Maternal and Infant Environmental Exposure Project (MIEEP)
a.k.a.
Chemicals in Our Bodies Project

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California Department of Public Health
Scientific Guidance Panel Meeting
February 9, 2010
Sacramento, California
Overview

- Current project status
- Project design
- Questionnaires and other materials
- Project timeline
Chemicals in Our Bodies
Project

**Collaborators**
- Biomonitoring California (CECBP)
- UC San Francisco, Program for Reproductive Health and the Environment
  - Tracey Woodruff/Jackie Schwartz
- UC Berkeley School of Public Health, Health Research for Action
  - Rachel Morello-Frosch, Holly Brown-Williams

**Funding**
- CDC Cooperative Agreement
- CA Wellness Foundation
- State CECBP resources
Project Aims

- Measure and compare levels of ~100 chemicals in blood and urine collected from ~100 maternal-infant pairs
- Identify leading sources of exposure to a subset of these chemicals
- Develop and test results communication/report back methods and materials
- Conduct exploratory analyses of the association between chemical exposure and pregnancy and birth outcomes
Project Aims (cont.)

- Develop and test protocols and procedures applicable to larger, more representative study
  - Recruitment/enrollment
  - Data collection
  - Biospecimen collection/processing
  - Laboratory analyses
  - Report back results to participants
Chemicals of Interest

- Metals (Pb, Hg, Cd, As, etc.)
- Environmental Phenols – Bisphenol A, parabens, triclosan
- Organophosphate pesticides
- Pyrethroid pesticides
- Phthalates
- Polycyclic aromatic hydrocarbons (PAHs)
- Perchlorate

To be analyzed by Environmental Health Lab/CDPH
Chemicals of Interest (cont.)

- Perfluorinated chemicals (PFCs)
- Brominated flame retardants (PBDEs, etc.)
- Polychlorinated biphenyls (PCBs)
- Organochlorine pesticides (DDT, hexachlorocyclohexane, hexachlorobenzene)

To be analyzed by Environmental Chemistry Lab/DTSC
Project Design Components

- Recruitment/Informed Consent/Enrollment
- Exposure Questionnaire administration
  - In-person Exposure Assessment Interview
  - At-Home Questionnaire
- Medical Records Data Abstraction
- Biospecimen collection (maternal urine and blood, fetal cord blood)

Green = CDC coop agreement
Purple = CA Wellness Foundation
Black = In-kind support
Project Components (cont.)

- Chemical analyses - CECBP labs
- Data Analyses / Report Generation
- Report back
  - Preliminary Interview
  - Feedback Session (a.k.a. usability tests)
  - Results Communication Interview

Green = CDC coop agreement
Purple = CA Wellness Foundation
Black = In-kind support
UCSF General Hospital (SFGH) Prenatal Population

- **Race/Ethnicity**
  - 60% Latina
  - 20% African-American
  - 12% Caucasian
  - 8% Asian/Pacific Islander

- Low income, tend to be uninsured
  - Medi-Cal eligible during pregnancy

- Tend to be lower literacy

- >50% are primary Spanish speakers
Chemicals in Our Bodies Project Design

28-34 weeks gestation
First Encounter

- Recruitment
  - Informed consent
- Enrollment
  - Preliminary interview
  - Provide at-home questionnaire

34-38 weeks gestation
Second Encounter

- Collect maternal urine sample
- In-person interview
- Collect at-home questionnaire

At delivery
Third Encounter

- Collect maternal blood
- Collect umbilical cord blood
- Medical record abstraction

After delivery

- 9 months – 1 year
  - Receive some results by mail
  - In-person Report Back Interviews

- 18 months – 2 years
  - Receive balance of results by mail and USCF and CECBP contact info provided

- 28-34 weeks gestation
- 34-38 weeks gestation
- At delivery
- After delivery
Chemicals in Our Bodies Project Design

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9 months – 1 year
- Receive some results by mail
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18 months – 2 years
Receive balance of results by mail and USCF and CECBP contact info provided
Project Design – 1st Encounter

1. Recruit/Consent/Enroll

- Inclusion criteria
  - Receive prenatal care at Women’s Health Center
  - Plan to deliver at SFGH
  - Low medical/ob risk
  - Spanish or English speaking
  - > 18 years of age

