Lifelong Impact: Why the United States Needs a National Birth Cohort Study

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Lifelong **Impact**

Why the United States Needs a National Birth Cohort Study

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Introduction

The well-being of our nation's children has great impacts on our nation's ability to thrive. We know that the well-being of adults has roots in early life. In order to increase our understanding of these processes, we need to study how our nation's children learn and develop across the life course from before they are born until adulthood. There is a consensus among many leading U.S. scientists that a nationally representative birth cohort study that begins in pregnancy has unique value for major advancements in our understanding of how children in this nation grow into healthy, successful, and happy adults. This perspective was voiced in the National Research Council (NRC) and Institute of Medicine's (IOM's) 2014 review of the National Children's Study, *The National Children's Study 2014: An Assessment.*

Efforts currently under way are not nationally representative or are insufficiently comprehensive in their focus, particularly with respect to assessing the environment across the life course. We now live in a time where the current technologies allow for collection of information in a manner that is cost effective, less burdensome to study participants, and secure. We can also process information more quickly and securely, allowing society to quickly reap the benefits of this research. Learning how all aspects of the environment work together to impact lifelong health and well-being has the potential to inform and transform evidence-based policies and practices to improve the prosperity of the nation.

In this two-part National Academy of Medicine Perspectives series, 17 experts discuss the reasons why a national birth cohort study is important for the future of health in the United States and how such a study could be designed in a way that is multidisciplinary, focuses on the main drivers of health, engages communities, employs a diverse set of data sources, and includes innovative techniques in data analysis.

BACKGROUND

With funding from the Robert Wood Johnson Foundation, the National Academy of Medicine and the Division of Behavioral and Social Sciences and Education of the National Academies of Sciences, Engineering, and Medicine held two expert meetings to identify the reason why the United States needs a longitudinal birth cohort study and the methods that can be used to make its implementation successful. The meetings drew on the NRC/IOM report *The National Children's Study 2014: An Assessment*. In addition to engaging a

diverse array of stakeholders from academia, philanthropy, local communities, industry, and government, the meetings included discussions about how to design a national longitudinal cohort study that is multidisciplinary, focuses on the main drivers of health, engages communities, employs a diverse set of data sources, and includes innovative techniques in data analysis. Discussions included how to use the findings from such a study to improve and direct resources toward improvements in the drivers of health.

2

Why the United States Needs a National Birth Cohort Study

In a list of 17 high-income countries, the United States ranks last in terms of life expectancy for males and second-to-last for females. The U.S. population also experiences worse outcomes compared with its peers in nine key areas: infant mortality and low birth weight; injuries and homicides; adolescent pregnancy and sexually transmitted infections; HIV and AIDS; drug-related deaths; obesity and diabetes; heart disease; chronic lung disease; and disability (NRC/IOM, 2013). In addition, the United States sees persistent racial, ethnic, socioeconomic, and geographic disparities in health (IOM, 2012).

Why does the United States fare so poorly compared with its peers? There are many possible reasons, ranging from adverse economic and social conditions to individual behaviors and environmental factors. For example, we know that people often have difficulty accessing or affording care in the United States; and the U.S. population has higher rates of risky health-related behaviors, such as alcohol use, injuries, and unprotected sex. The United States also sees greater income inequality, less social mobility, fewer family supports, and higher rates of poverty—especially child poverty—than its peers. Finally, elements of the built environment, such as inadequate public transportation infrastructure, may discourage physical activity and contribute to high obesity levels (NRC/IOM, 2013).

Each of these factors helps to explain the relatively poor health of the U.S. population, but none presents a complete picture. Many questions remain. For instance, why do nonsmoking Americans who maintain a healthy weight still experience higher rates of some diseases than their peers in other high-income countries (NRC/IOM, 2013)? This question is difficult to answer, because we do not know how individual behaviors combine with the vast multitude of social, economic, and environmental influences to affect health across a person's life span. Most existing population health studies are narrow in focus—examining a single population group, a limited number of environmental factors, or a single stage of human development. There is only one way to get a more complete picture: a nationally representative birth cohort study that begins prenatally and lasts throughout adulthood.

Without the comprehensive, longitudinal data provided by such a study, it will be difficult to identify and make wise investments in policies that will promote health at the individual, community, and societal levels. In short, a national birth cohort study is essential for developing evidence-based policies that are capable

of improving the United States' international health standing—and ensuring that every member of the U.S. population has an equal opportunity to thrive.

In this paper, we explain the unique benefits of such a study and outline three elements that are essential to produce the kind of comprehensive, cross-cutting data we need to build sound policies: (1) that the study is nationally representative; (2) that it begins before birth and continues through adulthood; and (3) that it explores a range of environmental influences on health and well-being, both harmful and protective.

THE CHILDREN'S HEALTH ACT OF 2000 AND CURRENT RESEARCH INITIATIVES

In 1999, the President's Task Force on Environmental Health Risks and Safety Risks to Children concluded that a large study to understand the association between environmental exposures and children's health was essential (NICHD, 2016). Following the task force, the U.S. Congress recognized the need for a national study to examine environmental influences on children's health and development. In a bipartisan effort, Congress passed the Children's Health Act of 2000, mandating a national study of children's health, well-being, and development until age 21. This act authorized the National Children's Study (NCS). The NCS was intended to be a birth cohort study that would follow a nationally representative cohort until the age of 21. The study was led by the National Institutes of Health (NIH) with a program office run out of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). A pilot study began in 2009 in seven locations and was later expanded to include 33 additional locations.

