TEXTE
168/2020

Establishment of human biomonitoring at EU level within the framework of the EHBMI (European Human Biomonitoring Initiative, HBM4EU)

Final report

German Environment Agency

Umwelt Bundesamt

TEXTE 168/2020

Ressortforschungsplan of the Federal Ministry for the
Enviroment, Nature Conservation and Nuclear Safety

Project No. (FKZ) 3716 62 200 0

Report No. FB000325/ENG

Establishment of human biomonitoring at EU level within the framework of the EHBMI (European Human Biomonitoring Initiative, HBM4EU)

Final report

by

Dr. Alexandra Polcher, Dr. Miriam Schöpel
Ramboll Deutschland GmbH, München

On behalf of the German Environment Agency

Imprint

Publisher
Umweltbundesamt
Wörlitzer Platz 1
06844 Dessau-Roßlau
Tel: +49 340-2103-0
Fax: +49 340-2103-2285
buergerservice@uba.de
Internet: www.umweltbundesamt.de

/umweltbundesamt.de
/umweltbundesamt

Report performed by:
Ramboll Deutschland GmbH
Werinherstrasse 79
81541 München
Deutschland

Report completed in:
March 2020

Edited by:
Section II 1.2 Toxicology, Health Related Environmental Monitoring
Lena Reiber

Publication as pdf:
http://www.umweltbundesamt.de/publikationen

ISSN 1862-4804

Dessau-Roßlau, September 2020

Berichtskennblatt

Berichtsnummer	UBA-FB 00
Titel des Berichts	Etablierung des Humanbiomonitorings auf EU-Ebene im Rahmen der EHBMI (European Humanbiomonitoring Initiative, HBM4EU)
Autor(en) (Name, Vorname)	Dr. Polcher, Alexandra Dr. Schöpel, Miriam
Durchführende Institution (Name, Anschrift)	Ramboll Deutschland GmbH Werinherstrasse 79 81541 München Deutschland
Fördernde Institution	Umweltbundesamt Postfach 14 06 06813 Dessau-Roßlau
Abschlussjahr	2020
Forschungskennzahl (FKZ)	3716 62 200 0
Seitenzahl des Berichts	57
Zusätzliche Angaben	
Schlagwörter	HBM4EU, Bridge Health, Humanes Biomonitoring, Gesundheitsstudien, internationale Veranstaltungen

Report Cover Sheet

Report No.	UBA-FB 00
Report Title	Establishment of human biomonitoring at EU level within the framework of the EHBMI (European Human Biomonitoring Initiative, HBM4EU)
Author(s) (Family Name, First Name)	Dr. Polcher, Alexandra Dr. Schöpel, Miriam
Performing Organisation (Name, Address)	Ramboll Deutschland GmbH Werinherstrasse 79 81541 München Deutschland
Funding Agency	Umweltbundesamt Postfach 14 06 06813 Dessau-Roßlau
Report Date (Year)	2020
Project No. (FKZ)	3716 62 200 0
No. of Pages	57
Supplementary Notes	
Keywords	HBM4EU, Bridge Health, Human Biomonitoring, health studies, international conferences

Abstract: Establishment of human biomonitoring at EU level within the framework of the EHBMI (European Human Biomonitoring Initiative, HBM4EU)

Protecting human health and the environment is one of the key aims of European policy. A lot has been achieved over the last decades but still a lot of substance related data are missing to enable politicians to take most appropriate decisions and actions. Especially human exposure data are necessary to verify estimates made in risk assessments and to monitor the presence of chemicals in the human body and hence in the environment. In order to obtain such human exposure data national authorities and research organisations in Europe joined efforts over the last years and are working towards a sustainable and harmonised human biomonitoring network in Europe. As the process is a step by step approach it is important to ensure that results are transferred among consecutive and parallel running projects. The present project aimed to use and further develop the knowledge and experience from the BRIDGE HEALTH project within the HBM4EU project (subtask 1). The experiences and results of BRIDGE HEALTH were assessed, and recommendations were made for relevant HBM4EU work packages.

Besides this task, organisational support was provided for the annual HBM4EU consortium meetings of the partners, as well as the annual general assembly of the state actors controlling the national monitoring programmes (Governing Board) involved in HBM4EU. A strategic workshop was organised for the management team of HBM4EU and first organisational steps to prepare a high level HBM conference under the auspices of the German EU Council Presidency, which will take place on 2nd October 2020, were completed.

Kurzbeschreibung: Etablierung des Humanbiomonitorings auf EU-Ebene im Rahmen der EHBMI (European Humanbiomonitoring Initiative, HBM4EU)

Der Schutz der menschlichen Gesundheit und der Umwelt ist eines der Hauptziele der europäischen Politik. In den letzten Jahrzehnten ist viel erreicht worden, aber es fehlen nach wie vor viele substanzbezogene Daten, die politischen Entscheidungsträgern eine Grundlage für Entscheidungen und die Ableitung geeigneter Maßnahmen bieten. Vor allem Daten zur Exposition des Menschen sind notwendig, um die in Risikobewertungen vorgenommenen Schätzungen zu verifizieren sowie die Verbreitung von verschiedenen Substanzen im Menschen und folglich auch in der Umwelt zu beobachten. Um solche Daten zur Exposition des Menschen zu erhalten, haben sich nationale Behörden und Forschungsorganisationen in Europa in den letzten Jahren zusammengeschlossen und arbeiten an einem nachhaltigen und harmonisierten Human-Biomonitoring-Netzwerk in Europa. Da es sich um einen schrittweisen Prozess handelt, ist es wichtig, dass die Ergebnisse von nachfolgenden bzw. parallel laufenden Projekten untereinander ausgetauscht und aufgegriffen werden. Das vorliegende Projekt zielte darauf ab, das Wissen und die Erfahrungen aus dem BRIDGE HEALTH-Projekt im HBM4EU-Projekt (Teilaufgabe 1) zu nutzen und weiterzuentwickeln. Die Erfahrungen und Ergebnisse von BRIDGE HEALTH wurden bewertet und Empfehlungen für relevante HBM4EU-Arbeitspakete erarbeitet.

Neben dieser Aufgabe wurden die jährlichen HBM4EU-Konsortialtreffen aller Partner sowie des obersten Entscheidungsgremiums (Governing Board, bestehend aus den staatlichen Akteuren, die die nationalen Monitoringprogramme steuern), organisatorisch unterstützt. Für das Managementteam von HBM4EU wurde ein strategischer Workshop organisiert. Des Weiteren wurden erste Vorbereitungen getroffen für eine hochrangige HBM-Konferenz unter der Schirmherrschaft der deutschen EU-Ratspräsidentschaft, die am 2. Oktober 2020 stattfinden wird.

Table of content

List of figures

List of abbreviations

BH	Bridge Health project
DG	Directorate General
DSGVO	Datenschutzgrundverordnung
EAP	Environmental Action Programme
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECHI	European Community Health Indicators
EEA	European Environment Agency
EFSA	European Food Safety Authority
EHP	European Environment and Health Process
EJP	European Joint Programme
HA	Horizontal Activity
HBM	Human Biomonitoring
HES	Health Examination Survey
HIREP ERIC	European Research Infrastructure Consortium on Health Information for Research and Evidence-based Policy
HIS	Health information survey
IPChem	Information Platform for Chemical Monitoring
IPCS	International Programme on Chemical Safety
JRC	Joint Research Centre
OECD	Organisation for Economic Cooperation and Development
SAICM	Strategic Approach to International Chemicals Management
UNEP	United Nation Environmental Programme
WHO-EU	World Health Organisation Regional Office for Europe
WP	Work package

1 Background and objectives

Since the beginning of the 20th century, but especially since the beginning of the 1950s, we have seen massive and sustained growth in global chemical production. According to Eurostat the total production of industrial chemicals in the EU-28 increased constantly, rising between 2004 and 2007 overall by 6.1 % to peak at 330 million tonnes in 2007. Only then and due to the financial and economic crisis, production decreased by 24 million tonnes in 2008 and by a further 37 million tonnes in 2009 (equal to about 18 % in total). Over the last ten years increases and decreases could be observed. However, in 2017, for the first time since 2010, there was again a noticeable increase of more than 10 million tonnes followed by a further slight increase in 2018. (EUROSTAT, 2020). With over 100,000 approved substances, chemicals are nowadays an essential part of everyday life and play an increasingly important role in global economic development. However, the benefits associated with the use of chemicals and chemical products can be associated with adverse effects on people and the environment. (EEA-JRC, 2013)

Substances can be released into the environment during manufacture, use and the waste phase and inhaled, skin contacted or ingested by air (outdoor air, indoor air), drinking water, food, consumer products or soil. Hazardous chemicals are found, for example, in care products, cosmetics, packaging materials or furniture. Dangerous substances also come from damp rooms, road traffic or domestic heating. A number of accidents and scandals since the 1950s have more and more led to the recognition that chemicals and other environmental stressors can have a whole range of harmful effects on human health and reproductive ability when exposed acutely or chronically. Some of these substances do not remain in the environment for long, while others degrade very slowly (persist) or accumulate in the food chain (bioaccumulate). Some chemicals are suspected of being carcinogenic, mutagenic, fertility-damaging or hormone disrupting. Bioaccumulation and persistence are feared because substances with these properties cause problems for decades once they are released into the environment, but prolonged exposure to shorter acting substances can also be dangerous.

Since the early 1970s, a variety of efforts have been made at international, European and national level to replace hazardous substances or at least reduce their emissions into the environment in order to control the risks posed by substances in the workplace or in the environment. Among the most important international initiatives are the establishment of the United Nations Environment Programme (UNEP) in 1972, the International Programme on Chemical Safety (IPCS) in 1980, the International Conference on Environment and Development in Johannesburg in 1992, the Rotterdam Convention on International Trade in Chemicals in 1998, the Stockholm Convention on Persistent Organic Pollutants in 2001, the Strategy on International Chemicals Management (SAICM) in 2006 and the Minamata Convention in2013. The European Environment and Health Process (EHP) of the World Health Organization is also important.

One of the problems in this context, however, is the lack of sufficient and appropriate data for risk assessment of many chemicals and the information on how a ban or restriction on use affects the level of exposure (Ganzleben, 2017). While classical risk assessment is primarily based on animal experiments, in vitro studies and in silico models, suitable data are needed to verify the estimates made in the risk assessment, especially for determining the exposure assessment of the population.

Human biomonitoring (HBM) is the only tool to determine the current total exposure of the body to environmental substances and to illuminate the causal chain between risks and possible health effects. HBM measures the internal exposure of the population or certain population

groups to selected environmental pollutants and their temporal trends and thus helps to clarify whether and to what extent substances are absorbed into the human body (Angerer et al., 2011).

The most important functions of HBM data are to provide a database for legal regulations to reduce and prevent pollution and to monitor the success of the measures taken by documenting pollution trends (Apel et al., 2017). HBM has long been a standard tool in the field of occupational health care. In public health care, HBM is used to identify persons at risk for the development of certain diseases.

In the field of environment and health, its central value at European level and the need for harmonisation have been recognised, particularly in the European Environment and Health Action Plan, from which the pilot projects COPHES and DEMOCOPHES have developed, based on preliminary projects such as ESBIO (2005-2007).

A project was launched in May 2015 with the aim of establishing a comprehensive, holistic and sustainable health information structure at EU level to support evidence-based health policy and research in Europe: "BRIDGE HEALTH" (BRidging Information and Data Generation for Evidence-based Health policy and research)[1]. Part of this project was, among other things, to promote the greater use of environmental health monitoring programmes within a European health information system. To this end, the exchange between HBM and birth cohort networks was facilitated and strengthened on the one hand, and on the other hand the experience gained from these EU projects were used to develop strategies and concepts for further harmonising and linking of environmental and health studies.

The European Human Biomonitoring Initiative - HBM4EU[2] is a European Joint Programme (EJP) under Horizon 2020 aiming to provide comparable, reliable data on exposure and health at EU level for the political decision making. It builds on the already mentioned initiatives of the past years and integrates the political level of the European countries. The planned duration is 01.01.2017 to 31.12.2021. An important goal of HBM4EU is also to establish HBM as a long-term instrument beyond the end of 2021 with political votes from the Commission and Member States.

Against this background, one objective of this research project was to use and further develop the knowledge and experience from the BRIDGE HEALTH project in the HBM4EU project (subtask 1). Therefore, it was necessary to analyse and evaluate the experiences and results of BRIDGE HEALTH and to compile recommendations to discuss the link between HBM and health studies. The experiences from the cooperation between environmental and health studies in GerES IV were taken into account.

