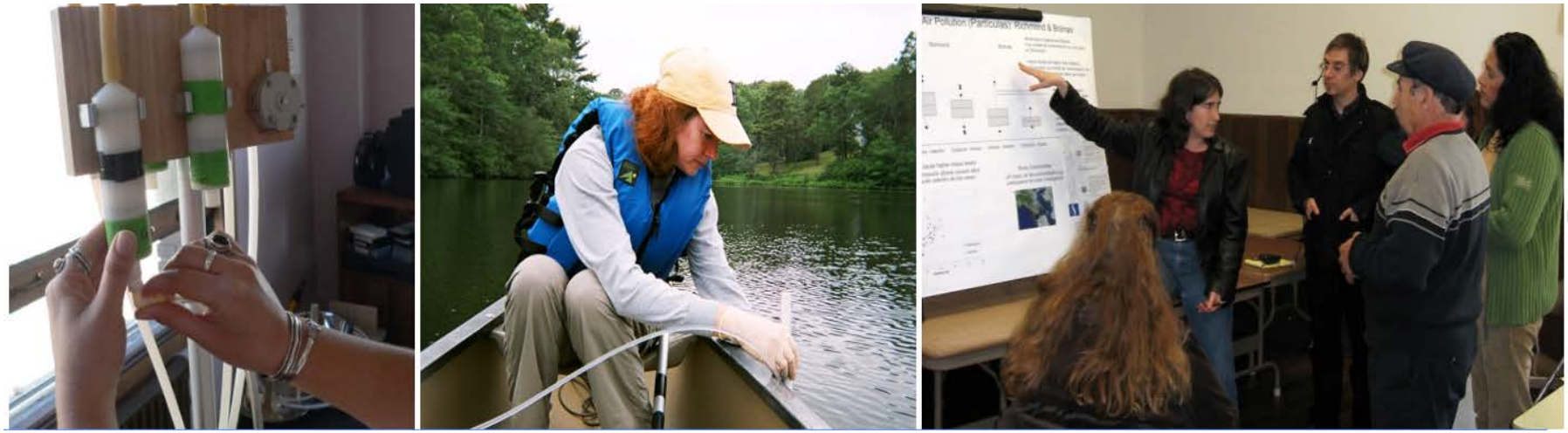
Educating Biomonitoring Participants About their Exposure to Environmental Chemicals: What Does the Science Say?



Rachel Morello-Frosch, Ph.D., M.P.H
University of California, Berkeley
School of Public Health & Department of Environmental Science Policy and Management
rmf@berkeley.edu

Overview

1. Scientific challenges in communicating about chemical exposures
2. Ethical frameworks
3. Lessons from genetics and brain imaging research
4. Study participant experiences with report-back on chemical exposures
5. Implications for ethical decision-making

Photo: R. Morello-Frosch

Biomonitoring: Opportunities and Challenges

New technologies for exposome research

- Increased capacity, specificity, sensitivity
- Techniques are more affordable and widely available

Technology outpaces knowledge about chemical impacts on health

- Particularly for "emerging pollutants"
  - Phthalates, flame retardants, others

Indicates exposures, but often says little about sources

- *"None of these chemicals come with a return address." - biomonitoring participant*

Photo: EHP

Example: Blood lead > guideline

- Beneficence
  - Avoid harm
  - Maximize benefit
- Autonomy - Respect for persons
- Justice

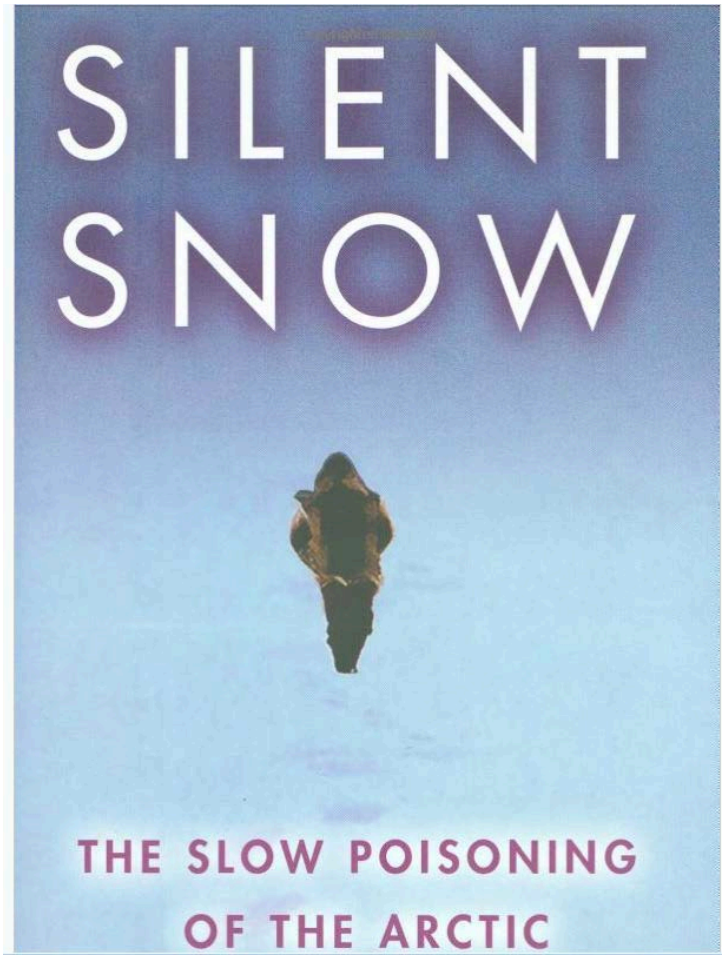
Harder examples:

- Phthalates, BPA, flame retardants, PFCs, DDT
- Pesticides in farmworker family

Ethical Tensions

- Individual vs. community protections
- Right to know vs. ability to act
- Scientific uncertainty and incidental findings

