

DOCUMENT RESUME

ED 332 831

PS 019 748

TITLE Pediatric, Adolescent, and Maternal AIDS Branch. Report to the National Advisory Child Health and Human Development Council.

INSTITUTION National Inst. of Child Health and Human Development (NIH), Bethesda, Md. Center for Research for Mothers and Children.

PUB DATE Jun 90

NOTE 14p.

PUB TYPE Reports - Descriptive (141)

EDRS PRICE MF01/PC01 Plus Postage.

DESCRIPTORS *Acquired Immune Deficiency Syndrome; Adolescents; Children; *Epidemiology; *Federal Programs; Infants; Medical Research; Medical Services; Mothers; Pediatrics; Pregnancy; Program Descriptions; *Public Health; Public Policy; *Research Projects

ABSTRACT

This report describes current research activities and future plans of the Pediatric, Adolescent, and Maternal AIDS (PAMA) Branch of the National Institute of Child Health and Human Development's Center for Research for Mothers and Children. The mission statement of the Branch notes that PAMA develops, implements, and directs a wide range of domestic and international research activities for the study of the pathogenesis, epidemiology, natural history, and risk factors and co-factors of human immunodeficiency virus (HIV) and related retroviruses in pregnant women, mothers, infants, children, adolescents, and the family unit as a whole; and develops and supports clinical trials of specific and adjunctive therapy for this population. In addition, the Branch works toward providing a more precise understanding of the modes of transmission of HIV and related retroviruses in this population and interacts to render treatment and services to the HIV population and to provide full coordination with other programs and other federal and non-federal research agencies. Activities of the Branch are organized around five areas of emphasis: (1) epidemiology and natural history of HIV infection in pregnant women, mothers, infants, and children; (2) therapeutic research in HIV infection in children and pregnant women; (3) pediatric and maternal biomedical HIV-related research issues; (4) adolescent HIV infection and disease; and (5) public health policy issues in maternal and pediatric AIDS. The Branch's budget for fiscal year 1990 is provided. (RH)

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REPORT TO

THE NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL

PEDIATRIC, ADOLESCENT, AND MATERNAL AIDS BRANCH
CENTER FOR RESEARCH FOR MOTHERS AND CHILDREN
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

JUNE 1990

PS 019748

INTRODUCTION

As noted in the Report to the National Advisory Child Health and Human Development Council from the Pregnancy and Perinatology Branch (presented in June of 1987), the Pregnancy and Perinatology Branch, under the leadership of Dr. Charlotte Catz, had a major responsibility for NICHD research activities in the area of human immunodeficiency virus infection (HIV) as it affected pregnant women, mothers, neonates, infants, children, and adolescents. In March of 1988, D. Sumner Yaffe convened a meeting chaired by Dr. Samuel Katz of Duke University. This meeting had, as its purpose, to generate a national research agenda for maternal, adolescent, and pediatric AIDS research. A summary of the proceedings of this meeting (Human Immunodeficiency Virus Infection in Childhood, Adolescence, and Pregnancy: A Status Report and National Research Agenda) was published in the journal Pediatrics in February of 1989. One of the recommendations which emerged from the work group moderated by Dr. King Holmes suggested that the National Institute of Child Health and Human Development consider structuring an organizational unit which would focus its full attention on the problem of HIV infection and AIDS in women, adolescents, and children. In response to the growing activity of this research area in the Institute and to the recommendations of the meeting convened by Dr. Yaffe, the Pediatric, Adolescent, and Maternal AIDS (PAMA) Branch was created in July of 1988. The mission statement of the Branch notes that the Branch "develops, implements and directs a wide range of domestic and international research activities for the study of the pathogenesis, epidemiology, natural history, and risk factors and co-factors of human immunodeficiency virus (HIV) and related retro-viruses in pregnant women, mothers, infants, children, adolescents, and the family unit as a whole; develops and supports clinical trials of specific and adjunctive therapy for this population either independently or in collaboration with other Institutes. In addition, it works toward providing a more precise understanding of the modes of transmission of HIV and related retro-viruses in this population in order to provide an opportunity to identify the most promising focal points for prevention and educational efforts; interacts to provide full coordination with all other NICHD, NIH, PHS and DHHS programs and other federal and non-federal agencies active in conducting research, and in rendering treatment and services to the HIV population." Because the PAMA Branch has existed for a relatively brief period of time, this report will focus on both the current activities of the Branch as well as plans for future emphasis.

