



The National Children's Study

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Jim Quackenboss, US EPA/ORD, National Exposure Research Lab.
For the NCS Interagency Coordinating Committee
and the NCS Program Office



**US Department of
Health and Human
Services**

NIH, CDC, NCHS, OS

**US Environmental
Protection Agency**



What is The National Children's Study?

- The National Children's Study will be the largest long-term study of children's health and development ever to be conducted in the U.S.
- *Longitudinal study*—meaning it will study the same group of children, their families, and their environment over an extended period of time (21 years or longer, from before birth)
- Study common range of “environmental” exposures and less common outcomes (100,000 participants needed)
- Examine genetic factors and expression
- Environment defined broadly—chemical, physical, behavioral, social, and cultural



Why Is the Study Important?

- Between 1980 and 1995, the percentage of children with asthma doubled
- The proportion of children aged 6-18 who were overweight increased from 6% in 1976-1980 to 15% in 1999-2000
- 3-8% of children born each year will be affected by a neurodevelopmental disorder
- Great disparities remain in infant mortality rates among ethnic groups



Why Conduct the Study Now?

- Study is needed to identify effects or to assure safety
 - Children generally have an increased vulnerability to environmental exposures
 - Exposures to some agents have caused serious developmental effects (e.g., lead, alcohol)
 - There are known current exposures of high frequency (e.g., pesticides, phthalates)
- Longitudinal design will allow examination of multiple exposures and multiple outcomes
- Previous and existing studies have been limited in size & scope



Why Focus on Children?

Children have:

- Increased vulnerability to environmental exposures
- Critical windows of vulnerability during development
- Immature mechanisms for detoxification and protection
- Differences in metabolism and behavior that may yield higher exposure in the same environments



Brief History of The National Children's Study



- President's Task Force on Environmental Health Risks and Safety Risks to Children (1998; 2001, 2003)
 - Charged with developing strategies to reduce risk of environmental exposures to children
- Conclusions:
 - Many risks to children are not clear or quantified
 - Need for additional study of effects of environmental exposures
 - Consultation in Jan. 2000 endorsed study: large, bold, multiple agencies, public private partnerships





Public Law 106-310: Children's Health Act of 2000



- (a) PURPOSE- to authorize NICHD to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.
- (b) IN GENERAL- The Director of NICHD shall establish a consortium of representatives from appropriate Federal agencies (including the CDC and EPA) to--
 - (1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
 - (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.





