

# Why Should There Be an NICHD?

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## KEY WORDS

research, pediatric research, pediatric disease, history

## ABBREVIATIONS

NICHD—Eunice Kennedy Shriver National Institute of Child Health and Human Development

NIH—National Institutes of Health

AAP—American Academy of Pediatrics

AMSPDC—Association of Medical School Pediatric Department Chairs

PSDP—Pediatric Scientist Development Program

Hib—*Haemophilus influenzae* type b

SIDS—sudden infant death syndrome

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## abstract



In its nearly 5 decades of existence, the Eunice Kennedy Shriver National Institute of Child Health and Human Development has expended \$23 billion in conducting and supporting research and translating discoveries to practice. The resulting dramatic impact on peoples' lives and improved health for children and families, chronicled herein, are a testament to the benefits of having this institute at the National Institutes of Health. *Pediatrics* 2011;127:325–333

By act of Congress there has been a National Institute of Child Health and Human Development (NICHD) at the US National Institutes of Health (NIH) since 1962. The ensuing nearly 5 decades have seen an enormous growth in medical knowledge and advances in ability to enhance healthy development and save lives. Nowhere have these changes been more dramatic than in obstetrics and pediatrics, and the NICHD often played a leading or facilitating role that is often unrecognized or underappreciated. Recounting the institute's historical role in these transformations provides a dramatic example of how the presence of the NICHD fostered and enhanced our ability to improve the well-being of our children and families, as well as the benefits to pediatricians and the American people from having an NICHD.

Setting the stage for the advent of the NICHD requires returning to look at the NIH of 1960. Like most of the rest of the federal government, the NIH was much different from what it is today. Mostly it was smaller. It had moved to the Bethesda campus, constructed for it only in 1940. The National Cancer Institute was the only separate institute until after World War II, and the extramural program did not exist until after the war. There were only 8 institutes, and the total NIH budget was \$400 million in 1960. The dramatic growth spurt of the NIH under Director James Shannon and his friends and allies Congressman John Fogarty and Senator Lister Hill, chairs of their appropriations subcommittees for the NIH, was just beginning, and the NIH budget doubled in the next 3 years. In this NIH research portfolio, there was little research on children or pregnancy.

This situation was about to change. The immediate precipitating factor was clinical research. The major focus of the NIH had been basic biomedical laboratory-based research. With a con-

gressional appropriation in the 1950s, the NIH built a large research hospital on its Bethesda campus that opened in 1953. Patients could be brought to this clinical center from all over the world to participate in research on their disease or condition and receive free care in return. The outside medical community had nothing like this and pressured the NIH to have a comparable clinical research program extramurally. In response, the NIH in 1959–1960 announced a new grant program for general clinical research centers that would provide support for the cost of hospitalization and research personnel for the study of patients with a spectrum of diseases. These grants were directed to adult medicine departments.

The exclusion of the possibility of funding for pediatrics infuriated Dr Robert E. Cooke, chair of the Department of Pediatrics at Johns Hopkins. He scheduled an appointment with NIH Director Shannon to protest this limitation and ask that eligibility for general clinical research center grants be expanded to include pediatric departments and children. As Dr Cooke described it,<sup>1</sup> Dr Shannon's response was that expansion was not necessary because children were basically small adults, and answers would be found from adult studies and extrapolated to children.

Cooke departed politely but determined to do something to change this situation if he got the chance. The opportunity came a few months later when John Kennedy was elected President. Through his friendship with the President-elect's sister, Eunice Kennedy Shriver, whom he had gotten to know through their mutual interest in mental retardation, Cooke was appointed to what we would today call the "transition team" to develop proposed initiatives in health, education, and welfare for the new administration. Chaired by Wilbur Cohen, with no

