National Children's Study Assembly Meeting
Breakout Session Summary: Community Engagement: Recruitment and Retention
November 29, 2005
Omni Shoreham Hotel
Washington, DC

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

Co-Chair: Pauline Mendola, Ph.D., Member, Interagency Coordinating Committee; Chief, Epidemiology and Biomarkers Branch, National Health and Environmental Effects Research Laboratory, Office of Research and Development, EPA

Co-Chair: Sarah Keim, M.A., M.S., Member, Interagency Coordinating Committee; Deputy Director, National Children's Study Program Office and Study Coordinator, NICHD, NIH, DHHS

Invited Participant: Loretta Jones, M.A., Executive Director, Healthy African American Families; Member, Federal Advisory Committee

(Two sessions of this breakout session were held on November 29, 2005.)

Opening Remarks

Ms. Keim, Dr. Mendola, and Ms. Jones introduced themselves and asked participants to introduce themselves. Ms. Keim explained that the purpose of the session was to convey the philosophy behind the community engagement efforts of the National Children's Study (Study) and to summarize previous activities and plans for future efforts.

Ms. Keim continued by stating that community engagement is essential for successful recruitment and retention of Study participants. The Study includes more than the Vanguard communities. Other communities, health care providers, teachers, families, and local, state, and federal agencies are also involved. The Study is lengthy, requiring sustained commitment.

Ms. Keim explained that research efforts are to be localized according to what works well in a community. The Study does not strictly adhere to a community-based participatory research model because the core research questions in the Study require that the same data be collected from all communities.

Activities to date include:

- Research into best practices through focus group meetings and literature survey
- Learning from previous studies, including EPA/NIEHS Children's Environmental Health Centers; Women's Health Initiative; Framingham Heart Study; Avon Longitudinal Study
- Consultations—Community Outreach and Communications Working Group, the Advisory Committee Community Engagement Subcommittee, and workshop on community outreach
- Tools development, such as publications and Web site
- Vanguard Centers and Coordinating Center.

First Set of Focus Groups

Ms. Keim noted that 18 EPA-led focus group sessions were held in a mix of 10 urban, suburban, and rural communities across the United States, beginning in February 2003.

Stakeholder groups included:
- Expectant parents (10 sessions)
- Parents of disabled children (2 sessions)
- Parents of non-disabled children (2 sessions)
- Health care providers (2 sessions)
- Community leaders and organizations (2 sessions).

The main topics were:
- Getting interest in the Study
- Extent of time commitment and of data collection
- Maintaining interest in the Study.

Results from all groups included:
- Excitement about Study idea
- Concern about convenience
- Desire for incentives, mainly monetary
- Concern about confidentiality.

Ms. Keim elaborated on results from sessions with parents. Parents wanted to learn about the Study from obstetrician/gynecologist offices, parent groups, daycare centers, and churches. Expectant parents did not favor the use of a celebrity spokesperson, but most other parents did. Urban and suburban parents and parents of disabled children were concerned about risks. Rural parents were concerned about confidentiality. Parents of non-disabled children were concerned about the Study's purpose and expectations.

To maintain interest, parents said that they would:
- Want monetary incentives, preferably combined with gifts
- Want to be kept informed of personal and overall Study results
- Prefer a newsletter that does not contain technical details
- Be interested in a Web site.

Parents did not regard incentives as a coercive measure to maintain interest. Parents sought convenient time commitments, and they agreed to answering questionnaires and to home environmental sampling.

A broad range of community leaders and organizations participated in their two sessions. To get their interest in the Study, leaders and organizations asked that the following be recognized:

- Individual community needs
- Benefit of community organization's support on recruitment
- Importance of organization's understanding Study objectives before it supports recruitment
- Interest in funds for organizational involvement
- Concern about many environmental health issues.

As for time commitment and data collection, community leaders and organizations sought:

- Understanding what is expected from them
- Involvement from the beginning
- Recognition of the importance of trust in the Study
- Participation made simple and straightforward
- Protection of participants
- Appreciation of organization's role as advocates for the Study
- Recognition as implementers of interventions arising from the Study.

For maintaining interest, community leaders and organizations advised:

- Use of continual incentives for participants, rather than an expensive, one-time incentive
- Funding to encourage involvement of community organizations
- Endorsement by community advisory boards
- Periodic updating through newsletters, community meetings, and Web site
- Appreciating that it is important for organizations to have a good understanding of the Study.

Dr. Mendola summarized challenging themes arising from focus groups:

- Unwillingness to provide some biospecimens: baby teeth; fingernails from disabled children
- Misunderstanding of requests for specimens: not all baby teeth required
- Necessity for clear explanation of what is needed
- Lack of trust in researchers and in government among minority participants.

Because the issue of lack of trust was not sufficiently asked about during the first set of focus groups, the Study undertook a second set.

Second Set of Focus Groups

Ms. Keim described the second set of focus groups, which were organized to address the challenging themes arising from the first set. The 14 focus groups were held during November and December 2003 at six sites across the United States. Representatives of racial and ethnic groups were involved to discern distrust of research. Two additional groups, teenage mothers and

couples attempting pregnancy, were also included. The topics of the second set of focus groups were the same as the first, with a special focus on biospecimen collection.

For getting interest in the Study, the second set of focus groups expressed the same themes as the first. Some groups recommended engaging their elders to provide permission to participate.

As for time commitment and data collection, the second set of focus groups agreed to the number of visits if visits could be piggybacked with regular visits to physician offices. Overall, the second set of focus groups was more receptive to biospecimen collection than the first, with some exceptions, such as:

- Apprehension about collecting blood from Chinese and Vietnamese participants because blood for them is "precious" and a source of life
- Apprehension about collecting hair samples in some communities because of concerns about voodoo; a regard for hair as sacred; a concern about practicality of collecting hair from boys who wear it short; and a fear of DNA and drug testing by police
- Apprehension about collecting placenta samples, a concern to some American Indians who regard the placenta as sacred, and a concern to teenage mothers, some of whom are fearful of secret experiments.

