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

in Selenge province, Mongolia

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 assess prenatal exposure to mercury in two soums of Selenge province (ASGM areas), Mongolia and to provide the data needed for the development of a global mercury monitoring plan which is developing by WHO. The survey implementation will:

- extend the knowledge on baseline levels and sources of human exposure to mercury in Mongolia;
- characterize the level and distribution of prenatal exposure in population groups exposed to mercury in ASGM areas in Mongolia;
- identify risk factors for exposure to mercury due to ASGM activities;
- assist Mongolia 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 and highly-exposed groups;

- develop national 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, e.g. every five years).

The objective of this protocol is to provide a framework for all activities and tasks associated with the collection, analysis, assessment and reporting on prenatal exposure to mercury. it will be applied consistently in Mongolia to ensure comparability of data through the country and globally. This protocol developed based on WHO Mater Protocol. Specific information related to the study in Mongolia is included. No changes are done agains WHO Master Protocol.

Through expert recommendations and technical meetings, WHO has developed the following approach:

- 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 questionnaire will be administered to participants to assess potential sources of exposure.
- The survey will use non-invasive sampling only (maternal hair, urine 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.

3. General principles

The following underlying principles are considered when applying this protocol to developing the Mongolia national protocol for monitoring of pre-natal exposure to mercury:

- Sampling of biological material (hair, cord blood and urine) 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; analytical laboratory should confirm credibility.
- Quality assurance of results should be independently confirmed through inter-calibration analysis.

3.1. Roles and responsibilities of WHO and Mongolia (Public Health Institute of Mongolia)

Both WHO and Mongolia 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 Mongolia 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 a questionnaire to be completed by the survey participants;
- as an owner of data collected in the national pilot surveys, to gather the data from Mongolia 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 Mongolia, 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 including Mongolia.

The role of Public Health Institute of Mongolia 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, cord blood and urine 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 (Ministry of Health and Ministry of Environment and relevant municipalities) and nongovernmental stakeholders at the 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 national protocol has been developed by the national coordinator based on the Master Protocol on the survey prepared by WHO to meet the aims of the survey. The national coordinator is responsible for overall planning and implementation of the survey in Selenge province, Mongolia, assisted by the appropriately trained field and laboratory staff. In particular, the national coordinator has to assure that the survey meets all national ethical requirements for studies involving human subjects. The national protocol fully corresponds to WHO Master Protocol. Deviations, if any, will be communicated to the WHO team, who will communicate them in good time to the WHO ERC, requesting approval of the modifications before they can be implemented.

The national protocol was developed by the national survey coordinator: Dr Davaadorj RENDOO, Researcher, Center for Environmental Health and Toxicology, Public Health Institute of Mongolia.

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 due to ASGM activities. Given the importance of involving the community and local representatives in the survey from an early stage, the community involvement actions, in particular, communication with local medical staff and local municipalities in both targeted areas will be taken. The actions include meetings with local physicians and gynaecologists if possible, sharing information with responsible person in local municipality. . The proposed community involvement strategy is in Annex 5.

The survey In Mongolia will be implemented in the area potentially contaminated by mercury in high concentrations and high-exposure populations in hotspots will involve samples of women who are suspected to have increased levels of exposure to mercury and/or its compounds.

This document provides a detailed description and sample size justification for the target population and sampling sites. A detailed approach for selecting maternity hospitals in high-exposure areas, and criteria for recruiting highly exposed individuals were done taking into account local conditions.

The proposed survey design includes a limited set of biomarkers (scalp hair, cord blood and urine). All biomarkers will be used in the survey.

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

5.1. Target population

The target population is mothers who have just delivered a child and living in Sukbaatar and Mandal soum in Selenge province.

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, and given that the main target population are women living in remoted areas of ASGMs, the recruitment is possible during admitting to hospital for the delivery. The following criteria should 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
- 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 will explain the purpose of the survey, specific activities and risks, and present the informed consent form (Annex 2). If consent is provided, the interviewer will then collect exposure information using the standardized questionnaire (Annex 3) during ante-natal visits or in a hospital, obtain medical and anthropometrical data from the medical records, and collect a sample of scalp hair (following relevant SOPs) (in a hospital). Samples of urine and cord blood will be collected by the medical personnel due to rules and procedures in the maternity units in Mongolia (following relevant 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, cord blood and urine. However, collection of hair and urine samples and interviews can also be conducted in other settings, such as at home right before the delivery and 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.

5.2. Selection of hospitals and number of participating mothers

5.2.1. Number of participants

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 intervals, 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.[1] Based on the data on variability in mercury levels in hair samples in women from

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

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.

As a minimum, 250 samples will be collected in the target areas with the proportion of 2/3 in in general and 1/3 in Mandal soum.

The Sukhbaatar soum of Selenge province has the main maternal hospital serving the whole area and the pregnant mothers living around other soums have to seek health care in this hospital for child delivery. Selected Mandal and Sukhbaatar districts have more densely population in comparison with other districts in Selenge province. In addition to environmental conditions, it was one of reasons of identification of target areas and hospitals. There are only two maternity hospitals in the Selenge province. Both will be involved in the survey.

The previous study was proven that mercury exposures among ASGM were comparatively higher in Mandal soum. The other soum which was Bayangol also proven to be mercury exposed at that time. The mothers from Bayangol soum are delivered in Sukhbaatar soum maternity hospital of Selenge province and in general it is also covered by the survey.

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) as well as for urine sampling.

5.2.3. Identification of high-exposure areas and hospitals

Emissions of inorganic mercury from industrial sources as well as mercury releases in waterbodies are relevant consideration for the identification of exposure hotspots.

Based on “Mercury health impact assessment on ASM” survey in 2014 which was implemented by the Public Health Institute with assistance of Swiss Development Agency, Selenge province has been selected as the target area with expectation of higher concentrations in Mandal soum. The survey revealed that mercury is still used in hidden way among ASM of Mandal soum. It is also well known that Selenge province has big freshwater bodies with substantial fisheries and exposure to methylmercury can’t be excluded.

Selenge province, 41200 km^2, is located in the North part of Mongolia on a distance of 321 kilometer from the capital, Ulaanbaatar city. The total population size is 108253 citizens. The Mandal soum and Bayangol are hotspots of ASGM and potential mercury contamination.

The following criteria have been taken into account when identifying target areas:

- size, location and other pertinent characteristics of active pollution sources of concern;
- historical contamination of the area (presence of polluting activities in the past);
- concentrations of mercury in environmental samples (air, soil, surface water or sediment, groundwater, locally produced food) exceeding health-based guidance values and/or high consumption of contaminated local food products from previous studies;
- health complaints by inhabitants or documented elevated rates of conditions related to mercury if any;

- meteorological and geographical characteristics of the area (e.g. wind direction, topography) in relation to the source of emissions;
- transport connection to the capital.

5.3. 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.

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

The 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.

5.4. 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 Mongolia, a lot of efforts were already taken to eliminate mercury from gold production. If level of mercury is still high additional actions are necessary and decision-makers

in the health, environment and economy sector as well as local authorities will be involved in the development of risk reduction measures. For the reduction of exposure to methylmercury, if found out, public and individual advice, including dietary recommendations and guidance, based on the available scientific knowledge *(19)*, will be made available to exposed groups.

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.

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

- for individuals with a high level of mercury in their urine, their doctors are contacted and a check-up of renal system functions is advised and arranged upon the woman's request;
- 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.

Capacities of the Selenge province hospital will be used for medical follow-up if necessary.

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 should precede risk communication and planning of protective measures.

Neurological and cognitive development surveillance will 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.

The national survey coordinator is responsible for contacting mothers with high mercury concentration and/or their doctors 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 will be managed by the survey national coordinator and includes, but not limited to, the follows:

- to develop fieldwork manual and other documentation in a national language using the standardized methodological documents provided by WHO;
- to form the national implementation team from the PHI staff and get approval from the Institute Director;
- to train field personnel and supervising their work;
- to select maternity hospitals and to get an agreement with local hospitals and authorities to implement the survey;
- to liaise with the local community, identifying and engaging local representatives to promote the survey;

- to develop information leaflets for maternity hospitals and for survey participants;
- to inform the recruited women, administer informed consent and conduct interviews;
- to collect, store and ship samples to the laboratory of Public Health Institute;
- to enter the data into a data file and performing preliminary data cleaning;
- to analyse national data and to submit the data to a WHO-affiliated data analysis centre;
- to communicate the results of the survey to the participants and national public health authorities.

Sixteen people are planned to be deployed for performing of field work including scientific staff from PHI and the maternity units of hospitals.

Responsibilities of the research staff:
- to contact women and getting agreement from women to participate in the survey (provision of information sheet, eligibility screening);
- to recruit (prior informed consent); NB! Staff members contacting women at non-clinical stage shouldn't be involved in the recruitment process in the hospitals);
- to collect epidemiological information (main questionnaire);
- to collect hair samples;
- to organize storage of urine samples;
- to collect medical records.