In 2013, Congress mandated that the National Research Council (NRC) and the Institute of Medicine (IOM) review the design of the NCS Main Study. The NRC/IOM report stated that the NCS had great potential to add to our knowledge about the impact of environment on health, but criticized its scientific oversight and leadership (NRC/IOM, 2014). Following the release of this report in 2014, Francis Collins, director of the NIH, formed an advisory committee that further reviewed the NCS. Following recommendations of this advisory committee, the NCS was shut down (NIH, 2014).

Given the unfortunate outcome of the NCS, it is important to note that both the NRC/IOM report and the report of the NIH advisory committee state that the NCS had laudable and important goals. The NRC/IOM report also supported two design features: the NCS's proposed use of a probability sample[1] and the recruitment of women prenatally (NRC/IOM, 2014).

Although the NCS was halted, numerous other pediatric research efforts continue. The National Institute of Environmental Health Sciences and the Environmental Protection Agency (EPA) have been studying children's health through the Children's Environmental Health and Disease Prevention Research Centers since 1998. Research from these centers has increased our understanding of the impact of the physical chemical environment on child health and development. In addition, the NIH has formed several children's health efforts, such as the Nulliparous Pregnancy Outcomes Study (NuMom2B) (begun in 2010), the Centers of Excellence on Environmental Health Disparities Research (grants awarded in 2014), and two major efforts in 2015 and 2016: CHEAR (Children's Health Exposure Analysis Resource) and ECHO (Environmental Influences on Child Health Outcomes).

CHEAR is designed to provide extramural researchers access to a laboratory and data resources to expand knowledge on environmental exposures through a National Exposure Assessment Laboratory Network; a Data Repository, Analysis and Science Center (a data and analytics support resource serving as a repository for all data and providing support for statistical analysis and interpretation); and a Coordinating Center (a center

[1] A probability sample selects a random sample of individuals to represent a larger number of individuals, such as the U.S. population. In probability sampling, every individual has a known, non-zero chance of selection in that sample. Therefore, the results of a national probability sample can be extrapolated to the entire population from which the sample was selected. Confidence intervals for estimates generated from the national probability sampling can be computed.

for administrative management). The goal of ECHO is essentially to create a synthetic cohort out of existing cohorts already being studied in the United States. The focus of ECHO is on key outcomes associated with early life exposures, where early life is defined as the period from preconception to age 5. The synthetic cohort created by ECHO will contain early life exposure data and include information on key outcomes such as upper- and/or lower-airway function (e.g., asthma, allergies, and sleep-disordered breathing); obesity (e.g., nutrition, metabolic risk factors, and activity level); pre-, peri-, and post-natal outcomes (e.g., birth defects, prematurity, and neonatal/infant mortality); and neurodevelopment (e.g., attention, cognition, emotion, and social/language/behavioral development).

CHEAR and ECHO have great potential for addressing scientific questions about factors associated with increases in chronic diseases in children. However, because ECHO will be built around existing cohorts, it will not address social, physical, nutritional, and chemical exposures in ways that reflect the different experiences and exposures of families and children in diverse cultures across the nation. As a consequence, inferences based on the study will not generalize as readily as those that would be generated by a study with a national probability sample frame.

Only a nationally representative birth cohort study that begins prenatally and continues into adulthood will provide a data infrastructure capable of identifying the "drivers" of health and development and informing solutions, or "levers," that can be activated to support better health and development, not only during the early years, but throughout the life course. Moreover, in order to calculate representative rates of exposures and levels of health and disease, and to understand the distribution of certain environments, this study should start from a national probability sample that properly represents cultural, racial, and ethnic subgroups in the United States.

A well-designed probability sample will not only support the estimation of descriptive statistics, but will also support inferences about drivers of children's health and well-being (Michael and O'Muircheartaigh, 2008), thereby shedding light on the causes of current disparities. Only a probability sample can provide nationally representative depictions of the environments in which children grow and develop across our nation's geographic regions and cultures. This broad sample of environments will add to our understanding of inequities in access to environments that support health and well-being and allow investigation into potential pathways to support positive health and development.

THREE ESSENTIAL QUESTIONS THAT CAN BE ANSWERED BY A NATIONAL BIRTH COHORT STUDY

Research that seeks to understand only one outcome—for example, how children develop medical conditions or why they fail in school—will not provide a comprehensive evidence base to develop policies that support a healthy, safe, and thriving U.S. population. Moreover, to inform investment and policy decisions, it is necessary to move beyond an incomplete understanding of health as simply the absence of disease to include outcomes that encompass positive development and well-being.

Answers to the following three cross-cutting questions are critical to understanding factors that affect health, development, and well-being through the life course. To help answer them, we must have a diverse, nationally representative birth cohort study starting prenatally.

1. What explains the disparities in health and well-being in the United States?
2. What are the drivers of health and well-being from the prenatal, infancy, and early childhood periods of development through adolescence and early adulthood?
3. How do the social, family, physical, nutritional, chemical, and digital environments together influence health and well-being across the life course?

