Enquête Nationale Périnatale

PROTOCOL

(NOVEMBER 2020)

I. Aims

Regular National Perinatal Surveys of morbidity and medical practices were instigated by the Ministry of Health in the 1994 Perinatal Care Plan and were included in subsequent plans. Each survey is based on the principle of the collection of information on perinatal health from a representative sample of births.

The first purpose of the National Perinatal Surveys is to describe the state of health of women and their children, medical practices, and risk factors. The data collected are used to monitor changes over time through the national surveys (1995, 1998, 2003, 2010 and 2016). Another important purpose of the National Perinatal Surveys is to estimate healthcare needs and to assess the outcomes of measures implemented by the public authorities, or of the clinical practice guidelines drawn up by healthcare professionals.

The 2021 National Perinatal Survey will be the sixth. For the first time, in 2021, the initial collection of information in the maternity ward (interviews of women and data from medical files) will be completed by a questionnaire administered to the women at 2 months and matched data from the National Health Data System. The aim of this data matching is, on the one hand, to describe in detail the medical follow-up before and during the pregnancy and in the first year of the infant's life, illnesses prior to pregnancy or after childbirth, as known from the medication intake of mother and child, and, on the other hand, to study variations in this follow-up and these illnesses as a function of the mothers' medical and social

characteristics and of complications of pregnancy and delivery as recorded in the maternity ward and at the two-month follow-up.

II. Methods

II.1 Population

Survey participation is voluntary. The 2021 National Perinatal Survey will cover all births recorded in maternity wards (public, private, and birthing centres) in France (metropolitan France and overseas departments and regions).

Inclusion criteria

The births are defined as all live births and stillbirths of gestational age at least 22 weeks and/or of birthweight at least 500 grams.

Exclusion criteria

- births not meeting the definition (live births and stillbirths below a gestational age of 22 weeks and/or birthweight below 500 grams).

- mothers who gave birth at home and were not transferred to hospital. This group accounts for less than 0.5% of births in France and cannot significantly affect the overall results.

- people subject to legal protection measures (limited judicial protection, guardianship, trusteeship)

- people subject to an administrative detention measure

- mothers under 15 years of age at the time of delivery

- women hospitalized because of mental disorders without their consent

II.2 Information provision and participants' rights

General information for pregnant women will be conveyed on posters in the consulting areas of maternity wards in the three months preceding the survey.

The midwives who work in the maternity ward and are recruited by Inserm to conduct the survey will give an information sheet to the women in the postpartum care section of the maternity ward, and will return at the latest the next day to the women's rooms and will verbally present the survey's objective and how it

will proceed. The midwives will invite the women to ask whatever questions they wish, so as to ensure understanding of the various stages of the National Perinatal Survey.

This information sheet explains that participation in the survey is independent of the care provided in the maternity ward and that the answers will have no affect on the quality of care. It also informs the women of their rights and how to assert them. So, the women will be free to agree or refuse to take part in the interview in the maternity ward and/or at the two-month follow-up, to oppose or not the collection of data from their medical file (data from the medical file or short-form questionnaire) and/or matched data from the National Health Data System for themselves or their child.

Several information sheet formats are planned for particular situations (woman or child with health problems, therapeutic abortion, intrauterine foetal death…). The woman will be given information sheets for the second holder of parental authority and for the parents of minors so that they can exercise their rights.

The information sheets detail how to exercise the right to access, oppose, or withdraw data. These rights can be asserted following childbirth and for up to 24 months after delivery. All the information is available on the website under the heading Families.

II.3 Stages of data collection

The survey comprises an active follow-up (in the maternity ward and at 2 months) and a passive follow-up (matched data from the National Health Data System).

II.3.a The active follow-up consists of four stages:

1) a telephone or face-to-face interview (administration of a questionnaire) lasting about 15 minutes with a member of the department, in order to characterize the childbirth environment, using an "institution questionnaire";

This stage takes place before the week of inclusion of births.

2) an interview (administration of a questionnaire) lasting about 15 minutes by the midwife with the women after childbirth;

3) data collection from the medical file on the delivery and the health of the child (medical file data, and short-form questionnaire if the medical file data cannot be collected);

Different data collection scenarios are envisaged, depending on the situation of women and on how the delivery went (Appendix 1).

4) a follow-up at 2 months by means of a questionnaire lasting about 20 minutes, online or by telephone.

Whatever the chosen method of contact, reminders are planned.

II.3.b The passive follow-up consists of data matching with data from the National Health Data System and the collection of the following data:

for each mother, data from the 6 years before the delivery and for the year after delivery;

for each child, data for the year after delivery.

Confidentiality

The data collected and digitized in databases are indirectly identifying. Given the aims of the survey, the data will be used only for research and statistical purposes. No result will be presented by maternity ward.

III. Length and organization of the survey

The survey will cover all births occurring during the week (7 consecutive days) of **15 to 21 March 2021**, or every other day for two weeks in healthcare institutions with more than 2000 births a year that prefer this data collection modality. The two-month follow-up will be done between May and June 2021.

Data requested from the National Health Data System should be available around the third quarter of 2022 and the data matching will be done no later than the third quarter of 2023.

Inserm is in charge of the processing of data from the active and passive follow-ups of the survey. It will implement data collection in the maternity ward. The two-month follow-up will be subcontracted to Public Health France, and the matching of data with data from the National Health Data System will be subcontracted to DREES (directorate of research, studies, evaluation, and statistics).

