

MCH/CSHCN Director Webcast
National Children's Study Presentation

February 10, 2005

PETER VAN DYCK: Well, good afternoon and welcome to the mchcom.com webcast.

Again coming to you from HRSA's Maternal and Child Health Bureau in Rockville, Maryland. This is for state MCH and children with special healthcare needs director. I'm Peter van Dyck. Director. We have an interesting program today but before I introduce today's speakers, let me review a little of the technical information about the webcast.

Note that in response to your suggestions the speaker's Power Point presentation is now available on mchcom.com so you can download the slides before the webcast. The slides, as always, will appear in the central window and should advance automatically. The changes are synchronized with the speaker's presentations. You don't need to do anything to advance the slides. You may need to adjust the timing of the slide changes to match the audio. To do that use the slide delay control at the top of the messaging window.

It is really important that you know how to ask the speaker questions any time during the presentation and please do that. You simply type in your question in the white message window on the right of the interface, select question for speaker from the dropdown menu and hit send. Please include your state and organization in your message so we know you're participating. If you don't have the opportunity to respond or if we don't during the broadcast to your questions, we'll email you after the broadcast. Again, we encourage you

to submit questions at any time. On the left of the interface is the video window. You can adjust the volume of the audio using the volume control slider, which you can access by clicking on the loudspeaker icon. Those who selected accessibility features when you registered will see text captioning underneath the window under the video window. At the end of the broadcast, the interface will close automatically and you'll have the opportunity to fill out an online evaluation. Please do that because we listen and read your responses and it does help us to plan future broadcasts and to improve the quality of our broadcast.

Well, on to today's presentation. It's really a pleasure to welcome Peter Scheidt today, Dr. Peter Scheidt from National Institute of Child Health and Human Development at NIH. He's a medical officer and director for the program office of the National Children's Study. He received an MD from Duke university. An MPA from Johns Hopkins. [Inaudible] And the director of the program office and co-chair of the interagency coordinating committee for the National Children's Study which is a large longitudinal study of environmental influences on child health and development. Please join me. We have a large audience in the room today as you might have gathered by hearing noise as I'm speaking and by people walking by the camera. We're pleased to have a large group from MCHB here and those in your offices we welcome you and join me in welcoming Peter Scheidt. Good afternoon, Peter.

PETER SCHEIDT: Thank you very much for the opportunity to talk with you and the directors of Maternal and Child Health Bureau about this National Children's Study. It's particularly important because this planned study will be conducted with the children of

most of the states and therefore very important to those working with Maternal and Child Health Bureau programs at the state level. The National Children's Study has been planned and carried out by a consortium of lead federal agencies, not only the National Institute of Child Health and Human Development but within the Department of Health and Human Services, the National Institute of Environmental Health Sciences and Centers for Disease Control and the U.S. Environmental Protection Agency. I'm speaking for the investigators and staff of those four lead agencies when I describe this study.

The National Children's Study -- and we can go to the next slide -- is the largest longitudinal study of children's health and development ever to be conducted in the United States. It's a longitudinal study not only of children, but their families and their environment to follow children from early in pregnancy until adulthood to assess the influence of environment on their health and development and environment is defined very broadly. And the children -- it is to be a national study which will include approximately 100,000 children not to be able to study important burden some high priority and even infrequent outcomes. Now, why is this study so important? It's important because of the many problems that we face in caring for our children. Between 1980 and 1995 the percentage of children with asthma in this country doubled and still is a major morbidity of our children. A portion of children are overweight increased from 6% in the late 1970's, to 15% in 1999 to 2000. 8% are born each year affected by neurodevelopmental disorders and there continue to be great disparities in the health of our children and infant mortality rates between minority and ethnic groups.

We can go to the next slide. That makes the point that children are at increased risk and vulnerability to environmental exposures in the same environment compared to adults. There are critical windows of vulnerability to environmental exposures because of the sensitivity of developing systems, especially the neurological system and children have differences in metabolism -- metabolism. They crawl, they mouth, they fall, they eat things that adults don't otherwise eat. There are physiologic differences that account for some differences in vulnerability. We know as childcare providers that body surface area is very much greater in young infants compared to older children which allows for absorption of agents through the skin at a much greater rate. The ventilation rate is significantly greater in young infants as shown in this slide compared to adults. Water intake is more frequent in younger children and mouthing and eating -- ingestion of soil and agents through similar mechanisms is much greater in infants compared to older children. Well, then with the next slide why the focus on these concerns about children now?

