TO: Hillary Rodham Clinton
FROM: Jennifer Klein J.K.
DATE: 6/26/95
RE: Meeting with Dr. Koop on HIV Testing

Dr. Koop is coming in tomorrow to talk about HIV testing of pregnant women and newborns. As you know, there are two major issues:

(1) *Should women be required to be tested during pregnancy or should they be given routine counseling and voluntary testing?*

Given the new study indicating that HIV transmission from mother to child can be dramatically reduced through the use of AZT during pregnancy, it is clear that pregnant women should know their HIV status. As you know, the Centers for Disease Control (CDC) recommend routine HIV counseling and voluntary testing for all pregnant women. (I have attached a summary of the CDC position.) Most people, including (according to his staff) Dr. Koop, who have considered this issue agree. The CDC and others support voluntary testing because: (1) in several studies, it has proven effective; (2) unlike mandatory testing, it will not drive women from seeking prenatal care; and (3) it helps establish a relationship of trust that is necessary to ensure ongoing treatment.

(2) *Should testing of newborns be mandatory?*

The more difficult question is whether newborns should be tested at birth.

The argument about mandatory testing of newborns began when Congressman Ackerman introduced an amendment to "unblind" the CDC seroprevalence study. The CDC study was designed to track the prevalence of HIV infection in women (because a test of a baby indicates its mother's HIV status). Because the study did not match the babies tested with their HIV test results, opponents charged that the CDC was withholding data from mothers and babies who could get treatment if they knew that they were HIV positive. The CDC responded by suspending the study for further review.

Now, Congressmen Ackerman and Coburn intend to introduce an amendment that would require all women who do not know their HIV status to have their infants tested at birth. In other words, if voluntary counseling and testing did not work during pregnancy, women would be forced to have their newborns tested. As you can see from the attached op ed from yesterday's *New York Times*, they firmly believe that we must mandate testing to ensure that babies do not go untreated.

The CDC and many advocates (including the American Academy of Pediatrics and

the Pediatric AIDS Foundation) believe that voluntary rather than mandatory testing is the best approach at birth as well as during pregnancy. (I have attached an article by the American Academy of Pediatrics recommending voluntary testing at birth.) They argue that, as during pregnancy, voluntary testing works better. Women must continue to bring their babies for treatment and to get treatment themselves, and will be more likely to do this if they have consented to testing.

Dr. Koop's staff did not know his views on mandatory newborn testing. (At the Pediatric AIDS Foundation event, he did note that he thought the CDC study was unethical.) Once you have heard his position, you may want to ask the following additional questions:

(1) What impact might mandatory testing of newborns have on the doctor-patient relationship? Does he think that it will erode trust between doctors and patients so much that women will not get treatment? Does this depend on whether the test is mandated at birth or during pregnancy?

(2) If he supports mandatory testing at birth, does he think that testing should be "purely" mandatory or that a woman should be allowed to "opt out" (i.e., be told that this is done routinely but that she can refuse)?

(3) Is HIV testing similar to other tests routinely performed at birth (e.g., syphilis, PKU) or is HIV a completely different type of disease that requires different standards for consent?

(4) Does he think that confidentiality will be maintained if newborns are tested at birth?

cc: Melanne Verveer

CDC HIV/AIDS PREVENTION

CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC Focuses on Preventing Perinatal Transmission

May 15, 1995 -- Helene Gayle, M.D., Associate Director of the Centers for Disease Control and Prevention (CDC) Washington Office and Acting Director of CDC's National Center for Prevention Services, announced the agency's goals for preventing mother-to-child, or perinatal, HIV transmission. Dr. Gayle was one of several witnesses testifying before the House Committee on Energy and Commerce's Subcommittee on Health and the Environment hearing on HIV testing for pregnant women and newborns held May 11, 1995.

In February 1995, the CDC released draft PHS Guidelines for HIV Counseling and Voluntary Testing for Pregnant Women. These guidelines, which will be published in June, were developed following a National Institutes of Health study (ACTG 076) that demonstrated that HIV-infected pregnant women could reduce transmission to their infants by as much as two-thirds by taking zidovudine (AZT) during pregnancy and delivery.

To give babies the best chance for a healthy life, free of the AIDS virus, HIV-infected women must be reached as early in pregnancy as possible. In order to achieve that, the guidelines recommend routine HIV counseling and voluntary testing for all pregnant women. This strategy has already proven to be effective in several communities nationwide and is the most effective way to identify women and children in need of care. Unlike mandatory testing, voluntary testing doesn't run the risk of driving women away from prenatal care. Instead it helps to establish the relationship of trust that is essential for discussions about complex medical issues.

