



SPECIAL ARTICLE

The uncertain fate of the National Institutes of Health (NIH) pediatric research portfolio

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BACKGROUND: The amount of federal dollars allocated to improving the health of our pediatric population can serve as an indicator of the priority placed on child well-being. Although Congress has established novel mechanisms that marginally increase pediatric research funding, the pediatric research portfolio is facing an increasingly uncertain fate.

METHODS: This work examines pediatric, perinatal and pediatric research initiative (PRI) spending using data collected by the NIH that uses the novel research, condition and disease categorization system. Further, this work reports on recent policy developments in pediatric biomedical research and offers recommendations to insulate this portfolio from future uncertainty.

RESULTS: Federal support for pediatric research has declined with average annual growth rates of NIH pediatric spending dropping from 12.8% (FY 1998–2003) to 1.7% (FY 2004–2015). After taking into account Biomedical Research and Development Price Index growth, the pediatric research portfolio's purchasing power has declined by 15.9% (FY 2004–2015).

CONCLUSION: Federal support for pediatric biomedical research has plateaued in nominal terms and declined significantly in real terms. Future congressional action will be necessary to protect gains and to expand the capacity of the pediatric portfolio.

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INTRODUCTION

The amount of federal dollars allocated to improving the health of our pediatric population can serve as an indicator of the priority placed on child well-being. Although the proportion of federal spending on children has increased from 3.2% (1960) to 10.7% (2010), future projections indicate that this will decline to 7.7% (2026). (Children were defined as individuals under 19 years of age who are not yet engaged in postsecondary education.) Thus, although child well-being may have been increasing as a national priority, the policy terrain may be shifting.^{1,2}

Prior reports have reviewed early political activity relevant to pediatric research funding.^{2–4} To summarize, basic science and adult research have historically been the primary focus of National Institutes of Health (NIH) funding.^{2,5,6} Our prior research efforts have characterized pediatric research funding trends over time and in relation to the NIH budget. For example, Gitterman et al. (2004) focused on NIH pediatric research funding during the doubling period (fiscal year (FY) 1998–2003) when Congressional appropriations nearly doubled (from \$13.6 to \$27.1 billion).³ Gitterman et al. (2009) provided an update during the post-doubling era (FY 2004–2009) when previous gains were eroded, both in terms of overall NIH and pediatric spending for research and research training.⁴ Gitterman et al. (2018) updated the status of the NIH pediatric research budget during the Obama era (FY 2010–2015).²

Consistent with prior research efforts, our purpose here is not to frame resource allocation as a zero-sum game between diseases that affect children versus those that impact adults. Rather, we report on the pediatric research portfolio over time and in relation to the overall NIH budget. Given that resolving diseases that originate at the origin of life will yield considerable benefits in

terms of both improved health and economic productivity to individuals later in life, we believe a spotlight on pediatric research is of critical importance.²

PUBLIC POLICY AND PEDIATRIC RESEARCH 2000–2018

In the 1990s, Congress recognized the lack of resources devoted to pediatric research and requested that performance indicators be developed so NIH could report on specifically identified progress toward strengthening the pediatric research portfolio.^{2,7} As a result, the NIH Budget Office instructed all Institutes and Centers (ICs) to report each research area's total funding, including pediatrics. (NIH categorizes its funding in a variety of manners to satisfy diverse reporting requirements. Funding is tracked for specific diseases [Alzheimer's disease, breast cancer, etc.], for various conditions [infertility, obesity, etc.] and specific areas of research [genetics, substance abuse, etc.]. See <http://www.nih.gov/news/fundingresearchareas.htm>)² The inaugural NIH report on Pediatric Research (1996) indicated a commitment to effectively measure NIH's progress toward a strengthened pediatric research portfolio. An extensive discussion of the specific performance indicators to be used was, however, absent.^{2,8}

In 2000, the Children's Health Act was passed by Congress to address underinvestment in pediatric research. This act authorized an expansion of pediatric research activities at the NIH through several mechanisms, including the Pediatric Research Initiative (PRI) and National Children's Study (NCS). (The Children's Health Act of 2000 [P.L. 106-310] merged a number of individual bills and provisions into one piece of legislation. The NCS would allow a comprehensive, life course, developmental approach to tracing the influences of genetic and other biological, social,

