



Office of the Assistant Secretary
for Health
Washington DC 20201

November 2, 1995

NOTE TO DR. LEE

SUBJECT: Implementation in PHS programs of the PHS Recommendations for Counseling and Testing of Pregnant Women, Prevention of Perinatal Transmission, and Links to Care of HIV-Infected Women and Children – INFORMATION

The attached document provides an update of activities undertaken by PHS agencies to implement the subject PHS recommendations. This document provides a brief update of activities undertaken since the July 1995 PHS Consultation meeting in Atlanta, and builds upon the more comprehensive summary of agency activities prepared at that time.

Eric P. Goosby, M.D.
Director,
Office of HIV/AIDS Policy

Attachment:
Update on PHS Activities
SAMHSA Letter to Grantees

cc: Dr. Boufford

COUNSELING AND TESTING OF PREGNANT WOMEN AND INFANTS

UPDATE ON PHS ACTIVITIES

November 2, 1995

The Public Health Service (PHS) has placed a high priority on implementing the PHS Recommendations for Counseling and Testing of Pregnant Women, Prevention of Perinatal Transmission, and Links to Care of HIV-Infected Women and Children in federally supported programs to reduce the rate of perinatal transmission of HIV and increase HIV counseling and testing opportunities among women of childbearing age. This document provides a brief update of activities undertaken by PHS agencies since the July 1995 PHS Consultation meeting in Atlanta, and builds upon the more comprehensive summary of agency activities prepared at that time.

In addition to implementation of the PHS recommendations, additional activities related to monitoring the epidemic among women and children and assisting providers to maximize counseling opportunities are underway. Proposals to provide discretionary grant funds to States to promote implementation of HIV counseling and testing activities are also currently pending in the conference committee on the Ryan White CARE Act reauthorization. The PHS will respond to the final legislation and any effect it may have on surveillance activities and State implementation of the PHS guidelines upon its completion.

In addition to PHS activities, the Health Care Financing Administration (HCFA) has continued its efforts to promote implementation of the PHS recommendations through State Medicaid agencies. A survey of State Medicaid reimbursement practices for HIV counseling and testing of pregnant women and follow-up treatment with zidovudine (AZT) and prophylaxis for opportunistic infections for women and children will be completed in the next few months. Data from 11 states with the highest HIV seroprevalence rates among pregnant women indicate that all already cover the costs of this care; preliminary findings from the remaining states indicate this trend is true across the country.

Implementation of PHS Guidelines

HRSA

- * Title I of the Ryan White CARE Act new Application guidance requires grantees to identify the steps being taken to coordinate with other programs in the development of a local strategy to assure access to HIV counseling/testing for all women, education about treatment, and primary care and treatment services for all women with HIV disease --

including access to zidovudine therapy for pregnant women with HIV infection and their infants to reduce the risk of perinatal transmission. The Division of HIV Services sets out the expectation that each Title I comprehensive HIV plan will be updated in FY 1996 to address how systems, written policies and procedures will ensure access to HIV counseling/testing, treatment education, primary care and follow-up treatment with AZT and other appropriate care for pregnant women during pregnancy, delivery and post partum period. Methods to assess the effectiveness of locally developed strategies are expected to include outcome measures. Title I funds 42 major metropolitan areas, of which 33 are in States (and DC and Puerto Rico) with the highest prevalence of pregnant women with HIV reported in the CDC survey of childbearing women.

- * **Title II of the Ryan White CARE Act new Application** guidance requires States to identify the steps being taken to develop a State strategy to assure access to HIV counseling/testing for all women, education about treatment, and primary care and treatment services for all women with HIV disease -- including access to zidovudine (AZT) for themselves and their infants. States must identify the entity responsible for developing a State strategy to ensure access to these services for HIV infected women and infants and the role of the State Title II agency in formulating the strategy, policies and procedures. States must also identify the publicly funded service providers that a) provide HIV counseling/testing to women, and how these services are linked to Title II funded primary care and support services, and b) provide medical care and treatment to women, describing how these services are linked to other providers serving women and pregnant women with HIV disease, such as substance abuse treatment programs.
- * **Title III (b) Ryan White CARE Act revised Application** guidance will require a plan for expanded counseling and testing for women, implementation of perinatal AZT therapy, and progress measures for evaluation. The Request for Applications (RFA) will be issued in February 1996.
- * **Title IV Ryan White CARE Act Application guidance for FY 1995** required grantees to describe efforts to implement counseling and testing guidelines and treatment for pregnant women. All Title IV grantees were required to develop a specific goal and objective to respond to HRSA's program directives on implementing 076 findings. This component of the grant application continues as a program priority for FY 1996 grantees.

- * WIN grants (Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission) were awarded to 10 project sites in June 1995. These grants focus specifically on 1) increasing voluntary testing and identification of HIV status among women; 2) facilitating access of HIV+ women to coordinated services throughout pregnancy, including AZT therapy; 3) reducing barriers women face in accessing and remaining in care; and 4) reducing perinatal HIV transmission. In July 1995 a needs assessment was completed to determine provider and consumer training needs to increase outreach, counseling, testing and follow-up care, with the assistance of the AIDS Education and Training Centers. Initial training sessions were provided in September 1995, with more extensive sessions planned for February 1996.
- * The MCH Bureau Title V program has finalized HIV Guidelines for State Title V Maternal and Child Health Programs, in collaboration with the Association for Maternal and Child Health Programs (AMCHP). The guidelines identify specific State Title V roles and expectations regarding assuring the integration of voluntary HIV counseling and testing of women into preventive health care services for women and infants. The guidelines and sample documents will be disseminated to all State Title V program directors and Ryan White Title IV grantees in November 1995. They will also be more widely disseminated to MCH leaders and providers at the state and national levels.
- * The Community and Migrant Health Centers Programs The Bureau of Primary Health Care (BPHC) has developed and begun implementation of a strategy to ensure that all pregnant women seen in BPHC funded programs are offered routine HIV counseling, voluntary HIV testing and that those identified as HIV+ have access to receive the services outlined by the medical protocol in the ACTG 076. Staff have begun developing a proposal to conduct an assessment of current HIV counseling and testing practices of pregnant women at BPHC funded programs, to be piloted in a representative sample of sites.

The BPHC will fund the AIDS Education and Training Centers (AETCs) program to conduct a comprehensive needs assessment of provider training needs at all C/MHCs, and to develop comprehensive activity plans to meet identified training needs -- with a strong focus on offering HIV counseling and testing, and appropriate therapies and follow-up care to women and infants. This project will begin in Region II which includes New York, New Jersey, Puerto Rico (where C/MHCs are now serving 68,040 pregnant women). The AETC

activity plans for C/MHCs trainings in this region were due by September 30, 1995.

- * The AIDS Education and Training Centers program has required information dissemination and training activities on ACTG 076 in all regions of the country, beginning in March 1994. There is extensive documentation of trainings and special intensive programs offered to date, and a prospective list for the coming months through May 1996, covering every State and region. These trainings reach providers in both the public and private sectors. Information dissemination and training regarding the PHS Recommendations issued in July 1995 are emphasized in each AETC plan.
- * HRSA developed a draft program advisory, ZDV Therapy for Reducing Perinatal HIV: Implementation in HRSA-Funded Programs. The public comment period ended August 10, 1995. Comments have been incorporated into a final document, now being cleared through the agency.

SAMHSA

- * In September 1995 the SAMHSA sent a letter to grantees providing information on the results of ACTG 076, and supporting implementation of the PHS Guidelines on counseling and testing in SAMHSA-funded programs (see attached letter and list of grant program addresses).

CDC

- * In September 1995, 4 competitive cooperative agreements were awarded for studies to evaluate the implementation and effectiveness of PHS guidelines for universal counseling and voluntary HIV testing of pregnant women, for offering AZT to HIV-infected pregnant women to reduce perinatal HIV transmission, and for providing needed health and social services for HIV+ women and their children.
- * The CDC Managed Care Steering Committee will propose to the HHS Public Health Functions Steering Committee that a Medicaid HEDIS measure -- the percent of pregnant women who were tested for HIV during pregnancy -- be added to the HEDIS report card. This measure will be forwarded to the Working Group for review in November.
- * The pediatric HIV/AIDS case report form was revised March 1995 to collect data on the use of AZT by mothers during pregnancy, labor and delivery, and use of neonatal AZT. A supplemental form is now being developed to collect additional information on children with reported HIV/AIDS including maternal receipt of HIV counseling, prenatal

care, etc. All States must collect and provide this information with AIDS case reports.

- * CDC plans to pilot test surveillance in three states which report HIV infection status to determine the proportion of women known to be HIV infected during pregnancy who receive AZT with FY 1996 funds.
- * A training curriculum entitled "Counseling Issues for Women of Reproductive Age," designed for HIV prevention counselors at publicly funded counseling and testing sites is under development. CDC expects that the curriculum will be pilot tested in selected training centers in early January 1996. Particular is focused on the unique counseling and testing needs of HIV-infected pregnant women.
- * Since the final release of the PHS guidelines in July 1995, CDC has continued an aggressive media campaign to disseminate the recommendations. CDC has granted over 50 interviews, generating over 100 print articles and roughly 200 broadcast stories. All major national print and broadcast media, and major medical trade publications have carried stories on the guidelines. The CDC National AIDS Clearinghouse has distributed more than 7,000 copies of the PHS guidelines, including mailings to more than 1,300 medical, health, and AIDS service organizations and over 600 media representatives.

Office of Population Affairs

- * At the most recent annual meeting of Title X providers, the membership accepted the recommendation of a working group that routine HIV counseling be implemented. This establishes an expectation that women will be offered HIV counseling and testing if they are pregnant.
- * OPA identified a great need for educational and training materials among providers regarding HIV counseling, testing, and the use of AZT and ways to counsel clients on these matters. OPA initiated a discussion in October 1995 with the AIDS Education and Training Centers program to design materials and provide trainings to Title X providers in each AETC region. Over 4 million women are served annually by Title X in 4200 clinics.

AHCPR

- * AHCPR is in the final stages of completing their consumer brochure, posters, video tapes, PSAs and audio tape messages for the targeted population of women of child

bearing age in high risk categories. The expected release date for these materials is December 1st, World AIDS Day.

Outreach to the Private Sector

- * There are ongoing concerted efforts to work with the American College of Obstetrics and Gynecology, American Academy of Pediatrics, Am. Society of Internal Medicine, and other professional trade groups to implement the PHS guidelines on counseling and testing among all providers.
- * As part of an evaluation methodology to assess the uptake of the PHS guidelines in practice, a sampling plan for private sector delivery systems is being considered.
- * CDC is exploring working with the Group Health Association of America, a trade industry organization for HMOs, to disseminate the guidelines and provider and consumer information to HMOs.

Assisting Care Providers to Implement PHS Guidelines

- * A protocol to assist health care providers in counseling pregnant women about the importance and benefit of HIV testing for herself and her infant is being developed by Eric Goosby, MD of the Office of HIV/AIDS Policy. A small group of nationally respected OB/GYN and pediatric providers who care for large numbers of HIV infected pregnant women and children are working with Dr. Goosby to examine successful models now in practice. Key elements of successful models will be incorporated into a protocol that assists providers to address key barriers to acceptance of HIV counseling and testing. This will be pilot-tested in a number of settings. The target date for a draft document for internal PHS consideration is February 1996.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 15 1995

Substance Abuse and Mental
Health Services Administration
Rockville MD 20857

Dear Colleague:

This letter is to inform you of one of the current and sensitive health care debates focusing on the issue of counseling and testing of HIV-positive pregnant women. HIV transmission from mother-to-child accounts for the majority of HIV infection in infants and children. Some of these mothers are injecting drug users or involved with a partner who is an injecting drug user. In February 1994, the National Institutes of Health (NIH) announced findings of a clinical trial sponsored by the Pediatric AIDS Clinical Trial Group 076 (ACTG 076). This study found that a three-part regimen of zidovudine (AZT) reduced perinatal transmission of HIV by two thirds in infants whose mothers met specific eligibility criteria. Further, no significant short-term side effects to either mother or infant resulting from AZT were evidenced. However, the long term effects of AZT therapy on infants and mothers are unknown.

Following the results of this study, the Centers for Disease Control and Prevention (CDC) published recommendations for counseling and testing HIV positive pregnant women. The recommendations suggest that all women who are pregnant be offered:

- o voluntary HIV counseling and testing;
- o clear, understandable information about benefits and potential risks of AZT regimens, in a noncoercive manner;
- o the opportunity to receive the AZT regimen through an interactive decision making process including client and provider, with the woman making the ultimate decision; and
- o continuous and ongoing care and services regardless of their decisions to participate in AZT regimens.

SAMHSA supports the PHS recommendations for voluntary, expanded access to HIV counseling and testing. We acknowledge that there are sensitive issues regarding implementation of these guidelines and what is required to provide appropriate counseling for women with addictive and mental illnesses. We are also concerned with the impact of these guidelines on women of color and underserved women. Ensuring that women understand the relationship between substance abuse and the transmission of HIV/AIDS and the importance of early prenatal care are important steps to decrease the transmission of the Human Immunodeficiency Virus.

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To further assist your efforts, the U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women and Recommendations of the U.S. Public Health Service Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of Human Immunodeficiency Virus (MMWR 1994;43(RR-11)), may be obtained by calling the Centers for Disease Control and Prevention (CDC) National AIDS Hotline at (800) 342-AIDS (2437). The guidelines are also available electronically through the CDC National AIDS Clearinghouse on-line bulletin board as well as through other HIV/AIDS bulletin boards, and the Internet.

SAMSHA would like to hear from you on the particular challenges and successes you experience in providing or facilitating appropriate referrals for women to receive testing and care. Comments will be received by Ms. Barbara Garcia, Associate Administrator for AIDS, at (301) 443-5305. For specific questions regarding implementation and technical assistance, please contact Melvyn R. Haas, M.D., Associate Director for Medical Affairs, Center for Mental Health Services, at (301) 443-2120.

Sincerely yours,



Melba Chavez, Ph.D.
Administrator

SAMHSA OFFICE ON AIDS

SAMHSA Works to Stem the Spread of HIV/AIDS

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the Federal Public Health Service Agency with a Congressional mandate to promote advances in the prevention and treatment of mental and addictive disorders through a grantmaking portfolio totalling more than \$2 billion.

Ensuring that all prevention and treatment services are accessible to and appropriate for all Americans, particularly those who are disproportionately affected by HIV/AIDS, is key to the SAMHSA mission.

SAMHSA Resources for HIV/AIDS Prevention

SAMHSA HIV/AIDS programs are coordinated through the Agency's Office on AIDS (Contact Barbara Garcia, Associate Administrator for AIDS, 301-443-5305). The annual grantmaking capacity for HIV/AIDS-specific services totals \$24.2 million. In addition, each of SAMHSA's three Centers -- Center for Substance Abuse Prevention, Center for Substance Abuse Treatment and Center for Mental Health Services -- invests substantial resources in other programs that also address the needs of individuals with or at high risk for HIV/AIDS.

Center for Substance Abuse Treatment Contact Warren Hewitt, 301-443-8462

- o **HIV/AIDS Community Outreach Program** funds projects targeting injecting and other high risk substance abusers and their sexual partners. Trained outreach workers access this hard to reach population and provide HIV/STD/tuberculosis risk reduction education and facilitate treatment referrals. Funds do not support direct substance abuse treatment. In FY 1995, \$7.5 million will support new projects and competitive renewals. Initial cycle is expiring (33 projects in 14 States, D.C., and Puerto Rico).
- o **CSAT/BPHC Linkage Initiative** is a collaborative effort with the Health Resources and Services Administration (HRSA) that provides funding for programs to develop comprehensive service demonstration models that link substance abuse treatment with HIV/AIDS/STD/tuberculosis, mental health and primary care services. Projects provide an array of services, including infectious disease screening and treatment, HIV/AIDS counseling, primary health care, outpatient addiction counseling, and family/collateral counseling. In FY 1995, \$7.8 million will support continuation of 18 projects in 10 States and D.C..

- o AIDS Training Grants help education and training programs for health care professionals to modify curricula and strengthen the training opportunities in comprehensive care for people with or at risk for substance abuse, mental illness and infectious disease including HIV/AIDS and tuberculosis. The impact of these problems on racial and ethnic minorities is a special focus. In FY 1995, \$2.8 million supports continuing projects.
- o National Drug and Alcohol Treatment Referral Hotline makes accurate, current information on HIV/AIDS available to substance abuse treatment providers through a professionally staffed toll-free telephone service. Call 1-800-662-4357 for English or 1-800-662-9832 for Spanish. FY 1995, \$.8 million.
- o Substance Abuse Prevention and Treatment Block Grant: States with AIDS case rates of 10 or more per 100,000 are required to set-aside 2% to 5% of their allotment, for early intervention services for HIV disease. FY 1995, Resources Not Yet Reported.

Center for Mental Health Services

Contact Melvyn Haas, M.D., 301-443-2120

- o AIDS Health Care Worker Training supports the education of mental health and other health care providers on the psychological and neuropsychiatric impact of HIV/AIDS. The program is being reannounced in FY 1995, with 5 to 6 new awards expected.
- o HIV/AIDS Mental Health Services Demonstration Program is a collaborative effort between SAMHSA, NIH, and HRSA. Cooperative agreements are awarded competitively for programs to develop or expand mental health services for people with HIV/AIDS, or experiencing serious psychological reactions as a result of HIV/AIDS antibody testing. In FY 1995, combined funds totalling \$4.5 million support continuation of 11 services projects and one coordinating center.

Center for Substance Abuse Prevention

Contact Lucille Perez, M.D., 301-443-1859

- o High Risk Youth grants are being supplemented to expand substance abuse prevention efforts to include HIV/AIDS prevention. In FY 1995, \$1 million supports 20 new awards. Program plans include possible expansion, with a concentrated focus on adolescent females.

SAMHSA PROGRAMS WITH INDIRECT HIV/AIDS RESOURCES

Center for Substance Abuse Treatment

Contact Warren Hewitt, 301-443-8462

- o **Target Cities** funds a full range of substance abuse treatment and related services in the U.S. cities most affected by substance abuse. To make services more effectively and timely and to move substance abuse services into the mainstream of primary care, strategies to keep patients in treatment and reduce the likelihood of relapse, as well as efforts to recruit and maintain quality staff, are a focus. Central intake, assessment and referral systems are mandatory program components. Several programs provide HIV/AIDS prevention education, testing, counseling and medical care.
- o **Addiction Treatment Training Grant Program** are awarded to State and local governments, hospitals, schools of medicine and osteopathic medicine, nursing, social work, and graduate programs in marriage and family therapy to increase the number of qualified addiction treatment providers. Training must include diagnostic and treatment issues related to HIV/AIDS and other infectious diseases.
- o **Rural, Remote and Culturally Distinct Populations** supports communities in creating alcohol and other drug treatment services appropriate for their own rural, remote or culturally distinct location. Outpatient detoxification, treatment and maintenance services, case management, and HIV/AIDS, STD and tuberculosis screening, counseling and treatment are emphasized.
- o **Residential Treatment for Pregnant/Postpartum Women & Residential Treatment for Women and Their Children** these service and demonstration programs support comprehensive residential services for pregnant and parenting women, including education, counseling and care for HIV/AIDS for both the women in treatment and their children.
- o **Treatment Improvement Protocols (TIPs)** manuals delineate substance abuse treatment standards of treatment for pregnant women, criminal offenders, and juveniles, among others. Each was developed by a non-Federal consensus panel and includes information regarding HIV/AIDS prevention and services.

One TIP about to be published, *Treatment for HIV-Infected Alcohol and Other Drug Abusers*, includes guidelines for the spectrum of core services and treatment approaches that should be available to all HIV-infected substance abusers.
- o **Criminal Justice (Incarcerated and Non-Incarcerated)** grants support partnerships to develop and expand prison-, jail- and community-based substance abuse treatment services for adult and juvenile offenders. Services include screening, testing, referral, and treatment services for HIV/AIDS.
- o **Critical Populations** grants support a range of services, including HIV/AIDS prevention, education and health services, to adolescents, racial and ethnic minorities, and residents of public housing.

