

**National Children's Study
Federal Advisory Committee 24th Meeting
April 27, 2010
5635 Fishers Lane Conference Center
Rockville, 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 and Introductions

Carol Henry, Ph.D., Interim Chair, National Children's Study Federal Advisory Committee (NCSAC)

Dr. Henry welcomed the participants and introduced herself, noting that she has been a member of the NCSAC for 2 years and has supported the Study from its inception.

Dr. Henry highlighted the agenda topics from the January 14, 2010, NCSAC meeting, which included the following:

- Study update
- Update on Vanguard Study recruitment and visits
- Rationale for additional or alternate recruitment strategies
 - Provider-based
 - Enhanced household enumeration
 - High-intensity/low-intensity (HiLo)
- Report on data access
- Overview of federated model of institutional review board (IRB) review for the Vanguard Study.

Dr. Henry reviewed the annotated agenda for the meeting, which included questions to consider during discussion.

Report from the Director's Office, NICHD

Alan Guttmacher, M.D., Acting Director, NICHD, NIH

Dr. Guttmacher said that in the past few months, representatives from the Office of Management and Budget (OMB), HHS, and congressional committees with interest in the Study visited the NICHD Director's Office. Dr. Guttmacher emphasized that data from the first seven Vanguard Centers show that some of the initial assumptions about the Study recruitment were inaccurate and he prefers the term overly optimistic. The Vanguard Study will explore three alternate recruitment strategies this summer to determine what strategies will be successful and cost-effective. In 1 year, the Study will have better cost projections for the Main Study.

Representatives of OMB, HHS, and congressional committees all expressed commitment to the Study, agreed with the logic of using data to rethink assumptions, and agreed to meet again in 1 year. Some groups have asked for interim updates in 6 months.

NICHD should have a permanent director by the next NCSAC meeting.

National Children's Study Update

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

Dr. Hirschfeld said the Program Office reviewed the minutes of the previous NCSAC meeting and acted on the committee's suggestions.

The goals of the Vanguard Study are to assess the feasibility, acceptability, and cost of recruitment, logistics and operations, and Study visit assessments. Operational and performance data are of primary interest in the Vanguard Study. Analytic data acquisition for exposure-response relationships is the goal of the Main Study.

The Vanguard Study has reached steady-state recruitment using the current household-based strategy and is exploring alternate recruitment strategies. The alternate recruitment strategies will use the same probability sampling strategy to select Study segments and will have the same resources. Changing the sampling strategy or resources could introduce additional bias. Such bias will be monitored. Alternate recruitment strategies are:

- Provider-based recruitment
- Enhanced household enumeration
- Two-tier high intensity, low intensity.

Each strategy will:

- Occur in 10 locations that are geographically and demographically diverse and that
 - May or may not have a population that can be generalized to the United States
 - Have a specific interest in examining potential sources of bias
- Have approximately the same resources expended
- Have a specific communications theme directed to the Study strategy.

The primary outcome measures are recruitment and retention rates for the three proposed recruitment strategies. Experience has shown that participants who are most difficult to recruit are most likely to leave the Study. The Study would like to quantify this effect and set recruitment parameters.

Key rates associated with recruitment include:

- The number of women identified for contact per month
- The number of women successfully contacted per month
- The number of women determined to be eligible per month
- The number of eligible women consented per month.

Retention parameters have been set to determine how to apportion resources in the most cost-effective way. Key proportions associated with retention include:

- The proportion of age- and geographically eligible women initially contacted when not pregnant who join the Study when subsequently becoming pregnant
- The proportion of consented women who participate in at least one data collection Study visit
- The proportion of women consented during pregnancy who participate in all data collection visits through the birth of a child
- The proportion of women who receive an antepartum data collection visit who also receive a birth visit.

The distribution of key characteristics of recruited women among the three recruitment schemas will be analyzed, including:

- Distribution of women enrolled before pregnancy, during pregnancy, or perinatally
- For pregnant women, distribution of gestational age at enrollment and at the first Study visit
- Monthly enrollment rate of infants among consented women with due date within that month
- Distribution of the primary source of entry into the Study for the women, such as self-referral, provider referral, household enumeration, community outreach events, and others
- Distribution of the ways and number of ways women heard about the Study, such as friends, mailings, community members, and others.

