

**National Children's Study
Federal Advisory Committee 22nd Meeting
October 21, 2009
Natcher Conference Center, National Institutes of Health (NIH)
Bethesda, MD**

This meeting was held in conjunction with the National Children's Study (the Study), which is led by a consortium of federal partners: the [U.S. Department of Health and Human Services](#) (HHS) (including the [Eunice Kennedy Shriver National Institute of Child Health and Human Development](#) [NICHD] and the [National Institute of Environmental Health Sciences](#) [NIEHS]) of the [National Institutes of Health](#) [NIH] and the [Centers for Disease Control and Prevention](#) [CDC]), and the [U.S. Environmental Protection Agency](#) (EPA).

Welcome from the Chair of the National Children's Study Federal Advisory Committee (NCSAC)

Alan R. Fleischman, M.D., NCSAC Chair; Senior Vice President and Medical Director, March of Dimes

Dr. Fleischman welcomed participants to the 22nd NCSAC meeting and noted that the committee is meeting in a time of transition to new leadership. Under the Federal Advisory Committee Act, the role of the NCSAC is to advise, and its meetings are open to the public. The NCSAC:

- Provides specific advice and recommendations to the NIH Director, NICHD Director, and the Study Director, regarding general direction and conduct of the Study, ethical concerns, community engagement and consideration, and hypotheses and other considerations of the Study
- Responds to specific requests for advice and recommendations
- Provides a forum for considering requests from the public and scientific community and provides opportunities for advocacy and industry perspectives and representation.

Dr. Fleischman reviewed the minutes from the May 26–27 NCSAC meeting:

- Study update
 - September 2008, contracts awarded to 27 Study Centers for 39 Wave 2 Study locations
 - The budget for 2009 is \$192.3 million; the 2010 budget request is \$194.4 million
 - March 23, 2009, NICHD Director's statement on cost and full evaluation of the Vanguard Study
- ICC report
 - Each lead agency (NICHD, NIEHS, CDC, and EPA) has an essential role to play in the Study and will ensure that the Study plays a role in fulfilling each agency's mission.
 - The ICC will lead efforts to inform agency heads about the Study.
- Obesity: challenges and opportunities
- Independent Study Monitoring and Oversight Committee (iSMOC) update
 - Initial meeting planned for June 8, 2009
- Vanguard pilot experience—Queens and Salt Lake City
- Follow up

- Autism as an outcome
- Formative research plans
- Subcommittee reports
 - Community Outreach and Engagement
 - Scientific Review
 - Ethics and Informed Consent.

Report from the Director's Office, NICHD

Susan Shurin, M.D., Acting Director, NICHD, NIH, HHS

Dr. Shurin reminded the group that NCSAC members, in their official capacity or as a group, are prohibited from directly or indirectly lobbying members of Congress. When authorized, members may inform or educate the public on policies or legislation, and members may speak with Congress upon request. If NCSAC members, in their official capacity, initiate contact with Congress, this should be coordinated through the Office of the Assistant Secretary for Legislation. Members may express personal views as private citizens during duty off-time, and they cannot use government equipment or resources to express personal views.

Dr. Shurin reviewed the changes at the NICHD. Duane Alexander, M.D., who served as NICHD Director for 23 years, has moved to the NIH Fogarty International Center to work on maternal and child health issues. A search for the new NICHD Director is being organized. A number of other NICHD senior level searches are ongoing, but some searches are on hold until the new NICHD Director is found, including the search for a new Scientific Director for the Intramural Program.

NIH American Reinvestment and Recovery Act funding has enabled some short-term investments. This funding process has raised awareness of unmet needs and unfulfilled capacity. The NIH budget is unlikely to increase in 2011. Fiscal discipline is required, and investments must be aligned with top priorities.

The National Children's Study is constituted differently than any other NIH study, in terms of its length, number of sites, and complexity. The usual models do not apply, and midcourse corrections have been necessary. It is important to prioritize questions that require the Study cohort and cannot be answered in any other study. The Study will be the framework for additional studies.

National Children's Study Update

Steven Hirschfeld, M.D., Ph.D., Acting Director, National Children's Study, NICHD, NIH, HHS

The goal of the Study is to improve the health and well-being of children. The Study is a congressionally mandated activity coordinated among federal agencies including the EPA, the CDC, and the NIH (the NIEHS and the NICHD [program lead]). The Department of Education (ED) may become a Study partner in the future.

The congressional appropriation for the Study is given to the NIH Director, and the NIH Office of the Director provides guidance for the Study. According to its charter, the NCSAC provides advice to the NIH Director, the NICHD Director, and the Study Director. The relationship between the Study and the NIH Director is being realigned. The Program Office briefed NIH Director Francis Collins, M.D., Ph.D., on September 11 and reported on the status of the Study to the NICHD Advisory Council on Child Health and Human Development on September 21. Barnett Kramer, M.D., M.P.H., and John Gohagan, Ph.D., serve as liaisons with the NIH Office of the Director.

The Study will examine the multiple effects of environmental and genetic influences on the health and development of 100,000 children across the United States by providing high quality data to analyze scientific hypotheses. The Study is a large, multicomponent, multiyear longitudinal study that is unprecedented in scope and complexity and necessitates a planning process that is systematic, dynamic, flexible, and evidence-based.

The Study is being implemented in several phases, and all components and phases together form the National Children's Study. The Vanguard Study is designed to evaluate the feasibility (technical performance), acceptability (impact on participants, Study personnel, and infrastructure), and cost (personnel, time, level of effort, and money) of Study recruitment, logistics and operations, and visits and visit assessments. The Vanguard Study precedes the Main Study and will continue for 21 years. The Main Study will continue for 21 years after the last participant is enrolled. The Vanguard Study is an important component that will ensure the optimal function of the Main Study.