- o **National Capital Area Demonstration Project** is a model treatment program currently under development in Washington, D.C. Central intake and referral services will be established and residential treatment and aftercare enhanced. Primary medical care and specialized HIV/AIDS services -- counseling and testing, prevention education, and prophylactic medications -- are key components. Program evaluation will explore the optimal duration of residential treatment and the relative efficacy of enhanced and standard outpatient services.
- o **Treatment Campus** cooperative agreements with States expand treatment capacity, improve treatment quality and act as a real-world laboratory for service innovations. Primary medical care and HIV/AIDS prevention education, testing and counseling are central to the campus concept, which brings together between six and eight health and human service providers in a common facility. Central intake, patient assessment, referral, and program evaluation are on-site. Providers are autonomous. The target patient population for each campus is 350.

Center for Mental Health Services**Contact Melvyn Haas, M.D., 301-443-2120**

- o **Homeless Demonstration Projects** support outreach, diagnosis, assessment and referral to treatment for homeless persons with serious mental illness. These projects identify patients with substance abuse disorders that place them at high risk for HIV/AIDS.

Center for Substance Abuse Prevention**Contact Lucille Perez, M.D., 301-443-1859**

- o **National Prevention Training System** teaches people who have access to populations at special risk for alcohol and other drug problems how to use that access to prevent both substance abuse and HIV/AIDS. Specialized curriculum is being developed for CSAP's **Community Partnership Program** to address HIV/AIDS and focus on the specific cultural and ethnic issues of affected communities.
- o **National Clearinghouse for Alcohol and Drug Information (NCADI)** distributes education materials, including monographs that describe HIV/AIDS prevention in adolescents and minority communities. A manual on HIV/AIDS in the workplace is also available through NCADI, 1-800-729-6686, English and Spanish.
- o **Conference Grants** support conferences on alcohol and other drug abuse prevention, and other relevant issues, such as HIV/AIDS.

- o **High Risk Youth Program** provides for outreach and support of community-based organizations which work with a broad range of youth "at risk". In addition to the HIV/AIDS supplements discussed under Direct Activities, this program focuses on support of general self-esteem enhancement, and empowerment activities. Specific attention is given to the prevention of HIV transmission in a new adolescent female module.
- o **The Workplace Program** has developed a manual specific to dealing with HIV/AIDS in the workplace.

NOTE FOR PATSY FLEMING & JEFF LEVI:

FROM: Russ Gerber

SUBJECT: Program Advisory on ZDV to Reduce Perinatal HIV

The attached program advisory regarding implementation of PHS recommendations for reducing perinatal HIV in HRSA-funded programs has received clearance for publication from the Department of Health and Human Services.

Because of concerns that you had expressed about the draft version that underwent a 45-day public comment period, as well as during subsequent telephone conversations, we wanted you to see the final version. We hope you will agree that your concerns regarding the tone and content of the document have been adequately addressed. We feel it is important to finalize the document and begin its distribution to all HRSA-funded programs before the end of calendar year 1995.

Please look over the document, and let either myself or Joe O'Neill know as soon as possible if you have any additional concerns. We look forward to hearing from you and we look forward to distributing this program advisory to Ryan White and other HRSA-funded programs. Thank you.

cc:

Joe O'Neill

U.S. Department of Health & Human Services
Public Health Service



Program Advisory

**Use of Zidovudine
(ZDV) to Reduce
Perinatal HIV
Transmission
in HRSA-Funded
Programs**

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Program Advisory

Use of Zidovudine (ZDV) to Reduce Perinatal HIV Transmission in HRSA-Funded Programs

This advisory is designed to guide the implementation of PHS recommendations for HIV counseling and voluntary testing for pregnant women¹ and for offering the ZDV perinatal regimen to pregnant women with HIV² in HRSA-funded programs. It is intended for use by primary care providers including nurses, physicians, social workers, counselors and outreach workers and for program administrators in all HRSA programs. This includes community and migrant health clinics, maternal child health programs, Ryan White programs and other HRSA grantees.

These recommendations (PHS Recommendations for Use of ZDV to Reduce Perinatal Transmission of HIV² and for HIV Counseling and Voluntary Testing for Pregnant Women¹) represent the standard of care for pregnant women and should be followed in all HRSA-funded programs.

HRSA grantees will provide counseling and voluntary testing for all pregnant women and for women considering pregnancy, either on-site or by referral to counseling and testing programs, and will strongly encourage all pregnant women to know their HIV status. Grantees will provide counseling on the availability of the ZDV perinatal regimen for all pregnant women with HIV in culturally, linguistically and age-appropriate language to enable women to make fully informed decisions. The annual application guidance will require grantees to address planning and reporting activities to assist in implementing these recommendations. Guidelines, strategies and options follow for implementing the ZDV perinatal regimen in HRSA-funded programs.

SUMMARY

Interim results of ACTG 076 in February 1994 showed a significant (two-thirds) reduction in transmission of HIV from mothers to infants. Based on these findings, NIH closed enrollment of the study and the Public Health Service developed recommendations for use of ZDV to reduce perinatal transmission of HIV. Results of subsequent studies confirm these findings.*

Benefits and Risks

The ZDV perinatal regimen has been shown to be very effective in reducing maternal-infant transmission of HIV, with minimal short-term effects on women and infants. Because long-term effects are unknown, mothers who choose this option, and their children, should receive follow-up care to monitor for long-term adverse effects.

Community Planning and Participation

Community planning, coordination and education are needed at all levels to implement PHS recommendations. Women with HIV and representatives from programs serving women and families should be an integral part of all local, state and regional planning. HRSA will work closely with grantees and with related agencies in Federal, State and local

*HRSA will make this information available to grantees when results are published.

government to facilitate coordination of planning efforts. HRSA will also work with Ryan White grantees to develop procedures for documenting implementation of the regimen, which will likely be required by the reauthorized CARE Act.

Provider Training and Technical Assistance

Health care workers should receive training in HIV counseling and testing, management of HIV disease, and implementation of the ZDV perinatal regimen. This includes training in cultural competency, clients' diverse educational and linguistic needs, non-coercive decision-making as well as the emotional, practical and support needs of women, adolescents and families. The Public Health Service is currently developing educational materials for clients which are projected to be available in January 1996. HRSA is also developing provider materials which will be available later in the year. Each HRSA Bureau will use a variety of mechanisms to assist grantees in implementing this advisory.

HIV Counseling and Testing and Informed Decision-Making

All HRSA programs that provide care to pregnant women and women considering pregnancy should provide routine counseling and voluntary testing on-site or by referral. All pregnant women with HIV should receive information on the benefits and potential risks of ZDV use during pregnancy to enable them to make fully informed choices. Information should be provided in clear, culturally, linguistically, and age-appropriate language. Women should be clearly informed that they will continue to receive ongoing care, whether or not they choose to take ZDV. Programs should ensure that women receive appropriate counseling and give written, informed consent (see Appendix D).

Comprehensive Care and Follow-Up

Providers should make the ZDV regimen available to women (and their infants) who choose this option, either on-site or by referral. Implementation requires coordination and strong linkages among primary care, obstetric, hospital/delivery and pediatric health professionals. Agencies should develop written policies and procedures for offering and providing the regimen.

All women and infants receiving the regimen should receive long-term follow-up care. Providers should document infection status and long-term clinical outcomes for both mothers and infants, while observing all laws, regulations and provisions that safeguard the confidentiality of medical records.

Implementation

HRSA will continue to work with grantees to provide technical assistance and guidance in implementing this advisory, and to ensure compliance with the reauthorized CARE Act in meeting the needs of all clients, in particular, women, adolescents and children.

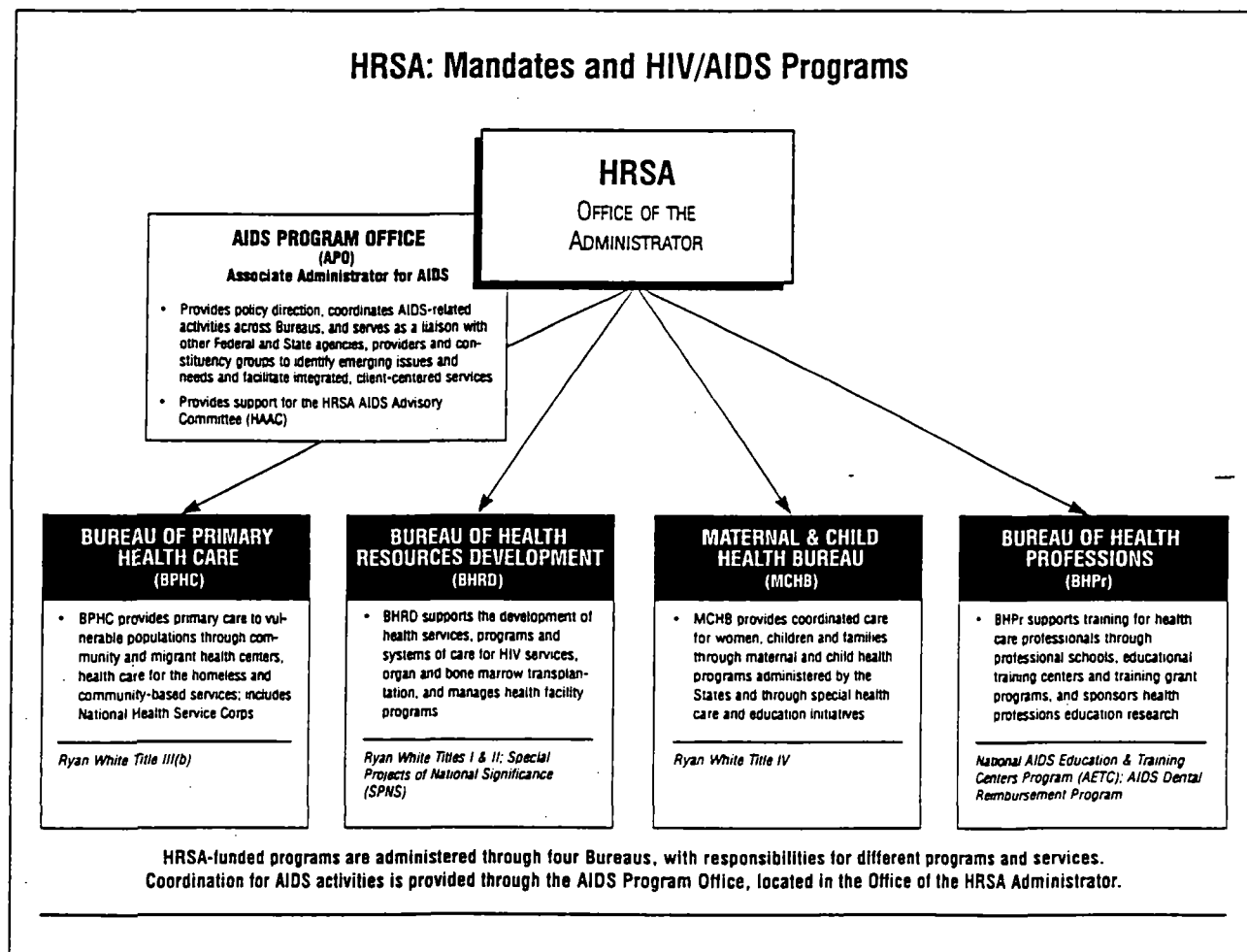
BACKGROUND

In February 1994, the National Institutes of Health (NIH) announced findings of a study sponsored by the Pediatric AIDS Clinical Trials Group (ACTG) which found that a regimen of Zidovudine (ZDV) reduced perinatal transmission of HIV by two-thirds in infants whose mothers met specific eligibility criteria. (Specifics of the trial and its findings are discussed under ACTG 076, page 5.) These findings have direct implications for the growing number of women with HIV disease, for their children, families and providers, and for the multiple systems that deliver ongoing services and care.

In response to these findings, agencies of the U.S. Public Health Service (PHS) developed recommendations for providing HIV counseling and voluntary testing to pregnant women¹ (see Appendix A) and for offering the ZDV perinatal regimen to pregnant women with HIV² (see Appendix B).

This program advisory was developed to assist providers in making the ZDV regimen available through the thousands of health service programs supported by the Health Resources and Services Administration (HRSA), the PHS agency responsible for facilitating access to quality care for underserved and vulnerable populations, and for promoting professional training related to primary care (see diagram on the following page).

This advisory provides background information and specific strategies and options for implementing PHS recommendations in all HRSA-funded programs. This includes: information on the epidemiology of HIV in women and children, results of ACTG 076, PHS guidelines, and principles and strategies for incorporating the regimen into routine management and care of women at risk for and infected with HIV.



These strategies and this advisory were developed through extensive consultation with HRSA constituents, including women with HIV, providers, representatives of national organizations, and program administrators at local, State and Federal levels, based on public meetings held during 1994.* A draft advisory was distributed for public review and comment in June 1995; all comments were carefully considered in preparing the final version.

In convening the public meetings, HRSA had the following goals:

- To examine women's HIV-related care and support needs and explore strategies for increasing women's awareness of their HIV status, of ZDV as an option for reducing transmission of perinatal HIV, and of the regimen's benefits and potential risks;
- To discuss the clinical, legal, ethical, and financial issues related to implementing PHS recommendations in HRSA-funded programs; and
- To obtain guidance from constituents in developing practical, comprehensive strategies to provide the ZDV perinatal regimen (within a comprehensive community-based system of care) as an option for women with HIV, through this program advisory and with ongoing consultation with consumers and providers.

Guiding principles developed by constituents during HRSA's initial public meeting in May 1994 formed the basis for subsequent activities. The principles were shared with participants at the joint NIH and CDC workshop in June 1994 where PHS recommendations for the perinatal regimen were developed.² The principles provided guidance in planning HRSA's follow-up meeting in September 1994 to discuss issues and concerns related to implementing the regimen in key program areas, including: community planning, provider training, client education and decision making, counseling and testing, clinical management during pregnancy, and long-term care and follow-up needs of women and children. They were endorsed by HRSA's Administrator as key principles in a letter sent to all HRSA-funded programs in January 1995. That letter urged providers to adopt PHS recommendations as the standard of care in implementing the ZDV perinatal regimen. Moreover, these principles provide the framework for program strategies and implementation discussed in this advisory.

In defining implementation principles and strategies for its providers, HRSA is attempting to respond to the challenge of making the ZDV regimen a widely available option, while seeking to promote counseling and care that respect the realities of women's lives — including their need for informed decision-making and the right to choose. These recommendations should be implemented in all settings where women routinely receive care. In making this option available, providers should acknowledge that pregnancy is a time-limited event and not all women become pregnant; quality care should be available to women at all life stages.

*HRSA Focus Group Meeting of Women with HIV, May 21, 1994; HRSA Working Group on Prevention of Perinatal Transmission of HIV, May 25, 1994; HRSA Meeting — ZDV Therapy for Reduction of Perinatal HIV Transmission: Implications for Care, September 19-20, 1994.

HIV/AIDS IN WOMEN & CHILDREN

AIDS has continued to increase steadily among women, accounting for a total of 68,021 reported cases as of June 1995. Of these, more than three-quarters are African-American and Hispanic; approximately half were infected through injecting drug use and one-third through heterosexual contact. As the epidemic has spread to smaller cities and rural areas, the proportion of cases among women has also continued to rise. Women currently account for 14 percent of all cumulative reported cases of AIDS, up from 10.4 percent in 1990. Of new cases reported during 1994, 18 percent were among adult and adolescent women, with an increasing proportion infected through heterosexual transmission.

AIDS has become a major cause of death among women and children, representing the fourth leading cause of death among women, ages 25-44, and the seventh leading cause of death among children, ages 1-4. In high incidence States and among African-American and Hispanic women, these rates are even higher.

Each year in the U.S., approximately 7,000 infants are born to women with HIV. Of these, 1,000 to 2,000 infants are estimated to be HIV-infected based on a perinatal transmission rate of 15-30 percent. Since routine screening of blood and blood products has essentially eliminated this route of transmission in children, virtually all new infections in infants and children are transmitted perinatally.

HIV is transmitted from mother to infant during pregnancy, labor and delivery or postpartum through breast feeding. According to current estimates, approximately 65-70 percent are infected at or around the time of delivery, with the remainder during pregnancy. In the U.S., only a small percentage of infants — approximately 1 percent — are infected through breast feeding. Several factors are associated with increased risk for maternal-infant transmission in pregnant women, including advanced HIV disease, low CD4+T-cell levels, high viral load (high level of virus in the blood), premature rupture of membranes and premature delivery.

A follow-up study of HIV/AIDS cases reported to the CDC found that 90 percent of women with HIV/AIDS had been pregnant at some time and 75-80 percent reported having given birth.³ Three-quarters had their first pregnancy by age 25 while half were less than 20 years of age at the time of their first pregnancy. These findings underscore the extent of teen pregnancy in women at risk for HIV infection and the need for awareness among providers of adolescents' risk for HIV. Awareness of HIV status for all pregnant women and women considering pregnancy and early diagnosis prior to and at initial stages of pregnancy are essential for appropriate prevention and optimal care for women and their children.

ACTG 076

In 1991, NIH initiated a clinical trial — ACTG 076 — to determine whether Zidovudine (ZDV) could reduce perinatal transmission of HIV. This study is one of many clinical trials which continue to evaluate treatments for adults and children affected with HIV disease.

Participation was limited to women between 14-34 weeks of pregnancy who had: 1) received no prior treatment with ZDV during their current pregnancy; 2) no clinical indications for antiretroviral therapy prior to pregnancy; and 3) a CD4+T-cell count of greater than 200/mL at the time of enrollment in the study. Women were randomly selected to receive either ZDV or a placebo which was taken orally for the remainder of their pregnancies, administered intravenously during labor and given orally to newborns during their first 6 weeks of life, within 24 hours after birth. A total of 477 women and their infants (421 babies were born during the study period) were enrolled as of December 1993. Participants reflected the ethnic and racial make-up of women with HIV in the U.S.; 79 percent were either African-American or Hispanic.

NIH announced interim results of the study on February 21, 1994. Preliminary findings on 363 infants showed that HIV transmission was reduced by two-thirds, from 25.5 percent in infants whose mothers were assigned to

DOSAGES ZDV PERINATAL REGIMEN

DURING PREGNANCY:
100mg orally 5x/day

DURING LABOR AND DELIVERY:
Loading dose: 2mg/kg IV
Followed by continuous
infusion of 1mg/kg

INFANTS: FIRST 6 WEEKS:
2mg/kg orally every 6 hours
for 6 weeks

the placebo group to 8.3 percent in infants receiving ZDV. Therapy was well tolerated by both mothers and infants with no significant short term effects other than reversible mild anemia in some infants who received ZDV. Based on

these findings, NIH accepted recommendations from an independent advisory board to close enrollment in the study and to offer ZDV therapy to mothers who received the placebo and had not yet delivered, and to their infants who were less than 6 weeks of age. The board stressed the importance of long-term follow-up to monitor for the possible development of adverse reactions at a later time.

Women were followed for 6 months after delivery. Those who could benefit clinically from on-going ZDV therapy were offered access to the drug. A follow-up study will monitor effects on women's health for 3 years after delivery. Infants will be followed until 18 months to confirm their HIV status. The study will end in January 1996, when all infants will have reached 18 months of age. All infants in the study are eligible to participate in a follow-up study (until age 21) to identify any long-term effects of ZDV (see box on page 7).

Limitations

Although ACTG 076 has shown that a regimen of ZDV can substantially reduce perinatal transmission of HIV in infants born to women whose immune systems are relatively intact, there are several important limitations:

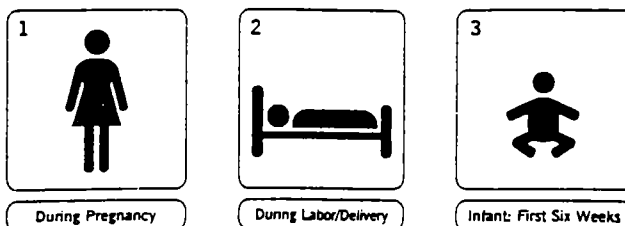
- Because researchers do not know when infection actually occurs, ACTG 076 was designed to interrupt perinatal transmission at three time points: during pregnancy, during labor and delivery, and in the infant (during the first 6 weeks of life). As a result, the study is unable to show whether a shorter regimen (for example, providing ZDV during

delivery alone) would be as effective in reducing transmission;

- Women with advanced HIV disease or previous antiretroviral therapy were not included in the study; nor were women who participated in the study tested for viral resistance to ZDV. As a result, the study provides no information on the regimen's effectiveness in reducing perinatal transmission under these conditions;
- The study provides no information on the long-term effects of ZDV on infected or uninfected infants;
- The study provides no information on the effectiveness of ZDV in treating postpartum women at later stages of HIV disease (following brief treatment during pregnancy);
- The study did not include women during the first trimester of pregnancy, so information is not available on the risk of taking ZDV during the first three months;
- Although the regimen can significantly reduce HIV transmission, ZDV does not prevent infection in all infants; one out of 12 babies born to mothers receiving ZDV who participated in the study still became infected; and
- Although ACTG 076 did not result in serious negative short-term effects, it is unclear if this will change when the regimen is more widely implemented with a larger number of women and children.