Background [illegible]

As public health and medical professionals prepare to implement the guidelines, CDC is taking steps to ensure that they are rapidly adopted and to evaluate their effectiveness. Within the next few weeks, CDC will begin a process, assisted by external expert consultants, to ensure that all pregnant women are offered HIV counseling and voluntary testing and that they and their children are entered into a continuum of medical and support services. In addition, this planning process will determine the best mechanisms for evaluating perinatal prevention efforts and for monitoring the epidemic in women and children.

The future of one of CDC's current monitoring tools, the Survey of Childbearing Women, will be assessed. This anonymous survey involves the "blinded" HIV testing of newborn blood samples and has been the subject of recent media reports as well as proposed federal and state legislation. According to Dr. Gayle, "The Survey of Childbearing Women has provided critical information for monitoring the epidemic in women and children. However, a lot has changed since that survey was first developed. With the tremendous opportunity that we now have to prevent most perinatal transmission, we must do everything possible to keep our eye on the goal of preventing HIV infection in children. I am confident that the planning process that CDC is beginning will provide us a strong foundation for determining how best to achieve this goal."

Until this process is completed, State Health Departments have been asked in a letter from Dr. Phil Lee, Assistant Secretary for Health, to suspend the Survey of Childbearing Women.

"With these recent advances," added Gayle, "CDC must re-evaluate how to best combine prevention and surveillance strategies to meet these important challenges. We are eager to begin the planning process and move forward with the task of implementing and evaluating perinatal prevention efforts."

CDC HIV/AIDS PREVENTION

CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC's Draft Guidelines for HIV Counseling and Voluntary Testing for Pregnant Women

The Centers for Disease Control and Prevention (CDC) has released draft guidelines that call upon medical professionals to provide HIV counseling and voluntary testing for all pregnant women.

In 1993 (the most recent year for which complete data are available), an estimated 7,000 HIV-infected women gave birth in the United States. The prevalence of HIV infection in women giving birth was about 1.6 per 1,000, or about 1 in every 625. Assuming an HIV transmission rate from mother to infant of about 15%-30%, about 1,000-2,000 HIV-infected infants were born in the United States in 1993.

For HIV-infected women and their infants to benefit optimally from AZT and other medical treatment, it is important for women to know if they are HIV-infected before or early in pregnancy. CDC's draft guidelines promote early HIV counseling and voluntary testing to help women learn if they are infected. This will enable women to seek and receive the care they need for themselves and for reducing the chances of transmitting HIV to their infants.

Research Showed AZT Significantly Reduces Mother-to-Infant Transmission

In February 1994, the results of the National Institutes of Health (NIH) AIDS Clinical Trial 076 were announced, indicating that zidovudine (ZDV, or AZT) could reduce perinatal HIV transmission by as much as two-thirds in some infected women and their babies. The results were reported in the New England Journal of Medicine in November 1994. In August, the Food and Drug Administration approved AZT use for pregnant women and the U.S. Public Health Service issued guidelines on using AZT during pregnancy (MMWR 1994;43[RR-11]).

The finding of a 67.5% reduction in HIV transmission is promising, and there were no serious short-term side effects observed in the study. But several questions remain unanswered. The trial included a select group of women in the early stages of disease, who had not previously taken AZT long-term, and who had access to prenatal care. The therapy may differ in effectiveness in women who differ from these characteristics. Since researchers do not know exactly how the therapy prevented transmission, they also don't know the effect of any therapy variations -- such as using AZT only during labor or later in the pregnancy, or using it for a shorter time during pregnancy. Moreover, scientists don't know about the long-term effects of AZT on both mothers and infants. Researchers continue to seek answers to these questions. NIH is continuing to monitor the mothers and babies in the trial.

Counseling for All Pregnant Women and Voluntary Testing Work

The combined strategy of HIV counseling for all pregnant women and voluntary HIV testing is already proving effective in several communities. Voluntary testing means that after a woman receives appropriate counseling from her health care provider, she is able to make an informed decision about having a test for HIV. Studies show that when her health care provider talks with a pregnant woman about the test and what it means for her and her baby, most women choose to be tested and then to be treated as their doctor recommends. For example, in one inner-city hospital in Atlanta, Georgia, 96% of women chose to be tested after being provided HIV counseling and offered voluntary HIV testing as part of prenatal care.

Offering all women voluntary testing in the context of HIV counseling establishes the trusting relationship between a woman and her health care provider that is essential for discussions about care and treatment options.

