

COPHES

Consortium to Perform
Human Biomonitoring
on a European Scale

DEMOCOPHES

Demonstration of a study to
coordinate and perform
human biomonitoring
on a European Scale

HUMANI BIOMONITORING V EVROPI



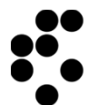
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**Harmonizacija
biomonitoringa v evropskem
in slovenskem prostoru**

Milena Horvat, Janja Snoj Tratnik,
Darja Mazej
Institut Jožef Stefan, Ljubljana

*4. posvet kemijska varnost za vse,
Novo mesto, maj 2012*



Institut "Jožef Stefan", Ljubljana, Slovenija



Twin projects : learning by doing

- COPHES

- FP7 funding
- Methodologies
- Support

1



- DEMOCOPHES

- LIFE+ funding
- Pilot survey
- Concrete results



Policy context

Action 3 of the EHAP - 2004

- *We will develop a coherent approach to human biomonitoring in Europe*
 - Council Conclusions 2007
 - Paris Conference 2008
 - Berlin and Brussels Conferences 2010
 - Council conclusions 2010
 - Budapest symposium 2011
 - HBM week 2011

Commitment to act – 2010

- *We will contribute to develop a consistent and rational approach to human biomonitoring as a complementary tool to assist evidence-based public health and environmental measures, including awareness-raising for preventive actions*
 - Collaboration WHO-COPHES 2011



COPHES

35 partners coming from 27
European countries

Work Package leaders:

WP1: Ludwine Casteleyn

WP2: Marike Kolossa-Gehring

WP3: Argelia Castaño
& Jürgen Angerer

WP4: Greet Schoeters

WP5: Ovnair Sepai

WP6: Milena Horvat
& Luis Bloemen

WP7: Lisbeth Knudsen

WP8: Anke Joas

1



2



3



4



5



DEMOCOPHES

21 partners coming from 21
European countries

TASKS:

1: National protocols – Ethics

2: Recruitment & sampling

3: Chemical analysis samples

4: Data analysis & interpretation

5: Communication



Objectives

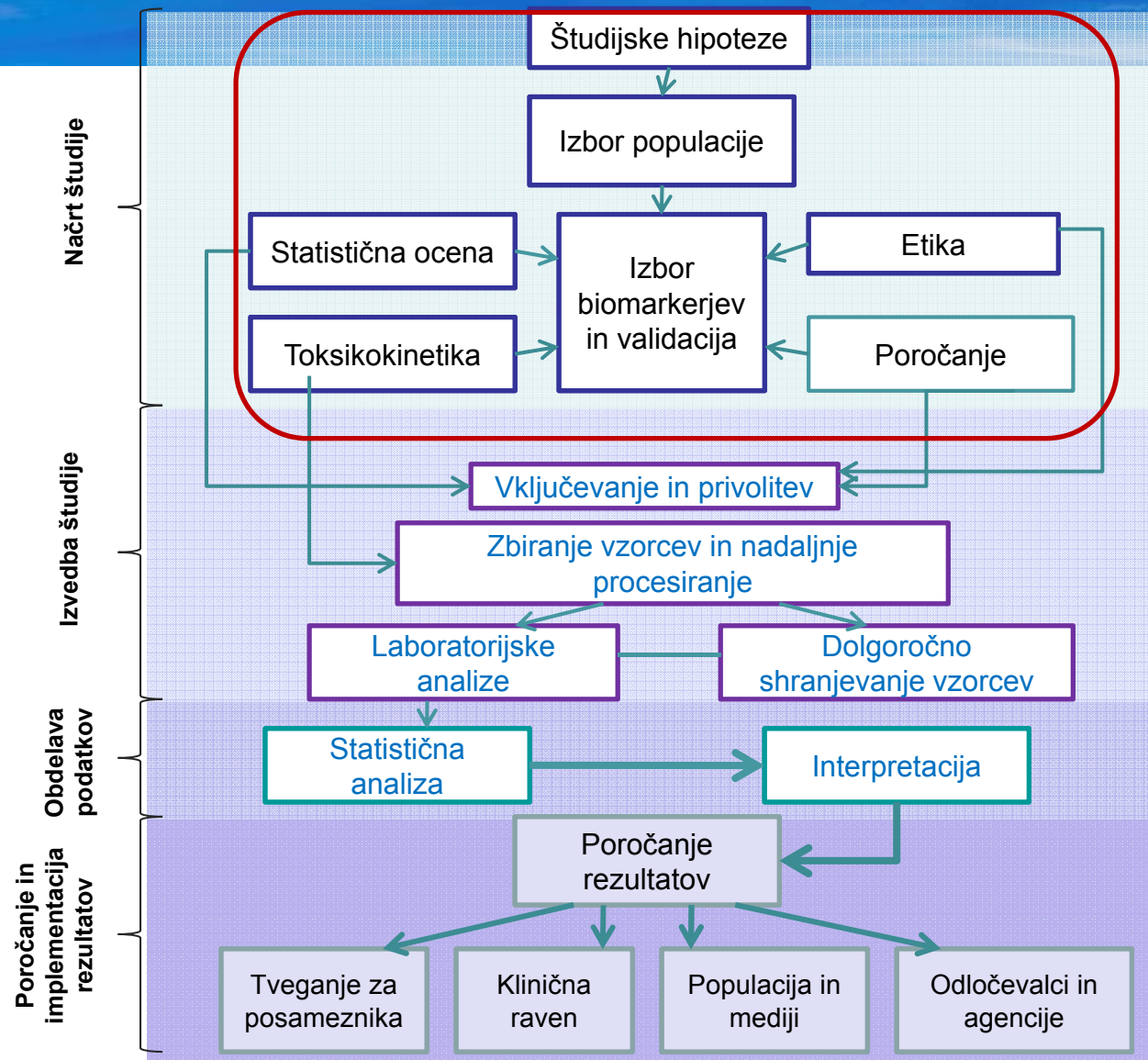
Demonstrate feasibility EU level human biomonitoring

- ⇒ Capacities, networks & infrastructure
- ⇒ Comparable results
- ⇒ Use of HBM for policy development across Europe





Stopnje izvajanja HBM





Sodelovanje v raziskavi

K raziskavi smo povabili:

- matere (do 45 let) in njihove otroke (6-11 let)
- moške iz istega gospodinjstva (20 do 45 let)

N (mama/otrok) = 60 za vsako območje

Območja raziskave:

- mestno okolje LJUBLJANA
- podeželsko okolje ŠMARJE PRI JELŠAH



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Cilji – HBM v Sloveniji

Kratkoročni cilji:

- Izpostavljenost prebivalcev kemikalijam in s tem povezanimi vplivi
- Referenčne vrednosti
- Prostorske razlike izpostavljenosti

Dolgoročni cilji:

- Izpostavljenost in ocena tveganja
- Izvedba ukrepov in spremljanje njihove učinkovitosti
- Ocena tveganja na podlagi strokovnih dognanj in podatkov (ozaveščanje, individualno svetovanje, komunikacija, ...)
- Časovni trendi.