- Res Asst (RA, Spanish speaking) to review medical charts, appointment logs, approach women in waiting area

- Participant Enrollment Packet
Project design: Informed Consent

Purpose of Project:

- “learn if certain kinds of chemicals in our environment are present in the bodies of pregnant women and their newborn babies”

- “understand where these chemicals come from and how to reduce exposure to them”

- “look at the ways pregnant women come into contact with these chemicals”

- “find the best way to tell women about the types and amounts of chemicals we find in their bodies”
Project Design: Informed Consent

What Participant can learn

- “expect to find at least some chemicals in everyone’s blood and urine”
- “able to learn and receive info about types and amounts of chemicals found in your body”
- “how to reduce exposures”
Project Design: Informed Consent

What Participant can’t learn

- “We will not be able to tell you if the amounts of chemicals in your body are harmful for your health.”

- “We also will not be able to tell you whether any health problems you have may be caused by the chemicals we find in your body.”
Project Design: Informed Consent

- “Participating or not does not change any procedures or care during pregnancy or delivery.”

- Taking part in this project is entirely your choice.
  - “You do not have to answer all the questions we ask you.”
  - “You can change your mind and stop participating …any time.”

- “We will never use your name or other identifying information in any meetings, reports, or articles.”
Project Design: Informed Consent - Stipends

- $25 – urine sample and in-person interview
- $20 – completed At-Home Survey
- $20 – blood samples
Project Design: Informed Consent

Participant is asked to indicate yes or no:

- “I want to participate in the Chemicals in Our Bodies Project”
- “I want to know my personal biomonitoring results” which may not be available for up to two years
- “I want to donate leftover blood and urine and personal information for use in future studies”
Project Design: Informed Consent

- If the participant indicates she would like to know her personal biomonitoring results, she is also asked to indicate her willingness to be contacted later for:
  - Feedback Session interview
  - Results Communication Interview
Questions regarding Informed Consent?
Project Design (1st Encounter)

2. Preliminary interview

- Baseline knowledge and expectations regarding participating in biomonitoring project (audio recorded)

  Example:
  - Why did you decide to participate in this project?
  - What do you hope to learn?
  - What might information about your exposure to chemicals mean for you or your family?
  - Where do you get information about environmental health issues or chemical exposures?
Questionnaire Development

- **Purpose** – identify potential sources and personal behaviors
  - Pesticides*
  - Perfluorinated chemicals*
  - Metals
  - Flame retardants
  - Phthalates
  - Environmental phenols
Questionnaire Development (Cont.)

- Administered in-person
- Self-administered at-home
- Minimize participant burden
  - Limit to 1 hour for each questionnaire
  - Translate documents into Spanish
- Timing of exposure to biospecimen collection (e.g., non-persistent vs. persistent chemical analyte)
Questionnaire Development (cont.)

- Scientific literature
- Sample questionnaires (examples)
  - CHAMACOS
  - National Children’s Study
  - Occupational Health Branch/CDPH
  - NHANES
  - MIREC (Health Canada)
  - CHirP (Canada)
- Data from prenatal and newborn medical records
- Preliminary data analysis plans
- Compiled selected questions
- Field test/Revise
Questions regarding Questionnaire Development Process or Considerations??
Project Design – 1st Encounter

3. At-Home Questionnaire & instructions

- Chemicals targeted:
  - Perfluorinated chemicals
  - Flame retardants
  - Parabens
  - Phthalates

- Information on potential exposure sources
  - Home environment
  - Cleaning and personal care products during pregnancy

- Mail back (postage provided) or return at next visit
At-Home Questionnaire
Personal Care Products (example)

“We would like to know about the products that you have used since you became pregnant.”

