

IV. Building the Research Base to Improve Health Care and Promote Healthy Development

A. Tracking and Measuring Health Status and Quality

Children's Health Surveillance Activities (CDC)

Funding Level: FY 1996 - \$13.3 million for children (not limited to age 0 -3)

Target Population: Children ages 0 -21 years old

Description: CDC conducts several surveys that produce a broad range of data on the health status of children. The following is a list of the surveys that include children age 0-3 years old:

- National Health and Nutrition Examination Survey
- National Hospital Discharge Survey
- National Survey of Ambulatory Surgery
- National Ambulatory Medical Care Survey
- National Hospital Ambulatory Medical Care Survey
- Natality Statistics from the National Vital Statistics System
- Mortality Statistics from the National Vital Statistics System
- Fetal Death Statistics from the National Vital Statistics System
- Linked Birth/Infant Death Data Set from the National Vital Statistics System
- 1991 Longitudinal Follow up to the National Maternal and Infant Health Survey
- 1993 NHIS Access to Care Survey
- The National Health Interview Survey on Disability
- National Health Interview Survey
- National Immunization Survey
- National Immunization Provider Record Check

Contribution: These childhood surveillance activities provide the information needed to monitor the health and well-being of children, particularly in this critical time of dramatic change in health and human services.

Infant Nutrition (FDA)

Target Population: Infants, Parents

Description: FDA strives to ensure the nutritional soundness of infant formulas for proper growth and development. Several contractual activities underway with the Life Sciences

Research Office of the Federation of American Societies for Experimental Biology are to 1) provide an up to date review of nutrient requirements for infant formulas for full term infants and 2) an up to date review of energy and macro nutrient requirements of pre-term infants in infant formulas for pre-term infants.

Contribution to Initiative: This review of infant formulas seeks to ensure that infants are receiving proper nutrition. Good nutrition plays an important part in the normal and healthy development of infants.

Medical Expenditure Panel Survey: Data on Children (AHCPR)

The Agency for Health Care Policy and Research's (AHCPR's) Medical Expenditure Panel Survey (MEPS) will begin to make data available in March of 1997.

Target population: MEPS contains data on 7,000 children ages 0 to 17, including 1,500 children ages 0 to 3.

Description and purpose: MEPS is a nationally representative survey that collects detailed information on the health status, health services use and costs, health insurance coverage, employment, income and job characteristics of individuals and families in the United States. Specifically MEPS data will be able to answer questions regarding children's access to insurance and care, their use of health care services, and their family's health care expenditures. MEPS data will also be used to make comparisons over three decades (1970s, 1980s, and 1990s).

Contribution to Initiative: Children ages 0 to 3 have been shown to benefit from certain health services (e.g., timely immunizations), and to suffer when certain health services are not available. Health insurance coverage is an important predictor of access to services. MEPS data will allow us to understand whether and how coverage for young children has changed over time, and the relationships among childhood disorders, conditions, and preventive interventions, family income, insurance coverage, expenditures and health status.

MCH Model Data Sets (MCHB)

Funding: The direct MCHB support of the entire project is about \$325,000 over a period of three years. This estimate includes the cost of two large meetings of data and MCH content experts in Washington, D.C., plus regular participation of a smaller group of developers with the breadth of expertise required for this task.

Description: The MCH Model Data Sets are a collection of indicators of 1) the health of infants, children, adolescents and women of reproductive age and 2) key factors that contribute to the health status of these populations. There are separate data sets for each of the populations listed above. The data set includes core indicators to serve such diverse functions as needs assessment, policy and program development, evaluation, resource allocation, monitoring, quality assurance,

and accountability. This multi-purpose set of indicators will be a blueprint for state and local development of MCH data bases and a foundation for development of more detailed and specialized data sets at the national, state and local levels.

The model data set will be disseminated widely on hard copy, diskettes, and via the Internet. A detailed dissemination plan has not yet been developed. However, the intent of this project is to produce a set of indicators that all providers and monitors of MCH services will be encouraged to collect and use. Data for the indicators will be collected primarily at the individual person level. They can be calculated, therefore, locally, at the state level, and nationally. Dissemination will be aimed at potential users at all of these levels.

Contribution to Initiative: These data sets will allow provide quality indicators of health status to researchers examining the health of our youngest children.

Effects of Early Discharge Policies (MCHB)

Funding: The cost for FY 97 (year two of a four year project) is \$230,000.

Description: Efforts are being made to establish a coordinated national strategy to obtain timely information and promote its translation into effective, humane, and cost-conscious policy on the first primary care services received by newborns and mothers. There is currently widespread public and professional concern regarding early maternal-newborn discharge. Although there have been many publications on this topic, scientific evidence is currently unavailable to guide clinical or reimbursement policies not only on hospital length of stay but also on the services needed immediately following discharge for the general maternal-infant population. Clinicians, hospitals, program managers, third party payers, the public, and policy-makers need reliable information to guide both the hospital and community-based primary care services received by most mothers and newborns in the first days of life and parenting.

Contribution to Initiative: The coordinating center team at the University of California at San Francisco is nationally recognized for its research on perinatal health services. The multi-disciplinary maternal and child health services research team has expertise in Epidemiology, statistics, outcomes research, cost-effectiveness analysis, and research on socio-economically and ethnically diverse populations. This team has published extensively in medical journal on early discharge. In addition they provide technical assistance to other researchers interested in early discharge, providing direct scientific coordination and promotion of national collaboration.

Regulatory Disorders and Development Outcomes (MCHB)

Funding level: Year 1: \$155,000; Year 2: \$150,000; Year 3:\$150,000; Year 4: \$150,000; Year 6: \$150,000

Description: This investigation proposes to test the efficacy of an assessment battery of tests

designed to predict those infants who will develop behavioral and emotional problems by three years of age. Many of the children who develop behavioral and emotional disorders are not identified until after two years of age. Some problems may not be detected until the child enters school.

Principal researcher: Stephen W. Porges, Ph.D. University of Maryland.

Contribution to Initiative: If successful, the assessment battery being tested by the study will have immediate application as it will aid clinical researchers and clinicians in developing effective preventive strategies to address infant vulnerabilities.

Validity of Neurobehavioral Symptoms reported in Children with Traumatic Brain Injury (MCHB)

Description: Headaches, inattention, poor memory, and other behavior complaints are common sequelae of traumatic brain injury (TBI) in children. In the present study, 68 children with moderate to severe TBI, together with 53 children with orthopedic injuries only, were followed prospectively from the time of hospitalization. Post-injury behaviors symptoms and other child and family outcomes were assessed at a baseline evaluation conducted soon after the injury and again at a 6-month follow-up. Overall, study findings support the utility of neurobehavioral symptoms as markers of injury severity and predictors of child and family sequelae.

Contribution to Initiative: This research furthers our understanding of symptoms associated with TBI and indicators of its presence and severity, and provides insight into how to help and treat children affected by TBI.

Pregnancy Risk Assessment Monitoring Systems (CDC)

Funding Level: FY 96 - \$8.9 million

Target Population: Women and Infants

Description: The Pregnancy Risk Assessment Monitoring System (PRAMS) is a surveillance system designed to identify and monitor selected maternal behaviors and experiences that occur before, during, and after pregnancy. In particular, PRAMS was designed to supplement data from vital records and to generate data for planning and assessing perinatal health programs in participating States. States select a sample of mothers who are asked about behaviors and experiences such as access to, and use of, prenatal and infant care, alcohol use, smoking, and violence during pregnancy.

Contribution to Initiative: PRAMS data are used to enhance understanding of maternal risk factors and their relationship with adverse pregnancy outcomes and aid in the development and assessment of programs designed to identify high-risk pregnancies and reduce adverse outcomes, including low birth-weight and infant mortality.

Quality Measurements and Improvement in Child Health Care (AHCPR)

The Agency for Health Care Policy and Research (AHCPR) is applying knowledge learned from the scientific research base in early childhood health to development of tools to measure and improve the quality of child health care.

Description: Several current projects suggest the extent of AHCPR's commitment to building quality measures, and improving quality of health care, for children.

- Consumer Assessments of Health Plans Study (CAHPS). AHCPR is funding a 5-year project to help consumers identify the best health care plans and services for their needs. The goals of the Consumer Assessments of Health Plans Study (CAHPS) are to (1) develop and test questionnaires that assess health plans and services, (2) produce easily understandable reports for communicating survey information to consumers, and (3) evaluate the usefulness of these reports for consumers in selecting health care plans and services. In addition to core items, CAHPS includes pediatric (families with children) items.
- CONQUEST 1.0. CONQUEST 1.0 is a computerized Needs-Oriented quality Measurement Evaluation system. It is a prototype system for collecting and evaluating clinical performance measures. CONQUEST 1.0 includes two interlocking databases with a user-friendly interface to help users find measures to fit their needs. It summarizes information on approximately 1,200 clinical performance measures developed by public- and private-sector organizations. Included in these performance measures are childhood immunization records, measures of prenatal care, numbers of cesarean sections per all deliveries, low birth weight measurements, and a gauge of the rates of infant mortality. All of these measures can then be used to develop quality guidelines and initiatives or to measure whether appropriate and adequate care for children.

AHCPR is also involved with efforts of the National Committee on Quality Assurance to build additional HEDIS measures for children, and convened a meeting in January 1997 to provide expert advice on this topic. AHCPR is also co-sponsoring the May 1997 research agenda conference on pediatric quality of care, also cosponsored by the Centers for Disease Control and Prevention, the National Institutes of Health, the Health Resources and Services Administration, the Health Care Financing Administration, the David and Lucille Packard Foundation, and Pfizer, Inc. The purpose of the conference is to create and disseminate a research agenda on quality of care measures for children and to bring attention to issues that require attention in the research community and from policy makers.

Contribution to Initiative: In order to assure that their dollars are buying high quality health care for covered children and parents-to-be, purchasers, including the Federal government, need valid measures of health care quality.

B. Prevention Research

Childhood Infectious Disease Research (CDC)

Ongoing research projects to control infectious disease in children

Funding Level: FY 1996 - \$4.4 million for children (not limited to ages 0-3)

Target Population: Children - ages 0 -21 years old

Description: Infectious diseases increasingly threaten public health and contribute significantly to the escalating costs of health care. CDC works to prevent illness and death from infectious diseases in children by: Epidemic investigation; surveillance of infectious diseases; Epidemiologic and laboratory research; and formulating, disseminating, and evaluating prevention and control strategies. The following are examples of CDC's infectious disease control activities targeted to children ages 0 -3:

- *Meningitis prevention:* During the early 1980s meningitis caused by *Hemophilus influenzae* type b (Hib) was a leading cause of morbidity and mortality in the U.S., affecting one out of every 200 children less than 5 years of age. CDC worked on the evaluation of the new conjugated Hib vaccines. Since the introduction of routine infant immunization to prevent Hib infection, the incidence of invasive Hib has fallen over 95 percent. As a result of this success, CDC has targeted invasive Hib disease for eradication in the U.S. by the year 2000.
- *Antibiotic Resistance Educational Material:* In response to the growing problem of antibiotic resistance in treating infectious diseases, CDC developed materials (pamphlet, posters, disease-specific fact sheets; videotape) to educate parents on the threat of antibiotic resistance and the association of resistance with overuse of antibiotics.

Contribution: CDC is working with its many partners to address the challenges of controlling preventing infectious diseases in children.

Prenatal and Perinatal Research (NIH / NICHD)

Target Population All pregnant women and their newborns

Description: NICHD pre- and perinatal research aims to improve pregnancy outcomes to reduce infant morbidity and mortality. Despite impressive strides, nearly 11 percent of the over 4 million infants born each year are premature or have very low birth weights. To focus on this problem, NICHD supports several major research efforts: the goal of the Maternal Fetal Medicine Units Network is to improve the management of high risk pregnancies, and prevent complications of labor and delivery including preterm labor; the D.C. infant mortality initiative is

another large effort, examining different models of prenatal care to assess their impact on birth outcomes, especially among high risk, minority populations.

NICHD also supports the Neonatal Intensive Care Unit Network to develop new and improved ways to prevent or treat the immediate disorders associated with prematurity, such as neonatal respiratory distress, severe eye problems, brain hemorrhage, and severe jaundice (which can lead to brain damage). NICHD supports a range of studies to understand and prevent nutritional deficits and intrauterine growth retardation, as well as intramural research to develop vaccines against infections that are particularly devastating to infants. The Pediatric AIDS Clinical Trial Group (PACTG), and other HIV-related studies reviewing obstetric and nutritional interventions, seek improved ways to prevent HIV transmission from the mother to the fetus or newborn. Most recently, the PACTG began planning to test protease inhibitors in infected pregnant women and newborns.

Contribution to Initiative: Since 1962, research in this area has helped to reduce the infant mortality rate by 70 percent, virtually eliminated several major causes of morbidity, and enhanced the chances for children to develop free of physical defects, visual or learning impairment, or mental retardation. Continuing this research holds promise for further improving the chances for infants to be born and remain healthy through infancy.

Accomplishments: Many achievements have emerged from these NICHD-supported and collaborative research efforts, including the overall improvement of pregnancy outcomes; RhoGAM™ to prevent Rh hemolytic disease; the identification and use of prenatal folic acid to reduce the risk of neural tube defects; surfactant to prevent respiratory distress syndrome; the *Hemophilus influenza* type b (Hib) vaccine to prevent Hib meningitis and mental retardation, the Back-to-Sleep campaign to reduce SIDS; the identification of bacterial vaginosis and group B strep vaginal infections as potentially causing premature delivery; and, the approval and use of AZT to prevent the vertical transmission of HIV.

Planned Activities: The NICHD will expand its efforts to identify the specific causes of and improve methods to prevent premature labor, including new clinical trials testing the use of antibiotics to treat women at high risk of bacterial vaginosis.

Vaccination Research (FDA)

Target Population: All US children

Description: The Center for Biologic Evaluation and Research through its Office of Vaccines Research and review and its Office of Establishment Licensing and Product Surveillance has on-going programs in the regulation of pediatric vaccines. The purpose of CBER's activities are to ensure that the highest quality vaccines are made available to children in a timely manner.

Activities under these programs include; 1) the licensing of new pediatric vaccines (recent examples include two acellular pertussis vaccines and the chicken pox vaccine); 2) the review of

Investigation New Drug application for future pediatric vaccines (examples include vaccines for rotaviral or Group B streptococcal infections); 3) safety and potency testing of pediatric vaccines; 4) monitoring of demonstrated or potential vaccine adverse events; 5) inspection of manufacturers of pediatric vaccines for, *inter alia*, compliance with current good manufacturing practices to ensure consistent, high quality vaccines; 6) research programs to study demonstrated or potential vaccine adverse events, including improved methodologies for safety monitoring; 7) research programs to develop new or improved childhood vaccines; 8) interaction with other governmental and non-governmental agencies to help ensure the most appropriate use of childhood vaccines.

Contribution to Initiative: This activity directly benefits the health and welfare of children through the elimination of childhood diseases and their attendant mortality and morbidity.

Prevention of Birth Defects / Centers for Birth Defects Prevention Research (CDC)

Ongoing research projects to prevent birth defects

Funding Level: FY 1996 - \$6.1 million

Target Population: Children - prenatal to newborns

Description: Birth defects are the leading cause of infant mortality in the United States and the primary cause of nearly 7,000 or 20 percent of all infant deaths each year. Each year, factors in the periconceptional and prenatal environment result in major birth defects that affect 120,000 babies. We know the causes of about 25 percent of these birth defects, and as a result, prevention is possible in some cases. CDC works to monitor trends in birth defects, developmental disabilities, and genetic diseases, link these health outcomes with the factors in the environment that increase risk; and identify effective means of reducing that risk.

Contribution to Initiative: CDC has established Centers for Birth Defects Prevention Research in 6 States which have initiated unique national collaborative research into the causes of birth defects. The role of environmental pollutants, drugs, specific behaviors, or genetic susceptibilities in causing birth defects, developmental disabilities, or other adverse reproductive outcomes is being explored. These new Centers will accelerate the process of finding the causes and risk factors for birth defects.

Prevention of Fetal Alcohol Syndrome / Prevention Strategies (CDC)

Ongoing program and research activities to prevent fetal alcohol syndrome

Funding Level: FY 1996 - \$6.3 million

Target Population: Children - prenatal to newborn

Description: Heavy prenatal alcohol use can result in fetal alcohol syndrome (FAS), one of the leading known causes of mental retardation and birth defects. In addition to FAS, studies have documented other growth and neurodevelopmental deficits among children whose mothers drank at lower thresholds during pregnancy. Estimates of the rate of FAS range from .67 to 2.2 per 1000 live births.

CDC is working to design, implement, and evaluate prevention strategies for specific high-risk groups to prevent occurrence of FAS and other alcohol-related birth defects. In addition, CDC is developing methodologies for improving FAS case detection and surveillance and for using existing data collection systems to estimate the incidence of FAS and perform descriptive Epidemiology.

Contribution to Initiative: Through these activities CDC will further understanding of women who give birth to children with FAS, increase the ability to identify high-risk women, and better define the spectrum of outcomes and needs of children exposed to alcohol in-utero.

Research Projects to Close the Racial Disparity in Infant Mortality (CDC)

Funding Level: FY 96 - \$2.2 million

Target Population: Women and Infants (less than 12 months)

Description: Pre-term delivery, the termination of pregnancy before completion of 37 weeks of gestation, together with low birth-weight, is the third leading cause of infant mortality in the United States. The percent of pre-term births has risen steadily from 9.4 in 1981 to 11.0 in 1994. Black women experience twice the risk of pre-term delivery as white women. In 1994, the percentage of black and white infants that were born pre-term was 18.1 percent and 9.6 percent, respectively. Risk factors for pre-term delivery include low socioeconomic status, low pre-pregnancy weight, inadequate weight gain during pregnancy, previous pre-term delivery, a history of infertility problems, vaginal spotting or light bleeding during pregnancy, antepartum hemorrhage and abnormal placental implantation , alcohol consumption before the third trimester of pregnancy, negative attitude about the pregnancy, smoking, multiple gestation, cervical factors, myometrial factors, problems with the fetal membranes and decreased utero placental blood flow.

The reasons for the disparity in pre-term delivery between black and white women remain unexplained. Therefore, CDC has begun to examine psychological, social, cultural, and environmental factors that may contribute to pre-term delivery using a community participatory approach in Harlem and Los Angeles. Full participation by the community is a necessity in improving the understanding of both risk and protective factors influencing maternal health and pregnancy outcomes. The community helps decide what questions should be asked, how prevention efforts should be conducted, and how the results should be interpreted. Additionally, because high levels of exposure to such factors as stressful life experiences put African-American women at increased risk for adverse reproductive outcomes, CDC is

examining the validity and reliability of stressful life event scales in African-American women.

Contribution to Initiative: This community-based prevention research project in an innovative approach to prevent infant mortality in communities that still have an excess burden of infant deaths.

Low Birth Weight and Other Perinatal Outcomes Research (AHCPR)

AHCPR has undertaken various projects, grants, and initiatives to help build the science base for health care in perinatal care. Selected examples include a Patient Outcomes Research Team (PORT) regarding prevention of low birth weight and other research on perinatal services.

Funding Level: The combined funding level for these projects totals \$24 million (cumulative total funding for active projects).

Target Populations: Pregnant women and infants.

Description and Purpose:

- **Low birth-weight PORT:** Low birth weight is a substantial risk factor for infant mortality and early childhood illnesses. Nearly 70 percent of all infant mortality and approximately one-third of all handicapping conditions are associated with low birth-weight. After extensive scientific review of the literature on the multiple causes of low birth-weight, AHCPR developed a comprehensive 5-year research project that focuses on areas where there is a wide variation in obstetrical practice and other practices to reduce low birth-weight, but little scientific evidence supporting these practices. The project, which is now in its last year, has already yielded several key findings.
- **Other Perinatal projects:** Beyond the PORT research the Agency has funded other projects regarding high-risk infants and their care. Two studies, which began in fiscal year 1996, focus on guidelines for care of low birth weight infants. One study will provide strategies for clinical care and for establishing policy, and the other research project focuses on chronic lung disease (CLD) and home care interventions necessary to control neonatal ICU costs. Other perinatal care studies are listed on the attachment.