ACTG 076 was carried out in controlled research settings with access to a full range of medical and

ACTG 076 Treatment Regimen: Intervention Points



Because ACTG 076 targeted 3 time points when transmission could occur, researchers do not know which part (or parts) of the regimen actually interrupt transmission of HIV.

support services and better treatment adherence than generally occurs in routine care settings; this may result in more effective outcomes for women and infants. When the regimen is implemented in community settings, the rate of perinatal HIV transmission may be different since community providers are more likely to treat women who do not receive a full course of therapy, including women at later stages of pregnancy or those who are already in labor. Because many women do not know they are infected with HIV and many do not receive prenatal or preventive care, community-based providers are also more likely to implement the regimen with women at more advanced stages of HIV disease.

RELATED RESEARCH

Some of the questions raised by ACTG 076 will be addressed when results of several other clinical trials are ultimately available. These include follow-up studies to assess the long-term effects of ACTG 076 on both women and their children, as well as a study of the ZDV regimen in pregnant women with advanced HIV disease. In the interim, however, long-term follow-up of mothers and infants in primary care settings is essential to monitor for potential negative health outcomes, such as carcinogenicity, teratogenicity (birth defects), and neuro-behavioral effects, which have been known to occur as a result of *in utero* exposure to other drugs.

Consumer education activities should include information on related research to help women and family members understand the incremental nature of clinical trials and assist them in interpreting results. Understanding the differences between these studies can also help address questions that may arise when results of other trials are publicized. For example, two pediatric studies involving use of ZDV — ACTG 152 (a treatment study) and ACTG 076 (a prevention study) — are sometimes confused. The results cannot be compared, however, since the design and purpose of both studies are very different. HRSA will provide grantees with updates on relevant research to include in

FOLLOW-UP STUDIES

ACTG 219 is a long-term follow-up study of infants and children who participated in ACTG perinatal and treatment studies — including ACTG 076 — to monitor for any long-term effects. The study will follow infants and children until 21 years of age.

ACTG 288 is a follow-up study of women enrolled in ACTG 076 (who received either ZDV or placebo) to evaluate health outcomes, such as disease progression, quality of life and response to antiviral therapy. Women will be followed for 3 years after delivery, with the study expected to end in July 1997.

provider training and consumer education activities as more information becomes available. This includes results of subsequent

studies of the ZDV perinatal regimen in diverse populations of women, which show similar findings but had not been released at the time this advisory was written.*

PROGRAM STRATEGIES AND IMPLEMENTATION

Implementing PHS recommendations for offering the ZDV perinatal regimen through HRSA-funded programs has the potential to prevent illness and death in many infants and children. However, effective implementation requires collaboration between providers and communities, broad availability of HIV counseling and testing services, well-coordinated long-term comprehensive care and close consultation between providers and women with HIV who will ultimately decide whether or not to choose this regimen. It also requires providers to adhere to ethical standards, in partnership with women with HIV and affected communities, and in accordance with applicable local and State laws and regulations. In implementing these recommendations, HRSA will work closely with State and local governments to promote maximum flexibility, support local control and enhance existing initiatives.

The multiple challenges of making this regimen available nationally have been addressed in HRSA-sponsored

*HRSA will make this information available to grantees when results are published.

meetings and through ongoing consultation with constituents, consumers and providers. These discussions have resulted in the development of this advisory, including the guiding principles and implementation strategies presented in four sections of this document. These sections are not intended to stand alone but rather constitute a programmatic whole; many of the issues raised cut across all four areas and many are directed to an ideal of comprehensive, coordinated care that may be difficult to achieve, given the realities of limited resources and competing needs.

Implementing this advisory takes place within systems of care that present long-standing barriers for women, racial and ethnic minorities, the poor and persons at risk for and infected with HIV. Poor coordination between HIV-related services, other categorical programs and mainstream health service delivery has further isolated women at risk for and infected with HIV who, before treatment options can even be made available, must first be identified. Successful implementation of this regimen and related comprehensive services, however, will improve access and services for all women and men by enhancing ongoing planning between multiple service delivery systems, and by increasing coordination and collaboration between diverse agencies and groups. The coordination and linkages required to implement this regimen for pregnant women with HIV are, essentially, no different than the coordination required to deliver comprehensive services to any other population with HIV or to persons with other health conditions that require ongoing care and support.

Successfully overcoming these barriers requires coordinated, systematic planning involving women with HIV; coordination among a range of providers to achieve an accessible, responsive continuum of care for women and their families; and appropriate training and technical assistance for providers and programs.

Implementing this advisory will also require ongoing collaboration and interaction with HRSA and other Federal agencies, local planning, access to technical

assistance and training, and information on model programs and educational materials. Prior to distributing this advisory, HRSA prepared an internal agency and Bureau plan for coordinating implementation of the ZDV perinatal regimen in HRSA-funded programs (see Appendix C for a description of primary coordination strategies). Each Bureau has identified ongoing mechanisms for providing information to grantees and to assist them in defining technical assistance (TA) needs related to this advisory. HRSA and its Bureaus will continue to collaborate with appropriate State and Federal agencies, national organizations, professional associations and constituents to facilitate coordination and information sharing. As additional clinical and related information becomes available, HRSA will make it available to grantees while continuing to solicit feedback on implementation. HRSA will also work with Ryan White grantees to develop procedures for documenting implementation of the regimen, which will likely be required by the reauthorized CARE Act.

Principles and related issues follow in each of four implementation areas.

Community Participation & Planning Systems of Care

Principles:

- Women with HIV should serve as an essential resource for policy development, planning, community outreach, and educational activities.
- Community planning, coordination and education are needed at all levels to implement PHS recommendations for HIV counseling and voluntary testing for pregnant women and offering the ZDV perinatal regimen.

Planning priorities include:

- developing appropriate services (e.g., primary care linked to counseling and testing sites, specialty care, case management and support services);

- providing follow-up care for women and children; and
 - coordinating care across a variety of programs and funding streams (HRSA, CDC, SAMHSA, Medicaid and private third-party insurers). This requires linkages between multiple systems of care including reproductive health services, substance abuse treatment, and mental health services.
- Programs, planning bodies and educational materials should be diverse, family-centered, culturally-competent and community-based.

Issues Related to Implementation

PARTICIPATION OF KEY INFORMANTS/GATEKEEPERS:

Women neither receive nor request all essential health-related information from medical providers. Much important information related to health and self-care is passed on by key informants within communities, including family members, clergy, community leaders or respected "elders." These gatekeepers should be included as primary participants in educational and outreach activities; their involvement can ensure a program's success. Lack of trust in health care providers coupled with a widespread misperception that ZDV is harmful to minorities (particularly African-Americans) is a significant barrier to making informed choices.

Women and family members are an important resource for increasing community awareness of available services and treatment options. As community members with established roots and personal networks within their communities, they can serve as a bridge between providers and consumers by explaining the benefits and potential risks of treatment, interpreting confusing medical jargon and helping providers understand the needs and concerns of their patients. Since women with HIV are more likely to be trusted by other community members, their involvement with a specific program can encourage and increase community participation.

REPRESENTATION:

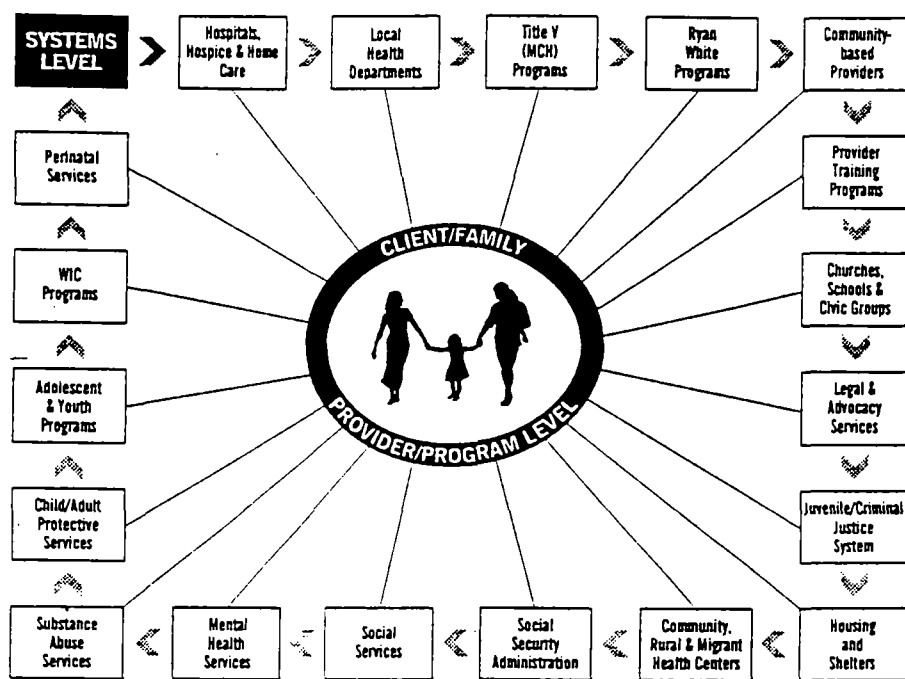
Historically, categorical funding and inadequate planning resources have contributed to fragmented or parallel services, particularly for women whose care has generally been organized around reproductive health needs. As a result of the Ryan White CARE Act and CDC HIV prevention community planning, comprehensive planning efforts have begun to improve coordination and access to care for some women with HIV.

However, additional planning efforts are needed that include the full participation of women, youth and family members in developing policies, services, educational materials and outreach strategies. Women with HIV and their families have been under-represented within community-based AIDS networks and organized planning groups (e.g., Title I HIV Planning Councils). As a result, their complex needs are often less understood by providers and less frequently addressed or incorporated within developing systems of care. Women, youth and family members should serve on planning groups at all levels including Ryan White Planning Councils and Consortia, CDC HIV prevention community planning groups, and substance abuse and mental health planning advisory groups. Representatives from Title IV programs should be included, where these programs are present.

COORDINATION:

Planning efforts to implement HIV perinatal recommendations should take place within the larger context of developing and implementing HIV-related systems of care for all affected populations, recognizing that strong linkages are required to address the fragmentation that generally characterizes women's health services. Because women enter the health delivery system at many different access points, planning should include a wide variety of institutions and settings. HIV, moreover, affects the entire family system, requiring coordination and integration between multiple systems, programs and agencies that provide services to women (e.g., social services, WIC, reproductive health clinics, Title V

Program and System Linkages for Community Participation and Effective Planning



include the full spectrum of care for women and children (e.g., pre/perinatal, pediatric and adult care) with appropriate linkages to related service and support needs. HRSA will work with grantees and related agencies in Federal, State and local government to facilitate coordination across systems and agencies.

Provider Training & Technical Assistance

Principles:

- Caregivers need to be sensitive to the high level of distrust and fear that many disenfranchised and racial/ethnic minority persons have toward health care providers and experimental protocols. Culturally appropriate interventions and provider training should be developed to increase trust and utilization of services, to help women with HIV make informed decisions and to promote adherence with treatment recommendations, when treatment is chosen.
- Health care workers should receive training on prevention intervention strategies, diagnosis and management of HIV disease in women and adolescents, and HIV counseling and testing for women. Content should include basic explanations/education in clear language; benefits and potential risks of ZDV use during pregnancy; and the importance of referrals for care, support services and long-term care. Training should include experiential, interactive methods to allow providers to expand communication skills and address clients' diverse educational

programs, substance abuse treatment, etc.).* In order to engage women in care, services need to reflect the reality of women's lives as individuals, caregivers and mothers. Whenever possible, care should be coordinated for women and children, co-locating services and providing care during a single visit.

Outreach and planning efforts should include representatives from the full range of institutions and programs that serve women. While some programs routinely provide health care, they may not provide HIV-related care or counseling and testing services, either on-site or by referral. Lack of inclusion of appropriate agencies and programs in planning and coordination activities can result in poor linkages and lack of awareness of the multiple needs of women and families.

Needs assessments, planning, community education initiatives, and allocation of resources should be coordinated at Federal, State and local levels, with Medicaid and within State plans. Planning should

*While relevance may vary according to community, this may include: State and local health departments (primary and special health care clinics, as well as publicly funded counseling and testing sites); STD, HIV, maternity, family planning, TB, case management, Title V – maternal and infant care programs; WIC, community health and rural health programs, substance abuse programs; perinatal service system; mental health system; juvenile and adult correctional system; programs funded by the Ryan White CARE Act (Titles I, II, III (b), IV); local social service departments and organizations; local Social Security Administration; community-based health providers; adolescent providers and youth-serving agencies; child/adult protection programs; hospice and home-based health services; local hospitals; provider training programs, (e.g., undergraduate professional education, graduate medical education) Area Health Education Centers [AHECs], legal services (e.g. legal aid); voluntary agencies (e.g. Red Cross, PTAs); housing programs, homeless shelters and health care for the homeless programs; community advocacy groups, churches and schools.

PROVIDER TRAINING NEEDS

Management of HIV Disease ZDV Perinatal Regimen HIV Counseling and Testing

- Communication skills
- Non-coercive counseling and informed decision making
- Cultural sensitivity and values clarification
- Adolescent care and support needs
- Social issues, including victimization and domestic violence
- Resource and support needs of women and families

and linguistic needs; sensitize providers to cultural diversity, values regarding childbearing and responses to experimental protocols; explore gender-related issues such as victimization and domestic violence; enhance counsel-

ing skills and understanding of non-coercive, informed decision making from the perspective of women with HIV; and increase awareness of the emotional, practical and support needs of women, adolescents and families.

- Training should also be provided for paraprofessionals, peer educators and outreach workers who serve as key information resources within communities.
- Training should include skills in negotiating systems and identifying and addressing barriers to care. These skills are particularly important in low-prevalence areas where services are limited and providers are required to locate referrals and follow-up to ensure that women receive care.
- Provider education should be consistent with appropriate professional roles and expectations and geared to the environment in which care is delivered.

Issues Related to Implementation

CULTURAL COMPETENCE AND SENSITIVITY:

Cultural competence involves understanding, respect and sensitivity for the diversity of affected populations. To provide appropriate care and facilitate treatment adherence, providers must be aware of and sensitive to

the needs of HIV-affected women and families. This requires training related to specific cultural, social and multi-system needs of women and their families, for all persons providing services and care. It also requires development of care and intervention plans that validate the client's cultural beliefs and practices, and culturally sensitive diagnostic and assessment tools. HRSA is currently supporting development of provider training materials and curricula which will be available in 1996.

In addition to sensitivity to clients' cultural and social diversity, providers should also be responsive to their linguistic and educational needs that directly affect comprehension and ability to make informed decisions. Because literacy levels and linguistic needs vary, educational materials should be provided in appropriate languages, presented in a variety of media. The Public Health Service is currently supporting the development of educational materials in English, Spanish, and Creole French which will be available in print format in January 1996; audio and video formats will be available later.

Providing effective services to adolescents requires

PROGRAM CHECKLIST

Enhancing Capacity to Provide Care for Adolescents

- ☐ Target outreach materials and strategies to encourage adolescents to use services and to identify health and information needs
- ☐ Identify staff who are interested and knowledgeable about adolescents and encourage additional training and continuing education, as needed
- ☐ Clarify existing confidentiality and adolescent right to care laws, and develop appropriate policies for clinic staff
- ☐ Develop linkages with other programs serving adolescents (e.g., school-based clinics, teen pregnancy programs, youth-serving agencies)
- ☐ Develop referral linkages with educational/vocational programs, mental health and specialty care

additional sensitivity and efforts, including heightened awareness of their risk for HIV infection and an understanding of their developmental and support needs. Educational materials, client/provider communication, and training materials should be adapted to reflect adolescent perspectives and

comprehension levels; peer-education strategies are particularly effective in reaching this population. Programs can enhance capacity to serve adolescents and families by targeting outreach activities; clarifying confidentiality laws and developing appropriate policies for adolescent care; and developing linkages with youth-serving agencies and appropriate referral resources.

CLIENT EDUCATION AND COUNSELING

Providers play a key role in providing basic educational information on perinatal HIV recommendations to women and families. Enabling women with HIV to make informed choices is a critical component in implementing these recommendations. Informed decisions are based on access to accurate information, presented clearly in culturally, linguistically and age-appropriate language. Many women lack in-depth medical knowledge to assist in decision-making, including basic

COUNSELING CONTENT - CLIENT EDUCATION

- Basic information on HIV disease
- Women's health and immune status
- ACTG 076 study design: 3 intervention points
- Results and limitations of study
- Benefits and potential risks, including potential for long-term effects
- Rationale and procedures for long-term follow-up

information about HIV disease. Moreover, many women learn their HIV status during pregnancy and thus may have limited time to make key decisions that affect their

infants and themselves; the compelling desire to protect their infant further complicates their choices.

Before describing available options including the perinatal regimen, providers should present the basic facts about ACTG 076 in clear, understandable language, including benefits, potential risks and limitations of the study, discussed in the context of the woman's health and immunological status and stage of pregnancy. Information should include what is known and not known regarding ZDV use during pregnancy, including

the potential for long-term adverse effects for the woman and her infant. Several counseling sessions may be needed to enable women to carefully consider their options. Providers can encourage active discussion by offering educational materials for women to review at home, prior to follow-up counseling sessions. Asking questions to ensure that clients understand key issues can facilitate informed decision-making.

AVAILABILITY OF EDUCATION AND TRAINING

Providing the ZDV perinatal regimen to women who choose this option involves extensive training and technical assistance (TA) for providers, programs and care delivery systems. HIV/AIDS education is available through HRSA's National AIDS Education and Training Centers (AETC) and Ryan White Programs, CDC's STD Prevention Centers, health professions schools, professional associations, and other agencies such as the Red Cross. To ensure the appropriate availability of training and technical assistance, collaboration is required between all entities — Federal, State and local government, professional associations, health professions schools, community groups and private organizations. Women with HIV should play an integral role in developing curricula, participating on multi-disciplinary training teams and providing peer support to other women with HIV.

HRSA will distribute provider and consumer educational materials to all grantees when final versions are available.* In addition, each AETC is required to develop a regional plan for training providers and disseminating information to implement this advisory. Each AETC is establishing a pediatric HIV liaison to coordinate training activities with Title IV programs and providers within the region. (For information on the National AETC Program and ongoing activities, see Resource Information, page 20.)

*Projected to be available in 1996

TECHNICAL ASSISTANCE

Implementing this regimen, which requires coordination between multiple systems and providers, will increase program needs for technical assistance. These needs range from client-level interventions (such as helping programs and providers understand and manage cultural conflict) to enhancing administrative or management systems (such as developing systems to ensure transferability of medical records or providing training on continuous quality improvement). Resources to initiate broad-based provider training and technical assistance should be sought and allocated to training programs best able to provide education and training on perinatal ZDV management.

Each HRSA Bureau will use a variety of mechanisms to assist grantees in implementing this advisory. These include special sessions during annual program meetings, identifying TA needs during site visits and ongoing monitoring, targeted needs assessments and evaluation activities and providing materials, curricula and protocols. Through the Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission (WIN) program funded in ten sites, the Maternal and Child Health Bureau will provide technical assistance as a follow-up to specific training for physicians, nurses, social workers, psychologists and peer mentors.

HIV Counseling and Testing/ Informed Decision Making

Principles:

- All settings that provide care to pregnant women and women considering pregnancy should provide routine HIV counseling and voluntary testing on-site or by referral. All pregnant women who have not been tested should be counseled on the benefits of knowing their HIV status (e.g., earlier access to care, PCP prophylaxis for their infants). Whenever possible, however, women should learn their HIV status prior to becoming pregnant. Programs that do not provide HIV testing on-site should provide

counseling on the importance of HIV testing and make arrangements for clients who wish to be tested to do so at an appropriate facility.