staff support for the 7 members, this was the vehicle Cooke used to put forth his idea to get the NIH to focus more research on children and disability. He proposed adding a new institute to the 8 existing institutes at the NIH to focus research not primarily on diseases of children, which were covered by other institutes such as the National Cancer Institute and National Institute of Allergy and Infectious Diseases, but on the processes of development, normal and abnormal, that led to healthy lives or to illness or disability. Much of the focus would be on improving pregnancy outcome, early detection and intervention to prevent disease and disability, and the interaction of social and educational and behavioral factors with biological status in ways that positively or negatively affect development. Cooke easily won the endorsement of the committee, and they traveled to Connecticut to present their ideas, which included Medicare, to Governor Abraham Ribicoff, who was designated to become Kennedy's Secretary of the Department of Health, Education, and Welfare. Ribicoff was cool to the idea of a new NIH institute (which the NIH opposed), and it was in jeopardy until Ted Sorenson, the great writer of Kennedy's inaugural address and other speeches, spoke up in favor of it. He pointed out that, from a political standpoint, the new administration was going to be talking about the youthful new president, the torch being passed to a new generation, and an administration called the New Frontier, and without Cooke's Child Health Institute, the only big program forthcoming from the Department of Health, Education, and Welfare team would be Medicare for the elderly. Cooke's institute was needed for balance to provide something for the younger generation. Sorenson's arguments were persuasive, and the new Child Health Institute remained in the plan forwarded to President Kennedy. His initial reluc-

tance because of cost was overcome by persuasion from his sister Eunice, and the proposal for a new Child Health Institute was part of the President's first health message to Congress. With strong support from child advocacy and disability groups, the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists, the national Parent-Teacher Association, and persuasion from Eunice Kennedy Shriver, Congress passed legislation establishing the NICHD\* at the NIH, and President Kennedy (with Eunice beside him) signed the bill into law on October 12, 1962.<sup>1</sup>

Since it became operative in 1963 as the ninth NIH institute, the NICHD has spent more than \$23 billion on research on maternal and child health and disability; its current budget is \$1.3 billion per year. It is appropriate to ask what the return has been on this investment for children, women, and families. Why do we need an NICHD? How have we benefited from having it? Any institute's activities can be categorized as passive or active. The passive activities are those funded in response to proposals initiated by non-NIH scientists that undergo a process of competitive scientific peer review to select the projects that are the most significant or promising. Institute staff provide advice and oversight but not initiation. This passive category constitutes approximately three-fourths of an institute's resources. The active category comprises research and related activities in which institute staff play an active role, with outside expert advice, in targeting, planning, soliciting, or managing the research of non-NIH scientists or serve as researchers in the institute's intramural program.

\*In 2007, Congress renamed the NICHD the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

Over the years there has been enormous scientific progress from the passive component; the NICHD alone has supported the research of 9 scientists who received the Nobel prize for their work. Nonetheless, it is the active role—the research solicited, the collaborations and partnerships established, the paths that otherwise would not have been taken—that relates most directly to the added value of having an NICHD or any institute. This active role includes efforts by the NICHD to enhance training and career development, selectively assist in moving a field ahead, answer a question or solve a problem in treatment or public health that is not otherwise being addressed, or translate research more rapidly to practice. The methods an institute uses in pursuing this active process include holding research conferences or consensus conferences on a targeted topic, developing special training mechanisms, establishing cooperative/collaborative research networks, initiating topical studies, mounting public education campaigns, contracting for specific research or product development, targeting intramural or extramural resources to a particular problem, and partnering with other agencies or organizations. All these methods have been used by NICHD staff in their active roles.

### TRAINING AND CAREER DEVELOPMENT

The starting point in building a research enterprise is attracting and training research scientists. Every field is attempting to get the “brightest and best” to work in their areas and have the research and grantsmanship skills needed to succeed in the highly competitive world of obtaining research funding support. As a new institute, the NICHD invested heavily in training from its beginning to help scientists in its fields of interest compete successfully.