OVERVIEW OF THE PROBLEM

In 1987, in an analysis conducted for the Department of Health and Human Services Secretary's Work Group on Pediatric HIV Infection and Disease, the Centers for Disease Control (CDC) noted that AIDS was the ninth leading cause of death for children between one and four years of age and was the seventh leading cause of death for young people between fifteen and twenty-four years of age. The Report which emerged from this Work Group predicted that, in the 1990s, AIDS would become one of the five leading causes of death for children and adolescents overall. In 1989, the CDC further noted that women accounted for more than 10% of all AIDS

cases, that more than three-quarters of all women with AIDS are in their reproductive years, and that 80% of all AIDS cases reported in children occurs because HIV-infected pregnant women transmit their infection to their children during gestation and/or delivery. Thus, it is clear that HIV infection and AIDS is having a significant and increasingly important impact on the mortality of children and adolescents in the United States and that HIV infection and AIDS is intimately linked to areas of research interest and focus for the National Institute of Child Health and Human Development. These areas include pregnancy, reproductive processes, mental retardation, congenitally transmitted infection, infant and childhood mortality, adolescent health and development, and biobehavioral issues affecting pregnant women, adolescents, and children.

PROGRAM OVERVIEW

The activities of the Pediatric, Adolescent, and Maternal AIDS Branch are organized around five areas of emphasis. It should be noted that the PAMA Branch strives to address those areas which are unique to the maternal-child dyad, to the at-risk and infected adolescent, and to groups traditionally of special concern to pediatricians (e.g. hemophiliac children). Considerable attention is devoted to, on one hand, avoiding overlap with other NIH Institutes and Public Health Service agencies and, on the other, to maximizing cooperation with other NICHD Branches and Programs, other NIH Institutes, other PHS agencies, and with interested private organizations which have a focus on maternal, adolescent, and pediatric HIV infection and disease. The five areas of emphasis include:

- (1) Epidemiology and Natural History of HIV Infection in Pregnant Women, Mothers, Infants, and Children. Because AIDS in children was not recognized until after this infection was noted in adult men, the extent of this disease in maternal and pediatric populations and the impact of this infection on the health and function of pregnant women and children currently requires further description and explanation. It is clear that certain areas (e.g. CNS pathology) will require particular emphasis and focus.
- (2) Therapeutic Research in HIV Infection in Children and Pregnant Women. The treatment of HIV infection and disease in pregnant women and children must necessarily take into account the unique biomedical makeup and problems of pregnant women and children and must further consider the fact that the women and children infected with this virus exist in social situations very different from many of the adult men infected with HIV.
- (3) Pediatric and Maternal Biomedical HIV-Related Research Issues. There are many processes and problems which are unique to the pediatric and maternal population infected with HIV. Examples of a few of these problems include the early diagnosis of HIV infection in the fetus, newborn, infant and young child and the role of the placenta in the transmission of HIV infection from mother to fetus.
- (4) Adolescent HIV Infection and Disease. One-fifth of all the AIDS reported in the United States is reported in individuals in their

twenties. Because there is a significant latent period between the time the infection is acquired and the diagnosis of full-blown AIDS (the mean time for this viral latency is now documented to be approximately eight years), it is likely that many of these young people acquired their infection during their adolescent years. Thus, it is crucial that the PAMA Branch address attention to the critical issues of HIV infection and disease in adolescents.