Responsibilities of the medical staff in the hospitals:
- to collect cord blood samples in maternity wards and urine samples before or after delivery.

All measures will be taken to minimize the survey impact on the regular personnel of the maternity units for the survey implementation and to increase motivation including:
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- personnel of the maternity staff (midwifes) should be responsible only for sampling of cord blood (in maternity wards) and urine before or after delivery; 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 hospital's 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;
- 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.
- joint publication of the survey results.

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

6.2. Timing of the survey

Exposure patterns, such as fish consumption and ASGM activities, may vary by the season. To avoid a seasonal bias, sampling will take place during non-snowy 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 the Mongolia will 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 which will be developed based on WHO recommendations and the example (Annex 2). 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.

The interviewers will be present at the maternity hospital.

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 (it is preferable to do this in an interview rather than to leave the questionnaire with the woman for self-administration);
- collect a hair sample;
- arrange for the collection of urine and 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 and urine 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 should 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. Questionnaire

All survey forms are translated into a national language. No changes are included in the questionnaire. 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 prior to the main survey during a national training workshop.

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

The main questionnaire (Annex 3) can be used to interview the participants at the time of hair sampling. Completion of this questionnaire takes about 30 minutes, if administered by an interviewer. 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.

Personal interviews conducted by trained interviewers are the most commonly used method to collect data on behavioural and nutritional exposure factors. However, this method has a tendency to under-report socially undesirable behaviours (for example smoking). This is known as the “social desirability” bias. On the other hand, interviews have the advantage over self-administered surveys that any misunderstanding can be resolved immediately, which leads to higher data completeness and quality. Training of the interviewers is essential 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.

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

6.5. Training of fieldwork staff

To ensure standardization of processes, the training must be organized as far in advance as possible. Training will involve a range of fieldworkers engaged in survey implementation, including interviewers, hospital staff, those responsible for collecting samples, those responsible for sample transportation and laboratory analysists. In particular, Chief of Health Department of Province, Director of General Hospital, Deputy Director for Clinical Services of Hospital, Head of Maternity Department and Head nurse will be involved.

The training materials will be prepared and the training will be conducted by the PHI staff designated for the project implementation. The training modules content will be as the following: overall information implementing survey, information leaflet, consent form, questionnaire, methodology and techniques of taking questionnaire, SOP of sampling, storage and transportation of biological samples.

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.

All procedures will be done by lectures and practical performances in the maternity department.
It is supposed that at the end of training, examination and evaluation was done by the national coordinator and lab analyst, and then discussion was taken.

Field survey leader will be responsibility for tailoring or substituting trained staffs when they had sick call or on a short leave.

All field staff will get compensatory allowances according to their performance which is included in the project budget.

A technical help desk during the survey, starting from the moment the general protocol is adapted to the national situation will be established in PHI to increase consistency and promote adherence to survey protocols.

6.6. Quality control measures

Quality control with respect to fieldwork and training of the project staff is considered by the national coordinator. It is in the interest of all partners involved that the fieldwork is controlled and checked. To avoid errors, checklists including all important steps of the procedures will be prepared. In addition, field visits by supervisors and from experts not directly involved in fieldwork are planned.

The following measures are planned to ensure the control the performance by the national laboratory:

- To carry out an analysis of 300 blank samples, standard solution, individual biological sample and reference materials in accordance with total mercury determination CVAAS SOP of Akagi and Nishimura method which is recommended by from WHO Regional Office for Europe.
- To participate in inter-laboratory comparison of mercury determination organized by Jozef Stefan Institute of Slovenia.
- To invite a senior mercury specialist to Mongolia in order to exchange practices of laboratory analysis on mercury determination, calibration of equipment and quality control issues, if necessary.
- To carry out the quality control analyzes.
- To check the project documents by appointed researcher and national lab analyst
- To visit the field hospitals before the survey and three time during the survey implementation.
- To participate in a mirror analysis organized by WHO.

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,[2] 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

[2] 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.

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 coordinators. 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 coordinators.

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

Based on the scientific information on biological matrices summarized above all three recommended matrices were chosen for assessment of exposure to mercury in ASGM sites in Mongolia for the following reasons:

- There are big freshwater basins in the target areas that can be contaminated due to ASGM activities; analysis of mercury in hair will provide information on methylmercury contamination through the food chain if freshwater fish is contaminated;
- Contaminated sites are characterized by complex exposure to mercury; assessment of cord blood will provide data both on organic and inorganic mercury content;
- The best matrix to characterize occupational exposure is urine; workers in ASGM are highly exposed to inorganic mercury due to their professional activity.

7.2. Transportation of samples

The appointed Head nurse in the field, the national lab analyst in the main lab will carried out quality evaluation control of all hair samples when before sent and after receiving samples.

Hair samples do not require any special transport conditions; they can be transported at room temperature. However, it should be checked that the corresponding documents, including a sheet listing all samples, is sent in the package and information on any event that occurred during sampling that could affect the sample, has also been included.

Cord blood and urine samples must be kept at 4°C until their arrival at the laboratory, where they will be aliquoted and analysed or stored until analysis. Alternatively, the samples can be aliquoted and frozen in the maternity ward, and then transported to the laboratory under proper conditions. Furthermore, urine and cord blood samples must be transported in compliance with the relevant shipping regulations for biological material.

All samples will be sent to mercury laboratory by regular intercity public transport in agreement with a transportation company, urine and blood samples in the storage cool box.

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 can be found in the SOP for analysis of mercury in hair.

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

Urine samples should be aliquoted (at least three aliquots) to enable mercury and creatinine analysis in the national and the reference laboratories.

7.4. Analysis of samples

The 250 individual samples of each matrix (scalp hair, cord blood and urine) are planned to be collected within the framework of the pilot surveys. All three matrices will be analysed in the pilot survey.

The samples will be analysed using the following methods.

Total Hg in maternal urine and cord blood: The total Hg concentration in maternal urine and cord blood was determined by Akagi and Nishimura method, using a RA-915+ cold vapor atomic absorption spectrometry with a RP-91C attachment in the Environmental Health and Toxicology laboratory of National Center for Public Health. The principle of this method is to add 1:1 ratio of concentrated nitric (HNO_3) and perchloric acid ($HClO_4$) and then heating at 200-230^{0}C for 30 minutes. Finally, stannous chloride was applied for the reduction of total mercury.

Total Hg in maternal hair: The total Hg in maternal hair was determined by pyrolysis technique in the combustion of 520-580^{0}C and 0.8-1.2 l/min flow rate, using a RA-915+ cold vapor atomic absorption spectrometry with a PYRO-915 attachment in the Environmental Health and Toxicology laboratory of National Center for Public Health. The principle of method based on combustion of hair sample and to reduce into Hg^0 state (Figure 5).

Creatinine in urine: The amount of creatinine in maternal urine was determined by using a semi-automatic photometer Humalyzer 2000 and Hospitex detector in the Nutrition laboratory of National Center for Public Health.

Samples of cord blood and urine will be analyzed using the methods recommended by WHO.

All samples will be analysed in the national laboratory (Public Health Institute of Mongolia).

7.5. Standardization

Results of the measurements must be analytically comparable between laboratories. To ensure this, the national survey will follow the SOPs for sampling and analytical methods, and develop 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) supports internal quality assurance. External quality assurance is done through international inter-laboratory comparison investigations (ICI)[3] by the Jozef Stefan Institute (Slovenia) in coordination with WHO.

7.6. Storage of samples remaining after the mercury analysis

According to the main PHI regulation, samples will be stored at the temperature -20^{0}C before mercury analysis including confirmation of high-contaminated samples and destroyed after that but no later than 1 year after sampling.

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 templates are provided by WHO. The data from each participant are identified by a unique identity number (ID number). Please see the following example:

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

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, is included in a codebook.

[3] ICI is a measure to harmonize analytical methods and their application so as to improve the comparability of analytical results. ICI is carried out before the laboratories begin to analyse the samples.

Mongolia, in consultation and agreement with the project coordinator in WHO, will choose its software for database management and statistical analysis 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.

Based on experience in other multicentre studies, statistical analysis programs like R, SPSS or SAS meet these criteria and are thus recommended.

Data processing will be conducted in each participating country, including Mongolia, while statistical data analysis will be conducted both at the national level and at WHO. Mongolia will transfer the data 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)

Mongolia will conduct statistical analyses at the national level and submit anonymized data for statistical analysis to a central 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.

The appointed researcher will create questionnaire data into Microsoft Excel datasheet. 10% of all databases will undergo to screening check by the laboratory analyst. The laboratory database will be created by national lab analyst. After completion of database, it will be transferred to SPSS Statistics 21.