In the mid-1980s, the leadership of academic pediatrics became concerned about the future supply of trained researchers as the next leaders and research-oriented department chairs. A committee was formed by the Association of Medical School Pediatric Department Chairs (AMSPDC) under the chairmanship of Dr Fred Battaglia of Colorado. He asked the NICHD to support and host a meeting of leading research-oriented academic pediatricians. This request was readily agreed to, and a dozen people met at the NICHD to address this issue. There was quick agreement on the need for improved intensive research training for new pediatricians with potential for leadership, providing protected time for this research training, and commitment to junior faculty status when completed. What was lacking was a mechanism to support such a program. The NICHD proposed using a new NIH career development program award (Physician Scientist Career Development Program Award [K-12]) that provided funds to a medical school department for research career development preparation for promising young physician-scientists for up to 5 years. The problems with these grants that resulted in little use were mainly the limited number of departments that had enough quality staff to train many people at once and the large out-year cumulative costs. The NICHD suggested that the grant time for NICHD support be shortened to 2 or 3 years, that years 3 through 5 be supported by the academic faculty site, that the AMSPDC be the grantee rather than a single medical school (to enable a central national recruitment and placement process to include the best laboratories in any discipline), that the AMSPDC augment NICHD funds by soliciting support from additional sources to permit a larger program, and that the progress of each trainee be monitored by an oversight committee of the AMSPDC. This

basic proposal with modifications was agreed to enthusiastically. A K-12 grant application was prepared, submitted for peer review, and funded by the NICHD as the Pediatric Scientist Development Program (PSDP). This program, currently led by Dr Peggy Hostetter, has been highly successful; its graduates have achieved high rates of NIH funding. Additional support has been provided by the AMSPDC, the AAP, the American Pediatric Society, the March of Dimes, pediatric hospitals, and others. Living up to expectations, some of its early participants have already become research-intensive department chairs. A counterpart program for Canadian pediatricians has been established and funded by Canada, sharing the organization infrastructure of the PSDP. Comparable programs have been established in the NICHD for reproductive scientists and for rehabilitation scientists. The PSDP is a prime example of what can be accomplished when an institute engages with its constituent scientific community to address a shared problem.

Valuable as the PSDP has been, the number of physician-scientists graduating from the program was less than 10 per year, only a fraction of the number needed. Again in consultation with the scientific communities, the NICHD in the 1990s initiated a program with features similar to those of the PSDP but based in individual pediatric departments rather than in the AMSPDC. These Physician Scientist Career Development Program Award grants to 20 sites, awarded competitively, constitute the Child Health Research Career Development Program and provide comparable research preparation for 3 to 4 scholars each per year, together graduating 20 to 40 newly trained research pediatricians per year who have an exceptional track record in acquiring research support.

In an effort to encourage and assist

pediatricians (especially neonatologists) and obstetrician-gynecologists (especially maternal-fetal medicine and infertility specialists) in pursuing research as a career and collaborating to address the problems of prematurity and neonatal mortality, the NICHD partnered with the University of Colorado beginning in 1988 to sponsor a conference on maternal-fetal-neonatal medicine in Aspen, Colorado. Led initially by Joe Butterfield and now by Bill Hay, this popular conference for fellows in these subspecialties has persuaded many of them to give research a try, and many have gone on to succeed in academic careers as NIH-funded investigators.

## NETWORKS

The National Cancer Institute and National Heart, Lung, and Blood Institute have a history of successfully using cooperative multisite clinical trial networks with common protocols to assess effectiveness and safety of therapeutic interventions. In the mid-1980s the NICHD made a decision to use this mechanism to conduct clinical trials in obstetrics (maternal-fetal medicine) and pediatrics (neonatology). These 2 networks were funded by peer-reviewed, competitively awarded cooperative agreement grants; NICHD staff participated in the group's governance and decision-making and supported a study and data-coordinating center. The group of principal investigators and NICHD staff select the topics and develop the study design and protocol, which receives outside review, and establish a data and safety-monitoring committee that reports to the institute's director. First funded in 1986, there are currently 14 maternal-fetal medicine and 16 neonatal sites, plus data centers. The networks have played a significant role in shaping and improving practice in their fields. For example, routine administration of intravenous immunoglobulin to prema-

ture infants, home uterine activity monitoring, and pulse oximetry during labor were all shown to have no benefit, and their use was stopped. On the other hand, antenatal steroid administration to women in preterm labor to accelerate lung development and reduce respiratory distress syndrome,<sup>†</sup> administration of 17-OH progesterone to prevent premature labor in women with a previous preterm birth,<sup>2</sup> and use of inhaled nitric oxide for hypoxic near-term neonates to reduce the need for extracorporeal membrane oxygenation<sup>3</sup> were all shown to be effective and have moved into practice. Beyond the immediate benefits, numerous scientists have learned clinical trial methodology by assisting in the networks and have gone on to design and conduct cooperative clinical trials on their own. The network mechanism has proved so successful that the NICHD has established other research networks in pediatric and obstetric pharmacology, pediatric injury and intensive care/rehabilitation, adolescent AIDS, and global maternal and child health.

