DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of the Secretary's Determination on Newborn HIV Testing

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

AUTHORITY: Section 2626(d) of the Public Health Service Act (42 U.S.C. 300 ff–34).

SUMMARY: The Secretary is required under Public Law 104–146 to make a determination as to whether it has become routine practice in the United States to carry out a number of counseling, testing and disclosure activities pertaining to a newborn infant's HIV serostatus. In making this determination, the Secretary has consulted with the States and with other public and private entities that have knowledge and expertise relevant to this determination. This notice is issued in fulfillment of the requirement of Section 2626(d) of PL 104–146. The Secretary determines, that with regard to the statutory provisions and legislative intent as defined by the Committee on Conference in Conference Report 104–545, it has not become routine practice to require testing of newborn infants for HIV infection in the United States.

DATES: The Secretary's Determination on Newborn HIV Testing is effective upon January 20, 2000.

FOR FURTHER INFORMATION CONTACT: Office of HIV/AIDS Policy, Office of Public Health and Science in the Office of the Secretary, 200 Independence Avenue SW, Room 736–E, Washington, D.C. 20201.

SUPPLEMENTARY INFORMATION:

I. Overview of the Secretary's Determination

Section 2626(d) of the Public Health Service Act, as added by the Ryan White CARE Act Amendments of 1996 (Public Law 104–146), requires the Secretary of the Department of Health and Human Services to make a determination as to whether it has become routine practice in the United States to carry out a number of counseling, testing and disclosure activities pertaining to a newborn infant's HIV serostatus. This document will review the relevant statutory provisions and legislative history; summarize the findings of consultations conducted as required by the statute; review the data regarding reductions in perinatal transmission and current HIV counseling, testing and disclosure practices; and provide the determination required of the Secretary in Section 2626(d). Attachment A highlights some of the Department's activities to reduce perinatal HIV transmission and ensure that HIV-exposed and HIV-infected infants and children have access to quality care.

II. Legislative Background

The Ryan White CARE Act Amendments of 1996 placed a new legislative emphasis on Federal and state efforts to reduce the perinatal transmission of the human immunodeficiency virus (HIV). The Congress required all States to certify that regulations or measures were in effect to adopt the guidelines issued by the Centers for Disease Control and Prevention for HIV counseling and voluntary testing for pregnant women, and it authorized a new grant program to assist States in their efforts to reduce perinatal HIV transmission. Additional provisions in Sections 2626, 2627, and 2628 directed the Secretary to make a determination about whether certain practices have become routine regarding HIV counseling and testing of newborns and disclosure of their HIV serostatus, and to request a study by the Institute of Medicine on State efforts to reduce perinantal transmission. The following section reviews both the statutory language and legislative background provided in the Joint Explanatory Statement of the Committee on Conference, as each of these sections are central to the Secretary's determination required under Section 2626(d).

Statutory Provisions

Section 2626(d) requires the Secretary to publish in the **Federal Register** a determination ''whether it has become a routine practice in the provision of health care in the United States to carry out each of the activities described in paragraphs (1) through (4) of section 2627. In making the determination, the Secretary shall consult with the States and with other public or private entities that have knowledge or expertise relevant to the determination.'' Section 2627 lists the activities or requirements for which the Secretary is required to make the determination of whether each has become a routine practice in the United States. Section 2627(5) was subsequently removed, through a technical amendment, as an element of the determination required under Section 2626, and thus is not further discussed here. The four activities or requirements to be included in the Secretary's determination are: ''(1) In the case of newborn infants who are born in the State and whose biological mothers have not undergone prenatal testing for HIV disease, that each such infant undergo testing for such disease. (2) That the results of such testing of a newborn infant be promptly disclosed in accordance with the following, as applicable to the infant involved: (A) To the biological mother of the infant (without regard to whether she is the legal guardian of the infant). (B) If the State is the legal guardian of the infant: (i) To the appropriate official of the State agency with responsibility for the care of the infant. (ii) To the appropriate official of each authorized agency providing assistance in the placement of the infant. (iii) If the authorized agency is giving significant consideration to approving an individual as a foster parent of the infant, to the prospective foster parent. (iv) If the authorized agency is giving significant consideration to approving an individual as an adoptive parent of the infant, to the prospective adoptive parent. (C) If neither the biological mother nor the State is the legal guardian of the infant, to another legal guardian of the infant. (D) To the child's health care provider. (3) That, in the case of prenatal testing for HIV disease that is conducted in the State, the results of such testing be promptly disclosed to the pregnant woman involved. (4) That, is disclosing the test results to an individual under paragraph (2) or (3), appropriate counseling on the human immunodeficiency virus be made available to the individual (except in the case of a disclosure to an official of a State or an authorized agency). ''Section 2628 directs the Secretary to undertake the following activities: ''(a) The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct an evaluation of the extent to which State efforts have been effective in reducing the perinatal transmission of the human immunodeficiency virus, and an analysis of the existing barriers to the further reduction in such transmission. (b) The Secretary shall ensure that, not later than 2 years after the date of enactment of this section, the evaluation and analysis described in subsection (a) is completed and a report summarizing the results of such evaluation and analysis is prepared by the Institute of Medicine and submitted to the appropriate committees of Congress together with the recommendations of the Institute.'' Joint Explanatory Statement of the Committee on Conference: In Conference Report 104–545, the House receded with an amendment described in the conference report as follows: ''(1) Within four months of enactment of this Act, the CDC, in consultation with states, will