The enrollment target for the Vanguard Study will be determined empirically by two factors:

- Recruitment data indicating a sufficient number of informative events to assess different strategies for scale-up to the Main Study
- An adequate cohort size to evaluate the visit assessments for the duration of the Study.

The selection of scientific hypotheses for the Main Study will be guided by:

- Empiric data of the Vanguard Study and other Study-funded substudies
- Efforts of the various work groups and interested parties that proposed and vetted hypotheses
- Potential scientific and public health impact
- A perceived requirement to use the Study and not another alternative as the data acquisition platform.

The Main Study will focus on data acquisition related to the interaction of genetics, environment, growth, and development and outcomes and the analyses of those data for multiple scientific hypotheses. The Vanguard Study and the Main Study have different goals, and the assessment types and assessment techniques used in each component may be different. There is no intent to categorically merge data among Study components. The Vanguard and Main Study will run in parallel and, with additional Study-funded substudies, will form the composite National Children's Study.

The outcomes of the Vanguard Study will have a continual and major impact on how the Main Study will be executed. It is imperative that the Vanguard Study be planned, implemented, and

monitored with a level of precision that enables it to serve as a reliable and valid platform to evaluate recruitment, study procedures, visits, scale-up potential, resource requirements, and other aspects for the Main Study.

The Study needs to use harmonized terminology, for example:

- Studies that integrate with the Vanguard Study, are funded by the Study, and focus on a limited question with limited duration will be known as *substudies*.
- Studies that integrate with the Vanguard Study and have independent funding will be known as *supplemental methodological studies*.
- Studies that integrate with the Main Study and have independent funding will be known as *adjunct studies*.

Data from the Study are intended to be shared and will be made accessible through the policies outlined in the Data Access Manual. Study data are a national resource and should be accessible to all. Dr. Hirschfeld noted that the 5-year survival rate in pediatric oncology has been increasing, while the 5-year survival rate in adult oncology has not. Many more drugs are approved for adults than are approved for children. He attributed the success in pediatric oncology to systematic inquiries through coordinated multi institutional clinical research studies and data sharing.

The NCSAC has recently made the following recommendations:

- The Study should develop a list of potential adjunct studies to guide investigators interested in adjunct studies (Janet Currie, Ph.D.). *This could be useful for the development of supplemental methodological studies as well.*
- The Study needs to reassess its priorities and optimize the pilot nature of the Vanguard Center activities (Maria Cancian, Ph.D., and John Butenhoff, Ph.D.). *This recommendation was in accordance with the National Academy of Sciences panel's recommendation to implement a discrete Vanguard Phase.*
- The Study needs to evaluate the methodologies and validity of assessments as it would evaluate the samples themselves (David Schonfeld, M.D.).

As the Program Office has increased in capacity, Study Coordinating Center and working group activities have been transferred to the Program Office to ensure alignment and consistency. The National Children's Study Scholars Program has been instituted to bring individuals from federal agencies and departments into the Program Office for part-time or full-time details. The point of contact for the Scholars Program is Marion Balsam, M.D. The program provides opportunities for the Program Office to gain technical and subject expertise and for individuals to enhance their careers and their agencies' missions.

The Program Office is committed to optimizing resources by:

- Establishing a Program Office Planning Committee, which has analyzed responsibilities and resources in the Program Office and performed a gap analysis
- Realigning to optimize resources to meet responsibilities
- Filling gaps and augmenting capacity through multiple mechanisms
- Undergoing process analysis
- Evaluating all Study components continuously and dynamically.

The Program Office is committed to:

- Compliance with the highest ethical and scientific standards
- Complete fiscal responsibility, accountability, and transparency
- Respect for all involved
- Listening to and working with Study partners
- Engaging subject matter experts and other advisors when needed
- Striving to ensure that adequate resources are in place in advance for operations
- Establishing performance metrics
- Monitoring and reporting progress
- Identifying potential risks and addressing them proactively
- Monitoring and adjusting based on empiric evidence and Study needs.

NCSAC Discussion and Recommendations

- Dr. Fleischman asked about recent Study activities. Dr. Hirschfeld said details would be presented later in the day. The Program Office met with the ICC, which has been helpful in adjusting to the evidence-based, data-driven environment. The Program Office met with the Vanguard Center investigators and staff on October 13 and met with Vanguard Center staff and the Executive Committee of the Steering Committee on October 14. The Program Office received input from each of the Vanguard sites.
- Dr. Currie asked whether studies that only use Study data and do not make additional demands on subjects would be a separate class that needs another term. Dr. Hirschfeld said that proposals for accessing and analyzing data and linking to other data sets would be a separate class. The Study should follow international standards for data acquisition, transmission, and archiving. The Study should be aligned with the NIH data sharing policy, which is being revised, and with data sets from other studies. This issue is under development.
- Michelle Williams, Sc.D., S.M., M.S., asked about the gap analysis. Dr. Hirschfeld explained that the Program Office develops statistical analysis plans for operations and logistics and for many technical visit assessments. The Program Office needs certain types of statistical advice, analytical capabilities, and expertise in process analysis and new media. The gap analysis focused on Program Office operations.
- Michael Greene, M.D., asked how the Study could get more medications approved for use in pregnant women. Dr. Hirschfeld said that this is a profound question and may technically be beyond the mission of the Study. The Study can leverage its activities by proposing studies that provide data that could lead to more focused investigations.
- Ellen Clayton, M.D., J.D., asked whether investigators would have a period of exclusive data use. Dr. Hirschfeld said the data access policy would be discussed at the January NCSAC meeting. Open data access is part of the mission of the Study. The Study operates through contracts instead of grants. The federal government owns the data and has the right to determine their disposition. Investigators have no expectation of a period of exclusivity.