## NEWBORN SCREENING

The excitement engendered by demonstration that the severe mental retardation associated with the genetic metabolic disease phenylketonuria could be prevented by neonatal detection and dietary treatment played a major role in the successful arguments for establishment of the NICHD. If a disease that inevitably resulted in severe-to-profound retardation could be identified in newborns by screening 1 drop of their blood for the disorder, and its symptoms could be prevented

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<sup>†</sup>The combination of antenatal steroid administration, surfactant treatment, and improved respiratory techniques markedly reduced respiratory distress syndrome. In 1963, President Kennedy's infant son Patrick was born prematurely. At his birth weight and gestational age he had a 90% chance of dying; today he would have had a 95% chance of surviving.

by dietary treatment, there was a huge potential not for phenylketonuria treatment alone but also from possibly finding other genetic metabolic disorders that could similarly be detected by newborn screening in time to initiate preventive treatment. One role for the NICHD would be to lead the search for other phenylketonurias. The first contribution of the NICHD to this field was to conduct a comparison study of physical and intellectual function at age 7 of children with phenylketonuria identified by newborn screening and treated with the protective diet in comparison to their siblings without phenylketonuria. The study showed that the treated children with phenylketonuria performed as well as their unaffected siblings.<sup>4</sup> With this information, the public health system moved to initiate universal screening of newborns for phenylketonuria, which every state implemented. But unfortunately, conditions like phenylketonuria were few and far between. Either the screen was difficult or very expensive or there was no effective treatment. One exciting exception was newborn screening for congenital hypothyroidism, developed by Dr Del Fisher in his University of California San Francisco laboratory with NICHD support. Using the same filter-paper blood spots obtained for phenylketonuria screening, he developed and automated microassays for thyroid hormone and thyrotropin to yield a diagnosis in time to begin thyroid hormone-replacement therapy before brain damage occurred. This assay added 1000 children who were annually spared mental retardation caused by congenital hypothyroidism to the 250 children annually avoiding the adverse effects of phenylketonuria.<sup>5</sup>

For a number of years these 2 disorders remained the only ones screened for in newborns in every state. Most states screened for several other disorders, but there was no consistency,

and the conditions for which a child was screened depended on the state in which he or she was born. People at the NICHD believed that newborn screening was a vastly underused technology and that the state-to-state variation was intolerable; they pushed an initiative to expand and standardize newborn screening, bringing Dr Rod Howell, one of the world's leading experts in newborn screening, to the NICHD to lead this effort. In cooperation with the Health Resources and Services Administration, the Centers for Disease Control and Prevention, the American College of Medical Genetics, and the Secretary's Advisory Committee on Hereditary Disorders in Newborns and Children (chaired by Dr Howell), this initiative moved forward rapidly. A standard list of 29 conditions for which all newborns should be screened has been agreed to and implemented in states with 90% of US births; the inconsistency is disappearing, and research is proceeding to develop screening tests and effective treatments for many other disorders.

## VACCINES

Research on vaccines is not a primary assignment for the NICHD (the National Institute of Allergy and Infectious Diseases has the lead role at the NIH). However, the contributions of Drs John B. Robbins and Rachel Schneerson in the NICHD intramural program represent a national treasure in vaccine development for the NIH. Captivated as pediatric residents by the devastating impact of *Haemophilus influenzae* type b (Hib) meningitis on children and families, this team made developing a vaccine to prevent this disease their life's work. They were fortunate to be in the NICHD intramural program with its long-term stable funding, because their creative and unconventional ideas would have given them difficulty in acquiring extramural funding. First, Robbins and Schneerson concluded