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environmental, and behavioral factors on human development, health, and disease from conception onward.)²

The purpose of the PRI was to expand various aspects of the pediatric research portfolio, including research funding, collaborations across the NIH, and loan repayment programs, as well as to accelerate clinical trials. Despite this commitment, additional funds were not allocated to expanded research efforts. This challenges NIH to expand its pediatric research portfolio while maintaining constant spending levels, clearly a difficult to impossible task. The NICHD was charged with coordinating the PRI and preparing an annual report detailing the status of the PRI and the pediatric research portfolio. (The CHA directed the OD to: "... be responsible for the oversight of any newly appropriated Initiative funds and annually report to Congress and the public on the extent of the total funds obligated to conduct or support pediatric research across the NIH, including the specific support and research awards allocated through the Initiative [PRI]" [Sec. 409D(c)(3), the Public Health Service Act].)⁹ The most recent report (FY 2016) highlights recent efforts across the NIH (link [here](#)).¹⁰

The NCS sought to test a range of hypotheses regarding how environmental factors affect children's health. The study plan included a large population sample, which would be representative of the United States. However, the study was curtailed in 2014 after >\$1.2 billion was spent on planning and preliminary data collection.¹¹ Swelling cost projections (\$3–\$7 billion) and allegations of mismanagement caused Congressional and NIH leaders to question the viability of the program.^{12,13} Ultimately, the program was discontinued.¹¹

Remaining NCS funds were redirected toward two initiatives. The first, the Environmental influences on Child Health Outcomes (ECHO) project, has similar goals to the NCS but seeks to reduce costs by narrowing the scope and improving recruitment by connecting existing studies.^{2,14–17} While ECHO does represent continued funding for pediatric-related research, the focus is limited to the effects of environmental influences on development.

In an effort to establish state-level research networks, the National Pediatric Research Network Act (NPRN, P.L. 113-55) was enacted by Congress in 2013. However, specific budget allocations have not been made. Thus it remains an unfunded mandate. Despite NPRN and ECHO having divergent aims, it is likely they will compete for the same resources within NICHD and NIH unless each program receives additional resources via Congressional appropriations. In the interim, NICHD and NIH will continue to provide evidence that they are either meeting or showing good faith in attempting to meet the aims of the two programs.

A second initiative aims to improve access to clinical trials for under-represented children via the Institutional Development Award program, which supports research in states with limited NIH funding.^{2,18} The goal is to provide the necessary resources to conduct pediatric clinical trials for children with a variety of conditions. (NIH RFA files [RFA-OD-16-001], 2015 [<https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-16-001.html>])² These efforts reflect the determination of NIH to achieve substantial goals under budgetary constraints.

Under the Gabriella Miller Kids First Research Act (inspired by a 10-year-old Virginian brain cancer patient), Congress authorized an estimated \$126 million toward pediatric research funding over a 10-year period.¹⁹ This authorization re-directed funds collected from a U.S. tax form check-off box, which originally provided funding for national political conventions. The funding is distributed annually through the NIH Common Fund and must be appropriated each year, concurrent with NIH funding.^{20,21} Based on current NIH pediatric research spending (\$3.5 billion annually), these funds have expanded resources by approximately one quarter of 1%.

Importantly, Congress and President Obama, with the 21st Century Cures Act (P.L. 114–255), adopted additional reforms with implications for pediatric research. Congress provided the NIH and US Food and Drug Administration with greater resources, reduced administrative burdens, and increased access to data. While it enjoyed bipartisan support, Democrats offered the critique that it lacked mandatory spending, meaning funding must be allocated annually.²²

The NIH responded to a Congressional mandate in the 21st Century Cures Act, and scientific need, by holding a workshop with experts to examine how to better include pediatric and older populations in human subjects research (June 1–2, 2017; Notice Number: NOT-OD-17-059). In December 2017, NIH revised (NOT-OD-18-116) its decades-old policy initially conceived in response to concerns that the pediatric population was not sufficiently represented in clinical research. (NIH Revision: NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects. Search Funding Opportunities and Notices, 2017 [<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>])²

