UC Irvine

UC Irvine Previously Published Works

Title

The Future of the National Children's Study.

Permalink

<https://escholarship.org/uc/item/16g0c7fp>

Journal

JAMA pediatrics, 169(6)

ISSN

2168-6203

Authors

Duncan, Greg J
McCormick, Marie C
Citro, Constance F

Publication Date

2015-06-01

DOI

10.1001/jamapediatrics.2015.0364

Peer reviewed

VIEWPOINT

Greg J. Duncan, PhD
School of Education,
University of California,
Irvine.

**Marie C. McCormick,
MD, ScD**
Department of Social
and Behavioral
Sciences, Harvard
School of Public Health,
Boston, Massachusetts.

**Constance F. Citro,
PhD**
National Research
Council, National
Academy of Sciences,
Washington, DC.

The Future of the National Children's Study

On December 12, 2014, National Institutes of Health Director Francis Collins, MD, PhD, announced his intention to discontinue the National Children's Study (NCS), ending nearly 15 years of planning and pilot testing at a cost of \$1.3 billion. As 3 of the authors and editors of the report by the National Research Council and Institute of Medicine *The National Children's Study 2014: An Assessment*,¹ we welcome the opportunity to provide our perspectives on future directions for the study.

The NCS was authorized by the Children's Health Act of 2000 (Pub L No. 106-310) to accord priority to (1) gathering data from birth to adulthood to evaluate environmental influences on diverse populations of children; (2) considering health disparities among children; and (3) incorporating behavioral, emotional, educational, and contextual consequences to enable complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being. The Program Office in the Eunice Kennedy Shriver National Institute of Child Health and Human Development designed the study as the first in the world to collect a broad range of environmental exposure measures for a national probability sample of about 100 000 children followed up from birth, or even before birth, to age 21 years.

Our panel's review of the study design concluded that the NCS had the potential to add substantially to scientific knowledge about the impact of environmental exposures, broadly defined, on children's health and development in the United States. The panel supported almost all of the basic elements of the proposed design for the NCS Main Study, including the use of a national equal probability sample for a large cohort of births (the panel recommended that almost all of the sample be recruited prenatally), its concept of the study as a data collection platform with a focus on health and development guided by exemplar scientific hypotheses, its concentration of measurement on the prenatal and early childhood periods, and the collection and storage of biological and environmental samples to permit subsequent analysis of archived specimens.

For many important issues regarding the NCS's proposed design, the panel did not receive sufficiently detailed information from the Program Office to provide an informed assessment. Because of this lack of information and related reasons, the panel concluded that achieving a scientifically grounded and cost-effective design and implementation 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 review.

Collins's December 12, 2014, statement about the NCS concluded that while research addressing the links between the environment and child health and devel-

opment is important, the NCS is not feasible. He called for alternative designs to be initiated within the scientific community that would employ the use of the growing number of clinical research networks. Neither Collins's statement nor the report of the Working Group he commissioned explains why the basic NCS design is infeasible, which handicaps our efforts to point to promising new directions. Our panel judged that the basic elements of the data collection plan were indeed feasible and noted that most had been incorporated into successful national longitudinal birth cohort studies in other counties or proved their worth in the Vanguard testing sites. Although we judged that the study's management structure and system of oversight needed to be reformed, we also pointed to a number of successful management models that could help to guide these efforts.

Perhaps the key to the Working Group's and Collins's "infeasibility" judgment was the cost of the study design. Our panel estimated that the data collection portion of study costs alone would range between \$200 million and \$300 million annually by the third year of data collection—amounts well above the past Congressional appropriations for the total costs of running the study. These high costs had little to do with the NCS Program Office's decision to adopt probability methods for drawing the study's sample, but instead were driven by the total sample size, the frequency of interviewing, and the need for periodic in-home visits to collect data on environmental exposures that could not be measured in blood or placentas. Any replacement collection of NCS-related studies—including those initiated in clinical research networks—involving similar total numbers of subjects and periodic in-home interviews would likely cost as much or more.

As a final prefatory note, the importance of understanding health disparities figured prominently in our panel's deliberation. Ensuring adequate representation of our nation's most disadvantaged children in studies such as the NCS is a formidable task. These children are unlikely to be well represented in studies that draw their samples from administrative records or patient pools. And the residential mobility of disadvantaged children makes them exceedingly difficult to follow up in studies operating in limited geographic areas. These concerns contributed to our panel's endorsement of a national scope and probability sampling methods for the study.