For maintaining interest, the second set of focus groups noted the following preferences:

- Monetary incentives
- Growth of incentives, such as savings bonds and college tuition payments, in parallel with growth of the children
- Meeting basic needs of pregnant teen parents: rent, furniture, clothing
- Receipt of test results as soon as possible
- Receipt of periodic Study updates.

The second set of focus groups described barriers to participation based on mistrust of researchers and of the federal government, including the following:

- Fears by African Americans and teens about being targeted
- Fears by American Indians and teens about "secret" research
- Concerns by several groups about use of biospecimens by law enforcement or insurance companies
- Concern by Mexican Americans and some Asians about language
- Concerns by many groups about transportation to Study sites.

For overcoming barriers, the second set of focus groups advised the following:

- Guarantee of confidentiality
- Display of credentials by research staff
- Endorsement by trusted local and national organizations
- Clarification of participation of all racial/ethnic groups; no group singled out or excluded.

Third Set of Focus Groups

Ms. Keim described a third set of nine focus groups, held during 2004, of health care providers (pediatric and obstetric physicians and nurses) and of community organizations. The Study sought to find out what providers and organizations needed to participate.

Provider focus groups wanted the Study to benefit their patients. Community organization focus groups wanted the Study to be aligned with their goals and values and to benefit their clients. Both groups wanted the Study to address barriers to participation and preferred to take the role of providing information and referring participants.

The following additional points were made by the session leaders:

- Outreach efforts have included briefings and meetings with many national organizations, and increased engagement is occurring at the local and county level now that the 105 counties have been selected for the Study.
- The requests for proposals issued during November 2004 for the Vanguard Centers and the Coordinating Center articulate the Study's expectations for community engagement. Pending adequate federal funding, the Study will provide an additional request for proposals for the remaining Study centers. Future requests for proposals will also emphasize the importance of community engagement.
- The Coordinating Center will be involved in community outreach and communications plans and in supporting the efforts of the Vanguard Centers.
- The Web site (http://nationalchildrensstudy.gov) has the publications *Growing Up Healthy*, a comprehensive overview of the Study, and *Communications Strategy*, which explains much of what was discussed in this meeting and discusses visions for the future. Brochures are being planned, and the Web site continues to be developed.

Key Points for Community Engagement in All Centers

Ms. Jones concluded by noting key points for community engagement:

- Developing a balance of power between the Study and communities
- Developing a common language between community and researchers
- Adhering consistently to Study schedules, which facilitates partnering with community
- Being patient in developing mutual trust
- Recognizing that long-term relationships are necessary to sustain a 21-year study
- Recognizing the community's concern about benefits of the Study.

Discussion

Participants asked questions or commented about the following issues:

- *How recruitment will take place, considering that the 2004 request for proposals stated that most recruitment would be by door-to-door, but this session noted that focus group participants prefer to learn about the Study from physician's offices.* Ms. Keim answered that focus group meetings preceded the decision to follow the household-based recruitment strategy. Unfortunately, therefore, the Study could not explore specific strategies of household recruitment with the focus groups. Focus groups were asked where they wanted to

hear about the Study, not necessarily where they wanted to be recruited. Ms. Keim did not believe that a household-based recruitment strategy is incompatible with the preference to learn about the Study from the physician's office.

- *How one encourages participants to buy into the process.* Ms. Jones answered the Study needs to impart its vision and figure out how the Study and communities "win" from participating, even if they win in different ways. Ms. Keim added that the Study concerns children's health and the prospect of providing valuable information to families should sustain interest.

- *What will happen if a family moves outside the reach of a Study Center.* Ms. Keim answered that if a family moves to another Study location, the family would be transferred to another Study Center. If a family moves outside any Study location, then the Coordinating Center becomes responsible for tracking and involving that family to the extent possible.

- *Whether undocumented persons will be eligible to participate.* Dr. Mendola answered that eligibility depends on geographic location.

- *Whether community engagement and involvement in sample recruitment adversely affect the selection of a truly representative sample.* Dr. Mendola answered that community contacts can explain what random, probability-based selection is.

- *Accessibility of Study data to individuals, communities, and Centers.* Dr. Mendola answered that policies are not firm, but there is a commitment to provide relevant data. The Study does not have a mechanism to provide community-specific data to communities, although there might be ways to provide local Centers with autonomy over their data. The Study is committed to ensure that the data are anonymous, and then providing public access.

- *The plan for data access for other studies.* Ms. Keim answered that she hopes to get public-use data sets made available as soon as possible, and that Study leaders regard the Study as a foundation for future research.

- *The extent to which the Study is willing to intervene in the event that results show problems.* Dr. Mendola answered that the Study is not set up for medical intervention, but has provisions for referral. Ms. Jones said that an ethical principle of research is to do no harm. It follows that if the Study finds harm, then the Study needs to work with agencies to inform about that harm. Dr. Mendola added that the Study should take opportunities to educate when unfavorable conditions or practices are observed.

- *How the Study will protect confidentiality, for example, not relaying information about child abuse to law enforcement authorities.* Dr. Mendola answered that consent forms note that some reporting, such as information about imminent harm to children, will take place. Ms. Jones added that the Study has to follow research guidelines from the Office for Human Research Protections, which creates liability for not reporting harm.

- *Whether certificates of confidentiality would be issued.* Dr. Mendola answered that she agreed that having a certificate is a good idea, but noted that certificates are not required.

Additional Participants

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