A further sub-task was the organisational support through the preparation of the annual HBM4EU consortium meetings of the partners, as well as the annual general assembly of the state actors controlling the national monitoring programmes (Governing Board) involved in HBM4EU. In addition, the project was expanded to include the organisation of a strategic workshop for the management team of HBM4EU and the preparation of a high level HBM conference under the auspices of the German EU Council Presidency, which will take place on 2nd October 2020.

[1] http://www.bridge-health.eu
[2] https://www.hbm4eu.eu

2 Knowledge transfer from the Bridge Health project to HBM4EU

The DG Santé funded the research project BRIDGE Health[3], which started in May 2015 and terminated in October 2017. The project was designed to merge knowledge from different existing EU projects in domains of population and health system monitoring, indicator development, health examination surveys, environment and health, population injury and disease registries, as well as clinical and administrative health data collection systems and methods of health systems monitoring and evaluation to generate the basis for a long-term EU wide infrastructure and research network to build and maintain a high quality and representative European Health information system. Besides this, BRIDGE Health deliberately did preparatory work for HBM4EU in terms of problem identification, gap analysis and the development of blueprint for use of HBM in the field of health information and public health policies.

In 2017 the HBM4EU project was established as a joint effort to advance human biomonitoring (HBM) in Europe in order to provide better evidence of the actual exposure of citizens to chemicals. HBM4EU works towards a robust interpretation of human biomonitoring data and the possible impact of chemical exposure on human health, using the most up to date scientific tools.

Specific parts of HBM4EU build directly on and expands the work of the FP7 and Life+ funded HBM pilot projects COPHES and DEMOCOPHES to establish a long-term sustainable EU wide HBM system as a science and policy tool. Furthermore, it explicitly builds on the results of BRIDGE Health, which has a number of similar topics in order to make best use of resources and to prevent double work.

In order to ensure that project results of Bridge Health are taken up in HBM4EU the project team, in collaboration with UBA prepared a report which was used in its final version as deliverable 11.1 within HBM4EU. It is available at https://www.hbm4eu.eu/deliverables/ as well as in Annex A of the present report. The deliverable takes a close look on the specific results of each BRIDGE Health Work Package (WP), with the objective to bring these in accordance with the progress of the HBM4EU project.

Within the deliverable it is concluded that the coverage of determinants of health defines the primary link between the future health information system and HBM4EU. Considerable potential for synergies exists with respect to the core activities of any health information framework, namely the indicator development, and the interoperability of repository platforms, but also as regards capacity building for population health surveys.

In addition, there is potential for synergies in the development of new and more efficient methods and tools, in the dissemination of research outcomes, the knowledge translation and 'meta-access' to data sources suited for international comparisons.

Against this background it is recommended that HBM4EU will focus on the further development of any HBM related tools and methods together with the set-up of a long-term EU wide network of specialists, whilst a Health Information infrastructure will focus on the further development of indicators, disease registries, and HIS.

Based on the results of the deliverable a first draft of a publication was elaborated and further developed together with UBA. The publication was finalised by UBA and is planned to be

[3] http://www.bridge-health.eu/

published under the title “EU funded projects HBM4EU and BRIDGE Health: benefits from related topics and potential for synergies”.

3 Organisation of the annual Consortium and Governing Board meetings

In 2017, 2018 and 2019 the annual Consortium meeting as well as the Governing Board meeting of HBM4EU have been organised. In the following the dates and venues of the meetings are listed:

- 1st HBM4EU Consortium Meeting, Thursday, September 07th, 2017, from 8:30 – 18:20

Venue: Tagungswerk, Lindenstr. 85, 10969 Berlin

- 1st HBM4EU Governing Board Meeting, Monday, September 04th, 2017, from 8:30 – 18:20

Venue: Tagungswerk, Lindenstr. 85, 10969 Berlin

- 2nd HBM4EU Consortium Meeting, Tuesday, September 25th, 2018, from 9:00 – 17:30

Venue: Vienna School of International Studies, Favoritenstraße 15A, 1040 Vienna, Austria

- 2nd HBM4EU Governing Board Meeting, Thursday, September 27th, 2018, from 09:00 – 17:30

Venue: Vienna School of International Studies Favoritenstraße 15A, 1040 Vienna, Austria

- 3rd HBM4EU Consortium Meeting, Tuesday, October 8th, 2019 from 13:30 – 17:30 & Wednesday, October 9th, 2019, from 9:00 – 17:00

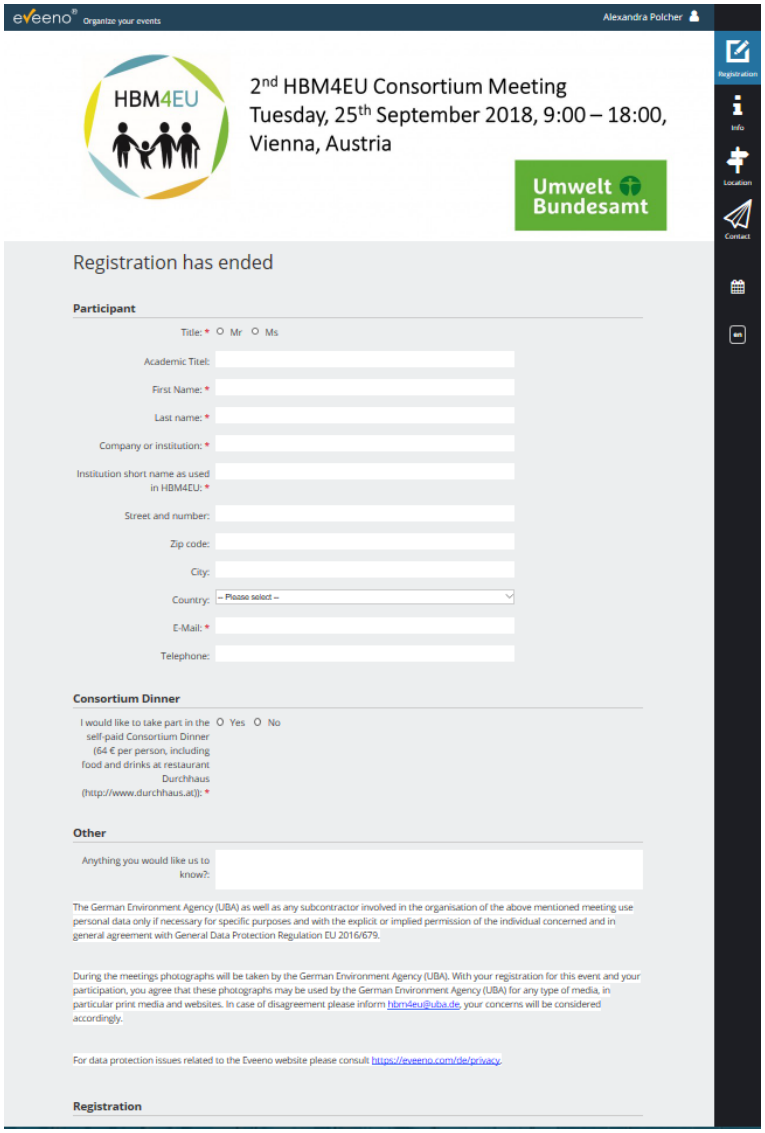
Venue: Tagungswerk, Lindenstrasse 85, 10969 Berlin

- 3rd HBM4EU Governing Board Meeting, Friday, October 11th, 2019, from 9:00 – 17:15

Venue: Tagungswerk, Lindenstrasse 85, 10969 Berlin

The agendas of the meetings are shown in Appendix B-G. In order to facilitate the registration for the participants, an online solution was provided by the project team. The provider eveeno was used who offers an online event software which ensures data protection according to DSGVO. For each event a separate eveeno registration webpage has been prepared including provision of general information and travel information and maps. The landing page of the event 2018 is shown in the figure below.

Figure 1: Online registration page with form to be filled in to participate in the meetings



Source: [Ramboll, 2019]

The registration website allowed the automatic preparation of participation lists and offered the possibility of payments for the event via the website. The payment option was first used for the consortium dinner in 2019 and worked very well for all participants.

For each of the meetings, technical equipment and catering has been organised. Five team members took care for registration of the participants, taking notes for the minutes and the overall local support for the meeting. The draft meeting minutes have been prepared and sent to UBA within the agreed time limits.

4 Organisation of a strategic workshop for the Management Board for HBM4EU

The event to be organised should aim to facilitate a targeted exchange on scope, priorities and innovative ideas for the future design of the HBM4EU project.

Different activities were undertaken to further improve the joint work.

The workshop of the Management Board took place on November 11th, 2017 from 9:00 to 22:30.

The organisation of the meeting included the logistical and technical preparation and follow-up and the selection of a suitable location.

5 Preparation of an HBM conference under the German EU Council presidency in 2020

In 2020, the annual HBM4EU meetings will take place in calendar week 40, with a high level HBM conference under the German EU Council presidency on Friday 2nd October 2020. It is planned that the conference starts with a reception on 1st October 2020 in the evening.

In total up to 250 participants are expected, high-level politicians and experts will be invited. An invitation text and a list of participants is being elaborated.

The project team reserved the Umweltforum, Pufendorfstr. 11, 10249 Berlin for the meeting and the evening reception. The foyer as well as the main hall and several separate meeting rooms are available.

Figure 2: Umweltforum – main hall

Source: [Besondere Orte, 2019]

6 List of references

Angerer, J., Aylward, L. L., Hays, S. M., Heinzow, B., & Wilhelm, M. (2011). Human biomonitoring assessment values: Approaches and data requirements. *International Journal of Hygiene and Environmental Health $V 214*(5), 348-360.

Apel, P., Angerer, J., Wilhelm, M., & Kolossa-Gehring, M. (2017). New HBM values for emerging substances, inventory of reference and HBM values in force, and working principles of the German Human Biomonitoring Commission. International Journal of Hygiene and Environmental Health, 220(2, Part A), 152-166.

EEA-JRC. (2013). Environment and human health, Joint EEA-JRC Report. European Environment Agency Report No 5/2013, Copenhagen, Denmark.

EUROSTAT. (2020) retrieved from: https://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_and_consumption_statistics#Total_production_of_chemicals (access date 10.02.2020)

Ganzleben, C., Antignac, J. P., Barouki, R., Castano, A., Fiddicke, U., Klanova, J., . . . Kolossa-Gehring, M. (2017). Human biomonitoring as a tool to support chemicals regulation in the European Union. Int J Hyg Environ Health, 220(2 Pt A), 94-97. doi:10.1016/j.ijheh.2017.01.007

7 Appendices

A Appendix – Deliverable for sub task 1

A.1 Authors and Acknowledgements

Lead author

Madlen David (UBA)

Contributors

Hanna Tolonen (THL) and Anna-Maria Andersson (RegionH)

External contributors

Anke Joas (BiPRO), Alexandra Polcher (BiPRO), Miriam Schöpel (BiPRO)

A.2 Abstract

The DG Santé funded research project BRidging Information and Data Generation for Evidence-based Health policy and research (BRIDGE Health[4]) started in May 2015 and will run until October 2017. The project was designed to merge knowledge from different existing EU projects in domains of population and health system monitoring, indicator development, health examination surveys, environment and health, population injury and disease registries, as well as clinical and administrative health data collection systems and methods of health systems monitoring and evaluation to generate the basis for a long-term EU wide infrastructure and research network to build and maintain a high quality and representative European Health information system. Besides this, BRIDGE Health deliberately did preparatory work for HBM4EU in terms of problem identification, gap analysis and the development of blueprint for use of HBM in the field of health information and public health policies.

In 2017 the European Human Biomonitoring Initiative – HBM4EU[5] (HBM4EU) project was established as a joint effort to advance human biomonitoring (HBM) in Europe in order to provide better evidence of the actual exposure of citizens to chemicals. HBM4EU works towards a robust interpretation of human biomonitoring data and the possible impact of chemical exposure on human health, using the most up to date scientific tools and the key objectives are:

- Harmonising procedures for human biomonitoring across the 26 participating countries, to provide policy makers with comparable data on human internal exposure to chemicals and mixtures of chemicals at EU level;
- Linking data on internal exposure to chemicals to aggregate external exposure and identifying exposure pathways and upstream sources;
- Generating scientific evidence on the causal links between human exposure to chemicals and health outcomes;
- Providing the most relevant tools to detect emerging chemicals and to identify the chemical mixtures of highest concern;

[4] http://www.bridge-health.eu/
[5] https://www.hbm4eu.eu/

- Adapting chemical risk assessment methodologies to use human biomonitoring data and account for the contribution of multiple external exposure pathways to the total chemical body burden;
- Feeding information on exposure pathways into the design of targeted policy measures to reduce exposure.

