Returning Results to participants in the CHAMACOS Birth Cohort Study

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Outline

- What is CHAMACOS?
- Community Assessment
- Case studies
- IRB Education
  - Community Involvement
  - Challenges by the medical community
  - Technical challenges – do results have any meaning?
  - Reporting to the general community.

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California Environmental Protection Agency
Protecting the Public Health and the Environment
Children's Hospital Oakland
Research Institute
CHAMACOS
CENTER FOR THE HEALTH ASSESSMENT OF MOTHERS AND CHILDREN OF SALINAS
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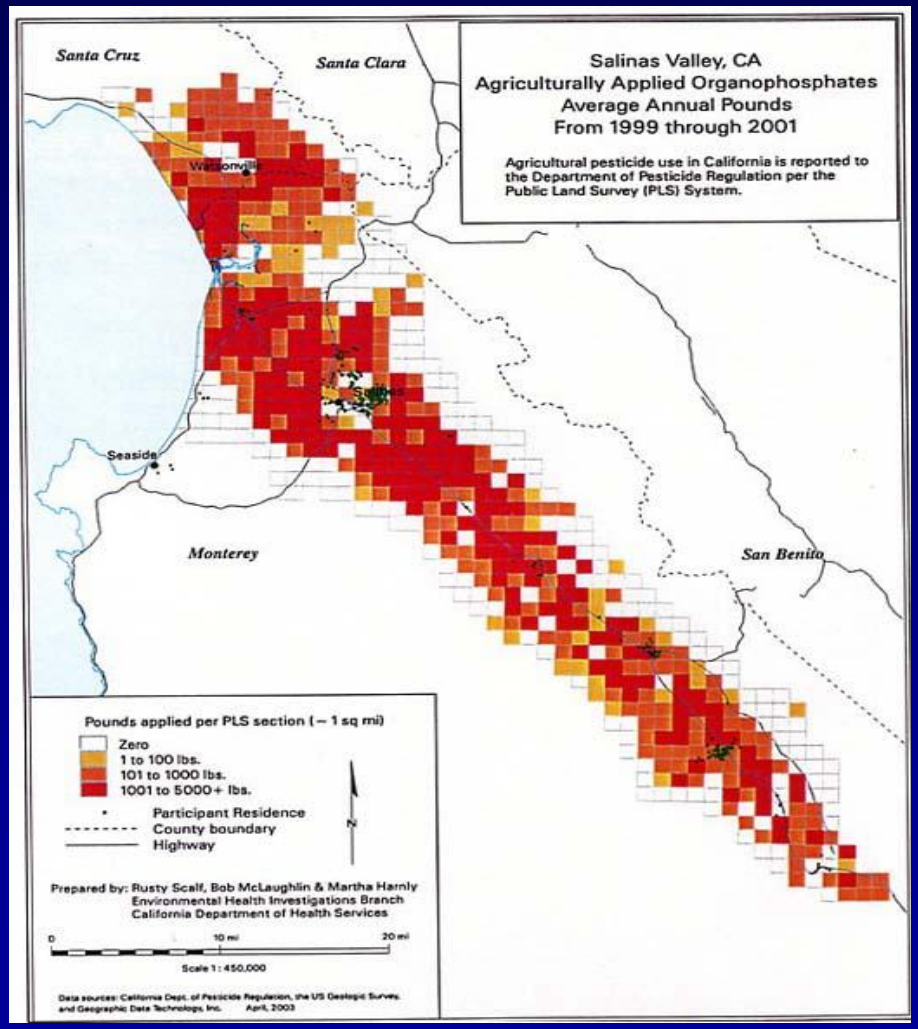
California Department of Health Services
Battelle
Laboratories
A Community-University Partnership
CALIFORNIA RURAL LEGAL ASSISTANCE
CRLA
Grower-Shipper Association
Of Central California
South County Outreach Effort
Clinica de Salud del Valle de Salinas
NATIVIDAD MEDICAL CENTER

CHAMACOS Study Area



Community Assessment

Children's Health is a priority concern in the Community.

"There is a need to know how the environment is affecting us."

"I think you will get a very positive response from the women. They are very interested in their children's health and how to improve it. You need to give them access to their results."