What Explains the Disparities in Health and Well-Being in the United States?

Because many health outcomes vary by socioeconomic status, ethnicity, race, and geography, it is imperative to study a full range of individuals across this increasingly diverse nation. Although health disparities by race, ethnicity, and income have been well characterized by past research, our nation has been changing in terms of its ethnic and racial make-up, as well as trends in family configuration. For example, the proportion of non-Hispanic whites in the U.S. population has declined substantially, from 84 percent in 1970 to 62 percent in 2015 (NASEM, 2015). This is in part due to the fast-growing representation of immigrants; today, one out of four people in the United States is either a first- or a second-generation immigrant. As of 2009, Asian immigrants have surpassed Latinos as the largest group emigrating to the United States, and both groups are growing faster than the non-Hispanic white population (NASEM, 2015). These rapid changes mean existing research may no longer represent the current U.S. population.

The socially organized systems into which children are born and develop are also important contributors to disparities in health and well-being. These systems drive options for where and how families live, the work parents can do, and the schools children attend. Past studies of these social forces may be less relevant today, as shifts in sociocultural forces have led to more nuanced practices and markers of identity, especially among younger generations, while sociopolitical forces have reconfigured processes of power and marginalization. Rapid sociodemographic shifts, such as a reduction in marriage rates, even among couples with children, and the legalization of same-sex marriage, have already and will continue to create changes in families and their access to benefits associated with marriage. A nationally representative cohort study would allow us to examine in more nuanced and innovative ways the forces and processes of marginalization that lead to social inequities in health and development. This is particularly important to account for processes and forces that produce inequalities associated with race, gender, immigration, class, sexuality, and dis/ability (e.g., Dixon-Román, in press; Suarez-Orozco et al., 2015).

Finally, it has recently become clear that health disparities encompass far more than access to care and health-promoting environments. Recent epigenetic studies showing differing amounts of DNA methylation and haplotypes by race, economic status, and stressful life events provide evidence that environmental factors actually impact how genes are expressed (Olden et al., 2014). This provides biological evidence for "embodiment" theories that argue that adverse events, including experiences of marginalization, "get under the skin" via neurochemical and physiological processes (Bourdieu, 1977; Gravlee, 2009; Krieger, 2005; Wynter, 2001). Growing research has demonstrated empirically the myriad ways in which negative social experiences—such as child abuse; domestic violence; racism and discrimination; sexism; unemployment; financial stress; lack of health insurance; and residing in communities that are segregated by race or class or lack supermarkets, have a high incidence of gun violence, or have high levels of environmental contaminants—materialize in neurobiological processes of the body. Only through a longitudinal study can we fully understand the ways in which social forces like these become incorporated into a person's health over time.

What Are the Drivers of Health and Well-Being from the Prenatal, Infancy, and Early Childhood Periods of Development Through Adolescence and Early Adulthood?

Health and development each builds on themselves; each period of development lays the foundation for the next (Halfon and Hochstein, 2002). This is important when it comes to understanding the drivers of health within a population. Even though the impacts of early exposures may not be evident for years or decades, they have consequences—not just in terms of life expectancy, disease, and disability but also for cognition, self-concept, emotional functioning, behavior, and school and work performance. Thus, early life growth and development creates the basis for lifelong health. But health is not static. As children move

through the life course, they engage, make choices about, and potentially influence their environments as well as being influenced by them.

Although family, peers, and school influences are the most powerful shapers of development (Bronfenbrenner and Morris, 2006), these influences are themselves shaped by social forces, including experiences of discrimination and marginalization over time. This interplay influences not only the development of physical health, but also behavioral and mental health, which are particularly important given that disorders across these dimensions are the leading causes of disease burden in the United States (Kyu et al., 2016). The effects of cumulative positive and negative exposures across the life course, as well as how certain types of exposures cascade to produce novel outcomes, can only be captured in a birth cohort study. Psychological assessments that can be generalized to real-life settings will reflect health and well-being in terms of a dynamic, emergent, continually changing set of indicators of adaptive functioning and development that is profoundly shaped by interactions within families in their proximal environments—which, in turn, expand as children mature to include schools and neighborhoods, all of which are further shaped by sociocultural, economic, and policy environments.

The United States continues to have one of the highest rates of infant mortality among developed nations; it is ranked number 32 out of 41 countries monitored by the World Bank (OECD, 2013). Much infant mortality is accounted for by preterm birth, which increased by 11 percent in the United States from 1990 to 2011 (OECD, 2013). Premature birth and infant mortality can only be understood fully by studying a diverse sample of women during, and even before, pregnancy. Moreover, neurodevelopmental disorders, such as autism spectrum disorder and attention deficit hyperactivity disorder, as well as asthma and obesity, are likely to be best understood by studying the prenatal period of development. This is because the foundation for all regulatory systems—neural, cognitive, cardiovascular, and immune—has its basis during gestation and the first years of life (Etzel and Landrigan, 2014). An in-depth study of these fundamental regulatory processes will not be possible in studies that begin after, rather than before, birth.