- Everett Rhoades, M.D., noted that communities from which data are collected are increasingly asserting partial ownership of data. Dr. Hirschfeld noted that an Institute of Medicine panel produced a report on this topic in spring 2009. The Study will not seek to redefine or extend the legal framework of data ownership but will be responsive to changes in the legal framework.
- Dr. Fleischman noted that the NCSAC has been very supportive of wide, early data access but has also been sympathetic to federal and Study Center investigators and concerned that the major hypotheses are answered through the Study. Dr. Currie noted that a significant minority of NCSAC members did not agree that Study investigators should have additional time or priority to look at particular hypotheses. Dr. Hirschfeld affirmed that Study investigators will not be given additional time or priority.
- Bruce Gelb, M.D., asked about access to limited resources such as biological samples. Dr. Hirschfeld suggested deferring discussion until the January meeting. The Program Office is considering mechanisms by which the results of specimen analyses would be shared.
- Ana Diez-Roux, M.D., Ph.D., M.P.H., asked about the transfer of some Coordinating Center functions to the Program Office. Dr. Hirschfeld explained that the Program Office has released a request for information about what functions are feasible to contract out to a Coordinating Center. Based on the responses, the Program Office will develop a Request for Proposals. The Study will formally examine this question every 5 years.

General Discussion

- Meredith Wadman, M.D., a reporter from *Nature*, informed the group that she was preparing a story for the November 5 issue. She asked about the report from the Senate appropriations committee. Dr. Wadman inquired about the process of reporting to the appropriations committee and what modifications would be required. Dr. Hirschfeld suggested she contact the NIH Office of the Director about this issue.
- Carol Henry, Ph.D., asked how incentives for investigators change in the contract research environment. Dr. Hirschfeld said that the Study has a unique mission and provides opportunities for investigators to collaborate with colleagues on important questions over decades. The Study offers resources and financial leverage opportunities that are of interest to academic institutions and investigators.
- Amelie Ramirez, Dr.P.H., asked about the biggest barriers to implementation of the Study. Dr. Hirschfeld said one major barrier is that there is no prior model for the Study.

ICC Report

Marshalyn Yeargin-Allsopp, M.D., ICC Chair; Medical Epidemiologist and Developmental Disabilities Branch Chief, National Center on Birth Defects and Developmental Disabilities, CDC, HHS

The ICC oversees broad Study issues, promotes interagency collaboration, ensures that the mission of the Study is maintained over time, and ensures that Study goals reflect the scientific priorities of the four lead agencies.

Interagency coordination is mandated under the Children's Health Act. The Program Office discusses Study needs with the ICC, and the ICC provides advice and assistance. The ICC reaches out to institutes and agencies for advice on the Study.

Dr. Yeargin-Allsopp described the areas of expertise of ICC members:

- Elizabeth Blackburn, B.S.N. (EPA): Home health, hospital nursing, pediatric environmental health issues
- Amy Branum, M.S.P.H. (CDC): Nutrition, perinatal epidemiology (preterm birth, low birth weight, multiple births, assisted reproductive technology)
- Adolfo Correa, M.D., Ph.D. (CDC): Birth defects, stillbirths, pregnancy outcomes, diabetes, obesity, hyperglycemia, nutritional factors in pregnancy, study design, epidemiologic methods, occupational exposures, pediatrics data linkages, survival analysis
- Sally Darney, Ph.D. (EPA): Reproductive physiology, reproductive health, reproductive toxicology, sperm function, infertility
- Nigel Fields, M.S.P.H. (EPA): Environmental toxicology, molecular epidemiology, exposure science, community-based participatory research
- Kim Gray, Ph.D. (NIEHS): Epidemiology (maternal/child health and neurobehavioral and developmental outcomes), exposure assessment, environmental health science, environmental chemicals and neurological outcomes (across development and aging), respiratory and cardiovascular disorders
- Steven Hirschfeld, M.D., Ph.D. (NICHD): Pediatric hematology-oncology, drug and research evaluation, research protection of children, regulation, policy and operations, data analysis and data standards
- Sarah Keim, Ph.D., M.A., M.S. (NICHD): Pediatric epidemiology—infant nutrition and development, life-course epidemiology/intergenerational factors
- Mark Klebanoff, M.D., M.P.H. (NICHD): Perinatal and reproductive epidemiology (especially preterm birth)
- Mary Mortensen, M.D., M.S. (CDC): Medical and environmental toxicology, clinical pharmacology, developmental pharmacology (susceptibility of children), interpreting background exposures to environmental chemicals (for example, reference ages)
- Sheila Newton, M.S., Ph.D. (NIEHS): Biochemistry, science policy
- Jim Quackenboss, M.S. (EPA): Study design (quality assurance), study management, survey design (probability samples), questionnaire design, communications, measurements, database design and review, statistical analyses and monitoring
- Marshalyn Yeargin-Allsopp, M.D. (CDC): Child development/behavior, developmental disabilities (especially autism and cerebral palsy).

Dr. Yeargin-Allsopp reviewed the leadership of the lead agencies:

- EPA Administrator Lisa P. Jackson, M.S.E.
- HHS Director Kathleen Sebelius, M.P.A.
 - NIH Director Francis Collins, M.D., Ph.D.
 - NIEHS Director Linda S. Birnbaum, Ph.D., DABT, ATS
 - NICHD Director (Acting) Susan Shurin, M.D.
- CDC Director Thomas R. Frieden, M.D., M.P.H.

The CDC Environmental Health Laboratory collaborates with the Study by:

- Providing operational expertise by assisting with protocol and procedure development for biological specimen (urine, blood, breast milk) collection, processing, labeling, and shipping
- Providing analytical expertise by measuring environmental chemicals and nutritional indicators in a subset of biological samples from each Vanguard Center.

The collaboration benefits both the CDC and the Study. The analytical results for pregnant women and infants will help characterize exposures that have not been well described and may be helpful to indicate exposures that are relatively high or are extremely low in these groups, compared with other age groups. The results may help inform future case-control studies.