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Študijska populacija

- Doječe matere in partnerji z istih območij
- starost: 20-40 let
- 12 območij: mestna, podeželska in onesnažena
- 50 žensk in 50 moških z vsakega območja (skupno 1200 preiskovancev)



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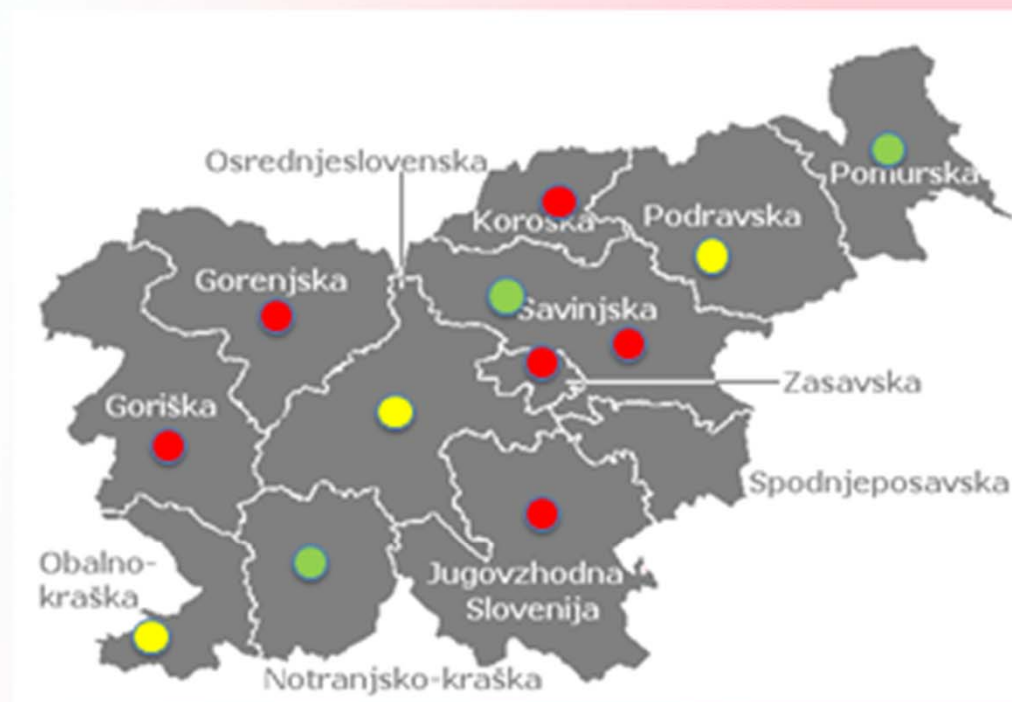
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Preiskovana območja



- Onesnažena območja
- Mesta
- Podeželje



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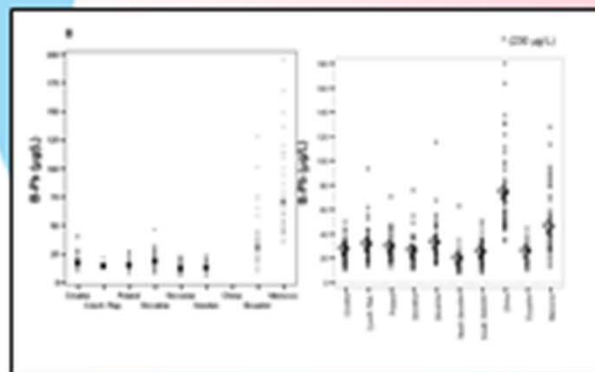
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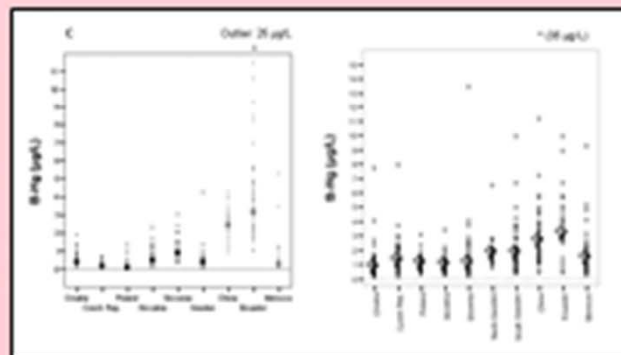
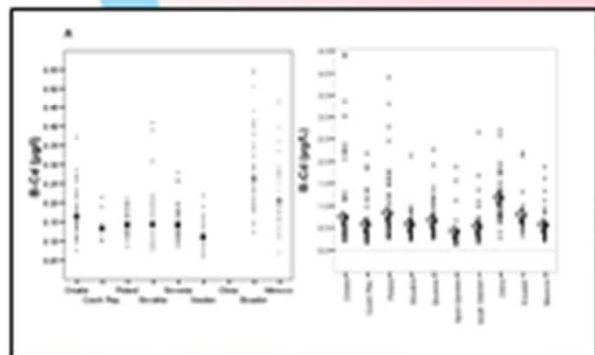
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Kovine v krvi: otroci in ženske (2003 – 2007)



- PHIME, 7th FP
- Študije na nacionalni ravni – kontaminirana okolja
- EU študije