“1. Gather your hair care products, makeup, and body and face products.
2. In the chart below, write the name and brand of each type of personal care product that you use. Include additional information on the label if you can.”
3. If you don’t use a product…, check “I don’t use”.
4. If you use a product not listed in the chart, write….at end of chart.
5. Please give as much information as possible. …write as much information as you can remember about it.”
## Hair Care Products

<table>
<thead>
<tr>
<th>Product</th>
<th>Brand/Company</th>
<th>Name of Product</th>
<th>Other Information</th>
<th>I use this but don’t have all the information</th>
<th>I don’t use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shampoo</td>
<td><em>Dove</em></td>
<td>Go Fresh Therapy</td>
<td>Cool Moisture Cucumber &amp; green tea scent</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Conditioner</td>
<td></td>
<td></td>
<td></td>
<td>☐</td>
<td>☒</td>
</tr>
</tbody>
</table>
At-Home Questionnaire (example)

- Is any of your furniture treated to be stain or water resistant?
  - [ ] Yes
  - [ ] No
  - [ ] I don’t know
  - [ ] I don’t want to answer
Have you had any furniture in your house like a sofa or chair that had exposed or crumbling foam?
- Yes
- No
- I don’t know
- I don’t want to answer

Examples of exposed foam:
Questions regarding At-Home Questionnaire?
Chemicals in Our Bodies Project Design

28-34 weeks gestation
First Encounter
- Recruitment
- Informed consent
- Enrollment
- Preliminary interview
- Provide at-home questionnaire

34-38 weeks gestation
Second Encounter
- Collect maternal urine sample
- In-person interview
- Collect at-home questionnaire
- Healthy You, Health Family Handout
- Stipends

At delivery
Third Encounter
- Collect maternal blood
- Collect umbilical cord blood
- Medical record abstraction

After delivery
- 9 months - 1 year
  - Receive some results by mail
  - In-person Report Back Interviews
- 18 months - 2 years
  - Receive balance of results by mail and USCF and CECBP contact info provided
2. In-person Exposure Assessment Interview
   - Occupational history
   - Hobbies and home activities
   - Diet
   - Behaviors/Use of certain items
   - Demographic information
Exposure Assessment Interview

1. Since you became pregnant, have you [**Activity**] at any of your job(s)? If yes, how many hours each week or each month?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes</th>
<th>No</th>
<th>DK</th>
<th>Refused</th>
<th>Hrs/wk</th>
<th>Hrs/mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upholstered furniture (cover with fabric, replace foam/cushion filling)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>Used, made or handled pesticides (bug spray) or weed killers</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>Removed paint by scraping, sanding, using a heat gun or using chemicals</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>Refinished furniture or cabinets</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>Welded or soldered</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>Installed carpet</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>______</td>
<td>______</td>
</tr>
</tbody>
</table>
Since you became pregnant, have you or anyone in your home done any [Hobby]?
[IF YES] How many hours per week or month?
[Show hobby cue card]

<table>
<thead>
<tr>
<th>Hobby</th>
<th>You</th>
<th></th>
<th>Ref</th>
<th>Hrs/wk or Hrs/mo</th>
<th>Someone else living in your home</th>
<th></th>
<th>Ref</th>
<th>Hrs/wk or Hrs/mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repainting or refinishing furniture</td>
<td></td>
<td>No</td>
<td>D</td>
<td>K</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upholstering furniture</td>
<td></td>
<td>No</td>
<td>D</td>
<td>K</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceramics or pottery</td>
<td></td>
<td>No</td>
<td>D</td>
<td>K</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Welding or soldering</td>
<td></td>
<td>No</td>
<td>D</td>
<td>K</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other activity/hobby (describe)</td>
<td></td>
<td>No</td>
<td>D</td>
<td>K</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
In the past 30 days, did you or anyone else in your home use chemicals to [Purpose]?

[If Yes] How many times in the past 30 days did you (anyone else) use these chemicals to [Purpose]?

[If Yes] Did you (anyone else) use these chemicals in the past 24 hours?

