



Overview of EPA's Continued Leadership for the National Children's Study (NCS)

Presenters: J. Quackenboss, N. Fields



Contributing Organizations: ORD: NERL, NCER, NHEERL, NCCT; OCHPEE; NCS Program Office (NIH/NICHD)

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RESEARCH & DEVELOPMENT

LTG 3 Poster 08

Science Questions

The Children's Health Act of 2000 authorized a consortium of Federal agencies, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the U.S. EPA, to develop and implement a prospective cohort study to evaluate the effects of both chronic and intermittent exposures (including physical, chemical, biological and psychosocial environments) that influence health and developmental processes.

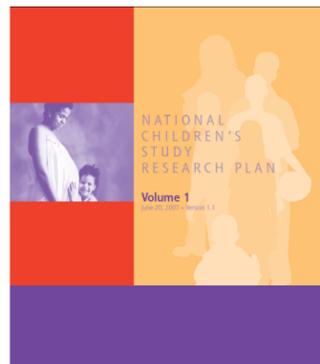
The size, scope, and design of the NCS will help address key research questions for Susceptible Subpopulations:

- Which methods and models are appropriate for longitudinal research with children?
- Is there differential life-stage responsiveness or exposure to environmental agents
- What are the long-term effects of developmental exposure to chemicals?
- How can we model exposure and effects to protect susceptible populations?

EPA's review of the NCS Research Plan identified opportunities and priorities for -Additional measures/analyses, or adjunct studies to make the Study more relevant to EPA's mission and programs;
- Potential uses/users of NCS data and results to protect children's health and the environment.

Research Goals

The goal of the NCS is to provide information that will ultimately lead to improvement in the health, development, and well being of children. The primary aim of the NCS is to investigate the separate and combined effects of environmental exposures (chemical, biological, physical, psychosocial) as well as gene-environment interactions on the primary outcomes of interest for the NCS, including asthma, obesity, diabetes and physical development, neurological development, injuries, pregnancy-related outcomes, and mental health.



NCS Overview:

The National Children's Study (NCS) will examine the effects of environmental influences on the health and development of 100,000 children in 105 locations across the United States from before birth to age 21. Within each location, about 10-15 communities are selected for enumeration of households and enrollment of women of child-bearing age. This design will also support evaluation of common, community-level environmental factors.

NCS Priority Exposures and Outcomes:

Priority Exposures	Examples	Priority Health Outcomes	Examples
Physical Environment	Housing quality, neighborhood	Pregnancy Outcomes	Preterm, Birth defects
Chemical Exposures	Pesticides, phthalates, metals, air & water quality	Neuro-development & Behavior	Autism, schizophrenia, learning disabilities
Biologic Environment	Infectious agents, endotoxins, diet	Injury	Head trauma, Injuries requiring hospitalizations
Genetics	Interaction between environmental factors and genes	Asthma	Asthma incidence and exacerbation
Psychosocial milieu	Families, SES, institutions, social networks	Obesity & Physical Development	Obesity, Diabetes, altered puberty

Findings and Conclusions

EPA's review of the NCS Research Plan, suggest that the NCS could (as examples):

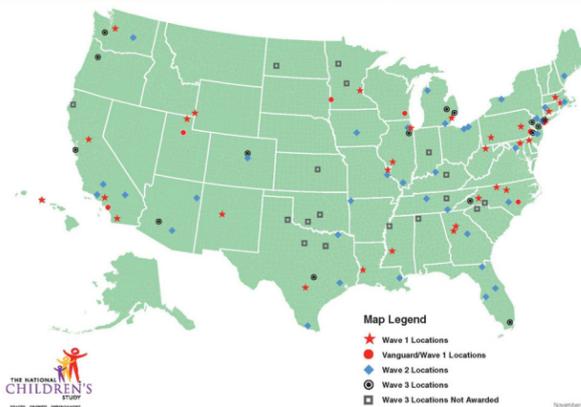
- Strengthen EPA's ability to assess effects of environments on children's growth and disease;
- Provide a rich data base to evaluate community-level cumulative risks;

- Identify and help reduce sources of hazardous pollutants, especially when combined with targeted add-on studies;
- Help EPA risk assessors interpret biomonitoring data relative to health outcomes (LTG-2); and
- Provide a national data base to help evaluate the effectiveness of regulatory decisions (LTG-4).

Many of the ORD-led method studies, reviews, and workshops were described at the 2005 BOSC, and are updated in Posters LTG3-04 (Longitudinal Studies) and LTG3-05 (Tools and Methods).