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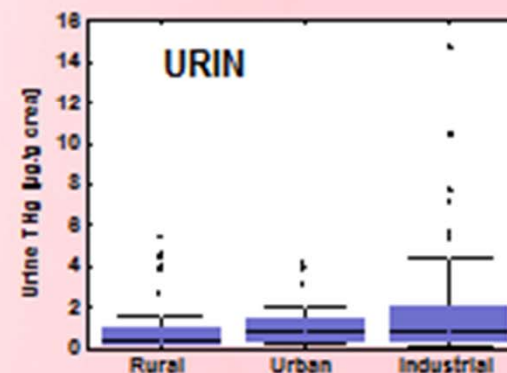
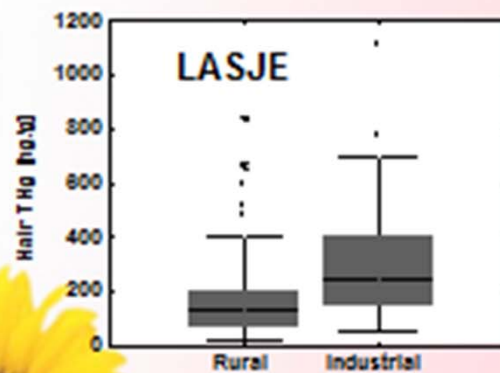
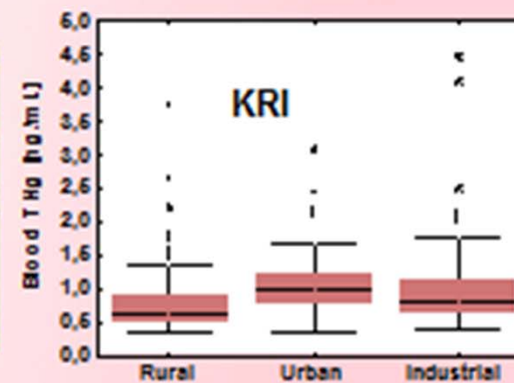
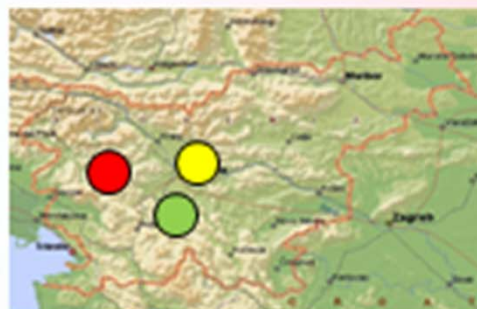
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HBM, 2008, otroci 6-11 let

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DEMOCOPHES – kdo?

- matere ali rejnice (do 45 let) in njihovi otroci (en otrok na družino) v starosti od 6 do 11 let (rojeni med letoma 2000 in 2005)
- Vsaj 5 let bivanja na istem območju
- Očetje ali partnerji oz. moški iz istega gospodinjstva (20-45 let)



Kriteriji za sodelovanje v raziskavi

Pogoji za vključitev v raziskavo:

- življenje in delo na območju zadnjih 5 let,
- za ženske: prvi otrok (ne dvojčki),
- normalna nosečnost,
- materino mleko je izključna hrana dojenčka,
- dostopnost matere 6 – 8 tednov po porodu.

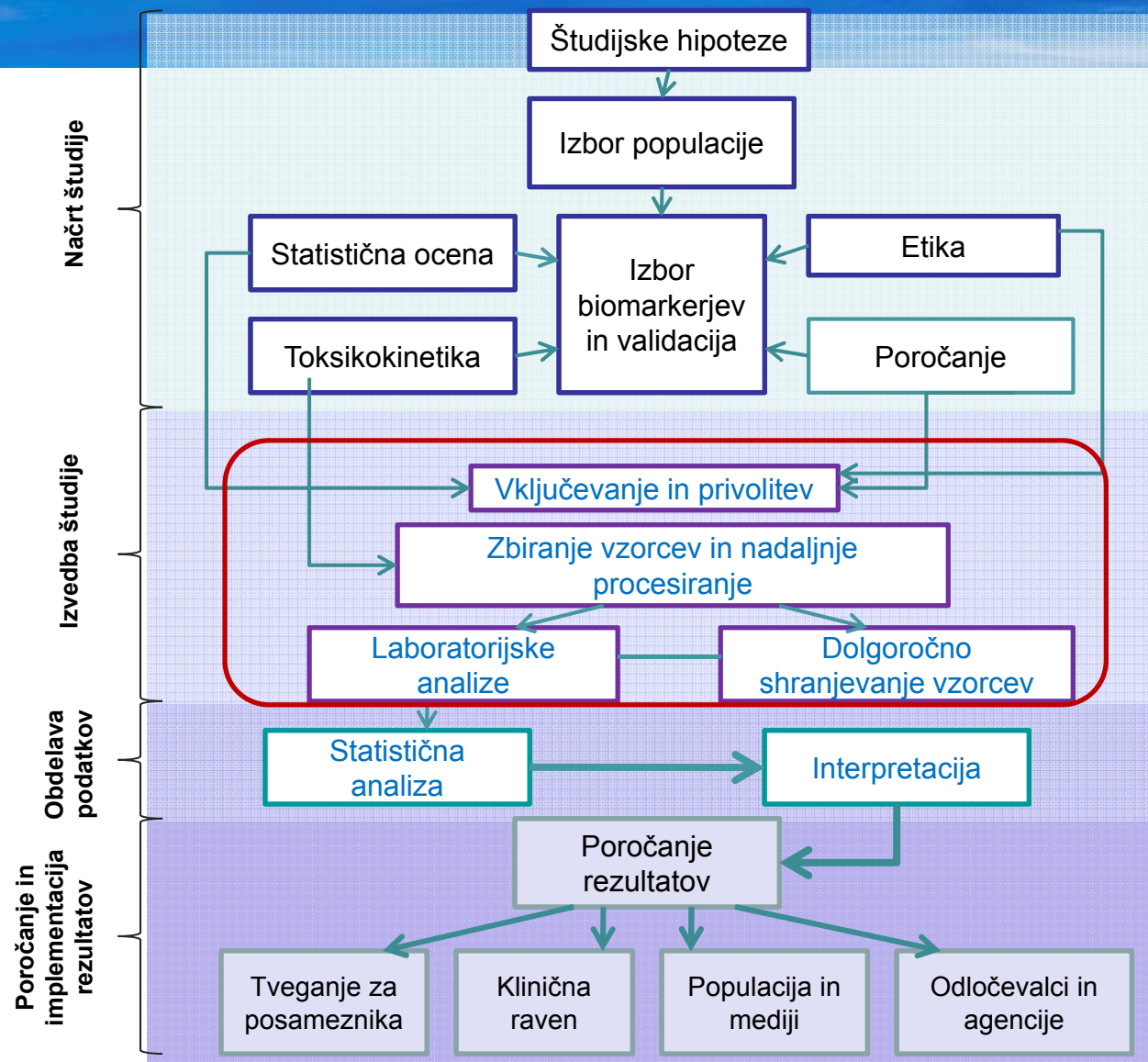
Izključitveni kriteriji:

- kronične bolezni (diabetes, ledvične, jetrne težave, resne prebavne težave, ...),
- poklicna izpostavljenost,
- kajenje,
- uživanje alkohola ali drugih narkotikov/drog,
- življenje v bližini deponij odpadkov ali drugih virov onesnaženja (razen v onesnaženem območju).