develop and implement a reporting system for states to use in determining the rate of new cases of AIDS resulting from perinatal transmission and the possible causes for that transmission. The Secretary of HHS is directed to contract with the Institute of Medicine to conduct an evaluation of the extent to which state efforts have been effective in reducing perinatal transmission of HIV and an analysis of the existing barriers to further reduction in such transmission. The Secretary shall report these findings to Congress along with any recommendations made by the Institute. (2) Within two years following the implementation of such a system, the Secretary will make a determination whether mandatory HIV testing of all infants born in the U.S. whose mothers have not undergone prenatal HIV testing has become a routine practice. This determination will be made in consultation with states and experts. If the Secretary determines that such mandatory testing has become a routine practice, after an additional 18 month period, a state will not receive Title II Ryan White funding unless it can demonstrate one of the following: (A) A 50% reduction (or a comparable measure for low-incidence states) in the rate of new AIDS cases resulting from perinatal transmission, comparing the most recent data to 1993 data; (B) At least 95% of women who have received at least two prenatal visits with a health care provider or provider group have been tested for HIV; or (C) A program of mandatory testing for all newborns whose mothers have not undergone prenatal HIV testing.'' p. 45–46, Conference Report 104–545.

III. Review of Consultation Processes

The Department undertook several activities to respond to the statutory requirements for external consultations found in Sections 2626 and 2628, the most extensive of which was a study conducted by the Institute of Medicine (IOM) of the National Academy of Sciences. The other activities included a formal consultation with state and local government organizations, and an invitation for public comment through a **Federal Register** notice to supplement those comments provided in the course of the IOM study. Each of these activities is described more fully below.

Report of the Institute of Medicine—Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States

In 1997, the Department contracted with the IOM for an evaluation of the extent to which State efforts have been effective in reducing the perinatal transmission of HIV and an analysis of the existing barriers to the further reduction in such transmission. The IOM assembled a 14-member expert committee with combined expertise in obstetrics and gynecology, pediatrics, preventive medicine, and other relevant specialities, social and behavioral sciences, public health practice, epidemiology, program evaluation, health services research, bioethics, and public health law. This committee, formally known as the Committee on Perinatal Transmission of HIV, reviewed a wide variety of quantitative and qualitative information pertaining to the prevention of perinatal HIV transmission, including current clinical practices to reduce such transmission. The committee held two public workshops which afforded the opportunity to consult with a wide array of state and local public health officials and other policy makers, health care providers, consumers, ethicists, advocacy groups for women and children with HIV, and others affected and concerned with these policy issues. The committee also conducted field visits to identify and discuss issues with women who are HIV-infected or at risk of HIV infection, health care providers, and state and local policy makers. On October 14, 1998, the IOM issued a report, *Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States,* which reviewed the implementation and impact of the Public Health Service (PHS) counseling and testing guidelines and made recommendations on strategies to further reduce perinatal HIV transmission. In brief, the IOM study identified that 22 States have policies on HIV testing, monitoring or treatment of newborns; 9 states permit disclosure of HIV test results to foster agencies or families; and 15 states permit disclosure to the newborn's pediatrician. Only one state, New York, required mandatory newborn HIV testing at the time of the report. Since that time, Connecticut has passed a legislative mandate to test all newborns whose HIV serostatus is unknown, but full implementation of this is pending litigation. A discussion of the major IOM study findings follows under the upcoming section on reducing perinatal transmission.

