

den norske *Mor & barn undersøkelsen*

PROTOCOL

The Norwegian Mother and
Child Cohort Study

Norwegian Institute of Public Health

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PROJECT DESCRIPTION

The Norwegian Mother and Child Cohort Study

Summary

In order to achieve better health for mothers and children in the future, we wish to test specific hypotheses about the causes of a number of serious diseases by recruiting 100,000 pregnant women to a cohort study. Possible causal factors will be linked to information obtained from questionnaires, blood samples from mother, father and child, and medical registries. The Norwegian Mother and Child Cohort Study has multiple endpoints. Primarily those associated with adverse pregnancy outcomes will be studied, as well as diseases affecting mother, father or child. Endpoints will be taken from questionnaires and medical registries. The study will be carried out nationally and researchers with relevant questions will be welcome to participate. No interventions will be undertaken, which means that any conditions that may, potentially, expose the families to disease will not be modified. Both basic and applied research will be undertaken, with projects spanning from molecular genetics to welfare. Data collection was started in the Hordaland region of Norway in 1999, and began in Akershus in autumn 2000. Extension of the project to several counties is an ongoing task; with national coverage being the ultimate aim. The project is largely funded within the public sector, supplemented by contributions from non-governmental organizations (NGOs) and industry.

Background

The background for the project is lack of understanding about the causes of disease. The main aim is prevention. This can be achieved by identifying the environmental factors that are the links in the causal mechanism leading to disease. The research has to be specific, and planned in a way that allows concrete questions to be answered. The prevalence of a disease, and the number of causal factors involved, must be taken into consideration. Many people are affected by the serious illnesses with which we are concerned, sometimes at a very young age. All of these diseases are the result of a chain of causal events with many components. There is no contradiction between our understanding of disease as multifactorial (or that health is a multidimensional concept) and looking for specific causes for disease. Much can be gained by understanding the critical points in the causal chain, as experience from the diseases we have been successful in preventing and treating has shown.

The causes of the many diseases and complications that can arise during pregnancy are largely unknown, for example still births or serious congenital abnormalities. We know little about why some births occur prematurely. For many diseases that occur throughout childhood, such as diabetes, autism, cancer, rheumatism and allergy, our knowledge is very incomplete, and treatment of these childhood diseases requires large resources. Many of the complaints and illnesses that occur during pregnancy are also poorly understood. These include nausea, pre-eclampsia, pelvic pain and depression.

Knowledge about the causes of disease (epidemiology) is important for several reasons. Finding specific causes can lead directly to prevention. If we know that a toxic substance or medicament causes damage to a fetus, then by avoiding contact with these substances, we can

prevent damage. Similarly, if the damage is caused by an infection, we can give advice in order to prevent infection and develop vaccines. Also, if we know more about the causes of disease here will be less unnecessary anxiety. We have a tendency to blame either ourselves or factors in our lifestyle or diet, when we are ignorant about the causes of disease. These claims can be tested in the Mother and Child Cohort Study.

Another reason for carrying out epidemiological research is to aid in the development of new medicines. Including mother, father and child in the cohort study will enable us to make effective use of new methods in genetic epidemiology. The transmission disequilibrium test can be used to identify the genes associated with disease. In turn, detailed laboratory work can be carried out which identifies the fundamental metabolic errors underlying disease. Medicines can, therefore, be targeted more efficiently. From this perspective, the cohort study will stimulate basic research in molecular genetics both in Norway and internationally.

It is also important to examine commonly held beliefs concerning the causes of disease. Many aspects of modern society can be sources of anxiety. One recent example is the question as to whether mobile telephones can lead to illness. From a biological point of view this seems unlikely, but without scientific evidence this cannot be refuted. Reduction of unwarranted anxiety is a valuable aspect of the project.

Yet another dimension of the project is to examine quality of life and positive aspects of health. The project can illuminate which environmental factors promote absence of illness and healthy living.

Norway has a social infrastructure that facilitates epidemiological research. We can track individuals and generations over long periods of time. The population is well educated and Norwegians have a long tradition of voluntary participation in responsibly carried-out medical research. In addition, several health registries with high quality data already exist.

The cohort study will be conducted over an extended period of time. Children will be followed up until they are adults, and parents will be followed up over many years. This will enable an investigation into serious adult diseases, such as cancer and cardiovascular disease. For example, all women can be monitored for breast cancer: an illness that is increasing in Norway, especially among the under fifty's. The data collected will enable the testing of many important causal hypotheses.

The project will also supply valuable information relating to the causes of long absences from work during pregnancy. Within the research that is being performed on the Norwegian welfare state system, there has been a lack of individual follow-up studies that include health variables. Which factors are most important in predicting long-term disability? Many women experience that illnesses such as pelvic pain, which start during pregnancy, can affect their subsequent health and ability to return to work.

We believe that if we can contribute to the understanding of even a few of the diseases that we will be investigating, the effort will be worthwhile. The knowledge that is derived will be applicable both to future generations and for mothers and children outside Norway. From a strict philosophy of science viewpoint, we acknowledge that it is impossible to demonstrate that a particular exposure is a cause. It is still correct to use causality models (rather than more diffuse risk models) in order to make the aims of the study more precise and easy to grasp.

Study aims

The study aims to calculate the degree of association between potential causal factors (exposures) and ill health in mother and child.

As the project evolves, new causal hypotheses will arise. Laboratory techniques in the years to come will ensure that improved methods are available for tracing exposures in the biological material. The main data set from the questionnaires and blood samples will be linked to information about many diseases through other databases. In this way, the main project can be seen to be fundamental to all the subprojects. Many research questions can be answered using the main data set alone, while others will require additional data. If a subproject requires further contact with the study participants in order to collect more data, new consent will be requested.

In addition, the distribution of exposures in the population will be described, and estimates of the incidence and prevalence of many diseases will be made. In the case of some diseases and conditions, natural progression can also be described. No interventions will be carried out as part of the main project.

A number of research questions and proposals for subprojects have been outlined. The breadth of interest in the project is apparent. The many projects focusing on women's health and working conditions during pregnancy will give results relatively quickly. Others, such as those focusing on childhood illnesses, will require follow-up over many years.

Diet, infections, hereditary factors, environmental toxins, medication and exposure to occupational hazards can be mentioned as examples of exposures that are of scientific interest. However, they will not be detailed in this protocol.

Design

This is a cohort study, which involves recruitment prior to the onset of the disease that is to be studied. The aim is to compare the incidence of disease in a group of exposed women/children with a group that has not been exposed, while controlling for other factors which can affect the risk. The main project will provide data regarding disease and exposure variables, which can be analyzed without further modification. Links to health registries (e.g. Medical Birth Registry or Cancer Registry) or exposure registries (National census data) will enable the generation of new data sets, simply and effectively.

Many of the subprojects will be based on the cohort design of the main project. When additional exposure data are required, or blood samples are being analyzed, the relevant design will be a nested case-control study. This involves identifying a sample of subjects that have developed the disease to be studied, and selecting controls that have not developed the disease, and measuring exposure for both groups.

In addition, subcohorts with particular exposures can be followed in more detail. Also, estimates of the joint effects of genes and disease can be made with the mother-father-child triad design.

Sample

The target is 100 000 pregnant women who will be recruited between 1999 and 2006. The intention is to continue the project until the goal of 100 000 participants is reached. In Norway, there are approximately 60 000 births annually. Table 1 shows population and birth statistics for all the counties in Norway in 1999. We aim to recruit women from every county.

A sample size of 100 000 is required because many diseases are relatively rare and exposures (e.g. certain infections) infrequent. A typical congenital malformation has a prevalence at birth of about 1 per 1000, so 100 cases can be expected. But such malformations are clinically heterogeneous, so in practice, it will be desirable to carry out analyses in subgroups. For some malformations, and for other rare conditions such as childhood cancers, collaboration with the Danish Mother and Child Cohort Study will therefore be indicated.

Four conditions can be seen to lead to a potential selection bias. Firstly, women who choose to terminate pregnancy prior to recruitment to the study or who have a spontaneous abortion will obviously be excluded from the study. Secondly, some women may not wish to participate in the study; thirdly women may withdraw from the study after recruitment and fourthly, women may leave the study because of natural causes such as death or emigration. These selection mechanisms will be described, so that it is possible to examine their likely effect on the study aims. The most important factor affecting selection is probably low recruitment. When calculating associations between exposure and disease this can be critical, but not necessarily. However, low recruitment will commonly bias estimates of disease prevalence, particularly if there is systematic variation according to parents' education or other factors which may be associated with willingness to participate.

Case-control sampling will be based on the number of cases that are found. Normally, two to four times as many control cases are required. These will be randomly selected from the whole cohort. A control group can be used for different groups of cases.

Variables

Exposure variables

An exposure variable is defined as one if it is named in the study aims as a potential causal factor. Many of the questions posed in the questionnaire will either directly or indirectly measure exposure. Similarly, specific blood factors will be exposure variables when they are analyzed as causal factors. A fuller understanding of the framework for these variables can be obtained from examining the content of the questionnaires (appendix 7-10) and the detailed description of blood sample collection and storage (appendix 2). Subprojects will also enable the collection of further exposure variables.

Health Variables

A health variable is defined as one that describes or defines a health condition, either from the questionnaire, registry or blood sample. Normally these variables become effect variables in a cause-effect model, but they can also be exposure variables for other health variables. For example a mother's mental health can be the cause of a child's future psychiatric complaint, and low birth weight can lead to a number of childhood ailments. Many health variables will be collected from links to other health registries or as part of subprojects.

Other variables

The questionnaire will also include a number of other variables which conceptually are neither exposure nor health variables. Some of these will correct for known associations, while others are included because they are of general research interest. Many of the questions relating to diet and use of medicaments are of this type.

Table 1

Examples of exposures and health outcomes to be investigated in the Norwegian Mother and Child Cohort Study.

Examples of exposures	Examples of diseases
Medication	Pelvic pain
Hereditary factors	Congenital malformations
Infections	Stillbirth
Dietary factors	Premature birth
Environmental toxins	Cancer
Physical activity	Diabetes
Work situation	Asthma/allergy
Occupational hazards	Rheumatism
Interpersonal relationships	Depression
Personal habits	Breast cancer

Data collection

Recruitment

An invitation for participation in the study is sent to women at their home address. The majority will receive this package three weeks before attending routine ultrasound examination in the 17th week of pregnancy. Names and addresses are obtained from the clinics that have received a request for ultrasound examination, either from a doctor or the woman herself. Each week the ultrasound clinics send a list of all women who have appointments to the Medical Birth Registry (MBR). This list includes names, addresses and national identity number, as well as the date of the appointment (see appendix 1). Permission to maintain such a list of names has been granted by the Norwegian Data Inspectorate. This list is used by the clinics to prepare labels, expected number of blood samples and also as a means of calculating the rate of non-participation.

The invitation which is sent out in collaboration with each participating hospital describes the purpose of the study, protection of privacy and practical details. It is emphasized that participation is voluntary, and that consent from children will be sought when they are older. The women are also notified that they can withdraw at any time. In addition, women are informed that additional invitations may be received requesting participation in subprojects. This may entail the collection of further data. Information brochures about the project and the MBR are enclosed, together with Questionnaires I and II. Also enclosed is a consent form, which requires a signature, and a return-paid envelope.

During autumn 2000, a pilot was run requesting paternal participation at Bærum hospital. Together with the invitation to the mother, a separate invitation to the father (with consent form and short questionnaire) was sent. Blood samples were also taken. The father is now routinely invited at most hospitals.

If a woman wishes to participate, the questionnaires and signed consent form are returned either by post to the Medical Birth Registry in Bergen, or handed-in at the ultrasound examination.

Ultrasound examination

At this examination, a midwife informs about the project and asks the woman if she wishes to participate. After obtaining consent, blood samples are drawn. Blood samples are also taken from the participating fathers. Blood samples are sent the Norwegian Institute of Public Health in Oslo. See appendix 2. If the mother and father are uncertain about participation, they can either consult the midwife or she may refer the couple to a project colleague who can clarify any misunderstandings. If the woman has said that she is willing to participate, but has not returned the questionnaires within two weeks, she is sent a single reminder.

A copy of the standardized ultrasound form where values can be entered and any abnormal findings noted is sent from the hospital to the Medical Birth Registry.

30th week

During the 30th week, the woman is sent a new questionnaire (Questionnaire III) with a reply paid envelope. If necessary, a reminder is sent after three weeks.

At Birth

Soon after birth, a blood sample from the umbilical cord and a second sample from the mother are taken. Both are sent to the Norwegian Institute of Public Health in Oslo.

Postnatal questionnaires

Further questionnaires are sent to the mother when the child is six months, eighteen months and six years old.

Data storage

Person identifiable data

Women who agree to participate are registered in a data base containing name, national identification number, a code number which corresponds to other files, information relating to when questionnaires or blood samples are sent and received, and whether reminders have been sent. No other information is stored in this database. All information about father and child will be linked to the woman, who is the index person in the project.

Questionnaires

Data files that contain information from the questionnaires and the ultrasound investigation have a code number. This code number, which is the same as the one in the person database, will only be used together with the national identification number in the event that links are to be made to other health registries or data is to be extracted for case-control studies. The questionnaire databases will be stored and checked at the Medical Birth Registry in Bergen. For content, see appendix 1

Collaboration with Medical Birth Registry (MBR)

Data from the standard notification form to MBR will be included in the database for the Norwegian Mother and Child Cohort Study. The Norwegian Data Inspectorate has granted a concession for this. This is an important link, as it will prevent the project contacting the parents of children who have died at, or soon after birth, as well as allowing the identification of multiple births. Case control studies that are directed towards the parents of children who are born with congenital abnormalities or other specific pregnancy outcomes will also be possible.

Blood samples

The aliquoted blood samples will be frozen to -85°C and stored in freezers at the Norwegian Institute of Public Health. Extracted DNA will be stored at -25°C. A specially constructed data application will be used to locate the blood samples. These can only be removed with a concession from the Norwegian Data Inspectorate.

Database links

All links to databases other than MBR should be approved by the Norwegian Data Inspectorate .

Table 3
Flowchart for data collection

What happens:			
Week/mth	Hospital	MBR	Inst.of Public Health
10-14	<u>Before ultrasound</u>		
	Receive name and address of pregnant women generally from referring GP. A copy of list sent to MBR each week.	Sends invitation by post to women with questionnaires 1 and 2 Receives consent form and questionnaires from participating mothers and fathers	
17	Ultrasound examination		
	Women are asked if they will/will not participate Blood samples taken	Receive copy of standard ultrasound form	Receive blood samples from mother and father
18 - 30 33	<u>Later in pregnancy</u>		
		Reminder for missing consent form and questionnaires Questionnaire 3 sent out Reminder sent after 3 weeks	
	<u>Birth</u>		
	Blood samples from mother and umbilical cord after birth		Receive blood samples from mother and child
6 mth	Age 6 months		
		Send out questionnaire 4	
18 mth	Age 18 months		
		Send out questionnaire 5	

Pilot surveys

A small-scale trial survey was completed and the questionnaires and routines for taking and sending blood samples tested. The overall experience was positive. Physicians working in primary health care collaborated in this study, but after discussion within the Norwegian Medical Association recruitment by this channel was abandoned. From summer 1999,

recruitment has been as described above. By December 2003, approximately 32 000 women had been recruited. The overall participation rate is about 45% of all invited women..

In September 2000, a pilot study was started with inclusion of the fathers. The reason for this is that occupational hazards, ill health and use of medications by the father may potentially cause mutations in reproductive cells, which can lead to illness in the child. Fathers were asked to complete a questionnaire and give a blood sample. The fathers are now included in all parts of the country.

The project will not be able to require that all the participating hospitals follow exactly the same routines in recruitment, ultra sound examination and the taking of blood samples. Therefore, the project must be flexible and able to adapt to local conditions. Special support has, for example, been given to the midwives working at some hospitals and to laboratory staff at others.