Inuit Example



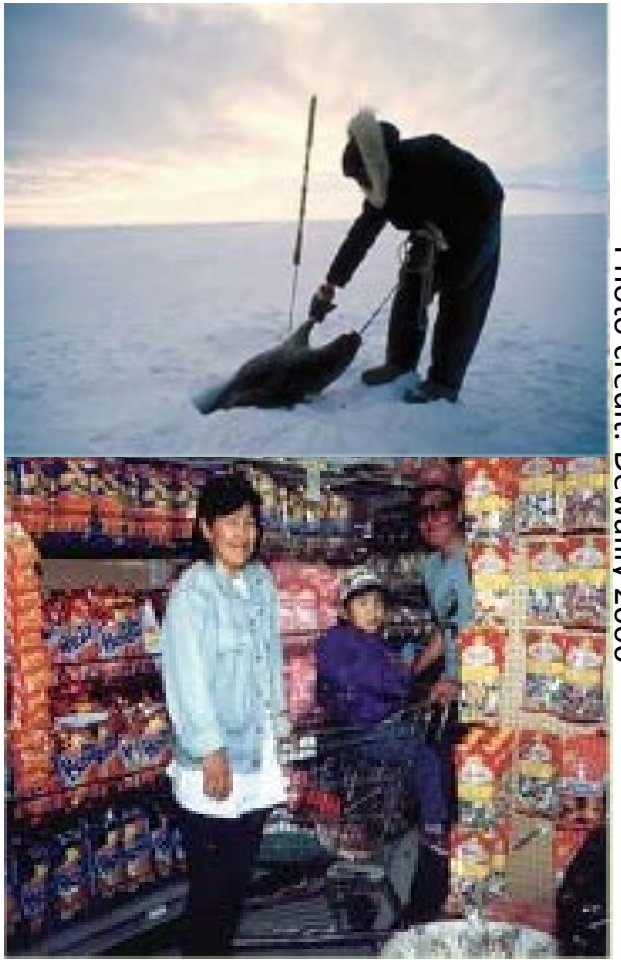


Photo credit: Dewailly 2006

With science uncertain…

What (if anything) should researchers tell study participants about chemical exposures?

- Particularly their personal exposure results from biomonitoring studies?

Clinical Ethics

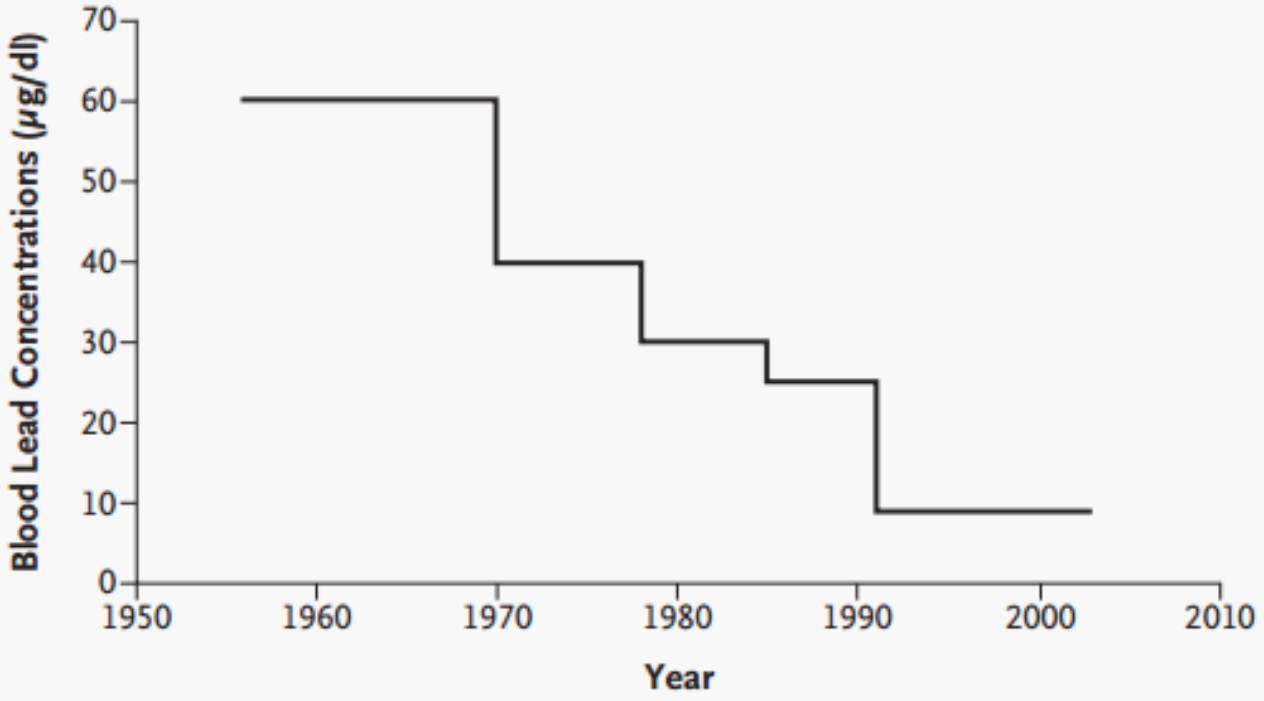
Premise: Report only on known relationships to health

- Biomedical orientation and expert-driven (e.g. health professionals decide)

Drawbacks: Contradicts current medical ethics of:

- Empowering patients to be proactive in directing their health care
- Limits participants' learning, opportunities for prevention
- Potential health effects below action levels
  - lead
  - mercury

Guidelines change based on new knowledge



Blood Lead Concentrations Considered to Be Elevated by the Centers for Disease Control and Prevention.

To convert the values for blood lead concentrations to micromoles per liter, multiply by 0.0483. Data are from the Centers for Disease Control and Prevention, 1991.[1]

Open Notes Project

Delbanco et al. 2010, 2012

Patients invited to view doctor visit notes online to:

- Improve understanding of indicators of their health status;
- Enhance communication & shared decision-making.

Results:

- Patients more likely to adhere to medication regimens;
- More informed and in control of health care;
- Few privacy concerns, worry or confusion.

http://www.myopennotes.org/about-opennotes/project-team/tom-delbanco/

Lessons from other fields

GENETIC RESEARCH

Advanced technology has catalyzed large-scale projects and increased access to genetic information.

NEUROIMAGING RESEARCH

Increased demands by study participants to know their individualized data in imaging studies, despite uncertainties about clinical significance.

How have these fields grappled with communicating results to study participants?

Does communicating with patients about chemical exposures cause undue worry or harm?