In order to identify health drivers across the life course, it is essential to measure development across different life stages with appropriate psychosocial measurements of health and well-being, relationships, and other aspects of the environment. Although the validity of any particular measure may be limited to a specific age range, there are key age-limited indicators that are known to be associated with health and well-being (e.g., quality of attachment relationships with caregivers; quality of early childcare settings and housing; residential and school mobility; maternal post-partum depression; and pubertal timing). All layers of the social environment—from the family to the community and the society in which we live—have impact on health and development across the life course (Bronfenbrenner, 1979; Bronfenbrenner and Morris, 2006; Elder et al., 2003).

These observations underscore our assertion that to understand the drivers of health and development we must have early and ongoing ecologically valid[2] assessments that characterize the timing, intensity, and duration of exposures across the life course. Many environmental exposures are episodic, occurring during particular times in life, in certain places, or with specific people. The most accurate way to collect data on life events and exposures is to do so as close in time to the event as possible, rather than months or years afterward. Beginning assessments after the birth of a child jeopardizes the accuracy of critically important information about pregnancy supports or social stressors, traumatic experiences, or fetal exposures to toxic chemicals in the air, water, food, or soil.

[2] Able to be generalized in real-life settings.

How Do the Social, Family, Physical, Nutritional, Chemical, and Digital Environments Together Influence Health and Well-Being Across the Life Course?

Simply identifying individual factors as drivers of health will not yield a full understanding of the dramatic increases in obesity, asthma, neurodevelopmental problems, and other health burdens now prevalent in the United States, such as behavioral and mental health disorders. An analysis of how different factors in the environment interact to disrupt or enhance health and well-being is urgently needed. For example, neighborhood poverty may be a driver of increased asthma in populations, but, without accounting for increased air pollution, we may be mistaken as to which exposure is most important. Many other exposures are either protective of insults from another exposure or exposures or can increase the effects of another exposure. In addition, chronic psychological stress might enhance a child's vulnerability to air pollution and contribute to the development of asthma (Chiu et al., 2014; Wright et al., 1998). Social support from families is associated with better adolescent nutrition (Larson et al., 2013); and some nutritional exposures can protect against negative environmental factors. Examples include iodine intake and perchlorate exposure or iron intake and lead exposure (Hennig et al., 2012). Thus, if we look at only one or two factors that influence health, rather than the whole picture, we might misidentify the chief drivers of health and disease.

Moreover, just as patterns of disease differ by income, so do chemical exposure patterns. Lower-income individuals have increased exposures to lead, cadmium, antimony, and bisphenol A, but higher-income individuals have increased exposures to mercury, arsenic, cesium, and thallium (Tyrrell et al., 2013). Without evaluating these differences in exposures, one could mistakenly conclude that the cause of a disease is a factor associated with lower income, such as decreased access to health care.

It is also critical to understand the developmental patterns and timing of nutritional environments for children, especially in the context of other aspects of the environment. Over the past several decades, nutritional influences from families, neighborhoods, the media, and the food industry have changed substantially. The health influences of dietary supplements; fortification of cereals and grains; dietary options and habits; and the role of advertising on food choices are poorly understood at the population level. It unknown how the nutritional environment interacts with the physical and chemical environments; or how these various factors worsen or ameliorate the dramatic increases in obesity, asthma, and other noncommunicable diseases in the United States. The developmental timing and patterns of such influences are also not well understood (e.g., we cannot yet identify predictors of overweight and obesity in the prenatal period, first 1,000 days, or early and middle childhood).

Another important change in the social environment is the rapid rise of digital technologies. As a sociotechnical force, digital technologies have become ubiquitous in the lives of the majority of Americans. As these technologies and methods advance and evolve, we continue to know little about how they affect child health and development—let alone how they might enable, mediate, and/or reconfigure the social dynamics and processes of health, health care, learning, and development. The social spaces and practices of the Internet have produced traumas, anxieties, and mental health concerns that need to be better understood. Thus, capturing the use of digital technologies and spaces, particularly in relation to disparities in quality of digital experiences and information, and how these experiences interact with other environmental exposures, will be necessary to have a full picture of how variations in environmental exposures influence health and well-being.

For a national longitudinal birth cohort study to be successful, we will need to break down scientific siloes across disciplines that typically assess only a small portion of environmental exposures. Currently, our understanding of health drivers and levers is unbalanced and incomplete. A nationally representative study that collects data on a cross-section of environmental exposures over time has the potential to inform resource allocation, service delivery, urban planning, and other policies that can improve the health and well-being of the nation. This requires repeated assessments that can account for the timing of environmental influences and characterize outcomes that may themselves become causes of shifts in trajectories of development. Health

problems arise not only from negative environmental exposures but also from missing or weak promotive and protective influences. Research on drivers and levers of health and well-being must include promotive/protective factors as well as risk factors, and must be embedded in a developmental perspective to expand our perspective on what drives health and well-being.

CONCLUSION

A nationally representative birth cohort study that begins prenatally will generate foundational data that can be analyzed to understand what drives health and well-being across the life course. There is a consensus among leading scientific and political organizations (NRC/IOM, 2014) that a national longitudinal study of a representative birth cohort, particularly one beginning in pregnancy and designed to examine disparities in health outcomes related to inequality of health care and sociodemographic diversity, has unique value for major advancements in our understanding of how children in this nation grow into healthy, successful, and happy adults. This goal cannot be accomplished through efforts currently under way in the United States, because these studies are not nationally representative or sufficiently comprehensive in their focus, particularly with respect to assessing cross-cutting environmental factors. Moreover, existing cross-sectional studies, smaller cohort studies, and health surveillance efforts will be substantially enriched by the ability to compare to these nationally representative data. A new, nationally representative longitudinal birth cohort study focused on the processes by which individuals and their environments interact to impact lifelong health and well-being has tremendous and unique potential to inform and transform evidence-based policies and practices to improve the health and well-being of the nation.