(5) Public Health Policy Issues in Maternal and Pediatric AIDS. A number of public health policy issues have emerged which must be addressed if the problem of pediatric and maternal AIDS is to be effectively confronted during the next decade. While a number of these issues are not unique to HIV infection and disease, the advent of this virus has focused new attention on some pediatric and maternal health problems. For example, who gives consent for a child in foster care to participate in clinical trials? What defines a problem for which obstetric or neonatal screening should be mandatory or routine? The PAMA Branch has been a key contributor to the effort of the Public Health Service to begin to address some of these problems which, although not unique to this epidemic, have been sharpened by it.

Because the PAMA Branch is relatively young and limited in scope, the number of research grants and contracts is currently small. A limited Institute AIDS budget has functioned to curtail some research activities in this area. In addition, the large majority of PAMA grants and contracts were relatively recently awarded. Therefore, the rest of this report will be organized by topical area of emphasis rather than by mechanism. Also, the report will focus on activities and plans rather than on specific accomplishments.

EPIDEMIOLOGY AND NATURAL HISTORY OF HIV INFECTION IN PREGNANT WOMEN, MOTHERS, INFANTS, AND CHILDREN

As noted above, much remains to be defined and described about the extent to which HIV infection has spread in maternal and pediatric populations. In addition, the natural course of this infection in these populations must be further elucidated. The PAMA Branch has begun to address the issue of the epidemiology and natural history of pediatric and maternal HIV infection in several ways:

(1) The Branch currently has a research contract which recruits pregnant women at risk for HIV infection in several settings in New York City. This study recruits these women during pregnancy and then follows them, together with their children, for four years. Over 300 mother-infant pairs have been enrolled. This study which is conducted in collaboration with the National Cancer Institute has demonstrated that the rate of transmission of infection from mother to child during gestation or delivery is approximately 30%. In addition, data emerging from this study suggested that premature infants delivered to infected women are at higher risk for vertical transmission of infection than full-term infants delivered to such women and that pregnant women with high levels of anti-gp120 were at less risk of transmitting their infection to their infants

than women with low or absent levels of this antibody. Recruitment into this study and data analysis will continue for three more years.

(2) The Branch supports and conducts a research study in New York City via a research contract mechanism which investigates the impact of the HIV on the neurological and neurodevelopmental outcome of children infected perinatally with the HIV. This study, using appropriate control populations, has demonstrated that the very large majority of vertically-infected children go on to have mental and/or motor retardation as a consequence of their infection. Future work and analyses conducted under this research contract will focus on the earliest signs of HIV-related neurodevelopmental impairment in infected infants and children.

(3) The Hemophilia Growth and Development Study, conducted in collaboration with the Prevention Research Program, is a cooperative effort involving the Bureau of Maternal and Child Health, the Division of Host Factors of the Centers for Disease Control, the National Hemophilia Foundation, and the New England Research Institute. This is a study involving fourteen hemophilia centers around the country and studies the impact of HIV infection and disease on the growth, development, neurological and neurodevelopmental outcome, and the immunology of HIV-infected hemophiliac children when compared to uninfected hemophiliac controls and to uninfected, non-hemophiliac male siblings. At the annual meeting held May 24-28, 1990, a report was presented by the Executive Committee to the Steering Committee. Three hundred and thirty-one study subjects had been recruited for participation, exceeding the targeted enrollment of 300. More than half of these enrolled subjects are HIV-infected. More than 10% of children who are HIV-infected appear to have some growth disturbance at baseline (compared with 3% of non-infected hemophiliac controls). More than one-quarter of the infected children have some abnormality on baseline neuropsychological testing (compared with 16.9% of controls). These data are clearly preliminary in nature and require further in-depth assessment and analysis. The subjects will be re-evaluated on a semi-annual basis. However, it is clear that this study will enhance not only our understanding of pediatric HIV infection, but also our understanding of the impact of hemophilia on non-infected pediatric patients.

