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ReachMD

www.reachmd.com
info@reachmd.com
(866) 423-7849

The National Children's Study: Essentials

WHAT PHYSICIANS NEED TO KNOW ABOUT THE NATION CHILDREN STUDY

ReachMD would like to wish you a happy and health New Year and with each New Year comes a fresh start. As we look ahead, ReachMD is proud to present this month's special series, Focus on Future Medicine.

The national children study will follow the health and development of more than 100,000 children across the United States starting from before birth until age 21. What these physicians need to know about this ambitious federally financed program, what are its main goals, how is it organized, what factors will the study examine? You are listening to ReachMD, the Channel for Medical Professionals. Welcome to a special segment, Focus on Future Medicine. I am your host, Dr. Jennifer Shu, practicing general pediatrician and author. Our guest is Dr. Peter Scheidt, pediatrician and a medical officer at the National Institute of Child Health and Human Development where he is a Director of a National Children Study.

DR. JENNIFER SHU:

Welcome Dr. Scheidt.

DR. PETER SCHEIDT:

Thank you. Glad to be here.

DR. JENNIFER SHU:

Can you tell us a little bit about the driving force behind this large study?

DR. PETER SCHEIDT:

Yes, the development of this study began in the late 1990s with a Presidential Task Force called the presidents task force on environmental health risks and safety to children that was convened by the President and charged with developing national strategies to reduce and control the risks of environmental exposures that our children may have. It stems from emerging concerns doing that period about the possibility that a variety of environmental exposures may cause harm to children, some chemical exposures, exposures to

behavioral experiences such as violence and even biologic exposures, infection and diet and also concerns about a number of conditions that our children experience such as autism and learning disabilities and even growth problems that may be caused by environmental exposures but the evidence is not clear. The convergence of these concerns led this task force to realize that in order to answer those important questions, it would require a large study of different life stages that could link exposure to outcome and be able to study infrequent conditions such as autism, diabetes, birth defects, and so on and that's basically where the impetus to start the study came from. I mentioned and emphasized that because it is important to understand that this did not come from a couple of scientists or physicians in laboratories at NIH or CDC or wherever thinking well this would be a new thing to have a study like this. It came from a very intentional, very high-level effort in our government to address the major unanswered questions about health and environment that our children face and this large intentional answer to those important questions. Once this recommendation was made and the agencies began to just start the very early thinking and planning about this study, Congress passed the Children's Health Active 2000 that authorized NICHD and the other lead federal agencies the CDC, EPA, and the National Institute of Environmental Health Sciences to go forward with the planning and the implementation of this study.

DR. JENNIFER SHU:

Okay. So, starting in the year 2000 and Congress appropriated funds for this and gradually that amount has been increase in anticipation of the study will start in 2009.

DR. PETER SCHEIDT:

Actually, it is not so.

DR. JENNIFER SHU:

Oh no, okay. Please clarify then.

DR. PETER SCHEIDT:

That's were we learned the difference between authorization and appropriation. Congress authorized a sum of money to begin work, but that was only permission. It didn't actually provide additional funds to any of those agencies. The planning for the first 6 years of the study actually came from the existing budgets of the agencies that I mentioned. It was in 2007 that Congress actually appropriated separate funds specifically targeted for the implementation of the National Children Study.

DR. JENNIFER SHU:

Now, are there are funds appropriated to continue the study from 2009 on?

DR. PETER SCHEIDT:

There are not because the federal budget doesn't work that way. All programs carried out by the federal government are appropriated on a yearly basis, but once they become established and integrated into the budgets of the agencies that carry them out, they pretty well continue unless there is a direct effort to stop them and that's were we are now with the National Children Study, although as its implemented the costs to get into the field increase over several years before they began to level out and then ultimately decrease.

DR. JENNIFER SHU:

Clearly, it is going to require lot of resources. Do you think there is any validity to the criticism that a project of this magnitude might strip resources away from small and more focussed research on pediatric and perinatal issues?

DR. PETER SCHEIDT:

I do not think so. We have been asked that question often and the assumption is that if this study was not funded that those funds would go into the investigator initiated research activities or other different studies and that is not the case because Congress has not decreased or allowed the Nation Children Study to impact the other existing federal budgets and has appropriated funds with this budget specifically unrelated to other federal programs and that point out that the nature of this study is such because of the size and because of the many measures and lines of investigation included in 1 study. It is able to investigate certain conditions because of its size and the interactions of many different factors in ways that a smaller study just simply can't do. So, the reason this study is so important is the ability to do things that other lines of research and other mechanism simply can't do.

