



The National Children's Study

Report to the Secretary's Advisory Committee on Genetics, Health, and Society

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Outline of Presentation

Background

Rationale for The National Children's Study

Current Status

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PL 106-310: Children's Health Act of 2000



- ✍ (a) PURPOSE - ... to authorize NICHD to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

- ✍ (b) IN GENERAL - The Director of NICHD shall establish a consortium of representatives from appropriate Federal agencies (including the CDC and EPA) to:
 - ✍ (1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
 - ✍ (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes...



Study Concepts

- ✍ Longitudinal cohort study, beginning prior to birth continuing through age 21 years
- ✍ National in scope
- ✍ Study of environmental influences on children's health and development
 - ✍ Environment defined broadly (physical, chemical, biological, and psychosocial)
- ✍ Study designed to allow measurement of both chronic and intermittent exposures





Study Concepts







- ✍ Hypothesis driven with primary outcomes related to child health and development
- ✍ Study common range of “environmental” exposures and less common outcomes
- ✍ Environment & gene-environment interactions
- ✍ Consortium of multiple agencies
- ✍ National resource for future studies



Why focus on children?

 Children have:

-  Increased vulnerability to environmental exposures
-  Critical windows of vulnerability during development
-  Immature mechanisms for detoxification and protection
-  Differences in metabolism and behavior that may yield higher exposure in the same environments



Physiological and behavioral factors that increase exposures in children*



Factors	Infants	Children	Adults
Surface Area : Body Mass Ratio (m²/kg)	0.067	0.047	0.025
Respiratory Ventilation Rate (ml/kg/m² lung surf. area/min)	133		2
Drinking water intake (ml/kg/day)	43.5	35.5	19.9
Soil Ingestion (mg/day)		20	0.4
Rate of lead absorption	42-53%	30-40%	7-15%

*Selevan et al. Environ Health Perspect 2000;108(suppl 3);451



Why now?

- ✍ Increasing concern about numerous exposures
- ✍ Increasing concern about diseases and conditions of children
- ✍ Growing experience with effects of exposures: lead, fetal alcohol, etc.
- ✍ Technological capabilities: genome, IT, measurement, tracking