Contribution to Initiative: The low-birth-weight project has already made several substantial contributions to the science base on perinatal care and prevention of low birth-weight. For example, it found a strong relationship between bacterial vaginosis in pregnancy and pre-term delivery, especially in African American women; the effectiveness of zinc supplementation for improving birth-weight in African American women; that de-regionalization of perinatal services can have a negative effect on neonatal mortality; that antenatal corticosteroids are effective in improving outcomes of pre-term newborns; and no evidence for the effectiveness of bed rest in preventing pre-term delivery and a variety of pregnancy problems. Taken together, these and other findings begin to provide the scientific basis for designing a more cost-effective package of prenatal and perinatal services. As they are replicated, individual findings can be

used to improve clinical practice and the organization of care, and to develop performance measures for health plans that deliver services to pregnant women.

C. Interventions and Developmental Practices

Evaluation of Hawaii's Healthy Start Program (MCHB)

Description: This is a five-year study designed to provide a comprehensive process and outcome evaluation of Hawaii's Healthy Start program (HSP), an established screening and outreach program for environmentally at-risk children and their families. In the HSP's early identification component, population-based screening and assessments are used to identify at-risk families of newborns. In the home visiting component, trained paraprofessionals provide direct support and education services to assure access to pediatric primary care and other community resources in the child's first five years of life.

Principal Researcher: Cal Cia, M.D., University of Hawaii.

Contribution to Initiative: This evaluation provides insight into the efficacy of models of social services service delivery to at-risk families and infants.

Planned Research Projects on Preventing Developmental Delays (CDC)

Funding Level: FY 96 - \$3.5 million

Target Population: Children - Birth to five
(No children are being served at this time)

Description: CDC is planning a set of quality scientific studies designed to provide policy oriented research data regarding "what works" in early intervention. These research studies will be directed at children and/or their families to prevent or remedy a wide variety of developmental delays or problems. CDC has joined with local research partners in multiple communities throughout the United States. Our local research partners will coordinate with existing community resources and services to conduct the study .

The interventions to be studied will occur between the prenatal period and the child's fifth birthday. They will be designed to assess whether the services provided will facilitate parent/child relationships, promote the development of the child and enhance family functioning. It will also examine whether these services, delivered during the preschool years can: 1) promote better relationships and more stable family patterns; and 2) prevent adolescent and adult problems such as school failure, illiteracy, teen pregnancy, substance abuse, unemployment, poverty, and welfare dependence.

The research goal of this study is to provide scientific data for state and national policy makers

and providers of services for young children and their families in order to determine: 1) What interventions are effective to promote child development; 2) What are the characteristics of children and families who benefit most from the intervention; and 3) What are the costs and benefits of intervention.

Contribution to Initiative: There is a continued need for solid scientific research on societal or community interventions that benefit young children and their families. It is important that these research efforts be long-term longitudinal studies. These studies are urgently needed to provide quality data to influence state and national policies and services for young children and their families. Not only will the immediate benefit of the interventions be determined, but the longitudinal data collected will enable researchers to address the long term impact of the interventions such as its effect on grade retention, special education, and teen pregnancy.

The Physical and Developmental Environment of the High Risk Infant (MCHB)

Funding: \$156,000 , FY 97

Description: Contemporary neonatal intensive care units are intensely busy places caring for seriously ill babies. The care environment is replete with high technology machines, generating significant noise in units that know no difference between morning and evening. Lights generally blaze 24 hours a day. Care must be immediate and deliberate given the high vulnerability of the infants. New treatments and new technology are often instituted without the full appreciation of their consequences. Retinopathy of prematurity (retrolental fibroplasia) is a classic example where premature low birth weight infants required oxygen to sustain life but were at-risk for blindness because too little oxygen would cause brain damage and too much would damage the retina. Early availability of oxygen therapy in the 1950's tragically resulted in an epidemic of retinopathy of prematurity, where the over reaction to this consequence--too little oxygen, resulted in a concomitant occurrence of brain injury known as cerebral palsy.

The Physical and Developmental Environment of the High Risk Infant project has brought together an interdisciplinary group of national experts and parents to systematically review the scientific literature--both human and animal-- examining the biological basis of growth and development of the fetus and newborn, particularly as it affects brain development and functioning. They have convened several work groups and national symposia to investigate the basic biophysiological and biopsychosocial science relating to the newborn in order to make recommendations to achieve an optimal therapeutic environment and establish a science of caring.

Principal Researcher: Stanley Graven, M.D., University of South Florida

Contribution to Initiative: To date they have explored 28 domains and over 345,503 references and have identified highly significant practices for professionals and parents that enhance and promote fetal and neonatal growth and development, especially for at risk-low birth weight infants. As a result of this effort, many neonatal intensive care units in the U.S. have become family friendly, where parents are no longer considered visitors but are involved in the

care of their baby. Based upon the findings of this project, the American Institute of Architects have revised their design standards to create physical spaces and ambient environments that are calming and inclusive of parent's needs while protecting the ability to provide state-of-the-art care.

Pediatric Health Supervision to Promote Literacy (MCHB)

Funding level: Year 1: \$175,000; Year 2: \$180,000; Year 3: \$180,000; Year 4: \$160,000; Year 5: \$140,000.

Description: This study seeks to assess the effectiveness of a pediatric health supervision intervention consisting of free picture books and anticipatory guidance about language and literacy development using a prospective, randomized controlled trial, with three-year follow-up. The intervention model tested has been in use in various pediatric hospitals in the East Coast but its' efficacy has never been proven conclusively. This research could provide pediatricians with an effective and easily adoptable means of addressing the problem of language delay and early reading failure. It could also be important in securing public and private support for pediatric clinic-based interventions to promote language and literacy development.

Principle Researcher: Robert D. Needleman, M.D., Case Western Reserve School of Medicine.

Evidence-based Practice Centers (EPCs): Children's Health Issues (AHCPR)

AHCPR newest endeavor as a 'science partner' with both public and private organizations is the Evidence-Based Practice Center (EPC) program. As part of its program to strengthen the scientific evidence base used by health care organizations to improve the quality, effectiveness, and appropriateness of clinical practice, AHCPR is accepting proposals to fund up to 8-10 Evidence-based Practice Centers (EPCs). The EPCs will produce evidence reports on topics and technologies for which there is significant demand by public and private health care organizations, providers, and purchasers. It is anticipated that the evidence reports will include areas in child health; applicants have been asked to include evidence of their expertise in child health. AHCPR is already working on two *pilot* evidence reports that concern children: a report on Attention Deficit Hyperactivity Disorder (ADHD), in coordination with the American Academy of Pediatrics; and an evidence report on valvular heart disease, in coordination with the American College of Cardiology, and the American Heart Association.

Funding: The average total cost per evidence report is expected to range between \$100,000 and \$250,000, although this cost may vary depending on the complexity of the topic. Each EPC is expected to produce multiple evidence reports at AHCPR's request. With the exception of two pilot projects on ADHD and valvular heart disease, neither the EPCs nor the topics for evidence reports have been selected.

Description: The EPCs will produce evidence reports that will be used by public and private systems of care, professional societies, providers, purchasers and others. These reports may also

assist professionals and consumers in making appropriate decisions about the relevance and significance of various types of technology within the health care system. Additionally, AHCPR will provide the evidence report for public access after completion to allow other interested groups to create their own quality improvement tools. Contractors (EPCs) will conduct scientific analyses and evidence syntheses and produce evidence reports and technology assessments. AHCPR will identify topics for which there is significant demand by public and private health care organizations, providers, and purchasers interested in developing their own guidelines, clinical pathways, performance measures, or other clinical quality improvement tools, or in making coverage policies related to the effectiveness or appropriateness of specific health care technologies. Interested organizations, including health plans, professional societies, public and private purchasers, and consumer organizations, have been asked to submit nominations for topics for potential evidence reports.

- The ADHD Pilot Evidence Report will focus on evaluation and diagnosis of attention deficit hyperactivity disorder (ADHD) in the primary care setting.
- The Valvular Heart Disease Evidence Report will include a literature review, synthesis, and summary on the evaluation of newly diagnosed heart murmurs in asymptomatic newborns and infants (0-23 months of age). The objective of the evidence report is to determine what findings (including medical history, physical examination with dynamic auscultation, and diagnostic testing) are useful in distinguishing benign (innocent) murmurs from those murmurs associated with underlying heart disease.

Contribution to Initiative: There are many child health services for which there is little scientific evidence of effectiveness in day to day clinical practice. AHCPR's evidence reports will add to the evidence base for coverage and practice in child health care, including prenatal care and care for children ages 0 to 3.

D. Basic Science Research

In addition to the research mentioned above, the National Institutes of Health have invested significant resources in basic science studies that advance the health and wellness of young children. Aggregate estimated funding: FY 96, \$852 million; FY 97, \$904 million; FY 98, \$935 million.

Early Learning (NIH / NICHD)

Target Population: The fetus/newborn, infants, and pre-school children

Description: Learning disabilities (LD) affect 10 million children in the U.S.; about one school-age child in every five has a reading disability. Given this fact, NICHD research aims to understand the normal development of learning, perception, and memory, as well as how learning disabilities develop, with the goal of identifying better ways to prevent or diagnose them *before* children enter school. Starting with innovative studies on fetal ability to habituate (a form of learning), other research targets understanding the development of infant's and young children's ability to sense, perceive and discriminate (through vision, hearing, and touch) among objects in their environment, learn and remember, become mobile, and become proficient in their native language. Most recently, NICHD researchers have focused on factors that influence an infant's ability to process and retain visual information, and link perceptual abilities to cognitive development. Other exciting areas involve research to 1) measure electronically and link changes in brain activity to different levels of cognitive and linguistic performance in infants, and 2) to understand the neural and cognitive mechanisms that allow infants and children to perceive speech and develop phonetic skills. Building on these studies, the NICHD initiated the Learning Disability Research Centers (LDRCs) to conduct long-term, prospective, longitudinal, multi-disciplinary research related to the causes, neurobiological correlates, developmental course, and cognitive and biological characteristics of learning disabilities, as well as to design and evaluate the effectiveness of different interventions.

Contribution to Initiative: Efforts to improve existing education and learning programs must be built on a strong scientific understanding of early learning process, starting *in utero*, as well as a better understanding of how to prevent, diagnose and treat problems that may develop. The LDRCs, and continuing basic and applied research efforts, will provide critical data to improve and evaluate the effectiveness of programs, such as Head Start.

Accomplishments: NICHD research has 1) shown that human fetuses can distinguish between auditory and speech stimuli; 2) identified the critical brain and neurologic systems that allow infants to understand language and read; 3) shown that very young infants can comprehend changes in numerical sequencing; 4) identified how differences in brain structure can help identify children with dyslexia, and how the condition develops; and 5) developed neonatal predictors of individual differences in language development.

Planned Activities: The NICHD plans to expand its basic and applied research programs, which includes expanding to new sites its novel intervention program for children at risk of reading disabilities, and extending studies that use data obtained during infancy and early childhood to identify children at risk for reading disabilities.

Early Brain Development (NIH /NICHD)

Target Population: The fetus/newborn, infants and pre-school children

Description: NICHD research aims to better understand the many biologic and environmental factors affecting early brain development, and to develop new and improved ways to detect, treat, and prevent related conditions from occurring, starting *in utero* through early child development. Ultimately, the goal is to reduce the number of children affected with neuromuscular, cognitive, learning, and behavioral disorders. In the U.S., there are nearly 6 million Americans with mental retardation, 750,000 with cerebral palsy, and 400,000 with autism -- just a few of the major neurologic conditions which affect infants and children. NICHD research starts with animal models to understand normal brain development including the biochemical and nutritional processes that regulate how and when the nervous system develops, and cause neural cell death or cell maturation; guide cells to their proper location; and, that induce proper cell function before birth. Human studies include those on brain plasticity, the notion that early stimuli can positively affect neural and, thus, cognitive development. NICHD investigators are also studying the neurodevelopment of infants and children who have been exposed to maternal malnutrition, HIV and HIV therapeutic drugs *in utero*; and children who are receiving long-term, HIV drug therapy.

With a major program in mental retardation and developmental disabilities, the NICHD seeks improved, non-invasive means to diagnose these conditions prenatally, as well as improved means to diagnose and treat autism, metabolic defects (i.e. PKU), X chromosome disorders (i.e., Fragile X Syndrome), and other conditions in young children. This includes the design of special intervention programs to improve school achievements for these children. The NICHD also supports a Pediatric Pharmacology Network to examine the use of drugs in children to treat, among other conditions, neurologic disorders including those related to metabolic defects; lead poisoning; and, chemical brain imbalances that cause depression, seizures, and self injury.

Contribution to Initiative: By targeting early brain development, starting *in utero*, these programs provide the biomedical basis for ensuring that all children are born with the capacity to learn and thrive, and the most effective means are available to help infants and young children overcome conditions that may severely affect their early learning and growth.

Accomplishments: NICHD research has identified 1) a chemical, ADNF-14, with the pharmacologic potential to reduce brain cell death from HIV infection or other conditions; 2) the key biochemical components for the basis of human memory; 3) the potential cause of brain lesions related to autism; 4) the gene responsible for a metabolic defect that causes many cases of neural tube defects; 5) sex differences in the way the brain is functionally organized for

language; and, 6) a non-invasive technique, using maternal blood, for prenatally diagnosing genetic disorders including those with neurologic sequelae.

Planned Activities: The NICHD is exploring opportunities to expand research on novel biomolecular, medical, pharmacologic, or surgical techniques to correct conditions involving early brain and other development during the fetal period. The Institute has an initiative on pediatric rehabilitation to improve ways of managing physical movement limitations in infants and children with a range of disabilities.

Early Social and Emotional Development (NIH / NICHD)

Target Population: Newborns, infants, and pre-school children

Description: NICHD research aims to understand how young children develop social, reasoning, and decision-making skills, and the factors that influence their emotional development. Starting with newborns, the NICHD supports research on the basic biological processes, the social influences, and the individual differences that affect the development of emotionally healthy children. For instance, NICHD-supported researchers are examining how infants develop their first emotional and social attachments, and how these crucial connections provide the basis for their future development. Other investigators are attempting to develop ways to measure emotions, stress, and temperament in infants and young children, and assess their reaction to different stimuli, based on physical and novel biological markers. Finally, the NICHD is interested in understanding such concepts as how young children 1) acquire the skills needed to respond to and discriminate between choices and make decisions in different situations; 2) interpret the relationship between the imagination and physical reality; 3) develop self-identities as well as racial and gender stereotypes; and 4) develop friendships, which in turn affects their social and moral understanding of situations.

Contribution to Initiative: The ability for children to "succeed," even in the early preschool years, goes beyond cognitive, neurobiological, and academic factors. Children must be equipped to interact socially with their peers, develop friendships, make a range of judgments and decisions, distinguish between right and wrong, and learn how to manage a range of emotions and stresses. Research to understand social and emotional development is key to designing policies and programs that prepare children for the diversity and challenges of a school situation.

Accomplishments: One of the most successful projects and initiatives developed from the ongoing work in this area is the landmark study on Early Child Care. Currently supported by the NICHD, this study is trying to determine how very early, non-maternal child care, obtained in a variety of day care settings, influences the social and developmental outcomes of children. This project and other applied research studies are covered separately.

Hearing Impairment in Infants and Young Children: Early Identification of Hearing Impairment NIH (NIDCD)

Target Population: Infants and children from birth to five years of age.

Description: The NIDCD hearing portfolio encompasses research studies on the *early identification of hearing impairment* to improve lifelong outcome for these infants and young children. In March 1993, NIDCD cosponsored a "Consensus Development Conference on the Early Identification of Hearing Impairment in Infants and Young Children." The purpose of this conference was to evaluate current research and provide recommendations regarding hearing assessment from birth through five years of age. An independent non-Federal consensus panel recommended universal screening of all infants for hearing impairment, adding that while the best opportunity to screen infants is before they are discharged from newborn nurseries, universal screening should be done no later than the first three months of life.

Contribution to Initiative: Several studies have begun as a result of the recommendations made by the consensus panel. Specific recommendations included: screening all infants for otoacoustic emissions; testing those who fail the otoacoustic emission screening for auditory brain stem responses (ABR); comprehensive diagnostic and habilitative evaluations no later than six months of age for those failing the ABR. The panel strongly urged that hearing screening continue at intervals throughout early childhood so that those children who develop hearing impairment following birth will be identified. The panel concluded that research is needed to evaluate the validity and reliability of infant hearing screening procedures and to compare various screening procedures for cost and time. They further recommended that the cost effectiveness of universal screening for hearing impairment be studied.

Accomplishments: As a result of the panel's recommendations, NIDCD is supporting research on improved screening methods that will identify neonatal hearing impairment, the goal of which is to develop optimal procedures for neonatal hearing screening. This is the first truly randomized controlled comparison of auditory brain stem response (ABR), distortion product otoacoustic emissions (DPOAE) and transient otoacoustic emissions (TOAE) in neonates validated by an independent measure of hearing, monaural behavioral thresholds. The database obtained from this study will contain the largest, most complete and most consistent set of information ever gathered concerning the characteristics in neonates and their relationship to behavioral hearing status.

Planned Activities: The information gained from this study can be used to develop simple, cost-effective automatic screening strategies.

Research on Early Learning NIH (NIMH)

Target Population: Children from birth to age 7

Description: The developing brain is very malleable with regard to an infant's experience. If

environmental stimulation and events are favorable, normal patterns of childhood development will result, but if the environment presents unusual and unfavorable conditions, development may be abnormal. Related research with animals has shown that development within enriched environments dramatically improves brain function. Infants and children, as well as adults, select the aspects of their environment to which they will attend; therefore, early experience can bias that selection in positive or negative directions. NIMH research studies ways in which early learning experiences can be optimized.

Research studies that target this particular age group represent a subset of a larger number of NIMH studies related to learning in school-age children and adolescents.

Contribution to Initiative: Early learning experiences play a major role in determining whether an individual reaches his or her full potential. Favorable environments and positive experiences enable a person to attain full potential, while hostile environments and negative experiences not only prevent the attainment of full potential but may even be extremely harmful by laying the foundation for later mental and behavioral disorders.

Accomplishments: NIMH supported investigators have studied how basic arithmetic knowledge emerges from infancy through preschool age, and have found that there are three main stages of arithmetic development. Infants have only approximate knowledge of quantities; they have an idea of relatively more or less, and of the effect of addition or subtraction. Around age three, children can represent quantities by means of mental models that are quasi-imagistic transformations of groups of objects. These mental models are utilized in other sorts of physical reasoning tasks, too, and reaching this stage correlates with overall intelligence. The third stage begins at preschool age when children acquire knowledge of numerals and the formal procedures of written addition and subtraction. They build this knowledge onto their mental-model-based abilities. This work shows that, especially during the second stage, children's arithmetic ability is a good marker of overall intelligence. Further, it suggests that a variety of cognitive interventions can help increase young children's arithmetic ability.

Planned Activities: Continued emphasis on research on early learning.

Research on the Effects of Child Care NIH (NIMH)

Target Population Children from birth to age 7

Description: Increasing numbers of women are entering the work force and relying on child-care arrangements for their young children. NIMH research examines the long-term effects of mothers' employment and the quality of early child care on the development of children—including their temperament, cognitive maturational status, and socio-emotional adjustment.

Contribution to Initiative: The quality of the child care provided has direct impact on the development of the children; it also potentially has indirect effects by influencing the mothers'

emotional well-being and, as a consequence, the child-maternal interaction.