In order to define differences between mercury concentration and risk factor, the Kruskal-Wallis and Mann-Whitney tests will be applied. When p value<0.05, differences will be considered statistically significant. Geometric mean (GM) and standard error of mean (SEM) will be calculated because of abnormal distribution of mercury concentration in the biological samples. In order to evaluate the correlation between mercury concentration and exposure sources, risk factors multiple linear regress will be used.

8.2.2. Data evaluation

The interpretation and evaluation of the HBM results will be dealt with in separate steps. Some of 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?

Data will be compared with existing data available in the literature and WHO reference levels.

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 national coordinator will provide targeted information to the general public, policy-makers 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 should 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 will start as soon as the protocol is ready.

In order to meet these goals, it is necessary to make sure information leaflets are tailored to the target population. The briefing of policy-makers will start at the same time.

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 of the survey coordinator (including name, address, telephone number and email address) and be available for participants.

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

- nature and aims of the survey;

- 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);
- responsible institution and the national coordinator 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; 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. Through survey implementation period field staff will be consulted regarding to recruitment, questionnaire, sampling, storage, transportation issues, as well as communication with recruited women. Recruited women also will be invited to get more information and ask questions if necessary.

9.3. Communication of the survey results

Before communicating the result of the HBM survey, careful consideration will 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. It is critically important to distinguish between 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 involve different stakeholders according to their roles and capacities.

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, local communities 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.

The most effective channels to communicate the message will be identified (through publications, mass media, scientific reports, leaflets, meetings).

The communication budget is planned in amont around 20% in the project budget.

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 (responsible person in the Ministry of Health and the Ministry of Environment), 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 if necessary.
A meeting will be organized to introduce the survey results to the MoH and MoE and discuss further actions 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.

Relevant recommendations on reducing exposure to mercury and/or preventing health risks will be developed for individuals on case-by-case bases.

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.

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 and will be considered in certain cases. The use of mass media will 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, will be put in the context of levels of mercury in the ambient environment.

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

In cases where high concentrations of mercury are observed, the results will be communicated to health-care professionals including 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. These could be paediatricians, gynaecologists and obstetricians, occupational physicians, and general practitioners serving specific communities (artisanal and small-scale miners, fishing communities, etc.). 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 will be provided to survey participants upon their wish indicated in the consent form. 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 considered in cases where a high level of mercury has been detected:
- - to repeat the mercury analysis to exclude any mistakes;
- to test the samples in a reference laboratory if it is possible;
- to evaluate risks using all available information on potential sources of exposure and the associated health risks.

When communicating risk-reduction measures, it needs to be remembered that they will differ in cases of exposure to methylmercury and inorganic mercury. Both forms can present in ASGM areas.

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 needs to be guaranteed. At the same time, all aggregated results can be made publically available, providing that no link can be made to specific individuals.

10. Ethics

All national and international rules related to research ethics will be followed during the survey.

The survey has been approved by the Ministry of Health Ethic Research Committee. The decision and guidance of ERC of MOH followed strictly in the survey. WHO Master Protocol laid a basis for the national survey protocol development.

The ultimate objective is to guarantee the optimal protection of the rights and dignity of every survey participant (data subject). Special attention is 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 (Annex 2):
    - 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 and urine;
    - 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:

_____

Хавсралт 1. Судалгаанд хамруулах шалгуур

1. Та 18 нас хүрсэн үү?
   - ☐ Тийм
   - ☐ Үгүй

   Хэрэв үгүй бол → Асуумж авахыг эелдэгээр зогсооно

2. Та хэдэн өдрийн өмнө төрсөн вэ (Асуумжийг төрсний дараа авсан бол)?
   _____ өдөр

   Хэрэв 14 өдрөөс дээш бол → Асуумж авахыг эелдэгээр зогсооно

3. Та [*эмнэлгийн ойр орчимд*] амьдардаг уу?
   - ☐ Тийм
   - ☐ Үгүй

   Хэрэв үгүй бол → Асуумж авахыг эелдэгээр зогсооно

4. Та энэ газар хэдэн жил амьдарч байгаа вэ?
   _____ жил

   Хэрэв 3-аас доош жил амьдарсан бол → Асуумж авахыг эелдэгээр зогсооно

5. Та сүүлийн 3 сард [эмнэлгийн ойр орчмын газраас]гадна хэдэн өдөр байсан бэ?
   _____ өдөр

   Хэрэв 14 өдрөөс дээш хугацаанд байсан бол → Асуумж авахыг эелдэгээр зогсооно

6. Асуумж авахад ямар нэгэн хэлний бэрхшээлгүй байсан эсэх? (асуумж авагчийн тодорхойлсноор)
   - ☐ Тийм
   - ☐ Үгүй

   Хэрэв үгүй бол → Асуумж авахыг эелдэгээр зогсооно

7. Үсний дээж авалт зөв болсон эсэх (Толгойн арын хэсгээс авсан үсний урт нь 3 см-ээс доошгүй байхыг харж тодорхойлсон)
   - ☐ Тийм
   - ☐ Үгүй

   Хэрэв үгүй бол → Асуумж авахыг эелдэгээр зогсооно

8. Судалгаанд хамрагдах шалгуурыг хангасан уу?
   - ☐ Тийм
   - ☐ Үгүй

9. Хэрэв тийм бол, судалгаанд оролцохыг зөвшөөрсөн үү?
   - ☐ Тийм
   - ☐ Үгүй

10. Судалгаанд оролцогч нь бичгээр зөвшөөрөл өгсөн эсэх (Тэмдэглэгээг хийнэ үү):
    - ☐ Үсний дээж

☐ Шээсний дээж
☐ Хүйн цусны дээж
☐ Өвчний түүхтэй танилцахыг зөвшөөрсөн

11. Судалгаанд орох боломжтой эсэх?
☐ Шалгуур хангаагүй
☐ Шалгуур хангасан боловч оролцох хүсэлгүй

☐ Судалгаанд оролцох боломжтой

ХЭРЭВ СУДАЛГААНД ОРОЛЦСОН БОЛ

Судалгаанд оролцогчийн нэр:
_____

Гэрийн хаяг:
_____

Эмнэлэгт хэвтсэн он, сар, өдөр:
_____

Хүүхэд төрсөн цаг, өдөр:
_____

Annex 2. Participant Information Sheet

Dear Madam,

Public Health Institute of Mongolia with support from World Health Organization is organizing a pilot survey aiming at evaluation of health risks of contamination of food and the environment by mercury and its compounds in Selenge Province of Mongolia. Based on this survey we will be able to assess exposure of population in Selenge Province to mercury and 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 to the environment as a result of its use or as a by-product during different type of combustion processed. Exposure to high concentrations of mercury and its compounds for a long time create a risk of neurological and urinary system disorders.

There are sources of mercury for the population in Selenge province such as mercury use in gold production at artisanal and small scale gold mining. The population in these areas can be exposed to inorganic mercury. In waters, marine and fresh, mercury 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 our organisms through assessment of its concentrations in scalp hair, cord blood and urine.

When a woman is exposed during pregnancy to high concentrations of mercury, mercury can be transferred to the fetus, and affect 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. That's why we are addressing you and willing to assess your child exposure to this chemical 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.

To analyse mercury concentration we will take samples of scalp hair, cord blood and urine 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. A nurse will instruct you how to collect urine sample when you are in hospital or after that.

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 4-5 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 analysis are completed. They won't be used for any other purposes except of the purpose of this survey.

The national survey coordinator

Dr Davaadorj Randoo

E-mail: davrendoo@gmail.com

Phone: 976-99185473

Оролцогчийн мэдээллийн хуудас

Хүндэт Хатагтай,

Дэлхийн Эрүүл Мэндийн Байгууллагын дэмжлэгтэйгээр Нийгмийн Эрүүл Мэндийн Хүрээлэн нь Сэлэнгэ аймаг дахь мөнгөн ус, түүний нэгдлүүдээр хоол хүнс, хүрээлэн буй орчны бохирдлыг эрүүл мэндийн эрсдлийн үнэлгээг хийх туршилтын туршилтын ажлыг зохион байгуулж байна. Энэхүү судалгаан дээр үндэслэн Сэлэнгэ аймагт хүн амын өртөлтийг мөнгөн ус руу үнэлэх, шаардлагатай бол урьдчилан сэргийлэх арга хэмжээг санал болгох, ДЭМБ-ын хүчин чармайлтыг мөнгөн усны өртөлтийг хянах дэлхийн хэмжээний төлөвлөгөөг боловсруулахад дэмжлэг үзүүлэх болно.

