Human biomonitoring survey
assessment of prenatal exposures to mercury
using biomarkers in cord blood and maternal hair

in the Republic of Karelia, the Russian Federation

The first survey protocol

2017

Contents

1. Background

Mercury is recognized by WHO as one of the top 10 chemicals or groups of chemicals of major public health concern. Its toxicity to human health has long been known, and the toxic effects of different forms of mercury extensively studied *(1)*.

Elemental and methylmercury are toxic to the central and peripheral nervous systems. The inhalation of mercury vapour can produce harmful effects on the nervous, digestive and immune systems, lungs and kidneys, and may be fatal. The inorganic salts of mercury are corrosive to the skin, eyes and gastrointestinal tract, and may induce kidney toxicity if ingested.

All humans are exposed to some level of mercury. Most people are exposed to low levels, often through chronic exposure (continuous or intermittent long-term contact). However, some people are exposed to high levels of mercury that can cause acute poisonings.

Fetuses are most susceptible to mercury. Methylmercury exposure in the womb can result from a mother's consumption of contaminated fish and shellfish. It can adversely affect a baby's growing and developing brain and nervous system, which leads to disorders of cognitive functions, memory, attention, language, and fine motor and visual-spatial skills later in life *(2, 3)*.

Human biomonitoring (HBM) is an effective and reliable tool to assess cumulative exposure to environmental pollutants and is an essential element in a strategy aiming to integrate health and environmental policies. Biomonitoring data directly reflect the total body burden (or biological effect) resulting from all routes of exposure, and inter-individual variability in exposure levels, metabolism and excretion rates. Determination of mercury levels in human tissues, such as hair, blood, nails, milk and urine, is recommended for assessing population exposure to mercury and its compounds *(4)*. The results of biomonitoring-based surveillance can be used for planning and assessing the effectiveness of risk prevention measures.

To protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds the Minamata Convention was adopted as the global legal instrument *(5)*. According to the Convention, the health sector is responsible for identification of population groups exposed to mercury and its compounds. HBM can be used by national governments to assess exposure to mercury for identification of populations at risks.

Since the period of in-utero development is the most vulnerable stage, in terms of long-term adverse neurodevelopmental effects of mercury, characterization of prenatal exposure is critical for evaluating the public health impact of mercury, and for assessing the public health benefits of reducing exposure. A harmonized approach is necessary to ensure provision of reliable and comparable results at national, regional and global level.

The basic intent of this document is to provide guidance for countries in constructing a national protocol for the monitoring of human exposure to mercury. This document was developed based on the outcomes of an international experts meeting held in Bonn, Germany on 24–25 June 2015 *(6)*. A number of other meetings and expert discussions provided important input to this methodology development.

The protocol comprises recommendations on survey design, recruitment and fieldwork, dealing with biological materials, data management and communication, and ethical considerations.

1.1. Scientific evidence and international consultations

This document is based on scientific information on mercury biomonitoring and health effects collected by WHO, including the following: *Guidance for identifying populations at risk from mercury exposure* (2008)*(4)*; *Mercury and Health* fact sheet (2016)*(1)*; *Mercury exposure and health impacts among individuals in the artisanal and small-scale gold mining community* (2014)*(7)*; documents on the work of WHO in coordinating the development of standardized protocols for HBM surveys on mercury, and planning pilot testing in volunteer countries, under the mandate of the Parma Declaration commitments to reduce early life exposure to environmental pollutants *(8)*; and the *Report on information on harmonized systems for measuring mercury body burden* (2011)*(9)*.

In April 2012, at a meeting in Catania, Italy, WHO experts discussed the overall approach, biological matrices and indicators for assessment of prenatal exposure to mercury for development of a harmonized approach to mercury HBM *(10)*. Women who had just delivered a child were agreed as the target population, and scalp hair, cord blood and urine as the matrices for assessment of prenatal exposure to mercury during last three months of pregnancy. *(10)*. The approach proposed by the experts was agreed by the representatives of WHO European Region Member States at the Second Extraordinary Meeting of the European Environment and Health Task Force (EHTF), The Hague, Netherlands, 31 May–1 June 2012 *(11)*.

The discussion continued during a number of forums including: the special session “Protecting human health from negative impact of mercury: from science to policy” at the International Conference on Mercury as a Global Pollutant (14–19 June 2015, Jeju, Korea)*(12)*; the session “Human biomonitoring as an instrument for assessment of exposure to mercury” at the meeting of representatives of the European Member States “Health sector involvement in the implementation of the Minamata Convention” (24–25 June 2015, Bonn, Germany)*(6)*; the international technical experts workshop “Harmonized approach to biomonitoring of human exposure to mercury” (26 June 2015, Bonn, Germany) (unpublished minutes); and during the session “Exposure assessment and health effects” organized by the National Institute for Minamata Disease, Japan, WHO Collaborating Centre for Studies on the Health Effects of Mercury Compounds at the Fifth Conference on Prenatal Programming and Toxicity (14–16 November 2016, Kitakuyshi, Japan)*(13)*.

International Ethical Guidelines for Health-related Research Involving Humans (2016) prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO laid the basis for the ethical requirements included in the protocol *(14)*.

2. Aims and approach of the survey

The primary objectives of the survey are to provide baseline data on prenatal exposure to mercury in Republic of Karelia, the Russian Federation characterised by high-level of fish consumption which also contribute to the development of a global mercury monitoring plan . The survey implementation will:

- extend the knowledge on baseline levels and sources of human exposure to mercury in Republic of Karelia (further Karelia);
- characterize the level and distribution of prenatal exposure in population groups in Russian Karelia;
- identify risk factors for exposure from different sources of mercury;

- assist the Russian Federation in the implementation of the Minamata Convention and development of effective measures to prevent the negative impacts of mercury on human health, and especially in vulnerable groups;
- provide analytical tools to monitor progress towards implementation of specific goals of the Minamata Convention (the WHO methodology involves assessment of exposure in a set of participants at a certain moment in time; such a cross-sectional survey is expected to be repeated at regular intervals, every five years).

The objective of this protocol is to provide a uniform framework for all activities and tasks associated with the collection, analysis, assessment and reporting on prenatal exposure to mercury. This has to be applied consistently in the survey conducted in Russian Karelia to ensure comparability of data at global level. The Russian Federation adjusted certain elements of the core WHO protocol to their realities, to choose only a subset of the proposed biomarkers, which are most important in the national context.

Through expert recommendations and technical meetings, WHO has developed the Approach accepted by the Russian Federation as following:

- Recruitment will be conducted during antenatal visits and exceptionally at maternity hospitals.
- Participants will be enrolled using a set of defined inclusion and exclusion criteria (legal adults, living in the catchment area of the hospital, live birth, etc.).
- A standardized epidemiological questionnaire adopted to the national realities will be administered to participants to assess potential sources of exposure.
- The survey will use non-invasive sampling only (maternal hair, and cord blood); standard operating procedures (SOPs) for no risk sampling are provided by WHO.
- National surveys will involve a capacity-building component, to enable analysis of samples in domestic laboratories; methodological support will be provided by WHO, its temporary advisers and reference laboratories.
- Proficiency test and duplicate quality control samples will be analysed in reference laboratories, to ensure comparability of the results from different countries.

The protocol has been developed by the survey national coordinator to be applicable for the survey for assessment of Karelian population exposure to mercury.

3. General principles

The following underlying principles were considered when applying this protocol to developing a national protocol for monitoring of exposure to mercury:

- Sampling of biological material (hair and cord blood) should not harm or pose an undue burden on recruited women.
- Safeguarding the confidentiality of information should be assured.
- Ethical standards, including prior informed consent, should be respected.
- The protocol should be practical, feasible and sustainable.
- Emphasis should be placed on proficiency.
- Quality assurance of results should be independently confirmed.

3.1. Roles and responsibilities of WHO and the Russian Federaion

Both WHO and the Russian Federation have roles and responsibilities in the application of the protocol.

The role of WHO in the protocol application is:

- to submit and get approval of the protocol from the WHO Research Ethics Review Committee (ERC) and to communicate modifications of national protocols to the ERC, requesting approval before their implementation;
- to organize a training for the national coordinator and the laboratory analyst on the survey design and implementation;
- to develop and provide the Russian Federation with training materials and SOPs for sampling of biological material, mercury analysis, and creation of national databases, as well as to develop and provide an eligibility screening form and an epidemiological questionnaire to be completed by the survey participants;
- as an owner of data collected in the national pilot surveys, to gather the data from the Russian Federation and to store them in a consolidated global database; to analyse the data gathered through the survey implementation, and to report on the level and distribution of the exposure to mercury at national, regional and global scales to interested governmental and nongovernmental stakeholders (including experts and academia) at an international level;
- to provide technical assistance to the Russian Federation, if necessary, including in implementation of the survey, interpretation of results and risk communication;
- to update the protocol on a global level before each round of mercury HBM, if necessary;
- to coordinate the quality control process to ensure the quality of laboratory analysis of mercury in participating countries.

The role of the Russian Federation (GBOU VPO I.M. Sechenov First Moscow State Medical University) in the protocol application is:

- to adapt the WHO protocol to national realities and to obtain approval from national ethics committees;
- to communicate any modifications in the WHO protocol to WHO before the survey implementation;
- to fully comply with the protocol principles when implementing the mercury HBM survey;
- to train the field staff involved in the survey implementation including, but not limited to, interviewers, maternity hospital staff, those responsible for collecting biological samples, those responsible for the storage and transportation of biological samples, laboratory analysts, those responsible for data handling and database creation, etc.;
- to collect data on exposure to mercury in target population groups; to fully comply with WHO SOPs on analysis of mercury in human scalp hair and cord blood including non-invasive sampling procedures;
- as an owner of the national data, to collect and store the data in a national database;
- to analyse national data on the level and distribution of exposure to mercury and to report the data to interested governmental and nongovernmental stakeholders at the national and sub-national level;
- to report on the application of the protocol and to submit the national protocol to WHO;
- to report to WHO on results obtained in the survey, conducted according to the WHO protocol.

4. Developing a national protocol

The WHO Master protocol assisted the national coordinator in developing a national protocol to meet the aims of the survey. The national coordinator is responsible for overall planning and implementation of the survey in the country, assisted by the appropriately trained field and laboratory staff. In particular, the national coordinator will assure that the survey meets all national ethical requirements for studies involving human subjects. In case of modification of the national protocol, any changes will be communicated to the WHO team by the national coordinator. WHO will communicate them in good time to the WHO ERC, requesting approval of the modifications before they can be implemented.

The survey will be coordinated by Prof Irina Ilchenko, Head of the Department of Public Health, I.M.Sechenov First Moscow State Medical University

5. Survey design

The survey involves mothers of newborn children recruited during antenatal visits, or at maternity wards if it was not possible to recruit during antenatal visits. The randomized clustered design of the survey allows assessment of prenatal exposure to mercury in the general population and in exposure hotspots, such as areas contaminated by industrial emissions or areas with high levels of consumption of contaminated foods (for example, fishing communities for methylmercury exposure). It is very important to involve the community and local representatives in the survey from an early stage, so as to ensure support for the survey and proper communication of healthy behavioural habits to pregnant women to prevent avoidable exposure, if necessary. The proposed community involvement strategy is in Annex 4.

The survey will be conducted in the Russian Karelia characterised by high-level of fish consumption that suppose high-exposure populations in hotspots involves samples of women who are known or suspected to have high levels of exposure to mercury and/or its compounds.

This document provides a detailed description and sample size justification high-exposure surveys. Relevant reference levels (COPHES/DEMOCOPHES survey, USA, and WHO) will be used for assessment of population risks. A detailed approach for selecting maternity hospitals in high-exposure areas, and criteria for recruiting highly exposed individuals given local conditions are described below.

The proposed survey design includes a limited set of biomarkers – hair and cord blood. Affordability and feasibility were important biomarker selection criteria.

The minimum recommended sample size for the general population survey is defined below, based on the experience of the European project COPHES/DEMOCOPHES, and selected previous national HBM surveys.

5.1. Sources of mercury/methylmercury for population in Russian Karelia

The evidence from published studies showed that biomarkers of MeHg intake were of greatest health concern among fish-consuming women and their infants in traditional Arctic populations

(including the Russian Federation); in subpopulations whose self-caught fish was from local waterways. Among meaningful predictors of exposure to mercury were the consumption of sea- and freshwater fish, land based wild animals and other food items, involving fishing, hunting, traditional forms of collecting berries and mushrooms.

Residents of Karelia also used to go fishing in local water ways as well as to collect wild berries and mushrooms. This region is very special due to a quarter of the territory is a water surface. There are more than 61 thousand lakes and 27 thousand rivers in Karelia. The main anthropogenic influence on the lakes of the Republic is the discharge of sewage from industrial facilities, with the dominating pulp and paper industry. Local sources of industrial emission are located predominantly in the southern part of the Karelia but they are not related directly to mercury (fig. 1).

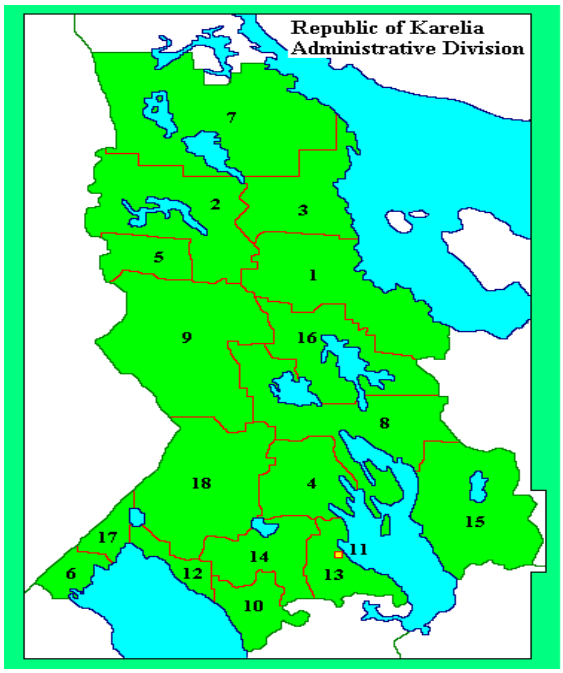
Another pressing problem for aquatic ecosystems is acidification. Natural reservoirs of Karelia have increased natural acidity of the waters due to the high content of humic acids. The data obtained by Gremyachich [Gremyachich VA ,. 2007] and Komov [Komov VT , 2010] showed that muscles of freshwater fish from small and big lakes of the southern part of Karelia accumulate mercury intensively and frequently exceeded the fish consumption advisory level of 0.22 ppm, the U.S. EPA reference dose. The overall tendency is that higher concentration of mercury were found in small lakes and in lakes with PH<5. Low pH is associated with a more intensive process of mercury methylation.

The most important source of non-occupational human exposure to mercury in the region is self-caught fish from local waters. There is no exact information on the consumption of local fish by pregnant women in the region, but traditionally local people used to go fishing, to bring and sell this fish on local markets, to cook fish at home. Locally self-caught fish is important component of diet in many families. Self-caught fish is 2-3 times cheaper then meat and sea fish in supermarkets.