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3

Methods for a National Birth Cohort Study

As we outlined in the previous paper in this series (Riley et al., 2016), our nation needs foundational data in order to understand how social, physical, chemical, and nutritional environments interact to impact how Americans grow, live, and prosper. To satisfy this need, we propose a nationally representative birth cohort study beginning in the prenatal period and following the children through adulthood. Existing research efforts are inadequate because their data are not sufficiently comprehensive and representative to identify both positive and negative factors affecting children's health or to fully understand health inequities in the United States.

A crucial element of the proposed study is a well-designed national probability sample from which conclusions can be drawn to the larger population from which the sample was randomly selected. In contrast, self-selection sampling consists of volunteers who elected to be part of a study. This technique introduces self-selection bias and can lead to a sample that is not representative of the population being studied. In fact, a report by the National Research Council (NRC) and the Institute of Medicine (IOM), *The National Children's Study 2014: An Assessment*, endorsed a probability sample design for a future national longitudinal birth cohort study (NRC/IOM, 2014; Riley et al., 2016). In this paper, we provide an overview of a feasible sample design, methods for stakeholder engagement, tools for data collection, and approaches for providing access to the data that would maximize their value.

SAMPLE DESIGN AND SAMPLE SIZE

The area-based sample design used in the National Children's Study (NCS) in 2009–2010 proved to be problematic and unsustainable as implemented. As a result, beginning in 2010 several variations of the initial design were tested or explored (Baker et al., 2014; Hirschfeld et al., 2011; Robbins et al., 2015; Trasande et al., 2011). One of the tested designs involved sampling pregnant women directly via prenatal care providers, rather than sampling women via the geographic areas in which they lived. A version of this approach was piloted from 2012 to 2014 in three NCS locations: Harris County, Texas; Jefferson County, Kentucky; and Worcester County, Massachusetts. The piloted version involved constructing lists of prenatal providers who served pregnant women in these counties, selecting samples of providers within each county, and then, for

each selected provider, sampling time periods during which all pregnant women making their first prenatal visits would be invited to enroll in the NCS (National Children's Study Program Office, 2015).

For the future national birth cohort study we propose in this series, we suggest an alternative version of this approach for establishing the birth cohort. This alternative version was discussed by the National Institute of Child Health and Human Development for use in the NCS around 2014 but was not implemented (NRC, 2014). The approach involves

- selecting a nationally representative sample of hospitals and birthing centers in the United States;
- obtaining lists of prenatal providers who have birthing privileges at the sampled hospitals;
- sampling providers from those lists; and
- sampling time periods to enroll pregnant women visiting the providers' offices for their first prenatal visits, as was done in the version used in the NCS pilot study.

There are two lists of U.S. hospitals—one maintained by the American Hospital Association and the other by Verispan LLC—that can serve as the basis for the sample frame construction of all hospitals with birthing facilities in the United States. Both frames have high coverage and contain valuable data on the hospitals for use in sampling, thus supporting the selection of an efficient hospital sample. In order for a study to make reliable estimates for certain demographic groups, those groups often need to be oversampled. The hospital-based sample design would allow for oversampling. For example, oversampling public hospitals located in low-income areas in order to over-represent disadvantaged women in the cohort. Within selected hospitals, a probability sample of prenatal providers with birthing privileges at the hospital would be invited to participate. One advantage of this approach is that the hospital connection will potentially increase prenatal provider participation. Another considerable advantage is that it restricts the collection of the birth biological specimens to the sampled hospitals.

We believe this design will yield a cost-effective and logistically feasible study. There are of course minor limitations. Data are not collected from sampled women during the preconception stage and the early stages of pregnancy before they seek prenatal care (although retrospective reports and record data may sometimes be useful). However, a sizable proportion of the sampled women would likely be enrolled within the first trimester of their pregnancies. In 2007, more than 70 percent of pregnant women who delivered a baby received prenatal care in the first trimester (HHS, 2016). Some pregnant women do not receive prenatal care, but they could be enrolled by study staff soon after the birth of the child (Kozinetz et al., 2016). Pregnant women who neither seek prenatal care nor give birth in a hospital are not covered by the design, but this non-coverage is minimal—in 2012, births outside of hospitals represented less than 1.4 percent of all births in the United States (MacDorman et al., 2014).

A solution that can address the limitation of lack of direct data before the first prenatal visit, including during the preconception period, is to include subsequent pregnancies within a specified period from families already enrolled in the study. Although such a sample is clearly not representative of all births, including the fact that the environment will be different for subsequent pregnancies, this approach would be very cost-effective in that information about the enrolled families would already be collected with respect to the first enrolled child.