It's really due to a convergence of factors. There is increasing concern about a number of known exposures, measured levels that we know from the CDC report card of environmental exposures, measurable levels of agents such as pesticides, persistent, and we are growing concern about these and there is not adequate information about whether they cause long-term effects. There is increasing concerns about a number of conditions that children experience. Autism, diabetes, those kinds of conditions. And we have cases of examples of problems such as early exposure to lead, etc. Well, the convergence of these factors led the last administration to appoint a task force, a very high level task force chaired by the Secretary of Health and Human Services and by the administrator of the

environmental protection agency with seven other cabinet officers to examine strategies for reducing these risks of environmental exposures could be developed.

It was called the president's task force on environmental and safety risks to children. And that task force, when concerned with these converging factors, quickly realized there was insufficient information and a program of research that would answer these important questions about effects of exposures and outcomes would be necessary. And from those deliberations came the proposal for a longitudinal study that could examine exposures early in life in relation to outcomes later in life with a sample large enough to be able to examine those important conditions. And with that, the lead agencies that I mentioned to you began work on actual planning and study. Following that initial work in the fall of 2000, as shown in this slide, Congress passed the Children's Health Act which authorized a consortium of federal agencies led by the National Institute of Child Health and Human Development to begin work in planning the study and implementing this large longitudinal study as described in detail. I won't read the actual text of the act but this was the charge to proceed with this from Congress.

The concepts of this study, as laid out -- as undertaken by the interagency coordinating committee and the planners of this study, and as have been carried out to date are shown in the following two slides. First, that the study be a longitudinal study of children of not only children but their families and their environment. That it be national in scope, that it be hypothesis driven in order to define the boundaries and in order to provide the necessary guidance for the design. That environment be defined very broadly. Not only

the kinds of chemical exposures I mentioned previously but physical exposures, behavioral exposures, social, cultural exposures as well. That it be able to study common ranges of environmental exposures in relation to less common outcomes such as diabetes, autism, cerebral palsy.

That exposure begin -- that the study is concerned about exposures in the very vulnerable early periods of gestation, of pregnancy and infancy and therefore observations should be made as early as possible in pregnancy. Therefore, it's not a birth cohort study but a study that begins as early as possible in pregnancy. That it include extensive information about genetics in order to understand the relationship between genotype and genetic factors and environmental factors and in order to be able to understand how environment affects the expression of genetic factors. That it very much be a state of the art technology, matter of fact, is made possible by technological developments over the past several decades for handling massive datasets, for tracking participants, for microassays and measurements and so on. That it be carried out with a consortium of all those federal agencies with an interest in child health and the environment. Not only the ones I've mentioned, but virtually every federal agency that at the cabinet level has been involved in the planning of this study as well as the Maternal and Child Health Bureau.

That it incorporate extensive public/private partnerships where applicable for adjunct studies along with a course study. In spite of the fact that it is a -- to be hypothesis driven, the planners should recognize the tremendous value as a national resource that this study would provide to be able to answer a number of hypotheses in the future and therefore the

samples collected and the data managed in a way to optimize this potential as a future national resource. I mention the hypotheses that are necessary for planning the study.

And I've listed some of these only -- only some of them that may be of interest.

Hypotheses are particularly important and necessary in order to assure that the big issue, important questions are, in fact, answerable and we have felt that if we're going to spend important national resources in carrying out components of the study, that hypotheses that are well worked out and can be addressed should justify the need for these resources.

Some of the hypotheses that are available in much greater detail on the National Children's Study website and I can give the address at the conclusion of the talk are listed in this slide such as the relationship between certain pesticides and neurocognitive development. The relationship between certain early life infections and asthma. Or the frequency of early life infections with asthma severity and prevalence and it's the hygiene hypothesis, if you will. All of these hypotheses are suggested by empirical evidence but are not resolved with enough certainty to guide healthcare and policy. I won't read all of the details of them but they're available for you to look at and to pursue in more detail from the website. How will this study produce results that are not otherwise available from other existing studies or from studies that can be carried out less expensively and more efficiently? Well, there are two major ways that this study provides important information that no other study would be capable of doing.

