

The National Children's Study Waukesha County, Wisconsin Vanguard Center

Jeanne B. Hewitt, PhD; Steven R. Leuthner, MD, MA; Marianne Weiss, DNSc; David Whelan, MSW; Leslie Athey, MS; Jane A. McElroy, PhD; Maureen S. Durkin, PhD, DrPH; Christine E. Cronk, ScD

ABSTRACT

The National Children's Study (NCS) is a large, long-term study designed to detect environmental influences on the health and development of children. Waukesha County, Wisconsin, was selected as 1 of 7 "Vanguard Centers" currently funded to finalize and lead the implementation of the study protocol. The authors provide an overview of key design and planning processes that will be used at all NCS Vanguard locations, the specific approaches to be used in the NCS Waukesha County Vanguard Center, and information about how

Wisconsin physicians and other health care professionals can become involved in working with the NCS.

INTRODUCTION

The National Children's Study (NCS) Waukesha Vanguard Center (VC) will be 1 of 7 sites to initiate the NCS study protocol¹ (see also Trasande et al, p 50). Information on the design and planning process are accessible at the NCS Web site¹ and in the literature.²⁻¹² The core NCS protocol is hypothesis driven¹³ and designed to: 1) limit participant burden (ie least invasive, intrusive, and time consuming); 2) provide reliable, valid measurements to address multiple hypotheses; 3) limit the cost; and 4) accommodate future improvements, and new technologies and hypotheses. This paper provides a brief summary of key design and planning processes that will be used at all NCS Vanguard locations, the specific approaches to be used in the NCS Waukesha County VC, and information about how Wisconsin physicians and other health care professionals can become involved in working with the NCS.

SAMPLE SELECTION AND ENROLLMENT PROCESS

After careful consideration, a national multistage, cluster probability sampling approach was chosen to maximize the generalizability of the findings.¹⁴ In the first stage, all 3141 primary sampling units (largely counties) stratified by major census divisions, urban/rural status, ethnicity, and low birth weight rate, were selected.¹ Once secondary sampling units (smaller areas within the counties known as segments) have been selected, household screeners will go door-to-door to locate and enroll eligible families. To be eligible for the study, households must include a potentially fertile woman between 18 and 39 years of age, who is without mental impairment and is not planning to move out of the area within 1 year of delivery. A sufficient number of women will be enrolled to yield 250 live births per year

This project has been funded in whole or in part with Federal funds from the National Institute of Child Health and Human Development, National Institutes of Health, under Contract Number HHSN275200503396C. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government. Dr Hewitt is co-investigator on the National Children's Study-Waukesha County Vanguard Center and associate professor at University of Wisconsin-Milwaukee NIEHS-funded Marine and Freshwater Biomedical Sciences Center and Institute of Environmental Health, Wis. Doctor Leuthner is co-investigator on the National Children's Study-Waukesha County Vanguard Center and associate professor of Pediatrics at Medical College of Wisconsin. Dr Weiss is co-investigator on the National Children's Study-Waukesha County Vanguard Center and associate professor of Nursing at Marquette University. Mr Whelan is co-investigator on the National Children's Study-Waukesha County Vanguard Center and director of research for the Children's Service Society of Wisconsin. Dr McElroy is co-investigator on the National Children's Study-Waukesha County Vanguard Center and an associate scientist at the University of Wisconsin Comprehensive Cancer Center. Dr Durkin is co-principal investigator on the National Children's Study-Waukesha County Vanguard Center, associate professor of Population Health Sciences, Waisman Center investigator, and affiliate of the Wisconsin Public Health and Health Policy Institute and the Center for Demography and Ecology. Dr Cronk is co-principal investigator on the National Children's Study-Waukesha County Vanguard Center, associate professor of Pediatrics, Medical College of Wisconsin, and member of the Children's Research Institute of Children's Hospital and Health Systems. Please address correspondence to: Jeanne B. Hewitt, PhD, Marine and Freshwater Biomedical Sciences Center and Institute of Environmental Health, University of Wisconsin, 1921 E Hartford Ave, Milwaukee, WI 53211; phone 414.229.5463; fax 414.229.5504; e-mail jbhewitt@uwm.edu.

