



National Children's Study Brief Overview

National Children's Study Research Day
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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



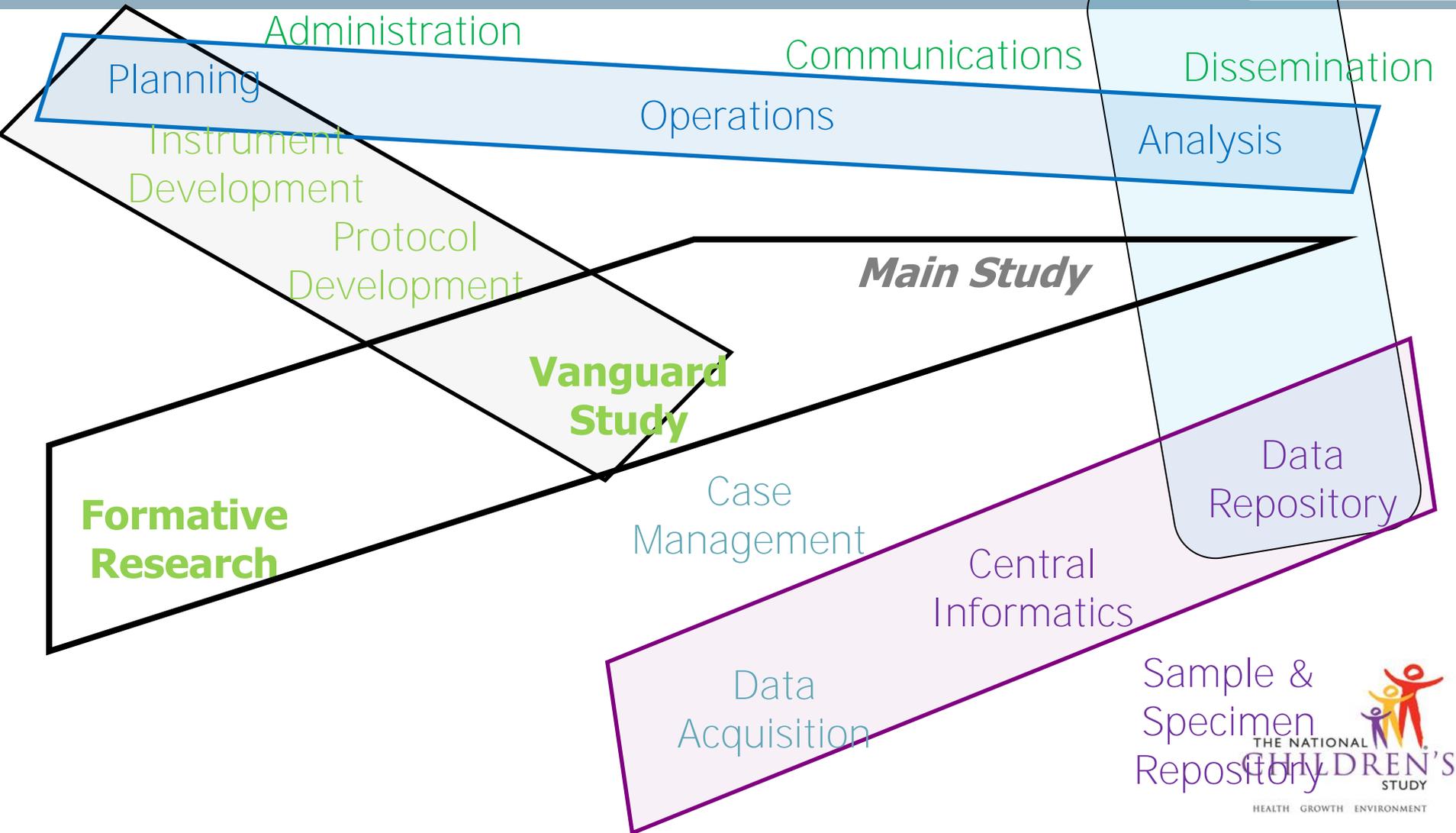
- Interpersonal relationships and bonding
- Inflammatory processes including allergies, asthma and infections
- Genetic and epigenetic status
- Epilepsy and other neurologic disorders
- Cardiovascular screening and function
- Childhood cancer
- Multidisciplinary multidimensional aspects of sensory input,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

