Human biomonitoring in artisanal and small-scale gold mining:

Ethical and scientific principles

World Health Organization

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Contents

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1. Introduction

Quality improvements in medical care and disease prevention are often informed by research that provides an increased understanding of social, physiological, cultural, economic and environmental factors that influence health. Arriving at such understanding often depends on research involving human participants. According to the World Health Organization (WHO), such research includes "any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge; in which human beings (i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or (ii) become individually identifiable through investigators' collection, preparation, or use of biological material or medical or other records" *(1)*.

Interest in conducting research in the context of artisanal and small-scale gold mining (ASGM), including the measurement of mercury biomarkers in human hair, blood and urine, has been increasing as a result of implementation of the Minamata Convention on Mercury *(2)*.

This guidance document provides an overview of internationally agreed ethical and scientific principles that should be adhered to as part of any research carried out in an ASGM context. It aims to provide guidance for (a) researchers and practitioners conducting assessments involving human biomonitoring in ASGM contexts; (b) government agencies, including ministries of health, mining, environment, labour, and others that may have an interest in such data; and (c) public or private bodies that fund or otherwise sponsor research or assessments in ASGM contexts.

In addition to ASGM, the principles outlined in this document apply equally to research conducted in other artisanal and small-scale mining contexts.

2. Human biomonitoring in an ASGM context

WHO defines human biomonitoring as "the direct measurement of people's exposure to toxic substances in the environment by measuring the substances or their metabolites in human specimens, such as blood or urine" *(3)*.

In ASGM contexts, applications of human biomonitoring typically include:

- exposure assessments conducted before and after the introduction of an intervention intended to reduce the use of, and exposure to, toxic substances (such as mercury or cyanide) in the ASGM process;
- assessments carried out to determine levels of exposure to toxic substances within a given community or population group.

Populations that are potentially exposed or affected include miners and others directly involved in ASGM activities, their families, and communities that live and work near ASGM sites. Potentially affected populations may also include communities living downstream of ASGM sites who are exposed to food products or water sources that are contaminated by ASGM activities *(4)*. For example, in ASGM contexts, fish commonly exhibit elevated levels of methylmercury. Because of methylmercury's toxicity during the development of the central nervous system, pregnant women, lactating mothers, and breastfed newborns are population groups particularly sensitive to the effects of mercury exposure *(5)*. WHO has issued survey protocols and standard operating procedures for the assessment of prenatal exposure to mercury *(6, 7)*. A further concern is that groundwater downstream of ASGM sites can be polluted with mercury, contaminating rice, vegetables and other crops that are then locally consumed. Communities living in contaminated sites (that is, those with legacy pollution from prior ASGM activities) are also considered potentially exposed populations.

3. Ethical and scientific principles relevant to biomonitoring in an ASGM context

The Council for International Organizations of Medical Sciences (CIOMS) issued in 2009 ethical guidelines for epidemiological studies *(8)*. Drawing on the CIOMS guidelines, the following provides an overview of issues considered to be prerequisites for conducting human biomonitoring activities in ASGM.

Research must be ethically justified and scientifically valid

Ethically justified research must be carried out in a way that is fair to the research participants and morally acceptable to the communities in which the research is being conducted. Scientifically valid research is based on and informed by adequate knowledge of pertinent scientific literature, designed in conformity with accepted scientific principles, and carried out by competent, appropriately qualified researchers.

Research proposals must be reviewed and approved by independent ethics review committees

Such reviews are necessary to ensure scientific merit and ethical acceptability of the proposed research approach and activities, and to ensure that the proposed research is aligned with the health needs and priorities of the community in which the research is being carried out. Where research is sponsored by an organization outside the country of research, the research protocols should be submitted for review in both the host country and the country of the sponsoring organization. This is to ensure that the ethical and scientific standards applied are not less stringent in one country than the other. Investigators must obtain approval or clearance from all review committees prior to the initiation of research activities.