The policy requires that people across the lifespan, including children and older adults, be included in clinical research studies unless a scientific or ethical justification can be provided. For NIH applications on or after January 25, 2019, researchers who propose a study involving human subjects must have a plan describing how participants across the lifespan will be included and justify the proposed age range of participants. Furthermore, grant progress reports will be required to include de-identified individual-level demographic data that would include age and sex.²³

FEDERAL BUDGETS AND PEDIATRIC RESEARCH

Other policy factors influenced the NIH pediatric research budget over the past decade. First, the 2009 American Recovery and Reinvestment Act provided additional resources to the NIH (\$10.4 billion) and the pediatric research portfolio (\$952 million). While this one-time boost expanded research capacity, it did not provide sustainable long-term resources. Second, sequestration in 2013 significantly reduced both the NIH budget (–5.0%) and pediatric spending (–5.3%).²⁴ This added considerable uncertainty to future research with potentially serious negative impacts on long-term research programs and individual careers of pediatric researchers.

President Trump's FY 2018 budget reduced NIH funding by \$6 billion (–22% relative to FY 2017).²⁵ This represented a departure from historical precedent as presidential budget requests for the NIH have not fallen below an annual growth rate of 3.5% since 2003.²⁶ Concerns were alleviated with the adoption of the FY 2017 Omnibus Bill, whereby Congress increased the NIH budget by 6.2%.²⁷

The Trump FY 2019 budget increases the NIH budget by \$538 million over FY 2017. However, this budget consolidates three Department of Health and Human Services health-related research agencies.^{28,29} Although Congress has not agreed upon a final budget, early indications suggest that an increase is expected (\$1–2 billion).²⁹ Nevertheless, given the current policy landscape, the future of federal support for biomedical and pediatric research remains a cause for concern.

ASSESSING THE NIH PEDIATRIC BUDGET: METHODS AND DATA

The NIH has an obligation to allocate resources commensurate with public health needs. However, estimating these needs is challenging, as several valid measures of disease burden exist (e.g., prevalence and incidence). Thus the NIH considers multiple data types and sources, and each disease or condition is considered on a case-by-case basis.²