Figure1. Main industrial enterprises located in Karelia.

The fact that the major part of the population lives in South Karelia which is more exposed to anthropogenic pollution was taken into account for selection of the **sample sites.** Eleven

administrative regions of Karelia were grouped in 5 areas for the implementation of the survey (see the map with administrative regions, Fig.2)



Pic. 2 Administrative devision of Republic of Karelia

Expected distribution of women from different target regions is in table 1.
Table 1. Distribution of recruited women by administrative regions of Karelia.

№	Part of RK	Administrative regions	Number of expected recruitments
1	South	Prionezhsky, Petrozavodsk	120
2	South	Olonets, Pitkyaranta, Pryazha	20
3	South-West	Sortavala, Lahdenpohye, Suojarvi	50
4	South-East	Medvezhyegorsk, Kondopoga, Pudozh	60
5	North-East	Kem, Kostomuksha	3

5.2. Target population

The target population is mothers who have just delivered a child.

All efforts will be made to gain consent from women during antenatal care visits. In cases where women do not have an antenatal care visit during the two weeks before delivery (Maternity in Suojarvi doesn't have any physician only one nurse; women from Kondopoga give births in Petrozavodsk and Medvezhhyegorsk) , they can be contacted in maternity hospitals shortly before or after the birth.[1] The following criteria will be applied to determine whether a woman can be recruited and consent given at the time of delivery:

- low level of stress (no fear at childbirth)
- normal development of the childbirth process
- satisfactory physiological condition of the mother
- satisfactory physiological condition of the fetus
- no severe pain

[1] No more than two weeks after delivery.

- no emergency signs *(15)*.

Survey interviewers will briefly describe the objectives of the survey and ask the women if they are interested in participating. If a positive answer is provided, the interviewer, using an eligibility screening form (Annex 1) will conduct a brief interview to check the eligibility of the candidate. If eligibility is confirmed, the interviewer should explain the purpose of the survey, specific activities and risks, and present information leaflet (Annex 2) and the informed consent form (Annex 2). If consent is provided, the interviewer will then collect exposure information using the standardized epidemiological questionnaire (Annex 3), obtain medical and anthropometrical data from the medical records, and collect a sample of scalp hair (following relevant SOPs). Samples of cord blood will be collected by the medical personnel in due course, depending on specific rules and procedures in the maternity ward (following relevant WHO SOPs).

Since the survey aims to characterize prenatal exposure to mercury, maternity hospitals are the preferred recruitment venue due to the availability of medical records and because they may be the easiest place for sampling hair and cord blood, especially given that mothers spend several days in hospital after delivery. However, collection of hair samples, and interviews can also be conducted in other settings, such as at home within two weeks after the delivery.

It is important to collect all relevant information on factors that may affect exposure to mercury (e.g. age, nutritional habits, occupation, socioeconomic status, education and use of chemicals and/or mercury-containing equipment at home).

The total time of a woman involvement in the survey should not exceed the time necessary for recruitment, sampling and questioning (not more than 1,5 hours) including:
Recruitment – 10-30 min (depending on time that is necessary for a women to read information about the survey);
Hair sampling – 10-15 min;
Urine sampling incl. explanation – 15-20 min;
Questioning – 30-35 min.
Women should be informed about that in the prior consent form.

5.3. Selection of hospitals

Hospitals serving potentially exposed population were considered for the survey purposes. Other criteria applied for selection of hospitals were: a number of hospital staff enabling the survey implementation; an average number of deliveries during the peiod of survey allowing recruitment of 250 women; agreement of the hospital administration and staff to support the survey; availability of specialists for medical follow up in necessary was considered as an adventage.

Five hospitals were selected applying the criteria listed above:

Maternity hospital named by Gutkin K.A. (70)
Karelian Republic Perinatal Center,
Central regional hospital in Sortavala,
Central regional hospital in Medveshegorsk
Central regional hospital in Suojarvi.

Agreement with the hospitals for the survey implementation should include information about conditions for ensuring privacy for recruitment, questionning and sampling of hair (e.g. separate room in an entrance and clinical department).

5.4. Number of participants

Due to population from big geographical area of Karelia is involved in the survey, methodology for evaluation of population size applied for the general population is used for this survey.

The International Federation of Clinical Chemistry (IFCC), endorsed by the International Union of Pure and Applied Chemistry (IUPAC), Clinical Chemistry Division, recommends the measurement of biomarker values in at least 120 individuals per group for the determination of baseline values (hereafter called "reference values"). The reference interval is defined as the 0.95 central interfractile interval, or the interval between the 2.5 and the 97.5 percentiles of the distribution *(16)*.

Clustered design reduces the cost and improves logistical feasibility but requires a larger sample size due to the loss of statistical efficiency. A factor of 2 is used to increase the IFCC recommended sample size of 120 to 240 participants, based on the existing literature *(17)*. This sample size estimate takes into account the clustered design of the proposed survey (samples from the same maternity hospitals are not statistically independent). It is recommended that samples are taken from 10 additional participants in case some participants drop out of the survey. Thus, 250 women is a minimum recommended sample size for each cross-sectional HBM survey in the general population.[2] Based on the data on variability in mercury levels in hair samples in women from Flanders *(18)*, a sample size of 250 women can be assumed to be large enough to demonstrate a 27% change in the geometric mean mercury level between a baseline survey and follow-up cross-sectional surveys in a different set of women in the same country, at the conventional level of statistical significance and with 80% study power. This effect size is relevant in view of differences between countries and temporal changes in mercury levels already reported in the literature.

Five maternity hospitals were selected for this survey purpose given a total number of hospitals in selected areas. The distribution of recruitments is not equal due to an average number of births in selected hospitals given particular interest to highly-contaminated small cities.

5.5. Criteria for enrollment of mothers

With regard to the selection of potential participants, the inclusion criteria are as follows:

- women at least 18 years of age (legally adult);
- live birth;
- normal term delivery (at least 37 weeks of pregnancy);
- singleton pregnancy;
- living in the catchment area of the maternity hospital (general population) or in the selected survey area (high-exposure group) for the last three years and for most of the time during the last three months of pregnancy (spending not more than two weeks outside the area);
- hair at least 3 cm in length on the back of the head.

Immigrants should not be excluded as long as they have sufficient language ability in the interview language(s) and meet the other eligibility criteria.

[2] The sample size calculation can be changed for other specified populations when the data on variability in mercury level in hair samples become available.

A potential occupational exposure will not be considered an exclusion criterion.

The recommended exclusion criteria are as follows:

- women younger than 18 years old;
- delivery before 37 weeks of pregnancy;
- still-birth or delivery of a lifeless child;
- not a singleton pregnancy (twins, triplets, etc.);
- living in the catchment area of the maternity hospital or in the selected high-exposure area for less than three years before delivery;
- living outside the selected high-exposure area for more than two weeks during last three months of pregnancy;
- having hair shorter that 3 cm on the back of the head;
- not having sufficient language skills to understand information about the survey, the informed consent and other relevant information;
- women with mental disorders.
- women with hepatitis C, malaria, HIV and other contagious conditions, according to the relevant national regulations;
- women having lacerations during child delivery;
- women having complicated pregnancy.

The above list will be followed as closely as possible to ensure the international comparability of data.

5.6. Project follow-up: medical surveillance of people with high mercury concentrations

The main objective of the HBM survey is to generate data on the levels and distribution of prenatal exposure to mercury, in connection with different potential sources of mercury exposure, and to develop a global plan for mercury monitoring.

Elimination of mercury sources is the most important follow-up measure to reduce exposure and the associated health risks. In order to reduce exposure from industrial or environmental sources, the Ministry of Health of Republic of Karelia and Ministry of Environment of Republic of Karelia as well as the Ministry of Health of the Russian Federation will be involved in planning in risk reduction measures if necessary. For the reduction of exposure to methylmercury, public and individual advice, including dietary recommendations and guidance, based on the available scientific knowledge *(19)*, should be made available to exposed groups. Monitoring of fish contamination with mercury is one of control potential exposure.

The health impacts of mercury depend on its form and the level of exposure. Exposure to mercury vapours can cause acute and chronic kidney disorder. People chronically exposed to high concentrations of inorganic and organic mercury develop neurological symptoms. The regions with high level of fish consumption were selected for the pilot survey. Given that no analyses of mercury in urine is planned to be done. See also below in selection of biological matrices.

If a high level of mercury is observed the survey coordinator should ensure that:

- for individuals with a high level of mercury in their hair and blood, their doctors are contacted and a visit to a neurologist is advised and arranged upon the woman's request. The local hospitals and polyclinics serving the highly exposed women will provide the medical follow up according to the agreement with the Ministry of Health of Karelia.

However, it is unlikely that such clinical cases would be detected through the HBM survey.

An individual medical follow-up will be considered on a case-by-case basis, only for mothers with a confirmed high level of mercury. Template letters to address a woman with high level of mercury in biological samples and template letter to her family doctor are in Annex 2. Additional investigation of potential sources of exposure will be done before risk communication and planning of protective measures.

Neurological and cognitive development surveillance could be considered for children delivered by mothers with a very high concentration of mercury, within the first control at three months from delivery. It will be framed within the usual surveillance programme for newborns on local polyclinics for children. Relevant information will be provided to relevant polyclinics and health insurance companies.

The national survey coordinator is responsible for contacting mothers with high mercury concentration and/or their doctors in local polyclinics and advising on neurological examination of a child.

6. Recruitment and fieldwork

The processes of recruitment and fieldwork are described briefly in this section.

6.1. Fieldwork management

Fieldwork is the responsibility of the Republic of Karelia (the Russian Federation). The organization of the fieldwork is planned based on WHO Master Protocol recommendations, including the following:

- using the standardized methodological documents provided by WHO as a starting point to prepare the SOPs, fieldwork manual and other documentation in a national language;
- training field personnel and supervising their work;
- selecting maternity hospitals;
- obtaining necessary permissions from regional and local authorities;
- liaising with the local community, identifying and engaging local medical staff to promote the survey;
- developing information leaflets for maternity hospitals and for the survey participants;
- informing the recruited women, administering informed consent and conducting interviews;
- collecting, storing and shipping samples to the respective laboratories;
- entering the data into a data file and performing preliminary data cleaning;
- analysing national data or submitting the data to a WHO-affiliated data analysis centre;
- communicating the results of the survey to the participants and national public health authorities.

Plan for the survey implementation will be agreed with the Ministry of Health of Karelia including detailed information on actions, their timing, role and responsibilities of involvement organizations: scientific staff from GBOU VPO I.M. Sechenov First Moscow State Medical University; responsible person in Karelian Ministry of Health; responsible person in each selected maternity.

The responsibilities are as following:

1. scientific staff from GBOU VPO I.M. Sechenov First Moscow State Medical University: training of hospital staff; provision of all necessary documents in national language;

provision of sampling materials; recruitment during ante-natal visits; hair samples collection; transportation of samples; quality control; medical records; organization of laboratory analysis; communication of results; organization of medical follow up if necessary in coordination with the Ministry of Health of Karelia; consult the hospital staff through the survey, if necessary;

2. responsible person in Karelian Ministry of Health: support the survey coordination; lease with local hospitals and support them in the survey implementation; communicated with local authorities if necessary; participate in communication of results at local and individual level and control the medical follow up if necessary; participate in planning risk reduction measures if necessary;
3. hospitals staff: collection of cord blood samples and their interim storage; recruit women living in areas where antenatal visits are not possible..

The responsible person in each hospital should consider the burden to medical staff not to harm medical service to women as well as to avoid/minimize the sense of pressure or obligation that might be felt by the women who are invited to participate. The following measures will be implemented:

- personnel of the maternity staff (midwifes) should be responsible only for sampling of cord blood (in maternity wards) and urine before or after delivery; exceptionally, they can be involved in the recruitment is it wasn't possible during antenatal visits; midwifes assisting with delivery should not be involved in recruitment and, especially, in recruitment of their own patients;
- physicians attending the birth should not be involved in recruitment and, especially, in recruitment of their own patients;
- the time schedule for the staff involved in the survey will be considered by the hospitals chief; together with the national coordinator he/she is responsible for exclusion of involvement of midwives assisting with delivery and physicians attending the birth in recruitment of their own patients;
- extra-hours for staff assisting with cord-blood sampling in maternity wards should be paid from the project budget or hospital budget if it will be agreed so;
- enough staff units should be trained to perform the survey tasks and to avoid influencing negatively on delivery service and unacceptable burden to the hospitals staff.
- mainstreaming of cord blood sampling with collection of cord blood for other purposes;
- involvement staff from entering department for eligibility screening;
- equal distribution of workload.

To ensure the adherence of hospital staff to the survey protocol, sufficient training, quality assurance and quality control measures must be in place.

6.2. Timing of the survey

Exposure patterns, such as fish consumption, may vary by the season. To avoid a seasonal bias, sampling should either take place over the course of an entire year or during a specified season. All data collection activities will be completed in a specific season.

It is envisioned that this survey will be repeated at regular intervals to monitor trends in exposure. Combining data from several data collection rounds would also increase the power of the statistical analysis of exposure determinants. Follow-up surveys in Karelia should use the same schedule (be conducted in the same season) to ensure data comparability. The baseline survey may produce important information on exposures and lead to policy interventions aiming at reducing exposures. Since new policy measures would require substantial time to take effect, conducting a follow-up survey is recommended.

6.3. Recruitment, interview, medical data collection and biological sampling

The recruitment of participants starts with distribution of an information leaflet. All efforts will be made to provide information about the survey to women during antenatal visits, and to make the information leaflets available for women to take home. This would give time to reflect on taking part in the study and would reduce the burden of consent process just before or after delivery. The leaflet can also be provided before or shortly after delivery.

The leaflet will give information on the survey's objectives, its scope, benefits for the women themselves, and the communication of the results. It will also provide information on the inclusion and exclusion criteria (Annex 2).

The interviewers will need to be present at the maternity hospital. These will trained employees of the hospitals.

A female fieldworker might generally be a better choice to contact women shortly after delivery. The fieldworker should introduce themselves, and do the following:

- handover the information leaflet (unless it was made available to the woman during one of her antenatal visits), briefly describe the survey and ask whether the woman is interested in participating;
- conduct the screening interview and administer the informed consent form;
- collect the data on exposure, socioeconomic status, etc. using the questionnaire (the questionnaire will be replied by women themselves with support of trained medical staff));
- collect a hair sample;
- arrange for the collection of cord blood samples, strictly following the procedure recommended by WHO for sampling (note: if the recruitment is conducted after the delivery, it may be necessary to collect cord blood samples prior to recruitment; if the woman is not eligible or does not agree to participate, the collected biological samples should be immediately discarded; samples must not be delivered to the analytical laboratory and analysed prior to obtaining informed consent; samples will be collected in the hospital and stored before shipment to an analytical laboratory; the national coordinator of the survey will ensure that only samples from consenting women are shipped to the analytical laboratory for an analysis);
- obtain medical data on the woman and her child, including ICD-10 codes of diseases and conditions during pregnancy and delivery: nephropathies (N00-N16); polyneuropathy and

encephalopathy (G50-G99); complications of labour and delivery (O60-O75) and delivery (O80-O84); and basic anthropometrical measurements of the infant (weight and height); such information could be used in the further analysis of the data on mercury concentration in biological matrices and the questionnaire data, and to facilitate formulation of exposure- and risk-reduction recommendations.