Voluntary and informed consent must be obtained

This applies to the prospective study participant. In the case of an individual who is not capable of giving informed consent to participate in a research undertaking, the permission of a legally authorized representative is needed in accordance with applicable law. This is necessary to ensure that study participants have decided of their own choice to participate in the study, based on full understanding of the purpose and intent of the research being conducted. Adequate time and resources must, therefore, be allocated in the study to explain the purpose of the research and obtain and document informed consent.

Potential benefits and harms need to be balanced and risks minimized

This requires demonstrating that potential risks or harm to the individuals who participate in the study will be minimized, and ideally eliminated. It will also require demonstrating that every effort will be made to ensure that the participants will benefit from the knowledge that is derived from the research, for example through improved access to diagnostic, therapeutic or preventive health services, exposure prevention, and increased knowledge of health and social hazards. In an ASGM context, risks to study participants may be significant, particularly if mining activities are informal or illegal in the study country. When research is being conducted in ASGM settings there may be expectations by the community that the results of the study will generate definitive actions that will improve health in that specific community. It is, therefore, critical to work with relevant health and other authorities, relevant other stakeholders and potentially affected communities to develop a mutually acceptable understanding of likely outcomes of the research conducted.

Special justification is required for inviting vulnerable individuals to participate

Individuals are considered vulnerable if they have limited capacity or freedom to either consent to or decline to consent to the proposed research activities. Vulnerable persons include children, adolescents or individuals who, because of mental or behavioural conditions or disorders, are incapable of giving informed consent. They may also include individuals who are disempowered or disenfranchised because of their social, economic or, as can be the case in ASGM, legal status. Inviting vulnerable individuals to serve as participants in research requires special justification. Moreover, the means of protecting participants' rights and welfare must be strictly applied in the broadest sense. For example, there is an ethical obligation for researchers to refer study participants who appear to be suffering from or who have been diagnosed with a condition to relevant health services.

Ensure confidentiality of data

This is particularly important in instances where the research participants may be vulnerable or disempowered as described above, and who might, as a result of the release of data

to third parties, be subject to harm or experience distress. The procedures and safeguards established to ensure the confidentiality of data need to be clearly communicated to study participants as part of the process of obtaining informed consent. Jurisdictional requirements obligating researchers to notify appropriate agencies, for example if they uncover evidence of human rights abuses, child labour, or other illegal activities, should also be clarified and communicated to participants as part of the process of obtaining informed consent.

Research projects should contribute effectively to national or local capacity

ASGM is a form of subsistence mining that occurs primarily in low- and middle-income countries. Research capacity and public health laboratory capacity can be limited in such settings. Careful consideration should, therefore, be given to identifying opportunities to integrate institutional or capacity-building activities into the design and delivery of biomonitoring studies. Particularly in externally sponsored collaborative research studies, sponsors and investigators have an ethical obligation to ensure that the research projects for which they are responsible contribute effectively to national or local capacity to design and conduct epidemiological research, and to provide scientific and ethical review and monitoring of such research.

Potential conflicts of interest must be declared

In an ASGM context, conflicts of interest can arise from a sponsor's interest in the study outcome, for example to demonstrate the effectiveness of a particular intervention or technology in reducing mercury exposure. Sponsorship by a private sector entity, such as a mining company, could be another potential conflict of interest. Investigators must declare potential conflicts of interest associated with the proposed research activities as part of the ethical review process.

Disclosure of findings

According to the CIOMS International Ethical Guidelines for Epidemiological Studies *(8)* and the Declaration of Helsinki *(9)*, every research study involving human participants has a duty to make the results of the research publicly available. In the ASGM context, this includes ensuring an effort is made to feed back the research findings, including human biomonitoring results, to the communities that were involved in the research. In addition, relevant local and national authorities need to be informed about the outcomes of the research.

4. Conclusion

While the ethical conduct of research in ASGM contexts comes with many issues to be addressed during the preparation and implementation of fieldwork activities, it must not be perceived as an additional burden but rather as an essential prerequisite that comes with several benefits: participants' rights and welfare are protected; the risk of harm to humans is minimized; researchers are protected from accusations of unethical practices; and the legitimacy of research findings is increased. The need for ethical clearance and associated benefits should be communicated early to project sponsors and other relevant partners in order to accommodate associated procedures in the planning process.

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