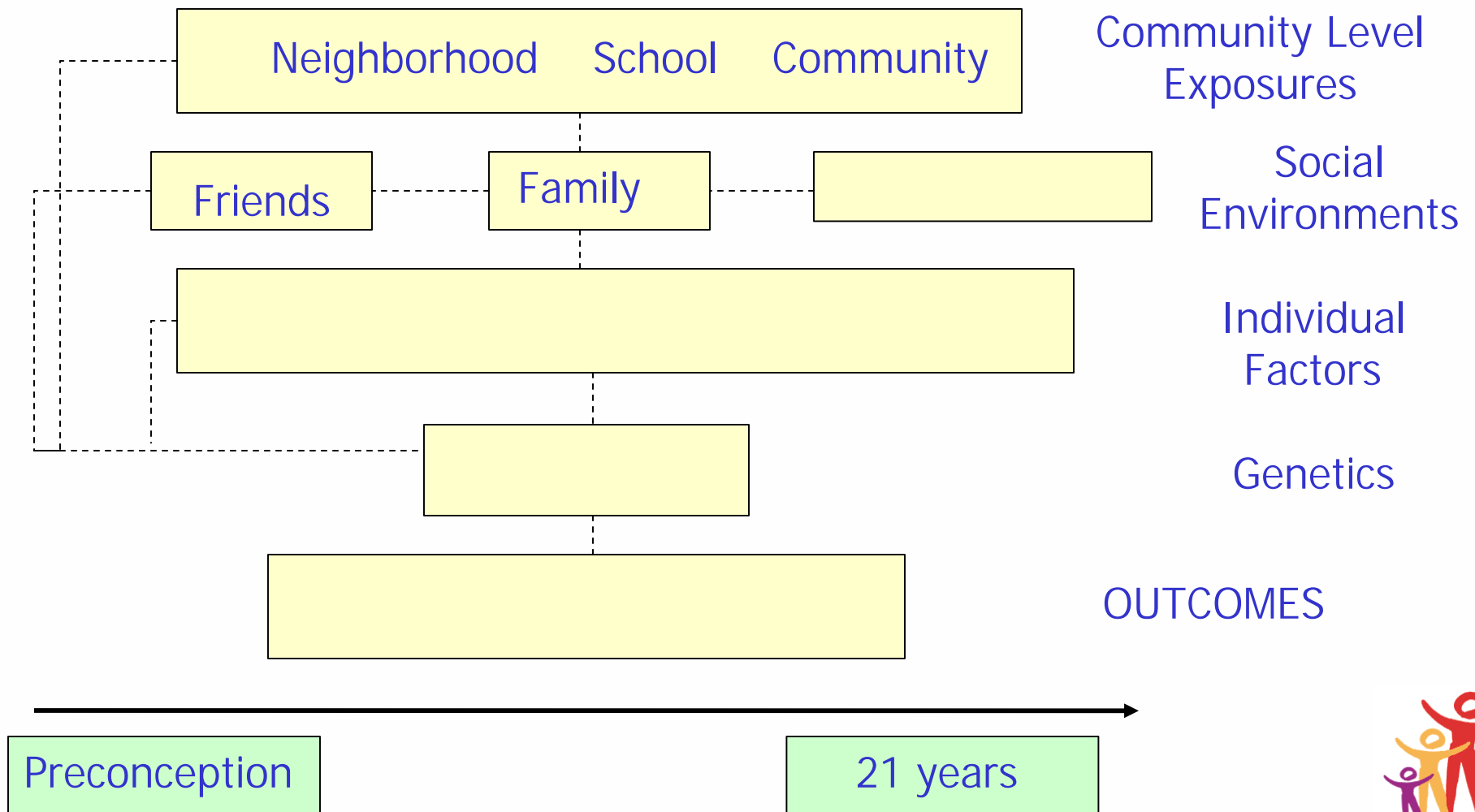


Why a Longitudinal Study?

- ✍ Allows inference regarding causality
- ✍ Allows study of multiple outcomes and multiple exposures
- ✍ Allows study of mediating pathways between exposure and disease
- ✍ Recall bias in relation to exposure is minimized
- ✍ Facilitates study of developmental trajectories



Multiple Levels of Measurement





Recent Milestones and Current Status



Recent Milestones

- ✍ Decision to utilize a National Probability Sample - June 2004