Community Assessment

The Center must share results with the Community.

"I think the reaction of the community is going to be positive but you … need to keep them informed about the study .. talk … about the community's long term benefits from the study, and plans to stay in the community for further studies."

Research must be culturally sensitive.

"Hire people who can work effectively with our community, people who understand the culture."

Objectives

- Assess exposures to pregnant women and children.
- Determine relationship with :
  - neurodevelopment
  - growth
  - respiratory disease
- Reduce exposures to children and pregnant women with interventions and community outreach.
- Inform policies to reduce the incidence of environmentally-related disease

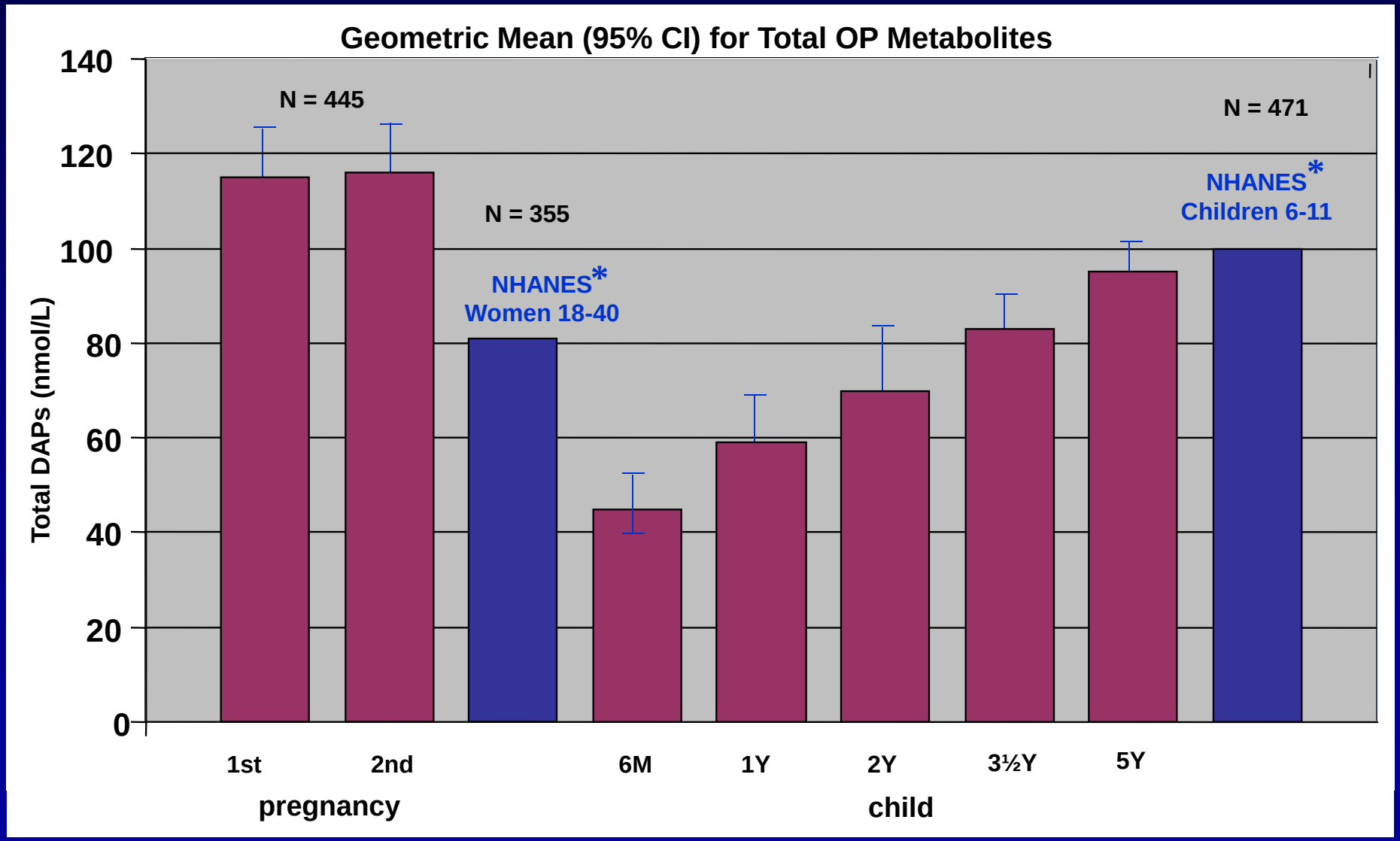
Biological Specimen Collection
Up to 100,000 samples stored