EPA Administrator Jackson has emphasized children's health. She named Peter Grevatt, Ph.D., Director of the EPA's Office of Children's Health Protection, and announced a five-point agenda for children's environmental health, which includes:

- Regulations and policy development
- Chemicals management and Toxic Substances Control Act reform
- Community-based children's health programs
- Research and science policy, including collaboration with the NICHD on the National Children's Study
- Measuring the effectiveness of the EPA's children's health activities.

The EPA is collaborating with the Study on exposure validation designs, laboratory methods for environmental samples, and two workshops.

The NIEHS has collaborated with the Study on the following:

- An August 2009 meeting with the Study and the EPA on recruitment strategies and environmental and biological sampling
- A September 2009 NIEHS Environmental Health Sciences Core Centers meeting featuring children's health and the National Children's Study
- Dr. Birnbaum's September 2009 testimony for the U.S. Senate Committee on Environment and Public Works lauding the National Children's Study
- The October 2009 children's environmental health issue of *Environmental Health Perspectives*, which included the National Children's Study
- Exposure Biology Program grantee meeting involving National Children's Study staff in discussions about innovative technologies and devices for measuring environmental exposures.

The NIEHS and the EPA will announce new Children's Environmental Health and Disease Prevention Research Center grants in early 2010. The Recovery Act will fund grants on developmental effects of bisphenol A and autism spectrum disorder, and the National Cancer Institute program on Breast Cancer and the Environment will examine environmental factors that influence puberty.

In 2009, ICC members:

- Advised the Program Office on cost-saving measures
- Served as liaisons to the Steering Committee/Executive Steering Committee, Data Access and Confidentiality Subcommittee, and the Publications Subcommittee
- Served as reviewers for the Vanguard Center protocol and other relevant scientific documents
- Represented the Study to their respective agencies and at scientific meetings.

In 2010, the ICC will:

- Raise the profile and visibility of the Study
- Provide scientific input on feasibility, acceptance, and cost of the Vanguard Study
- Advise the new Study Director and Program Office regarding the Vanguard protocol and institutional review board (IRB) amendments as needed
- Review and make recommendations regarding evaluation of Study outcome assessments
- Promote and support the Scholars Program and collaborate on the Vanguard Study as a dynamic platform for advancing clinical research methodology
- Continue to provide oversight and guidance to ensure that the Study achieves its stated mission and remains aligned to the interests of the lead agencies.

NCSAC Discussion

- Dr. Butenhoff asked about the Scholars Program. Dr. Hirschfeld explained that the program would leverage resources and provide opportunities for federal scientists to collaborate with the Study. The program will be flexible, allowing scientists to work with the Study full time or part time, onsite or offsite. Details are available on the NICHD and Study Web sites.
- José Cordero, M.D., M.P.H., asked about opportunities to implement cost-saving measures. Dr. Yeargin-Allsopp said the Program Office organized a meeting with individuals with specific expertise to develop models to reduce costs; this is an ongoing process. The ICC made recommendations about changes in NIH business processes but does not have the authority to implement changes.
- Joan Reede, M.D., M.P.H., M.B.A., asked about extending the Scholars Program beyond federal agencies and linking it with other NIH programs to engage younger investigators. Dr. Henry agreed and suggested expanding the program to students and retirees. Dr. Hirschfeld said that the program will begin with federal employees but will eventually expand beyond the federal government.

- Dr. Fleischman noted that there is consensus in support of beginning and expanding the Scholars Program. The program has the potential for engaging young and diverse scientists. Melissa Tassinari, Ph.D., added that recent retirees would be a good resource for the Study.
- Dr. Fleischman asked about the ICC's efforts to inform the new CDC leadership about the Study. Dr. Trevathan said that Dr. Frieden has been informed of the Study. He previously served as the Director of the New York City Health Department, and he was well informed about the Study because one of the Vanguard locations is in New York City.
- Dr. Fleischman asked about the ICC's view of the change in Study leadership. Dr. Yeargin-Allsopp said that change is difficult, and the ICC was surprised by the change in leadership. The ICC is passionate about the Study and will do all it can to promote it.
- Dr. Greene asked about the Study's role in addressing popularly held beliefs about exposures and outcomes. Dr. Yeargin-Allsopp said the Study is the perfect vehicle to examine exposures and outcomes of concern, such as the popular belief that vaccines are related to autism even though a number of studies have not shown an association.
- Helen DuPlessis, M.D., M.P.H., asked about the process of inviting additional agencies such as the Department of Education into the ICC. Dr. Hirschfeld said that the language of the Children's Health Act is very comprehensive and contains no limitations on including other agencies in the Study. Dr. Fleischman noted that there have been positive interactions between the Study and the ED. Dr. Yeargin-Allsopp described the meetings of the Federal Consortium. The ICC has talked about involving more federal partners in 2010.
- Dr. Tassinari noted the Food and Drug Administration (FDA) is absent from the Study. Dr. Hirschfeld said he and Dr. Keim have met with FDA representatives and are working on formal FDA involvement. The Study has also had contact with the Department of Defense.
- Dr. Fleischman said that the NCSAC applauds efforts to reach out to and engage other federal agencies. The NCSAC is ready to invite ex officio members at the recommendation of the Study Director and the ICC.

NCSAC Recommendations

The Committee recommended that the Scholars Program be initiated and, when possible, expanded beyond federal agencies to include academia, students, and recent retirees.

Recruitment Strategies

Dr. Hirschfeld

Christina Park, Ph.D., Senior Scientist and Study Center Project Officer, National Children's Study, NICHD, NIH, HHS

Dr. Hirschfeld explained that recruitment is a process of data acquisition and distribution, followed by a process of data archiving and access. Two models of data collection are:

- The “FedEx” model, in which participants go to one central depot and a highly efficient system acquires the data
- The “Domino’s Pizza” model, in which data collectors go out to participants to collect the data.