The large sample size of the NCS was identified by the NRC/IOM report as being a very costly goal. The NCS called for a sample size of 100,000 births in order to enable evaluation of outcomes with relatively low prevalence on the order of 2 per 1,000 (0.2 percent), such as cerebral palsy and type 1 diabetes (Branum et al., 2003). As the first paper in this series describes (Riley et al., 2016), there are many important outcomes that are more widespread in our nation, such as preterm birth (9.6 percent of births [March of Dimes, 2015]) and childhood asthma (10 percent of the population [Bloom, 2013]). A much smaller sample size would

suffice for studying these higher-prevalence outcomes. For a future study, we suggest that the sample size could be reduced to as few as 30,000 to 50,000 births (Barksdale Boyle et al., 2015; Duncan et al., 2015). This smaller sample size sacrifices very few possible study goals and would make for a more manageable study as well as a very sizable reduction in cost. An analysis presented in the NRC/IOM report indicated a roughly proportional relationship between 21-year project costs and sample size, implying that a sample size of 50,000 births would cost roughly half as much as a study with a sample of 100,000 births (Duncan et al., 2015; NRC/IOM, 2014).

STAKEHOLDER ENGAGEMENT

Studies of this magnitude have many stakeholders: funders, participants, the research community, and the public at large. Engagement of these stakeholders and sensitivity to the sociopolitical context are critical to study execution, as well as the level and duration of political support and financing. For longitudinal studies in particular, the duration and ongoing resource requirement pose additional challenges to maintain stakeholder enthusiasm and support, and speak to the need for innovative approaches in funding, implementation, and sustainability (Bennett et al., 2011).

To begin designing engagement strategies, the study should aim to gather information on factors that resonate, as well as elements that cause concern, among members of the communities served by the selected hospitals. The engagement strategies should consider common barriers to successful community engagement in research—geography, culture, and socioeconomic status (Sapienza et al., 2007). Community input can be gleaned from a variety of methods, such as in-person community events, focus groups, social media campaigns, etc. The specific methods used to obtain community input should be consistent with how each community typically engages with those outside the community. Information gained from communities should be used to develop study recruitment and retention materials to improve community members' trust of the researchers, which in turn may increase participation rates (Booker et al., 2011).

To increase engagement of study participants, the research community, funders, and the population at large, one strategy is to deliver general, easily digestible, aggregated descriptive results of the study in a timely manner. However, within longitudinal studies, there are concerns related to reporting results. One is that reporting results could lead to behavior change among study participants. Yet, if the behavior change improves health, it would be unethical not to share the information. This concern could be balanced by determining how information is presented to stakeholders—whether it is individual results delivered to study participants, aggregate results for a national or a regional demographic group, or a general national data brief of study findings (e.g., a national study on post-partum depression and child development).

Communication of study findings can be enhanced by clear, proactive, and high-impact messaging and communication practices culled from the fields of science and risk communication (Fischhoff, 2013). Robust communication of research results will allow stakeholders throughout the nation to develop a vested interest in the study outcomes, which will in turn increase the impact of the science by increasing uptake and sustainability of the public health agenda and promoting evidence-based decision making in policy (Woolf et al., 2015).

DATA COLLECTION METHODS

Since the initial planning of the NCS in the early 2000s, data collection methodologies have evolved rapidly. Today, methods are available to collect survey data more cost-effectively and in ways that are less burdensome to respondents. For example, respondents can complete questionnaires online rather than scheduling a home interview, which holds promise for a longitudinal study with geographically mobile par-

ticipants. When designing the specifics of a particular protocol, researchers could leverage features like these to reduce study costs and respondent burden. The study could collect various types of data, including survey questionnaires, physical measurements, administrative records, and neighborhood conditions, from existing social and environmental data. Although challenging now, it will be possible in the not-too-distant future to substitute administrative data for some of the information now collected in interviews. The collection of global positioning system (GPS) coordinates for sample participants is common and will fulfill a number of important needs for data collection and interpretation now and in the future (Lioy et al., 2009). Smartphones are now routinely used to passively collect data on movement, exercise, and standing activity (del Rosario et al., 2015) and define exposures throughout the day (Browning and Soller, 2014).

Next, we briefly outline three key dimensions of the data that need to be collected for a national longitudinal birth cohort study.

Measurement of Health

The study should include measures of the physical and mental health, as well as the well-being, of the study participants. The study should rely on outcome measurement tools that have been developed through the National Institutes of Health in recent years for children and adults, such as the Patient Reported Outcomes Measurement Information System (PROMIS). To assess child outcomes, PROMIS pediatric self-reported instruments are available for children ages 8–17, and parent proxy reports are available for children ages 5–17. PROMIS covers the physical health domains—fatigue, mobility, asthma, and pain behavior—and the mental health domains—anxiety, depression, and anger (NIH, 2016).

The study should also collect blood and urine samples from participants frequently. These samples can be analyzed for a variety of measures, including genetics, epigenetics (DNA methylation and histone modification), and common biomedical indicators, such as glucose, lipids, and hormones, etc. Given that the study will have already partnered with hospitals and prenatal providers for recruitment, it may also be possible to extend that partnership to pediatricians, who could report common health measures such as height, weight, pulse, blood pressure, vision, hearing, other developmental measurements, and assessments to monitor well-being. Finally, while not quite a reality today, within the timeframe of the study we propose, it is probable that the complete medical history of each child will be available to researchers through electronic medical records (EMRs). Sampled persons' EMRs will be a vital data resource within a cohort study because they allow for phenotyping and public health surveillance without undue burden on the study participants. EMRs hold great promise for epidemiological research, although they have not yet been used in a national cohort study across hospital systems (Hruby et al., 2016).