On a national level, the survey is overseen by a steering committee composed of the 5 following bodies (the composition is detailed in Appendix 2: DREES (directorate of research, studies, evaluation, and statistics), DGS (health directorate), DGOS (general directorate of healthcare services), Public Health France, and the EPOPé team of Inserm (U1153).

Organization of data collection at birth

National coordination

The EPOPé team of Inserm will coordinate the study nationally. The aims of coordination are to make contact with each department before survey implementation and during data collection, to centralize

receipt of the questionnaires after the survey, and to check the exhaustiveness and quality of the data in paper format.

Departmental coordination

Coordination among French departments (done by a professional from the PMI [maternal and child protection] and/or a member of the Perinatal Health Network and/or a member of the Regional Health Agency and/or a member of Inserm) ensures good monitoring of the survey at the local level, in cooperation with the EPOPé team of Inserm. The person responsible contacts all the maternity wards to ask them to participate and to ensure that there is a go-to person (principal investigator) in each maternity ward. He or she must also supervise the recruitment of one or more interviewers for each maternity ward, organize the training sessions for the midwives who do the interviewing, ensure that the survey proceeds as planned, and check that the data collection is of good quality. He or she must in particular check that the questionnaires have been completed for all births concerned.

Principal investigator

The Principal Investigator (most often the head midwife of the maternity ward):

- identifies a principal midwife interviewer
- keeps the survey documents

The principal midwife interviewer, in close collaboration with the Principal Investigator:

- Sets up the survey in the maternity ward
- Identifies the midwife interviewers
- Supervises the conduct of the survey and the midwife interviewers
- Centralizes the birth questionnaires before their dispatch to Inserm

Midwife interviewers

The midwife interviewers:

- identify the women to include
- give them the information sheet and present the survey verbally
- conduct the interviews
- use the medical file to complete the 'Medical file data' section of the birth questionnaire or the short-form questionnaire
- ensure that the women are able to exercise their rights (to object to, or not, the different parts of the survey)

Organization of the two-month data collection

The women are contacted principally by email, but also by telephone (if their level of written French is inadequate, if they have difficulty accessing the internet, or if there is no reply to emails inviting them to complete the questionnaire online). Reminders are planned by email, text, or telephone. IPSOS, a service provider for Public Health France, will set up and conduct the two-month follow-up.

IV. Opinions and authorizations

For regulatory purposes, authorizations/approvals will be sought from:

- CNIS (National Council for Statistical Information)

- Public Statistics Committee

- CPP (Institutional Review Board) for the active follow-up

- CESREES (Ethics and Science Committee for Research, Studies, and Evaluations) for the passive follow-up

- CNIL (French Data Protection Authority) for the active and passive follow-ups

Public Health France and DREES are the recipients of the databases (National Perinatal Surveys database from the active follow-up and the matched database), provided the requisite regulatory authorizations are obtained (Committee on Statistical Confidentiality and French Data Protection Authority).

V. Information processing and dissemination

Inserm will prepare a final report including the main results from the data collected at birth and at two months, in cooperation with the members of the steering committee.

This report, which will be published in the autumn of 2022, will present national and regional results. It is not possible to have representative results for the departments, because of the size of the sample surveyed in one week. As an indication, to know the rate of prematurity (about 5%) with a precision of $\pm$ 1%, a sample of at least 2000 births is needed.

The databases from the survey conducted in the maternity ward and at two months will be made available to the scientific community on a secure platform. Access to the databases is subject to current regulatory authorizations.

All information on the survey is available on the dedicated website://enp.inserm.fr

APPENDIX 1: Data collection scenarios according to the women's situation

	Interview + MFD + 2-month follow-up + matching with National Health Data System	MFD only	Short-form question-naire
Women aged 18 or over not presenting the characteristics below	X		
Minors aged 15-17 not presenting the characteristics below	X		
Therapeutic abortion			X
Intrauterine foetal death			X
Anonymous birth			X
No understanding of French			X
Women with health problems		X	
Women whose child has a health problem		X	

Collection of data from the medical file: MFD = medical file data (information on mother's health before pregnancy and delivery, and on the child's health) or short-form questionnaire (ten items)

APPENDIX 2: List of people involved in the project at the Ministry of Solidarity and Health, National Institute of Health, and Public Health France

Health Directorate (DGS)

Caroline Bussière, office manager

Khadoudja Chemlal, assistant to office manager

Nathalie Rabier-Thoreau, task officer

General Directorate of Healthcare Services (DGOS)

Frédérique Collombet-Migeon, perinatal care task officer

Directorate of Research, Studies, Evaluation, and Statistics (DREES)

Thomas Deroyon, methodologist

Jeanne Fresson, public health physician, epidemiologist

Philippe Raynaud, head of the Population Health Office

Sylvie Rey, public health physician, epidemiologist

Annick Vilain, study manager

French National Institute of Health and Medical Research (Inserm)

Béatrice Blondel, emeritus researcher

Hélène Cinelli, national coordinator

Nathalie Lelong, scientific co-manager

Camille Le Ray, scientific manager

Public Health France

Virginie Demiguel, scientific study manager

Nolwenn Regnault, coordinator of the programme for monitoring perinatal health and early infancy, epidemiologist

Benoit Salavane, scientific project manager, epidemiologist