The Study mandate is to enroll women as early in pregnancy as possible, with a target of enrolling at least 20 percent of women before pregnancy.

The Study is interested in a demographic evaluation of participants. Communications should be linguistically and culturally appropriate. The Study does not use the term “representative”; rather, the Study is looking for a statistically valid generalizable population.

The Vanguard Study will collect data to evaluate costs, including:

- The cost of recruiting and enrolling women, by timing of entry
- The cost of media and community outreach for each recruited and enrolled woman.

The Study has developed a business model called “facilitated decentralization.” This model is characterized by:

- Centralized development of specifications, quality controls, and policies
- Local implementation, which allows integration of skills, talent, and resources and flexibility to adapt to local factors.

The Study informatics model is an example of facilitated decentralization. The Program Office develops:

- Specific questions to address in the Study through the Data Analysis Team
- Data fields, data tables, and data table relationships
- Data transmission standards
- Structured Query Language (SQL) Server data archive to receive data
- Specifications and guidelines for data security and regulatory compliance.

Study Centers select the case management system, data acquisition platform, and data collection tools. Centers have flexibility to adapt tools and resources that best fit local needs. All data are collected and transmitted based on specifications. The process is analogous to collecting

information in multiple languages or currencies but converting all to English or the dollar for harmonization, consolidation, and analysis.

The Study specifications encourage use of open source platforms and collaboration. The original seven Vanguard locations will be phased into the new system with similar options for local implementation. All Study Centers will develop local implementation of data security procedures, including background checks and accreditation.

A phased approach to data collection is planned, with initial infrastructure and logistics testing. Study visits will at first consist of minimal questionnaires designed to characterize system logistics and not to produce analytic data sets for other types of analyses. After logistics are established, visits will become more complex and more robust, with phased introduction of biospecimens and environmental samples.

Minimal visits will use questionnaires with items excerpted or adapted from instruments already approved and in use for the Vanguard Study. Questionnaires are developed for enumeration, preconception, pregnancy screening, early pregnancy, late pregnancy, and the birth visit.

Ruth Brenner, M.D., M.P.H., oversees all of the alternate recruitment strategies and is the lead for the provider-based recruitment strategy. Sarah Keim, Ph.D., M.A., M.S., oversees enhanced household enumeration, and Brian Haugen, Ph.D., oversees the two-tier high intensity, low intensity strategy.

The current experience with Study visits is undergoing systematic evaluation, and the catalog of visit assessments will receive structured analyses. The inventory of about 122,000 samples and specimens is undergoing assessment of stability, storage, and analyte evaluation.

The Study will have a facilitated decentralization model of communications with a three-armed approach:

- National campaign for Study goals of general applicability—health, development, and antecedents of conditions
- Local implementation of population-specific and targeted messaging, including events
- Federal partners for leveraging existing programs, resources, and contacts for awareness and potential participant identification.

Dr. Hirschfeld reviewed the regulatory timelines for the Vanguard Study:

- OMB review
 - 60-day notice published
 - Ongoing exchanges between the OMB, the NICHD, and the Program Office
 - Submission in mid May
 - Approval expected mid June
- IRBs
 - Revised Vanguard Protocol approved by the NICHD IRB
 - Recruitment schema submitted as protocol amendment
 - IRB approval at 30 locations expected before July
 - Federated IRB preparations continue.

Additional formative research projects have been proposed to address specific technical questions related to Study implementation, and Centers have volunteered to perform additional tasks based on their interests and expertise. In the next 2 weeks, formative research will begin on a broad scope of topics, including environmental assays, models, behavioral assessments, fetal cell and placental genetic assessments, dietary intake, and operations research.