HBM4EU builds directly on and expands the work of the FP7 and Life+ funded HBM pilot projects COPHES and DEMOCOPHES to establish a long-term sustainable EU wide HBM system as a science and policy tool. Furthermore, it explicitly builds on the results of BRIDGE Health, which has a number of similar topics in order to make best use of resources and to prevent double work.

In the framework of the transition from BRIDGE Health to HBM4EU, this report takes a close look on the specific results of each BRIDGE Health Work Package (WP), with the objective to bring these in accordance with the progress of the HBM4EU project.

A.3 Background and introduction

The EU Health Strategy Health for Growth[6] underlines the need of best scientific evidence derived from sound data and information, and relevant research to respond effectively to population health and health systems' challenges. The health information and knowledge system (HI) shall contribute to an evidence-based decision-making in various policy areas and is the supporting pillar for all four objectives of the 3rd EU Health Programme[7] [8].

The focus of the Programme is on accurate and up-to-date information regarding population health and health system performance and understanding of health determinants.

HI is mainly based on indicators that are collected in a standardised way by EU agencies and the European Commission, such as Eurostat, European Centre for Disease Prevention and Control (ECDC) or the Joint Research Centre (JRC), or international organisations, such as the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation Regional Office for Europe (WHO-EUR).

Only a system operating at EU-level in a harmonised and comparable way will be able to identify differences in health outcomes at both geographical and socio-economic levels.

EU funded projects have been working towards the development of harmonised methods, that allow comparable evidence in the field of health.

However, there is a high diversity of health information (infra)structures in Europe, a fragmentation of databases and registries, health information inequalities regarding the availability and quality; and lack of sustainability of health information activities, and there is no established mechanism to include results from research projects in the European Health statistics.

To overcome these deficits, "BRIDGE Health" (BRidging Information and Data Generation for Evidence-based Health policy and research) funded under the EU Public Health Programme started with a consortium of 31 partner organisations in May 2015 to work towards a

[6] http://ec.europa.eu/health/programme/docs/prop_prog2014_en.pdf

[7] http://ec.europa.eu/health/programme/docs/ev_20141104_co01_en.pdf

[8] http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf

comprehensive, integrated and sustainable EU-HI supporting evidence-based health policy and research for the EU and MSs by providing blueprints and/or concepts of building blocks for a future EU-HI structure, by using knowledge and expertise from previous research projects.

BRIDGE Health covered population and health system monitoring, indicator development, health examination surveys (HES), environment and health issues, population injury and disease registries, clinical and administrative health data collection systems, and methods of health systems monitoring and evaluation, and seven Horizontal Activities (HA) which address cross sectional issues of relevance such as policy transfer, health inequality, data quality and ethics.

In environmental and health issues BRIDGE Health aimed at further developing and integrating the FP7 funded research projects COPHES (Consortium to Perform Human Biomonitoring on a European Scale) with the ENRIECO[9] (Environmental Health Risk in European Birth Cohorts).

Therewith BRIDGE Health included aspects that are of relevance for the HBM4EU initiative (European Human Biomonitoring Initiative – HBM4EU) that will further develop a European Human Biomonitoring Network and improve knowledge for environmental and public health policies.

A.4 HBM4EU

Based on the experiences from BRIDGE Health, COPHES, and DEMOCOPHES, a European Human Biomonitoring Initiative (HBM4EU) was established. It is a joint effort of 26 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020 and will run from 2017 to 2021. HBM4EU will coordinate HBM initiatives at national and EU level, with a special focus on linking research to evidence-based European policymaking, ensuring exploitation of results in the design of new chemicals policies and the evaluation of existing measures. By this, HBM4EU will generate knowledge to inform the safe management of chemicals and to protect human health in Europe. This initiative contributes directly to the improvement of health and well-being for all citizens, by investigating how exposure to chemicals affects the health of different vulnerable groups, such as children, pregnant women and workers. Taken together, the key project objectives are:

- Harmonising procedures for human biomonitoring across the 26 participating countries, to provide policy makers with comparable data on human internal exposure to chemicals and mixtures of chemicals at EU level;
- Linking data on internal exposure to chemicals to aggregate external exposure and identifying exposure pathways and upstream sources;
- Generating scientific evidence on the causal links between human exposure to chemicals and health outcomes;
- Providing the most relevant tools to detect emerging chemicals and to identify the chemical mixtures of highest concern;

[9] http://www.enrieco.org/

- Adapting chemical risk assessment methodologies to use human biomonitoring data and account for the contribution of multiple external exposure pathways to the total chemical body burden;
- Feeding information on exposure pathways into the design of targeted policy measures to reduce exposure.

The activities developed to deliver these objectives are organised into 17 individual WPs clustered under three pillars: science to policy, European HBM platform, exposure to health.

The first three WPs are devoted to organisational questions (program management and coordination, knowledge hub, internal calls). WP4 aims prioritisation and input to the annual work plan, whereby the legislative and organisational inputs of all partners will be made available on the HBM4EU website. The overall goal of WP5 is the translation of results into policy, what will be fulfilled by the derivation and adoption of health-based HBM values; these will help to improve chemical risk assessment. The identification of need and options for a sustainable HBM initiative in Europe is the main aim of WP6, this involves the building of a support system for key institutional actors and stakeholders that should work in a long-time perspective. The second pillar is built up by four WPs (WP7-10), all devoted to the establishment of a European HBM platform. WP7 aims for the identification of existing data and data gaps and the harmonization of survey and fieldwork strategies. Connected to this harmonization is WP8´s EU-wide alignment of current studies and the execution of targeted surveys (if required). WP9 addresses laboratory analysis and quality assurance, what is accompanied by WP10´s data management and analysis. The third pillar includes WP11-WP17. Whereby, WP11 will evaluate opportunities and obstacles related to linking HBM, health surveys and administrative data sources. This WP will also provide tools for improved cost-benefit analysis and human exposure-health outcome correlations. In regard of supporting risk assessment, WP12 will focus on the causal interference between HBM and exposure. WP13 will focus on the effect of exposure on health outcomes using mechanistic information. This will result in the definition of adverse outcome pathways (AOPs). Fundamental for the translation of HBM data into health risk, is the identification and validation of biomarkers, what is the goal of WP14. WP14 will also identify new biomarkers, if needed. WP15 will identify the health risk of chemical mixtures by the characterisation of real-life exposure patterns. WP16 addresses emerging chemicals, what includes the inventarisation of already known chemicals and the identification of yet unknown chemicals. The last WP, WP17, is devoted to ethical requirements.

A.5 BRIDGE Health

BRIDGE Health was established in 2015, with the goal to merge (or bridge) already existing EU projects, which worked on similar or related topics devoted to the promotion of health in different age groups, with a focus on elderly, pregnant women, as well as children, and young people. The specific topics included:

- population and health system monitoring
- indicator development
- health examination surveys (HES)
- environment and health

- population injury and disease registries
- clinical and administrative health data collection systems
- methods of health systems monitoring and evaluation

By bridging these topics and related projects, it was aimed to generate the basis for a long-term EU wide infrastructure and research network. This network builds and maintains a high quality and representative European Health information system. The project itself consists of twelve individual Work Packages (WPs), WP1-3 dealt with coordination, dissemination and evaluation.

WP5–13 cover different thematic aspects ranging from indicator development, over perinatal health and HBM to disease registries, and health system performance with its register data.

In addition, BRIDGE Health comprises seven Horizontal Activities (HA) which address cross sectional issues of relevance for all vertical WPs. Both vertical WPs as well as HAs[10] provide results, which are identified to be of relevance for HBM4EU. An assessment of the potential contributions of BRIDGE Health to HBM4EU is therefore best based on an individual assessment of the contributions of both vertical WPs and HAs to the HBM4EU WPs.

The most relevant BRIDGE Health WP for HBM4EU is WP6 on Impact of environmental chemicals on health. Other results which will be of use for HBM4EU come from the different HAs, as well as from WP5, WP4, WP7, WP8, and WP11. In the following, for each of the above-mentioned relevant WPs and all HAs, a comprehensive overview is given on objectives and results.

A.6 Objectives & Results of BRIDGE Health´ WPs

A.6.1 WP6 – Impact of environmental chemicals on health

This WP aims at promoting the use of environmental health surveillance in European health information and contributes to sustainable and integrated EU health information regarding environmental determinants of ill-health. It builds on the work done in the EC FP7 funded research projects COPHES that established a first European wide protocol for HBM, and of ENRIECO, that established a network of European birth cohorts for environmental health research. WP6 aims at identifying the options to link HBM data with register information, Health examination surveys (HES) and to investigate the options to develop an indicator for impacts of environmental chemicals on health, in an intensified exchange between COPHES and ENRIECO networks.

WP6 published two important deliverables. The first report gives an overview of HBM initiatives in Europe. The latest knowledge of biomarkers (BM) and non-invasive sampling, prioritisation of substances, analytical methods, study design, data storage, and ethical issues in the light of health information, is included to provide an up-to-date inventory of human biomonitoring in cross-sectional surveys and longitudinal cohort studies. Finally, it provides considerations on integration of HBM and HES.

[10] HA 1: Transferability of health information and data for policy, HA 2: Health information inequalities within the EU and MS, HA 3: Health information at regional level and for specific population groups, HA4: Standardization methods of the collection and exchange of health information, HA5: Data quality methods including internal and external validation of indicators, HA6: Priority setting methods in health information, HA 7: Ethical and legal issues in health information

The second report contains an overview on efforts done so far and future needs and tools available for inter-linking HBM, health, and environmental registries. Valuable information is provided related to available indicators linked to human exposure. Furthermore, an approach to define new indicators based on HBM is provided in a first example.

The work carried out in WP6 should be regarded as a basis for HBM4EU, continuation in the frame of HBM4EU is essential.

A.6.2 WP5 – Health Examination Surveys

WP5 deals with HES, population-based surveys with questionnaires; objective measurements such as height, weight and blood pressure, and collection of biological samples (blood, urine, saliva, etc.) that provide data for many health indicators which cannot be obtained through any other data sources. Key objective is to explore further synergies in data collection procedures, in the establishment of a centralised database, in definitions of indicators to be used in reporting and in the establishment of reporting systems.

WP5 published a blueprint for actions to enhance the organisation of national HESs in the EU Member States[11]. Therein key EU-level actions needed to enhance the standardisation of national HES are categorised according to their status.

The first action considered is the availability of guidelines and standardised protocols. During the BRIDGE Health project, the guidelines for organising a national HES (Part A)[12] and the standardised protocols for EHES core health measurements and collection of biological samples (Part B[13]) have been updated and are now available in the 2nd edition. Currently still no link to or integration of HBM is available in the documents. A further planned activity indicated is a library of existing international standard protocols and standard questionnaires for additional survey modules. The further actions addressed by WP5 are the network of national HES organisers and the professional support by the EHES coordination centre. The network as well as e-mail consultation is operational, annual meetings and more personal consultation visits are a future planned action. The relevant experts can be found on the website[14]. The next action considered in the blueprint is quality assurance, covering training activities as well as laboratory quality assessment. Training material is available as well as training seminars. Regarding the laboratory quality assessment, an assessment scheme has been tested during the EHES pilot project and is therefore categorised in the blueprint as only partially operational. Similarly, as above, this aspect is highly relevant for an HBM survey as well. An assessment scheme has been tested in DEMOCOPHES. Experiences should be brought together to develop a future coordinated approach. As a final important action data sharing and joint reporting are addressed by WP5. This aspect covers in particular the work on indicators (EHES manual, Part C[15]). The EHES manual has been updated; however, no new indicators have been added.