First is in order to be able to understand and to assess the influence of exposures on big issue, low frequency outcomes on the order of those experienced with the frequency of

autism, diabetes, still birth, birth defects all in the range of less than one per hundred or less than 1% requires observations of exposures early in life and following this infrequent outcome later in life with a sample size sufficiently large in order to see significant differences. In order to power the study to be able to be large enough in order to do this requires about 100,000. And a study that's not of sufficient size simply can't provide these answers. But the second mechanism by which this study can provide very important answers is to be able to look at the ways that environments interact to results and outcomes both environment interactions and environment and genetic interactions or gene/environment interactions, if you will. To do these kinds of -- the concept here is that a certain environmental exposure, a certain class of infection, may place a sub group at risk so that subgroup when exposed to another agent such as a chemical exposure, results in an adverse outcome that those without the first exposure would not experience.

Those kinds of interactions require subgroup analysis and large sample size in order to do these subgroup analyses and measures of multiple classes of exposure in the same individuals followed over time looking at multiple classes or outcomes. Only by those -- that combination of factors can these interactions be examined. And there are a number of interesting examples that I'd be happy to share if we have time and you're interested.

Given these approaches to how the study will provide the necessary information, what are the anticipated measures? The environmental exposure measures anticipated are in the classes that I've already mentioned. The physical environment, we anticipate measuring attributes of housing, of neighborhoods, of communities, even climate, radiation. Looking at factors such as the effect of physical housing. Of urban sprawl, density of housing.

Those kinds of things as well as other physical exposures. Chemical exposures, the study plans to include actual samples of water, of air, of soil. Those kinds of -- of samples taken in those environments where children spend significant amounts of time. Both in the home and in childcare outside the home if that childcare is of significant portion of the child's time.

Then the study also plans to include biological exposures. You know, such as indicators of intrauterine infection, early life infections, evidence such as serology and other indicators of infection and diet, nutritional factors as well. Genetic factors are very much a part of this study and both genotype and certain measures of genetic expression will be included. And finally, the psycho social factors such as parenting, approaches to parenting, family structure, neighborhood and community characteristics such as measures of social capital collective advocacy and those kinds of well-defined measures. The outcome measures anticipated are outcomes of pregnancy, including the frequency of pre-term birth, birth defects, fetal influences on adult health, etc. These classes of measure will allow us to examine early results so that we will not have to wait until 2010 -- excuse me, until 2020 or 2030 to be able to begin to see benefits from this study. Neurodevelopment and behavior is an extraordinarily important and high priority outcome to include cognitive development and conditions such as autism, schizophrenia, depression, learning disabilities and the ability to learn in various ways.

Injuries are expected as a priority outcome because of the role that injuries play in childhood morbidity and mortality after the first year of life. Asthma, because of the role

that I've already mentioned, as a highly prevalent morbidity and an increasing morbidity of our children. And then finally growth and physical development and to include sexual development, obesity and so on. So those are the anticipated measures for the study. Turning to the next major consideration is the sample itself. Who is included and why? To summarize what has been for us a very extensive and vigorous, to say the least, debate about who is included, we have carefully examined the various aspects of sample consideration and have concluded that the most appropriate sample for the study is that of a national probability sample. This is for two reasons. First of all, it's important to understand this study is not being carried out to estimate prevalences of either exposures or outcomes. Those can be done in much less expensive and more efficient ways.

But the major goal of this study is to understand exposure outcome relationship. However, if those exposure outcome relationships are important for all of our children, and need to be applied to -- and extended to all of our children, and therefore we felt that in order to generalize this understanding of exposure outcome relationships to all the important subgroups of our children, that national probability sample is the most appropriate sample in order to be able to do that. The second major concern is about the sample is that the different classes of exposures of concern are highly varied. And the distribution of those exposures also varies greatly across the -- the children of our country. If we were to design a study focused on one type of exposure, it would miss other types of exposures. And to be sure that we don't miss important exposures, the best way to do that is with a national probability sample. For these two reasons we felt this was the most appropriate

sample. However, we also felt that it was equally important to gain the broad scientific input from scientific expertise among centers of excellence throughout the country.