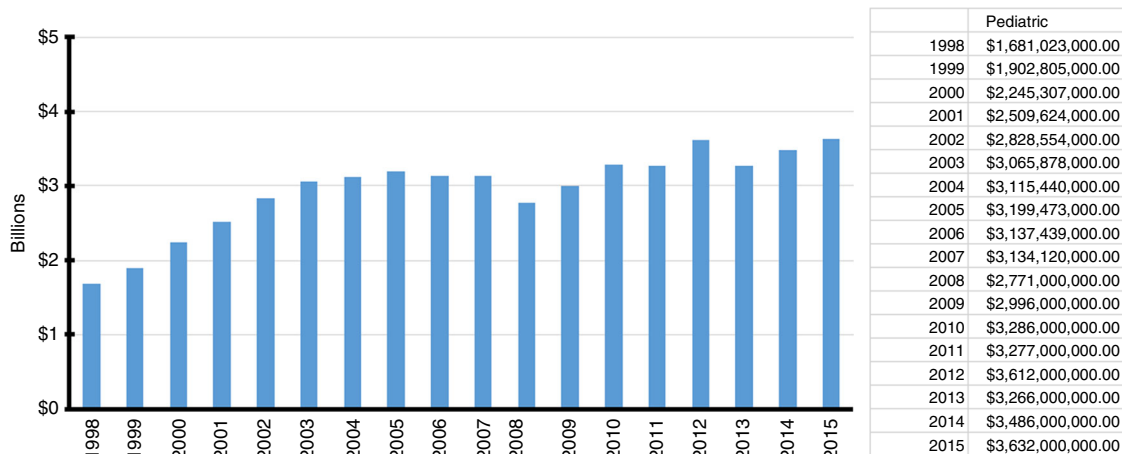


Fig. 1 Pediatric research spending (FY 1998–2015, nominal dollars). (In 2008, the NIH adopted the research, condition and disease categorization (RCDC) system, changing the method by which it estimates pediatric research funding. The RCDC system utilizes a text data mining program, together with NIH-wide definitions to match projects to disease categories. This improves consistency and eliminates variability in category reporting. The pediatric spending data presented here represent two data sources; pre-2008 data were estimated by each institute and provided by the NIH budget office,^{2,4} post-2008 data were estimated via the RCDC system and obtained via the NIH website.^{2,40} The RCDC system is modified on an annual basis, therefore grants that are identified as pediatric vary considerably over time. However, the data presented here represents the best NIH estimates and is consistent with other data sources.^[2,41] [NIH internal data, National Institutes of Health, Office of Budget. Pediatric Research - FY2008 through FY2013 Actual Annual Funding. Obtained under the Freedom of Information Act from NIH, 2017.]^{40,41}

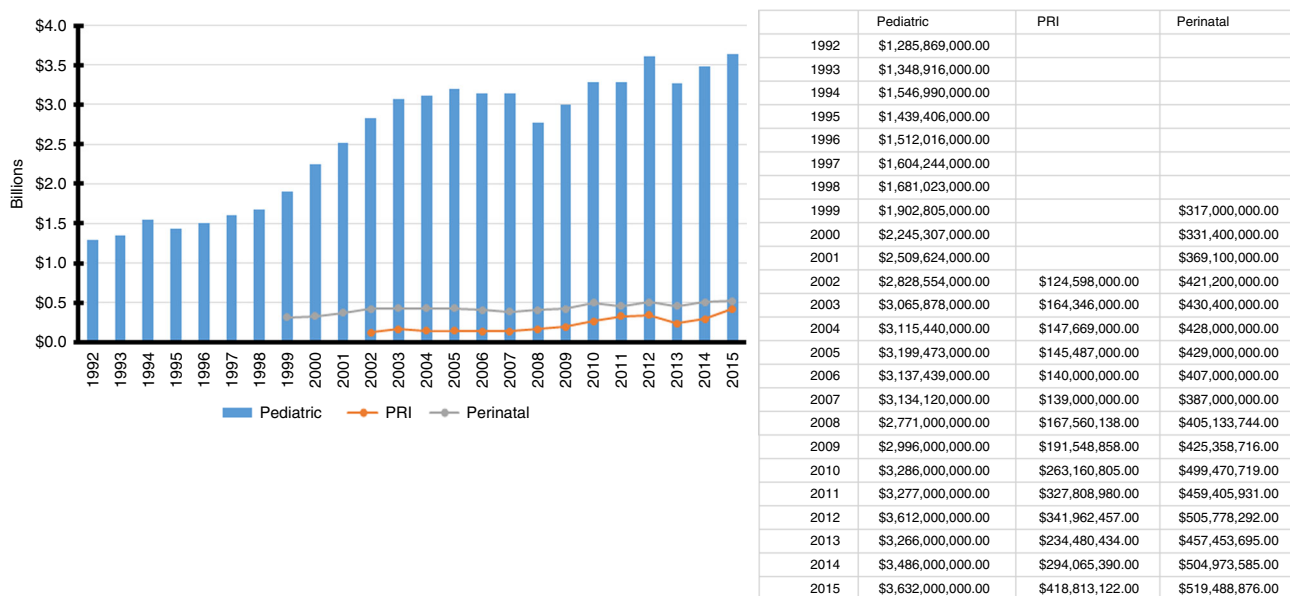


Fig. 2 Pediatric Research Initiative (PRI) and perinatal funding relative to total pediatric research funding (FY 1992–2015). Each of these values represents grant expenditures. (NIH internal data, National Institutes of Health, Office of Budget. Pediatric Research - FY2008 through FY2013 Actual Annual Funding. Obtained under the Freedom of Information Act from NIH, 2017.)^{4,40,41}

The NIH has defined pediatric research as “studies in all categories of biomedical research (basic, clinical, epidemiologic, behavioral, prevention, treatment, and diagnosis, as well as outcomes and health services) that relate to diseases, conditions, or the health/development of neonates, infants, children, and adolescents up to age 18.” (NICHD internal memo on definition of research on children, June 12, 1997).^{2,4,30}