[11] http://www.ehes.info/publications/Blueprint%20for%20actions%20to%20enhance%20the%20organization%20of%20national%20HESs.pdf

[12] EHES manual part A: http://www.julkari.fi/handle/10024/131502

[13] EHES manual part B: http://www.julkari.fi/handle/10024/131503

[14] http://www.ehes.info/contact/contact_countries.htm

[15] EHES manual part C: http://www.julkari.fi/handle/10024/131504

A.6.3 WP4 – European Core Health Indicators

WP4 aims to update the European Community Health Indicators (ECHI)-shortlist indicators and to improve the knowledge to support the effective development and use of health indicators for health policy purposes. Over the last years a core set of public health indicators was developed by the ECHI initiative and its implementation was initiated. This WP of the BRIDGE Health provides project updates, evaluates and improves the existing ECHI indicators, aiming to generate a more concise and policy-focused health indicator set. As a long-term strategic objective, the WP aims to reduce or close this HI-gap by disseminating relevant knowledge, sharing expertise, building capacity and supporting a dedicated interactive and sustainable network.

WP4 prepared two reports, from which the first one deals with the status of the ECHI indicators. Currently the ECHI shortlist contains 88 indicators and is divided into three sections, namely the implementation, work-in-progress, and development section. A survey has been carried out focusing on data availability at national level. Data on health status (prevalence and incidence/mortality) are available from more than 90 % of the participating countries. A slightly lower availability rate is reported for the policy area "Determinants of Health".

The second report covers a concept for a long-term institutional memory in the form of a sustainable web-based repository. According to the authors a primary functionality of the indicator repository is to be able to provide access to the available ECHI-related (meta-)information for researchers, policymakers and the interested public. This would include information about definitions, operationalisations, quality, availability and purpose of the indicators brought together to monitor and assess public health, in an EU comparable manner. Other (possible future) functionalities could be the addition of other information related to indicators, such as methods and tools, providing access to information on comparable and/or new indicators from other organisations and supporting the exchange of expertise among researchers.

The system should distinguish between two types of information, namely ECHI historical context and background and ECHI indicators and their meta-data. The first aspect includes background reports and scientific articles about the ECHI indicators and their use as well as background reports from EU-funded projects that have delivered some of the indicators and their meta-information to the ECHI and ECHIM projects and Joint Actions such as EURO-URHIS, ISARE and EHLEIS, while for the latter one ECHI meta-data is summarised in the documentation sheets. These sheets cover data on ECHI indicator name, definition of indicator, calculation of the indicator, additional underlying concepts, relevant dimensions (subgroups), (preferred) data source(s), rationale, data availability, quality, periodicity, references and work to do. Both types of information will be collected as far as possible within the BRIDGE Health project following an intensive research.

A.6.4 WP7 – Birth Registers

Key aim of this WP is to improve and to strengthen information and data collection on reproductive, maternal, new-born and child health (RMNCH) by bridging efforts for health information in RMNCH and creating a roadmap for further development. It reinforces capacity and reduces inequalities in data production, transfer, sharing, analysis and use of perinatal health indicators from routine data systems on the national and EU levels. In addition, it aims to promote harmonisation and integration by creating a research observatory for both (routine) RMNCH registries and (research) cohorts in Europe, building on the combined work of previous

EU funded projects on birth cohorts (CHICOS) and child health research strategy (RICHE). WP7 will show what sources are available and what indicators are being tracked. RMNCH databases include generic health sources such as WHO, EUROSTAT, OECD, as well as RMNCH specific data sources such as UNICEF, EURO-Peristat. Other sources are assessed.

As part of BRIDGE Health, the Euro-Peristat project on maternal and new-born health developed and pre-tested a new data collection protocol to simplify data transmission and improve the quality of its indicators. This protocol uses multivariable tables (MVT) based on a minimum core set of data items. 27 countries have provided data for the feasibility study and data compilation is in process in 4 other countries. At least 17 can provide all or some data in a MVT format and these data can be easily exported into Euro-Peristat reporting tables. This feasibility study provides encouraging results for improving the availability and relevance of maternal and child health indicators in Europe.

A.6.5 WP8 – Health Registries

Maintaining and strengthening the implementation of population-based registries for chronic diseases with standardisation of methodologies for producing standardised EU-wide indicators is the objective of WP8. In the EU, an extensive experience of population-based registers has been accumulated in cancer, acute myocardial infarction, stroke and diabetes through projects such as EUROCISS and EUBIROD. However, collected data are rarely standardised. Harmonisation and dissemination of procedures/methods and best practice to improve and guarantee quality of data collection of population-based registers, facilitate their implementation, sustainability and maintenance are essential. Two tasks will contribute to the realisation of the work, namely task 1 focusing on chronic disease occurrence and task 2 focusing on quality of health care.

Recently, a report has been prepared by WP8, which provides a guideline to support and stimulate implementation of population-based registers in those countries lacking them. Such a population-based registry should aim to assess the frequency, distribution and prognosis of the disease in the general population providing indicators, such as attack rate, incidence rate, prevalence and case fatality rate and survival rate to evaluate trends and changing pattern, to monitor non-communicable diseases (NCD) prevention programs, outcomes and treatment effectiveness. In case a population-based registry focus on the general population a comprehensive picture of a disease in the community, highlight problem areas and suggest where action is needed.

The prepared guideline starts from the experience of former population-based registries and recommends a minimum data set following a step-wise procedure based on standardised data collection, appropriate record linkage with different sources of information, validation methods, data processing procedures, and population under surveillance. Besides, it provides a standardised model for producing reliable and comparable estimates of indicators for monitoring temporal trends and geographical gradients of current data. WP8 emphasise the importance of the definition of the event. The application of the recommended standard methodology will result in the availability of reliable, valid and therefore comparable data on the event occurrence at the European level and will facilitate implementation of preventive actions.

In general, data of a population-based registry can be helpful for any HBM study and are an important source for linking HBM to health data. Data can be used e.g. to investigate or to confirm links between chemical exposure and specific health trends. The report highlights the

example of the Northern countries, in which a personal identification number (PIN) is used to link health registries with any other available information.

A.6.6 WP11 – Patient data

The aim of WP11 is to develop a coherent methodology to integrate HIS from existing data sources, covering both population- and disease-based data from administrative, survey and registry sources.

Using a step by step approach, BRIDGE Health WP11 aims at creating databases to enable comparison of performance in the care of specific patient groups between countries, within countries (regions and hospitals), and over time, using patient-level administrative health care data. In a first step, the project will update and further develop the EuroHOPE research infrastructure with the aim of evaluating the performance of health care systems in terms of outcomes, quality, use of resources, and cost, by making use of available databases. This includes maintaining and updating the protocols of selected diseases. WP11 will assess legal issues (e.g. privacy, data transfer, statistical methods) related to the approaches with respect to the feasibility and quality of performance information and will test the building of a data linkage infrastructure capable of securely and safely managing HI.

WP11 published a report on "Building register-based performance indicators for acute coronary syndrome (ACS) and acute myocardial infarction (AMI) using individual-level administrative health care data". It updates the earlier version of the protocol for AMI. The protocols include e.g. inclusion/exclusion criteria, definition of cycle of care (when it starts, follow-up etc.), comorbidities (used in risk adjustment), and specification of process, utilisation, cost and outcome measures. The updated national and regional indicators[16] are based on data of all new acute hospitalised patients in Finland, Denmark, Hungary, Norway, Sweden and the autonomous region of Friuli-Venezia Giulia in Italy between 2006 and 2014. The report shows that within countries, there is huge regional level variation in the outcomes of care in the three analysed conditions. These national and regional differences in performance have sustained over time.

A.7 Objectives & Results of BRIDGE Healths´ Horizontal Activities

A.7.1 HA1: Transferability of health information and data for policy

Policy makers need clear messages to prioritise and take policy measures, whereas science in general provides results with uncertainties that need interpretation against other factors and weighing against pros and cons. The main objective of this HA is to develop an outline and blue-print on how the scientific knowledge and the uncertainty behind health information data will be translated to policy makers in an efficient way. The major result of HA1 is that there is an abundance of data and data platforms for HI within the European Union, at national level and around the globe, but that there is a lack of interlinkage, strong inequalities in data availability and quality, as well as a lack of appropriate means and formats for data transfer. Collectively, increased and improved communication between researchers and policy makers (and other stakeholders), strategic planning, tool development and data harmonisation are the key approaches in tackling challenges in transfer of health information and data to policy.

[16] http://www.eurohope.info/

A.7.2 HA2: Health information inequalities within the EU and MS

This HA used the expertise of the health information projects participating in BRIDGE Health, as well as other European health information initiatives, to identify strategies for reducing inequalities in health information capacity in the MS. This HA will also aim to identify the extent of HA inequality with respect to the main themes and information systems covered by BRIDGE Health. HA2 on “Health information inequality in Europe and MS" focused on project participation and knowledge about HI. In the resulting scoping paper, it concludes that in health information, there is a strong inequality and heterogeneity in country wise project participation, as well as in national HI knowledge. The paper recommends a HI inequality index that could help identify priorities for action in individual MS.

A.7.3 HA3: Health information at regional level and for specific population groups

HA3 aims at outlining a pathway to include subgroup and sub-regional analysis in an eventual European Health Information System (EU-HIS). The main objective is to incorporate multiple level/multiple strata (ML/MS) approach and the use of meaningful units of analysis in the HIREP-ERIC, to get research results that can support decision-making. In the framework of HA3 the authors conducted a non-systematic ad-hoc review of the BRIDGE Health projects and projects listed in the Health Data Navigator developed by the EuroREACH project, as well as some institutional initiatives using routinely collected data on health system performance. This review proofs, that most of the European health research projects and institutional initiatives yield country level results, which may not result useful to health decision-making. Research and reporting should be conducted using the units of analysis that are more relevant for health and health care decision-making. Also, regarding research meaningfulness, it should be considered that multiple levels and multiple strata of analysis enhance meaningfulness.

A.7.4 HA4: Standardisation methods of the collection and exchange of health information

Standardisation is a process of developing and implementing standards. Standardisation can help to maximise comparability, reliability, repeatability and quality of collected information. HA4 aims at identifying existing standardisation processes for the collection of health information among participating projects/information areas as well as at international/European level and to create an overview of health information areas which used standardised methods for data collection and identify areas where such standardisation processes are missing. In addition, a similar approach is followed to identify methods used for exchanging/sharing health information. HA4 discusses the value of standardisation methods for the collection and exchange of health information. Based on a questionnaire that was distributed to Consortium participants, the authors compiled what kind of health information, and on which level of aggregation and anonymisation has been collected by previous or ongoing EU funded projects on health information. Additionally, they provide a summary about used data sharing rules and methods among previous EU projects. The authors stress the challenges for exchange of personal data, due to privacy and ethical issues namely prior informed consent and the EU General Data Protection Regulation (GDPR)[17]. A combination of pseudonymisation and the use of privacy protecting restricted access platforms is recommended to tackle these issues. There are specific derogations from the requirement for consent, where this is not feasible, for processing personal data for medical research and statistical purposes. The practical implications of the

[17] http://www.eugdpr.org/

GDPR and increasing consideration of data protection and ethical issues around the management of data by many organisations and member states is likely to influence the extent to which data, whether identifiable, pseudomised or anonymised are transferred across borders.

A.7.5 HA5: Data quality methods including internal and external validation of indicators.

The availability of powerful technology offers the possibility to build health indicators through linkage of electronic records routinely collected; quality of sources of information is crucial together with validation process to ensure reliability and comparability of health information among countries, across regions and over time periods. This process is time and cost consuming. HA5 identified existing methods of quality assessment in the data sources/data collection as well as the elaboration process among participating projects to create an overview of health information areas where quality issues are faced. HA5 identified existing methods of quality assessment in the data sources/data collection as well as the elaboration process among participating projects in order to create an overview of health information areas where quality issues are faced. The corresponding report gives a detailed description of quality dimensions of data and data sources (relevance, accuracy, timeliness, accessibility, comparability, coherence), a description of systematic and random errors, methods to assess quality and validity of indicators, implications and limitations, including description of major difficulties encountered to ensure data quality in different European projects. Examples of quality checks for data provided by ad hoc surveys, population-based registries and administrative databases are described as well as main steps to improve quality methods.

A.7.6 HA6: Priority setting methods in health information

Priority setting is a challenge at all levels (global, national, and local) and for all contexts in health systems because demand for health care usually exceeds available resources. The development of health goals is used in many countries to address emerging health needs and increasingly to govern investment decisions to respond to social values. HA6 addresses the following aspects:

- What health problems do we face?
- What health status do we aspire to?
- How effective are our health services, activities and policies?
- What are the prices of inputs?
- Are there better uses of funds for other ends?