(4) The Women and Infants Transmission Study is a research contract being collaboratively conducted between the National Institute of Allergy and Infectious Diseases and the NICHD. This study will focus on the biological factors which may promote or mitigate the transmission of HIV infection from mother to child, the impact of HIV infection on the pregnancy outcome of HIV-infected women, the impact of HIV on the developing immune and neurological status of infected infants and children, and the impact of a variety of therapeutic interventions in pregnant women and their children. This study initiated enrollment two months ago and will be conducted over a four-year period in four medical centers around the country: the University of Illinois, Columbia University, the University of Puerto Rico and a consortium of Boston hospitals.

(5) The Seroepidemiologic Study of HIV Infection in Child-bearing Women in the United States is a research contract awarded by the PAMA Branch to the Theobald Smith Research Institute, the research arm of the State Department of Health in Massachusetts. Dr. Rodney Hoff, the Principal Investigator, had reasoned that, if samples of newborn blood which were routinely collected on filter paper at the time of birth could be tested for HIV antibody which is transferred from mother to fetus during gestation, estimates of the prevalence of HIV infection in an important segment of the United States population (i.e. childbearing women) could be made. Further, since reasonable estimates of the rate of transmission of HIV infection from mother to child were available from NICHD-sponsored and other studies, he realized that it would be possible to predict quantitatively the future course of the pediatric HIV epidemic. Under contract to NICHD, he demonstrated that routinely collected samples of newborn blood could be reliably and validly tested for the presence of HIV antibody. Having demonstrated this, he went on to test samples of newborn blood collected in the state of Massachusetts and showed that approximately 2 out of every 1000 women who gives birth in the state is HIV-infected. Dr. Hoff then with NICHD support, assistance, and cooperation was able to transfer this technology to the Centers for Disease Control which has disseminated it to state laboratories which are now participating in a nationwide survey of HIV seroprevalence in childbearing women in 44 states, Puerto Rico and the District of Columbia. Results of the most recent survey demonstrated that 5600 HIV-infected women gave birth in the U.S. last year and, therefore, approximately 1700 children who will ultimately die of AIDS were born in 1988. This number surpasses the number of children with perinatally acquired AIDS reported to the Centers for Disease Control through 1989. Continuation of this serosurveillance activity which was developed by an NICHD contractor will continue to provide important epidemiologic information on the maternal and pediatric HIV epidemic during the next decade. In its report entitled AIDS: Sexual Behavior and Intravenous Drug Use, the Committee on AIDS Research and the Behavioral, Social and Statistical Sciences of the National Research Council noted this seroepidemiologic study "... is unique among the surveys planned ... It is the only survey to provide seroprevalence data that, by design, can be generalized to an identifiable population. The CDC/NIH (NICHD) neonatal survey will perform HIV tests using the dried blood specimens that are routinely collected from all (hospital-born) newborns (to test for metabolic disorders). Because children born to HIV-infected mothers carry the mother's antibodies (without necessarily being infected themselves), the HIV seroprevalence rates derived from this screening can be projected both to the population of newborns and to the population of childbearing women. The statistics derived from this survey will provide a basis both for projecting future AIDS cases among infants and, perhaps most importantly, for monitoring the prevalence of infection among an important part of the population of heterosexually active women."

(6) Through interagency agreements and via research grant awards the PAMA Branch also supports research activity concerning the genetic epidemiology of in utero HIV transmission, the epidemiology of HIV infection in mothers and children in Nairobi, Kenya, and other parts of Africa, the

epidemiology and natural history of HIV infection in mothers and infants in the Bay Area of San Francisco, epidemiology of HIV infection in military families, and the epidemiology of HIV infection in drug-using women.