We define the NIH pediatric research portfolio as the total NIH expenditures used to conduct or support pediatric research, both clinical and basic. Our analysis does not attempt to examine whether pediatric funding levels are commensurate with disease

burden. Instead, we report the pediatric research budget over time and in relation to the overall NIH budget.^{2–4} The data presented in Figure 1 represents pediatric spending from FY 1998 to FY 2015.² During the doubling era (FY 1998–2003) the average annual growth rate of pediatric spending (12.8%) was strong. Recently (FY 2004–2015), the average annual growth rate of pediatric spending (1.7%) has plateaued. This and Biomedical Research and Development Price Index growth rates (3.1%) have reduced the purchasing power of the pediatric research portfolio (–15.9%). This has significantly diminished investigators’ capacity to conduct research.²

Figure 2 reports PRI and perinatal spending in relation to overall pediatric spending between FY 1992 and 2015. The PRI, which is a portion of all pediatric research funding, has been defined by the NIH Inter-Institute Committee on Pediatric Research. It is defined as new, IC-initiated, research and substantial expansions of previously initiated research. These are initiatives for which specific funds had been allocated by ICs (e.g. requests for applications or RFAs, requests for proposals or RFPs, and program announcements with set asides or PASs).

“Significant expansions” include expanding existing IC initiative resources beyond initial commitments. This includes expanding an existing initiative by adding a grant or site, expanding or adding a pediatric population to a current study, establishing an inter-IC collaboration to enhance pediatric research, or expanding the pay line of pediatric research career development grants. PRI reporting does not capture new and expanded investigator-initiated pediatric research projects.

The term perinatal refers to the time period just before and after delivery. The funding categorization system used here, NIH’s Research, Condition, and Disease Categorization system, specifically defines the perinatal period as “beginning the twentieth week of gestation and ending four weeks after birth.”^{31–33} Consistent with other trends, perinatal spending has recently been relatively weak (2004–2015 mean annual growth rate: 1.9%). Correspondingly, it has remained a relatively constant proportion of the overall pediatric research portfolio (13.7–14.3%).

Again, consistent with other trends, the purchasing power of the perinatal portfolio has been diminished (–12.4%) over this period. Moreover, perinatal spending is a small fraction of overall pediatric spending.

CONCLUSIONS AND RECOMMENDATIONS

Although Congress has focused new attention on the pediatric research portfolio, the increase in spending has been on the margins. As the current budget environment remains uncertain, the NIH and pediatric portfolios will become increasingly vulnerable.

First, the PRI was intended to provide “dedicated, identifiable dollars that represented new funding.” However, Congress has yet to follow through on this intention. (According to a key staffer familiar with the original CHA debate, Congress never intended to make earmarked appropriations, consistent with its usual practice of funding ICs but not disease areas or subpopulations. Accordingly, “it was expected that NIH would allocate dollars from within its overall budget to fund research consistent with the PRI.”)² The PRI has been funded by two mechanisms, a one-time allotment provided by the NIH Director’s Discretionary Fund (\$5 million, FY 2002) and grants and contracts within existing IC budgets. Thus the PRI has become an “unfunded mandate.” If Congress hopes to expand the capacity of the current pediatric research portfolio, specific appropriations dedicated to the PRI must be made.²

Second, pediatric researchers and disease advocates need to develop and communicate novel evidence and arguments regarding the benefits of pediatric biomedical research, both in terms of enhanced individual health outcomes for children and adults and in terms of economic and societal benefits.² Indeed, research conducted across the NIH reveals a considerable body of evidence showing the benefits to child health.^{2,34–37} Perhaps even more persuasively, it has been shown that these benefits continue throughout the lifespan.^{2,38,39} Moreover, an increased proportion of pediatric research support should be directed toward investigations conducted alongside obstetricians and maternal–fetal medicine specialists. This perinatal approach recognizes that a healthy mother is much more likely to produce a healthy infant, child, adolescent, and, ultimately, adult.² As we plan for the future, it is imperative that policymakers support and NIH prioritize investment in lines of inquiry that elucidate the

mechanisms of developmental processes, which direct the emergence and progression of disorders both early in life and through adulthood.

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AUTHOR CONTRIBUTIONS

All the authors contributed to study conception and design, data analysis and interpretation, drafting and revising the article, and final approval of the published version.

ADDITIONAL INFORMATION

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