Consultation With State and Local Government Organization

The IOM committee convened a broad spectrum of state and local government and public health organizations as part of its efforts to identify the range of scientific data and public health expertise regarding perinatal HIV transmission. The Department also held a second, separate consultation with representatives of state and local governmental organizations on December 4, 1998. Eight organizations were represented at the meeting, including the National Governors Association (NGA), U.S. Conference of Mayors (USCM), National Association of Counties (NACo), National Association of County and City Health Officials (NACCHO), National Organization of Black County Officials (NOBCO), National Alliance of Latino Elected Officials (NALEO), the National Association of State and Territorial AIDS Directors (NASTAD) and National Association of State Alcohol and Drug Abuse Directors (NASADAD). NASTAD provided written comments at the meeting, as did NGA subsequently, which stated that HIV testing of each newborn whose biological mother has not undergone prenatal testing for HIV disease is not a routine practice in the United States. All organizations attending the consultation supported this statement. Subsequently, the National Governor's Association provided the Department with a Resolution on HIV/AIDS that the Governors adopted at the NGA's 1999 Winter Meeting. Sections 38.2.2 and 38.5 of the Resoulation state that HIV testing of newbords is not a routine practice in the United States.

Federal Register Notice Soliciting Public Comment

The Institute of Medicine study and subsequent Departmental activities represented an extensive effort to gather and review the breadth of scientific data and professional, public health and consumer experience relevant to the issue of preventing perinatal HIV transmission. While recognizing the substantial outreach of the IOM committee in identifying and engaging knowledgeable voices on these issues, the Department pursued a supplemental strategy of inviting further public comment through publication of a notice in the **Federal Register** on November 9, 1998 following release of the IOM report. A total of 287 written comments were received in response to this notice, including 21 letters from state health departments stating that HIV testing of newborns was not routine practice in their jurisdictions. Three additional state health departments did not support mandatory HIV testing of newborns and described public health strategies, other than mandatory testing, to accomplish the goals of identifying HIV-exposed newborns. Two elected officials from one state provided comment that their state has implemented mandatory HIV testing of

newborns. A form letter submitted by 234 organizations and individuals who oppose mandatory testing of pregnant women and newborns accounted for the majority of comments received.

IV. Reducing Perinatal Transmission

Overview

It has been estimated that between 6,000 and 7,000 HIV-infected U.S. women delivered infants each year from 1989 to 1995. Without intervention, a 25% mother-to-infant HIV transmission rate would result in the birth of an estimated 1,750 HIV-infected infants annually in the United States. To reduce rates of perinatal HIV transmission, CDC published, in 1994, the U.S. Public Health Service (PHS) recommendations for using zidovudine (ZDV, also known as AZT) to reduce perinatal HIV transmission and, in 1995, PHS recommendations for routine counseling and voluntary HIV testing for pregnant women. In 1998, the earlier 1994 chemoprophylaxis guidelines were revised to include discussion of the use of newer antiretroviral drugs during pregnancy to treat maternal infection. Since the publication of these guidelines, nearly all relevant health professional organizations (including the American College of Obstetricians and Gynecologists and American Academy of Pediatrics) developed practice recommendations that generally conformed with the PHS recommendations for routine counseling and voluntary testing of pregnant women (the American Medical Association was alone in recommending a more stringent approach—that of mandatory testing of pregnant women and infants), and providing zidovudine chemoprophylaxis. Additionally, most states moved quickly to implement them through law, regulation, or policy; they also supported broad implementation of the guidelines through active dissemination, public and provider education, and health professional training. States and health care providers have placed their emphasis on reaching pregnant women with HIV counseling and testing so that the full benefits of HIV prevention through use of antiretroviral medications can be achieved among women with HIV infection. States have not made a specific investment in additional surveillance systems to track the HIV status of each newborn infant, with the exception of a very few States. Currently, only two states (New York and Connecticut) require mandatory HIV testing of newborns whose mothers did not undergo prenatal HIV testing and only New York has fully implemented this requirement. This section describes the impact of efforts by the Center for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) to reduce perinatal HIV transmission. It also summarizes the major findings and central recommendation of the Institute of Medicine's report Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States.

Impact of Implementing PHS Recommendations for Routine Counseling and Voluntary Testing of Pregnant Women

The CDC has established a number of surveillance and research studies to evaluate the impact of these guidelines as an intervention, and the effect of this intervention has been substantial.

- HIV/AIDS surveillance data indicate that the number of perinatally acquired AIDS cases in the United States declined by 74% between 1993 and 1998 due in part to increased HIV testing among pregnant women and receipt of ZDV by HIV-infected women.
- A CDC-funded study in eleven states indicated that 60–84% of pregnant women are counseled about HIV, and that acceptance of testing is high—over 70%—in most settings.
- More than 90% of women known to be HIV-infected who are in prenatal care receive zidovudine (AZT) prophylaxis.
- Studies indicate that HIV transmission rates among HIV-positive women in the U.S. are dropping to as low as 5%.