THERAPEUTIC RESEARCH IN HIV INFECTION IN CHILDREN AND PREGNANT WOMEN

At the present time, therapeutic research in pregnant women and in children lags far behind that in adult men. Many questions must be addressed. These include: (1) Can the transmission of HIV infection from mother to fetus be interrupted by chemoprophylactic or other measures? (2) If a child is infected during the perinatal period, can the progression of that infection from the asymptomatic state to frank disease be interrupted, delayed or mitigated? (3) Do infected children benefit from early therapeutic intervention as is the apparent case in adults? (4) Can the profound neurologic consequences of infection in infants and children be prevented or reduced? (5) Can more effective measures against the often fatal complications of opportunistic infections be devised? (6) Can the progression of lymphocytic interstitial pneumonitis be prevented? Only one drug, AZT, is licensed for use in HIV-infected children and that license was granted only via a waiver mechanism that stated that well-controlled studies of the efficacy of AZT in children were lacking. Thus, it is clear that appropriate protocols aimed at the evaluation of therapeutic strategies using well-designed and well-controlled study methodologies must be implemented in sufficient numbers of children and pregnant women such that convincing proof is provided so that clinicians can undertake treatment of this disease in the maternal and pediatric population affected by this virus.

In March of 1988, the NICHD implemented a study of the efficacy and safety of intravenously administered pooled human immunoglobulin in HIV-infected children. This study had as its purpose to determine if this agent (IVIgG) could reduce the occurrence of serious bacterial infections and death in HIV-infected symptomatic children. This study was implemented in collaboration with the Prevention Research Program by a research contract mechanism in 28 medical centers around the United States. In many of these centers, this research protocol was the only one available to HIV-infected children as NIAID-supported therapeutic research in children was limited to a small number of centers in the United States. Since the research strategy had been developed with the social difficulties of the target patient population in mind, compliance with the very rigorous and demanding protocol was excellent. More than 90% of all treatment administrations and all data collection points were made on time in a population consisting largely of children of drug-using families. Because of the success that this trial had in the design and implementation of a rigorous study protocol, in the recruitment and retention of hard-to-reach patients, and in the outreach to the majority of medical centers treating HIV-infected children in the United States, Drs. Anthony Fauci, Duane Alexander and James Wyngaarden mandated that the NICHD-supported group of research investigators join with the smaller group of NIAID-supported investigators for the purpose of devising and conducting therapeutic research in HIV-infected pregnant women and children. This merger was

implemented in May of 1990 and will offer access to NIH-sponsored therapeutic research to the majority of HIV-infected pregnant women and children in the U.S.

Currently, Drs. Anne Willoughby and Lynne Mofenson serve on the Pediatric Core Committee of the AIDS Clinical Trials Group. This Core Committee has as its mandate to oversee the development of a national research agenda in maternal and pediatric HIV therapeutic research in the United States. Dr. Robert Nugent serves as methodologic consultant for therapeutic research activities in the PAMA Branch.

In 1989, the AIDS Clinical Trials Group sought to develop a protocol which would test the efficacy of AZT in interrupting transmission of HIV infection from mother to child. This protocol planned to administer AZT vs. placebo to HIV-infected pregnant women in the last trimester of pregnancy and during parturition and to the offspring of these women for the first six weeks of life. The purpose of this study will be to determine if AZT is effective in the interruption of vertical transmission of HIV infection from mother to child. It was clear that the participation of obstetricians and gynecologists from the medical centers participating in the AIDS Clinical Trials Group was essential for the development and implementation of this protocol and future protocols which will seek to address this key issue. These types of therapeutic studies (i.e. those undertaken in pregnant women) are key for two reasons. First, if transmission can be interrupted during gestation, then the beginning of the end of this epidemic in children will be achieved as virtually all pediatric HIV disease in the future will emerge as the result of vertical transmission. Secondly, because the large majority of U.S. women interact with the health care system around issues of reproduction, obstetricians and gynecologists are the logical health care professionals through whom HIV-infected women can be reached for purpose of research, care, and treatment. In order to enlist the participation of this key group of physicians and researchers, Dr. Pamela Stratton of the PAMA Branch, with cooperation with the NIAID, developed and chaired a two-day meeting entitled "Research and Health Care Role for Obstetricians and Gynecologists Involved in Prevention and Treatment of HIV Infection in Women and Their Children" in December of 1989. As a followup to this important meeting, Dr. Stratton has been largely responsible for the initiation and subsequent activities of an Obstetric Subcommittee to the AIDS Clinical Trials Group.

