

## Tracking the lives of 20,000 children Launch of the Elfe child cohort study

*Marie-Aline Charles\*, Henri Leridon\*, Patricia Dargent\*, Bertrand Geay\* and the Elfe team*

Twenty thousand children born in France in 2011 will be followed from birth to adulthood to understand how the environment, their family life and their living conditions affect their health and development. The lead scientists of this study co-ordinated by INED and INSERM – the first of its kind ever conducted in France – explain the reasons behind its launch, the method used to recruit and follow the cohort of children, and the results they expect to achieve.

Child development depends partly upon genetic makeup, but is determined above all by a process of constant interaction with the environment. This environment has changed considerably in recent decades. For example, children now spend more years in education, eat differently, do less physical exercise and are exposed to higher levels of air pollution and to new chemical pollutants. Their family backgrounds are also much more diverse than in the past.

The Elfe longitudinal study of children (Étude longitudinale française depuis l'enfance), launched in the field at the end of March 2011, will follow 20,000 children in France from birth to adulthood. The aim is to gain new insight into the ways in which, from pre-birth to late adolescence, their environment affects their development, their health, their socialization and their school career (<http://www.elfe-france.fr>) [1].

\* Elfe joint research unit of the Institut national d'études démographiques (French National Institute of Demographic Studies, INED) and the Institut national de la santé et de la recherche médicale (French National Institute for Health and Medical Research, INSERM).

### ◆ Multiple factors affect child development

The experiences of the first years of life, and even before birth, are decisive in shaping the adult that a child will later become. It has been shown that environmental factors in the prenatal and early postnatal period (diet, physical activity and stress levels of the mother, exposure to infectious agents, drugs, environmental pollutants, etc.) influence the onset of obesity, asthma, allergies, certain mental disorders and even conditions occurring in adulthood, such as diabetes, cardiovascular diseases and osteoporosis. This particular vulnerability of the fetus and baby is due mainly to the immaturity of their rapidly growing organs and tissues.

Given the multiple factors involved and their numerous interactions, research in this field is particularly complex. It calls for detailed observation of children's trajectories, involving the identification and sequencing of key events during childhood, and of changes in a child's situation or state (for example, entry into or exit from poverty, transition from childhood to adolescence,

family events, etc.), measurement of cumulative exposure to specific environmental conditions, and assessment of their consequences in terms of social and health inequalities. Children's outcomes can only be understood by studying the history and evolution of their social, familial, physical and health environments.

### ◆ A cohort followed from birth to adulthood

The best way to make this type of analysis is through a cohort study. This involves selecting a large sample of children whose lives are followed throughout their development, if possible until they reach adulthood. In the specific context of child development, it is important to begin the observation as early as possible (from birth or even pre-birth), to adopt a multidisciplinary approach, and to build a sample that is representative of the population as a whole so that an accurate picture of all children born in a particular year can be obtained. Such cohorts have existed in other countries for many years, but not, until now, in France. Yet the socioeconomic context and the degree of exposure to environmental risks vary greatly between countries.

The United Kingdom was a pioneer in this field, with the creation of the first nationally representative cohort in 1946 (The 1946 National Birth Cohort, NBC: 5,360 children), and further cohorts in 1958, 1970 and 2000 (Millennium Cohort: 18,800 children). Cohorts have also been set up in the United States, in Canada, in Ireland, in Scotland, in the Netherlands and in Australia (see article [2] for a detailed description of the different cohorts across the world).

### ◆ The origins of the Elfe project

Elfe is a multidisciplinary project born out of the questions raised by researchers and the concerns expressed by various public bodies over the last ten years. It was the national health and environment plan (Plan national Santé-environnement) of 2004 that provided the decisive impetus for the project to go ahead. The study took practical shape in 2006 and has been run by a joint INED-INSERM research unit(\*) since March 2010. It is supported by its two host institutions, by the French Institute for Public Health Surveillance (InVS), INSEE, three ministerial departments, and the national family benefits fund (Caisse nationale des allocations familiales).<sup>(1)</sup>