The availability of economic resources has determined the study's progress. The project is now recruiting women from all parts of Norway, but some of the larger hospitals are not yet participating.

Project Organization

Two teams engaged in perinatal epidemiological research started the project: One consisting of researchers at the Medical Birth Registry and The Department of Public Health and Primary Health Care at the University of Bergen; the other attached to the Section for Epidemiology, National Institute of Public Health, Oslo. After 01.01.02 both groups are parts of The Division of Epidemiology, Norwegian Institute of Public Health, where the study is anchored (Head: Camilla Stoltenberg). The project is headed technically, financially and administratively by the Director of The Norwegian Institute of Public Health, Geir Stene-Larsen. Furthermore, the study has a leader team, consisting of 4 members from the division. The principal investigator is Per Magnus. The Norwegian Mother and Child study was evaluated by a governmental committee in spring 1998. The initiative for this was taken by general practitioners. In Parliament, a large majority approved the study and the Ministry of Health and Social Affairs requested that the National Institute of Public Health carry out the study.

An advisory board consisting of representatives from the main five health regions in Norway will meet about twice a year and act as a link to the health authorities in the whole country.

In order to carry out the data collection, the study has engaged full- or part time, laboratory technicians/midwives at the main participating hospitals. The period of employment is related to the length of time data will be collected in each region. The project has also employed staff in Bergen to manage the databases at MBR in Bergen.

International collaboration

The National Institute of Environment Health Sciences in the US has signed a contract for 1,2 million dollars, giving them access to urine and blood samples from participating women. The purpose of their study is to examine the effect of environmental toxins on childhood illness. The US National Institute of Health (NIH) is funding part of this project. Together with a group of researchers at The Columbia University, New York, a sub-study of Autism

related disorders is planned (The ABC – Autism Birth Cohort). An amount of \$ 13 mill from NINDS (National Institute of Health National Institute of Neurological Disorders and Stroke) will be granted in 2003 for this study. We collaborate with a group carrying out similar research in Denmark.

Funding

At today's recruitment level, a unit price of about NOK 3 375 (\$ 450) per woman has been estimated. This estimate is subject to revision.

The Norwegian Ministry of Health granted the project a budget of NOK 1 million for 1998, 1999 and 2000 , NOK 5 million for 2001 and 2002 and 6.5 million for 2003 and 2004.

Through the Norwegian Research Council, funds have been set aside for research in functional genomics. 50 mill. NOK over 5 years has been given to a technology platform for human biobanks and health studies, consisting of the Cohort of Norway (a cohort of 200 000 adults) and the Norwegian Mother and Child Cohort Study. In 2002, 4.5 million NOK was allocated to The Mother and Child Study.

The Confederation of Norwegian Business and Industry (NHO) has given NOK 1 million to the project through its occupational environment fund in 2000 and 2001. Private organizations and non-governmental research organizations are currently considering a number of applications.

Concessions from the Norwegian Data Inspectorate

In October 1996, the project was granted a concession by the Norwegian Data Inspectorate. This was renewed in September 2003. The Director at the Norwegian National Institute of Public Health is responsible for the registers. Together with the concession, the Norwegian Data Inspectorate also made recommendations relating to participant information and consent. The concession includes information from the Medical Birth Register and information and blood samples from the father. Meetings and correspondence between the Norwegian Data Inspectorate and the project have lead to, amongst other things, changes in the recruitment procedure.

The project involves collecting sensitive personal information. Much effort has already been, and will continue to be, expended on ensuring that third parties cannot link data from the project to a specific name. We require participants to state name, address and national identity number for two reasons. Firstly, so we can communicate with participants during data collection and secondly, so we can link data to external data sources, such as hospital records.

Data from the questionnaires and blood samples will be stored with a linkable code number. The code number and national identity number will only be linked when required in the course of data collection, and later when links to other databases are made. All the data made available to researchers (internal and external) will be stripped of personal identifiers; that is identification will be possible using the code number, but not directly to the person who has provided that information. As a general rule, the results from analyses of blood samples will be transferred back to the central database so that others can utilize them, but this can be evaluated in each individual case. When new data are being collected (in connection with a

subproject requiring additional consent), consent shall also be obtained to transfer the data to the main database.

It should be particularly noted that the use of all blood samples will require approval from the Norwegian Data Inspectorate and the Regional Ethical Committee. All links to external data sources require a concession from the Norwegian Data Inspectorate.

The consent forms, letter inviting study participation and the brochure (see appendices) shall all give information regarding the scope of the study and consequences of participation. Later, newsletters will keep participants informed. Children will be informed personally about the study when they are 15 years. They will be asked to give active consent to continue in the study when they are 18.

Ethical considerations

"Contract" between participants and researchers

While rights and obligations have not been negotiated, the consent form in many ways resembles a contract, whereby participants agree to donate biological material and information about themselves. In exchange a guarantee is given that the researchers will use the material to study the causes of disease. This involves a fundamental trust on the part of the participants; it will be unethical on the part of the researchers not to utilize the material in the manner intended, or to use it for other purposes. New subprojects, which require active participation (completion of new questionnaires, clinical investigations, evaluation of exposure or new biological samples) beyond what is explicitly stated in the signed consent form, will require new consent. Subprojects that require collection of new data will need approval from Regional Ethics Committees and the Norwegian Data Inspectorate. Participants on subprojects must also give permission that data will be channeled into the main project.

Project value

The purpose of the project is to investigate the causes of disease. Knowledge about the causes of disease can lead to good interventions and further laboratory research which can reveal both the mechanisms that underlie disease processes, and lead to new treatment forms. It is also important to disprove false theories regarding the cause of disease and investigate which factors promote good health and absence of disease.

Potential Harm

No interventions will be undertaken in connection with the project, in the sense that conditions resulting in an exposure will not be wittingly modified in order to prevent disease. Participants will not receive the results of blood tests, or other information about themselves, that they are not already aware of. Participants can be recruited to projects on the basis of disease information (e.g. pelvic pain or incontinence) or pregnancy outcomes about which they are already informed (e.g. congenital abnormalities) or based on geographical location, child's date of birth etc. As a guiding principle, recruitment cannot occur on the basis of lifestyle; for example, smoking. If participants are to be recruited on the basis of findings from a blood analysis, they must previously have given written consent stating that they are aware that they will be informed of the results of the blood analysis.

Some participants may find some questions offensive, others may find that the scope of the questionnaire is wider than they had expected. The drawing of blood samples can also be experienced as unpleasant.

Conflicts of interest between researchers

The study is a national resource that will be available to all bona fide researchers with a legitimate request for data. If different research groups have similar study aims and wish to use the same data, then flexibility will be encouraged and collaboration sought. The leader group's decision will be final in such matters.

Dissemination of results

Publications will be made according to further guidelines (see Appendix 4) Norwegian public health risk evaluations and advice will be given according to the existent guidelines.

Ethical evaluation

Ethical aspects of the project were discussed in a seminar in 1995. A transcript of contributions at this seminar is available on request (Norwegian only). Further, the project has been evaluated by the Regional Ethics Committees for medical research, Health Region II (REK II). This committee has been kept informed of all modifications and has approved, for example, the trial project including fathers. From spring 1997 to spring 2000, the project had its own committee advising and making recommendations to the project's executive and working groups.

Appendix 1: Description of the person database

Introduction

The Norwegian Mother and Child Cohort Study uses an advanced database (tracking system) to register and follow the progress of participants through the various phases of the study. Oracle 7.3 has been used to create and access the database, and the screen formats have been developed using Oracle Forms 5.0 and Oracle Reports 3.0. The computers in which the tracking system is installed, are connected to the local network at the Medical Birth Registry. To ensure the security of the database, MBR's standard password system is used.

The main menu of the tracking system shows the most important tasks in the Norwegian Mother and Child Cohort Study. The description in this appendix follows these tasks. All the tasks are important, but screen layouts are not shown.

The unit that is followed by the tracking system is the pregnancy, not the woman. This is because a woman can participate in the project during several pregnancies.

Registration of new ultrasound appointments

A list of all women receiving ultrasound appointments is compiled at each hospital. These lists are transferred to the person database at MBR either manually or in encrypted electronic form.

Electronic transfer is direct, while paper lists are keyed in manually. If a woman is already registered in the system, the information will be updated.

Data relating to pregnancies being registered for the first time are entered. This information includes name, address, date, and where the ultrasound will be carried out. If a woman is already registered, either for this or a previous pregnancy, notification will automatically appear on the screen and the date for the new ultrasound can be checked.

A pregnancy being registered for the first time in the tracking system is given the status **INNREG (Registered)**. The only information about the pregnancy at this stage is the actual registration.

Registration of new ultrasound forms

The hospital sends a copy of the ultrasound form for all women who have agreed to participate in the study. Estimated delivery date and date of last menstruation are entered from this form. These variables are important so that future mailings from the project are sent out at the correct time. In addition a number of parameters are registered (*para*, *ab* and *gravida*) to ensure that individual pregnancies are kept completely separate. A variable noting the number of foetuses is used after the birth to ensure that the correct number of umbilical cord samples have been taken. Further information from the ultrasound examination is registered in a separate data file (see appendix 3).

Mailings, reminders and returned forms

Appendix table 1: Mailing overview

Mailing	Timepoint for mailing	Timepoint for reminder	Target group
Questionnaires 1 and 2 + consent form ¹⁾	approx. 3 weeks before u.s. exam.	at u.s. exam.	women with status INNREG (Registered)
Questionnaires 1 and 2 ^{1,2)}	after consent form received	3 weeks after mailing	women with status DELTAKER (Participant)
Questionnaire 3	in 30th or 31st week of pregnancy	3 weeks after mailing	women with status DELTAKER (Participant)
Questionnaire 4, one for each child	When the child is 6mths old	3 weeks after mailing ³⁾	women with status DELTAKER (Participant)
Consent form reminders		monthly	women for whom samples or questionnaires have been received, but status INNREG (Registered)

1. Women attending ultrasound examination at hospitals where fathers are also being recruited will also receive an invitation for the father containing questionnaires and consent form.
2. Only sent to women who have entered the tracking system from other sources than through ultrasound clinics.
3. Does not apply to triplets who are treated individually.

When questionnaires 1 and 2 are sent out (line 1, table 1), status changes from INNREG (registered) to INVITERT (invited)

The return date for each kind of questionnaire is entered in the tracking system. Consent form reminders (last line, table 1) are only sent to women from whom samples, or one or more completed questionnaires, have been received.

Questionnaires that have been returned, are scanned and interpreted by a high capacity Fujitsu scanner and the program Eyes and Hands in Windows NT. This program reads marked and numbered fields and also allows the operator to manually enter data that the program finds difficult to interpret. The questionnaires are scanned and stored as optical images, which are then displayed on the screen as they are read by the program. This allows the operator to add or modify codes when necessary. Each scanned questionnaire is allocated a code consisting of a pregnancy identification number and a number indicating the type of questionnaire. These code numbers are transferred to the person database to keep track of the questionnaires that have been scanned.

Returned consent forms

The consent form is an important item in the tracking system. When returned, the consent date is noted and the pregnancy is given the status DELTAKER (participant). Only pregnancies that have been allocated this status are considered to be part of the study, and will be followed up with further questionnaire mailings.

Change of status

It is apparent from the description so far, that the status of the pregnancy is decisive in allowing progress through the tracking system. As soon as a pregnancy is registered, it is

given the status INNREG (registered). Thereafter, and for as long as it remains in the system, it will always have a status. The different types of status are shown in appendix table 2. When a woman, the Biobank or a hospital contacts the project indicating that the status of a pregnancy should be changed, a special command is used.

Appendix 1 table 2 Overview of events which alter status in the tracking system

Status	Event resulting in change of status
INNREG (registered)	The pregnancy is registered in the tracking system.
INVITERT (invited)	First mailing to the expectant mother with status INNREG is sent out.
DELTAKER (participant)	Consent form returned.
ABORTERT (abortion)	Notification of abortion either from the woman herself or the hospital.
UTMELDT (withdrawn)	Notification of withdrawal from the study.
VIL SLETTES (wants to be deleted)	Notification of withdrawal and that all data is to be deleted.
SLETTET (deleted)	Notification from the Biobank that blood samples with status VIL SLETTES are deleted.
DØDFØDSEL(still birth)	Notification that the baby died (after 16th week) from MBR or woman herself.

Deleting a pregnancy

A pregnancy can be deleted if a woman having first agreed to participate and later wishes to withdraw and have all the data concerning her pregnancy deleted. The resulting status is VIL SLETTES (to be deleted), and the Biobank is requested to delete blood samples. Data already registered from questionnaires can also be deleted from the main data files. However, data that have been made anonymous and already given to researchers cannot be deleted.

On receipt of an acknowledgement from the Biobank that blood samples have been deleted, the pregnancy is again called up and the date for deletion of the blood sample entered. The status of the pregnancy is then automatically registered as SLETTET (deleted). At this stage, the only information remaining in the system is that the woman has participated in the study during the pregnancy. A letter is sent to the woman , stating that all the information about her has been deleted.

Data from the Biobank

Once a week, a computer generated encrypted list of newly registered blood samples is sent to the project from the Biobank. Data from this list are entered into the tracking system. This enables consent form reminders to be sent and compilations of pregnancies with complete sets of blood samples to be made.

Linking data from MBR and DSP

Before questionnaire 4 is sent out, data from the Medical Birth Registry (MBR) and National census data (DSP) are linked to the tracking system. This is to confirm the date of birth and ensure that questionnaire 4 is only sent to women having one or more living children in the registered pregnancy. In addition, information about multiple births (twins, triplets) enables an appropriate number of questionnaires to be sent.

Appendix 2: Biobank description

Biological samples will be collected from participants during the Norwegian Mother and Child study.

At ultrasound examination: 100 000 samples from pregnant women

At and after the birth:

100 000 umbilical cord samples from the child

100 000 maternal samples

A pilot project, inviting the child's father to participate has been undertaken at Bærum hospital near Oslo. During the first recruitment period (October - November 2000) approximately 65 % of women, and approximately 80 % of their partners agreed to participate. Fathers are now also being asked to participate at other hospitals. Assuming that 80% of fathers will wish to participate, we shall have approximately 80 000 paternal samples nationwide.

A contract is signed with the National Institute of Environmental Health Sciences in the US to study the influence of environmental toxins for illhealth in mother and child. For this study, special blood samples and urine sample will be taken from the mother at ultrasound examination. In December 2000, an international advisory group visited the National Institute of Public Health in Oslo and gave recommendations.

SAMPLING TECHNIQUE

All samples are taken at the hospital and sent to the Biobank at The Division for Epidemiology, Norwegian Institute of Public Health, Oslo for registration, processing and storage.

At ultrasound examination:

Samples taken from pregnant women, the K1-sample:

Tube 1: 7 ml EDTA vacutainer-tube with whole blood

Tube 2: 7 ml EDTA vacutainer-tube with whole blood

Tube 3: 2.5 ml plasma in a plastic tube (transferred from tube 2)

Tube 4: 3 ml whole blood (EDTA)

Tube 5: 7 ml whole blood (EDTA)

Tube 6: 10 ml urine

Tube 2 is centrifuged in a standard centrifuge (not a chilled centrifuge) and 2.5 ml plasma is transferred to a 5 ml empty plastic tube.

To be sent to the Norwegian Institute of Public Health in Oslo:

Tube 1: 7 ml whole blood (EDTA)

Tube 2: 4.5 ml blood (2.5 ml plasma removed)

Tube 3: 2.5 ml plasma

Tube 4: 3 ml whole blood (EDTA)

Tube 5: 7 ml whole blood (EDTA)

Tube 6: 10 ml urine

See figure 1.