Stopnje izvajanja HBM





Potek raziskave - DEMOCOPHES

**Povabilo in
seznanitev z
raziskavo**

Odgovor

Dogovor

Vzorčenje

**Analiza
vzorcev**

september 2011

oktober – december 2011

2012

ŠOLA
roditeljski
sestank

Otrok prinese
obrazec z
odgovorom učiteljici

Raziskovalec
pokliče mamo in
se dogovori za
vzorčenje

Na dom
prejmejo
lonček za
zbiranje urina

Informiran pristanek
Prezem vzorcev
urina
Odvzem vzorcev
krvi in las
Vprašalnik

Prejem
rezultatov

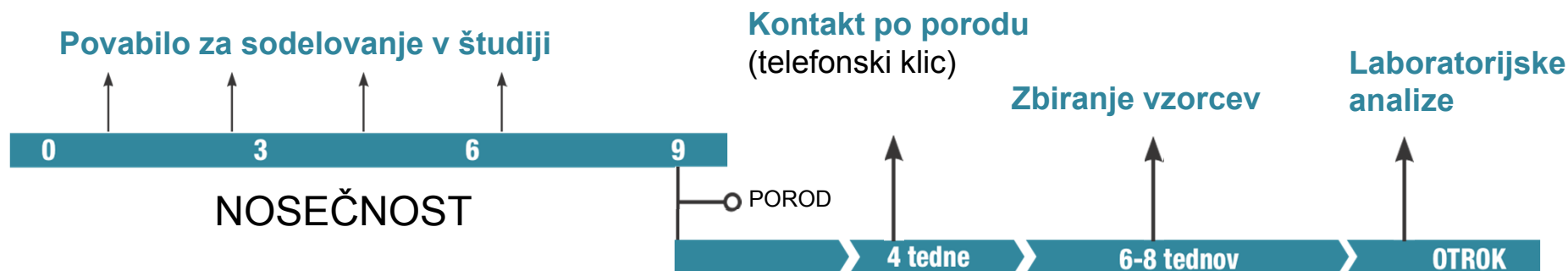
*Identifikacijska številka zagotavlja
zasebnost podatkov.*



Protokol študije v RS

- Šola za starše
- ginekolog
- porodnišnica

- ginekolog
- zdravstveni dom - laboratorij
- obisk na domu



1. Informiran pristanek
2. Vprašalnik
3. Mati prejme posodice za vzorčenje urina in mleka ter pumpico za mleko

1. Prejem vzorcev urina
2. Odvzem vzorcev las
3. Vprašalnik po porodu

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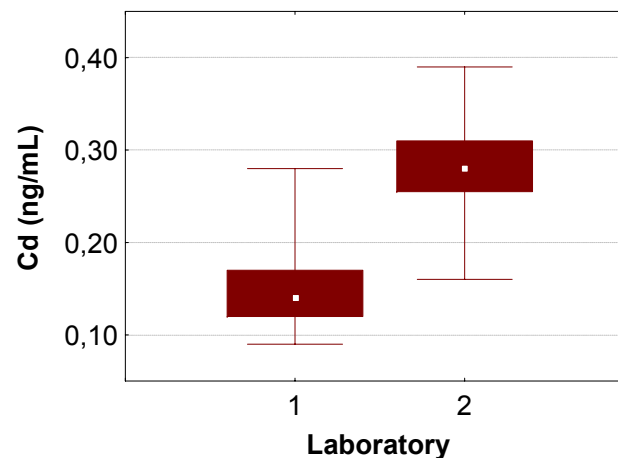
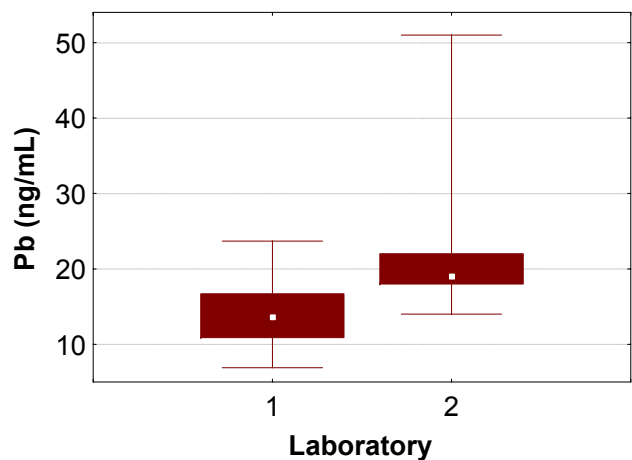


Chemical analysis

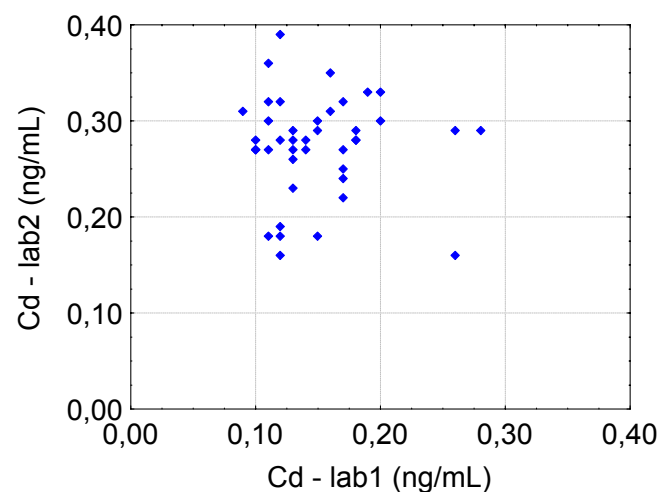
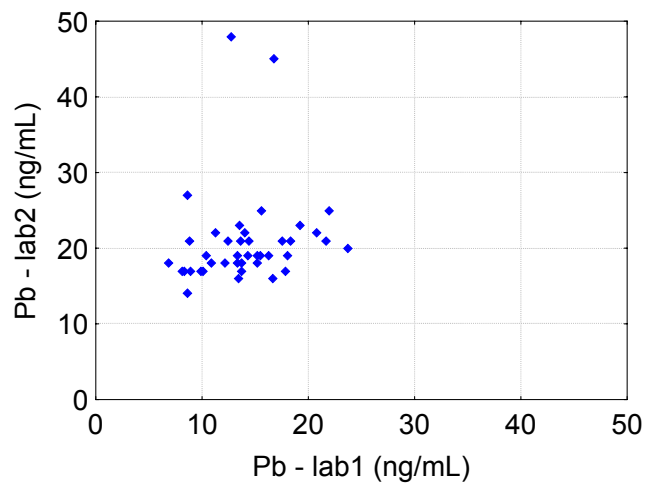
- Measurements of low concentration
⇒Challenges:
 - Apt methods used: low LOQ
 - Differences between labs < differences measured
 - Calibrating analytical results
- 1 year procedure for quality assurance:
ICI / EQUAS
 - About 20 reference labs
 - Around 30 labs selected out of around 40 labs



