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

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 HHSN2752005003396C. 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, Wisc. 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.

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 protocol (see also Trasande et al, p 50). Information on the design and planning process are accessible at the NCS Web site and in the literature. The core NCS protocol is hypothesis driven and designed to: 1) limit participant burden (i.e., 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. 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. 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.
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 institutions 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.

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 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. 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-

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.
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 workshops 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

The mission of the *Wisconsin Medical Journal* is to provide a vehicle for professional communication and continuing education of Wisconsin physicians.

The *Wisconsin Medical Journal* (ISSN 1098-1861) is the official publication of the Wisconsin Medical Society and is devoted to the interests of the medical profession and health care in Wisconsin. The managing editor is responsible for overseeing the production, business operation and contents of the *Wisconsin Medical Journal*. The editorial board, chaired by the medical editor, solicits and peer reviews all scientific articles; it does not screen public health, socioeconomic or organizational articles. Although letters to the editor are reviewed by the medical editor, all signed expressions of opinion belong to the author(s) for which neither the *Wisconsin Medical Journal* nor the Society take responsibility. The *Wisconsin Medical Journal* is indexed in Index Medicus, Hospital Literature Index and Cambridge Scientific Abstracts.

For reprints of this article, contact the *Wisconsin Medical Journal* at 866.442.3800 or e-mail wmj@wismed.org.

© 2006 Wisconsin Medical Society