HBM4EU occupational biomonitoring study on e-waste

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Primary Objective: The general objective of the study is to increase the share of processing e-waste that EU member states are producing, using EU*s own processing capability, instead of exporting e-waste. In a partnership with the recycling sector...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51191

Source
ToetsingOnline

Brief title
HBM4EU occupational biomonitoring study on e-waste

Condition

- Other condition

Synonym
not applicable

Health condition

niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Finnish Institute of Occupational Health
Source(s) of monetary or material Support: EU Horizon

Intervention

Keyword: e-waste, hazardous substance, human biomonitoring, occupational exposure

Outcome measures

Primary outcome

* chromium, cadmium, lead in blood,

* brominated flame retardants and polychlorobiphenyls in blood

* chromium, cadmium, lead, mercury in urine

* organophosphate flame retardants in urine,

* phthalates in urine

* metals (and possibly some organics) in hair

Secondary outcome

* cytotogenetic markers in peripheral blood lymphocytes in blood

* reticulocyte micronuclei, epigenetic markers in blood

* oxidative stress markers in blood

* inflammatory markers in blood

* telomere length/metabolomics in urine

* Cotinine in urine

* Creatinine in urine

Study description

Background summary

HBM4EU (Human Biomonitoring for Europe, www.hbm4eu.eu/about-hbm4eu) is a European Joint Programme, which aims to harmonise and use human biomonitoring to understand human exposure to chemicals in the environment, via their occupation or use of consumer products and the related health risks, in order to improve chemical risk management. The programme is funded by the European Commission and national governments and includes experts from 28 countries and European Union agencies and will run from 2017 to 2021.

HBM4EU includes both the use of biomonitoring in the characterisation of the exposure and risks to the general population and to workers. Occupational exposure to specific chemicals may in many instances be several times higher than the exposure of the general populations. Human biomonitoring provides important information on the combined exposure via all routes of exposure; via inhalation, oral, dermal and via hand-to-mouth contact. It usually complements environmental measurements and can inform us on the effectivity of preventive and protective measures (including personal protective equipment).

E-waste is defined (Encyclopedia Britannica, 2016) as: *various forms of electric and electronic equipment that have ceased to be of value to their users or no longer satisfy their original purpose [*] including both *white goods* such as refrigerators, washing machines, and microwaves and *brown goods* such as televisions, radios, computers, and cell phones.* A classification of e-waste items is provided in a report endorsed by ESCAP, ESCWA, ITU, OECD, UNCTAD, UNECA, EUROSTAT, UNEP/SBC and UNU, referring to two existing EU waste classification systems (Baldé et al., 2015). In the FP7 project CWIT (2012) it was estimated that only 35% (3.3 million tonnes of 9.5 million tonnes) of used (but still functioning) e-waste was processed within the EU. Annually approximately 400,000 tonnes of discarded electronics left the EU as part of *undocumented mixed exports*. When taking into account the EU new circular economy policy (EEA, 2019) and the need to enhance the recycling of e-waste, the waste management/recycling sector is expected to grow. This e-waste stream is complex because it contains many composite materials such as circuit boards, cathode ray tubes, flat screen monitors, batteries, connectors and transformers, plastic casings and cables. The e-waste stream contains a broad range of hazardous ingredients, including toxic metals, polybrominated diphenyl ether (BPDE) and organophosphate ester (OPE) flame retardants, phthalates, polychlorobiphenyls (PCBs), hexabromocyclododecanes (HBCDs), polychlorinated dibenzo-p-dioxins (PCDD), polybrominated dibenzo-p-dioxins (PBDD) and polychlorinated dibenzofurans (PCDF). Plastic materials may contain chemicals that were legal at the time they were manufactured but are now either restricted or banned, such as lead, PCBs, some phthalates and flame retardants (Grant et al., 2013). The recycling of these materials can result in exposure of workers involved in different steps in the chain of waste processing such as collection, sorting, dismantling, shredding and further pre-processing and purification of waste components for the market of recycled polymer plastics and metals.