that the protective antigen of Hib was its capsular polysaccharide and not a protein, as widely thought. Their research confirmed this hypothesis, and they contributed to the development of a successful Hib capsular polysaccharide vaccine by using this sugar as the antigen. Unfortunately, it was not sufficiently immunogenic to induce protective levels of antibody formation in children younger than 15 months, the time at which the incidence of Hib meningitis was highest. Their innovative solution to this problem was to covalently bind (conjugate) the Hib capsular polysaccharide to a protein to form a conjugate that induced protective levels of antibody when administered concurrently with routine bacterial vaccines of infants (diphtheria-tetanus toxoids-pertussis vaccine). A Hib conjugate vaccine was licensed by the Food and Drug Administration in 1987. Soon thereafter, Hib meningitis and other systemic infections caused by this organism at all ages quickly began to disappear. Before the use of Hib conjugate, there were 15 000 to 20 000 cases of Hib meningitis in the United States annually; today it is rarely seen. Hib meningitis exerted a mortality rate of ~10% plus a high (30%) rate of morbidity including deafness or brain injury, which made it the nation's leading cause of acquired mental retardation. Eliminating this disease is one of the NIH's all-time major contributions to public health, and it earned Robbins and Schneerson the Lasker Award and the World Health Organization Louis Pasteur Award. A bronze plaque at the entrance to their NICHD laboratory notes the historic significance of the site at which their research "eliminated the scourge of this disease for children everywhere."

Subsequently, their conjugate concept has been used to develop licensed vaccines for pneumococcus and meningococcus, which are now part of stan-

dard care for children. They also developed licensed vaccines for typhoid fever and pertussis. They continue their research into the development of vaccines for *Shigella*, *Escherichia coli* 0157, cholera, anthrax, and malaria.

## OTHER INTRAMURAL RESEARCH CONTRIBUTIONS

The NICHD's own scientists in its intramural program have produced significant advances through their research beyond the work on vaccines. Three examples illustrate the far-reaching impact of this research. One of these examples is the use of luteinizing-hormone-releasing hormone analogs for effective treatment of precocious puberty. This research built on the NICHD-supported Nobel Prize-winning research by Drs Roger Guillemin and Andrew Schally that first isolated and identified releasing factors from the hypothalamus that cause the pituitary gland to secrete its hormones into the circulation. Intrigued by their possible use in treating infertility or providing contraception, the NICHD extramural program supported by contract the creation of more potent analogs of these factors for clinical use. The analogs proved useful for treating prostate cancer and inducing ovulation. The intramural pediatric endocrinology program, led by Dr Gordon Cutler, in collaboration with Dr Bill Crowley at the Massachusetts General Hospital, initiated a protocol to study use of one of these analogs to stop the early initiation of puberty caused by too-early hormone secretion. This intervention worked spectacularly, reversing or stopping the signs of precocious puberty and restoring the lives, physical features, and growth of these children to normal. It is now the standard therapy for these children.

Another major discovery, made by Drs Griff Ross and Judy Vaitukaitis in the

NIH Clinical Center, was that the  $\beta$  subunit of human choriogonadotropin appeared in a pregnant woman's blood even before the first missed menstrual period and, thus, served as the earliest marker of pregnancy and could serve as an early pregnancy test. Until that time, definitive early diagnosis of pregnancy (including ectopic pregnancy) required a bioassay that exposed frogs or rabbits to the woman's urine and took several days. Industry seized on this discovery and quickly developed the home pregnancy test kit, which gave an instant result from a urine dipstick, and sells them over-the-counter today.

A third major advance from the NICHD intramural program was the work of Dr Bill Gahl in developing effective treatment for the rare disease cystinosis. The research progress against this disease was demonstrated dramatically ~15 years ago when Senator Ted Kennedy visited the NIH and asked to see some research patients from the clinical center. The NICHD's Bill Gahl was chosen to present 2 families with the rare genetic metabolic disease cystinosis. This disease results from inability to remove cystine from the cells of the body, which crystallizes in the eyes, kidneys, and other organs, resulting in severe kidney disease, growth-stunting, loss of vision, and death by adolescence. Dr Gahl described a family with children affected by the disease. The oldest boy and girl were not present; they had died before their teenage years from severe kidney disease. A third child was present; his life had been saved at the age of 10 by kidney transplantation, which had not been available to his older siblings, but he was blind and his growth was severely stunted. A fourth child from another family was also present; he was born after NICHD research had helped develop a drug called cysteamine that solubilized the cystine and fa-

cilitated its removal from the body. An NICHD clinical trial had shown this treatment to be safe and highly effective. This child had been diagnosed with cystinosis before the age of 1 and was begun on cysteamine immediately. At the age of 8 he appeared in every way like a normal third-grader—his vision and physical size were normal, his kidney function was normal, he was doing well in school, and he loved playing baseball. Senator Kennedy left awed by this demonstration of how children were being helped by research from the institute his family began.