<table>
<thead>
<tr>
<th>Purpose</th>
<th>You</th>
<th>Anyone else</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control fleas, cockroaches, ants, termites, flies, or other insects in your home like bug bombs, ant killing chalk</td>
<td>□ Yes _________ □ No □ DK □ Refused □ How many times?</td>
<td>□ Yes _________ □ No □ DK □ Refused □ How many times?</td>
</tr>
<tr>
<td>Control fleas on pets (flea powder, flea collar, liquid drops)</td>
<td>□ Yes □ No □ DK □ Refused □ How many times?</td>
<td>□ Yes □ No □ DK □ Refused □ How many times?</td>
</tr>
<tr>
<td>Kill weeds, insects or other pests in your yard or outside your home</td>
<td>□ Yes □ No □ DK □ Refused □ How many times?</td>
<td>□ Yes □ No □ DK □ Refused □ How many times?</td>
</tr>
</tbody>
</table>
Questions about types of pots, pans, and appliances that you use for cooking and whether or not they are non-stick. Non-stick coatings are smooth and usually black or gray. Here are some pictures of non-stick or Teflon cookware.
Do you use a non-stick [Item]? [If YES] How old is it? Does it have any scratches? How often do you use it? Do you wash it by hand or in the dishwasher?

<table>
<thead>
<tr>
<th>Item</th>
<th>Use</th>
<th>How old</th>
<th>Scratches</th>
<th>Freq of use</th>
<th>Washed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rice cooker</td>
<td>☐ Yes</td>
<td>_yrs_mos_wks</td>
<td>☐ Yes</td>
<td>_yrs_mos_wks</td>
<td>☐ Hand</td>
</tr>
<tr>
<td></td>
<td>☐ No</td>
<td>_wks</td>
<td>☐ No</td>
<td>_wks</td>
<td>☐ Dishwasher</td>
</tr>
<tr>
<td></td>
<td>☐ Don’t</td>
<td>☐ Refused</td>
<td>☐ Don’t</td>
<td>☐ Refused</td>
<td>☐ Don’t know</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>know</td>
<td></td>
<td>☐ Refused</td>
</tr>
<tr>
<td>Electric grill or frypan (ex - Foreman grill)</td>
<td>☐ Yes</td>
<td>yrs_mos_wks</td>
<td>☐ Yes</td>
<td>yrs_mos_wks</td>
<td>☐ Hand</td>
</tr>
<tr>
<td></td>
<td>☐ No</td>
<td>_wks</td>
<td>☐ No</td>
<td>_wks</td>
<td>☐ Dishwasher</td>
</tr>
<tr>
<td></td>
<td>☐ Don’t</td>
<td>☐ Refused</td>
<td>☐ Don’t</td>
<td>☐ Refused</td>
<td>☐ Don’t know</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>know</td>
<td></td>
<td>☐ Refused</td>
</tr>
</tbody>
</table>
Since you became pregnant, how often do you eat [food item]?

- Meat
- Poultry
- Fish or shellfish from stores, markets or restaurants
- Fish or shellfish caught by you or someone you know
- Milk and dairy products
- Rice
- Pasta/noodles
- Fruit
- Vegetables
- Canned foods
- Canned drinks
Taking Care of Your Child

Wash your child’s hands and toys often. Regular hand washing with soap and water helps prevent illness.

Mom’s milk is best! Breastfeed as long as you can. If you use formula, use powdered formula. For baby bottles, use glass and avoid plastic ones.
Questions regarding Exposure Assessment Interview or educational handout?
Chemical in Our bodies – Feedback Session

Recruitment
Informed Consent
Enrollment

Participate in Report Back component?

Preliminary Interview (pre-biomonitoring questionnaire)

16 - 20 women @ 34 -38 weeks gestation

Feedback Session (Usability testing)
Refine Materials
Feedback Session
Refine Materials
Feedback Session
Refine Materials
Feedback Session
Feedback Session
Feedback Session
Project Design – Feedback Session 34-38 wks gestation

- Four rounds of usability testing (English & Spanish)
  - 16-20 women
  - Example:
    - Show hypothetical test results in different formats
    - “Tell us in your own words what this _____ figure tells you.”
    - “What did you like or not like about how these results were presented?”
    - “Is there anything you would like to know about your test results that this example doesn’t tell you?”
Chemicals in Our Bodies Project Design

28-34 weeks gestation

First Encounter

- Recruitment
  - Informed consent
- Enrollment
  - Preliminary interview
  - Provide at-home questionnaire

34-38 weeks gestation

Second Encounter

- Collect maternal blood
  - In-person interview
- Collect umbilical cord blood
  - Collect at-home questionnaire