Similarly, HRSA has instituted several activities to increase HIV counseling and testing, particularly during the perinatal period, and to monitor the progress of Ryan White grantees in further reducing perinatal HIV transmission. The results in many geographic sites have been remarkable. Some examples of these achievements appear below.

- In a St. Louis care center, 100% of pregnant women living with HIV who were counseled about ZDV also accepted prenatal ZDV. Perinatal HIV transmission decreased from 44.4% in 1994 to 0% in both 1996 and 1997.
- In Massachusetts, ZDV acceptance has risen dramatically among pregnant women living with HIV. In 1993, acceptance of ZDV chemoprophylaxis was 9%; acceptance rose to 74% in 1994 and 93% in 1995. In the latter half of 1995, acceptance actually rose to 95%.
- At a Seattle program, approximately 20–30 pregnant women with HIV receive care each year. No child has been diagnosed with perinatal HIV infection from 1994 through 1997.
- Ninety-one percent of women accepted testing among all of those who received pre-test counseling through the HRSA Special Projects of National Significance Adolescent Care projects. This percentage increased to 94% for pregnant women.
- At the University of Miami, 158 pregnant women living with HIV were served in 1996, 95% of whom accepted ZDV prophylaxis. Of the perinatally exposed children born, two out of 110 (2%) were determined to be HIV-infected after one year. In the first half of 1997, 60 perinatally exposed children were born, none of whom were determined to be HIV-infected.
- In 1995, 28 perinatally exposed children were born to mothers living with HIV in one HRSA-supported agency in Chicago. Only 10 of these women (36%) participated fully in the ZDV regimen, and thus 32% of the children born were HIV-infected. In 1996, 50% of the HIV-infected pregnant women elected to participate in the ZDV regimen. The rate of perinatal transmission decreased 15% in this population. In the first three months of 1997, six additional infants were born, none of whom were determined to be HIV-infected. Despite these promising findings, some children in the U.S. continue to become infected with HIV through maternal transmission. Some of the possible reasons for continuing perinatal HIV transmission include:
- Nationally, less than 2 percent of all pregnant women receive no prenatal care. However, in a four State study, 14 percent of pregnant women with HIV infection receive no care. Moreover, 35% of HIV-infected pregnant women who use drugs receive no prenatal care, compared with only 8% of HIV-infected pregnant women who do not use drugs.
- Some providers still do not offer HIV testing to pregnant women. Reasons cited by these providers include a lack of time and resources, the perception that the woman is not at risk, and legal requirements for pretest counseling.
- While test acceptance rates are high and improving, not all women who are offered HIV testing accept it. Some of the major reasons for refusal of testing include the belief that one is not at risk for HIV, and the lack of a provider's strong recommendation for testing. Additionally, some women continue to express mistrust of provider information and concerns about being forced to accept testing and/or ZDV chemoprophylaxis.

Summary of Institute of Medicine Study Findings and Recommendations

The Institute of Medicine study found that: (1) There have been substantial

public and private efforts to implement the PHS recommendations; (2) prenatal care providers are more likely now than in the past to counsel their patients about HIV and the benefits of ZDV, and to offer and recommend HIV tests; (3) women are more likely to accept HIV testing, and accept ZDV when indicated; and (4) there has been a large reduction in perinatally transmitted cases of AIDS. The IOM also found that: (1) for a variety of reasons, prenatal testing of pregnant women has not yet become universal; (2) even when testing is conducted, it does not always lead to care; and (3) not all women necessarily receive the quality treatment and services they need. The IOM concluded that the reduction in the number of children born with HIV infection, while substantial to date, could be greater. The primary IOM recommendation for further decreasing rates of perinatal HIV transmission in the United States is summarized below:

- The IOM committee recommends the adoption of a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care.

* HIV tests would be integrated into the standard battery of prenatal tests for all pregnant women, regardless of their risk factors or local prevalence rates.

* Women would be informed that the HIV test will be conducted and that they have a right to refuse it.

* Requirement for extensive pre-test HIV counseling should be eliminated.

* Initial refusal of the HIV test by women should not necessarily be considered final; clinical circumstances may suggest that counseling should be provided on the benefits of testing at later prenatal care visits. Patients who continue to refuse testing should never be coerced or denied services.

For a complete discussion of the IOM findings and recommendations, the full report Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States can be found at the National Academy Press website (http://www.nap.edu.).