Меркури болон түүний нэгдлүүд нь янз бүрийн төрлийн бүтээгдэхүүн үйлдвэрлэхэд ашиглагддаг ба боловсруулалтын явцад янз бүрийн төрлийн шаталтын явцад бүтээгдэхүүнийг ашиглах замаар үр дүнд хүрч болно. Мөнгөн ус болон түүний нэгдлүүдийн өндөр концентрацид өртөх нь мэдрэлийн болон шээсний системийн эмгэгийг үүсгэдэг.

Сэлэнгэ аймгийн хүн амд гар аргаар алт олборлох үйл ажиллагаанд мөнгөн усны хэрэглээ ордог. Эдгээр газруудын хүн ам нь органик бус мөнгөн ус руу нэвтэрч болно. Ус, далай, цэнгэг, мөнгөн ус нь загас, далайн бусад бүтээгдэхүүнийг хуримтлуулж чадах метилийн мөнгөн ус руу хувиргадаг. Метил мөнгөн усаар бохирдсон загас, бусад хүнс нь нийт хүн амын мөнгөн усны гол эх үүсвэр болдог. Судалгааны зорилго нь хүйх, цусны шээс, шээсний агууламжийг үнэлэх замаар манай организмд мөнгөн усны агууламж ямар хэмжээгээр хуримтлагдаж байгааг судлах зорилготой юм.

Ургамлын гаралтай нянгийн хортой нөлөөнөөс болж ургийн эм нь метилмоскроскопт өртөхөд илүү эмзэг байдаг. Ийм учраас бид сүүлийн гурван сарын туршид энэ химийн бодисоор хүүхдэд үзүүлэх нөлөөллийг үнэлэхийг хүсч байна.

Судалгааны дараа бид таны бие махбодын бохирдол, мөнгөн усаар хордох эрсдлийн талаар мэдээлэл авах болно. Энэхүү мэдээллийг авахад бид мөнгөн усыг хэрхэн багасгах, түүнээс зайлсхийх талаар зөвлөгөө өгөх болно.

Мөнгөн усны концентрацийг шинжлэхийн тулд бид та нараас хуйх үс, цус, шээсний дээж авч болно. Эдгээр бүх процедур танд хор учруулахгүй. Бид толгойноосоо хэд хэдэн ширхэг үсийг авах болно. Энэ нь мэдэгдэхгүй байх болно. Хуухдийн болон хуухдийн телеелегчийн дараа хуухдийн цусыг жирэмслэлтийн ереенд мэргэжлийн хумуус авна. Эмнэлэгт хэвтсэн эсвэл дараа нь шээсний дээжийг яаж цуглуулахыг сувилагч танд зааварчилна.

Судалгаанд оролцсон сайн дурынхан. Та янз бүрийн шалтгааны улмаас оролцохоос татгалзаж болно. Энэ нь эмнэлгийн тусламж үйлчилгээний түвшин, чанарт ямар ч нөлөө үзүүлэхгүй. Үүнээс гадна, та эмнэлэгт хэвтэхээсээ өмнө өөрийн оролцоогоо цуцалж болно. Бүх хэрэгцээ нь таны шийдвэрийн талаар үндэсний зохицуулагчид мэдэгдэх явдал юм. Үндэсний зохицуулагчидтай холбоо барих мэдээллийг доор үзүүлэв.

Судалгааны үеэр бид хэд хэдэн төрлөөс хамаарч 4-5 сарын хугацаанд судалгаа дуусгахаар төлөвлөж байна. Судалгаанд хоёр зүун тавин эмэгтэй тантай хамт оролцоно.
Судалгаанд хамрагдагсад таньд үнэ төлбөргүй байдаггүй.

Судалгаанд хамрагдагсад танай эмнэлэгт хэвтэн эмчлүүлэх хугацаанд таны цаг хугацаа ойролцоогоор 1.5 цаг зарцуулна.
Энэхүү судалгаа нь ёс зүйн бүх стандартыг чанд мөрддөг. Судалгааны явцад цуглуулсан мэдээлэл нууц байх болно. Таны хүүхдийн нэр, нэрийг нийтэлж, тайлагнахгүй. Бүх өгөгдөл нь нэргүй болох бөгөөд танд өгөгдсөн ID кодыг дүн шинжилгээ хийх зорилгоор ашиглах болно. Бүх шинжилгээнүүд дууссаны дараа цуглуулсан дээжийг лабораторид устгах болно. Тэд энэ судалгааны зорилгоос бусад зорилгод ашиглахгүй.

Үндэсний судалгааны зохицуулагч

Дэвидорж Рандоо нар
И-мэйл: davrendoo@gmail.com
Утас: 976-99185473

Informed consent form

CONSENT FORM for participation in a human biomonitoring survey to assess exposure to mercury, a research project carried out by Public Health Institute of Mongolia, in the framework of the World Health Organization (WHO) global initiative.

Dear Madam,

We are kindly inviting you to participate in a study conducted by the Public Health Institute of Mongolia in the framework of the WHO global initiative. The study aims at assessment of exposure to mercury. All people are exposed to certain levels of mercury from the environment. You are living in an area where mercury is used for gold production. We would like to check if it is posed a health risk for you and your child. Mercury use is regulated and we don't expect that it is risky. However, to confirm that and to advise the government on additional protective measures if necessary, we are conducting this survey. The survey also will support WHO actions to assess risk in similar places like you are living in other countries.

The main purpose of this study is to assess your personal and your child's exposure to mercury. For that, we will measure mercury concentration in your hair, cord blood and urine. You will receive individual results; in a case in which high concentrations of mercury are detected, you will receive advice on individual actions to reduce exposure, or recommendations to seek health advice, if needed.

Together with you, 250 women from Selenge province will be involved in the survey.

Based on the results of the survey, we will provide data on your child exposure to mercury in womb, assess the level and distribution of exposure and the main risk factors from mercury for you and your child. We will advise the government on protective measures to reduce exposure if needed

Some background information on mercury

Mercury is present in air, soil and food and finds its way into the human body, disturbing biological processes and in some cases affecting our health. When a woman is exposed during pregnancy to high concentrations of mercury, mercury can be transferred to the fetus, and affect 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. Analysis of biological material from mothers (such as hair and urine) and of cord blood helps to characterize prenatal exposures to mercury and to provide valuable information. This helps to assess health risks for you and your child as well as at the population level and to support policy interventions aiming at reducing pollution and protecting health. It can also be used to provide recommendations on how to protect you and your child from exposure to mercury and reduce risk in cases of detected higher mercury concentrations.

The study is supported by WHO as a part of a global initiative. An assessment of exposure to mercury during the last trimester of pregnancy, through measuring concentrations of mercury and its compounds in the cord blood, scalp hair and urine will be done in the survey framework. The most valuable data to assess prenatal exposure to mercury can be obtained if samples of biological material are taken immediately after delivery. For that reason, we approach women during their stay at maternity hospitals. If you are interested in getting more information about your and your

child's exposure to mercury, and you meet the eligibility criteria, you are invited to participate in the survey.

What participation means for you

To assess exposure to mercury and its compounds, we will ask your permission to take samples of your hair, cord blood and urine, answer a questionnaire and agree our access to your and your child medical records . All samples will be collected in a non-invasive manner that will not harm you and/or your child. A sample of umbilical cord blood will be collected by the midwife at birth; a sample of your hair will be collected by cutting a small strand of hair close to the scalp from the back of your head; and, a spot sample of your urine will be collected in the container provided by survey staff. We will also ask you to answer a questionnaire with a number of questions about your diet, home and work environment, lifestyle and health. This information will help us to learn more about potential sources of mercury. Completion of the questionnaire should not take more than 30 minutes. All procedures will be conducted by trained personnel, who will also be ready to answer your questions.

We would highly appreciate it if you allowed us to access the following information from your and your child's medical records: your child's weight and height at birth, as well as your diseases and conditions during pregnancy and delivery. This information, together with the analysis of mercury concentrations, will allow the national survey coordinator to provide you with advice on how to minimize your exposure, if necessary.

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

Voluntary participation/discontinuing participation

Participation in the survey is voluntary. You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your treatment at this hospital in any way.

Also, if you decide to participate in the survey, you will be able to discontinue your participation at any time. All you have to do is to inform the researchers that you no longer want to participate. Furthermore, you can ask for all the samples that you have provided to be destroyed. If you decide to withdraw your participation and ask for the destruction of your samples, please do it before leaving the hospital. Withdrawing your participation will not affect your medical treatment or access to medical services in any way.

The results of the analyses that have already been completed will remain in the survey database and will be used in survey reports.

Benefits of the survey

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.

Costs

No costs associated with this study will be charged to the participants.

Possible risks

No risks are anticipated associated with participation in this survey. There is no health risk related to the collection of cord blood. The procedure will not have any influence on the normal delivery procedures. Possible inconveniences are limited to the time you will have to spend on providing the hair and urine samples and responding to the questionnaires. The questionnaires and medical records contain information that can be viewed as sensitive. However these data will be kept strictly confidential. We will use coding and anonymized data at the data analysis stage. Your personal information will only be available to authorized investigators.

