

SCIENTIFIC REPORT

Workshop on Consent and Network Objectives February 17-18th, 2009 Paris, France

SUMMARY

The ESF Research Networking Programme EUCCONET, the European Child Cohort Network, started its activities with a first two-day workshop taking place on February 17-18th 2009, in Paris, France. This workshop was hosted by the French National Institute for Demographic Studies, home institution of the Co-Chair of the EUCCONET Steering Committee and Director of the French national child cohort ELFE, Henri LERIDON. These two days were meant to engage the first steps toward the achievement of the objectives of the network which are: (i) identifying cohort expertise in Europe; (ii) sharing knowledge and experience with a broad range of cohort experts, including from outside Europe, and establishing a forum for an easy accessible expertise on these issues in Europe; (iii) offering opportunities to go deeper on the cross-country comparison by sharing tools and questionnaires.

The first day focused on discussions about the working methodology of the network. In the morning, partners were introduced and addressed the issue of the communication strategy of the network, particularly as regards the creation of a EUCCONET website and the collaboration with other European cohort networks and projects. In the afternoon, partners were invited to express their views and expectations for the network in an open discussion chaired by both EUCCONET Steering Committee chairs Heather Joshi and Henri Leridon. The discussion was based on a survey which was conducted in 2008 among key partners of the network. The survey proposed several themes, for each of which people were supposed to indicate if they would like to participate in a working group on the subject and/or whether they would like to attend to a meeting on the subject. Themes which gathered the greatest interest were discussed and by the end of the day eight interest groups and their leaders were identified to organise further activities in 2009 and 2010. The outcomes of this day's discussions were later approved by the EUCCONET Steering Committee which met straight after the workshop.

The morning session of the next day was reserved for a scientific discussion on the subject of **Consent**, which is a subject of fundamental importance for cohort studies, since the participants' consent is an absolute prerequisite to starting a cohort study in the first place. In the case of child cohorts, the issue of consent raises specific questions such as: who should give the consent: one or both parents? Should children be at some point asked for their personal consent? And more generally, the issues of the form and content of the consent, and how to communicate with the families and secure their long-term commitment, were also addressed. Several European cohort representatives presented the way they secure consent in their study. Especially, the failure of one Swiss project presented the obstacles that can be met while planning to create a cohort.

DESCRIPTION OF CONTENT AND DISCUSSIONS

1. Network objectives

Firstly a round table allowed all participants to introduce themselves and present their cohort study(ies). This is very important for the synergy of the network and to ensure the good communication that could lead to further collaborations in the future, especially since it was the first time that network partners got together. Following a previously given format, each cohort representative presented their study, including the number of children enrolled, the year it started and the different stages at which children and families were interviewed, as well as the various scientific fields covered by the study. Partners also mentioned the collaborations they have with other cohorts or cohort networks, as well as their own expectations about EUCCONET.

During this round table, the themes mostly evoked were:

- the importance for generalist cohorts to develop common questionnaires
- and for them to collaborate with specialised cohorts, on the one hand to share their experience on very specific issues,
- the opportunity given by the network to reflect on data comparison and to collaborate with each other in view of making data comparable

Afterwards, Martine Vrijheid, who works for the INMA cohort in Spain and the RHEA cohort in Greece, presented two EC projects on health-focused cohorts which are both coordinated by her host institution CREAL (Center for Research in Environmental Epidemiology):

- **‘ENRIECO - Environmental Health Risks in European Birth Cohorts’** - This project was granted by the European Commission in the frame of the 2008 FP7 call for ENVIRONMENT “Databases based on European cohort studies and their exploitation for advancement of knowledge of environment-health relationships”, and start in March 2009. In order to advance knowledge on specific environment and health relationships in pregnancy and birth cohorts by providing support to data exploitation, this coordinating action intends to create an inventory of European birth cohorts studying environmental exposure, evaluate their data and tools, and especially the obstacles to create efficient databases.
- **‘CHICOS - Developing a Child Cohort Research Strategy for Europe’** - This proposal was submitted in response to the 2009 FP7 call for HEALTH “Birth/Mother - Child cohorts coordination” and awaits the answer of the European Commission. The objectives of this project are to create an inventory of birth/child cohorts in Europe, evaluate the existing information on child health outcomes and determinants, and then to make recommendations to improve the contribution of child cohorts to European policy makers. If granted, funding would not start until 2010.