- ✍ Study Plan Presented to the Federal Consortium – September 2004
- ✍ Request for Proposals –Vanguard Centers - November 2004
- ✍ Request for Proposals -Coordinating Center - November 2004
- ✍ Publication of the Growing up Healthy November 2004



The National Probability Sample

✍ 1st Stage

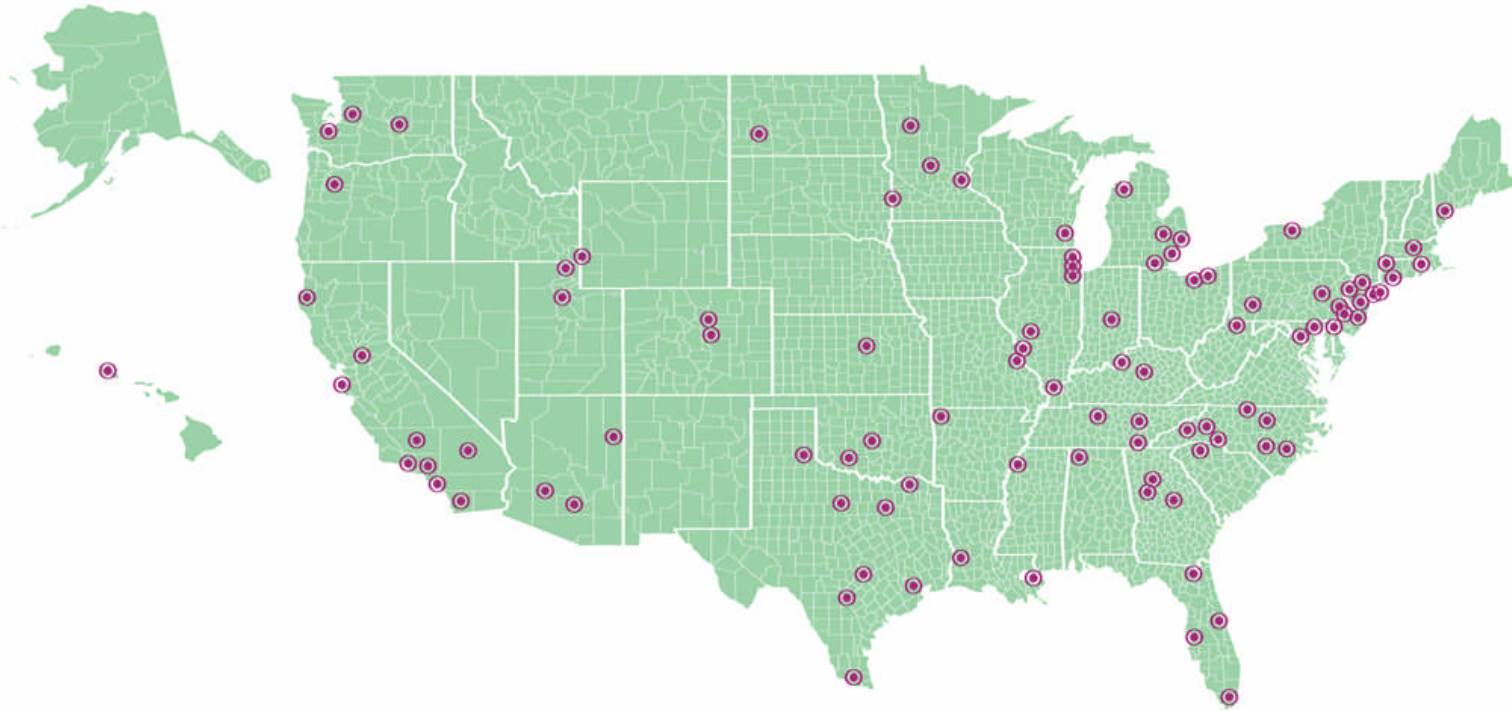
- ✍ 101 study locations drawn from the full list of all counties in the United States
- ✍ 13 self representing locations, 62 metropolitan, 26 non-metropolitan locations