Confidentiality

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.

Additional information about the survey

You have the right to ask for additional information about the research project and the procedures described in this document. All reasonable requests for information will be answered by the principal investigator to the best of their knowledge. The researchers will inform you if and when any major changes in the procedures, risks or benefits of this study occur.

Information on the progress of the survey can be requested from the national coordinator *((Dr* Davaadorj RENDOO, Researcher, Center for Environmental Health and Toxicology, Public Health Institute of Mongolia).

The principal investigator is responsible for this research, to be carried out under the conditions described in this document.

Name of principal investigator: Davaadorj RENDOO (national coordinator), Researcher, Center for Environmental Health and Toxicology, Public Health Institute of Mongolia

_____

Other contact people*:* Baatartsol DAYANJAV (laboratory analyst), Head, Toxicology laboratory, Public Health Institute of Mongolia

_____

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 of Ethics Research Committee of Public Health Institute of Mongolia.

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):

_____

Communication of results

The quality checked human biomonitoring survey results, including concentrations of mercury in hair, urine 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:

_____

_____

Таниулсан зөвшөөрлийн хуудас

ДЭМБ-ын техникийн дэмжлэгтэй Монгол Улсын Нийгмийн эрүүл мэндийн хүрээлэнгийн хийж гүйцэтгэсэн “Мөнгөн усны өртөлтийг тодорхойлох хүний биомониторингийн судалгаа”-ны ажлын таниулсан зөвшөөрлийн хуудас

Хүндэт эрхэм хатагтай танаа,

Таныг ДЭМБ-аас хэрэгжүүлж буй төслийн хүрээнд Монгол Улсын Нийгмийн эрүүл мэндийн хүрээлэнгээс хийж гүйцэтгэж буй судалгаанд оролцохыг урьж байна. Энэхүү судалгааны зорилго нь мөнгөн усны өртөлтийг үнэлэх юм. Хүмүүс хүрээлэн буй орчин дахь мөнгөн усаар тодорхой түвшинд өртөж байдаг. Таны амьдарч буй газарт алт ялгах үйл ажиллагаанд мөнгөн усыг ашигладаг. Бид энэхүү судалгааны хүрээнд алт олборлох үйл ажиллагаанд ашиглаж буй мөнгөн ус нь таны болон таны хүүхдийн эрүүл мэндэд эрсдэл учруулж байгаа эсэхийг тогтоох болно. Мөнгөн усны хэрэглээ нь журамлагдсан учир бидний зүгээс мөнгөн ус нь эрсдэл болохгүй гэж таамаглаж байгаа болно. Гэсэн хэдий ч дээрх таамаглалыг батлах, Засгийн Газрын зүгээс эрүүл мэндийг хамгаалах нэмэлт арга хэмжээ авах шаардлагатай эсэхийг тогтоохын тулд бид энэхүү судалгааг хийж байна. Түүнчлэн энэхүү судалгаа нь бусад орнуудад та бүхэнтэй ижил нөхцөлд амьдарч буй хүмүүсийн эрсдлийг үнэлснээр ДЭМБ-ын зүгээс авах арга хэмжээнд дэмжлэг үзүүлэх болно.

Судалгааны ажлын гол зорилго нь эх болон хүүхдийн мөнгөн усны өртөлтийг үнэлэх юм. Иймд бид таны үс, шээс, хүйн цусанд мөнгөн усны агууламжийг хэмжих болно. Та нууцлал бүхий өөрийн шинжилгээний хариуг хүлээн авах ба хэрэв танд мөнгөн ус өндөр илэрсэн тохиолдолд өртөлтийг бууруулах талаарх хувь хүнд чиглэсэн зөвлөмж болон эрүүл мэндийн зөвлөгөө өгөх болно.

Таньтай нийлээд Сэлэнгэ аймгаас нийт 250 эхчүүд судалгаанд хамрагдах болно. Судалгааны үр дүнд үндэслэн таны хүүхдийн мөнгөн усны өртөлтийн талаарх мэдээллээр хангах, өртөлтийн түвшин болон тархалт, мөнгөн уснаас танд болон таны хүүхдэд нөлөөлж буй гол эрсдэлт хүчин үнэлнэ. Шаардлагатай тохиолдолд өртөлтийг бууруулах хамгаалах арга хэмжээ авах талаар Засгийн газарт зөвлөмж өгөх болно.

Мөнгөн усны талаарх зарим суурь мэдээлэл

Мөнгөн ус нь агаар, хөрс, хүнсээр дамжин хүний биед нэвтрэн орж, биологийн процессуудад саад учруулдаг ба зарим тохиолдолд бидний эрүүл мэндэд нөлөөлдөг. Жирэмсэн байх хугацаанд өндөр агууламжтай мөнгөн усанд өртсөн тохиолдолд, мөнгөн ус нь ураг руу нэвтрэн орж, хөгжиж буй эрхтэн тогтолцоонд нөлөөлдөг байна. Пренаталь үеийн мөнгөн усны өндөр түнгийн өртөлт нь хүүхдэд тодорхой өвчин тусах эрсдлийг нэмэгдүүлдэг. Эхийн биологийн материал (тухайлбал, үс болон шээс) болон хүйн цусны шинжилгээ нь пренаталь үеийн мөнгөн усны өртөлтийг тодорхойлох болон ач холбогдол бүхий мэдээллээр хангахад тусалдаг байна. Түүнчлэн таны биологийн материал нь та болон таны хүүхдийн эрүүл мэндийн эрсдлийг үнэлэх болон бохирдлыг бууруулах, эрүүл мэндийг хамгаалах зорилго бүхий бодлогын оролцоонд дэмжлэг үзүүлэхэд тусалдаг. Мөн мөнгөн усны агууламж өндөр илэрсэн тохиолдолд эрсдлийг бууруулах, мөнгөн усны өртөлтөөс та болон таны хүүхдийн хэрхэн хамгаалах талаарх зөвлөмжийг өгөхөд ашиглана.

Судалгааг ДЭМБ дэмждэг бөгөөд энэ нь дэлхийн санаачлагын нэг хэсэг юм. Энэхүү судалгаагаар эхийн шээс, үс, хүйн цусан дахь мөнгөн ус болон түүний нэгдлүүдийн агууламжийг

тодорхойлсноор жирэмсний сүүлийн 3 сар дахь мөнгөн усны өртөлтийг үнэлэх боломжтой юм. Эх төрсний дараа хурдан хугацаанд биологийн дээжийг цуглуулснаар пренаталь үеийн мөнгөн усны өртөлтийг үнэлэх чухал мэдээллийг олж авдаг. Иймээс бид таныг төрөх эмнэлэгт байх үед танд хандаж байгаа болно. Хэрэв та өөрийн болон хүүхдийн мөнгөн усны өртөлтийн талаарх илүү их мэдээллийг сонирхож байгаа бол бид таныг судалгаанд хамруулах болно.

Судалгаа авах үе дэх таны оролцоо

Мөнгөн үс болон түүний нэгдлүүдийн өртөлтийг үнэлэхийн тулд бид таны шээс, үс, хүйн цусыг цуглуулах, асуумж авах, та болон таны хүүхдийн өвчний түүхд нэвтрэх зөвшөөрлийг авах болно. Бүх дээжүүдийг танд ямар нэгэн хатгалт хийхгүйгээр, та болон таны хүүхдэд аюул учруулахгүйгээр цуглуулах болно. Эх баригч нь таныг төрөх үед хүйн цусны дээжийг, судалгааны ажилтан нь таны толгойн арын хэсгээс хуйхтай ойр хэсгээс чимх үсийг болон шээсний саванд шээсний дээжийг тус тус цуглуулна. Түүнчлэн бид хоол хүнс, таны гэр болон ажлын орчин, амьдралын хэв маяг болон эрүүл мэндийн талаарх асуултуудыг багтаасан асуумж судалгаа авах болно. Асуумж судалгаа нь ойролцоогоор 30 минут үргэлжилнэ. Энэхүү мэдээлэл нь мөнгөн усны боломжит эх үүсвэрийн тухай илүү ихийг мэдэхэд туслах болно. Бүх үйл ажиллагааг сургагдсан эмнэлгийн ажилтан гүйцэтгэх учир асуултанд хариулахад амархан байх болно.

Хэрэв та өөрийн болон хүүхдийн талаарх доорх мэдээлэлд нэвтрэхийг зөвшөөрвөл бид маш их баярлах болно. Үүнд: Төрөх үеийн хүүхдийн жин, өндөр, жирэмсний болон төрөх үед туссан өвчин болон нөхцлүүд, мөнгөн усны өртөлттэй холбоотой архаг өвчин (бөөрний болон мэдрэлийн тогтолцооны өвчин). Энэхүү мэдээллийг мөнгөн усны шинжилгээний үр дүнтэй холбосноор шаардлагатай тохиолдолд судалгааны үндэсний зохицуулагч нь таны мөнгөн усны өртөлтийг бууруулах зөвлөмжийг өгөх болно.

