



National Children's Study Introduction

Washington Statistical Society
October 18, 2011

Steven Hirschfeld, MD PhD
Captain, U.S. Public Health Service
Eunice Kennedy Shriver
National Institute of Child Health
and Human Development



National Children's Study



- Congressionally mandated by Children's Health Act of 2000
- An integrated system of activities to examine the relationships between environmental exposures and genetics on growth, development and health
- Environment is broadly defined to include factors such as air, water, soil, dust, noise, diet, social and cultural setting, access to health care, socio-economic status and learning.

What the law says



The Study is required to:

(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) Consider health disparities among children, which may include the consideration of prenatal exposures."

NCS Principles



- Data driven
- Evidence based
- Community and participant informed

Examples of Exposure Areas of Interest



- Exposure to industrial chemicals and byproducts in the air, water, soil and commercial products
- Exposure to natural products in the air, water, soil and commercial products
- Exposure to pharmaceuticals used for therapy and in the environment
- Radiation exposure
- Effects of proximity to manufacturing, transportation and processing facilities

Examples of Exposure Areas of Interest



- Living with animals, insects and plants
- Media and electronic device exposure, noise
- Access to routine and specialty healthcare
- Learning opportunities that are structured and unstructured
- Diet and exercise
- Family and social network dynamics in cultural and geographic context

Examples of Outcome Areas of Interest



- Interpersonal relationships and bonding
- Inflammatory processes including allergies, asthma and infections
- Genetic and epigenetic status
- Epilepsy and other neurologic disorders
- Cardiovascular screening and function
- Childhood cancer
- Multidisciplinary multidimensional aspects of sensory input, learning and behavior
- Precursors and early signs of chronic diseases such as obesity, asthma, hypertension and diabetes

Prevalence of Conditions of Potential Interest



- Of 100,000 children, an estimated
 - 30,000 will be overweight; 17,000 with obesity
 - 5,000 with learning disorders
 - 5,000 with asthma
 - 1,000 with autism spectrum disorders
 - 750 with congenital heart disease
 - 320 with childhood cancers
 - 125 with Down syndrome
 - 50 with Fragile X syndrome

NCS Structure



- The NCS is an integrated system of activities
- All components and phases together form the NCS
- Current major components are the
 - NCS Vanguard Study- pilot phase for methods-runs for 21 years-started in 2009 with 7 centers- expanded in 2010 with 30 additional centers
 - NCS Main Study-exposure response phase- runs for 21 years about 3 years time shifted from Vanguard Study-planned start in 2012
 - NCS Substudies- studies within studies
 - Formative Research-short term limited studies, often methods development, to support and inform the Vanguard and Main Studies

NCS Activities



Administration

Communications

Dissemination

Planning

Operations

Analysis

Instrument
Development

Protocol
Development

Main Study

*Vanguard
Study*

Data
Repository

*Formative
Research*

Case
Management

Central
Informatics

Data
Acquisition

Sample &
Specimen
Repository



NCS Vanguard Study Goals



- Vanguard Study designed to evaluate:
 - Feasibility (technical performance)
 - Acceptability (impact on participants, study personnel, and infrastructure)
 - Cost (personnel, time, effort, money)
- of
 - Study recruitment
 - Logistics and operations
 - Study visits and study visit assessments

Current Sampling Frame (simplified)



- Random selection of about 100 of ~ 3000 counties in the United States
 - Counties = Primary Sampling Unit
- Counties divided into segments that are normalized to have ~ 250 live births per year. Some sparsely populated areas involves merging counties
 - Segments = Secondary Sampling Unit
- Recruitment is restricted to the Secondary Sampling Units

Alternate Recruitment Substudy



- NCS Vanguard is now at 37 locations across the country with 30 engaged in new recruitment using one of three different strategies
 - Household based- participants learn about the study through field workers walking through neighborhoods
 - Provider based- participants learn about the study through trusted health care providers with a broad definition of provider including physicians, public health nurses, midwives, etc.
 - Direct to the public- participants learn about the study directly through media and community outreach
- The goal is compare strategies to assemble a toolkit for cost effective directed recruitment for the Main Study launch
- Both direct data analysis and predictive modeling employed

NCS Recruitment Status

-based on data as of 10/06/11



| | Provider | Enhanced Household | Direct Outreach | All Alt. Recruitment | Initial Household‡ | All Vanguard |
|------------------------------------|----------|--------------------|------------------|----------------------|----------------------------|--------------|
| Locations | 10 | 10 | 10 | 30 | 7 | 37 |
| Recruitment Duration, months | 10 | 10 | 10 | | 18 full + 12 monitoring | |
| Women Identified | 2350 | 22700 | 12550 | 37550 | 34900 | 72450 |
| Women Screened | 2050 | 17400 | 12500 | 32000 | 30900 | 62900 |
| High probability or pregnant Women | 1450 | 2100 | 1850 | 5400 | 3450 | 8850 |
| Women Enrolled | 1150 | 1300 | 1500 | 3950 | 2000 | 5950 |
| Babies Enrolled | 350 | 300 | 150 [^] | 800 | 1000 | 1800 |

Person and participant numbers above have been rounded to the nearest 50, following the NCS Rounding policy.

[^] - Implementation of Birth Visit data collection for Low-Intensity women was delayed due to logistical reasons.

‡ - Initial Household includes participants from the initial protocol and the minimal visit protocol

For further information



- <http://nationalchildrensstudy.gov>
- ContactNCS@mail.nih.gov