Samples taken from fathers, the F-samples:

- Tube 1: 7 ml whole blood (EDTA)
- Tube 2: 7 ml whole blood (EDTA)
- Tube 3: 2.5 ml plasma transferred from tube 2 (after centrifugation)

The tubes are sent to The Norwegian Institute of Public health

At birth

Cord blood, N:

- Tube 1: 7 ml whole blood (EDTA)
 - Tube 2: 7 ml whole blood (EDTA)
- Tubes are filled as much as possible using aspiration or squeezing the cord.

To be sent to The Institute of Health:

- Tube 1: 7 ml whole blood (EDTA)
- Tube 2: 7 ml whole blood (EDTA)

Maternal sample, K2:

- Tube 1: 7 ml whole blood (EDTA)
- Tube 2: 7 ml whole blood (EDTA)
- Tube 3: 2.5 ml plasma in a plastic tube (transferred from tube 2 after centrifugation)

All samples are labeled with mother's date of birth and name, together with information on type of blood sample: K1, K2, N or F. This information is also labeled to a note stating where and when the sample was taken.

If, for some reason, blood samples are not taken, the hospital sends notification to the Biobank at the Norwegian Institute of Public Health.

TRANSPORT

All samples are stored at 4°C until they are sent to the Norwegian Institute of Public Health.

If possible, blood samples should be sent the same day that they have been taken. The samples are sent as usual - not on ice or frozen. They can be sent as ordinary mail, by messenger or express delivery (over night). Information notes are sent together with the samples.

The samples are processed as soon as they arrive at the Norwegian Institute of Public Health. Exception: samples arriving on Saturdays will be stored at 4°C until Monday morning.

THE BIOBANK

A specially constructed data application (the Mother-Child-program) has been made for the Biobank. Its function is to keep track of where each individual sample is stored and ensure that samples cannot be mixed up. The program communicates with the software in a pipetting robot so that all the samples in the pipetting robot are correctly registered in the Mother-Child-program.

Registration of samples:

All in-coming samples are labeled with the woman's name and national identification number. The samples are registered in the specially constructed program using name, national identification number and the type of sample (K1, K2, N, F). In addition, the hospital's name and dates for sampling and arrival at the laboratory are registered. The contents of the sample (whole blood, plasma) are also registered, together with comments when these apply, e.g. coagulated umbilical cord sample, too little blood in tube, etc.

On storage, each sample is given a sample code, and the national identity number is encrypted/protected. Access to the file which allows the data to be decrypted will be strictly limited to authorized personnel.

Cord blood samples:

Umbilical cord blood will not be centrifuged at the hospitals. This will take place in the laboratory at the Norwegian Institute of Public Health, so that a plasma sample can also be obtained.

Subdividing the samples:

A robot-aided pipetting system is used to distribute full blood and plasma between 96-well microtiter and deep-well plates. All the plates are mechanically heat-sealed before they are frozen.

Whole blood: 1860 μ l is transferred to a single well in a deep-well plate. A single plate will therefore store blood from up to 95 people and at least one control. Storage tp. -86° C. (fig 1). 3 ml whole blood (EDTA) is frozen without any processing

Plasma: A total of 1.8 ml plasma is divided on microtiter plates. 300 μ l plasma from each person is stored, for example, in position 1B on six separate plates. Storage tp. -86° C (fig 1).

Urine: Subdivided and frozen in deep well plates.

DNA-extraction:

In addition to whole blood and plasma, DNA is also stored.

DNA is extracted from the rest of the blood, using a DNA-extraction kit (Examples: PureGene, Genra, FlexiGene). Approximately 150 – 700 mg DNA is obtained from each participant. The critical steps in the procedure, implying a risk that either samples or reagents are accidentally exchanged, are supported and controlled by the computer program. After the DNA is diluted leaving all samples with the same concentration, 100 ng/ μ l, a robotic system pipettes out 4 aliquots of 1,5 ml into deep-well plates. Storage tp. -20° C. (fig 1).

DNA from umbilical cord blood is extracted using the same kit. The samples that have coagulated are frozen at -20°C. During thawing, clotted samples are crushed using a wooden spatula before the standard procedure is followed.

Storage:

Each sample has a unique laboratory code and a unique location.

The sample will have a designated location on a plate. The plates are previously marked with two labels with a unique code and are placed in a containing rack, which is also marked with unique codes. The freezers also have code numbers.

Samples from each participant are stored in at least two separate freezers, and there will always be an empty back-up freezer in case of breakdown. Alarms that have been installed on the freezers, are activated if the temperature in the freezer rises 10 °C above the optimal.

Retrieval:

When samples are to be retrieved, the starting point is a list of national identity numbers. This will be entered into our computer program, and the program will find the correct location for the sample. As all samples are stored in 96-well plates, they will be subject to thaw-freeze cycles each time a plate is retrieved. As certain analytic techniques require that a sample has only been subject to a limited number of thaw-freeze cycles, it is important to keep a record of how often plates have been thawed. Other samples from the same individual will always be available at another location, which has not been thawed. The seals on the plate are only broken for the samples in question, and these are rapidly resealed prior to refreezing.

Deleting samples:

In the event a woman wishes to leave the project and that all her data and biological material be removed, a delete function is found in the data program. All information about the woman and her samples is then deleted permanently from the files. Blood samples will remain in the freezer, but no data will be connected to these.

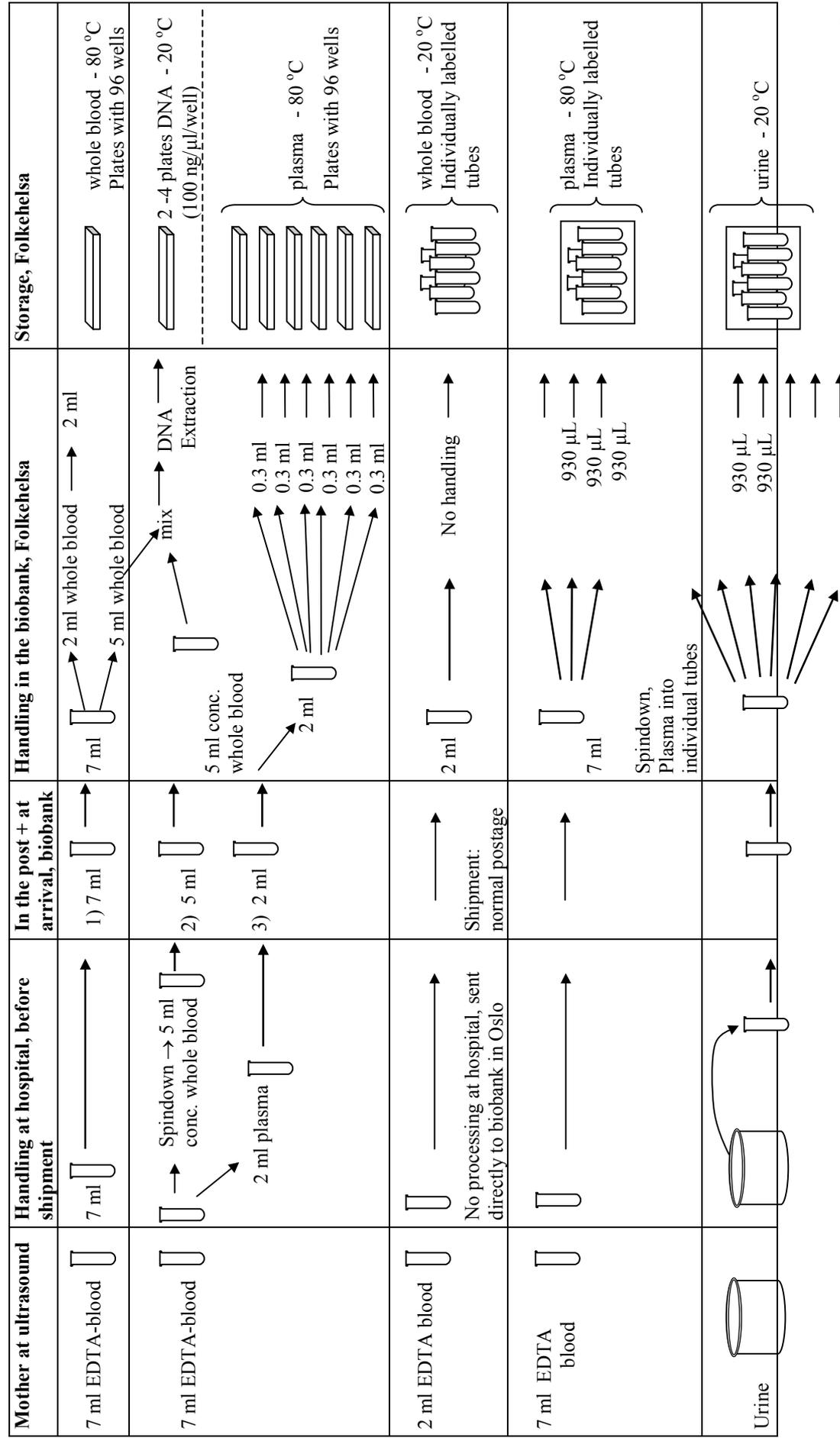
Communication with the Medical Birth Registry, Bergen:

Once a week a report is sent to MBR listing the samples that have been received at the laboratory. This information is encrypted and sent by electronic mail.

Information that a blood sample has not been taken is forwarded to MBR.

Figure 1
The Norwegian Mother and Child Study

Blood specimen at all stages from mother at ultrasound to biobank storage, final plan September 2001



<p>Vacutainer specimen cup</p>	<p>10 ml into tube</p>	<p>10 ml</p> <p>Shipment: normal postage</p>	<p>10 ml</p>	<p>930 µL 930 µL 930 µL 930 µL</p>	<p>Individually labelled tubes</p>
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Appendix 3: Description of the questionnaire database

Images of the questionnaires are scanned. These raw data files are stored. They make the starting point for coding variables which the scanner cannot manipulate directly, e.g. information about employment.

A database is constructed for each of the questionnaires and the ultrasound form. The databases can be linked using a serial number.

Quality controls will be carried out during and after the scanning process and before final storage. Personnel will be employed to undertake quality control and manual entering of specific variables if required.

A working group has been formed consisting of one person from The Norwegian Institute of Public Health in Oslo and one from MBR, who will make detailed instructions for quality control. The working group will ensure these instructions are carried out and that quality control is adequately documented. They will also suggest methods for checking the validity of the data.

Questionnaires having passed through the quality control will be stored in the databases. Each month, a copy of the databases at MBR in Bergen will be sent to The Division of Epidemiology in Oslo. Access to the data and agreements regarding analysis and publication, will be decided by the publications group.

The databases will be constructed and accessed using Oracle. Files intended for use by researchers for analysis, will be in SPSS format with a built-in codebook.

Appendix 4: Rules for access to data and publication

Aims

The aims are:

- to ensure rapid publication of all the important results of the study
- to ensure high scientific quality of the publications
- to ensure high availability of data for researchers working both internally and externally with the project group
- to set up procedures which enables the project's executive group to take responsibility for the professional content of the publications
- to maintain a complete list of all publications from the project
- to maintain a list over all sub-projects and ensure that access permission and obligations are complied with

Access to data

A major objective of the project is that data will be available to all researchers with relevant projects. Members of the project group and their collaborators will have free access to the questionnaire data and analysis files arising from linking the databases. These files will be available both at The Norwegian Institute of Public Health in Oslo, and MBR in Bergen.

Other researchers, nationally and internationally, will have access on request and following approval from the project's leader group. If necessary, contracts will be drawn up with external researchers. New sub-projects will be evaluated by the leader group. If several subprojects are found to be investigating the same or an overlapping topic, this will be resolved as far as possible by engaging in a direct dialogue with the parties involved.

In order for a request for data to become a recognized subproject, a short description that details the research question, variables to be investigated and the sample to be analyzed must be submitted. External researchers will be able to obtain an overview of the variables which are available by referring to the website.

For all subprojects, there will be conditions that either publication, or concrete plans for publication, will take place within three years after the data are made available. If this condition is not fulfilled, the data can be given to other researchers to study the same research questions. During the three years, the researchers will have exclusive rights to a particular research question. However, a high degree of specificity will be required in relation to the research questions.

If an external researcher requests a link between databases which is not of general usefulness, and if much work is required with preparation and delivery of blood samples, a request for payment to cover costs will be made.

Publication

The leader group will coordinate research between The Norwegian Institute of Public Health and external researchers. The group is composed of two representatives from The Division of Epidemiology in Oslo and two from Bergen (MBR). Membership in the group is for a two-year period, but reappointment is possible.

Co-authors from The Norwegian Institute of Public Health both in Oslo and MBR will be required for major articles that describe associations between exposure and effect in the whole

sample. Suggestions for articles should be sent to the leader group who appoints an authors' committee with a named first author having overall responsibility for the data analysis and structure of the article as recommended in the Vancouver recommendations. The authors' committee is responsible for arranging working procedures and deciding the corresponding order of authors in the published manuscript. The leader group must approve all article drafts before they are submitted to a journal.

For articles that cannot be defined as major articles, it will be sufficient that only one institution is represented. In these cases, however, the leader group will also require a description of the research question, variables and selection, and approve the final draft of the manuscript.

Articles from subprojects will be required to cite at least one major publication from the project and will contain standardized paragraphs in the methods and materials section giving a brief account of the Norwegian Mother and Child study. This description will be available in English and Norwegian and will be written by the leader group. A copy of each article will be sent to the leader group prior to submission to a journal. The project's leadership will not have the authority to censure the professional content of the article, but will ensure that there are no factual errors about the project.

Appendix 5: Consent form

Consent form

for participation in the Norwegian Mother and Child Cohort Study

I have read the letter inviting participation and the information brochure about the Norwegian Mother and Child study and understand that the information I give will be treated strictly confidentially. I am aware that the project has been recommended by the Regional Ethics Committee for medical research and approved by the Norwegian Data Inspectorate.

Participation in the Norwegian Mother and Child Cohort Study will entail the following:

- that I complete questionnaires, during and after pregnancy, about my own and my child's health and about possible causes of disease
- that I give a blood sample and if possible a urine sample, during pregnancy and one after the birth, and that a sample is also taken from the umbilical cord at birth
- that the results from ultrasound examinations carried out during the pregnancy will be made available to the project
- that no results (either concerning my own or my child's health) will be sent by the project to me
- that the blood samples from myself and my child will be stored and used in the future in research to study causes of diseases, including heredity. Laboratories in Norway and other countries will carry out this research following approval by the Regional Ethics Committee for medical research and the Norwegian Data Inspectorate that the blood samples can be used for this purpose.
- that the blood sample which is taken from my child to test for PKU (phenylketonuria) may be made available to the project
- that information about myself and the child can be obtained from other sources, for example the Medical Birth Registry and hospital records, following approval by the Norwegian Data Inspectorate
- that I can be asked to participate in further projects where I will be required to give additional information (or biological samples). Participation will be voluntary, and all such additional projects will satisfy conditions laid down by the Norwegian Data Inspectorate and the Regional Ethics Committee for medical research
- that information and blood samples will be stored indefinitely. This is a long-term study that will also investigate the reasons why diseases occur in adulthood. My child will be informed about the project when he/she is 15 years old, and consent requested from the child that he/she remains in the project when they are 18 years old
- that no information or biological samples will be made available to researchers before name and national identity number have been removed

I am aware that participation is voluntary and that I can withdraw from the study at any time by writing to the Norwegian Mother and Child Cohort Study, Norwegian Institute of Public Health, Medical Birth Registry, Kalfarveien 31, 5018 Bergen or telephone 22042718.

I have read the information above and agree to participate in the Norwegian Mother and Child Cohort Study.

Name: _____

National identity number (11digits): _____

Date: _____ Signature: _____

My address on the invitation letter is wrong, the correct address is:

Consent from the father

For participation in The Norwegian Mother and Child Cohort Study

I have read the invitation letter from The Norwegian Mother and Child Cohort Study and I understand that the information I give will be treated strictly confidentially. I am aware that the project has been recommended by The Regional Ethics Committee for medical research and approved by the Norwegian Data Inspectorate.