6.4. Epidemiological questionnaire

All survey forms are translated into a national language. The questionnaire has been adopted to the local cultural attitudes, lifestyle patterns and education level of the participants. A computerized system will be used to assure correct transfer of the questionnaire information into the data management system.

Preliminary questionnaire versions in national languages will be pilot tested during field staff training prior to the main survey.

Screening interviews and obtaining consent (annexes 1 and 2) have to be done prior to administering the questionnaire.

The main questionnaire (Annex 3) will be used to interview the participants at the time of hair sampling. Completion of this questionnaire takes about 30 minutes. Section A comprises personal information, anthropometric data, ethnic origin, educational level of the family and socioeconomic status. Section B focuses on potential exposure pathways to mercury, and is divided into four parts: (1) occupational exposure, (2) exposure in the residential environment, (3) personal care and lifestyle (e.g. smoking behaviour), and (4) food and beverage consumption.

Self-administered questionnaire surveys approach will be taken and any misunderstanding will be resolved immediately by the present trained field staff, that guarantees data completeness and quality. Training of the interviewers will be done to ensure that the interviews are conducted in a standardized way. The training of interviewers has been shown to improve their performance, particularly in reducing under-reporting of pertinent information.

The national coordinator is in charge of generating a file with data from the questionnaire and assuring data quality using a template developed by WHO. The national survey coordinator is also responsible for developing SOPs for data handling and data quality control procedures, and for conducting pilot testing and evaluation of these procedures prior the beginning of a national survey.

The national coordinator will retain questionnaires from all the respondents until the end of the study and they will be kept for future reference for three years. Retention of all records conforms to national requirements and international norms concerning confidentiality. The national coordinator will complete a summary of information form about mothers donating samples and will also provide scanned copies of the questionnaires to WHO upon request.

6.5. Training of fieldwork staff

To ensure standardization of processes, the training will be organized as far in advance as possible. Training will involve a range of fieldworkers engaged in survey implementation, including scientific

and hospital staff, those responsible for collecting samples, those responsible for sample transportation and laboratory analysists.

A train-the-trainer approach will be utilized as the most cost-effective way to exchange of knowledge and experience and to minimize the survey costs.

During the survey a technical helpdesk will be established involving the University staff, starting from the moment the general protocol is adapted to the national situation to increase consistency and promote adherence to survey protocols. The help desk staff is responsible for providing answers that have been formulated by experts in the field in a timely manner.

WHO Standard Operating Procedures (for quality control, sampling and mercury analysis) should be used for the training. Special attention should be paid to non-invasive sampling that allows avoiding any risks for women involved in the survey. Hospital staff involved in cord blood sampling should be instructed that according to WHO recommendations cord blood samples for this project may only be obtained by ex-utero collection of samples after delivery of placenta and clamping of the umbilical cord.

Additional motivation is considered for organization of epidemiological questionnaire interviews (see the measures that will be implemented to support hospital staff above,p.6.1) .

The laboratory of the Geological Institute of the Russian Academy of Science is sub-contracted for mercury analysis. The Institution laboratory analyst has been trained by WHO and the laboratory passed successfully through a proficiency test organized by WHO.

6.6. Quality control measures

The national coordinator is responsible for survey quality control. Five visits are planned to the target regions and hospitals, as a minimum. It is in the interest of all partners involved that the fieldwork is controlled and checked. The checklist including all important steps of the procedures will be developed and provided to field staff to avoid errors. In addition, field visits by supervisor from the Ministry of Health of Karelia will be conducted periodically.

7. Biological material

7.1. Overview of biomarkers for assessment of exposure to mercury

Justification for the selection of biomarkers of prenatal exposure to organic and inorganic mercury
In population-based HBM surveys, non-invasive matrices are preferred for assessing exposure to mercury in order to maximize the response rate. The selection of biological matrices for assessing human exposure depends on the mercury compounds (organic vs. inorganic), exposure pattern (chronic or acute) and time of sampling after the exposure *(4)*.

Maternal scalp hair
Exposure to methylmercury is reflected in the level of mercury in scalp hair *(4)*. Once incorporated into hair, mercury does not return to the blood, providing a good long-term marker of exposure. Mercury in maternal hair (close to the scalp) is a proxy of fetal mercury exposure *(20)*. Mercury concentration in 3 cm of scalp hair taken close to the scalp shortly after delivery reflects the

exposure of the fetus during the last three months of pregnancy. However, the concentrations of mercury in hair can change to a certain extent due to the changing growth rate of hair *(21)*.

Hair-mercury concentrations can be affected by several factors, including hair colour and variable growth rates *(20)*. Previously conducted studies have shown that total mercury in maternal hair is a predictor of long-term neurotoxic effects in children *(22)*, despite some studies reporting inconsistent results, particularly when assessing the effects of exposure to low mercury levels *(23)*.

Mercury levels in populations consuming a very small amount of fish are normally below 0.5 µg/g in hair; in populations with moderate fish consumption total mercury in hair varies from below 1 to 2 µg/g; while people with frequent consumption of fish (once or more per day) may have mercury levels in hair exceeding 10 µg/g. The United States Environmental Protection Agency (US EPA) reference dose of 0.1 µg methylmercury per kilogram of body weight per day corresponds to approximately 1 µg/g mercury in hair in people with low fish consumption.

More recent calculations resulted in an adjusted biological limit corresponding to 0.58 µg/g in hair, the validity of which is supported by recent studies of developmental neurotoxicity at exposure levels close to the background *(24)*.

A tolerable limit proposed by WHO corresponds to a hair-mercury concentration of approximately 2.5 µg/g, which takes into account the possible compensation for methylmercury toxicity by beneficial nutrients in seafood. Due to the ease of collection and handling, maternal hair-mercury level is one of the most widely used biomarkers of prenatal exposure to methylmercury in population studies.

Cord blood

In contrast to hair, the presence of mercury in blood represents short-term exposure to organic and inorganic mercury, and does not provide information on long-term exposure and its variations *(4)*. Total mercury concentrations in cord blood are proportional to methylmercury concentrations in hair. As a biomarker of prenatal exposure, mercury in cord blood is preferable, as it provides information on both the exposure of mothers and prenatal exposures of their children *(25)*. Mercury in cord blood may have a stronger association with neurobehavioural deficits in the child compared to mercury in maternal hair *(26)*. Concentrations of total mercury in cord blood of individuals who do not eat fish are normally in the range of 0.5–5.0 µg/L. In cases of high fish consumption, values higher than 10 µg/L are frequently occurring. The reference value for mercury in cord blood based on the US EPA's reference dose is 5.8 µg/L. Mercury levels in cord blood and hair are recommended biomarkers of prenatal low-level methylmercury exposure due to its selective transfer through biological barriers such as blood, hair and placenta *(27–29)*. Cord blood is a non-invasive matrix, but should be collected by the nurse after birth.

Maternal urine

Urine is the matrix of choice for assessing exposure to inorganic and elemental mercury *(30, 31)*. In an occupationally non-exposed population, the number of amalgam surfaces was found to be associated with urinary mercury *(32)*. In the general population, urinary mercury can be elevated also due to high fish consumption, as a consequence of demethylation and excretion of inorganic mercury and partially also due to limited excretion of methylmercury through urine. Urine is a non-invasive matrix, is easy to collect and is commonly used to assess exposure to elemental and inorganic mercury, particularly in occupational health settings where biomonitoring of random spot urine samples is routinely practiced.

Due to wide variability in urinary excretion rates among individuals, as well as the great temporal variability in urine composition within individuals *(33)*, the results should be expressed per gram of creatinine or adjusted for the specific gravity. Concentrations of total mercury in urine of non-exposed individuals are normally in the range of <0.1–5.0 µg/L. In cases of non-occupational exposure to inorganic and elemental mercury, values of up to 10 µg/L have been reported, while workplace exposures can result in levels higher than 50 µg/L. The health-based German HBM I,[3] which corresponds to the concentration of total mercury in urine below which adverse health effects are not expected, is 7 µg/L, or 5 µg/g creatinine; the German HBM II value that corresponds to the concentration above which there is an increased risk of adverse health effects in susceptible individuals of the general population is 20 µg/L, or 25 µg/g creatinine *(34)*.

7.1.1. Choice of the matrices for the survey and sample collection

The literature provides adequate evidence that mercury in maternal hair (close to the scalp) is an appropriate biomarker of fetal mercury exposure *(26)*. Moreover, this biomarker has been used to show an association between prenatal mercury exposure and long-term neurotoxic effects in children *(22)*.

Human hair has the advantage of being a non-invasive matrix that is easy to collect through a simple procedure that requires minimal training of survey personnel. Hair samples can be transported and stored in a zipper bag or a paper envelope at room temperature *(35)*. Hair samples have been used extensively in studies of methylmercury exposure from fish consumption *(36, 37)*.

Once incorporated in the hair, mercury remains there, providing information on exposure during the hair growth period. Most mercury in hair is in the form of methylmercury, especially among populations that consume fish. It is an accurate and reliable method to measure methylmercury intake levels. The relevant SOP for analysis of mercury in hair, provided by WHO to the national coordinators, describes in detail the place on the head for collecting hair samples, the amount of hair to be collected and the principles of sample storage.

Cord blood can be collected by the nurse after birth and does not cause any pain to the mother or baby. Mercury levels measured in cord blood reflect exposure of the fetus to mercury and its compounds. A detailed description of the collection of cord blood is given in the relevant SOP for analysis of mercury in cord blood, provided by WHO to the national coordinator. The procedures described in this SOP are only suitable for mercury.

Urine is another non-invasive matrix, which is easy to collect. Urinary concentrations of pollutants, including mercury, can be influenced by the composition of urine. Therefore, creatinine levels or special gravity should be measured as well. The results for primary biomarkers are expressed as adjusted for the creatinine content or special gravity measurement results. Urine collection is described in detail in the SOP for analysis of mercury in urine, provided by WHO to the national coordinator. However, no urine samples will be collected in the survey in Russian Karelia due to assess of non-occupational exposure. No meaningful sources of elemental and inorganic mercury are identified in Karelia so far. The survey focuses of assessment of prenatal exposure to methylmercury. Relevant matrices (hair and cord blood) are selected.

[3] These values are based on the German Environmental Surveys (GerESs), nationwide population surveys that have been carried out in Germany periodically since the mid-1980s.

For the collection of cord blood samples, appropriate containers should be used to prevent background contamination. Prior to sample collection, the batch of containers for blood is tested in WHO reference laboratory for the presence of interfering chemicals. The containers for the collection of cord blood will contain ethylenediaminetetraacetic acid (EDTA) to inhibit blood coagulation.

7.2. Storage and transportation of samples

Interim storage of cord blood samples will be organized in selected hospitals. Necessary facilities to keep samples at the temperature – 20^{o}C are available in all hospitals.

The national coordinator is responsible for transportation of samples from hospitals to the laboratory. Five field visits are planned to enable that. In preparing samples for transportation, the national coordinator will ensure that samples will not be destroyed or lost during transportation and that any person coming into contact with them will not be infected.

Hair samples do not require any special transport conditions; they can be transported at room temperature. The national coordinator will check that the corresponding documents, including a sheet listing all samples, are in the package and information on any event that occurred during sampling that could affect the sample, has also been included.

Cord blood samples will be transported in cooling bag to be kept at 4°C until their arrival at the laboratory, where they will be aliquoted and analysed or stored until analysis. Furthermore, cord blood samples will be transported in compliance with the relevant shipping regulations for biological material.

7.3. Preparation of samples

A specific form will be used to document the sampling, labelling, processing and shipping of the samples.

Detailed instructions for hair sampling and sample pre-analytical treatment are in the WHO SOP for analysis of mercury in hair.

The cord blood samples will be aliquoted (at least two aliquots) to enable mercury analysis in the national laboratory and the reference laboratory.

7.4. Analysis of samples

The 250 individual samples of scalp hair and cord blood will be collected within the framework of the pilot surveys as selected by the national coordinator based on analysis of existing scientific literature and WHO recommendations.

Analysis of samples will be performed in the laboratory of Institute of Geography of National Academy of Science. Mercury analysis in human hair and cord blood was carried out in the sub-contracted laboratory of the Geological Institute of the Russian Academy of Science. Mercury was determined by AAS with cold vapor according to the WHO SOP. The laboratory performed well a proficiency test organized by WHO.

In Russia for determination of total mercury in human blood and hair will be carried out by cold vapor atomic absorption spectrometry using mercury analyzer "YULIYA - 5M" (Metrology Inc., Qazan, Russia). The mercury concentration will be measured at a wavelength of 253.7 nm after samples' decomposition by the mixture of nitric and perchloric acids in a flask with reflux condenser and after reduction of mercury ions to the elemental state.

The analyzer will be operated under the control of a personal computer (PC). Data processing program "Gauss 8.0" is included in program package.

The metrological parameters of the procedure are given below.
Limits of mercury quantification (LOQ) are:
for blood - 0.25 ng/ml at analyzed aliquote sample 5 ml;
for hair - 12.5 ng/g at analyzed size sample 100 mg.
Uncertainty of determined mercury concentration in hair is:
not more 20 % at mercury concentration in hair in range 12.5 - 50 ng/g;
not more 10 % at mercury concentration in hair more than 50 ng/g.
Uncertainty of determined mercury concentration in blood is:
not more 30 % at mercury concentration in blood in range 0,25 – 1,0 µg/l;
not more 15 % at mercury concentration in blood more than 1,0 µg/l.
There were used nitric acid (70% m/m, ACS, Mosinter Group Ltd., China); perchloric acid (70% m/m, TraceMetal Grade Seastar Chemicals Inc., Canada); hydrochloric acid (35% m/m, chemically pure, "Sigma Tec" Ltd., Russia); tin (II) chloride dihydrate (For analysis, MERK, Germany), potassium dichromate (ACS, MERK, Germany) and deionised water (18.2 MΩ.cm).

7.5. Standardization

Results of the measurements must be analytically comparable between laboratories. To ensure this, the national survey will follow strictly the SOPs for sampling and analytical methods, and procedures for quality assurance and quality control that cover the pre-analytical phase. The availability of appropriate reference materials (samples with a certain level of mercury) is assured. External quality assurance is done through international inter-laboratory comparison investigations (ICI) organized by WHO.