Lessons from genetics research

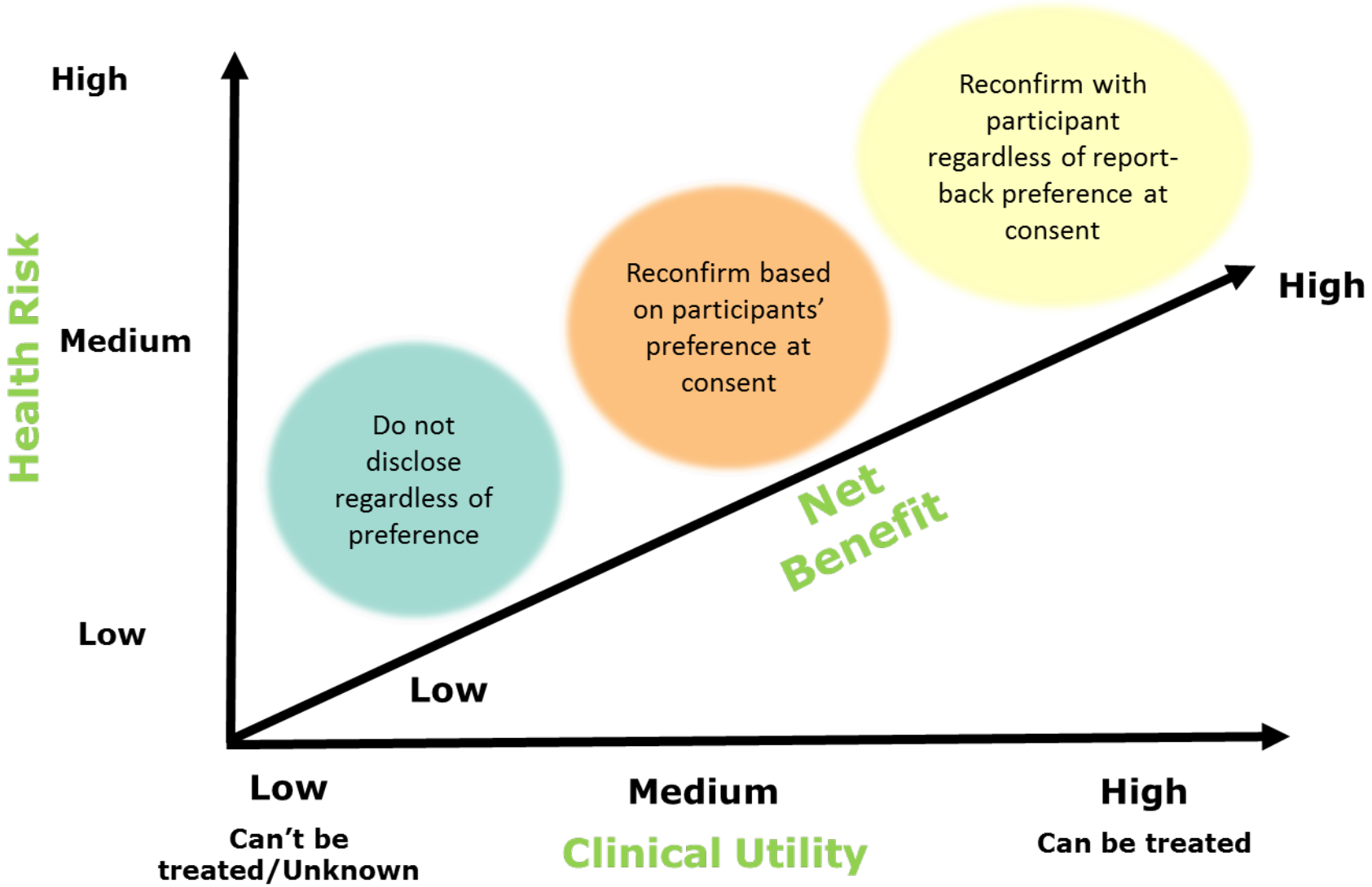
Strong patient support for genetic results, despite uncertainties regarding health implications

- Learning results major motivator for study participation
- 75% of 4500 respondents (Kaufman et al. 2008)

Reporting of genetic results may not cause undue worry

- Randomized study on psychological effects of disclosure of apolipoprotein E (APOE) associated with Alzheimer's disease did not lead to more anxiety and depression (Green et al., 2009)

A Priori Considerations for Incidental Findings



Does communicating chemical exposures cause undue worry or harm?

Patients/study participants (including pregnant women) want personal information on exposures to environmental chemicals.

- Majority believe they have the right-to-know

  (Brody et al., 2007; Morello-Frosch et al., 2009 2015; Nelson et al., 2009a; Sly et al., 2009; Wu et al., 2009).

- 97% of participants wanted exposure information even if health implications are unclear (Brody et al., 2007).

Knowledge of chemical exposures does not necessarily lead to counter-productive responses

- Concern about chemical exposures does not change duration of breastfeeding (Wu et al. 2009)

New research ethics statements – movement toward "right to know"

"…any information collected about a person should be provided to that person if requested."
–*Statistics Canada*

"…subjects should be told…whatever researchers know (or do not know)."
-National Academy of Sciences

What participants want to know.

What did you find?

How much?

Is that high?

Is it safe?

Where did it come from?

What should I do?

Personal Exposure Report-Back Ethics (PERE) Study

Methods

- Interviews with researchers, study participants, IRB members in 8 studies
- Workshop for 44 stakeholders
- User testing of biomonitoring reports
- DERBI - digital exposure report-back interface
- Collaborators: Silent Spring Institute, UC Berkeley, Northeastern, Harvard, and Commonweal, funded by NIH
- Prior evaluation of personal exposure report-back methods on our own studies funded by NSF

Interviews with study participants

- 60-90 minutes, in-person
- Participants from different exposure/biomonitoring studies
- Transcribed,
- Coded and analyzed for themes using NVivo

- How do people find meaning in their results?
- What is their experience?

Chemicals in Our Bodies Study
(aka: Maternal and Infant Envt. Exposure Project)

- Pregnant women obtaining prenatal and delivery care at San Francisco General Hospital
- Measure chemicals in mothers and their babies at delivery
- Pilot biomarkers of stress response – telomeres
- Pilot questions about perceptions of chronic psychosocial stress
- English or Spanish speaking
- Collaborators: Biomonitoring California, UCSF, UC Berkeley

Characteristic	%
Race/Ethnicity	
Latina	74
Black	13
White	7
Other	7
Country of origin	
US	32
Mexico	35
Other	33
Educational attainment	
Below high school	26
High school graduate	45
College or above	27

UCSF University of California San Francisco

Program on Reproductive Health and the Environment

BIOMONITORING CALIFORNIA

What did people learn?

- Many chemicals are detected
- Banned substances are found today
- Many sources
- Comparisons to study distributions and guidelines
- Common household chemicals are unregulated, understudied

What was their experience?