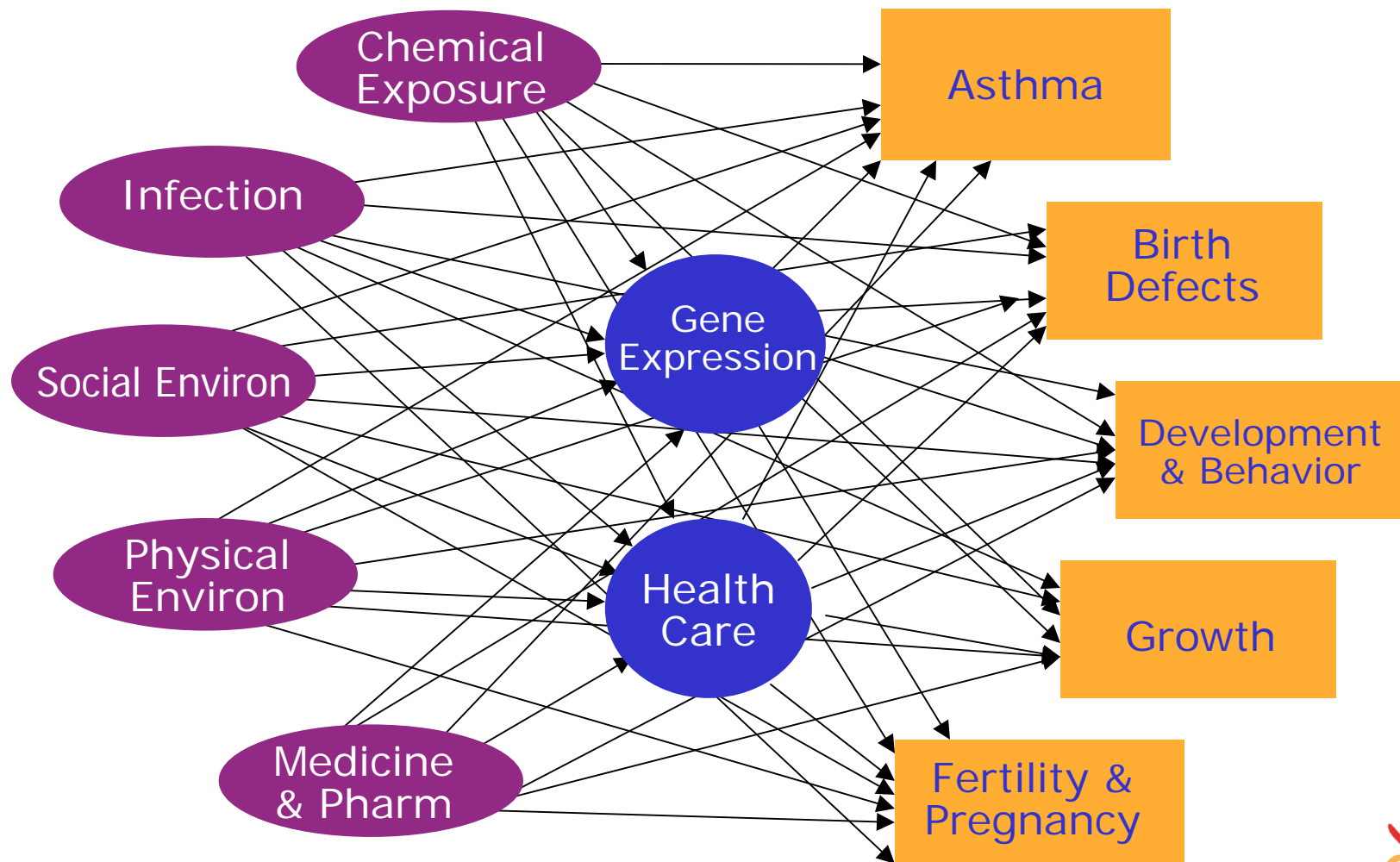
Study Concepts



- Longitudinal study from before birth to adulthood
- National probability sample; clustered design
- Sufficient size (~100,000) to study less common outcomes & lower exposures
- Environment broadly defined
- Application of the human genome project
- Use of state-of-the-art technology
- Consortium of multiple agencies
- Extensive public-private partnerships
- Hypothesis driven
- National resource for future studies



Priority Exposures, Outcomes, and Interactions





EPA and the NCS

EPA's Role – Lead with DHHS

- Assessment of environmental exposures
- Health outcomes associated with environmental exposures
- Cumulative exposures and gene-environment interactions
- Funding for methods development & planning

Benefits to EPA

- Rich database for risk assessment
- Increased efficiency through leveraging of funding for EPA



Value for Environmental Health Risk Assessment

The NCS will address important issues, such as

- Contribution of exposures to childhood disease
- Long-term health effects from early exposures
- Factors that alter susceptibility (e.g., specific genetic polymorphisms, immune deficiencies)
- Disparities in health outcomes (e.g., race, ethnicity, poverty, housing, income, nutrition)
- Effects of aggregate or cumulative exposures
- Uncertainty factors and defaults in risk assessment for protecting children



What is The Projected Timeline?

| | |
|---------------|---|
| 2000-2004 | Pilot study/methods development work |
| 2001-2002 | Form Advisory Committee and Working Groups |
| Periodically: | Meetings, peer reviews, consultations |
| Mid 2004 | Finalize specific hypotheses, develop Study design |
| Late 2005 | Select initial centers or alternatives and pilot test core protocol |
| Late 2006 | Begin full study with initial centers |
| 2006-2007 | Enroll additional centers |
| 2009-2010 | First preliminary results available from pregnancy |
| 2007-2030 | Analyze data as collection continues, publish results throughout: hypothesis specific, public use datasets, RFA's |



Milestones this fall

- A draft scientific study plan (protocol) for the study of will be posted for public review and comment. This will provide
 - more specificity for how to relate priority outcomes, child development and mental health to children's environments
 - description of how study sites will be chosen and how participants will be selected
- Requests for proposals - a study coordinating center and a few initial study sites
 - All institutions meeting the requirements are welcome to apply
- These represent the
 - culmination of an extensive (and inclusive) planning phase
 - commencement of study implementation phase



What is The Funding Status?