Participation in the Norwegian Mother and Child Cohort Study will entail the following:

- that I complete a questionnaire about my own health, life style and occupational environment
- that I give a blood sample at the time of my partner's ultrasound examination
- that no results will be sent by the project to me
- that the blood sample will be stored and used in the future for research purposes in order to study causes of disease, including heredity. Laboratories in Norway and other countries will carry out this research following approval by The Regional Ethics Committee for medical research and The Norwegian Data Inspectorate that the blood samples can be used for this purpose
- that I can be asked to participate in further projects where I will be required to give additional information (or medical samples). Participation will be voluntary, and all such additional projects will satisfy conditions laid down by The Norwegian Data Inspectorate and The Regional Ethics Committee for medical research
- that information and blood samples will be stored indefinitely
- that no information or medical samples will be made available to researchers unless name and national identity number have been removed.

I am aware that participation is voluntary and that I can withdraw from the study at any time by writing to The Norwegian Mother and Child study, Norwegian Institute of Public Health, Medical Birth Registry, Kalbarveien 31.5018 Bergen or telephone 22042718

Date:

Name:

Address:

National identity number:

Mother's name

Mother's National identity number:

Signature:

Appendix 7: Questionnaire 1

The Norwegian Mother and Child study

Questionnaire I

This questionnaire will be processed by a computer and it is therefore important that you follow the instructions below: -

- Please use a blue or black ballpoint pen
- Put a cross in the box that is most relevant, like this:
- Should you put a cross in the wrong box correct it by filling in the box completely, like this:-
- In the large green boxes write a *number* or a *capital letter*
- Several questions in this questionnaire concern the week of pregnancy; e.g. fill out week 5 for something that occurred 5 weeks following your last period
- Specific information e.g. medication or profession should be written in the box on the corresponding line

Please write clearly in CAPITAL LETTERS

Return the form in the stamped addressed envelope provided.

Date questionnaire was completed: ____ Day Month Year ____ (Year should be written with 4 nos. e.g. 2001)

Question	Answer
Menstruation	
1. How old were you when you had your first menstrual period?	Years old
2. How many days between the first day in your menstrual period and the first day in your next menstrual period?	Days
3. Are you usually depressed or irritable before your period?	No/ Yes, but just slightly/ Yes noticeably/ Yes, very much
4. If yes, does this feeling disappear after you get your period?	No/ Yes
5. Were your periods regular the year before you became pregnant?	No/ Yes
6. During the last year before you became pregnant, did you lose your period for more than three months without being pregnant?	No / Yes due to another pregnancy / Yes for other reasons
7. Date of first day of last menstrual period	day / month / Year
8. Did your last menstrual period come at the expected time	No/ Yes
9. Are you certain about the date of first day of last menstrual period?	Certain/ Uncertain
10. Describe the duration, amount of bleeding and period pains of your last period	<i>As usual/ More than usual/ Less than usual</i> Duration/ Amount of bleeding/ Pain
Contraception	
11. Have you/your partner at any time during the last year used the following methods to avoid becoming pregnant? (fill in those that are relevant)	Condom/ Diaphragm/ IUD/ Hormone IUD/ Hormone injection/ Mini pill/pill/ Spermicides (foam, cream, suppositories)/ Safe period/ Withdrawal/ No such methods/ Other
12. If you have used the pill/mini-pill, how long have you used them?	<i>Pill/ Mini-pill</i> Less than one year/ 1-3 years/ 4-6 years/ 7-9 years/ 10 years or more
13. If you have used the pill/mini-pill, how old were you when you first used it?	Years old
14. Were you taking the pill/mini pill during the last 4 months before this pregnancy?	No/ Yes
15. If yes, how long before your last menstrual period did you stop taking the pill/mini-pill?	Weeks
16. Was this pregnancy planned?	No/ Yes
17. If yes, how many months did you have regular intercourse without contraception before you became pregnant?	Less than 1 month/ 1-2 months/ 3 months or more/ Number of months if more than 3
18. Did you become pregnant even though you or your partner used contraceptives	No (go to question 21) / Yes

19. If yes, which type? (fill in more than one if applicable)	Condom/ Diaphragm/ IUD/ Hormone IUD/ Hormone injection/ Mini pill/ Pill/ Spermicides (foam, cream, suppositories)/ Safe period/ Withdrawal/ Other
20. If you became pregnant while using an IUD, has it now been removed?	No / Yes
21. How long have you and the baby's father had a sexual relationship?	Months or years
22. How often did you have sexual intercourse during the four weeks before you became pregnant and during the last four weeks?	<i>Before/ Now</i> Every day/ 5-6 times a week/ 3-4 times a week/ 1-2 times a week/ 1-2 times every two weeks/ More seldom/ None
23. Have you ever been treated for infertility?	No / Yes
24. If yes, was it in connection with this pregnancy or an earlier pregnancy and what type of treatment did you have?	Surgery on the ovaries / Other surgery / Medication for endometriosis / Hormone treatment / Insemination (injection of sperm) / Test-tube method / Other
25. Have you been given information about amniocentesis?	No / Yes
26. What was your blood pressure at your first antenatal visit?	Highest/ Lowest
27. What did you weigh at the time you became pregnant and what do you weigh now?	<i>When I became pregnant/ Now</i>
28. How tall are you?	cm
29. How tall is the baby's father	cm
30. How much does the baby's father weigh?	kg
Previous pregnancies	
31. Have you been pregnant before? (this includes any pregnancies that ended in abortion, miscarriage or a stillbirth)	No (go to question 36) / Yes
32. If yes cross off for all earlier pregnancies. Include those pregnancies ending in abortion, miscarriage or still birth as well as those outside the uterine wall. State the year the pregnancy began, how many kilos you gained and the number of months you breast-fed each baby. State whether or not you smoked during earlier pregnancies	Pregnancy no. / Year of pregnancy / Live infant / Spontaneous abortion / Termination of pregnancy / Pregnancy outside the uterus / Week of pregnancy for abortion/still birth / No. of months breast feeding / Weight gain in pregnancy / Smoked during pregnancy
33. Cross off if you have had any of the following problems in previous pregnancies	<i>No/ Yes</i> Pelvic girdle pain resulting in sick leave/ Pelvic girdle pain resulting in bed rest/ Serious nausea and vomiting/ Eclampsia of pregnancy/ Diabetes of pregnancy/ Sugar in urine/ Problems with incontinence
34. If you had pelvic girdle pain in a previous pregnancy, which led to bed rest or sick leave, when did the pain start?	No. of months after start of pregnancy
35. When did the pain stop?	Months after pregnancy / Still have pain
Illnesses and health problems during this pregnancy	
36. Have you had bleeding from the vagina once or more during this pregnancy?	No / Yes

<p>37. If yes, describe the first and last period of bleeding. Give the date the bleeding started, how many days it lasted and how much you bled.</p>	<p><i>Date when bleeding started/ No. of days variation/ Amount</i> First bleed/ Last bleed Trace of blood/ More than just a trace/ Coagulated blood. <i>If more than two episodes of bleeding, how many?</i></p>
<p>38. Have you experienced any of the following problems during this pregnancy? If you have used medication in connection with these problems give the name of the medicine; in which week you took the medicines and how many days you took them. <i>(Include all types of medication, both prescription and over the counter medicines. Do not include vitamins and dietary supplements as these are discussed elsewhere.)</i></p>	<p><i>Illness/ Use of medication</i> If you were ill - in which week of pregnancy/ If you took medication - in which week of pregnancy/ No. of days used Pelvic girdle pain/ Abdominal pain / Back Pain / Neck and shoulder pain / Nausea / Nausea with vomiting/ Vaginal thrush / Vaginal discharge/ Itchy rash/ Constipation/ Diarrhoea/ gastric flu / Unusual tiredness/sleepiness/ Sleeping problems / Heartburn/reflux/ Oedema/ Fever with rash/ Fever over 38 C/ Common cold/ Throat infection/ Sinusitis/ear infection/ Influenza/ musculoskeletal pain/ Pneumonia/bronchitis/ Sugar in your urine/ Albumin (protein) in your urine</p>
<p>Past and present illnesses and health problems</p>	
<p>39. Do you have or have you had any of the following illnesses or health problems? If you have taken medication (tablets, mixtures, inhalation etc.) give the names of the medication and when you took them.</p>	<p><i>Illness/ Use of medication</i> <i>Before pregnancy/ During pregnancy/ Name of medicine/ Last 6 months before pregnancy/ 0-4 weeks/ 5-8 weeks/ 9-12 weeks/ 13+ weeks/ No. of days used</i> Asthma/Allergy/Skin disorders Asthma/ Hay fever, pollen allergy/ Animal hair allergy/ Other allergy/ Atopic dermatitis(childhood eczema) /Urticaria(hives)/ Other eczema/ Psoriasis/ Cold sores(herpes)/ Acne/spots (serious) Diabetes Diabetes treated with insulin/ Diabetes treated without insulin Heart / Blood / Metabolism / Circulation Congenital heart defect/ Other heart disease/ High cholesterol/ High blood pressure/ Hypothyroidism/ Hyperthyroidism/ Anaemia/ Low haemoglobin/ B-12/folic acid insufficiency Gastrointestinal Hepatitis/ jaundice/ Gall stones Duodena/stomach ulcer/ Crohn's disease/ Ulcerative colitis/ Celiac disease / Other gastro-intestinal problems Musculo-skeletal/Connective tissue Rheumatoid arthritis/Ankylosing Spondylitis / Lupus(SLE)/ Sciatica / Myalgia Genital and urinary tract</p>

	<p>Ovarian / fallopian tube infection/ Endometriosis/ Descent of the uterus/ Ovarian cyst/ Myoma/ Cervical cell changes/ Herpes/ Venereal warts/ Gonorrhoea / Chlamydia/ Kidney stones/ Kidney infection/ Repeated infection of urinary tract/ Incontinence</p> <p>Other disorders</p> <p>Sleep disorders/ Extreme tiredness/ Anorexia, bulimia/ Migraine/ Other headache/ Epilepsy/ Multiple sclerosis/ Cerebral palsy/ Cancer / Depression/ Anxiety/ Other long illnesses or health problems / Which</p> <p>No/ Yes</p>
40. Do you have a congenital deformity?	
41. If yes, which?	
42. Do you bleed from your gums when you brush your teeth at present?	No, rarely or never / Yes, sometimes / Yes, often / Yes, nearly always
43. If you had diabetes before you became pregnant, what was your last long-term blood sugar level (HbA1c) before you became pregnant?	Less than 7.5/ 7.5-12/ More than 12/ Do not know
Other medication	
44. Have you used other medication not previously mentioned? If yes, which and when did you take them?	<i>Last 6 months before pregnancy/ During 0-4 weeks/ 5-8 weeks/ 9-12 weeks/ 13+ weeks of this pregnancy/ No of days used</i> Name of medication e.g. Valium Rohypnol, Paracetamol
Vitamins, minerals and dietary supplements	
45. Do you take any vitamins, minerals or other dietary supplements?	No (go to question 49) / Yes
46. Fill out the table below for the vitamins and minerals found in the contents list on the vitamin package/bottle.	<i>When did you start taking supplements? Before last period 9+ weeks/ 8-5 weeks/ 4-0 weeks. After last period 0-4 weeks/ 5-8 weeks/ 9-12 weeks/ 13+ weeks</i> <i>How often do you take these? /daily/4-6 times a week/1-3 times a week</i> Folic acid/ Vitamins B1 (Thiamine)/ B2(Riboflavin) / B6 (Pyridoxine) / B12/ Niacin /Pantothenic acid/ Biotin / Vitamins C/ A/ D/ and E / Selenium/ Zinc / Copper /Iron Chromium / Magnesium /Calcium/ Fluoride/ Cod liver oil/ omega -3
47. Give the complete name(s) of all the vitamin and dietary supplements you use. Include herbal remedies and slimming products. (<i>Write clearly using capital letters as this will be processed by a computer</i>)	E.g. VITAPLEX WITH IRON
48. If you use multivitamins (with or without minerals) do these contain folic acid?	Yes / No / Don't know
Civil status and education	
49. What is your civil status?	Married/ Live-in partner / Single/ Divorced, Separated/ Widow/ Other.
50. What education do you and the baby's father have? (<i>Cross off one box only for the highest</i>	<i>You/ Father</i>

<p><i>completed education. Cross also off for current studies)</i></p>	<p><i>Completed/ Study in process</i> 9 years compulsory education/ 1-2 year junior high school/ Technical high school/ Senior high school/ 3 year college and up to 4 year university degree/ More than 4 year university degree/ Other education</p>
<p>Work and leisure</p>	
<p>51. What was your and the baby's father work situation when you became pregnant? (You may put in several answers)</p>	<p>Student/ Housewife/ Apprentice/ Military service/ Job seeking/ disability pension/ Public employee/ Private company employee/ Self-employed/ Family business/ Other</p>
<p>52. Did you have an extra job when you became pregnant?</p>	<p>No/ Yes, describe</p>
<p>53. Have you been absent from work more than two weeks during this pregnancy?</p>	<p>No/ Yes</p>
<p>54. Are you absent from your work at the present time?</p>	<p>No/ Yes</p>
<p>55. If yes, what is the reason for your absence?</p>	<p>Sick leave/ Unpaid leave of absence/ Sick child/ Other.</p>
<p>56. No. of paid working hours a week before you became pregnant and at present.</p>	
<p>57. Describe the type of work carried out at your and the baby's father's place of work. (For example :- hospital department for children with cancer, body workshop for diesel vehicles, work in the home)</p>	<p>You / Baby's father</p>
<p>58. Occupation/ job title for you and the baby's father (e.g. staff nurse, mechanic, foreman, lecturer, student, cleaner, housewife)</p>	<p>You Baby's father</p>
<p>59. Indicate the appropriate answer for each of the following questions concerning your present work situation.</p>	<p><i>Yes, daily, more than half of the working day/ Yes, daily, less than half of the working day/</i> <i>Yes, periodically, but not daily/ Seldom or never</i> Do you sometimes have so much to do that your work situation becomes taxing? Do you have to turn and bend many times in the course of an hour? Do you work with your hands above shoulder level or higher? Do you mostly walk or stand at work? Can you choose to work a little faster some days, and a little slower on other days? Are you subjected to a lot of uncomfortable background noise? Are you subjected to a lot of background noise which makes you have to raise your voice when talking to others, even at a distance of one metre? <i>Agree/ Agree mostly/ Do not agree very much/ Do not agree at all</i></p>
<p>60. Consider the following statements of your work situation (cross off the answer that is most appropriate)</p>	<p>I have physically heavy work. / My work is very stressful / I learn a lot though my work / My work is very monotonous / My work demands a high working tempo / I am able to decide how my work is to be carried out / There is a good team spirit at my place of work / I enjoy my work</p>

