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National Pediatric Conference 5/23/94

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National Pediatric HIV Resource Center
Title IV Pediatric, Adolescent & Family
HIV Service Demonstration Program
Public Policy Conference

Washington Vista Hotel
1400 M Street, NW
Washington, D.C.

AGENDA

Confirmed Speakers
as of May 11, 1994

Monday May 23, 1994

9:00am — Welcome

Beth Roy, MS
Branch Chief
Hemophilia and AIDS Program
Maternal and Child Health Bureau
Rockville, MD

Carolyn Burr, RN, MN
Associate Director
National Pediatric HIV Resource Center
Newark, NJ

9:15 am — **Plenary Panel: Ryan White CARE Act Reauthorization**

Moderator:
David Harvey, MSW
Coordinator for Public Policy
National Pediatric HIV Resource Center

Presenters:
Mary Boland, RN, MSN, Director
National Pediatric HIV Resource Center;
Chair, HRSA AIDS Advisory Committee
Newark, NJ

Cornelius Baker
Director of Public Policy and Education
National Association of People With AIDS
Washington, DC

Dorothy Mann
Executive Director,Circle of Care Project;
Family Planning Council of Southeastern Pennsylvania
Philadelphia, PA

10:45am **Plenary Panel: Public Health Implications of ACTG 076**

Chair:
Kristine Gebbie, RN, MN, FAAN
National AIDS Policy Coordinator
The White House

Presenters:
NIAID Presenter

Lynn Mofensen, M.D.
Associate Branch Chief for Clinical Research
National Institutes of Health
Bethesda, MD
Chair, PHS 076 Taskforce

Gina Brown, M.D.
Department of OB-GYN
Columbia Presbyterian Medical Center
New York, NY

Cheryl Healton, Ph.D.
Associate Dean, Columbia University School of Public Health:
Northern Manhattan Women & HIV Demonstration Program
New York, NY

12:00 Noon **Keynote Address: Health Care Reform and Children, Youth and Families With Special Health Care Needs**

Lisa Simpson, MD, MPH, FAAP
Office of the Assistant Secretary for Health
Department of Health & Human Services
Washington, DC

FOUR CONCURRENT WORKSHOP SESSIONS FROM 1:45pm-3:15pm

1:45pm

ACTG 076 Clinical Implementation Issues

Moderator:
Sandi Lewis, Sc.D.
Psychologist Educator
National Pediatric HIV Resource Center
Newark, NJ

Presenters
Peter Vink, M.D.
Director, Pediatric AIDS Care & Evaluation Clinic
University of Maryland at Baltimore
Baltimore , MD

Consumer

Ryan White CARE Act Reauthorization

Moderator:
Raquel Whiting
Public Policy Fellow
National Community AIDS Partnership
Washington, D.C.

Presenters:
Dorothy Mann
Executive Director, Circle of Care Project;
Family Planning Council of Southeastern Pennsylvania
Philadelphia, PA

Julia Hidalgo, Sc.D.
Associate Director, Maryland AIDS Administration
MD Pediatric AIDS Health Care Demonstration Project
Baltimore, MD

Chris Hall, MS
Director, Public Policy
Project AHEAD
Special Programs for Youth
San Francisco, CA

Brian Feit
Manager
Boston Pediatric AIDS Project
Dimock Community Health Center
Roxbury, MA

ACTG 076 Policy Implications

Moderator:
Ernest C. Hopkins
Chair, Washington Metropolitan Area HIV Services Planning Council
Washington, D.C.

Presenters:
Cheryl Healton, Ph.D.
Associate Dean, Columbia University School of Public Health:
Northern Manhattan Women & HIV Demonstration Program
New York, NY

Marilyn Crain, M.D., MPH
Director, Pediatric HIV/AIDS Health Care Demonstration Program
University of Alabama
Birmingham, AL

Donna Futterman, M.D.
Associate Director
Adolescent HIV Comprehensive Care Center
Montefiore Medical Center
Bronx, NY

Consumer

CDC Community Planning Prevention Initiative

Moderator:

Presenters:
Julie Scofield
Executive Director
National Association of States AIDS Directors
Washington, DC

Jay Coburn
Legislative Representative
AIDS Action Council
Washington, DC

Manuel Migaz
Director of Technical Assistance
National Minority AIDS Council
Washington, D.C.

