



## Presenter Disclosures





**WENDY HELLERSTEDT, MPH, PHD**  
**Associate Professor**  
**Co-PI, Ramsey Location National Children's Study, University of Minnesota, School of Public Health**

No relationships to disclose



## The National Children's Study: What Will it Tell Us About Reproductive Health?






**Wendy Hellerstedt, PhD**


**Patricia McGovern, PhD**

**Nancy Nachreiner, PhD**


**Sarah Keim, MPH**




## The National Children's Study






- Led by a consortium of federal partners from the US Department of Health and Human Services (including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development) and the US Environmental Protection Agency
- Longitudinal study of children, their families, and their environment (before birth through age 21)
- Largest long-term study of children's health and development ever conducted in the US
- 105 counties or groups of counties in 4 phases:
  - 7 Pilot Centers in the field in mid-2009
  - Wave I Centers will enter in early 2011, followed by 2 other Waves
- Enroll approx 100,000 children and their families



## Sampling & Enrollment



**All Births in the Nation**

~4 million births in 3,141 counties

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**Sample of Study Locations**

105 Locations

↓

**Sample of Study Segments**

Selection of neighborhoods

↓


**Study Households**

All or a sample of households within neighborhoods



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**Study Women**


All eligible women in the household. Will ultimately enroll 100,000 offspring




## Etiology, Prevention and Treatment of Many Conditions

- **Study mothers/fathers:**
  - Poor pregnancy outcomes (e.g., preterm, birth defects)
- **Offspring:**
  - Reproductive development
  - Asthma
  - Birth defects
  - Diabetes
  - Obesity, body composition & growth
  - Child health and physical development
  - Neurodevelopment and behavior
  - Autism & other mental health conditions
  - Injuries




## Exposures




Priority Exposures	Examples
Physical Environment	Housing quality, neighborhood, noise
Chemical Exposures	Pesticides, phthalates, heavy metals
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

<http://NationalChildrensStudy.gov>  
**28 meta-hypotheses; >100 specific hypotheses**



## Data Collection



**Frequency**





- Preconception (3 measures)
- Pregnancy (6 measures)
- Birth: (2 visits in hospital)
- Postnatal for 3 - 24 months: (6 measures)
- 2 years to 21 years: to be determined

**Measurement Type**

- Phone call, home visits, field visits, hospital/clinic abstraction

**Types of measures**


- Parental and offspring biological, genetic, anthropometric
- Parental and offspring psychosocial
- Family demographics
- Residential, neighborhood and childcare environmental quality


## What Will We Learn about Reproductive Health?

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## Parent sample




- Women in the first trimester of pregnancy (approx  $\frac{3}{4}$  of sample)
- Pre-conception (approx  $\frac{1}{4}$  of sample)
  - Intent is to enroll women at high risk of pregnancy within 12 months
  - Risk is based on age, sexual activity, parity, and contraceptive use
- Focus is on women (mothers) but data will be collected from biological fathers




## Example: Birth Defects




- 1 of every 33 infants is born with a birth defect.
- The etiology of birth defects is largely unknown, making prediction and prevention almost impossible.




## Maternal Impaired Glucose Metabolism and Birth Defects



- Study Hypothesis:
  - Among women without diabetes before pregnancy, impaired glucose metabolism during pregnancy is associated with risk of major congenital malformations of the heart, central nervous system, musculoskeletal system, and all birth defects combined.
- Justification:
  - Birth defects associated with poor glycemic control can be lethal
  - Effects of impaired glucose control can be lessened
  - Prevalence of obesity and impaired glucose metabolism is increasing




## Example: Preterm Births



- 12% of all births in the U.S. are preterm
  - < 37 weeks gestation
- 2/3 of all infant deaths are among preterm infants
  - High morbidity among survivors
- Costs: in 2007, \$18.1 billion in hospital charges for preterm or low birth weight infants
  - Half of all hospital charges for all infants

