Infrastructures and procedures for a sustainable HBM applied in the U.S. National Health and Nutrition Examination Survey (NHANES)

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From HUMAN BIOMONITORING to European and national policies: meeting the MS representatives
September 17, 2012
Paris, France
What is NHANES?

- Annual survey (since 1999) conducted by the National Center for Health Statistics, CDC
  - Focus is to generate clinical & nutritional data
- Stratified, multistage probability sample of the civilian, noninstitutionalized U.S. population
  - Yearly: ~5,000 persons and ~15 counties
  - Results released for combined 2-year cycles (e.g., 1999-2000)
- Includes physical examination, and collection of medical history, demographic, socioeconomic & behavioral data
- Also collects biological specimens
  - Clinical chemistry laboratory tests
  - Exposure to nutritional biomarkers & environmental chemicals

http://www.cdc.gov/nchs/nhanes.htm
Selection of Chemicals

- **Open process: Federal Register**
  - Solicitation of nominations for inclusion of candidate chemicals or chemical categories
  - Scientific criteria

- **Criteria for inclusion of chemicals**
  - Data suggesting exposure in the U.S. population
  - Seriousness of health effects known or thought to result from exposure
  - Need to assess the efficacy of public health actions to reduce exposure(s)
  - Adequate analytical methods
  - Availability of NHANES blood or urine
  - Affordable analytical costs

- **Criteria for removal of chemicals**
  - Better biomarkers, detection rates and trends

Biomonitoring Logistics for NHANES

- **U.S. Congress funding**
- **Matrices: blood and urine**
  - NHANES contractor collects, processes & ships HBM samples
  - HBM performed at the National Center for Environmental Health, CDC
    - Residual HBM specimens returned to NHANES for permanent storage
- **HBM in randomly selected subsets of participants**
  - Average sample size ~ 2500 people/chemical for each 2-year cycle
    - Urine biomarkers: Age $\geq 6$ years
    - Blood biomarkers: Age $\geq 12$ years
      - Exception: blood Pb, Cd & Hg ($\geq 1$ year) & serum cotinine ($\geq 3$ years)
- **HMB data management**
  - Final participants & QC results reported to NHANES contractor
    - Data reporting schedule is chemical dependent

Communication of HBM Results - Individual

- "Report of Findings" only for Pb, Cd & total Hg
  - Final report of findings mailed 12-16 wks after exam to participants’ homes


http://www.cdc.gov/nchs/nhanes/participant.htm
Communication of HBM Results - Population

- **Survey & HBM “raw” data publicly available on NHANES website**
  - Updated monthly
    - [http://www.cdc.gov/nchs/nhanes/new_nhanes.htm](http://www.cdc.gov/nchs/nhanes/new_nhanes.htm)
  - Link HBM exposure to clinical, nutrition, and demographic data

- **Descriptive presentation of HBM data by age group, sex, race/ethnicity released on NCEH website**
  - National Reports on Human Exposure to Environmental Chemicals
    - [www.cdc.gov/exposurereport](http://www.cdc.gov/exposurereport)
    - Periodic updates
    - Tabular presentation
    - General text on uses, sources, biologic fate, and health effects of the chemicals
    - Comparisons to other human biomonitoring studies
CDC’s National Reports on Human Exposure to Environmental Chemicals

- Ongoing biomonitoring assessment of the exposure of the U.S. population to selected environmental chemicals
  - Metals, POPs, non-persistent chemicals

Urinary Trioclosan (2,4,4'-Trichloro-2'-hydroxyphenyl ether)

Geometric mean and selected percentiles of urine concentrations (in μg/L) for the U.S. population from the National Health and Nutrition Examination Survey.

<table>
<thead>
<tr>
<th>Survey years (90th, 95th)</th>
<th>Geometric mean (95% confidence interval)</th>
<th>Selected percentiles (95% confidence interval)</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>9.26 (7.90-10.69) 47.4 (39.2-59.4) 249 (186-304)</td>
<td>468 (363-522) 2517</td>
<td>95th</td>
</tr>
<tr>
<td>05-06</td>
<td>10.3 (8.30-17.2) 35.4 (23.8-49.8) 97.3 (67.4-181)</td>
<td>248 (189-563) 356</td>
<td>50th</td>
</tr>
<tr>
<td>07-08</td>
<td>6.06 (4.00-4.50) 20.7 (14.3-31.6) 123 (60.4-163)</td>
<td>157 (113-260) 314</td>
<td>75th</td>
</tr>
<tr>
<td>95th</td>
<td>8.2 (6.80-9.40) 35.4 (23.8-49.8) 97.3 (67.4-181)</td>
<td>248 (189-563) 356</td>
<td>75th</td>
</tr>
<tr>
<td>Age group</td>
<td>14.5 (11.0-19.1) 36.4 (26.5-46.4) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
<td>75th</td>
</tr>
<tr>
<td>6-11 years</td>
<td>8.06 (6.20-10.5) 30.9 (21.8-39.7) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
<td>75th</td>
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<td>12-19 years</td>
<td>14.5 (11.0-19.1) 36.4 (26.5-46.4) 104 (53.6-189)</td>
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<td>248 (189-563) 356</td>
<td>50th</td>
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<tr>
<td>20 years and older</td>
<td>8.06 (6.20-10.5) 30.9 (21.8-39.7) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
<td>75th</td>
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<td>248 (189-563) 356</td>
<td>50th</td>
</tr>
<tr>
<td>Gender</td>
<td>14.5 (11.0-19.1) 36.4 (26.5-46.4) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
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</tr>
<tr>
<td>Males</td>
<td>8.06 (6.20-10.5) 30.9 (21.8-39.7) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
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<tr>
<td>Females</td>
<td>8.06 (6.20-10.5) 30.9 (21.8-39.7) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
<td>75th</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>8.06 (6.20-10.5) 30.9 (21.8-39.7) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
<td>75th</td>
</tr>
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<td>Mexican Americans</td>
<td>8.06 (6.20-10.5) 30.9 (21.8-39.7) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
<td>75th</td>
</tr>
<tr>
<td>Non-Hispanic whites</td>
<td>8.06 (6.20-10.5) 30.9 (21.8-39.7) 104 (53.6-189)</td>
<td>165 (108-254) 424</td>
<td>75th</td>
</tr>
</tbody>
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www.cdc.gov/exposurereport
The Reports (NHANES HBM Data) Don’t Include…

