The HOME Study: A Cincinnati Cohort Examining Health Outcomes & Measures of the Environment

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Data and Biospecimen Sharing in Environmental Health
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Overview

Current Principal Investigators:

- Bruce Lanphear, MD, MPH  Simon Fraser U
- Kimberly Yolton, PhD  CCHMC
- Aimin Chen, MD, PhD  UC
- Joseph Braun, PhD  Brown U

Pregnancy and birth cohort study examining the impact of a wide range of environmental exposures on child outcomes
HOME Study History

- Established through a Children’s Environmental Health Center grant awarded in 2001 by the NIEHS and US EPA (PIs: Lanphear & Dietrich)
- 5 integrated research projects focused on exposures to environmental toxicants and child health
- 2 of these projects created the HOME Study
- Study of this cohort has continued for over 14 years through multiple grant mechanisms
Primary Objective

To improve our understanding of the impact of exposures to *common environmental toxicants* on infant and child *health, development, and behaviors.*
Focus on Common Environmental Toxicants

**Original Toxicant List**
- Lead
- Tobacco (cotinine)
- Pesticides (OP, OC)
- Methyl mercury
- PCBs

**Toxicants Added**
- Phthalates
- Bisphenol-A
- Flame retardants
- Perfluorinated chemicals
- Air pollution
- Other metals (As, Cd)
Study Design: Randomized Trial and Longitudinal Observation

- Enrollment: 16 weeks GA
- Randomization
- Lead Reduction
- Injury Prevention
- Delivery: 1-4d, 4-5w
- Infancy
- Childhood: 1y, 2y, 3y, 4y, 5y, 8y

Environmental Sampling – Prenatally to age 3y

Biological Sampling – Prenatally through childhood
Study Design: Randomized Trial

Lead Hazard Reduction
• Primary Prevention
  • Before delivery = before exposure
• Lead-Safe Contractors
  • Stabilize paint
  • Replace windows
  • Dust control
  • Cover soil
  • Install water filter

Injury Prevention
• Primary Prevention
  • Before mobility = before injury
• Reduce falls, cuts, burns
  • Smoke detectors
  • Stair gates
  • Safety latches
  • Outlet covers
  • Window guards

Average Renovation Cost:
Lead Hazard Reduction: $5585
Injury Prevention: $321
**Study Design: Phases**

**PHASE 1:**
- Enrollment at OB office
- Maternal Measures
- Birth and Infant Measures
- Early Infant Neurobehavior
- 1, 2, 3y Home visits
- 1, 2, 3y Clinic visits
- Cognitive and Motor Development
- Behavior
- Growth

**Neurobehavioral Assessment:**
- Parent report
- Direct assessment of skills
- Child report

**PHASE 2:**
- 4 and 5y Clinic Visits
- Language Development
- Cognition (IQ)
- Reading Readiness
- Executive Function
- Behavior
- Growth

**PHASE 3:**
- 8 Year Clinic Visit
- Cognition (IQ)
- Reading and Math Achievement
- Executive Function
- Spatial Reasoning
- Gender Identity
- Behavior
- Growth

**Planned Future PHASE 4:**
- 11 to 13 Year Outcomes
- Anxiety
- Depression
- Social Impairment
- Behavior
- Growth
- Neuroimaging
- Adiposity
Study Enrollment

5,184 Women screened for eligibility

1,263 Eligible

3,921 Not eligible

795 Refused

468 Initial Participants (37% of eligible)

60 (12.8%) Dropped out during Run-In Phase

398 Women remained to deliver 407 Infants

2 Women and 3 Children re-enrolled in Phase 3

400 Women
410 Children
## Characteristics of the Cohort (Phase 1)

<table>
<thead>
<tr>
<th>Maternal Characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>32%</td>
</tr>
<tr>
<td>Age at delivery</td>
<td>29y</td>
</tr>
<tr>
<td>Married</td>
<td>64%</td>
</tr>
<tr>
<td>Household income</td>
<td>$55,000</td>
</tr>
<tr>
<td>Employed</td>
<td>81%</td>
</tr>
<tr>
<td>&gt;HS or GED</td>
<td>75%</td>
</tr>
<tr>
<td>Urban</td>
<td>61%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Child Characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>46%</td>
</tr>
<tr>
<td>Birth weight</td>
<td>3360 g</td>
</tr>
<tr>
<td>Gestational age</td>
<td>39.0 weeks</td>
</tr>
</tbody>
</table>
## Mean Exposure Characteristics (Phase 1)