61. When are your working hours?	Permanent day work / Permanent evening work/ Permanent night shift/ shift work (day and night)/ No set times (extra shift work/ temporary employment)/ Other.
62. Do you lift anything that weighs more than 10 kg now, while pregnant? (10 kilos is the equivalent of a full bucket of water)	At home/ At work Yes, more than 20 times a day/ Yes, 10-20 times a day/ Yes, more than 20 times a week/ Yes, less than 20 times a week/ Seldom or never.
63. How often have you worked near a radio transmitter or radar after becoming pregnant?	Never/ A few times a week/ Daily/ On average more than an hour a day.
64. How often do you talk on a cellular phone?	Never/ A few times a week/ Daily/ On average more than an hour a day
65. Do your cellular phone calls last more than 15 minutes?	Never/ Seldom/ Often
66. How often do you work with a computer, laser printer or copying machine (at a distance of less than two metres) after you became pregnant?	Never/ A few times a week/ Daily/ On average more than an hour a day.
67. How often have you worked with x-ray equipment (at a distance of less than two metres) after you became pregnant? (This does not include treatment as a patient)	Never/ A few times a week/ Daily/ On average more than an hour a day.
68. Have you been in contact with any of the following substances either at work or in your spare time during the last six months?	Yes/no /If yes, no. of days in the last six months/ Did you use a ventilator or mask/ did you use protective gloves. Lead gas, lead dust, lead particles or lead alloys / Chrome, arsenic, cadmium or a combination of these / Petrol or exhaust (does not apply to filling up your own car) Mercury gas, mercury or work with amalgam fillings (not including own dental treatment) / Disinfectant products or insect repellents / Garden chemicals (insecticides, weed killer, fungicides) Oil based paint / Water based or latex paint / Paint solvents, paint varnish, glue remover or other solvents (e.g. white spirit, toluene, carbon tetrachloride) /Industrial colouring or printers ink / Motor oil, lubrication oil or other types of oil / Photo-chemicals (fixatives or developers) Welding agents / Soldering agents/ Formalin /formaldehyde / Chemotherapy materials (excluding personal treatment) / Laughing gas or other anaesthetic gases (excluding personal treatment) / Other chemicals or conditions- describe
69. How often have you been to a discotheque since you got pregnant?	1-2 times a week / Less often / Never
70. Are you in contact with animals either at work or in your spare time?	No / yes
71. If yes, what sort of animals and how often are you in contact with them on a weekly basis?	Daily 7 3-6 times a week 7 1-2 times a week / Less than once a week Dog / Cat / Guinea pig / Hamster / Rabbit / Budgerigar or other birds/ Aquarium fish / Cow / Pig / Sheep or goats / Horse / Poultry / Other
Household conditions	
72. With whom do you live?	Spouse/ Partner/ Parents/ Parents-in-law/ Children/ Alone/ Others, describe
73. How many people share your home, including yourself?	No. of people over 18 /No. of people between 12 and 18

		No of people between 6 and 11/ No of people under 6
74. How many children are at nursery school?		Children
75. Do you or the baby's father have another mother tongue than Norwegian		Yes / No
76. If yes, which language?		Sami / Urdu / English / Other / Which You / Baby's father
77. Do your parents or the baby's father's parents have another mother tongue than Norwegian?		No / Yes
78. If yes, which language?		Sami / Urdu / English / Other, which
79. What is your and the baby's father's yearly income before tax? (<i>Including child support, unemployment benefit and other allowances</i>)		No income/ Under 150.000 NOK/ 151.000-200.000 NOK/ 201.000-250.000 NOK/ 251.000-300.000 NOK/ 301.000-400.000 NOK/ 401.000-500.000 NOK/ Over 500.000/ Don't know
80. Is it possible for your household to manage financially without your income?		No/ Yes, but with difficulty/Yes, without difficulty
81. What type of house do you live in?		Detached house/ Farm/Semidetached/ Four-flat house/ Maisonette/ terraced flat/ basement flat/ block of flats/ tenement - which floor?/ Other
82. Has there been water damage or a smell of mould or mildew in your home in the past 3 months?		No / Yes water damage / Yes signs of fungus and mould / Yes a smell of mildew
83. Where does your drinking water come from?		Public or private water supply/ from a local source (e.g. well)
84. How many times have you moved in the last 3 years?		Times
85. Has anyone in your home had influenza, a prolonged cough or an illness with fever and a rash while you have been pregnant		No/ Yes
86. If yes, which illness		German measles/ Chicken pox/ Measles/ "4th infant disease"/ influenza/ Fever and rash/ Prolonged cough/ Tuberculosis/ Mouth, hand and foot disease/ Other
Habits		
87. Did your mother smoke when she was pregnant with you?		No/ Yes / Do not know
88. Are you exposed to passive smoking at home?		No/ Yes
89. If yes, how many hours a day are you exposed to passive smoking?		No of hours
90. Are you exposed to other people's smoking at work?		No/ Yes
91. If yes, how many hours a day are you exposed to other people's smoking?		No of hours
92. Did the baby's father smoke before you became pregnant?		No/ Yes
93. Does he smoke now?		No/ Yes
94. Do you, or have you ever smoked?		No (go to question 104) / Yes
95. Do you smoke now (after you became pregnant)?		No/ Sometimes/ Daily / No of cigarettes per week /No of cigarettes per day
96. Did you smoke regularly during the last 3 months before you became pregnant this time?		No/ Sometimes/ Daily / No of cigarettes per week / No of cigarettes per day

97. How old were you when you started to smoke on a daily basis?	Years of age
98. Have you stopped smoking completely?	No / Yes
99. If yes, how old were you when you stopped smoking?	Years
100. If you stopped smoking after you became pregnant, in which week of pregnancy did you stop?	Week
101. How long after you get up in the morning until you light your first cigarette?	5 minutes/ 6-30 minutes/ 31-60 minutes/ More than an hour
102. Do you smoke when you are ill?	No/ Yes
103. Do you smoke more often during the first few hours after you wake up than you do during the rest of the day?	No/ Yes
104. If you have used other kinds of nicotine indicate which and when you used them.	<i>Before pregnancy/Now</i> Chewing tobacco / snuff / Nicotine chewing gum/ Nicotine plaster/ Nicotine inhaler
105. What was your fluid consumption per day before and during pregnancy? (no of cups/glasses of tea coffee and soft drinks)	<i>Before pregnancy/ Now/ Decaffeinated /Ecological</i> Filter coffee/ Instant coffee/ Percolated coffee/ Tea/ Herbal tea/ Coca cola Pepsi/ Diet coke/ Other diet sodas/ Tap water/ Bottled water/ Squash/ Diet squash/juice/ Skimmed milk/ Semi-skimmed milk/ Full cream milk/ Other types of milk
106. Have you used any of the following substances?	<i>Never/ Previously/ Last month before pregnancy/ during pregnancy</i> Hash/ Amphetamine/ Ecstasy/ Cocaine/ Heroin
107. Have you ever drunk alcohol?	No (go to question 117) /Yes
In order to compare the different types of alcohol, we ask about what we call alcohol units (= 1.5 cl. pure alcohol). 1 alcohol unit means: 1 bottle cider or low alcohol soda = 1 alcohol unit 1 beer glass of beer = 1 alcohol unit 1 wine glass red or white wine = 1 alcohol unit 1 wine glass sherry or other fortified wine = 1 alcohol unit 1 snaps glass spirits or liqueur = 1 alcohol unit	
108. Approximately how often did you drink alcohol in the 3 months before you became pregnant and what are your drinking habits during pregnancy?	<i>Before pregnancy/ During pregnancy</i> Never/ Less than once a month/About. 1-3 times a month/ once a week/ 2-3 times a week/ 4-5 times a week/ 6-7 times a week
109. What type of alcohol do you usually drink?	Light beer/ Beer/ Red wine/ White wine/Low alcohol sodas / Fortified wines (<i>sherry, port wine / Spirits (vodka, gin, snaps, brandy whisky, liqueurs)</i>)
110. Did you drink 5 units or more at least once during the last 3 months before pregnancy or during pregnancy?	Last 3 months before pregnancy/During pregnancy Several times per week/once a week/1 – 3 times per months/ less than once per month/never

111. How many units of alcohol do you usually drink when you drink alcohol?	<i>Last 3 months before pregnancy/ During pregnancy</i> Less than 1/ 1-2/ 3-4/ 5-6/ 7-9/ 10 or more
112. How many units of alcohol do you have to drink before you feel any effect?	No/ Yes
113. Have other people annoyed you by criticising how much you drink?	No/ Yes
114. Have you ever felt that you ought to drink less?	No/ Yes
115. Have you ever drunk alcohol in the morning to calm your nerves or to get rid of a hangover?	No/ Yes
116. Have you ever experienced any of the following problems during the last year in relation to your use of alcohol? Argue with, or had negative feelings for, a member of your family / Suddenly found yourself somewhere without knowing how you got there / Been absent from work/school / Fainted or passed out suddenly / Had a depressive period	<i>Never / Once / Several times</i>
Weight and weight control	
117. Do you think you were overweight before this pregnancy?	Yes, a lot/ Yes, a little/ No
118. Are you worried about putting on more weight than necessary during this pregnancy?	Yes, very worried/ Somewhat worried/ No, not especially worried
119. Has anyone said that you were too thin, while you yourself think that you were too fat during the last 2 years?	Yes, often/ Yes, occasionally/ No
120. Have you ever lost control while eating and not been able to stop before you have eaten far too much?	<i>Last 6 months before this pregnancy Now</i> Yes, at least once a week/ Seldom-never
121. Have you ever used any of the following to control your weight? At least once a week/ Seldom-never Vomiting/ Laxatives/ Fasting/ Hard physical exercise	<i>Last 6 months before this pregnancy/ Now</i> Yes, very important/ No, not especially important
Physical activity	
123. How often do you usually exercise at the present time? Last 3 months before pregnancy/ During pregnancy Activity / Walking/ Brisk walking/ Running/ Jogging/orienteering/ Bicycling/ Training studio/ weight training / Special gymnastics/ Aerobics for pregnant women/ Aerobics/gymnastics/dance without jumps and running/ Aerobics/gymnastics with running and jumping/Folk dancing/swing/ Rock/disco dancing/ Skiing/ Team sports/ Swimming/Riding/ Other Never / 1-3 times a month / No. of times a week / No. of minutes each time	
124. How many times a week do you do exercises for the following muscle groups? Abdominal muscles / Back muscles / Pelvic floor muscles <i>Never / No. of times a week / No. of minutes each time</i>	
125. How often, at present, are you so physically active that you sweat and are breathless? (<i>fill in for both work and leisure</i>) Last 3 months before pregnancy/ During pregnancy Never / Less than once a week / Once a week / 2-3 times a week / 4-6 times a week /	

		Almost every day <i>At work / At leisure</i>
You and your feelings		
126	Indicate whether or not you agree with the following statements?	<i>Completely disagree/ Disagree/ Disagree somewhat/ Indifferent/ Agree somewhat/ Agree/ Agree completely</i> In most respects, my life is everything I want it to be/My life circumstances are fantastic I am happy with my life/So far, I have achieved the things that are important to me in life/If I could live my life again I would change very little
127.	How much do you agree with these statements about your relationship with your partner (<i>only answer if you have a partner</i>)	<i>Agree completely/ Agree/ Agree somewhat/ Disagree somewhat/ Disagree/ Disagree totally</i> There is a close relationship between me and my partner/ My partner and I have problems in our relationship/ I am very happy in my relationship with my partner/ My partner is generally very understanding/ I often think about ending our relationship/ I am satisfied with my relationship with my partner/ We often disagree on important decisions/ I have been lucky in my choice of a partner/ We agree on how to bring up children/ I think my partner is satisfied with our relationship
128.	Do you have anyone you can ask for advice in a difficult situation besides your husband/partner?	<i>No / Yes 1-2 people / Yes more than 2 people</i>
129.	How often do you meet or talk on the telephone with your family (outside your home) or close friends in the course of two weeks?	<i>Once a month or less / 2-8 times a month / More than twice a week</i>
130.	Do you ever feel lonely?	<i>Almost never / Seldom / Sometimes/ Usually/ Almost always</i>
131.	Have you been bothered by any of the following during the last two weeks?	<i>Not bothered/ Slightly bothered/ Quite bothered/ Very bothered</i> Worried or concerned/ Nervousness/ uneasiness/ Feelings of hopelessness regarding the future/ Depressed / Very anxious and uneasy
132.	Have you, in your adult life, ever been slapped, hit or kicked or been bothered in any way physically? (<i>you may cross off several</i>)	<i>During this pregnancy /Last 6 months before pregnancy/ Earlier</i> No/ Yes/ Do not remember
133.	Have you during the last 12 months, or earlier, been pressured or forced into having sexual intercourse?	<i>During this pregnancy / Last 6 months before pregnancy / Earlier</i> No, never/ Yes, Pressed/ Yes, Forced with violence/ Yes, raped
134.	How do you see yourself?	<i>Agree totally/ Agree/ Disagree/ Totally disagree</i> I have a positive attitude to myself / I feel useless at times / I do not feel as if I have much to be proud of/ I feel that I am as good as anyone else
135.	Has there ever been a continuous period in your life of 2 weeks or more when you:	No/ Yes Felt depressed or sad/ Lost your appetite or ate too much/ Felt weak or lacked energy/ Really blamed yourself and felt worthless/ Had problems concentrating or making decisions/ Had at least three of the above problems at the same time
136.	If you have had 3 or more of these problems at the same time how many weeks did the longest period last?	No of weeks
137.	Was there a special reason for this?	No, no special reason/ yes (e.g. death, divorce, miscarriage, accident)

Appendix 8: Questionnaire 2

The Norwegian Mother and Child Study

Questionnaire 2

What do you eat?

In this form we ask about your dietary habits, what you normally eat. We realise that diet may vary from day to day. Try therefore to give an 'average' of your habits the year before you became pregnant. If you are unsure, try to give your best estimate.

A machine will read the form. It is therefore important that you emphasise the following:

- Use blue or black ballpoint pen.
- Place a cross in the box most closely reflecting your intake.
- If you put a cross in the wrong box, correct it by filling in the whole box, like this:
- In the big green boxes you may write numbers or capital letters
- "<1" means less than once
- "+" means more than

It is important that you only write in the white boxes, like this:

Example, completing question 1:

Jane eats five slices of bread and a piece of rye crisp bread daily. She usually eats light whole grain bread, but in the weekends this is often exchanged for white bread. She completes question 1 like this:

1. How much bread do you usually eat?

Add up what you normally eat for meals during a day (1/2 roll = 1 slice, 1 baguette = 5 slices, 1 ciabatta = 4 slices)

No. of slices per day

Light bread
(white bread, baguettes, white bagels etc)

Whole grain bread
(light whole grain bread, light home-made, wheat bagels etc)

Full fibre bread
(fibre-rich whole flour bread, dark whole flour bread, full fibre home-made, full fibre bagels)

Rye crisp bread

No. of slices per day $6 \times 7 = 42$ no of slices per week.

To English-speaking readers:

On the following pages you will find our dietary questionnaire. Most questions have been translated directly, but a number of foods exist in varieties not known on the American market. Thus the questions have to be regarded as indicators of the food groups we ask about, and should not always be taken literally.