The Study will adopt a combination of data collection methods.

Study recruitment strategies must build long-term relationships and trust in several phases:

- Introducing the Study
- Educating about the Study
- Offering the opportunity to be engaged
- Becoming collaborators
- Eventually transitioning away from the Study.

Individuals participate based on four levels of considerations: concern for their child, their community, their country, and children everywhere. Recruitment strategies should engage people on all of these levels. All of the recruitment processes must be integrated.

Dr. Park provided a brief overview of the sampling design and showed a map of the 105 Study locations, including the seven Vanguard locations. The Vanguard locations are intended to be representative of the U.S. population.

Two Vanguard Centers began collecting data in January 2009:

- University of North Carolina—Duplin County
- Mount Sinai School of Medicine—Queens.

The other five Vanguard Centers began collecting data in April 2009:

- Children’s Hospital of Philadelphia—Montgomery County, PA
- South Dakota State—Four adjacent counties in Minnesota and South Dakota (BYPL)
- University of California, Irvine—Orange County, CA
- University of Utah—Salt Lake County, UT
- University of Wisconsin—Waukesha County, WI.

The Vanguard Centers listed all households in the selected segments (about 7,000–16,000 households per location) and sent staff to enumerate residents, which includes:

- Identifying whether age-eligible women are in the household
- Screening to identify pregnant eligible women (assigning women who are not pregnant to follow-up groups based on pregnancy probability)
- Obtaining informed consent if pregnant eligible (first trimester).

The seven Vanguard Centers have listed 83,017 households and completed enumeration for 55,060 households. Pregnancy screening interviews have been completed for 21,800 age-eligible women, and 557 women in the first trimester of pregnancy have been identified. A little more than half—328—have consented for the Study, and there have been 22 births.

The Vanguard Study has implemented additional strategies to identify and recruit women, including self-referral and referral through health care providers and community organizations.

Dr. Park presented preliminary recruitment data from the field:

- Close to 40 percent of enumeration respondents are male.
- The sample is diverse in terms of race and ethnicity.
- Most screening interviews were conducted in English, but a few were conducted in Spanish or other languages.
- The percentage of pregnant eligible women in their first trimester who consented is close to 60 percent, and the rate varies among Vanguard Centers.
- Various types of media outreach were used. Among eligible women, 36 percent had heard of the Study before recruitment, and 40 percent of enrolled women had heard about the Study. The most common source from which women learned about the Study was the advance letter; mass media was the second most common source.
- More enrolled women heard about the Study from a trusted source.
- The percentage of eligible and enrolled women who heard about the Study before recruitment varied across Vanguard Centers.

Dr. Park presented the following conclusions:

- More time is needed to evaluate the success of recruitment because the outcomes are time-dependent.
- Once women enroll, data collection visits are generally being conducted as planned.
- National and community-specific marketing and media outreach efforts are needed and are being implemented to enhance recruitment.
- Additional recruitment and enrollment efforts such as provider-based referral are under way to enhance Study accrual.

NCSAC Discussion

- Dr. Clayton asked whether the enrollment rate would be a problem and what the Study would do if there was very low uptake in some communities of interest. Dr. Park said that alternative recruitment strategies might include provider-based sampling and other strategies.
- Dr. Clayton noted that many women do not get prenatal care in the first trimester. She asked whether the Study would enroll women in the second trimester. Dr. Hirschfeld said that the protocol allows the Study to enroll women any time during their pregnancy. The Vanguard Study will examine how many women the Study will need to follow from preconception or the first trimester. In the first 6 months of the Vanguard Study, the sites will enroll women in their first trimester. After 6 months, the criteria will be less restrictive.
- Dr. Hirschfeld said the Study is also enrolling women through care providers. The Study has a very broad definition of care provider that includes obstetricians, midwives, family physicians, nurse practitioners, and other individuals who come into contact with women before or during pregnancy. The cost and effectiveness of that approach is being determined. Another approach would be to have care providers encourage women who have been

contacted by the Study to enroll. Engaging care providers will build a sense of trust. Dr. Clayton recommended that the Study consider Title X providers.

- Dr. Gelb noted that about 40 percent of the respondents to the enumeration were male. He asked whether the subsequent enrollment success rate depended on whether the respondent was male or female. Dr. Park will follow up with the Committee to address this question.
- Dr. Gelb asked about the potential for bias in using referral by health care providers. Dr. Hirschfeld said that the U.S. population is dynamic, and the Study is aiming to be representative of the population. The current segments are based on a 2005 snapshot but future strategies will continue to evolve. The Study is developing strategies to ensure that its inferences are generalizable. Mechanisms other than sampling fixed geographic areas are being considered. The Vanguard Study and the sites formerly known as Wave 1 and Wave 2 sites will test different strategies.
- Dr. Henry asked how long it would take to reach recruitment goals based on the current rate and whether the Program Office had received feedback from the field about recruitment strategies. Dr. Park said that the original target number for the Vanguard Study was 1,750 births—250 from each Vanguard Center. She had not yet analyzed the rate to determine the timeline for reaching these goals.
- Dr. Reede suggested reaching out to mothers and potential mothers at programs such as Women, Infants, and Children (WIC) and Head Start and at drugstores where women purchase pregnancy tests.
- Dr. Fleischman asked Dr. Greene and Elena Gates, M.D., to comment on the question from the October 9 recruitment strategies memorandum about incentives for prenatal care providers to refer women to the Study. Dr. Greene said that recruitment strategies and the potential for selection bias would be important issues for the validity and generalizability of the Study. Infertility clinics have a very different patient population than other providers. Only 50 percent of pregnancies in the United States are intended, and pregnancy outcomes are very different for intended and unintended pregnancies. The Study will not be able to address certain exposure–outcome questions if it is unable to recruit women in the first trimester.
- Dr. Gates agreed with Dr. Greene’s points. She suggested using Medicaid-focused clinics in the geographic areas that are part of the Study sample. Providers could encourage women to listen to Study recruiters without encouraging them to sign up. She was not supportive of offering financial payments to care providers. Dr. Gates suggested that the Study find ways to decrease the disincentive of additional paperwork, such as providing training for office staff.
- Dr. Greene noted that the protocol mentions electronic medical records. The Study should be modest in its expectations of electronic records. If they are not structured, electronic data are not easier to sort through than paper data.