Consumer/Youth

FOUR CONCURRENT WORKSHOP SESSIONS FROM 3:30pm-5:00pm

3:30pm

Health Care Reform

Moderator:
Sharon Novey, M.P.H.
Health Care Reform Consultant
National Pediatric HIV Resource Center
Washington, D.C.

Presenters:
Nora Wells
Senior Policy Specialist
Family Voices
Boston, MA

Christine Lubinski
Deputy Executive Director
AIDS Action Council
Washington, DC

Merle McPherson, M.D.
Director, Division of Children with Special Health Care Needs
Maternal & Child Health Bureau
Rockville, MD

ACTG 076 Clinical Implementation Issues

Moderator:
Ernest C. Hopkins
Chair, Washington Metropolitan Area HIV Services Planning Council
Washington, D.C.

Presenters:
Peter Vink, M.D.
Director, Pediatric AIDS Care & Evaluation
University of Maryland at Baltimore
Baltimore, MD

Consumer

Title IV Evaluation & Research: Data Collection Forms

Presenters:
Lela Noland Baughman
Macro International
Atlanta, GA

Jean Setzer, Ph.D.
The University of Texas Health Sciences Center
South Texas AIDS Center for Children & Families
San Antonio, TX

Adolescent Clinical & Services HIV Research Issues:
Future Public Policy Issues

Moderator:
Stormy Schevis
Project Manager
Comprehensive Pediatric AIDS Project
Ft. Lauderdale, FL

Presenters:
Audrey Rogers, Ph.D., M.P.H.
Pediatric, Adolescent and Maternal AIDS Branch
National Institute of Health
Bethesda, MD

Gloria Weissman, M.A.
Associate Director for Special Projects
Health Resources Services Administration
Rockville, MD

Sean Sasser
Youth Empowerment Service Project
Health Initiative for Youth
San Francisco, CA

Donna Futterman, M.D.
Medical Director
Montefiore Medical Center
Bronx, NY

Implications of 076

Pediatric AIDS Conference

I. Framework of policy development is what we have come to expect:

A. Science is not altogether crisp

1. study did not include all classes of HIV+ women

2. implications of drug for non-infected kids not fully known

B. Public awareness/debate practically preceded scientific one / seen as a specific opportunity—

C. Most involved group (women) is not fully enfranchised

II. Complex of agencies involved

A. NIH on the science

B. CDC on the prevention implications

C. HRSA on the service implications

D. FDA on the regulatory implications

E. HCFA and the states on payment issues

F. Other potentials

1. AG--WIC

2. HUD--public housing

3. IHS/DOD--potential populations

state govt
local govt
major med groups—
major legal advocacy groups

III. Working group has been established, and begun work

A. Chair will speak

B.Other agency level considerations being developed

IV.What we must not lose in the process

A.This is a human dilemma, not just a scientific puzzle

B.There are TWO individuals involved: mother AND child

C.The system implications for access to care are enormous

1.access to prenatal care for mothers

2.access to continuing services for children

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May 11, 1994

Kristine Gebbie, RN, MN, FAAN
National AIDS Policy Coordinator
The White House
Washington, DC 20500

Dear Kristine:

Thank you for agreeing to deliver a presentation at the Third Annual Public Policy Conference of the National Pediatric HIV Resource Center. Your presentation on the public health implications of ACTG 076 is scheduled for Monday, May 23, 1994, from 10:45am-12:00 Noon. The session will take place at the meeting room level of the Washington Vista Hotel, 1400 M Street, NW, Washington, D.C. Upon arrival at the Vista Hotel, please check with the NPHRC conference registration desk for the room location.

