Goals and challenges of population surveys and biomonitoring

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Cophes WP leaders

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COPHES
Consortium to Perform Human Biomonitoring on a European Scale

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Contents

1/ Context and definitions

2/ Goals and stakes of Human Biomonitoring (HBM)

3/ Challenges

A) An integrated approach

B) Developing efficient biomarkers

C) Improving our ability to design biomonitoring studies

D) Interpreting what biomonitoring data mean for public health

E) Addressing ethical uses of the data

F) Communicating results to study participants, policy-makers, and the public

Illustrated by

- National HBM surveys (Nhanes, GerES, ENNS)
- European HBM programme (Cophes)

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1. Context





- **Population:** anxious to know its exposure to environmental contaminants and their health effects

- **Political and regulatory requirements**

Regulation on Environmental Contamination and Human Exposure and Uptake

- Management of the chemicals, pesticides,…
- Food safety
- Environmental protection

Public Health Policy : Protection of Health and Prevention

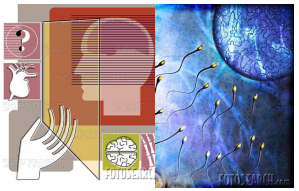
- Surveillance/Monitoring/Indicators
- Strategy related to environmental health: e.g. lead poisoning, anti-tobacco campaigns
- Investigation of polluted sites
- Tolerable Daily Intakes...

- **European level**
  - Cross boundary comparison and regulation (REACH/ECHA)
  - Council of Europe: harmonization of HBM in Europe

HBM
The missing link between environment and health effects

Environmental monitoring → **Biomarkers of exposure** → **Biomarkers of effects** → **Adverse health effects**

Uptake of pollutants through biological barriers



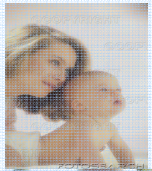
air

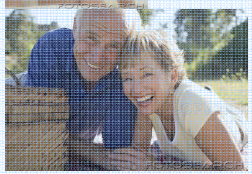
food

water

dust/ soil

consumer products





Pollutant levels in

- Blood
- Urine
- Hair
- Breast milk
- …

Early biological effects

- Enzyme activity
- Hormone levels
- DNA damage
- Immunological biomarkers
- …

Biomarkers of susceptibility

Gene expression

- Respiratory dis.
- Cancers
- Endocrine disrupt.
- Reprotoxicity
- Neurodevelopment
- Immunotoxicity
- …

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2. Goals and Stakes of HBM

Offering far wider scope for evidence-based policy

1. **Exposure of the population to chemicals**
2. **Reference values** (Background levels)
3. **Risk factors** (Social/ environmental differences – susceptible populations)
4. **Spatial and temporal trends**
5. **Retrospective exposure assessment** (Biobanks)
6. **Emerging issues**
7. **Orient and monitor existing policies**
8. **Health impact assessment**
9. **National and international comparisons**

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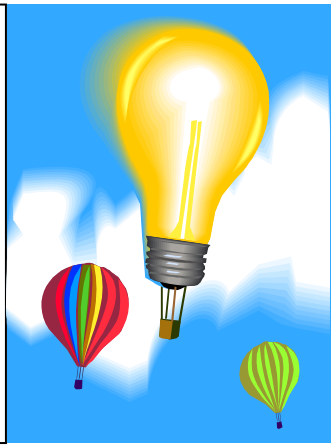
Science to Policy

Risk assessment

- Difference of biomarkers levels in population? Effects?
  (with regard to reference value, anomalies,...)
  - Identify highly exposed population
  - Identify health endpoints of concern
- Cause? Source? Pathways? Risk factors?



Risk management

HBM studies can help

- to support policy actions to reduce exposure
- to assess chemical regulations (e.g. REACH)
- to improve environment and health (monitoring, surveillance, research)

I- Definition of policy actions / II- Policy actions / III- Evaluation

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Reduction of dioxin exposure

Following trends (time, geographic)

Orient & monitor policies

Nat. & intern. Comparisons

Identify and reduce risk factors

Policies to reduce dioxins in environment
incinerators, industries, food…



↓

Serum and breast milk dioxin decrease (~50% in 20 yrs)

e.g. National HBM studies and WHO breast milk study in diff. countries

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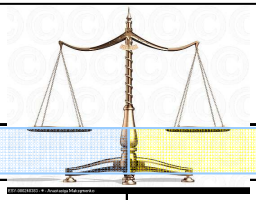
3. Strengths, weaknesses and opportunities of HBM