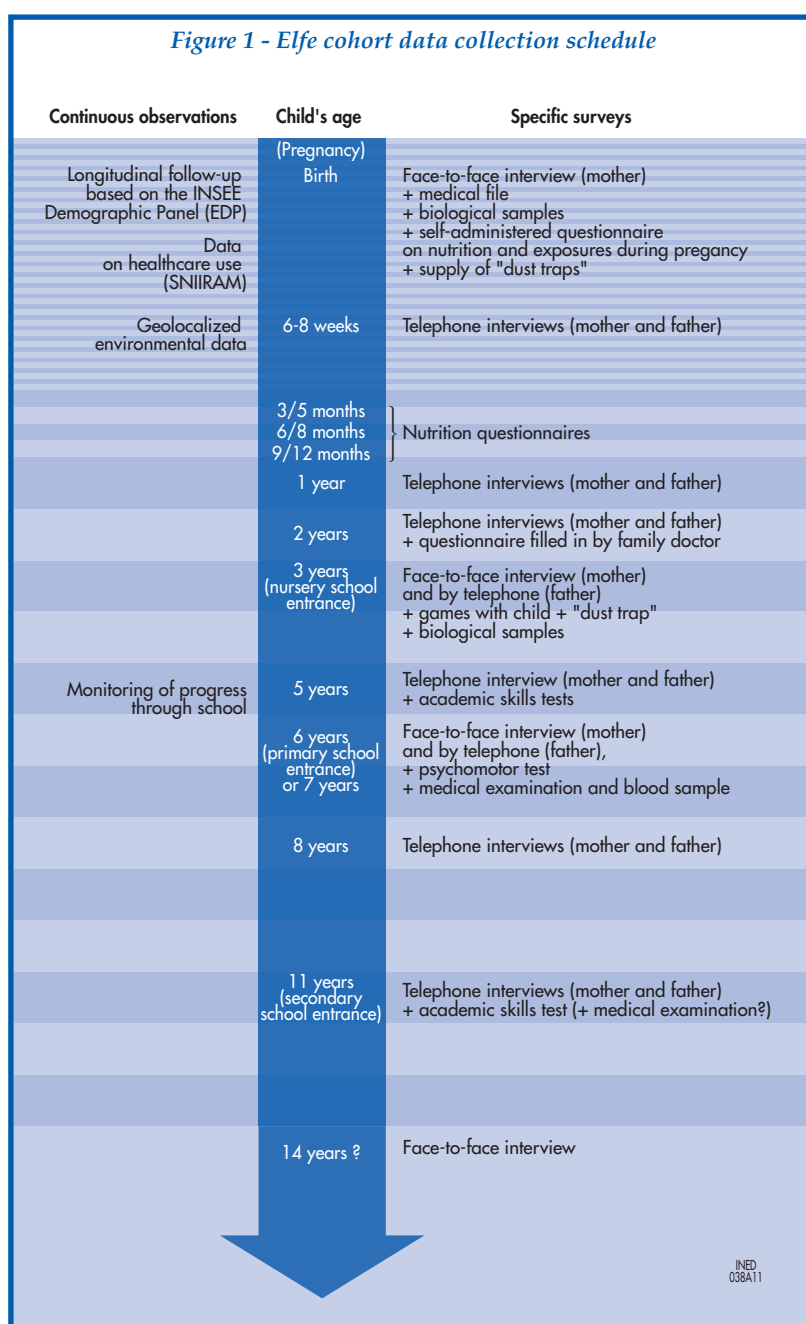
(1) The decision to earmark public funds for the project was taken in mid-2009, and three ministries – those in charge of research, health and the environment – are directly involved. Funding for the study launch was obtained at the end of 2009, when Elfe was designated as a “major research infrastructure” by the Ministry of Research.

It will form a veritable “infrastructure” to disseminate Elfe data among the entire scientific community, under strict conditions of data security and confidentiality. More than 90 research projects involving almost 400 researchers have already been defined and will make use of the information obtained.

### ◆ Frequent and wide-ranging observations

In the Elfe study, observation of child development begins at the maternity hospital, in the days immediately following delivery. The mother is interviewed, medical information concerning her pregnancy and the newborn baby is recorded, a questionnaire is filled in by the mother about her eating habits and any exposure to pollutants etc. during pregnancy, and biological samples are taken. The following stage is a 50-60 minute telephone interview with the mother and a 20-30 minute interview with the father that take place 6-8 weeks after the birth.