## HIV/AIDS

When the AIDS epidemic began, the medical community was slow to recognize that children were infected by the HIV virus, too, and that it could be transmitted from a mother to her fetus or infant. Once recognized, treatment studies were initiated in HIV-infected children at the National Cancer Institute by Dr Phil Pizzo in the NIH Clinical Center. The NICHD made the decision to commit staff and resources to HIV/AIDS and established a new extramural branch directed just to this condition, the Pediatric, Adolescent, and Maternal AIDS Branch. Under the superb leadership of Drs Anne Willoughby and Lynne Mofenson, this branch became the global center of research and information on this epidemic in women and children. With a major focus on prevention of mother-to-child transmission and collaboration with the National Institute of Allergy and Infectious Diseases, the first trial of the antiretroviral drug azidothymidine in pregnancy and given to the newborn reduced the transmission rate in the United States from 27% to 7%. Subsequent combination-drug and altered timing regimens have reduced the transmission rate in the United States to 1% to 2% and 4% to 8% in Asia and Africa. Current work focuses on further improving these figures, pre-

venting breast milk transmission, and reducing acquisition of disease by adolescents. Treatment trials in children continue but are mostly done outside the United States, because instead of an epidemic of pediatric AIDS, the number of new cases in infants and children in the United States has become too small to provide an adequate sample size for study.

## AUTISM

Autism, similar to HIV/AIDS, is an area in which the NICHD saw a developing need and moved in early. The NICHD held a major conference on autism research before the condition became a visible public concern and initiated a new centers program (the Collaborative Programs of Excellence in Autism) to expand research. The NICHD director was designated by Congress to chair the first Inter-Institute Autism Coordinating Committee. Today, the NICHD is second only to the National Institute of Mental Health in the amount of funding provided for autism research.

## PUBLIC EDUCATION CAMPAIGNS

Sometimes a public education campaign is the best way to get research results into practice. The best known of those initiated by the NICHD is the “Back to Sleep” campaign to reduce the risk of sudden infant death syndrome (SIDS). When early data from Europe and Australia indicated that back-sleeping infants had a lower incidence of SIDS than stomach-sleeping infants, the NICHD worked with an expert committee established by the AAP to review and evaluate all the scientific data on this topic. The expert committee concluded that the new data were convincing and that the AAP should recommend that infants be placed on their backs to sleep to reduce the risk of SIDS. An advisory group convened by the NICHD recommended (1) not proceeding with a public information campaign until the impact of the AAP recommendation was assessed and un-

til the NICHD obtained data to show whether back-sleeping increased the risk for aspiration pneumonia or suffocation and (2) that this information be evaluated after 2 years. That advice was followed. The group of advisors reconvened in 2 years (1994) and learned that only a slight nonsignificant increase in back-sleeping had occurred along with a nonsignificant decline in the SIDS rate and that data collected from 2 countries showed no increase in the risks of aspiration pneumonia or airway obstruction from back-sleeping. The advisors unanimously endorsed moving ahead with the Back to Sleep public education campaign. Multiple agencies of the Public Health Service (Centers for Disease Control and Prevention, Health Resources and Services Administration/Maternal and Child Health Bureau, Indian Health Service) joined in the planning of the campaign, led by the NICHD and the AAP. The campaign was launched by the US Surgeon General in June 1994, who urged public adoption of the recommendation of the AAP, not of the government. Change followed quickly: in 5 years back- or side-sleeping increased from ~15% to nearly 80%, and the SIDS rate was cut in half. Reductions since then have continued at a much slower pace, but SIDS moved from the second leading cause of infant death to third. Similar campaigns that are focusing on increasing calcium intake and reducing obesity have been initiated by the NICHD.