How best to address the priorities dictated by the Children's Health Act of 2000 at considerably lower cost? Although it may be sensible to mount a number of valuable low-cost specialized studies, we see no substitute for a national study that follows up diverse groups of children through adolescence and engages in intensive assessments of a variety of environmental exposures through periodic home visits. And we reiterate the endorsements of our panel and the Working Group for

**Corresponding
Author:** Greg J.
Duncan, PhD, School of
Education, University
of California, Irvine,
2001 Education, Irvine,
CA 92697-5500
(gduncan@uci.edu).

the use of probability samples to accomplish these goals. In the context of these parameters, the only effective way of cutting costs substantially is to reduce total sample size well below its current $n = 100\,000$ level.

How damaging would this be? Some hypotheses regarding very common exposures and children's health conditions can be tested with much smaller samples. Assessing the associations between uncommon exposures and rarer conditions, however, may not be possible. Moreover, much smaller samples might not be adequately powered to investigate some important issues of health disparities (eg, regarding differences in socioeconomic health "gradients" across groups). Perhaps a study with a sample size in the 30 000 to 50 000 range would strike a feasible balance, although optimal sample sizes would depend on a reformulated set of study goals. Steps may be needed to oversample children with uncommon exposures, with rare conditions, or who are members of groups thought to have health disparities. Fortunately, methods for oversampling these kinds of groups within the context of a probability sample have a long and successful history.

It is impossible to render specific judgments about design elements in the absence of well-articulated hypotheses that need to be addressed over the course of the study. Of course, scientific progress between now and the end of a revitalized NCS will produce a

flow of important new hypotheses that will need to be incorporated into the ongoing study design. But a conceptual framework that is much stronger than the small set of "exemplar hypotheses" provided for our panel's deliberations is needed to guide selection of samples, exposures, and outcomes. Fortunately, a tremendous volume of background work has been conducted by the Vanguard sites and/or presented at NCS workshops and is available to help address most of the contingencies generated by a freshly conceived set of hypotheses regarding environmental exposures and health disparities.

In sum, we believe that the bulk of study objectives outlined in the Children's Health Act of 2000 can be addressed with a scaled-down version of the original study design. Due regard would need to be paid to uncommon environmental exposures of interest, as well as to groups of children susceptible to health disparities; however, these elements can be handled within the context of a national sample drawn with known but unequal sampling probabilities. There are many successful examples of US longitudinal health studies (eg, the Fragile Families and Child Well-being Study, the Health and Retirement Study, and the National Longitudinal Survey of Adolescent Health) with broadly similar designs, all of which use national probability samples and all of which centralize strong, scientifically credible leadership and advisory structures within a university setting.

ARTICLE INFORMATION

Published Online: April 6, 2015.
doi:10.1001/jamapediatrics.2015.0364.

Conflict of Interest Disclosures: None reported.

Additional Contributions: A full list of National Research Council/Institute of Medicine panel members includes Dean B. Baker, MD, MPH (University of California, Irvine), Paul P. Biemer, PhD (RTI International, Research Triangle Park, North Carolina and University of North Carolina at Chapel Hill), Barbara Lepidus Carlson, MA (Mathematica Policy Research, Princeton, New Jersey), Ana V. Diez Roux, MD, PhD, MPH (School of Public Health, Drexel University, Philadelphia, Pennsylvania), Greg J. Duncan, PhD (University of California, Irvine),

Virginia Lesser, DrPH (Oregon State University, Corvallis), Marie C. McCormick, MD, ScD (Harvard School of Public Health, Boston, Massachusetts), Sara S. McLanahan, PhD (Princeton University, Princeton, New Jersey), George Saade, MD (University of Texas Medical Branch at Galveston), S. Lynne Stokes, PhD (Southern Methodist University, Dallas, Texas), and Leonardo Trasande, MD, MPP (New York University, New York), with Constance F. Citro, PhD, and Nancy Kirkendall, PhD (National Academy of Sciences, Washington, DC), representing the National Research Council. Randall Olsen, PhD (Ohio State University, Columbus) and Lisa Schwartz, PhD (Mathematica Policy Research) served as cost consultants to the panel.

REFERENCE

1. Panel on the Design of the National Children's Study and Implications for the Generalizability of Results; Duncan GJ, Kirkendall NJ, Citro CF, eds; Committee on National Statistics; Division of Behavioral and Social Sciences and Education; Board on Children, Youth and Families; National Research Council; Institute of Medicine. *The National Children's Study 2014: An Assessment*. Washington, DC: The National Academies Press; 2014.