NCSAC Discussion and Recommendations

- Bruce Gelb, M.D., asked whether minimal questionnaires would reduce participant burden and change retention rates. Dr. Hirschfeld said the Program Office had discussed this question with the HHS Office of Human Research Protections and the OMB Office of Information and Regulatory Affairs. They advised that all IRBs should review the full protocol, and every participant should sign consent as though all the assays might occur. As visits become more complex, the Study can evaluate the effect of increasing burden on retention. There is no evidence of people dropping out of the Study because of burden.
- Michael Lebowitz, Ph.D., said later presentations would provide more detail about retention and recruitment data, and he hoped meeting attendees would have additional opportunities to provide input. Dr. Hirschfeld said advice and recommendations would be welcome during and after the meeting.
- Ellen Wright Clayton, M.D., J.D., asked for more details about data security. Dr. Hirschfeld said he would provide the NCSAC members and the public with the data security guidelines and the telephone number for a data security conference call scheduled for Friday, April 30, at 2:00 p.m. ET. The data security plan is based on experience with Vanguard Centers and consultation with organizations that have experience with distributed data security models. The Program Office will provide specifications, and the local site will develop the security plan. The Program Office will ensure compliance with Study guidelines and the Federal Information Security Management Act (FISMA). The Study guidelines are more stringent than the law requires, having a broader definition of personally identifiable information. Dave Songco and Jennifer Park, Ph.D., are overseeing data security.
- Melissa Tassinari, Ph.D., D.A.B.T., asked about the development of and precedents for facilitated decentralization. Dr. Hirschfeld said the concept was developed empirically by evaluating the strengths and weaknesses of the operations of the Program Office, contractors, Coordinating Center, and Study sites and by consulting colleagues involved in other NIH longitudinal studies. The process that led to the federated IRB model was a precedent. The Program Office systematically evaluated various approaches and assembled a hybrid model that will be better suited for the National Children's Study.
- Dr. Henry asked whether facilitated decentralization was used to decide on alternate recruitment strategies and whether additional strategies were being considered. Dr. Hirschfeld said facilitated decentralization was developed concurrently with implementation of the three alternate recruitment strategies. The Program Office has been looking at other strategies and talking with federal partners, particularly the National Cancer Institute (NCI).

The Study chose the three alternate recruitment strategies because they were sufficiently different from one another. The formative research includes proposals for small pilot studies of other recruitment methods to help inform the Main Study.

- Patricia O’Campo, Ph.D., said the experience and expertise of staff might affect outcomes. She asked how the Study would measure and control for this factor. Dr. Hirschfeld said sites were selected for the alternate recruitment strategies based on their resources and experience. The Program Office will build a toolkit with strategies and approaches that can be used in different circumstances. The sites implementing each alternate recruitment strategy represent a balance of resources, geographic areas, and demography.
- Elena Fuentes-Afflick, M.D., M.P.H., said it would be important to provide the investigator community and the public with information about how the recruitment strategies were developed, implemented, and assessed. Dr. Hirschfeld said the Program Office is responsible for creating materials and building partnerships to increase participation, with the expectation that materials will be further disseminated to reach those who have an interest in the Study.

National Children’s Study Data Update

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

Dr. Park provided an update on Study recruitment and retention. Two Vanguard Centers began data collection in January 2009, and five began data collection April 2009. Women are recruited through household field surveys in designated geographic areas to find women who meet eligibility criteria. Women also enter the Study through self-referral and referral by others. As of the end of March 2010, recruitment status was as follows:

Recruitment Stage	Number of Cases	Response Rate
Total listed households	83,394	
Household enumeration completed	65,737	84%
Age-eligible women identified	32,288	
Pregnancy screening completed	28,641	89%
Study eligible women identified	1,459	
Consented/enrolled women	806	61%

Dr. Park presented graphs and charts showing the following:

- Cumulative recruitment rate trend—Recruitment reached a steady state by March 2010.
- The monthly number of Study-eligible women by consent outcome—There were lower consent rates in August and December.
- Consent rate by race and by ethnicity—At this time, Asian women have a lower consent rate than other groups.
- Consent rate by ethnicity and survey language—Hispanic, non-English-speaking women have the highest consent rate. Non-Hispanic, non-English-speaking women have a very low consent rate.
- Cumulative number of enrolled women and births—The graph included women enrolled before conception.

- Number of enrolled women by due date and births obtained—The Study has recorded 70 percent of the expected births from enrolled women.
- Prenatal visit data collection—Women who have completed the first trimester (T1) visit are the largest group, and the data collection completion rate is 72 percent.
- Percent distribution of women entering various Study events.

Dr. Park discussed the impact of media outreach. The percentages of women who have heard of the Study are:

- 35 percent among age-eligible women
- 41 percent among Study-eligible women
- 46 percent among enrolled women.