The laboratory involved in the national survey will follow the standard SOPs for sampling and analytical methods, and the procedures for the quality assurance and quality control also in the pre-analytical phase. The availability of the appropriate control/reference materials supports internal quality assurance. External quality assurance will be organized by WHO. [4]
Internal quality control will include control of vials' purity, control of blank, control of inter-series repeatability and control of accuracy.
Control of vials' purity is described in part 7.1.1. Choice of the matrices for the survey and samples collection.
Control of blank will be performed for an estimation of mercury contribution from environment, chemicals and materials during routine sample treatment for mercury measurement. There will be analysed 2 blanks within a batch of 25 routine samples blood/hair. The range of blank mercury concentration is 0,01 – 0,04 µg/L.

[4] ICI is a measure to harmonize analytical methods and their application so as to improve the comparability of analytical results. As ICI is the 'step before' with the aim to learn and to get comparable results, ICI is carried out before the laboratories begin to analyze the samples.

Control of inter-series repeatability will be performed using routine samples of blood and hair by comparison of two independent results of the mercury determination in the same sample, obtained after its analysis in different batches [GOST R ISO 5725-1-2002. Accuracy (trueness and precision) of measurement methods and results. Part 1. General principles and definitions.]. The permissible scatter for two independent results in blood, urine and hair of unexposed population must not exceed 25 - 45 % of their average value according to guidelines of Ministry of Health of Russian Federation [MUK 4.1.1470-03. « Atomic-absorption determination of mercury mass concentration in biological material (urine, hair, condensate of alveoles moisture) at hygienic researches»; MUK 4.1.1483-03. «Determination of chemical elements in biological substrates to be diagnosed, the drugs and biologically active additives by method of mass spectrometry with inductively coupled argon plasma»; МУК 4.1.1898-04. «Atomic-absorption determination of mercury mass concentration in urine».]
There will be analyzed 10 % of duplicate blood and hair samples.

Inter-series repeatability will be calculated in according with formula

$$\frac{\sqrt{\frac{\sum_{i=1}^{n}(C_i-\overline{C})^2}{n-1}}}{\overline{C}}\bullet 100 \text{, \%,}$$

where $\overline{C} = \frac{\sum_{i=1}^{n} C_i}{n}$ - average value

Inter-series repeatability of results of the mercury determination in the routine samples in frame of the present project is:
15 % for blood at mercury concentration less 1 µg/L;
5 % for blood at mercury concentration in the range of 1 – 10 µg/L;
10 % for blood at mercury concentration more 10 µg/L;
15 % for hair at mercury concentration less 150 µg/kg;
7,5 % for hair at mercury concentration in the range of 150 – 1000 µg/kg;
10 % for hair at mercury concentration in the range of 1000 – 2500 µg/kg;
6 % for hair at mercury concentration more 2500 µg/kg;

Control of accuracy will be performed using reference materials blood and hair with assigned total mercury concentration. According to guidelines of Ministry of Health of Russian Federation the obtained result can differ not more than 30 - 35 % from assigned value.
There will be analyzed 1 -3 standard/control reference materials of hair or blood within a batch of 25 routine samples.

A proficiency test of the analysis of total mercury in cord blood and urine will be organized by the reference laboratory selected by WHO using freeze-drying samples. A mirror analysis of 20 samples of each biological matrix will be performed in the reference laboratories identified by the WHO.

7.6. Storage of samples remaining after the mercury analysis

Due to long sample storage procedures are not on place neither in the University not in the laboratory, all samples will be destroyed after mercury analysis will be completed.

8. Data management, analysis and evaluation

8.1. Data management

Data generated during the fieldwork will be further processed and merged in order to allow for final evaluation and results. A database will combine the laboratory data files and the questionnaire database. The database is constructed as a matrix with one row per subject and all separate variables in columns. The data from each participant are identified by a unique identity number (ID number). The ID number of each woman will have 4 digits: the first digit is a country, the second digit is maternity, the 3and 4 digits is the number of woman.
The example of database is provided below:

ID number	Variable name	Matrix	Biomarker	Unit	Data source
XXXXX	HM_HG	Hair Blood Urine	Total mercury	ng/mg	Lab result

The data will be stored in a uniform format provided by WHO. Information on the structure of the database, including variable names, formats, units and rules for handling missing values or values below the limit of quantification, will be included in a codebook.

A software for database management and statistical analysis will be chose by the national coordinator in consultations with WHO based on the following criteria:

- suitable for importing data from external data files provided by chemistry laboratories (most commonly Excel or Access files);
- allows input of the questionnaire data;
- sufficient database management functionality;
- capacity to perform statistical analyses;
- possibility to deliver external databases to a WHO database.

It can be statistical analysis programs like R, SPSS or SAS which meet these criteria. The national coordinator has an experience of working with these softwares.

Data processing will be conducted in the Russian Federation, while statistical data analysis will be conducted both at the national level and at WHO. The data collected in the Russian Federation will be transferred to WHO for creation of a database at the global level, and analysis of levels and distribution of exposure to mercury at national, regional and global levels.

8.2. Statistical analysis

8.2.1. Data analysis at the national and the international level (recommended approach)

The Russian Federation will conduct statistical analyses at the national level and submit anonymized data for statistical analysis to a WHO database. The aim of a statistical analysis at the international level is to assess associations between biomarker values and predictors such as age, gender, fish

consumption habits, etc. in a pooled dataset. However, in some cases WHO can make its own statistical analysis based on data provided by the national coordinator.

Data analysis will involve descriptive statistics and regression analysis. At the descriptive statistics stage, response rates and distributions of parameters will be evaluated, outliers identified and checked.

The regression analysis stage will involve analysis of biomarker data in relation to predictors. The associations will be studied using univariate and multiple regression models.

8.2.2. Data evaluation

The interpretation and evaluation of the HBM results will be dealt with in separate steps. The questions that the HBM survey aims to answer are outlined below:

- Are the observed levels of exposure important/significant in terms of health risk?
- Are elevated exposure levels associated with specific types of exposure source?
- How specific biomarkers are distributed among defined/selected survey population strata/subgroups of the general and exposed populations?
- What is the spatial variability in exposure levels in participating countries globally?
- Should risk reduction measures be planned and implemented at individual and/or local/sub-regional level?
- Is there a need for medical follow up for some individuals.

Additionally, it will be valuable to compare the results of the HBM survey with existing data available in the literature.

9. Communication

Communication campaigns aim to promote awareness, encourage stakeholder involvement, maximize recruitment and retention, ensure transparency and openness towards stakeholders, and to safeguard translation into precautionary and preventive policy. Apart from providing information to the survey participants, the survey leaders have to provide targeted information to the general public, policy-makers in health and environment sectors and public health professionals.

Effective communication can help to raise awareness in the population and to stimulate preventive action at the population and individual levels. At the same time, it is important to avoid inducing anxiety in survey participants when corrective actions are not warranted at the individual level.

Three periods of extensive communication campaigns are identified: prior to and at the onset of the sampling period, during the survey, and at the results dissemination stage.

9.1. Communication prior to the survey

Measures to enhance recruitment will start before the recruitment itself begins. The recruitment process has two main goals: (1) to recruit individuals that adequately represent the target population; and (2) to recruit a sufficient number of participants to meet the sample size and power requirements. Therefore the initial campaign should start as soon as the protocol is ready.

In order to meet these goals, an information leaflets tailored to the target population is prepared (Annex 2). The briefing of policy-makers started at the stage of the survey planning and agreement of the Russian Federation in the survey with WHO.

It is important that the participants have sufficient opportunities to ask questions, to encourage uptake and to reduce withdrawal from the survey. The survey information leaflet and other materials will have contact details (including name, address, telephone number and email address of the survey coordinators) and be available for the field staff and participants.

The information leaflet and informed consent form provide a brief summary of the survey and its aims, in language understandable for a non-professional audience. The leaflet and consent form also explain what participation means in practice: how long it takes, where it takes place and what it involves. The main list of the main topics that will be covered includes:

- nature and aims of the survey;
- promise of confidentiality, that the participant's responses will not be linked to their name or any other identifiable information;
- description of what participation means in practice (when, where, who, what);
- inclusion and exclusion criteria for participating in the survey;
- possible risks, inconveniences or discomforts that could reasonably be expected to result from the survey;
- possible benefits for participants (if relevant, as there might not be any direct benefits);
- participating country's institutional contact details;
- information about how the survey leader obtained the potential participant's contact information;
- information about what will happen to the results;
- explanation that participation is always voluntary and that participants can withdraw at any time;
- explanation about how privacy and confidentiality will be maintained over the time data is stored;

A withdrawal form will be prepared for any survey subject who decides that they would like to withdraw from the survey. Survey participants may withdraw at any time before the samples analysis done; they will be asked to confirm their withdrawal with a signature.

9.2. Communication during the survey

Communication will continue during the survey implementation to react quickly and effectively to any upcoming questions.

To facilitate communication, a contact points be identified (with their name, phone number and email address) to receive and answer questions and queries.

9.3. Communication of the survey results

Before communicating the result of the HBM survey, careful consideration needs to be given to the assessment of individual and population risks, based on the measured concentrations of mercury and the questionnaire data, as well as on the main goals of risk communication, taking into account different target groups and their needs. The level and distribution of mercury levels and the

associated risk determine the main communication aims. For example, if the HBM survey reveals low exposure levels and low or negligible health risks, the main purpose would be to inform participants of the results and to use this as an opportunity to raise awareness and educate. Whereas, if the survey showed a high level of exposure to mercury, communication of results would include more information about health risks and risk-reduction measures, including on preventing exposure and promoting safer behaviours. Different approaches to communication addressed to individuals and to the wider population (e.g. different approaches to risk assessment, recommended risk-reduction measures, and defining of responsibilities of individuals and relevant authorities, etc.) as well as to different stakeholders according to their roles and capacities will be considered.

In general, the fundamental goal of risk communication is to provide meaningful, relevant and accurate information in clear and understandable terms, targeted to a specific audience. It should facilitate understanding of complex technical issues – such as exposure to mercury, the associated health risks and risk-reduction measures – to bridge the gap between lay people and experts and to help people make more informed and healthier choices.

All stakeholder categories – including policy-makers, health-care professionals, the general public, and individuals involved in the survey – will be included in the mercury risk communication. When communicating the results, consideration will be given to the meaning of HBM results, their interpretation at individual and population level, and their potential health relevance (health risk, predictive value of biomarkers, etc.), including communication about uncertainty. Furthermore, communication on available protective and preventive measures at individual and population level, especially in the case of observed high mercury concentrations, is an obligation.

9.3.1. Communication of the survey results to policy-makers, including government health-care and environmental protection bodies

Policy-makers, particularly in the health and environment sectors, in particular Ministry of Health and Ministry of Environment of Karelia, will receive a summary of the HBM survey findings with recommendations on further steps and available risk-reduction measures. The summary will include information about the levels and distribution of exposure to mercury in a population, existing and projected health risk at population level, the main sources of exposure to mercury, as well as available and feasible actions and measures to reduce exposure and health risk. A preventive action plan will be developed, with a proposed timeline and economic analysis of its implementation if necessary.

9.3.2. Communication of the survey results to the general population and communities involved in the survey

Risk-communication messages for the general public and communities will be formulated in a way that avoids misunderstandings and undue concerns. Prior to formulating risk-communication messages the population-level risks will be carefully evaluated, using all information available, and population groups at higher risk (of exposure and health effects) will be identified. A clear distinction will be made between interpretation of HBM results at individual and population levels.

The meaning of the HBM survey results will be clearly communicated, focusing on population groups at risk; it should include recommendations on reducing exposure to methylmercury and/or preventing health risks. Mostly, it will be fish consumption advice taking into account local conditions (fish and seafood types, fishing patters, cultural aspects, etc.) and will be presented in the context of the health benefits of fish consumption.

The public perception of risks might affect the acceptability and the appropriateness of risk-reduction measures. Therefore, it is essential to ensure that the risk-communication process takes into consideration general public perceptions, for example of the risk of mercury exposure associated with fish consumption.

The most effective way to communicate risks is through mass media; for example, as an article in the newspaper, or a programme on regional or local radio and/or television. Involvement of topical experts can strengthen the message and support the recommended risk-reduction measures in certain cases. The use of mass media should allow the message to be presented in a manner understandable to a broad audience, and provide the opportunity to discuss the problem, answer questions and give clarifications. Information about the results of the HBM survey, including on the observed levels and distribution of mercury, should be put in the context of levels of mercury in the ambient environment and relevant safety levels, as well as any accidental mercury exposure, particularly of at-risk populations.

9.3.3. Communication of the survey results to health-care professionals

In cases where high concentrations of mercury are observed, communication prepared for health-care professionals will include general information on mercury and its health effects, the main sources of exposure, principles of diagnosis and treatment, risk-reduction measures and vulnerable population groups, for example pregnant women. Identification of target groups for communication efforts among health-care professionals depends on the population groups at higher risk. could the target group will be paediatricians, gynaecologists and obstetricians, and general practitioners serving the exposed population groups . Organization of training for health-care professionals can be considered to help gain support for implementation of risk-reduction measures.

9.3.4. Communication of the survey results to participants

Individual results should be provided to survey participants, except those who do not wish to know their results. In sensitive situations, experts in social sciences and communication might be consulted in order to understand public perceptions and to develop optimal communication strategies.

Prior to communicating the survey results to participants, the following measures will be implemented in cases where a high level of mercury has been detected. First, the analysis should be repeated to exclude any mistakes, and to test the samples in a reference laboratory. The next step, after checking the quality of the measurements and confirming the result, is to evaluate risks using all available information on potential sources of exposure and the associated health risks.

It is important to explain to participants the meaning of their results as clearly as possible. The results can be communicated to the survey participants through direct contact or through their family doctors.

Personal communication with individuals at high risk is the most effective way to discuss the problem and the recommended preventive measures and risk minimizing actions. Involvement of a family doctor and/or family members might be considered, subject to agreement of the participant. It is critical to be prepared to provide clear evidence-based answers to questions about the health effects and medical follow-up, to avoid any misunderstanding or exaggeration of the problem.

Confidentiality of personal data and testing results will be guaranteed. At the same time, all aggregated results will be made publically available, providing that no link can be made to specific individuals.

10. Ethics

The survey will adhere to the legal and ethical framework established by international directives, conventions and guidelines, and by domestic laws in participating countries.

Approval of a ethical committee has been obtained in the stage of discussion of the Russian Federation participation in the survey.

The ultimate objective was to guarantee the optimal protection of the rights and dignity of every survey participant (data subject). Special attention has been paid to:

- defining and explaining the specific, explicit and legitimate purposes of the survey to all actors involved;
- asking for written consent (informed, free, explicit, specific and documented) prior to the commencement of research. Informed consent includes:
    - the survey objective;
    - the targeted population and recruitment method;
    - possible risks and benefits to the participants;
    - approval of the survey protocol by an ethics committee;
    - the right to refuse consent or to withdraw consent at any time without giving reasons and without being subject to any form of discrimination;
    - the right to access personal results and the wish of participants to know or not to know their personal results;
    - the right for privacy for the enrolment discussion , screening process, answering questionnaire and taken samples of hair;
    - the procedure for dealing with critically high biomarker values;
    - recipients of the survey data;
    - measures to assure the confidentiality of personal data.