- Dr. Cordero said that diverse recruitment strategies may be needed. In recruiting children for immunization, the media is an effective outreach tool in Hispanic communities, but outreach through religious groups is more successful in African-American communities.
- Dr. Williams said that in order to provide advice on recruitment strategies, the group needed more information about the expected and observed recruitment rates.
- Dr. Tassinari hoped that data reporting would be a regular part of future NCSAC meetings. She agreed that additional context is needed. She asked whether the Vanguard Study had been successful in recruiting the preconception cohort and had provided insights into retention.
- Dr. Clayton said that epidemiologists have made important observations based on electronic medical records, and the group should acknowledge the value of electronic medical records.
- Dr. Hirschfeld responded to some of the participants' questions and comments. He noted that the Study is using numerous outreach methods to educate people before they are approached to enroll in the Study. The Study does not want to filter the population too much; the goal is to have a nationally representative sample.

The NCSAC will be meeting every 90 days to review the Vanguard Study data. The Program Office will set up a mechanism to send the data to NCSAC members with sufficient time to review so that they can provide substantive advice and recommendations. It is planned that future meetings will be held in the Natcher Center or other government buildings to reduce costs.

The current recruitment model is door-to-door household sampling. The Vanguard Study is expected to contact about half of the households in each geographic area within 6 months. After 6 months, the Study can enroll pregnant women after the first trimester. The goal is 5 births per Center per week or 250 births per Center per year. The target rate for enrolling eligible women is 70 percent. Currently, the enrollment rate varies from 45 to 70 percent, with an average of about 55 to 60 percent. Several substudies will test the strategy of using care providers and other approaches to recruitment. The target enrollment rates were based on assumptions and models. The Vanguard Study needs to continue to generate recruitment data.

- Dr. Ramirez noted that the demographics of the country will change over the time period of the Study, and a flexible sampling strategy is important. She suggested that data presented to the NCSAC include demographic data. Dr. Hirschfeld said the Program Office had recently developed a process to examine demographic data.
- Dr. Rhoades suggested that field workers may have valuable insights into which outreach and enrollment strategies are working.

- Dr. Henry asked whether the group should respond to the questions listed in the October 9 recruitment strategies memorandum. Dr. Fleischman said that the group would return to those questions in future meetings.
- Dr. Fleischman noted that health care provider organizations have effective methods of communicating with their members, which may be useful to the Study.

NCSAC Recommendations

- Concern was expressed that there is the potential for bias in using referral by health care providers.
- As an alternative to a capitation fee provided to health care providers, the Study should find ways to decrease the disincentive of additional paperwork, such as providing training for office staff.
- The Committee requested additional data including demographic data and context in order to provide meaningful advice on the Study recruitment strategies. The hope is that data reporting will be a regular part of future NCSAC meetings.
- The field workers' insights should be elicited and documented to understand their perceptions of effective outreach and enrollment strategies.
- Health care provider organizations should be engaged to assist in communicating with their members.

Vanguard Study Logistics

Jessica Graber, Ph.D., Coordinating Center Project Officer, NICHD, NIH, HHS

The Vanguard Study will serve as a platform for the design, development, and evaluation of state-of-the-art research methods to inform the Main Study, with a focus on:

- Multidisciplinary approaches
- Meeting/exceeding all ethical and scientific standards for research with human subjects
- Evidence-based assessments for possible inclusion in the Main Study
- Early scientific contributions to research literature
- Training new researchers.

The Program Office seeks to optimize Study methodologies, enhance data collection models, and manage resources. The Program Office will evaluate methodologies based on three criteria:

- Feasibility
- Acceptability
- Cost-effectiveness.

The Program Office will consider key priorities and trade-offs in making decisions based on these three criteria.

Information technology systems must be flexible, scalable, and modular. The Vanguard Study is compliant with the Federal Information Security Management Act, but this has led to some constraints. The information systems must be nonproprietary, must meet national and

international data standards, and must be accessible and consistent with data sharing and data access policies.

The Vanguard Study is considering using open-source methodologies instead of proprietary methodologies, subsampling for select measures, and using technologies that take better measurements (for example, self-collection of environmental samples).

The Vanguard Study seeks to enhance data collection models. Input is needed about how, where, and by whom data acquisition occurs, including:

- Innovative methods to collect data in a broad range of locations, such as health care settings, homes, schools, day cares, and public spaces where privacy is possible (for example, libraries)
- Multimodal data collection options such as interviewer-administered or self-administered computer-assisted interviewing or paper-and-pencil instruments
- Data collection activities such as field training, household listing and enumeration, recruitment, field data collection, and observational research
- Possible staffing models for data collection through primary contractors, subcontractors, health care providers, and participants (through self-administered instruments)
- Whether teams should travel to participants' homes or participants should travel to central locations.

The Vanguard Study must manage the competing interests of the federal government, local investigators, health care providers, and other stakeholders. The Study must also maximize enrollment, minimize attrition, and minimize nonresponse and opt-outs. The Study will retain investigators by providing opportunities for training and career development.

Upcoming challenges and opportunities in the Vanguard Study include:

- Developing, evaluating, and validating methodologies that are cost-effective, feasible, and scalable
- Maintaining a broad range of data collection domains
- Developing and sustaining innovative and collaborative partnerships
- Keeping participants (and those who influence them) engaged
- Continuing to evaluate logistics, methods, and operations.