And the study is planned in such a way as to require the expertise and the facilities of centers throughout the country and, therefore, a center-based strategy for implementing this study is also appropriate. Consequently, carrying out a national probability sample with a center-based structure is a unique combination of both sampling strategy and implementation strategy. And requires centers to actually carry out a probability sample and probability sample determined on a national basis. This requires flexibility and adaptation of centers to the scientific design, which is a unique and challenging plan. It requires flexibility and adaptation of the centers to this design. It's important to also mention that the sample will be highly clustered. It's important to understand the attributes of the neighborhoods in the communities where children live. In order to be able to do that, one needs multiple data points from these communities. It's also much more logistically feasible to carry out a clustered sample with multiple participants in communities rather than a widely disbursed sample scattered widely throughout the country and it will be highly clustered.

For those familiar with the FRAMingham study think of it as that. In developing the sample, a team of leading sampling statisticians from the National Center for Health Statistics worked with us to actually develop the sample and they pulled for us 101 study locations. This slide says 96 and I'm sorry, that's been updated to 101 and is a last-minute change that I was not able to make. So there are 101 study locations drawn from the full

list of more than 300 counties or primary sampling units throughout the country. These -- this 101 study locations, or counties, include 13 self-representing counties. And that is, when you go to pull a sample of approximately 100 primary sampling units there will be 13 of them that will always appear with a sample of that size. They're called certainty sampling units or self-representing sampling units or counties so it includes these 13 self-representing counties and then the remaining counties stratified by geographic attributes by density, metropolitan status, geography, number of births per year, race, ethnicity and percent low birth weight.

Now, in the next slide it's important to point out the difference between sites or locations where the study will be carried out and centers. The sites are the geographic locations from which participants will be recruited. As I mentioned, there are 101, not 100 as shown in this slide. They will be selected by stratified probability sample of primary sampling units as I've just described. The centers, on the other hand, are the entities or institutions that will carry out the study in the designated 101 sites. We anticipate somewhere between 30 and 50 centers. Depending on the available funding and depending on the quality of the applications or the proposals and depending on the geography of the sites and the centers respectively. Centers, on the other hand, will be selected by a competitive process in response to anticipated, planned requests for proposals or RFP's. The actual sample that we are -- that have been selected is shown in the next slide. The next slide, as you see, there are the individual dots represent the primary sampling units or the counties that have been selected.

There are eight counties designated as vanguard locations. That will be -- that are possible locations where the study -- the sites will be first started. And the request for proposals for the vanguard locations was posted as a procurement in mid-November. And centers are invited and have been invited to submit proposals to carry out the work in one of these eight sites. Now, the full sample will be selected in three separate stages. This is a multi-stage sampling process. The first stage you have just seen as the primary sampling units, or the first stage in selecting the primary -- the initial primary sampling units and you've seen the eight vanguard locations. From each of these primary sampling units, those locations, or counties, where there are large numbers of births, where all births are not included, which includes virtually all of them except the rural counties, segments will be selected that represent the county where the study will actually be carried out. So that's a second sampling stage.

Then finally, households or individuals will be recruited from within the segments of the secondary sampling stage. The segments will be defined through defining boundaries based on either census boundaries, neighborhood boundaries, school areas. The decision of how those will be selected has not been made yet because we're anticipating useful information from the centers that will be participating with us and therefore we are still leaving the guidance of how those sections -- those segments will be selected open at the moment. Now, the recruitment of the study participants in the next slide will be primarily, at least initially, through a household recruitment approach to -- in the segment to identify households that have women of child bearing age who are at some risk or likelihood of becoming pregnant. So that we can obtain environmental information, information about

environmental exposures from women who are not yet pregnant so that we can understand influences that may affect that very vulnerable first few weeks of pregnancy.

This household recruitment approach will be supplemented with recruitment through other mechanisms as well. We know that women will be missed through this recruitment approach and we expect to enlist the support of childcare providers to help us enroll women as early as possible in pregnancy, to use community-based promotion of this study, to enroll volunteers who are eligible by coming from collected in the home. Some in clinical settings where more detailed and clinical assessments are made. In addition, we anticipate information and data to be collected through phone interviews and through other devices in between these visits. I'm often asked, as shown in the next slide, what are the likely incentives for participants to want to participate? First of all, a number may want to participate just for the altruistic aspect of contributing to this very important study that will guide our children's healthcare and health policy for some time to come. We also do plan monetary compensation for the time and inconvenience and expenses for participation in an appropriate fashion.