STRENGHTS	WEAKNESSES
• Detection of time trends and difference in sub-populations for pollutants • Evaluation of public policies • Existing example of policy-relevant outputs and Public Health actions (Pb, Hg…) • Awareness raising and education (politicians and citizens)	• Puzzle of ongoing activities • Heterogeneity and lack of actual reference and guidance-limit values to take actions • Lack of adequate capacities and of understanding of the possibilities of HBM • Lack of research regarding notably effect indicators
OPPORTUNITIES	**THREATS**
• Development ongoing worldwide and EU • Development for EU policies (REACH) and for local policy questions • Development of EH strategies and plans (WHO, EU, NEHAPs) • Cost efficiency of HBM in comparison of dedicated problems • Saving of costs at EU and national level (mutualisation of tools and works)	• Complexity and need for inter-sectoral and interdisciplinary work • Competition for funding (cost effectiveness) for other surveillance activities Paris Conference on HBM http://www.invs.sante.fr/surveillance/biosurveillance/default.htm

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4. Challenges of HBM

Level	
International	• Promote HBM as a tool for EH policy making and its use in existing Conventions and Protocols
European	• Develop harmonisation for data comparability and cost efficiency ➢ Guidelines (recruitment, sampling, analysis, communication and ethics) ➢ Reference and HBM values ➢ Pool competences and capacities of MS together when needed (emerg. pollut.) • Provide a framework for a HBM integrated with EH concerns ➢ Short term EHES (Health exam surv.) ➢ Long term INSPIRE (Geo. Info System) to integrate data at global level • Provide a powerful tool for implementation of existing legislation (REACH) with the focus on authorisation • Support and fund research (new biomarkers, kinetic models, internal doses – effects relationships, communication, ethical aspects, public involvement, etc.)
National	• Commit and fund a global integrated approach enforced in legislation ➢ Define national priorities ➢ Develop programmes at regular basis in a multidisciplinary team • Provide a tool box for effective implementation of HBM or use of biomarkers for investigation at regional and local level
Regional	• Define priorities and develop capacities to ➢ Handle hot spots, socio-economics inequalities and sub-populations ➢ Help decision making at local level ➢ Rise awareness about HBM
Local	• Involve, train and inform stakeholders (health professionals -at school, -at work, teachers, NGO's, local authorities) • Ask advice and arrange a transparent debriefing

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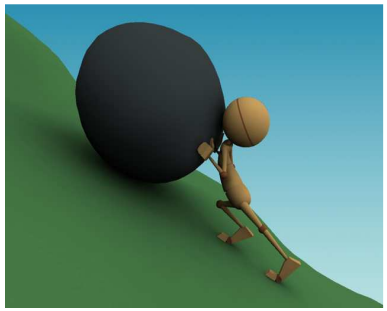
4. Challenges of HBM



A) An integrated approach

B) Develop efficient biomarkers

C) Improve our ability to design biomonotoring studies

D) Interpret meaning of HBM data for public health

E) Address ethical uses of the data

F) Communicate results to study participants, policy-makers, and the public

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4. Challenges – A) An integrated approach

Multidisciplinary team

- Chemistry
- Statistics
- Epidemiology
- Toxicology
- Risk assessment
- Communication
- Sociology
- Politics

Increase integration, interaction with other programmes

➔more effective use of data, at national, international level

Fragmented approach

Integrated approach

- INTARESE: www.intarese.org
- ESBIO, WP3: www.eu-humanbiomonitoring.org/sub/esbio/docs.htm

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Summary table of HBM programmes

Country Framework	WHO	USA	CAN	DE	FR	BE (FI)	SWE	CZ	SLO
Programme	2005-2007	1999-2004…	2007-2010	2003-2006	2006-2010...	2007-2011	1993-…	1994-…	2008-2012
Age group	Breast-fed mothers	6-59	6-79 divided in 5 groups	3-14	18-74, mothers at delivery	Newborns/ mothers 14/15 20/40	10-12, pregnant women, breast-fed mothers, adults	Blood donors, 8-10, breast-fed mothers	Breast-fed mothers and partners
Environ. indic	-	-	-		-	-		Some	2010
House survey	-				-	-	Some	-	-
Biobanks	Pooled	-	-					-	-
Health interv. s	Quest					Quest	Quest	Quest	Quest
Health exam s.	-					-	-	-	-

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Summary table of HBM programmes

Country Chemicals	WHO	USA	CAN	DE	FR	BE (FI)	SWE	CZ	SLO
Exposure biom									
POP's									
Metals, oth. Elem.	-								
Phtalates	-							-	-
Cotinine	-						-		-
PFC	-				-			-	-
Pest OP	-						-	-	-
Pest PYR	-						-	-	-
BFR's	-		-		-			-	
Pest HERB	-				-	-	-	-	-
PAH	-		-		-		-	-	-
Bisphenol A	-						-	-	-
Pest CARB	-		-	-	-		-	-	-
Effects biom									

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4. Challenges – B) Develop new relevant biomarkers

- Which biomarker (chemical, metabolites, exposure, effect, susceptibility)?
- Which relevant biological matrix?
- When and how to collect sample?
- How to measure?
- How to interpret results?