Social Environment Tools

As discussed in the previous paper in this series, the study we propose will need to collect extensive data on the social environment, including the family environment, accessibility of health care, cultural factors, experiences of violence, social networks and support, media exposure and use, screen time, and the built environment.[1] A growing literature suggests that, individually and together, aspects of the social environment have consequences for the health and well-being of children and adults (Duong and Bradshaw, 2016; Golding et al., 2009; Wright et al., 1998).

Some data on the social environment are routinely collected in many surveys. For example, household roster data can be used to measure the presence and characteristics (age, occupation, education, etc.) of the biological mother and father, social mother and father, siblings, and other adult relatives, including grandpar-

[1] The man-made parts of the environment where respondents live and work or attend school.

ents. As part of this, it is important to measure not only race and ethnicity, but also the immigrant status and home country of the parents and grandparents, as well as languages spoken. It is also important to measure the resources available, including family income, parental education, labor force status, and availability and type of health insurance. Life events—such as the death, serious illness or injury, or incarceration of a family member—are socially patterned and help to shed light on health disparities. Social networks can be evaluated by leveraging information about how contacts that are provided to the study for tracing purposes change over time, as was done in the Framingham Heart Study.

Another class of important social factors, such as parenting style, interpersonal relationships, family conflict, control, and organization, are less commonly measured. However, because they are most proximal in children's lives, these factors are often the most powerful (Bronfenbrenner and Morris, 2007). When determining what tools to use to measure these important social factors, we can look to studies such as the Early Childhood Longitudinal Study-Birth Cohort (ECLS-B). There are well-documented measures of social factors for the neighborhood—such as cohesion and social control, crime and safety, concentrated disadvantage and affluence, ethnic and racial segregation, neighborhood turnover, availability of green spaces, walkability, food store availability, and accessibility of health care and other services. Some neighborhood measures require input from the respondent, but many draw on external resources, such as street maps and other data sources, like the American Community Survey, which serves to reduce respondent burden.

Recently, studies are also beginning to measure the impact of digital technologies on child health and development. Access to and use of these technologies can be measured via questionnaire, as is already being done in many studies (Duch et al., 2013). These questionnaire-based measures can be complemented by observations of devices in the home.

Chemical, Physical, and Nutritional Environment Tools

Measures of the chemical, physical, and nutritional environments of children and their parents are necessary to understand health outcomes across development, socioeconomic, and geographic boundaries. Highly promising technologies provide an unprecedented measurement platform for collecting these data. Examples include more efficient dietary intake assessments, remote sensing, passive personal monitors, improved analytical chemistry, and new types of biological samples. Dietary intakes can now be measured with reasonable accuracy using Web-based 24-hour recalls or mobile phone–based food diaries (Diep et al., 2015; Ravi et al., 2015; Thompson et al., 2015). Remote sensing enhances our ability to assess exposure to air toxicants because it can fill in gaps in time and place left by traditional ground-based monitoring systems (Al-Hamdan et al., 2014). As an example, remote sensing and available data have been used to develop well-established models to estimate exposures to air toxicants in populations across the globe (Geddes et al., 2016; van Donkelaar et al., 2015). Passive personal monitors, such as silicone wristbands, can be used to measure exposures from a suite of environmental chemicals. These wristbands do not require calibration, batteries, or extensive preparation and can provide individualized exposure data for both parents and children (Kile et al., 2016; O'Connell et al., 2014a,b). With recent improvements in analytical chemistry, targeted and untargeted analytical chemistry approaches can be used to obtain measurements of hundreds of chemicals in relatively few assays.

New types of biological samples, such as deciduous teeth, hair, and blood spots, can be used for exposure assessment purposes. For example, after deciduous teeth fall out, participating parents can mail them to the study coordinating center, where they can be sent to a laboratory and analyzed with sophisticated methodologies that combine histological and chemical analysis to precisely sample tooth layers that correspond to specific life stages. These analyses have the potential to reconstruct exposure in the second and third trimesters of prenatal development and during early childhood (Arora and Austin, 2013). Much like

tooth analysis, shafts of hair can provide a temporal record of exposures and response to metals and other chemicals, and can also record biological responses, such as cortisol content in the hair (Kirschbaum et al., 2009; Moro et al., 1992; Raeppel et al., 2016). Deciduous teeth and hair samples allow for more specific characterization than can be produced using other relatively inexpensive measures, such as questionnaires. They also reduce the number of samples needed, as exposures from more than one time point can be measured in a single sample.

Other Data Collection Considerations

It is very likely that available data collection technologies will expand and improve during the course of following a birth cohort through infancy, childhood, adolescence, and adulthood. Therefore, the study we propose will need to be flexible and able to adopt new technologies as they become accepted for use in research. Numerous technologies undergoing development and testing will expand the study's ability to collect data in more cost-effective and less burdensome ways.