Both projects intend to update the inventory www.birthcohorts.net , a website created as part of EC projects ChildrenGenoNetwork (FP5) and EARNEST (FP6) which currently focuses on studies of how nutrition and specific gene environment interactions affect child health, with information on cohorts with environmental exposure data on the one hand (ENRIECO), later including cohorts without biologic material and cohorts focusing on social determinant of child health (CHICOS).

This presentation started a big discussion on how EUCCONET should collaborate with these projects and with other websites presenting cohort inventories (e.g. the cohorts' own websites), since it was also a mandate of EUCCONET to create an inventory of child cohorts in Europe. The general opinion was that it was not necessary to put work into something that's already done or being done and that EUCCONET should avoid creating any overlap or redundancy. EUCCONET should collaborate with those projects by providing information on the cohorts which are not covered by them and fall within its scope and providing links to more detailed information existing elsewhere. A working group was created to reflect on those collaborations and more broadly on the functionalities that should be developed on the EUCCONET website.

The vision of the EUCCONET website being a single portal linking to cohorts and cohort networks has also been evoked. This would reinforce EUCCONET's function of coordination of child cohort information and communication at European level. To this end, child cohort studies and networks should be approached.

In the afternoon the plan to create interest groups on specific themes was particularly addressed. With the impulse of both Steering Committee Chairs, seven interest groups were identified to organise event in the following years, i.e. 2009 and 2010:

◆ **Specific instruments for measuring child development –**

Leader: Alexander Grob

This group will cover the measurement of health outcomes alongside cognitive and socio-emotional development of children. ...

◆ **Designing specific materials for children interviews –**

Leader: Kate Smith

Obviously children are an audience which requires very specific material adapted to their age and level of perception and understanding. It is important to know from what point the children can be personally interviewed, what questions can be asked at what age and how the study should be presented to them as to ensure their willingness to fully participate. This requires specific materials and techniques to communicate with children.

◆ **Different modes of data collection –**

Leader: Joachim Heinrich

There are different ways of collecting data: face-to-face interviews, phone interviews, questionnaires sent per post; should the people be met at school, at home or in a specific place? Although this greatly depends on various factors such as the type of data being collected, from whom and at what stage, this interest group will try to define pros and cons for each mode of data collection.

◆ **The role of fathers in child cohorts –**

Leader: Harald Werneck

At the early stage, most cohorts interview the parents in order to have information on the children's environment and behaviour. In most cases mothers are more involved in the study, which raises the issue of the role of fathers in cohort studies. Certainly they would bring another view of their child than mothers do. But the issue of fathers raises the question whether the biological father or the everyday-caring father should be taken into account (this depends whether the focus is on genetic follow-up or day-to-day social environment and exposure). How should fathers be included in the

studies? How should cohort studies deal with couples' break-up, new unions and non-resident fathers? ...

◆ **The maintenance of large cohorts –**

Leader: Lisa Calderwood

The European Child Cohort Network focuses on studies having a sample size of minimum 1000 children, but most cohorts represented deal with much bigger samples. A lot of questions are linked to this factor: How do we ensure the participation of the families in follow-up surveys and into the long term? What means are used to keep track of respondents and retain their consent to participate? Another aspect of cohort maintenance is the problem of assuring funding from short-term sources for a long-term enterprise.

◆ **Record linkage –**

Leader: Andy Boyd

It is very interesting for cohort studies to be able to link the data collected to the other data existing for example in police or social security files about the people being followed. This can be very easy, for example, in Norway where each person gets one single identity number which is used in all aspects of his/her administrative life, but very difficult when all administrations use different numbers, which is mostly the case in European countries. Which information is relevant? Does this linkage require another specific consent from participants? How should the linkage be technically managed?