Attached is a conference agenda that reflects a confirmed list of speakers and presentations. The final draft of the agenda has not yet been printed. If you have any corrections to the agenda, please call Earlease Jackson at the Washington office of the Resource Center as soon as possible. In addition, so that the moderator of your session may properly introduce you, please prepare a brief paragraph that describes your current position and relevant experience. This paragraph should be sent by fax or mail to Earlease Jackson **by no later than May 19, 1994.**

Due to the number of speakers during your session, please limit your remarks to 15 minutes so that adequate time can be allowed for questions and answers. The objective of the plenary panel on the public health implications of ACTG 076 is to update meeting participants on the following issues: (1) inter-agency coordination by The White House Office of the National AIDS Policy Coordinator as well as national policy implications; (2) Public Health Service inter-agency taskforce and new clinical standards of care; (3) public health implications and multidisciplinary coordination; and (4) the New York state experience related to screening and testing policy and access to care. Please note that afternoon workshop sessions will allow meeting participants additional time for discussion and dialogue about ACTG 076 issues.

Again, thank you for agreeing to present at the NPHRC public policy conference. I will contact you by phone next week to again confirm all logistical arrangements for your presentation. In the meantime, please do not hesitate to contact me with any questions.

Sincerely,

David C. Harvey
Coordinator for Public Policy
NPHRC Washington Office

Talking Points for The Third Annual Public Policy Conference of the National Pediatric HIV Resource Center, May 23, 1994

ACTG 076 Panel

Stats:

* It is estimated that 15,000 to 20,000 children, 110,00 women, and 1 million men are HIV infected but not yet diagnosed with AIDS. Women are the fastest growing segment of the AIDS population, with 93% of the children with HIV under the age of 13 who contracted the disease from their mother, perinatally.

* Through September, 1993, 4,906 children, up to age 13, 14,000 young people ages 13-24, and 40,700 adult women have been diagnosed with AIDS.

* By 1995, the number of children of children that will be orphaned by AIDS will be 24,600 under the age of 13, 21,000 between the ages of 13-17, and by the year 2000, that number will rise to more than 80,000.

ACTG 076

* In February, 1994, The National Institutes of Health released preliminary results of clinical trial ACTG-076. This Phase III, randomized, double-blind, placebo-controlled trial was designed to evaluate the efficacy, safety and tolerance of zidovudine (ZDV; also known as AZT) for the prevention of maternal-fetal transmission of HIV. This study was conducted in 50 sites in the USA and 9 sites in France.

* The results indicated a two-thirds reduction rate---8.3% when both mother and infant received ZDV, compared to a rate of 25.5% among those who received a placebo.

* There were 477 women and 364 infants enrolled in the study at the time of the analysis of the data presented. A total of 421 infants were born as of December, 1993. Of those, 364 infants had at least one culture result available.

* The women involved in this study initiated ZDV treatment between 14-34 weeks gestation, had received no other antiretroviral treatment during the pregnancy, had CD4 level greater that 200 cells/mm3 and had no clinical indications for ZDV therapy prior to the pregnancy.

* More extensive research is needed to determine the long term effects of ZDV therapy on the infants, since the vertical transmission rate of HIV would only include 20-25% of the infants born to HIV infected mothers. This leaves 80-75% of those children who would not have become infected anyway, but would be exposed to ZDV in utero.

* There were no significant short term effects to either the mother or infant other than anemia in the infant which was reversed shortly after treatment ended. Additional studies are indicated to determine the long term efficacy and safety of ZDV therapy for the mother and the child. At present the women will be only be followed for 6 weeks after delivery and the infants(both HIV+ and HIV-) followed up to 21 years after perinatal exposure to ZDV.

* The implications of this study highlight the need to broaden our outreach efforts to women of childbearing years to seek HIV counseling and testing. Clinicians who provide services to these women must be alerted to the need to counsel them regarding the potential impact of ZDV therapy. It is important to note that 8 out of every 100 babies in the study was HIV infected, even though the mother and infant had received ZDV.

* For women who participate in high risk behavior, ie. injecting drugs and unprotected sex with someone whose HIV status is unknown, it is imperative that they have access to adequate counseling, testing and treatment regardless of whether they are pregnant or not. The rights of the woman to adequate treatment should not be abrogated to the rights of the unborn child.

