THE NATIONAL CHILDREN'S STUDY

Alan E. Guttmacher, M.D.

Director

***Eunice Kennedy Shriver* National Institute of Child Health and Human Development**

January 29, 2013

Overall Goal of the NCS

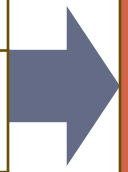
- To improve the health and well-being of children and to identify antecedents of healthy adulthood
  - By examining the multiple effects of environmental influences and biological factors on the growth, health, and development of ~100,000 children across the U.S., following them from before birth until age 21 years

- Largest and most ambitious U.S. long-term study of child health and development ever
- Longitudinal study of biological and broadly defined environmental factors, such as:
  - Air; water; soil; dust; noise; diet; social and cultural setting; access to health care, socio-economic status, and learning; etc.

- Data resource with linked environmental and biological samples, not a conventional "study"
- "Exemplar hypotheses," but not designed to answer specific hypotheses only
- All data generated will be quickly and freely available to all researchers, whether or not they are funded through the NCS

NCS: Examples of Exposures and Health Outcomes

Exposures	Examples
Physical Environment	Housing quality, neighborhood
Chemical Exposures	Pesticides, phthalates, heavy metals, BPA
Biologic Environment	Infectious agents, endotoxins, diet
Genetics	Interaction between genes and environment
Psychosocial milieu	Family structure, socio-economic status, parenting style, social networks, exposure to media and violence



Health Outcomes	Examples
Pregnancy Outcomes	Prematurity, birth defects
Neurodevelopment & Behavior	Autism, learning disabilities, schizophrenia, conduct and behavior problems
Injury	Head trauma, injuries requiring hospitalizations
Asthma	Asthma incidence and exacerbation
Obesity & Physical Development	Obesity, diabetes, altered puberty

NCS: Components

- Major components:
  - **Vanguard Study**: ~4,000 children; started 2009; 40 diverse sites; designed to inform Main Study science, logistics, and costs
  - **Main Study**: ~100,000 children; runs ~4 years behind Vanguard Study; planned start in 2013
  - **Formative Research**: Short term studies, often methods development, to inform Vanguard and Main Studies; will also inform many non-NCS research efforts

NCS Main Study: Sample Size

- Of 100,000 children, an estimated
  - 30,000 will be overweight (17,000 obese)
  - 12,000 will be born preterm (before 37 weeks)
  - 5,000 will have learning disorders
  - 5,000 will have asthma
  - 1,000-3,000 will have autism spectrum disorders
  - 320 will develop childhood cancers
  - 125 will have Down syndrome
  - 50 will have Fragile X syndrome

Main Study Design Principles

- Anchored in a national probability sample
- Recruitment through health care providers
  - Birth cohort: via selected hospitals and birthing centers
  - Prenatal cohort: via community based prenatal providers and clinics that refer to the selected hospitals and birthing centers
- Sample size of 100,000
  - Birth and prenatal cohorts to total about 90,000
  - Additional convenience cohorts to total up to 10,000 for preconception and additional targeted populations

In Case You Should Ask

Q: “If kids have autism, when will you find out?”

A: Using screening instruments currently planned for NCS study visits (including the Ages and Stages questionnaire and the Modified Checklist for Autism in Toddlers) the lowest age would be ~18 months. We also plan to have access to medical records to learn about any other assessments that might allow earlier diagnosis.

(The NCS has a return of results policy for medically actionable findings and will work with parents and primary care providers to share outcomes.)

In Case You Should Ask

Q: “Would you consider other instruments, testing, etc., for kids at elevated risk for autism?”

A: Yes! And, NCS has already invested in formative research to see if autism screening sensitivity and specificity for all children can be improved. A current multisite study on autism assessment tools will conclude later this year. It compares a battery of three brief novel assessments (a video-guided parent self-report; a parent interview, and a direct observation) that can be implemented by NCS field staff to “gold standard” ASD case confirmation (an Autism Diagnostic Observation Schedule by a research-reliable assessor and a DSM-based diagnostic assessment by a qualified clinician).

NCS: Summary

- Longitudinal data on ~100,000 children from before birth to age 21
- With linked biological and environmental (broadly defined) exposure samples

- An unparalleled resource to understand childhood health, growth, and development