	1st Tri	2nd Tri	Delivery	6 M	1 Y	2 Y	3½ Y	5 Y	7 Y
• Maternal Urine	✓	✓	✓	✓					
• Paternal Urine			✓						
• Maternal Blood		✓	✓						✓
• Cord Blood			✓						
• Breast Milk			✓	✓					
• Child Urine				✓	✓	✓	✓	✓	
• Child Blood					✓	✓		✓	✓
• Child Saliva							✓	✓	

Organophosphate Pesticide Use in the Salinas Valley, 2001

OP Pesticide	Pounds	Excreted in urine as
Malathion	96,520	Dimethyl (DM) phosphates ~220,000 lbs. (42%)
Oxydemeton-methyl	57,859	
Dimethoate	34,224	
Naled	17,045	
Methidathion	14,220	
Diazinon	133,537	Diethyl (DE) phosphates ~199,000 lbs. (38%)
Chlorpyrifos	54,945	
Disulfoton	10,216	
Acephate	71,725	Other ~104,000 lbs. (20%)
Bensulide	32,669	
Total	**~520,000**	

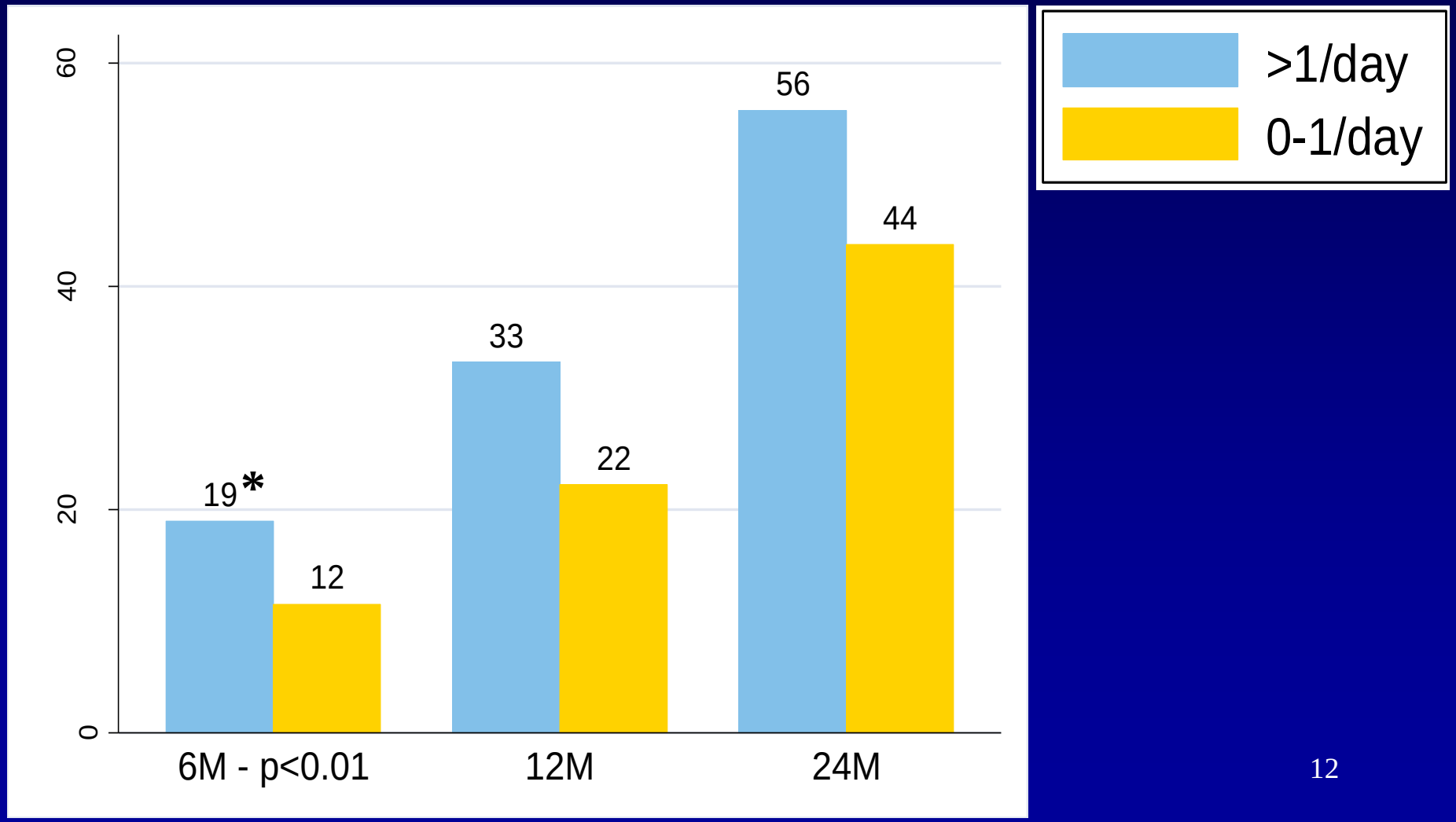
Prenatal and child OP metabolites in CHAMACOS and National Reference*