Pb in Cd primerjava rezultatov dveh laboratorijev (n=50)

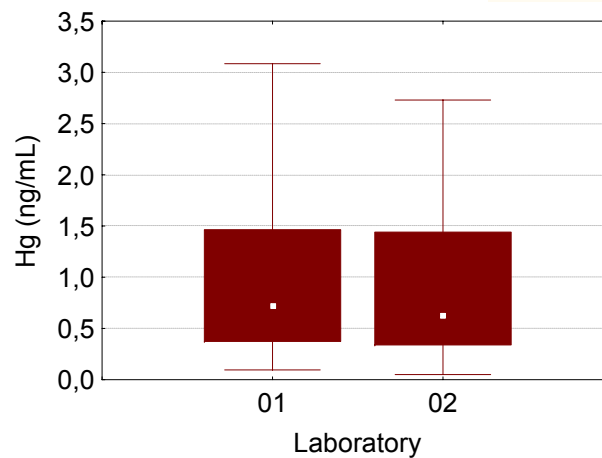
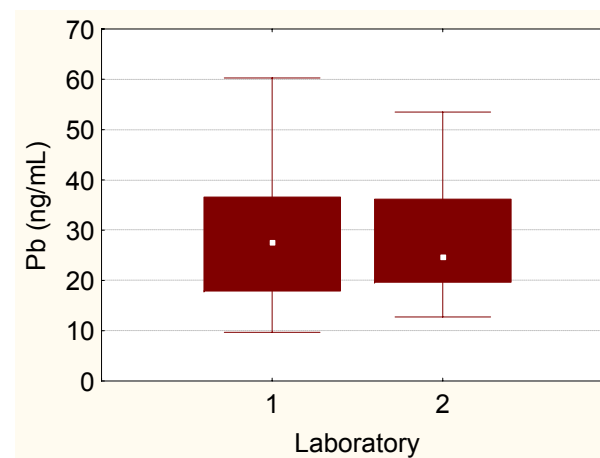
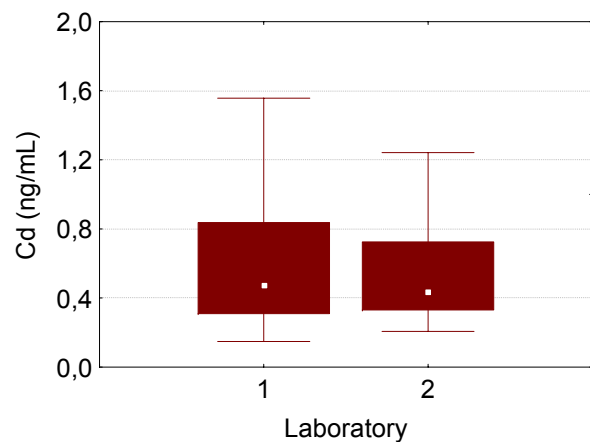


Legend:
□ Median
 25%-75%
| Min-Max



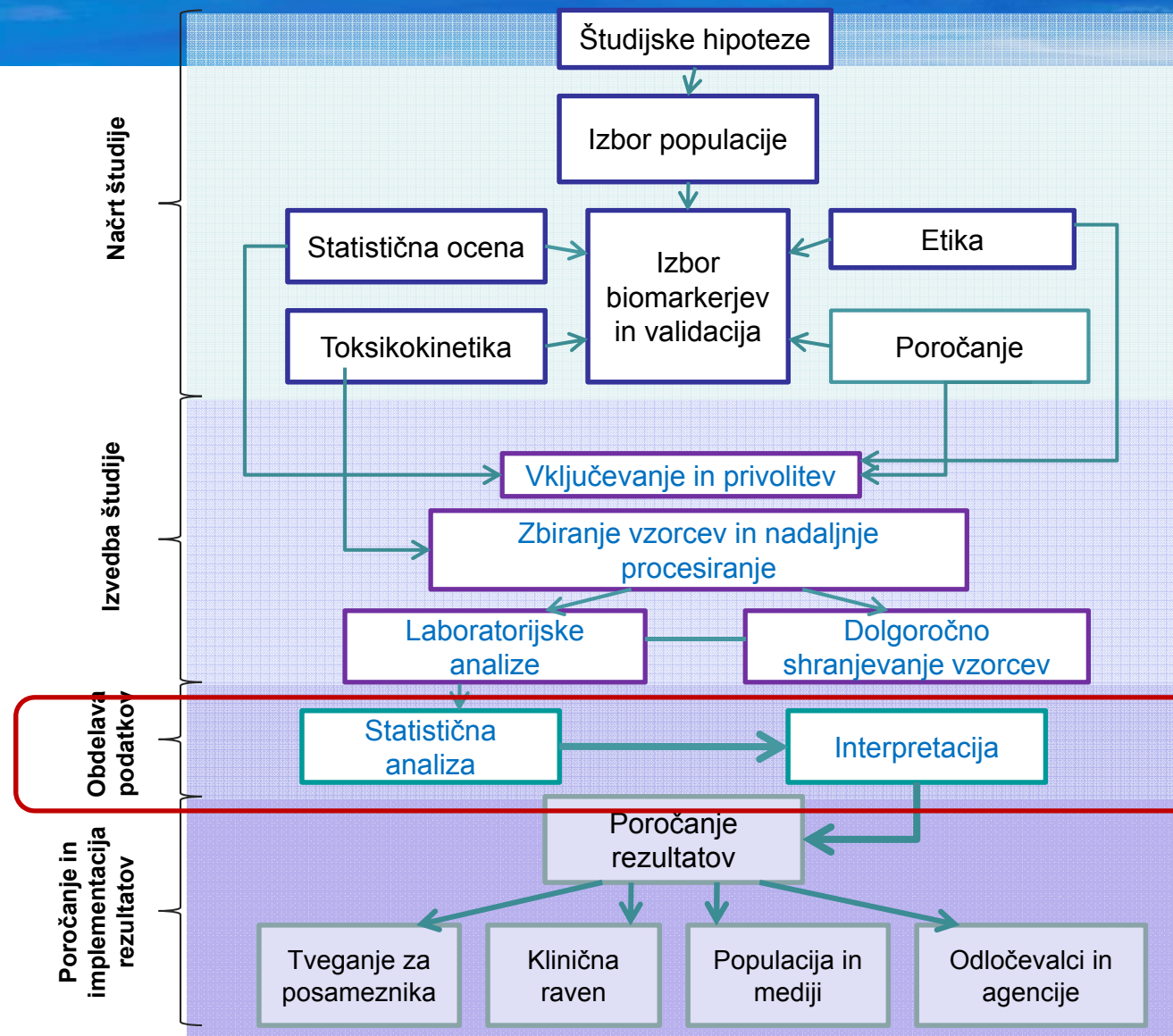


Cd, Pb, Hg v krvi: primerjava dveh laboratorijev (n=50) – po korektivnih ukrepih





Stopnje izvajanja HBM





Interpretacija (1)

Osnovne kemikalije



- **Hg: ribe**
⇒ poškodbe osrednjega živčnega sistema v razvojni dobi



- **Kadmij: baterije, hrana na kontaminiranih območjih**
⇒ poškodbe ledvic, okvare srčno-žilnega sistema in povečano tveganje za raka. Negativno vpliva na kostno gostoto.