And there are guidelines that will guide us in this so that it's both adequate but not coercive. A number of women may find, as they do in a number of other studies, that it's of value to be engaged and to have a sense of participation and membership and there are techniques to encourage this with frequent contacts with remembering birthdays and with creating a sense of belonging that many studies very successfully use and we certainly will be incorporating. But we anticipate that the major incentive for participating will be

what families and parents can learn about their children's health and the children's environment. We will be collecting quite extensive information about the children's development and health and we will share what we learn with -- about these children with their parents when it is important and when it is relevant for them. And when we learn about risks that are known risks that were otherwise unknown, we are obligated to inform them and initiate interventions as needed. And so we think that will be probably the most valued motivation for participation.

How will this study use its information to inform us all about the environmental and health concerns? First, there are planned targeted analyses to answer those important hypotheses that were used in planning the study. The planning of the study includes insurance that these analyses are done in a prospective way. And those will be done by the various teams of investigators, including both federal, non-federal scientists and those agencies involved in planning the study. In addition, we are planning the preparation and release of successive waves of public use datasets with each phase of the study as appropriate. Included in the budgeting for the study are planned requests for analyses -- requests for applications, RFA's to support and encourage investigator-initiated analyses of these data to ensure as much outcome of an output from the study as possible. All of these, of course, leading toward the translation of results into important prevention strategies for our children.

The projected timeline of the study shows that we are on schedule to select the initial centers and the coordinating Center for the study by September of 2005. And then over

the following year to complete the details of the protocol, the study plan, that is a broad guide for the protocol is already available and posted on the website. But the final details of the protocol should be completed by September of 2006, with initial enrollment of the first participants early in 2007. And in 2007, the establishing the remaining centers that will carry out this study. We anticipate the first preliminary results of this study in the range of 2010 looking at those outcomes of pregnancy. I invite you to visit the National Children's Study website and it includes a great deal of information. This is on the last slide. A great deal of information about the planning of this study. There have been now approximately 30 workshops with in-depth reviews of the state of the science of various areas that are of concern and that are important in planning the measures and design of the study and the results of those workshops and working group meetings and advisory meetings are posted on the website.

The study plan is posted on the website. The map and the list of locations is posted on the website. If you have questions in addition to those I would happy to entertain them today, please contact us at the -- our email address ncs@mail.nih.gov. With that I would be happy to answer any questions that either the group here at the Maternal and Child Health Bureau or the webcast would like me to address.

PETER VAN DYCK: Thank you very much, Dr. Scheidt. A lot of information. For you folks sitting at your desks, please type in your questions and send them in and we will ask Dr. Scheidt to respond to those. I'm going to ask a question in the meantime and then ask people in the room if they have one. Say for a few minutes for our audience, when you say

national probability survey, what that means. How is that different from another kind of survey?

PETER SCHEIDT: Well, what makes it a probability survey is that it weights up to the entire population of children in the U.S. so that the attributes of the sample and findings from the sample can be applied to all of the children of the U.S. In order to do that, one has to start with a sampling frame that includes all of the children in the U.S. And it was pulled in a way that all communities in the U.S. had a known chance of being included in this study. And -- and it's that attribute that makes it a probability sample. And every county, you know, had a known chance of being in the sample. Now, it was pulled by stratifying -- developing strata based on regions of the country, based on the number of live births to -- in each of the sampling units, each of the counties, and strata or groups of those counties were then -- individual counties were pulled from groups of the county that were otherwise similar so that we could assure that every county had a known chance of being selected.

PETER VAN DYCK: So would it be sensitive enough to give you the probability of an occurrence like diabetes or asthma or a couple of those you mentioned birth defects? For different racial or ethnic categories and the probability of that occurring nationally in those racial or ethnic groups?

PETER SCHEIDT: For those racial and ethnic groups that are sufficiently large, yes. The smaller the group, the less certain those findings would be, you know, for that group.

