Evaluating a Coordinated Research Network: an Enterprise Approach

Christie Drew, Ph.D.
Kristi Pettibone, Ph.D.
NIEHS – Program Analysis Branch
NIEHS Mission: Reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease.

Division of Extramural Research and Training
Funds a broad portfolio of research

Program Analysis Branch:
Evaluation, Communication, Tool Development
Enterprise evaluation is focused on:

- Collective impact of funded projects
- Fostering awareness and collaboration among interrelated projects
- Deliberately incorporating cross-project coordination and collective impact measures
- Intentional effort and strong partnerships among practitioners

**Enterprise Evaluation: A New Opportunity for Public Health Policy**

Mya Sherman, MA; Hannah Covert, PhD; Lisanne Brown, PhD, MPH; Jennifer Langhinrichsen-Rohling, PhD; Tonya Hansel, PhD, LMSW; Timothy Rehner, PhD; Ayanna Buckner, MD, MPH; Maureen Lichtveld, MD, MPH

Sherman et al 2018: DOI: 10.1097/PHH.0000000000000862
Overview

• Objective: place a recent evaluation in the Enterprise Evaluation context

• Relevant to many of us at AEA because public agencies often fund coordinated programs.

• Children’s Health Exposure Analysis Resource (CHEAR) Program
  – Awards Made in September, 2015
Children's Health Exposure Analysis Resource

Goal 1

Advance understanding of the impact of environmental exposures on children’s health and development

Goal 2

Provide infrastructure for adding or expanding exposure analysis to studies involving research in children’s health
• Children are uniquely susceptible to environmental exposures during distinct developmental windows
  – Implement the exposome for existing children’s health studies
  • Exposome = totality of exposures across a person’s lifetime

• 4 Year Program =

• Renewal decision ~2 years after the first grantee meeting in Spring 2018
CHEAR infrastructure:

- Administrative management and interface with clients
- Laboratory analysis of existing biological samples
  - 6 different laboratories
- Data repository and statistical analysis and interpretation
Enterprise evaluation is focused on:

- Fostering awareness and collaboration among interrelated projects
- Deliberately incorporating cross-project coordination and collective impact measures
- Intentional effort and strong partnerships among practitioners
- Collective impact of funded projects

Sherman et al 2018: DOI: 10.1097/PHH.0000000000000862
Fostering awareness and collaboration

- Participatory logic modeling at the first Consortium meeting
- Confirmation of collective goals and measurement approaches
- Buy in for data collection strategy

Pictured: Dana Barr, Emory University at the first CHEAR program meeting
Spring 2016

Photo Courtesy of Kristi Pettibone
CHEAR Application & Review Workflow

DRAFT 1/16/2017

CHEAR Application and Review Workflow

Approved & Prioritized

CC-3
Assign LH for initial consultation and feasibility assessment (via committee)

CC-4
Document outcome of feasibility; if feasible, application may be submitted

CC-5
Application review

CC-6
Assign CAC reviewers

CC-7
Record outcome of CAC review, notify PI

CC-8
Initiate clearance activities (lab analysis plan, approvals, agreements)

CC-9
Confirm LH assignment

CC-10
Complete clearance activities (checklist); project cleared for initiation

DC-1
Assess data feasibility

DC-2
Review/approve IRB letter and data sharing agreements

DC-3
Receive project data linked to PIDs; approve data and data dictionary/codebook

DC Portal

P-1
Submit Request for CHEAR Services

P-2
Submit full application, data dictionary, codebook and questionnaire(s)

P-3
Consult with DC for data feasibility, revise application as needed

P-4
Consult with the LH for feasibility

P-5
Initial consultation w/ PI and assess feasibility, present findings to committee. Determine need for and timing of pre-test

LH-1
Initial consultation w/ PI and assess feasibility

LH-2
Develop Lab Analysis Plans (one per analysis). Complete pre-test, if needed

LH-3
Request associated data files (sample characteristic and phenotypic data) as needed

CAC-1
Review of pending applications, approve and prioritize applications

Italics = Form
--- = Optional flow
Deliberately incorporating cross-project coordination and collective impact measures