HHS/PHS Task Force

* The Task Force entitled, "The Public Health Service/Health and Human Services Task Force on the Use of Zidovudine to Prevent Perinatal HIV Transmission" has had its first meeting on April 14, 1994. This panel convened to discuss implications of ACTG 076 for the woman and child, specific issues that the task force would address and propose timelines for the development of recommendations and policies.

* Specifically, NIH would develop draft documents regarding treatment issues and begin evaluation of how on-going natural history studies of HIV infection in women and children could provide information regarding long term effects of this therapy.

* CDC would draft a document pertaining to counseling and testing issues for pregnant women, outline issues regarding long term follow up registry for those infants exposed to ZDV in utero, and also begin evaluation of how CDC funded natural history studies could provide further information regarding the impact of this therapy on women and children.

* FDA would review their process of labeling indication assessment of ZDV for use in pregnancy.

* HRSA is responsible for developing plans to implement the counseling, testing and clinical care recommendations. The implementation of the clinical findings of 076 into broader settings including Ryan White programs will require early identification of HIV infected women.

* The second meeting of the Task Force will be held on May 20, 1994. This meeting would be followed by an early June meeting of Task Force members, outside consultants and observers from scientific, professional, public health and community advocacy representatives to discuss treatment recommendations and screening options. We anticipate that by August, 1994 the recommendations from the June meeting will be finalized.

Indications

* Indications for pregnant women and her child - who may be potentially infected(25%) and potentially unaffected (75%) is confounding. Placement in follow up studies are available for adolescent women and all infants, yet not for the other mothers. Provision of care services for the mothers and their children will require increased allocation of funds for this population.

* Evaluation of Title IV programs demonstrate remarkable success in identifying HIV positive youth and women, retaining them and their newborn infants in comprehensive care and supporting them to participate in early medical treatment. Early identification and follow up care for HIV exposed infants by Title IV programs reduces morbidity and mortality through a coordinated, comprehensive medical, social and family support programs. (see attached sheets)

* Of additional concern is the fact that the mothers are already HIV infected and will develop life threatening diseases, which will increase the orphan population in this country. This will require additional funding streams to assist the social services agencies with placement and financial subsidy for these children.

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THE RYAN WHITE COMPREHENSIVE AIDS RESOURCES ACT OF 1990

Title IV Background Summary

Pediatric and Adolescent AIDS Demonstrations

Section 2671 Statutory Title

Demonstration Grants for Research and Services for Pediatric [Pediatric, Adolescent, Pregnant Women, Families] Patients Regarding Acquired Immune Deficiency Syndrome.

Intent of Statutory Language

The purpose of these grants is to support the development of infrastructure to provide outpatient care to patients and their families and to facilitate linkages between comprehensive care and clinical trial sites as well as increase the participation of HIV infected children, adolescents, pregnant women and families in clinical research trials.

Background

How did Title IV get established?

Section 2671 of Title IV was authorized in 1990 as part of the overall Ryan White CARE Act. However, Congress never appropriated funds for Title IV until fiscal year 1994.

How did funding get started for Title IV?

The President's Economic Stimulus Package of 1993 included $200 million for the Ryan White CARE Act. Of this amount, $5 million was requested for the first time for Title IV. The Economic Stimulus Bill was not passed by Congress. The President's budget request for 1994 again included funds for Title IV at $6 million. In addition, in a separate line item, $20.9 million was requested for pediatric/family AIDS demonstrations (essentially level funded for three years).

What is the funding situation for FY 1994?

The House of Representatives in June of 1993, approved a consolidation of the $20.9 million funding for the Pediatric/Family AIDS Demonstration Program and addded $1 million for Title IV. The Senate concurred and Congress appropriated a total of $22 million for Title IV in FY 1994.

Why was funding consolidated for the Pediatric/Family AIDS Demonstration Program and Title IV?

Through policy development work of the National Pediatric HIV Resource Center, the Pediatric/Family AIDS Demonstration projects and the Pediatric AIDS Coalition in Washington, D.C., a formal policy position was adopted that called for consolidation of funding for services and access to clinical trials for children, adolescents, pregnant women and families under Title IV. The rationale for this decision included the fact that (1) the demonstration program was not a permanently authorized program; (2) the infrastructure already created by the demonstrations was important to preserve as health care reform is considered; and (3) funding should be consolidated within a larger statutory framework to ensure that the program will expand to meet increased demand for services.