The most common way women heard about the Study was through a letter received in the mail. Dr. Park presented the demographic characteristics of women who had heard of the Study. The percentage of women who had heard of the Study was lowest among Asian women. Younger women and non-English-speaking women were less likely to have heard about the Study than older women and women who speak English.

Dr. Park summarized Study recruitment and retention:

- Enrollment reached a steady state with an average of 13 infants per week from 7 sites combined.
- Enrollment (consent) rates are lower for Asian and for non-Hispanic women whose consent was conducted in a language other than English.
- Pregnancy visit completion occurs at above 70 percent.
- Media outreach appears to have a positive impact on recruitment, but outreach penetration varies by population characteristics.

NCSAC Discussion and Recommendations

- José F. Cordero, M.D., M.P.H., asked how the Study would increase visibility among Asian women and others, and how the finding that an advance letter has a positive impact would affect future recruitment efforts. Dr. Park said the Community Outreach and Engagement team would develop plans for outreach to hard-to-reach population subgroups. Dr. Cordero said that he had to find alternate outreach methods for the children's immunization initiative, and the Study may want to look at that experience.
- Dr. O'Campo asked about the recruitment of fathers. Dr. Park said she had not completed the analysis of recruitment data for fathers. There are a number of barriers to recruiting fathers.
- Dr. Henry asked about the kinds of questions asked of fathers. Dr. Hirschfeld said fathers completed a social inventory and had high completion and satisfaction rates. Fathers were asked to provide DNA and blood samples and to answer questions about exposures.
- Ana V. Diez-Roux, M.D., Ph.D., M.P.H., said the participation rates were quite good. She asked whether the Study was collecting data on reasons for refusal. Dr. Park said the Study would collect that data. Dr. Hirschfeld said that after the Vanguard Study started, the focus

shifted to methodologies. For the three alternate recruitment strategies, operational questions will be systematically built in from the beginning. Benjamin Wilfond, M.D., suggested that data be collected from fathers postnatally, which may be a better time to engage fathers.

- Dr. Lebowitz asked about evaluation of other factors such as differences in socioeconomic status, urban/rural settings, regions, and so on. Dr. Hirschfeld said the Study would begin collecting logistical and operational data in July.
- Dr. Fuentes-Afflick asked whether immigration status was a factor in enrollment. Dr. Park said participants were not asked about immigration status until the T1 visit, so the Study cannot determine whether immigration status affects enrollment at this time.
- Dr. Fuentes-Afflick asked which Asian languages are used in the field. The most common Asian languages are Chinese and Korean. The Study translates materials into Traditional Chinese, Vietnamese, and Korean. Dr. Hirschfeld said the Study would initiate data collection and develop materials to target Asian women. Dr. Park noted that written materials are translated into Spanish. Dr. Henry suggested that the Study consider broadening the languages in which written materials are available. It was noted after the meeting that the consent materials and visit information sheets are routinely translated into 10 approved languages.
- Michelle A. Williams, Sc.D., S.M., M.S., noted that the Study is only recording 70 percent of expected births from enrolled women. She asked about the other 30 percent. Between enrollment and the third trimester (T3) visit, 3 percent of women withdraw from the Study, 5 percent move out of Study segments, and 7 percent have a pregnancy loss or false pregnancy. Dr. Williams asked whether the Study could look at loss of follow-up in terms of the time of enrollment, which would be an important indicator of retention. Dr. Park did not have these data yet.
- Everett Rhoades, M.D., asked about the denominator used to calculate the mail response rate. Dr. Park said she used the number of enrolled women as the denominator to calculate the percentage that heard about the Study through the advance letter. She did not have data on the number of households that received mailings. Vanguard Centers attempt to send the advance letter to all listed households. Dr. Hirschfeld said the National Cancer Institute (NCI) looked at the response rate to mailings and postcards, and a response rate of 1 percent in the United States is highly successful. Other countries have higher response rates; for example, the United Kingdom has a 10 percent response rate.
- Dr. Gelb asked about recruitment data by Study Center. Dr. Park said recruitment rates vary, with higher enrollment at rural sites than at urban sites. Dr. Hirschfeld said recruitment varied by less than a factor of two among Study Centers. The Program Office is considering how to display data with the addition of 30 Vanguard Centers. Data may be displayed for groups of Study Centers, such as urban and rural Centers. Currently there are too few Study Centers to draw inferences. Each Study Center has different characteristics and faces unique problems.