Ongoing Challenges

Many challenges remain in further reducing the number of children with perinatally-acquired HIV infection. Of great importance is increasing the use of prenatal care by women at risk for HIV infection, with a particular emphasis on bring women with substance abuse addictions into prenatal care, and the continued development of more effective antiretroviral regimens and other methods to prevent or reduce perinatal transmission. Other challenges include the monitoring for emergence of antiretroviral resistance to current therapies, addressing the potential toxicities of antiretroviral therapies, assisting HIV-positive pregnant women to remain adherent to antiretroviral therapy, and increasing provider practices to routinely offer and encourage HIV testing of all pregnant women regardless of perception of risk. Diligence and commitment will be required by individual care providers, program planners, and prevention organizations at every level—public and private local, state and national—to make substantial further reductions in perinatal HIV transmission a reality. The Department of Health and Human Services continues to address these challenges through a variety of HIV prevention and service delivery programs, provider training, research efforts, substance abuse prevention and treatment, and the Medicaid program. Highlights of these efforts appear in Attachment A.

V. Findings and The Secretary's Determination

Pursuant to Section 2626 (d), the Secretary must determine ''whether it has become a routine practice in the provision of health care in the United States to carry out each of the activities described in paragraphs (1) through (4) of section 2627.'' The term routine practice is not defined in statute, and the legislative intent must be derived from the Joint Explanatory Statement of the Committee on Conference. On page 46 of Conference Report 104–545, the following explanatory text is provided: ''Within two years following the implementation of such a system, the Secretary will make a determination whether mandatory HIV testing of all infants born in the U.S. whose mothers have not undergone prenatal HIV testing has become a routine practice.'' The Conference Report did not provide guidance for Sec. 2627 paragraphs (2), (3), or (4). To address the issue of routine practice for these elements, information is provided on what has been recommended and the available data on compliance with those recommendations. It should be noted that health care providers usually do not record information regarding to whom test results are disclosed.

Findings

Newborn HIV Testing

States have widely implemented the PHS guidelines for universal HIV counseling and voluntary testing of pregnant women and their infants. Only two States (New York and Connecticut) have a requirement for the mandatory HIV testing of all newborn infants and only New York is currently collecting data on all registered births in that State. Mandatory newborn HIV testing is not routine practice, as this term is defined in Conference Report 104–545, in other States. Provisions in two States for newborn HIV testing are conditional upon a provider's assessment that the test is medically necessary (FL, IN), and a third State requires newborn testing unless a parent objects (TX). The IOM study made no recommendation regarding mandatory newborn testing, but noted that it has limited utility in preventing HIV transmission from mother to child.

Disclosure of Newborn HIV Test Results

Timely disclosure of the results of a newborn's HIV test to the biological mother or guardian and to the health care provider is consistent with national and local recommendations for HIV counseling and testing. Surveillance and other data indicate that the majority of HIV-infected pregnant women are aware of their serostatus during pregnancy and their newborns are receiving therapy. However, no standardized data are regularly documented in medical records or collected on the disclosure of new HIV test results to the biological mother, legal guardian, or agents of the State (where the State is the legal guardian) upon which to certify that this is routine practice. Other studies indicate that failure to disclose results in a timely manner is often due to logistical issues such as a lengthy interval before specimens are tested and results noted, or failure of the baby's guardian to return to the testing site for receipt of test results. Improving strategies to increase the number of tested persons who learn of their test results, including guardians of newborns, is an ongoing activity of CDC in partnership with the States. Specific research and programmatic efforts are being directed at pregnant women who have not received prenatal care to assure that they are offered rapid HIV testing in a timely manner to begin preventive therapy for the newborn.

Disclosure of HIV Test Results to Pregnant Women

Timely disclosure of test results to all tested persons, including pregnant women, is consistent with national and local guidelines for HIV counseling and testing. However, as with disclosure of newborn test results, standardized data are not consistently recorded in medical records or collected to document that the results of prenatal HIV tests are promptly disclosed to the pregnant women involved. Such prompt

disclosure remains the goal of appropriate medical care. Available HIV/AIDS surveillance data indicate that over 80% of HIV-infected pregnant women in 1996 were aware of their status before or during their pregnancy. This percentage has likely increased in 1997 and 1998, although data are not yet available to confirm this increase.