1. Build and launch the network / process the CHEAR data
2. Inter-laboratory data comparability
3. Harmonization in public use data repository
4. Expand capacity to measure multiple exposures (e.g. chemical mixtures)
5. Methods and tools for exposome science
6. Ability to explain value added
7. Disseminate findings
8. Team Science
9. Coordination with NIH ECHO program
<table>
<thead>
<tr>
<th><strong>Outcome 1</strong></th>
<th>Build and launch the network / process the CHEAR data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Metrics</strong> (All data will be pulled in the August/September 2017 timeframe.)</td>
<td>Data Source</td>
</tr>
<tr>
<td># of Clients submitting RFS</td>
<td>Data to inform these metrics are submitted to the Coordinating Center through the RFS Form and myCHEAR.</td>
</tr>
<tr>
<td># of clients who have not had ES (Environmental Science) grants before</td>
<td></td>
</tr>
<tr>
<td># of clients who don’t have a background in environmental health</td>
<td></td>
</tr>
<tr>
<td># of requests assigned an ID</td>
<td></td>
</tr>
<tr>
<td># of requests per Client (how many clients submit more than 1 RFS)</td>
<td></td>
</tr>
<tr>
<td># of requests per Institution</td>
<td></td>
</tr>
<tr>
<td># of requests related to a specific cohort</td>
<td></td>
</tr>
<tr>
<td># and % of requests for which a Lab Hub consultation and Feasibility Assessment is completed</td>
<td></td>
</tr>
<tr>
<td>Timing and types of consultation provided by lab hub</td>
<td></td>
</tr>
<tr>
<td># and % of requests for which a DCFA is completed</td>
<td></td>
</tr>
<tr>
<td># and % of full applications reviewed</td>
<td></td>
</tr>
<tr>
<td># and % of full applications approved</td>
<td></td>
</tr>
<tr>
<td>List of analytes processed</td>
<td></td>
</tr>
<tr>
<td>List of health outcomes/ condition/disease categories addressed</td>
<td></td>
</tr>
<tr>
<td><strong>Data Processed</strong></td>
<td>Data Center will collect from labs</td>
</tr>
<tr>
<td># analytes processed (DC will receive data on these analytes)</td>
<td></td>
</tr>
<tr>
<td># of biomarker panels for which data have been received</td>
<td></td>
</tr>
<tr>
<td>Summary of geographic regions</td>
<td></td>
</tr>
<tr>
<td>Summary of aggregate demographic/lifestage information</td>
<td></td>
</tr>
<tr>
<td><strong>Publicly Available CHEAR Data</strong></td>
<td>Data Center will report from DUAF</td>
</tr>
<tr>
<td><em>Note: Data will be embargoed for up to year potentially, until clients/PIs have completed first publication. Data analysis that uses these metrics will be delayed until these embargoes are over.</em></td>
<td></td>
</tr>
<tr>
<td># of clients that submit requests to use publicly accessible CHEAR data</td>
<td></td>
</tr>
<tr>
<td># and % of DUAF requests that are approved</td>
<td></td>
</tr>
<tr>
<td># of requests that use NIH supported cohorts</td>
<td></td>
</tr>
<tr>
<td>List of NIH supported cohorts</td>
<td></td>
</tr>
</tbody>
</table>
Intentional effort and strong partnerships

- Commitment to evaluation from NIH leadership and program Steering Committee
  - Coordinating center
  - Data center
  - Laboratories

- Evaluation working group with representatives from every program component

- Clear schedule and timelines

- Maximize data already collecting

- Regular consortium meetings
Collective impact
Quality Assurance

- Within Study (Batch)
  - Method Blanks
  - Labeled Standards

- Within Laboratory (Between Studies)
  - QC Samples/standards
  - Pools

- Between Laboratory (Within CHEAR)
  - Round Robin
  - Common QC materials
  - NIST Samples

- Between Laboratory (External to CHEAR)
  - NYDOH PT Program (Trace Elements)
  - G-EQUAS (organics)
<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Requests for Service</td>
<td>58</td>
</tr>
<tr>
<td>Number of Clients</td>
<td>51</td>
</tr>
<tr>
<td>Number of Clients with 2 Requests</td>
<td>6</td>
</tr>
<tr>
<td>New to NIEHS</td>
<td>24</td>
</tr>
<tr>
<td>Number of Institutions</td>
<td>39</td>
</tr>
</tbody>
</table>

