



National Children's Study
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The National Children's Study

- Largest long-term study of children's health and development ever to be conducted in the U.S.
- Longitudinal study of children, their families and their environment (over 21 years or longer, from before birth)
- Environment defined broadly (chemical, physical, behavioral, social, cultural)
- Will include approximately 100,000 children to study important but less common outcomes
- Environment & genetic expression



Why is the Study Important?

- Between 1980 and 1995, the percentage of children with asthma doubled
- The proportion of children 6-18 who were overweight increased from 6% in 1976-1980 to 15% in 1999-2000
- 3-8% of children born each year will be affected by a neurodevelopmental disorder
- Great disparities remain in infant mortality rates among minority and ethnic groups



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 (m ² /kg)	0.067	0.047	0.025
Respiratory Ventilation Rate (ml/kg/m ² lung surf. area/min)	133		2
Drinking water intake (m/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



**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...
- (e) AUTHORIZATION OF APPROPRIATIONS - There are authorized to be appropriated to carry out this section \$18,000,000 for fiscal year 2001, and such sums as may be necessary for each the fiscal years 2002 through 2005.



Study Concepts

- Longitudinal study of children, their families and their environment
- National in scope
- Hypothesis driven
- Environment defined broadly (chemical, physical, behavioral, social, cultural)
- Study common range of "environmental" exposures and less common outcomes (n ~ 100,000)



Study Concepts (cont.)

- Exposure period begins in pregnancy
- Environment & genetic expression
- State-of-the-art technology
 - Tracking
 - Measurement
 - Data management
- Consortium of multiple agencies
- Extensive public-private partnerships
- National resource for future studies



Some Hypotheses

- Pesticides/other chemicals – neuro-cognitive devel.
- Early life infections – asthma incidence and severity
- Maternal infection/inflammation – pre-term birth
- Maternal infection/inflammation – Schizophrenia
- Media exposure, content - development, cognition
- Social environment - gene interactions – unintentional injury, violence and aggression
- Maternal hypothyroidism – cognitive development
- Built environment – obesity, health
- Family structure/function – child health, develop.
- Endocrine active compounds – sexual development



How will Study size produce results not otherwise available?

- Exposures for “big issue” low frequency outcomes
 - Autism
 - Diabetes
 - Still birth
 - Birth defects, etc.
- Sub-groups and multi-factor interactions
 - Obesity
 - Asthma
 - Behavior, etc



Priority Environmental Exposures

- **Physical** environment: housing, neighborhoods and communities, climate, radiation...
- **Chemical** exposures: air, water, soil, food, dust, industrial products, pharmaceuticals...
 - complex ubiquitous low-level exposures
 - unique exposures (special sub-studies)
- **Biological** environment: intrauterine, infection, nutrition; inflammatory and metabolic response...
- **Genetics**: genetic components of disease; effects of environmental exposures on gene expression...
- **Psychosocial** milieu: influence of family, socio-economics, community, stress...



Priority Outcomes

- **Pregnancy outcome:** preterm birth, birth defects, fetal influences on adult health. **EARLY results!**
- **Neurodevelopment and Behavior:** cognitive development (IQ), autism, learning disabilities, schizophrenia, depression, adjustment, normal variation, resilience...
- **Injury:** intentional and unintentional; violence...
- **Asthma:** enviro/genetic/infectious/immune factors..
- **Obesity and Physical Development:** diabetes, pubertal/reproductive development, growth, obesity 'epidemic'...



Sampling and Center strategies

- **National probability sample important**
 - Exposure-outcome relationship representative of the U.S. population
 - Important exposures with varied and unknown distributions are not missed
- **Centers of excellence important**
 - Broad scientific input
 - Measures require center based expertise and facilities
- **Probability sample by Centers**
 - Unique combination
 - Requires flexibility and adaptation of center to the scientific design
 - Requires support and guidance by coordinating center



The Sample

- National probability sample
- Highly clustered
 - To study community characteristics
 - Logistical efficiency
- 96 study locations were drawn from the full list of all counties in the United States
- 13 self representing counties
- Remaining counties were placed into strata based on:
 - Metropolitan status
 - Geography
 - Average number of births per year
 - Race, ethnicity, percent low birth weight



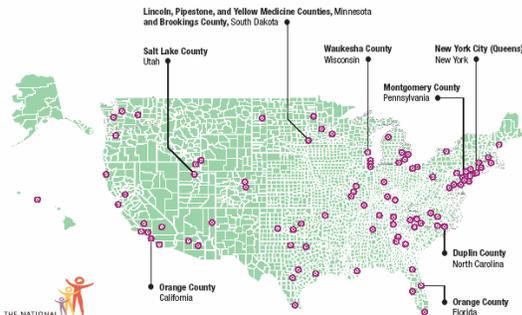
Sites vs. Centers

- Sites – the geographic locations from which participants will be recruited
 - 100
 - Selected by stratified probability sample of primary sampling units
- Centers – the entities or institutions that will carry out the study at the sites
 - 30 – 50
 - Selected by competitive process in response to RFP's



National Children's Study Locations

Vanguard locations identified by name



National Probability Sample

- Three stages of sample selection
 - Selection of primary sampling units
 - Selection of segments within counties
 - Selection of households/individuals



Selection of Segments

- Several options for defining boundaries of segments
 - Census boundaries
 - Neighborhood boundaries
 - School catchment areas
- 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



Recruitment of Study Participants

- Household Recruitment Approach
- Supplemented with recruitment through other mechanisms such as prenatal care providers
 - Anticipate that some groups of women (e.g. women not planning pregnancy) might be under-represented in the household screening approach
- Offerors can suggest alternative approaches that would meet the goals of The Study



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)	



Participation Incentives

- For the benefit of our children
- Monetary compensation for time, inconvenience and expenses
- Membership and engagement with study
- Information about child's and family's
 - Health
 - Development
 - Environment



Use of Data to Maximize Output

- Results available beginning ~2010
- Targeted hypotheses-testing analyses
- Successive public-use data sets with support
- Successive funding for investigator initiated research and analyses
- Expected translation of results into related prevention initiatives



Projected Time Line

2000- Pilot study/methods development work

Periodically: Meetings, peer reviews, consultations

Mid 2004 Finalize specific hypotheses, develop study design

Late 2005 Select initial centers

2006 Complete and pilot full 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



Contact Information

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