✍ 2nd Stage

- ✍ Selecting segments or groups of households within the study locations
- ✍ Anticipate a highly clustered sample to facilitate study of community characteristics and logistical efficiency
- ✍ Solicit input from the successful offerors to help define the segments
- ✍ To maintain the integrity of the sample, offerors will not be involved in the actual selection of segments



National Children's Study Locations





Selection of Vanguard Locations

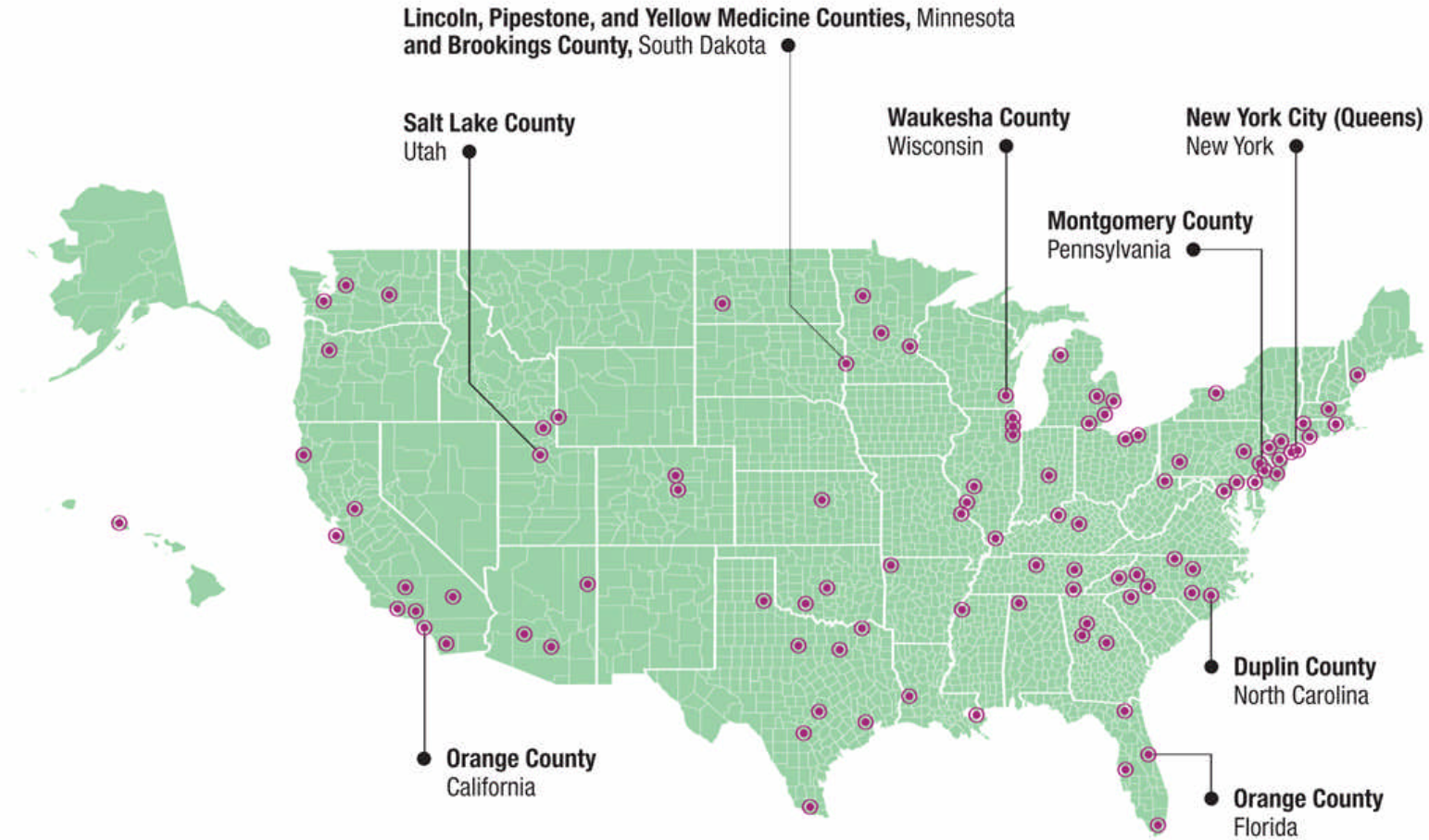


- ✍ From the initial list of Study Locations, eight locations were selected to potentially serve as the Vanguard Locations
- ✍ 2 certainty, 4 metropolitan, non-certainty, 2 non-metropolitan
- ✍ 2 Locations in each of the 4 U.S. Census Regions



National Children's Study Locations

Vanguard locations identified by name





Anticipated Awards



- ✍ The number of awards that are made is dependent on availability of funds and the quality of proposals received
- ✍ Anticipate a total of 3-8 awards
- ✍ There will be no more than 1 award for collection of data in a single location
- ✍ If there are three awards, our goal is to make one award in each of the three categories of certainty, non-certainty, and non-metropolitan
- ✍ If there are 4 awards, our goal is to have one Vanguard Location in each of the four census regions



Other Aspects of the Study Plan

- ✍ Enrolling women and their partners prior to or early in pregnancy, with follow-up of children until 21 years of age
- ✍ Enrollment is over a four-year period
- ✍ Data will be collected in both face-to-face visits and remote data collections
 - ✍ Questionnaires and Interviews
 - ✍ Environmental samples and observations
 - ✍ Clinical and behavioral assessments
 - ✍ Biologic samples
 - ✍ Blood, Urine, Cord Blood, Placenta, Breast milk



Proposed Schedule of Visits

Screening	18 months (Home)
Preconception	3 years (Clinic)
1 st Trimester (home)	5 years (Clinic)
2 nd Trimester (clinic)	7 years (Home)
3 rd Trimester (clinic)	9 years (Clinic)
Delivery	12 years (Clinic)
1 month (Home)	16 years (Home)
6 months (Home)	20 years (Clinic)
12 months (Home)	



Challenges

- ✍ Combination of a probability sample with actual data collection conducted through Centers of Excellence
- ✍ Collect multiple levels of data in a variety of settings
 - ✍ Environmental specimens in the home
 - ✍ Biologic samples at the time of delivery
 - ✍ Measures in the community
- ✍ Capture both intermittent and chronic exposures
- ✍ Capture exposures during critical periods of development



Projected Time Line

- | | |
|------------------|---|
| Early 2005 | Closing date for receipt of proposals for Vanguard Centers and Coordinating Center |
| Late 2005 | Select initial centers |
| 2006 | Complete and pilot initial protocol |
| Early 2007 | Enroll first participants with initial centers |
| 2006-2007 | Select additional centers |
| 2009-2010 | First preliminary results available from pregnancy |
| 2007-2030 | Analyze data as collection continues, publish results throughout: hypothesis specific, public use datasets, RFA's |
| Ongoing | Periodic meetings, peer reviews, workshops, consultations |



Workshop on Collection and Use of Genetic Information



- ✍ Brought together experts in the federal government (NIH, EPA, CDC, FDA) to explore opportunities and challenges, and provide recommendations to the NCS
- ✍ Focus on appropriate collection and storage of biologic samples
- ✍ Workshop report and recommendations will be available on the National Children's Study website



Contact Information

- ✍ Check the Web site:
<http://NationalChildrensStudy.gov>
- ✍ Join the listserv for news and communication
- ✍ Contact us at ncs@mail.nih.gov