- Dr. Clayton asked whether there was a mechanism to look at the efficiency of various data collectors and institutions. Dr. Park said the Study will develop a mechanism for evaluating the efficiency of data collectors and institutions.

Legislative Update Pertinent to Pediatric Research

Lisa Kaeser, J.D., Senior Program Analyst, Office of Program and Public Liaison, NICHD, NIH

Ms. Kaeser reviewed legislation pertinent to pediatric research since the Study was authorized in the Children's Health Act of 2000. She provided a history of Study appropriations:

- Fiscal year (FY) 2001–2006—NICHD and its federal partners fund early planning stages
- FY 2007–2010—Congress provides specific funding through the NIH Office of the Director
- FY 2011—President's Budget requests full funding
- Starting in FY 2007, the annual Appropriations Committee report includes language supporting the Study.

The Appropriations Committee remains firmly committed to the Study and included language supporting the Study and the plans for the Vanguard Study in the FY 2010 report.

Congressional oversight authority for the Study includes the following:

- Authorizing legislation—Section 400 of the Public Health Service Act
- Authorizing committees—House Energy and Commerce Committee and Senate Health, Education, Labor, and Pensions Committee
- Frequent requests for briefings and correspondence.

Any member of Congress can request a briefing, but the authorizing committees have special authority. California Representative Doris Matsui, who leads the House of Representatives working group to support the Study, has recently requested an update.

The NIH Reauthorization Act of 2006 had the goal of preventing future disease/condition-specific legislation. It consolidated and reconciled previous piecemeal NIH legislation and reauthorized pediatric provisions, including the Study; the Pediatric Research Initiative; and research on autism, fragile X, and contraceptives. The Act did not prevent new disease/condition-specific laws. Many such laws have been passed and proposed since 2006.

Ms. Kaeser discussed aspects of the Patient Protection and Affordability Act that affect NICHD and NIH research:

- Cures Acceleration Network—emphasizes the need for the NIH to develop cures
- Comparative Effectiveness Research—calls for an independent nonprofit institute to do comparative effectiveness research
- Postpartum Depression Research
- Pain Research
- Emergency Medicine Research—adds a new research area for the NIH
- Access to Clinical Trials
- Home Visitation Programs—requires the NICHD to be consultant for this program.

NCSAC Discussion and Recommendations

- Dr. Lebowitz noted that the immigration legislation recently passed in Arizona might affect the Study. He recommended that the Study not ask about immigration status.
- Steven K. Galson, M.D., M.P.H., asked whether legislation authorizing the Study included language expressing the intent of Congress to provide long-term funding. Ms. Kaeser said it did not. Appropriations authorize funding for 1 year, and Congress can choose not to appropriate funds. Dr. Henry said the NCSAC has recognized that long-term congressional funding cannot be guaranteed. The Study needs support from federal agencies and from Congress. Congress supported the Study even when it was not included in the President's budget.
- Dr. Tassinari asked whether any pieces of legislation include sunset clauses. Ms. Kaeser said some pieces do and some do not.

National Children's Study Communications Plan

John McGrath, Ph.D., Chief, Public Information and Communications Branch, NICHD, NIH

Dr. McGrath described communications efforts to support the Vanguard recruitment pilot study. The NICHD communications team will develop, test, produce, and assess a range of communications products, and each Vanguard Center will develop its own set of products in alignment with the facilitated decentralization approach.

To date, NICHD communications team has:

- Conducted a literature review
- Summarized feedback about recruitment from the seven original Vanguard Centers
- Developed a marketing/communication plan
- Initiated a plan for qualitative research
- Developed a social media schema for the Study
- Created the template for a communications and outreach tool kit.

Dr. McGrath discussed an example of literature review findings about barriers to health care provider involvement. The literature showed that personal contacts and personal media were more effective than mass media in overcoming barriers.

Some general guiding principles regarding communications emerged from meetings with the seven original Vanguard Centers, including:

- Saturate with all-inclusive marketing campaign
- Use concise and consistent messaging across Centers
- Find credible sources for local and national endorsements
- Share best practices across Centers
- Help grassroots efforts with local events
- Recognize key role of men and fathers
- Use social media outreach.