- HIV testing should be voluntary and should include specific informed consent. Mandatory HIV testing has not been justified. Except for blinded HIV seroprevalence studies, HIV testing without informed consent is unethical.
- HIV counseling and voluntary testing should be made available to women, and men, in all primary care settings and through collaboration with HIV counseling and testing programs.
- Follow-up care for all people with HIV should be

COUNSELING CONTENT - HIV TESTING

- Rationale for knowing HIV status:
 - assistance in making reproductive decisions
 - appropriate medical care for woman and infant
- Risk reduction information:
 - reduce number of partners
 - avoid unprotected sex with HIV-infected partners
 - use condoms during intercourse
 - avoid sharing needles
- Risk of HIV transmission to infant:
 - 15-30% of infants born to mothers with HIV are infected through perinatal transmission, without preventive intervention
- Availability of ZDV perinatal regimen to reduce maternal-infant transmission of HIV

provided at HIV counseling and testing sites or by referral. Primary care programs should establish close linkages with HIV counseling and testing sites to ensure optimal follow-up care.

- All pregnant women with HIV should receive information on the benefits and potential risks of

ZDV use during pregnancy to enable them to make fully informed choices. Information should be provided in clear, culturally, linguistically, and age-appropriate language. Women should be clearly informed that they will continue to receive ongoing care, whether or not they choose to take ZDV.

Programs should ensure that women receive appropriate counseling and give informed consent on use of ZDV to reduce perinatal HIV (see Appendix D).

Issues Related to Implementation

GOALS OF HIV COUNSELING AND TESTING:

When first introduced in 1985, the HIV test was used to screen donated blood to protect the nation's blood supply. As it became a widely used diagnostic tool to determine HIV infection status and assess potential treatment needs, testing coupled with counseling became a standard of care. The goals of HIV counseling and testing were redefined to: 1) help people learn their HIV status; 2) facilitate risk-reducing behavioral change; 3) provide access and referrals to follow-up care and services; and 4) provide access and referrals for partners.

Meeting these goals is an ongoing challenge for HIV prevention and early intervention programs. Provider training in HIV counseling and testing has been insufficient and the quality of HIV counseling and testing services varies widely. Although a follow-up visit is required to obtain test results, in some settings, such as STD clinics, less than half of persons tested consistently return for their results.⁵ Return rates are substantially higher when trained providers offer testing to clients who consent to testing and agree to return for results⁶. When testing is offered by trained providers women trust, more than 9 out of 10 women agree to be tested.

HIV counseling and testing has not been well integrated into most primary care services or other settings where women receive care. As a result, many women with HIV are not aware of their HIV status and are not tested until they become symptomatic or until their infants are found to be infected.

RISK ASSESSMENT & PERCEPTIONS OF RISK

Previously, HIV counseling and testing strategies targeted persons with self-identified high risk behaviors or who had partners with identified high risk behaviors. Such strategies, however, depend on accurate risk assessments carried out by trained providers and by accurate self-assessment of potential risk factors by

clients. Using targeted risk assessment to identify women at risk for infection does not identify more than half of all seropositive women. Many women do not know that they or their partners are infected and do not consider unprotected sex to be a risk behavior. Outreach efforts and services should be targeted to all women, not just those perceived by providers as being "high risk," especially in high seroprevalence areas and settings. PHS guidelines for HIV counseling and voluntary testing of pregnant women recommend that all pregnant women receive counseling on the importance of HIV testing.¹

LINKAGES AND REFERRALS FOR SERVICES AND CARE

Inadequate linkages between counseling and testing programs and HIV-related services have resulted in lack of appropriate referrals, poor follow-up and inadequate care. Referrals for follow-up services and care should

INFORMED DECISION MAKING

- Use clear, understandable language
- Provide non-coercive counseling
- Clearly state that decision will not jeopardize ongoing care • Empower women to make an informed decision
- Include family members, partners, confidants
- Allow sufficient time to fully discuss concerns
- Address linguistic and literacy needs
- Provide age-appropriate discussion for adolescents
- Document counseling and decision on written, signed consent form

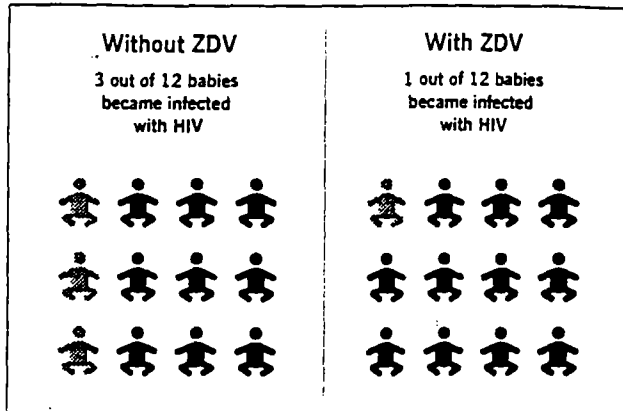
be provided for all persons with HIV; services should be provided on-site or by referral to designated facilities.

Programs should collaborate to make optimal use of available

resources. For example, Ryan White funds can be used to provide transportation services, including taxi vouchers, to ensure that clients have access to counseling and testing and follow-up care. Maternal child health programs, family planning clinics and other programs serving women should collaborate with Ryan White programs and counseling and testing sites to incorporate the needs of women into local and regional planning efforts.*

*Ryan White grantees are asked to describe such planning in their funding application

Results of ACTG 076



COUNSELING FOR INFORMED DECISION-MAKING

Deciding to take an HIV test or to seek related treatment are major steps that require access to accurate information and culturally relevant counseling from knowledgeable and sensitive providers. Women must fully understand the results of ACTG 076 to make informed choices. The decision to use ZDV during pregnancy should ultimately be made by the woman without coercion, with a clear understanding that her decision will not jeopardize ongoing services and care.

Counseling should be provided with the goal of informing and empowering women to make their own decisions. ACTG 076 is a complicated study; women may need several counseling sessions, involving family members, partners, friends and others to make fully informed decisions. They need time to review HIV test results and medical findings, ask questions and discuss their concerns. Adolescents will need age-appropriate discussions.

In addition to discussing benefits, providers should ensure that women clearly understand the study's limitations. For example, women should be informed that while they may follow the regimen, some infants will still become infected: ZDV reduces risk of perinatal HIV transmission — it does not completely prevent transmission in all infants. Inaccurate description of the impact of ZDV may influence a woman's decision by giving a misleading impression that ZDV will prevent transmission of HIV in all infants.

*Projected to be available in 1996

CONSENT

After a woman has completed counseling and has received information on all aspects of the regimen, counseling should be documented on a written, signed consent form (see Appendix D). The form should specify that she has received basic information about the ZDV perinatal regimen and fully understands her options. The form should provide basic information about the regimen, including benefits and potential risks in clear, understandable language, appropriate to the educational level and linguistic needs of the client. A model consent form is included as Appendix D, which may be used or adapted for use in HRSA-funded programs. Additional materials will be provided when HRSA-sponsored consumer and provider educational materials are distributed.*

Comprehensive Clinical Care & Support Service Needs During Prenatal/Perinatal Period & Post-Treatment Follow-Up

Principles:

- Providers should make ZDV available to women (and their infants) who choose this option, either on-site or by referral. ZDV protocols are complicated; advanced planning and strong linkages are needed to coordinate services among primary care, obstetric, hospital/delivery and pediatric health professionals. For example, appropriate doses of ZDV should be available at all sites where women and infants routinely receive pre-, perinatal and post-natal care.
- All women and infants receiving the ZDV regimen should receive long-term follow-up care. Providers should document infection status and long-term clinical outcomes for both mothers and infants, observing all laws, regulations and provisions that safeguard the confidentiality of medical records.
- Access to a full range of support services and referrals to specialty and subspecialty care should be

coordinated at the primary care site or through a lead agency or coordinating agency (when case management or clinical coordination is not available on-site). Whenever possible, medical and core support services should be co-located; this includes counseling and testing, mental health services, substance abuse treatment and child care/respite care.

- Care for pregnant women with HIV should be initiated as early as possible from any point in the system where women access health or related services.
- Agencies should develop written policies and procedures for ZDV management of pregnant women. These should include existing confidentiality provisions, patient's rights, quality assurance and quality improvement standards.*
- Outreach and peer support services should be considered an integral component of comprehensive care; such services enhance continuity of care and increase treatment adherence.

Issues Related to Implementation

COMPREHENSIVE CARE:

The ZDV perinatal regimen, administered within a comprehensive care system, should be considered a standard of care for pregnant women with HIV; however, the decision to follow the regimen will be ultimately made by the woman. Mainstream care settings provide the most likely opportunities for identifying women with HIV before conception and during early stages of pregnancy, to allow optimal treatment and maximum options. Providing the regimen within this broad context of health care services requires extensive coordination and linkages between multiple service systems.

Comprehensive care and support services for women with HIV — from pre-natal through post-treatment care — include a full range of medical, support services and basic life needs provided in a supportive, client-centered environment. Key needs for managing care include: provision of care by supportive individuals or a multi-

disciplinary team, access to peer and professional support (particularly during the period immediately following diagnosis), case management, comprehensive assessment of the woman's needs, comprehensive client education providing options for care, primary care and a plan for managing the birth process. (See implementation diagram on the following page.)

NEED FOR FOLLOW-UP

ACTG 076 studied only short term effects of the ZDV perinatal regimen. Eventually other studies (see page

17) will provide information on long-term effects; until then, long-term follow-up care of mothers and infants in primary care settings is essential to monitor for potential negative health outcomes.

Follow-up should help:

- provide information on possible adverse reactions and outcomes to allow for early detection and treatment, should these occur;
- provide information on the effects and outcomes of an incomplete regimen (e.g., when women

COMPONENTS OF COMPREHENSIVE CARE

HEALTH CARE

Primary and specialty care (including adolescent care), HIV-related care and pharmaceuticals, preventive care, emergency and acute care, linkage to pediatric care, access to clinical trials, dental care, nutritional services, substance abuse services, counseling and mental health services, health education and partner related services

SUPPORT SERVICES

Case management, social services, family support services, child and respite care, youth and school-based services, health education, entitlements counseling, peer support and outreach. (These services are needed to help women access and remain in care. Protocols that involve frequent visits to primary care providers call for informed clients who are active care partners.)

BASIC LIFE NEEDS

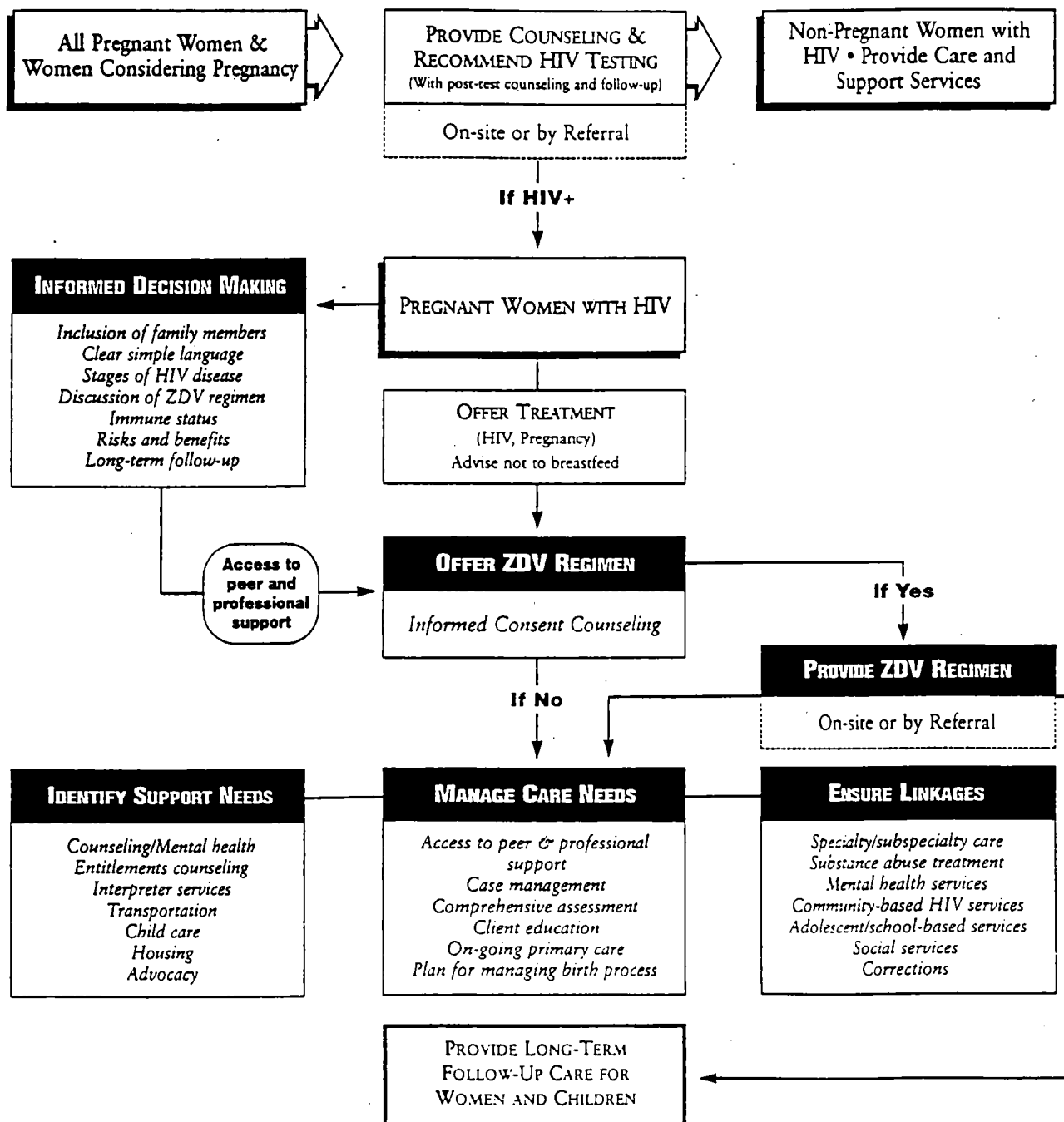
Housing assistance, food, transportation, and interpreter services help meet basic survival needs

LEGAL AND ADVOCACY SERVICES

Services to help manage discrimination or assist with preparing wills, adoption or permanency planning; these services may be particularly important for homeless women and those who inject or have injected illegal drugs.

*For example, see N.Y. State Department of Health, AIDS Institute, Clinical Guidelines for the Use of Zidovudine Therapy in Pregnancy to Reduce Perinatal Transmission of HIV, October 1994, for model policy and procedures. This document is available from the HRSA AIDS Program Office

IMPLEMENTATION OF ZDV PERINATAL THERAPY IN HRSA-FUNDED PROGRAMS



receive treatment later during pregnancy or delivery or when only the infant receives ZDV after delivery);

- generate mechanisms to accurately report health outcomes for women and uninfected and infected infants;
- provide information to help define service and care needs for women and children who receive the regimen.

ENCOURAGING FOLLOW-UP

Long-term follow-up may occur in a variety of settings, including medical centers, HIV specialty programs, primary care clinics or private practitioners' offices. Participation is voluntary. Women and children are more likely to remain in care and participate in follow-up care when: 1) the care setting is welcoming; 2) providers are supportive and accepting of women's needs and are flexible when appointments are missed or women return infrequently; 3) women and families clearly understand the importance of follow-up (i.e., both the client's and provider's expectations are clearly defined); 4) providers share findings after each visit, reinforcing the value of a consistent care team and long-term follow-up; 5) providers stay in touch with families between visits (e.g., sending birthday cards or notes) particularly if families are seen infrequently, and outreach workers routinely follow-up when visits are missed; 6) support services (e.g., child care, transportation, food vouchers) are directly linked to care, enabling women and children to keep appointments; 7) contact information is updated during each visit, including telephone, address and information on extended family members and close friends; and 8) mothers receive psychosocial support for child custody or permanency planning, including periodic discussion of how follow-up care will be maintained after her death.

SUGGESTED PROTOCOL FOR LONG-TERM FOLLOW-UP

Primary care programs should develop a follow-up protocol for women and children who received the regimen (see protocol on page 19). Follow-up monitoring should be integrated into routine and regular care. Providers should document clinical and laboratory results for mothers and children, maintained as part of the client's medical record, until standardized forms are developed to facilitate reporting and follow families to other care settings. Confidentiality of both mother and child should be protected; in many cases, women do not disclose their HIV status or their child's to others, even to family members.

Adverse events should be reported through established mechanisms such as FDA's MedWatch, Western Stream and the Wellcome registry, or coordinated through special studies for uniform long-term data collection conducted by NIH, CDC and HRSA (e.g., Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission).

PROGRAM IMPLEMENTATION

Implementing these recommendations involves planning and coordination at all levels and across multiple service delivery systems. Close collaboration with women with HIV, affected communities, local agencies and providers is essential. Clearly, implementing the regimen requires commitment of staff, time and financial resources. At a more basic level, moreover, implementation compels providers, program managers and public health officials to more closely integrate prevention and primary care services, at both planning and service delivery levels. Above all, the need to carefully weigh the benefits and potential risks of taking the regimen requires careful consultation between women and their providers.

HRSA will work closely with grantees to identify technical assistance and planning needs and to incorporate feedback and share effective strategies as implementation needs evolve.

Recommended Protocol for Long-term Follow-up of Women and Children

Follow-up care should be provided for women and infants who have received the ZDV perinatal regimen. This should include the following guidelines, at a minimum, as well as any additional visits or assessments that are medically indicated.

WOMEN

- Women should receive ongoing personal medical care appropriate to their health status, and not limited to HIV-related care.
- Routine visits should occur at 6, 12, 18, 24 and 36 months, post-partum, and yearly thereafter.
- Each visit should include history and physical, pap smear, routine chemistry and hematology bloodwork and CD4+ T-cell levels.
- Indicated HIV care (STD, TB and OI screening, PCP prophylaxis).

INFANTS

- Routine visits for all infants should occur at 2 and 6 weeks of age (while receiving zidovudine), and then every three months until infection status is determined. HIV culture and PCR should be used to establish infection status.
- Provide preventive medical care including PCP prophylaxis⁴ and immunizations according to current guidelines and as medically indicated.
- When HIV status is determined (6 months - 2 years), infected infants/children should be seen every 3 months with additional visits or assessments as medically indicated. Each visit should include a history and physical, routine hematology and chemistry tests, evaluation of immune function and office-based neurodevelopmental assessment including both mental or cognitive and motor function (e.g., Denver developmental test). The older child should also be assessed for school performance, peer relations and support needs.
- Uninfected infants/children should be seen as appropriate for routine health care and immunization (e.g., every 3 months through 24 months of age) then yearly until age 21, to monitor for long-term effects of zidovudine exposure. Visits should include a history and physical, routine hematology and chemistry tests, office-based neurodevelopmental assessment including both mental or cognitive and motor function (e.g., Denver developmental test), and assessment of school performance, peer relations and support needs (for older children).
- Give special consideration during each visit to assessing the mother's health status and her plans for custodial care if she becomes unable to care for her child. Incorporate continuity of the child's health care into this plan.

Share findings with the mother and family after the visit.

