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Health Priorities of the National Children's Study

FOCUS ON FUTURE MEDICINE - HEALTH PRIORITIES OF NATIONAL CHILDREN'S STUDY

Every New Year we look to the future and dream of what is possible. ReachMD radio is proud to present our special series Focus on Future Medicine.

From the air they breathe to the food they eat, to where and how they live, the environment in which our children grow effect their development and lifelong health. The National Children's Study is a large longitudinal investigation, which will track these environmental influences on participants from before birth to early adulthood. What are the study's current hypotheses and priority health outcomes and how might these findings impact patient care. 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 Medical Officer at the National Institute of Child Health and Human Development where he is the Director of The National Children Study.

DR. JENNIFER SHU:

Welcome Dr. Scheidt

DR. PETER SCHEIDT:

Thank you I am glad to be here with you.

DR. JENNIFER SHU:

There are several priority health outcomes that are being studied in the National Children Study. Can you tell us some of these top health themes are and how these priorities were determined?

DR. PETER SCHEIDT:

Yes I would be happy. Health outcomes and these priority exposures were based on a number of hypotheses that were defined to guide the planning and boundaries of the study. So the major outcomes of pregnancy such as preterm birth, birth defects, and stillbirth, neuro development and behavior outcomes, such as autism, learning disabilities, schizophrenia that would require the study to go to late adulthood and other behavior problems and conduct problems, injuries because of the magnitude of injuries as both the cause of





mortality and morbidity in children until well into adulthood and the factors in both genetic and biologic and environmental factors that contribute to injuries are important to understand. Asthma is an important outcome because it is so prevalent and so refractive to many of the efforts to control it and because it's so complex, that requires multiple factors to understand how children experience asthma and develop asthma and then of course obesity and physical development because of the epidemic of obesity that we have experienced in this country and other places around the world. How the various classes of exposure, physical environment, chemical exposures, biologic environment, genetic factors, and psychosocial factors all interact either between exposures or exposures in genetic factors to result in those various types of priority outcomes is the aim of the study.

DR. JENNIFER SHU:

Lets talk a little bit specifically about the health measures and what those hypotheses are. Why don't we start with obesity because it is so prevalent. What are some of the hypotheses that you are working with right now?

DR. PETER SCHEIDT:

Well we are looking at the ways in which genetic factors, which we all know play a prominent role in the development of obesity, but not totally. How they interact with a variety of early life experiences to effect obesity? How early feeding practices will result in obesity interacting with the genetic factors? How mothers the environment in the uterus and for instance in the glucose in the mothers who are not diabetic, but may have insulin resistance and glucose abnormalities intrauterine will end up influencing the development of obesity is an important hypothesis that will be examined and of course this is all complicated by a variety of psychosocial factors and others as well and the advantage of the National Children's Study is that by collecting information about both the biologic environment, psychosocial environment, and the genetic factors and being able to do subgroup and hierarchical analyses to dissect out those relationships requires very large sample sizes like the National Children's Study with multiple classes of exposures in the same individuals to be able to understand how they interact to result in obesity and other outcomes.

DR. JENNIFER SHU:

So another outcome might be asthma for example, what are you hoping to find out from the study regarding asthma?

DR. PETER SCHEIDT:

First of all we are hoping to test a very simple and straightforward hypothesis, the hygiene hypothesis that projects that children who experience decreased infections are early in life as a consequence of availability of antibiotics and of accessible medical care may actually experience greater prevalence of asthma, as they grow older. We are testing that specific hypothesis and a study of this size can provide information about to a degree that much smaller hypotheses cannot. In addition, asthma is a very complex condition with clear evidence for genetic factors that influence the development of asthma. In this sense it's like obesity as well. Genetic factors influence development of obesity, exposure to infection, influences the development of asthma in addition to exposure to allergens, to chemicals, environmental air pollution and virtually all these classes of exposures may influence development of asthma, but which subgroup is vulnerable to the development of asthma under which conditions is much less clear and by understanding how various individuals and subgroups are at risk of developing asthma according to the various exposures and experiences that they have, can provide important guidance for developing individualized treatment and understanding the much more effective approaches to the management and treatment of asthma.





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's Study at National Institute of Child Health and Human Development. We are discussing working hypotheses and priority outcomes of the National Children's Study.

We are just getting into little bit detail, we have talked about obesity and asthma. One more broad category, I would like to visit right now is learning problems and mental health disorders. We are seeing an increase in autism in this country. What is the hypothesis that your group is using regarding autism?