The communications plan has two approaches:

- A population-focused approach to establish communitywide awareness of the Study and its benefits
- A participant-focused approach to support recruitment.

A broader, ecological model of Study recruitment is needed. Individual decisions are made within the following complex systems:

- Microsystem—family, peers, health care providers
- Exosystem—health agencies, community groups, media
- Macrosystem—political systems, culture, economics, society.

Dr. McGrath discussed the process of developing concise, consistent, and simple recruitment messages for each recruitment strategy using a message map. The message map included draft messages that would serve as the foundation for the final recruitment messages.

A series of focus groups and in-depth interviews will be used to test messages and materials. OMB approval for focus groups is almost final.

In the summer and fall of 2010, the Program Office will conduct national media outreach through print, broadcast, and online media, as well as outreach in local markets for the 30 new Vanguard Centers. The Study will engage in partnership outreach to organizations such as the American Academy of Pediatrics and the American Congress of Obstetricians and Gynecologists.

The outcome of communications efforts will be a toolkit with tools for media outreach, advertising, community outreach, and partnership contact for each recruitment strategy. Rollout of the toolkit is scheduled for summer 2010.

The communications team has developed a plan for using social media. The plan will adhere closely to the recently issued HHS social media policies.

Dr. McGrath presented a communications timeline, showing that message development and testing is currently under way, and production and distribution will begin in summer 2010.

NCSAC Discussions and Recommendations

- Dr. Fuentes-Afflick asked about translating materials. Dr. Hirschfeld said the Study starts with premise that people respond to people with whom they feel an affinity. Field staff members reflect the population of interest. Contractors do forward and back translation of materials. The 30 new Vanguard sites are performing environmental scans to determine where to apply resources.
- Dr. Cordero asked about efforts to identify trusted partners in the Asian community. Dr. McGrath said the Study will identify key organizations and meet with leaders to develop plans to reach out to organization members. Dr. Hirschfeld said the Study would be borrowing from a plan that former Surgeon General Galson developed to target childhood

obesity. The plan involves coordination with regional health administrations and programs that provide services. The Study will work with Vanguard Center community advisory boards.

- Dr. Galson asked about involving sports and entertainment celebrities in national branding campaigns. Dr. Hirschfeld said it is difficult to define a global message for the Study and identify an appropriate spokesperson. Spokespeople often represent specific diseases or conditions. Dr. McGrath added that a spokesperson must be closely associated with a topic to be credible.
- Dr. Clayton asked whether attention was paid to different types of Spanish during translation. Dr. McGrath said yes; different dialects were taken into account.
- Dr. Clayton noted that messages for the enhanced household enumeration and HiLo recruitment strategies were similar. Dr. McGrath agreed that there is overlap in messaging for these strategies, but for the HiLo strategy, it is reasonable to say that participants can contribute to the Study without a large burden.

National Children's Study: Study Visit Assessments Evaluation

Margot Brown, Sc.D., M.S.P.H., Senior Scientist and Study Center Project Officer, NICHD, NIH

Dr. Brown described the process of evaluating visit assessments, which may include questionnaires, physical and laboratory measurements, biological samples, environmental samples, and other assessments. For each assessment, an *a priori* analysis is under way to determine the estimated number of informative events needed to provide 95 percent confidence limits around the reproducibility of the assessment to determine whether to:

- Scale up with an acceptable standard deviation
- Modify the outcome assessment and retest empirically
- Eliminate the outcome assessment from consideration for the Main Study.

The empiric data from the visit assessments will help guide the selection of measures for the alternate recruitment strategies and measures to be included in the Main Study.

Dr. Brown reviewed the original Vanguard Study visit schedule and presented a table of assessment types and the number of assessments per person. There are 246 assessment types, including anthropometric measures, biospecimens, environmental measures, physical measures, and questionnaires. Currently, there are about 122,000 biospecimens and environmental samples in the Study repository.

Evaluation criteria for visit assessments include:

- Feasibility—technical performance of the Study visit measure
- Informative value—whether the results provide the intended information
- Scalability
- Lack of redundancy
- Cost—time and money
- Acceptability—completion rate

- Ability to address questions that
 - Have a potentially important public health impact
 - Require a study of the size and robustness of the National Children’s Study
 - Are unlikely to be answered in another context.