Post-test Counseling

Both national and local guidelines recommended post-test counseling at the time of disclosure of HIV test results. There is no standardized data system that directly measures performance and quality of post-test counseling among all pregnant women in the U.S. Likewise, data are not routinely collected or documented in the medical record to assess whether, in disclosing an infant's HIV test results to the biological mother or legal guardian, appropriate HIV counseling is made available to that individual. Nonetheless, other data indicate that in 1996 about 85% of HIV-infected pregnant women who were aware of their HIV status during pregnancy were offered zidovudine during pregnancy, thereby suggesting that at least this percentage of women likely received counseling about the benefit of zidovudine prophylazis.

Secretary's Determination

With regard to the statutory provisions and legislative intent as defined by the Committee on Conference, the Secretary has determined that required testing of newborns of HIV has not become routine practice in the United States. The Secretary further notes that even though disclosure of the results of HIV testing, accompanied by post-test counseling, are recommended for all persons who undergo HIV testing, specific standardized data systems to measure these elements are not in place and such data are not routinely recorded in medical records nor collected in all states. All States have placed a focus on reaching women early in pregnancy to reduce perinatal HIV transmission, certifying their implementation of the PHS guidelines for universal HIV counseling and voluntary testing of pregnant women.

The Secretary further finds that remarkable success has already been achieved in lowering the incidence of perinatal transmission of HIV. Further reduction in transmission can best be achieved by increasing the number of HIV-infected women who utilize prenatal care, including the targeting of substance abuse treatment services for women who use drugs; increasing the number of providers who recommend HIV testing to all their pregnant patients; continuing the development of more effective antiretroviral regimens; improving access, utilization and adherence to recommended treatment and other interventions; enhancing linkages among HIV prevention, substance abuse and mental health providers; and assuring quality health care, including substance abuse treatment and mental health services, for all HIV-infected women and their children. These activities are the focus of a new grant program in Section 2625 of the Public Health Service Act, which received its first appropriation in FY99.

Attachment A Highlights of Federal Public Health Efforts to Reduce Perinatal HIV Transmission.

Centers of Disease Control and Prevention

The CDC has taken a number of steps towards reduction of perinatal HIV transmission, including:

• Dissemination of the USPHS Guidelines for prevention of perinatal HIV transmission. Following publication of the U.S. Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women in July 1995, as part of the CDC's Morbidity and Mortality Weekly Report (MMWR) series, CDC widely distributed and publicized these guidelines through numerous avenues. Additional copies of the MMWR were mailed to all state and local health departments, and to both public and private health organizations and professional associations. The guidelines were posted on CDC's Internet home page and were widely promoted in newsletters and additional mailings. They were also distributed on request through the CDC National Prevention Information Network (NPIN, formerly known as the National AIDS Clearinghouse) by calling toll free numbers at NPIN or the CDC National AIDS Hotline.

• Establishment of a comprehensive surveillance system to both monitor and evaluate the impact of the USPHS guidelines. At the core of this effort is a surveillance system for HIV and AIDS case reporting. In addition, ancillary studies that provide additional data on reported cases have also been conducted and results reported. A population-based survey on prenatal care of recently-delivered women in 11 states has also provided data on HIV testing among pregnant women. Finally, surveillance of all children under medical care in seven areas of the United States who have been exposed to or are infected with HIV provides additional information.

• Conduct of research to further evaluate the effectiveness of perinatal HIV prevention efforts. The CDC-sponsored Perinatal Evaluation Project was established to examine specific factors associated with acceptance of interventions aimed at preventing perinatal HIV transmission, adherence to recommended therapies by HIV-infected pregnant women, and access to follow-up care.

• Training to support implementation of the USPHS guidelines. CDC developed a training curriculum, ''HIV Prevention Counseling for Women of Reproductive Age,'' designed to provide a detailed explanation of each recommendation and to sensitize counselors to issues many women of reproductive age have related to HIV counseling and testing. In addition to the normal distribution channels for CDC training materials for counseling and testing, this curriculum was mailed directly to nearly 100 individual HIV counselors across the country. CDC has also developed and is in the process of finalizing a second course specifically focusing on HIV prevention counseling in prenatal clinics. This training curriculum will be released in the near future.

• Establishment of a new grant program. Ten million dollars was appropriated in Fiscal Year 1999 by Congress to establish a new grant program to States for prevention of perinatal HIV transmission. CDC awarded these funds to the 16 most heavily affected States to reduce perinatal HIV transmission.

• Revision of USPHS Guidelines. CDC has begun the process of examining the current USPHS guidelines in view of the recommendations by the Institute of Medicine. CDC is intending to revise the current guidelines to incorporate new scientific information and perspectives following the standard process of inviting public comment. These new guidelines are expected to be released within the coming year.

