a recent call for new birth cohorts to involve fathers as a traditionally hard-to-reach, low-responding group in order to provide a fuller understanding of life-course epidemiology and the intergenerational transfer of health risk [32].

2. More specific details for the measurements are needed (time schedules, tools, questionnaires (e.g. ISAAC questionnaire for asthma)).

(Page 8). The focus will be on doctor-diagnoses of health outcomes (which will be uploaded and anonymously linked at the individual level in the SAIL databank) rather than parental report. Doctor diagnoses were selected as the optimum measure of
outcomes because, and despite other findings to the contrary (e.g. [33, 34]), parental report of symptoms has been shown to be sometimes inaccurate [35, 36] and influenced by symptom understanding, perception, and underestimation [37-39], and the duration of recall and the seriousness of the health event being recalled [40]. This potential inaccuracy of parental report may in turn limit researchers’ investigations of socio-demographic and ethnic variations in asthma prevalence [37], and so will be avoided in this study.

(Page 11). The home visit will occur at any time during pregnancy.

(Page 12). Mothers and fathers will be requested to complete a seven-day diet diary, noting all meals (breakfast, lunch, dinner), snacks and drinks consumed each day. This will be recorded using a validated, self-reported seven-day food diary, supplemented by a questionnaire, for dietary assessment [47]. The food diary will be analysed by Health Options Ltd (Health Options Ltd, Cirencester, Gloucester, UK). Average daily kilojoules, percentage total fat, saturated fat, carbohydrate, protein and fibre will be calculated. Objective measurements of maternal physical activity will be achieved using Actigraph accelerometers [48]. Mothers will be requested to wear the accelerometer around the waist for seven continuous days, removing the device only for sleeping, bathing and swimming. The accelerometer will record data relating to the frequency and duration of light, moderate, and vigorous physical activity.

(Page 12). Measurements will be taken of noise levels, temperature, relative humidity, and nitrogen dioxide over seven days, beginning at the time of the home visit.

(Page 13). Nitrogen dioxide will be measured using Palmes-type, passive diffusion tubes [51]. Four will be employed at each home visit: in the parental bedroom, the
living room, the kitchen, and immediately outside the home in the vicinity of the front
door, away from gas appliances on all occasions. The noise meter, Data Loggers, and
diffusion tubes (as well as the diet diaries and accelerometer) will be collected by a
researcher seven days after the home visit. In addition, a Home Assessment will be
completed by the researcher with assistance from the participant/occupant. Information
included in the Home Assessment will cover: the age of the home, and the presence and
extent of double glazing, loft and cavity wall insulation, and mould and/or water
damage.

(Page 13). A further aspect of the Home Assessment is the researcher’s visual
inspection of the home for hygiene, cleanliness and general presentation. The ‘family
cleanliness scale’, used by social workers in the UK to assess children at risk of neglect,
is used for this purpose [53]. Information will be recorded by the researcher(s)
immediately after the home visit.

(Page 14). Participants will be asked to consent to researchers having access to their
maternity notes following the birth of their baby. These notes will provide data
regarding the pregnancy (and previous pregnancies), family health histories, and the
health and development of the baby up to age six weeks.

3. More specific details about biological samples (only cord blood?), also DNA,
urine samples?

(Page 7)...Due to issues of feasibility, we will not collect biological samples from
mothers during pregnancy or DNA from the offspring, as has been done elsewhere (e.g.
[30]).
4. Why perform this study in this region? What is the region like? Please provide any population characteristics.

(Pages 10-11). Having the sample concentrated in one geographical area (in and around Swansea) is anticipated to assist the face-to-face recruitment of participants (either by researchers or local midwives) and the collection and storage of umbilical cord blood samples.

Swansea is located in south Wales, and is Wales’ second largest city. Latest figures show that Swansea has a population of 229,100 and an annual birth rate of 2,700 [42]. Swansea’s population is growing year-on-year, largely driven by inward migration from outside the UK [42]. Swansea has a mixture of different social backgrounds, housing types, and urban and rural areas. Currently, Swansea has the third largest black and ethnic minority population in Wales [43], and is ranked fifth highest amongst local authority areas in Wales for child poverty (the proportion of children in household with income poverty) [44]. The latest Welsh Index of Multiple Deprivation (2008) shows that Swansea has the single most income deprived (Castle 2) and single least income deprived (Killay North) areas in Wales [45]. Similarly, in terms of employment, Swansea has the second most deprived (Castle 2) and the least deprived (Killay North) areas in Wales [46]. This diversity of the population of Swansea will enable researchers to investigate area and locality effects and the spatial distribution of services, amenities and greenspace, and to conduct geographical mapping of incidence.
5. A figure presenting different data collections (also link with registries) might be relevant.

Figure 1: Data collection sources with links to routine data

**Home/neighbourhood**
- EHL data collection:
  - Noise
  - Temperature
  - Humidity
  - Nitrogen dioxide
  - Mould and damp
  - Home Assessment

**Gestational environment**
- EHL data collection:
  - Parental diet
  - Parental body composition
  - Maternal physical activity
  - Maternal medication use

**Routine data:**
- Pollution maps
- Noise maps
- Home Assessment (in maternity notes)
- Geographical mapping data

**Socio-economic status**
- Parental education
- Family medical histories
- Lifestyle/health behaviours
- Umbilical cord blood

**Routine data:**
- Maternity notes
- Foetal ultrasound scans
5. Results from pilot studies available?

(Page 10). EHL is currently in its pilot phase to determine the efficiency of its recruitment and data collection processes. To date, and after the first five months of recruitment efforts, 137 women have expressed their interest to participate in EHL. Home visits are already underway with a good geographic spread and cross-section of the Swansea community in terms of household income, employment and housing conditions. No results from this pilot study are currently available.

We thank you for the opportunity to respond to the reviewer’s comments, which we feel have been highly valuable to this manuscript.

EHL has gained ethical approval from the South East Wales Research Ethics Committee (09/WSE02/37), as is funded by Swansea University.

The Study Protocol has not been submitted for publication nor has it been published in whole or in part elsewhere.

I declare that no authors others than those listed on the title page were involved in drafting and approving the manuscript. The authors have no competing interests.

With many thanks and best wishes

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