The process for Study visit assessment evaluation includes the following steps:

- Step 1—Identify data sources and data elements currently being collected
 - Create frequency distributions of Study visit activity completion rates
 - Rank completion rates by Study visit activity
 - Determine what current activities have a low completion rate
- Step 2—Develop Study visit assessment evaluation plan
 - Define evaluation criteria and metrics
 - Prioritize Study visit measures for evaluation
- Step 3—Analyze Study visit assessment measures
 - Conduct operational, quality assurance/quality control, and analytic evaluation of Study visit measures
- Step 4—Develop implementation plan
 - Determine the most efficient approach for the selection and integration of select Study visit measures into the Main Study.

Dr. Brown discussed the example of visit assessment evaluations for the T1 and T3 home visits and presented of the following data on completion rates:

Assessment Type	Percent Complete	
	T1-1st (N = 599)	T3-1st (N = 157)
Biospecimens		
Urine	68%	64%
Vaginal swab	64%	61%
Blood	50%	48%
Questionnaires		
3-day food checklist	53%	42%
3-day time-and-place	50%	39%
Food frequency	49%	40%
Environmental		
Vacuum dust	67%	58%
House dust	64%	56%
Structu ral assessment	53%	47%

Development of a detailed evaluation plan will begin in June, and analysis of Study visit measures will begin in July. The next steps are to:

- Evaluate all dimensions of Study visit assessment data, including
 - Detailed frequencies for each assessment type
 - Assessments for new visits—P1, T1-prior, 6 month, and 12 month
- Refine Study visit assessment metrics
- Analyze Study visit assessment measures

- Formative research to complement structure analysis
- Develop implementation plan.

NCSAC Discussion and Recommendations

- Dr. Fuentes-Afflick asked about the literacy level of take-home questionnaires and suggested sending text messages to remind participants to complete instruments. Dr. Brown said text message reminders had been considered. Dr. Keim said the Study was using the NCI diet history questionnaire, which has been validated in a number of studies. She did not know the reading level. Vanguard Centers are considering using online dietary recall in English and Spanish as an alternative to the questionnaire. Dr. Brown said she did not know the reading level of the 3-day time-and-place activity diary, but simple illustrations accompany the text.
- Dr. Lebowitz noted that ineligible women and women who failed to show up for their scheduled visits were included in assessment completion rates. If those women were excluded, the completion rates would be higher.
- Dr. Wilfond said getting participants to complete the forms would be critical. Dr. Hirschfeld said the Program Office had requested formative research to address this issue.
- Dr. Diez-Roux asked about the criteria for dropping an assessment from the Main Study. Dr. Brown said factors considered would include feasibility, informative value, scalability, lack of redundancy, cost, and acceptability, as well as quantitative data about completion rates. Formative research will help determine whether there are better assessments. Dr. Diez-Roux said the importance of assessments to the scientific goals of the Study should be considered. When reviewing assessments for inclusion in the Main Study, the assessments are considered in terms of scientific goals.
- Dr. Tassinari asked about Letters of Interest (LOIs), and Dr. Hirschfeld explained that LOIs are used to request the 37 Vanguard Centers to volunteer for various tasks.
- Dr. Tassinari asked whether the Vanguard Study would be able to derive an understanding of tolerance of new assessments as supplemental methodological studies and adjunct studies are added. Dr. Brown said that as the Vanguard Study and supplemental methodological studies proceed, changes would continue to be made to the Main Study. Dr. Hirschfeld added that the Vanguard Study would continue for 21 years, have its own cohort, and provide a continuing platform for innovative data acquisition.
- Michael Greene, M.D., asked about the relationship between Study participants and data collectors. Dr. Brown said data collectors are highly trained and understand the limits of their relationships with participants.
- Dr. Henry asked how assessors should respond if high exposure levels are found in environmental samples. She suggested that this issue be discussed at a future meeting.

- Dr. Clayton asked about training for data collectors. Dr. Brown said a consistent training protocol is used across all Vanguard Centers. Data collectors receive several weeks of training before going into the field. Dr. Hirschfeld added that individuals from each Vanguard Center are trained, and these individuals return to their Centers and train other data collectors. The Program Office is looking for ways to further decentralize training and has asked for input from the Centers.

NCSAC Members

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



June 16, 2010

Date

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