What will Title IV mean to existing pediatric/family AIDS projects?

Title IV will be implemented through the existing care infrastructure created by the Pediatric/Family AIDS Demonstration Program. This means that existing projects will now be funded through Title IV according to their current three year grant cycle.

Congress started the Pediatric/Family AIDS demonstration program in 1988 to serve children, adolescents, women and families under general authority of the Public Health Service Act. Between 1988 and 1993, the Pediatric/Family AIDS Demonstration Program expanded to 35 direct service lead sites in 20 states, Washington D.C. and Puerto Rico.

The projects have been highly successful in providing and organizing services for needy children, adolescents and their families affected by HIV and AIDS where no service infrastructure has existed. Access to clinical research trials is one element of comprehensive HIV care in almost all projects.

How was planning for Title IV initiated within the Federal government?

From 1990 until 1992, the Maternal & Child Health Bureau of Health Resources Services Administration and the National Institutes of Health formulated a plan for the implementation of Ryan White Title IV. This planning included meetings with researchers and community providers and focused on identifying barriers to the linkage of care and research.

Administration

What federal agency administers Title IV?

Congress has indicated that the Maternal Child Health Bureau (MCHB) should be the lead administering agency for Title IV. MCHB will cooperate with The National Institutes of Health (NIH) to coordinate services and access to clinical trials.

What are the legislative requirements for grantees?

The applicant must arrange for or provide primary care for a significant number of pediatric, adolescent, and pregnant women patients with HIV disease. The applicant must have an agreement with a biomedical or other institution administering clinical trials to refer patients for voluntary access. Other elements of comprehensive services must be provided in a family-centered, community based, coordinated and culturally competent environment and include such services as mental health, substance abuse, in-patient hospitalization, social support services and other incidental services such as transportation and child care. Evaluation, training, and technical assistance must be offered to projects.

What other intent has been given by Congress related to Title IV?

Congress has indicated an intent that current grant recipients should be "grandfathered" in to Title IV so that current services are not disrupted and that no current grantee loses grant funds. This includes projects that are in the process of developing access to clinical trials for their patients. In addition, Congress has indicated that projects should collaborate with CDC prevention projects to emphasize primary and secondary prevention efforts within comprehensive care, especially for adolescent girls.

Philosophy of Care

What is the philosophy of care to be provided through Title IV?

Title IV will provide funds for comprehensive services that are family-centered, community-based, coordinated, and culturally competent that will provide as one element of care the capacity to offer voluntary access to clinical trials. Congress also states that clinical trials for medically underserved HIV-affected children, adolescents, pregnant women and families are only successful when research is conducted within an established comprehensive care system that supports the entire family.

Are there other expectations?

Technical assistance on pediatric, adolescent and family HIV services and clinical trials should be offered to projects on a national basis. Congress also recognizes that Title IV will be the primary means of delivering HIV family-centered HIV care for children, adolescents, and families affected by HIV and AIDS.

Funding Categories

What is the Appropriations Committee report language state for funding Title IV in 1994?

The majority of funds are expected to be granted to existing Pediatric/Family AIDS Demonstration Projects. Other funds will be granted for planning and technical assistance to geographic areas where no comprehensive care system or clinical trials is organized.

How can I get more information from the government and a grant application packet for the next round of competitive awards?

You may contact the Bureau of Maternal & Child Health at the following address and phone number:

Beth Roy, M.S.
Branch Chief
Hemophilia and AIDS Program
Maternal and Child Bureau
U.S. Department of Health & Human Services
5600 Fishers Lane, Room 18A-19
Rockville, MD 20857
301-443-9051
301-443-1728 (fax)

Date Prepared: July 7, 1993

Updated: October 29, 1993

Prepared by: David C. Harvey, M.S.W.
Coordinator for Public Policy

Ryan White CARE Act
Title IV
Pediatric and Adolescent AIDS Service Projects

Congressional Action

- Congress consolidated FY 1994 funding for pediatric and adolescent HIV service projects in Title IV of the Ryan White CARE Act. Senate report language requires that existing pediatric and adolescent HIV demonstrations be "grandfathered" in to Title IV and that projects should ensure voluntary access to institutions and facilities conducting HIV clinical trials. In addition, Congress directed that projects link with CDC prevention programs to provide primary and secondary HIV prevention services, especially for adolescent women.