Accomplishments: Scientists have identified two fundamental aspects of caregiving that are particularly important for children's adjustment or maladjustment. The first is how much warmth, nurturance, and acceptance (versus hostility and rejection) caregivers convey to children. The second is how much control structure, and involvement (versus permissiveness and detachment) caregivers display toward children. High levels of warmth are associated with elevated self-esteem, compliance with caregiver demands, internalized moral standards, cognitive competence, and social adjustment. Giving children developmentally appropriate levels of structure and control helps them attend to and focus on important features of the environment and acquire the skills necessary for self-control and self-management.

Planned Activities: Continued emphasis on research on child care.

Research on Childhood Cancers, AIDS and Infant Mortality (NIH/NCI)

Target Population: Infants and children from birth to 21 years of age

Description: In the United States, less than 1% of all cancers occur in children under 15 years of age. However, this accounts for over 8800 cancers diagnosed annually among children and the second leading cause of death among children, trailing only accidents. Although rates may vary for a particular cancer from 0-4 year age group and older age groups, research generally includes children through the entire age range.

The research and educational activities of the National Cancer Institute (NCI) covers all the cancers relevant to children 0 to 5 years of age. NCI conducts and supports a range of intramural and extramural laboratory and clinical studies of childhood cancers such as leukemia, lymphoma, muscle tumors (e.g., rhabdomyosarcoma), renal tumors (e.g., Wilms' tumor), brain tumors, neuroblastoma, and retinoblastoma. Moreover, NCI, in collaboration with other NIH institutes, supports research to improve bone marrow transplantation for the treatment of potentially fatal childhood blood and immune disorders, including severe aplastic anemia, leukemia, and severe combined immunodeficiency. The genetic causes of hereditary cancers that affect children as well as adults are also being actively explored. As the ability to identify families at increased risk for these cancers improves, the effects of childhood screening programs will also need to be evaluated.

The NCI also conducts and supports research into the prevention, control and treatment of pediatric AIDS. NCI-supported research has shown that mother-to-infant rate of HIV transmission can be reduced from 26% to 7% by administering AZT to pregnant HIV-infected women. Additional studies involve basic science and epidemiological surveys of other human retroviruses.

Contribution to Initiative: Through the efforts of the NCI clinical trials program, pediatric patients have greater access to advanced therapeutic approaches. About 70% of children who

develop cancer in the United States annually are treated in the NCI-sponsored Cooperative Groups clinical trials.

Accomplishments: The NCI has developed public education materials for children with cancer, their families, teachers, and friends. Materials suitable for parents and teachers present topics related to talking to children about cancer, the common types of childhood cancer, cancer treatments and side effects, and other issues that may arise when a child is diagnosed with cancer.

Planned Activities: NCI will continue to support research on childhood cancers, pediatric AIDS, and infant mortality.

Research on Visual Disorders of Childhood (NIH/NEI)

Target Population: Children from birth to five years of age

Description: The National Eye Institute (NEI) is conducting basic and clinical research on the normal development of the eye and visual systems, as well as the pathology and etiology of childhood diseases and disorders that cause visual loss and disability in infants and children. It is estimated that between 1 and 4 percent of the childhood population is affected by strabismus and 1 to 2 percent suffer from amblyopia. Amblyopia is the primary cause of visual loss in young children in the United States. The NEI is also supporting clinical studies to evaluate a variety of treatments and interventions for retinopathy of prematurity (ROP). ROP is a disorder of retinal vascular maturation manifested by an abnormal proliferation of blood vessels in the immature retina of a premature infant. Proliferation of new vessels in the vitreous may lead to irreversible retinal detachment. Retinoblastoma is a life threatening intraocular malignancy of childhood and is diagnosed in children from birth to age seven. The predisposition to retinoblastoma can be inherited as a dominant genetic trait, or the tumor can arise from the spontaneous transformation of a single cell in the retina.

Contribution to Initiative: A greater understanding of the basic mechanisms of development of the eye and visual system will provide opportunities to develop effective therapies and interventions to prevent visual loss and disability in infants and young children.

Accomplishments: A nationwide randomized clinical trial has demonstrated the beneficial effect of peripheral retinal cryotherapy in reducing the risk of progression from the moderate "threshold" stage of ROP to more severe, sight damaging stages and the long-term preservation of sight. NEI supported research has also been responsible for isolating, cloning and sequencing the gene responsible for retinoblastoma.

Planned Activities: Activities include: understanding the function of the retinoblastoma gene product at both the cellular and molecular level in the etiology of retinoblastoma and the development of the retina; determining what factors affect the pathogenesis of ROP; and, investigating the time-course and developmental program of all visual subsystems that become

functional during the critical period during which strabismus and amblyopia develop in the child.

Cardiovascular Research (NIH/NHLBI)

Target Population: Children from prenatal development to 5 years old.

Description: The National Heart, Lung, and Blood Institute (NHLBI) supports a large portfolio of basic, clinical, and behavioral research relating to cardiovascular diseases of early childhood. Major efforts include studies of surgical intervention to correct congenital heart defects in infants; research for diagnosis, treatment, and prevention of these genetic defects; and research on other genetic diseases such as familial hypercholesterolemia, Liddle's syndrome (a severe early form of hypertension), and hypertrophic cardiomyopathy that manifest early in childhood. Genes for many of these diseases have already been identified and are being used to develop prenatal and neonatal screening tests as well as targeted drug- and gene-based therapies. Another focus is on complex interactions between genes and environmental factors in heart disease. Examples include research on the effect of nutrients on prenatal heart development and the mechanisms by which infectious agents in Kawasaki syndrome cause coronary inflammation and eventually aneurysms in young children.

Contribution to Initiative: NHLBI-supported research has led to major reductions in infant mortality from congenital heart disease (by more than half since 1968) and molecular genetic research presents the best chance for diagnostic screening and prevention. Molecular genetic methods are also identifying the mechanisms of many inherited and acquired cardiovascular diseases that cause stroke, heart attacks, aneurysms, and sudden cardiac death in very young children. Knowing the causes will allow researchers to develop targeted therapies to prevent cardiovascular damage and reduce childhood mortality.

Planned Activities: Working groups are planned for FY 1997 to determine strategies for research on pediatric arrhythmias and their treatment and to explore scientifically based strategies for evaluating the safety and efficacy of pediatric cardiovascular therapies through randomized clinical trials.

Lung Research (NIH/NHLBI)

Target Population: Children from prenatal development to 5 years old.

Description: The National Heart, Lung, and Blood Institute (NHLBI) has several research programs in the areas of lung development, diseases such as neonatal respiratory distress syndrome (RDS) and asthma that frequently manifest at birth and in early childhood, and other genetic lung diseases. Important medical advances from past and current research include prenatal screening and antenatal corticosteroid treatment to prevent RDS, respirators and lung surfactant replacement for premature infants with RDS, family asthma management and prevention of acute attacks in young children, risk factors for asthma, new drugs and self-

management regimens for cystic fibrosis (CF) patients, the Back-to-Sleep Campaign to reduce Sudden Infant Death Syndrome (SIDS), and the discovery that SIDS occurs more frequently in families with adult members who have sleep apnea than in unaffected families. Recently, a method has been discovered for stimulating growth of new air sacs in the lungs that may some day provide a cure for neonatal RDS and related conditions. Current research focuses on developmental, genetic, inflammatory, infectious, and environmental aspects of asthma and CF; treatment and prevention of these diseases and their complications; and new RDS treatments.

Contribution to Initiative: Problems in early lung development and severe lung diseases that begin in early childhood increase childhood and infant mortality and cause life-long debilitation. NHLBI-sponsored research has been critical to reducing infant mortality from RDS (to one-sixth the level in 1968; surfactant drugs have reduced the rate to less than half that in 1989). The Institute's comprehensive approach to research on causes, diagnosis, treatment, prevention, and patients' roles in management of chronic diseases such as asthma and CF is decreasing the need for frequent hospitalization and enabling young children to live fuller and more active lives.

Planned Activities: The new NHLBI Specialized Centers of Research in the Pathology of Lung Development will study genetic and physiological factors affecting lung development, growth, and repair in health and disease. Recent research indicates that some early viral infections may protect young children from developing asthma. A new initiative will further investigate the role of infection in asthma development and explore strategies for preventing asthma and halting its progression.

Blood Research (NIH/NHLBI)

Target Population: Children from prenatal development to 5 years old.

Description: The National Heart, Lung, and Blood Institute (NHLBI) supports an intensive program of prenatal, perinatal, and early childhood research in genetic blood diseases such as sickle cell anemia, Cooley's anemia, hemophilia, and Fanconi anemia. Genes for these diseases and for diseases that are fatal in infancy, such as X-linked severe combined immunodeficiency disorder, have been discovered through NHLBI-supported research. Major areas of achievement include prenatal screening and prevention, neonatal diagnosis, disease management, development of targeted drug therapies, prevention of serious complications such as stroke and opportunistic lung infections in young children with sickle cell disease, and prospects for gene-based therapy. NHLBI-supported research is also developing bone marrow and blood stem (progenitor) cell transplantation technology to treat these and other blood diseases such as severe aplastic anemia and childhood leukemias.

Contribution to Initiative: The NHLBI's comprehensive approach to chronic disease management and prevention of complications has resulted in a greatly increased average life span for sickle cell anemia, Cooley's anemia, and hemophilia patients in the past 25 years, and has reduced the need for hospitalization.

Accomplishments: Recent advances in genetic disease research include hydroxyurea therapy for sickle cell anemia, successful cures of sickle cell anemia through bone marrow transplantation, and blood product-free recombinant DNA forms of blood clotting factors VIII and IX for hemophilia patients. Advances in transplantation research include reduction of immune reaction risks from transplantation, use of blood stem cells from umbilical cords discarded after birth as a painless and readily available alternative to bone marrow, and a successful demonstration of bone marrow transplantation in utero to cure a rare fatal blood disorder before birth.

Planned Activities: The NHLBI is planning workshops on the immunogenetics of inhibitor formation in hemophilia and research plans for Fanconi anemia in FY 1997.

AIDS Research (NIH /NHLBI)

Target Population: Children from prenatal development to 5 years old.

Description: National Heart, Lung, and Blood Institute (NHLBI) programs addressing pediatric AIDS include a clinical trial to determine whether hyperimmune globulin (HIVIG) treatment in HIV-infected pregnant women can prevent HIV transmission to their fetuses, a clinical trial of HIVIG in HIV-infected newborns, and a study of pediatric pulmonary and cardiovascular complications in HIV-infected infants (P2C2 Study). Preliminary results from P2C2 reveal that HIV-infected children often have depressed left ventricle (LV) function in their hearts which can be missed or misdiagnosed and can lead to numerous complications. Further studies will determine whether tracking methods for LV function can be used to diagnose early heart and lung complications of HIV so children can be treated more effectively.

Contribution to Initiative: AIDS has been diagnosed in more than 4,700 children in the United States. In the past year, about 800 pediatric AIDS cases were diagnosed, more than 90 percent of which were infections transmitted from mother to child during pregnancy or at birth. These research efforts are leading to new strategies for preventing maternal transmission of HIV infection and to earlier diagnosis and treatment of HIV-infected children with heart and lung abnormalities.

Planned Activities: A new NHLBI initiative for FY 1997 will fund basic research on the development of monoclonal antibodies to interrupt or slow maternal-fetal transmission of HIV.

Research on Fetal Alcohol Syndrome (NIH/NIAAA)

Target Population: Infant and Prenatal Development

Description:

Infant Development: Pre-and perinatal nutrition have been shown to be significant factors in the proper development of the fetus and infant. Recently, it has become increasingly clear that the principal nervous system polyunsaturated fatty acid, docosahexaenoic acid

(DHA), is important for optimal brain development. Although newborn infants as small as 2 kg have the capacity to produce DHA, the amounts that can be produced are limited and do not appear adequate for proper development of the brain and retina. Since alcohol can lower tissue levels of DHA, a fetus of an alcoholic mother can be expected to receive a triple insult. The mother's diet is likely to be poor and contain inadequate DHA, as well as inadequate antioxidant vitamins that help to maintain this essential fatty acid in organs. Secondly, the mother's tissue and blood levels of DHA may be lowered by alcohol abuse, thus diminishing her capacity to supply the fatty acid to her fetus. And finally, alcohol, itself, likely leads to a loss in fatty acid biosynthetic capacity and an increase in fatty acid break-down in the fetus and newborn.

Accomplishments: These results point to obvious therapy or preventative strategies to prevent these DHA related deficiencies by simply supplementing infant formula with DHA. It is a very inexpensive measure that could lead to enormous public health dividends, if this line of research pans out.

Planned Activities: The above description forms the basis for a hypothesis concerning the development of FAS that is actively being pursued in NIAAA's intramural program.

Prenatal Development: Fetal Alcohol Syndrome (FAS) is a cluster of defects that includes physical abnormalities, growth retardation, and mental impairments such as mental retardation and behavioral dysfunction and is the severe end of a continuum of birth defects caused by exposure to alcohol during prenatal development. Alcohol is one of a number of chemical compounds that are toxic to the developing central nervous system of humans. Of all drugs of abuse, alcohol produces by far the most serious neurobehavioral effects in the fetus. Throughout gestation, the fetus is in a continual state of orderly biochemical and structural transitions during which new tissues are being formed and spatially rearranged. At any time in the total span of development, these ongoing processes can be subtly deflected, severely perturbed, or abruptly halted. Alcohol causes the characteristic features of FAS, craniofacial defects of the eyes, upper lip, and jaw, arising from improper development of the cranial neural crest during embryogenesis. The effects of alcohol exposure during specific stages or "critical periods" of development are probably best documented in their anatomical or dysmorphogenic effects (malformation, disruption, and deformation). NIAAA's research is dedicated to determining the mechanisms involved in the teratogenic effects of alcohol in an effort to develop treatment and prevention strategies for alcohol-related birth defects. Additional research supported by NIAAA employs neuroimaging techniques, in conjunction with sophisticated neuropsychological tests, to provide clues about impaired behavioral and cognitive function in children exposed prenatally to alcohol. Other studies are using a new form of magnetic resonance image (MRI) analysis in conjunction with behavioral tests to determine the feasibility of this approach for developing clinical protocols for the detection of alcohol-related brain damage.

Accomplishments: Progress on elucidating the mechanism of alcohol's effect on fetal development is leading to areas for potential therapeutic interventions. One reasonable mechanism for alcohol's effects on human fetal development leading to the manifestations of FAS has recently been. The data indicate that a dose of alcohol

equivalent to one drink completely inhibits the process of cell-cell adhesion which is critical during embryonic development. Additional recent studies have demonstrated that alcohol induces excessive cell death through the formation of free radicals in pre-migratory neural crest cells. This may, in part, explain the craniofacial malformations in children with FAS. The investigators also found a potential point for intervention by noting that the addition of a free-radical scavenger, for example, superoxide dismutase (SOD), ameliorates this alcohol-induced cell death.

Contribution to Initiative: These projects are an excellent example of the inter-related nature of basic and clinical science and the applications to disease. They also show the critical nature of nutrition in modulating the damaging actions of alcohol in both mother and child. An important public health benefit may be obtained through this line of research if future studies can show that dietary supplementation of infant formulas with DHA result in more optimal neural development. Knowledge of the etiology of birth defects, such as from neuroimaging studies, helps clinicians to make a proper diagnosis and to recommend the most beneficial treatment. Recent results from neuroimaging studies suggest that it may be possible to distinguish FAS from other forms of mental retardation.

Protecting the Health of Newborns (NIH/NIAID)

Target Population: Pregnant women and newborns

Description: Newborns can acquire a variety of infectious diseases from their mothers during the prenatal and perinatal periods, i.e. during development or delivery. Maternal infections such as cytomegalovirus, herpes, and syphilis can have severe consequences for the fetus, including premature birth, low birth weight, sensory impairments, and other developmental abnormalities. An overwhelming majority of pediatric AIDS cases in the United States, especially among children under age 5, are acquired perinatally.

NIAID research strives to prevent mother to infant transmission of such diseases through early diagnosis and treatment of infectious diseases in pregnant women. Researchers supported by NIAID are working to develop better, less costly diagnostic tests for syphilis, gonorrhea, chlamydia, and other infectious diseases which would allow large-scale screening for these infections to become a routine part of health care. The development of maternal vaccines is another important focus of NIAID research to prevent mother to infant transmission of infectious diseases. Maternal vaccines against Group B streptococcus, a microbe that causes serious invasive infections in infants, are being studied in NIAID-supported clinical trials. Researchers have succeeded in developing an effective way to prevent perinatal transmission of HIV, but studies continue in an effort to evaluate other preventive approaches and to identify factors, such as co-infection with Hepatitis C, that promote perinatal transmission of HIV.

Accomplishments: Examples of recent NIAID accomplishments in this area include: research co-funded by the National Institute of Child Health and Development (NICHD) that led to the

finding that AZT administration to pregnant women significantly reduces the risk of HIV transmission from mother to infant; the development of new rapid and sensitive tests to detect chlamydial and gonorrheal infections; and the development and testing of a vaccine against Group B strep, which causes pneumonia, meningitis, and other serious illnesses in infants.

Planned Activities: NIAID will continue to support research on diagnostics, therapies, and vaccines to prevent transmission of infectious diseases from mother to infant. Studies are ongoing and are planned to evaluate additional anti-HIV therapies to prevent HIV infection of newborns.

Advancing the Development of Childhood Vaccines NIH /NIAID

Target Population: Infants and young children

Description: Because their immune systems are immature and have not learned how to mount a protective response to infectious pathogens, infants and young children are very vulnerable to infectious diseases. Vaccines have contributed significantly to protecting the health of infants and young children against diseases such as polio, measles, meningitis, and whooping cough (pertussis). By protecting the health of children against infectious diseases, vaccines also contribute to the healthy development of children, including their ability to learn and do well in school.

NIAID supports research on the development of new or improved vaccines against infectious agents that are responsible for a significant amount of morbidity and mortality. Among the childhood vaccine efforts currently underway are those for respiratory syncytial virus, rotavirus, pneumococci, other streptococci, influenza and parainfluenza viruses, measles, and pertussis. NIAID has been recognized by Congress as the lead agency within the U.S. Public Health Service to provide the scientific and programmatic direction for the Children's Vaccine Initiative (CVI). The goal of the CVI is to accelerate the development of new types of vaccines that can be administered orally, with fewer doses, and at younger ages.

Accomplishments: Examples of NIAID's childhood vaccine accomplishments include: the development of a vaccine against *Hemophilus influenzae* type b (Hib) which has virtually eliminated Hib-associated meningitis in the U.S., saving thousands of infants' lives and sparing many others from permanent neurological damage; the development of an acellular vaccine for pertussis that has fewer side effects than the existing whole cell vaccine; and the testing of a vaccine against rotaviruses which cause severe diarrheal diseases in children and kills more than 870,000 children under age 5 worldwide every year. The new rotaviral vaccine could prevent more than one million cases of rotaviral diarrhea among children under 5 years of age in the United States annually.

Planned Activities: NIAID will continue to support basic and clinical research to develop safe and effective vaccines against infectious diseases in order to improve the health of infants and young children. Novel vaccine approaches, such as naked DNA vaccines, will continue to be

studied for several diseases. Naked DNA vaccines, because they are stable, inexpensive, easy to administer, and do not require refrigeration for storage, provide a promising alternative for immunization, particularly in developing countries. NIAID will also continue to strive toward achieving the goal of the Children's Vaccine Initiative.

Developing Treatments for Infectious and Immunologic Diseases of Early Childhood (NIH/NIAID)

Target Population: Infants and young children

Description: Infectious diseases and immunologic disorders contribute significantly to childhood mortality and illness. Asthma is one of the most common chronic diseases of childhood, disproportionately affecting African-American children. Infants and children under 5 years of age are especially susceptible to serious consequences of airway obstruction due to asthma. In addition to basic research on the immune system, NIAID supports research to apply knowledge of the immune system to studies that attempt to diminish asthma morbidity by reducing the amount of indoor allergens in the home. NIAID also funds asthma demonstration and education research projects that focus on children with asthma.