HBM4EU could support the development of sustainable practices in e-waste management by providing suitable methods for exposure assessment to support the development of sound practices in professional processing of e-waste. This would prevent e-waste from being dumped in, and also outside European countries and would support a development towards more sustainable processing of this waste stream in line with the Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal (Basel Convention, 1989). A recent literature review by Arain and Neitzel (2019) shows that so far occupational exposures were only studied in few European countries and only one study used biomonitoring to assess the level of exposure (Julander et al., 2014). A HBM4EU study could focus on a range of substances on the first and second list of priority substances (EEA, 2018) for which biomonitoring methods have been developed and tested in multiple laboratories as part of HBM4EU and may also include substances for which this process is still ongoing.

1.1 Biomonitoring of exposure
No human biomonitoring guidance has been adopted under Carcinogens and Mutagens Directive (CMD), although biomonitoring can support the exposure assessment under both REACH and CMD since it provides a good estimate of the internal dose and e.g. on the effectiveness of the respiratory protection to reduce exposure.

1.2 Effect biomarkers
The characterisation of effect biomarkers is of utmost importance to establish a relationship between the exposure to e-waste components and its human health impact, given that they comprise sensitive endpoints that reflect early biochemical/subclinical changes before the onset of disease.

Study objective

Primary Objective:
The general objective of the study is to increase the share of processing e-waste that EU member states are producing, using EU*s own processing capability, instead of exporting e-waste. In a partnership with the recycling sector in Europe (EEA, 2019), HBM4EU can help to ensure the sustainable processing of e-waste. For this study our focus will be on the occupational health and safety aspects. By conducting a HBM study we hope to contribute to awareness of potential hazards and stimulate good work practices that will lead to further improved protection of the worker*s health from the risk of exposure to toxic components, including that of combined exposures.

Secondary Objective(s):
1. Identify the most relevant compounds in the e-waste processing and use of available knowledge developed and available in HBM4EU to support an exposure study.
2. Collaborate with employers and employees of parties in the public and private sectors to collect the biological specimen for HBM.

3. Develop a study protocol, information materials and informed consent forms and documentation for ethics approval in each of the collaborating member states.
4. Re-use and revise existing standard operating procedures (SOPs), already available from the chromium study and develop new SOPs if needed.
5. Set up a collaboration with those labs that could support the analysis of the most relevant biomarkers in matrices that can be obtained.
6. Implement the HBM study with sufficient supportive measurements and contextual data to be able to identify opportunities for further improvements of occupational hygiene practice and herewith address questions and concerns that employers and employees might have.

Study design

The study design is a cross sectional study design, including 10 European countries and in each country 2-4 companies with activities related to e-waste processing.

For the aim of the study it is important that a wide range of industrial recycling activities are covered and that the study population represents a wide range of work practices. The results will then reflect real life exposures in the participating European countries. E-waste processing is often described in a step-wise process where different parties work together in a chain: general waste is collected and treated in a chain of service providers who are offering services to the market of general (household) waste. Other parties may also buy/accept/treat specific (industrial) waste streams for processing. They provide services for collection, transport, sorting and processing. E-waste is a part of this waste stream for which additional/specialized services have been developed for more-or-less specialised treatment by companies who focus on specific components as recycling products, e.g. polymers or metals in different industrial sectors.

Study burden and risks

The burden for the participants consists of:
* the effort of collection of urine samples (two times);
* undergoing blood collection by vena puncture (one time);
* participating in taking of hand wipes (five times);
* carrying air sampling equipment during work hours (five times);
* participating in an interview related to collect contextual information such as information on lifestyle and work-related determinants of exposure to relevant e-waste components (one time);
* participating in a short daily interview regarding the tasks performed during the shift (five times).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Employment in one of the participating companies
Access to occupational healthcare

Exclusion criteria

None

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-04-2021
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	20-01-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75692.091.20