Resource Information

AIDS Clinical Trials Information Service: 1-800-TRIALS-A, TTY/TDD 1-800-243-7012

Early HIV Infection Clinical Practice Guidelines

Clearinghouse for Primary Care Information: 703-821-8955

HRSA/AIDS ETC National HIV Telephone Consultation Service (for health care providers) 1-800-933-3413

HIV/AIDS Treatment Information Service 1-800-HIV-0440

National Institute of Allergy and Infectious Diseases (NIAID), NIH

NIAID Office of Communications: 301-402-1663

National Institute of Child Health and Human Development (NICHD), NIH

NICHD Office of Communications: 301-496-5133

National HIV/AIDS Education and Training Centers (AETC) Program, HRSA: 301-443-6364

National AIDS Information Clearinghouse, CDC: 1-800-458-5231

National Pediatric and Family HIV/AIDS Resource Center, HRSA: 1-800-362-0071

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3. CDC. Unpublished data, March 1994 (Supplement to HIV/AIDS Surveillance Project).
4. CDC. 1995 Revised Guidelines for Prophylaxis Against *Pneumocystis carinii* Pneumonia for Children Infected with or Perinatally Exposed to Human Immunodeficiency Virus. MMWR 1995;44 (No. RR-4).
5. Valdiserri RO, Moore M, Gerber AR, Campbell CH, Dillon BA, West GR. A study of clients returning for counseling after HIV testing: implications for improving rates of return. Public Health Rep 1993; 108: 12-18.
6. Lindsay MK, Adefris W, Peterson HB, et al. Determinants of acceptance of routine voluntary human immunodeficiency virus testing in an inner-city prenatal population. Obstet Gynecol 1989; 78:678-80.
7. CDC. Technical Guidance on HIV Counseling. MMWR 1993;42 (No. RR-2).
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APPENDIX A

Recommendations for HIV Counseling and Voluntary Testing of Pregnant Women¹

HIV Counseling and Voluntary Testing of Pregnant Women and Their Infants

- Health care providers should ensure that all pregnant women are counseled and encouraged to be tested for HIV infection to allow women to know their infection status both for their own health and to reduce the risk for perinatal HIV transmission. Pretest HIV counseling of pregnant women should be in accordance with previous guidelines for HIV counseling.⁷ ^aSuch counseling should include information regarding the risk for HIV infection associated with sexual activity and injecting-drug use, the risk for transmission to the woman's infant if she is infected, and the availability of therapy to reduce this risk. HIV counseling, including any written materials, should be linguistically, culturally, educationally, and age appropriate for individual patients.
- HIV testing of pregnant women and their infants should be voluntary. Consent for testing should be obtained in accordance with prevailing legal requirements. Women who test positive for HIV or who refuse testing should not be a) denied prenatal or other health-care services, b) reported to child protective service agencies because of refusal to be tested or because of their HIV status, or c) discriminated against in any other way.
- Health care providers should counsel and offer HIV testing to women as early in pregnancy as possible so that informed and timely therapeutic and reproductive decisions can be made. Specific strategies and resources will be needed to communicate with women who may not obtain prenatal care because of homelessness, incarceration, undocumented citizenship status, drug or alcohol abuse, or other reasons.
- Uninfected pregnant women who continue to practice high-risk behaviors (e.g., injecting drug-use and unprotected sexual contact with an HIV-infected or high-risk partner) should be encouraged to avoid further exposure to HIV and to be retested for HIV in the third trimester of pregnancy.
- The prevalence of HIV infection may be higher in women who have not received prenatal care. These women should be assessed promptly for HIV infection. Such an assessment should include information regarding prior HIV testing, test results, and risk history. For women who are first identified as being HIV infected during labor and delivery, health care providers should consider offering intrapartum and neonatal ZDV according to published recommendations.² For women whose HIV infection status has not been determined, HIV counseling should be provided and HIV testing offered as soon as the mother's medical condition permits. However, involuntary HIV testing should never be substituted for counseling and voluntary testing.
- Some HIV-infected women do not receive prenatal care, choose not to be tested for HIV, or do not retain custody of their children. If a woman has not been tested for HIV, she should be informed of the benefits to her child's health of knowing her child's infection status and should be encouraged to allow the child to be tested. Counselors should ensure that the mother provides consent with the understanding that a positive HIV test for her child is indicative of infection in herself. For infants whose HIV status is unknown and who are in foster care, the person legally authorized to provide consent should be encouraged to allow the infant to be tested (with the consent of the biologic mother, when possible) in accordance with the policies of the organization legally responsible for the child and with prevailing legal requirements for HIV testing.

- Pregnant women should be provided access to other HIV prevention and treatment services (e.g., drug treatment and partner-notification services) as needed.

Recommendations for HIV-Infected Pregnant Women

- HIV-infected pregnant women should receive counseling as previously recommended.¹ Post test HIV counseling should include an explanation of the clinical implications of a positive HIV antibody test result and the need for, benefit of, and means of access to HIV-related medical and other early intervention services. Such counseling should also include a discussion of the interaction between pregnancy and HIV infection, the risk of HIV perinatal HIV transmission and ways to reduce this risk, and the prognosis for infants who become infected.
- HIV-infected pregnant women should be evaluated according to published recommendations to assess their need for antiretroviral therapy, antimicrobial prophylaxis, and treatment of other conditions. Although medical management of HIV infection is essentially the same for pregnant and nonpregnant women, recommendations for treating a patient who has tuberculosis have been modified for pregnant women because of potential teratogenic effects of specific medications (e.g., streptomycin or pyrazinamide). HIV-infected pregnant women should be evaluated for their need for psychological and social services.
- HIV-infected pregnant women should be provided information concerning ZDV therapy to reduce the risk for perinatal HIV transmission. This information should address the potential benefit and short-term safety of ZDV and the uncertainties regarding a) long-term risks of such therapy and b) effectiveness in women who have different clinical characteristics (e.g., CD4+ T-lymphocyte count and previous ZDV use) than women who participated in the trial. HIV-infected pregnant women should not be coerced into making decisions about ZDV therapy. These decisions should be made after consideration of both the benefits and potential risks of the regimen to the woman and her child. Therapy should be offered according the appropriate regimen in published recommendations.² A woman's decision not to accept treatment should not result in punitive action or denial of care.
- HIV-infected pregnant women should receive information about all reproductive options. Reproductive counseling should be nondirective. Health care providers should be aware of the complex issues HIV-infected women must consider when making decisions about their reproductive options and should be supportive of any decision.
- To reduce the risk of HIV transmission to their infants, HIV-infected women should be advised against breast feeding. Support services should be provided when necessary for use of appropriate breast milk substitutes.
- To optimize medical management, positive and negative HIV test results should be available to a woman's health care provider and included on both her and her infant's confidential medical records. After obtaining consent, maternal health care providers should notify the pediatric care providers of the impending birth of an HIV-exposed child, any anticipated complications, and whether ZDV should be administered after birth. If HIV is first diagnosed in the child, the child's health care providers should discuss the implication of the child's diagnosis for the woman's health and assist the mother in obtaining care for herself. Providers are encouraged to build supportive health care relationships that can facilitate the discussion of pertinent health information. Confidential HIV-related information should be disclosed or shared only in accordance with prevailing legal requirements.
- Counseling for HIV-infected pregnant women should include an assessment of the potential for negative effects resulting from HIV infection (e.g., discrimination, domestic violence, and psychological difficulties). For women who anticipate or experience such effects, counseling should also include a) information on how to minimize these poten-

tial consequences, b) assistance in identifying supportive persons within their own social network, and c) referral for appropriate psychological, social, and legal services. In addition, HIV-infected women should be informed that discrimination based on HIV status or AIDS regarding matters such as housing, employment, state programs, and public accommodations (including physicians' offices and hospitals) is illegal.

- HIV-infected women should be encouraged to obtain HIV testing for any of their children born after they became infected or, if they do not know when they became infected, for children born after 1977. Older children (i.e., children > 12 years of age) should be tested with informed consent of the parent and assent of the child. Women should be informed that the lack of signs and symptoms suggestive of HIV infection in older children may not indicate lack of HIV infection; some perinatally infected children can remain asymptomatic for several years.

Recommendations for Follow-up of Infected Women and Perinatally Exposed Children

- Following pregnancy, HIV-infected women should be provided ongoing HIV-related medical care, including immune-function monitoring, antiretroviral therapy, and prophylaxis for and treatment of opportunistic infections and other HIV-related conditions. HIV-infected women should receive gynecologic care, including regular Pap smears, reproductive counseling, information on how to prevent sexual transmission of HIV, and treatment of gynecologic conditions according to published recommendations.
- HIV-infected women (or the guardians of their children) should be informed of the importance of follow-up for their children. These children should receive follow-up care to determine their infection status, to initiate prophylactic therapy to prevent PCP, and, if infected, to determine the need for antiretroviral and other prophylactic therapy and to monitor disorders in growth and development, which often occur before 24 months of age. HIV-infected children and other children living in households with HIV-infected persons should be vaccinated according to published recommendations for altered schedules.
- Because the identification of an HIV-infected mother also identifies a family that needs or will need medical and social services as her disease progresses, health care providers should ensure that referrals to these services focus on the needs of the entire family.

APPENDIX B

PHS RECOMMENDATIONS FOR USE OF ZDV TO REDUCE PERINATAL HIV TRANSMISSION²

Clinical Situations and Recommendations for Use of Zidovudine to Reduce Perinatal HIV Transmission

These recommendations should be followed by all providers implementing the ZDV perinatal regimen in HRSA-funded programs:

- I. Pregnant HIV-infected women with CD4+ T-lymphocyte counts $\geq 200/\text{mL}$ who are at 14-34 weeks of gestation and who have no clinical indications for ZDV and no history of extensive (>6 months) prior antiretroviral therapy.

Recommendation:

The health care provider should recommend the full ACTG Protocol 076 regimen to all HIV-infected pregnant women in this category. This recommendation should be presented to the pregnant woman in the context of a risk-benefit discussion: a reduced risk of transmission can be expected, but the long-term adverse consequences of the regimen are not known. The decision about this regimen should be made by the woman after discussion with her health care provider.

- II. Pregnant HIV-infected women who are at >34 weeks of gestation, who have no history of extensive (>6 months) prior antiretroviral therapy, and who do not require ZDV for their own health.

Recommendation:

The health care provider should recommend the full ACTG Protocol 076 regimen in the context of a risk-benefit discussion with the pregnant woman. The woman should be informed that ZDV therapy may be less effective than that observed in ACTG Protocol 076, because the regimen is being initiated late in the third trimester.

- III. Pregnant HIV-infected women with CD4+ T-lymphocyte counts $<200/\text{mL}$ who are at 14-34 weeks of gestation, who have no other clinical indications for ZDV, and who have no history of extensive (>6 months) prior antiretroviral therapy.

Recommendation:

The health care provider should recommend initiation of antenatal ZDV therapy to the woman for her own health benefit. The intrapartum and neonatal components of the ACTG Protocol 076 regimen should be recommended until further information becomes available. This recommendation should be presented in the context of a risk-benefit discussion with the pregnant woman.

- IV. Pregnant HIV-women who have a history of extensive (>6 months) ZDV therapy and/or other antiretroviral therapy before pregnancy.

Recommendation:

Because data are insufficient to extrapolate the potential efficacy of the ACTG Protocol 076 regimen for this population of women, the health care provider should consider recommending the ACTG Protocol 076 regimen on a case-by-case basis after a discussion of the risk and benefits with the pregnant woman. Issues to be discussed include

her clinical and immunologic stability on ZDV therapy, the likelihood that she is infected with a ZDV-resistant HIV strain, and, if relevant, the reasons for her current use of an alternative antiretroviral agent (e.g., lack of response to or intolerance of ZDV therapy.) Consultation with experts in HIV infection may be warranted. The health care provider should make the ACTG Protocol 076 regimen available to the woman, although its effectiveness may vary depending on her clinical status.

V. Pregnant HIV-infected women who have not received antepartum antiretroviral therapy and who are in labor

Recommendation:

For women with HIV infection who are in labor and who have not received the antepartum component of the ACTG Protocol 076 regimen (either because of lack of prenatal care or because they did not wish to receive antepartum therapy), the health care provider should discuss the benefits and potential risks of the intrapartum and neonatal components of the ACTG Protocol 076 regimen and offer ZDV therapy when the clinical situation permits.

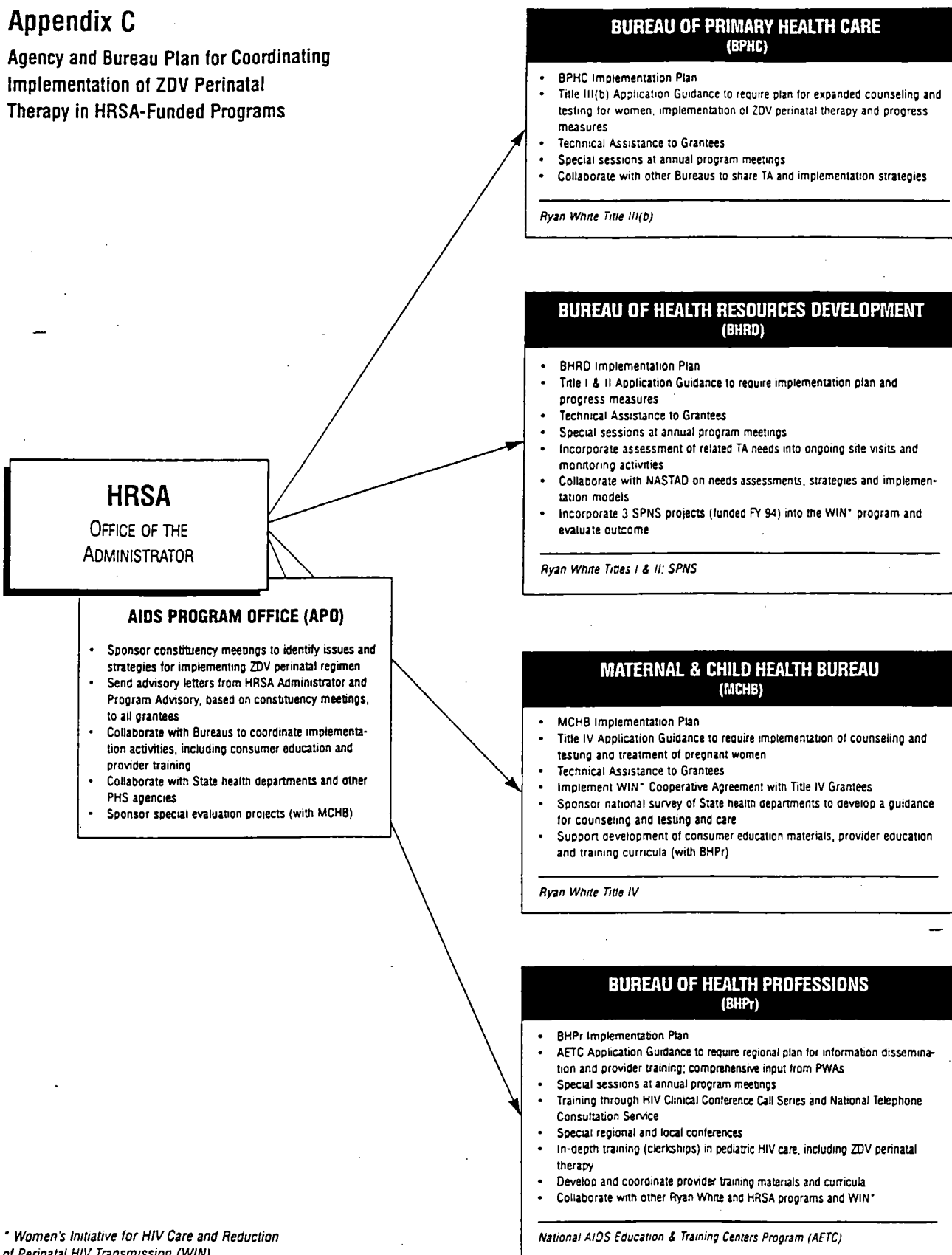
VI. Infants who are born to HIV-infected women who have received no intrapartum ZDV therapy.

Recommendation:

If the clinical situation permits and if ZDV therapy can be initiated within 24 hours of birth, the health care provider should offer the ACTG Protocol 076 postpartum component of 6 weeks of neonatal ZDV therapy for the infant in the context of a risk-benefit discussion with the mother. Data from animal prophylaxis studies indicate that, if ZDV is administered, therapy should be initiated as soon as possible (within hours) after delivery. If therapy cannot begin until the infant is >24 hours of age and the mother did not receive therapy during labor, no data support offering therapy to the infant.

Appendix C

Agency and Bureau Plan for Coordinating Implementation of ZDV Perinatal Therapy in HRSA-Funded Programs



* Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission (WIN)

APPENDIX D

This form has been developed as a draft for use by HRSA-funded programs. It is based on informed consent forms used by programs implementing the ZDV perinatal regimen. Providers are encouraged to use or adapt this form as needed to ensure that appropriate counseling is provided and to help avoid potential legal problems that may occur if counseling is not adequately documented.

Following counseling session(s), providers should ask women to read and sign such a form to indicate that they have received specific information about the regimen, have had an opportunity to discuss their concerns, and have made a decision about whether or not to accept the regimen. When women are unable to read the form, providers should read it to them, clearly reviewing the information it contains to ensure that women make fully informed decisions.

Model Form To Document Counseling and Consent for Administration of the ZDV Perinatal Regimen

I have been counseled by my care providers on use of ZDV (AZT) to reduce the chance of passing HIV from mother-to-infant. If my CD4+T-cell count drops below 500 or if I develop symptoms of HIV disease, my provider may suggest that I take ZDV for my own well-being (not only to reduce the chance of passing HIV to my infant).

My care provider has discussed the following information with me in language I can understand:

- ZDV *regimen* to reduce the chance of passing HIV from mother to infant (*Regimen* means how ZDV is given to women and infants. Women take ZDV during pregnancy, labor and delivery and infants take it during the first 6 weeks of life)
- Benefits and potential risks of the ZDV regimen
- My right to make this decision on my own, without pressure from my health care providers
- My rights (and my infant's rights) to confidentiality
- Need for long-term follow-up care
- Basic information on HIV/AIDS
- Counseling on why I should not breast feed my infant
- My health and immune status

ZDV Regimen: Benefits and Risks

My care provider has explained that women with HIV have about a 1 out of 4 chance of passing HIV to their infants. This means that 3 out of 12 infants born to mothers with HIV will also have HIV. A large study of more than 500 pregnant women showed that ZDV could lower the chance of passing HIV from mothers to infants. In the study (ACTG 076), only 1 out of 12 infants born to mothers with HIV also had HIV. Other studies have also shown that ZDV can lower the risk of passing HIV from mothers to infants. My provider has explained these new studies to me as they completed.

I understand that this is considered to be an important option to reduce the risk of passing HIV from mother to infant. Even though I may decide to take ZDV, my infant may still get infected because ZDV does not completely prevent HIV in all infants. I also understand that no one knows the long-term effects of ZDV on infants (or mothers).

My provider has explained that women in the study (ACTG 076)

- Received early prenatal care
- Did not take ZDV for their own health before the study began
- Started taking ZDV between 14 weeks (3 1/2 months) and 34 weeks (8 1/2 months) of pregnancy
- Had T-cell counts above 200 when the study began, and more than half had T-cell counts above 500.

Most of the women were African-American or Hispanic (79%) and their average age was 25. I understand that women in the study received care under the best conditions to reduce the risk of passing HIV to their infants. In other words, they had early prenatal care, knew their HIV status, had higher T-cell counts and took a full course of ZDV (during pregnancy, labor, delivery; infants took it for 6 weeks). My provider has explained that ZDV may not have the same result if my history is different from women in ACTG 076. My provider has also explained other new studies that have reduced HIV in infants and how I compare to women in those studies.

I have received basic information on HIV disease and my provider has explained my T-cell count and stage of HIV disease.

Right to Decide

I understand that I have the right to decide if I want to take ZDV or not. If I choose to take ZDV, I understand that I can change my mind at any time — for myself or my infant. If I do not take ZDV or if I decide to stop taking it, my infant and I will still receive care.

Medical Monitoring

I understand that while I take ZDV, my providers will continue to check my health status. This includes taking a blood test (complete blood count) each month and checking my CD4+T-cell count (key immune system cells) to measure my immune status. If I decide to take ZDV, I understand that I will take it 5 times a day during pregnancy, during labor and delivery through an IV, and my infant will take it 4 times a day for 6 weeks.

Short-term Effects

I understand that some people who take ZDV may have short-term side effects that usually go away after they stop taking ZDV. These may include, low blood count (anemia), upset stomach, nausea, vomiting, rashes, muscle aches (myalgia), headache, difficulty sleeping (insomnia), numbness or tingling feelings on the skin (paresthesia) and hepatitis in adults and infants.

Women and children who were in the study did not have serious short-term side effects. Some infants had mild anemia, but this cleared up after they stopped taking ZDV.

Long-term Effects

I understand that the study did not last long enough to know if the ZDV regimen will cause health problems for women and children at a later time. (For example, I understand that some other drugs have later caused birth defects or cancer in children or adults when their mothers took these drugs during pregnancy.) There are two other studies looking at women and infants who were in the ACTG 076 study. But these will not be finished for several years. For this reason, women and children will receive long-term follow-up care to see if serious health problems develop.

Long-term Follow-up

I understand that if I decide to take ZDV, my child and I will be asked to come in for medical check-ups every year until my child reaches age 21. During these visits, providers will check for possible side effects, share information on health status and help with long-term planning for my child's care.

Confidentiality

I understand that my providers must protect my confidentiality and my infant's under State laws. My providers have explained State and local laws about confidentiality of HIV. In some cases they may have to share my HIV status with other persons. If they are required to share my HIV status, they will tell me who else must know my health status and my infant's. I understand that my decision about taking ZDV will not be shared with others unless the law requires them to know.

Decision About Use of ZDV

I have read this form or had it read to me in a language I can understand. I understand what I have read and what my provider has told me about HIV disease and the ZDV regimen. I have discussed this information with my provider and have asked questions about HIV disease and the ZDV regimen. I feel that I have enough information about ZDV and its benefits and risks to make an informed decision.

