

Communicating Individual Level Biomarker Data to Participant Families



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Outline

- **Background on BCERC/CYGNET**
 - Study Design
 - Chemicals measured
- **Focus Groups on Reporting Biomarker Levels**
 - Participants
 - Materials Tested
 - Results



Puberty Studies within BCERC

- **Prospective, Cohort Study**
 - Girls 6-8 at baseline, follow 5 years
 - Diverse race/ethnicity
- **Of Pubertal Maturation**
 - Anthropometry, Tanner staging
 - Parent questionnaires
 - Biospecimens: urine, serum, sputum
- **At Multiple Sites**
 - NYC (Community clinics)
 - Cincinnati, Ohio (School-based)
 - SF Bay Area, CA (Kaiser members)



Primary Urinary Biomarkers

- **Cotinine** (marker of nicotine)—detected in 98% of girls
- **Phytoestrogens** (CDC panel of 6)
 - Enterolactone, Daidzein, Genistein focus
- **Phthalate Metabolites** (CDC panel of 10)
 - 8 detected in > 95% of samples
 - 3 primary focus: mEP, mBP, mBzP
 - Sum into high and low molecular weight metabolites
- **Phenols and Parabens** (CDC panel of 9)
 - 4 detected in > 95%
 - Bisphenol A (BPA)
 - Plus Triclosan (detected in 82%)

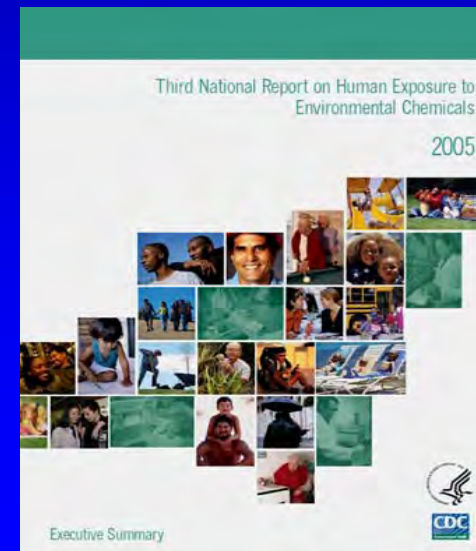
Detection of Serum Compounds

- **Brominated Flame Retardants**
 - 11 PBDE congeners measured at CDC
 - 7 detected in > 60% of girls' samples, 4 in > 98%
- **Poly-Chlorinated Biphenyls**
 - 35 PCB congeners
 - 10 detected in > 60% of girls, 5 in > 90%
- **Persistent Chlorinated Pesticides**
 - 9 analytes
 - 3 detected in > 60% (*p,p'*-DDE, HCB and *t*-nonachlor)
- **Per-fluorinated Compounds**
 - 8 PFCs analyzed
 - 6 detected in >60%, 5 in > 95%

Varies slightly by site

Issues in Reporting Results

- **Ethical considerations**
 - Right to know, participatory research
 - Do no harm, clinical/medical approach
- **Sheer volume of technical information**
 - Which chemicals? (of 80+!)
 - How much information?
 - Comparison group?
 - Method of presentation
- **Technology outpaces interpretation**
 - Few “safety” standards
 - Few clinical ramifications



Goals of Focus Groups with Parents

- **Gauge level of interest in receiving individual results**
- **Determine preferences about report-back process**
 - Format and content of materials
 - Method of providing results—by and to whom?
- **Context for providing results**
 - Participants' experiences during the study
 - Understanding or fears about environmental exposures and health effects
 - Literacy levels
 - How results will be used

Focus Group Methods

- **Four groups of 8-12 participants**
 - One mono-lingual Spanish
 - Held in two locations
 - Randomly recruited families (45 recruited of 128 called)
 - Light dinner provided and \$50 stipend
- **Procedures**
 - Consent and survey on demographics, literacy
 - Focus group script developed, with 3 report examples
 - Groups led by experienced facilitators
 - Discussion recorded and transcribed
 - Analyzed with software for qualitative data

Example 1—Text Letter

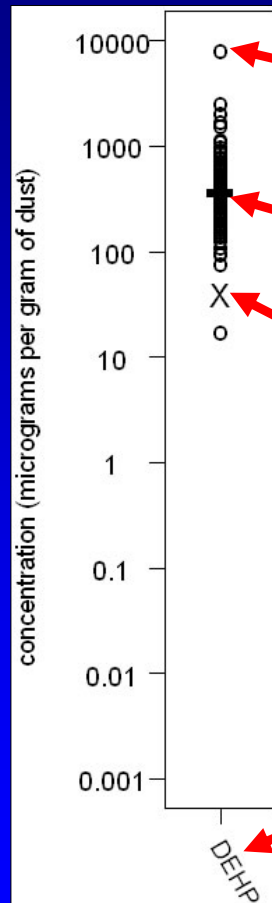
Today I am going to tell you the results of the tests that measured the amount of pesticides in your child's urine. No one knows what level of pesticides is normal for babies and young children. We can only tell you how your child's levels compare to other children in this study.

1. We tested for a pesticide called (DDD) in your child's urine. Your child's level was _____.

This level is:

- a) Relatively low. Most participants had higher levels.
- b) About average. About half the participants had higher and half lower levels than your child.
- c) Relatively high. Most participants had lower levels.

Report of individual results



Each \circ represents one other home in the study

— is the sample from your home

X is the EPA Guideline

DEHP common uses: Plastics, inks, insect repellent, cosmetics, rubbing alcohol, liquid soap, detergents, lacquers, munitions, industrial lubricant.