- Participants wanted their results
- Participation motivated in part by “research altruism”
- Pollution becomes personal
- Reflections on health implications
- Surprise at lack of regulation and health information
- Sense of “toxic trespass”

Key reflections

- Frustration at information gaps
- Evolving interpretations, brainstorming
- Motivation to reduce exposure

"… what I would want from this study, is give me something I can do about it. Don't just give me information that tells me I have problems….Because that's frustrating, you know? But I'm proactive enough that I'll say, 'Ok, I have this information now it's up to me to do something.'"

Differences in reactions to receiving results

The first that caught my attention was how I was exposed. Like I had said, I don't work with any radiation; I don't have strong chemicals at home; I don't have anything out of the ordinary that some other person wouldn't have, so that's what…what did I do to get such harmful things in my body? And more than anything, what can I do to eliminate them? Because I don't know how much they can negatively affect me. (CIOB #337)

"I know the world we live in." (CIOB #134)

"Because I knew I was exposed to chemicals, strong chemicals. Because I had said that I was working in housekeeping (CIOB #323)"

Differences across communities

- Struggle for control
  - Lifestyle change, community action, "distancing"
- Individual vs. community action
  - Lack of trust in industry, government

"I would like to see an increase in about a factor of a hundred in the governance interference in the manufacturing process. We are at an absolute low point in governmental regulation. We are so far from what the government should be doing."

"Well, it was useful knowing that it doesn't matter how cautious you are because you are always exposed to all kinds of chemicals, also one is more aware of what one can do and the precautions one should take"(CIOB 323).

Reflections by researchers

- Opportunity for discovery
- The temptation to reassure
  - "…there's no evidence that…"
  - Outdated EPA guidelines
- Public health and good vs. bad worry
- Rethinking "health literacy" in light of
  - universal capacities and agency
  - democracy

"When science is uncertain, the goal is not a public health message to tell people what to do, but to stimulate a public conversation. Heaven knows we need to find a way to talk about health policy above the first grade level."

Recommendations

- Consider cultural context (of course)
  - Cultural competency ≠ literacy
- Engage multiple learning and visual styles (verbal, graphic, text)
- When appropriate, reinforce benefits of existing behavior (e.g., breastfeeding)
- Challenges:
  - Time gap
  - Comparison benchmarks
  - Info overload – lots of analytes

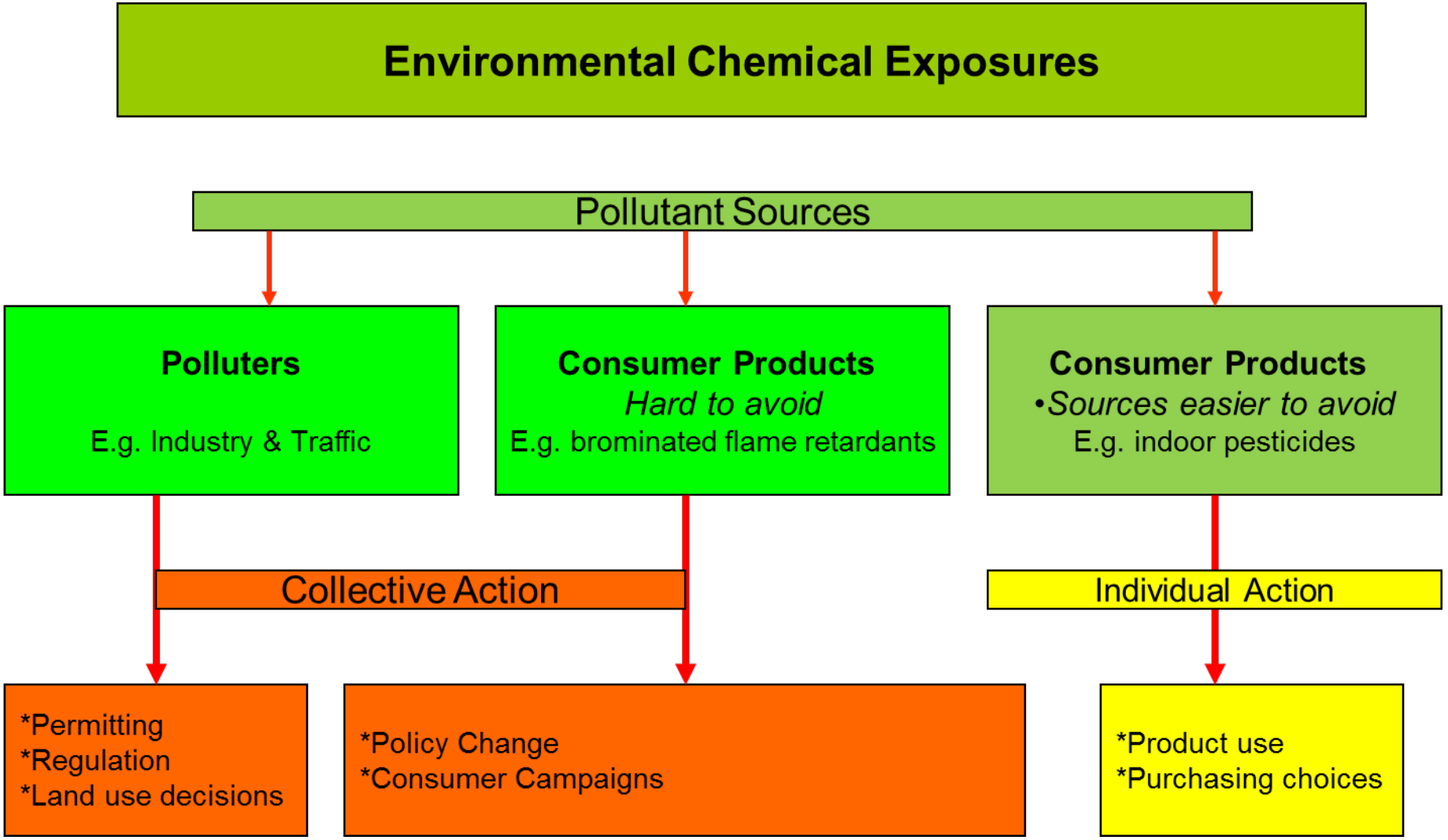
Recommendations (2)

- Address report-back ethics at consent phase:
  - Begin with "right to know …not know"
  - Set expectations for what science can/can't say about exposure and health
- Provide context to make individual results meaningful
- Address opportunities for individual and collective action