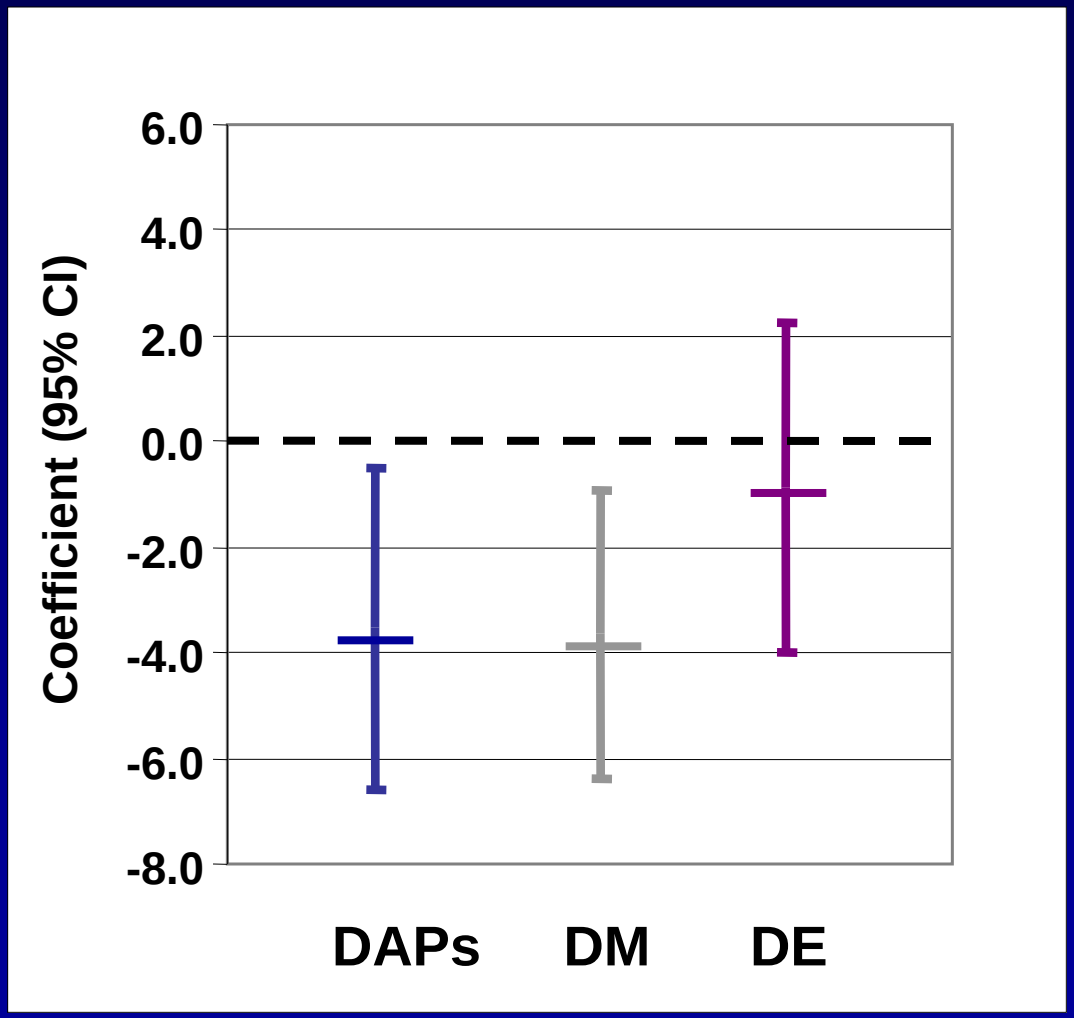
* National Health and Examination Survey