National Institutes of Health

• The NIH continues to support research focused on development, implementation and direction of a wide range of domestic and international research activities. These include study of the pathogenesis, epidemiology, natural history, and risk factors and co-factors of HIV and related retroviruses in pregnant women, mothers, infants, children, adolescents and the family unit as a whole. Studies focused on prevention of perinatal and sexual transmission and the treatment of HIV

disease and its complications among HIV-infected pregnant women, infants, children and adolescents are also important NIH activities. Examples of these activities include: (a) Clinical trials on the prevention of HIV transmission, including development and evaluation of prophylactic and therapeutic vaccines and development of new, non-AZT-based methods of preventing perinatal transmission; (b) Research focused on the etiology and pathogenesis of HIV infection in infants and children, including the study of children exposed in utero to AZT and other antiretroviral agents and the etiology of any potential adverse effects from this exposure; (c) studies of the natural history of HIV infection and disease in pregnant and nonpregnant women, infants, children and adolescents.

• The current goal of the Pediatric AIDS Clinical Trials Group (PACTG) is to lower the rate of perinatal transmission in the United States to under 2%. This will entail evaluation of combination therapies in pregnant women and newborns, and the proactive development of alternatives to AZT, because as AZT resistant strains of HIV become more common, the efficacy of the PACTG 076 AZT regimen may decrease.

• A major prospective study of perinatal transmission funded by the NIH is the Women and Infants Transmission Study (WITS). The WITS is the only large perinatal observational cohort study in the U.S. that is continuing to enroll patients; the study maintains extensive longitudinal clinical, virologic and immunological evaluations of pregnant and postpartum women and their infants. A critical part of the study has been the development of an extensive repository of maternal and infant specimens which has enabled both WITS and interested non-WITS investigators to examine the role of virologic, immunologic, and genetic factors in perinatal transmission, particularly in an era of antiretroviral therapy for pregnant infected women.

• The rational design to additional interventions to reduce perinatal and sexual transmission requires a more complete understanding of factors contributing to transmission. Since the majority of perinatal transmission occurs during birth, viral exposure during labor and delivery is thought to be an important mechanism of transmission. The NIH is funding the Women's Interagency Health Study, the largest multicenter, longitudinal study of HIV disease in women in the United States, to define the immunologic environment of the female genital tract in uninfected as well as HIV infected women, the properties of HIV found in the genital tract, and the factors that influence these parameters. These studies will provide insight into how to develop better interventions to further the goal of prevention.

Health Resources and Services Administration

Since the results of the ACTG 076 trial became available in 1994, HRSA has engaged in numerous activities to reduce perinatal HIV transmission and facilitate the development of health care systems for pregnant women with HIV and their families. Selected activities are highlighted below.

• In 1994, HRSA convened two public meetings which brought together women living with HIV, providers, advocates, ethicists, and policy makers as well as representatives of State and local governments, and HRSA grantees. The purpose was to identify issues in implementing expanded HIV counseling and voluntary testing and providing access to zidovudine chemoprophylaxis for pregnant women with HIV who are served by HRSA's programs and to recommend practical strategies for implementation. The findings from these two meetings formed the basis for subsequent HIV/AIDS program initiatives.

• HRSA published and disseminated the Program Advisory ''Use of Zidovudine to Reduce Perinatal HIV Transmission in HRSA-Funded Programs'' to its grantees in December 1995.

• A collaboration was formed with the Agency for Health Care Policy and Research, the Health Care Financing Administration, and Columbia University, NY, to produce consumer educational materials (including written documents, audio and video tapes) in English, Spanish, and Haitian Creole, entitled ''Is AZT the Right choice for You and Your Baby?'' Over 20,000 copies of these materials have been circulated to HRSA and Medicaid constituents since 1995. HRSA subsequently commissioned and widely circulated an updated consumer document, ''What Women Need to Know: The HIV Treatment Guidelines for Pregnant Women'', based on the January 1998 USPHS Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and for Reducing Perinatal HIV-1 Transmission in the United States.

• HRSA produced and implemented several provider training programs on the topic of perinatal zidovudine chemoprophylaxis and reduction of perinatal HIV transmission. These include: (1) two international State-of-the-Art Clinical Conference calls (1994, 1998) and one international satellite broadcast in 1998; (2) an extensive training program through the AIDS Education and Training Centers utilizing the HRSA manual ''Reduction of Perinatal HIV Transmission: A Guide for Providers''; (3) a National Telephone Consultation Service that tracks and analyzes all provider consultations related to the reduction of perinatal HIV transmission; (4) a manual entitled ''Creating a Circle of Care: Comprehensive Service Delivery to HIV-Positive Pregnant Women and Their Newborns''; and (5) a monograph entitled ''Comprehensive Services for HIV-Infected Pregnant Women and Their Newborns: Seven Case Studies.'' All documents have been widely circulated to HRSA providers.