Primary immunodeficiencies result from various genetic abnormalities of the immune system and cause recurrent, and often life-threatening, infections. While the frequency of any one of these diseases is low, in aggregate they constitute a major health problem among children. NIAID-supported research on particular primary immunodeficiencies aims toward identifying the responsible gene, defining its role in immune responses, and utilizing this information to design improved therapies and diagnostic procedures.

Autoimmune diseases, such as insulin dependent diabetes mellitus (IDDM), are also a significant health concern among young children. NIAID is supporting research projects that combine investigations of basic, molecular, immunologic, and genetic mechanisms in the pathogenesis of autoimmunity and the development of innovative therapies for autoimmune diseases.

Some diseases of childhood can result in organ failure. NIAID supports research to better understand the body's reaction to transplants and supports pediatric clinical trials to examine new treatments to prevent the rejection of transplanted kidneys in children. NIAID-supported basic research leads to a better understanding of the pathogenesis of various childhood infections and to new and improved treatments for these infections. NIAID supports clinical trials to evaluate therapies for a variety of infectious diseases, including HIV, cytomegalovirus, herpes, and recurring respiratory papillomatosis, in children under age 5. Treatments for HIV-infected children are evaluated in clinical trials through the Pediatric AIDS Clinical Trials Group.

Accomplishments: Examples of recent NIAID accomplishments in treatments include: the identification and characterization of genes that cause a number of primary immunodeficiency diseases including: Severe Combined Immunodeficiency, X-linked Agammaglobulinemia, Wiskott-Aldrich Syndrome, Chronic Granulomatous Disease, Leukocyte Adhesion Deficiency

and many of the Complement Deficiencies; and the identification of factors determining asthma severity and morbidity among inner-city children in the National Cooperative Inner-City Asthma Study (NCICAS).

Planned Activities: NIAID will implement a Primary Immunodeficiency Disease Registry in FY 1998. The registry will help enhance participation of affected children in research studies and provide accurate and up-to-date information to clinicians and genetic counselors. NIAID is planning an initiative to encourage research on immune tolerance, a topic that applies to several areas of research, including autoimmune diseases, organ and cell transplantation, asthma and allergy, and infectious diseases.

Research on Osteogenesis Imperfecta (NIH / NIAMS)

Target Population: Affected individuals, primarily young children

Description: Osteogenesis imperfecta (OI) is a genetic disorder that results in brittle bones, leading to frequent fractures and, in severe cases, to skeletal deformity. Most often, the underlying cause is a defect (mutation) in the gene for a collagen protein, which is essential for the normal structure of bone. The disease occurs in about 1 in 20,000 to 30,000 births. It affects individuals of both genders and of all racial and ethnic origins equally. Milder forms of the disease reflect the failure of bone cells to synthesize normal amounts of collagen. More severe forms arise from mutations that alter the structure of the collagen itself, leading to abnormal interactions between the mutant collagen and other components of bone.

Contribution to Initiative: This research will benefit children affected with this difficult disease of childhood and increase their ability to fulfill their full potential

Accomplishments: Researchers have new insights into the causes of osteogenesis imperfecta. It had been expected that mutations resulting in deficient collagen synthesis would reside in the region of the gene that controls synthesis of messenger RNA, the first step in the synthesis of a protein. However, investigators have now analyzed collagen genes from a number of OI patients and found that this is not usually true. Instead, mutations are found in the regions of the gene that determine the structure of the messenger RNA. Unexpectedly, these mutations do not simply alter the structure of the collagen protein but instead prevent the synthesis of normal amounts of the protein. This observation suggests complexities in the process of protein synthesis that had not previously been recognized. It appears that even very subtle changes in specific parts of the messenger RNA can substantially reduce the amounts of collagen protein synthesized.

Planned activities: The therapy of genetic disorders such as OI is a very difficult problem. It is especially difficult in the instances of severe OI in which a mutant collagen is produced. In such a disease, a way must be found to inactivate the mutant gene without also inactivating normal genes that may be very similar to the mutant gene. The discovery that certain minor changes in the structure of a messenger RNA can largely prevent the synthesis of the corresponding protein

suggests ways in which mutant genes might be inactivated. In principle, agents can be designed that will recognize the small differences between mutant and normal collagen messenger RNAs and effect changes resembling those now known to prevent synthesis of certain mutant collagens. Effectively, this would convert a severe form of OI into a milder form. This strategy, if it can be made to work, could also be applied to many other genetic diseases in which mutant genes produce abnormal proteins with pathological effects.

In September 1994, NIAMS began funding the National Resource Center on Osteoporosis and Related Bone Diseases to generate a nationwide prevention and education effort. The project is being carried out by a consortium of organizations led by the National Osteoporosis Foundation (NOF). Joining NOF are The Paget's Foundation for Paget's Disease of Bone and Related Disorders and the Osteogenesis Imperfecta Foundation. The National Resource Center will provide state-of-the-art information on bone diseases to health professionals, patients, and the public.

Research on Epidermolysis Bullosa (NIH/primarily NIAMS)

Target Population: Affected individuals, primarily children

Description: Epidermolysis bullosa (EB) is a group of rare, hereditary blistering disorders that involve the skin and mucous membranes. More than 20 different forms of this disease have been described. EB can range from a relatively mild condition to a severely disabling and sometimes fatal disease. The skin of patients with EB is extremely fragile, and the slightest friction can cause painful blistering. In severe or dystrophic EB, blisters can cover most of the body and occur in the digestive tract. Often wounds from severe EB resemble serious burns.

It is estimated that one out of every 50,000 infants is born with EB. It is diagnosed by skin biopsy, in which a small amount of skin is removed for microscopic analysis. Skin care for all EB patients centers around trauma protection, prevention of skin infections, and rapid wound healing. There is no special treatment available for the condition, but a variety of dressings, antibacterial soaps, antibiotic creams, and topical steroids are used. EB is a life-long disorder and can cause extreme physical, emotional, and financial hardships for the afflicted patients and their families.

Researchers are exploring a treatment possibility for EB using cultured grafts in which skin cells are genetically altered and transplanted back into patients. Work is also rapidly expanding on factors that regulate skin cell gene expression and cell growth, and an animal model has been developed that may allow preliminary screening of new treatments and prevention strategies.

Contribution to Initiative: This research will benefit children affected with this difficult disease of childhood and increase their ability to fulfill their full potential

Accomplishments: Researchers have identified, with precision, the layers of skin that are affected by EB. In some types of EB, wounds occur in the outer layer of skin, the epidermis. In

other types, blistering wounds form in the basement membrane zone, which lies immediately below the epidermis, or in the inner layer of skin, the dermis, which is located below the basement membrane zone. In addition, type VII collagen has been identified as the major protein of anchoring fibrils, which link the epidermis to the dermis.

More than 10 years ago, clinicians began to note reduced or absent type VII collagen in skin samples from patients with dominant dystrophic EB (DDEB) which is characterized by deep blistering in the dermis. More recently, an NIAMS-supported research team discovered that DDEB is linked to the gene for type VII collagen. This strongly suggests that disruption of type VII collagen production leads to DDEB.

Two other research teams have discovered that defects in genes for fibrous skin proteins known as keratins--the most abundant protein in epidermal cells--are linked to a form of the disease called EB simplex. In EB simplex, non-scarring blisters form in the outer skin. Research results from these three teams (and from other investigators) continues to shed light on the genetic origin of the various forms of EB.

NIAMS-supported skin diseases research centers have made significant contributions to our understanding of many skin diseases, including EB and they have served to attract many new investigators to the field. The NIAMS funded the National EB Registry for 10 years. This Registry provides genetic and diagnostic information about the disease and also serves as an interface between researchers interested in EB and patients willing to participate in therapeutic protocols. Research discoveries of the genetic causes of some forms of EB made the Registry a good source for applying gene therapy directly to the skin.

Planned Activities: Continued support of a broad spectrum of studies of EB is planned. Particular focus is being placed on advancing the technology of keratinocyte gene transfer.

Research on Arthritis in Children (NIH /primarily NIAMS)

Target Population: Children from birth through adolescence.

Description: Arthritis in children is a broad term that includes all of the rheumatic diseases that afflict children. These diseases may affect not only the joints but also other connective tissues of the body, including important supporting structures such as muscles, tendons, and ligaments, as well as the skin and certain internal organs. The most common types of arthritis in children include juvenile rheumatoid arthritis (JRA), ankylosing spondylitis (arthritis of the spine), juvenile dermatomyositis (which affects the skin and muscles), juvenile psoriatic arthritis (which occurs with the skin disease psoriasis), and juvenile systemic lupus erythematosus (a chronic inflammatory disease). The purpose of this research is to gain new insights into the causes of these diseases so that therapeutic treatments--and possibly cures--of these disorders can be learned.

Contribution to Initiative: Gaining a better understanding of the causes of these debilitating

disorders can lead to new approaches in the treatment and management of these diseases. This in turn can improve the quality of life for children afflicted with these disorders as well as their parents and families.

Accomplishments: Arthritis in children is the focus of a research center grant that was awarded to the Children's Hospital Medical Center in Cincinnati, Ohio. The research being carried out at this center includes 1) a long-term outcome study in patients with JRA to determine ways to predict the course and severity of the disease; 2) experiments with immune cells suspected of initiating and sustaining chronic joint inflammation in JRA; and 3) a project on Kawasaki disease to determine if bacteria or viruses trigger the disease.

The NIAMS has awarded other research projects dealing with juvenile rheumatoid arthritis, juvenile dermatomyositis and lupus in children. In addition, a training grant was awarded to the Children's Hospital Medical Center in Cincinnati, Ohio, to train pediatric rheumatologists and other junior scientists in research in juvenile arthritis.

The NIAMS has also awarded contracts for the establishment of research registries focusing on childhood rheumatic diseases. These registries focus on areas such as juvenile rheumatoid arthritis, juvenile dermatomyositis and neonatal lupus.

Planned Activities: The NIAMS plans to continue to place a high priority on these disorders and stands ready to support additional meritorious research in any of these areas.

Prenatal and Perinatal Research on Humans and Animals (NIH / NIDA)

Target Population Drug dependent pregnant women and their infants

Description: The 1994 National Pregnancy and Health Survey estimated that 221,000 women used one or more illicit drugs during pregnancy. Prenatal drug exposure has the potential to influence the development and health of infants and children in many ways. Human studies have been examining consequences of prenatal cocaine/polydrug exposure over the first three years of life. These include individual-institution projects, as well as a NIDA/NICHD/CSAT/ACYF multi-site project which is currently following the development of a large group of prenatally exposed infants through three years of age. Animal studies are being conducted on a variety of issues regarding prenatal drug exposure, such as effects on pregnancy outcome, the newborn, and development. Factors which may contribute to variability in human studies are amenable to laboratory research with animals, including the uncertainty of the woman's temporal pattern and extent of drug abuse, potential confounding variables, such as use of legal drugs, the health status of the mother during pregnancy, and various postnatal factors.

Contribution to Initiative: Findings from longitudinal research on consequences of prenatal marijuana exposure are indicating a possibility of later emergence of behavior deficits associated with prenatal exposure. The studies alert educators and other child care providers to seek further information on the preschool and school age group in order to address needs appropriately (e.g.,

develop appropriate interventions to prevent or minimize negative consequences).

Planned Activities: Given the strong possibility that effects of prenatal drug exposure may emerge as new areas of functioning are expected to develop (e.g., language and problem solving), it is essential to conduct longer-term follow-up studies into the preschool and school years. The planned approach to addressing needs in this area is to build on the strengths of existent longitudinal research, by supporting studies to follow children beyond the third year of age. Animal models research will be enhanced and directed at (a) investigating the effects of prenatal maternal and paternal drug abuse and its biological mechanisms, and in particular the study of the offspring throughout the life-span, and (b) investigating the genetic and environmental determinants of vulnerability to drug abuse.

Prenatal and Perinatal Research related to HIV (NIH/ NIDA and NIAID)

Target Population Pregnant women with HIV and their children

Description: Research is still very much needed on drug abuse aspects of mother-infant HIV transmission and child HIV disease. The HIV/AIDS research program specific to children includes research on drug abuse aspects of (a) mother-infant transmission and the course of pediatric HIV disease progression, (b) the spectrum of HIV disease and associated conditions and consequences, and (c) effectiveness of HIV risk-reduction strategies for children. In FY 1994, NIDA and NIAID began collaborative funding and formal staff involvement on a large cohort study, Women and Infants Transmission Study (WITS II), a natural history study of HIV/AIDS.

Contribution to Initiative: Maternal-infant transmission of HIV is often an indirect health consequence of injection drug use. Of the 7,296 cases of AIDS among children younger than thirteen years of age reported to the Centers for Disease Control and Prevention through June 1996, 90 percent were attributable to perinatal HIV transmission, with 55 percent being drug related (mother an injection drug user or having sexual contact with an injection drug user). Therefore, research into maternal-infant transmission of HIV could result in a dramatic reduction in infants and children with AIDS. Recent multi variate analyses in WITS indicated an almost two-fold increase in the risk of mother-to-infant HIV transmission associated with prenatal drug use. These results not only document a prenatal drug use-perinatal transmission relationship, but also provide a basis for further hypotheses as to the timing and mechanisms of transmission.

Planned Activities: The planned approach to continued advancement of the NIDA mission regarding pediatric HIV/AIDS is twofold. First, NIDA will maintain planned ongoing collaborative support with NIAID for the WITS II pediatric cohort study, and second, it will encourage applications from and provide support for individual, high-quality investigator-initiated projects addressing focused issues on drug abuse aspects of pediatric HIV disease.

Prenatal, Behavioral and Epidemiological Research (NIH / NIDA)

Target Population: All children

Description: Parental and societal substance abuse has the potential to influence the development and health of infants and children in many ways, via direct effects, such as prenatal drug exposure or postnatal passive drug exposure, and via indirect effects associated with drug abuse. Some of these indirect effects may be very specific, such as the transmission of HIV from mother to infant, and some may be complexly interwoven, such as violence in the home and the community, and dysfunctional parenting associated with substance abuse. Outcomes of interest range from fetal development to infant and child developmental functioning, to vulnerability to drug abuse among the children. Research on the etiology and epidemiology of drug use and abuse includes studies to identify familial, environmental, genetic, social, biologic, and intrapsychic vulnerabilities to drug use, such as psychiatric or behavioral problems, child abuse and neglect, and growing up in drug abusing families and communities.

Contribution to Initiative: Special survey and studies, such as the National Pregnancy and Health Survey, are conducted to identify patterns of drug use among pregnant women. Additionally, a variety of animal models of drug abuse investigating both genetic factors and environmental factors (e.g., stress, nutrition) that contribute to vulnerability to drug abuse are supported. The findings of these surveys and studies contribute to the development of effective interventions which will reduce the incidence of drug use by parents, child abuse and neglect, and psychiatric or behavioral problems, thereby ensuring children of healthier environments in which to grow up.

Planned Activities: Research announcements currently seek applications on family interventions to prevent drug use, drug use and abuse in minority and underserved populations, etiology and prevention of drug use by children in other countries, and statistical and methodologic studies to enhance epidemiologic research. Scientific meetings are planned to promote and support program initiatives on development of children growing up in drug-abusing environments, and on childhood psychopathology as a risk for drug abuse.

Pharmacological Research NIH (NIDA)

Target Population: Drug dependent pregnant women and their children

Description: Problems in pharmacological drug abuse treatment continue to be greatest for pregnant women. In the past, many treatment programs automatically excluded pregnant women because of liability concerns. When pregnant women succeed in gaining access to treatment, they face yet another hurdle-- the lack of pharmacotherapies specifically approved for use in pregnancy. Pharmaceutical firms rarely, if ever, seek approval for use of their product by pregnant women, mostly because of liability concerns. Therefore, medications specifically developed for addicted pregnant women which do not affect the fetus must be developed.

Specific research needs include the development of ligands for specific opioid receptors which are present in the adult but not expressed during early fetal development, taking advantage of the natural barrier properties of the placenta and designing medications which would not pass the placenta, and designing bipolar antibodies which interact with both a placental antigen and a drug of abuse to prevent or reduce fetal exposure. Also needed are therapies safe for use with infants and young children with drug dependence.

Contribution to Initiative: This is a new initiative which has yet to yield measurable results. However, this research effort holds the potential for dramatically reducing the number of infants born with a dependence on drugs.

Planned Activities: A Request for Applications (RFA) was recently released which calls for research on safe and natural therapies for psychostimulant dependence and comorbid disorders, such as depression and Attention Deficit/Hyper-activity Disorder. The proposed treatments include medically designed nutritional therapies combined with effective behavioral therapies. It is hoped that this RFA will result in the development of effective treatments which will be safe and acceptable for children or pregnant women. In addition, basic animal research is being conducted to develop novel opioid peptide analogs which have fewer adverse effects on the mother and the fetus when used for pain relief during labor and delivery.

Hearing Loss in Infants and Young Children: Otitis Media NIH (NIDCD)

Target Population: Infants and children from birth to five years of age.

Description: The NIDCD hearing portfolio encompasses research studies on the causes of otitis media (OM), as well as therapies to improve outcome for infants and children with OM. Otitis media is the major reason cited for emergency room and physician's office visits by infants and young children. An important goal of the NIDCD is the development of a vaccine against OM. The most common bacterial pathogens in OM are the *Streptococcus pneumoniae* (pneumococcus), *non-typeable Hemophilus influenzae* (NTHi) and *Moraxella catarrhalis*. All three of these bacterial pathogens have polysaccharide capsules. Polysaccharide vaccines alone have not been successful in preventing OM since they lack immunogenicity when administered to infants and young children. However, vaccines using polysaccharides conjugated with protein such as the *Hemophilus influenzae* type B vaccine against meningitis have been effective in stimulating immunity in infants and young children.

NIDCD is also supporting research to examine the risk factors for chronic OM in Native American mothers and their children on the White Earth Reservation in Minnesota. The study protocol includes hearing screening and tympanometry of Native American children. Results to date suggest a high rate of chronic OM in this group (approaching 50%), with half of the affected children exhibiting an associated hearing loss.

Contribution to Initiative: There is a worldwide need for the development of a vaccine against OM. NIDCD intramural and extramural scientists, are conducting research related to the

development of a vaccine against OM. A vaccine to combat OM would reduce the human and financial toll on infants, children, their families and upon the health care system.

Accomplishments: Stage I clinical trials of conjugated vaccines against the pneumococcus in infants and children have been completed, and Stage II clinical trials are underway. NIDCD scientists have successfully prepared a detoxified lipooligosaccharide (dLOS)-based conjugate antigen from NTHi that induces a bactericidal humoral immune response in two animal models and reduces the incidence of OM in the only reliable animal model of the disease, making it a promising vaccine candidate.

Planned Activities: Plans are underway to initiate a Stage I clinical trial of the detoxified lipooligosaccharide (dLOS)-based conjugate antigen from NTHi as a vaccine candidate. In addition, intramural scientists are beginning work on a candidate vaccine against *M. catarrhalis* otitis media.

Voice, Speech, and Language Disorders in Infants and Young Children: Autism (NIH/NIDCD)

Target Population: Infants and young children

Description: The acquisition of a mature "theory of mind" is a major achievement of the preschool years. The understanding that other persons have knowledge and beliefs different from one's own and that those beliefs can be true or false is a major breakthrough in conceptual understanding and representational ability. Existing research fails to determine whether language plays a critical causal role in the ontogenesis of this theory of mind, since no population has been tested that lacks language during the critical years. The goals of one research program are to advance understanding of the language impairments in autism and how these impairments are related to social-cognitive deficits, specifically of the mind, that are at the core of the syndrome. NIDCD scientists are also evaluating communication development in normally developing infants and in infants with hearing impairment, Down syndrome, and autism. Intramurally, NIDCD scientists are examining the gastrin releasing peptide-receptor gene from patients with autism to determine if any allelic variants are associated with this disorder.

Contributions to Initiative: Taken together, these experiments will advance our understanding of the language impairments in autism within a particular lexical domain. Furthermore, these experiments will explore whether autistic individuals use their knowledge about the structure of language, particularly embedded sentence complements, to promote their understanding of representational mental states, and whether there is a genetic link involved as well.