- **Kotinin: kajenje**
⇒ povečano tveganje za raka, astmo in srčno-žilne bolezni

- **Ftalati: dodatki v plastiki**
⇒ hormonske motnje (npr. prezgodnje rojstvo, genitalne okvare, zmanjšanje produkcije sperme, prezgodnja puberteta).





Interpretacija (2)

Dodatne kemikalije

- **Bisphenol A:** proizvodnja barv, lakov in lepil ter termo-papirja
⇒ Plodnost, razvojne motnje, bolezn srca in ožilja, diabetes
- **Triclosan:** v sredstv za osebno nego
⇒ Motnje delovanje ščitnice, dermatitis&alergije



- **Parabeni:** medicina, kozmetika & prehrana
⇒ Plodnost, razvojne motnje, bolezn srca in ožilja, diabetes



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Biomarkerji

Analize		
Vzorec		
Materino mleko	Cd, Hg, As, Pb, Se PCBs (28, 52, 101, 138, 153, 180) trigliceridi, holesterol	PCDD, PCDF, dioksinom podobni PCB, PBDE
Kri - ženske	Hemogram Pb, Cd, Hg, As, Cu, Zn, Se	
Kri - moški	Hemogram Pb, Cd, Hg, As, Cu, Zn, Se PCBs (28, 52, 101, 138, 153, 180) trigliceridi, holesterol	PCDD, PCDF, dioksinom podobni PCB, PBDE
Urin	Cd, Hg Kazalci ledvične funkcije (albumin, alfa-1- mikroglobulin, IgG, NAG), TSH, kreatinin	
Lasje	Hg	

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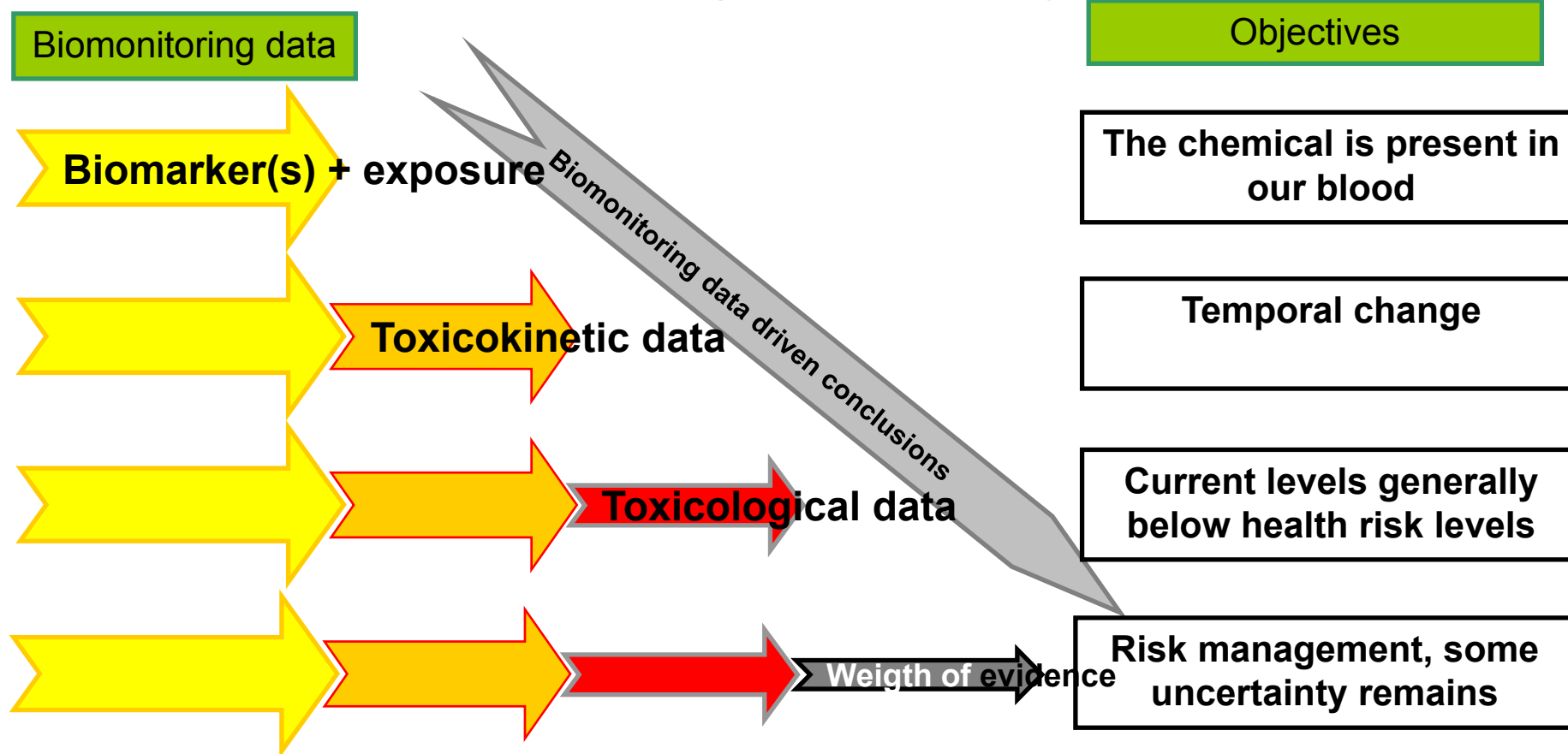


Are the observed levels reason for concern?