At delivery

Third Encounter

- Collect maternal urine sample
  - Stipend
- Medical record abstraction
  - 9 months – 1 year
    - Receive some results by mail
    - In-person Report Back Interviews

After delivery

- 18 months – 2 years
  - Receive balance of results by mail and USCF and CECBP contact info provided
Mother’s Specimen Collection and Analysis

110 ml Urine Cup

Blood
- 5 mL Blue top EDTA
- 10 mL Red top #
- 10 mL Red top #2
- 10 mL Red top #3

Pyrethroid pesticides
Organophosphate pesticides
Metals (arsenic, mercury, etc.)
Polycyclic aromatic hydrocarbons
Phthalates
Perchlorate
Environmental phenols (BPA, etc.)
Creatinine

Pb, Cd, Hg

Blood

PCBs, PBDEs, Newer BFRs, DDT/DDE, HCH

PFCs

Lipid Panel

Splits/Archive

WEEKLY

Shipment to CECBP Refrigerated

Shipments to CECBP Frozen

Shipment to CECBP Frozen
Cord Blood Specimen Collection and Analysis

5 mL Blue top EDTA

Pb, Cd, Hg

WEEKLY Shipment to CECBP Refrigerated

10 mL Red top #1
Centrifuge
PCBs, PBDEs, Newer BFRs, DDT/DDE, HCH

10 mL Red top #2
Centrifuge
Lipid Panel PFCs

10 mL Red top #3
Centrifuge
Splits/Archive

Shipment to CECBP Frozen
Critical Values/Follow-Up

- Comparison with clinical reference values
  - Lead - >4.5 ug/dL for pregnant women
    >10 ug/dL for infants
  - Mercury
  - other

- Protocol for follow-up
  - Review by UCSF or CECBP staff
  - Contact participant by phone and mail immediately if needed
  - Contact Dr. Naomi Stotland at Women’s Health Center for referral to UCSF Occupational and Environmental Medicine Clinic
Chemicals in Our Bodies Project Design

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Project Design: Report Back

- Participants indicated desire to receive results
- Receive by mail at two time points
  - 9 months-1 yr after delivery
    - Results Communication Interview with ~50 women
  - 18 months – 2 yrs after delivery
    - Participants will be provided name and contact information of designated UCSF or CECBP staff
Chemical in Our bodies – Report Back Component

16 – 20 women @ 34 - 38 weeks gestation

Recruitment
   Informed Consent
   Enrollment

Participate in Report Back component?

Preliminary Interview (pre-biomonitoring questionnaire)

Usability testing
   Refine Materials

Usability testing
   Refine Materials

Usability testing
   Refine Materials

Usability testing

Results communication interviews (In-Person)

~50 women, 9 months-1 year after delivery
Data Analysis

- Presence and distribution of levels of chemicals measured in pregnant women; compare with NHANES data for pregnant women
- Presence and distribution of levels of chemicals measured in infants (cord blood)
- Compare maternal levels to infant (cord blood) levels
Data Analysis

- Demographic differences on chemical levels
- Associations between chemicals and exposure sources
- Relationships between perinatal outcomes and chemical levels
- Metrics of cumulative maternal and infant exposures to chemicals to be developed
# Project Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan 20, 2010</td>
<td>UCSF/UCB Institutional Review Board (IRB) Submission</td>
</tr>
<tr>
<td>Feb 18</td>
<td>CDPH IRB Submission</td>
</tr>
<tr>
<td>Mar</td>
<td>IRB Responses</td>
</tr>
<tr>
<td>Mar-Apr</td>
<td>Field test instruments and procedures</td>
</tr>
<tr>
<td>Apr</td>
<td>Submit revisions to respective IRBs</td>
</tr>
<tr>
<td>May-Jun</td>
<td>Begin recruitment</td>
</tr>
<tr>
<td>Dec</td>
<td>Complete all data and biospecimen collection</td>
</tr>
<tr>
<td>Jan 2011</td>
<td>Lab and data analysis begins</td>
</tr>
<tr>
<td>Oct 2011</td>
<td>Report generation</td>
</tr>
</tbody>
</table>
Questions?