DR. JENNIFER SHU:

If you have just joined us, you are listening to a special segment, Focus on Future Medicine on ReachMD, the Channel for Medical Professionals. I am your host Dr. Jennifer Shu. Our guest is DR. Peter Scheidt, Director of the National Children Study at the Nation Institute of Child Health and Human Development. We are discussing what physicians need to know about the Nation Children Study.

There are multiple study locations across the country. Can you tell us a little bit about how these locations were selected?

DR. PETER SCHEIDT:

Yes, I can. The first major decision that we had to make in planning the National Children Study was who would participate and a good deal of work and deliberation went into determining that the best sample of participants would be a nationally representative sample of children in this country basically based on the frequency of live births across the country to represent the experience that all of our children and all the major groups of our children have and this is because the exposure outcome relationships that the study will address, need to apply to all of our children and it also offers the best way to be sure that we don't miss key exposure factors that would be missed if we targeted this study for any 1 group or type of exposures, so it nationally representative sample. In order to develop that sample, we asked the help of the leading sampling statisticians at the National Center for Health Statistics who work with us to develop a sample of 105 locations that are we call them primarily sampling units that our selected largely counties from the total of 3141 counties across the country and then with each of these counties segments of the counties where the counties are large enough will be picked in a similar fashion to actually enroll women and participate in the study.

DR. JENNIFER SHU:

So, the women will be enrolled before they have the child. So, during pregnancy or before they think about becoming pregnant, is that correct?

DR. PETER SCHEIDT:

Yes, it is. We will approach the women on a household basis primarily, but we will also and this is very important for physicians to understand only the study but the approach that it is taking. We will also seek referrals from prenatal care providers for those women that we miss in the household recruitment approach and we will certainly miss many women that we hopeful be referred by referring pediatricians, and so with each of these segments in the 105 counties across the country, we will notify the communities, work with the communities to inform as much of the population as possible about this study, let women know in advance that this study is being conducted, and then contact them to ask if they would be willing to participate, and we will contact households to identify women of childbearing age and then any women of childbearing age who may become pregnant over the 4-year enrollment period will be followed and if and when she becomes pregnant, will be invited to enroll and participate in the study. Any women we encounter who is actively engaged in trying to become pregnant with the good probability of being able to become pregnant, we will also invite them to participate and collect data and information from them actually prior to pregnancy, so we can identify factors that may be influencing those very early weeks of pregnancy.

DR. JENNIFER SHU:

So, you are talking about gathering data, may be some laboratory samples from the women and the children. Why not require that the fathers also participate in this study?

DR. PETER SCHEIDT:

We are inviting the fathers to participate in the study.

DR. JENNIFER SHU:

Inviting right. I suppose to making sure every father participate.

DR. PETER SCHEIDT:

We cannot make sure that anyone participates. All the women in the families who participate are of course volunteers, but for those women who enroll in the study we will ask the partner or husband or the father of the children also participate by providing information and interviews and biologic samples as well as the mother. So, in fact, we are as much as they are willing to participate getting the fathers to participate as well.

DR. JENNIFER SHU:

Do you anticipate any challenges in keeping the participants in the study for the 21 plus years?

DR. PETER SCHEIDT:

Oh, yes we do.

DR. JENNIFER SHU:

What you are going to do to try to encourage them to continue.

DR. PETER SCHEIDT:

It is very challenging. First of all, it is a big study with a fair amount of burden and quite a substantial commitment and there are a number of things that we will be doing to both encourage women to enroll in the study and then to stay with us once the study is underway. First of all, we will be offering an appropriate amount of compensation financial compensation for the inconvenience and the time that they put in doing this and it is appropriate to provide some incentive to participate, but not be so much as to be cohesive. In addition, of course we will be making the case that this is a really important contribution to our children and our future children and we hope that many women will just want to participate from that aspect and Eucharistic motives. We will do many things to make them feel both comfortable belonging to an important effort you know such as celebrating birthdays, favors, and activities, but probably the thing that we will be most valued for participants will be the opportunity overtime to learn additional information about their children and their children's environment. The information that we can't share with them that we do obtain that is available to share with them we will do so. To some degree, we will also be sharing information to the communities where the participants will confirm that may benefit the communities as well. So, our experience from the women's health initiative, they did all of these things as well. The women who participated in that study reported back that the thing they valued most was what they learned about themselves and their health from participating in that study. We think that will end up being important for the participants in the national children' study as well.

DR. JENNIFER SHU:

I would like to thank our guest, Dr. Peter Scheidt. We have been discussing what traditions to know about the national children study.

I am Dr. Jennifer Shu. You are still listening to a special segment focus on future medicine on ReachMD, the Channel for Medical Professional. Please visit our website at www.reachmd.com, which features on demand pod casts of our entire library.

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