NCSAC Discussion

- Dr. Gates asked whether the Program Office was taking advantage of the experience of the Vanguard Centers. Dr. Graber said that the Coordinating Center has held interviewer debriefings at the Centers to discuss lessons learned during field work. Data collector and participant focus groups are being planned.
- Dr. Cancian asked about the gap between the Vanguard Study and the Main Study and whether evidence-based learning was feasible in that time frame. Dr. Hirschfeld said data targets are being established for each component of the Study. Elements will be scaled up to the Main Study when there is sufficient evidence of the technical feasibility, acceptability, and cost. Different questions will require different data profiles, and the Vanguard Study will

search for confidence limits around the answers. Elements will be added and subtracted from the Vanguard Study as needed. For recruitment, the goal will be to reach a steady state, which may require enrolling 1,000–2,000 women.

- Dr. DuPlessis asked whether a complex system methodology called collaborative innovation networks had been considered. Dr. Hirschfeld said that various models had been considered, and the Study is not restricted to collecting data sequentially. The Centers formerly known as Wave 1 and Wave 2 Centers will be engaged in projects and substudies, and the Scholars Program will bring in additional expertise. Some of the individuals working on the Study are from math and engineering backgrounds and have looked at systemwide approaches.
- Dr. Tassinari asked whether the Vanguard Study questions had been prioritized and when enough questions would be answered to begin the Main Study. Dr. Hirschfeld said the Vanguard Study would need to meet multiple data collection thresholds before the Main Study would begin. A major priority will be developing recruitment strategies. As the Vanguard Study continues to collect data, recruitment strategies will change. Dr. Tassinari asked about data targets for other elements of the Study. Dr. Graber said that some elements would be easily quantifiable, but some elements of the Study would simply evolve.

NCSAC Recommendations

- The Study should take advantage of the experience at the Vanguard Centers to guide future Study sites.
- It was suggested that evidence-based learning or collaborative innovation networks be considered as a mechanism to relay experiences from the Vanguard Centers to the Main Study.

General Discussion

- Ann Vinup, from the Learning Disabilities Association of America, said that her organization was concerned with collecting preconception data such as thyroid levels. Dr. Graber said there were plans to enroll women preconception, and enrollment may begin in spring 2010. The Vanguard Study has identified women who have a high probability of becoming pregnant.

National Children's Study Visit Assessments

Kenneth Schoendorf, M.D., M.P.H., Director of Protocol Development and Study Center Project Officer, National Children's Study, NICHD, NIH, HHS

Michael Dellarco, Dr.P.H., Senior Scientist, Environmental Exposures, and Study Center Project Officer, National Children's Study, NICHD, NIH, HHS

Dr. Schoendorf said that the Vanguard Study will determine the feasibility, acceptability, and costs of recruitment strategies, operations and logistics, and visit assessments. The evaluations will be data-driven and may lead to changes in the protocol. The Vanguard Study is designed so that empiric data will be used to refine analyses and methods through an iterative process that

will lead to the Main Study. The initial intent was for the Main Study to roll out in three waves. The Wave 1 Centers and most of the Wave 2 Centers are currently under contract and available.

Dr. Schoendorf reviewed the schedule of visits for the Vanguard cohort. The first trimester home visit was revised because the original plan required too much equipment and time. Study assessments must be evaluated to determine whether they are feasible, informative, valuable, not redundant, and suitable for the Study.

The Vanguard visits have been revised to be more dynamic and flexible. All of the measurements may not be performed on all participants. Other changes include moving from working teams to Program Office leadership, relying primarily on solicited advice rather than solicited and unsolicited proposals, and involving all Center investigators in the Vanguard Study.

Vanguard locations will be collecting data for the following types of studies:

- Protocol amendments, which do not require OMB approval or additional funding
- Substudies of part of the Vanguard population, which do not require additional funding but may require OMB approval
- Supplemental methodological studies, which do require additional funding and may require OMB approval.

Dr. Dellarco said that the Study should be cognizant that there are unknowns and should try to anticipate future needs. The Study needs robust methodologies and uses an evidence-based assessment approach to find methods that provide value, efficiency, and economy and meet measurement needs. Measurement considerations include:

- Numbers of samples and specimens
- Costs for sample collection, storage, and analyses
- Burden on Study participants
- Quantity and stability of environmental samples and biological specimens for future analyses.

He discussed two examples of measurement assessments: the development of a less obtrusive particulate matter collection device and the evaluation of pesticide dust wipes. Study assessments under consideration include using Department of Motor Vehicle records to identify eligible women, self-collection of samples by participants, and evaluation of environmental sample collection procedures.