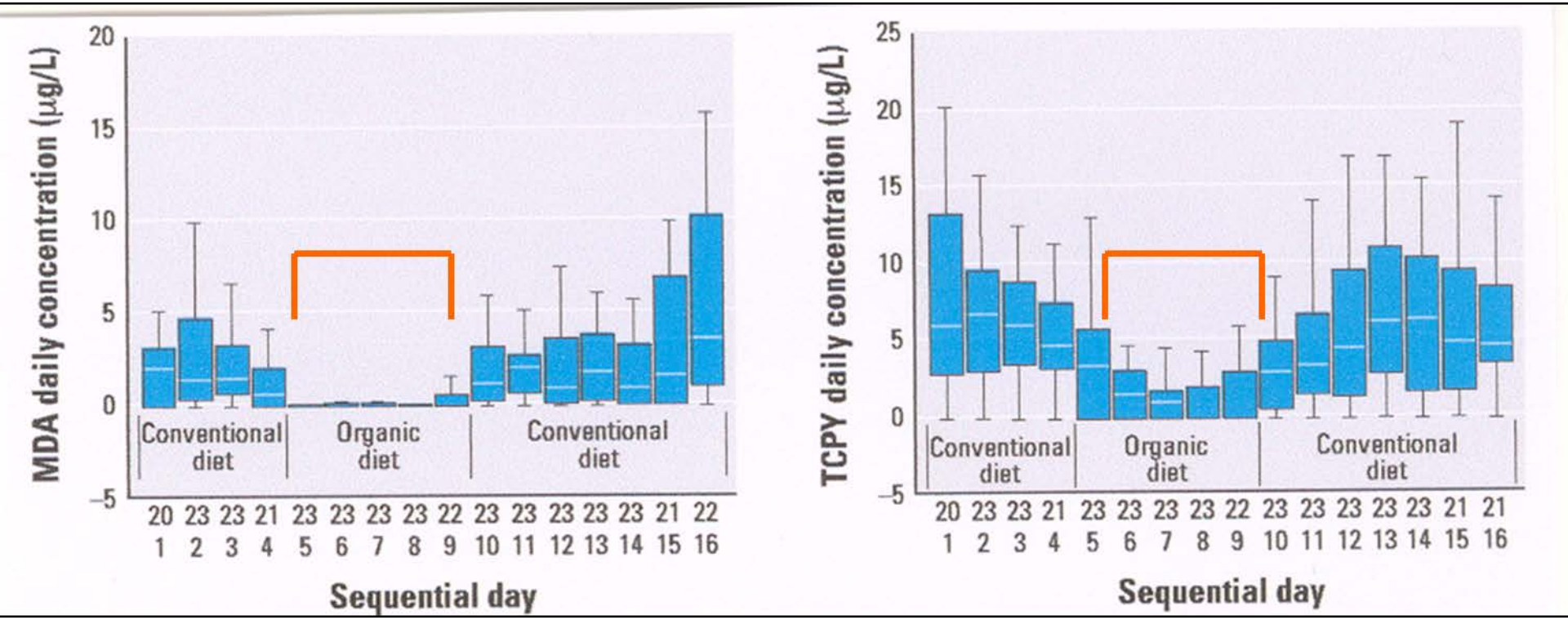
Report-back and public health

At first I was thinking, "God, I wish I didn't know all this." But the more I think about it, the more I understand it, the more I feel like it helps me to, … do whatever I can…if you know the information then you can't not participate in trying to make change.

What Can Individual Patients/Study Participants Do?



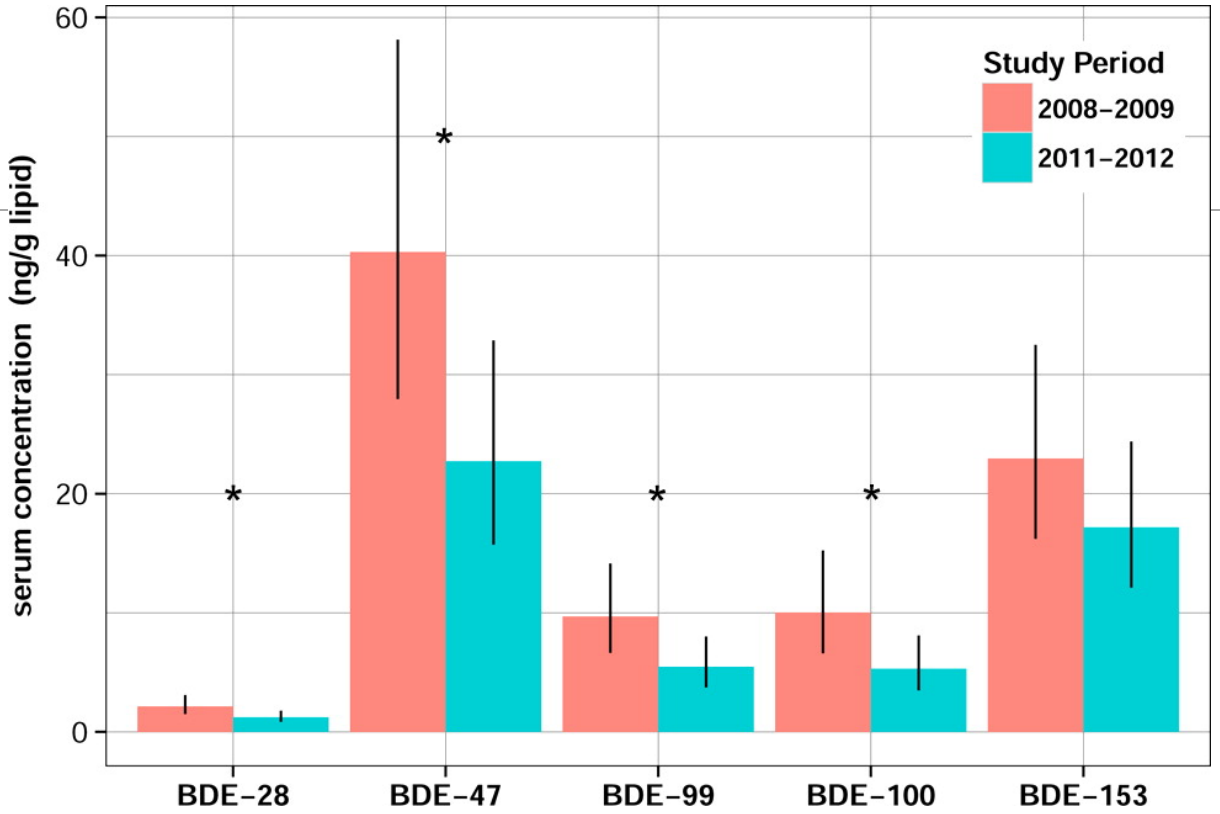
Organic Diet Lowers Pesticides in Kids



Metabolites of malathion and chlorpyrifos in urine

Lu *et al*. (2006) EHP 114:260-263

Policy change reduces PBDE levels in CA



Least square geometric mean serum concentration for individual PBDE congeners by cohort after adjustment by maternal age, gestational age, race/ethnicity, parity, and insurance status. Error bars indicate 95% confidence intervals and asterisks reflect statistically significant differences ($p < 0.05$).