- How to deal with a huge number of substances and mixtures?
- BM:
  - Past or recent exposure?
  - Emerging pollutants?
  - Link with environment?
  - Link with health effects?
  - Variability?
- How to reach all the populations?

Development of knowledge:

- in toxicokinetic
- in toxicodynamic
- in epidemiology
- of the link BM-External exposure
- of the link BM-Health effects
- of analytical methods

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4. Challenges – B) Develop new relevant biomarkers

Laboratory analysis

- Sensitivity: low limit of quantification (LOQ)?
- Specificity? Interference?
- Precision, uncertainty
- Repeatability, reproducibility
- Accuracy: bias, contamination?
- Method: - validated?
  - micro method available?
  - feasible in routine?
- Capacity of the lab (numerous samples)?

QA/QC

- Reference and Certified Materials (RMs, CRMs) at low conc., blanks
- Proficiency test
- Interlab. comparisons
- A common glossary in metrology
- Inventory of Ref. labs

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4. Challenges – B) Develop new relevant biomarkers

Analytical development: New biomarkers

- BM of exposure (surveillance)
  - classical methods, but new BM
  - new methods, mixture

e.g. DNA, protein adduct, Calux, bioassay, generic screening syst.

- BM of effect (research)
  - cancer, reprotox., immunotox.,…
  - omics: genomics, proteomics, metabolomics

- BM of susceptibility (research still nescient)

Polymorphisms encoding for susceptibility-predisposing genes,
Battery of phenotypic assays for DNA stability and repair,…

- Non invasive BM
  - urine, hair, saliva…: increase participation

e.g. children

Beware how to use it !

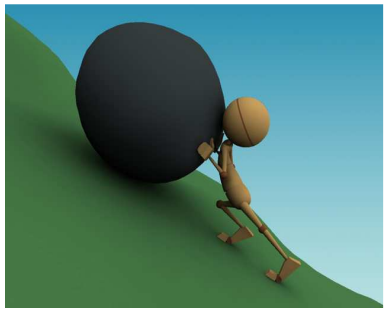
Vuvuzela

New methods

- Cooperation among labs
- Development in toxicology
- Non invasive BM

www.ecnis.org (cancer)
www.newgeneris.org (genotoxic)
www.intarese.org

4. Challenges of HBM



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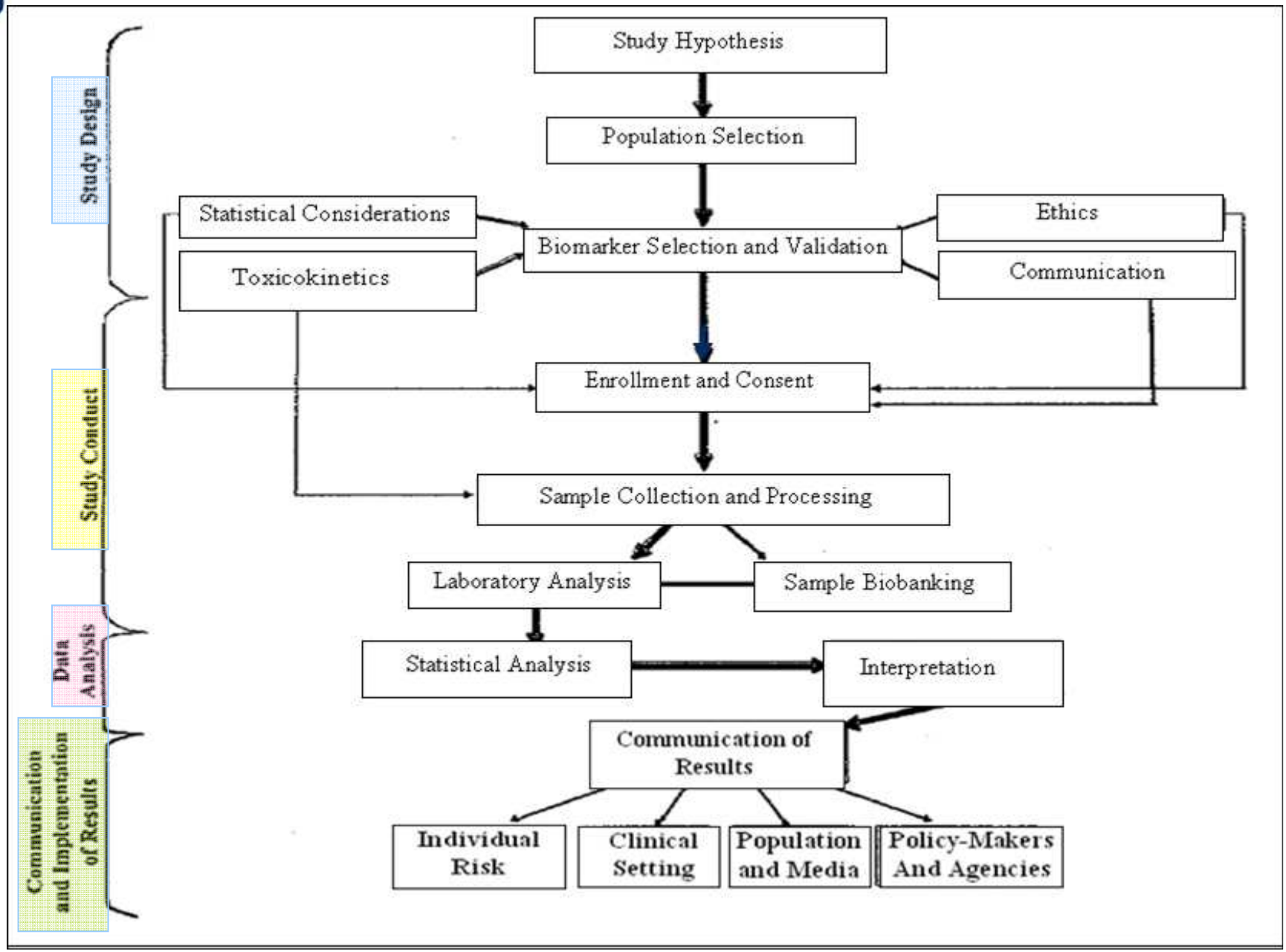
4. Challenges – C) Improve our ability to design HBM studies