◆ **Data management –**

Leader (provisional): Andy Boyd, Wenche Nystad

This group will gather the data managers of the partner cohorts in order to discuss the informatic systems used to store, secure and anonymize the data.

Other themes that could be explored in the following years are for example the methods for data analysis or the acceptability, feasibility, and ethics of collecting biological samplings on children.

Another group was also created to define specifications for the EUCCONET website, which will present a register of child cohorts as well as a register of literature and documents on cohort maintenance and on the research emanating from the studies. As such it is intended to become a major portal of information about cohort studies.

● **Results and Impact**

- Sense of belonging
- Synergy
- Networking and Positioning at European and global level
- Plans for staff exchange visits between teams
- Meeting international counterparts
- Awareness of opportunities given by the programme: making international collaborations and data comparison projects
- Securing involvement in the programme
- Sharing experience
- Expressing expectations

2. Consent

Parents of child cohorts have to answer various questionnaires on their child's physical and psychological development as well as on the family environment. The creation of a child cohort requires the effective consent of the parents either that their child should be followed up through his or her childhood, or that they will be open to a succession of invitations to participate. In some studies they may be asked for formal consent at the outset to commit their cooperation for the long-term (and indeed to agree that once the child is able to respond personally he or she should be contacted to answer further questionnaires). Alternatively, instead of one long-term consent at the start, it may be possible to ask for consent one survey at a time, in the knowledge that the study would like to keep in touch with them later, but without insisting immediately and formally on a long-term engagement. In either approach to the engagement of the parents in the long term, it appears nowadays to be much more difficult to get parental consent and thus to create and sustain a sample. The success of follow-up may depend more on interest in the experience *ex post* rather than eliciting an obligation *ex ante*. Therefore it is important to discuss how should the researchers communicate about their study in order to encourage more people to sign up, within the principles of research ethics?

The first presentation was from Prof Alexander Grob, from the Faculty of Psychology of the University of Basel, in Switzerland. He presented the SESAM project, for which he was deputy director. *SESAM, the Swiss Etiological Study of Adjustment and Mental Health*, was designed to focus on the complex multi-directional interactions of psychosocial and genetic-biological variables across time and between generations by combining longitudinal, cross-sectional, and experimental approaches in an interdisciplinary strategy that included both pathogenic and salutogenic trajectories. Beginning with pregnancy and including the entire risk period for the development of most mental disorders, a non-treatment population sample of 3,000 children should be studied together with their parents and grandparents. The integration of psychological, social, and biological factors in a truly interdisciplinary framework was expected to allow for the conceptualization of multilevel phenotypes and the analysis of complex dynamic interactions with genetic and psychobiological variables. Comprehensive, detailed, and valid assessments was assumed to go beyond the usual self-reported data, e.g., structured interviews, behavioral observations, cognitive assessment, vagal tone, genetic polymorphisms etc. *SESAM* was granted funding with highest priority from the Federal Government on recommendation of the Swiss National Science Foundation after competitive evaluation and selection in a strict international review process. But, very early local left-wing and green political parties were critical of the study, local media reports were negative, and a non-profit organization succeeded in collecting 12000 votes against the study. The public and leading psycho-analysts alike questioned the study's approach to mental health. Others were suspicious of the collection of genetic data. Most importantly, due to the public attention the local ethic commissions evaluated the NCCR *SESAM* in a different manner, i.e., much more rigorous, repeatedly changing former decisions, criticizing the scientific value of the study, influencing importantly the study design, and communicating these changes to the media without contacting the study group. In parallel, a Swiss wide political debate started on the ethical legality when research is conducted with children who are not able to give their consent and when subjects do not have a direct benefit from participating in a study. Finally the project had to be stopped before the end of the pilot stage.