Appendix 9: Questionnaire 3

The Norwegian Mother and Child study

Questionnaire 3

Question	Answer
Antenatal care and health	
1. Where, and how often, have you been to antenatal check ups? (<i>You may fill in more than one box</i>)	Health center/ Doctor's office /Hospital polyclinic /no. of times
2. Who has examined you each time? (<i>You may fill in more than one box</i>)	Midwife /General practitioner /Gynaecologist / Community health nurse /no. of times
3. Is your doctor male or female?	General practitioner /Gynaecologist / Male / female
4. If you attend, or have attended, a gynaecologist or hospital polyclinic for your antenatal check ups, what was or is the reason?	Referred due to complications during pregnancy /Referred due to previous illness or complications in earlier pregnancies /On your own initiative without a referral
5. Do you agree with the following statements concerning your antenatal check ups?	<i>Agree completely / Agree / Agree a little /Disagree / Disagree a lot</i> I have been given sufficient information and advice /I have been well looked after as a person /There was not enough time during the consultation /I feel secure during these check ups /I have been able to discuss everything I needed to during the check ups /I am satisfied with the way I have been followed up by the health service
6. Have you needed to contact a midwife or doctor apart from your normal check ups?	Midwife /Doctor /Yes /No
7. If yes, was it difficult to get an appointment?	<i>Not difficult /A little difficult /Very difficult /Midwife /Doctor</i>
8. Have you had a gynaecological examination during your pregnancy (an internal examination)? If so how many times?	Yes /No /No. of times
9. How many ultrasound examinations have you had during your pregnancy?	External examination / Internal examination/ No. of times
10. Have you been offered an amniocentesis or placenta biopsy?	No (go to question 15) Yes
11. If yes, were any tests carried out and what did they show?	Amniocentesis /Placenta biopsy /Was the test(s) carried out /Yes /No /Was the test(s) normal/ Yes/ no If the tests were abnormal explain the findings
12. If an amniocentesis or placenta biopsy was performed, what was the reason for this?	Because of my age (normally 38 or older at the time of delivery)/ Previous child with a chromosome disease/ Previous child with spina bifida/Epilepsy(medication for

	epilepsy)/Ultrasonic findings /Other Yes / no
13. Were there complications in the first 2 weeks following the amniocentesis?	Vaginal bleeding /Leakage of amniotic fluid/ Abdominal pain (like period pains only stronger) No /Yes
14. If yes, what sort of complications?	
15. Have you taken an X-ray during pregnancy?	<i>Week of pregnancy 0-12/ 13-16/ 17-20/ 21-24/ 25-28/ 29+/ No. of times</i>
16. If yes, what part of the body was X-rayed? How many X-rays were taken and in which week of pregnancy?(You may fill in more than one box)	Teeth/ Lungs/ Limbs/ Pelvis/abdomen/back /Other
17. Have you ever had treatment to prevent a premature birth during this pregnancy?(You may fill in more than one box if applicable)	No / Yes relax or bed-rest /Yes medication
18. If you took medication what type was it?	
19. Have you been vaccinated during this pregnancy?	Yes/ No Which vaccine
20. Have you had high blood pressure during your pregnancy?	No/ Yes/ Don't know
21. If the answer was yes what was the highest reading during this pregnancy? (Look at your health card)	/ Example 150/95 Don't know
22. Have you had high blood pressure without being pregnant?	Yes/ No /Don't know
23. If yes then what was the highest recording before you became pregnant?	/ Example 150/95 Don't know
24. What was your haemoglobin percentage during this pregnancy? (Look at your health card and note the lowest, highest and most recent percentage)s	Haemoglobin/ Week of pregnancy Most recent/ Highest during pregnancy/ Lowest during pregnancy
25. How much did you weigh at your last antenatal check up? (Look at your health card)	Weight / kilos Date of antenatal check up/ Day /Month/Year
26. Have you been admitted to hospital since you became pregnant?	No/ Yes/which hospital
27. If the answer was yes then why and when were you hospitalised?(You can fill in more than one box)	In which week of pregnancy were you admitted 0-4/5-8/ 9-12/ 13-16/ 17-20/ 21-24/ 25_28/ 29+ Recurrent nausea and vomiting/ Bleeding/ Leakage of amniotic fluid/ Early labour/ High blood pressure/ Preeclampsia/Other
28. Do you have or have you ever had any of the following?	<i>How often have you had problems? /Never/ 1-4 times a month/ 1-6 times a week/ Once a day/ More than once a day/ How much at a time? Drops/ Large amounts</i> <i>Before this pregnancy/ In this pregnancy /Urine leakage when you cough, sneeze or laugh/ Urine leakage during physical activity(running or jumping)/ Sudden need to urinate (problems in reaching the bathroom in time)/ Problems with stool leakage/ Problems with passing gas</i>
29. Do you have or have you had pain in any of the following parts of your body? Cross off for where and when. (You may fill in several boxes)	In this pregnancy/ Prior to my first pregnancy/ In earlier pregnancies/ Between pregnancies Mild pain/ Severe pain In the lower back/ In one of the pelvic-sacral joints/ In both pelvic-sacral joints/ Over the coccyx (tailbone)/ In the buttocks/ In the pubic area/ In the groin/ Other back pain

30. Do you wake up at night due to pelvic pain?	Yes frequently/ Yes sometimes/ No never
31. Do you have so much difficulty walking due to pelvic pain that you have to use a stick or crutches?	No never/ Yes but not every day, pain varies from day to day/ Yes I have to use crutches or stick every day
32. Have you had an anaesthetic in connection with surgery or dental treatment during this pregnancy?	No/ Yes
33. If so what type of anaesthetic did you have? <i>(You may cross off several)</i>	General (full) anaesthetic/ Spinal anaesthetic (in your spine)/ Local anaesthetic/ Don't know
34. Have you been to the dentist during this pregnancy?	No/ Yes
35. If yes then did the dentist carry out any of the following treatments? <i>(You may cross off more than one)</i>	Yes/ No Put in an amalgam filling (silver filling)/ Removed /replaced an amalgam filling/ Put in a white filling
36. How many teeth do you have and how many are filled with amalgam? <i>(Look in the mirror and count)</i>	Total number of teeth/ Number of teeth with amalgam fillings
37. Do your gums bleed when you brush your teeth?	No never or seldom/ Yes occasionally/ Yes frequently/ Yes nearly always
38. Have you had a tattoo or body piercing done?	No/ Yes
39. If so where and when was it done?	Tattoo/ Body piercing In Norway/ Abroad/ Before pregnancy/ During pregnancy
40. Have you ever had a blood transfusion?	No/ Yes during this pregnancy/ Yes earlier
41. If yes in which country and which year?	Country/ Year
42. Have you ever had surgery on your breast(s)?	No/ Yes
43. If yes then was it:	Breast enlargement/ Breast reduction/ Cancer/biopsy/ Other- describe
44. Have you ever had an injection of gamma globulin? <i>(Used to prevent infection of hepatitis A when travelling abroad)</i>	No/ Yes If yes which year?
How have you felt recently?	
Some questions about the time that has elapsed since you filled in the last questionnaire	
45. If you have had one or more episodes of vaginal bleeding since you filled in the last questionnaire indicate the amount of blood lost, how long it lasted and in which week of pregnancy. <i>(You can put in more than one cross. If there have been more than 3 episodes please describe the last 3)</i>	The amount of blood / In which week of pregnancy did the bleeding occur? 13-26/ 17-20/ 20-24/ 25-28/29+/ No. of days it lasted Drops/ More than a few drops/ Large amounts More than 3 episodes. Describe
46. Do you know why you bled?	No/ Yes
47. If yes for what reason?	The placenta is in a difficult position/ placenta previa/ abruptio/ablatio placenta / Threatening miscarriage / premature birth/ A sore on the cervix, bleeding of the mucus membrane in the vagina / Following intercourse/ Other reasons
48. Have you been bothered by uterine contractions?	No/ Yes a little/ Yes a lot
49. Have you experienced any of the following problems since you	In which week of pregnancy did you have problems? /13-16/17-20/21-24/25-28/29+ /The

<p>completed the previous questionnaire and if so in which week of pregnancy? Did you use any medication and if so which? Which weeks of your pregnancy did you use medication and for what length of time? (You may cross off several) (This applies to all types of medication both regular and intermittent as well as herbal medication. Do not include vitamins etc. since these will be considered later.)</p>	<p>name of the medication used/ In which week of pregnancy did you use medication? / 13-16/17-20/21-24/25-28/29+/ No. of days used Nausea/ Long-term nausea and vomiting/ Vaginal thrush/ Other forms of vaginitis/ Itching due to pregnancy/ Constipation/ Diarrhoea /vomiting/ Unusual tiredness/sleepiness/ Heartburn/indigestion/ Swelling in the body (oedema)/Common cold/Cough/ Throat infection/ Sinusitis/ear infection/ Influenza/ Pneumonia/bronchitis/ Asthma/ Hay fever/allergies/ Headaches/ Back pain/ Pelvic girdle pain/ Other joint and muscle pain/ Leg cramps/ Sugar in the urine/ Albumin in the urine/ Cystitis/Urine incontinence/ High blood pressure/ Depression Other psychological problems</p>
<p>50. If you have had a high fever once or more since completing the first questionnaire indicate in which week of pregnancy, the highest fever and the name of any medication used to bring down the fever. (If more than 3 times indicate the last 3)</p>	<p>Which week of pregnancy did you have a fever 13-16/17-20/21-24/25-28/29+ / Name any medication used to lower the fever./ Highest recorded temperature (e.g. 38.9 C)/ Temperature not recorded 1st time 2nd time 3rd time / Fever more than 3 times</p>
<p>51. Have you used other medication, not previously mentioned, since you completed the first questionnaire? Name and indicate when in your pregnancy they were used.(You may cross off several) (Include all types of medication prescription, non-prescription and herbal remedies but not vitamins or dietary supplements - these are included in the following question)</p>	<p>Name of medication (e.g. Valium, Rohypnol, Paracetamol) / Us of medication in week of pregnancy/ 13-16/ 17-20/ 21-24/ 25-28/ 29+/ No. of days used</p>
<p>Vitamins and dietary supplements</p>	
<p>52. If you have used dietary supplements since you filled in the last questionnaire please look at the container and look at the contents. Put a cross in each box for those vitamins and minerals they contain. (You can fill out several) The name of the product should be given in question 53.</p>	<p>How often did you use the following?/ Daily/ 4-6 times a week/ 1-3 times a week / In which week of pregnancy did you use dietary supplements?/ 13-16/ 17-20/ 21-24/ 25-28/ 29+ Cod liver oil/ Vitamin B2 (Riboflavin)/ Vitamin B6 (Pyridoxine)/ Vitamin B12 (Cyanocobalamin)/ Folic acid/ Vitamin C/ Vitamin A/ Vitamin D/ Vitamin E/ Iron/ Selenium /Calcium/ Fluoride tablets</p>
<p>53. Give the complete name(s) of the vitamin and dietary supplement products that you use. Include also herbal remedies and slimming products. (Write clearly using capital letters since this will be read by a machine)</p>	<p>e.g. VITAPLEX WITH IRON 1.2.3.4.5.6.</p>
<p>54. Have you had any kind of accident or injury during this pregnancy? (e.g. car accident, fall, a blow to your abdomen)</p>	<p>No/ Yes</p>
<p>55. If yes, in which week of pregnancy?</p>	
<p>Work and leisure</p>	
<p>56. Do you have paid work? (Ignore sick leave, maternity leave or other temporary breaks)</p>	<p>No (Go to question 59)/ Yes</p>
<p>57. What kind of work arrangements do you have?</p>	<p>Permanent daytime hours/Permanent afternoon/evening hours/ Permanent night hours/ Shift work or duty roster/ No permanent arrangement (extra help, temporary work)/ Other</p>

<p>58. Answer each of the following questions concerning your present work.</p>	<p>arrangements Yes daily more than half my working hours/ Yes daily less than half my working hours/ Yes in periods but not daily/ Seldom if ever Do you ever have so much to do that your work situation becomes stressful and harassing? / Do you have to bend and turn many times a day? / Do you work with your hands at shoulder height or higher? / Do you stand or walk during work? / In some jobs it is possible to decide yourself how much, and how rapidly, you work each day. One can for example work hard one day and take it a little easier the next. Do you have that opportunity? / Is there so much noise at your workplace that it is uncomfortable? / Is there so much noise that you have to raise your voice to speak even at a distance of one metre? Home/ At work Yes more than 20 times a day/ Yes 10-20 times a day/ Yes more than 20 times a week/ Yes less than 20 times a week/ Seldom if ever No/ Yes</p>
<p>59. Do you lift over 10 kilos now while you are pregnant? (10 kilos is equivalent to a full bucket of water)</p>	<p>Home/ At work Yes more than 20 times a day/ Yes 10-20 times a day/ Yes more than 20 times a week/ Yes less than 20 times a week/ Seldom if ever No/ Yes</p>
<p>60. Are your working arrangements the same as they were when you answer the previous questionnaire? (this does not include sick leave maternity leave or other temporary breaks)</p>	<p>No/ Yes</p>
<p>61. If you have stopped working - in which week of pregnancy did this occur?</p>	<p>Week of pregnancy</p>
<p>62. If you have stopped work, why did you do so?</p>	<p>I handed in my notice/ It was temporary work (seasonal, limited contract)/ I was laid off/ Other</p>
<p>63. Have your working conditions changed since you became pregnant making it easier for you?</p>	<p>No/ Yes</p>
<p>64. If no, then why have your working conditions remained unchanged?</p>	<p>Not necessary/ Impossible or nearly impossible/ I have asked for changes to be made but have not got them/ It is difficult to ask/ None of the above (explain why)</p>
<p>65. Have others taken greater part in housework or child care to help you during this pregnancy?</p>	<p>Yes a great deal/ Yes a little/ No/ Not necessary</p>
<p>66. Have you been absent from your normal work for more than two weeks during this pregnancy?</p>	<p>No / Yes</p>
<p>67. Are you absent from work at the present time?</p>	<p>No/ Yes</p>
<p>68. If yes, why are you absent?</p>	<p>Absent on sick leave/ Absent due to a sick child/ Laid off with compensation/ Absent with maternity allowance due to the working environment/ Absent with maternity allowance/Service leave/ Other (explain)</p>
<p>69. If you have started maternity leave, when did you start?</p>	<p>Date: Day/ Month/ Year</p>
<p>70. Write in the table below the reason for sick leave (e.g. pelvic girdle pain, pneumonia) and indicate when and for how long.</p>	<p>Reason for sick leave e.g. <i>Pneumonia</i>/ On sick leave in following weeks of pregnancy/ 13 -16/ 17-20/ 21-24/ 25-28/ 29+ /No. of days all together</p>
<p>Living habits</p>	
<p>71. How often do you use a cellular phone?</p>	<p>Seldom/never/ A few times a week/ Daily/ On an average more than 1 hour a day</p>

72. Does a call on a cellular phone last more than 15 minutes?	Never/ Seldom/ Often
73. Do you live close to high voltage cables?	No/ Yes closer than 50 metres/ Yes between 50 - 100 metres/ Yes more than 100 metres
74. How many times a week do you exercise the following muscle groups at present?	No. of times a week/ No. of minutes each time/ Never Abdominal muscles/Back muscles/ Pelvic floor muscles
75. How often have you been to a discotheque since you answered the previous questionnaire?	Never/ 1-2 a week/ Less often
76. How often do you exercise now?	Never/ No. of times a week/ No. of minutes each time Walking/ Brisk walking/ Jogging/running/orienteering/ Bicycling/ Training studio/ weight training/ Gymnastics/ aerobics for pregnant women/ Exercising without jumps/Exercising with jumps/ Folkdance /swing/ Rock/ disco dance/ Skiing/ Ball games/ Swimming/ Riding/ Other
77. How often have you had sexual intercourse during the last months?	Daily/ 5-6 times a week/ 3-4 times a week/ 1-2 times a week/ Less often/ Never
78. Have you been abroad in the last year?	No/ Yes
79. If yes then which countries did you visit and when?	Land/ Month/ Year
80. Have you had contact with animals either at work or in your spare time?	No/ Yes
81. If yes then which animals have you had contact with and how often?	Daily/ 3-6 times a week/ Once a week/ Less often Dog/ Cat/ Guinea pig/ hamster/ rabbit/ rat etc/ Budgerigar or other caged birds/ Hens and other poultry/ Cow/ Sheep/ Goat/ Horse/ Pig/ Other
82. How many hours a day do you usually sleep now while pregnant?	Over 10 hours/ 8-9 hours/ 6-7 hours/ 4-5 hours/ Less than 4 hours/ Varies
83. Do you at present use a waterbed or electric blanket?	Yes/ No Waterbed/ Electric blanket
84. Can you rest during the day?	No/ Yes
85. Have you been in a sauna while you have been pregnant?	No/ 1-5 times/ 6-10 times/ More than 10 times
86. Have you been in a solarium while you have been pregnant?	No/ 1-5 times/ 6-10 times/ More than 10 times
87. Are you subjected to passive smoking either at home or at work?	No/ Yes/ No. of hours Home/Work
88. Do you smoke at present? If so then how many cigarettes do you smoke a day?	No/ Sometimes/ Daily Cigarettes per week/ Cigarettes per day
89. Does the baby's father smoke at present? If so then how much does he smoke?	No/ Sometimes/ Daily/ Cigarettes per week/ Cigarettes per day
90. If one or both of you have stopped smoking recently then in which week of pregnancy did this occur?	Myself/ Baby's father /Week of pregnancy
91. If there have been times during your pregnancy when you, or the baby's father did <u>not</u> smoke, then when was that? (Cross off for the weeks during pregnancy when you did not smoke)	Weeks of pregnancy without smoking/ 0-4/ 5-8/ 9-12/ 13-16/ 17-20/ 21-24/ 25-28/ 29+ You/ Baby's father
92. If you have used other forms of nicotine please show which type and when.	Earlier in pregnancy/Now Nicotine chewing gum/ Nicotine plasters/ Nicotine inhaler/ Chewing tobacco/ Snuff