Published in: Ami R. Zota; Linda Linderholm; June-Soo Park; Myrto Petreas; Tan Guo; Martin L. Privalsky; R. Thomas Zoeller; Tracey J. Woodruff; *Environ. Sci. Technol.* **2013,** 47, 11776-11784. DOI: 10.1021/es402204y

Emerging Ethics

- Address tensions between right-to-know versus right-to-act
- Acknowledge uncertainty
- Distinguish between individual versus collective exposure prevention opportunities
- ***Research participants and communities have insights about best communication strategies.***
  - ***Seize opportunities to co-produce results communication protocols***

Usability Testing
Chemicals in our Bodies

Assesses prototypes with participants to inform communication protocol

- Are main messages clear?
- Is interpretation of results meaningful?
- Are materials understandable for diverse linguistic and educational attainment levels?
- Are there confusing or unappealing elements that may hinder comprehension & use of materials?
- What information are we missing?

Initial Summary of Results for Metals

Part 1: Metals in Blood

Summary of Your Results

We tested for 2 metals: lead and cadmium. We tested 85 mothers and their babies.

Your lead results: We found lead in your blood sample. We found lead in most mothers tested. Your lead level was higher than the average level for pregnant women in the U.S., and lower than the benchmark. Levels above the benchmark may be a health concern. We found lead in your baby's blood sample. We did not find lead in most babies we tested.

Lead is commonly found in	Possible risks to people	Possible ways to reduce exposure
▪ Peeling paint and dust inside and outside houses built before 1978 (when lead in house paint was banned). ▪ Metal water pipes in older homes. ▪ Jobsites in painting, construction, battery recycling, and radiator repair. ▪ Some consumer products: some old, imported, or handmade glazed dishes; some toys, art supplies, cosmetics, costume jewelry, hair dyes, medicines from China, and candies from Mexico.	▪ Can affect brain development and cause learning and behavior problems in babies and young children. ▪ Can cause high blood pressure, heart disease, kidney disease, anemia, reproductive problems, and memory loss in adults. ▪ Can cause miscarriage and low birth weight.	▪ Have a trained professional remove or cover old peeling or chipping paint. ▪ Vacuum and clean regularly. ▪ If you have lead pipes, use cold water from the faucet for drinking or cooking. Consider using a water filter certified to remove lead. ▪ Do not use old, imported, or handmade pottery for storing, cooking, or eating food, unless you know it does not contain lead.

- To have your home checked for lead, call the San Francisco Department of Public Health at 415-252-3956.
- For more information, go to **www.dhs.ca.gov/childlead**.

HEALTH RESEARCH FOR Action
UC Berkeley

Final Summary of Results for Metals

Part 1: Metals in Blood

Summary of Results for You and Your Baby

Lead

We tested for lead. Lead is a metal that is found in nature and is used in many industries and products.

Have you found lead in my blood or in the blood of my baby?

Yes. We found lead in you and your baby.

Can I compare my levels to other levels?

You can use the *Results Chart* in this packet to compare your lead levels to:

- **Other women and babies in the study.** We found lead in most mothers tested. Your lead level was lower than most mothers. We did not find lead in most babies we tested.
- **National average.** This is the most common level for pregnant women in the U.S. Your lead level was higher than the national average. The national average for babies is not known.
- **Level of health concern.** Levels above these may be a health risk. Your lead level was lower than the level of health concern. A level of health concern has not been set for lead in babies.

The next page explains more about lead.

HEALTH RESEARCH FOR Action
UC Berkeley

More information about lead

Lead is found in	▪ Peeling paint and dust inside and outside houses built before 1978 (when lead in house paint was banned). ▪ Metal water pipes in older homes. ▪ Jobsites in painting, construction, battery recycling, and radiator repair. ▪ Consumer products: o Some old, imported, or handmade glazed dishes o Some toys, art supplies, cosmetics, costume jewelry, hair dyes o Some medicines from China o Some candies from Mexico
Possible risks to people	▪ Lead can affect brain development and cause learning and behavior problems in babies and young children. ▪ Lead can cause high blood pressure, heart disease, kidney disease, anemia, reproductive problems, and memory loss in adults. ▪ Lead can cause miscarriage and low birth weight.
Possible ways to reduce exposure	▪ Have a trained professional remove or cover old peeling or chipping paint. ▪ Vacuum and clean regularly. ▪ If you have lead pipes, use cold water from the faucet for drinking or cooking. Consider using a water filter certified to remove lead. ▪ Do not use old, imported, or handmade pottery for storing, cooking, or eating food, unless you know it does not contain lead.

- To have your home checked for lead, call the San Francisco Department of Public Health at 415-252-3956.
- For more information, go to www.dhs.ca.gov/childlead.