## LEARNING

The process of learning is a major component of human development and has been studied by the NICHD since its earliest days. In 1985, at the instigation of the Association for Children With Learning Disabilities, Congress established an Interagency Committee on Learning Disabilities to be chaired by the director of the NICHD and charged with providing a report to Congress on learning disability with recommendations for actions. One major recommendation was to establish

learning disability research centers for an integrated multidisciplinary research approach. The NICHD funded 5 of these centers, and from them came the basic information on how children normally learn to read and factors that interfere with this process. A key concept was the role of “phonemic awareness,” the matching of letters and sounds that needed to be present to learn to read or remediated for children with problems in learning, along with techniques for successfully teaching this concept. Dr Reid Lyon, who led this program, was charged with developing “clinical trials in the classroom” to conduct translational research in applying what had been learned in reading research into teaching practice. The Department of Education was brought into this process of solicitation, peer review, and joint funding with the NICHD of the research and its oversight and dissemination. Congress was so impressed with this work that they established the National Reading Panel, led by the NICHD, to review the scientific literature and provide research-based recommendations for effective teaching. The National Reading Panel did its work so well that Congress established the Institute of Education Sciences in the Department of Education to operate on the NIH model of competitive peer review and funding of top-quality research and required schools to use research-based instruction to receive federal funding assistance. With these changes, the quality of research funded by the Institute of Education Sciences became on a par with the NIH and the National Science Foundation and is being used to improve instruction; student scores on performance tests are moving slowly upward. Research from the NICHD and the Institute of Education Sciences is now moving beyond reading into math and science learning.

## DAY CARE

By the mid-1980s more than 50% of mothers of infants were in the work-

force, which was a marked increase. Social and behavioral scientists, pediatricians, and parents themselves were raising concerns about family impact, care quality, and child learning and behavior after this substantial change. The studies of this phenomenon that had been performed were small and short-term and had inconsistent results. Only the NICHD had the staff expertise and resources to put together a study of sufficient size and duration to answer the significant questions being asked and address the anxieties felt by many people. Dr Ed Zigler, a leading expert on Head Start and day care, strongly endorsed the need for a study that only the NICHD could do. The NICHD agreed to proceed and asked Dr Sarah Friedman, a developmental psychologist on the institute's staff, to lead the effort. It would be a quite different study for the behavioral science community. It would involve multiple sites (10) to recruit a large enough number of children in a short time for the study. There would be a common protocol developed by the principal investigators and implemented at each site, children would be recruited at birth before child care arrangements were made, and they would be followed at least into school age with standard observations and tests to answer specific questions on which everyone agreed beforehand. After some initial reluctance, this process was accepted with cooperation and commitment from the investigators. Results at ages 3, 5, and 7 years were reassuring: care was variable; good-quality care was beneficial; there was little or no evidence that the day care experience was harmful; and the relationship of the child to the mother was a far more powerful predictor of outcome than the day care experience. Parents became comfortable with the day care experience, which was generally seen as positive, and the study findings led to promulgation of standards

that raised the safety and quality of child care facilities and providers.

### CONGRESSIONAL DIRECTIVES

With the NICHD's positive performance, Congress assigned it more responsibilities.

- In 1990 Congress established the National Center for Medical Rehabilitation Research and located it in the NICHD. Believing that rehabilitation is, in a sense, a recapitulation of development and that it would be compatible with the institute's research on disability, Congress and the community felt that the NICHD was the best home for it. The NICHD has provided resources to grow and mature this research program to ensure that the rehabilitation needs of children are addressed.
- Congress directed the NICHD to conduct a study of adolescent health and take a comprehensive and longitudinal look at the health and well-being of this understudied population in which much disease and positive or negative health behaviors begin. The NICHD, with much support from other organizations, has funded three 5-year waves of this study, which is the nation's major source of information on the health of its adolescents.
- The Best Pharmaceuticals for Children Act, championed by the AAP, assigned the NICHD the responsibility for testing generic drugs in children for dose and safety, if industry did not do the testing, and working with the pediatric community in prioritizing these studies.
- The Newborn Screening Saves Lives Act of 2008 assigned the NICHD lead responsibility for developing and assessing new newborn screening tests and treatments.
- The Children's Health Act of 2000 charged the NICHD with leading a

consortium of federal agencies to design and implement a longitudinal study of environmental influences on children's health and development. That work is still in progress, and pilot studies in vanguard centers are being performed to determine the final National Children's Study methodology, content, and protocol.