93. Have you used any of the following substances in the last three months?	Hashish/ Amphetamine/ Ecstasy/ Cocaine/ Heroin/ Other
Food and drink	
94. How often do you eat the following foods?	Never/ A few times a year/ 1-3 times a month/ Once a week or more Crabs/ Shrimps/ Shellfish (e.g. mussels, oysters)/ Fish liver/ Tuna fish or halibut/ Flounder/ other flat fish/ Pike/Other fresh water fish/Reindeer meat/ Mutton/ Liver or kidney from game/ Wild mushrooms
95. How often do you eat the following types of food?	Never/ A few times a year/ 1-3 times a month/ Once a week or more Restaurant/ canteen/ street vendors or the like/ Meat (not including canned) bought in other countries/ Meat (including poultry) that is raw or undercooked (pink in the centre)/ Raw ground meat/ meat mixtures (even to taste)/ Smoked or treated salmon or trout (uncooked)/ Soft cheeses (e.g. cream cheese, camembert, blue cheeses)/ Unwashed raw vegetables, unwashed fruit
96. What type of drinking water do you have?	Own water (e.g. well)/ Water supply (public or private)/ Name of water company/ Don't know
97. Is your water treated (chlorinated or radiated with UV)	No/ Yes, by UV radiation/ Yes, chlorinated/ Don't know
98. How many cups or glasses of the following have you drunk every day in the past week? (1 mug = 2 cups, 1 plastic bottle (0.5l) = 4 cups, 1 large plastic bottle (1.5l) = 12 cups)	No. of cups/ glasses/ Decaffeinated Filter coffee/ Instant coffee/ Percolated / Tea/ Herbal tea/ Other warm drink/ Coca cola, Pepsi etc./ Other carbonated drink/ Coca cola light Pepsi light etc./ Other light carbonated drink/ Tap water/ Bottled water/ Fruit cordial/ juice/ Sugar free cordials/juice/ Skimmed milk/ Semi skimmed milk/ Whole milk/ Other
99. How often did you drink alcohol before and how much do you drink now?	In the 3 months before last menstruation/ <u>In this pregnancy</u> , week of pregnancy/ 0-12/ 13-24/ 25+ Approximately 6-7 times a week/approximately 4-5 times a week/ Approximately 2-3 times a week/ Approximately once a week/ Approximately 1-3 times a month/ Less than once a month/ Never
Alcohol units	
<p><i>In order to compare different types of alcohol they are considered as units (= 1.5cl of pure alcohol) In practice this means:-</i></p> <p><i>1 glass (1/3 litre) beer = 1 unit</i> <i>1 wineglass red/white wine = 1 unit</i> <i>1 glass sherry or other fortified wine = 1 unit</i> <i>1 liqueur glass spirits or Liqueur = 1 unit</i> <i>1 bottle cider = 1 unit</i></p>	
100. In the period just before you became pregnant and during this	<i>In the 3 months before last menstruation/<u>In this pregnancy</u>, week of pregnancy/ 0-12/ 13-24/</i>

pregnancy how many times have you drunk 5 units or more (See the above explanation)	25+ Several times a week/ Once a week/ 1-3 times a month/ Less than once a month/ Never <i>In the 3 months before last menstruation/ In this pregnancy, week of pregnancy/ 0-12/ 13-24/ 25+</i> 10 or more/ 7-9/ 5-6/ 3-4/ 1-2/ Less than 1
101. How many units do you usually drink when you drink alcohol? (See the above explanation)	<i>Modified to less amount/ Modified to a greater amount</i> Last 3 months before last menstruation/ In week of pregnancy 0-6/ 7-12/ 13-24/ After week 24
102. If your drinking habits have changed during or before this pregnancy when did the change occur? (You may cross off several alternatives)	<i>Not relevant/ Not so important/ Quite important/ Important/ Very important</i>
103. If you have modified your use of alcohol how important were the following factors? (You may choose several alternatives)	Nausea/discomfort/ Altered taste/ For the baby's sake/ Depression/problems/ Other reasons
You and your life now	
104. What is your civil status now?	Married/ Cohabitant/ Single/ Divorced/separated/ Widow/ Other
105. Do you have anyone you can really talk to (besides your husband / partner)?	No./ Yes, 1-2/ Yes, more than 2
106. How frequently do you meet or talk on the telephone to close friends or family (excluding those you live with)?	Once a month or less/ 2-8 times a month/ More than twice a week
107. Is there anyone you can rely on to help you with practical things (besides your husband /partner)?	No/ Yes 1-2/ Yes more than 2
108. Do you often feel lonely?	Almost never/ Rarely/ Sometimes/ Usually/ Almost always
109. How much do you agree with the following statements related to your thoughts and feelings?	<i>Agree completely/ Agree/ Agree somewhat/ Disagree somewhat/ Disagree/ Disagree totally</i> I want to give birth naturally without painkillers or intervention/ I am really dreading giving birth/ I want to have medication so that the birth will be painless / If I could choose then I would have a caesarean/ I think the woman herself should decide whether or not to do a caesarean/ I worry all the time that the baby will not be healthy or normal/ I am really looking forward to the baby coming
110. How much do you agree with these statements about your relationship with your partner (only answer if you have a relationship)?	<i>Agree completely/ Agree/ Agree somewhat/ Disagree somewhat/ Disagree/ Disagree totally</i> There is a close relationship between me and my partner/ My partner and I have problems in our relationship/ I am very happy in my relationship with my partner/ My partner is generally very understanding/ I often think about ending our relationship/ I am satisfied with my relationship with my partner/ We often disagree on important decisions/ I have been lucky in my choice of a partner/ We agree on how to bring up children/ I think my partner is satisfied with our relationship
111. Have you been bothered by any of the following during the last two weeks?	<i>Not bothered/ A little bothered/ Quite bothered/ Very bothered</i> Frightened or anxious/ Nervous, inner turmoil/ Feeling of hopelessness with regard to the future/ Depressed, sad/ Too worried or uneasy
112. How do you feel at the moment?	<i>Incorrect/ Partly correct/ Almost correct/ Completely correct</i> I often feel happy/ I am usually enthusiastic/ I am often eager/ I often feel in a good mood/ I am usually cheerful

<p>113. How correct are these statements about you?</p>	<p><i>Incorrect/ Partly correct/ Almost correct/ Completely correct</i> I always manage to solve difficult problems if I try hard enough/ If anyone opposes me I find a way to get what I want/ I am sure that I can cope with unexpected events/ I am calm when I encounter difficulties because I trust my ability to cope/ When I am in a difficult situation I usually find a solution</p>
<p>114. Indicate whether or not you agree with the following statements?</p>	<p><i>Completely disagree/ Disagree somewhat/ Indifferent/ Agree somewhat/ Agree/ Agree completely</i> In most respects, my life is everything I want it to be/My life circumstances are fantastic I am happy with my life/So far, I have achieved the things that are important to me in life/If I could live my life again I would change very little</p>
<p>115. How do you feel about yourself?</p>	<p><i>Agree totally/ Agree/ Disagree/ Disagree totally</i> I have a positive attitude to myself / I feel useless at times / I do not feel as if I have much to be proud of/ I feel that I am as significant as anyone else</p>
<p>116. Have you, in the last 12 months, experienced any of the following?</p>	<p><i>No / Yes / If yes / Not too serious / Painful/difficult / Very painful/difficult</i> Have you had problems at work or where you study? Have you had economic problems? Have you been divorced, separated or ended the relationship with your partner? Have you had any problems or conflicts with your family, friends or neighbours? Have you been seriously ill or injured? Have any of those closest to you been seriously ill or injured? Have you been involved in a serious traffic accident, house fire or robbery? Have you lost someone close to you?</p>
<p>117. Life experiences - Have you ever experienced any of the following?</p>	<p><i>No, never / Yes as a child (under 18) / Yes as an adult (over 18) Who was responsible for this? / A stranger / Family or relative / Another known person / Has this occurred during the last year / Yes / No</i> That anyone has over a long period of time systematically tried to subdue, degrade or humiliate you? That anyone has threatened to hurt you or someone close to you? That you have been subjected to physical abuse? That you have been forced to have sexual relations?</p>
<p>Miscellaneous</p>	
<p>118. If you have other children <u>do any of them</u> have any of the following problems?</p>	<p><i>No / Yes but no contact with health and social services / Yes, and has had contact with health and social services</i> Withdrawn, uninterested in others. Late speech development. Late motor development. Attention or concentration deficit.</p>
<p>119. <u>Did you</u> have any of these problems as a pre-school child?</p>	<p><i>No / Yes but no contact with health and social services / Yes, and had contact with health and social services</i> Withdrawn, uninterested in others. Late speech development. Late motor development.</p>

	Attention or concentration deficit
120. Has anyone living with you had any of the following illnesses during your pregnancy? Influenza Childhood diseases (fever and rash) /Long lasting cough /Other infectious diseases	<i>In which week of pregnancy? / 0-9 / 10-19 / 20-29 / 30+</i>
121. Have you ever lost a child?	<i>No (go to question 127) / Yes</i>
122. If yes, what was the cause of death and when did it happen?	<i>Stillbirth / Cot death / Accident / Illness / birth defect / Which illness Child 1 / Child 2 / Year / Child's age / Year(s) month(s)</i>
123. Did you and your family have counselling from the health services or others in the time immediately following the death? How many times did you meet health professionals and /or parent support groups, family and friends and for how many weeks were you followed up	<i>Health professionals / Parent support group, family, friends / No. of meetings (approximately) / No. of telephone conversations (approximately) / Weeks of follow up</i>
124. Did you feel that you and your family were followed up sufficiently after the child's death?	<i>No offer of follow up / Very good / Good enough / Could have been better / Poor</i>
125. Has this death made you more anxious in this pregnancy?	<i>No not at all / No not significantly / Yes a little more / Yes very much more</i>
126. Have you felt that health care workers at the antenatal check ups have taken this painful experience into consideration in your contact with them?	<i>Yes considerably / Yes somewhat / No not at all</i>
127. Have there been any instances of cot death in your family or your partner's family?	<i>No / Don't know / Yes in my family (see question 128) / Yes in the baby's father's family (see question 129)</i>
128. The child that died in my family was:	<i>My sister / My brother / My sister's child / My brother's child / My mother's sibling / My father's sibling / Other / Boy / Girl / sex unknown</i>
129. The child that died in my family was:	<i>The baby's father's sister / The baby's father's brother / The baby's father's sister's child / The baby's father's brother's child / The baby's paternal grandmother's sibling / The baby's paternal grandfather's sibling / Other / Boy / girl / sex unknown</i>
Do you have any comments on any of these questions? Is there anything that should be changed?	
We would like to know what you thought of the questions.	
Did you think that any of the questions were difficult to understand?	<i>No / Yes question number</i> Comments
Did you feel that any of the questions were too personal?	<i>No / Yes question number</i> Comments
Are there any questions you would advise us to remove?	<i>No / Yes question number</i> Comments
Other comments	<i>No / Yes question number</i>

Comments

Thanks for your help

The Norwegian Mother and Child study

Questionnaire 4

This questionnaire is divided into two parts. It contains questions about both you and your child. The first part concerns your child and the second part is about you. To make it easier for you we suggest that you have your child's health card at hand when you fill out this questionnaire. If you think any of the questions are difficult to answer go on to the next question.

If you gave birth to twins or triplets please fill out one questionnaire for each child.

A computer will process this questionnaire and it is therefore important that you follow these instructions: -

- Please use a blue or black ballpoint pen
 - Put a cross in the box that is most relevant thus
 - Should you put a cross in the wrong box correct it by filling in the box completely thus
 - In the large green boxes write a *number* or a *capital letter*
- It is important that you only write in the white area of each box, thus:**
- Several questions in this questionnaire concern the week of pregnancy e.g. fill out week 5 for something that occurred 5 weeks following your last period
 - Specific information e.g. medication or profession should be written in the box on the corresponding line

Please write clearly in CAPITAL LETTERS

Please return the form in the stamped addressed envelope provided.

Date: - Day month year

Question	Answer
Your child - Nutrition	
1. What did the baby drink during its first few weeks? (you may fill in more than one)	Breast milk / Water / Sugar water / Formula / Other, describe / Don't know/don't remember
2. What kind of milk has the baby had until now? (one cross or more for each month)	Milk type / Child's age on months / 0, 1, 2, 3, 4, 5, Breast milk / Regular / Collett / Collett with omega 3 / Regular Nan / Nan HA1/ Other milk, describe
3. How often does the baby drink any of the following? (one cross for each)	Never / rarely / 1-3 times a week / 4-6 times a week / At least once a day / Breast milk / Formula / Normal cow's milk / Milk cultures e.g. yoghurt, buttermilk / Ecological milk products / Boiled water / Tap water / Bottled water / Baby cordial / Other cordial, with sugar / Cordial with artificial sweeteners / Juice / Other, describe
4. How often does the baby eat any of the following foods?	Never / rarely / 1-3 times a week / 4-6 times a week / At least once a day/ How old was the baby when he/she first ate these foods? / Months Commercially produced cereals (instant) / Rice /cornmeal cereals / Oatmeal, all types / Wheat cereals, all types / Home made cereals of:- Wheat, fine/coarse/Rusk /semolina /oatmeal / Iron enriched wheat / Ecological baby cereals (wheat) / millet / Commercial baby dinner Vegetables / Vegetables and meat / Home made dinner /Mashed potatoes/vegetables / Meat/vegetables/potato / Fish and vegetables/potato / Other home made dinners / Snacks / Dessert / Home made fruit compote/mashed fruit/ Conserved fruit/ berries / Rusks/ biscuits / bread / Other, describe
5. Do you think, or know, that the baby reacts to milk products?	No / Yes
6. If yes, which products?	Whole milk / Skimmed/semi-skimmed milk / Cream /ice-cream / Yoghurt/buttermilk / Breast milk when you have had milk / Other
7. Do you give the baby cod-liver oil, vitamins, iron or other nutritional supplements?	No / Yes
8. If yes state which product, the amount and how frequently this is given. How old was the child when you first gave him/her this product?	Cod liver oil / Biovit / Sanasol Collett infant vitamins / Fluoride / Other dietary supplement, which Amount each time / Teaspoons /How often / Daily / occasionally /Age of child when first given product / Months / weeks
Growth, health and medication	
9. How many times have you taken the child to the well baby clinic?	Never / 1-2 times / 3-5 times / More than 5 times / Take the child elsewhere for check ups
10. Has the child had all the recommended vaccinations?	Yes / No, we do not want vaccination / No, child has been sick a great deal / No, vaccination postponed for practical reasons / Don't know
11. With reference to the child's health card please fill in the child's weight, length and head circumference at 3 and 6 months.	Date when measured 3 months/ 6 months/ day/month/year / Weight / Length / Head circumference
12. With reference to the child's health card please fill in which	Vaccine / Triple (diphtheria/tetanus/whooping cough) / Diphtheria/tetanus / Hib / Polio /