4. Challenges – C) Improve our ability to design HBM studies

- Network
- Exchange of experience
- Guidelines

USA (CDC, NRC…)

www.nap.edu

Europe

- Cophes
- Democophes
- Esbio

www.euhumanbiomonitoring.org/sub/esbio.htm

- Scale

STROBE, STROBE ME: guidelines

www.strobe-statement.org

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4. Challenges – C) Improve our ability to design HBM studies

EU-Initiative to harmonize HBM
(dec.2009-nov.2012)

http://www.eu-hbm.info/

COPHES

Develop **guidelines**, scientific tools

- Collection of comparable HBM data
- Integration of environmental and health information
- Ethics for collection, storage of human material & data
- Training and capacity building programme
- Communication strategy

DEMOCOPHES

Pilot Study to test harmonization

Network

27 MS

35 Institutions

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4. Challenges – C) Improve our ability to design HBM studies

To obtain the right estimate of BM levels

➔ Importance of the recruitment of the population:

- **Sampling of the population?**
  - **Where to sample** (localities)
  - **Which population**
  - **Statistical considerations** (representativeness?)

- **How to obtain addresses of participants?**
- **Incentive to increase participation?**
- **Ethical questions**
- **Important logistic**
- **Place for the visit** (home, exam. health centre?)

➔ Importance of the collect of data

Biological samples

- **What kind of biomarkers**
- **What kind of matrices, body fluid/tissues**
- **Sampling – SOP** (timing, sampling devices, aliquots, storage, transport, biobank, etc)
- **Selection of analytical methods, laboratories, QAQC**

Questionnaires

- **Sources** (environ., occupation, dietary habits)
- **Variation factors** (socioeconomic, demographic)

- **Database**
- **Data evaluation, presentation, interpretation**

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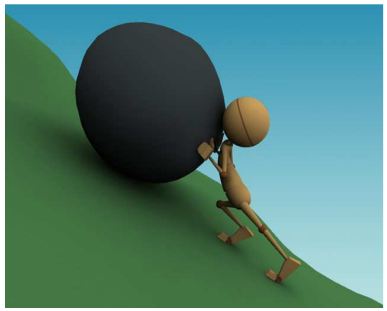
4. Challenges of HBM



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4. Challenges – D) Interpretation of HBM data

HBM data:**- Is it high? In the range of the general, non-occupationally exposed population?**
- Does the HBM data indicate a health risk?
- Source of exposure? Risk factors?

Example: **French ENNS Study**, a population-based survey

- **Blood lead:**
  - **National comparison, time trend**: a decrease of 60 % in 10 years
  - **International comparison**: similar in Europe, above North American data
    → probably due to a difference in policies
  - **Risk factors**: residence and renovation works in an old housing (paints,…)
  - **Health risk**: existing biomarker dose-response relationship

- **Organochlorine pesticides:**
  - **International comparison**:
    - similar to those in USA and Germany
    - below those in other European countries
    - except for 2-5 DCP (paradichlorobenzene):
      - 10 fold above German data observed 10 years ago
      - still recently used as moth-killer, deodorizer or disinfection pr.