Although AZT therapy is not 100% effective and the long-term risks to both the mother and her child are not yet known, the dramatic reduction in HIV transmission in the trial dictates that every HIV-infected pregnant woman should certainly be offered AZT therapy to reduce the risk of transmitting the virus to her baby. Because of the uncertainties, a woman should make a personal decision about taking AZT only after she discusses the benefits and potential risks for herself and her child with her health care provider.

Finalizing the Recommendations

CDC is seeking public comment to ensure the final recommendations will promote the best care possible for all pregnant women and their babies. After the public comment period, which runs from February 23 through April 9, 1995, the draft guidelines will be modified as needed and published in the Morbidity and Mortality Weekly Report (MMWR).

A notice of the public comment period for the draft guidelines appears in the February 23, 1995, Federal Register. Printed copies of the draft guidelines 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]) which has more information about AZT treatment during pregnancy are available from the CDC National AIDS Clearinghouse (CDC NAC). Printed copies may be ordered by calling the CDC National AIDS Hotline (1-800-342-AIDS). The Hotline can also provide information about any AIDS-related issue. The guidelines are also available electronically through the CDC NAC On-line bulletin board as well as through other HIV/AIDS bulletin boards, including the Internet.

For specific information regarding the 0-76 Clinical Trial or any other HIV/AIDS clinical trial, call the AIDS Clinical Trial Information Service (ACTIS) at 1-800-TRIALS A. For information regarding treatment and care of HIV infection and AIDS, including use of AZT in pregnant women, call the HIV/AIDS Treatment Information Service (ATIS) at 1-800-448-0440.

February 1995

Perinatal Human Immunodeficiency Virus Testing

Provisional Committee on Pediatric AIDS

Continuing technologic and medical advances in the detection, treatment, and prevention of pediatric human immunodeficiency virus (HIV) infection require an ongoing assessment and review of recommendations relating to pediatric HIV infection, including issues that involve prenatal and perinatal HIV counseling and testing.

Changes in the epidemiology of HIV infection in women require that prenatal testing recommendations based on risk group and geographic prevalence be reconsidered. The following factors support the importance of the evaluation of HIV infection status in reproductive-age women and newborns: the recent finding that administration of zidovudine to some HIV-infected pregnant women and their newborns significantly reduced perinatal transmission of HIV,[1] the requirement that prophylaxis to prevent *Pneumocystis carinii* pneumonia be initiated in the first few months of life for maximal efficacy, improvements in diagnostic confirmation of pediatric HIV infection in early infancy, and the recommendation that HIV-infected women should not breast-feed their infants if safe alternatives are available.

CHANGING EPIDEMIOLOGY OF HIV INFECTION IN WOMEN OF CHILDBEARING AGE

The annual proportionate increase in cases of acquired immunodeficiency syndrome (AIDS) in women currently exceeds that observed among men.[2] Although in 1982 only 6% of newly diagnosed AIDS cases involved women, in 1993 12.6% of new cases were diagnosed in women. Currently, more than 80% of women with AIDS are of childbearing age, and the increasing rate of AIDS among adolescent females portends a further increase among women of childbearing age. The increase in the rate of AIDS in women has been reflected by a similar increase in children; more than 95% of AIDS cases in children from birth to 4 years old are caused by perinatal infection.

In addition to the increasing incidence of AIDS in women, cases are no longer confined to urban areas of the United States; currently, more than 25% of women with AIDS are from smaller cities and rural areas of the United States.[3] Furthermore, behavioral risk factors for HIV infection in women are shifting. Since 1992, heterosexual contact has exceeded intravenous drug use as the primary exposure category in women with AIDS. A significant proportion of HIV-infected women are not aware of their own or partner's risk for HIV infection. Evaluation of national data from publicly funded HIV counseling and testing services from 1989 to 1990 indicates that 35% of women found to be HIV-infected do not report risk factors that have been commonly associated with HIV acquisition, such as intravenous drug use or having sex with a partner at known high risk for HIV infection; 44% of black seropositive women did not report these behaviors.[4] Unprotected sexual intercourse may be the only high risk factor for HIV acquisition for these women.

In geographic areas with low HIV seroprevalence among childbearing women, the ethnic distribution of HIV infection in women may differ substantially from that observed in areas of the country with high HIV seroprevalence. A recent report from San Diego County indicated that 34% of mothers with perinatally infected infants were Caucasian.[5] Similar to the data cited above, heterosexual contact was the only risk factor for HIV infection in 43% of mothers.

Because surveillance of AIDS cases detects only infected individuals who have progressed to end-stage disease, use of AIDS case surveillance reports to detect population trends in HIV infection will reflect the scope of the HIV epidemic 7 to 10 years ago. However, anonymous HIV antibody seroprevalence surveys provide estimates of HIV infection trends that are independent of disease stage, and depict more recent patterns of HIV infection in women. Serosurveys indicate that HIV infection, like AIDS, has become widespread among women of childbearing age in nonurban areas of the country.[6]

It is evident that HIV infection in women has spread beyond previously defined risk groups and geographic areas.