Methods/Approach

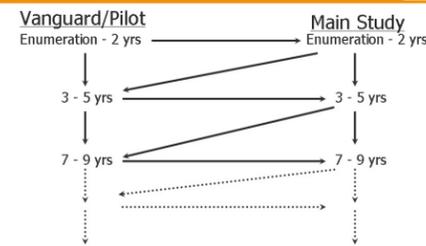
National Children's Study Locations



Implementation Phase:

- EPA scientists from ORD and the Office of Children's Health Protection and Environmental Education (OCHPEE) will continue to provide oversight and represent Agency interests through the Interagency Coordinating Committee (ICC).
- EPA scientists will also serve on the Executive Steering Committee, and other key NCS committees concerning publications, data access and confidentiality, protocol review, and adjunct studies.
- EPA scientists will contribute expertise on NCS Working Teams and Expert Teams. These teams will consider the National Academies' and lead federal agencies' reviews in revising protocols for the main study (for ages 0-2 yrs), and in developing protocols for future stages of the Study (e.g., ages 3-5 yrs).

Protocol Development



Planning Phase

- Scientists across EPA and ORD have been key leaders in the planning, development, and implementation of the NCS since 2000.
 - ORD scientists have led or participated in studies, literature reviews, white papers, and workshops.
 - EPA scientists from ORD and the Office of Children's Health Protection and Environmental Education (OCHPEE), serve on the Interagency Coordinating Committee (ICC).
- ORD scientists have worked with the NCS Program Office, the first seven Study Centers (Vanguard Centers) and the Study Coordinating Center (Westat) to provide scientific expertise, especially for environmental and biological exposure measures.
 - The NCS Research Plan—which EPA scientists helped inform through research, publications and white papers—was reviewed by the National Academies, lead federal agencies, and the public.
 - EPA's ICC members led an Agency-wide review of the research plan. Comments and recommendations were prioritized these with input from program offices and regional offices, and were to the NCS Director.
- An ORD scientist has coordinated International Childhood Cancer Cohort Consortium (I4C) workshops to identify common approaches for children's longitudinal cohort studies, and OCHPEE has provided funding to support this effort. (Brown, et al., 2007).
- EPA scientists have been active in representing the NCS at national and international meetings, including helping to organize sessions at scientific conferences.

Future Directions:

- EPA's continued involvement in the NCS will allow ORD to leverage its HHRP resources for children's environmental health research:
 - Formulate and conduct analyses to evaluate hypotheses relating exposures to health outcomes,
 - Examine the influence of community-level environments (e.g., social factors) on exposure and health effects, and
 - Use longitudinal measurements of early exposures and of health status in later life to test the DOHaD hypothesis (Developmental Origins of Health and Disease—see LTG3-06).
- Results from EPA's review of the NCS Research Plan will be used to identify
 - Potential uses of NCS data to support EPA needs, and
 - Possible adjunct studies that could be conducted using the NCS as a cost-effective platform for the agency to conduct children's environmental health research.
- EPA's STAR Grants Program will continue to support research applicable to the NCS, such as the Children's Centers, and research on early indicators of outcomes and exposure assessment.

Impact and Outcomes

- EPA's scientific leadership and collaboration with the other lead federal agencies has improved the scientific basis for the NCS by
 - helping to develop and update hypotheses—which provide a framework for the Study,
 - providing scientific input on designs and methods—used in the development of the NCS Research Plan;
 - leading efforts to select the sampling design for the Study—which includes a wide range of exposures and population sub-groups, and will represent exposure-outcome relationships,
 - contributing to the development and review of the Study and Research Plans—which provides the background, rationale, and specific approaches for peer and agency reviews.
- EPA scientists have provided scientific expertise for development of operational procedures (OPs) for biological and environmental samples—to help ensure consistency at all Study locations and laboratories.
- EPA's participation on the ICC and review of the NCS Research Plan have helped to ensure that issues of concern to EPA's program offices and regions are at the forefront in the planning and implementation of the NCS.
 - For example, EPA's recommendation to change indoor particle measurements from PM₁₀ to PM_{2.5} was adopted by the NCS.
- Results of the NCS could help determine (as examples)
 - if early life exposures to chemicals such as pesticides increase the risk of conditions such as autism and other developmental disabilities;
 - the effects of prenatal and early childhood exposures with potential immune-modulating effects on the incidence and severity of asthma; or
 - how individual, family, and community factors affect the incidence, severity, and outcome of childhood injuries.



Contributors:

Elizabeth Blackburn (OCHEE), Nigel Fields (NCER), Sally Darney (ORD), Rebecca Brown (NCEA), Danelle Lobdell (NHEERL), Suzanne Fenton (NHEERL), Elaine Hubal (NCCT), Peter Scheidt (NCS, NIH/NICHD), Kevin Teichman (ORD)

Susceptible Populations