Figure 1 - Elfe cohort data collection schedule



Information about the introduction of solid foods in the baby's diet is recorded between ages 3 and 9 months. The family is contacted again by phone around the child's first birthday, and again on his or her second birthday. When the child is 3 years old, an interview is held in the child's home. Medical information is recorded and non-invasive samples are taken. From then on, the observations become less frequent (Figure 1).

An original feature of the Elfe cohort is the involvement of the child's father. Very few cohorts in other countries take an interest in the father's viewpoint, and most rely on the mother to obtain data on the child. The place and function of the father in the family sphere have changed considerably in recent decades, with each parent more frequently assuming new roles. Men now represent a more active and affective presence in the child's life. The father will be contacted almost as frequently as the mother, taking account of their conjugal situation (separations, etc.).

Biological sample collections will provide accurate measures of certain types of early exposure (toxic substances, nutrients, etc.) and various health markers. The children's immediate environment (water, air) will also be monitored, along with their exposure to certain pollutants measured by means of dust traps installed inside their homes. Thanks to the geographical coding of the children's addresses, the results obtained will then be compared with local and national pollution indicators and matched against the structural characteristics of the neighbourhood (proximity of certain industrial sites, etc.).

Data on health and healthcare consumption will also be collected by requesting access – subject to the parents' consent – to the social security data management system (SNIIRAM). This approach is important for a cohort which was not set up for "clinical" purposes, i.e. which does not exclusively concern patients with a particular health problem for whom specific medical follow-up is organized. This should make the survey less burdensome for families by avoiding the need for detailed and complex questions on their healthcare use. When the time comes, we also hope to access data on children's progress through school. All processing of the information collected will respect the participants' anonymity (See Box 1).

### ◆ The sampling frame

It is not easy to obtain a large representative sample of births when the sampling procedure involves personal contact with mothers in the maternity hospital. Mothers spend only a short time in hospital after giving birth (often just two or three days), and births take place in 540 different maternity units spread across the country. It was decided to proceed in four successive waves over a one-year period (to take account of any seasonal

(2) Each person born on one of the 16 days selected for the EDP is included in a "passive" follow-up procedure: their personal data contained in vital records, successive censuses and in the employment records submitted annually by employers are systematically recorded together in a single file.

#### Box 1

##### Strict ethical standards

The collection of data and information in a project of this scale calls for very careful precautions to guarantee the respondents' anonymity and to inform the families of the study objectives. In other countries, this type of project is generally overseen by an ethics committee. In France, it must be approved by the personal data protection authorities (Conseil national de l'Information statistique (CNIS), Commission nationale de l'informatique et des libertés (CNIL)), and for biological samples and health examinations, by a Comité pour la protection des personnes dans la recherche biomédicale (CPP). An "authorization to collect biological samples" must be obtained from the Ministry of Health, as well as the approval of the Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé (CCTIRS). Very close attention has been paid to the issue of data protection and anonymization. By its very nature, a cohort study involves the storage (and updating) of the names, addresses and telephone numbers of families in the sample. For this reason, data cannot be totally anonymized after each survey wave. Two main principles have been laid down: first, the name and address files must be separate from the file(s) containing collected data, and second, it is prohibited to create a single database containing all the information collected. The chosen solution is that of a specific computer platform, activated and deactivated on command by a data access committee (CADE) to form connections between the individuals taking part in the Elfe study, the data and the identifiers. No memory of these connections will be saved after execution. This procedure is made possible by a new technique – probably implemented for the first time in a project of this type – which ensures the total "atomization" of data files, making it practically impossible to reassemble them illegally, and ensuring complete traceability of all operations (all access to data, even by the project managers, will be recorded).