Almost 50% of clients are new to NIEHS

As of 5/31/18
## CHEAR Application Process – By the Numbers

<table>
<thead>
<tr>
<th></th>
<th>Request for Service Submitted</th>
<th>Lab Hub Feasibility Assessment Completed</th>
<th>Full/Revised Application Submitted</th>
<th>Data Center Feasibility Assessment Completed</th>
<th>CHEAR Access Committee Review</th>
<th>NIH Review</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>58</td>
<td>52</td>
<td>32</td>
<td>29</td>
<td>27</td>
<td>25</td>
</tr>
<tr>
<td><strong>Completed</strong></td>
<td>58</td>
<td>43</td>
<td>29</td>
<td>28</td>
<td>25</td>
<td>23</td>
</tr>
<tr>
<td><strong>In Progress</strong></td>
<td></td>
<td>9</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td># and reason to ‘drop out’</td>
<td>6 were not eligible for CHEAR Services</td>
<td>11 were determined not to be analytically feasible</td>
<td></td>
<td>1 was determined not statistically feasible</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **20 Projects Approved**
- **3 Projects Not Approved**
- **2 Pending Review by NIEHS**

As of 5/31/18
## 43,000 Samples Approved for Analysis by June 2018

<table>
<thead>
<tr>
<th>Project Type</th>
<th>Projects</th>
<th>Targeted Analysis</th>
<th>Targeted Analysis Panels</th>
<th>Untargeted Analysis</th>
<th>Biological Response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHEAR</td>
<td>12</td>
<td>19,821</td>
<td>BFRs, Phenols, PFASs, Phthalates, PAHs, Tobacco, Trace elements, VOCs, Other</td>
<td>3,989</td>
<td>2,841</td>
<td>26,651</td>
</tr>
<tr>
<td>ECHO Cohort but with CHEAR funding</td>
<td>7</td>
<td>6,417</td>
<td>Phenols, Pesticides, Phthalates, Tobacco, Trace elements</td>
<td>1,181</td>
<td>1,814</td>
<td>9,412</td>
</tr>
<tr>
<td>ECHO</td>
<td>1</td>
<td>4,474</td>
<td>Phenols, PFASs, Pesticides, Phthalates, Trace elements</td>
<td>0</td>
<td>0</td>
<td>4,474</td>
</tr>
<tr>
<td>Pilot &amp; Feasibility Program</td>
<td>6</td>
<td>322</td>
<td>BFRs, PCBs, PFASs, Trace elements, Other</td>
<td>186</td>
<td>TBD</td>
<td>508</td>
</tr>
<tr>
<td>ECHO UG3</td>
<td>4</td>
<td>1,180</td>
<td>PCBs, Phenols, Phthalates, Trace elements, Other</td>
<td>575</td>
<td>20</td>
<td>1,775</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>30</strong></td>
<td><strong>32,214</strong></td>
<td></td>
<td><strong>5,931</strong></td>
<td><strong>4,675</strong></td>
<td><strong>42,820</strong></td>
</tr>
</tbody>
</table>
Broad Exposure-Outcome Patterns Studied

- Asthma
- Autism & Neurodevelopment
- Diabetes
- Obesity
- Infectious Disease
- Respiratory Health
- Cardiovascular Disease Risk
- Liver Disease
- Metabolic Disorders
- Pregnancy Outcomes
- Infant Growth
- Questionnaire Validation

# Samples
- 163
- 2,000
- 4,000
- 6,120

- Untargeted
- Phthalates
- Trace Elements
- PFASs
- Smoking Metabolites
- Phenols
- PAHs
- Pesticides
- OPFRs
- PBDE
- VOCs

- # Studies
- 1
- 4
Generally Successful!

- Fostering awareness and collaboration among interrelated projects
- Deliberately incorporating cross-project coordination and collective impact measures
- Intentional effort and strong partnerships among practitioners
- Collective impact of funded projects
Human Health Exposure Analysis Resource (HHEAR)

- RFA-ES-18-010, U24 – Coordinating Center
- RFA-ES-18-011, U2C - Targeted Exposure Analysis Labs
- RFA-ES-18-012, U2C - Untargeted Exposure Analysis Labs
- RFA-ES-18-013, U2C - Environmental Monitoring Labs
- RFA-ES-18-014, U2C - Data Repository, Analysis & Science Center

Due October 29, 2018
Thank you!

Christie Drew, Program Analysis Branch Chief, NIEHS
• E-mail: drewc@niehs.nih.gov
• Phone: 984-287-3255

Kristi Pettibone, Evaluator, Program Analysis Branch
• E-mail: pettibonekg@niehs.nih.gov
• Phone: 984.287.3303
• Website: http://www.niehs.nih.gov/research/supported/dert/pab/index.cfm