HA6 addresses the methods that are available for priority setting in HI. The authors identified examples on how these priorities are being set within the context of the European Commission. This was done focusing on health and health system topics that frame Europe´s strategy. These examples include common approaches, tools and methods used to prioritise health research as well as common decision criteria that facilitate the process of priority setting. The authors conclude, in line with a review (Bryant et al. 2014), that it is “not possible to provide strong evidence-based recommendation about optimum methods to set research priorities”.

A.7.7 HA7: Ethical and legal issues in health information

The horizontal issue HA7 aims at performing a survey on current practices in legal and ethics and to identify upcoming regulations and obstacles for cross-country studies. HA7 compiles an overview about current practice and ethical challenges in HI. The paper exclusively targets the challenges with collection of personal human samples and data. Based on new EU data protection regulations the HA proposes the use of a Health Data Navigator (HDN), which brings together information on MS level in relation to ethical and legal issues. This HDN is one of the major instruments of EU data protection law and aims at achieving a minimum level of data protection in the MS. For the HBM-related ethical questions the HA advises to take the outcome of DEMOCOPHES in account. The corresponding guidelines describe the processes needed to follow when initiating HBM studies in the EU and the different regimes for applications for approvals of HBM studies to national ethics committees. HA7 concludes that a harmonisation of ethical requirements within EU is not practicable, though it has been discussed for decades to aim at more uniform requirements.

A.8 Contributions of BRIDGE Health to HBM4EU

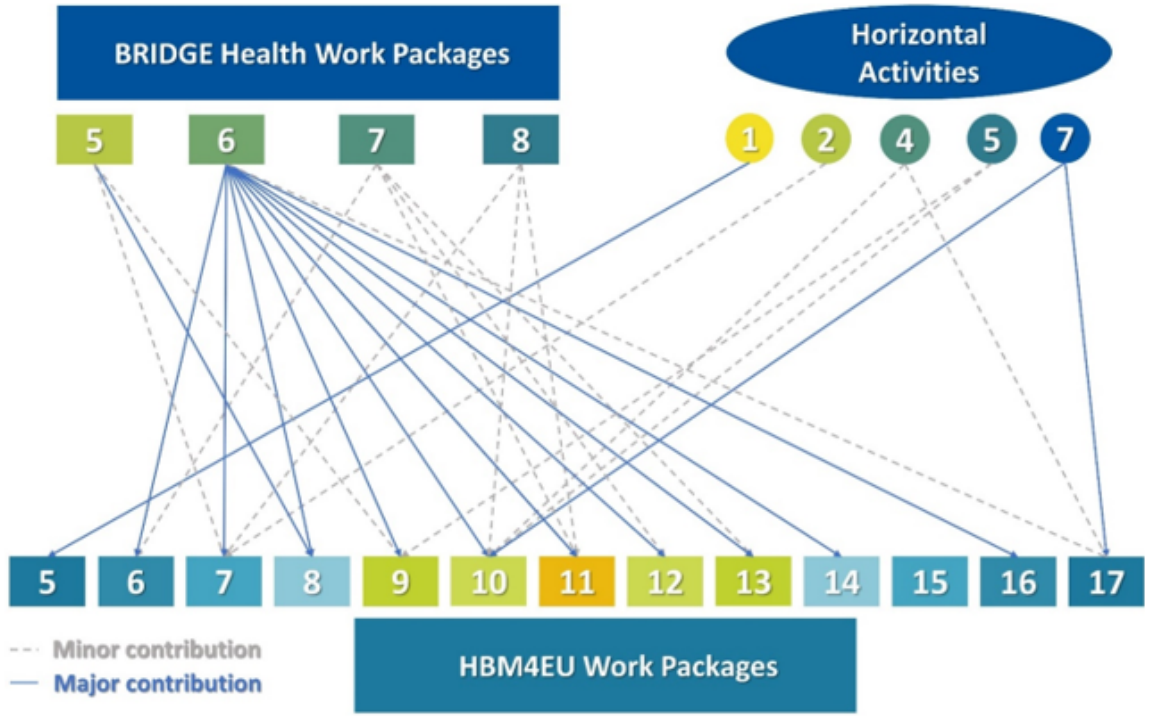
As stated in the HBM4EU Grant Agreement, the work of HBM4EU shall build on the work done by BRIDGE Health to foster the inclusion of HBM data in a European Health Information system, as part of the European Health Information strategy to be proposed by BRIDGE Health.

Several of the HBM4EU Work Packages (WP) and tasks can benefit directly from experience gained under BRIDGE Health, this relates to both vertical Work Packages as well as cross-cutting Horizontal Activities (HA).

The BRIDGE Health project did fundamental work on the use of HBM in public health policies and health information, and on generic method developments, which forms a valuable basis for future work in HBM4EU. This is especially true for WP6, whose results contribute to the majority of HBM4EU´s WPs. The contributions from BRIDGE Health are particularly relevant for HBM4EU work packages WP5-8, WP10-13, and WP17. HBM4EU work packages WP14-16 have less been covered by BRIDGE Health but have been identified as research priorities.

BRIDGE Health WP5 has focused on the optimisation of health examination surveys but does not yet include any alignment with HBM surveys. The BRIDGE Health work packages on disease registries WP7 and WP8 accordingly worked on the optimisation and harmonisation of registry set-up and data collection but did not yet investigate options to integrate additional parameters to allow for use in HBM interpretation and impact assessment of environmental stressors on health. These may be considered priority tasks to be done in the future to ensure a synergistic data generation and data use for environmental and public health policies. The BRIDGE Health WPs on health system performance and administrative data are not relevant for HBM4EU.

Figure 3: Schematic overview on how BRIDGE Health WP5-8 and HAS contribute to respective HBM4EU WPs.



Source: [UBA, 2017]

In the following the main contributions of BRIDGE Health are presented in the context of the related HBM4EU WP.

HBM4EU WP5 (translation of results into policy) is focused on the derivation and adaption of health-based HBM-values as a mean to establish the basis for improvement of chemical risk assessment and management. BRIDGE Health contributes to this work via its WP6[18] and HA1[19]. Whilst WP6 provides information on the gaps between health-based guidance values (HBGVs) derived based on standard risk assessment tools and HBM based reference values, and substance groups identified as potential causes for disease, HA1 is providing information on the theoretical background of science to policy transfer, and its application in HI at the current stage.

HBM4EU WP6 (sustainability and capacity building) concerns the identification of need and options for a sustainable HBM initiative in Europe, to provide a robust justification for a long-term HBM4EU. The main contributions of BRIDGE Health to this work package are provided from WP6. Further minor contributions may be derived from WP7.

WP6[20] presents a comprehensive overview about existing HBM initiatives in the European Union, and about the coverage of environmental health aspects in international and European public health and consumer protection policies. It further identifies the options to link with environmental and health registry information and with health examination surveys. The roadmap that will be a major outcome of BRIDGE Health WP6 will discuss in detail the

[18] http://www.bridge-health.eu/content/environmental-chemicals-and-health

[19] Will be accessible via http://www.bridge-health.eu/HAReports

[20] http://www.bridge-health.eu/content/environmental-chemicals-and-health

requirements to implement HBM as a policy tool in HI and public health policies. The work package hence contributes to both, identification of need and options for a sustainable HBM.

WP6 highlight the wealth of information on environmental contaminant exposures that is collected by means of cross-sectional HBM surveys and birth cohorts, and clearly shows the challenges and deficits in knowledge concerning data collection as well as causality. It further provides an excellent overview of the options and deficits to link HBM data with environmental contamination and health information collected in other surveillance schemes.

HBM4EU WP7 (survey design and fieldwork preparation) is focused on the harmonisation of methods and tools of an HBM survey, based on an EU-wide inventory of existing data and their respective gaps. It shall further develop harmonised strategies, questionnaires, and standard operational procedures (SOPs) on this basis. Contributing BRIDGE Health WPs are mainly WP6 and WP5. Some information is contributed in addition by WP8, and HA2. BRIDGE Health WP5 updated the EHES manuals, which provide the harmonised protocol for health examination surveys (HES). Since these guidelines only consider HES related measurements (anthropometry data), they are only partially transferable to HBM. However, basic considerations are also applicable to HBM and are of special significance in the light of the potential development of a merged HBM and HES protocol. These considerations include an EHES questionnaire, detailed guidance for QA/QC, and data management and reporting system rules. The manual and a supporting blueprint can be found online ([21],[22],[23], [24]).

BRIDGE Health WP6 summarises the key prerequisites to perform HBM both in cross-sectional surveys as well as in birth cohorts, and the principles of study design. It provides an updated inventory of existing surveys and cohorts, and their respective scope and data gaps[25]. BRIDGE Health WP8 further developed guidance for the establishment of chronic disease registries (acute myocardial infarction, stroke, and diabetes)[26]. This involves standardised methodologies about information and diagnostic criteria, what can also be useful for the corresponding processes in HBM. HA2[27] gives an overview about HI related multinational projects and the participating countries. In addition, a correlation is made between the participating countries/institutions and the GDP per capita (for 2015), which shows strong inequalities in country participation and a deficit in HI data. Based on this observation, the authors recommend establishing a HI inequality benchmarking index that could help identify priorities.

HBM4EU WP8 (targeted field work surveys an alignment on EU level) focus on the alignment of current HBM studies, with the goal to produce EU level data. This was not a topic of BRIDGE Health, but some potential minor contributions come from BRIDGE Health WP5 and WP6 as mentioned above.

BRIDGE Health WP6 provides an updated inventory of recent HBM surveys and longitudinal cohorts, which can be used as a direct basis for further HBM4EU work[28]. The key outcome of WP5 is the updated EHES protocol, containing detailed guidance for standardisation and

[21] EHES manual Part A: http://www.julkari.fi/handle/10024/131502

[22] EHES manual Part B: http://www.julkari.fi/handle/10024/131503

[23] EHES manual Part C: http://www.julkari.fi/handle/10024/131504

[24] http://www.ehes.info/publications/Blueprint%20for%20actions%20to%20enhance%20the%20organization%20of%20national%20HESs.pdf

[25] http://www.bridge-health.eu/content/environmental-chemicals-and-health

[26] http://www.bridge-health.eu/content/platform-population-based-registries

[27] http://www.bridge-health.eu/sites/default/files/BRIDGE%20Health_HA2_April2017.pdf

[28] http://www.bridge-health.eu/content/environmental-chemicals-and-health

harmonisation, including respective QA/QC guidelines[29]. The blueprint is dedicated to the actions needed to enhance the organisation of national HES. Some of the considerations are also applicable to the actions needed in the context of HBM. For example, it is recommended to establish a transnational network, where experiences can be shared. This could be supported by e-mail consolidation, a FAQ section, and/or a helpdesk.

HBM4EU WP9 (laboratory analysis and quality assurance) aims at the EU-wide harmonisation of chemical analysis of biomarkers in HBM surveys and cohort studies. This WP is mainly supported by the WP6 of BRIDGE Health. Some generic contributions come also from WP5 and HA5. WP6 provides a summary information on the prerequisites for harmonisation of chemical analysis of biomarkers in HBM surveys and cohort studies based on the experience and lessons learnt from COPHES/DEMOCOPHES and from ENRIECO, which can be used as a direct input in future HBM4EU work[30]. Also, WP5 considers interlaboratory QA/QC, and provides detailed guidance for HES-studies. HA5 was devoted to the topic of data quality methods in HI[31]. As a main result, the HA5 states that the first steps to plan and organise a quality data collection is to prepare a manual of operations. This manual should include a detailed description of exams, data, and questions that should follow international standardised protocols. Also, collection and processing of data should be done on same basis.

HBM4EU WP10 (data management and analysis) deals with the development of procedures and a plan for data consolidation, -management, -harmonisation, -sharing, statistical analyses, and database construction. The most important contributions of BRIDGE Health are stemming from WP6 and HA7 regarding ethical issues. Besides this, data management and data analysis not related to HBM was the overall focus of BRIDGE Health and a core element of all WP as well as the objective of HA4 and HA5. It however, must be stated that only the population health related WPs 5 and 8 provide results, which may be of relevance for HBM4EU. Data management in WP4 is exclusively related to indicator work. For WP7 there is not yet enough information to evaluate recommendation for data management. All other WPs deal with health system performance or disease registries and are not relevant. As already stated earlier, BRIDGE Health WP5 updated the EHES manuals. Even though these considerations are meant for HES studies, they are also important in terms of HBM data management. For WP10 of HBM4EU the detailed data management guideline of manual part A is of highest relevance. It covers general aspects about the forms of data collections, preparation of the fieldwork, and error checking guidelines. WP6 of BRIDGE Health summarises lessons learnt of COPHES/DEMOCOPHES, and from ENRIECO for data transfer, data management, data analysis, and data interpretation, which can be used as a direct starting point for HBM4EU work. WP8 deals, among other topics, with the data management in chronic disease registries[32]. The authors recommend, that the data which should be included must be chosen by a team of experts, preferably by those from biostatistics or epidemiology. In addition, each variable should relate to the purpose of the registries and specific objectives. Throughout this, the data should address the central questions of the registry. It is also useful to consider generalisability of the collected information and to focus on the core data set variables, based on which data is already available and which data is to be collected (usually a minimum data set, MDS).