Accomplishments: A longitudinal study of infant vocal development has yielded important new information on early differences between normally developing and infants with disabilities. Down syndrome and deaf infants show clear anomalies in vocal patterning in the first year of life, and there is preliminary reason to believe that other disorders (e.g., autism) may also be marked by early vocal abnormalities. While this pattern of coordination is found in both

normally developing and infants with disabilities, there are notable differences in the pattern of coordination that are found in children with disabilities. For example, autistic children show different patterns of vocalization and gesture than do normally developing, Down syndrome or deaf infants. This research has also indicated that assessment of disorders of communication can be fruitfully moved down in age to infancy. In addition, the results indicate that standardized instruments of assessment need to consider not only delays in developmental patterns for children and infants with disabilities, but also differing patterns of coordination of action across modalities in children with specific disabilities.

Planned Activities Future efforts would focus on deepening the study of early markers of linguistic disability, by expanding the frames of description of vocal development. Within the expanded frames of evaluation, it is anticipated that the proposed work will yield new means of identifying characteristics of disorders early in life and may also yield implications regarding appropriate interventions. Analysis on the molecular level with regard to autism will also continue.

Voice, Speech, and Language Disorders in Infants and Young Children: Specific Language Impairment NIH (NIDCD)

Target Population: Infants and young children.

Description: Children with Specific Language Impairment (SLI) have unexpected and unexplained difficulties learning and using spoken language in the presence of normal hearing and age-appropriate development in all other areas. Although these difficulties are most apparent during the preschool and early school years, evidence now exists that these problems are usually present well into adulthood and are probably present throughout the person's life. Impairments in reading and writing are often associated with difficulties in spoken language that first become evident during early childhood. As a result, individuals with this condition are at high risk for academic difficulties.

Contributions to Initiative: Despite the life-long academic, social, and occupational consequences of SLI on those affected, there had been, until recently, little information on the prevalence of this condition or the factors that place persons at risk for SLI. The few studies that did exist suffered from small sample sizes, poor study designs and inadequate diagnostic procedures; furthermore, none of these studies had been performed in the United States.

Accomplishments: The NIDCD, through a contract with the University of Iowa, conducted an epidemiologic study of SLI in five-year-old children based upon a sample of more than 7,256 children in the states of Iowa and Illinois. The prevalence rate of SLI in the total population is estimated to be 8.36%. Of those children with SLI, 28% presented receptive only impairments, 33% presented with expressive only impairments, 35% presented with generalized impairments, and 4% showed no deficit based on modality composite scores. Of those children with SLI, 34% also presented phonological impairments; 24% of the children with normal language status were found to have a phonological impairment. Prevalence estimates for SLI among five-year-old

boys was 8.6% and for girls was 7.1% resulting in a 1.21:1 male to female ratio. These results differ from earlier anecdotal information suggesting male to female gender ratios of around 2:1 for children with SLI. These current findings, however, are very consistent with recent epidemiologic findings for dyslexia.

Voice, Speech, and Language Disorders in Infants and Young Children: Developmental Language Disorders NIH (NIDCD)

Target Population: Infants and young children

Description: The NIDCD has awarded two clinical center grants on the origins of communication disorders. This investigation will study the nature and causes of developmental language disorders. Projects draw from a common pool of experimental methods, allowing systematic comparisons by age, domain and population. Clinical groups under study include late-talking children, children with focal brain injury, and children exposed prenatally to cocaine.

Contributions to Initiative: If not adequately addressed, developmental language disorders can seriously impair a child in his or her learning ability. By investigating the etiology of developmental language disorders in children, our greater understanding of such disorders will lead to an improved ability to design effective preventive and rehabilitative strategies for children at risk.

Voice, Speech, and Language Disorders in Infants and Young Children: Velo-cardio-facial Syndrome NIH (NIDCD)

Target Population: Infants and young children

Description: Velo-cardio-facial syndrome (VCFS) is an autosomal dominant disorder causing a spectrum of abnormalities which include: cleft palate, speech and learning disabilities, typical facial appearances and cardiac defects. Scientific cytogenetic and molecular analysis of a group of VCFS patients provides insights into its genetic basis. Understanding the pathogenesis of this disorder will require identification of the deleted genes and investigations into the role that these genes play in normal embryonic and postnatal development.

Contributions to Initiative: The identification and characterization of the gene(s) responsible for VCFS should greatly increase our understanding of the etiology of this developmental disorder and will also contribute to our understanding of normal craniofacial development. Early diagnosis of VCFS will allow timely intervention to optimize speech and language development and to avoid some of the stigma encountered as a result of defective communication skills.

Accomplishments: The majority of velo-cardio-facial syndrome (VCFS) patients (approximately 90%) have been shown to have microdeletions at chromosome 22q11.2. The region deleted is large and is likely to code for several contiguous genes. To begin to understand

how hemizygoty of this chromosomal segment gives rise to multiple defects, including cleft palate and the characteristic craniofacial dysmorphism seen in VCFS, this region must be carefully analyzed and the genes identified. These findings support the use of molecular or molecular-cytogenetic analysis for the diagnosis of patients with VCFS.

Planned Activities: A consortium of experienced basic scientists and clinical investigators at the Children's Hospital of Philadelphia, Wistar Institute, the Children's Seashore House, the University of Pennsylvania, and the University of Oklahoma have established a program dedicated to a multi-disciplinary clinical and laboratory-based investigation of VCFS. These efforts will contribute to the development of objective phenotypic criteria which will aid clinicians in recognizing those at risk for VCFS.

Rehabilitative Strategies in Infants and Young Children NIH (NIDCD)

Target Population Infants and young children

Description: Strategies are underway to prevent the disorder or alleviate the symptoms that arise in children affected by communication disorders. Hearing aids continue to be the principal form of remediation for most children with permanent hearing loss. Studies are being conducted about the best ways to select, fit and use hearing aids in children.

Basic and clinical research is being directed at better understanding the factors affecting cochlear implant performance and programming the cochlear implant to provide optimum patterns of stimulation for infants and young children. Research continues to indicate that children implanted at an early age (i.e., by 5-years old) may make greater and more rapid speech perception gains than children implanted after this age. In addition, results continue to demonstrate that children who get minimal benefit from hearing aids might benefit more from a cochlear implant.

Research into the pre-linguistic gestures of deaf children reared in signing environments will enable comprehensive comparisons between the acquisition of sign and speech. A detailed understanding of the acquisition of sign languages in deaf children will contribute toward the development of tests that will enable the identification of language delays in signing children.

Contributions to Initiative: In the United States, approximately one of every 1,000 infants are born deaf and many more will develop or be diagnosed with less severe hearing impairment later in childhood. Continued research in hearing aid and cochlear implant development and ASL acquisition will provide the tools to promote the emotional, social, educational and cognitive development in children who are deaf or hearing impaired.

Planned Activities: 1997 NIDCD/NASA/VA Hearing Aid Improvement Conference: Facilitating Partnerships for Technology Transfer; 1997 NIDCD/VA Hearing Aid Research and Development Conference.

Chronic and Infectious Diseases of Childhood NIH (NIDDK)

Target Population: Children from birth and their families to age 45.

Description: An NIDDK-sponsored multi-center clinical trial, the Diabetes Prevention Trial-1 (DPT-1), will test whether intervention during the time prior to onset of Type 1 diabetes can prevent or delay the clinical appearance of the disease in at-risk relatives of individuals with established Type 1 diabetes. Individuals will be able to enroll in either one of two studies based on their degree of risk for developing diabetes over the next 5 years. Individuals with a greater than 50 percent chance of developing Type 1 diabetes will participate in the Insulin Injection Trial and receive two shots of long-acting insulin per day. Individuals with a 25 to 50 percent chance of developing Type 1 diabetes will participate in the Oral Insulin Trial and receive a daily pill comprised of insulin and/or beta cell products. To be eligible to participate in this trial, other factors considered, individuals must be at least 3 or 4 years of age. Researchers will screen children under age 3 for possible future participation in this study. In addition, the NIDDK supports a number of childhood diabetes registries. Highlights include a population-based registry of black and Latino childhood diabetes patients in Chicago; population-based registries throughout China; and a childhood population-based diabetes registry in Finland.

In the area of infectious diseases of childhood, the NIDDK supports nutrition research related to HIV infection. The purpose of this research is to detect body composition changes in HIV-infected children, to develop an algorithm to predict impending malnutrition, to determine both resting and total energy needs at different stages of infection, and to develop intervention modalities that are appropriate for the clinical stage of disease. HIV-infected children will periodically undergo nutritional evaluation to determine dietary intake and growth in body proportions such as size and weight. Quality of life assessments as well as selected biochemical studies will also be undertaken. Children will be enrolled in intervention studies when they meet criteria for mild, moderate, and severe nutritional deficits. Information gained will be used to correlate metabolic needs and quality of life with nutritional status.

Contribution to Initiative: These chronic and infectious diseases are debilitating and very costly to society to treat. For example, Type 1 diabetes has the potential to damage virtually every major organ system. Poor nutrition in HIV-infected children leads to increased infection and morbidity and possibly increased mortality.

Accomplishments: DPT-1 centers and clinics are presently recruiting, screening, and enrolling patients in this study. Once diabetes registry populations are established, further studies allow for the assessment of natural history of the disease, genetic associations, incidence and prevalence of childhood diabetes, and the social and financial impact of the disease on families. Currently, nutritional therapy for HIV-infected patients is often based on practical experience and is not consistent. We expect that the combination of early detection of body composition changes, determination of metabolic requirements, and successful nutritional rehabilitation will significantly improve resistance to infection, morbidity, quality of life, and possibly mortality of HIV-infected children.

Inherited and Other Diseases that Emerge in Childhood NIH (NIDDK)

Target Population: From birth on

Description: Identification and cloning of the CF gene has provided an opportunity for exploring gene therapy approaches to cystic fibrosis (CF). The NIDDK is now supporting phase one clinical trials involving small numbers of CF patients to evaluate vectors based on adenovirus and adeno-associated virus as well as liposome-mediated gene transfer. Past advances have also made neonatal CF screening feasible using routinely collected blood specimens and determining immunoreactive trypsinogen (IRT) levels and CF mutations by DNA analyses. Applying the IRT assay and a two-tiered IRT/DNA method, investigators have successfully conducted a unique controlled study of both benefits and risks of CF neonatal screening. Using a randomized design, investigators screened half of the Wisconsin newborn population in the neonatal period to generate an early diagnosis/treatment group, whereas the other half has "blind" IRT or IRT/DNA testing performed, with the results not reported until the child is 4 years old. Prior to that time, CF is diagnosed in the control group based on a standard approach requiring either symptoms or a positive family history. This study should answer key questions about pulmonary benefits, delineate epidemiological characteristics of CF, allow for definition of the course of childhood CF, and elucidate risk factors for colonization and infection with *Pseudomonas aeruginosa* in the respiratory tract.

A small NIDDK-supported clinical trial is designed to test the hypothesis that alternate-day prednisone will retard or prevent the expected decline in renal function in children, adolescents and young adults affected with IgA nephropathy, who are at risk of progressive disease. The clinical trial began in September of 1994 and hopes to study a total of 140 patients ages 45 and under. This study has the potential to enroll children through age 5. A third arm has been recently added to the existing study to examine the potential role of omega-3 fatty acids found in fish oil to alter renal hemodynamics and inflammation.

Contribution to Initiative: Cystic Fibrosis (CF) is the leading hereditary cause of death in children of European descent in the U.S. Just a few decades ago, parents of the one in three thousand American babies born with CF could expect these children to live less than five years. Research, however, has led to improved antibiotic therapy, aids for clearance of lung secretions, and improved nutritional support, so that the median survival of CF patients is now 30 years of age.

IgA Nephropathy is the most common kidney disease in the world and is also one of the most frequent causes of end-stage renal failure. Currently there is no effective treatment for IgA nephropathy and the pathology of the disease is not well understood.

Accomplishments: Randomized screening has been underway in the Wisconsin study for almost nine years and progress is good. Results thus far indicate a number of potential advantages for neonatal CF screening. Continuous accrual of study patients from over 600,000 screening tests has generated sufficient statistical power for generating strong conclusions. However, statistical analyses have not yet demonstrated significant pulmonary or nutritional

benefits in the screened group, although favorable trends are emerging.

Chronic and Infectious Diseases of Childhood NIH (NIDDK)

Target Population: Children from birth and their families to age 45.

Description: An NIDDK-sponsored multi-center clinical trial, the Diabetes Prevention Trial-1 (DPT-1), will test whether intervention during the time prior to onset of Type 1 diabetes can prevent or delay the clinical appearance of the disease in at-risk relatives of individuals with established Type 1 diabetes. Individuals will be able to enroll in either one of two studies based on their degree of risk for developing diabetes over the next 5 years. Individuals with a greater than 50 percent chance of developing Type 1 diabetes will participate in the Insulin Injection Trial and receive two shots of long-acting insulin per day. Individuals with a 25 to 50 percent chance of developing Type 1 diabetes will participate in the Oral Insulin Trial and receive a daily pill comprised of insulin and/or beta cell products. To be eligible to participate in this trial, other factors considered, individuals must be at least 3 or 4 years of age. Researchers will screen children under age 3 for possible future participation in this study. In addition, the NIDDK supports a number of childhood diabetes registries. Highlights include a population-based registry of black and Latino childhood diabetes patients in Chicago; population-based registries throughout China; and a childhood population-based diabetes registry in Finland.

In the area of infectious diseases of childhood, the NIDDK supports nutrition research related to HIV infection. The purpose of this research is to detect body composition changes in HIV-infected children, to develop an algorithm to predict impending malnutrition, to determine both resting and total energy needs at different stages of infection, and to develop intervention modalities that are appropriate for the clinical stage of disease. HIV-infected children will periodically undergo nutritional evaluation to determine dietary intake and growth in body proportions such as size and weight. Quality of life assessments as well as selected biochemical studies will also be undertaken. Children will be enrolled in intervention studies when they meet criteria for mild, moderate, and severe nutritional deficits. Information gained will be used to correlate metabolic needs and quality of life with nutritional status.

Contribution to Initiative: These chronic and infectious diseases are debilitating and very costly to society to treat. For example, Type 1 diabetes has the potential to damage virtually every major organ system. Poor nutrition in HIV-infected children leads to increased infection and morbidity and possibly increased mortality.

Accomplishments: DPT-1 centers and clinics are presently recruiting, screening, and enrolling patients in this study. Once diabetes registry populations are established, further studies allow for the assessment of natural history of the disease, genetic associations, incidence and prevalence of childhood diabetes, and the social and financial impact of the disease on families. Currently, nutritional therapy for HIV-infected patients is often based on practical experience and is not consistent. We expect that the combination of early detection of body composition changes, determination of metabolic requirements, and successful nutritional rehabilitation will

significantly improve resistance to infection, morbidity, quality of life, and possibly mortality of HIV-infected children.

Inherited and Other Diseases that Emerge in Childhood NIH (NIDDK)

Target Population: From birth on

Description: Identification and cloning of the CF gene has provided an opportunity for exploring gene therapy approaches to cystic fibrosis (CF). The NIDDK is now supporting phase one clinical trials involving small numbers of CF patients to evaluate vectors based on adenovirus and adeno-associated virus as well as liposome-mediated gene transfer. Past advances have also made neonatal CF screening feasible using routinely collected blood specimens and determining immunoreactive trypsinogen (IRT) levels and CF mutations by DNA analyses. Applying the IRT assay and a two-tiered IRT/DNA method, investigators have successfully conducted a unique controlled study of both benefits and risks of CF neonatal screening. Using a randomized design, investigators screened half of the Wisconsin newborn population in the neonatal period to generate an early diagnosis/treatment group, whereas the other half has “blind” IRT or IRT/DNA testing performed, with the results not reported until the child is 4 years old. Prior to that time, CF is diagnosed in the control group based on a standard approach requiring either symptoms or a positive family history. This study should answer key questions about pulmonary benefits, delineate epidemiological characteristics of CF, allow for definition of the course of childhood CF, and elucidate risk factors for colonization and infection with *Pseudomonas aeruginosa* in the respiratory tract.

A small NIDDK-supported clinical trial is designed to test the hypothesis that alternate-day prednisone will retard or prevent the expected decline in renal function in children, adolescents and young adults affected with IgA nephropathy, who are at risk of progressive disease. The clinical trial began in September of 1994 and hopes to study a total of 140 patients ages 45 and under. This study has the potential to enroll children through age 5. A third arm has been recently added to the existing study to examine the potential role of omega-3 fatty acids found in fish oil to alter renal hemodynamics and inflammation.

Contribution to Initiative: Cystic Fibrosis (CF) is the leading hereditary cause of death in children of European descent in the U.S. Just a few decades ago, parents of the one in three thousand American babies born with CF could expect these children to live less than five years. Research, however, has led to improved antibiotic therapy, aids for clearance of lung secretions, and improved nutritional support, so that the median survival of CF patients is now 30 years of age.

IgA Nephropathy is the most common kidney disease in the world and is also one of the most frequent causes of end-stage renal failure. Currently there is no effective treatment for IgA nephropathy and the pathology of the disease is not well understood.

Accomplishments: Randomized screening has been underway in the Wisconsin study for almost nine years and progress is good. Results thus far indicate a number of potential advantages for neonatal CF screening. Continuous accrual of study patients from over 600,000 screening tests has generated sufficient statistical power for generating strong conclusions. However, statistical analyses have not yet demonstrated significant pulmonary or nutritional benefits in the screened group, although favorable trends are emerging.

Prenatal and Perinatal Related Research NIH (NIDR)

Target Population: All pregnant women and their infants

Description: Every 3.5 minutes a baby is born with a birth defect in the United States, and three-fourths of all congenital malformations affect the head, face, and neck. Research to identify pregnancy-related risk factors and understand basic developmental biology related to congenital craniofacial anomalies, such as cleft lip/palate and craniosynostosis, and genetic diseases that manifest in infancy, such as osteopetrosis, ectodermal dysplasia, and Waardenburg syndrome, is a major effort within this program. The goal, ultimately, is disease prevention, but it also encompasses research to ameliorate disease symptoms in and improve quality of life for affected individuals. Examples of this effort include studies to improve surgical methods of cleft lip and palate repair to reduce orofacial scarring and increase the chance for development of normal speech patterns without multiple, additional surgeries. An additional research focus is perinatal infection, including mechanisms of maternal to infant transmission of oral microbiota, early development of the oral mucosal immune system, factors leading to infant caries, and methods for promoting oral health and preventing tooth decay at the earliest ages. Other studies examine the role of nutritional and other factors in tooth development and diseases such as amelogenesis imperfecta and enamel fluorosis, with the ultimate goal of prevention of disease and improved oral health.

Contribution to Initiative: Research in this area has led to an understanding of the role of infant formulas and baby feeding practices in development of infant caries and formulation of public health programs to promote breast feeding for a healthy, disease free baby.

Accomplishments: In 1996, a team of 14 international researchers announced the discovery of the gene that causes the most common form of ectodermal dysplasia, the hypohydrotic or anhydrotic form, and a genetic test has been developed to identify women who are carriers for the gene to provide genetic counseling before they become pregnant. To-date, genetic "misspellings" associated with over fifty syndromes involving head and face abnormalities have been identified.

Respiratory Health, Asthma, and a Child's Environment (NIH/NIEHS)

Target Population: Infants and young children

Description: In the United States, respiratory problems, especially asthma, are the most common chronic diseases and leading causes of disability among children. Asthma is on the increase, affecting 2 million to 5 million children. It appears to affect African-American and Hispanic children disproportionately. The NIEHS is pursuing several lines of investigation on the environmental components of this disease. In one study, The Inner-City Asthma Study, NIEHS and NIAID are conducting cooperative intervention trials to evaluate a comprehensive, culturally appropriate and cost-effective intervention to reduce asthma morbidity and mortality among inner-city children. Another study will determine whether environmental intervention aimed at reducing dust mite and cockroach allergen levels in low-income homes can prevent sensitization to these allergens and reduce the prevalence of asthma in these high-risk children.