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



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

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 8/11/11



	Provider	Enhanced Household	Direct Low	Direct High [^]	All Alt. Recruitment	Initial Household	All Vanguard
Locations	10	10	10	10	30	7	37
Recruitment Duration, months	9	9	9		9	18 full + 11 monitoring	
Women Identified	1900	19700	8200	<i>n/a</i>	29800	33650	63450
Women Contacted*	1200	10800	8050	<i>n/a</i>	20000	30800	50800
Women Eligible	750	1150	1200	100	3100	2600	5700
Women Consented	700	800	1100	100	2500	1600	3100
Babies	200	150	-	100	450	700	1150

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

[^] - High numbers are not included in the two bolded columns, *All Alt. Recruitment* and *All Vanguard* to avoid double counting.

n/a - Not applicable to High Intensity, because women are identified and screened first for Low-intensity participation.

*- PPG status determined

Examples of Accomplishments



- Recruited 3000 families while testing 4 different strategies
- Established the elements for a 21st century infrastructure
 - Published Concept of Operations of Data Life Cycle document
 - Developed new data systems and operational data elements
 - Harmonized terminology for neonatal research
 - Established a network for defining health in positive quantitative terms across the life course
 - Pioneered new regulatory approaches
 - Built a learning community that will continue to dynamically evolve
- Launched about 300 formative research projects over a period of 18 months with more than 200 currently in the field
- Established information sharing and collaborations with longitudinal cohort studies around the world

...and next



- Listen to the data, the innovations, the spirit and passion, the voices of the children and their communities
- Join us to learn together

RADM Boris D. Lushniak, MD MPH

Early start in a uniform



RADM Boris D. Lushniak, MD MPH Training



- Doctor of Medicine (Northwestern), 1983 (6 year program for BS and MD)
- Master of Public Health (Harvard), 1984
- **Residency in family medicine at St. Joseph's Hospital in Chicago, 1987**
- Commissioned Officer, USPHS 1988.
- Board certifications in dermatology and occupational medicine.

RADM Boris D. Lushniak, MD MPH

Career



- Centers for Disease Control and Prevention- 1988
- Epidemiology Intelligence Service, then National Institute for Occupational Safety and Health (NIOSH), where he served as a senior medical officer with the Division of Surveillance, Hazard Evaluations and Field Studies in Cincinnati, Ohio.
- Developed expertise in counterterrorism activities, disaster response, medical epidemiology and occupational skin diseases

RADM Boris D. Lushniak, MD MPH

Career



- Food and Drug Administration- March 2004 joined as the Chief Medical Officer, Office of Counterterrorism Policy and Planning in the Office of the FDA Commissioner, and was promoted to Assistant Commissioner in May 2005.
- April 3, 2006 was promoted to the rank of Assistant Surgeon General and Rear Admiral.

RADM Boris D. Lushniak, MD MPH

Deployments



- RADM Lushniak has worked on assignments in St. Croix, U.S. Virgin Islands, Russia, Kosovo and Bangladesh; was part of the CDC/NIOSH team at Ground Zero in New York City; served as part of the CDC anthrax team in Washington, and was a PHS team leader in the Hurricane Katrina response.

RADM Boris D. Lushniak, MD MPH Awards



- USPHS- Two Outstanding Service Medals, a Commendation Medal and two Achievement Awards, two Outstanding Unit Commendations and eight Unit Commendations.
- Civilian- AMA Dr. William Beaumont Award in Medicine, the AMSUS Sustaining Member Lecture Award, the DHHS Secretary award and the FDA Commissioner award.

RADM Boris D. Lushniak, MD MPH Deputy Surgeon General-2010

