National Children's Study Assembly Meeting
Breakout Session Summary: Information Technology Issues and Data Collection
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: David C. Songco, M.E.A., Chief Information Officer, Office of Administrative Management, NICHD, NIH, DHHS

Co-Chair: Lewis E. Berman, M.S., Chief, Information Management Branch, National Center for Health Statistics, CDC, DHHS

Marsha A. Hasson, M.S., IMS Support and Operations Team, National Children's Study Coordinating Center; Computer Systems and Applications Staff, Westat

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

Session Summary

Mr. Songco opened the session by welcoming attendees and asking for individual introductions. He provided a summary of the agenda for the breakout session. He informed participants that he would outline National Children's Study (Study) stakeholder roles and responsibilities, a description of the Information Management System (IMS), key challenges, and a timeline for information technology (IT) issues related to the Study.

Mr. Songco noted that the session would conclude with a question and answer period. He described the IMS system and its purpose: to support the operation of the Study's protocol and the Study's administrative needs by sustaining the implementation, tracking, and management of Study activities.

The IMS development approach involves:

- Defining study processes and requirements with key stakeholders
- Performing technology assessments to evaluate the use of existing products
- Piloting key technical concepts to support technology decisions
- Utilizing an iterative approach for system development in order to deliver incremental results and accommodate evolving requirements
- Tracking progress, ensuring stakeholder representation, and facilitating decision-making.

Mr. Songco noted that there are many functional challenges and far more questions than answers at this juncture. Despite the challenges, Mr. Songco stressed great excitement and enthusiasm about the Study and said that Dr. Duane F. Alexander, Director, National Institute of Child Health and Human Development, NIH, DHHS, is committed to getting data out as early as possible.

Mr. Songco referenced an organizational chart that highlighted lead federal agencies, stakeholders and the Study contractors involved in the Study IMS effort. He stressed the importance of synergy and coordination among these entities in IMS development. Mr. Songco briefly described the contract roles of Booz Allen Hamilton, the IMS development contractor and Westat the contractor that will coordinate Study operations and the Vanguard Centers.

Mr. Songco said everyone on the project has a passion for the Study and understands its importance, but it will be a real challenge to connect all the stakeholders involved in such a large national project. Funding, too, will continue to be a major issue. The project is currently understaffed and success will depend largely on teamwork and leveraging partners and contractors to maximize performance and long-term success.

Mr. Songco said the IMS team must remain flexible to meet the changing requirements and characteristics of local sites. Flexibility is also required to support the multiple data collection methods, functions, and technologies. The team also recognizes that requirements will continue to be refined with protocol decisions and development of procedure manuals.

Part of the discussion focused on how the IMS was planned a little differently than in other studies. IT planning and development was engaged in the early stages to get a running start to determine data requirements. It is important to determine what IT requirements are needed now to avoid costly changes later. This is a major reason why coding cannot be done until data requirements are completed.

Mr. Songco noted that each Study team member has an important role to play in the planning and execution of the project.

- The Program Office directs and approves all activities related to the IMS.
- The Coordinating Center supports the Vanguard Centers and serves as the Vanguard Centers' primary point of communication for the IMS.
- The IMS team develops and integrates the IMS.
- The Vanguard Center will use the IMS and support the implementation.

Mr. Songco pointed out that the IMS will support all aspects of the Study, including:

- Communication and collaboration among all stakeholders
- Vanguard Centers' management of IMS operations
- Coordinating Center's monitoring of the Study conduct
- Management lab and repositories
- Data analysis for publication
- Preparation of public data sets.

Mr. Songco also discussed how the IMS will integrate data and operations at all Study locations. The integration includes sampling frame implementation, study operations, participant management, data collection, study reporting, data analysis, artifact management, and raw data interpretation.

The requirements defined for the IMS ensure that it addresses the unique characteristics of the Study. Requirements have been drafted in the areas of:

- Data collection
- Participant management
- Physical sample management
- Assignments and scheduling
- Informed consent
- Incentive management
- Inventory and supply management.

It was noted that the IMS team will collaborate with the Coordinating Center and Vanguard Centers to further refine the requirements and implement the IMS.

Mr. Songco touched on how the IMS team worked closely with the Program Office to define and establish the IMS framework. The IMS team initially worked with the Program Office to understand the Study processes and define preliminary requirements. The team began to scope the IMS and define the salient characteristics in terms of potential IMS "modules" (for example, data collection, participant management, assignment, and scheduling).

Also discussed was how the IT team established development processes and began more detailed requirements and design. While waiting for the Coordinating Center contract to be awarded, the team slowed down the IMS development and focused their efforts on establishing the Study Collaboration Portal. The IMS team is also leading several key IMS-related initiatives in the areas of informed consent, event-driven data collection, and environmental measures.

Mr. Songco noted that the IMS team is now working closely with the Program Office, Coordinating Center, and Vanguard Centers to continue development work. Rescoping, replanning, and validation work has been undertaken since October 2005. Currently, the IMS team is working to validate the requirements and evaluate existing technical solutions that may satisfy fundamental needs.

Future architectural implementation will include application integration, requirements, design, development, testing, and implementation. In January 2007, protocols and pilots are projected to begin. The target date of July 2007 has been established to start the Study, but it will be challenging to meet that date, Mr. Songco said.