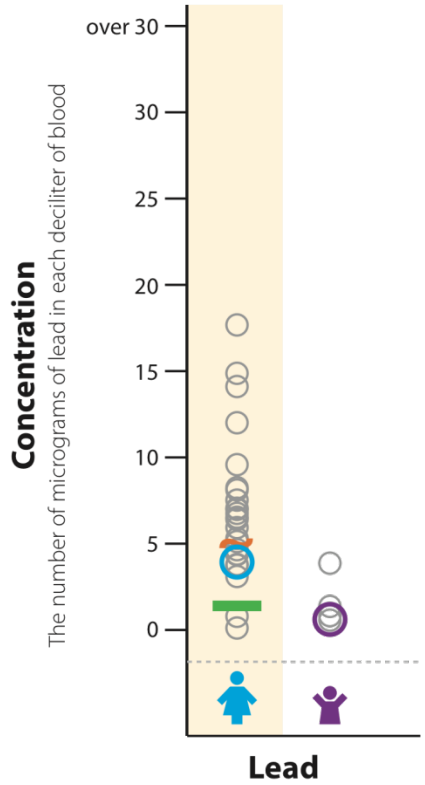
HEALTH RESEARCH FOR Action
UC Berkeley

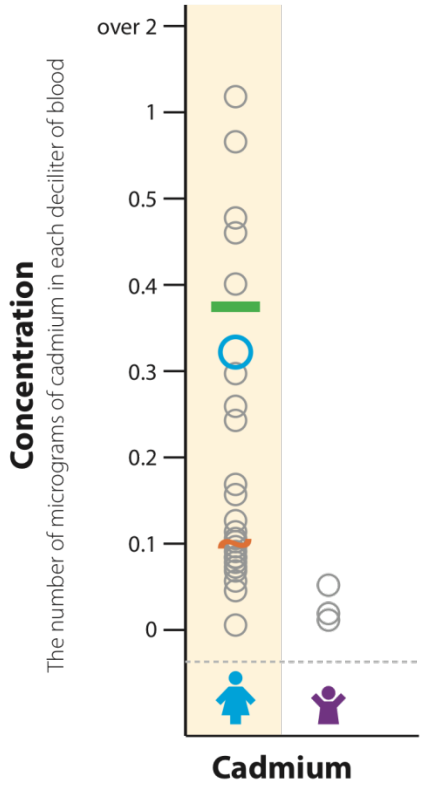
INITIAL

Participant number: 43

Part 1: Metals in Blood Results Chart

Your level There is no blue circle if we did not find this chemical in your blood.
Your baby's level There is no purple circle if we did not find this chemical in your baby's blood.
Other people's levels Each circle represents a person in the study.
National average in pregnant women.
Benchmark Levels above this may be a health concern.





Your exact levels	3.85	0.98

Your exact level	0.326

HEALTH RESEARCH FOR Action
UC Berkeley

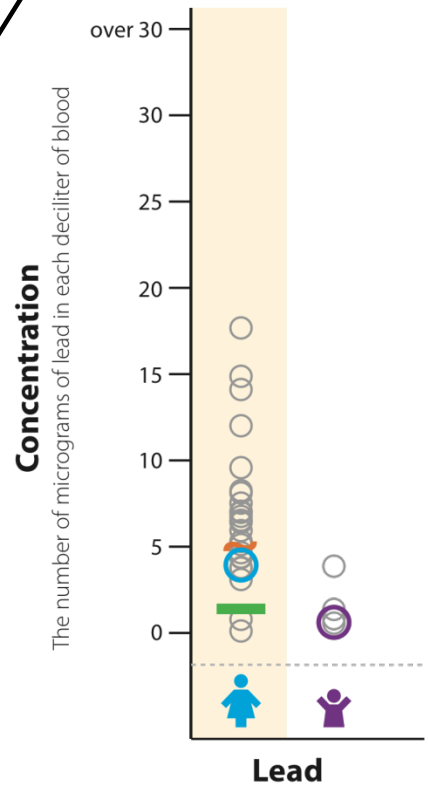
FINAL

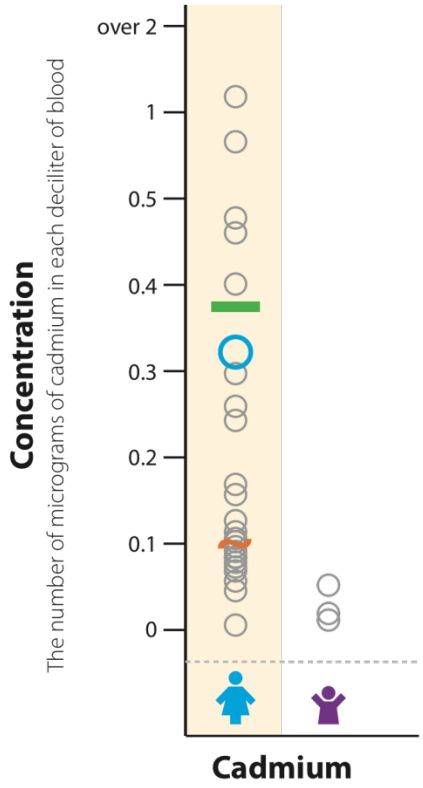
Participant number: 43

Part 1: Metals in Blood Results Chart

How to read this chart:

- **Your level** (There is no blue circle if we did not find this chemical in your blood.)
- **Your baby's level** (There is no purple circle if we did not find this chemical in your baby's blood.)
- **Other people's levels** Each circle represents a person in the study.
- **National average** The most common level for pregnant women in the U.S.
- **Level of health concern** Levels above this may be a health risk.





Your exact levels	3.85	0.98

Your exact level	0.326	Not Found

HEALTH RESEARCH FOR Action
UC Berkeley

Key Successes

- Participants appreciated reviewing prototypes.

"I got a lot of information here that I didn't know already. The study people already told me things, but there was a lot more here. The reason why people get cancer might be here. I grew up in the 70s and 80s and they didn't know much about all this. Maybe something back then contributed to my future bad health. The summary pages were very interesting."

- Nearly all correctly identified their own results in the charts, either exact number of rough estimate from the chart scale.
- Most could identify whether they were lower or higher than other women in the study.

"At first I'd think, "oh my God, there's a blue circle." Then I'd see that for some, none were found, then I'd see where I was compared to the other ladies and the national average, then I'd see how I feel."

Tips and examples

Download our Handbook!

WHEN POLLUTION IS PERSONAL

HANDBOOK FOR REPORTING RESULTS TO PARTICIPANTS
IN BIOMONITORING AND PERSONAL EXPOSURE STUDIES

The Personal Exposure Report-back Ethics (PERE) Study
This publication reports on work supported by NIEHS grants R01ES017514 and R25ES013258.

SILENT SPRING INSTITUTE

Brody *et al. Environmental Health* 2014, 13:40
http://www.ehjournal.net/content/13/1/40

ENVIRONMENTAL HEALTH

COMMENTARY Open Access

Reporting individual results for biomonitoring and environmental exposures: lessons learned from environmental communication case studies

Julia Green Brody[1*], Sarah C Dunagan[1], Rachel Morello-Frosch[2], Phil Brown[3], Sharyle Patton[4] and Ruthann A Rudel[1]