Etiology of all preterm births is unknown and US has not seen an improvement in preterm rates in more than a decade



## Preterm Risk and Inflammation



- **Hypothesis:**
  - Intrauterine exposure to mediators of inflammation due to infection of either vaginal, cervical, or uterine sites or of more distal sites (e.g., oral) is associated with an increased risk of preterm birth
- **Justification:**
  - Preterm rates have not decreased for over a decade
  - It is likely there is an association with infection
  - The mechanism is unclear



## Example: Offspring Reproductive Development



- The Study will examine prenatal and postnatal exposure to hormonally active environmental agents to assess whether they are associated with alterations in the reproductive system development.
- Select questions for which the Study is designed:
  - Is male in utero exposure to phthalates associated with hypospadias?
  - Is exposure to bisphenol A in early childhood associated with the acceleration of puberty in girls?
  - Is exposure to phthalates in early childhood associated with polycystic ovarian syndrome?
  - Are there critical time windows for lead exposure and associated delays in age of onset of puberty for girls?



## The Study will Describe Critical Features of Reproductive Health



- Contraceptive patterns
- Unintended pregnancy
- Pregnancy loss
- Paternal involvement
- Prenatal substance use and nutrition
- Pregnancy and postpartum weight gain
- Sexual behaviors and reproductive events of Study offspring



## Postpartum Health: Psychosocial Measures



- Depression (6 mo.)
- Mental Health & Cognition (12 mo.)
- Perceived stress (6 mo.)
  - Global stress (control over life, self confidence, nervousness, irritation, anger)
  - Racism/discrimination
  - Major life events
  - Parenting stress (attachment, role restrictions, competence)
  - Work/family conflict (strains & benefits)



## Postpartum Health: Psychosocial Measures



- Social support (size & satisfaction with network) (6 mo.)
- Family process (6 mo., 12 mo.)
  - Relationship quality (life philosophy, goals, time together, communication, happiness)
  - Domestic violence
  - Division of labor (child care, domestic chores)



## Other Measures to Characterize the Postpartum Period



- Employment (6 mo, 12 mo)
  - Number, types & hours of jobs/schooling
  - Job activities
  - Exposures (ETS, drinking water, indoor /outdoor activities, chemicals)
- Breastfeeding (3, 6 and 9 mo)
- Parenting and childcare
  - Childcare (location, provider information) (3 mo., 6 mo., 12 mo.)
  - Parenting practices (attachment, attitudes & practices)(6 mo., 12 mo.)



## Strengths of the Study for Examining Reproductive Health



1. Large sample size
2. Longitudinal design and length of follow-up
  - Possibility of documenting time to pregnancy and pregnancy loss (over a short period for a sub-sample)
  - Following children through early reproductive development
3. Breadth of variables – outcomes and exposures, e.g.
  - Environmental quality
  - Pre-conception health
4. National probability sample
5. Design and implementations by a multidisciplinary team of scientific leaders



## Weaknesses of the Study for Examining Reproductive Health



1. Conceptual model
  - Feasibility of the pre-conception cohort sampling and assessment
  - Ability to engage fathers
  - How will residential transience be effectively handled
2. Cost and scope
3. Limited to biological parents and to some degree, adult parents
4. Not specifically designed to examine income or race /ethnic disparities
5. Likely attrition
  - May affect exposure and outcome prevalence, but may not affect estimates of association between the two
6. Inadequate pilot phase (phase has been extended to allow first Centers to enter the field in early 2011)



## Further Information



- NCS Web sites
  - National <http://NationalChildrensStudy.gov>
- Minnesota Medicine article on prenatal exposure assessment in the NCS
  - *Hellerstedt, et al. Prenatal Environmental Exposures and Child Health: Minnesota's Role in the National Children's Study.* Minnesota Medicine, September 2008.  
[http://www.minnesotamedicine.com/Past Issues/](http://www.minnesotamedicine.com/Past%20Issues/)