- **PLANNING** (Fiscal Year (FY) 00-03)
 - \$20.7 million (existing HHS & EPA budgets)
- **START-UP** (FY04)
 - \$12 million (existing budgets)
- **IMPLEMENTATION** (FY05-29)
 - \$27 million – need for FY05 in order to be ready to enroll participants in 2006 (\$12m in FY05 President's budget)
 - \$2.7 billion total cost spread over 25 years (approx. \$100 million/year)



Annual Disease Burden and Costs

| | Annual Cost – all ages | Number in US |
|---------------|--|--|
| Injury | \$224 billion 1999-2002 | 10.8 million (<18 y, 2000-01) |
| Diabetes | \$ 132 billion 2002 | 206,000 (total < 20y, 2002) |
| Obesity | \$117 billion 2000 | 9 million (6-19 y 1999-2000) |
| Asthma | \$ 14 billion in 2002 Pediatric only \$6.6 billion, 1997 | 9 million (age < 18, 2002) |
| Autism | \$7.6 billion, 1997 | 93,000 (age: 3-21, 2000-1) |
| Schizophrenia | \$65.2 billion Pub in 1996 | 2.2 million (age ≥18, 1998) Average Age onset 18 men; 25 in women |



How Can Your Organization Help?

- Identifying important topics, research questions and approaches not already specified
- Ideas for incorporating important concerns of local regional areas and specific groups while implementing a strong core national study
- To assure decisions of the government entities involved in planning and funding are made to carry out the best possible research to guide the medical care and health policy decisions for our children over the next generation
- Preparing to participate in and support the study
- Spreading the word



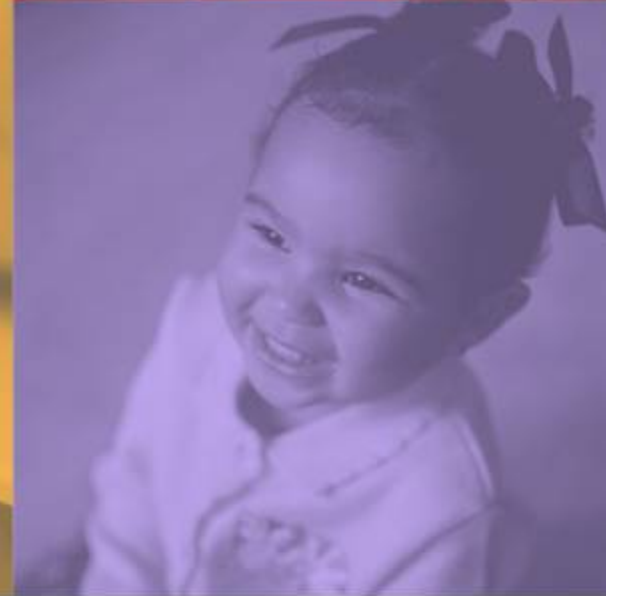
What It's All About!



Contact Information

- Check the Web site:
<http://NationalChildrensStudy.gov>
- Join the listserv for news and communication
- Contact us at ncs@mail.nih.gov





Additional
information



Priority Environmental Exposures



- **Physical environment:** e.g., housing, neighborhoods and communities, climate, radiation
- **Chemical exposures:** e.g., air, water, soil, food, dust, industrial products, pharmaceuticals
 - complex ubiquitous low-level exposures
 - unique exposures (special sub-studies)
- **Biological environment:** e.g., intrauterine, infection, nutrition, inflammatory and metabolic response
- **Genetics:** genetic components of disease, effects of environmental exposures on gene expression
- **Psychosocial milieu:** e.g., influence of family, socio-economics, community, stress



Measures Anticipated: Exposures

- Environmental samples: air, water, dust
 - Validation sub-studies for detailed exposure assessment
- Bio-markers for chemicals: blood, breast milk, hair, tissue, etc.
- Interview and history
- Serology and medical data
- Housing & living characteristics
- Family and social experiences
- Neighborhood and community characteristics



Priority Outcomes

- **Pregnancy outcome:** preterm birth, birth defects, fetal influences on adult health. **EARLY results!**
- **Neurodevelopment and Behavior:** cognitive development (IQ), autism, learning disabilities, schizophrenia, depression, adjustment, normal variation, resilience
- **Injury:** intentional and unintentional; violence
- **Asthma:** etiology, environmental-genetic-infectious-immune factor interactions
- **Obesity and Physical Development:** diabetes, pubertal/reproductive development, growth, obesity 'epidemic'





Measures Anticipated: Outcomes

- Fetal growth and outcome of pregnancy
- Birth defects and newborn exam
- Growth, nutrition, and physical development
- Medical condition and history: illness (e.g. asthma, obesity), conditions, & injuries
- Cognitive and emotional development
- Mental health, developmental and behavioral conditions