Mr. Songco also discussed key challenges of the Study, including evolving requirements and a compressed development timeline, communications, and coordination. To address the challenge of evolving requirements and a compressed schedule, the IMS team deploys several strategies:

- Adopt an iterative approach to system development.

- Include IMS team members as part of the Study protocol and operations teams to capture evolving requirements.
- Involve Vanguard Centers in the IMS requirements definition.
- Leverage existing technology where appropriate.
- Extend the capabilities of the existing data collection system and Coordinating Center management systems.
- Utilize commercial off the shelf products.

To address the challenge of communication, Mr. Songco said the IMS team will use the Study Collaboration Portal to facilitate information sharing among Study stakeholders. The Study Collaboration Portal, which is scheduled to go live on December 13, 2005, is a Web-based system designed to support document management and collaboration between teams for the Study.

Current functionality includes document management, alerts, surveys, searches and links. Functionality to be implemented with later releases will include events lists, forums/discussion boards, calendars, tasks, and a contact directory.

The IMS team will use a real-time, interactive tool to support live collaboration among Study stakeholders. This Web-based tool will be used to support real-time meetings among Study teams located in dispersed locations. A training schedule for the system is also being worked out.

Key functionalities include:
- Application and desktop sharing
- Document viewing
- File sharing
- Internet audio and video broadcasting
- Microsoft Office and Outlook integration
- Multiple presenters
- Instant messaging
- Whiteboard and annotation tools.

Another major challenge is the diversity and sheer size of the Study. More than 70 percent of large IT projects fail, which demonstrates how difficult achieving success can be with complex initiatives. Another challenge will be working with universities where security issues may arise from “hackers” trying to get into the system. The IMS environment needs to be secure in all cases, and accessible, available and usable, even when connectivity to the Coordinating Center is lost.

Mr. Songco then introduced Marsha Hasson, who is the IT manager for the Coordinating Center. Ms. Hasson noted that the IMS will be developed by the Study IT contractor, which is Booz Allen Hamilton. The Coordinating Center, for which Westat is the contractor, is responsible for working with all collaborators (Study Centers, laboratories, repositories) to provide a full service computing infrastructure and user support. She explained the role of the Study Coordinating Center is emerging and will evolve throughout the initial Vanguard period.

Ms. Hasson also illustrated collaborative activities in the Study, including:

- Protocol/questionnaire development
- Data and specimen collection
- Laboratory processing and analysis
- Biorepository storage and handling
- Data entry, coding, editing, and quality assurance
- Data storage and archiving
- Analysis and publication
- Data and specimen release.

Ms. Hasson briefly highlighted the functional support that will be provided during implementation of the Study. It will involve a wide range of areas. Some examples are recruitment, enrollment, laboratory management, specimen management, specimen tracking, data investigation, online support, telecommunications, data coding, appointments, document management, participant tracing, requests for information, hospital and physician tracking, standard, and ad hoc reports.

She also explained that planned technology solutions will be designed to require minimal levels of ongoing local support at the Vanguard Centers. Hardware, software, and network support will be provided by the Coordinating Center.

The Study Center IMS Point of Contact will be the central contact for the Coordinating Center and will provide ancillary support including:

- Participation in user acceptance testing
- Participation in installation and testing of IMS components
- Provision of internal user training and assistance
- Working with the Study Coordinating Center to provide network technical support to ensure efficient operations
- Coordination of pilots, dress rehearsals, and other preparatory activities
- Implementation of local disaster recovery operations, as needed.

Discussion

Participants asked questions or commented about the following issues:

- *How and when Vanguard Centers will be kept informed about IMS.* Mr. Songco answered that a new Web-based portal will be available December 13, 2005, and it will be a major communication channel for keeping everyone informed and up-to-date on IMS activities.

- *The usability of the system.* It was explained that manuals and operating procedures will be created and tried. Adjustments will be made as needed to ensure that the system works for participating Vanguard Centers. It was noted that more than one person at each center will need to know how to use the system.

- *The degree of discipline, security, and order of the system, especially since universities will be involved with the Study.* Mr. Songco said it will be very challenging to work in some of the university environments, but there will be a degree of government control since the project is not grant-based.

- *Repairs and technical assistance.* Mr. Songco assured attendees that the government would pay for the equipment, replacements, and fix problems as they occur, including providing new equipment and technical support when necessary. Mr. Songco noted that there will be a site visit to each Vanguard Center to determine needs. Westat or a third-party will install the system, and it may vary depending on the location of the center.

- *When hardware equipment would be purchased.* Mr. Songco said he is not concerned about solicitations at this point, but it may occur in the next 4 to 6 months. Other options may also be explored.

- *How the data will be managed to maintain quality, integrity, and consistency.* Ms. Hasson noted that there will be a core system with some standardization. Error prevention, reporting, tracking, quality assurance measures, and monitoring will be used to ensure the highest possible data control and reliability.

- *Coordination with laboratories. Not all laboratories have the same systems and it may be burdensome for some laboratories to change procedures to accommodate IMS requirements.* Mr. Berman acknowledged the challenge in working with diverse laboratories and said that a degree of flexibility should be allotted to laboratories.

- *Potential delays in the Study schedule and associated costs.* Mr. Songco said it is not easy to predict the future, but he recommended doing a risk analysis to best determine when to engage certain costs.

Additional Participants

Session A:

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