

NEWS FROM NICHD



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Specifically...



- The National Children's Study
- NICHD's Scientific Visioning process



The National Children's Study



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 health and development of ~100,000 children across the U.S., following them from before birth until age 21 years



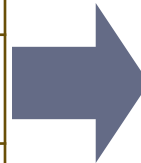
IMPROVING THE HEALTH
OF AMERICA'S CHILDREN



- Mandated by Children's Health Act of 2000; largest and most ambitious long-term study of child health and development ever in U.S.
- “Environment” as broadly defined: factors such as air, water, soil, dust, noise, diet, social and cultural setting, access to health care, socio-economic status, and learning
- A data and biosample resource, not a conventional “study”

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	Preterm, 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

Sample Size



- Vanguard Study: ~4,000 children
- Main Study: ~100,000 children
- 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
 - 320 with childhood cancers
 - 125 with Down syndrome
 - 50 with Fragile X syndrome

NCS Components



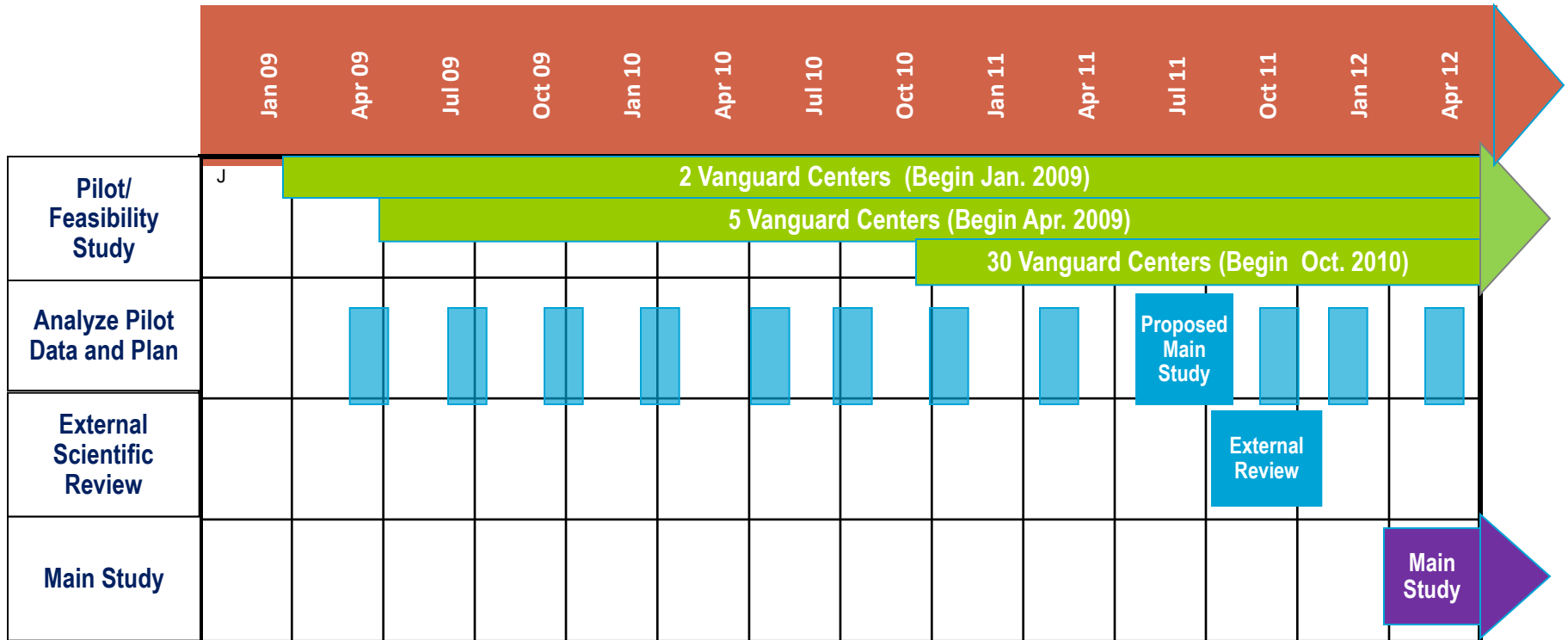
- Major components:
 - **NCS Vanguard Study:** 21-year pilot phase for methods; started in 2009 with seven centers; added 30 more centers in 2010
 - **NCS Main Study:** 21-year exposure response phase; runs ~three years behind Vanguard Study; planned start in 2012
 - **Formative Research:** short-term studies, often methods development, to inform the Vanguard and Main Studies

Changes in Past Two Years



- Original recruitment and enrollment assumptions proved faulty, so new approaches now being field-tested at Vanguard sites
- Moved from assumption-based to evidence-based planning
- NCS timeline modified, with ~1 year delay (to early 2012) in Main Study implementation
- Later this year, will have recommendations and cost estimates for the Main Study

NCS Projected Timeline



New Recruitment Strategies



- The original ten Vanguard sites used household-based recruitment
- Three alternate strategies now being field-tested:
 - Enhanced household recruitment
 - Provider-based recruitment
 - Two-stage recruitment

NCS Recruitment as of April 2011



	Alternate Recruitment	Initial Household	Total
Locations	30	7	37
Locations currently in the field	29	7	36
Recruitment Duration, months	5	18	—
Women Identified for contact	21550	33000	54550
Women contacted	13800	30000	43800
Women Eligible	2100	2450	4550
Women consented	1350	1400	2750
Babies	100	600	700

(Recruitment numbers rounded to the nearest 50.)