New environmental causes of respiratory disease continue to be discovered. For example, the last few years have seen a large number of lung hemorrhage (acute pulmonary hemosiderosis) cases among infants in inner-city Cleveland that often result in death. The cause appears to be related to toxins produced by the fungus, *Stachybotrys atra*, acting in concert with high moisture in the homes, stress, and the ability of fungal spores to penetrate deeply into the rapidly developing infant lungs. CDC has been actively involved in remediation and tracking efforts, and the NIEHS is investigating grant support.

Contribution to Initiative: Healthy lung function is vital to proper support of the growing body and developing brain. Prevention programs that identify and eliminate pulmonary toxicants would be the most cost-effective means of protecting childhood respiratory health while avoiding the expense and trauma of medical treatment for preventable conditions.

Accomplishments: The NIEHS has funded long-term studies on the effects of air pollution on human health. These studies have shown a positive association between chronic exposure to acid aerosols, particulate matter, and respiratory symptoms in children. The Environmental Protection Agency (EPA) used these results to develop guidelines for sulfur dioxide and particulate matter emissions.

Planned Activities: NIEHS will continue clinical and basic research investigations of environmental components of respiratory health in children.

Neurobehavioral and Cognitive Development Deficits (NIH/ NIEHS)

Target Population: Pregnant women, their infants and young children

Description: Reduced intelligence and behavioral problems are the unfortunate legacy of fetal and early childhood exposure to many common contaminants, including lead, polychlorinated biphenyls (PCBs), and mercury. Ongoing research is focused primarily on investigating the parameters of the neurobehavioral and cognitive deficits arising from early exposure to these

compounds, including the contribution of maternal sources of these contaminants through placental transfer to the fetus and through a mother's milk during lactation. A clinical trial has been initiated by NIEHS to assess the treatment of low lead levels with the use of the oral chelating compound, Succimer, and nutritional supplementation. This study is also evaluating the ability of this regimen to reverse the reduced intelligence levels that result at even low blood lead levels.

Contribution to Initiative: Every child deserves the opportunity for full mental development. Many are denied this opportunity due to unintentional exposures to neurotoxins at an early age. As the environmental contributions to mental development become more completely understood, we can better protect our children during the critical early years of brain development. It will be increasingly imperative that we do so as our society becomes more technologically-based and intellectually demanding.

Accomplishments: Based on studies by NIEHS and others that showed measurable adverse neurobehavioral and cognitive effects in children at even low blood-lead levels, the CDC amended their safety standard to reflect this new information. NIEHS studies on PCBs have also led to revised health practice. Our research has shown that nursing mothers can transfer their own internal supply of PCBs to their infants through the mother's milk and a recent study showed that PCB exposure is even more serious when the exposure happens to the developing fetus. At this time of life a child is uniquely sensitive to PCB toxicity and fetal exposure translates later into lower I.Q. scores, poor reading comprehension, memory problems, and difficulty in concentration. Although PCBs have long been banned, partly in response to earlier NIEHS study results, they still contaminate many waters and soils. For this reason women of child-bearing age and children under 15 are now advised to avoid fish taken from PCB-contaminated waters.

Planned Activities: Studies of the environmental components of intellectual and behavioral development continue, including investigations on the contribution of environmental exposures to hyperactivity and aggression.

Effects of Prenatal and Perinatal Environmental Exposures NIH (NIEHS)

Target Population: Pregnant women, their infants and young children

Description: The early years of life represent particularly sensitive targets for environmental agents. Every year 150,000 babies are born in the US with serious birth defects of which 60% have no clear identifiable causes, although environmental components are suspected. Young children are also vulnerable because their smaller body mass and formative stage of development can make them more sensitive to environmental exposures than adults. The many endocrine disrupting compounds, such as the organochlorines, released into the environment have been shown to have adverse effects on the young of wildlife, and the effects of these compounds at the lower levels experienced by people remains to be defined. The NIEHS, under the auspices of the National Toxicology Program, regularly conducts bioassays to assess the ability of chemicals to

cause birth defects and toxic effects in young animals. The NIEHS has a large portfolio of research investigating the effects of endocrine disrupting compounds on every stage of life. Epidemiologic studies are conducted to explore the environmental contributions to birth defects and childhood diseases.

Contribution to Initiative: The developing fetus and infant are particularly vulnerable targets for environmental agents. Adverse effects sustained at this time can cause health problems throughout an individual's life. When examined over the course of a lifetime, even small decrements in functioning can exact tremendous costs in unfulfilled potential. These costs are borne both by the individual and by society.

Accomplishments: Risk assessment and regulatory exposure levels have traditionally been based on the needs and susceptibilities of an adult person. Research from NIEHS and other health agencies over the last ten years has shown that infants and children might represent a more vulnerable population, requiring a reworking of standard risk assessment models. NIEHS research on dioxins and diethylstilbestrol (DES) illuminated the greater risk to the developing organism at exposures that do not affect adults. This awareness has led Congress to incorporate new wording in reauthorization of regulatory law, such as the Clean Water Act and the new Food Quality Protection Act, where the need to base regulatory standards on the "most vulnerable" population is now required.

Planned Activities: NIEHS has new initiatives to investigate the effect of endocrine disrupting compounds on the developing organism and young children.

Research on Autism in Early Childhood NIH (NIMH)

Target Population: Children from birth to age 7

Description: Autism, a severe disorder of communication and behavior with lifelong impairment, usually begins at birth or by age three. The disorder is estimated to cost the U.S. \$13 billion per year. NIMH supports studies on the diagnosis and symptomatology, genetics, neurochemistry and immunology, neuroimaging, neuropsychology, and treatment of autism. Our understanding of autism has been revolutionized by research within the past decade. There is now consensus that the condition is a neurodevelopmental disorder in which specific cognitive deficits play a key role. Further, family and twin studies suggest a genetic etiology, particularly in families in whom multiple cases occur; the prevalence rate among siblings of autistic individuals is approximately 75 times higher than the prevalence in the general population. NIMH, NICHD, and other NIH Institutes are working together to stimulate research into all aspects of autism, with emphasis on the genetics, treatment and neurobiology of the disorder. Historically, infantile autism has been nearly impervious to all attempts at uncovering the neuroanatomical abnormalities that underlie its characteristic behavioral deficits. Now, for the first time, specific neuroanatomical abnormalities are being linked to neurobehavioral deficits involved in autism. As we unravel the mysteries of the neurogenetic factors involved in this devastating disorder, new approaches are being developed that will enhance not only the search

for etiology but also for better treatment of the disorder.

Contribution to Initiative: Given the importance of early intervention in initiatives targeting the first years of life, the diagnosis of young, nonverbal children with autism takes on added importance. The importance of finding genes responsible for autism lies in their value as a diagnostic marker in the earliest years and in providing essential information about the regulation of early brain development.

Accomplishments: Research in autism has continued to refine definitions, nomenclature, and diagnostic criteria. Recently, a standardized observation schedule has been shown to be a reliable means of observing communication skills, interactive abilities, and other behaviors thought to be qualitatively different in young children with autism.

Planned Activities: A continued commitment to this research effort is essential for progress in clarifying the developmental origins, dynamics, and characteristics of autism.

Research on Child Abuse and Neglect NIH (NIMH)

Target Population Children from birth to age 7

Description: Large numbers of children experience significant traumatic events early in life that can profoundly affect their psychological, biological and social development both immediately and in later developmental periods. Types of trauma and victimization include (a) physical and sexual abuse and trauma (child physical and sexual abuse, severe physical injuries, e.g., accidents, burns); (b) traumatic separation and loss (sudden loss of parent, loss of home in disaster or war, foster placement); c) deprivation (child physical and emotional neglect, refugee displacement); and (d) forms of oppressive environments (psychological abuse, chronic intimidation or threat). One major form of family violence that affects young children (in addition to direct physical and sexual victimization) is witnessing domestic violence between parents or other adults.

NIMH research topics include: how maltreatment is related to the development of mental health problems throughout life, why some children are severely damaged by maltreatment while others are able to cope; what are the mental health needs of maltreated children; what types of treatment programs can help maltreated children, adolescents, and adults; what types of approaches can effectively prevent the occurrence of child maltreatment; and what characteristics and experiences of perpetrators play a role in their maltreatment of children. Research studies that target this particular age group represent a subset of NIMH studies related to the effects of child abuse and neglect, many of which target school-age children and adolescents. NIMH also is the lead institute for the NIH Child Abuse and Neglect Working Group which works to advance and coordinate child abuse research across all NIH institutes.

Contribution to Initiative: Childhood maltreatment experiences are associated with the development and/or exacerbation of significant mental health problems and disorders, and are

precursors to the cycle of abuse in adulthood by persons who once were abused or neglected as children.

Research on Childhood Behavioral Disorders NIH (NIMH)

Target Population Children from birth to age 7

Description: Understanding the factors influencing the onset and developmental course of behavior problems in young children is a major challenge for research on development. Research has shown that the antecedents of conduct disorder can be detected in children as early as the toddler age. NIMH supports prevention and early-intervention studies on externalizing and disruptive behavior disorders in young children. These studies rely on two primary approaches: 1) improving behavior management skills in parents, teachers, and child care providers and fostering early language and communication skills; and 2) a comprehensive program of home visiting during the prenatal and infancy periods aimed at improving the outcomes of pregnancy, the quality of care that the mothers provide to their children, and the women's own development through education, employment, and subsequent family planning.

Contribution to Initiative: Understanding the origins of behavioral disorders in young children and learning how to prevent or manage these disorders will enable large numbers of children to attain their full potential.

Accomplishments: Prenatal and infancy home visitation improved a wide range of maternal and child health outcomes among poor, unmarried, and teen-aged women bearing their first children. Compared to controls, nurse-visited mothers reduced cigarette use, improved their diets, experienced greater informal social support, and made better use of childbirth education and nutritional supplementation programs. They also had 75% fewer pre-term deliveries and babies with higher average birth weights. During the first 4 years after delivery, participating mothers were significantly more likely to hold jobs and bore 43% fewer children than control mothers. Nurse-visited children were significantly less likely to experience abuse or neglect and require emergency room visits for injuries during their first two years of life. By the time children were four, average per-family government savings were \$1,772 for the sample as a whole, and \$3,498 for low-income families. Government savings were defined as intervention differences in expenditures for AFDC, Food Stamps, Medicaid, and Child Protective Services, minus tax revenues gained through maternal employment.

Planned Activities: A follow-up study is currently examining long term effects on child adjustment, school performance, and maternal functioning.

Research on Cognitive and Language Development NIH (NIMH)

Target Population Children from birth to age 7

Description: A growing understanding of how a child's capacities to think and reason, and to communicate through language, develop will make it possible to maximize early learning experiences and to help children who have difficulties in these areas. Research on language development suggests that maturational age, reflecting development of the nervous system, is critical to the acquisition of language, rather than just extent of exposure to language. Greater understanding of how infants learn language will benefit children who have hearing loss, developmental language disorders, autism, and various brain abnormalities affecting language and thought. It will also allow us to detect and prevent environmental influences that interfere with intellectual and language development.

Contribution to Initiative: Knowledge of how to maximize every child's ability to think and to communicate through language will facilitate learning processes and continue to enrich the child's life.

Accomplishments: Recently developed tests of infant intelligence are being used to study how children's intellectual development is affected by early exposure to various substances such as alcohol, cocaine, lead, and mercury.

Planned Activities: Continued emphasis on research on cognitive and language development.

Research on the Development of Emotion and Personality NIH (NIMH)

Target Population Children from birth to age 7

Description: During early development, the emotional repertoire of humans grows steadily richer and more varied. Research on children's emotional development and how it may go astray can reveal the roots of many mental disorders, including clinical depression, conduct disorder, and attention deficit/hyperactivity disorder. This research holds promise for predicting and possibly preventing later emotional and behavioral problems and mental disorders. Personality, which determines how an individual deals with life's challenges, also begins developing in early childhood and is linked with emotional development. Resilience and vulnerability depend on social skills and self-esteem as well as on individual genetic predispositions. Research on personality development seeks ways to foster and strengthen those personality traits that help children grow up to be psychologically well adjusted. It has been shown that personality patterns can change for the better under certain circumstances and interventions are needed that build on these findings. Studies of personality development will also help understand the linkages between certain personality traits and particular physical diseases, such as that between hostility and heart disease.

Contribution to Initiative: Understanding better how children's emotions and personality

develop will lead to new ways to predict and prevent mental and behavioral disorders later in life—disorders that often make it impossible for an individual to attain his or her full potential.

Accomplishments: A recent research study found that the personalities of boys and girls who became severely depressed in late adolescence differed considerably during childhood. The boys had been described as under-controlled, unsocialized, and aggressive; by contrast, the girls were seen as over-controlled, over-socialized, shy, and introspective. These findings suggest not only that depression has deep roots in early life, but that early personality patterns associated with later depression differ in important ways for males and females.

Planned Activities: Research on the development of emotions and personality in early childhood will continue to be emphasized by NIMH.

Research on Social Experience and Development NIH (NIMH)

Target Population: Children from birth to age 7

Description: The results of millions of years of biological evolution are built into every newborn infant, but the results of millions of years of cultural evolution have to be acquired through social contact. For children, family relationships provide the earliest and most enduring social contact, and as a result, family life experiences deeply affect the competence, resilience, and well-being of each of us. While for most people, the family's influence is extremely positive, for an significant segment of society, family effects are profoundly negative. In these cases, the family provides the context for severe violence and long-term patterns of physical and emotional abuse that can have dire effects on the mental health of children and adults. In an effort to understand the factors that lead to effective and ineffective family interactions, researchers are examining the specific relationships that make up family life and the structural and cultural differences among families.

Contribution to Initiative: The processes and dynamics within family and other social support relationships are vitally important to normal and abnormal mental and emotional development. Research seeks to determine how good relationships can be made better and how harmful relationships can be prevented or compensated for.

Accomplishments: Research has revealed that children in families with high-intensity conflict are at greater risk than other children for developing "internalizing disorders," such as depression, and "externalizing disorders," such as conduct problems. Identifying the specific behavioral and physiological mechanisms that link family conflict to psychopathology in children is a high priority for future research.

Planned Activities: Continued emphasis on research on the effects of early social experience on development.

Research on Infant Disorders NIH (NIMH)

Target Population Children from birth to age 7

Description: The NIMH Infant Disorders Program seeks to fund research that elucidates early pathology by integrating research on basic and developmental theory into our conceptualizations of the problems in infancy and toddlerhood (from ages birth to three). This research addresses problems of assessment, diagnosis, and treatment of disorders in infancy and toddlerhood, including feeding disorders or failure to thrive, sleep disorders, reactive attachment disorders, post-traumatic stress disorder, mood disorders and relational disorders. Current research efforts are aimed at assessment and measurement of these problems in the earliest years.

Contribution to Initiative:: Early assessment and accurate diagnosis are critical components in effective intervention before early problems are consolidated into more rigid and maladaptive patterns of functioning. Research in this program will increase our understanding and advance our efforts to identify early clinical disorders and develop intervention approaches.

Planned Activities: Continued emphasis on research on infant disorders.

Research on Mental Health Services for Young Children NIH (NIMH)

Target Population Children from birth to age 7

Description: A major national challenge is to find ways to provide effective care and services to the millions of Americans, young and old, who suffer from mental disorders. NIMH supports mental health services research with the goal of improving the organization, financing, quality, accessibility, delivery, outcomes and cost-effectiveness of those services. Models of service integration systems that provide coordinated services to children, adolescents and their families are being studied in a number of programs funded by NIMH. These program are finding significant changes in placement patterns for children and adolescents enrolled in these systems of care, particularly in the decreased use of restrictive placements, such as hospitalization and residential treatment centers.

Contribution to Initiative:: For the many children that need care and services for mental disorders, the availability and use of such care can produce a dramatic improvement in their life course, enabling them to attain their full potential.

Accomplishments: NIMH helped fund the Fort Bragg Demonstration and Evaluation Project, the first and largest attempt to study an innovative approach to service delivery for children and adolescents with mental health problems. This project tested the effectiveness of a Federal and State contract for providing a case-management based alternative delivery system of mental health services tailored to individual needs and featuring the use of a full continuum of community based services. In addition, the evaluation was designed to see if this continuum of services would result in improved treatment outcomes while cutting the cost of care per patient.

There were five major findings: 1) the quality of care was high; 2) access to mental health services tripled and parents were more satisfied with services; 3) children improved on measure of mental health outcomes at all sites; 4) there was no difference in improvement between sites; and 5) the cost per client at the demonstration site was more than 1.5 times higher than at the comparison site and direct treatment costs were not offset by reductions in indirect costs borne by families.

Planned Activities: Continued emphasis on research on mental health services for children.

Development of the Nervous System NIH (NINDS)

Target Population: Children

Description: For the nervous system to work it must develop properly. From conception through birth, a well-orchestrated cascade of events must occur that involves the division and growth of cells, the movement of cells to their proper places, normally-occurring nerve cell death as the final architecture takes shape, and the establishment of connections among cells. Areas of research include the factors (e.g., growth factors and genes) that control the survival of developing nerve cells and their specialization, chemical signals and nerve cell activity that guide the formation of appropriate connections, and the mechanisms by which experience contributes to shaping the nervous system. Research progress in developmental neurology benefits from correspondence of findings between vertebrates and simpler organisms. NINDS also focuses on research to understand how normal development can be interrupted, setting the stage for diseases and dysfunction of the brain.

Contribution to Initiative: How the nervous system develops is one of the great mysteries of biology, a puzzle whose solution has profound implications for the treatment of developmental disorders and other brain diseases and for efforts to promote regeneration of damaged nerves. For example, more than a third of all genetic disorders affect the nervous system; hundreds of these manifest themselves in infants and children.

Accomplishments: Understanding of how the nervous system develops is progressing rapidly on many fronts. For example, a century ago it was first speculated that diffusible chemical signals might help to guide growing neurons in finding their proper paths. Two years ago scientists isolated the first such molecules, called netrins, and others soon followed. This year researchers learned how molecules called agrin, MuSK, and ARIA control critical steps in the formation of synapses. In the future these kinds of signals may be harnessed to help heal the nervous system following injury or disease. Research has also demonstrated dramatic benefits of folic acid supplements, taken by the mother around the time of conception, in reducing the incidence of neural tube defects such as spina bifida, believed due to low levels of folic acid. More recently, NINDS-investigators have shown that children born to women who consumed high levels of vitamin A (greater than the recommended daily allowance) before their seventh week of pregnancy have a higher incidence of birth defects.

Planned Activities The NINDS has strengthened the connections among programs in basic and clinical neuroscience important to development of the brain and many neurologic diseases affecting children.

Disorders of the Brain and Nervous System in the Newborn NIH (NINDS)

Target Population: Newborns and their families

Description: The brain of the newborn is vulnerable to bleeding, seizures, hydrocephalus, and white matter disorders that affect neurological development and function. Increasing numbers of babies are born prematurely. Survival of the smallest babies is improving but these babies are especially vulnerable to damage which can lead to lifelong mental deficits, epilepsy, cerebral palsy, and behavioral problems. For example, very low birth weight babies are at much greater risk of cerebral palsy than children born with normal weight. NINDS supports and conducts research relevant to the prevention of neurodevelopmental and related problems that result from prematurity.

Contribution to Initiative:: Disorders of the brain and the nervous system in the newborn pose a significant burden to children and their families as well as to the education and health care systems in the U.S. Research to treat and prevent brain disorders in the newborn and, thus, maximize the individual's capacity for cognitive and motor development, has consequences that truly last a lifetime.

Accomplishments: Several advances can be reported that contribute to efforts in the prevention and treatment of brain disorders in newborns. For example, an NINDS-supported clinical trial has shown that very low birth weight babies who are treated with indomethacin within 6-12 hours after birth have a lower incidence and reduced severity of one type of brain bleeding, known as intraventricular hemorrhage. The study is ongoing to track cognitive and developmental outcome. In other areas, NINDS has supported research to understand the impact of neonatal seizures and to study neuroprotective agents. Progress has also been made in developing more relevant animal models of postnatal premature brain injury and neonatal meningitis which will facilitate further research.