Судалгаанд оролцсон нийт хугацаанд таны цагийг 1,5 цаг зарцуулна.

Сайн дурааpаа оролцох/судалгаанаас гарах

Судалгаанд таныг сайн дурын үндсэн дээр оролцуулна. Хэрэв та судалгаанд оролцохыг хүсэхгүй байвал судалгаанд оролцохгүй байж болно. Та судалгаанд оролцохоос татгалзсан ч эмнэлгийн зүгээс танд хийж буй эмчилгээнд ямар нэгэн аргаар нөлөө үзүүлэхгүй.

Та судалгаанд орохоор шийдсэн ч хүссэн үедээ судалгаанаас гарах эрхтэй. Судалгаанд үргэлжлүүлэн оролцохыг хүсэхгүй байгаа тохиолдолд та судлаачдад(судлаачийн мэдээллийг доороос харна уу) мэдээлэх ёстой. Түүнчлэн, та өөрийн дээжүүдийн талаар асуух, устгуулах эрхтэй. Хэрэв та судалгаанаас гарахаар шийдсэн бол өөрийн дээжүүдийг устгасан эсэхийг асуух, эмнэлгээс гарахаас өмнө устгуулах эрхтэй. Судалгаанаас гарсан тохиолдолд ямар нэгэн аргаар таны эрүүл мэндийн үйчилгээнд нэвтрэх эсвэл эмчилгээнд нөлөөлөхгүй.
Шинжилгээний үр дүнг судалгааны нэгдсэн мэдээллийн санд хадгалах ба зөвхөн судалгааны тайланд ашиглана.

Судалгааны ажлын танд болон бидэнд үлдэх ашиг тус

Мөнгөн усны өртөлтийг тодорхойлох, нийгмийн эрүүл мэндийн судалгааны үр ашгийг дээшлүүлэхэд бодлого боловсруулагчдыг мэдээллээр хангах үүднээс бүх судалгаанд оролцогчдын үр дүнд дүн шинжилгээ хийсэн байна. Энэ нь мөнгөн усны өртөлтөөс эрүүл мэндийг хамгаалах ажил юм.

Таны шинжилгээний үр дүнг эрүүл мэндэд суурилсан зөвлөмж хэмжээтэй харьцуулж, судалгаанд сонгосон хүн ам, танд болон таны хүүхдэд учирч болох эрсдлийн талаарх мэдээллийг өгөх болно.
Танд болон таны эмчид илгээсэн шинжилгээний хариуг та асуух эрхтэй. Хэрэв та шинжилгээний хариуг эмчид илгээхээр сонгосон бол бид эмчийн нэр, хаягийг бичгээр авах болно. Хэрэв та өөрийн шинжилгээний хариуг мэдэхийг хүсэхгүй байгаа бол шинжилгээний хариугаа авахгүй байж болно.
Хэрэв таны шинжилгээний хариу өөрчлөлттэй гарсан тохиолдолд ирээдүйд гарах эрсдлээс сэргийлж өртөлтийг хэрхэн бууруулах талаарх зөвлөгөө авч болно. та хүсвэл
Бид танд хүүхдийн эрүүл мэндийн иж бүрдэлийг олгох ба хэрхэн ашиглах талаарх зааварчилгааг сувилагч өгөх болно.

Зардал
Судалгаанд оролцогчид ямар нэгэн төлбөр төлөхгүй.

Гарч болох эрсдлүүд
Энэхүү судалгааны үед ямар нэгэн эрсдэл гарахгүй гэж бид үзэж байна. Хүйн цусыг цуглуулахад ямар нэгэн эрүүл мэндийн эрсдэл гарахгүй. Судалгааны үйл ажиллагаа нь хэвийн төрөлтөд нөлөөлөхгүй. Үс, шээсний дээж цуглуулах, асуумж авах үйл ажиллагаа нь тодорхой хэмжээний хугацаа шаарддаг тул танд төвөг удаж болох юм. Асуумж болон өвчний түүхийн мэдээлэл нь хувь хүний нууцтай холбоотой тул бид мэдээллийг чанд нууцлах болно. Мэдээллийг авах, боловсруулахад бид өгөгдлийг кодлоно. Таны хувийн мэдээлэл зөвхөн сонгогдсон судлаачдад нээлттэй байх болно.

Нууц хадгалах
Судлаачид асуумж болон дээжүүдээс мэдээллийг цуглуулж, боловсруулна. Таны нэр болон хаяг кодлогдсон байна. Судалгааны үр дүнг тайлагнах, шинжлэх ухааны сэтгүүлд хэвлүүлэхэд таны нэр хаяг, дүрдагдахгүй. Бүх мэдээллүүд холбогдох эрх зүйн актын дагуу нууцлагдсан байна. Бид таны үс, шээсний дээжийг цуглуулах, түүнчлэн асуултанд хариулахын тулд таны нууцлалыг хангах болно.

Судалгааны талаарх нэмэлт мэдээлэл
Энэхүү баримт бичигт дурдагдсан судалгаа болон үйл ажиллагааны талаарх нэмэлт мэдээллийг асууж лавлах эрхтэй. Таны асуусан асуултанд судалгааны удирдагч нь өөрийн мэдлэгийн хэмжээнд бүрэн хариулах болно. Судалгааны үед гарах эрсдэл, ач холбогдол болон үйл ажиллагааны өөрчлөлтийг судлаачид танд мэдэгдэх болно.
Судалгааны явцын талаарх мэдээллийг судалгааны үндэсний зохицуулагчаас асууж болно. *(Рэндоогийн Даваадорж*, Нийгмийн эрүүл мэндийн хүрээлэнгийн Орчны эрүүл мэнд, хор судлалын төвийн судлаач, хүний их эмч).
Судалгааны удирдагч нь энэхүү баримт бичигт дурдсан бүхий л үйл ажиллагааг хариуцан ажиллана.

Судалгааны удирдагчийн нэр: Рэндоогийн Даваадорж (үндэсний зохицуулагч), Монгол Улсын Нийгмийн эрүүл мэндийн хүрээлэнгийн Орчны эрүүл мэнд, хор судлалын төвийн судлаач

Бусад судлаач: Даянжавын Баатарцол (лабораторийн шинжээч), Монгол Улсын Нийгмийн эрүүл мэндийн хүрээлэнгийн Хор судлалын лабораторийн эрхлэгч

Миний бие хүний биомониторингийн судалгаанд оролцох тухай мэдээллийн хуудсыг уншаад, судалгаанд оролцохыг зөвшөөрч байна. Би энэхүү судалгаанд сайн дураараа оролцож байгаа

бөгөөд судалгааны ач холбогдол, гарч болох эрсдэлийг ойлгосон. Судалгааг явуулах зөвшөөрлийг ДЭМБ-ын Ёс зүйн хороо болон [Монгол Улсын ЭМЯ-ны Анагаах ухааны ёс зүйн хяналтын хорооноос] бөгөөд судалгааны мэдээллийг чанд нууцалсан болохыг би ойлгож байна.

Судалгаанд оролцогч эхийн нэр (том үсгээр бичих):

_____

Эхийн гарын үсэг:

_____

Хүүхдийн овог нэр (Хэрэв нэр өгсөн бол):

_____

Хүүхдийн төрсөн он сар өдөр(өдөр/сар/жил):

_____

Үр дүнг эргэн мэдээлэх
Дээж авснаас хойш 3 сарын дотор үс, шээс, хүйн цусан дахь мөнгөн усны агууламжийг тодорхойлсон хүний биомониторингийн судалгааны үр дүнг нарийвчлан гаргасан байна. Та өөрийн шинжилгээний хариуг авах хэлбэрийг сонгоно уу.

[ ] Би өөрийн шинжилгээний хариуг авахгүй.
[ ] Би өөрийн шинжилгээний хариуг гэрийн хаягаар авахыг хүсч байна:
_____

[ ] Би өөрийн шинжилгээний хариуг эмчид илгээхийг хүсч байна.
Эмчийн овог, нэр:
_____
Эмчийн хаяг:
_____

Letter to a family doctors of women with high level of mercury in biological sample(s) (template)

Dear Mr/Ms -----

Public Health Institute of Mongolia 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

Dr Davaadorj RENDOO, Researcher, Center for Environmental Health and Toxicology
Phone: +97611 327870
E-mail: davrendoo@gmail.com

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 Public Health Institute of Mongolia 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, call or write me if additional information, clarification or support is necessary.