- **No legally binding standards** for dose
- (Occupational) standards exist
 - Biological Exposure Indices
 - Threshold Limit Values
- **Health-based guidance values**
(WHO, TDI, German HBM-I & HBM-II)
- **Comparison** to international data
 - CDC reports
 - German, Flemish HBM
- **Increases** in time or space
 - Requires repeated sampling or historical data
 - GerES & the German Environmental Specimen Bank



INTERPRETATION = CHALLENGE



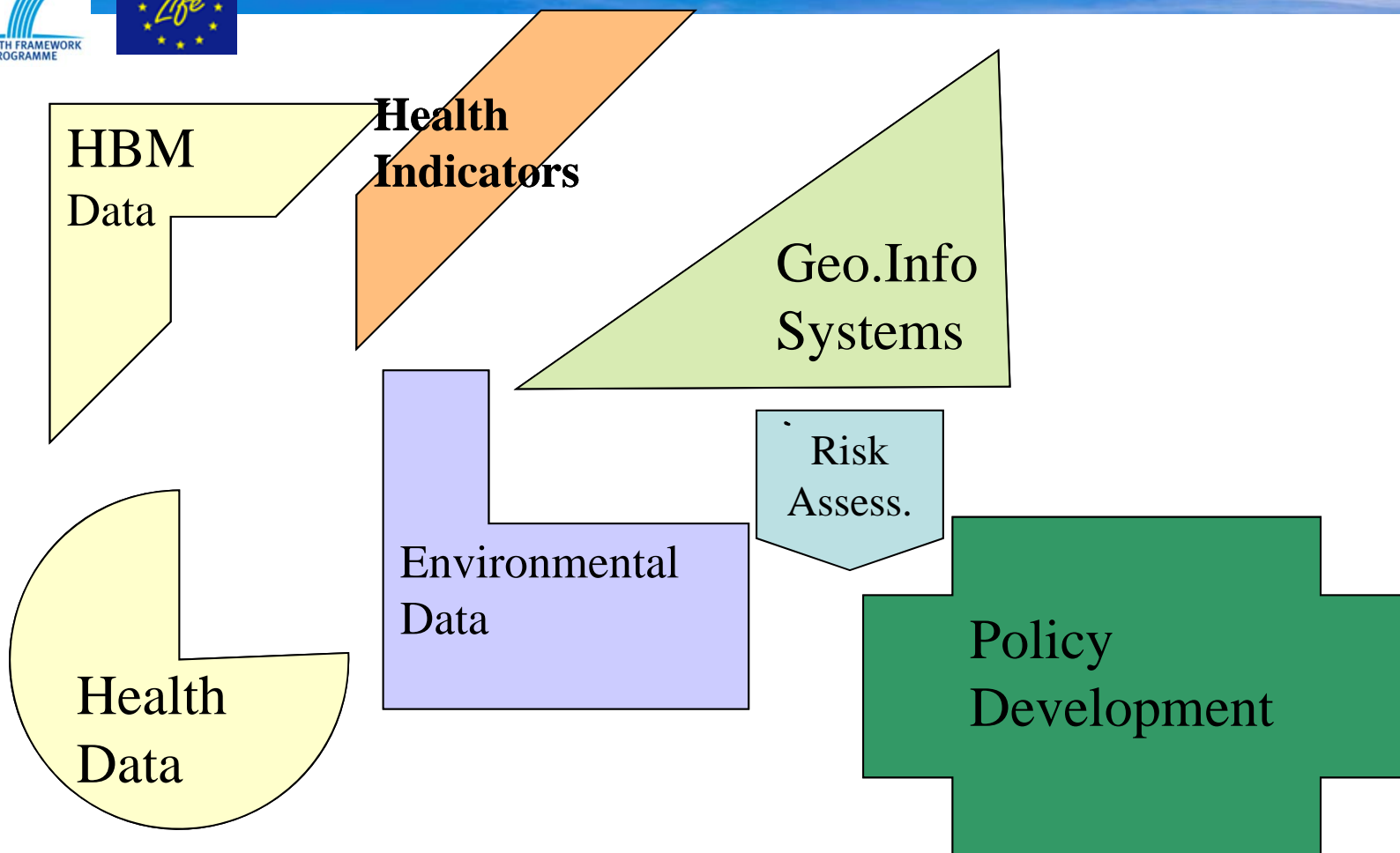
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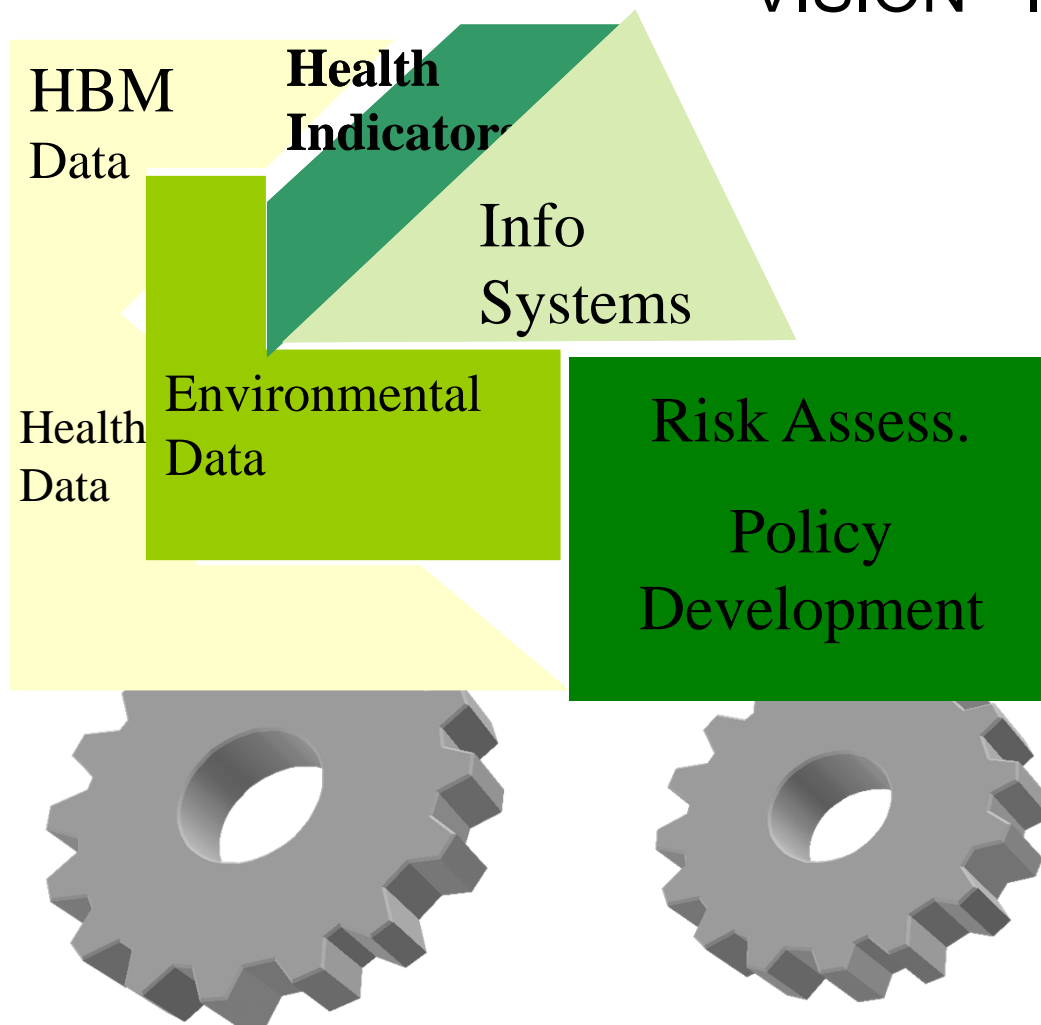
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VISION - Integrated approach