4. Challenges – D) Interpretation of HBM data

Need of a multidisciplinary team

A descriptive approach

A risk-based approach

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Descriptive approaches

Statistical considerations (mean, percentiles)

Reference range, reference value

- To identify the most and the least exposed levels (individual, population, subgroup)
- To describe their characteristics
- Definition of the reference population
- At a moment (change with time) → to update with new surveys

Reference value (Upper limit value)

- Upper margin of the current background exposure of the general population

~ 95th percentile

Occupational reference value (BEIs, BAT, VLB…)

- Give an indication
- But not appropriate for general population (different exposure pathway, time exposure ...)

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Example of Reference range in USA

NHANES

US. **N**ational **H**ealth **a**nd **N**utrition **E**xamination **S**urvey

Population-based survey: ~2400 people every 2 years

National **R**eport on **H**uman **E**xposure to **E**nviron. **C**hemicals

HBM: 212 chemicals in the 4th report

www.**cdc.gov/ExposureReport/pdf/FourthReport.pdf**

Urinary Cadmium

Geometric mean and selected percentiles of urine concentrations (in µg/L) for the U.S. population from the National Health and Nutrition Examination Survey.**

	Survey years	Geometric mean (95% conf. interval)	Selected percentiles (95% confidence interval) 50th	75th	90th	95th	Sample size
Total	99-00	.193 (.169-.220)	.232 (.214-.249)	.475 (.436-.519)	.858 (.763-.980)	1.20 (1.06-1.34)	2257
	01-02	.210 (.189-.235)	.230 (.207-.255)	.458 (.423-.482)	.839 (.753-.919)	1.20 (1.07-1.28)	2690
	03-04	.211 (.196-.226)	.210 (.200-.230)	.450 (.400-.500)	.800 (.730-.880)	1.15 (.980-1.26)	2543
Age group							
6-11 years	99-00	*	.078 (.061-.101)	.141 (.115-.173)	.219 (.178-.233)	.279 (.211-.507)	310
	01-02	.061 (<LOD-.081)	.077 (.067-.092)	.140 (.112-.160)	.219 (.184-.262)	.282 (.260-.326)	368
	03-04	.077 (.065-.090)	.080 (.060-.090)	.120 (.100-.160)	.180 (.160-.310)	.310 (.170-.610)	287
12-19 years	99-00	.092 (.067-.126)	.128 (.107-.148)	.203 (.183-.232)	.329 (.272-.372)	.426 (.366-.596)	648
	01-02	.109 (.087-.136)	.135 (.114-.157)	.210 (.189-.247)	.327 (.289-.366)	.452 (.366-.480)	762
	03-04	.121 (.109-.134)	.130 (.110-.150)	.200 (.170-.210)	.300 (.260-.360)	.390 (.330-.490)	724
20 years and older	99-00	.281 (.253-.313)	.306 (.261-.339)	.551 (.510-.623)	.980 (.836-1.13)	1.32 (1.13-1.57)	1299
	01-02	.273 (.249-.299)	.280 (.261-.308)	.545 (.493-.607)	.972 (.855-1.06)	1.28 (1.20-1.43)	1560
	03-04	.260 (.238-.284)	.270 (.240-.300)	.530 (.470-.580)	.890 (.800-.990)	1.25 (1.09-1.46)	1532
Gender							
Males	99-00	.199 (.165-.241)	.227 (.193-.263)	.462 (.381-.539)	.892 (.748-1.15)	1.41 (.980-1.83)	1121
	01-02	.201 (.177-.229)	.223 (.191-.257)	.445 (.393-.481)	.875 (.741-1.03)	1.22 (1.12-1.38)	1335
	03-04	.206 (.190-.222)	.210 (.190-.230)	.440 (.390-.490)	.790 (.700-.870)	1.01 (.890-1.25)	1277
Females	99-00	.187 (.153-.229)	.239 (.220-.255)	.492 (.456-.540)	.818 (.705-.980)	1.10 (1.01-1.19)	1136
	01-02	.219 (.192-.251)	.234 (.202-.265)	.466 (.433-.519)	.817 (.733-.886)	1.17 (.918-1.36)	1355
	03-04	.216 (.195-.238)	.210 (.200-.240)	.450 (.400-.530)	.820 (.700-.960)	1.20 (1.02-1.37)	1266

Examples of Reference values
in France and Germany

GerES German Environmental survey Population-based survey, up to ~ 5000 people				ENNS Study (2006/07) French Nutrition, Health, HBM Survey Population-based survey, HBM ~2000 people		
Parameter & matrix	Population group	Year of study	Reference Value (µg/L)	Parameter & matrix	Population 18-74 yrs	Reference Value (µg/g crea)
Lead in blood	Children (6-12 yrs) Women (18-69 yrs) Men (18-69 yrs)	2001/03 1997/99 1997/99	50 70 90	Arsenic in urine Asi+MMA+DMA	No Fish eaten 3 days before collect	10
Cadmium in urine	Non-smokers: Children (6-12 yrs) Adults (18-69 yrs)	2001/02 1997/99	0.5 0.8	Cadmium in urine	Non-smokers: < 40 years Men ≥ 40 yrs Women ≥ 40 yrs	0.5 0.7 1.2
Cadmium in blood	Non-smokers: Children (6-12 yrs) Adults (18-69 yrs)	2001/02 1997/99	0.5 1	Chromium in urine	< 60 yrs ≥ 60 yrs	0.5 1