Some groups for which it's important to be able to report results may need to be oversampled in order to do that. One such group might be the Native Americans. There are Native Americans in the sample and several primary sampling units, but additional oversampling can be required in order to be able to apply results to that as a subgroup. There are sufficient numbers of the larger minority groups, African-Americans and Hispanics to not require oversampling at least as of the moment.

PETER VAN DYCK: Are there any questions in the room here?

UNIDENTIFIED SPEAKER: I was wondering what languages the survey was in.

PETER VAN DYCK: Let me repeat the question in case the audience couldn't hear it. The question was, what languages will the survey be conducted in.

PETER SCHEIDT: The language consideration is really very interesting. I've learned something about this. Certainly Hispanic, you know, that's a given. But -- we've looked at the distribution and the frequency of other languages and as it turns out, there is not a clear third or fourth. There is -- I have forgotten the exact percentage but, if you will in the range of what is it, 20%, approximately Hispanic, and then you drop down to between 3% and 6% and there is a whole lot of languages that occur in that frequency. And it's very regional specific. In some areas it's Asian language, some areas it's Russian and it's very regional specific. So we do anticipating translating to other language in very regional

areas. But not necessarily for the whole sample. And there is -- there wouldn't be a third or fourth. We probably have to do it with six or eight of them. But again, it's very -- it's very regional.

PETER VAN DYCK: Any other questions within the room here before I go to the other group? Yes.

UNIDENTIFIED SPEAKER: I was wondering, sir, if you would say something about your RFP, when it will be announced and what are the eligibility criteria.

PETER VAN DYCK: The question was, when will the RFP's for the center sites be issued and give us an idea of what the eligibility requirements would be.

PETER SCHEIDT: The RFP for the coordinating center and the vanguard centers was announced on November 16. And the due date for the coordinating center is passed and we do have proposals. So that's very much alive. The due dates for the vanguard centers is next week on February 16. The RFP for the remaining centers no date has been set. We anticipate -- that is still dependent on sufficient funding. We have funds sufficient to go forward with the coordinating center and the vanguard centers and we anticipate subsequent funding in the next one to two years and ideally the RFP for the remaining centers would occur in 12 to 18 months from now. The -- when that RFP was announced on November 16, we also sent notices to all the involved -- every involved state government, county health department, county executive, academic medical school,

departments of research, chairmen of pediatrics and chairmen of obstetrics and gynecology. The eligibility to be a center is very open. Though we anticipate a high level of interest from medical schools and academic centers, by no means is this exclusively to be academic centers. It could be a health department, it could be an HMO, it could be a combination of partner entities. Does that answer your question?

PETER VAN DYCK: I'll turn to Chris DeGraw who coordinates who is minding the computer today. Do you have questions?

CHRIS DEGRAW : We have a couple of questions now. A participant from New York asked if you could talk more about the most compelling hypotheses and research questions. Discuss the top five or so.

PETER SCHEIDT: The -- one of the first things we had to learn in planning this study was that there -- it took me about a year to come to the understanding and to accept that there is no single, if you will, Holy Grail hypothesis that is driving this study. There are a number of them. There are actually 29 posted on the website and we viewed this as I've done as a dynamic process. We understand that there are things we will have missed that ought to be included and as we become aware of important additional hypotheses we're prepared to incorporate them up to a point. And we also understand that some of the hypotheses that we've posted will be outdated and will need to be discarded. Hypotheses about a certain exposure that may no longer be relevant. But some of the more compelling hypotheses are certainly those related to the kinds of exposures of concern that I've

mentioned. Concerns about, for instance, exposures to heavy metals in tissue in breast milk in infancy and the questions that those have raised versus the benefits of breastfeeding and Omega 3 fatty acids and its risk benefit equations are incorporated as hypotheses. The interactions between certain genetic variations and exposures, particularly behavioral exposures are particularly compelling.