My provider has recommended that I take the ZDV regimen.

I understand that ZDV may help lower the chance of passing HIV to my infant. I also understand that it may not work as well for me as it did for women in the study (ACTG 076) because some infants still became infected even after their mothers took ZDV. No one has made any promises to me about what to expect from taking ZDV.

I understand that I will still receive ongoing care if I decide not to take ZDV and I have the right to change my mind at any time.

CONSENT

- ☐ I CHOOSE to take the ZDV regimen.
- ☐ I CHOOSE to allow my infant to receive ZDV after he/she is born.

Patient's Signature

Date

Witness's Signature

Date

If Patient is Unable to Sign

Relationship

Date

I have discussed all of the information included in this form with my client and have provided an opportunity for her and her family to ask questions and discuss their concerns.

Health Care Provider

Date

DO NOT CONSENT

- ☐ I CHOOSE NOT to take the ZDV regimen at this time.

Patient's Signature

Date

Witness's Signature

Date

If Patient is Unable to Sign

Relationship

Date

I have discussed all of the information included in this form with my client and have provided an opportunity for her and her family to ask questions and discuss their concerns.

Health Care Provider

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207 - 5187

SEP 10 1995

Dear State Medicaid Director:

The American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) recently issued a joint statement that recommends an aggressive strategy to ensure that all pregnant women receive HIV education and counseling as part of their regular prenatal care. The joint statement also recommends HIV testing of consenting pregnant women in light of the availability of treatments that significantly reduce HIV transmission from mother to infant, and to protect the health of the newborn.

This statement was developed in response to the recently issued recommendations of the Centers for Disease Control (CDC) that pregnant women receive HIV counseling which should "include information regarding the risk of HIV infection associated with sexual activity and injecting drug use, the risk for transmission to the woman's infant if she is infected, and the availability of therapy to reduce this risk." (Source: MMWR 1995;44, No. RR-7) The CDC further states that knowledge of HIV infection during pregnancy can permit treatment before the onset of opportunistic infections and disease progression, as well as early identification and treatment of HIV-exposed infants.

The AAP/ACOG actions strongly suggest that these services should be considered part of the routine standard of care for pregnant women. In our continuing effort to ensure that Medicaid eligible individuals have access to appropriate care based on contemporary standards, we bring these developments to your attention and strongly encourage all States to cover HIV counseling and education, as well as voluntary and informed testing, for pregnant women who are Medicaid eligible. You may wish to review the covered services under your Medicaid plan to determine whether any action is appropriate in your state.

Please feel free to contact me, or the Associate Regional Administrator for Medicaid in your HCFA Regional Office, if you require additional information.

Sincerely,

Sally K. Richardson
Director
Medicaid Bureau

Attachments

cc:

All Regional Administrators
All Associate Regional Administrators,
Division of Medicaid
Director, Health Policy Unit,
American Public Welfare Association
Director, Health Committee,
National Conference of State Legislatures
Senior Policy Analyst, Human Resources Group,
National Governor's Association
Association of Maternal and Child Health Programs

- the potential zeroing out of the Economic Development Initiative--the Department's prime economic development program. HUD seeks \$200 million for this program;
 - the severe funding reduction in HUD's staffing account--apparently set at \$40 million below the President's request--crippling HUD's staffing, staff training, and relocation needs as we move to a reinvented agency;
 - insufficient capital funding for the Department to dramatically reform public housing through demolition and site revitalization;
 - the transfer of HUD's office of Fair Housing and Equal Employment to the Department of Justice;
 - the elimination of federal preferences in the tenant-based Section 8 program; and
 - the arbitrary micromanagement provision requiring HUD to eliminate one Assistant Secretary provision, and capping Schedule C employees at 77.
- **Nation of Islam Asks Federal Court to Halt HUD Decision on Terminating Security Contract:** On November 15th, a security firm associated with the Nation of Islam (NOI) asked a federal court in Maryland to reverse HUD's decision to terminate their contract with the Housing Authority of Baltimore (HABC) to provide security services in the City's public housing developments.

On November 9th, HUD called for the immediate termination of the Nation of Islam Security Agency (NOISA) contract due to the housing authority's violation of federal procurement regulations during the bidding process of the security contract.

Secretary Cisneros taped an interview with NBC Dateline this afternoon, November 17th, to discuss this matter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

- **Newborn AIDS Prevention Pilot Program to be Announced on World AIDS Day.** On December 1, the Health Care Financing Administration (HCFA) will announce the establishment of pilot programs in Delaware, Florida, New York and Rhode Island to reduce the transmission of the AIDS virus (HIV) to newborns. Medicaid eligible pregnant women will be provided with Public Health Service (PHS) information on HIV transmission, testing, and the use of drug therapy to prevent the transmission of HIV from mother to child. Bruce

J. Klein
Pls. get more info.
Pls. also brief
FLOTUS

Vladeck, Administrator of HCFA, will announce the initiative at a press conference, along with a senior PHS representative, who will announce the release of the informational materials.

- **Department Continues Waiver Amendment Negotiations with Oregon:** The Department will continue discussions with Oregon concerning two proposed amendments to the State's current 1115 demonstration program, the Oregon Health Plan. The State seeks to collect premiums from "new" enrollees (those not categorically eligible), but terms for an appropriate exception procedure for hardship cases remain unresolved. Additionally, we are awaiting data from the State before making a decision on whether to permit the State to "raise the line" thereby reducing covered procedures.
- **Discussions Continue with New York State on Medicaid Demonstration Process:** The State of New York continues to press for a rapid decision on its 1115 demonstration proposal. The State is still hopeful that it will be able to enroll the State-only, home relief recipient population in the demonstration by January 1, 1996. On November 13, Health Care Financing Administration (HCFA) officials had a telephone discussion with the Commissioner of Health for the State of New York, and her principal consultant to discuss the ongoing process of waiver negotiations and the effects of the government shutdown on our analytic efforts. We are awaiting data from New York necessary for budget neutrality calculations.
- **New Aids Drug:** Today FDA announced accelerated approval for the drug lamivudine, or 3TC, for use in combination with AZT (zidovudine) in treating AIDS and HIV infection. AZT and 3TC are members of the nucleoside analogue class of drug compounds, and both interfere with the replication of HIV. *Patsy Let's get a plain English memo for POTUS on this drug plus the other recent approval (protease).*
- **Child Support Enforcement:** The Report to Congress on Child Support Enforcement will show record collections in FY 1994 and FY 1995. Collections are up 40 percent since 1992, but \$24 billion more could still be collected.
- **Morbidity and Mortality Weekly Report on Children and Airbags.** CDC will issue an abbreviated Morbidity and Mortality Weekly Report: One article will reiterate warnings that have already received press coverage concerning the safety of children in cars with airbags -- this article is intended to reach audiences prior to Thanksgiving travels. If a second article is published, it will concern HIV-positive drug using men who continue to engage in unprotected sex.

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Jennifer Kline

FAX NUMBER: _____

FROM: JH

DATE: _____

PAGES INCLUDING COVER SHEET: 5

COMMENTS:

Part of an HHS (PHS) plan
Whether this, do all this
is another story . . .

DEPARTMENT OF HEALTH & HUMAN SERVICES
BUREAU OF PRIMARY HEALTH CARE

Public Health Service

Memorandum

Date . AUG 30 1995

From Director

Subject Bureau of Primary Health Care Response to Results of ACTG 076

To Patsy Fleming, Director, White House Office on HIV/AIDS Policy

I appreciate your interest in the Bureau of Primary Health Care's (BPHC) activities regarding the results of ACTG 076. This memorandum serves to update you on our progress.

In February, 1995, a team of staff from several BPHC program areas was formed to create and implement BPHC's response to the results of ACTG 076. The mission of the BPHC team is to ensure that all pregnant women served by BPHC funded programs are offered routine HIV counseling and voluntary testing and that all HIV positive pregnant women served by BPHC funded programs receive appropriate options counseling which includes information about the 076 protocol. In keeping with this mission, the BPHC team created the **Special Strategy: Services for HIV-Infected Pregnant Women and Their Newborns**. The strategy has six major components.

1. **Provider Needs Assessment and Training** - BPHC is working with Bureau of Health Professions (BHPr) to assess the level of knowledge among providers from Community and Migrant Health Centers and other BPHC funded programs about HIV, the 076 protocol, and issues associated with HIV counseling and testing of pregnant women. A needs assessment will be conducted by region using the BHPr's AIDS Education and Training Centers (AETC). HIV seroprevalence will dictate the order in which the regions will be assessed. Due to its high level of seroprevalence, Region II will be the first to receive the needs assessment which is scheduled to occur around October, 1995.

A training and technical assessment package will be designed as a result of the needs assessment and will be delivered in part by the AETC program. Additional training will be supported through the BPHC Clinical Support Strategy.

We are hopeful that all regions will have received both the needs assessment and the training by the end of the FY 1996.

2. **Provide routine HIV Counseling and Voluntary Testing Services for All Pregnant Women Seen in BPHC**

Page 2 - Patsy Fleming

Supported Programs - Our first step for this component is to target all pregnant women for counseling and testing services. Because we recognize the importance of women learning of their serostatus before becoming pregnant, we plan to expand routine HIV counseling and voluntary testing to all women of child bearing age. Eventually, we plan to expand services to all sexually active patients.

3. Case Studies on Model BPHC-funded Programs - The BPHC will develop case studies on model BPHC funded programs that are providing a full range of services to HIV positive pregnant women. These case studies will be distributed to all BPHC funded programs as part of the technical assistance package.

4. Baseline Assessment of Current Practices - The BPHC will conduct an assessment of current HIV counseling and testing practices of pregnant women at BPHC funded programs. This study will examine the number of pregnant clients offered HIV counseling and testing, the number who refuse testing, the number that are HIV+, and the protocols for pregnant women who test HIV positive.

5. Provide AZT to HIV Positive Pregnant Women (and Their Newborns) Who Participate in the 076 Protocol.

6. Provide Care Coordination Linkage Services (via a linkage coordinator, care coordinator, or case manager) for All HIV-Infected Pregnant Women Who Receive Care in BPHC Funded Programs - The Care Coordinator is responsible for determining eligibility for support services and securing support services and funding; tracking the woman throughout her pregnancy, during the intrapartum and postpartum period; tracking the baby through entry into care at the C/MHC or elsewhere; confidential transfer of medical records between the C/MHC and the delivery site; and long term follow up of the mother and baby for one year.

The BPHC is very excited about this strategy and pleased to be working with the AETC program. In addition to our strategy, the BPHC has made several other accomplishments in its response to the results of ACTG 076 (see Attachment A). If you have questions or suggestions about our strategy or the attached list of accomplishments, please feel free to contact me.


Marilyn H. Gaston, M.D.
Assistant Surgeon General

Attachment

**BPHC ACCOMPLISHMENTS TO IMPLEMENT STRATEGIES TO DECREASE
PERINATAL TRANSMISSION OF HIV
August 28, 1995**

INFORMATION DISSEMINATION

1. Dr. Gaston sent a letter to all BPHC funded programs containing information about the results of ACTG 076 and its clinical implications. (6/94)
2. BPHC issued the Policy Information Notice (PIN# 94-44), "Services for Patients with HIV," to all BPHC funded programs encouraging providers to care for people with HIV. The notice included a description of the results of ACTG 076. (9/94)
3. BPHC sent the draft document "USPHS Recommendations for HIV Counseling and Testing for Pregnant Women" to all Ryan White Title III(b) grantees. (3/95)
4. BPHC has been working with OA/OASH/AHCPR to develop the PHS 076 media campaign. (ongoing since 3/95)
5. Dr. Gaston presented the BPHC 076 strategy to the HRSA AIDS Advisory Committee. (5/95)
6. BPHC distributed an article on the Results of ACTG 076 to all BPHC funded programs through the newsletter "HIV FOCUS". (8/95)
7. BPHC developed a slide presentation on the BPHC 076 Strategy. (8/95)

PLANNING

1. BPHC contributed to the HRSA 076 Implementation Plan. (1/95)
2. A team of BPHC staff was created to develop and implement a BPHC 076 strategy. (ongoing since 3/95)

Team Members include: Carolyn Aoyama, Magda Barini-Garcia, Sharon Barrett, Diane Cairns, Mechelle Johnson, Patricia Milon, Deborah Parham (Chair), Pat Salomon, Nate Stinson, and Terri Watkins
3. BPHC staff serve on the HRSA Working Group on Prevention of Perinatal Transmission of HIV which was formed to coordinate policy development and implementation for HRSA funded programs regarding the results of ACTG 076. Magda Barini-Garcia serves as a representative to the workgroup and Terri Watkins is the alternate. (ongoing)

4. A FY 1997 budget for the BPHC 076 strategy was prepared and submitted. (5/95)
5. BPHC staff participated in the CDC sponsored meeting, "Implementation and Evaluation of USPHS Recommendations for Counseling and Testing of Pregnant Women, Prevention of Perinatal Transmission, and Links to Care of HIV-Infected Women and Children." (7/95)

TRAINING AND TECHNICAL ASSISTANCE

1. BPHC notified all of its funded programs about the AETC 1-800 number. (4/95)
2. BPHC encouraged all of its funded programs to participate on the International HIV Conference Call on June 8, 1995 which focused on the results of ACTG 076. (6/95)
3. BPHC coordinated a clinical conference on ACCESS (BPHC's electronic bulletin board) regarding the results of ACTG 076. (pending)
4. BPHC conducted training sessions on the 076 protocol at the Ryan White Title III(b) Grantee Meeting. (8/95)
5. BPHC shared information about 076 at the PCP/PCA meeting (7/95) and will present information at the National Association of Community Health Centers meeting. (9/95)

SYSTEM DEVELOPMENT

1. BPHC met with the Glaxo-Wellcome Company to discuss the possibility of the company supplying AZT to pregnant women and infants who are receiving care at BPHC funded programs. (6/95)

MONITORING

1. BPHC incorporated the results of ACTG 076 as part of the clinical outcome measure data required to be collected by its Community and Migrant Health Centers, Health Care for the Homeless Programs and Health Care for Residents of Public Housing Programs.
2. BPHC incorporated a review of the 076 protocol into its Primary Care Effectiveness Review (PCER) Document. The PCER is used to evaluate all BPHC funded programs.

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO:

Jennifer Klein

FAX NUMBER:

FROM:

J. J. Fero

DATE:

9/27/95

PAGES INCLUDING COVER SHEET:

4

COMMENTS:

**The American Academy of Pediatrics****The American College of
Obstetricians and Gynecologists****JOINT STATEMENT
OF****THE AMERICAN ACADEMY OF PEDIATRICS
THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS**

The HIV/AIDS epidemic is increasing in women of childbearing age and spreading beyond previously defined risk groups and geographic areas. This increase has been paralleled by a similar increase in children. We applaud congressional concern for and support of efforts to prevent the spread of the AIDS epidemic, but urge that the emotion of this complex issue not overshadow the doctor/patient relationship which is the foundation to providing effective and efficient medical care to these women and children.

As the primary caretakers of this population, both the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) strongly believe that the answer lies in an aggressive HIV education and counseling initiative, not in governmental medical protocols. The best defense is a strong offense. We recommend that all pregnant women should receive HIV education and counseling as part of their regular prenatal care. We further recommend HIV testing in all pregnant women with their consent. In the event of refusal of testing, this should be documented.

Clear medical benefits of knowing the HIV status of pregnant women and newborns have been documented. Treatments are currently available to significantly reduce the HIV transmission from mother to infant (zidovudine/AZT). This finding represents the most important medical breakthrough in this area in recent years. In addition, the lives of the infants, not protected by the AZT treatments in utero, may be prolonged by initiating medical care within the first months of life. For newborns whose mother's HIV status was not determined during pregnancy, the infant's health care provider should educate the parent(s) concerning HIV testing and recommend HIV testing for the newborn.

We believe that this is the most viable and prudent approach in resolving this important issue. We welcome the opportunity of working with policy makers in this regard.

Approved: August 1995

The American Academy of Pediatrics 202/347-8600

The American College of Obstetricians and Gynecologists 202/863-2509

CDC HIV/AIDS PREVENTION

CENTERS FOR DISEASE CONTROL AND PREVENTION

September 27, 1995

**"Prevalence and Incidence of Vertically
Acquired HIV in the United States"**
Journal of the American Medical Association

Data published in the September 27, 1995 issue of the *Journal of the American Medical Association (JAMA)* define both the magnitude of the current HIV epidemic among children and the number of future infections that could be prevented if women are reached early in pregnancy with the opportunity to learn their HIV status and consider treatment.

Need for Services and Care

CDC estimates that over 14,920 HIV-infected infants were born between 1978-1993, and an estimated 12,240 (82%) were living as of January 1994. More than half of these children were born after 1988 and thus were younger than 5 years of age. These results provide a basis for determining the medical and other resource needs required to care for these children.

Defining the Epidemic in Children

The epidemic in children is closely associated with the epidemic in women. Vertical transmission (from mother to child during pregnancy, labor, and delivery, or by breastfeeding) accounted for 92 percent of all new AIDS cases reported in children in 1994. Without preventive treatment, the mother-to-child transmission rate is within the range of 15-30%.

These data indicate that as the HIV epidemic grew among childbearing women in the 1980's, the incidence (number of estimated infections each year) of HIV infection in children increased dramatically. In 1978, an estimated 70 babies were born infected with HIV. Since 1986, estimates have begun to level at between 1,100-1,760 children born infected each year (assuming a mother-to-infant transmission rate of 25%).

Estimating the Impact of Prevention

A breakthrough study last year showed that some pregnant women who are infected with HIV but don't yet have any signs of AIDS can reduce the chances of transmitting HIV to their babies by as much as two-thirds if AZT therapy is begun early in pregnancy, continued through labor and delivery, and provided to the child

SEP-28-95 20:32 FROM AIDS POLICY CENTER
SEP. -26'95(TUE) 12:12

ID:2027853579

PAGE 4/4
P.003

for the first 8 weeks of life.

In the current JAMA analysis, CDC researchers estimate that as many as 1,200 HIV infections in children could be prevented each year with AZT treatment. The authors conclude that "Now with the opportunity to reduce the risk of vertical transmission with zidovudine, it is even more important to develop strategies to ensure that all pregnant women are offered HIV testing."

In July 1995, to provide pregnant women with the opportunity to learn their HIV status as early in pregnancy as possible, the Public Health Service (PHS) issued guidelines calling for routine counseling and voluntary HIV testing for all pregnant women. If women do not receive prenatal care, or if for any reason their HIV status is unknown at the time of delivery, the guidelines recommend that HIV testing be offered to them or their babies at or shortly after delivery. Implementing these guidelines will reduce the number of children who get AIDS. Just as important, targeted prevention programs for women are critical for the health of both women and children. The best way to prevent infection in babies is to prevent infection in women.

Role of Surveillance

These surveillance data have allowed us to define the scope and nature of the epidemic in women and children, determine their health care resource needs, and to develop and target prevention programs to those who need them. As the PHS guidelines are implemented and new prevention programs are initiated, surveillance will continue to play a critical role in ensuring that prevention efforts are working and that resources are directed where they do the most good.

**HEALTH CARE FINANCING ADMINISTRATION****ADDRESSEE:***Jennifer Klein*PHONE: 456-2878**FROM:***Anne Wade*
OFFICE OF THE ADMINISTRATOR
200 INDEPENDENCE AVE., S.W.
ROOM 314G
WASHINGTON, DC 20201PHONE: 202-690-6726
FAX : 202-690-6262**TOTAL PAGES:***1+C***ADDRESSEE'S FAX MACHINE NUMBER:****DATE:***8/10/95***REMARKS:***Jennifer,**Per your request.**Anne*

**JOINT STATEMENT
OF
THE AMERICAN ACADEMY OF PEDIATRICS
THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNCOLOGISTS**

The HIV/AIDS epidemic is increasing in women of childbearing age and spreading beyond previously defined risk groups and geographic areas. This increase has been paralleled by a similar increase in children. We applaud congressional concern for and support of efforts to prevent the spread of the AIDS epidemic, but urge that the emotion of this complex issue not overshadow the doctor/patient relationship which is the foundation to providing effective and efficient medical care to these women and children.

As the primary caretakers of this population, both the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) strongly believe that the answer lies in an aggressive HIV education and counseling initiative, not in governmental medical protocols. The best defense is a strong offense. We recommend that all pregnant women should receive HIV education and counseling as part of their regular prenatal care. We further recommend HIV testing in all pregnant women with their consent. In the event of refusal of testing, this should be documented.