- Congressional funding levels for pediatric and adolescent HIV services have remained essentially level funded for over 3 years. In FY 1994, despite separate requests of $6 million for Title IV and $21 million for pediatric and adolescent HIV demonstrations, Congress consolidated funding within Title IV at $22 million. This is despite an overall increase of $210 million for Titles I and II in FY 1994.

Services Provided

- Title IV pediatric and adolescent HIV care projects provide or arrange for primary HIV care, mental health and substance abuse, family support, transportation, day care, nutrition, developmental services, screening and prevention services, as well as providing access to or linkages with HIV therapeutic research programs and clinical drug trials, and other services.

- Title IV requires service projects to link with institutions or facilities conducting research on HIV therapeutics or clinical trials. Currently, approximately 4000 children and 340 adolescents are enrolled in NIAID sponsored AIDS clinical trial units for children.

- Title IV is administered by the Maternal & Child Health Bureau of HRSA. Currently 38 lead projects in 20 states, PR and D.C. provide comprehensive HIV care through 199 affiliate clinical service sites. These projects already provide or are in the process of providing access to HIV clinical trials.

Clients Served

- The total number of clients served in 1992 was 28,738. This represents an 87% increase from 1991. The total number of families served in 1992 was 10,163, a 28% increase from 1991. Demand for services at project sites has increased over 50% for each of the previous three years.

- The total number of women served in 1992 was 11,989, which represents a 124% increase from 1991. The total number of children (age 0-12) and adolescents (age 13-21) served in 1992 was 10,297 and 2,817 respectively. This represents a 81% increase for children and a 74% increase for adolescents. Five of six clients reported in 1992 were African-American or Hispanic.

- The total number of outpatient encounters reported in 1992 was 103,008, representing a 117% increase over the previous year. The average number of outpatient encounters per client reported in 1992 was 4.17, as compared to 5.45 in 1991. The total number of inpatient admissions reported in 1992 was 3,718, representing a 62% increase over the previous year. A majority of clients (70%) reported in 1992 were insured by Medicaid and 9% were uninsured.

Funding Rationale

- Women, adolescents and children with HIV are now the fastest growing segment of the HIV population in the United States, and currently constitute 12.8% of persons identified with HIV. Demand for services has increased over 50% from the previous year.

- Pediatric and adolescent participation in NIH sponsored HIV clinical trial programs may be increased by linking Title IV service projects with clinical trials, especially for underserved African-American and Hispanic groups. Barriers to participation in trials include a lack of coordination between care and research which may be alleviated through requirements of Title IV; lack of transportation, day care and other support; and lack of understanding about participation in protocols.

- 30 states, which includes low HIV incidence states, have no centrally organized capacity for delivering comprehensive HIV care and providing access to clinical trials. Title IV is one important means of delivering pediatric and adolescent HIV care.

- By increasing funding for Title IV from $22 million to $62 million, it is estimated that the number of clients served could further be increased by approximately 75% (20,000) additional clients that includes women, adolescents and children), and that sites could better provide access to clinical trials and other research programs sponsored by NIH.

- Many states, especially those in the low to middle incidence areas, have not begun to assess needs or plan for how HIV/AIDS services will be delivered to children, adolescents and families. Initial planning grants are needed to support data collection, needs assessments, and local planning meetings among service providers to begin to identify areas of needed infrastructure.

- Specifically, additional funds could be spent in the following categories:

    - $6 million for initial planning and development of 15 new care/research programs and to implement new services.
    - $16 million to support existing comprehensive care sites to serve more clients, hire additional staff and provide more services to link with clinical research sites.
    - $14 million to strengthen and expand programs specifically for adolescents affected by HIV, who are grossly underserved in comprehensive care and clinical trials.
    - $4 million to enhance evaluation and data collection activities associated with provision of services and clinical research.