[29] EHES manual Part B: http://www.julkari.fi/handle/10024/131503

[30] http://www.bridge-health.eu/content/environmental-chemicals-and-health

[31] http://www.bridge-health.eu/sites/default/files/BRIDGE%20Health_HA5-draft_2017-04-18.pdf

[32] http://www.bridge-health.eu/content/platform-population-based-registries

In general, the authors recommend, that a registry should avoid accomplishing too many goals. HA4 states, that easy access to HI by researchers is essential for quality research with the aim to transform results into policy[33]. Against this background, a special focus is on the exchange of HI as well as data security and confidentiality. The authors state that exchange of HI in an EU-wide context, needs European level harmonisation protocols depending on different data sources and indicators. These protocols should ensure the reliability and comparability of HI. HA5 is entitled "Data quality methods including internal and external validation" and is therefore focused on the quality of data, the authors state that in general, quality concerns data quality, data sources, and data indicators[34]. A detailed description of data, data sources, their size and characteristics, process to compute indicators, and all related measures of quality is fundamental for aggregation, harmonisation and comparison of indicators. HA7 is about ethical requirements that must be considered when an HBM survey is planned[35]. This important topic will be covered by a separate WP of HBM4EU (WP17, Ethics Requirements). However, this activity partially also covers comments data management and analysis. It states, that when initiating HBM studies in EU to national and EU-regulations on human participation in studies must be applied including description of: Study persons/tissues, who, where, how, informed consent, data privacy, bio banking, secondary use.

HBM4EU WP11 (linking HBM, health studies and registries) is devoted to investigating the opportunities and obstacles related to linking HBM, health surveys, and administrative data sources. The main contribution to this WP is provided by BRIDGE Health WP6. Minor contributions come from WP5, WP7, WP8, and WP11. BRIDGE Health WP6 discusses in detail a potential linkage between HBM, environmental contamination data, and health studies and/or registers[36].

To link results from cross-sectional HBM surveys with exposure sources and potential health effects at local, regional or national level, it was helpful if data could be matched with information from environmental and health registries. For this purpose, WP6 provides an overview on which data are collected in existing databases and which indicators exist that could be linked to environmental stressors (chemicals). The author states that indicators specific for the context of environmental health are rare. Nevertheless, the author underlines that it is possible to combine all the indicators and data available on European or national level. WP6 emphasises that the organisational synergies between HBM and HES surveys and describes the necessary steps as well as the challenges to combine the two surveillance systems from different points of view. Furthermore, WP6 provides concrete proposals for environmental health indicators based on HBM to be included in the European ECHI list.

WP5 point of view is again based on HES and the authors highlight that a potential linkage of HES data with administrative registers had an impact on the value of HES data[37]. By this linkage, HES data is part of the Big Data, which has a major potential for health information and research.

WP7 covers the Euro-Peristat project on maternal and new-born health and organised one of the most important EU wide collections for perinatal health[38]. To facilitate monitoring and evaluation of perinatal health in EU, Euro-Peristat has developed valid and reliable indicators.

[33] http://www.bridge-health.eu/sites/default/files/HA4_standardisation%20methods.pdf & http://www.bridge-health.eu/sites/default/files/HA4_exchange%20of%20HI-2017-03-03.pdf

[34] http://www.bridge-health.eu/sites/default/files/BRIDGE%20Health_HA5-draft_2017-04-18.pdf

[35] http://www.bridge-health.eu/sites/default/files/HA7reportApril2017.pdf

[36] http://www.bridge-health.eu/content/environmental-chemicals-and-health

[37] EHES manual Part B: http://www.julkari.fi/handle/10024/131503

[38] http://www.bridge-health.eu/content/reproductive-maternal-newborn-child-and-adolescent-health

For HBM4EU WP7 states, that it is strongly recommended to continue work related to birth registers to investigate possibilities to make data entries useable for HBM.

WP8 concludes that a registry is not only an integration of different information, rather the information itself must be identified in terms of a core data set and validated in terms of considering bias from diagnostic practices and changes in coding system. WP11 is devoted to NCDs and their registration, thus the data collected is not usable in terms of HBM.

HBM4EU WP12 (from HBM to exposure) investigates the options to correlate HBM data with exposure, whereas HBM4EU WP13 (establishing exposure-health relationships) is focused on the elucidation of the link between HBM body burden and a potential health risk.

Again, for these two WPs, WP6 of BRIDGE Health is the major information source. Minor contributions are provided by WP7. WP6 provides a detailed comparison of substance related data collected in environmental registries and HBM, as well as an overview on currently available PBPK models. For elucidation of health risks WP6 provides an updated inventory of evidence on causality derived from birth cohorts, a detailed evaluation of data collected in health registries compared to HBM, as well as a list of HBM and BEq values compared to HBGVs, which can be used as a direct starting point for HBM4EU work[39]. WP6 emphasises the importance of the IPCheM platform, as it is planned to use this platform in the context of HBM4EU to bring together HBM data, outdoor and indoor environment, and food. WP7 updated its indicator list in the framework of the BRIDGE Health project; these can also be used to correlate exposure with HBM data[40].

HBM4EU WP14 (effect biomarkers) aims at the identification and validation of biomarkers, which provide a tool for the understanding of the environmental exposures impact on human health. Investigation on effect biomarkers was not a focus of work in BRIDGE Health. However, it has been an element of WP6[41], where effect biomarkers are discussed as a recent research approach, and where the outcomes of recent Omics research with birth cohort data is presented and evaluated. It will be the task of HBM4EU to further elucidate the potential of effect markers in routine surveillance or in health risk assessment.

HBM4EU WP15 (mixtures, HBM and human health risks) is devoted to the development of summary indicators that should compromise the effect of mixtures regarding their exposure and body burden. This WP is addressed in WP6 as an existing deficit, where future work needs to be done in HBM4EU.

HBM4EU WP16 (emerging chemicals) shall elucidate the role of emerging chemicals in HBM. This topic is addressed in WP6 in terms of prioritisation of chemicals, and as a regulatory issue. It is considered as an upcoming priority to be addressed. WP6 gives an overview of the regulatory framework and the main initiatives on EU and international level[42]. This includes actions of ECHA, EFSA, IARC for listing of substances. It is recommended to utilise all the mentioned lists and the corresponding substances as starting points for the prioritisation process of emerging chemicals. A second starting point is outlined by the updated inventory of cross-sectional surveys and longitudinal cohort results.

The last **WP17** of HBM4EU involves the ethic requirements of HBM. The main contribution to this WP stems from HA7, which was devoted to ethical and legal issues in health information.

[39] http://www.bridge-health.eu/content/environmental-chemicals-and-health

[40] http://www.bridge-health.eu/content/reproductive-maternal-newborn-child-and-adolescent-health

[41] http://www.bridge-health.eu/content/environmental-chemicals-and-health

[42] http://www.bridge-health.eu/content/environmental-chemicals-and-health

Minor contributions are provided by WP6 and HA4. Building on the results of COPHES/ DEMOCOPHES and ENRIECO, WP6 summarises, that any HBM activity must be approved by ethics committees and data protection authorities in the country performing the study and that for EU projects special rules apply[43].

Based on DEMOCOPHES, the author report challenges with ethical issues, which must be considered also for HBM4EU. However, specific recommendations are not made. HA4 deals with standardisation methods of the collection and exchange of health information. In this context the authors state, that consent is generally required for the processing of personal data. Pseudonymisation is strongly encouraged as is the removal of sufficient identifying information to make the information truly anonymous and hence not subject to the general data protection regulation (GDPR). HA7 stresses, that it is important to implement the project in accordance with the rules in each country regarding ethics committees, data protection and providing individual level data[44]. They recommend designing a new EU data protection regulation, since it could be useful in the development of a structure which systematically brings together information on MS level in relation to ethical and legal issues. A starting point could be Health Data Navigator (HDN), which is one of the major instruments of EU data protection law and aims at achieving a minimum level of data protection in the Member States.

A.9 Future steps towards a European Health Information System

Overall it can be stated, that the BRIDGE Health focus is on classical HI tools, such as HES, health registries, and indicator development, and that in the light of HBM4EU the future joint EU project work on HI, in terms of a HIREP ERIC or a comparable joint action/infrastructure will continue this path.

The BRIDGE Health concept paper for the future European Health Information System[45] describes in detail the need for new evidence and information, the mission, vision, scope, goals and tasks, as well as structural options, potential services and governance structures for the HIREP-ERIC.

The scope of the HIREP-ERIC shall cover health status, health systems and determinants of health. In the latter topic area reference is made to life style, socio-economic conditions and environment.

As tasks of the European Health information system the concept paper identifies the following:

1. Foster coherence in activities in health information between the Member States and EU institutions to contribute to a common EU health information strategy;
2. Identify health information needs and priorities in a methodological and systematic way;
3. Map data sources and identify data gaps;
4. Set up an EU data/indicator repository;

a) Collection (standardised tools)

b) Compilation (access and/or transfer)

c) Integration (data extraction)

d) Transformation (harmonisation and loading processes)

[43] http://www.bridge-health.eu/content/environmental-chemicals-and-health

[44] http://www.bridge-health.eu/sites/default/files/HA7reportApril2017.pdf

[45] Technical Report BRIDGE Health N° WP1_2016_03

e) Analysis (data quality and production of outputs)

f) Research (study data) and

g) Inference (conclusion reached on the basis of evidence and reasoning)

5. Identify legal and ethical issues related to data ownership, sharing, access, transfer, storage, processing and reporting, and contribute to the development of common standards and best practices;
6. Link and exchange with stakeholders: support research-to-policy interaction, transferability of health information and data for policy and outline the information dissemination strategy and tools;
7. Ensure outputs are datasets for research, surveillance and monitoring purposes, public reporting of health and healthcare performance indicators; manuals/guideline/methods for data quality, for data analysis, for data interpretation and communication;
8. Create guidelines for training and capacity building for the Member States to reduce health information inequalities;
9. Ensure sustainable funding for the EU health information system;
10. Ensure regular evaluation of the EU health information system.

The concept paper evaluated expansion of existing structures[46] with the set-up of new structures[47], or the combination of both, and concluded that an ERIC would be the most feasible option.

Such an ERIC, called European Research Infrastructure Consortium on Health Information for Research and Evidence-based Policy (HIREP-ERIC) should cover the following core activities:

11. indicator development
12. repository platforms
13. capacity building.

As regards indicator development, the ERIC shall provide technical and expert support for comparable, standardised and accessible indicators for health and health determinants, health services and health systems. This includes updating indicators, developing new indicators and improving existing ones. In terms of repositories it shall facilitate and support the development and hosting of platforms for:

- health data;
- metadata;
- data collection protocols, including guidelines and handbooks for implementing surveys and developing and maintaining registries;
- tools and methods for: pre- and post-harmonisation; data collection, quality assessment, analysis, reporting and knowledge translation; to facilitate the access and use of data for research.

In addition to the core activities the ERIC shall provide:

[46] Expanding tasks of Eurostat, Extension of the scope of the European Centre for Disease Prevention and Control (ECDC), Reorganisation of DG Health and Food Safety (SANTE), Extending work plan of DG Joint Research Centre (JRC), or Outsource to the World Health Organization (WHO) Europe or the Organisation for Economic Co-operation and Development (OECD)

[47] Creating an independent new EU agency, European Research Infrastructure Consortium (ERIC)), and concluded that an ERIC would be the most feasible option

- Support for research methodology development namely new and more efficient methods and tools for data collection, quality assessment, use, analysis and reporting as well as knowledge translation.
- Support for the dissemination of research outcomes
- Create 'meta-access' to data sources suited for international comparisons.
- Research to improve the knowledge translation of health research outcomes from the ERIC activities to the general public and to policymakers as a central activity in the HIREP-ERIC strategy.

