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A pilot study on the feasibility of European harmonized Human Biomonitoring: Strategies towards a common approach, challenges and opportunities

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ABSTRACT

In 2004 the European Commission and Member States initiated activities towards a harmonized approach for Human Biomonitoring surveys throughout Europe. The main objective was to sustain environmental health policy by building a coherent and sustainable framework and by increasing the comparability of data across countries. A pilot study to test common guidelines for setting up surveys was considered a key step in this process. Through a bottom-up approach that included all stakeholders, a joint study protocol was elaborated.

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From September 2011 till February 2012, 17 European countries collected data from 1844 mother–child pairs in the frame of DEMOnstration of a study to COordinate and Perform Human Biomonitoring on a European Scale (DEMOCOPHES).[1] Mercury in hair and urinary cadmium and cotinine were selected as biomarkers of exposure covered by sufficient analytical experience. Phthalate metabolites and Bisphenol A in urine were added to take into account increasing public and political awareness for emerging types of contaminants and to test less advanced markers/markers covered by less analytical experience. Extensive efforts towards chemo-analytical comparability were included.

The pilot study showed that common approaches can be found in a context of considerable differences with respect to experience and expertize, socio-cultural background, economic situation and national priorities. It also evidenced that comparable Human Biomonitoring results can be obtained in such context. A European network was built, exchanging information, expertize and experiences, and providing training on all aspects of a survey. A key challenge was finding the right balance between a rigid structure allowing maximal comparability and a flexible approach increasing feasibility and capacity building. Next steps in European harmonization in Human Biomonitoring surveys include the establishment of a joint process for prioritization of substances to cover and biomarkers to develop, linking biomonitoring surveys with health examination surveys and with research, and coping with the diverse implementations of EU regulations and international guidelines with respect to ethics and privacy.

1. Introduction

Estimates of the impact of environmental exposures on health are limited and contradictory. Part of the uncertainty lies in the high level of misclassification of exposures that hampers environmental health risk assessment (Weuve and Yonasky, 2012; Willett, 2002; Blair et al., 2009). Scientists, policy-makers and the general public have long focused mainly on external exposure assessments for regulation and control. In analogy with practices in occupational health and as technologies evolved, focus has now increasingly turned to pollution in the body, seized by the notion of body burden: the presence of chemicals in the body. Such body burdens can be assessed through Human Biomonitoring (HBM), which integrates information on exposure to potentially toxic chemical elements and substances from all sources (soil, water, air, food, packaging and consumer products) as well as bioavailability, toxicokinetics and metabolism (Angerer et al., 2007). HBM and other biomarker studies have shown their use in research, in surveys and in advocacy efforts. Whilst research projects are typically hypothesis driven and geared at the collection of data to link health outcomes causally to exposures, the objective of surveys typically is to support and evaluate public health policy by producing information on the prevalence of exposure to environmental toxicants based on periodic monitoring (European Commission, 2004; ECETOC, 2005; National Research Council of the National Academies, 2006).

HBM is a powerful tool in the democratization of knowledge of exposure. Personal exposure information in particular might have a strong impact on societal perception of environmental pollution. Human biomarkers data make pollution 'personal' and can raise awareness, support preventive actions at individual and collective level, and contribute to policy making (Stokstad, 2004). The full exploitation of the potential benefits of HBM surveys in environmental health requires accurate knowledge transfer and integration. Findings of HBM efforts however, often fail to find their way into policy and practice, resulting in a limited impact on public health policies and programs. Often single teams have proprietary control of their data and specimens; the inner workings of protocols and analyzes are invisible to outsiders and raw data do not become available (Khoury et al., 2013). HBM surveys increasingly obtain a legal embedding at national or regional level, permitting repeated cycles of measurement (Viso et al., 2009). In 2004, the European Commission started discussions on a harmonized approach throughout Europe (European Commission, 2003; European Commission, 2004; Casteleyn et al., 2007) so to improve comparability. A European pilot study was proposed to "*test the hypothesis that human biomonitoring in the field of environment and health can be performed in a coherent and harmonized approach throughout Europe by means of commonly developed protocols, strategies and scientific tools ensuring reliable and comparable data, whilst also leading to a more effective use of resources*". In an interdisciplinary context, epidemiologists, chemists, toxicologists, geneticists, exposure scientists, medical professionals, social scientists and environmental health experts and policy makers, working in the fields of environmental health, public health, research and policy evaluation and support, worked closely together to develop the framework. A stakeholders group set up by the European Commission (European Commission, 2003)[2] was involved in this process. Study population, exposures and outcomes, as well as parameters to be estimated, were partly defined during a broad negotiation process from 2004 until 2010. Finally a consortium of scientists from 27 European countries completed the decisions during the final negotiation process from September 2010 until March 2011 and developed a common European HBM study protocol, despite dissimilarities in approaches, technical jargon, understanding of concepts and national priorities. An extensive exchange system was set up to take into account national particularities, existing experience, expertize and infrastructure. Organizations from 17 countries, all member of the consortium, implemented the pilot study DEMOCOPHES.[3] This article reports on the opportunities and the challenges for a European harmonization of HBM surveys in environmental health. It addresses the set-up of a pilot feasibility study and related discussions on data sharing, prioritization, linking with health examination, research and policy. Finally, it also discusses ethics and privacy issues as the transboundary nature of the study in a legal framework with diverse transpositions of EU regulations or of international guidelines into national laws was thought to be an additional obstacle for harmonization of methodologies and comparability of results.

2. A common study protocol

The common European study protocol was built in line with STrengthening the Reporting of OBservational studies in Epidemiology: Molecular Epidemiology (STROBE ME) guidelines (Gallo et al., 2011) developed to facilitate reporting of biomarker-based

[1] http://www.eu-hbm.info/democophes (last accessed October 15 2014).

[2] http://ec.europa.eu/health/healthy_environments/working_groups/index_en.htm (last accessed April 8 2014).

[3] http://www.eu-hbm.info/democophes/project-partners (last accessed October 15 2014).

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