DR. PETER SCHEIDT:

Autism, its now clear is primarily a genetic condition. It occurs at approximately 80% in monozygotic twins. However, it is also becoming clear that from the fact that not 100% twins express autism, but that environmental factors may significantly influence the expression of these genes that are associated with autism and there are intrauterine factors that have been suggested that are candidates for possible influencing the expression of autism in children as they age, it has been suggested there are certain nutritional factors and chemical factors and agents that we will look for associations with the development of autism. Concerns about vaccines in autism, we will look at in The National Children's Study to the extent that participants in this study either delay or do not receive immunizations, but the expectation that most children will receive immunizations and we may not be able to provide additional information on that particular question. The way that we will approach the study of autism will be primarily through embedded case control strategies, so that we don't have to conduct assays of all of the chemicals for instance and other agents and other factors that we would want to test in association with asthma. And in that way, we will wait until the expected 600 to 700 children in the study show signs of and then are diagnosed with autism and then be able to do the necessary chemical analysis on their specimens from early in pregnancy and infancy on these 600 adequate controls. For instance 1200 or so controls and in that way we will do what chemical assays we need to do on only about 1800 to 2000 children instead of the full 100,000. We could not afford to do all of the chemical tests on all of the 100,000 that we might want to examine up front and therefore and save a good deal of resources to be able to do many other analyses.

DR. JENNIFER SHU:

At the end of our segment, I will have you let our listeners know how they can learn more about the National Children's Study and may be read more about the hypotheses for some of the other conditions that are priorities. When don't we switch gears right now and talk more broadly about the National Children's Study. Now I understand that there are similar studies being internationally in places like Great Britain, Denmark, and Norway. Are there any efforts to try to collaborate with different countries based on the information that we are gathering here in the United States?

DR. PETER SCHEIDT:

Yes there are, we realized early on in planning The National Children's Study that certain conditions that we would very much like to study especially childhood cancer are too uncommon to be able to be adequately studied even with a study as large as 100,000 like the National Children's Study. So we asked the question, well how can we be able to study autoimmune conditions where less frequent birth defects and especially childhood cancer and we realized that are a number of other childhood and especially birth cohort studies around the world. The Chinese have 250,000 or so, the Norwegians 100,000, birth cohort that is just in the field and the Danes have a study of 100,000 and other studies around the world and with them we formed a consortium called The International Childhood Cancer Cohort Consortium. It is a cohort consortium of all of the large longitudinal cohort studies around the world and we are exploring the methods and the feasibility of merging data from these various studies together in order to be able to reach a sample size of over half a million and with those kinds of sample sizes, we can hope to look at conditions such as childhood cancer. We have just participated in starting





a proof of concept analysis to look at some fairly simple hypothesis of folic acid level and paternal age of both with some empirical suggestive evidence in relation to acute lymphoblastic leukemia and that work is just beginning now, but we are hopeful that this kind of international collaboration can provide insights and research opportunities that we would not otherwise have for these very infrequent conditions.

DR. JENNIFER SHU:

Now the study is design to enroll a cross section and representative sample to include various different races, ethnicities, genders, and socioeconomic, and other background to study some possible health disparities, but by the time the study ends, isn't it possible that the demographics of our country will have changed significantly by then.

DR. PETER SCHEIDT:

It almost certainly will happen that the demographics will have changed, that doesn't mean that we would have to repeat The National Children's Study, but the findings of the National Children's Study will certainly be applicable to all of the major groups who are participating in the study and the enrollment period over 4 years with a staggered enrollment will be of enrolling participants in the study at the 105 locations for a total at least 6 years. So the transitions over that period will be incorporated to some extent in the sample, but there will be changes in the demography of the population of our children over time and that we will have to live with.

DR. JENNIFER SHU:

Dr. Scheidt, when do you expect the first finding to be reported?

DR. PETER SCHEIDT:

We can expect to see preliminary results from the outcome pregnancy as early as midway into the enrollment period. This is a 4-year enrollment period, so preliminary results from the outcome of pregnancy, we could expect to see as early as 2012. It's important to emphasize that we don't need to wait for 25 years to see important results from the study and already we are publishing results from the various methods development and pilot studies that we are conducting to develop the methods for the study, but the first outcome results we can hope to see in 2012.

DR. JENNIFER SHU:

And finally, could you please tell us where our listeners can get more information about The National Children's Study.

DR. PETER SCHEIDT:

Yes, I would be glad to. We have a web site on which we post a great deal of information about the study. Its located at www.nationalchildrensstudy.gov, and there is a great deal of information on the study. Let me main point out 2 features. If physicians are interested in a general overview of the study midway on the introductory page, there is a video that you can click on that gives a very good overview and portrays what The National Children's Study is all about and why its so important. For specific scientific aspects of the study, especially the hypothesis and the research plan that The National Academy of Science has just recently reviewed, if you click





on the research under that tab, you can find the research plan for the study and that may be of interest to many of your listeners.

DR. JENNIFER SHU:

I would like to thank our guest, Dr. Peter Scheidt. We have been discussing working hypotheses and priority outcomes of The National Children's Study. I am Dr. Jennifer Shu.

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