Kind regards,
The national survey coordinator

Dr Davaadorj RENDOO, Researcher, Center for Environmental Health and Toxicology
Phone: +97611 327870
E-mail: davrendoo@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

“Пренаталь үеийн мөнгөн усны өртөлтийг тодорхойлох биомониторинг”-ийн судалгааны асуумж

Судалгаанд оролцогчийн овог нэр	
Судалгаанд оролцогчийн дугаар:	Нас: .....
Өвчний түүхийн дугаар:	Регистрийн дугаар:
Асуумж авсан хүний овог нэр	
Асуумж авсан : 2016 он …. сар ..... өдөр	Эх амаржсан: 2016 он …. сар ..... өдөр

А. Хувийн мэдээлэл

А.1. Эхийн мэдээлэл

А.1.1. Яс үндэс: ..... /бичих/

А.1.2. Та өмнө нь хүүхэд төрүүлж байсан уу?

O Үгүй O Тийм бол ..... /хүүхдийн тоог бичих/

А.1.3. Та ямар боловсролтой бэ?

O Бага /3-4 жил/
O Бүрэн бус дунд
O Бүрэн дунд
O Тусгай дунд /тусгай мэргэжлийн сургууль/
O Дээд

А.2. Эцгийн мэдээлэл

А.2.1 Та ямар боловсролтой бэ?

O Бага /3-4 жил/
O Бүрэн бус дунд
O Бүрэн дунд
O Тусгай дунд /тусгай мэргэжлийн сургууль/
O Дээд

А.3. Танай гэр бүлийн орлого амьжиргаанд чинь хүрдэг үү?

O Үгүй
O Бага орлоготой, гэхдээ амьжиргаанд хүрдэг
O Боломжийн амьдардаг, гэхдээ амьжиргаанаас илүү гардаггүй
O Тийм, хүрдэг

Б.Мөнгөн усны өртөлт

Б.1. Ажлын байран дахь өртөлт

Б.1.1. Төрөхийн өмнө та ямар нэгэн ажил эрхэлж байсан уу?

O Үгүй (*Хэрэв ҮГҮЙ бол шууд **Б. 1.5.** асуултад хариулна)* O Тийм

Б.1.2. Доорх хүснэгтэд жагсаасан ажлыг хийж байсан уу? /олон хариулттай байж болно/

Ажлын төрөл	Үгүй	Жирэмсэн байх хугацаанд үе, үе	6 сар хүрэхгүй хугацаанд	6 сараас илүү, жил хүрэхгүй хугацаанд	1-5 жил	5-аас дээш жил
Хими/газрын тос	O	O	O	O	O	O
Төмөрлөгийн үйлдвэр	O	O	O	O	O	O
Химийн лаборатори	O	O	O	O	O	O

Шүдний эмнэлэг	О	О	О	О	О	О
Бичил уурхайн үйл ажиллагаа	О	О	О	О	О	О

Б.1.2.1. Та жирэмслэхээс өмнө болон жирэмсэн байх хугацаанд хаана ажиллаж байсан бэ?

……

Б.1.2.2. Өрхийн тэргүүлэгч ямар ажил эрхэлдэг вэ? ……..

Б.1.3. Та ажлын байранд доорх хүснэгтэнд заасан бохирдуулагчид өртөж байсан уу? /олон хариулттай байж болно/

Бохирдуулагч	Мэдэхгүй	Үгүй	Жирэмсэн байх үедээ үе, үе	6 сар хүрэхгүй хугацаанд	6 сараас дээш, жил хүрэхгүй хугацаанд	1-5 жил	5-аас илүү жил
Металл агуулсан тоос	О	О	О	О	О	О	
Мөнгөн ус	О	О	О	О	О	О	
Шүдний амальгам	О	О	О	О	О	О	
Хортон шавьж устгагч /пестицид/	О	О	О	О	О	О	
Нүүрсний утаа	О	О	О	О	О	О	

Б.1.4. Б.1.2-Б.1.3-д асуултанд ТИЙМ гэж хариулсан бол доорх хүснэгтийг бөглөнө үү.

	Байнга	Үе үе	Үгүй
Та ажлын хувцсаа гэртээ орохоосоо өмнө сольдог уу?	О	О	О
Та ажлын гутлаа гэртээ харихаасаа өмнө сольдог уу?	О	О	О
Та ажил дууссаны дараа шүршүүрт ордог уу?	О	О	О
Та бохирдсон ажлын хувцсыг гэртээ авч ирж байсан уу?	О	О	О
Хэрэв ТИЙМ гэж хариулсан бол бохирдсон ажлын хувцсыг бусад хувцаснаас тусад нь угаадаг уу?	О	О	О

Б.1.5. Таныг жирэмсэн байх хугацаанд гэр бүлийн гишүүдийн нэг нь хүснэгтэнд заасан ажил хийж байсан уу? /олон хариулттай байж болно/

Ажлын төрөл	Тийм	Үгүй	Мэдэхгүй
Хими/газрын тос	О	О	О
Төмөрлөгийн үйлдвэр	О	О	О
Химийн лаборатори	О	О	О
Шүдний эмнэлэг	О	О	О
Бичил уурхайн үйл ажиллагаа	О	О	О

Б.1.6. Таныг жирэмсэн байх хугацаанд гэр бүлийн гишүүдийн нэг нь хүснэгтэнд заасан бохирдуулагчид өртөж байсан уу?

Бохирдуулагч	Тийм	Үгүй	Мэдэхгүй

Металл агуулсан тоос	О	О	О
Мөнгөн ус	О	О	О
Амалгам	О	О	О
Хортон, шавьж устгагч /пестицид/	О	О	О
Нүүрсний утаа	О	О	О

Б.1.7. Таныг жирэмсэн байх хугацаанд гэр бүлийн гишүүдийн нэг нь Б.1.5 – Б.1.6 асуултанд ТИЙМ гэж хариулсан бол доорх хүснэгтийг бөглөнө үү /олон хариулттай байж болно/

	Байнга	Үе үе	Үгүй
Тэр ажлын гутлаа гэртээ харихаасаа өмнө сольдог уу?	О	О	О
Тэр ажил дууссаны дараа шүршүүрт ордог уу?	О	О	О
Тэр гэртээ бохирдсон ажлын хувцсаа авч ирдэг үү?	О	О	О
Хэрэв дээрх асуултанд ТИЙМ гэж хариулсан бол бохирдсон ажлын хувцсыг нь бусад хувцаснаас тусад нь угаадаг уу?	О	О	О

Б.2. Амьдралын орчин

Б.2.1. Та хаана оршин суудаг вэ?

О Хот /дүүргийн нэр ...../ О Хөдөө, орон нутаг /сумын нэр .....

Б.2.2. Таны оршин суудаг газрын ойролцоо (2 км хүртэлх зайд) хүснэгтэд заасан үйл ажиллагаа явуулдаг үйлдвэр, аж ахуй, нэгж байдаг уу? /олон хариулттай байж болно/

	Тийм	Үгүй	Мэдэхгүй
Төмөрлөгийн үйлдвэр	О	О	О
Хог хаягдал шатаах цэг, үйлдвэрийн хог хаягдал булах цэг	О	О	О
Цементийн үйлдвэрлэл	О	О	О
Ахуйн хог хаягдал булах цэг	О	О	О
Уул уурхайн үйл ажиллагаа	О	О	О
Бичил уурхайн үйл ажиллагаа	О	О	О
Дулаан, цахилгаан эрчим хүчний үйлдвэрлэл	О	О	О

Б.2.3. Та гэртээ ямар түлш, эрчим хүч, дулааны эх үүсвэрийг ашигладаг вэ?

Түлшний эх үүсвэр	Хоол хийх	Гэрээ халаах
Нүүрс, сайжруулсан түлш	О	О
Цахилгаан эрчим хүч	О	О
Мод, аргал	О	О
Төвлөрсөн халаалтын шугам, нэгдсэн бойлуур	О	О

Б.2.4. Та хоол ундандаа ямар эх үүсвэрийн ус ашигладаг вэ?

Усны эх үүсвэр	Уух ус	Хоол хийх ус
Төвлөрсөн шугам сүлжээ	О	О
Хувийн худаг	О	О
Гол, нуур, байгалийн булаг гэх мэт гадаргуугийн ус	О	О

Б.2.5. Сүүлийн 2 жилд танай гэрт халууны шил, даралт хэмжигч зэрэг мөнгөн ус агуулсан багаж хагарч байсан уу?