The second presentation was from Kate Smith and Lisa Calderwood, both Survey Managers for the *Millennium Cohort Study* of the Center for Longitudinal Studies in London,. The *UK Millennium Cohort Study* is a longitudinal birth cohort study following the lives of around 19000 children living in the four countries of the UK, born between September 2000 and January 2002. There have been four surveys to date, at age 9 months and ages 3, 5 and 7. This presentation described the ways in which consent has been gained to date and discussed some of the issues for the future as the children become the focus of the study. Informed consent has been obtained for every survey one at a time, and for linkage to administrative records. The initial contact was on the basis of a face-to face (unwritten) opt-in, on the doorstep, of families who had not already opted out on an approach by post. From the second survey, parents have been asked to provide written consent for various elements of each survey. Each consent form is accompanied by an information sheet. Although it has no legal value per se, they decided to ask the children's personal (so far unwritten) consent from age 7

Wenche Nystad works for the National Norwegian Institute for Public Health as Manager of the *Mother and Child Cohort Study "MoBa"* which focuses on environment exposure and genetic factors. The study aims to recruit 100.000 pregnancies by 2008. Women coming to the hospitals for an ultrasound are automatically listed and contacted to participate to the survey. Since Norwegians all have a single identification number for all public services, it clearly eases the procedures of linkage to medical registries etc. Both parents give their consent once for the first seven years of the study.

Details of the *Born in Bradford* study were presented by Pauline Raynor (Programme Manager) and Neil Small (Academic Lead and Professor of Health Research at the University of Bradford). *Born in Bradford* is a birth cohort study in the process of recruiting 10000 pregnant women in the city of Bradford in the north of England. Partners are also recruited where possible. The local Research Ethics Committee has interpreted consent in a relatively wide ranging way to include ongoing data collection around a range of research questions, and to include access to routine data collected by all local health personnel. They discussed the nature of this consent and the implications for the cohort and also questioned what consent might be required for a study whose aim is linked to a public health agenda around changing community understandings, attitudes and practices in areas related to infant and child health. *Born in Bradford* seeks to operate a system of "community consent" whereby both cohort members and members of the public input their views about specific research questions and in so doing act to both scrutinize research that is proposed and advocate for subjects not yet included. Community consent is particularly important in Bradford where half of the cohort members are of Pakistani origin and it is necessary to both engage with their priorities and to initiate change in ways that can be sustained in their community.

James Williams presented the *Growing Up in Ireland* cohort study. This study is funded by the Government and operated as part as the National Statistical System. The objective is to study the lives of 2 cohorts of children aged 9 months and 9 years, for at least 2 interviews. The 9-year-olds are recruited directly in a random sample of 850 schools, which clearly eases the process of securing the initial informed consent. Once the

children within the age scale are selected, they are given an information pack to give back home to their parents containing all necessary information, in different languages, about the background and purpose of the study, what the participation involves, and more importantly everything about confidentiality and withdrawal issues. Consent is then secured through the signature of both parents and children are also required to sign an “assent form”. For the infant cohort, families are selected randomly from the Child Benefit Register and first contacted per post then met personally. Consent forms, including consent to linkage to various health records, have to be signed before interviews and measurements can start.

- **Results and Impact**

The round of discussion recognised that different ways of securing consent depend greatly on the study design but also on the rules that can be imposed on the researchers by the Ethical Committees and/or the State. It is very important to be aware of the legal context surrounding all cohort related issues and also of all the necessary procedures. This workshop helped all participants realize the many possible ways to secure consent but most of all apprehend differently their local situation as regards rules and authorizations.

Along with securing the initial consent, the importance of communicating with the participating families all along the study has clearly been underlined. Special material should be developed for children and parents so as to explain the objectives and the functioning of the study, and also to ensure their continuing involvement in it. The material can present the results of the study, which helps people realize to what they contributed, but also prepare them to the coming of a next stage of interviews.

Since the topic of consent is closely intertwined with the one of communicating with the participants, it also raises the issue of adapting to the local context. Nowadays cities and countries are multicultural and if the study wants to be representative of the population, it should take care to include immigrant communities. This may require sets of documentation in different languages or the interviewers to follow specific training for intercultural communication.

This represents expense lines which have to be thought of at the very beginning of the study design.

The session was also an occasion for the participants to discuss the issue of whether or not to include the fathers, and whether it should be the biological and/or caring father, but mostly the answer to this question obviously depend on the research focus of the study.

