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The National Children's Study 2014: Commentary on a Recent National Research Council/Institute of Medicine Report

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Much of this commentary is drawn from NRC/IOM (2014).
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THE NATIONAL CHILDREN'S Study (NCS) was authorized by the Children's Health Act of 2000 (Public Law 106-310) and is being implemented by a dedicated program office in the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). In the words of the program office, the NCS is planned to be a "longitudinal observational birth cohort study to evaluate the effects of chronic and intermittent exposures on child health and human development in US children."[1] The NCS would be the first US study to collect a broad range of environmental exposure measures for a national probability sample of about 100,000 children followed from birth or before birth to age 21.

Detailed plans for the NCS were developed by 2007 and reviewed by an outside panel.[2] At that time, sample recruitment for the NCS Main Study was scheduled to begin in 2009 and to be completed within about 5 years. However, results from the initial 7 Vanguard Study (pilot) locations, which recruited sample cases in 2009–2010, indicated that the proposed household-based recruitment approach would be more costly and time-consuming than planned. In response, the program office conducted additional pilot tests in 2011–2013 to evaluate alternative recruitment methods. Based on these results, the study design was revised in early 2013, and a tentative 2015 start date was set for the Main Study.

In March 2013, Congress requested a review of the revised study design by a panel of the National Research Council and Institute of Medicine. Congress stated the panel should "conduct a comprehensive review and issue a report regarding proposed methodologies for the NCS Main Study, including whether such methodologies are likely to produce scientifically sound results that are generalizable to the United States population and appropriate subpopulations."[2]

NICHD specified that the panel's review should cover such aspects of the Main Study design as the national probability sample's overall sample size and design; the use of hospitals and birthing centers as the primary sampling unit; the relative size of the prenatal and birth strata in the probability sample; the size of the supplemental convenience samples; optimal use of sibling births; use of health care providers to refer prospective participants; the proposed study visit schedule, with emphasis on more frequent data collection in pregnancy and early childhood; the proposed approach to assess health and developmental phenotypes; and the proposed approach to define and characterize health disparities.

The panel concluded that to meet its charge of evaluating the scientific merit of the Main Study, the NCS program office would need to provide specific documentation on the sampling design, the sample frame, the data collection protocols, and the study instruments, rather than just describe the conceptual framework, strategies, and anticipated processes to design the Main Study. The panel reviewed what the NCS program office provided by way of documentation and responses to several sets of written questions from the panel. The panel also listened to public comments during open meetings that included the NICHD staff. In addition, the panel engaged consultants to provide an expert cost analysis to support comparison of various design alternatives.

OVERALL ASSESSMENT

The National Research Council and Institute of Medicine released the panel's report, *The National Children's Study 2014: An Assessment* (NRC/IOM, 2014), on June 16, 2014.[3] The panel concluded that the National Children's Study has the potential to add immeasurably to

scientific knowledge about the impact of environmental exposures, broadly defined, on children's health and development in the United States. The panel supported a number of elements of the proposed design for the NCS Main Study, including the following: the use of a national equal probability sample for a large cohort of births, the concept of the study as a data collection platform with a focus on health and development guided by exemplar scientific hypotheses, the inclusion of siblings born within the 4-year recruitment window, and the collection and storage of biological and environmental samples to permit subsequent analysis of archived specimens.

The panel did not endorse 2 other elements of the proposed design: first, the plan to recruit only half of the 90,000 births in the probability sample prenatally and the other half at the time of birth, and second, the plan to recruit a 10,000 birth convenience sample to study the preconception period and to be available for various less defined purposes. The panel concluded that almost all the sample births (excepting only when the mother does not seek prenatal care) should be recruited prenatally. This conclusion was based on the scientific consensus concerning the importance of prenatal exposures on child health and development. The panel's cost analysis showed that it is feasible to have close to 100 percent prenatal recruitment by dropping the planned convenience samples, which the panel judged to add little scientific value.

The panel did not receive sufficiently detailed information from the program office to assess other aspects of the proposed design, including the choice of hospitals as primary sampling units instead of geographic areas as in the earlier pilot testing, the quality of available hospital sampling frames and whether they support the stratified sampling necessary for the study to adequately investigate health disparities, the details of the sampling and recruitment strategies, the scientific merit of the proposed exemplar hypotheses that are to guide data collection, the schedule and content of data collection in early waves, and the extent and impact of data collection burden on respondents.

Because of this lack of information and related reasons, the panel concluded that achieving a scientifically grounded and cost-effective design and implementation for the Main Study would require expansion of the scientific expertise in the program office, establishment of an authoritative multidisciplinary oversight structure to review the program office's decisions, and regular independent outside reviews.

CONCLUSIONS

The NCS Main Study offers enormous potential, but it also presents a large number of conceptual, methodological, and administrative challenges. In addition, funding uncertainties make it difficult to plan a study of this magnitude and duration. Like the scientists associated with the study itself, the panel is eager for it to succeed. The panel presented their recommendations in the hope that as it goes forward the NCS will achieve its intended objective to examine the effects of environmental influences on the health and development of American children.

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