Clear medical benefits of knowing the HIV status of pregnant women and newborns have been documented. Treatments are currently available to significantly reduce the HIV transmission from mother to infant (zidovudine/AZT). This finding represents the most important medical breakthrough in this area in recent years. In addition, the lives of the infants, not protected by the AZT treatments in utero, may be prolonged by initiating medical care within the first months of life. For newborns whose mother's HIV status was not determined during pregnancy, the infant's health care provider should educate the parent(s) concerning HIV testing and recommend HIV testing for the newborn.

We believe that this is the most viable and prudent approach in resolving this important issue. We welcome the opportunity of working with policy makers in this regard.

REVISED DRAFT

HCFA ACTION PLAN TO PROMOTE IMPLEMENTATION OF CDC GUIDELINES ON HIV COUNSELING AND TESTING FOR PREGNANT WOMEN

1. SURVEY OF STATE MEDICAID AGENCY ACTIVITIES

HCFA's Medicaid Bureau and Regional Offices have developed, and will conduct, a comprehensive survey of State Medicaid agency activities to promote implementation of the counseling and testing guidelines, and the use of AZT to reduce perinatal transmission of HIV. The survey will assess Medicaid coverage and reimbursement policies, outreach activities, and inter-agency coordination at the State level. An initial survey of the "high impact" states has been completed; further refinement and targeting of comprehensive survey will be done based on these results.

Timeframe: Initial survey completed by August 3; additional surveys to be conducted based on those results.

2. LETTER TO ALL STATE MEDICAID DIRECTORS

A letter will be sent from the Director, Medicaid Bureau to all State Medicaid Directors. The letter will identify voluntary testing for HIV and counseling for pregnant women as the standard of care based on recently released CDC guidelines on HIV testing and counseling, as supported by the joint statement from the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) supporting and promoting voluntary testing/counseling as the most viable, prudent approach. The letter will strongly encourage HIV testing and counseling for pregnant women within the State Medicaid programs and will include the joint AAP/ACOG statement as an enclosure.

Timeframe: September 1

3. 076 CONSUMER INFORMATION STRATEGY

HCFA is working with States to facilitate development of three State-designed pilot programs to disseminate information to Medicaid-eligible women on the use of AZT during pregnancy to reduce perinatal HIV transmission. Delaware and Rhode Island have agreed to participate, and negotiations are underway to add a third state (New Jersey is a strong possibility). An intra-agency workgroup (HCFA, HRSA, CDC and AHCPR) has developed materials to be distributed under the auspices of the State pilots through State Medicaid programs and a variety of outreach settings. These materials include consumer information translated into appropriate languages, and audio/video/newspaper-ready public service announcements. The pilots will demonstrate the effectiveness of the materials and outreach strategies targeting Medicaid eligible pregnant women and Medicaid providers, which can then be adapted and replicated in other

states.

Timeframe: Consumer information and other publicity material are almost finalized (AHCPR lead). Printing, production and distribution will be completed by end of October 1995. The pilots are scheduled to begin on December 1, World AIDS Day, with kick-off announcements in Washington, DC and three pilot states. Pilots to be completed by end of March 1996.

4. HCFA PHS WORKGROUP

HCFA and PHS will establish a workgroup to identify and resolve policy and operational issues in an effort to promote better coordination on AIDS issues; including coordination between Ryan White and Medicaid programs, specifically focusing on implementation of the CDC guidelines on counseling, testing and AZT for pregnant women. Better coordination of federal policies and actions will foster improved coordination at the state level. HCFA will also use information generated by the workgroup to regularly communicate with State Medicaid agencies on improving Ryan White/Medicaid coordination.

Timeframe: Can begin immediately; ongoing

5. PERIODIC EVALUATION OF STATE MEDICAID AGENCY IMPLEMENTATION

Results from the first three activities will provide the basis for regular evaluation of State Medicaid agency implementation efforts, and the collection and analysis of State-level data to measure outcomes among pregnant women served by Medicaid. We will develop an evaluation design in collaboration with other Departmental agencies and States, and conduct the evaluation through HCFA Regional Offices.

Timeframe: Evaluation design can begin once first survey is completed. Need to determine periodicity for evaluation activity.

6. QUALITY IMPROVEMENT INDICATORS FOR MEDICAID MANAGED CARE PLANS

CDC is developing strategies to promote managed care plan's use of the CDC guidelines on counseling, testing and the use of AZT during pregnancy. HCFA has been working with States to develop quality improvement and performance measures for Medicaid managed care plans through the Quality Assurance Reform Initiative (QARI), terms and conditions for statewide health care reform waivers ("1115 waivers"), and the development of a new version of HEDIS for use by State Medicaid programs. HCFA and CDC, along with other interested parties, will discuss the feasibility of performance measures and quality improvement projects relating to the CDC guidelines.

Timeframe: Six months

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Jennifer Klein

FAX NUMBER: _____

FROM: Jeff Lewis

DATE: 8/4/95

PAGES INCLUDING COVER SHEET: 3

COMMENTS:

We cover it... but we won't
tell anyone — Seems to be
the result of this survey.

DRAFT

**RESULTS - INITIAL SURVEY OF STATE MEDICAID AGENCIES
COVERAGE AND OUTREACH FOR HIV TESTING AND AZT FOR PREGNANT WOMEN
AUGUST 4, 1995**

This survey was conducted by HCFA Regional Office Staff based on questions developed by the HCFA Central Office and the White House AIDS Coordinator's Office. The final version will be discussed at the August 10, 1995 meeting in OEOB by HCFA representatives. A detailed survey instrument with more specific questions pertaining to coverage, access to services, and financing issues is undergoing final review; its status will also be discussed at the 8/10 meeting.

1. Does the State Medicaid Agency generally cover HIV counseling and testing for pregnant women without regard to presentation of symptoms of HIV/AIDS?

STATE	Q.1
Connecticut	Y
Massachusetts	Y
Rhode Island	not available
New Jersey	Y
New York	Y
Puerto Rico	not available
DC	Y
Delaware	Y
Maryland	Y
Florida	Y
Georgia	Y

2. (A) Has the State Medicaid Agency initiated any outreach campaigns to inform pregnant or HIV positive women about the 076 protocol, or about Medicaid coverage of the 076 protocol?

(B) If not, are there plans to do so?
3. Has the State Medicaid Agency participated with other State or Federal agencies in outreach campaigns to inform pregnant or HIV positive women about the 076 protocol or about Medicaid coverage of the 076 protocol?

07/09/1992 06:10 4104853726

U S TAG & LABEL

PAGE 03

STATE**QUESTION****(2A)****(2B)**

Connecticut	N	N
Massachusetts	N	Y (with Health Department)
Rhode Island	Y*	-
New Jersey	N (Health Dept function)	N(Health Dept function)
New York	N (Health Dept function)	N(Health Dept function)
Puerto Rico	not available	.
DC	N	N
Delaware	Y*	.
Maryland	N (Health Dept function)	N(Health Dept function)
Florida	N	N
Georgia	N	N

NOTE: Answers to #3 are combined with answers to 2A or 2B, as appropriate

(* State is a pilot site for HCFA's Maternal AIDS Consumer Information Strategy Initiative)

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

04-Aug-1995 05:42pm

TO: Jennifer L. Klein

FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: Medicaid coverage of testing

Patsy just spoke to Bruce Vladeck: HCFA is going to send out a letter to the states saying that since routine counseling and testing of pregnant women is the state of the art -- counseling and testing is now considered medically necessary! It pays to have the right person asking the lawyers the questions!

The survey I just faxed you is still interesting...focusing on outreach is definitely the next step.

Stay cool this weekend.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROPOSAL

This proposal provides the framework for a comprehensive federal response to the issues of maternal and newborn testing for HIV. The key issues are: 1) early identification of HIV-infected pregnant women so that preventive AZT therapy can be offered; 2) early identification of HIV-exposed newborns so that prophylactic treatment for infections may be started; and 3) a surveillance capacity that can evaluate how effectively PHS guidelines are implemented by health providers, and tracks the epidemic's movement among women and children.

COMPONENTS

- I. **Aggressive implementation of PHS guidelines for counseling and testing among all PHS agencies.** PHS programs serve the majority of women at highest risk for HIV infection. Extensive outreach to States and private providers to support uptake and implementation of the recommendations.
- II. **Discretionary grant program to assist States with highest incidence of HIV+ childbearing women to implement the guidelines.** House and Senate proposals provide \$10 million for 3-5 years.
- III. **Design a protocol for health care providers to follow when confronted with a mother who refuses testing for her infant.** A clear sequence of steps to be taken that attempts to address and resolve mother's reasons for refusal, while providing clinicians a clear endpoint at which it is reasonable to request a court order if necessary. This supports engaging mothers who ultimately must provide treatments, and protects children's needs.
- IV. **Maximal involvement of Medicaid to support reimbursement for counseling, testing and drug therapies.**
- V. **Modified surveillance tool to assess the extent of the HIV epidemic among childbearing women and infants, and evaluate implementation of PHS recommendations.** CDC is designing this tool now. If it involves blinded testing of infants, parallel offering of counseling and testing to mothers must be assured.

THE WHITE HOUSE
WASHINGTON

Meeting on Preventing Perinatal Transmission of HIV

3 p.m.
July 21, 1995

Agenda

Summary of Atlanta consultation on PHS guidelines regarding preventing perinatal transmission

Status of decision making regarding child-bearing women survey

Status of Coburn amendment to Ryan White CARE Act

Assuring access -- PHS and HCFA plans for:

Outreach
Increased access to counseling and testing
Linkage to services

Discussion of policy options regarding newborns whose mothers' HIV status is unknown

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION**



REGIONAL OFFICE AIDS COORDINATORS

REGION I

JFK Building, Room 2375
Boston, MA 02203

BOSTON

617/ 565-1198
fax 565-1339

SARAH ANN TAYLOR- CHARVIS

REGION II

28 Federal Plaza Room 38-130
New York NY 10278

NEW YORK

212/ 264-2775
fax 264-2580

STEVE SHAW

REGION III

3535 Market Street Room 3450
Philadelphia, PA 19104

PHILADELPHIA

THERESA RUBIN

215/ 596-1300
fax 596-5084

REGION 1V

101 Marietta St. (404)730-2733
Atlanta, GA 30323

ATLANTA

MICHAEL MCDANIEL MAL WILLIAMS

404/ 331-5889
fax 331-0068

REGION V

105 W. Adams St.
Chicago, IL 60603

CHICAGO

BOB WHITELOCK

312/ 353-1589
fax 353-5927

REGION VI

1200 Main Tower Suite 2000
Dallas, TX 74202

DALLAS

JERRY TAYLOR

214/ 767-0263
fax 737-8400

REGION VII

601 E. 12th, Room 227
Kansas City, KS 64106

KANSAS CITY

JAMES SCOTT

816/ 426-3406
fax 426-3851

REGION VIII

1961 Stout St., Room 1185
Denver, CO 80294

DENVER

STEPHEN BLAKE

303/ 844-6216 (x377)
fax 844-3753

REGION IX

75 Hawthorne St., 5th floor
San Francisco, CA 94105

SAN FRANCISCO

CASEY JONES

415/ 744-3600
fax 744-3761

REGION X

2201 6th Ave., M/S RX-43
Seattle, WA 98121

SEATTLE

LIZ TRIAS

206/ 615-2340
fax 615-2435

**QUESTIONS ABOUT: MEDICAID MEDICARE
HEALTH STANDARDS & QUALITY
DISCRIMINATION BY A PROVIDER
COMPLAINTS ABOUT QUALITY OF CARE**

**Maternal AIDS (076) Project
Health Care Financing Administration**

Purpose: To develop and implement a fast-track campaign to inform HIV-infected, Medicaid-eligible pregnant women and their providers about the value of AZT therapy, in order to significantly reduce the transmission of the HIV virus to their infant(s).

Background:

There are approximately 18 million Medicaid-eligible women in the United States. Of these, 32,000 are estimated to have HIV/AIDS. Preliminary estimates from CDC and OACT indicate that there may be 3000 HIV-infected, Medicaid-eligible women giving birth each year. Mother-to-infant HIV transmission has been shown to be the primary cause for pediatric AIDS. Approximately 7000 infants are born to HIV-infected women each year in this nation, and 25% of these infants become HIV-infected themselves during the course of pregnancy and delivery.

Medicaid is estimated to cover nearly 90% of those persons under 18 years of age with HIV/AIDS, most of whom contracted the disease prior to or during birth. HCFA therefore has a strong and compelling interest in preventing HIV transmission in this group. The agency can play a major role in encouraging the clinical application of major scientific findings that can effectively reduce such transmission.

The NIH-sponsored AIDS Clinical Trials Group Protocol 076 recently demonstrated in a randomized, double-blind clinical trial that oral administration of Azidothymidine (AZT) to HIV-infected women during pregnancy, and to their infants in the six weeks following delivery, resulted in a 66% reduction in transmission of HIV to the infants.

As a result of these dramatic findings, the White House AIDS Office and the Department of Health and Human Services has urged all appropriate federal agencies to establish, and conduct on a fast-track basis, efforts to increase patient and provider knowledge about the 076 trial and encourage rapid implementation of its findings in standard clinical obstetrics care through informed, empowered decision-making by pregnant women (in consultation with their providers).

HCFA has already significantly contributed to federal efforts in this area by sending a letter on December 5, 1994, to all State Medicaid Directors informing them of the 076 trial, and the importance of assuring AZT therapy for HIV-infected, Medicaid-eligible pregnant women (attached).

Overview:

We are conducting a small, multi-level (Central Office, Regional Office(s) and specific States) Maternal AIDS pilot project under the general oversight of the Consumer Information Strategy Initiative. The HCFA AIDS project focuses on the development of informational materials to alert Medicaid-eligible, HIV-infected pregnant women in selected states of the benefits and implications of AZT therapy and to assist them, in conjunction with their health care providers, in making an informed decision on AZT therapy. The goal, in concert with the activities of the other federal and state agencies, is to reduce as much as possible mother-to-infant HIV transmission in the United States.

Sites:

We have used CDC AIDS prevalence estimates, Medicaid databases and actuarial estimates to focus our campaign efforts on HHS Regions I - IV (the Northeast and Southern regions), where female HIV prevalence is highest (attached). In consultation with the HCFA AIDS Coordinators in those regions, we have identified three states (Rhode Island, Delaware and South Carolina) where we can implement our campaign. We have begun discussions with Medicaid agency officials in those states, and are incorporating their advice in operational aspects of this project, including the development of informational materials and dissemination strategies.

Materials:

Specific data-related activities will include development of surveys, tables and maps identifying female HIV prevalence, Medicaid eligibility, HIV counseling/testing and AZT coverage patterns (by state) under Medicaid, and/or identification of obstetrics-oriented providers by jurisdiction. Much of this information will be derived from a detailed survey (in final development), which will allow HCFA (through its Regional AIDS Coordinators) to followup on state implementation of 076-related efforts subsequent to their receipt of the December 5 State Medicaid Director letter.

Specific information products to be disseminated will include those referred to above, as well as PHS (AHCPR, CDC or NIH) guidelines on the use of AZT during pregnancy, which will be produced in audio, video and print form. They will be modified to include information on reimbursement under Medicaid programs, and provide 1-800 contact numbers for individuals to obtain further Medicaid-related information.

The information products will be primarily targeted at Medicaid-eligible, HIV-infected pregnant women by the participating states in partnership with HCFA regional and central office staff. The information will alert recipients to the benefits and risk potential of AZT therapy, inform them of the availability of Medicaid coverage for the service, reinforce the concept of their making an informed choice, and encourage them to follow-up with their health care provider. Secondary target groups will include providers, state offices and media outlets which are seen most often by Medicaid-eligible women.

Timeframe:

We envision that the project will take three months to complete. We anticipate launching the project on December 1, 1995 (World AIDS Day). The launch will include the issuance of press releases, video/audio PSA's, and distribution of informational materials to target audiences (beneficiaries, providers and media outlets) through the involved states. An evaluation instrument will be developed to assess effectiveness of the pilot project, and results of that evaluation will be utilized in determining potential expansion of the project on a national basis in 1996-7.

Participants:

In order to successfully complete this task, we have established an 076 workgroup to oversee project activity development (attached). This workgroup is comprised of participants from Central Office components (MB, AACRC, OACT, ORD, OLIGA, etc.), Regional Offices, and will also include state Medicaid agency representatives from Rhode Island, Delaware and South Carolina. The workgroup meets at least once each month to coordinate the project, with significant inter-meeting time commitment necessary from key components (MB, RO's and the selected States).

We are also establishing ongoing liason activities for this project with key staff from both public sector organizations (PHS, APWA, SMDA, etc.) private sector groups (ACOG, AAP, AAFP, NMA, Burroughs-Wellcome, etc.). Through our state partners, we will also closely link our efforts with community groups in order to maximize material distribution and recipient participation. Much of our effort is being simultaneously coordinated with efforts of other agencies within DHHS, and the White House AIDS Office. We will therefore need to be flexible in our objectives and activities as the campaign is being developed, in order to maximize the efficacy of our efforts.



6325 Security Boulevard
Baltimore, MD 21207

DEC 5 1994

* Dear State Medicaid Director:

The purpose of this letter is to encourage States to make available adequate coverage of drugs for Medicaid eligible persons living with AIDS and HIV infection. Additionally, this letter provides new information concerning the use of AZT (Zidovudine) to prevent perinatal transmission of AIDS.

The optional drug benefit is offered by every State, with 39 States covering both the categorically and medically needy populations. While it is within the discretion of each individual State to establish certain limitations on the provision of drugs under the boundaries of the drug rebate program, the effect on Medicaid AIDS and HIV infected patients can have serious ramifications. If there are excessive limits on drug prescriptions, such as limiting the number of refills, limiting the quantity of each prescription and limiting the number of prescriptions in a given month, the access of Medicaid AIDS and HIV infected patients to medically necessary and appropriate therapies is diminished.

Furthermore, some States may restrict access to prescribed drugs by requiring prior authorization for off-label uses. Because a great deal of standard HIV care depends heavily on off-label drug use, restriction of these drugs can result in the denial of effective drug therapies for Medicaid AIDS and HIV infected patients. Accordingly, we encourage States to examine their drug benefits to ensure the limitations do not excessively and unreasonably restrict coverage of effective treatments for AIDS and HIV infected individuals.

In addition, I would like to inform you that the Food and Drug Administration (FDA) recently amended the approved indications for the use of AZT to include the inhibition of maternal-fetal transmission in HIV positive women. Perinatal transmission accounts for most HIV infection among children. In the United States, approximately 7,000 HIV-infected women give birth each year with an estimated transmission in 25 percent of these births. In efforts to seek effective interventions,

Page 2 - State Medicaid Director

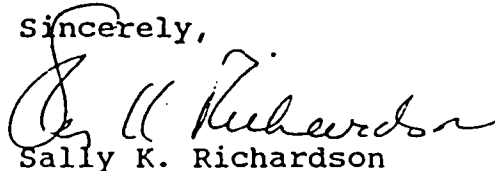
NIH funded the AIDS clinical trial protocol 076, which demonstrated that under specified conditions, AZT reduced the rate of maternal-fetal transmission by two-thirds.

Under the drug rebate program, States are required to cover medically accepted indications of FDA approved drugs and off-label uses which are accepted by one or more of the compendia listed at section 1927(g)(1)(B)(i) of the Social Security Act. As such, States are required to cover AZT for the prevention of perinatal transmission of HIV.

HCFA has long been concerned with the objective to assure that Medicaid eligible individuals living with HIV infection or AIDS have access to appropriate benefits which should be available under the program. Similarly, HCFA is interested in improving and assuring optimal birth outcomes. In ensuring access of Medicaid eligible AIDS patients to effective drug treatments which now includes the use of AZT to prevent maternal-fetal HIV transmission, HCFA is striving to meet both of these objectives. I would like to encourage State participation in this endeavor.

If you have any questions concerning Medicaid drug coverage for AIDS patients, please contact your HCFA Regional Office.