For the next three years the concept paper identified the following HIREP-ERIC priorities:

h) Map the existing entities producing health information, and/or contributing to the production of health information

i) Develop a prioritisation method for the uptake of research networks in the ERIC

j) Provide a continuous set of core services to the members of the ERIC

14. Provide technical support for members
15. Provide expertise on a wide range of health information activities only available through ERIC due to its far-reaching network of networks
16. Guide researchers and policy makers to requested health information
17. Carry out forecast and horizon scanning activities to support agenda setting
18. Organise annual conference with relevant health information stakeholder
19. Enhance national health information and research capacity through sharing know-how and setting up a first cohort within a training program
20. Assist members to obtain funding for health information activities, to which the ERIC will have better access
21. Liaise with international organisations whilst representing members interest
22. Increase visibility of national health information activities through dissemination of reports and papers
23. Set-up virtual repository for policy briefs

In the project running time of BRIDGE Health it was not possible to start the drafting of the HIREP-ERIC and get sufficient support from Member States in the Expert Group on Health Information (EGHI). Therefore, it was decided to continue work towards an ERIC or another long-term infrastructure via a Joint Action (JA), which shall pave the way towards and ERIC in close collaboration with the Commission Expert Groups on HI and on Health system performance assessment (HSPA), Eurostat, DG Research and other relevant DGs, as well as WHO and OECD. This JA is currently under development.

A.10 Conclusions and recommendations

The coverage of determinants of health defines the primary link between HIREP-ERIC and HBM4EU.

Considerable potential for synergies exists with respect to the core activities of the HIREP-ERIC, namely the indicator development, and the interoperability of repository platforms, but also as regards capacity building for population health surveys.

In addition, there is potential for synergies in the development of new and more efficient methods and tools, in the dissemination of research outcomes, the knowledge translation and 'meta-access' to data sources suited for international comparisons.

Against this background it is strongly recommended that HBM4EU will focus on the further development of any HBM related tools and methods together with the set-up of a long-term EU wide network of specialists, whilst a HIREP-ERIC or a comparable infrastructure will focus on the further development of indicators, disease registries, and HIS.

A.11 References

Bryant J., Sanson-Fisher R., Walsh J. and Stewart J. (2014): Health research priority setting in selected high income countries: a narrative review of methods used and recommendations for future practice. Cost Eff Resour Alloc, 12, 23.

Casteleyn L., Dumez B., Becker K., Kolossa-Gehring M., Den Hond E., Schoeters G., Castano A., Koch H. M., Angerer J., Esteban M., Exley K., Sepai O., Bloemen L., Horvat M., Knudsen L. E., Joas A., Joas R., Biot P., Koppen G., Dewolf M. C., Katsonouri A., Hadjipanayis A., Cerna M., Krskova A., Schwedler G., Fiddicke U., Nielsen J. K., Jensen J. F., Rudnai P., Kozepesy S., Mulcahy M., Mannion R., Gutleb A. C., Fischer M. E., Ligocka D., Jakubowski M., Reis M. F., Namorado S., Lupsa I. R., Gurzau A. E., Halzlova K., Jajcaj M., Mazej D., Tratnik Snoj J., Posada M., Lopez E., Berglund M., Larsson K., Lehmann A., Crettaz P. and Aerts D. (2015): A pilot study on the feasibility of European harmonized human biomonitoring: Strategies towards a common approach, challenges and opportunities. Environmental Research, 141, 3.

Di Iorio C. T., Carinci F. and Oderkirk J. (2014): Health research and systems' governance are at risk: should the right to data protection override health? J Med Ethics, 40, 488.

Joas Anke, Knudsen Lisbeth E., Kolossa-Gehring Marike, Sepai Ovnair, Casteleyn Ludwine, Schoeters Greet, Angerer Jürgen, Castaño Argelia, Aerts Dominique, Biot Pierre, Horvat Milena, Bloemen Louis, Reis M. Fátima, Lupsa Ioana-Rodica, Katsonouri Andromachi, Cerna Milena, Berglund Marika, Crettaz Pierre, Rudnai Peter, Halzlova Katarina, Mulcahy Maurice, Gutleb Arno C., Fischer Marc E., Becher Georg, Fréry Nadine, Jensen Genon, Van Vliet Lisette, Koch Holger M., Hond Elly Den, Fiddicke Ulrike, Esteban Marta, Exley Karen, Schwedler Gerda, Seiwert Margarete, Ligocka Danuta, Hohenblum Philipp, Kyrtopoulos Soterios, Botsivali Maria, DeFelip Elena, Guillou Claude, Reniero Fabiano, Grazuleviciene Regina, Veidebaum Toomas, Mørck Thit A., Nielsen Jeanette K. S., Jensen Janne F., Rivas Teresa C., Sanchez Jinny, Koppen Gudrun, Smolders Roel, Kozepesy Szilvia, Hadjipanayis Adamos, Krskova Andrea, Mannion Rory, Jakubowski Marek, Fucic J. Aleksandra, Pereira-Miguel Jose, Gurzau Anca E., Jajcaj Michal, Mazej Darja, Tratnik Janja Snoj, Lehmann Andrea, Larsson Kristin, Dumez Birgit and Joas Reinhard (2015): Policy recommendations and cost implications for a more sustainable framework for European human biomonitoring surveys. Environmental Research, 141, 42.

A.12 Annex

A.12.1 Conclusion of BRIDGE Health for Pillar 1 of HBM4EU

Pillar 1 - Results into Policy (WP4-6)

- Development of a policy concept by the alignment of data collection purpose with the need for epidemiological conclusions and evaluation;
- Information needs should be communicated in a top-down approach by knowledge brokers (expert networks and partnerships);
- Use of social media and visualisation in a user adopted language
- Improvement of trust by the engagement of social scientist that work on understanding and visibility;
- Development of new/improved records, registers, reports and data flow procedures by use of open access and brief communication;
- Improvement of causal inference by the installment of a long-term infrastructure, for which already existing expertise and data in cross-sectional surveys and birth cohorts form the basis.

A.12.2 Conclusion of BRIDGE Health for Pillar 2 of HBM4EU

Pillar 2 – European HBM platform (WP7-10)

- Identification of a core data set is important, since the maintaining of registries is time and money consuming;
- Establishing a HI inequality benchmarking index, that could help identify priorities;
- Support for translational networks by e-mail consolidation, a FAQ section, and/or a helpdesk;
- Widening of expertise to improve methodological approaches
- Analytical methods must be suitable, reliable, and must be assessed by internal/external QC;
- Use of QA plans by laboratories, that considers SOPs, staff training, and the regular analysis of blank samples, blind samples, spiked samples, duplicates and (certified) reference materials;
- As external QA/QC measures, the laboratory should participate in interlaboratory and external supervisory authorities;
- Preparation of operation manual, including detailed description of exams, data, and questions, that should follow international standardised protocols;
- Preparation of a code book for coded data transfer;
- The transfer, management, analysis, and interpretation of data should be done accordingly COPHES/DEMOCOPHES, and ENRIECO.

- Data which should be included must be chosen by a team of experts, preferably by those from biostatistics or epidemiology;
- Minimum data set (MDS): Variables should relate to the registries´ purpose, specific objectives, and central questions;
- Implementation of European level harmonisation protocols depending on different data sources and indicators.

A.12.3 Conclusion of BRIDGE Health for Pillar 3 of HBM4EU

Pillar 3 - Exposure and Health (WP11-17)

- Combination of all the indicators and environmental data available on European or national level is possible;
- There are synergies between HES and HBM and combination is possible and needed;
- HBM based health indicators are to be included in the European ECHI list;
- HES data is part of the Big Data, which has a major potential for HI and research;
- Continuation of work related to birth registers to investigate possibilities to make data entries useable for HBM;
- Use of substances, which are already classified by regulators as health-based guidance values (HBGV) or as biomonitoring equivalents (BE) as a starting point for future work;
- Derivation of values using the PBPK (physiologically based pharmacokinetic) model, as they contribute to the characterisation of AOPs (adverse outcome pathway);
- Use of the IPCheM platform, to bring together HBM data, outdoor and indoor environment, and food;
- Future development of a new breed of biomarkers by the exposome concept (as part of the omics research) as an opportunity for studying many exposures at the time;
- Utilising of ECHA, EFSA, IARC-lists as starting points for the prioritisation process of emerging chemicals;
- Pseudonymisation is encouraged to make the information truly anonymous and not subject to the general data protection regulation (GDPR);
- Designing a new EU data protection regulation to develop a structure which systematically brings together information on MS level in relation to ethical and legal issues
- Health Data Navigator (HDN), which aims at achieving a minimum level of data protection in the MS.

B Appendix – Agenda Consortium Meeting 2017

08:30 – 09:00	Registration and welcome
09:00 – 09:30	HBM4EU – Where are we now? *HBM4EU Coordinator, UBA*
09:30 – 09:40	Welcome from the European Commission *Scientific Officer, EC*
09:40 – 10:10	Management Topics (Communication, deadlines etc.) incl. Knowledge Hub, Internal Calls *HBM4EU Coordinator, UBA*
10:10 – 10:30	NHC Report *National Hub Coordinator, DH*
10:30 – 11:00	Coffee
11:00 – 11:20	Pillar 1: Report *Pillar 1 Leader, VITO*
11:20 – 11:40	Knowledge Hub – overview of available tools and materials, *EEA*
11:40 – 12:00	Prioritisation strategy- from mapping of needs to prioritization, *ANSES*
12:00 – 12:20	List with indicators and criteria to monitor the implementation and achieved impact, *LNE*
12:20 – 12:30	Pillar 1: Conclusion and future perspective *Pillar 1 Leader, VITO*
12:30 – 13:20	Lunch
13:20 – 13:40	Pillar 2: Report *Pillar 2 Leader, ISCIII*
13:40 – 14:00	Identification of existing data and samples and data gaps, *FMUL*
14:00 – 14:20	Progress on the alignment of National studies and how this may be taken forward, *VITO & DH*
14:20 – 14:40	Data Management and data access in HBM4EU, *VITO*
14:40 – 14:50	Pillar 2: Conclusion and future perspective *Pillar 2 Leader, ISCIII*
14:50 – 15:20	Coffee
15:20 – 15:40	Pillar 3: Report *Pillar 3 Leader, INSERM*
15:40 – 16:00	Report of Criteria for prioritisation of biomarkers of effect, *UGR*
16:00 – 16:20	Integrated exposure models, *AUTH*
16:20 – 16:40	Complementary strategies for suspect and untargeted screening of emerging substances in human matrices, *INRA*

16:40 – 16:50	Pillar 3: Conclusion and future perspective *Pillar 3 Leader, INSERM*
16:50 – 17:00	Short Break
17:00 – 17:45	Panel Discussion with the MB
17:45 – 18:00	Wrap up and Questions *HBM4EU Coordinator, UBA*

C Appendix – Agenda Governing Board Meeting 2017

08:30 – 09:00	Registration and welcome
09:00 – 09:15	Welcome by the President of UBA
09:15 – 09:30	Past, presence and future of HBM4EU from the European Commission's perspective, *EC*
09:30 – 10:00	Introduction to HBM4EU, Progress so far (incl. Annual Summary Report), Approval of Agenda, *HBM4EU Coordinator, UBA*
10:00 – 10:30	Approval of Rules of Procedure
10:30 – 10:45	Election of the Chair and the Vice-Chair
10:45 – 11:10	Coffee
11:10 – 11:20	Decision results
11:20 – 11:30	Introductory words from the Chair
11:30 – 11:45	Approval of Advisory Board, *UBA*
11:45 – 12:00	Approval of Stakeholder Forum, *UBA*
12:00 – 12:15	Approval of Ethics Board, *UBA*
12:15 – 12:30	Overview of changes required to the budget of 2017 and related to the Annual Work Plan 2017, *UBA*
12:30 – 12:45	Approval of changes to the budget of 2017, *UBA*
12:45 – 13:00	Amendment of WP 3, *INSERM*
13:00 – 13:15	Approval of Internal Call topics, *INSERM*
13:15 – 13:30	Amendment: Inclusion of Hungary (represented by the National Public Health Institute of Hungary) into HBM4EU, *UBA*
13:30 – 13:45	Amendment: Inclusion of Luxembourg (represented by the National Health Laboratory) into HBM4EU, *UBA*
13:45 – 14:35	Lunch
14:35 – 14:45	Decision results
14:45 – 15:00	Overview of the AWP 2018, *UBA*
15:00 – 15:30	Overview of Project Budget 2018, *UBA*
	Approval of the Project Budget 2018, *UBA*
15:30 – 15:45	Approval of the AWP 2018, *UBA*
15:45 – 16:00	Prioritisation strategy and criteria, including tasks 4.1 on the mapping of needs, 4.2 on the strategy, 4.3 on the rapid response mechanism and 4.4 on the scoping documents, to provide the full overview of the process, *EEA*
16:00 – 16:15	Presentation of the strategy for deriving representative HBM data of the EU population, *VITO*
16:15 – 16:30	Data management plan, *VITO*