- No data interpretation
- No health outcomes analysis
  - The presence of a chemical in the body does not mean it causes disease
- Data per se do not identify levels that cause disease
  - Additional exposure-health effect studies
- Per NHANES design:
  - No geographical (local, State or region) information
  - No seasonal data
  - No target populations with potential low/high exposures
  - Most HBM data are unavailable for the very young
- Need for additional studies of specific populations
  - Collaborative studies
  - National, State or local efforts
    - NCS, NYC HANES, Biomonitoring California
Public Health Uses of the *Reports*

- Who is exposed? How much? Which chemicals?
- Establish reference ranges
- Monitor time trends and effectiveness of interventions
  - Lead in gasoline; FQPA; POPs; ETS
- Prevalence above thresholds
- Assist in risk assessments
- Set new research directions
- Data to link environmental exposures with genes, nutrition, and demographic data → health outcomes
  - Cross-sectional study design
  - Single spot sampling approach
    - Categorize “average” exposure for non-persistent chemicals
Prevalence above Thresholds: Percentage of U.S. children 1-5 years Old with Blood Lead Levels ≥ 10 µg/dL

<table>
<thead>
<tr>
<th>Year Range</th>
<th>Percent</th>
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<tbody>
<tr>
<td>1976-1980</td>
<td>88.2</td>
</tr>
<tr>
<td>1988-1991</td>
<td>8.6</td>
</tr>
<tr>
<td>1991-1994</td>
<td>4.4</td>
</tr>
<tr>
<td>1999-2004</td>
<td>1.4</td>
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</tbody>
</table>

Monitor Time Trends & Effectiveness of Interventions: Decline in Exposure to Secondhand Smoke in the Non-smoking U.S. Population

Median serum cotinine (ng/mL)

Age group (years)

<table>
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<tr>
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<tbody>
<tr>
<td>3-11</td>
<td>0.30</td>
<td>0.08</td>
</tr>
<tr>
<td>12-19</td>
<td>0.28</td>
<td>0.07</td>
</tr>
<tr>
<td>20+</td>
<td>0.15</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Pirkle et al. EHP, 2006, 114:853–858
Assist in Risk Assessments: Triclosan

- **Synthetic broad-spectrum antimicrobial agent**
  - Uses of triclosan regulated by EPA & FDA
  - First registered as a pesticide in 1969

- **Risk Assessment for Triclosan for the Purpose of Issuing a Reregistration Eligibility Decision (US EPA, October 2008)** relied in part on the 2003-2004 NHANES measurements of urinary concentrations of triclosan
  - Biomonitoring data: accurate predictor of aggregate exposure (not for children <6 years old)
    - Triclosan specific
    - Based on actual consumer use of triclosan-containing products
    - Inclusive of all triclosan-related exposures (i.e., EPA & FDA regulated uses)

http://www.epa.gov/oppsrrd1/REDs/factsheets/triclosan_fs.htm
HBM Public Health Impact – U.S. Examples

- Smoking bans in public places
- Major U.S. health organizations demanded mandatory labeling of PVC medical devices containing DEHP
  - Some hospitals no longer use DEHP-containing materials
- Since 2010, some phthalate-containing drugs include cautionary language on use during pregnancy and lactation
- Certain companies have pledged to eliminate phthalates from nail polish and cosmetics, and BPA from select products
  - "No phthalates" or "BPA-free" labels
- In 2012, Campbell’s Soup Company agreed to eliminate BPA from its canned food packaging
HBM Policy Impact – U.S. Examples

- U.S. Consumer Product Safety Improvement Act of 2008 restricting use of some phthalates in children’s toys and child care articles
- U.S. FDA’s Family Smoking Prevention and Tobacco Control Act of 2011
- U.S. FDA to re-evaluate its assessment of BPA for use in food contact applications (ongoing)
  - In July 2012, U.S. FDA banned the use (already abandoned) of polycarbonate resins in baby bottles and spill-proof cups
- U.S. EPA is developing a proposed national primary drinking water regulation for perchlorate
- U.S. EPA is relying on NHANES data to propose future actions under the Toxic Substances Control Act (TSCA)
  - Hearings in the US Congress about the need to reform TSCA are underway
Final Thoughts

- NHANES can provide ongoing data on the exposure of the U.S. population to environmental chemicals
- Biomonitoring, clinical and nutritional NHANES parameters can be linked to evaluate health outcomes
- NHANES cannot answer all public health issues
  - Cross-sectional design
  - National estimates: no geographical or seasonal information
  - No data for specific population groups, sources & uses of chemicals
  - Limited data for children <6 years of age
- Need for additional studies to assess exposures in select populations
- Separate studies of varying exposure levels and health effects are required to determine which blood and urine levels are safe and which result in disease
- HBM data can be used to support public health guidelines
For more information please contact Centers for Disease Control and Prevention

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Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov  Web: www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.