When communicating results at the individual level, explaining their health significance (if known) is extremely important. When further evaluation or intervention is warranted due to a critically high biomarker value, communication at the individual level will involve professional counselling.

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Annex 1. Eligibility screening form

1. Are you at least 18 years of age?
   - ☐ Yes
   - ☐ No

   If no → not eligible, stop the interview politely

2. How many days ago was your delivery (if done after delivery)?

   _____ days

   If more than 14 days → not eligible, stop the interview politely

3. Do you live in [*the catchment area of the hospital*]?
   - ☐ Yes
   - ☐ No

   If no → not eligible, stop the interview politely

4. How long have been living in this area?

   _____ years

   If less than three years → not eligible, stop the interview politely

5. How many days during the last three months have you spent outside the [*catchment area of the hospital*]?

   _____ days

   If more than 14 days → not eligible, stop the interview politely

6. Sufficient language ability in the interview language? (assessed by the interviewer)
   - ☐ Yes
   - ☐ No

   If no → not eligible, stop the interview politely

7. Hair sampling possible (based on visual assessment – hair length of at least 3 cm on the back of the head)?
   - ☐ Yes
   - ☐ No

   If no → not eligible, stop the interview politely

8. Eligible for enrolment?
   - ☐ Yes
   - ☐ No

9. If eligible, consented to participate?
   - ☐ Yes
   - ☐ No

10. Participant gave written consent to (please mark all that apply):

- ☐ Hair sample
- ☐ Urine sample
- ☐ Cord blood sample
- ☐ Access to medical records

11. Enrolled in the survey?

- ☐ Not eligible
- ☐ Eligible but not willing to participate
- ☐ Enrolled to participate

IF ENROLLED IN THE SURVEY

Name of participant:

_____

Home address:

_____

Date of admission to the hospital:

_____

Date of delivery of child:

_____

Анкета по выявлению соответствия критериям включения в исследование

1. Вам уже исполнилось 18 лет?

↑ да

↑ нет

Если нет - кандидатура не подходит; опрос заканчивается в вежливой форме

2. Сколько дней прошло после Ваших родов?

___ дней

Если больше, чем 14 - кандидатура не подходит; опрос заканчивается в вежливой форме

3. Вы живёте в районе, прикреплённом к клинике?

↑ да

↑ нет

Если нет - кандидатура не подходит; опрос заканчивается в вежливой форме

4. Как давно Вы живёте в этом районе?

___ лет

Если меньше, чем 3 - кандидатура не подходит; опрос заканчивается в вежливой форме

5. Сколько дней в последние 3 месяца Вы провели за пределами района?

___ дней

Если больше, чем 14 - кандидатура не подходит; опрос заканчивается в вежливой форме

6.Достаточное владение языком, на котором проходит опрос (оценивается интервьюером)

↑ да

нет

Если нет - кандидатура не подходит; опрос заканчивается в вежливой форме

8. Кандидатура подходит для участия в исследовании?

↑ да

↑ нет

9. Если ДА – согласна ли она участвовать?

↑ да

↑ нет

10. Участница дала письменное согласие на (отметьте соответствующее)

↑ взятие волос для анализа

↑ взятие мочи для анализа

↑ взятие пуповинной крови для анализа

↑ доступ к медицинским записям

11. Кандидатура включена в исследование?

↑ кандидатура не подходит по критериям

↑ подходит по критериям, но не желает участвовать в исследовании

укажите причину _____

↑ подходит и будет участвовать

- - - - - - - - - - - - - -

ТОЛЬКО ДЛЯ УЧАСТНИКОВ

Имя участника _____

Домашний адрес _____

_____

↑ нет

Если нет - кандидатура не подходит; опрос заканчивается в вежливой форме

Дата поступления в больницу _____

Дата родов _____

7. Возможность взятия волос на анализ (основывается на визуальном осмотре – не короче 3 см. на затылке)

↑ да

Annex 2. Information leaflet and informed consent form

PARTICIPANT INFORMATION SHEET

Dear Participant,

I.M. Sechenov First Moscow State Medical University with support from World Health Organization is organizing a pilot survey aiming at evaluation of health risks posed by contamination of the environment with mercury and its compounds in the Republic of Karelia, the Russian Federation. Based on this survey we will be able to propose prevention actions, if necessary, as well as to support WHO efforts in developing of global plan for monitoring of exposure to mercury.

Mercury and its compounds are used for production of different types of products and can be released into the environment directly as well as a by-product during different type of combustion processes. Exposure to high concentrations of mercury and its compounds for a long time creates a risk of neurological and urinary system disorders.

There are a number of sources of mercury in Karelia such as coal combustion, cement plants, metallurgic production, etc. Being released into the air mercury can sediment in waters, marine and fresh, where it is transformed to methylmercury which can accumulate in fish and other sea products. Fish and other food contaminated by methylmercury is the main source of mercury for general population. The survey is aiming at investigating what concentrations of mercury are accumulated in human organisms through assessment of its concentrations in scalp hair and cord blood.

When a woman is exposed during pregnancy to high concentrations of mercury and methylmercury, mercury can be transferred to the fetus, and affects the developing organs and systems. Prenatal exposure to mercury in high concentrations is linked to an increased risk of certain diseases and conditions in a child. Our survey will allow assessing your and your child exposure to these chemicals during last three months of pregnancy.

After the survey we will have information about your body contamination by mercury and risks of your child exposure to mercury. Having this information we will provide you with advice on how to minimise or avoid exposure to mercury and prevent its harmful effects to your child, if it will be necessary, in case of very high concentrations of mercury will be observed in the hair and cord blood. We will inform you about results of our investigation if you wish to have them.

To analyse mercury concentration, we will take samples of scalp hair and cord blood from you. All these procedures won't harm you. We will take several strands of hair from back of your head. It won't be notable. Cord blood will be taken by professionals in maternity room after delivery of the child and the placenta.

Participation in the survey is voluntary. You can refuse to participate for different reasons. It won't influence anyhow to the level and quality of medical care. Moreover, you can withdraw your participation any time before living hospital. All need is to inform the national coordinator about your decision. The national coordinator contact details are provided below.

We plan to complete the survey in 2-3 months depending of a number of deliveries during this period. Two hundred fifty women will participate in the survey together with you.

Participation in the survey is no cost for you.

In total, participation in the survey will take around 1.5 hour of your time during your staying in a hospital.

This survey strictly follows all ethical standards. Information we collect during the survey will be treated as confidential. Neither your name nor name of your child will be published or reported. All data will be anonymized and ID code given to you will be used for analysis purpose.

Samples collected in the survey will be destroyed in a laboratory after all analyses are completed. They won't be used for any other purposes except of the purpose of this survey.

The national survey coordinator

Prof Irina Ilchenko
E-mail: irinailchenko9@gmail.com
Phone: +7 906 053 10 72

ИНФОРМАЦИОННЫЙ ЛИСТ УЧАСТНИКА

Уважаемый участник,

Первый Московский государственный медицинский университет имю И.М.Сеченова при поддержке Всемирной организации здравоохранения организует пилотное обследование, направленное на оценку рисков для здоровья, связанных с загрязнением окружающей среды ртутью и ее соединениями в Республике Карелия, Российская Федерация. На основе этого опроса мы сможем предложить, при необходимости, профилактические меры, а также поддержать усилия ВОЗ по разработке глобального плана мониторинга воздействия ртути.

Ртуть и ее соединения используются для производства различных видов продуктов и могут быть выброшены в окружающую среду непосредственно, а такжев качестве побочных продуктов при различных сжигания. Воздействие высоких концентраций ртути и ее соединений в течение длительного времени создает риск нарушений нервной и мочеполовой систем.

В Карелии существует ряд источников ртути, таких как сжигание угля, цементные заводы, металлургическое производство и т. д. Попав в воздух, ртуть может осаждаться в водах, морских и пресных, где она трансформируется в метилртуть и может накапливаться в рыбе и другие морские продукты. Рыба и другие продукты, загрязненные метилртутью, являются основным источником ртути для населения в целом. Исследование нацелено на оценку концентраций ртути в организме путем оценки ее концентраций в волосах головы и пуповинной крови.

Когда женщина подвергается воздействию высоких концентраций ртути и метилртути во время беременности, ртуть может преодолевать плаценту и влиять на развивающиеся органы и системы плода. Пренатальное воздействие ртути в высоких концентрациях связано с повышенным риском некоторых заболеваний и состояний у ребенка. Наше исследование позволит оценить воздействие на Вас и вашего ребенка этих химических веществ в течение последних трех месяцев беременности.

После обследования у нас будет информация о контаминации населения ртутью и о рисках воздействия ртути на вашего ребенка. Имея эту информацию, мы предоставим вам рекомендации о том, как свести к минимуму или избежать воздействия ртути и предотвратить ее вредное воздействие на вашего ребенка, если это будет необходимо, в случае, если очень высокие концентрации ртути будут обнаружены в волосах и/или пуповинной крови. Мы сообщим вам о результатах нашего исследования, если вы хотите их получить.

Чтобы проанализировать концентрацию ртути, мы возьмем у Вас образцы волос с головы и пуповинной крови. Все эти процедуры не причинят вам вреда. Мы возьмем несколько прядей волос с затылка. Это не будет заметно. Пуповинная кровь будет собрана специалистами в родильном отделении после родов ребенка и плаценты.

Участие в опросе является добровольным. Вы можете отказаться от участия по разным причинам. Это никак не повлияет на уровень и качество медицинской помощи. Кроме того, Вы можете снять свое участие в любое время, прежде чем покинете больницу. Все, что нужно для этого сделать - информировать национального координатора о вашем решении. Контактная информация национального координатора приведена ниже.

Мы планируем завершить опрос через 2-3 месяца в зависимости от количества родов за этот период. В опросе участвуют двести пятьдесят женщин вместе с вами.

В общей сложности, участие в опросе займет около 1,5 часов вашего времени во время вашего пребывания в больнице.

Этот опрос строго следует всем этическим стандартам. Информация, которую мы собираем во время опроса, будет считаться конфиденциальной. Ни ваше имя, ни имя вашего ребенка не будут опубликованы. Все данные будут анонимизированы, и идентификационный код, предоставленный вам, будет использоваться для целей анализа.

Образцы, собранные в ходе обследования, будут уничтожены в лаборатории после завершения всех анализов. Они не будут использоваться для каких-либо других целей, кроме цели этого опроса.

Маловероятно, что участие в опросе может нанести вам вред или вашему ребенку. Но это произойдет, и вы получите компенсацию за любые неудобства, вызванные опросом.

Национальный координатор

Проф. Ирина Ильченко
E-mail: irinailchenko9@gmail.com
Телефон: +7 906 053 10 72

INFORMED CONSENT FORM

(For obtaining voluntary informed consent)

We invite you to take part in the survey on development of a plan for human biomonitoring and monitoring of mercury to assess the impact in the early life of the child.
Before you decide whether you want to participate in this survey, it is important that you know why it is carried out and what it is.

Who organizes and conducts the survey?
With the support of the United Nations Environment Program and, the World Health Organization, the First Moscow State Medical University named after IM Sechenov of the Ministry of Health of Russia organizes and conducts the survey to assess exposure to mercury in Karelia population.

Reference Information:
Some chemicals or contaminants present in the ambient air, drinking water, soil and food, enter the human body, disrupting biological processes, and affect our health. During pregnancy, these chemicals can be partially transmitted (through the placental barrier) to an unborn child who is more sensitive to such effects, since all the fetal system is in a state of formation and development. Mercury is cumulated by our body in high concentrations due to exposure for a long time and to high concentrations in the environment can pose the risk of some neurological and urinary system disorders. The most common source of the mother and fetus exposure to mercury is consuming fish and seafood contaminated by methylmercury.
The determination of the mercury content in the human body is considered to be the most effective method for estimating the total mercury exposure. The level of accumulation of mercury in the body can be estimated by its content in the samples of hair and urine of the mother, in the cord blood after the delivery.

What will be studied?
The main purpose of the survey is to provide data on the pre-exposure –to mercury. This will allow us to characterize the level and nature of the impact on you and on all other women who agreed to participate in this survey - the residents of the Republic of Karelia - 250 people. Repeating such a survey in a few years in a new group of participants, we will be able to assess the changes in time by the nature and extent of the impact, and evaluate the effectiveness of measures taken to reduce the intake of mercury by mothers and their children. The results obtained will be compared with the results of other countries of the world, summarized in the technical reports of the World Health Organization and the United Nations Environment Program.

What will happen to me if I agree to participate?
If you participate in the survey, we ask you to agree to perform the following procedures:
- Collect the cord blood from the afterbirth (this procedure is not associated with harm or unpleasant feelings for you).
- Cut a few strands of your hair from the back of the head.
- To answer questions on the information on the nature of your diet, the environment, lifestyle, health and production risk factors (if you have encountered them).
- Permit to receive the following information from the medical documentation about you: address, profession and place of work, about the presence of diseases, about obstetric-gynecological history, complications of pregnancy and childbirth, body weight and its increase during pregnancy, about your child (gender, weight and Body length, what week of pregnancy the birth occurred, the Apgar score, the diagnosis at discharge).

In total, participation in the survey will take around 1,5 hours of your time.

Clarification on the collection of hair samples from the scalp and blood from the afterbirth:
A strand of hair (about 50 hairs) is taken directly on the border with the skin of the occipital part of the head.
Blood from the afterbirth is collected in a test tube in the amount of 15-20 ml after delivery.
The urine is collected in an amount of 50-100 ml.

What will happen to me if I do not give my consent to participate?
You are not required to participate in this survey unless you want to do so. In any case, refusal to participate in the survey will not affect your treatment in this institution of obstetrics.

Can I withdraw my consent?
Even if you signed this consent to participate, you can opt out of this at any time. To do this, you will only need to inform the responsible investigator that you no longer want to participate in the survey. In this case, we will destroy the samples collected from you.

What happens if I withdraw my consent?
If you withdraw your consent, this will not affect the quality of the medical care provided to you. You can do it any time before we performed the mercury analysis. To do that you just need to contact the national survey coordinator or the laboratory analyst (contact details are provided below)

What are the possible disadvantages and risks associated with participation?
We do not expect that participation in the survey involves any risks for you or your child.
Taking a hair sample will not change your appearance.
Collection of blood from the afterbirth will be conducted in accordance with international requirements, which implies compliance with all hygienic rules.
You will have to spend time filling out the questionnaire, which is the only possible inconvenience.
We guarantee the confidentiality of all data received. During the analysis, the information will not contain the name, because it will be coded for anonymity, no other information will be provided to identify you. Access to your personal information will be allowed only to the responsible investigator.

What is the possible benefit?

The results from all survey participants will be analysed collectively to characterize exposures to mercury and to guide policy-makers to make informed decisions for the benefit of public health. This is necessary to ensure health protection from mercury.

Your results will be compared to health-based guidance values, when they are available and we will have information about risks for you and your child and the population.
You can ask that your individual test results be sent to you or to your doctor. If you choose to have the results sent to your doctor, we will ask you to provide their name and address in writing.