PEDIATRIC AND MATERNAL BIOMEDICAL HIV-RELATED RESEARCH ISSUES

The Pediatric, Adolescent, and Maternal AIDS Branch, as noted above, attempts to focus its resources and activities in AIDS-related biomedical research on those issues which are unique to pediatric and maternal disease. In this regard, the Branch has

- (1) issued in 1989 an RFA entitled "Improved Methods for the Early Diagnosis of HIV Infection in Neonates, Infants, and Children." This solicitation invited grant applications to support basic research on the improvement of methods which can be utilized early in life for the

diagnosis of human immunodeficiency virus infection in children. This RFA was necessary because there was and is a notable lack of reliable methods for the diagnosis of HIV infection early in life. This dearth of reliable technology was and is an impediment to the effective and efficient conduct of clinical trials of anti-HIV therapies in infants and children. As a result of this solicitation, there is now very active research in this area ongoing in six medical centers in the United States. In October of 1990, the NIAID and the NICHD, in cooperation with the Centers for Disease Control, plan to sponsor a conference on the state of the art of early diagnosis of HIV infection in fetuses, neonates, and infants. This conference will review in depth information including unpublished data in this important area and will identify future research directions for both of the Institutes and the research community.

(2) issued an RFA to invite grant applications to support basic research on the role of the placenta in transmitting infection from mother to infants and the role of the placenta in the development of in utero therapies for HIV infection. The response to this solicitation and the subsequent review will be presented at the National Advisory Child Health and Human Development Council meeting in June of 1990.

(3) supported research activities in a variety of areas including fertility-related behavior of women at risk for HIV, the impact of HIV infection in pregnancy, the interaction of HIV with other infectious cofactors in pregnant HIV-infected women, immunoglobulin structure and function, the impact of HIV infection on the fetus, fetal toxicity of zidovudine, and the impact of HIV infection on maternal, fetal, and pediatric immune function.

ADOLESCENT HIV INFECTION AND DISEASE

As noted above, the adolescent population of the United States is of concern with regard to the HIV epidemic. Risk-taking behavior is normally present in this group. In addition, significant and abnormal risk-taking (e.g. drug use) also occurs with some frequency in adolescents. Because adolescence is a unique developmental period from both a biological and biobehavioral point of view and because HIV infection has already made significant inroads into this population, the adolescent is of special concern to the PAMA Branch in its AIDS-related activities.

In an effort to foster the research effort and focus in this area, the NICHD together with the National Institute on Drug Abuse, the National Institute of Mental Health, and the Society for Adolescent Medicine in collaboration with divisions of adolescent medicine in major medical centers around the country sponsored six regional conferences. These conferences all focused on consortium building for high-risk youth through coordination of efforts in prevention, service, and research. Beginning in the fall of 1988, these meetings were held in Washington, D.C., Chicago, San Francisco, Houston, New York, and Miami. A key focus of each meeting was to present state-of-the-art information on HIV infection in adolescents and to identify areas which required further research. Subsequent to these meetings, staff from the PAMA Branch has

continued to meet with other interested federal and private organizations and to work with individual investigators concerning their research interests and potential research proposals. In January of 1989, the PAMA Branch organized and conducted a technical advisory meeting on HIV infection and disease in adolescence which presented information on the epidemiology and natural history of infection in this group and then sought advice from an expert panel on research areas which required further focus, definition, and work. A member of the PAMA staff organized and conducted a research roundtable at the most recent Society for Adolescent Medicine meeting in order to highlight ongoing research activities in this area and to assist potential grantees in the development of their ideas on this important topic.

