



National Children's Study U.S.A.

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What the Law Says



"(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;

(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes."


The Study is required to:

"(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;


(2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) Consider health disparities among children, which may include the consideration of prenatal exposures."

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National Children's Study




- Congressionally mandated by Children's Health Act of 2000
- An integrated system of activities to examine the relationships between environmental exposures and genetics on growth, development and health
- Environment is broadly defined to include factors such as air, water, soil, dust, noise, diet, social and cultural setting, access to health care, socio-economic status and learning.

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NCS Principles



- Data driven
- Evidence based
- Community and participant informed

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Examples of Exposure Areas of Interest



- Exposure to industrial chemicals and byproducts in the air, water, soil and commercial products
- Exposure to natural products in the air, water, soil and commercial products
- Exposure to pharmaceuticals used for therapy and in the environment
- Radiation exposure
- Effects of proximity to manufacturing, transportation and processing facilities

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Examples of Outcome Areas of Interest



- Interpersonal relationships and bonding
- Inflammatory processes including allergies, asthma and infections
- Genetic and epigenetic status
- Epilepsy and other neurologic disorders
- Cardiovascular screening and function
- Childhood cancer
- Multidisciplinary multidimensional aspects of sensory input, learning and behavior
- Precursors and early signs of chronic diseases such as obesity, asthma, hypertension and diabetes

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Examples of Exposure Areas of Interest



- Living with animals, insects and plants
- Media and electronic device exposure, noise
- Access to routine and specialty healthcare
- Learning opportunities that are structured and unstructured
- Diet and exercise
- Family and social network dynamics in cultural and geographic context

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Prevalence of Conditions of Potential Interest



- 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 – 3,000 with autism spectrum disorders
 - 1000 with schizophrenia
 - 750 with congenital heart disease
 - 320 with childhood cancers
 - 125 with Down syndrome
 - ~ 65 = Federal threshold for rare disease
 - 50 with Fragile X syndrome

Many conditions of potential interest are along a biological and clinical continuum with the most affected people generally diagnosed but others in the general population also affected

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NCS Structure



- The NCS is an integrated system of activities
- All components and phases together form the NCS
- Current major components are the
 - NCS Vanguard Study- pilot phase for methods-runs for 21 years-started in 2009 expanded in 2010 and 2011 with additional locations
 - NCS Main Study-exposure response phase- runs for 21 years about 3 years time shifted from Vanguard Study-planned start in 2012
 - NCS Substudies- studies within studies
 - Formative Research-short term limited studies, often methods development, to support and inform the Vanguard and Main Studies

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NCS Vanguard Study Goals



- Vanguard Study designed to evaluate:
 - Feasibility (technical performance)
 - Acceptability (impact on participants, study personnel, and infrastructure)
 - Cost (personnel, time, effort, money)
- of
 - Study recruitment
 - Logistics and operations
 - Study visits and study visit assessments

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Attrition and Retention



- Attrition-anticipate differential attrition for various subpopulations
- Item and Visit Completion rates will vary per participant and over time
- Modeling using 3 different methods indicates potential attrition over 21 years to yield a population of about 40% of initial enrolled population
- Vanguard Study will systematically address retention globally and in specific subpopulations

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Vanguard Study Current Sampling Frame (simplified)



- Random selection of about 100 of the approximately 3000 counties in the United States
 - Counties = Primary Sampling Unit
- Counties divided into segments that are normalized to have about 250 live births per year. Some sparsely populated areas involve merging counties
 - Segments = Secondary Sampling Unit
- Recruitment is restricted to the Secondary Sampling Units

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Recruitment Strategies



- The goal is cost-effective recruitment for the Main Study, employing direct data analysis and predictive modeling
 - Household based - participants learn about the study through field workers going door-to-door
 - Provider based - participants learn about the study through trusted health care providers (broad definition of provider, including pediatricians, obstetricians, public health nurses, midwives, etc.)
 - Direct outreach- participants learn about the study through media and community outreach