Of course, the families' consent must be obtained before they participate in each part of the project. They will be kept informed of its progress, first through information received at the maternity unit and then twice a year via newsletters written especially for them. Since the end of 2010, pregnant women who are likely to give birth during the collection periods have received information about the Elfe project via their family benefits office when it sends out its information booklet to future fathers.

variations), to limit the number of maternity units to 344, and to partially match the sampling dates with those of the INSEE permanent demographic panel (EDP)<sup>(2)</sup> so that the representativeness of the sample can be monitored over time. The maternity units were drawn at random, taking account of their size, in order to weight the sample of births taken from each unit. For reasons of cost and feasibility, biological samples will be collected for only half the total sample (10,000 births). The collection and storage of biological products will be managed by the Établissement français du sang (EFS), the body responsible for managing blood donations in France. The various collection and survey procedures have been



## Box 2

**Pilot studies conducted in France**

To test the feasibility and acceptability of the Elfe project, two pilot studies were launched in 2007. The first began in April in the maternity hospitals of Burgundy and Picardie, and the second in October in the four *départements* of the Rhône-Alpes region and in Seine-Saint-Denis. More than 300 families are currently being followed. They were contacted again in their homes at the end of 2010 for the child's third birthday.

The Elfe project is also drawing upon the methodological experience of several specific studies to develop data collection tools suited to the French context, to the interview method and to the potential length of interviews. Biological samples collected in October 2007 have also been analysed.

tested in pilot studies (see Box 2).

Very preterm babies (less than 33 weeks gestation) will be followed by the EPIPAGE 2 survey which will cover all the Elfe recruitment periods. The Elfe team is working in close collaboration with the leaders of this project (<http://www.ffrsp.fr/8.html>).

### ◆ Some of the research questions covered

The Elfe project should permit major scientific advances in many areas. It aims to:

- identify, among the environmental pollutants currently causing concern (flame retardants, phthalates, bisphenol A, pesticides, heavy metals, indoor and outdoor air pollutants in general), those which present a short- or long-term risk for vulnerable persons (pregnant women, unborn babies, young children) at the concentrations currently observed in France. The study data will also provide information on ways of reducing this risk;
- describe practices of infant feeding and nutrition for which no national information is available in France (duration of breastfeeding, introduction of solid foods, etc.), their social and cultural diversity, their relationship with subsequent eating habits and health (obesity, allergies, etc.). The aim is to find answers to certain key questions. For example, to reduce the frequency of food allergies, should infants be exposed to food allergens or, on the contrary, should they avoid exposure? Does the introduction of solid foods before 6 months encourage a more varied diet in later life, and can it help to prevent obesity?
- study social inequalities in health affecting children: even at birth, a social gradient for prematurity, intra-uterine growth retardation and big baby syndrome (macrosomia) is observed. How do these inequalities evolve over time, particularly in relation to differences in healthcare use? At what age does the social gradient appear for child pathologies such as obesity? Is there an opportunity to reduce these social inequalities by providing early support to pregnant women and new parents?
- understand more fully the different factors (individual characteristics, physical environment, places of socialization) which interact at a very early age to

influence progress through school and in particular the development of cognitive, language and socio-affective skills. Can these data provide new insights for reducing the high school failure rate in France?

- analyse the effects of changes in conjugal behaviour and the growing numbers of lone-parent or reconstituted families on children's social, health and educational development. These observations will be examined in relation to the types of skills learning within the family;
- measure the impact of exposure to the media and to new communication technologies on children's physical and intellectual development;
- draw up new physical growth curves for children's individual health records: the standard curves currently in use do not take account of changes in lifestyles, eating habits, etc. over the last 50 years.

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This project will help to define strategies for optimizing the development, health and socialization of children, and thereby to formulate policy recommendations in the fields of social welfare and public health. The ultimate goal of Elfe is to produce knowledge that will improve the health and well-being of all children.

### REFERENCES

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### ABSTRACT

New research is needed to understand how the ongoing changes in children's early environment affect their development, their health and their socialization. The multiple factors involved and their numerous interactions make this type of research particularly complex. The best way to track detailed trajectories through childhood is a cohort study. This involves selecting a large sample of children whose lives are followed throughout their development, if possible until they reach adulthood. Such cohorts have existed in other countries for many years, but not, until now, in France. The Elfe longitudinal study of children (Étude longitudinale française depuis l'enfance), launched in the field in 2011, aims to fill this gap. It will follow a cohort of 20,000 children from birth to adulthood via a multidisciplinary approach. Elfe was born out of the questions raised by researchers and the concerns expressed by various public bodies. The national health and environment plan (Plan national Santé-environnement) of 2004 provided the decisive impetus for the project to go ahead.