<table>
<thead>
<tr>
<th>Toxicant Measured</th>
<th>Original Cohort (n=398)</th>
<th>% Detectable</th>
<th>NHANES Females 2003-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Blood Lead (ug/dL)</td>
<td>1.68</td>
<td>100</td>
<td>1.7</td>
</tr>
<tr>
<td>Maternal Blood Lead (ug/dL)</td>
<td>0.67</td>
<td>99.7</td>
<td>1.19</td>
</tr>
<tr>
<td>Blood Mercury (ug/L)</td>
<td>0.58</td>
<td>92</td>
<td>0.78</td>
</tr>
<tr>
<td>Serum Cotinine (ng/mL)</td>
<td>0.073</td>
<td>64</td>
<td>0.05</td>
</tr>
<tr>
<td>Serum PBDE47 (ng/mL)</td>
<td>20.7</td>
<td>100</td>
<td>19.6</td>
</tr>
<tr>
<td>Serum PFOA (ng/mL)</td>
<td>5.5</td>
<td>100</td>
<td>3.5</td>
</tr>
<tr>
<td>Total PCB (ng/g lipid)</td>
<td>61.6</td>
<td>100</td>
<td>79.2</td>
</tr>
<tr>
<td>OP pesticides DAP (nmol/L)</td>
<td>63</td>
<td>100</td>
<td>n/a</td>
</tr>
<tr>
<td>Phthalates DEHP (nmol/L)</td>
<td>365</td>
<td>100</td>
<td>n/a</td>
</tr>
<tr>
<td>Phthalates DBP (nmol/L)</td>
<td>152</td>
<td>100</td>
<td>n/a</td>
</tr>
<tr>
<td>BPA (ng/mL)</td>
<td>2.2</td>
<td>99</td>
<td>2.4</td>
</tr>
<tr>
<td>Enrolled Children are Typically Developing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number completed</td>
<td>Mean</td>
<td>SD</td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>------</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td>Cognitive Development/IQ *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bayley II MDI – 1y</td>
<td>337</td>
<td>93</td>
<td>10</td>
</tr>
<tr>
<td>WPPSI FSIQ – 5y</td>
<td>210</td>
<td>102</td>
<td>15</td>
</tr>
<tr>
<td>WISC-IV – 8y</td>
<td>231</td>
<td>102</td>
<td>16</td>
</tr>
<tr>
<td>Behavior Problems (BASC2) **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Externalizing</td>
<td>239</td>
<td>50</td>
<td>9</td>
</tr>
<tr>
<td>Internalizing</td>
<td>239</td>
<td>48</td>
<td>9</td>
</tr>
<tr>
<td>Behavior Symptoms</td>
<td>239</td>
<td>50</td>
<td>9</td>
</tr>
</tbody>
</table>

* Standardized Mean = 100, SD = 15
** Standardized Mean = 50, SD = 10
Variables Collected

- Exposures
- Covariates & Confounders
- Outcomes
Variables Collected

~32,000 survey questions:
- Exposure surveys
- Demographics
- Maternal and child health

Growth (child and parent)

Derived Variables such as:
- Reported tobacco smoke exposure
- Breast feeding duration
- Maternal supervision

- Comprehensive Neurobehavioral Battery:
  - Infant neurobehavior
  - Child development
  - Intelligence and Achievement
  - Behavior (multiple dimensions)
  - Executive function
  - Visual-spatial learning
  - Parent traits

> 1 million variables collected,
> 10GB of data storage
Biospecimens Collected

Maternal Samples
- Urine
- Whole blood & serum
- Hair
- Saliva
- Extracted DNA
- Breast milk and/or formula

Child Samples
- Umbilical cord blood & serum
- Vernix
- Meconium
- Urine
- Whole blood & serum
- Hair
- Shed deciduous teeth
- Exhaled NO
- Extracted DNA

37,555 biological samples collected
Environmental Specimens Collected

- Soil
- Vacuum dust
- Dust wipes
- Water

<table>
<thead>
<tr>
<th>Pregnancy</th>
<th>1y</th>
<th>2y</th>
<th>3y</th>
<th>Renovation</th>
<th>Move</th>
</tr>
</thead>
</table>

15,000 environmental samples collected from the homes of 410 participants
Data Sharing

• We welcome secondary projects that can benefit from the richness of the HOME Study data

• 2012 – Implemented a protocol for applying for use of data

• Ensures there is no overlap with ongoing or planned projects

• Ensures proper acknowledgement of key investigators

• Acknowledges key funding sources and investigators
Data Sharing

• Data use form must be completed indicating all variables requested, available funding for data management support, publication intent
• Approval by committee of 5 investigators including 1 biostatistician/epidemiologist
• Evaluation by data manager regarding feasibility and time line for delivery of data set(s)
• Per CCHRF, the protocol mandates that 1 investigator from CCHMC be included on all manuscripts
• Have approved >30 projects through this mechanism
Challenges

• Keeping track of the multiple projects and analyses
  – Ensuring adequate progress
  – Status of publications
• Ensuring all data users comply with protocol
• Ensuring destruction of data following analysis
• Data management is not FREE
The HOME Study Team

**Investigators**

**Cincinnati**
- Mekibib Altaye
- Aimin Chen
- Kim Dietrich
- Tanya Froehlich
- Richard Hornung
- Jane Khoury
- Kieren Phelan
- Paul Succop
- Heidi Sucharew
- Kim Yolton

**External**
- Joseph Braun
- Amy Kalkbrenner
- Bruce Lanphear
- Adam Spanier
- Heather Stapleton

**Dedicated Staff**

- Sam Morgan
- Yingying Xu
- Stacey Liddy
- Ann Popelar
- Leah Tyzinski
- W Mim Larkin
- Sarah Stewart
- Sharon Penko
- Suzette Baez
- Hadley Sauers
- Will Bell
- Jason Meyer
- Diana Henderson

**Summer Students and Interns**

- Jessica Cruey
- Hafiz Mohamed
- Keith Payne
- Rick Hutchinson
- Donna Strauss
- Robert Tamer

**HOME Study Participants**

- Joseph Braun
- Amy Kalkbrenner
- Bruce Lanphear
- Adam Spanier
- Heather Stapleton