Abstract

Measurement methods for chemicals in biological and personal environmental samples have expanded rapidly and become a cornerstone of health studies and public health surveillance. These measurements raise questions about whether and how to report individual results to study participants, particularly when health effects and exposure reduction strategies are uncertain. In an era of greater public participation and open disclosure in science, researchers and institutional review boards (IRBs) need new guidance on changing norms and best practices. Drawing on the experiences of researchers, IRBs, and study participants, we discuss ethical frameworks, effective methods, and outcomes in studies that have reported personal results for a wide range of environmental chemicals. Belmont Report principles and community-based participatory research ethics imply responsibilities to report individual results, and several recent biomonitoring guidance documents call for individual reports. Meaningful report-back includes contextual information about health implications and exposure reduction strategies. Both narrative and graphs are helpful. Graphs comparing an individual's results with other participants in the study and benchmarks, such as the National Exposure Report, are helpful, but must be used carefully to avoid incorrect inferences that higher results are necessarily harmful or lower results are safe. Methods can be tailored for specific settings by involving participants and community members in planning. Participants and researchers who have participated in report-back identified benefits: increasing trust in science, retention in cohort studies, environmental health literacy, individual and community empowerment, and motivation to reduce exposures. Researchers as well as participants gained unexpected insights into the characteristics and sources of environmental contamination. Participants are almost universally eager to receive their results and do not regret getting them. Ethical considerations and empirical experience both support study participants' right to know their own results if they choose, so report-back should become the norm in studies that measure personal exposures. Recent studies provide models that are compiled in a handbook to help research partnerships that are planning report-back. Thoughtful report-back can strengthen research experiences for investigators and participants and expand the translation of environmental health research in communities.

Keywords: Bioethics, Biomonitoring, Community-based participatory research, Exposure assessment, Health literacy, Informed consent, Research ethics, Risk communication

* Correspondence: brody@silentspring.org
[1]Silent Spring Institute, Newton, MA, USA
Full list of author information is available at the end of the article

These resources and more at: ***silentspring.org/research-area/reporting-individual-exposure-results***

Digital Exposure Report-back Interface (DERBI)

www.mychdsreport.com

Participant 1 Graph Style

CHDS | Summary | Chemicals | Health Concerns | What You Can Do | Study Results

Summary of Your Results

We found many chemicals in every person we tested. Some people may want to make changes to reduce their chemical levels. We hope these results will help you make informed decisions.

Chemicals We Found

Your headlines:

- We found several PFCs (perfluorinated chemicals) in your blood sample.
- We found elevated levels of PBDE flame retardants in your blood sample.

All your results:

Pesticides
Flame Retardants
PCBs
PFCs
Lipids

Where do these chemicals come from?

Flame retardants are used in furniture cushions made of polyurethane foam. Flame retardants are also used in plastics, electronics, textiles, building insulation, and other products.

This study focused on a group of flame retardants called PBDEs (polybrominated diphenyl ethers), which were widely used in furniture foam from 1960 until 2004. PBDEs have been phased out due to heath concerns, but they have been replaced by other flame retardants with concerning or unknown health effects.

Why might these chemicals be a health concern?

PBDEs affect thyroid hormones or the brain and nervous system, so they can affect brain development and IQ, weight, depression, energy, and muscle control.

Other types of flame retardants can have similar effects on the thyroid and brain, and some are carcinogens – that is, they cause cancer. Others haven't been studied yet for health effects.

ed?
don't know
whether it's dangerous?
- What makes something a "headline"?
- What chemicals did we test for?
- Why are you testing for chemicals that are banned?

more questions about this page

Democratizing Ethics of Results Communication

Biomonitoring projects provide opportunities for:

- Participant engagement
  - Results communication development
- Transparent results communication
  - Takes participant expectations into account *a priori*
- Continuous report back process evaluation
  - Protocols are always in “beta” mode

Collaborators

Silent Spring Institute

UC Berkeley
Department of Environmental Science, Policy and Management &
School of Public Health

Northeastern University
Social Science & Environmental Health Institute

Harvard Law School
Emmett Environmental Law and Policy Program

Personal Exposure Report-back Ethics (PERE):

- National Institute of Environmental Health Sciences (R01ES017514)
- National Science Foundation (SES-0450837, SES-0822724)

Chemicals in Our Bodies (aka MIEEP)

- Wellness Foundation

Resources

Morello-Frosch R, Varshavsky J et al. 2015. The Challenge of Communicating Results in Post-Belmont Era Biomonitoring Studies: Lessons from Genetics and Neuro-Imaging Research. *Environmental Research*, 136: 363–372.

Brody, J.G., Dunagan, S Morello-Frosch, et al. 2014. Reporting individual results for biomonitoring and environmental exposures: lessons learned from environmental communication case studies. *Environmental Health*. doi:10.1186/1476-069X-13-40.

Dunagan, S, Brody, J.G. et al. 2014. When Pollution Is Personal: Handbook for Reporting Results In Biomonitoring and Personal Exposure Studies http://www.silentspring.org/personal_exposure_report_handbook.pdf

Delbanco, T., Walker, J., et al., 2012. Inviting Patients to Read Their Doctors' Notes: A Quasi-experimental Study and a Look Ahead. Ann. Intern. Med. 157, 461–470.

Adams, C, Morello-Frosch, R. et al. 2011. Disentangling the Exposure Experience: The Roles of Community Context and Report-back of Environmental Exposure Data. *Journal of Health and Social Behavior,* 52(2): 180-196. doi: 10.1177/0022146510395593

Brown, P., Morello-Frosch R, et al. 2010. *Institutional review board challenges related to community-based participatory research on human exposure to environmental toxins. Environmental Health, 9:39. doi:10.1186/1476-069X-9-39 (Highly accessed)*

Brody, J.G., Morello-Frosch, et al. 2009. Letter to the editor: Reporting Individual Results for Environmental Chemicals in Breastmilk in a Context That Supports Breastfeeding. *Breastfeeding Medicine,* 4(2): 121-121. doi:10.1089/bfm.2009.0006.

Morello-Frosch, R., Brown P, et al. 2009. Toxic Ignorance and Right-to-Know in Biomonitoring Results Communication: A Survey of Scientists and Study Participants. *Environmental Health,* 8(6). doi:10.1186/1476-069X-8-6

Wu, N., McClean, M.D., et al., 2009. Participant experiences in a breastmilk biomonitoring study: A qualitative assessment. *Environmental Health* 8, 4. doi:10.1186/1476-069X-8-4

Altman, R.G., Morello-Frosch R, et al. 2008. Pollution Comes Home and Gets Personal: Women's Experience of Household Chemical Exposure. *Journal of Health and Social Behavior,* 49(4): 417-435.

Brody, J.G., Morello-Frosch, R et al. 2007. Improving disclosure and consent: "Is it safe?": New ethics for reporting personal exposures to environmental chemicals. *American Journal of Public Health,* 97:1547-1554.

National Academy of Sciences: *Human Biomonitoring for Environmental Chemicals. Washington, DC* 2006. http://www.nap.edu/catalog.php?record_id=11700