Sincerely,



Sally K. Richardson
Director
Medicaid Bureau

cc:

All Regional Administrators
All Associate Regional Administrators
Division of Medicaid
Director, Health Policy Unit
American Public Welfare Association
Director, Health Committee
National Conference of State Legislatures
Senior Policy Analyst, Human Resources Group
National Governors' Association
Association of Maternal and Child
Health Programs

Figure 1. Male adult/adolescent AIDS annual rates per 100,000 population, for cases reported in 1993, United States

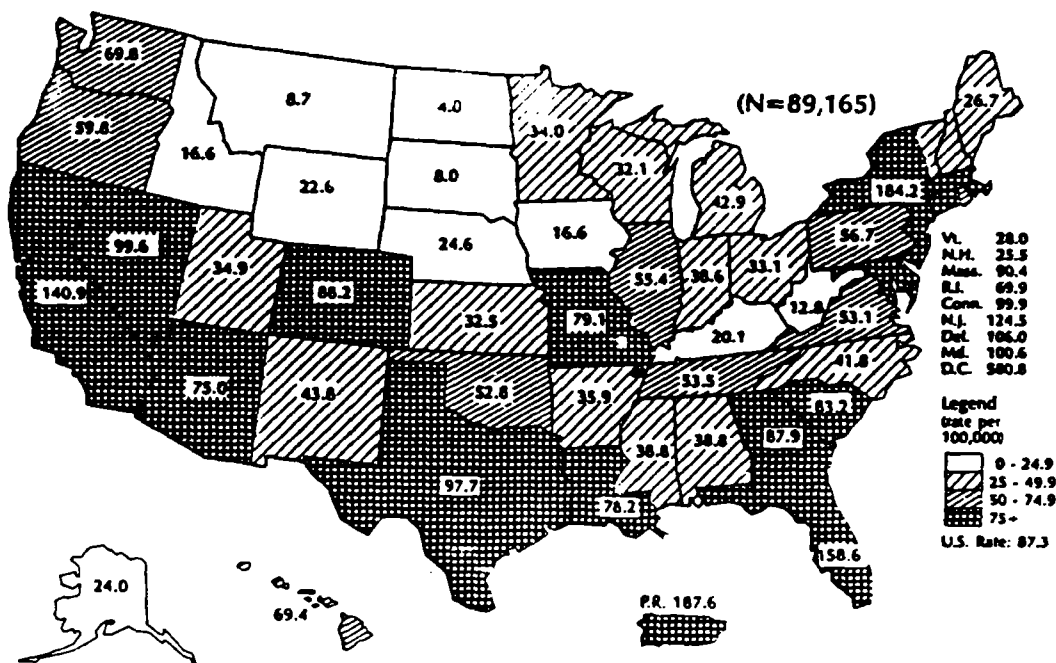
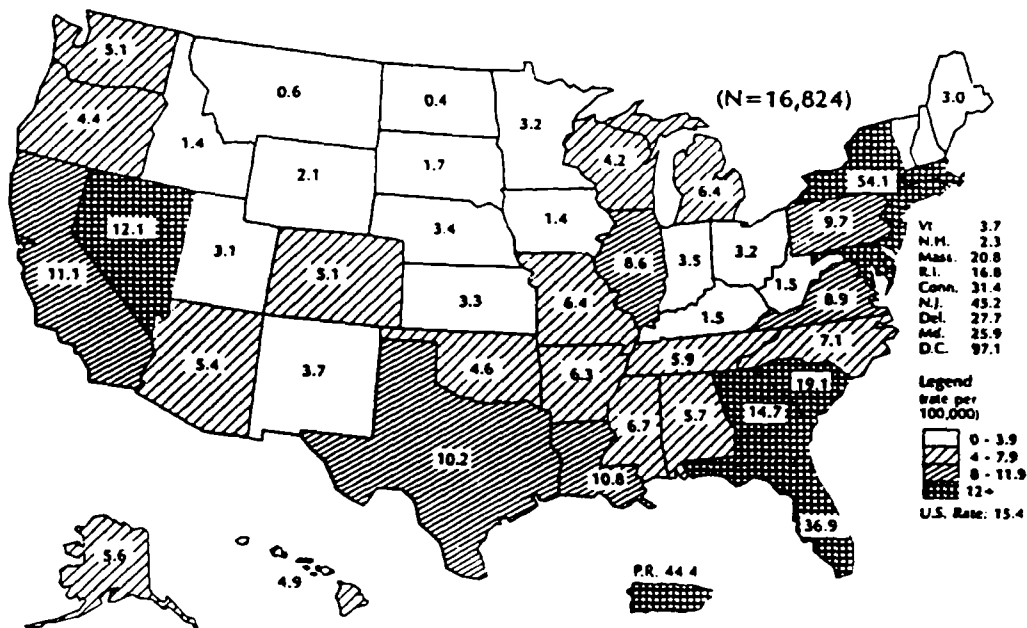


Figure 2. Female adult/adolescent AIDS annual rates per 100,000 population, for cases reported in 1993, United States



Office of HIV/AIDS Policy

Office of the Assistant Secretary for Health

U.S. Public Health Service/DHHS

200 Independence Avenue, S.W.

Washington, D.C. 20201

Tel. (202) 690-5560



☐ Room 733-E
Fax. (202) 690-6584

☐ Room 730-E
Fax. (202) 690-7560

Deliver to:

Jennifer Klein

Fax:

456-2878

Tel:

From:

Erie Gersh, MD

Date:

Call HEC -

- Coburn Am
Thursday
- Strong statement
of Admin. steps
(July 11-12)
meeting

This fax contains 20 pages + cover

If transmission problems occur, please call _____

Comments:

As requested.

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
C D C	Consumer Advocacy Groups and Providers	C&T Guidelines for Pregnant women	Publication Changes from comment period incorporated. Final sent to MMWR - negotiating pdate	To be published July 7, 1995
Contact: Melissa Sheppard (404) 639-0956	Consumer/Media	C&T Fact Sheet	Released to Media and Public	February 1995
	Consumer	Evaluation of Effectiveness	RFP to assess acceptance of CT and ZDV therapy	May 1995
	Consumer/Pregnant Women	PSA/Brochure with Pediatric AIDS Foundation	Released at WH by Glasser/Hilary Clinton	May 11, 1995

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
C D C	Health Care Professionals	502- Co-op Agreement with Georgetown U to provide information on CT pregnant women to medical schools (train the trainer program)	Funded	June 1995
	Community Planning Groups	Discussion on 076 and CT guidelines	Workshop held during March meeting	March 1995
	Community Planning Groups	Fact sheet for community planning grp co- chairs/CBOs	In development- epidemiology, risk- behaviors, treatment, prevention info	Draft due to Dr. Curran June 8

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
CDC Contact: Melissa Sheppard (404) 639-0956	Consumer	Perinatal Transmission studies	Assess effect ZDV i A on perinatal transmission	
	Consumer	International Clinical Trials	Eval. practical interventions for developing countries	

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
A H C P R (with other PHS Agencies)	Consumer	Consumer Guide on ZDV Therapy	Draft pilot tested in 400 women by Columbia U. Results of pilot due week of June 5 Comments from PHS rec'd.	Revisions done in June
	Consumer	4 Targeted Pieces	In revision -shorten	June 1995
	Consumer	Consumer Guide on ZDV Therapy	Final Product Distribution	Mid-July 1995
	Consumer	Video Tapes 10 minutes each	3 of 5 shot	Mid-June
	Consumer	PSAs	in progress	End of June
	Consumer	Audio Tapes	in progress	Mid - June

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
Contact: Peter Garrett (301) 594-1364 x 173	Consumer/Provider	Distribution Plan	Developing Plan	

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
H C F A Contact: Samuel Shaker, MD (202) 690-5727	State Medicaid Directors	Letter re covering AZT for HIV+ pregnant women	Done	December 1994
	State Medicaid Directors	Distribute AHCPR Consumer Guidelines	AHCPR Guideline in Progress	July 1995

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
H R S A Contact: Russell Gerber, MD (301) 443-4588	Providers	Letter to Grantees on results of 076		June 1994
	Providers	require grantees to provide C&T and offer ACTG 076	Letter to grantees from Sumaya	January 1995
	Providers	Program Advisory on ZDV therapy as standard of care for grantees	Draft being reviewed by HRSA AIDS Advisory Committee	June 1995
	Providers	Technical Assistance to States and Title I EMSs	Dev. implementation strategies	Ongoing
	Consumers/ Providers	Bureau specific implementation plan	Bureaus planning process in progress	Ongoing

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
	Providers	AETC Provider Guide	Being developed by AETC and Columbia U	Field test - September 1995
H R S A	Providers	AETC National Plan for training providers	All AETC's have plans filed with HRSA - some revisions in progress	June 1995
	Providers	AETC International State of the Art Clinical Conference Call on 076 implementation		June 1995
Contact: Russell Gerber, MD (301) 443-4588	Grantees (BHRD)	Annul Meeting RWCA Title I and Title II - Plenary and Workshops on 076		June 1995

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
H R S A	Grantees (BHRD)	SPNS Project for Comprehensive Care Services for Women including ACTG 076	Grantees hiring staff, developing programs and evaluation tools	Funded
	Grantees (MCHB)	AMCHP Survey of State DOH on guidance for C&T and provision of care for ACTG 076	Draft Survey went out 3/95 - Report being reviewed by MCHB and HRSA.	September 1995
Contact: Russell Gerber, MD (301) 443-4588	Grantees (BPHC)	Publish Newsletter notifying grantees about 076	Under development	June 1995

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
	Grantees (MICHB)	WIN-Women's initiative for HIV Care and Reduction of Perinatal HIV transmission	6 Projects receiving awards	Funded June 1, 1995

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
I H S Contact: Emmett Chase (505) 837- 4116	IHS Providers	Distributed info on 076 results and TA recommendation - ACOG input on recs.	Offering TA to all HIV+ preg. women	

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
N I H	Providers Consumers	Treatment Guidelines	Done	August 1994
	Providers	Publication ACTG 076 results	Done	November 1994
Contact: Robert Eisinger, Ph.D. (301) 402-8655 (with other PHS Agencies)	Providers Consumers	Technical Assist. to Med. Orgs. and consumer grps.	Ongoing	
	Consumer	US/ International Clinical Trials	Evaluation of prevention interventions	Ongoing and planned trials
	Providers Consumers	International HIV Prevention Proj.	Investigator meeting	Summer 1995
	Consumers	Prospective long term follow-up of infants in 076 ACTG		Ongoing

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
N I H	Consumers	Prospective studies for follow-up of adult women in ACTG 076 for 3 yrs post delivery		Ongoing

**HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND
IMPLEMENTATION OF 076**

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
S A M H S A Contact: Cynthia Prather (301) 443-5305	Providers	Letter to Grantees	Recommendations being developed for approval by Administrator	
	Providers	Implementation Plans	Internal meeting to discuss implementation plans	Week of June 5

Prepared by: Johanne Messoré: Office of HIV/AIDS Policy: OASH 6-2-95

FEDERALLY FUNDED PROGRAMS PROVIDING ACCESS TO HEALTH CARE FOR HIV+ WOMEN

DEPARTMENT OF AGRICULTURE

Women, Infants, and Children

Programs vary depending on State implementation. WIC considers their programs to be a *gateway to health care*. An assessment of health care needs is provided at the initial contact interview with their clients. Clients are referred into the public health care system to address these needs. This would include HIV+ pregnant women. In addition, WIC provides prescriptions for nutrition needs, nutrition education, education regarding substance abuse and referral for treatment and education about and encouragement of breast feeding. As of February 1995, WIC was servicing 1,551,294 women.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

ACF programs are broad service programs which serve HIV/AIDS-infected persons as they would all others in the eligible population. Some of these programs provide access points for HIV+ pregnant women through referral services. Five programs serving pregnant women, children, and families with HIV/AIDS are summarized below:

I. Administration on Developmental Disabilities - University Affiliated Programs

The University Affiliated Program funds universities, usually teaching hospitals, to provide exemplary services to the developmentally disabled, as well as carrying out teaching, training, and research activities. Twenty-seven of the 51 current grantees operate pediatric HIV/AIDS clinics. Many of these hospitals/clinics are also funded by PHS.

II. Head Start.

For the last five years, ACF has funded, as a demonstration program, approximately 65 Family Service Centers. These are comprehensive family support programs associated with a Head Start Center, usually in an urban area. The Centers focus on prevention, education assistance, and support of Head Start families. The programs primarily address substance abuse prevention and treatment, literacy, and employability. The Centers also address problems associated with HIV/AIDS including accessing health care.

One Head Start center, Babyland, in Newark, New Jersey, serves only children and families with HIV/AIDS. It has been in operation for a number of years and works closely with the PHS Perinatal Resource Center in developing training and technical assistance programs and materials.

III. Child Welfare, Child Abuse and Neglect, Foster Care, Adoption.

Federal funding to States for child and family services supports a broad range of prevention, intervention, and treatment services. These services may include services to HIV/AIDS infected pregnant women, parents, and children.

IV. Abandoned Infants Assistance Program

Enacted in 1988 to address the "boarder baby" problem, funds are awarded both to public and private nonprofit grantees, including State agencies and hospitals. Grantees, parents, and often extended families, provide services to such babies most of whom have been exposed to maternal substance abuse and/or HIV/AIDS.

V. Programs Serving Runaway and Homeless Youth

ACF funds more than 400 programs which provide shelter, assistance, and transitional living services to runaway and homeless youth. These programs also provide education and prevention related to HIV/AIDS, diagnostic medical services, and referral to other services, including medical services.

HEALTH CARE FINANCING ADMINISTRATION

HCFA has advised all State Medicaid Directors that AZT for HIV+ pregnant women should be provided to all those eligible. Other prenatal care provisions are already provided in various degrees depending on individual State reimbursement plans.

PUBLIC HEALTH SERVICE

Centers for Disease Control and Prevention

CDC's National HIV Prevention Cooperative Agreement funds over 3000 counseling, testing and partner-notification sites nationwide. These sites provide referrals to public health care systems to all those who return for post-test counseling and who are HIV seropositive, including pregnant women. These services are also provided at many CDC funded STD clinics throughout the country.

Health Resources and Services Administration

A program advisory will be sent to all HRSA grantees specifying Zidovudine treatment as the standard of care for HIV pregnant women being treated by all grantees. HRSA-funded programs

provide access to a broad range of services and care for women with HIV, through mainstream settings such as community health centers, primary care and maternal child health clinics and through specific AIDS programs. These programs are located throughout the United States in major urban centers, cities and rural communities. Services are provided in diverse settings including medical centers, public health and school-based clinics, public housing health programs and community-based programs.

Non-HIV/AIDS Programs

Women with HIV enter the health delivery system at a variety of access points. Many learn their HIV status as a result of routine care provided in HRSA-funded non-AIDS programs. These include health care programs located in a broad range of settings.

HRSA provides community-based primary care services through community health centers located throughout the United States and in programs targeted to special populations. These include migrant health centers, health care for the homeless programs, school-based and school-linked clinics and public housing primary care centers. HRSA also jointly administers integrated primary care and substance abuse treatment programs that provide coordinated care for substance abusers at risk for HIV infection, in collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA). Through provision of ongoing care, these programs identify women with HIV and provide linkages to HIV-related support and specialty services.

Women with HIV also access care through HRSA-funded Title V maternal and child health programs administered through block grants to the States. These programs provide a range of health services for women and children in prenatal, family health, school-based and school-linked clinics where women with HIV may be identified and referred for follow-up and specialty care.

HIV/AIDS Programs

Women with HIV/AIDS receive services through Title I, II, III (b) and IV of the Ryan White CARE Act and through the AIDS Dental Reimbursement Program authorized under Title VII of the Public Health Service Act. Ryan White services include comprehensive health and support services and planning for systems of care for HIV/AIDS.

Title I programs provide a full range of comprehensive health and support services in eligible metropolitan areas (EMAs). Services include primary health care, dental care, home health, food and nutritional services, substance abuse and mental health services, case management and a variety of support services, such as child and respite care, transportation, peer support and interpreter services. In FY 94, HRSA required all EMAs to identify and address unmet needs and barriers to care for women with HIV in assessment and planning activities. As a result, services for women with HIV have increased in these communities.

Title II programs provide targeted services for women, children and families with HIV, including case management, outreach and support services. HRSA has required grantees to include plans for increasing these services in their application for funds. Programs report expanding the

availability of family-centered case management in neighborhood health clinics, increasing access to care for adolescents with HIV through outreach activities and increasing the availability of peer support for women with HIV.

In addition to comprehensive primary care and support services, Ryan White programs provide coordinated and specialized care in three areas: early intervention services, linking HIV counseling and testing with outreach and primary care, through Title III (b); model programs for coordinated service needs, through Special Projects of National Significance (SPNS); and comprehensive, community-based care for women and families, through Title IV.

Title III (b) programs provide coordinated primary care, case management and access to support services for people with HIV/AIDS in settings where women and families routinely receive care. These include federally funded community and migrant health centers, health care for the homeless programs and city and county health clinics. Integration of HIV services into primary care settings permits early identification of HIV infection, a critical element in providing optimal care to pregnant women with HIV.

Projects funded through the SPNS program provide services to women in multiple care settings. These include special programs funded in FY 94 to develop model comprehensive care systems for women with HIV; special programs to identify and meet the needs of adolescents; outreach programs to provide linkages to care and pre-treatment support groups for active substance users; model programs to integrate mental health services into primary care settings; and culturally sensitive case management services to Native Americans with HIV/AIDS. In addition to providing a range of services for women with HIV/AIDS, these programs are designed to provide implementation data, offering providers the potential of replicating these services in other communities.

The Bureau of Primary Health Care (BPHC) which includes the Title III (b) programs, estimates that of the 4.8 million women it served in calendar year 1993 through all of the BPHC programs, approximately 2,285,000 were women of child bearing age.

Title IV has as its sole mandate the development of community-based systems of care for families, especially women. Grantees include medical centers and comprehensive care programs that provide coordinated care for women and families with HIV. In the six months from July to December 1993, Title IV providers served 3,021 HIV positive pregnant women and adolescents and followed 8,900 children born to HIV+ women.

Through a special initiative funded in FY 95, the Women's Initiative for HIV Care and Reduction of Perinatal Transmission (WIN), Title IV will increase outreach to women at risk for and infected with HIV to ensure early identification and access to care.

In addition to dental services available through some other Ryan White programs, women with HIV receive dental care through dental schools that participate in the HIV/AIDS Dental Reimbursement Program, which was developed to increase access to care through partial funding of uncompensated and under-reimbursed dental services.

Provider training, to enhance the ability of health care workers to provide appropriate medical care and HIV counseling and testing services and to assist in client decision-making related to treatment, such as ZDV perinatal therapy, is provided through HRSA's National HIV/AIDS Education and Training Centers Program and is a key component of the WTB program. Additional training is provided to health care workers, care givers and women with HIV through the National Pediatric and Family HIV Resource Center, a HRSA-funded program.

To assess the capacity of Ryan White programs to address the needs of women with HIV, HRSA has sponsored a four-city study of planning and implementation activities related to services for women, provided during the first five years of the CARE Act. Results will be available shortly.

Indian Health Service

The IHS provides prenatal care for Native American women both living on the reservations and in urban areas. IHS is offering Zidovudine therapy to all HIV+ pregnant women.

National Institutes of Health

NIH continues to research the effects of Zidovudine and other drugs on the perinatal transmission of HIV. The women studied on the ACTG 076 are being followed on a new trial, ACTG 288 to determine whether there were any adverse consequences of their clinical course resulting from exposure to a short course of Zidovudine during pregnancy. New trials continue to enroll HIV+ pregnant women to provide data on some of the unanswered questions from the original 076 trial and to determine if other drugs or drug combinations can prevent perinatal transmission using a less complex and less expensive regimens. Phase I clinical trials of candidate HIV vaccines have also begun in pregnant women and newborns in order to determine ability of these substances to produce an immune response. Women in these studies will receive care throughout their pregnancies.

Information regarding access to clinical trials for pregnant HIV+ women is available through the NIH sponsored AIDS Clinical Trial Information System. Information on the treatment regimen is also provided by the AIDS Treatment Information Service. Both services are accessible by 800-number to both patients and providers.

Substance Abuse and Mental Health Services Administration

SAMHSA administers substance abuse block grants to the states. In addition, they have numerous demonstration grants that are linking substance abuse treatment with primary care. This linkage will provide an access point to the public health care system for HIV+ pregnant women who access substance abuse treatment. Also, SAMHSA and the CDC have been encouraging substance abuse treatment facilities to refer at risk individuals to HIV counseling and testing sites to determine their HIV serostatus. These testing sites can refer any HIV+ women into the health care system.

Office of Population Affairs

Title X Family Planning Program - Provides voluntary family planning services in over 4000 family planning clinics nationwide for approximately 1.2 million predominantly low income women. Pregnant women are referred for pre-natal care regardless of HIV anti-body status.