Table 1. National Children's Study Proposed Study Schedule and Representative Data to be Collected*

Time	Venue	Representative Assessments
Pre-pregnancy (2 to 4 visits)	Home	<i>Interview:</i> Demographics, family and exposure history <i>Biometrics:</i> Urine, saliva, hair, vaginal swab, blood, anthropometrics <i>Environment:</i> Air, dust, paint, water, soil
Pregnancy (Initial, 1st, 2nd, 3rd Trimesters)	Home and Clinic	<i>Interview:</i> Demographics, psychosocial and occupational exposures, medical events, product use, diet <i>Maternal/parental Biometrics:</i> Urine, saliva, hair, vaginal swab, blood, anthropometrics, blood pressure, periodontal exam, ultrasound, fetal heart rate <i>Environment:</i> Air, dust, paint, water, soil
Birth	Hospital	<i>Interview:</i> Planned health behaviors, recent social and environmental history <i>Biometric:</i> Cord blood, placental weight, quantitative ultrasound, neonatal exam <i>Environment:</i> None
Postnatal (1, 6, 12, 18 months)	Home and Clinic	<i>Interview:</i> Psychosocial and occupational exposures, product use, child development, child/parent health behaviors <i>Biometric:</i> <i>Child:</i> Physical exam, anthropometrics, body composition, development, blood, urine, hair <i>Mother:</i> Breast milk <i>Environment:</i> Air, dust, water, soil, food
36 months	Clinic	<i>Interview:</i> Child development, child/parent health behaviors, psychosocial <i>Biometric:</i> Child blood, hair, urine, saliva, standardized physical and developmental exam, parent-child observation, lung function, body composition, audiometry <i>Environment:</i> None

* The draft protocol outline can be viewed at: www.nationalchildrensstudy.gov/research/study_plan/index.cfm. Accessed March 3, 2006.

over 5 years (total of 1250 live births). A target 25% of these births will be to women recruited prior to conception with the remainder enrolled during the first or second trimesters through prenatal care professionals and other strategies, allowing exposures during pregnancy to be measured. All children born to women participating in the NCS during the 5-year enrollment period will be included in the study.

Finalization of the Protocol

The Study protocol describes the measures and detailed study design including the types of bio-specimens and timing of collection, venues where data collection will take place, and identification of environmental matrices and measurement methods (Table 1) (see also NCS Plan¹⁵). Over the next 2 years, the principal investigators from the 7 VCs, their local study teams, the NCS Program Office and the Coordinating Center (Westat, an employee-owned independent research firm) will finalize the protocol and carry out pilot testing of some measurements.

The Operation of the NCS Waukesha County VC

Work at the NCS Waukesha County VC will be executed by a consortium of Wisconsin academic institu-

tions and community partners (Table 2), and will emphasize strong community (including medical/health care establishments) commitment and engagement.

Study Planning Phase

Teams made up of scientists and representatives from the community (including health care professionals) will participate in local protocol finalization and pilot testing, preparation for human subjects review, and community outreach and engagement. A study center office (in Waukesha County) will house study staff and be used as a venue for planning activities and some data collection. A formal needs assessment will be completed to consider community concerns related to the study protocol and to identify specific issues that may be included either in the national study protocol (all study sites) or in special Waukesha VC adjunct studies.

Approach to Community Engagement

Our approach to community engagement uses the following principles of community-based participatory research (CBPR).¹⁶⁻¹⁹

- Emphasize local relevance of the research to increase likelihood of individual participant buy-in.

- Facilitate co-learning that promotes more acceptable protocol design and methods.
- Build adaptable relationships with individuals, agencies, and health care professionals needed for a long-term study.
- Enable participation of community members to improve the research process.
- Promote timely sharing of study information with individuals and, where appropriate, with the community-at-large, and engage the community in the dissemination process.

We believe use of these principles will support recruitment and retention, and contribute to the quality of data collection.

STUDY IMPLEMENTATION

Community Outreach

Using approaches developed during the planning phase, we will implement a community outreach campaign. Physicians and nurses from the Medical College of Wisconsin, Marquette University, University of Wisconsin-Milwaukee, and University of Wisconsin-Madison will work with Waukesha hospitals, health care professionals, and medical practices on building relationships within the community and aspects of study implementation.