PUBLIC HEALTH POLICY ISSUES IN MATERNAL AND PEDIATRIC AIDS

The human immunodeficiency virus is a new and deadly infectious agent which has its devastating effect on the human body by disabling the body's immune system. Termed a "molecular pirate" by Dr. Samuel Broder, Director of the National Cancer Institute, this clever virus presents a significant challenge to the integrity of the human body and, thus, also a momentous challenge to the ingenuity and the resourcefulness of the scientific and medical research community. Simultaneously, especially in the case of women, adolescents, and children, this virus and its effects present a marked challenge to our society and its sense of social responsibility. By falling on those segments of our pediatric and maternal society least able to respond to it (poor, urban, minority, disenfranchised, out of the mainstream of medical and social services), this virus has proven doubly diabolical in its effects. In some evaluations, this virus is seen to represent one of the foremost biomedical and biosocial challenges of our times. Because it is impossible to separate the biological from the social impact of this disease and because true efficacy of response by responsible and dedicated research and medical scientists depends on their willingness to recognize the dual nature of the challenge, the PAMA Branch has attempted to respond to requests and needs of the pediatric and maternal public health community in such a way as to increase the efficacy of the biomedical and biosocial response to the effects of this virus on mothers and children. Participation in the public health response to the HIV epidemic in women and children on the part of the PAMA Branch has included:

- (1) serving as coordinating staff for the Department of Health and Human Services Secretary's Work Group on Pediatric HIV Infection and Disease
- (2) serving as one of the National Institutes of Health representatives to the Public Health Service Panel on Women, Adolescents, and Children with AIDS
- (3) generating the cross-cutting pediatric report for the Report of the Second Public Health Service AIDS Prevention and Control Conference
- (4) serving on the Public Health Service Executive Task Force Epidemiology and Surveillance Subgroup

- (5) sponsoring a recent Institute of Medicine conference on Prenatal and Newborn Screening for HIV Infection: Opportunities for Prevention and Treatment
- (6) serving as expert consultant to the New York State Department of Health concerning the evaluation and treatment of children with HIV infection
- (7) serving on the National Planning Committee for the annual National Pediatric AIDS Conferences
- (8) serving on the National Planning Committee for the 1987 Surgeon General's Workshop on Children with HIV Infection and Their Families and the Follow-Up to the 1987 Surgeon General's Workshop on Children with HIV Infection and Their Families
- (9) serving on the Pediatric Core Committee of the AIDS Clinical Trials Group
- (10) serving as a consultant to the FDA's Antiviral Advisory Committee.

In addition to the above list of activities, Branch staff very frequently respond to the requests of professional societies, local departments of health, state health agencies, private foundations and groups, and international organizations to provide expert consultation, guidance and information concerning the appropriate response of the biomedical and public health community to the AIDS epidemic in women and children.

PLANS FOR THE FUTURE

The Pediatric, Adolescent, and Maternal AIDS Branch of the National Institute of Child Health and Human Development has made an initial attempt to respond to the biomedical and biobehavioral challenge presented by the AIDS epidemic. Plans to enlarge, refine, and direct the future response of the Branch include:

- (1) convening an expert panel of advisors to assist in the development of a five year plan for the Branch
- (2) increasing emphasis on the design and conduct of useful research on HIV infection and disease in the adolescent community with particular focus on risk-taking behaviors in adolescents
- (3) assessment of the biomedical research questions unique to pediatric and maternal AIDS and appropriate assistance that the NICHD can offer to the medical research community in supporting research which will address and answer these questions

(4) expansion of the clinical trials network which functions to evaluate promising therapeutic agents which will mitigate the effects of the HIV on women and children while offering state of the art care and treatment to infected pediatric and maternal populations

(5) increased coordination of all Branch research and public health activities with other NICHD programs, NIH Institutes, PHS agencies, and DHHS components in order to increase the efficiency and efficacy of the Branch response to the pediatric, adolescent, and maternal HIV epidemic.

PEDIATRIC, ADOLESCENT, AND MATERNAL AIDS BRANCH - FY 1990 BUDGET

	<u>Type</u>	<u>Number</u>	<u>Cost</u>
(1)	Program Projects (P01)	1	1,330,066
(2)	Research Grants (R01)	19	6,413,925
(3)	Research Contracts (NO)	5	11,048,641
(4)	Inter/Intra-Agency Agreements (YO)	3	2,850,000
	Total		<hr/> 21,642,632