### CONCLUSIONS

Clearly both the active and passive components of the NICHD have value and made major contributions. Two things to look at in considering these contributions are changes in indicators and statistics and changes in people's lives, due in part to this research. Changes in indicators include the following:

- The NICHD budget grew from \$307 million in 1986 to \$1.3 billion in 2010.
- The US infant mortality rate declined from 25.3 in 1000 live births in 1962 when the NICHD was established to 6.7 in 1000 in 2008.
- The birth weight at which 50% of neonates survive declined from ~1500 g in 1960 to ~750 g in 2008.
- Newborn screening has increased from 1 disorder (phenylketonuria) in 1963 to 29 today, and the number continues to grow.
- The mother-to-child transmission rate of HIV in the United States has declined from 27% in 1994 to 1% to 2% in 2010.
- Hib meningitis in the United States has declined from 15 000 to 20 000 cases per year before 1987 to nearly zero today.

Effects on lives include the following:

- A newly married young couple today that wants to postpone childbearing has numerous reliable contraceptives from which to choose; they were made safer and more effective by research from the NICHD.

- If the couple has difficulty conceiving, diagnosis and effective treatment are available because of research from the NICHD.
- To diagnose pregnancy, they can use an over-the-counter pregnancy test kit that was developed from NICHD research.
- If problems occur during pregnancy, effective management is available for many (diabetes, preeclampsia, preterm labor) as a result of NICHD research.
- Screening during pregnancy for severe congenital anomalies in the fetus is available routinely by maternal blood tests, ultrasound, amniocentesis, or chorionic villus sampling developed by NICHD research.
- If a newborn infant has problems, treatments such as resuscitation, surfactant, respirators, intravenous fluids, and special nutrition, developed from NICHD research, are available.
- Every newborn infant leaves the hospital with a Band-Aid on his or her heel from where drops of blood were obtained for 29 different disorder screenings (the same in all states), which were developed through NICHD research.
- The infant's first ride home is in an infant safety car seat, fostered and promoted by NICHD research.
- When infants are put down to sleep for a nap or the night, they are placed on their back rather than their stomach, which is an applica-



**FIGURE 1**

Robert E. Cooke, MD, "father" of the NICHD. Shown is Dr Cooke (center) receiving the Surgeon General's Medallion from Dr Antonia Novello (right) as NICHD Director Duane F. Alexander, MD (left), looks on (1992).

tion of NICHD research and information from an NICHD education campaign to reduce the risk of SIDS.

- When infants get their 2-month immunizations, the Hib vaccine and other conjugate vaccines they receive routinely were developed by or with assistance from NICHD research.
- If a child attends day care, parents are reassured by the results of NICHD research that it will benefit and not harm the child.
- When the child begins school, the mainstreaming of children with physical or mild intellectual disability into regular classrooms exists because of NICHD research that has shown mutual benefit, and the techniques used to teach reading will have come from NICHD research.

From this record of accomplishment it would be easy to conclude that there is not another institute at the NIH whose research has had such a widespread

and beneficial impact on people's lives as that from the NICHD.

It has been 50 years since Dr Cooke put forward the proposal for a new NIH institute focusing on child health and development as a way to improve pregnancy outcome and reduce death and disability in infants and children.

He is shown here (Fig 1) at the NICHD's 30th anniversary celebration in 1992 receiving the highest honor of the US Public Health Service, the Surgeon General's Medallion, from Surgeon General Antonia Novello, formerly Deputy Director of the NICHD. He has said that even he did not foresee the enormous progress that has been made from implementation of his idea.

It is to be hoped that all pediatricians and others who care for mothers and children will feel a sense of pride in being part of this magnificent institution and have a better sense of why there should be an NICHD.

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## Why Should There Be an NICHD?

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