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NCS Recruitment Status

-based on data as of 12/15/2011



| | Initial Household (2009 cohort) | Alternate Recruitment (2010 cohort) | All Vanguard to date |
|---|---------------------------------|-------------------------------------|----------------------|
| Locations | 7 | 30 | 37 |
| Recruitment Duration, months | 18 active+ 14 follow up | 12 | |
| A. Women eligible for contact | 35000 | 45600 | 80550 |
| B. Contacted for Pregnancy Screen (% of eligible) | 34350 (98%) | 40000 (88%) | 74350 (92%) |
| C. Completed Screen (% of contacted) | 30900 (90%) | 34850 (87%) | 65730 (88%) |
| D. Pregnant or Trying (% of screened) | 3100 (10%) | 6550 (19%) | 9650 (15%) |
| E. Enrolled (% of pregnant or trying) | 2000 (64%) | 4800 (73%) | 6750 (70%) |
| F. Babies Enrolled | 1050 | 1150 | 2200 |



Vanguard Study Progress



- 2009-Began field activities using household based (door to door contacts in designated neighborhoods) at 7 locations
- 2010- expanded from 7 initial locations to an additional 30 locations for a total of 37 using additional recruitment strategies
- 2011- completed initial recruitment phase with about 6750 families

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Alternate Recruitment Substudy Recruitment Summary

- as of 12/15/2011



| | Provider Based | Enhanced Household | Direct Outreach |
|---|----------------|--------------------|-----------------|
| A. Women eligible for contact | 3350 | 26000 | 16250 |
| B. Contacted for Pregnancy Screen (% of eligible) | 3000 (89%) | 20800 (80%) | 16200 (99%) |
| C. Completed Screen (% of contacted) | 2050 (69%) | 19450 (93%) | 13350 (82%) |
| D. Pregnant or Trying (% of screened) | 1750 (84%) | 2500 (13%) | 2300 (14%) |
| E. Enrolled (% of pregnant or trying) | 1400 (81%) | 1500 (60%) | 1850 (81%) |
| Proportion of enrolled who are pregnant / trying | 87%/ 13% | 52%/ 48% | 54%/ 46% |
| F. Babies Enrolled | 500 | 400 | 250 |



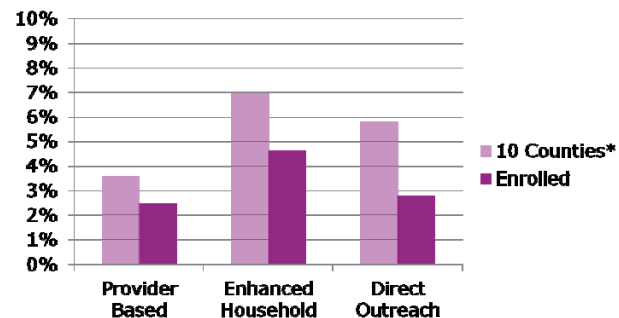
Alternate Recruitment Substudy Screening Efficiency



| | Provider Based | Enhanced Household | Direct Outreach |
|--|----------------|--------------------|-----------------|
| Number of Locations x Weeks in field | 403 | 479 | 471 |
| Mean number of women enrolled per week | 3.5 | 3.2 | 3.9 |
| Mean number of women screened per woman enrolled | 2.1 | 13.7 | 8.7 |

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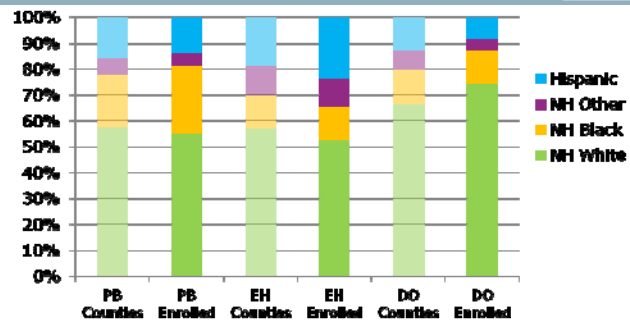
Percent Asian Among Study Eligible and Enrolled Compared to County Population by Strategy



*Average percent Asian in 10 counties from 2010 Census data.

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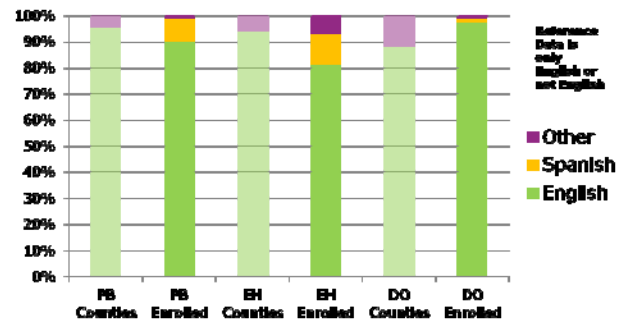
Percent Distribution of Enrolled Women by Race/Ethnicity According to Recruitment Strategy



*Average race/ethnicity distribution in 10 counties from 2009 American Community Survey data.