Bradman *et al.*, 2005

Median DM Metabolite Levels by Fruit and Vegetable consumption



Total DAPs, DMs, and DEs and 2-Year Bayley Mental



*** All models adjusted for psychometrician, gender, age, parity, assessment location, breastfeeding duration, maternal PPVT, poverty status, and HOME score.**

Eskenazi *et al.*, 2007

CHAMACOS Biomonitoring Uses

- Characterize exposure*
- Evaluate exposure trends*
- Identify exposure predictors*
- Evaluate health effects
- Estimate risks*

*Likely use of state data

Case Studies in Communication

- IRB education
- Community involvement
- Challenges by the medical community.
- Final approach.
- Technical challenges
- General community

UC Berkeley CPHS

IRB initially unsupportive about returning restults.

Example:

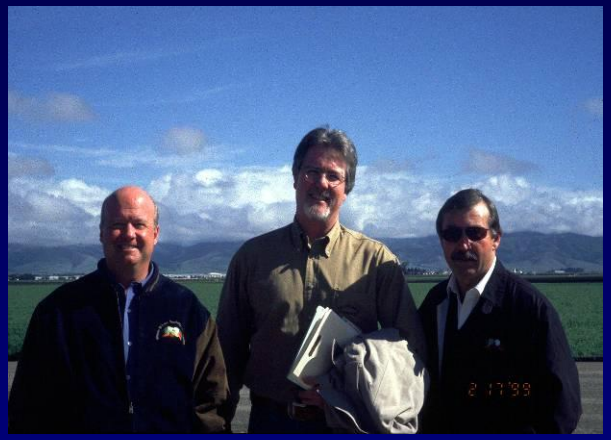
"test results for individual subjects … not …meaningful and … likely to cause unnecessary alarm … members felt strongly that… subjects … only be provided with a copy of the manuscript."

Community Engagement

- CPHS agreed to reevaluate decision dependent on outreach to community.

- Convened meetings with wide range of community and research partners.

Community Advisory Board & Intervention Farmworker Council



Community Engagement

•Doctors strongly objected to returning individual results – concern about doing harm and burden of interpreting non-clinical tests.

•Advocates strongly supported returning individual results – right to know.

•Industry supported returning individual results – individual right.

Change in Views

- Results to be returned in person by study staff.
- Placed in context of research, not as a clinical test.
- Ability to compare to national reference data – (NHANES).*

*Key turning point.

Final approach accepted by IRB

- Participants can request results (opt in).
- Participants informed:
  - In person (phone not permitted);
  - Results placed in context of population and reference data (NHANES);
  - Emphasize research context;
  - Offer follow-up testing;
  - Don’t stigmatize;
  - If known risk (e.g., lead), follow guidelines.
- Consent process is key point for conversation with participants.

Operational Challenges

Must budget for staff time for in-person meetings.

Research staff must be blinded to results.

Challenge to meet schedules of workers.

- Initially <5% receiving results.
- Now, ~60% requesting results.

Technical Challenges

No known standard to define “high exposure” from biomonitoring data (except lead).

Biomarkers may not reflect exposure.

For example, DAPs in the environment and food suggest urinary OP biomarkers require additional interpretation.

- Barr et al 2009

Technical Challenges

For many non-persistent compounds, good intra-individual correlation over a day. Poor over several days.

