NIH Tribal Consultation Advisory Committee

ECHO
Environmental influences on Child Health Outcomes

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Asking TCAC Advice

- ECHO committed to consultation with Tribal Nations
- Collaborate with our AI/AN partners
  - Attend to cultural and historical issues
  - Research that both
    - Serves AI/AN communities directly
    - Enhances the ECHO commons for consortia-wide research
Asking TCAC Advice

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• Collaborate with our AI/AN partners
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    • Serves AI/AN communities directly
    • Enhances the ECHO commons for consortia-wide research
  – Sharing data and biospecimens
    » Work in progress
Question—General

- Best ways for...
  - NIH ECHO Program Office and
  - Investigators

...to build relationships with Tribal Nations and collaborate to address concerns?
Questions—Specific
Sharing data and biospecimens—work in progress

• What data and specimens tribal communities able to share
  – With whom
• Self-identified tribal-identified affiliation
• Conditions of use by
  – ECHO investigators
  – Wider scientific community
• Privacy, safety, security
• Duration of storage/use
  – Final disposition, ownership
Questions—Specific
Sharing data and biospecimens—work in progress

• What data and specimens tribal communities able to share
• Self-identified→tribal-identified affiliation
• Conditions of use
• Privacy, safety, security
• Duration of storage/use
• Genetics
  – Same principles? Special case?
Today

• ECHO
  – Goals
  – What are we doing
  – How we are doing it

• Return to the questions
ECHO Mission

Enhance the health of children for generations to come
ECHO
A Nationwide Program
Guiding Principles

• **Teamwork**
  Working well together

• **Impact**
  Research that has an impact on health

• **Responsibility**
  Scientifically & ethically sound research

• **Value**
  Good stewardship, return on investment
ECHO Overall Scientific Goal

Answer crucial questions about effects of broad range of early environmental exposures on child health and development
A good start to life…
...can last a lifetime...

...and over many generations
To ensure a good start, need to understand potential risks…
To ensure a good start, need to understand potential risks…
…and to whom they apply…
... then take action
Broad Range of Early Environmental Exposures

From society to biology
Broad Range of Early Environmental Exposures

From society to biology

- Exposures from conception to age 5 years
- Health outcomes throughout childhood and adolescence
Health Outcomes
Focus on High-Impact Pediatric Conditions

1. Pre/peri/postnatal outcomes
2. Obesity
3. Upper & lower airway
4. Neurodevelopment
5. Positive health
Health Outcomes
Focus on High-Impact Pediatric Conditions

1. Pre/peri/postnatal outcomes
2. Obesity
3. Upper & lower airway
4. Neurodevelopment
5. Positive health
   • Well-being
     – Life satisfaction
     – Positive affect
     – Meaning and purpose
   • Sleep duration and quality
ECHO Components

Coordinating Center

Data Analysis Center
CHEAR
PRO Core

Cohort Sites
IDeA States Network
Genetics Core

Observational studies
Intervention trials
Meet Scientific Needs and Inform Programs, Practice, Policy

- Observational studies
  - Ask solution-oriented questions
    - “So what” questions that have impact
- Intervention trials
  - Children underrepresented in clinical trials
  - Especially hard-to-reach populations
    - Rural, medically underserved
- Both
  - Answer broad scientific questions
  - Apply to specific communities
Major Observational Objective: Create The ECHO-wide Cohort

- Start with multiple existing cohorts (longitudinal studies) of moms & kids
  - Increase likelihood of early successes
  - Continue to recruit new & follow existing participants
- Combine into single *data platform* to conduct solution-oriented observational research
  - Harmonized existing measures
  - Standardized new measures
- To be used
  - By ECHO investigators, then
  - As a national research resource

National Institutes of Health
Environmental influences on Child Health Outcomes (ECHO)
The ECHO-wide Cohort
Many people, many layers of data, many stages of life course
35 awards
74 PIs, 84 cohorts

-Majority started prenatally-

Cohort Prime Awardees
Cohort Sub-Awardees
The ECHO-wide Cohort

- Goal >50,000 children
  - Less common exposures & outcomes
  - To whom do results apply?
On our Way to 50,000 ECHO Children