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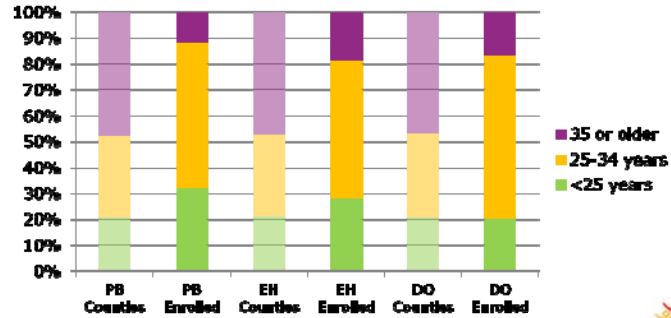
Percent Distribution of Enrolled Women by Primary Language According to Recruitment Strategy



Reference Data is only English or not English

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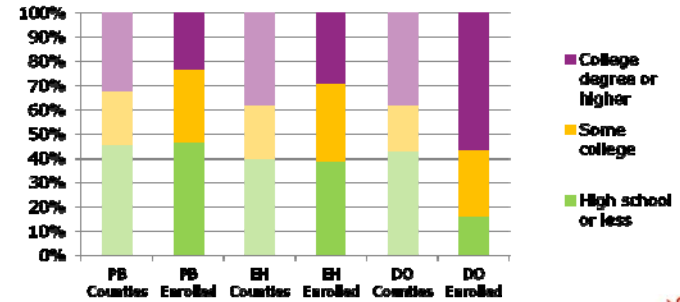
Percent Distribution of Enrolled Women by **Age** According to Recruitment Strategy



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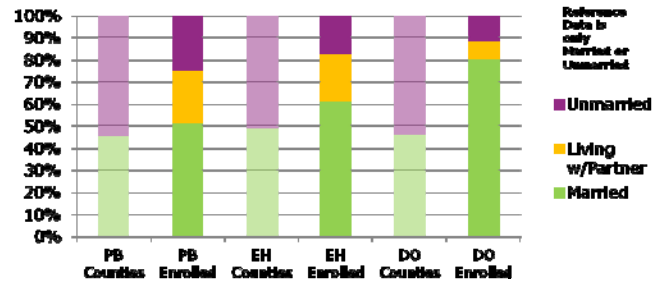
Percent Distribution of Enrolled Women by **Education** According to Recruitment Strategy



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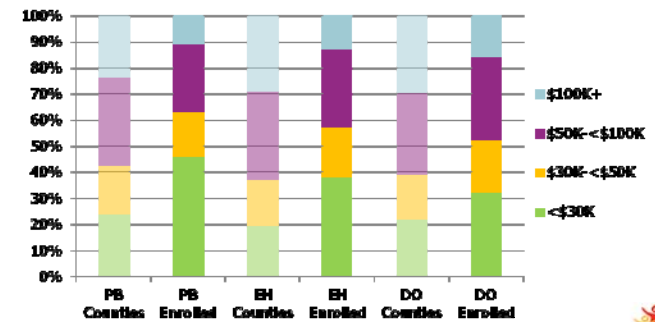
Percent Distribution of Enrolled Women by **Marital Status** According to Recruitment Strategy



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Percent Distribution of Enrolled Women by **Family Income** According to Recruitment Strategy



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Some Preliminary Findings



Each one of the three recruitment strategies was assigned to a group of 10 study locations

- Efficiency of enrollment differed among each recruitment strategy
- Baseline demographics for each recruitment strategy locations were generally similar
- Demographics of women enrolled for each recruitment strategy differed by varying degrees from baseline and from each other

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Summary



- NCS is Congressionally mandated longitudinal activity beginning prior to or during pregnancy.
- Complex system to function as an integrated data collection platform
- Use of standards and harmonization efforts to leverage data collection and analyses
- For further information
 - <http://www.nationalchildrensstudy.gov>
 - ContactNCS@mail.nih.gov

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