17:00 – 17:15	Criteria for selecting laboratories, *ISCIII*
17:15 – 17:30	List with indicators and criteria to monitor the implementation and achieved impact, *LNE*
17:30 – 17:45	Selection of the HBM4EU Ambassador, *INSERM*
17:45 – 18:10	AOB
18:10 – 18:20	Decision results
18:20 – 18:30	Wrap-up and closure by the Chair

D Appendix – Agenda Consortium Meeting 2018

08:30 – 09:00	Registration and welcome
09:00 – 09:20	HBM4EU – Where are we now?
	HBM4EU Coordinator, UBA
09:20 – 09:30	Welcome from the European Commission
	Scientific officer, EC
09:30 – 09:50	Management Topics, including financial aspects
	HBM4EU Coordinator, UBA
09:50 – 10:00	News from the Knowledge Hub, *EEA*
10:00 – 10:10	Internal Call: Next topics
	Pillar 3 Leader, INSERM
10:10 – 10:20	NHC Report
	National Hub Coordinator, DH
10:20 – 10:30	CGL Report, *VITO*
10:30 – 11:00	Coffee
11:00 – 11:05	Pillar 1 – Science policy translation in HBM4EU
	Pillar 1 Leader, VITO
11:05 – 11:15	The prioritisation process and the results (Task 4.2), *ANSES*
11:15 – 11:25	The needs for HBM data in risk assessment – results from an inventory (Task 5.3), *FIOH*
11:25 – 11:35	Strategy for deriving HBM-Health-based Guidance Values: consultation process, outcome, future plans and significance for risk assessment in EU (Task 5.2), *UBA & ANSES*
11:35 – 11:45	Performance and impact of HBM4EU, how to evaluate?, *DOMG*
11:45 – 11:55	Policy related research under HBM4EU – progress on PFAS, *EAA, CGL for PFAS*
11:55 – 12:05	Policy questions for pesticides, challenges for HBM4EU, *SDU, CGL for pesticides*
12:05 – 12:30	Panel discussion with WP4 WP5 WP6
	Chair: *Pillar 1 Leader, VITO*
12:30 – 13:30	Lunch
13:30 – 13:35	Pillar 2 – Overview, progress, results, perspectives
	Pillar 2 Leader, ISCIII
13:35 – 13:42	Identification of data gaps (Task 7.1), *FMUL*
13:42 – 13:50	Questionnaire design (Task 7.3), *EASP*
13:50 – 13:57	Progress with the alignment of national studies (Task 8.1), *VITO*

13:57 – 14:05	Assessment of occupational exposure to chromium (Task 8.5), *FIOH*
14:05 – 14:12	Analyzing HBM samples: Developing new methods (Task 9.3), *IPA*
14:12 – 14:20	Analyzing HBM samples: Establishing QA program and selecting labs (Task 9.2), *ISCIII*
14:20 – 14:35	Analysing HBM data: analysis plan, transfer data and establishing reference values: plans and concerns (WP 10), *VITO*
14:35 - 15:00	Panel discussion with WP7, WP8, WP9, WP10
	Pillar 2 Leader, ISCIII
15:00 – 15:30	Coffee
15:30 – 15:35	Pillar 3 – Overview, progress, results, perspectives
	Pillar 3 Leader, INSERM
15:35 – 15:45	Description of the integrated exposure modeling platform (WP 12), *AUTH*
15:45 – 15:55	Linking first priority chemicals to AOPs with focus on bisphenols and Flame retardants (WP 13), *MU*
15:55 – 16:05	Recommended effect biomarkers for the first priority substances (WP 14), *UGR*
16:05 – 16:15	Relevant health measurements for the first priority chemicals (WP 11), *THL*
16:15 – 16:25	Progress in Mixture research; analysis of existing data, joint survey and case studies on health effects (WP 15), *RIVM*
16:25 – 16:35	Harmonisation of methods for the detection of emerging substances (WP 16), *INRA*
16:35 – 17:00	Panel discussion with WP11, WP12, WP13, WP14, WP15, WP16
	Pillar 3 Leader, INSERM
17:00 – 17:30	Wrap up and Questions
	HBM4EU Coordinator, UBA

E Appendix – Agenda Governing Board Meeting 2018

09:00 – 09:15	Registration and Welcome
09:15 – 09:30	Opening by the Governing Board Chair
	Approval of Agenda
09:30 – 10:00	Welcome by the European Commission
10:00 – 10:30	Approval of Rules of Procedure Progress of HBM4EU, *UBA*
	Approval of Annual Summary Progress Report 2018, *UBA*
10:30 – 11:00	Coffee
11:00 – 11:10	Decision Results
11:10 – 12:00	Overview of the AWP* and Project Budget 2019, *UBA*
	Approval of the AWP and Project Budget 2019, *UBA*
SUSTAINABILITY	
12:00 – 12:15	Options for a long-term sustainability for HBM in Europe, *INSERM*
12:15 – 12:30	Results on the stakeholder survey towards expectations on sustainability, *EEA*
12:30 – 13:30	Lunch
13:30 – 13:40	Decision results
13:40 – 13:55	Evaluation of national frameworks reported by the national hubs, *DH as NHC*
13:55 – 14:10	Approval of HBM4EU Ambassador, *INSERM*
14:10 – 14:35	Recommendations and ideas from the GB (e.g. regarding funding possibilities, capacity building, etc.)
FIELD STUDIES, DATA AND ETHICS	
14:35 – 14:50	Field studies: plans, aims and financial resources, *DH/VITO*
14:50 – 15:05	Progress and next steps of the Quality Assurance and Quality Control program, ISCIII
15:05 – 15:20	Centralization of data on EU level: progress and obstacles, *VITO*
15:20 – 15:35	Approval of updated Legal and Ethics Policy Document, *UCPH/THL*
15:35 – 16:05	Coffee
16:05 – 16:10	Decision results
16:10 – 16:25	2nd list of HBM4EU priority substances, *EEA*
16:25 – 16:40	New health-based EU HBM guidance values, *VITO/UBA*
16:40 – 16:55	Update and perspectives from the Joint Horizon2020 Mixture projects, *RIVM*
16:55 – 17:10	Emerging substances: first results and involved labs, *INRA*
17:10 – 17:25	AOB

17:25 – 17:40 Wrap-up and closure by the Governing Board Chair

F Appendix – Agenda Consortium Meeting 2019

13:00 – 13:30	Registration and welcome
13:30 – 14:00	HBM4EU: Where are we now, what have we achieved?
	HBM4EU Coordinator, UBA
14:00 – 14:15	Welcome from the European Commission
	Scientific officer, EC
14:15 – 14:30	Management Topics
	HBM4EU Coordinator, UBA
14:30 – 14:45	Knowledge Hub, *EEA*
14:45 – 15:00	New Partner Countries, *Estonian Health Board*
15:00 – 15:15	Flash presentations by poster presenters, *Moderator: UCPH*
15:15 – 15:45	Coffee break
HBM Platform	
15:45 – 16:00	EU wide collection of HBM data: update on the aligned studies, *VITO*
16:00 – 16:15	Update on occupational studies, *FIOH*
16:15 – 16:30	Update on Pesticides studies, *RIVM/IRAS*
16:30 – 16:45	Update on HES-HBM studies, *THL*
16:45 – 17:00	Exposure biomarkers and performing labs, *ISCIII*
17:00 – 17:15	Data management analysis at EU level, *ANSP*
17:15 – 17:30	Questions and Discussions
Research and Results	
09:00 – 09:15	Implementation of effect biomarkers in HBM studies, *VITO*
09:15 – 09:30	What computational studies tell us about exposure to bisphenols and phthalates, *AUTH*
09:30 – 09:45	Suspect and non-targeted screening of emerging chemicals: first results and harmonization issues, *INRA*
09:45 – 10:00	Methods to link priority substances to AOP, *MU*
10:00 – 10:10	Questions and Discussions
Communication and uptake of the results	
10:10 – 10:25	Policy uptake of HBM results, *EEA*
10:25 – 11:10	Coffee and time for poster session
11:10 – 11:25	Science-policy dialogue on HBM results: what, why, first steps and future plans, *UAntwerpen*
11:25 – 11:40	HBM-GVs, *UBA*
11:40 – 11:55	HBM in risk assessment, *INSA*

11:55 – 12:05	Questions and Discussions
CGL reports	
12:05 – 12:20	Bisphenols, *INSERM*
12:20 – 12:35	PAH, *AUTH*
12:35 – 13:35	Lunch and time for poster presentation
13:35 – 13:50	Acrylamide, *KI*
13:50 – 14:05	Questions and Discussion
NHCP Reports	
14:05 – 14:15	Introduction, *DH*
14:15 – 14:25	Latvia, *RSU*
14:25 – 14:35	Hungary, *NPHI*
14:35 – 14:45	Portugal, *FCT*
14:45 – 14:55	Poland, *NIOM*
14:55 – 15:05	Questions and Discussion
15:05 – 15:45	Coffee and time for poster presentation
15:45– 16:15	Sustainability and Future Years of the Project
	HBM4EU Coordinator, UBA, Scientific Officer, EC, Pillar 3 Leader, INSERM
16:15 – 16:30	Questions and Discussion
16:30 – 16:45	Award for best posters, UCPH
16:45 – 17:00	Wrap-up and Questions
	HBM4EU Coordinator, UBA

G Appendix – Agenda Governing Board Meeting 2019

08:30 – 09:00	Registration and welcome
09:00 – 09:10	Welcome by the president of UBA, *UBA*
09:10 – 09:25	Opening by the Governing Board Chair, *BMNT*
	Approval of Agenda
09:25 – 09:35	Welcome by the European Commission
	Scientific Officer, EC
09:35 – 10:15	Progress of HBM4EU
	HBM4EU Coordinator, UBA
	Approval of Annual Summary Progress Report 2019
10:15 – 10:25	Overview of the activities of the HBM4EU Ambassador,
	HBM4EU Ambassador
10:25 – 10:55	Coffee
10:55 – 11:05	Decision Results
11:05 – 11:20	Amendment of the GA
	HBM4EU Coordinator, UBA
	Inclusion of Estonia
	Inclusion of the Republic of North Macedonia
	Approval of the Amendment of the GA
11:20 – 12:30	Overview of the AWP2 2020, draft AWP 2021 and remaining budget, *UBA*
	Approval of the AWP and Project Budget 2020
	Approval of the draft AWP and Project Budget 2021
12:30 – 13:30	Lunch
13:30 – 13:40	Decision Results
Sustainability	
13:40 – 13:50	Horizon Europe Partnership on Chemical Risk Assessment
	Scientific Officer, EC
13:50 – 14:05	Options for a sustainable biomonitoring initiative
	Pillar 3 Leader, INSERM
	Consultation and Discussion of D6.5
14:05 – 14:45	Update: Development of a Europe wide biomonitoring network – from a national perspective:

Spain - Ministry of Health, Consumer Affairs and Social Welfare

Sweden - Swedish Environmental Protection Agency

Iceland - University of Iceland

Cyprus - Ministry of Health

14:45 – 15:10	Recommendations and ideas from the GB (e.g. regarding funding possibilities, capacity building, etc.)

HBM Platform and Results

15:10 – 15:25	Update on trend and HES-HBM studies, *THL*
15:25 – 15:40	Collecting newly harmonized EU wide HBM data in 21 countries: status and foresights, *VITO*
15:40 – 16:10	Coffee
16:10 – 16:25	Update on the occupational studies, *FIOH*
16:25 – 16:40	Update on joint survey on pesticides mixtures, *RIVM*
16:40 – 16:55	Progress report of the Quality Assurance and Quality Control Program, *ISCIII*

Data and Ethics

16:55 – 17:10	Data exchange at EU level – Privacy perspective, *HBM4EU DPO*

Lookout and Achievements

17:10 – 17:25	Publications
	Selected publications linking AOPs to priority chemicals and effect markers, *AUTH*
17:25 – 17:50	Wrap-up and closure by the Governing Board Chair