vaccinations the child has had, when and any side effects they produced.	Hepatitis B / Other vaccine, which Has the child had the vaccine? / Were there any side effects? / Did the side effects result in contact with a doctor? / Did any of the side effects result in hospital admission? / Yes/No No (go to question 16) / Yes
13. Has anything discovered at the health clinic resulted in the child being referred to a specialist?	Weight / Late development / Hip problems / Congenital malformation, which / Heart /Hearing / Sight / Head circumference / Other, describe Everything was fine / Still questionable/further tests / Don't know / Has the following diagnosis
14. If the answer was yes was there a problem with:	
15. What were the results of further examination?	
16. Has the child had any of the following illnesses/problems? If so did you see a doctor or go to the hospital? (fill out each box)	Illness Cold/throat infection / Ear infection / False croup / Bronchitis/ Bronchiolitis (RSV)/ Pneumonia/ Asthma / Gastric flu / Urinary infection / Colic / Childhood eczema/atopic eczema / Nappy rash / Food intolerance/allergy / Eye infection / Fever seizures / Other seizures (without fever) / Congenital malformations/ Developmental delay / Accident or injury / Other , describe No / Yes
17. Has the child ever had medication?	
18. If yes please give the name of the medication and when it was used. (Include all types of medication, including herbal remedies both permanent and temporary)	Name of medication (e.g. .Penicillin, paracetamol) / Age when medication was used / 1-2 months / 3-4 months / 5-6 months / Number of days used
19. Has the child been examined or admitted to hospital since birth?	No / Yes, which hospital?
20. Has the child ever had surgery or a condition requiring surgery?	No / Yes, which condition
Development, child care and lifestyle	
21. Following are some questions concerning the child's development. If you have not yet noticed then please observe and see what you child can do.	Does the child play with his/her feet when lying on his/her back? / When lying on the stomach does he/she lift the trunk with arms straight? / Does the baby roll over from back to stomach? / When you talk to the baby does he/she try to "reply" to you? Does the baby make babbling noises when alone? / Do you know how the baby is feeling by listening to the sounds he/she makes (e.g. hungry, tired, happy, sad, in pain)? / Does the baby smile back at you if you smile at him/her (without touching, tickling or holding a toy)? / When you say your baby's name does he/she turn to look at you one of the first times you say it? / Does the child reach out for a toy given to it and put it in his/her mouth or hold it? / When the child sits on your knee does he/she reach out for toys or objects on the table in front of you? / Does the child hold an object in both hands when examining it? Yes, often / Yes, but rarely / Not yet / Don't know
22. Where is the child cared for during daytime?	Home with mother/father or another family member / Home with carer/nanny / With a child carer in a family unit / Day-care centre

23. How many children is your child normally with during the day?	Children
24. Does the child take part in baby swimming?	No/Yes
25. How much time does the child spend outdoor?	Rarely / Often but less than an hour a day / More than an hour a day
26. Does the child use a pacifier?	Rarely or never / Only when going to sleep / Often / Most of the time
27. How many hours does the child sleep altogether during a 24-hour period?	Less than 8 hours / 8-10 / 11-12 / 13-14 / More than 14 hours
28. How is the baby laid down to sleep? <i>(fill in for each line)</i>	Right after birth / At 2 months / At 4 months / At 6 months <i>On the back / On the side / On the stomach</i>
29. Does the baby sleep (at least half the night) in the same bed as mother/father <i>(Fill in for each line)</i> ?	Right after birth / At 2 months / At 4 months / At 6 months <i>No / Sometimes / Often</i>
30. Say whether you agree or disagree with the following statements about the child's moods and temperament. Think about how it is on a daily basis. <i>(fill in for each line)</i>	The child cries and complains a lot / The child is easy to calm when he/she cries / It takes very little before the child gets upset and starts to cry / When the baby cries he/she usually screams loudly / He/she is an easy child / The child requires a lot of attention / When the child is left alone he/she will usually play alone and is contented / The child is so demanding that it would represent a considerable problem for most parents / The child smiles and laughs frequently <i>Completely disagree / Disagree / Disagree somewhat / Neither agree or disagree / Agree somewhat / Agree / Agree completely</i>
About yourself	
The last time you filled out a questionnaire was approximately in the 30 th week of pregnancy. The following questions concern the time after this up until the baby is 6 months old	I felt safe and in good hands / I had a great deal of pain / I was not given enough pain killing medication / <i>Applies well / Partly applies / Does not apply</i>
31. How do the following descriptions of giving birth apply to you?	
32. Was there a member of your family or close friend with you during the birth?	Yes, baby's father / Yes another / No
33. How long were you in hospital when you gave birth?	Days
34. Were you transferred to another department or hospital as result of complications during birth (concerning yourself)?	No/Yes
35. If yes, which?	Department / Hospital
36. Did you contact a doctor, midwife or district nurse in the first month after birth as a result of health problems related to yourself?	No / Yes / Times
37. If yes what was the cause?	Episiotomy/ Vaginal problems/ wound after caesarean/ Mastitis/ Sore nipples/ Nursing problems / Other, describe
38. When you look back at the period following the birth, were	No / Yes, how long / Weeks

you depressed?	
Health and use of medication	
39. Apart from when you gave birth, have you been admitted to hospital since you answered the previous questionnaire?	No / Yes, which hospital
40. Have you developed a chronic /long term disease since you answered the previous questionnaire?	No / Yes, which
41. All things considered, how would you describe your physical health at present?	Very good/ Good / Poor / Very poor
42. Have you experienced any of the following problems/illnesses since you answered the previous questionnaire? If so, do you use, or have you used medication for these problems? (<i>This includes all types of medication including herbal remedies both permanent and temporary</i>)	<i>Have you had problems? / If you used medication Illness/problem / 1. Sugar in the urine / 2. Albumin (protein) in the urine / 3. High blood pressure / 4. Swelling in the body (oedema) 5. Urinary tract infection / 6. Constipation / 7. Diarrhoea/vomiting /8. Heartburn/indigestion / 9. Common cold/fluenza /10. Ear or throat infection/sinusitis/ 11. Pneumonia /Bronchitis / 12. Asthma/hay-fever / 13 Headaches and other pain /14. Vaginal infection / 15. Psychological problems / 16. Breast infection / 17. Other, describe / No / Yes towards the end of pregnancy / Yes after the birth Name of medication used / Towards the end of pregnancy / First 3 months after the birth / Previous 3 months / Number of days used</i>
43. Have you used any other medication not mentioned above? (<i>e.g. sleeping tablets, tranquilisers, pain killers</i>)	No / Yes
44. If yes, name the product(s) and when they were taken (this includes all types of medication including herbal remedies)	Name of medication (<i>e.g. Valium, Rohypnol, Paracetamol</i>) <i>Last part of pregnancy / First 3 months after the birth / During the last 3 months Used medication / no. of days</i>
45. Do you or have you used, cod liver oil, vitamins or any other dietary supplements since you completed the previous questionnaire?	No / Yes
46. If yes, which products did you use, when and how often? (<i>One line for each product</i>)	Name of product <i>Used in / Last part of pregnancy / The first 3 months after the birth / During the last 3 months / How often / Daily / occasionally</i>
47. Have you had back or pelvic pain since you completed the previous questionnaire?	No (<i>Go to question 51</i>) / Yes
48. If yes, fill in where and when you had the pain and how severe it was.	Where was the pain? In the lower back/ In one of the pelvic-sacral joints/ In both pelvic-sacral joints/ In the coccyx (tailbone)/ In the buttocks/ In the pubic area/ In the groin/ Other back pain Last part of pregnancy / The first 3 months after the birth / During the last 3 months / Mild pain/ Severe pain
49. Do you, at present, wake up at night because of pelvic pain?	No, never / Yes, occasionally / Yes frequently
50. Do you, at present, have so much pelvic pain that you have to	No, never / Yes, but not every day / Yes every day

	use crutches or a stick?	
51.	Have you ever had treatment for pelvic pain?	No / Yes
52.	If yes, which type of treatment and when?	Physiotherapy / Chiropractor / Medication / Other, describe <i>Before this pregnancy / During this pregnancy / After the birth</i>
53.	How long after birth did you resume sexual relationship?	Weeks / Have not had sexual intercourse
54.	Have you, at present, any of the following problems, if so, how often and how much? (<i>fill out each line</i>)	Problems: Urine leakage when you cough, sneeze or laugh/Urine leakage during physical activity(running jumping)/ Sudden need to urinate (difficulty in reaching the bathroom in time)/ Problems with stool leakage/ Problems with passing gas <i>How often have you had problems? /Never/ 1-4 times a month/ 1-6 times a week/ Once a day/ More than once a day/ How much at a time? Drops/ Large amounts</i>
55.	How many times did you have an echogram during your pregnancy?	No. of times
56.	Was the echogram normal?	Yes (<i>go to question 58</i>) / No
57.	If not, what was the problem?	The baby's growth was slow / Suspicion of malformation, describe / Other, describe
58.	How much did you weigh at the end of your pregnancy and how much do you weigh now?	At the end of pregnancy / kg Now / kg
59.	Were you off sick during your pregnancy	No (go to question 62) / Yes
60.	If yes, how long were you off sick?	Days or weeks
61.	In which period of your pregnancy were you off sick? (<i>you can fill in more than one</i>)	First 3 months / Middle 3 months / Last 3 months
Economy and lifestyle		
62.	Is your economy so good that you could pay an unexpected bill of \$350 - a dental or repair bill for example?	No / Yes / Don't know
63.	Have you, during the last 6 months, had problems paying your monthly bills - food rent, transport etc.?	No, never / Yes,, but very rarely / Yes, sometimes / Yes, often
64.	Are there any animals in the baby's home?	No / Yes
65.	If yes, what sort of animal(s)?	Dog / Cat / Guinea pig, hamster mouse, rat / Budgerigar or other caged bird /Other – which animal
66.	How many times a week do you do exercises for the following muscle groups?	Abdominal muscles / Back muscles / Pelvic floor muscles <i>Never / No. of times a week / No. of minutes each time</i>
67.	How often do you usually exercise at the present time?	Activity /Walking/ Brisk walking/ Running/ Jogging/orienteering/ Bicycling/ Training studio/ weight training / Gymnastics/ Aerobics / Aerobics/gymnastics/dance without jumps and running/ Aerobics/gymnastics with running and jumping/Folk dancing/swing/ Rock/disco dancing/ Skiing/ Team sports/ Swimming/ Riding/ Other <i>Never / 1-3 times a month / No. of times a week / No. of minutes each time</i>
68.	How often, at present, do you take part in physical activity that makes you sweat and breath heavily? (<i>fill in for both work and</i>	<i>Never / Less than once a week / Once a week / 2-3 times a week / 4-6 times a week / Almost every day</i>

<p><i>leisure)</i></p> <p>69. What were your smoking habits while you were pregnant and in the period following the birth? (<i>fill in for each period</i>)</p>	<p>Non-smoker / Smoked occasionally / Smoked daily / <i>First 3 months of pregnancy / Middle 3 months / Last 3 months / After the birth / First 3 months / Last 3 months / No. of cigarettes a day</i></p>
<p>70. What were the smoking habits of the baby's father while you were pregnant and in the period following the birth? (<i>fill in for each period</i>)</p>	<p>Non-smoker / Smoked occasionally / Smoked daily / <i>First 3 months of pregnancy / Middle 3 months / Last 3 months / After the birth / First 3 months / Last 3 months / No. of cigarettes a day</i></p>
<p>71. Is the baby in a room where people smoke?</p>	<p>No / Yes sometimes / Yes several times a week / Yes daily / If yes, how many hours a day</p>
<p>72. Have you used any of the following substances before or since you gave birth?</p>	<p>Hash / Amphetamine / Ecstasy / Cocaine / Heroin / Other, describe <i>No / Yes the last part of pregnancy / Yes after the birth</i></p>
<p>73. How often did you drink alcohol while you were pregnant and how often do you drink now?</p>	<p>Approx. 6-7 times a week / 4-5 times a week / 2-3 times a week / Once a week / 1-3 times a month / Less than once a month / Never <i>While pregnant / First 3 months / Middle 3 months / Last 3 months / After the birth / First 3 months / Last 3 months</i></p>
<p>In order to compare the different types of alcohol, we ask about what we call alcohol units (= 1.5 cl. pure alcohol). 1 alcohol unit means:</p> <ul style="list-style-type: none"> 1 beer glass of beer = 1 alcohol unit 1 wine glass red or white wine = 1 alcohol unit 1 wine glass sherry or other fortified wine = 1 alcohol unit 1 snaps glass spirits or liqueur = 1 alcohol unit 1 bottle/can energy drink or cider = 1 alcohol unit 	
<p>74. How many units of alcohol do you normally consume when you drink? (both when you were pregnant and afterwards) (<i>see above explanation of alcohol units</i>)</p>	<p>No. of alcohol units / 10 or more / 7-9 / 5-6 / 3-4 / 1-2 / Less than 1 <i>While pregnant / First 3 months / Middle 3 months / Last 3 months / After the birth / First 3 months / Last 3 months</i></p>
<p>You and your feelings</p>	
<p>75. Do you have a partner / husband</p>	<p>Yes / No</p>
<p>76. How much do you agree with these statements about your relationship with your partner (fill in each line)</p>	<p><i>Agree completely/ Agree/ Agree somewhat/ Disagree somewhat/ Disagree/ Disagree totally</i> There is a close relationship between me and my partner/ My partner and I have problems in our relationship/ I am very happy in my relationship with my partner/ My partner is generally very understanding/ I often think about ending our relationship/ I am satisfied with my relationship with my partner/ We often disagree on important decisions/ I have been lucky in my choice of a partner/ We agree on how to bring up children/ I think my partner is satisfied with our relationship</p>
<p>77. How do you feel at the moment?</p>	<p><i>Incorrect/ Partly correct/ Almost correct/ Completely correct</i> I often feel happy/ I am usually enthusiastic/ I am often eager/ I often feel in a good mood/ I am usually cheerful</p>

78. Indicate whether or not you agree with the following statements?	<p><i>Completely disagree/ Disagree/ Disagree somewhat/ Indifferent/ Agree somewhat/ Agree/ Agree completely</i></p> <p>In most respects, my life is everything I want it to be/My life circumstances are fantastic I am happy with my life/So far, I have achieved the things that are important to me in life/If I could live my life again I would change very little</p>
79. Have you experienced any of the following during the last 12 months?	<p><i>No / Yes / If yes / Not too serious / Painful/difficult / Very painful/difficult</i></p> <p>Have you had problems at work or where you study?</p> <p>Have you had economic problems?</p> <p>Have you been divorced, separated or ended the relationship with your partner?</p> <p>Have you had any problems or conflicts with your family, friends or neighbours?</p> <p>Have you been seriously ill or injured?</p> <p>Have any of those closest to you been seriously ill or injured?</p> <p>Have you been involved in a serious traffic accident, house fire or robbery?</p> <p>Have you lost someone close to you?</p>
80. Have you experienced any of the following feelings during the past week? (<i>fill in each line</i>)	<p><i>Yes, nearly all the time / Yes, sometimes / Not often / No, never</i></p> <p>Blame yourself, for no reason, when things go wrong / Been nervous or worried for no apparent reason / Been frightened or had feelings of panic without reason / Been so unhappy that you had problems sleeping / Been depressed or sad / Cried because you were so unhappy</p>
81. How do you feel about yourself?	<p><i>Agree totally / Agree / Disagree / Disagree totally</i></p> <p>I have a positive attitude to myself / I feel useless at times / I do not feel as if I have much to be proud of/ I feel that I am as good as anyone else</p>
82. Have you been bothered by any of the following during the last two weeks?	<p><i>Not bothered/ A little bothered/ Quite bothered/ Very bothered</i></p> <p>Frightened or anxious/ Nervous, inner turmoil/ Feeling of hopelessness with regard to the future/ Depressed, sad/ Frequently worried or uneasy</p>