You can also specify to not receive your results if you do not wish to know. If necessary, you will receive recommendations on how to reduce the level of a pollutant in your body or to avoid future exposures.

Should I pay for the mercury analysis?

Sampling and analysis are free of charge. The cost of such a survey in paid from the project funds is about 4500rubles.

Who will have access to my personal data?

Researchers will process the information from the questionnaires and the samples. Your name and address will be replaced by a code. If the results of this study are published in a report or scientific journal your name will not be mentioned and no information that can identify you will be included in such a report or publication. All information will be treated confidentially in accordance with relevant privacy laws. We will ensure your privacy for collection of hair and urine samples as well as for answering questionnaires.

Samples collected in the survey will be destroyed in a laboratory after all analyses are completed. They won't be used for any other purpose except of the purpose of this survey.

I have read the information leaflet about participation in the human biomonitoring survey and want to participate in the survey. I understand the potential risks and benefits of this survey and take part voluntarily in this study. I understand that the information will be kept strictly confidential and that the survey was approved by the independent ethics committee of WHO and by the Local Ethics Committee of the First Moscow State Medical University named after I.M. Sechenov.

Mother's name (printed or written in capitals):

_____

Mother's signature:

_____

Child's first and last names (if given):

_____

Child's date of birth (DD/MM/YYYY):

_____

Will they inform me of the results?
The quality checked human biomonitoring survey results, including concentrations of mercury in hair and cord blood, are expected to be available no later than three months after the sampling. Please indicate below, whether and how you want to obtain your individual results.

[ ] I do not wish to receive my results.
[ ] I wish to receive my results at my home address:

_____

_____

[ ] I wish that my results be sent to my doctor.
Doctor's first and last name:

_____

Doctor's address:

_____

Who conducted the examination of the survey?
This survey was prepared with the participation of experts from the World Health Organization and was approved by the Ethics Committee of the State Higher Medical Education University of Moscow. IM Sechenov of the Ministry of Health of Russia.

Contact Information:
You have the right to seek information about a preventive examination and the procedures described in this document. For all the questions that arise, you can get an answer from the national project coordinator

Dr Irina ILCHENKO (national coordinator)
Head of the Department, Public Health
I.M.Sechenov First Moscow State Medical University
Trubetskaya st. 8-2
119991, Moscow
Russian Federation

Email: irinailchenko9@gmail.com
Tel: +7 906 053 10 72

Executive Officer from the State Inspectorate for Horticulture First Moscow State Medical University. IM Sechenov of the Ministry of Health of Russia - Professor Irina Nikolaevna Ilchenko tel. 8 906 0531072.

ФОРМF ИНФОРМИРОВАННОГО СОГЛАСИЯ

(для получения добровольного информированного согласия)

Предлагаем Вам принять участие в обследовании **«Разработка плана мониторинга содержания ртути в организме человека для оценки воздействия в раннем периоде жизни ребёнка»**.

Прежде, чем Вы решите, хотите ли Вы участвовать в этом обследовании, важно, чтобы Вы знали, зачем оно проводится, и в чем заключается.

Кто организует и проводит обследование?

При поддержке Программы Организации Объединенных Наций по окружающей среде, Всемирной организации здравоохранения в организации и проведении обследования участвуют представители ГБОУ ВПО Первый Московский Государственный Медицинский Университет им И.М.Сеченова Минздрава России.

Справочная информация:

Некоторые химические вещества или загрязнители, присутствующие в атмосферном воздухе, в питьевой воде, почве и пище, попадают в организм человека, нарушая биологические процессы, и влияют на наше здоровье. Во время беременности эти химические вещества могут частично передаваться (проникать через плацентарный барьер) еще не рожденному ребенку, который очень чувствителен к подобным воздействиям, так как все системы организма плода находятся в состоянии формирования и развития. Ртуть накапливается нашим организмом, и в высоких концентрациях может создавать риск развития неврологических расстройств и расстройств моче-выводящей системы. Чаще всего она попадает в организм матери и плода при потреблении рыбы и морепродуктов, в связи с воздействием от промышленных и других менее значимых источников. Воздействие ртути в высоких концентрациях может навредить развивающемуся организму, напрмер, к задержке психомоторного развития ребенка.

Определение содержания ртути в организме человека считается наиболее эффективным методом оценки суммарного воздействия ртути. Уровень накопления ртути в организме можно оценить по её содержанию в пробах волос и мочи матери, в крови от последа.

Что будет изучаться?

Обследование проводится для оценки источников поступления ртути в организм женщины. Основная цель обследования представить данные о дородовом воздействии супертоксиканта - ртути. Это позволит нам охарактеризовать уровень и характер воздействия на Вас и на всех других женщин, согласившихся принять участие в данном обследовании – жительниц Республики Карелия – всего 250 человек. Повторив подобное обследование через несколько лет в новой группе участников, мы сможем оценить изменения во времени по характеру и степени воздействия, и оценить эффективность принятых мер по снижению поступления токсических веществ данной группы в организм матери и ребенка. Полученные результаты будут сопоставлены с результатами других стран мира, обобщены в технических докладах Всемирной организации здравоохранения и Программы организации объединенных наций по окружающей среде.

Что со мной будет происходить, если я дам согласие на участие?

Если Вы будете участвовать в обследовании, то мы просим Вас дать согласие выполнить следующие процедуры:

- Собрать акушерке кровь от последа (данная процедура не связана с неприятными ощущениями для Вас).

- Провести забор нескольких прядей Ваших волос с затылочной части головы.

- Ответить на вопросы анкеты, касающиеся информации о характере Вашего питания, окружающей природной среде, образе жизни, здоровье и производственных факторах риска (если Вы с ними сталкивались).

- Разрешить получить следующую информацию из медицинской документации о Вас: адресе, профессии и месте работы, о наличии заболеваний, об акушерско-гинекологическом анамнезе, осложнениях беременности и родов, массе тела и ее прибавке в течении беременности, о Вашем ребенке (пол, масса и длина тела, на какой неделе беременности произошли роды, оценка по шкале Апгар, диагноз при выписке).

В целом, участие в исследовании займет не более 1,5 часов.

Разъяснение по забору образцов волос с волосистой части головы и крови от последа:

Прядь волос (около 50 волосинок) берется непосредственно на границе с кожей затылочной части головы.

Кровь от последа собирается в пробирку в количестве 15-20 мл после родов.

Моча собирается в количестве 50-100 мл.

Что со мной будет происходить, если я не дам свое согласие на участие?

Вы не обязаны принимать участие в этом обследовании, если Вы не хотите делать это. В любом случае, отказ от участия в обследовании не повлияет на Ваше лечение в данном учреждении родовспоможения.

Могу ли я отозвать свое согласие?

Даже если Вы подписали это согласие на участие, Вы можете отказаться от этого в любое время. Для этого необходимо будет только информировать ответственного исполнителя о том, что Вы больше не хотите участвовать в обследовании. Кроме того, Вы можете просить уничтожить те образцы, которые Вы предоставили для обследования.

Что произойдет, если я отзову свое согласие?

Если Вы отзовете свое согласие – это никак не скажется на качестве предоставляемой Вам медицинской помощи.

Каковы возможные неудобства и риски, связанные с участием?

Мы не ожидаем, что участие в обследовании сопряжено с какими-либо рисками для Вас или Вашего ребенка.

Взятие пробы волос не изменит Вашего внешнего вида.

Сбор крови от последа будет проводиться в соответствии с международными требованиями, что предполагает соблюдение всех гигиенических правил.

Вам придется потратить время на заполнение анкеты, что является единственным возможным неудобством.

Мы гарантируем сохранение конфиденциальности всех полученных данных. Во время анализа информация не будет содержать ФИО, т.к. будет закодирована для соблюдения анонимности, не будет представлена никакая другая информация, позволяющая идентифицировать Вас. Доступ к Вашей личной информации будет разрешен только ответственному исполнителю.

Все образцы, собранные в рамках исследования, будут уничтожены, как только анализ ртути будет завершен. Они не будут использованы ни в каких других целях, кроме целей данного проекта.

Какова возможная польза?

Отбор проб и их анализ проводится бесплатно. Стоимость подобного обследования в платных лечебных учреждениях составляет около 4500р.

Вы можете получить результаты Ваших анализов, а также получить индивидуальные заключения по источникам поступления ртути в Ваш организм, по уровням данного токсиканта у Вас в организме, а также в сравнении с другими участниками обследования, в случае, если концентрации ртути будут превышать безопасные для здоровья значения.

Я прочитала информационный листок об участии в опросе биомониторинга человека и хочу принять участие в опросе. Я понимаю потенциальные риски и преимущества этого опроса и добровольно участвую в этом исследовании. Я понимаю, что информация будет строго конфиденциальной и что опрос был одобрен независимым комитетом по этике ВОЗ и Локальным Клмитетом по Этике Первого Московского государственного медицинского института им. Сеченова .

Имя матери (напечатано или написано в столицах):

_____

Подпись матери:

Имя и фамилия ребенка (если дано):

Дата рождения ребенка (ДД / ММ / ГГГГ):

Проинформируют ли меня о результатах?

Ожидается, что результаты обследования биомониторинга человека, в том числе концентрации ртути в волосах и пуповинной крови, будут доступны не позднее, чем через три месяца после отбора проб. Просьба указать ниже, как и как вы хотите получить свои индивидуальные результаты.

[] Я не хочу получать мои результаты.
[] Я хочу получить результаты на своем домашнем адресе:

[] Я хочу, чтобы мои результаты были отправлены моему доктору.
Имя и фамилия доктора:

Кто проводил экспертизу обследования?

Данное обследование подготовлено с участием экспертов Всемирной организации здравоохранения и получило одобрение Комитет по этике ГБОУ ВПО Первый Московский Государственный Медицинский университет им. И.М.Сеченова Минздрава России.

Контактная информация:

Вы имеете право обратиться за информацией о профилактическом обследовании и о процедурах, описанных в этом документе. На все возникающие вопросы Вам может ответить сотрудник роддома _____.

фамилия, имя, отчество *тел.*

Д-р Ирина ИЛЬЧЕНКО (национальный координатор)
Начальник отдела общественного здравоохранения
И.М.Сеченов Первый Московский государственный медицинский университет
Трубецкая ул. 8-2
119991, Москва
Российская Федерация
Эл. адрес:

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+7 906 053 10 72

A letter to the family doctors of women with high level of mercury in biological sample(s) (template)

Dear Mr/Ms -----

The First Moscow State Medical University named after I.M. Sechenov of the Ministry of Health of the Russian Federation with support from World Health Organization conducted a survey to evaluate the population exposure to mercury.

We recruited women in maternity hospitals and assessed concentration of mercury in scalp hair, cord blood and urine.

Your patient Ms ------- participated in the survey. We found exceeded level of mercury in her *hair/blood/urine*. She instructed us to inform you about the results of laboratory analysis of her biological samples. The observed level of mercury in your *hair/urine/cord blood* is ----- *µg/g (µg/L).* The normal range of total mercury in blood varies from 1.0 to 5.0 µg/L, in hair – from 1.0 to 5.0 µg/g, and in urine from 0.4 to 7.0 µg/L. In some cases, clinical manifestations of mercury poisonings were not observed with mercury level in biological samples 10-50 times and even higher than average level in population.

However, medical examination is necessary to exclude mercury poisoning.

Please, find below some information about mercury and its health effects for your consideration.

There are three main forms of mercury: metallic mercury, inorganic mercury (mercury salts) and organic mercury (methylmercury). These forms of mercury differ in their degree of toxicity and in their health effects. High level of mercury in hair reflects exposure mostly to methylmercury, in urine – mostly to inorganic mercury, and in cord blood – to both organic and inorganic mercury.

Repeated or continuous exposure ***to elemental mercury*** due to briefing of contaminated air in occupational environment or evaporation from mercury spills (broken thermometers or fluorescent lamps) can result in damage to the nervous system and kidneys. Classic symptoms of poisoning include neuropsychiatric effects and renal impairment. The neuropsychiatric effects include tremor, anxiety, emotional lability, forgetfulness, insomnia, anorexia, erythrism (abnormal irritation, sensitivity, or excitement), fatigue, and cognitive and motor dysfunction.

Methylmercury may affect many different areas of the brain and their associated functions, resulting in a variety of symptoms. These include personality changes (irritability, shyness, nervousness), tremors, changes in vision (constriction (or narrowing) of the visual field), deafness, muscle incoordination, loss of sensation, and difficulties with memory. The main source of exposure to methylmercury is contaminated fish or shellfish.

Exposure to ***inorganic mercury*** is unlikely in investigated population groups. The inorganic salts of mercury are corrosive to the skin, eyes and gastrointestinal tract, and may be toxic for kidney if ingested.

All forms of mercury can cause kidney damage if large amounts enter the body. Kidney effects can range from increased protein in the urine to kidney failure in case of a massive poisoning. The kidneys are likely to recover once the body clears itself of the contamination.

All mercury effects to adults are reversible. But measures should be taken to reduce the mercury body burden.

We kindly ask you organize medical follow-up for your patient to check if there is a clinical manifestation of mercury poisoning.

We are ready to provide you with advice what measures can be recommended to reduce exposure and prevent any negative health impact.

Feel free to contact me if additional information or clarifications are necessary.

The national survey coordinator

Prof Irina Ilchenko, Head of the Department of Public Health,
Phone: +7 906 053 10 72
E-mail: irinailchenko9@gmail.com

A letter to a woman with high mercury level in biological sample(s) *(template)*

Dear Madam/Ms ------,

We would like one more time to thank you for the participation in the survey on evaluation of exposure to mercury organized by the First Moscow State Medical University named after I.M. Sechenov of the Ministry of Health of the Russian Federation with support from World Health Organization.

Following your instruction to contact you directly provide the survey results we would like to inform you about mercury level in your hair and urine, and in the cord blood.

We found elevated level of mercury in your *hair/urine/cord blood* sample(s). We would like to stress that it doesn't mean that you have health disorders caused by exposure to mercury. Clinical symptoms are developed only as a result of exposure to very high concentrations of mercury for a long time and significantly depend on many other factors e.g. form of mercury, pathways of exposure, nutrition status, etc.

The observed level of mercury in *your hair/urine/cord blood is ----- µg/g (µg/L)*. The normal range of total mercury in blood varies from 1.0 to 5.0 µg/L, in hair – from 1.0 to 5.0 µg/g, and in urine from 0.4 to 7.0 µg/L. In some cases, clinical manifestations of mercury poisonings were not observed with mercury level in biological samples 10-50 times higher than average level in population.

However, it does mean that actions should be taken to reduce your and your child exposure to mercury.

We kindly recommend you to have medical examination to exclude any symptoms of mercury effects to your health. Please, address your family doctor. Very simple tests such as investigation of your neurological and kidney functions can be done. Your family doctor can do it and recommend more specific medical examination if needed.