N=50,865
Data Safety & Security

Data Analysis Center
ECHOPortal.org
Hybrid cloud environment for data capture, storage, & analysis, and to foster collaboration

Researchers have controlled access—only to parts relevant for their specific work
  • 2-factor authentication—prove identity twice before logging in
ECHOPortal.org
Purpose-built security and functionality

• Security controls
  – “FISMA Moderate”: severe risk if information compromised

• Data
  – Encrypted
  – Stay in restricted data vault
  – Controlled access
    • Particular researchers for particular analyses

• Tracking of all user actions

• Independent security audit, continuous monitoring
Diversity in geography, age, sex, social class, race/ethnicity

<table>
<thead>
<tr>
<th></th>
<th>Asian</th>
<th>Black or Af-Am</th>
<th>AI/AN</th>
<th>White</th>
<th>Multi</th>
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<td>3%</td>
<td>66%</td>
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Preliminary Data
Navajo Birth Cohort Study
J. Lewis, PI; M-G. Begay & D. Begay, Collaborators

~400 families followed from prenatal period through 4 years
Navajo Birth Cohort Study

Uranium and other metals, often from abandoned mines
Navajo Birth Cohort Study

Uranium and other metals, often from abandoned mines

Examine relationships of exposure to metals in pregnancy with
- Brain development
- Excess weight gain
And how development of the immune system explains the relationships
Navajo Birth Cohort Study

• Addresses concern of Navajo Nation
  – Individual cohort analysis, N ~400
  – Could spur further mitigation activities
Navajo Birth Cohort Study

• Addresses concern of Navajo Nation
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• Contributes to broader understanding of metals exposure and important child health outcomes
  – ECHO-wide analyses, N ~ 10,000s
  – With large sample of children, see how relationships vary by
    • Geography
    • Race/ethnicity
    • Socioeconomic position
    • Child sex
    • [Mother’s or child’s genes?]
  – Informs policies with impact on many populations
IDeA States Pediatric Clinical Trials Network

Overarching Goals

• Provide access to state-of-the-art clinical trials
  -Medically underserved and rural populations
• Build national pediatric research capacity
  -To conduct clinical trials
    • professional development for faculty
    • infrastructure and team support
• In formative stages…
IDeA States Pediatric Clinical Trials Network
Capacity Building

• Mentoring emerging scientists
• Training and support for staff
IDeA States Pediatric Clinical Trials Network
17 Clinical Sites & DCOC

Clinical Sites
Data Coordinating and Operations Center (DCOC)
IDeA States Pediatric Clinical Trials Network
5 states with high % indigenous populations

- American Indian
- Native Alaskan
- Native Hawaiian
Getting the (Team)work Done

- Foster culture of collaboration
NIH in partnership role

Investigators drive the science
...working groups...
Getting the (Team)Work Done

• Guidance by External Scientific Board
  – Reports to NIH Director via Council of Councils
    • Includes Dr. William Freeman, Northwest Indian College
Long-term

• Conduct innovative observational and intervention research
  – Answer crucial questions about child health and development
  – Inform programs, policies, and practices that improve health of children and adolescents
Enhance the health of children for generations to come
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Extra slides
Ex 2: Prenatal Alcohol in Sudden Infant Death Syndrome and Stillbirth Network Safe Passage Study (PASS, A. Elliott, PI)
~25% AI/AN
~75% Non-Hispanic White

Relationships of prenatal exposure to tobacco, alcohol, drugs with
- Brain development
- Asthma
Within the social context of families
## Disparities in Health Outcomes
### South Dakota

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<th>Health Outcome</th>
<th>SD overall</th>
<th>SD Non-Hispanic White</th>
<th>SD AI/AN</th>
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<tbody>
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<td>Infant mortality (per 1K)</td>
<td>7.0</td>
<td>5.7</td>
<td>11.5</td>
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<tr>
<td>Obesity</td>
<td>32%</td>
<td>30%</td>
<td>47%</td>
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<tr>
<td>Asthma</td>
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