NCSAC Discussion

- Dr. Clayton noted that the protocol excludes women who are at risk for domestic violence. These women would be a population of interest to the Study, and there are ethical and legal issues in excluding them. Dr. Hirschfeld agreed that these women were a population of interest. Dr. Gates said the exclusion was intended to address situations in which women may be at risk for domestic violence because of their participation in the Study.
- Dr. Hirschfeld said the protocol addressed excluding women at risk for violence in the section on early withdrawal. The intent of the clause is to protect women for whom participation in the Study may trigger domestic violence. He suggested that the language should be clarified. Dr. Clayton said she and Dr. Gates could revise the language. Dr. Fleischman suggested they coordinate with Julia Slutsman, Ph.D.
- Dr. Henry asked whether the exclusion of women at risk for domestic violence was anticipatory or based on real incidents. Dr. Hirschfeld said the exclusion was based on incidents in the Vanguard Study. Dr. Slutsman explained the Study's incident reporting mechanism and noted that a number of incidents of suspicious domestic violence had been reported. In cases where data collectors and their supervisors feel that participation in the Study puts the participant at additional risk, the Study would need to consider ceasing contact with the participant. The protocol should include policies for bringing the participant back into the Study if the participant contacts the Study.
- Liliana Lengua, Ph.D., suggested that the policy should not be included in a section on withdrawing participants and deleting their data. The policy would be more appropriate in a section on high-risk situations. She expressed concern about the Study deleting the data for women at risk of domestic violence. Dr. Hirschfeld said the Study would not delete the data, but the data would not become part of the open access data set. The data would be available to investigators with questions about people who withdraw from the Study or women at risk of violence.
- Dr. Clayton said that women at risk of domestic violence are an important demographic, and withdrawing these women from the Study without consulting them would be a demonstration of their lack of agency.
- Dr. Rhoades asked whether the risk of domestic violence should be explicitly addressed in the informed consent forms.
- Dr. Trevathan asked how the Program Office would seek the advice of principal investigators (PIs). Dr. Schoendorf answered that Program Office staff will serve as leads for specific topic areas and will reach out to PIs with requests for information. This approach is intended to be more inclusive than the working teams. Dr. Fleischman expressed concern that the Program Office would get less input from PIs without the working teams. Dr. Trevathan added that the Study needs to consider retaining and maintaining the enthusiasm of PIs by soliciting their input. Dr. Schoendorf noted these concerns.

- Dr. Currie asked that the protocol discuss making some level of geographic identification available. Without information about locations, it will be difficult to merge data with other data sets. Dr. Hirschfeld said this would be a topic for the next NCSAC meeting.
- Dr. Hirshfeld acknowledged the work of Dr. Slutsman and Brian Haugen, Ph.D., in assembling the Vanguard Protocol in a short time.
- Dr. Fleischman asked whether the Vanguard Study protocol contained sufficient information about the Office of Management and Budget (OMB) directive to reveal no findings to subjects. He asked what findings would be considered clinically important enough to reveal to families. Dr. Hirschfeld said this topic would be discussed at the January meeting. The Study will inform caregivers or health care providers of findings that are medically informative and either of concern or treatable. He asked for written comments to clarify this issue in the protocol. The Study should be consistent with the NIH policy on revealing findings, which is being revised.
- Dr. Fleischman thought the Study protocol had been approved by OMB only if the Study did not reveal findings to pilot study subjects. Dr. Schoendorf said that the OMB had concerns about providing information to participants that could not be followed up. This was one of the reasons for the creation of the Independent Study Monitoring and Oversight Committee (iSMOC), which seemed to be a satisfactory solution for the OMB. Dr. Hirschfeld added that the iSMOC will meet on November 2. The protocol submitted to the OMB was a prototype of the Main Study protocol, and the OMB was concerned with early analyses of exposure–outcome data. The Vanguard Study will focus on process and will not include early analyses of exposure–outcome data. Dr. Fleischman noted that the NCSAC had addressed the question of revealing findings to participants several times in the past and agreed that it would be good practice to reveal findings of clinical importance to participants.
- Dr. Tassinari asked how she could submit detailed comments on the protocol. Dr. Hirschfeld said comments could be sent to Dr. Slutsman or to ncs@mail.nih.gov by November 1. The document will be sent to the NICHD IRB 1 or 2 days after all comments are received.
- Dr. Tassinari asked about the eligibility of pregnant adolescents. The issue was raised in several sections of the protocol, but the issue needs to be clarified. Dr. Hirschfeld said participants must be at least 18 years of age, and this will be clarified in the protocol.
- Dr. Cancian noted that the protocol mentions medical records and seemed to imply that the Study will be linking to no other records. Dr. Hirschfeld said that this implication was not intended. The Study will be a platform for interoperability of all types of information.
- Dr. Reede suggested that the protocol should discuss methodologies for contact with primary care providers. Dr. Hirschfeld said this issue would be addressed in an appendix or the Manual of Operations. NICHD is preparing a draft policy on working with health care providers and transitioning research participants from studies back to their community health care setting.

- Dr. Greene raised three concerns:
 - Will distinctions be made between studies that address prior hypotheses and ad hoc questions that arise during the Study?
 - Will distinctions be made between exploratory studies and validation studies?
 - Many NIH-sponsored observational studies inadvertently become interventions. It is difficult to observe participants over a long time without unintentionally affecting the process and provision of care.

Dr. Hirschfeld said he did not know how to formally address the potential for affecting participants. It was hoped that the sheer size of the sample will accommodate a range of reactions. The Vanguard Study protocol does not represent the epidemiological probing that will be part of the Main Study. These concerns should be addressed later but will not be addressed in this phase of the Study.

- Dr. Greene requested that the NCSAC receive copies of the ICC presentation and a full roster with contact information for NCSAC members. Ms. DiBari will provide these documents to the Committee.

NCSAC Recommendations

- The current protocol should not exclude women who are at risk for domestic violence. Drs. Clayton and Gates will provide written comments to improve the protocol language.
- The Committee expressed some concern about the working teams being disbanded and encouraged the Study to continue to obtain input from and engage the PIs and other appropriate scientists at the various Study Centers.
- A Committee member encouraged the Study to make some level of geographic identification available in order to facilitate the merging of Study data with other data sets.
- It was suggested that the section of the protocol that pertains to women at risk of domestic violence should be included in the section on high-risk situations rather than the section on withdrawing participants.
- Women at risk for domestic violence should not be forced to withdraw from the Study unless there is evidence that being engaged in the Study is increasing risk of violence.
- The Study may wish to include language in the informed consent forms addressing the issue of domestic violence.
- The protocol section about the eligibility of adolescents should be clarified.
- The methodologies for contacting primary care providers should be addressed in the protocol document as well.

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I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

11-13-09

Date



Alan R. Fleischman, M.D.

Chair

National Children's Study Federal Advisory Committee