Two more examples that have been tested in smaller-scale or cross-sectional studies are GPS tracking of participants and mobile phones that are enhanced with applications and sensors. These can collect a range of exposure and outcome information and have the potential to provide major advancements in understanding how children and adolescents move through and interact with environments and exposures. Tracking this movement with GPS-enabled devices will not only provide more precise exposure measurements, but will also shed light on socioeconomic and racial/ethnic differences in those exposures. Pilot studies collecting this kind of data are currently under way in different locations across the country. While it is not yet possible to bring this work to a national scale, it will be possible to do so within the foreseeable future (Browning and Soller, 2014; Elgethun et al., 2003; Fenske et al., 2005; Viet et al., 2013).

Studies have used mobile phones to monitor noise (Neitzel et al., 2016) and exposure to air pollutants (Nieuwenhuijsen et al., 2014, 2015). By monitoring changes in behavior, phones can be used to track daily stress levels (Bogomolov et al., 2014a), social networks (Onnela et al., 2014), and, when coupled with demographics, possibly crime risk (Bogomolov et al., 2014b). As with GPS technologies, these tools show great promise, but work is still needed to bring them to a national scale. Thus, although valid and reliable measures to capture key aspects of the social and physical environment are available now, we can reasonably expect measurement opportunities to improve in the near future.

DATA ORGANIZATION, MANAGEMENT, AND RELEASE

Good data management practices will help the proposed birth cohort study maximize its benefits to the research community and public. The study will repeatedly collect substantial amounts of data on study participants through a variety of means, including questionnaires, diaries, biological specimens and environmental samples, direct monitoring, EMRs, GPS coordinates, and links to administrative data. Providing security for collection and initial transfers of data—and organizing, documenting, storing, and releasing appropriately protected versions of these data to the research community—requires considerable effort, diverse expertise, and advance planning. Fortunately, solutions to these problems have been developed in a number of national studies over the past several decades. Furthermore, the experience and expertise needed to adapt these solutions to the evolving landscape with respect to data collection modality and participant engagement are already available.

The two most important components to consider in a data organization plan are (1) standardization of protocols and data management procedures and (2) data release to and dialogue with the general research community. The most successful national data collection studies are highly centralized, with a central office

overseeing the design of the data collection instruments, field data collection operations, data coding and cleaning, linkages across data components and to external data, and documentation and release of the collected data with appropriate levels of protection for the confidentiality/privacy of the respondents. Distributing these duties to regional centers can create inefficiencies and introduce opportunities for data noncomparability. Specialized tasks, such as assembling administrative records and performing specimen assays, may be subcontracted to third parties, but it is vital to monitor these processes centrally.

Timely release of data to the research community increases the scientific benefits generated from large public investments in studies such as the one proposed. We recommend that the data be released to the research community as soon as they are cleaned and documented. Existing national studies such as the Panel Study of Income Dynamics have been releasing data shortly after cleaning for more than 40 years. In addition, the National Longitudinal Study of Adolescent to Adult Health shares many of the characteristics of the study we propose, such as data collected from questionnaires, biological, and administrative data. This program has applied a policy for immediate data release over the past 20 years.

In planning for data release, it is vital to maintain the confidentiality of the study participants. This is difficult to do in longitudinal studies, but various data access modes (statistical enclaves, restricted use and public use files), and a variety of statistical disclosure control methods, can be employed to protect participant privacy while allowing researcher access to the data (Domingo-Ferrer and Muralidhar, 2016; Duncan et al., 2011; Hundepool et al., 2012).

Different organizational structures could be considered to manage the proposed study. In the United States, some large-scale longitudinal studies have been managed by statistical agencies with extensive statistical and survey experience, but these have often included collaborations with survey organizations for data collection. Other such studies have been managed by university-based groups with one or more principal investigators who bring scientific and survey knowledge to the project with funding obtained from a federal grant or cooperative agreement. A university research group can collaborate with or subcontract to a survey research organization for data collection, training, and management. While there are advantages and disadvantages to both approaches, considerations should be made to allow for flexibility, bureaucracy, and regulatory burdens (e.g., Office of Management and Budget clearance, compliance with the Federal Information Security Modernization Act).

CONCLUSION

The NCS, as well as a number of similar studies conducted both in the United States and abroad, have produced a wealth of information regarding methodologies that can be used to design a nationally representative birth cohort study. A study of this magnitude requires a breadth of expertise and ample time for design. In terms of content, the designers of this new study can tap into lessons learned from the NCS and other studies to make well-informed decisions about measures to be included—balancing the scientific importance of the measures with their logistical feasibility, costs, and respondent burden. Designers should engage stakeholders early in the implementation phase to get input for recruitment and as results are being released to show funders, other stakeholders, and society at large the benefits of the research.

In this paper, we provide reasonable and actionable guidance regarding what can be moved forward from the NCS and other experiences and outline how that work may be coupled with improvements in technology for data collection to make a new birth cohort study logistically feasible and cost-effective. This guidance, coupled with recommendations for study management and oversight in the NRC/IOM review of the NCS (2014), provide a solid platform on which such a study could be built.

Our nation desperately needs data that can be collected only in a nationally representative birth cohort study of the type we have outlined. Such data will allow policy makers, researchers, and others to under-

stand how the social, physical, chemical, and nutritional environments all interact to impact how Americans grow, live, and prosper. Such data are critical to identify those at heightened risk so that interventions may be applied early to promote optimal development and help end health disparities.

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