Planned Activities Several efforts are ongoing. For example, NINDS and NICHD are planning to start a feasibility study for a randomized trial of the benefit of magnesium sulfate to prevent cerebral palsy. This is based on an earlier study that suggested that magnesium sulfate administered to the mother before delivery of her baby correlated with a decrease in cerebral palsy in very low birth weight newborns. New studies will also increase understanding of the pathophysiology of injury to the developing brain and methods of intervention and prevention.

Learning and Brain Disorders of Early Childhood NIH (NINDS)

Target Population: Infants and children

Description: The NINDS supports and conducts research into neurogenetic disorders of infancy and childhood, including studies of genetics to establish modes of inheritance and search for defective genes, of biochemistry to understand the molecular basis of metabolic defects, of brain imaging and pathology to find clues about brain dysfunction and correlations with clinical findings, of epidemiology to study the interaction of genetic and environmental factors that may determine whether clinical disease occurs, and of strategies to develop therapies. Normal and abnormal learning and language development are a focus of NINDS research interest and cover a wide range of topics including mental retardation, acute closed head injury, the relationship between brain damage and intellectual function, learning disabilities, and autism and other behavioral disorders.

Contribution to Initiative: Many neurogenetic diseases of childhood and infancy are uncommon, but collectively they cause enormous suffering to children and their families. However, with further research, treatment strategies may be developed that may be widely adaptable to several disorders. Advances in cell biology, biotechnology and brain imaging offer unprecedented opportunities to understand the biological bases of learning and language and offer clues to some of the most troubling disorders faced by children and their parents.

Accomplishments: In the last several years, remarkable progress in identifying genetic defects responsible for inherited disorders of the nervous system has energized research. For example, researchers have isolated the defective genes responsible for Becker and Duchenne muscular dystrophy, neurofibromatosis 1 & 2, ataxia-telangiectasia, spinocerebellar ataxias, Friedreich's ataxia, spinal muscular atrophy, Machado-Joseph disease, and Williams syndrome. Other research is revealing how experience as well as genes shape the development of the brain. New brain imaging technologies now allow non-invasive imaging of brain activity in living persons and are facilitating new studies to understand cognitive disorders in children. Overall, research progress has improved the diagnosis of many brain and neuromuscular disorders in children.

Planned Activities New research studies are encouraged in a number of areas including epilepsy and neurogenetic disorders of infancy and childhood.

IV. Resources and Messages

National Hispanic Prenatal Hotline Project (OPHS)

A cooperative agreement between the National Coalition of Hispanic Health and Human Services Organization and the Office of Minority Health, Office of Public Health and Science.

Funding Level: \$250,000

Target Population: Pregnant Hispanic Women

Description: One of the activities under the Cooperative Agreement with the National Coalition of Hispanic Health and Human Services Organizations is the National Prenatal Hotline Project. The Hotline is intended to strengthen and increase the effectiveness of prenatal care for Hispanic women by increasing access to appropriate prenatal information for consumers and providers.

Contribution to Initiative: The programs of the OMH focus on health problems identified as being the leading causes of "excess deaths" among minority populations, including infant mortality. The program seeks to increase the number of Hispanic women seeking prenatal health care, thereby contributing to their health and well-being and that of their newborn infants.

Handbook: Participant-Driven Managed Supports - Breaking New Ground (ADD)

Funding Level: \$15,000

Target Population: Parents and individuals with developmental disabilities. Approximately 10,000 copies to be distributed

Description: The Administration on Developmental Disabilities is funding the development of a consumer-friendly handbook which is written in an easy to read format and covers the basics of managed care and the elements of a participant-driven system. The handbook, "Participant-Driven Managed Supports - Breaking New Ground," places an emphasis on the need for parents and individuals with developmental disabilities to take an interest in current political and financial developments, and to take action to guide whatever reforms unfold.

Contribution to Initiative: This publication will provide information on the complex and confusing topic of managed care to parents and others who need timely information on acute and long-term services and supports for their infants and children with developmental disabilities. The handbook provides the reader with information about the money available to fund these services, and the power that comes with that money. Most of all, it is about being active in the face of change--changes in Federal and State disability policy that are occurring now.

Resources on HIV, Sickle Cell Disease, Otitis Media with Effusion, and Pain (AHCPR)

As appropriate, AHCPR has disseminated information to health care providers who provide services to children ages 0-3 as well as to the parents and other care givers of these children. Four of the most prominent examples of the sharing of information involve the use of AZT by HIV-positive pregnant women and newborns, parents' and providers' guidelines for sickle cell screening and diagnosis, guidelines for otitis media, and guidelines for treatment of pain in children.

Target Populations: Pregnant women, parents, health providers

Description and Purpose:

- *Pregnancy, HIV, and AZT: Your Health, Your Baby, Your Decision.* This project addresses AZT use during pregnancy, labor, and childbirth, and for 6 weeks following birth. Together with other agencies within the department of Health and Human Services, AHCPR created consumer education materials in several languages and formats (brochures, audio tapes, and videotapes). These materials were distributed widely to HIV-infected pregnant women.
- *Sickle Cell Disease: Screening, Diagnosis, Management, and Counseling in Newborns and Infants* This AHCPR-supported clinical practice guideline recommends screening of all newborns for sickle cell disease, administering protective doses of penicillin to ward off infection in infants whose initial test reveals presence of the disease, and improving genetic counseling for couples with the sickle cell trait. A guide for parents and a Quick Reference Guide for Clinicians were also developed and made available widely.
- *Clinical practice guideline: Otitis Media With Effusion in Young Children* This AHCPR-supported guideline recommends "watchful waiting" for most young children with otitis media with effusion because the condition usually disappears without treatment within 3 to 6 months. A Quick Reference Guide for Clinicians is available, as is a guide for parents is available in both English and Spanish. Both the Quick Reference Guide for Clinicians and the Parents Guide were made available through the American Academy of Pediatrics' publications catalog, for widespread distribution in pediatricians' offices.
- *Acute Pain Guideline, and Cancer Pain Management Guideline.* The acute pain guideline has a quick reference guide for clinicians specific to infants and children, stating that "For infants and children, the provider should recognize the potential for pain or suspect that a child is in pain." It also states, "Children are likely to talk less about pain than adults. Thus, the burden of vigilance for pain rests with the health care provider." The guideline also includes pediatric dosing information and techniques for assessing pain in children. There also is information specific to children in the cancer pain management guideline.

Contribution to Initiative: These products, derived from scientific research and put into

appropriate language, enable health care providers, pregnant women and parents, to take better care of children. By providing consistent information to all parties, the materials also enable parents and health providers to act in informed partnership.

Resources: Substance using Pregnant and Postpartum Women - Treatment Protocols
(SAMHSA)

Funding Level: approximately \$550,000 for two publications

Target Population: State and community program designers, treatment program staff, State legislators, and health professionals

Description: The SAMHSA disseminates information on substance abuse and mental health treatment and service delivery. The following are two publications especially relevant to pregnant and drug and alcohol exposed infants:

- *“Pregnant Substance-Using Women, Treatment Improvement Protocol 2.”* The Treatment Improvement Protocols are particularly designed to assist drug treatment programs that receive block grant funding through their State substance abuse agencies. This publication focuses on the drug treatment, medical care and follow-up services needed by pregnant substance using women, and outlines a set of guidelines for these services.
- *“Improving Treatment for Drug-Exposed Infants, Treatment Improvement Protocol 5.”* This publication focuses on in utero exposure of infants to illicit drugs and medical and psychosocial services for drug exposed infants up to 18 months of age. It presents guidelines for professionals working with this population of young children.

Contribution to Initiative: These guidelines provide important guidance to those working with or planning service delivery systems for pregnant women who are, or are at risk of, delivering a child exposed to alcohol or other drugs in utero. Intervening in substance use during pregnancy is a critical tool for preventing unwanted outcomes and early intervention postpartum provides diagnosis and support for vulnerable children.

Forthcoming Publication: Child Abuse and Neglect and Substance Abuse Treatment
(SAMHSA)

Funding Level: Estimated \$175,000 in FY 98

Target Population: Staff of state agencies responsible for planning, funding, and evaluating substance abuse treatment programs; staff of community based substance abuse treatment programs, including clinical directors, counselors, nurses, administrators, and outreach workers with an emphasis on those serving women in the publicly funded drug treatment system; Staff of secondary and tertiary health care facilities that serve victims of violence and substance using

women.

Description: Substance abuse and child abuse and neglect are connected in both obvious and subtle ways. This publication will explore the connection, and provide guidance to professionals working with children and their families impacted by substance abuse and consequential child abuse and neglect.

Contribution to Initiative: It is critical that the link between parental substance abuse and child abuse and neglect be exposed, understood and addressed. Comprehensive family-centered treatment for substance abuse will address the critical needs of children living under conditions imposed by parental substance abuse.

Publication: "From the Source: A Guide for Implementing Perinatal Addiction, Prevention and Treatment Program" (SAMHSA)

Funding Level: FY 96 - \$14,000

Target Population: State and local agencies; practitioners and program administrators charged with planning or providing services to pregnant and postpartum women and their infants.

Description: From the Source was written for professionals who work with perinatal addiction issues. This guide provides common-sense advice, practical suggestions, and experience-based strategies in a user-friendly format.

Contribution to Initiative: Infants affected by perinatal use of alcohol or drugs may present a wide range of developmental problems. This publication is a guide to helping professionals deal with this population.

Forthcoming Resources on Medical Management and Detoxification of Pregnant Women and Neonatal Assessment (SAMHSA)

The following publications are pre-publication resources.

Medical Management and Detoxification of Pregnant Women Using Alcohol and Other Drugs:

This resource is targeted to clinicians who work with high-risk pregnant and postpartum women and their infants, federal and state agencies responsible for administrative oversight for substance abuse prevention, treatment and health care. This comprehensive publication effectively communicates critical information about substance abuse and how service providers can be responsive to the special needs of these women and their families. The incidence of fetal alcohol syndrome (FAS) is estimated to be 1 to 3 per 1,000 live births, with lesser fetal alcohol effects (FAE) found in more children. Problems related to perinatal abuse of alcohol and other drugs are being encountered and handled by the medical community, maternal and child health programs, prevention and treatment programs, child welfare agencies, courts, day care agencies and

schools. This publication will contribute to improving services to child-bearing women and hereby the birth outcomes and the provision of services to prenatally exposed infants. (Funding: \$13,700)

Neonatal Assessment Reference Manual: This manual is intended for use by health care providers, early intervention staff and child educators, social workers from the child welfare system, and others providing services to the children of women with substance abuse problems. The manual provides guidelines for neonatal assessment with special attention to findings for neonates prenatally exposed to alcohol, tobacco, and other drugs. There is great variability in outcomes for infants exposed to drugs.

Other Publications and Resources:

Medicaid and Early Childhood Services

EPSDT - A Guide for Head Start Programs, U.S. Department of Health and Human Services, Administration for Children and Families

Child Care and Medicaid - A Guide for Child Care Providers, U.S. Department of Health and Human Services, Health Care Financing Administration, Administration for Children and Families (currently being developed)

See also: Breast-Feeding Initiative, Put Prevention into Practice, and Bright Futures, Outreach and Primary Health Services for Homeless Children

APPENDIX

**MEMORANDUM FOR THE HEADS OF EXECUTIVE
DEPARTMENTS AND AGENCIES ON
FEDERAL POLICIES TARGETED TO CHILDREN IN
THEIR EARLIEST YEARS**

Office of the Press Secretary

For Immediate Release

February 24, 1997

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Federal Policies Targeted to Children in Their Earliest Years

Over the past few years, scientific research has demonstrated that the earliest years of life -- before children reach school-age -- are critical to cognitive, emotional, and physical development. We know that emotional nourishment, intellectual stimulation, parental and community support, good nutrition, proper health care, quality child care, and safe housing during the first years of life form the foundation for a child's ability to learn, thrive in school, work productively, and contribute fully to society.

Across the Federal Government, we are making great strides to enhance development during the earliest years of life by investing in research, educating parents and caregivers, and supporting programs that provide early intervention to disadvantaged families. I am committed to accelerating our efforts to target the earliest years of life. We all have a stake in ensuring that every child is given the opportunity to fulfill his or her God-given potential.

Today, I am directing the heads of executive departments and agencies to report to me within 30 days with:

1. a comprehensive list and assessment of existing projects and programs funded by your agency that target the earliest years of life -- including any existing qualitative or quantitative evidence of success, as well as current funding levels and number of clients served -- and a description of any proposed improvements to such projects and programs.
2. a comprehensive list and assessment of any planned projects and programs of your agency that target the earliest years of life, including projected funding levels and number of clients to be served; and
3. specific proposals for additional projects and programs this year that could be undertaken to improve the earliest years of life that do not require new spending or that fall within the proposals in the FY 1998 Budget, or that could be developed for consideration in the FY 1999 Budget, within the limits of my Balanced Budget Plan.

I am also directing the establishment of a senior level interagency working group to share, examine, and develop these assessments and proposals.

WILLIAM J. CLINTON

#

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: HUD



U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
THE SECRETARY
WASHINGTON, D.C. 20410-0001

March 24, 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

In response to your memorandum of February 24, 1997, in which you directed all Federal departments and agencies to report on Federal policies targeted to children in their earliest years, I am submitting the report of the Department of Housing and Urban Development on HUD policies targeted to children in their earliest years.

HUD is fully supportive of your commitment to the American people to accelerate efforts by the Federal Government to support programs that focus on early childhood development and learning.

Respectfully,

A handwritten signature in black ink, appearing to read "Andrew Cuomo", is written over the typed name.

Andrew Cuomo

Enclosure



DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

REPORT

ON

HUD POLICIES TARGETED TO CHILDREN

IN THEIR EARLIEST YEARS

MARCH 24, 1997

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

REPORT ON HUD POLICIES

TARGETED TO CHILDREN IN THEIR EARLIEST YEARS

I THE PRESIDENT'S DIRECTIVE

On February 24, 1997, President Clinton issued a memorandum to the heads of executive departments and agencies on the subject of "Federal Policies Targeted to Children in Their Earliest Years." In this memorandum, the President directed the heads of the executive departments and agencies to prepare a report, within 30 days of issuance of the February 24, 1997 memorandum, that provided the President with the following:

1. A comprehensive list and assessment of existing projects and programs funded by your agency that target the earliest years of life -- including any existing qualitative or quantitative evidence of success, as well as current funding levels and number of clients served -- and a description of any proposed improvements to such projects and programs.
2. A comprehensive list and assessment of any planned projects and programs of your agency that target the earliest years of life, including projected funding levels and number of clients to be served.
3. Specific proposals for additional projects and programs this year that could be undertaken to improve the earliest years of life that do not require new spending or that fall within the proposals in the FY 1998 Budget, or that could be developed for consideration in the FY 1999 Budget, within the limits of my Balanced Budget Plan.

04/10/97 09:33 NO. 838 003

2

II. HUD'S RESPONSE

The Department of Housing and Urban Development administers many different programs that protect and support young children and their parents both directly and indirectly. HUD was created to carry out the Nation's commitment to work for healthy growth in cities and adequate housing for all. HUD's programs reflect this mission. Decent and safe housing gives families and individuals dignity, self-respect and the platform they must have to meet their other needs.

HUD's public and assisted housing programs provide a stable supply of rental housing that is affordable to families with very low incomes. Additionally, public and Indian housing programs seek to empower residents by giving them opportunities to take control of their lives. Many of these programs include educational services, child care services or job training components that help residents to move toward financial independence. Also, HUD's Community Development Block Grant program provides for public services that directly benefit lower-income persons by making assistance available for a variety of services including youth services, child care, counseling for battered spouses, and transportation services that provide access to employment centers, health care facilities, and retail stores within communities. HUD's homeless programs also assist families with children. Families with children are a growing faction of the homeless and a growing faction of those whose acute housing needs make them vulnerable to becoming homeless. HUD's transitional housing program supports innovative approaches for providing housing and supportive services that people need to move into independent living, especially homeless families with children.

This report does not cover all such HUD efforts that support the family and thereby directly or indirectly support children in their earliest years. This report describes only those programs and proposals that focus primarily on the health and development of our youngest children.

1. Existing HUD Projects and Programs That Target the Earliest Years of Life

The following provides a comprehensive list and assessment of existing projects and programs funded by HUD that target the earliest years of life, and includes existing qualitative or quantitative evidence of success, as well as current funding levels and number of clients served -- and a description of any proposed improvements to such projects and programs.

Lead-Based Paint Hazard Control Grant Program

HUD's Office of Lead Hazard Control (OLHC) administers a grant program that funds lead abatement activities in communities across the country. The mission of OLHC is to control childhood lead poisoning without disrupting the housing market.

Lead poisoning is a major environmental disease among young children in the United States, adversely affecting their intelligence, behavior, and development. This disease disproportionately affects minority and poor children living in older housing, most often in inner cities.

The most recent National Health and Nutrition Examination Survey (NHANES) conducted by the Centers for Disease Control and Prevention shows that there are still nearly a million children with blood lead levels above the threshold of 10 $\mu\text{g/dL}$ (micrograms of lead per one-tenth liter of blood). There is little dispute within the scientific community that lead-based paint is the principal source of lead exposure in young children. Of the 64 million dwelling units that contain lead-based paint, 4 million have lead-based hazards and are currently occupied by young children; owners of 400,000 of those units have no ability to privately finance lead hazard control efforts.

Combined with other local, state and federal funds, HUD's program targets privately-owned houses where lead poisoning rates are highest and where private financing is not feasible.

HUD's lead hazard control program:

- Empowers communities to address lead hazards in the context of other locally-determined housing needs;
- Develops the infrastructure of licensed inspectors and abatement contractors to ensure the work is done safely and efficiently;
- Creates jobs in low income communities;
- Funds research to develop low-cost hazard control methods; and
- Provides technical assistance to disseminate the most cost-effective state-of-the-art techniques.

The table below summarizes funding history for HUD's Lead Hazard Control Grant Program:

Fiscal Year	Average Actual Start Date	Funding Level (Millions)	No. Units Projected	Units Tested or In Progress	Units Completed
1992	Jul 93	\$ 47.4	4,578	3,287	1,428
1993	Sep 94	\$ 93.5	11,718	2,830	490
1994	Apr 95	\$139.7	14,297	1,345	97
1995		Rescinded*	--	--	--
1996	Oct 96	\$ 55.0	~ 8,000	--	--
Total**	-----	\$335.6	38,593	7,462	2,015

In 1995, HUD decided to request a rescission of funds requested for this program. Program managers found that grantees lacked the ability to spend grant money quickly and effectively, with the result that previously delivered funds remained unspent. Over the past few years, the Office of Lead Hazard Control has worked with local communities to develop necessary capacity, and we expect no further difficulties with the funding pipeline. One example of increased capacity is that 26 states now have licensing laws for lead inspectors, which is a requirement of the HUD grant program.

**HUD plans a competition to award \$55 million to 15-20 grantees in FY 1997.

Research indicates that this program works. HUD recently released the 1997 interim report on the evaluation of the HUD Lead-Based Paint Hazard Control grant program. This important study covered over 2,500 homes in 12 states in order to learn what lead hazard control methods cost and how effective they are in protecting children. The evaluation was initiated in 1993 when the grant program was started and will continue to the year 2000.

Interim findings show that State and local grantees have been successful in achieving major reductions in lead-contaminated house dust, which is a key source of childhood lead exposure, as well as controlling other lead-based paint hazards. In low-income, owner-occupied homes treated under the program, median dust lead levels on interior window sills were reduced by 85 percent. On floors, the reduction was 23 percent and 91 percent in occupied and vacant units, respectively. Preliminary findings show that six months after treatment, the levels on floors remained low. There was some reaccumulation on sills, but the median level was still 54 percent lower on sills than before treatment.