APPENDIX - FINAL PROGRAMME AND LIST OF PARTICIPANTS

Participants:

1	Henri Leridon	Growing up in France ELFE	INED, France	SC
2	Anne-Claire Blanchard	Coordinator	INED, France	-
3	Heather Joshi	Millenium Cohort	Center for Longitudinal Studies, UK	SC
4	Lisa Calderwood	Millenium Cohort	CLS, UK	-
5	Kate Smith	Millenium Cohort	CLS, UK	-
6	Joachim Heinrich	LISA	Helmhotz Zentrum, Institute for Epidemiology, Germany	SC
7	Wenche Nystad	Norwegian Mother and Child Cohort Study	Norwegian Institute for Public Health, Norway	SC
8	Stéphanie Vandentorren	Growing Up in France, ELFE	INED, France	-
9	Alexander Grob	SESAM	University of Basel, Switzerland	SC
10	Vincent Jaddoe	The Generation R Study	Erasmus Medical Center, Netherlands	SC
11	John Bynner	<i>in planning</i>	Longview, UK	-
12	Harald Werneck	-	University of Vienna, Austria	SC
13	Lynn Molloy	ALSPAC	University of Bristol, UK	SC
14	Andy Boyd	ALSPAC	University of Bristol, UK	-
15	Haluk Topaloglu	---ESF EMRC----	Hacettepe University, Turkey	SC
16	James Williams	Growing up in Ireland	Economic and Social Research Institute, Ireland	-
17	Martine Vrijheid	INMA Spain, RHEA Greece	CREAL, Spain	-
18	Monica Guxens	INMA Spain	CREAL, Spain	-
19	Paul Bradshaw	Growing up in Scotland	Scottish Center for Social Research, UK	-
20	Pauline Raynor	Born in Bradford	University of Bradford, UK	-
21	Neil Small	Born in Bradford	University of Bradford, UK	-
22	Sandra Buchholz	NEPS	University of Bamberg, Germany	-
23	Kristine Vejrup	Norwegian Mother and Child Cohort Study	Norwegian Institute for Public Health, Norway	-
24	Pierre Turcotte	ELDEQ/NLSCY	Statistics Canada	-
25	Pascal Arduin	ELFE Growing up in France	INED, France	-

Programme

Venue: INED, Room “Alfred Sauvy”, 1st floor

- Tuesday, February 17th -

Welcome coffee

Morning Session - 9h-13h

PRESENTATION AND WORKING SESSION

9h00 - Round table for the presentation of partners

11h -Health break

11h30 - Potential for collaboration between EUCCONET and other European birth/child cohort coordination projects

Martine Vrijheid, Center for Research in Environmental Epidemiology

12h00 - Building up EUCCONET

Anne-Claire Blanchard, EUCCONET Coordinator

13h - Lunch at INED + Coffee

Afternoon Session - 14h-18h

Chairs: Henri LERIDON and Heather JOSHI

- Discussion on the identification of thematic working groups and elaboration of a work plan

19h30 - Collective Diner at the restaurant Les Bas Fonds

- Wednesday, February 18th -

Morning Session - 9h-13h

THEMATIC WORKSHOP ON CONSENT

**9h- SESAM - Swiss Etiological Study of Adjustment and Mental Health Study
Design and Steps towards the Impossibility to Take-off**
Alexander Grob, University of Basel

9h50- Issues of Consent in the Millenium Cohort Study
Kate Smith, Center for Longitudinal Studies, UK

10h25 - Health break

**10h45- Informed consent - experiences from The Norwegian Mother and Child
Cohort Study**
Wenche Nystad, Norwegian Institute of Public Health

11h20- Community consent in the Born in Bradford birth cohort study
Neil Small and Pauline Raynor, University of Bradford

11h55- Securing informed consent - Growing up in Ireland
James Williams, Economic and Social Research Institute, Ireland

12h30- Final Discussion

13h -Lunch at INED + Coffee

Afternoon Session - 14h-17h

STEERING COMMITTEE MEETING

(reserved)

Agenda:

- Output from previous day - Activities for 2009
- Communication plan (logo, website, newsletters...)
- Budget 2009
- Bylaws (creation of sub-group for acceptance of applications)
- AOB