Household Screening and Recruitment and Data Collection

The National Opinion Research Center (NORC), which has conducted many national surveys, will employ and train the household screeners who will go door-to-door in the neighborhoods to recruit participants. Field teams composed of nurses (affiliated with Marquette University) and social workers (hired through the Children's Service Society of Wisconsin) will do all in-home data collection and assist with data collection in the birth hospital. To the extent possible, a single nurse-social worker team will follow a participating family throughout their involvement in the study. Nurses will collect specimens and other biometric data. Social workers will complete interviews with families, be responsible for building relationships with participants, assist with service referrals requested by the family, and monitor participant satisfaction. Field team hours will facilitate evening and weekend appointments. When possible, visits will be coordinated with prenatal and pediatric visits. Health care professionals may be asked to provide a limited amount of data required for the study. Study staff will work with 1 individual at each practice to develop a system that minimizes the time and interruption of clinic schedules.

Table 2. Partners in the NCS Waukesha Vanguard Center*

2A Major Collaborating Institutions

- University of Wisconsin-Madison: Lead Institution, scientific development and oversight
- Medical College of Wisconsin/Children's Research Institute: Lead Institution, community engagement, scientific oversight
- Marquette University Colleges of Nursing and Communication: Community outreach, field logistics, data collection
- Children's Service Society of Wisconsin: Recruitment and retention, interviewing, community engagement
- National Opinion Research Center: Field operations, recruitment and retention, sampling/segment selection
- University of Wisconsin-Milwaukee: Scientific support, community outreach
- Wisconsin Department of Health and Family Services: Environmental health and sampling, vital records access, community engagement

2B Community Partners

- ProHealth Care: Field logistics, community engagement
- Waukesha County-(Department of Health and Social Services): Field logistics, community engagement
- Waukesha Family Practice Center: Community engagement
- Casa de Esperanza: Community engagement

2C Supporting Community/Medical Agencies

- Covenant Health Care
- Froedtert and Community Memorial
- Wisconsin Association for Perinatal Care
- March of Dimes

* Only established relationships have been listed. Part of community outreach activities will involve actively seeking to form additional partnerships.

Hospital Data Collection

A liaison in each birth facility will help plan a system to identify study participants on admission to that hospital for childbirth. A sample collection kit will be provided to the birth facility. Biologic specimens (eg, cord blood) will be collected by obstetric technicians or nurses trained by NCS staff and stored in specially marked containers. The field team nurse will work with hospital staff in preparing for the birth data collection, retrieving biologic samples, and performing newborn assessments. Birth hospitals will be compensated for staff time devoted to training and data collection.

Adjunct Studies

NCS Waukesha VC will support the development of adjunct studies.¹ These studies will address concerns specific to Waukesha County and build on the core protocol using the specific research, public health, and clinical strengths available in Wisconsin and Waukesha County. The design of the NCS will particularly facili-

tate the examination of gene-environment interactions contributing to health and developmental outcomes. Adjunct studies can be performed on all or a portion of the full cohort (ie either from all NCS Study Sites or just the Waukesha enrollees). Because Waukesha County has demographic characteristics that are different from other NCS Locations, adjunct studies will offer the opportunity for studying the Waukesha sample alone or in contrast to enrollees from other sites.

Adjunct studies will be funded separately using National Institutes of Health investigator-initiated grants or other public/private partnership monies. A mechanism to support and review adjunct studies proposed by the scientific and clinical community in Wisconsin is under development.

Getting Involved in the NCS Waukesha VC

Forums directed at physicians (especially obstetricians, pediatricians, and family practice physicians) and other health care professionals, as well as other community members who wish to provide input and feedback about the study process will be held regularly. Additionally, there will be workgroups in which these groups can collaborate with the NCS Waukesha VC Team to devise the best ways to implement the study protocol. For all health care professionals in Wisconsin, we encourage collaborations leading to possible adjunct studies in which hypotheses of importance to Wisconsin children and families can be studied. Questions about and ideas for the NCS and potential adjunct studies should be directed to Dr Cronk (ccronk@mcw.edu).