You also should know that mercury health effects are reversible and fully disappear when mercury is released from your organism. We will provide you with an advice on how to reduce exposure to mercury and decrease its level in your body. It can be done by correcting your life habits.

We also can provide your doctor with the advice to support you if you decide so.

Please, write me if additional information, clarification or support is necessary.

Kind regards,

The national survey coordinator

Prof Irina Ilchenko, Head of the Department of Public Health,
Phone: +7 906 053 10 72
E-mail: irinailchenko9@gmail.com

Annex 3. Main questionnaire for participants

Name of participant	
Medical record number	
Identity number of participant	
Date of interview	Date (day/month/year): _ _/ _ _/ _ _ _ _
Date of child delivery	Date (day/month/year): _ _/ _ _/ _ _ _ _

A. Personal information

A.1. Mother of the child (survey participant)

A.1.1. What is your ethnicity (or nationality)?

.....

A.1.2. Have you had children previously?

O No

O Yes How many? _____

A.1.3. What is your education level? *Please select **ONE** answer.*

O Primary (completed primary school)
O Secondary (completed secondary/high school)
O Post-secondary (college, university)

A.2. Farther of the child

A.2.1. What is the education level of the farther? *Please select **ONE** answer.*

O Primary (completed primary school)
O Secondary (completed secondary/high school)
O Post-secondary (college, university)

A.3. Economic status of your household

A.3.1. How easy is it for you to cope financially? *Please select **ONE** answer.*

O Difficult, not always able to afford the necessities
O Income is limited but can afford the necessities
O Live comfortably, but no excess in disposable income
O Stable financial situation, able to afford high-quality products and services

B. Potential exposure to mercury

B.1. Occupational exposure

B.1.1. Before your maternity leave/pregnancy, did you have a paid full-time or part-time job?
(as an employee, employer or self- employed)

O No
O Yes

If NO, please go directly to section B.1.5.

B.1.2. Have you ever worked in the following industries or sectors? *Please mark all that apply.*

Industry type	Never	Less than 6 months	Between 6 months and 1 year	1–5 years	More than 5 years	Any time during this pregnancy
Chemical/petroleum	O	O	O	O	O	O
Metal smelting	O	O	O	O	O	O
Metalworking	O	O	O	O	O	O
Chloralkali plant	O	O	O	O	O	O
Chemistry laboratory	O	O	O	O	O	O
Dentistry	O	O	O	O	O	O
Waste management (general)	O	O	O	O	O	O
Electronic waste management	O	O	O	O	O	O
Artisanal and small-scale gold mining	O	O	O	O	O	O
Production of goods that contain mercury, such as traditional remedies, cosmetics, etc.	O	O	O	O	O	O

B.1.2.1. Please provide the name and address of the industrial enterprise where you were working before/during this pregnancy.

……...

……

B.1.3. In your job, did you have contact with the following substances? *Please mark all that apply.*

Substance	Don't know	Never	Less than 6 months	Between 6 months and 1 year	1–5 years	More than 5 years	Any time during this pregnancy
Metallic dust	O	O	O	O	O	O	O
Mercury	O	O	O	O	O	O	O
Amalgam	O	O	O	O	O	O	O
Pesticides	O	O	O	O	O	O	O

Fumes from burning coal	O	O	O	O	O	O	O
Fumes from burning electronic waste	O	O	O	O	O	O	O

B.1.4. If you have worked in any of the previously mentioned industries or have had exposures as listed in the previous questions (you answered YES to any questions in B.1.2–B.1.3), please provide additional information below. *Please mark all that apply.*

	Always	Occasionally	No
Did you change work clothes before entering your home?	O	O	O
Did you change work shoes before coming home?	O	O	O
Did you take a shower after your work shift before coming home?	O	O	O
Did you ever bring your dirty work clothes or other contaminated items home?	O	O	O
If you answered YES to the previous question – Did you wash your work clothes separately from any other clothes?	O	O	O

B.1.5. During your pregnancy, did your husband/partner or anyone else living in your household work in the following industries/sectors? *Please mark all that apply*.

Industry type	Yes	No	Don't know
Chemical/petroleum	O	O	O
Metal smelting	O	O	O
Metalworking	O	O	O
Chloralkali plant	O	O	O
Waste management (general)	O	O	O
Electronic waste management	O	O	O
Chemistry laboratory	O	O	O
Dentistry	O	O	O
Artisanal and small-scale gold mining	O	O	O

B.1.5.1. Please provide the name and address of the industrial enterprise where your husband/partner worked before/during this pregnancy.

……

……

B.1.6. During your pregnancy, did your husband/partner have regular occupational or hobby-related contact with the following substances?

Substance	Yes	No	Don't know
Metallic dust	O	O	O
Mercury	O	O	O
Amalgam	O	O	O

Pesticides	O	O	O
Fumes from burning coal	O	O	O
Fumes from burning electronic waste	O	O	O

B.1.7. If your husband/partner or any other member of your household worked at an industrial enterprise (you answered YES to any question in B.1.5–B.1.6), please provide additional information below. *Please mark all that apply.*

	Always	Occasionally	No
Did your husband/partner change work clothes before entering your home?	O	O	O
Did your husband/partner change work shoes before coming home?	O	O	O
Did your husband/partner take a shower after work, before coming home?	O	O	O
Did your husband/partner bring dirty work clothes or other contaminated items home?	O	O	O
If you answered YES to the previous question – Did your husband/partner always wash work clothes separately from any other clothes?	O	O	O

B.2. Residential environment

B.2.1. Where is your place of residence located?

O In the city
O In a rural area

B.2.1.1. In what neighbourhood or residential area do you live?

O *Please provide name of the city/village*: ……..
O *Please provide the name of the area*: ……

B.2.2. Are there any of the following in the vicinity of your home (up to 2 km)? *Please mark all that apply*

	Yes	No	Don't know
Metalworking business	O	O	O
Waste incineration plant	O	O	O
Cement production plant	O	O	O
Chloralkali plant	O	O	O
Municipal landfill	O	O	O
Landfill for industrial by-products/waste	O	O	O
Crematorium	O	O	O
Mining operation	O	O	O
Artisanal small-scale mining	O	O	O
Thermo-power plant	O	O	O
Electronic waste dismantling	O	O	O

B.2.3. What fuel or energy source do you mainly use for cooking and for heating inside your home? *Please mark only one fuel source for each*.

Fuel source	Cooking	Heating
Natural gas	O	O
Coal or charcoal	O	O
Electric power	O	O
Wood or biomass	O	O
Hot water or hot air from central heating system (district heating or central boiler for a multi-apartment building)	O	O
Kerosene	O	O

B.2.4. What is your main source of water for drinking and cooking? *Please select only one water source for each*.

Water source	Drinking	Cooking
Public water supply	O	O
Private well or spring	O	O
Bottled water	O	O
Surface water (river, lake, etc.)	O	O

B.2.5. Has a thermometer or any other device containing liquid mercury (like a sphygmomanometer) been broken in your home during the last two years?

O No
O Yes. If yes, how long ago? Please specify below:
  O Less than 30 days ago
  O from 30 to 90 days (three months) ago
  O From 91 days to 6 months ago
  O More than 6 months ago but within the last 2 years
O Don't remember/don't know

B.2.6. Has an energy saving fluorescent lamp been broken in your home during the last three months (90 days)?

O No
O Yes. If yes, how many days ago? _____days
O Don't remember/don't know

B.2.7. Has anyone worked regularly with metals in your home in the last three months (e.g. soldering metals as part of do-it-yourself and hobby activities)?

O No
O Yes
O Don't know

B.3. Personal care and lifestyle

B.3.1. Do you have any dental amalgam fillings (dark-coloured fillings)?

O No
O Yes. If yes, how many amalgam dental fillings do you currently have? .....
O Don't know

B.3.2. Do you often use chewing gum or habitually chew (leaves/tobacco, etc.)?

O No
O Yes

B.3.3. Have you ever smoked cigarettes or other tobacco products in your life time?

O I have never smoked. *Go to question B.3.5.*
O I used to smoke, but quit prior to this pregnancy
O I was smoking during this pregnancy

B.3.4. How often did you smoke, on average, before and during pregnancy?

Frequency	**Before**	**During**
Did not smoke	O	O
Smoked less than once per week	O	O
Smoked at least once per week, but not every day	O	O
Smoked daily	O	O

B.3.5. How often did you drink alcoholic beverages during this pregnancy?

O Never
O At least once per month
O At least once per week

B.3.6. Do you regularly use skin-lightening products?

O No
O Yes

B.3.7. Did you use skin-lightening products during this pregnancy?

O No
O Yes. If yes, how often? *Please specify below*:
    O At least once per day
    O At least once per week
    O At least once per month
    O Less that once per month

B.3.8. Do you regularly use traditional remedies/medicines that may contain mercury (containing cinnabar)?

O No
O Yes

B.3.9. Did you use traditional remedies/medicines that my contain mercury (cinnabar) during this pregnancy?

O No
O Yes. If yes, how often? *Please specify below*:
- O At least once per day
- O At least once per week
- O At least once per month
- O Less that once per month

B.4. Food and beverage consumption

B.4.1. How often do you eat the following foods? *Please mark each category.*

Type of product	At least once per day	At least once per week	At least once per month	Less than once per month
a. Any type of fish/shellfish/sea weed (such as tuna in salad or sandwich, pizza, prawn cocktail, etc.)	O	O	O	O
a.1. Fish from shop	O	O	O	O
a.2. Shellfish from shop	O	O	O	O
a.3. Seaweed	O	O	O	O
a.3. Locally produced seafood (any type)	O	O	O	O
b. Cereal and grain products (any type)	O	O	O	O
b.1. Rice and rice products from shop	O	O	O	O
b.2. Bran and germ	O	O	O	O
b.3. Locally grown rice				
c. Meat and meat products (any type)	O	O	O	O
c.1. Game meat	O	O	O	O
c.2. Edible offal (liver, kidney, etc.)	O	O	O	O
c.3. Chicken	O	O	O	O
d. Vegetables and mushrooms	O	O	O	O
d.1. Wild mushrooms	O	O	O	O
d.2. Leafy vegetables from shop	O	O	O	O
d.3. Legumes from shop	O	O	O	O
d.4. Root vegetables from shop	O	O	O	O
d.5. Locally grown vegetables (your own or purchased at a local market)	O	O	O	O
g. Herbs collected locally	O	O	O	O

(including in herb teas)				

B.4.2. How often did you eat the following types of fish during the last three months?

Types of fish	At least once per day	At least once per week	At least once per month	Less than once per month
a. Swordfish, tuna	O	O	O	O
b. Oily fish (sardines, herring, mackerel, salmon, etc.)	O	O	O	O
c. Whitefish, cod, haddock, plaice	O	O	O	O
d. Freshwater fish (trout, perch, others) from shop	O	O	O	O
e. Freshwater fish locally caught	O	O	O	O
f. Shellfish	O	O	O	O
g. Seaweed	O	O	O	O
h. Canned fish	O	O	O	O

Основной вопросник для заполнения женщинами

Фамилия, имя и отчество матери	
Номер истории родов	
ID – идентификационный номер матери	
Дата опроса	(день/месяц): _ _/ _ _/ 2016
Дата родов	(день/месяц): _ _/ _ _/ 2016

C. Личная информация

A.1. О матери новорожденного (участницы исследования)

A.1.1. Ваша национальность?

.....

A.1.2. Есть ли у Вас еще дети, кроме новорожденного ребенка?

O Нет

O Да Сколько? _____

A.1.3. Какое у Вас образование? Укажите ***ОДИН*** *ответ.*

O Неполное среднее
O Среднее или среднее специальное
O Незаконченное высшее или высшее

A.2. Об отце новорожденного

A.1.3. Какое образование у отца новорожденного ребенка? Укажите ***ОДИН*** *ответ.*

O Неполное среднее
O Среднее или среднее специальное
O Незаконченное высшее или высшее

A.3. Экономическое положение Вашей семьи

A.3.1. Какой уровень доходов у Вашей семьи? Укажите ***ОДИН*** *ответ.*

O Трудное финансовое положение, не всегда хватает средств даже на самое необходимое
O Располагаем ограниченным доходом, но можем позволить себе все необходимое
O Живем комфортно, но излишков не остается
O Устойчивое финансовое положение. Можем позволить себе высококачественные товары и услуги не являющиеся предметами первой необходимости

D. Возможные источники поступления ртути в организм матери

B.1. Производственные (профессиональные) воздействия

B.1.1. Была ли у Вас постоянная работа до ухода в декретный отпуск?

O Нет

O Да

*Если **НЕТ**, то переходите к вопросу B. 1.5.*

B.1.2. Работали ли Вы на перечисленных в таблице производствах когда-либо в течение жизни и/или во время беременности? *Отметьте то, что подходит.*

Вид промышленного производства или характер труда	Никогда	Менее 6 месяцев	От 6 до 12 месяцев	1-5 лет	Более 5 лет	Во время настоящей беременности
Химическая промышленность	O	O	O	O	O	O
Металлоплавильные установки	O	O	O	O	O	O
Металлообработка (токарь, слесарь, другое)	O	O	O	O	O	O
Хлор щелочное производство	O	O	O	O	O	O
Химическая лаборатория	O	O	O	O	O	O
Стоматология	O	O	O	O	O	O
Переработка мусора (отходов)	O	O	O	O	O	O
Переработка электронных отходов	O	O	O	O	O	O
Производство товаров, содержащих ртуть	O	O	O	O	O	O

B.1.2.1. Укажите название и место расположения предприятия, на котором Вы работали до- или во время беременности.

……..

……

B.1.3. Во время Вашей работы был ли у Вас контакт со следующими веществами? Отметьте то, что подходит.

Тип веществ, с которыми Вы контактировали	Не знаю	Никогда	Менее 6 месяцев	От 6 до 12 месяцев	1-5 лет	Более 5 лет	Во время беременности
Металлическая пыль	O	O	O	O	O	O	O

Ртуть	O	O	O	O	O	O	O
Амальгама	O	O	O	O	O	O	O
Пестициды	O	O	O	O	O	O	O
Дым от сжигания угля	O	O	O	O	O	O	O
Дым от сжигания электронных отходов	O	O	O	O	O	O	O

B.1.4. Если Вы работали на любом из отмеченных производств или контактировали с отмеченными веществами (Вы ответили ДА на любой из вопросов B.1.2 – B.1.3), ответьте на следующие вопросы. Отметьте то, что подходит.

	Всегда	Иногда	Никогда
Меняли ли Вы рабочую одежду до прихода домой?	O	O	O
Меняли ли Вы рабочую обувь до прихода домой?	O	O	O
Принимали ли Вы душ до прихода домой?	O	O	O
Приносили ли Вы когда-либо грязную рабочую одежду или другие предметы домой?	O	O	O
Если ДА, то стираете ли Вы свои рабочие вещи отдельно от другой одежды?	O	O	O

B.1.5. В период Вашей беременности работал ли Ваш муж или кто-либо другой, проживающий совместно с Вами на следующих производствах? *Отметьте то, что подходит.*

Вид промышленного производства или характер труда	Да	Нет	Не знаю
Химическая, нефтехимическая промышленность	O	O	O
Металлоплавильные установки	O	O	O
Металлообработка (токарь, слесарь, другое)	O	O	O
Хлор щелочное производство	O	O	O
Химическая лаборатория	O O	O O	O O
Стоматология	O	O	O
Переработка мусора и электронных отходов	O	O	O

B.1.2.1. Укажите название и место расположения предприятия на котором работал Ваш муж или кто-либо другой, проживающий совместно с Вами, до- или во время настоящей беременности.