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Risk-based approaches

Health considerations

Dose-based risk assessment: Expertise from toxicological, epidemiological data

→ **to update with new knowledge**

- **International toxicol. reference value (WHO, JECFA)**
- **HBM value (German HBM Commission)**
- **Biomonitoring equivalents (BEs)**

- **Biomarker dose-response relationships: very few available**
  e.g.: Blood lead, hair mercury, urinary cadmium

- **Use existing traditional risk assessment → HBM data into a risk context**

- **Use available guidelines values, pharmacokinetic models and POD (NOELs, LOELs, BMD)**

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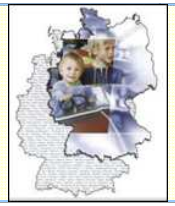
Examples of HBM values
in Germany

HBM-I: conc. of chemical **below** which **no adverse health effect** is expected
→ **Alert threshold**

HBM-II: conc. of chemical **above** which **adverse health** effect may occur
→ **Action threshold**

German HBM Commission



Human Biomonitoring (HBM) Values

Urinary cadmium & mercury

Parameter and Matrix	Population group	HBM I Value	HBM II Value
Cadmium in urine	Children, adolescent and adults <25 yrs. Others	1 µg/g creatinine 2 µg/g crea	3 µg/g crea 5 µg/g crea
Mercury in urine	Children and adults	5 µg/g crea 7 µg/L	20 µg/g crea 25 µg/L

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Biomonitoring Equivalent (BE)

Using pharmacokinetic models, the level of biomarker:

- **is converted into chemical intake doses**
- **and compared to existing health-based exposure guidelines values (RfC, RfDs, MRLs, TDIs)**

Guidelines for the derivation and communication of BEs

Hays et al., 2007, 2008
Lakind et al., 2008

e.g. BEs (PCDDs/Fs/DL-PCBs): Aylward et al.

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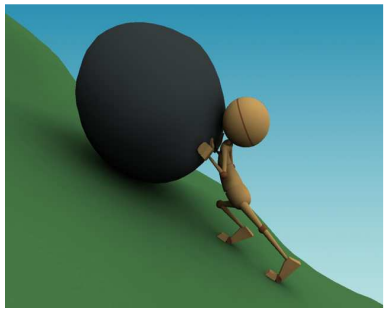
4. Challenges of HBM



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4. Challenges – E) Ethics

Protection of participant
Individual interest

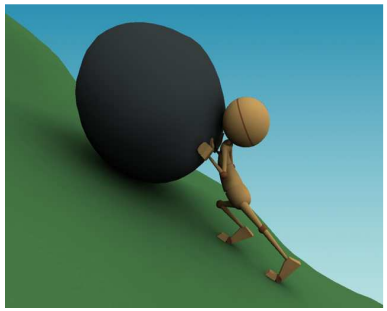
EH progress
Public Health interest

- **Privacy issues** (list of addresses, GIS)
- **Reduce burden for participants as far as possible**
  (volume of biological sample, non invasive BM,
  time requested, place of visit, incentive)
- **Consent**
  - Participant:
    - Informed consent
    - Biobank: consent for future uses of HBM data
    - Genetic purpose
    - Right to withdraw
    - Right for information (right to know, right not to know)
  - Research group:
    - Approval by ethical committee for each study
    - Transnational use of data

Protection Directive (95/46/EC)
Oviedo Convention,
Rec(2006)4
Helsinki declaration
www.ecnis.org
www.newgeneris.org

Beneficence
Adequate, not excessive
Justice
Respect for dignity
Veracity
Transparency
Privacy
Confidentiality