Chemical abbreviation (di(2-ethylhexyl) phthalate)

Brody, Morello-Frosch, et al. *AJPH*, 2007

Example 3— Chart by Individual

Casa	Pesticidas agrícolas						Pesticidas del hogar										
	A-1	A-2	A-3	A-4	A-5	A-6	C-1	C-2	C-3	C-4	C-5	C-6	C-7	C-8	C-9	C-10	C-11
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Figure 2. Figure used to allow study participants to compare the number and types of pesticides found in their residences with those of others in the study. A key was shown on the reverse side of the figure to tell what agricultural pesticides were represented by A-1 to A-6, and what residential pesticides were represented by C-1 to C-11. The headings translate as "Agricultural pesticides," "Residential pesticides," and "House number."

Characteristics of 35 FG Participants

Age:	45y (30-73y)
Gender:	89% female
Ethnicity:	40% Hispanic
Race:	49% White, 14% Black, 26% “other”, 3% Asian (9% missing)
Marital Status:	80% married or living together All but 1 was a parent
Education:	34% HS or less, 32% some college, 34% college degree +
Language:	8 Spanish-speaking (23%)

Literacy in Focus Group Participants vs. California Health Interview Survey, 2007

	Focus Group	CHIS
<i>Written info from doctor</i>		
Very easy to understand	57.1%	51.3%
Somewhat easy	37.1%	31.0%
Somewhat difficult	5.7%	10.4%
Very difficult	0%	4.4%
Don't get written information	0%	2.9%
<i>Instructions on prescription bottle</i>		
Somewhat or very difficult	2.9%	7.9%

Findings on Receiving Results

Receive individual levels? All but 1 said YES

Even if no safety standards? Similar

- *“There could be some information a few years from now. And maybe, if the study doesn’t keep happening, we could refer back”. (40-y.o. female)*
- *And also just to do our own research. (UK female)*
- *Just to see ,,, what they’ve got in them. Who knows. You know, ten years from now, we may not have been able to catch it with our girls but maybe [the findings can help other] girls.... (48-yo female)*
- *—the reason why I want to know what the chemicals levels are is because it might actually (gear me up) to change some things in the way that we live... (30-yo female)*

Feedback on Example Materials

1) Letter with result and whether hi, low, average

- Easy to read and understand, short
- Too vague, not enough information, prefer graphics

2) Scatterplot with own and others' results

- Lots of information on one page, including all chemicals, comparisons, and EPA standards
- Too much information, too busy, hard to read/see

3) Chart with chemicals by individuals

- Attractive, liked color, easy to read, not too overwhelming
- Did not provide quantified individual levels, or much info

Themes on Receiving Results

Background Information to Include

- Chemical Information
 - Toxic levels
 - Sources
 - Persistence
 - Known or suspected health effects, why tested



... *I would find it helpful to have a kind of paragraph explaining what you think the chemical is and what you think it **might** do instead of just listing the chemical and saying this is where it's toxic and this is where it is. (54-y.o. female)*

- Comparison to Levels in Others
 - Girls in CYGNET and even sub-groups
 - Girls at other sites in BCERC
 - Children in other studies (adults of less interest)

Themes on Receiving Results

Other Information Wanted

- Daughter's blood type
 - Effects of diet, exercise and lifestyle on pubertal onset
 - Daughter's stage of development in relation to other girls
- Well, I think you asked—you had a very extensive survey that we all took which sort of questions how much makeup you use, how much lipstick you use, how much plastics you use, you drink, you know, whatever. It would be good to give a scale and where my daughter lies on this scale. (51-y.o. male)*

Emotional Response

- Worry, especially if daughter's levels comparatively high
 - Concern about future effects
 - Desire to reduce exposure
- ... But I would think, uh-oh, is that bad? You know, it's high, is she going to die tomorrow? I mean I'm very much exaggerating [but] My gut reaction would be to panic if it was high ... (47-y.o. female)*

Methods for Receiving Results

Mail, E-mail, In-person

- Mail (or e-mail) OK, with follow-up (phone or in-person)
- Liked idea of tea talk if individual consult impractical

After [receiving] a letter like this, I would love to go to a big meeting where Larry or somebody would answer questions about what this all means. ... yeah, because I'd rather hear from somebody really high up. And I'm sure a lot of people have the same kind of questions....

Physician Involvement

- Mixed; helpful if physician knows results and add to med record vs. physician not expert on these topics
- Spanish FG assumed their physician would explain results

Daughter's Involvement

- English-speakers mixed; daughter may be curious, listen better to someone else vs. creating worry among girls
- Spanish-speakers did not want daughters present

Conclusions

- FG participants had somewhat higher education and literacy levels than general population, so results may not be generalizable
- Parents in FGs had generally good experience in CYGNET and were appreciative of information provided
- Large majority wanted individual results, despite unknowns
 - Use for own research or making changes
 - Useful in the future?
- Common Themes
 - Want detailed background information on chemicals
 - Want multiple comparisons
 - Prefer graphs, in color that are not too detailed
 - Want opportunity to discuss results or ask questions

Conclusions, *Next Steps*

- Resolve issues regarding amount of information desired vs. ease of presentation/interpretation
 - Select chemicals
 - Select comparison groups
- Develop materials and conduct additional testing
- Recruit participants, for much greater commitment
- Requires additional funding, which we have pursued, as often not included in research proposals

Acknowledgements

- **Funding provided by EHIB/CDPH through Prop 99**
- **BABCERC Colleagues and Staff**
 - Lawrence Kushi, P.I., Kaiser DOR
 - Julianna Deardorff, UC Berkeley
 - Janice Barlow, Zero Breast Cancer, COTC Dir
 - CYGNET clinic staff
- **Partnership with Health Research for Action**
 - Under direction of Holly Brown-Williams and Carrie Graham
 - HRA facilitators and staff