REFERENCES

1. The National Children's Study Plan. 2004. Available at: www.nationalchildrensstudy.gov/research/study_plan. Accessed March 3, 2006.
2. Barr DB, Wang RY, Needham LL. Biologic monitoring of exposure to environmental chemicals throughout the life stages: requirements and issues for consideration for the National Children's Study. *Environ Health Perspect*. 2005;113(8):1083-1091.
3. Bradman A, Whyatt RM. Characterizing exposures to non-persistent pesticides during pregnancy and early childhood in the National Children's Study: a review of monitoring and measurement methodologies. *Environ Health Perspect*. 2005;113(8):1092-1099.
4. Dietrich KN, Eskenazi B, Schantz S, et al. Principles and practices of neurodevelopmental assessment in children: lessons learned from the Centers for Children's Environmental Health and Disease Prevention Research. *Environ Health Perspect*. 2005;113(10):1437-1446.
5. Eggleston PA, Diette G, Lipsett M, et al. Lessons learned for the study of childhood asthma from the Centers for Children's Environmental Health and Disease Prevention Research. *Environ Health Perspect*. 2005;113(10):1430-1436.
6. Eskenazi B, Gladstone EA, Berkowitz GS, et al. Methodologic and logistic issues in conducting longitudinal birth cohort studies: lessons learned from the Centers for Children's Environmental Health and Disease Prevention Research. *Environ Health Perspect*. 2005;113(10):1419-1429.
7. Gilliland F, Avol E, Kinney P, et al. Air pollution exposure assessment for epidemiologic studies of pregnant women and children: lessons learned from the Centers for Children's Environmental Health and Disease Prevention Research. *Environ Health Perspect*. 2005;113(10):1447-1454.
8. Kimmel CA, Collman GW, Fields N, Eskenazi B. Lessons learned for the National Children's Study from the National Institute of Environmental Health Sciences/US Environmental Protection Agency, Centers for Children's Environmental Health and Disease Prevention Research. *Environ Health Perspect*. 2005;113(10):1414-1418.
9. Ozkaynak H, Whyatt RM, Needham LL, Akland G, Quackenboss J. Exposure assessment implications for the design and implementation of the National Children's Study. *Environ Health Perspect*. 2005;113(8):1108-1115.
10. Wang RY, Needham LL, Barr DB. Effects of environmental agents on the attainment of puberty: considerations when assessing exposure to environmental chemicals in the National Children's Study. *Environ Health Perspect*. 2005;113(8):1100-1107.
11. Needham LL, Ozkaynak H, Whyatt RM, et al. Exposure assessment in the National Children's Study: introduction. National Children's Study. *Environ Health Perspect*. 2005;113(8):1076-1082.
12. Lobdell DT, Mendola P. Development of a biomarkers database for the National Children's Study. *Toxicol Appl Pharmacol*. 2005;206(2):269-273.
13. National Children's Study Hypotheses. 2005. Available at: www.nationalchildrensstudy.gov/research/hypotheses. Accessed March 3, 2006.
14. White Paper on Evaluation of Sampling Design Options for the National Children's Study. 2003. Available at: www.nationalchildrensstudy.gov/research/hypotheses. Accessed March 3, 2006.
15. The National Children's Study Locations. 2005. Available at: www.nationalchildrensstudy.gov/about/locations/. Accessed March 3, 2006.
16. Lyman WD, Barone C, Castle V, et al. Making the National Children's Study a real partnership with academic pediatrics. *J Pediatr*. 2005;147(5):563-564.
17. Israel B, Schultz A, Parker EA, Becker AB, Allen III AJ, Guzman JR. Critical issues in developing and following community based participatory research principles. In Minkler M, Wallerstein N, eds. *Community-Based Participatory Research for Health*. San Francisco: Jossey-Bass; 2003:53-76.
18. Baker EA, Homan S, Schonoff S, Kreuter M. Principles of practice for academic/practice/community research partnerships. *Am J Prev Med*. 1999;16(3, Suppl 1):86-93.
19. Israel B, Parker EA, Rowe Z, et al. Community-based participatory research: lessons learned from the Centers for Children's Environmental Health and Disease Prevention Research. *Environ Health Perspect*. 2005;113(10):1463-1471.