The report found that children's blood lead levels also showed declines. That result matches NHANES data from the Centers for Disease Control and Prevention (CDC), which show that the number of lead poisoned children dropped from 1.7 million in the late 1980s to about 930,000 in the mid-1990s.

Grantees under the HUD program are free to select lead hazard control strategies that are most appropriate for the housing in their local communities. Methods range from paint repair and specialized cleaning to more expensive strategies involving window replacement and enclosure or encapsulation of lead-based paint on walls. Many grantees combine lead hazard controls with other housing renovations to reduce costs. In single family houses, the median lead hazard control for specialized cleaning treatments was only \$125 per unit. For more expensive treatments involving paint repair and window replacement, the median cost was \$11,500 per house. In multifamily dwellings, median costs ran from \$500 to \$7,000.

All HUD Lead-Based Paint Hazard Control grantees must establish significant public education and outreach components to ensure broad dissemination of information about the dangers of lead based paint and ways of reducing childhood exposure. We estimate that the average expenditure per grantee for public education is between \$75,000 - \$100,000 over the course of each multi-year grant. Thus, our current grantees (84) will expend between \$6 - \$8 million on public education in conducting their grant efforts. This information will not only benefit the 35,000 - 40,000 families directly served by our program (i.e. whose homes are treated) but hundreds of thousands of other families in these communities who are also being reached by the broader media efforts.

The HUD Office of Lead Hazard Control has its own aggressive outreach campaign geared towards educating industry, HUD constituents, realtors, health care professionals, media and others interested in eliminating lead poisoning as the number one environmental health hazard to young children. Some of those activities include:

- ***The Lead Past.*** A quarterly newsletter that focuses on information exchange and lessons learned to help effectively facilitate the grant programs across the board. Each issue features a grantee spotlight which highlights an innovative and successful lead hazard control effort.
- ***Lead Office World Wide Web Home Page.*** The Lead Office is now on the Internet to offer the latest information on lead abatement and poisoning prevention. Established to respond to growing interest about lead poisoning, the web site covers several program areas such as training development, outreach activities, hazard control grant program and research and guideline development. The address is:
<http://www.hud.gov/lea/leahome.html>.
- ***Moving Toward A Lead-Safe America*** video. This video puts a human face on the need for lead poisoning prevention. It is shown at training workshops, conferences and other fora to provide background information on the extent of the problem and the personal testimonies of families who have been touched by it.

- **Fact Sheet.** The Office of Lead Hazard Control publishes a Fact Sheet that provides comprehensive detail on the lead issue, including challenges and solutions, references for more information, publications available on lead, and related information of interest to industry, realtors, health care providers, media and the general public.

Lead Paint Disclosure Requirements

Approximately three-quarters of the nation's housing stock built before 1978 (approximately 64 million dwellings) contains some lead-based paint. When properly maintained and managed, this paint poses little risk. However, lead from paint, chips, and dust can pose serious health hazards if not treated properly.

On March 6, 1996, HUD and the Environmental Protection Agency (EPA) jointly issued regulations implementing Section 1018 of Title X. This law requires sellers and landlords of housing built before 1978 to notify prospective buyers and tenants about lead-based paint hazards and to disclose any known information about such hazards. Cooperatively with EPA, HUD launched an outreach campaign to target industry, health care professionals, the media, and general public, not only to provide much needed information on this regulation, but other lead issues as well.

The federal law requires that individuals receive certain information before renting, buying, or renovating pre-1978 housing:

Landlords must disclose known information on lead-based paint hazards before leases take effect. Leases will include a statement about lead-based paint hazards;

Sellers disclose known information on lead-based paint hazards before selling a house. Sales contracts must be accompanied by a written statement about lead-based paint hazards. Buyers will have up to 10 days to check for lead hazards;

Renovators must provide an information pamphlet on lead paint hazards before starting work.

04/10/97 09:36 NO. 838 010

7

Early Childhood Development Program

HUD's Early Childhood Development program began as a demonstration program in 1988. In 1990, HUD signed a Memorandum of Understanding (MOU) with the Department of Health and Human Services (HHS) to more effectively help low-income families and individuals move toward independent living and economic self-sufficiency. Under the MOU, HUD signed an Interagency Agreement with HHS to transfer more than \$14 million to expand the availability of full-day, year-round child care services for parents or guardians obtaining training and/or education necessary to enter and remain in the workforce. Since 1988, more than \$30 million has been awarded to over 200 non-profits, resident councils, resident management councils, and Head Start organizations. Funds help to initiate or expand comprehensive child care services in or near public or Indian housing developments, including care for infants, toddlers, preschoolers, as well as before- and after-school care for school-aged children. The funds also may be used for the operating expenses and/or for minor renovations of child care facilities located in or near public housing developments.

The Early Childhood Demonstration Program provided critical funding for the establishment of developmental child care and pre-school at the Ounce of Prevention Fund's Center for Successful Child Development (CSCD) in Chicago. Through the HUD grant, the CSCD developed an infant/toddler child care center in the Robert Taylor Homes serving children from ages birth to three with quality developmental child care. The Center was, until recently, the only infant child care center in all of Chicago Public Housing, and became one of the models for the Department of Health and Human Services' Early Head Start Program.

In FY 1995, localities and non-profits competed for \$21 million in urban and rural Empowerment Zones' and Enterprise Communities' Early Childhood Development funds. In September 1996, HUD announced awards to 45 communities to fund child care for 4,800 poor and homeless children. HUD did not request funding for this program in FY 1997 or FY 1998.

Historically Black Colleges and Universities Grants

Historically Black Colleges and Universities (HBCUs) are in an excellent position to assist the neighborhoods and communities in which they are located. HBCUs currently receive support from HUD's Office of Community Planning and Development and the Office of University Partnerships. The HBCU program provides financial assistance to certain educational institutions to enable them to expand their roles and effectiveness in addressing community development/neighborhood revitalization needs in their localities, especially through housing and economic development activities. HUD awards HBCU grants competitively. Last year, HUD awarded a grant to St. Philip's College of San Antonio, TX, for \$300,000 specifically for early childhood development

activities. St. Philip's is using the funds for construction of a family resource center to house a child care center, training center for early childhood development, violence counseling programs, supportive services for families, homeownership information, mobile health care services and education and life skills for low income residents.

Early Childhood Immunization Program

Approximately 80 percent of vaccine doses are required before the age of 2 when a child is most vulnerable to contracting vaccine-preventable diseases. Childhood vaccines prevent nine infectious diseases: polio, measles, diphtheria, mumps, pertussis (whooping cough), rubella (German measles), tetanus, hepatitis-B, and Hib (the most common cause of spinal meningitis). Children need at least 12 shots before their second birthday in order to be adequately protected against these vaccine preventable diseases.

Although school laws have effectively increased the immunization rate for children over the age of 5, inadequate immunization of children age two and younger is a national problem. While no single factor accounts for under immunization, studies have shown that various risk factors include low parental education, large family size, low socioeconomic status, use of public clinics, young parental age, and lack of prenatal care. Consistent with the findings of these studies, highest risk children are often concentrated in public housing communities.

In January 1996, HUD's Office of Special Actions initiated a meeting with Department of Health and Human Services officials to propose a joint initiative to immunize children age 2 and under living in public housing developments. As a result of that meeting, HHS and HUD and the Corporation for National Service are joining together in federal partnership to provide the resources and technical support needed to implement the Joint Immunization Initiative.

This is a national initiative to protect our youngest children who live in public housing against vaccine-preventable diseases. Under the demonstration program, HHS will provide \$800,000 for three years to fund four projects to immunize children who live in public housing, working in partnership with HUD. The CDC will collect data on the success of pilot projects, and make program recommendations based on those results. Depending on the success of the demonstration program, HUD and HHS can commit resources to expanding this project nationwide. Applications for this program are currently under review, and the Departments plan to announce grant winners in early May.

2. Planned HUD Projects and Programs That Target the Earliest Years of Life.

This year, HUD will finalize lead-based paint regulations to streamline lead-based paint requirements across all HUD housing programs. This will greatly expand the Department's efforts to make lead hazard control a routine part of the maintenance and rehabilitation of federally-assisted housing.

HUD's FY 1998 budget submissions contains no plans for new programs specifically targeted to early childhood development. As noted above, many HUD programs strive to improve conditions for raising children, including very young children.

3. Specific HUD Proposals for Additional Projects and Programs That Could Be Undertaken to Improve the Earliest Years of Life.

The following provides specific proposals for additional projects and programs this year that could be undertaken to improve the earliest years of life that do not require new spending or that fall within the proposals in the FY 1998 Budget, or that could be developed for consideration in the FY 1999 Budget, within the limits of my Balanced Budget Plan.

Use Day-Care Centers in Public Housing as Conduits for Information

Most public housing authorities sponsor day-care programs for residents. In order to give parents of young children access to the latest research and information on early childhood development, HUD could require each public housing authority to set up "Early Childhood Info Centers" to carry brochures and newsletters focusing on health, nurturing and development for the youngest children. HUD field offices would be responsible for ensuring that day-care center staff understand the importance of getting available information to parents.

Establish Partnerships for Family Investment Centers

The Family Investment Center (FIC) Program's mission is to provide families living in public and Indian housing communities with better access to educational and employment opportunities, encouraging families to achieve self-sufficiency and independence. Eligible activities under the program include supportive services, such as child care. The program provides grants to Public Housing Authorities and Indian Housing Authorities to provide families with better access to education and job opportunities to achieve self-sufficiency and independence. Services offered to the youngest children and their parents can vary according to each community and their particular needs.

A new and exciting partnership between HUD, the Chicago Housing Authority, and the Ounce of Prevention Fund is building a new FIC in Chicago. The FIC will include a parent/child area designed specifically to meet the needs of infants and toddlers and their families. This early childhood center will feature developmentally appropriate toys, books, and equipment to provide young children the opportunities they need to crawl, climb, and learn. An additional feature of the center will be parenting education classes that are activity-based, allowing parents to practice their newly acquired skills.

This new center can serve as a model for similar partnerships across the country, and HUD will work to make sure other housing authorities and nonprofit organizations realize the potential of this model in addressing early childhood needs.

Use Campuses of Learners to Promote Positive Parenting

First launched in 1995, the Campus of Learners (COL) Initiative designated 25 public housing authorities who receive funding and technical assistance to create innovative strategies to provide residents with education, job training, and employment opportunities. A Campus of Learners involves residents with computer and telecommunications technology in a college campus-style setting. The initiative depends on public housing authorities forming partnerships with local school districts, colleges and universities, and other non-profits.

A major component of COL is providing child care to those parents participating in the program. To that end, some of the COL designees have forged partnerships with FICs located in or near their developments. HUD can encourage COL sites to set up early childhood centers within these day-care facilities and FICs to provide activities and guidance on better parenting for young children.

Build on Success of Public Housing Immunization Pilot Project

As noted above, the Joint Immunization Initiative is a demonstration program involving the Department of Health and Human Services (HHS), the Department of Housing and Urban Development (HUD), and the Corporation for National Service. HHS will provide \$800,000 for three years to fund four projects to immunize children who live in public housing, working in partnership with HUD. The Centers for Disease Control will collect data on the success of pilot projects, and make program recommendations based on those results. Depending on the success of the demonstration program, HUD and HHS can commit resources to expanding this project nationwide.

Focus University-Community Partnerships on Early Childhood Development

The tremendous physical and economic resources of America's colleges and universities - and the knowledge, creativity, and energy of their faculty and students - are vital to locally based efforts to create stronger, healthier communities. The Community Outreach Partnership Centers (COPC) Program is an initiative of HUD's Office of University Partnerships. This program provides 2- to 3-year grants of up to \$400,000 to encourage institutions of higher education to join in partnerships with their communities. COPCs must play an active and visible role in community revitalization by applying research to real urban problems, coordinating outreach efforts with neighborhood groups and residents, acting as a local information exchange, galvanizing support for neighborhood revitalization, developing public service projects and instructional programs, and collaborating with other COPCs.

Generally, COPC grantees focus on more traditional needs of urban communities, such as job training and counseling to reduce unemployment, resident-backed strategies to spur economic growth and reduce crime, housing discrimination and homelessness, mentoring programs for neighborhood youth, and financial and technical assistance for new businesses. HUD would propose to have a special round of COPC grants focusing solely on early childhood development research and outreach.

Focus Historically Black Colleges and Universities on Early Childhood Development

The example of an HBCU grantee choosing to focus on early childhood development provides a model for HUD to promote in encouraging similar proposals. HUD awards HBCU grants competitively, and HUD could encourage demonstration projects focusing on early childhood development with appropriate eligibility criteria.

Utilize Service Resources as "Community Workers"

Though information may be readily available, harried and hurried parents may not have the time -- or the ability -- to stop and absorb written information that would help them improve their children's development. By partnering with programs such as VISTA, Volunteers of America and the Corporation for National Service, HUD could help provide "community workers" to talk directly and frankly with parents about development and nurturing their babies. The community workers could meet people at a local day-care center, or even in their homes.

Help the Faith Community be an Early Childhood Resource

HUD's Office of Special Actions initiated an effort to reach out to the faith community. Former Secretary Henry Cisneros believed that the faith community can act as a catalysts for community development, because of four unique strengths:

- They often have a longstanding presence in their neighborhoods, and tend to remain as a source of community support after other institutions have left distressed areas;
- They have traditional missions of charity that extend beyond their congregations;
- They can leverage other resources, because of linkages to the outside world and because of leaders with great organizational skills;
- They can provide nurturing and support, especially for youth in distressed neighborhoods.

Many religious institutions sponsor housing rehabilitation and development projects, even more ambitious commercial development, credit access, housing counseling, social services, and employment programs.

Through HUD's Religious Organization Initiative, HUD can provide outreach to engage churches in partnerships with local public housing authorities to provide early childhood services. Churches could identify volunteer mentors who could be trained to work with mothers of infants and young children to teach them how to nurture and care for their children. These volunteers could also connect mothers with community services for the early identification of developmental problems, as well as other health and social services. Through such outreach, HUD could help the faith community become a two-way conduit of information on early childhood development: research information can flow through churches to their members and organizations, and they in turn can provide others with practical, hands-on ideas from the faith community.

Expand Support for Organizations that Support Parents of Lead-Poisoned Children

As part of its Lead Hazard Control grant program, HUD will provide some funding and technical assistance to organizations of parents of lead-poisoned children, and the non-profit community organizations that promote lead-poisoning prevention. The outreach effort will find new ways to help parents teach other parents how to recognize and protect children from the dangers of lead poisoning.



U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20410-0001

Elena -
FYI

- Pauline

MEMORANDUM

FOR: Pauline Abernathy
FROM: Mark Engman
DATE: March 18, 1997
SUBJECT: Early childhood proposals

Pauline, attached is a memo of POSSIBLE proposals that HUD might put forth for the Early childhood conference. This list may not be complete, nor has it been cleared with senior staff. It represents ideas from various sources in the Department on reaching out to people who need information on early childhood development. These ideas leave out proposals that would require lots of new money.

HUD's Office of Native American Programs brought up an excellent point regarding the American Indian community. One of the biggest and saddest problems in the Native American community is Fetal Alcohol Syndrome. I would propose that one of your medical experts be able to discuss that disease, and also that your audience include a couple of representatives of the Native American community with knowledge of FAS and its costs. I will send you a couple of names tomorrow.



**U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20410-0001**

MEMORANDUM

FOR: Elena Kagan
FROM: Mark Engman
DATE: March 18, 1997
SUBJECT: Early Childhood proposals

Here is a quick "preview list" of HUD proposals for new initiatives:

Use day-care centers in public housing as conduits for information Most public housing authorities sponsor day-care programs for residents. In order to give parents of young children access to the latest research and information on early childhood development, HUD could require each public housing authority to set up "Early Childhood Info Centers" to carry brochures and newsletters focusing on health, nurturing and development for the youngest children. HUD field offices would be responsible for ensuring that day-care center staff understand the importance of getting available information to parents.

Establish partnerships for Family Investment Centers Family Investment Centers (FIC) are for families living in Public and Indian Housing. The program provides grants to Public Housing Agencies and Indian Housing Authorities to provide families with better access to education and job opportunities to achieve self-sufficiency and independence. However, the services offered to the youngest children and their parents can vary greatly.

HUD hopes to form partnerships with organizations that run successful programs targeted at early childhood development. One great example is the Center for Successful Child Development (CSCD) in Chicago aims to prepare children through age five in all areas of their development so they are ready to learn as soon as they enter school. CSCD focuses on the family to help create a positive, nurturing environment outside as well as inside the classroom. Soon the CSCD's program for 0-3 year olds will be moving into the Chicago Housing Authority's Family Investment Center (FIC). The CSCD will take over 8000 square feet inside of the FIC. This example should serve as a model for partnerships across the country.

Build on success of public housing immunization pilot project The Joint Immunization Initiative is a demonstration program involving the Department of Health and Human Services (HHS), the Department of Housing and Urban Development (HUD), and the Corporation for National Service. HHS will provide \$800,000 for three years to fund four projects to

immunize children who live in public housing, working in partnership with HUD. The Centers for Disease Control will collect data on the success of pilot projects, and make program recommendations based on those results. Depending on the success of the demonstration program, HUD and HHS can commit resources to expanding this project nationwide.

Focus University-Community Partnerships on early childhood development The tremendous physical and economic resources of America's colleges and universities - and the knowledge, creativity, and energy of their faculty and students - are vital to locally based efforts to create stronger, healthier communities. The Community Outreach Partnership Centers (COPC) Program is an initiative of HUD's Office of University Partnerships. This program provides 2- to 3-year grants of up to \$400,000 to encourage institutions of higher education to join in partnerships with their communities. COPCs must play an active and visible role in community revitalization by applying research to real urban problems, coordinating outreach efforts with neighborhood groups and residents, acting as a local information exchange, galvanizing support for neighborhood revitalization, developing public service projects and instructional programs, and collaborating with other COPCs.

Generally, COPC grantees focus on more traditional needs of urban communities, such as job training and counseling to reduce unemployment, resident-backed strategies to spur economic growth and reduce crime, housing discrimination and homelessness, mentoring programs for neighborhood youth, and financial and technical assistance for new businesses. HUD would propose to have a special round of COPC grants focusing solely on early childhood development research and outreach.

Focus Historically Black Colleges and Universities on early childhood development Historically Black Colleges and Universities (HBCUs) are in an excellent position to assist the neighborhoods and communities in which they are located. HBCUs currently receive support from both CPD and other HUD offices, including the Office of University Partnerships. The HBCU program provides financial assistance to certain educational institutions to enable them to expand their roles and effectiveness in addressing community development/neighborhood revitalization needs in their localities, especially through housing and economic development activities. HUD awards HBCU grants competitively, and HUD could encourage demonstration projects focusing on early childhood development with appropriate eligibility criteria.

Utilize service resources as "community workers" Though information may be readily available, harried and hurried parents may not have the time -- or the ability -- to stop and absorb written information that would help them improve their children's development. By partnering with programs such as VISTA, Volunteers of America and the Corporation for National Service, HUD could help provide "community workers" to talk directly and frankly with parents about development and nurturing their babies. The community workers could meet people at a local day-care center, or even in their homes.

Teach the Faith Community to be an early childhood resource HUD's Office of Special Actions initiated an effort to reach out to the faith community. Former Secretary Henry Cisneros believed that the faith community can act as a catalysts for community development, because of four unique strengths:

- They often have a longstanding presence in their neighborhoods, and tend to remain as a source of community support after other institutions have left distressed areas;
- They have traditional missions of charity that extend beyond their congregations;
- They can leverage other resources, because of linkages to the outside world and because of leaders with great organizational skills;
- They can provide nurturing and support, especially for youth in distressed neighborhoods.

Many religious institutions sponsor housing rehabilitation and development projects, even more ambitious commercial development, credit access, housing counseling, social services, and employment programs. HUD should help the faith community become a two-way conduit of information on early childhood development: both providing research information to the faith community, and receiving practical, hands-on ideas from the faith community.