• Since 1995, all HRSA Ryan White grantees are expected to annually revise and implement program plans to increase routine perinatal HIV counseling and voluntary testing to further reduce perinatal HIV transmission.

• In 1995, the HRSA Ryan White Title IV program developed and implemented the Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission (WIN). WIN is a ten site, four year demonstration project focusing on perinatal HIV counseling, voluntary testing, and improving the care system for women with HIV disease. In the first two and a half years of WIN, 33,000 women have been contacted through outreach and informed of the benefits of knowing their HIV status and where they could obtain care. Additionally, more than 1,300 pregnant women with HIV and 2,000 infants were enrolled in care through WIN programs. Within WIN, both clients and providers have been interviewed in order to explore the health services needs of women with HIV and the training and technical assistance needs of their providers.

• HRSA has also supported the Association of Maternal and Child Health Programs (AMCHP) to survey state health departments and develop a guidance document for expanded HIV counseling and testing and provision of care for pregnant women with HIV infection.

Health Care Financing Administration

Maternal HIV Project

HCFA began a consumer information project in 1995 to inform women of childbearing age about the findings from the AIDS Clinical Trials Group 076 which showed that, when a regimen of

zidovudine is given to HIV-infected women during pregnancy and delivery, and to the infant after birth, the rate of transmission of HIV from mother to child is greatly reduced. This project, which was initially begun in only four states, has been greatly expanded. Currently, 41 States, the District of Columbia, and Puerto Rico have campaigns to inform women about the AZT regimen. HCFA has a National Performance Review goal to expand this information campaign to all States by the year 2000. Materials are now available in English, Spanish, Haitan Creole, Russian, Chinese, Japanese, Vietnamese, Korean, French, and Bosnian. HCFA intends to publish materials in four additional languages—Portuguese, Khmer, Hmong, and Yupik. A ten minute video targeting all women of childbearing age will be available in 2000.

• The Maternal HIV Project also maintains a website to provide information for both providers and women of childbearing age regarding HIV counseling and testing, and Medicaid coverage of these services. The website can be accessed from a banner on the HCFA homepage, http://www.hcfa.gov.

Substance Abuse and Mental Health Services Administration

• The Treatment and Systems Improvement Branch within the Center for Substance Abuse Treatment currently funds 9 Residential Women and Their Children (RWC) and 3 Pregnant and Postpartum women (PPW) grant programs. Both of these programs offer comprehensive, high quality residential treatment services for women suffering from alcohol and other drug problems, and their children. The RWC program serves women and their children ages birth through age 10. The PPW program serves pregnant women and their children up to age one. Both grant programs include a broad range of services, including medical and mental health assessments, screenings and services which can address the HIV counseling, testing and health care needs of pregnant women and their infants. In each program, education, counseling and medical services or referrals are offered around HIV/AIDS. One of the many goals of these programs is to reduce the incidence of HIV, TB, and STDs.

• SAMSHA also supports HIV counseling and testing activities among individuals in substance abuse treatment programs through the HIV Set Aside in the Substance Abuse Prevention and Treatment Block Grant. The Community Outreach Grants program also targets information, resources, counseling and testing to women and men at risk for HIV because of their injection drug use. While not specifically targeted at pregnant women, these efforts reach many women of childbearing age to increase their knowledge of serostatus and to provide referrals for needed services.

Indian Health Service

• The IHS has disseminated the USPHS Guidelines for HIV Counseling and Voluntary Testing for Pregnant Women to IHS health providers. IHS also sponsors a Postgraduate OB/GYN course with a comprehensive syllabus, which has been an excellent vehicle for disseminating the guidelines to IHS providers.

• Ongoing assessments of HIV counseling and testing for pregnant women are conducted in IHS sites. For example, in the Phoenix, AZ area, all IHS Service Units offer HIV testing at the first prenatal visit. At Phoenix Indian Medical Center, one to two women are treated during the prenatal period for positive HIV tests each year, but as yet no infant has been born with HIV infection. A recent audit from the Navajo Area Office reviewing HIV counseling rates by primary prenatal provider specialty showed that rates of HIV counseling were highest in clinics where nurses were trained to do all of the counseling (97% of patients were provided counseling).

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Donna E. Shalala,

Secretary.

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