О Үгүй

О Тийм бол хагараад хэдий хугацаа өнгөрч байгаа вэ?
О 1 сарын өмнө О 3 сарын өмнө О 6 сарын өмнө О Сүүлийн 2 жилд О Мэдэхгүй

Б.2.6. Сүүлийн 3 сард танай гэрт өдрийн гэрэл хагарч байсан уу?
О Үгүй О Тийм бол хэдэн өдрийн өмнө _____ бичих О Санахгүй/Мэдэхгүй

Б.2.7 Сүүлийн 3 сарын хугацаанд танай гэр бүлийн аль нэг гишүүн гэртээ гагнуур хийх, зай баттерейтэй харьцаж байсан уу?
О Үгүй О Тийм О Мэдэхгүй

Б.3. Хувийн эрүүл ахуй, амьдралын хэв маяг

Б.3.1. Та амальгам шүдний ломботой юу?
О Үгүй О Тийм бол шүдний тоо ..... бичих О Мэдэхгүй
Б.3.2. Та байнга бохь зажилдаг уу?
О Үгүй О Тийм
Б.3.3. Та тамхи татдаг уу?

О Үгүй, бол *В 3.5.-р асуултад хариулна уу*
О Би тамхи татаж байсан, гэхдээ жирэмсэн болоод татахаа больсон
О Би жирэмсэн байхдаа тамхи татаж байсан

Б.3.4. Та жирэмсэн болохоос өмнө болон жирэмсний хугацаанд тамхийг ямар давтамжтай татаж байсан бэ?

Давтамж	Жирэмслэхээс өмнө	Жирэмсний хугацаанд
7 хоногийн дотор	О	О
7 хоногоос дээш хугацаанд	О	О
Өдөр бүр	О	О

Б. 3.5. Та жирэмсний хугацаанд согтууруулах ундаа хэрэглэж байсан уу?
О Үгүй О Сард 1 удаа О 7 хоногт 1 удаа
Б.3.6. Та арьс цайруулах үйлчилгээтэй гоо сайхны бүтээгдэхүүн тогтмол хэрэглэдэг үү?
О Үгүй О Тийм
Б.3.7. Та жирэмсний хугацаанд арьс цайруулах үйлчилгээтэй гоо сайхны бүтээгдэхүүн хэрэглэж байсан уу?
О Үгүй
О Тийм бол ямар давтамжтай хэрэглэж байсан вэ?
О Өдөрт 1 удаа
О 7 хоногт 1 удаа
О сард 1 удаа
О сар бүр хэрэглэдэггүй

Б.4. Хоол, хүнсний хэрэглээ

Б.4.1. Дараах хүнсийг ямар давтамжтай хэрэглэдэг вэ?

Бүтээгдэхүүний төрөл	Өдөрт 1 удаа	7 хоногт 1 удаа	Сард 1 удаа	Улиралд 1 удаа	Хэрэглэдэггүй
Голын загас	О	О	О	О	О
Лаазалсан загас	О	О	О	О	О
Дэлгүүрт зардаг замаг	О	О	О	О	О
Бүх төрлийн гурилан бүтээгдэхүүн	О	О	О	О	О

Цагаан будаа	O	O	O	O	O
Бүх төрлийн мах, махан бүтээгдэхүүн	O	O	O	O	O
Дотор мах (элэг, бөөр, г.м)	O	O	O	O	O
Тахианы мах	O	O	O	O	O
Мөөг	O	O	O	O	O
Өөрсдөө тарьсан эсвэл тухайн орон нутагт тарьсан ногоо	O	O	O	O	O
Худалдааны ногоо	O	O	O	O	O

Б.4.2. Сүүлийн 3 сард хүснэгтэнд заасан загасны төрлийг хоол хүнсэндээ ямар давтамжтайгаар хэрэглэсэн бэ?

Загасны төрөл	Өдөрт 1 удаа	7 хоногт 1 удаа	Сард 1 удаа	Улиралд 1 удаа	Хэрэглэдэггүй
Лаазалсан туна загас	O	O	O	O	O
Лаазалсан сардин, май, хар амар, яргай загас	O	O	O	O	O
Өөрсдөө барьсан загас	O	O	O	O	O
Дэлгүүр болон орон нутгийн захаас худалдан авсан загас	O	O	O	O	O
Дэлгүүрт зардаг замаг	O	O	O	O	O

Танд маш их баярлалаа

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. All efforts will be taken to involve the community in all stages of the project implementation: 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.

Several steps are recommended for the development and implementation of the strategy and action plan for community involvement.

1. Learn more about the community

Information about the community in AASGM area in Mongolia is available and will be summarised including information on: community profile and organization, main problems and needs; environmental conditions; general health status of the population; results of previous investigations; and opportunities, potential risks and threats to the survey; medical surveillance system.

2. Develop a communication package about the survey

Information about the project will be adapted to the target audience; development of a different set of information for the local authorities and community members is considered. Information on the survey should be easily understandable and based on scientific knowledge. The information package should explain: the rational for the survey and its objectives; who will be involved; how the survey

will be implemented; what risks it could pose to the community and its members, if any; what the benefits for the community are; how the survey results will be communicated; what the follow-up is, in particular, if high levels of exposure to mercury are detected.

3. Ensure support from influential people

Information about the planned survey will be first communicated to public health authorities and local administration in the survey areas. Engagement and support from those people will allow better understanding of the community's needs, and help to gain trust of the community in the planned survey.

4. Communicate information about the survey to community members

Information about the survey can be communicated to community members in several ways, including through:

- developing and disseminating an information leaflet about the planned survey; this allows outreach to a wider audience but does not allow immediate answering of questions and providing clarifications;
- reaching out directly to potential survey participants (pregnant women) and their families during ante-natal visits;
- agreeing joint antenatal visits with gynaecologists and obstetricians serving the community;

5. Keep contact open during the survey implementation

Communication channels will be maintained during the implementation of the survey 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. 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 will be discussed at the final workshop (see Communication)

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. Further to providing information at individual level, risk-reduction measures will be implemented at the community level. This requires active interaction and full engagement of the local authorities in the development and implementation those measures.

Annex 5 Budget

N	Budget line/expenses	Cost per unit (MNT)	Total costs of the budget line	
			MNT	USD
1	***Staff cost***			
1.1	Chief maternity	1 person x 2 hospitals x 500.000	1,000.000	487.00
1.2	Supervisor	1 person x 2 hospitals x 1,000.000	2,000.000	974.00
1.3	Nurses	8 nurses x 1,100.00 per sample x 250 samples	6,600.000	3,213.00
1.4	Staff responsible for recruitment and questionnaire data collection	(10.000 per woman x 250 women)	2,500.000	1,217.00
		Sub-total for staff	***12,100.000***	***5,891.00***
2.	***Field staff training workshop***			
2.1	Rent for a meeting room	20.000 per hour x 8 hours x 2 provinces	320.000	156.00
2.2	Meal (coffer breaks, lunch)	13.000 per person x 6 persons x 2 provinces (lunch) 3.000 per person x 14 persons x 4 days (coffee breaks)	156.000 168.000	76.00 82.00
2.3	Travel	Travel costs and DSA for the training participants 20.000 x 12 persons x 2 days Travel costs for trainers (the WS) Travel costs for controllers In provinces travel, telephone, etc/	480.000 888.000 1,056.000 150.000	234.00 432.00 514.00 73.00
2.4	Handout for the participants	2300 per page x 100 pages	230.000	112.00
		Sub-total for the training workshop	***3,448.000***	***1,679.00***
3	Translation and copying (questionnaires and other relevant WHO documents)	20000 x 100 pages	2,000.000	974.00
4	In-land samples transportation	6-8 samples x 22 times x 43.83 (Selenge province) 6-8 samples x 15 times x 43.83 (Mandal province)	1,622.000	790.00
5	Travel (national coordinator and lab analysts to sampling sites)	To Selenge province: To Mandal province:	1,080.000 1,880.000	526.00 915.00
6	Out-land transportation (hair samples)		616.000	300.00
7	***Laboratory analysis***			
7.1	Consumables for hair sampling		616.000	300.00
7.2	Hair	15.000 per sample x 250 samples	3,750.000	1,826.00
7.3	Cord blood	10.000 per sample x 250 samples	2,500.000	1,217.00

7.4	Urine	10.000 per sample x 250 samples	2,500.000	1,217.00
7.5	Urine creatinine	2.400 per sample x 250 samples	600.000	292.00
7.6	Specific urine gravity	600 per sample x 250 samples	150.000	73.00
7.7	Samples transportation equipment	150.000 per unit x 4 units	600.000	292.00
		Sub-total for laboratory analysis	***10,716.000***	***5217.00***
8	Preparation of a report on the national survey	Statistical analysis, database, translation, edition	6,700.000	3,262.00
9	Communication of the survey results	Travel and post-costs	300.000	146.00
10	Stationary	Toners, papers, etc.	705.000	343.00
11	Communication costs	Telephone	100.000	49.00
12	PHI Scientific Committee review fee	200.000	200.000	97.00
13	Ethic Committee review fee	753.000	753.000	367.00
		TOTAL	**42,220.000**	**20,556.00**