NCS Budget: History of Congressional Funding



Fiscal Year	Funding
2007	\$ 69 million
2008	\$ 111
2009	\$ 180
2010	\$ 194
2011	\$ 191
2012	\$ 194 (President's budget request)

NICHD Scientific Vision



The NICHD Mission is to Ensure...



- That every person is born healthy and wanted
- That women suffer no harmful effects from reproductive processes
- That all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability
- The health, productivity, independence, and well-being of all people through optimal rehabilitation



Why a Scientific Visioning Process



- To identify the most promising scientific opportunities of the next ten years across that mission
- To set an ambitious agenda that inspires the research community to achieve critical scientific goals and meet important public health needs

Goals of the Process



- Give external communities ample opportunity to participate
- Foster cross-collaboration among NICHD, other ICs, and external partners
- Add early-stage investigators and other new stakeholders to the conversation
- Produce a publication worthy of a leading scientific journal

It Is About...



- The future, **not** the past
- Science, **not** strategic planning
- What the entire research community might do together, **not** NICHD-centric

Key Steps



- Workshops (January-March)
 - Nine workshops, organized by external scientists
- White Papers (March-June)
 - Posted online for public input
- Large Meeting (June 23-24)
 - Diverse group of external experts and NIIHers refine white papers

Key Steps



- NICHD Council Review (September)
 - In-depth discussion of proposed vision
- NICHD Scientific Vision (December)
 - Vision published in leading journal and posted online
- Further Dissemination (2012)
 - Scientific presentations, newsletters, etc.

Then, Based upon the Science...



- NICHD Strategic Planning (2011-2012)
 - NICHD staff and our advisory councils determine how NICHD can best help achieve this Scientific Vision



Workshop Scientific Themes

- Plasticity
- Reproduction
- Development
- Developmental Origins of Health & Disease
- Behavior
- Pregnancy & Pregnancy Outcomes
- Diagnostics & Therapeutics
- Environment
- Cognition



Key Questions for the Workshops



- What should the future look like in key scientific areas? Where should we be in ten years?
- What would we like to look back at in ten years and be proud to have accomplished?
- What science is needed to address critical knowledge gaps and health needs?

And, Also...



- What basic, clinical, and translational research questions must we answer?
- What research tools, methods, or approaches should we develop?
- What are the innovative training and workforce development needs and opportunities particular to this area?

Cross-Cutting Elements



- Analytic and measurement tools and methods
- Animal and computational models
- Bioethics
- Bioinformatics
- Biotechnology/bioengineering, including high-throughput and assistive technologies
- Developmental lens
- Differences/disparities across populations

Cross-Cutting Elements



- Epigenetics
- Functional status
- Global health
- Implementation science and health economics
- Nutrition
- Prevention/personalized medicine
- Stem cells
- Systems biology
- Training and mentoring

A Smattering of Preliminary Thoughts from the Workshops ...



A very early, partial, pre-pro version of what is to come...



Scientific Data



- Require a data-sharing plan in all relevant applications
- More effective ways to gather data, including those the private sector employs
- Better ways to process, store, and analyze masses of data
- Make data available to the entire scientific community

Conduct of Studies



- Enhance research capacity in low resource settings
- Use of social media and new technologies; e.g., to measure diet or movement
- Studies that can be linked in systematic ways and methods to merge data sets



Conduct of Studies



- Better IRB harmonization across multiple sites
- Methods to reduce bias when RCTs are inappropriate
- A centralized archive of data on interventions and evaluations of them
- Every patient a potential research participant

How We Think



- Replace dichotomies (e.g., healthy/unhealthy; ADHD/non-ADHD; obese/non-obese) with dimensional systems, which have advantages – greater power to detect effects, etc.
- Research that anticipates changing morbidity/mortality
- More orientation toward biological processes, rather than disease

How We Think



- What are the positive impacts of disabilities on individuals, families, and society?
- Getting beyond “SES”:
disadvantage, disability, stress
(toxic vs. beneficial), adversity
- Need to distinguish between social and scientific definitions of function (frequently used to qualify for economic benefits)



Doing Transdisciplinary Science



- Study sections that deal more effectively with transdisciplinary research
- Funding opportunities that favor/require co-PIs across disciplines
- Group sabbaticals



Transdisciplinary Science: Training



- Train people with expertise in one area and fluency in other area(s)
- Effective training programs across multiple departments and institutions
- Academic recognition for team science, including junior members of the team

Benefit: Community Involvement



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May 31, 2011

Society members are encouraged to provide feedback to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) as it develops a scientific vision to guide the coming decade of research the Institute will support. NICHD has requested the input of the scientific community, and the Society urges its members to provide their perspectives so that endocrinology continues to thrive at NICHD.

White papers have been produced from nine workshops centered on individual scientific themes. The white papers will form the basis of the 10-year vision and are available for comment on the NICHD Vision [website](#). The Society has submitted formal comments in response to four topics with broad relevance to endocrinology: Reproduction, Development, Pregnancy and Pregnancy Outcomes, and Developmental Origins of Health and Disease <http://www.endo-society.org/advocacy/legislative/letters/index.cfm>.

The nine themes are:

- Reproduction
- Plasticity
- Development
- Cognition
- Behavior
- Pregnancy and Pregnancy Outcomes
- Developmental Origins of Health and Disease
- Environment
- Diagnostics and Therapeutics

The opportunity for public comment ends June 10. Don't miss this chance to help shape the future of science at NICHD.

For More



- Enter “nichd vision” in your search engine
- Or, visit:

www.nichd.nih.gov/vision



Thoughts and Questions?