Correlation of DAP metabolites in spot urine samples collected 1-6 days apart

Days between collection (n)

	1 (288)	2 (241)	3 (210)	4 (144)	5 (72)	6 (25)
Total DAPS	0.34**	0.21**	0.12	0.03	0.13	-0.05

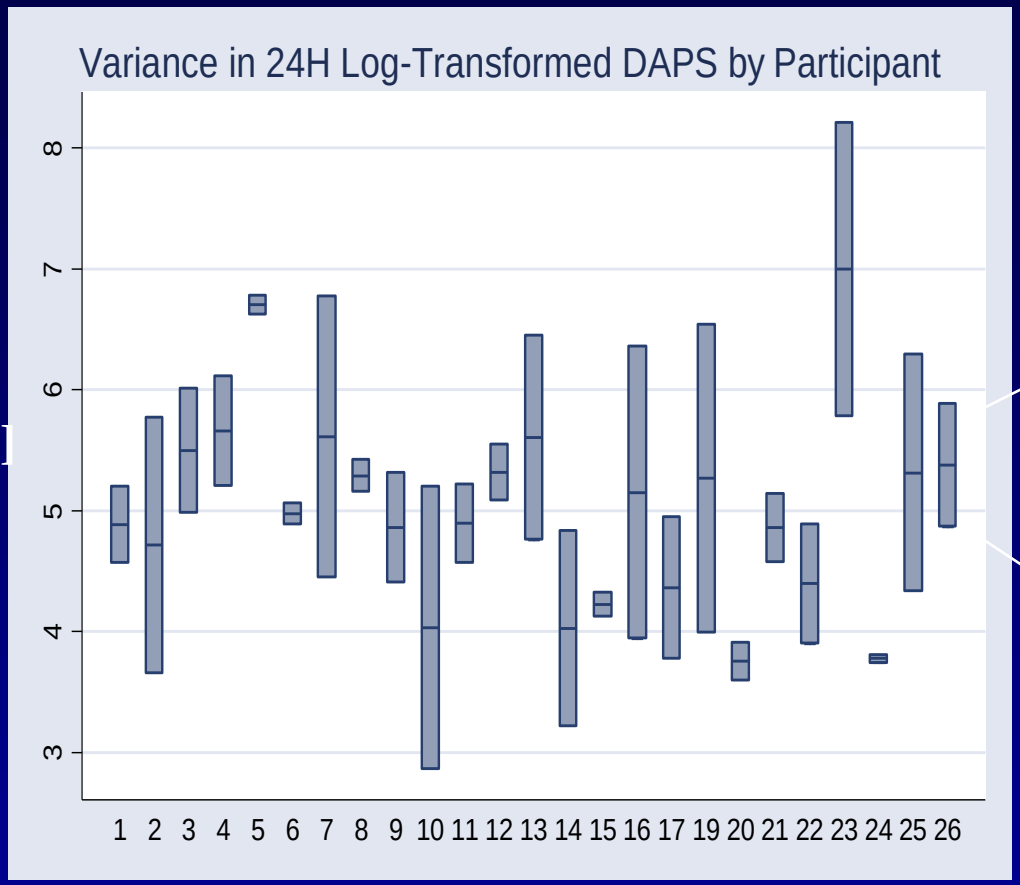
***p<0.05**

Correlation of 24 hr samples collected three days apart (n=25)

Total DAPS	0.11

p>0.6

24 hr urine samples: Within and between individual variability



Estimated within and between variability (SD)

Between	**0.36**
Within	**1.01**

Technical Challenges

- Individual sampling results for some non-persistent chemicals may be meaningless.
- Whereas population exposure range is well characterized.

Reporting results to the General Community

Research partners and advisory boards:

- All findings presented during in-person meetings;
- Submitted journal articles provided for comment;
- Press releases distributed for comment;
- Review is advisory only;

Participants and General Community:

- Frequent participant fora.
- Presentations to broad cross-section of community:
  - Migrant education;
  - Community groups
  - Churches;
  - Local governments;
  - Grower organizations

Synopsis

- Work with communities and potential participants ahead of time – focus groups, meetings, etc to inform approach.
- Address concerns of constituents.
- Budget resources for returning results.
- Communicate with IRB and identify key concerns.
- Understand the limitations of biomonitoring data and the utility of comparisons to reference data or health interpretation.

- California Wellness Foundation
- Switzer Foundation
- UC Mexus