……

……

B.1.6. Во время Вашей беременности были ли у Вашего мужа или кто-либо другого, проживающего совместно с Вами, регулярные профессиональные или любительские контакты со следующими веществами?

Тип веществ, с которыми Вы контактировали	Да	Нет	Не знаю
Металлическая пыль	O	O	O
Ртуть	O	O	O
Амальгама	O	O	O
Пестициды	O	O	O
Дым от сжигания угля	O	O	O
Дым от сжигания электронных отходов	O	O	O

B.1.7. Если **Ваш муж или кто-либо другой, проживающий совместно с Вами, работал на промышленном предприятии (Вы ответили ДА на любой вопрос B.1.5 – B.1.6), то ответьте на следующие вопросы**. *Отметьте то, что подходит.*

	Всегда	Иногда	Никогда
Меняли ли он рабочую одежду до прихода домой?	O	O	O
Меняли ли он рабочую обувь до прихода домой?	O	O	O
Принимали ли он душ до прихода домой?	O	O	O
Приносил ли он когда-либо грязную рабочую одежду или другие предметы домой?	O	O	O
Если ДА, то стираете ли Вы его рабочие вещи отдельно от другой одежды?	O	O	O

B.2. Характеристика окружающей природной среды по месту жительства

B.2.1. Где располагается Ваше жилище /квартира?

O В городе
O В сельской местности

B.2.1.1 Укажите название места Вашего проживания?

O Название города/села, деревни*:* ……..
O Название района*:* ……

B.2.2. Располагается ли какой-либо из следующих объектов поблизости от Вашего дома/квартиры (до 2 км по удаленности)? Отметьте то, что подходит.

	Да	Нет	Не знаю
Предприятия по металлообработке (машиностроительные заводы, мастерские)	O	O	O
Мусоросжигательный завод	O	O	O
Завод по производству цемента	O	O	O
Хлор-щелочное производство	O	O	O
Муниципальный полигон захоронения отходов	O	O	O

Полигон захоронения промышленных отходов	O	O	O
Крематорий	O	O	O
Предприятия добывающей промышленности	O	O	O
Теплоэлектростанция	O	O	O
Производство по утилизации электронных отходов	O	O	O

B.2.4. Какой источник топлива или энергии используется для приготовления пищи и отопления в Вашем доме? Выберите только **ОДНО** для приготовления пищи, **ОДНО** для отопления.

Источник топлива	Приготовление пищи	Отопление
Природный газ	O	O
Уголь или солярка	O	O
Электрическая энергия	O	O
Древесина или биотопливо	O	O

B.2.5. Из каких источников Вы используете воду для приготовления пищи и питья? Выберите только **ОДНО** для приготовления пищи, **ОДНО** для питья.

Please select only one for each.

Источник водоснабжения	Питьевая вода	Приготовление пищи
Коммунальное водоснабжение	O	O
Индивидуальная скважина или колодец	O	O
Бутилированная вода	O	O
Вода из реки, озера и других поверхностных водоисточников	O	O

B.2.6. Разбивался ли в течение последних 2-х лет термометр или другое устройство (ртутный прибор для измерения артериального давления), содержащее ртуть в Вашем доме/квартире?

O Нет
O Да. Если да, то когда?
  O Менее 30 дней назад
  O От 30 до 90 дней назад
  O От 3-х месяцев до 6 месяцев назад
  O Более 6 месяцев , но менее 2-х лет назад
O Не помню/Не знаю

B.2.7. Разбивалась ли флюоресцентная энергосберегающая лампа в Вашем доме, квартире в течение последних 3-х месяцев (90 дней)?

O Нет
O Да. Если да, то сколько дней назад? _____дней
O Не помню/Не знаю

B.2.8. Работал ли кто-то регулярно с металлами в Вашем доме/квартире в течение последних 3-х месяцев (например, чеканка, пайка металлов)?

O Нет
O Да
O Не знаю

B.3. Характеристика предметов личной гигиены и образа жизни

B.3.1. Есть ли у Вас зубы, запломбированные амальгамой (темные пломбы)?

O Нет
O Да. Если ДА, то сколько таких пломб у Вас насчитывается? .....
O Не знаю

B.3.2. Используете ли Вы регулярно жевательную резинку?

O Нет
O Да

B.3.3. Вы когда-либо курили сигареты или другие табак содержащие продукты? Отметьте все, что подходит.

O Я никогда не курила. *Переходите к вопросу B 3.5.*
O Я курила, но бросила когда забеременела
O Я курила во время беременности

B.3.4. Как часто Вы курили в среднем до и во время беременности?

Частота	**До беременности**	**Во время беременности**
Не курила	O	O
Меньше, чем 1 раз в неделю	O	O
По крайней мере 1 раз в неделю, но не каждый день	O	O
Ежедневно	O	O

B. 3.5. Как часто Вы употребляли алкогольные напитки во время беременности?

O Никогда
O По крайней мере 1 раз в месяц
O По крайней мере 1 раз в неделю

B.3.6. Пользуетесь ли Вы регулярно косметикой, отбеливающей кожу?

O Нет
O Да

B.3.7. Пользовались ли Вы косметикой, отбеливающей кожу, во время беременности?

O Нет
O Да Если да, то как часто:
- O По крайней мере 1 раз в день
- O По крайней мере 1 раз в неделю
- O По крайней мере 1 раз в месяц
- O Реже, чем 1 раз в месяц

B.3.8. Пользуетесь ли Вы регулярно нетрадиционными лекарственными/косметическими средствами, содержащими киноварь?

O Нет
O Да

B.3.9. Пользовались ли Вы нетрадиционными лекарственными/косметическими средствами, содержащими киноварь во время беременности?

O Нет
O Да Если да, то как часто:
- O По крайней мере 1 раз в день
- O По крайней мере 1 раз в неделю
- O По крайней мере 1 раз в месяц
- O Реже, чем 1 раз в месяц

B.4. Характеристика потребления пищевых продуктов и напитков

B.4.1. Как часто Вы употребляете в пищу следующие виды продуктов? *Проверьте каждую категорию.*

Вид продуктов	По крайней мере 1 раз в день	По крайней мере 1 раз в неделю	По крайней мере 1 раз в месяц	Реже, чем 1 раз в месяц
a. Все типы рыбы/ракообразных/водорослей (такие как салат или сэндвич с тунцом, пиццу с морепродуктами, коктейль из креветок, *другое*).	O	O	O	O
a.1. Рыба из магазина	O	O	O	O
a.2. Ракообразные из магазина	O	O	O	O
a.3. Водоросли	O	O	O	O
a.4. Местная рыба(всех видов)	O	O	O	O
b. Злаки и зерновые продукты (всех видов)	O	O	O	O
b.1. Рис и продукция из риса из магазина	O	O	O	O
b.2. Отруби и зародыши пшеницы	O	O	O	O
b.3. Местно выращенный рис				

c. Мясо и мясные продукты (всех видов)	O	O	O	O
c.1. Мясо дичи	O	O	O	O
c.2. Субпродукты (печень, почки, другое)	O	O	O	O
c.3. Мясо птицы	O	O	O	O
d. Овощи и грибы	O	O	O	O
d.1. Лесные грибы	O	O	O	O
d.2. Листовые овощи из магазина	O	O	O	O
d.3. Бобовые из магазина	O	O	O	O
d.4. Корнеплоды из магазина	O	O	O	O
d.5. Местные овощи (выращенные Вами или купленные на рынке)	O	O	O	O
g. Местно выращенные травы (включая травяные чаи)	O	O	O	O

B.4.2. Как часто Вы ели следующие типы рыбы в течение последних 3-х месяцев?

Типы рыбы	По крайней мере 1 раз в день	По крайней мере 1 раз в неделю	По крайней мере 1 раз в месяц	Реже, чем 1 раз в месяц
a. Рыба-меч, тунец	O	O	O	O
b. Жирные сорта рыбы (сардины, сельдь, макрель, лосось, другое)	O	O	O	O
c. Сиг, треска, пикша, камбала	O	O	O	O
d. Пресноводная рабы из магазинов (форель, окунь, другое)	O	O	O	O
e. Пресноводная рыба, выловленная в местных водоемах	O	O	O	O
f. Моллюски и ракообразные	O	O	O	O
g. Водоросли	O	O	O	O
h. Консервированная рыба	O	O	O	O

Annex 4. Community involvement strategy

Community involvement in the survey has the potential to positively influence the response rate and retention of participants, as well as implementation of possible risk-reduction measures, as the project follow-up. The community needs to be involved in all stages: prior to the survey, during its implementation and in survey follow-up, especially if risk-reduction measures are to be implemented.

Community involvement will be beneficial and is necessary:

- to enable planning of the survey to take into account community needs;
- to ensure support for project implementation from the local authorities and population, and get a higher response rate for the survey; this will positively influence the reliability of survey results;
- to create a sense of participation and co-ownership, and to build trust towards the survey and the survey field staff;
- to increase acceptance of the survey results;
- to strengthen community knowledge and skills to understand the problem and implement risk-reduction measures;
- to ensure implementation of risk-reduction measures if they are needed.

Development of a comprehensive community involvement strategy will add value to both the professionals involved in the survey matter and to society. The main guiding principles to be followed in this process include:

- align the strategy with stakeholders needs
- establish the goals and expected outcomes of the strategy
- explore best practices for community involvement.

The next steps involve creation and execution of a community involvement plan, following the main principles:

- establish an evaluation plan, including measuring, assessing and reporting
- build effective communication skills and strategies to advance community involvement
- advance community relationships into shared value partnerships
- institutionalize community involvement within your organization.

The survey is planned to be implemented in 11 Karelia regions that cover big territory. Communication strategy has been developed given that in consideration. The main focus is done on involvement of medical and public health practitioners and potential communities through the medical personal served at certain areas.

Several steps were considered for the development and implementation of the strategy and action plan for community involvement.

1. Learn more about the community

The following information about population in Karelia and specifically South-Karelia should be collected: size of population in different regions; density of population; main occupation; the level of high school education and up; food consumption and local habits; results of previous investigations, if any; and opportunities, potential risks and threats to the survey.

2. Develop a communication package about the survey

Information about the project is adapted to the target audience; participant information sheet is developed using plain language to provide information about survey; training programs prepared for professional staff involved in the survey include information on mercury and its health effects, prenatal exposure to mercury, clinical manifestation, prevention measures in addition to the information on the survey as such; different information is prepared for Minister of Health of the Russian Federation and the Minister of Health of Karelia.

3. Ensure support from influential people

Information about the planned survey will be first communicated to people with authority: Minister of Helath of the Russian Federation and the Minister of Health of the Republic of Karelia.. Professional communicator will be invited to the training to support the community informing about the survey. Information about the survey will be published in professional newspaper for medical workers to involve all level of medical practitioners.

4. Communicate information about the survey to community members

Information about the survey will be communicated to potential participants through mass media and involved in the survey and informed about the survey medical staff: paediatricians, gynaecologists and general practitioners conducting ante-natal visits.

5. Keep contact open during the survey implementation

Communication channels will be maintained during the implementation of the survey with field staff as well as participants in order to respond quickly and effectively to any problems which the survey field staff might face, but also to answer any questions and to provide further clarification to the community and its members, if requested.

6. Communicate the survey results

The survey results will be communicated irrespective of the measured concentrations of mercury to the regional medical authorities, health care and public health professionals and individuals. In cases where high levels of exposure to mercury are detected, the communication of the project results should include a proposal for risk-reduction measures (see Section 9 Communication). Furthermore, information about possible future (longer-term) actions be provided by scientific staff involved in the project including plans for a follow-up survey in 3–5 years. The survey results will be published in relevant scientific literature. The survey report will be provided to the Ministry of Health of the Russian Federation, Ministry of Health of the Republic of Karelia and the Ministry of Environment of the Republic of Karelia.

7. Follow up with community members who need specific attention and support in implementation of risk-reduction measures, if necessary

In cases of high level concentrations of mercury in biological samples, the participants will receive additional information on how to interpret the results and recommendations on individual preventive measures to reduce exposure. In the unlikely case of very high mercury concentrations, recommendations for individual medical consultations with health-care workers will be communicated directly to the affected participants and their doctor in local polyclinics. Relevant information on risk reduction measures will be provided to local administration in areas in which high-level of mercury is observed. Special radio or TV program will be initiated to communicate the survey results if needed.

Annex 5 Budget

N	Budget line/expenses	Cost per unit, USD	Total cost for the budget line, USD	WHO project budget, USD	Country contribution, USD
1	***Staff costs***				
1.1	National coordinator	93.0 USD per day x 90 days	8,375.00	5,000.00	3,375.00
1.2	Field work (staff)	2 persons (project team) x 30 days x 40 USD per day 6 persons (from maternities) x 42 days x 24,9 USD per day	8,680.00	4,680.00	4,000.00
		Subtotal for staff costs	**17,055.00**	**9,680.00**	**7,375.00**
2	***Organization of the training for hospital staff/volunteers***				
2.1	Rent for a meeting room	125 USD per hour/ 5 hours	625.00	625.00	0.00
2.2	Meal (coffee breaks, lunch)	15 persons x 7,5 USD each	112.50	112.50	0.00
2.3	Travel	1 person travel from project team for training	250.00	250.00	0.00
2.4	Handout for the participants			0.00	In-kind contribution
		Subtotal for the training WS	**987.50**	**987.50**	**0.00**
3	Travel of the project team	250 USD per travel x 8 times	2,000.00	2,000.00	0.00
4	Translation and copying(questionnaires and other relevant WHO documents)			0.00	In-kind contribution
5	In-land samples transportation	will be delivered by the project team member visiting hospitals	0.00	0.00	0.00
6	Out-land transportation (hair samples)		300.00	300.00	0.00
7	***Laboratory analysis***				
7.1	Hair	16 USD per sample x 250 samples	4,000.00	4,000.00	0.00
7.2	Cord blood	16 USD per sample x 250 samples	4,000.00	4,000.00	0.00
7.3	Consumables (for analysis)		800.00	800.00	0.00
7.4	Consumables for hair sampling		532.50	532.50	0.00
		Subtotal for laboratory analysis	**9,332.50**	**9,332.50**	0.00

	Total: items 1-6 (field work) **Item 7** (laboratory analysis)		**20,342.50** **9,332.50**	**12,967.50** **9,332.50**	**7,375.00** **0.00**
		TOTAL	**USD 29,675.00**	**USD 22,300.00**	**USD 7,375.00**