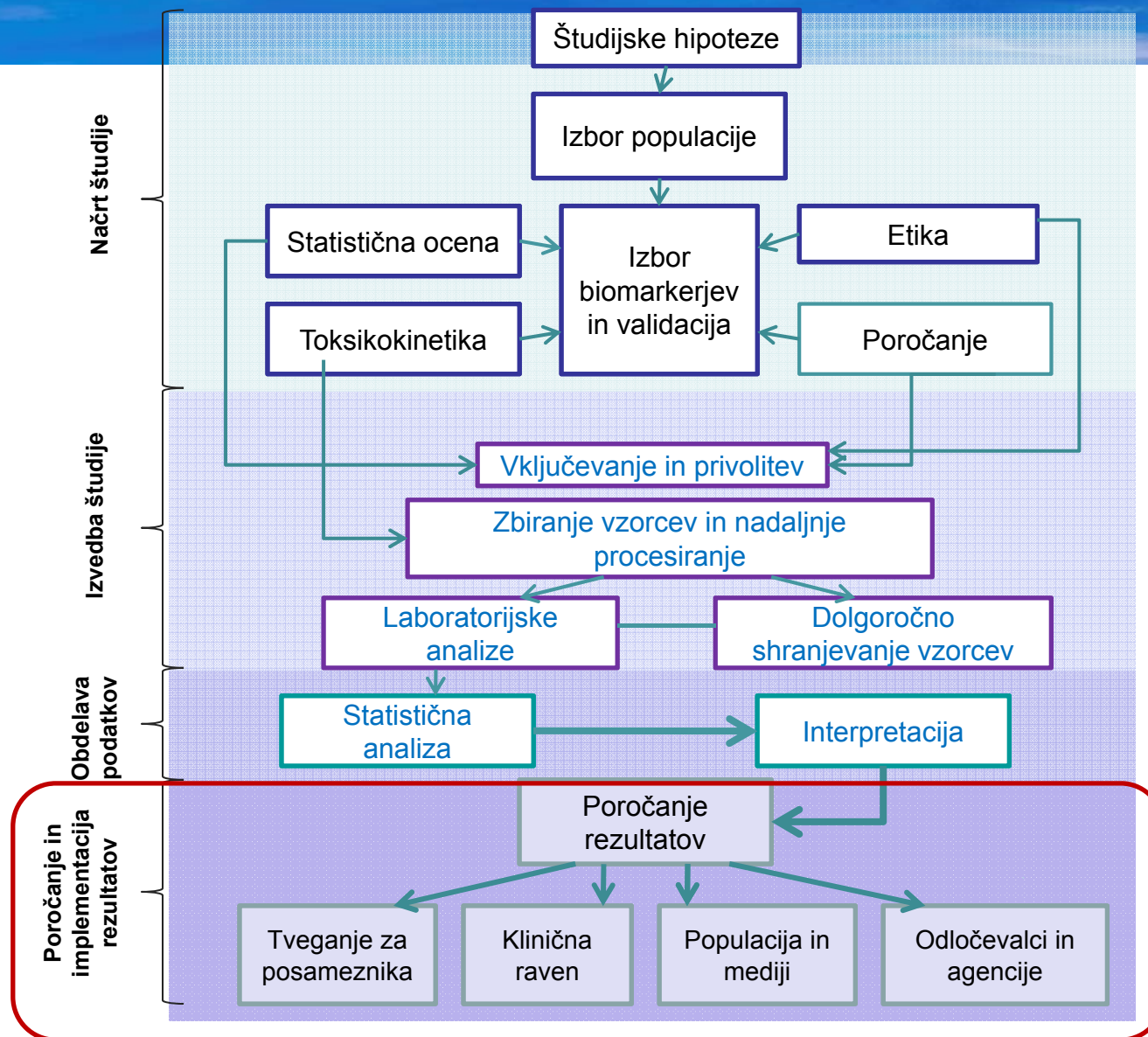


Difficulties

- Integrative uptake makes **source identification** difficult
- **Invasive methods** may hamper routine application
- Toxicology/Pharmacokinetics not always known
- Lack of **interpretation capacity**



Stopnje izvajanja HBM



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CHALLENGES FOR COMMUNICATION

- How to deal with the ‘right to know’ of the study participants when the links with health risks, especially at the individual level, are not well defined?
- How to feed public debate/raise awareness, without raising unnecessary alarm?
- How to report (uncertainty) to the relevant authorities?
- How to assure accurate translation of results into policy?
- How to deal with the controversial discussion on (potential) low dose effects and “correctness” of TDI?



History of risk communication

- All we have to do is get the numbers right
- All we have to do is tell them the numbers
- All we have to do is explain what we mean by the numbers
- All we have to do is show them they've accepted similar risks in the past
- All we have to do is show them that it's a good deal for them
- All we have to do is treat them nice
- All we have to do is make them partners
- All of the above

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DATA PROTECTION IS HIGHLY DEVELOPED IN THE EU

- Central piece: [Directive 95/46/EC](#)
- Regulates the protection of individuals with regard to the processing of personal data and the free movement of such data.
- Framework law
- Implemented into national laws
- Applies to all EU MS, as well as to Iceland, Liechtenstein and Norway.



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Recommendations

- Including upcoming regulatory changes which are not yet implemented
- Including current discussions at regulatory level but for where consensus is lacking at the moment
- Including discussions at scientific level that did not yet reach the policy field
- **THE PRECAUTIONARY PRINCIPLE**



Zaključek – HBM Slovenija

Nabor preiskovancev je najzahtevnejša stopnja izvajanja programa HBM v Sloveniji. *(Komunikacija !!!!)*

Implementacija rezultatov:

Organiziranost sodelovanja med ključnimi institucijami (MZ, IVZ, ZZV-ji, okoljski sektorji na ministrstvih, znanost&izobraževanje, itd..) *(Komunikacija!!!).*



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“The ability to generate new biomonitoring data often exceeds the ability to evaluate whether and how a chemical measured in an individual or population may cause a health risk or to evaluate its sources and pathways of exposure” (NRC 2006)