4. Challenges of HBM



A) An integrated approach

B) Develop efficient biomarkers

C) Improve our ability to design biomonotoring studies

D) Interpret meaning of HBM data for public health

E) Address ethical uses of the data

F) Communicate results to study participants, policy-makers, and the public

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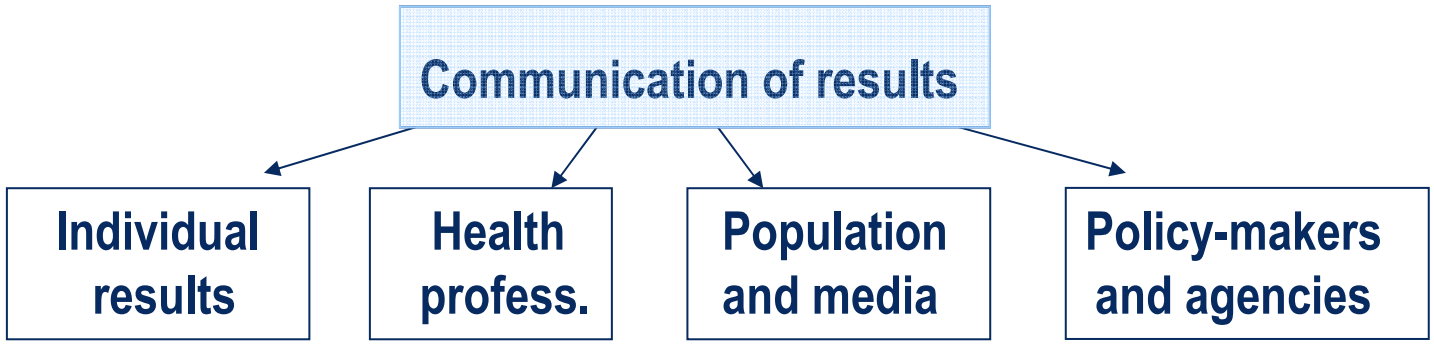
4. Challenges – F) Communicating results to study participants, policy-makers, and the public

What? How? Who? To whom?

- A good communication for a proper interpretation and use of HBM data
- Deal with uncertainty, complexity, context
- Each communicative act may affect trust in the study
- Time to translate results in preventive actions and policy making
- Participation of stakeholders in the policy process well defined
- Individual results / collective results



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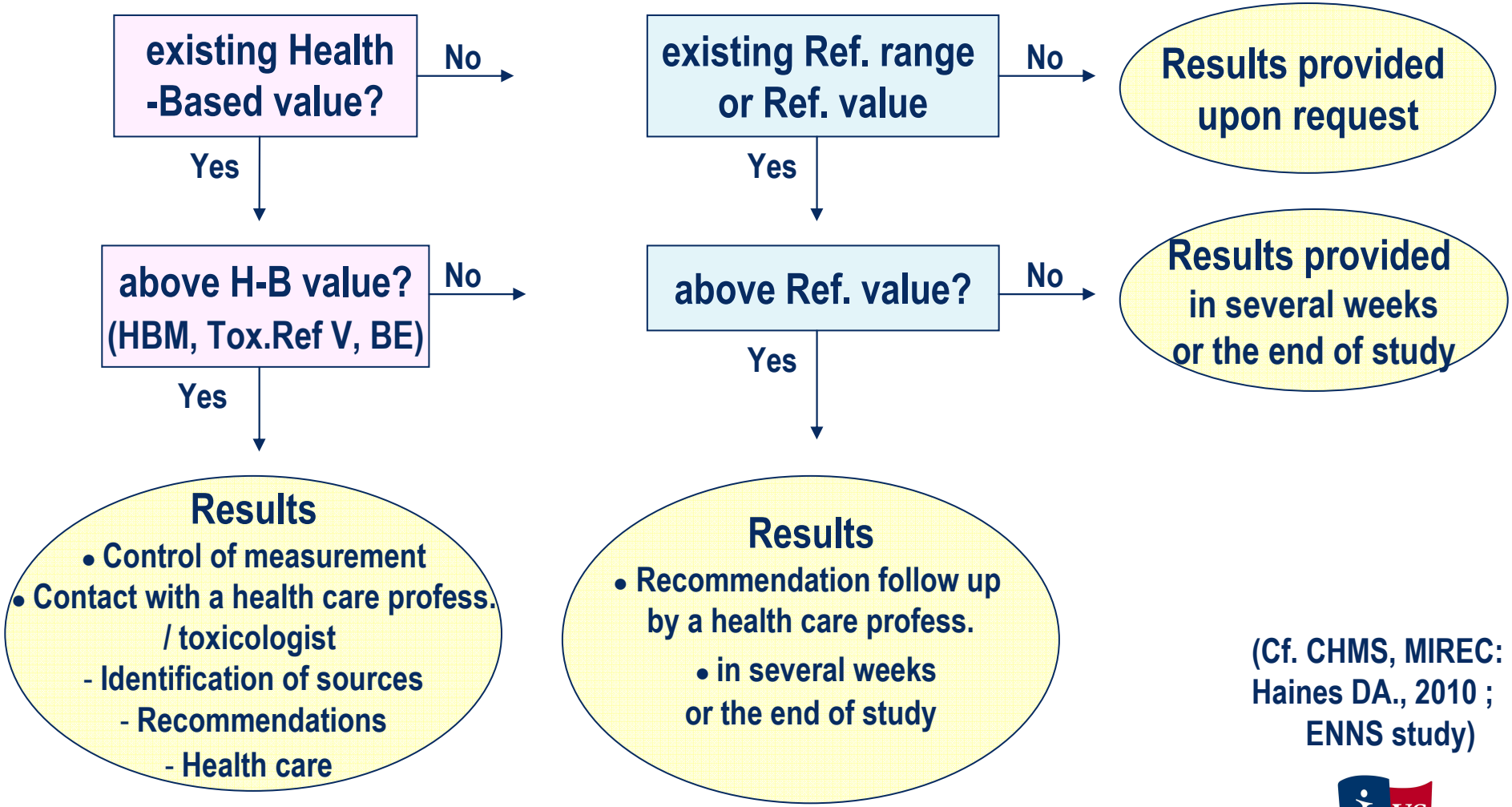
Right for information