This gets to some of the basic science of the development of behavior. There is empirical evidence from work at NIH looking at genetic variations of serotonin metabolism that, when present, cause in his monkey colonies, pathologically abnormalities that actually makes them totally dysfunctional and they're killed by their monkey peer. But when raised with highly, highly nurturing mothers the exact opposite happens. They become highly functional and leaders of their peers and resistant to the addictive behavior that they otherwise have. That interaction of early life exposure with outcome, with genetic variation, could, when applied to sort of human behavior, could provide very important guidance. The work of others looking at the interaction between child abuse in early life interacting with an MAO genetic variant is of similar kind of interaction. And so those are -- that's another class of interaction. There is an important group of hypotheses that is looking at the complex interactions that result in asthma and asthma prevalence. You've got enzyme systems interacting with infection, interacting with exposure to antigens and behavioral exposures and that complex set of interactions requires a very complicated analyses and examination of these multiple factors that can be examined in this study. So I think those are a couple of, I think, the leading, more intriguing examples. The outcomes of pregnancy are another particularly important group, especially the puzzle of still births.

It's clearly evidence of some suggestive evidence of environmental exposures and the problem of still births is where SIDS was several decades ago and we're hopeful of being able to provide important information about hypotheses related to that as well as other outcomes of pregnancy.

PETER VAN DYCK: Another question?

CHRIS DEGRAW : Along the same topic. If new hypotheses are added during the course of the study, will that cause changes in the data collected?

PETER SCHEIDT: Clearly we can't go back and collect data after the cohort ages but -- after the cohort has passed a period when exposure data could be collected but up to the point that new concerns could be incorporated into the protocol, we would be receptive to important new considerations.

PETER VAN DYCK: I would think that maybe the samples that you draw would be saved and might have to be resampled as well. Something like that might occur, depending on what the new hypothesis was.

PETER SCHEIDT: Very much the case. In fact, we expect to collect and preserve a wide array of samples. Not only the environmental samples that I've described, but bio markers of blood, for not only genetic testing but other samples, breast milk, hair, teeth, placenta and we can't do all the possible assays of these. Many of the chemical assays are

extremely expensive and we would see most of those carried out later as case control studies where let's say you were hypothesizing the exposure to other certain agents and its relationship to autism. So you would have a small group of three to four per thousand of participants that actually develop autism with a selected -- appropriately selected controls from the cohort and therefore there you could carry out an analysis in a very much smaller number of -- and much less expensive number of assays looking for the chemical exposures.

PETER VAN DYCK: Other questions?

CHRIS DEGRAW : Finally, as a Title V director in a state with a county whose participation is planned, how can I join any conversation going on in our state about this study?

PETER SCHEIDT: Until the initial site -- this the sites are selected competitively, it's not possible for me to guide that individual to a particular entity that may be proposing to submit -- to participate.

PETER VAN DYCK: But those grants are now in to you, the proposals are now in to you?

PETER SCHEIDT: Not for the initial vanguard sites. They'll be in next week.

PETER VAN DYCK: Next week and then you have an expected date, award date?

PETER SCHEIDT: That's correct.

PETER VAN DYCK: That date is--

PETER SCHEIDT: It will be this fiscal year, by September.

PETER VAN DYCK: The person out there who is asking, it's not going to be until September that you would know who even the contact person would be in that county.

PETER SCHEIDT: That's correct. That does not preclude that person from networking and anticipating who would be candidates. And we would encourage that. In fact, our thinking is that the community involvement is so important to carrying out this study. An essential ingredient. It's heavily emphasized in the RFP that they must be able to incorporate the important components of the community.

PETER VAN DYCK: That person could look at the RFP on the website.

PETER SCHEIDT: They could. I would anticipate that entities planning to propose to be a center would be engaging health departments and important community organizations.

PETER VAN DYCK: Well, thank you, Dr. Scheidt, very much. It was a very informative session on the National Children's Study. We know it's a very complicated process that's

been in planning for several years now. But I think you really helped us understand in a very short time the scope of this national probability sample. It's amazing. We want to thank you out there very much for joining us for the mchcom.com webcast this afternoon. I would like to thank the Center for Advancement of Distance Education at the University of Illinois in Chicago School of Public Health for making all the technology work. Today's webcast, as with all our webcasts, will be archived and available within a couple of days on the website, mchcom.com. Please let your colleagues know about the website especially if they have questions about the National Children's Study. We want to make these webcasts as responsive to your needs as possible. If you have suggestions for topics or you would like to see things addressed in the future, please let us know. You can either call or you can go to the email, the email address is info @ mchcom.com. Again, thank you very much. Chris, thank you for coordination. Thanks for all the people in the room. Nice turnout and we want to look forward to your participation again in the future. Have a nice week and weekend ahead. Good night.