Biomonitoring California

Evaluation of Activities under the CDC Cooperative Agreement 2009-2014

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Purpose of Evaluation

- Assess Program success in meeting the objectives set forth in the CDC cooperative agreement (*FY 2009-2014*)

- Provide recommendations for Program improvement

Methods

- Program document review
- Onsite laboratory evaluation
  - Performed by a laboratory auditor
- One-on-one interviews and online surveys
  - Selected Program staff and managers
  - SGP members
  - External collaborators and stakeholders
- Results from document review, laboratory evaluation, and interview and survey results integrated to develop findings and recommendations

Major Findings

Biomonitoring California:

- **Achieved impressive accomplishments under each objective of the CDC cooperative agreement**
- **Made important contributions to public and environmental health**

Findings and Recommendations by Objective

Objective One

Establish laboratory capability (14 classes of chemicals) and capacity (13,000 assays per year) in human blood or urine

Objective One: Selected Findings

- Exceeded capability objective (16 classes)
- Increased laboratory capacity significantly to 10,350 assays
  - Full capacity not reached due to sample availability, staffing, and equipment access
- Demonstrated ability to complete major projects and laboratory collaborations
  - Completed sample analyses from over 4,000 individuals
- Achieved new efficiencies in laboratory methods
  - For example, can conduct simultaneous analysis of up to 12 metals, with decreased analysis times and improved detection limits

Objective Two

Demonstrate success of our quality management system to receive, transport, track, inventory, process, and analyze biospecimens; generate reports; and maintain biospecimen archives

Objective Two: Selected Findings

Findings from the laboratory evaluation:

- Quality systems for sample and data management at both laboratories have continuously expanded and improved to meet the needs of the Program
- Data quality is consistently supported by successful participation in numerous external quality control and proficiency testing programs
- Sample and data management of the four laboratory methods chosen for the audit were satisfactory

Objective Two: Recommendations

Priority recommendations from laboratory evaluation

- Develop Quality Assurance Program Plan (QAPP) for the overall Program
- Achieve ECL accreditation under ISO17025
- Better integrate biomonitoring activities into EHL's internal audit and management review process
- Improve documentation and decrease time necessary to finalize Standard Operating Procedures (SOPs)

Objective Three

Apply laboratory biomonitoring methods to assess and track trends in exposure levels for selected environmental chemicals among targeted populations, including vulnerable groups, such as pregnant women and their infants

Objective Three: Selected Findings

- Carried out complicated, large-scale, full project collaborations requiring coordination across multiple external partners and state departments
- Leveraged Program resources through laboratory collaborations, which contributed to building capacity and capability and added to the results database
- Measured priority chemicals in diverse populations, with varying demography, types of exposures, and geographic areas
- Built database of biomonitoring results that provides an initial picture of exposures in California
- Analyzed trends where possible
  - For example, measured decline in PBDEs in one study, providing evidence for the effectiveness of California's ban
- Maintaining biorepository of samples that can be analyzed for new chemicals of concern in the future

Objective Three: Recommendations

- Strategically target new populations to add depth and breadth to database of environmental chemical exposures across California
- Continue to improve internal and external communication and coordination
- Identify opportunities to link exposure data (such as measurements in dust) with biomonitoring results
- Use results collected to date as baseline for examining future trends in chemical exposures

Objective Four

Assess exposure to and track trends in selected environmental chemicals in a representative group of Californians by determining the levels of those chemicals in biospecimens, and determining the prevalence of levels above known toxicity or clinical action thresholds among California residents.

Objective Four: Selected Findings

The Program has doggedly pursued recommendations and opportunities to biomonitor a representative sample, in the absence of full funding:

- Pilot and Expanded BEST provide data on adult Kaiser Permanente members in the Central Valley and will help inform efforts to approximate a sample that is representative of California
- Program overcame significant obstacles to achieve collaboration with Genetic Disease Screening Program (GDSP)
- Laboratory methods for small volumes provide avenue to measure chemicals in representative sample of pregnant women through archived samples at GDSP

Objective Four: Recommendations

- Continue efforts to obtain sustainable funding to measure chemicals in a representative sample of Californians

- Build on BEST and GDSP collaborations to inform efforts to approximate a representative sample

Objective Five

Demonstrate the ability to engage and collaborate with stakeholders and communities in exposure assessment investigations and in the development of outreach and educational materials and results return materials

Objective Five: Selected Findings

- Program consistently followed through on intention to engage with and develop understandable materials for stakeholders, the public, and biomonitored populations:
  - Developed Public Involvement Plan
  - Convenes public SGP meetings and workshops with opportunity for comment
  - Launched highly praised new website, with fact sheets and interactive results database
  - Created Biomonitoring Guide based on Program brochure (multiple languages)
  - Developed template for results return materials, with improvements based on usability testing, and returned results to ~650 participants
- Results return is a worthwhile but resource intensive effort
  - Results return is a unique, highly valued principle for the Program
  - Availability of template with fact sheets, as well as automation in generating packets, provides new efficiencies

Objective Five: Recommendations

- Identify opportunities for additional stakeholder engagement
- Consider establishing an advisory body made up of stakeholders, the public, and others with expertise tuned to issues relevant to community concerns
  - Identify sustainable funding source
- Utilize SGP members' expertise and networking potential to further publicize the Program

Program Projects

- Full Project Collaborations

  Maternal and Infant Environmental Exposure Project (MIEPP)

  Firefighter Occupational Exposures (FOX) Project

  Biomonitoring Exposures Study (BEST) (Pilot and Expanded)

  Genetic Disease Screening Program (GDSP)

- Projects with Environmental Health Tracking Program

  Pesticide Drift 2 Study

  Imperial County

Program Projects (cont.)

- Laboratory Collaborations

  Cohort of Young Girls' Nutrition, Environment, and Transitions (CYGNET)

  Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS)

  Markers of Autism Risk in Babies- Learning Early Signs (MARBLES)

  Health and Environmental Research in Make-up of Salinas Adolescents (HERMOSA)

  California Childhood Leukemia Study (CCLS)

  Women's Health and the Environment (WHE)

  California Teachers Study (CTS)

  Three Generations Study (3Gs)

  Environmental Chemistry Laboratory Pilot Study

  UCSF Studies of Second-Trimester Pregnant Women

Selected Program Contributions to Public and Environmental Health

- Identification of elevated blood mercury in a San Francisco family prompted further health education efforts on adulterated face creams
- MIEEP demonstrated that infants have higher levels of certain chemicals than their mothers
- FOX showed higher levels of PBDEs and benzophenone-3 in firefighters
  - FOX found that use of protective gear and following occupational hygiene guidelines could reduce firefighter exposure to flame retardants
- Downward trend in PBDEs in small study of pregnant women provides evidence for effectiveness of California ban
- Consistently lower levels of lead in California residents compared to national surveys provide evidence that government initiatives have been successful
- Publicly available results inform California policy initiatives, such as the Safer Consumer Products program

Additional Recommendations

- Develop a Program vision
- Develop a sustainability plan, including stable state funding
- Seek additional external funding
- Develop an evaluation plan
- Strengthen relationships with external partners and stakeholders