Individual results



(Cf. CHMS, MIREC: Haines DA., 2010 ; ENNS study)

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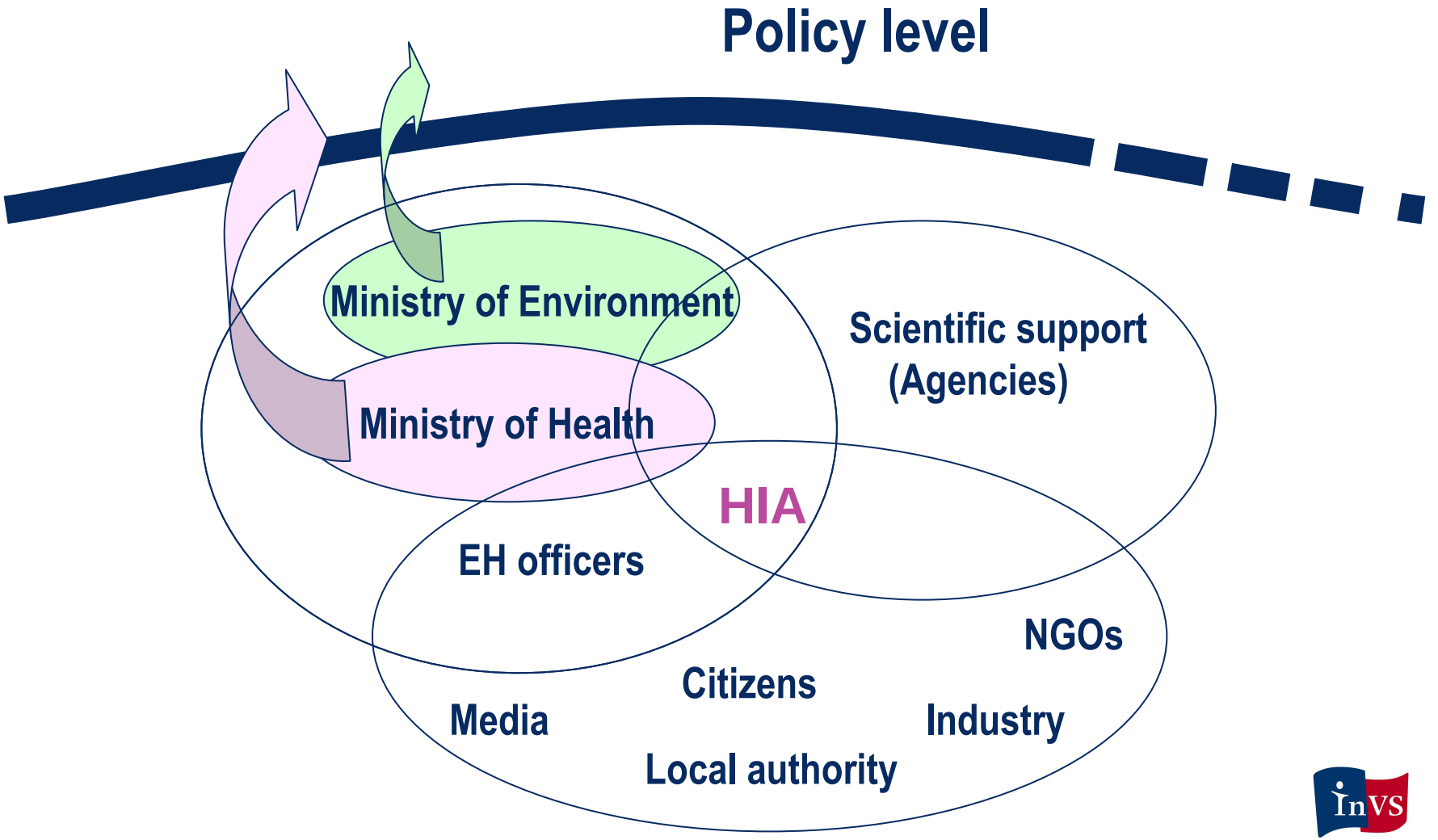
Collective results



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COPHES
Consortium to Perform Human Biomonitoring on a European Scale

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Thank you for your attention !

- At the beginning of the adventure
- Enthusiastic
- And in the good direction

http://www.invs.sante.fr/surveillance/biosurveillance/default.htm

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