USE OF ZIDOVUDINE TO REDUCE PERINATAL HIV TRANSMISSION

The risk of perinatal HIV transmission can be reduced through the administration of zidovudine to HIV-infected pregnant women and their infants. Interim results have recently been reported from a randomized, double-blind, placebo-controlled clinical trial, AIDS Clinical Trial Group (ACTG) Protocol 076, that evaluated the use of zidovudine administered during pregnancy, labor, and to the newborn to reduce perinatal HIV transmission.[1] This trial enrolled HIV-infected pregnant women with early stage HIV disease (CD4 count of 200 cells/mm^3 or above at the time of entry into the study, who had

The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate.

PEDIATRICS (ISSN 0031 4005).

received no antiretroviral therapy during their current pregnancy and had no clinical indications for antiretroviral therapy). Oral zidovudine was administered beginning between 14 and 34 weeks of gestation and was continued for the remainder of the pregnancy. During labor, a continuous intravenous infusion of zidovudine was administered, followed by the administration of oral zidovudine to the newborn for 6 weeks. Analysis of data available through December 1993 demonstrated a two-thirds reduction in the estimated rates of HIV transmission at 18 months of age, from 25.5% in placebo recipients to 8.3% in those who received zidovudine; the difference between the two groups was highly statistically significant ($P = .00006$). No significant short-term side effects were observed from zidovudine use other than mild, reversible anemia in the infants. Although the short-term safety concerns appear minimal for the mother and child, the study has not yet provided information about the long-term risks for mothers and infants (both infected and uninfected) treated with the ACTG 076 zidovudine regimen.

Although the ACTG 076 zidovudine regimen may not yield the same results in HIV-infected women who are severely ill with low CD4 counts, those who have been receiving zidovudine for an extended period before pregnancy, or those who present very late for prenatal care, it is possible that zidovudine may be associated with some reduction in transmission in such situations. A variety of other therapeutic interventions to interrupt perinatal transmission of HIV are currently or soon to be under evaluation.[7] The US Public Health Service recently published recommendations regarding the use of zidovudine to prevent perinatal HIV transmission.[8] These recommendations cover a variety of clinical situations that commonly occur in clinical practice, and highlight the factors to be considered by the woman and her health care provider when making decisions regarding use of zidovudine to prevent perinatal transmission. The health care provider and mother need to discuss the potential benefits, unknown long-term effects, and gaps in knowledge relating to the woman's specific clinical situation to ensure that the woman can make informed decisions about her treatment.

DIAGNOSIS AND MANAGEMENT OF PEDIATRIC HIV INFECTION

Early identification of infected infants is essential for adequate medical management. *Pneumocystis carinii* pneumonia (PCP) is the most frequent opportunistic infection associated with pediatric HIV infection, occurs most commonly between 3 to 6 months of age, is the most common initial disease to occur in infants and children with previously unrecognized HIV infection, and is associated with high mortality. Effective prophylaxis is available to prevent PCP, and in March 1991, the US Public Health Service issued guidelines for PCP prophylaxis in pediatric HIV infection.[9]

Because of the age distribution of infants with PCP, PCP prophylaxis should begin in the first months of life, which requires recognition of the infant's HIV serostatus. PCP, however, continues to be the presenting manifestation of previously unrecognized HIV infection in nearly half of reported PCP cases.[10] In these children, HIV status was unknown until the child developed PCP; this suggests that early identification of patients requiring prophylaxis is incomplete. To adequately prevent the complications of HIV disease, identification of an infected child must be followed by the provision of appropriate medical care. In addition, education of the parents and other guardians regarding the need for close follow-up of these infants and instruction in administration of necessary medications is also crucial for the prevention of PCP and other complications of HIV infection.

Early identification of HIV-infected infants enables appropriate modifications and additions to the routine schedule of pediatric immunizations; early monitoring of nutritional status and implementation of aggressive nutritional supplementation at early stages of growth failure; initiation of antiretroviral therapy; careful monitoring of immunologic and neurologic/neuropsychologic function to evaluate the need for change in antiretroviral therapy and the need for special educational interventions; consideration of other adjunctive therapies, such as intravenous immunoglobulin for the prevention of bacterial infections; screening and treatment for tuberculosis; appropriate management of communicable disease exposures; and the provision of other needed services.[11]

With virologic diagnostic techniques such as HIV culture, polymerase chain reaction, and immune complex-dissociated p24 antigen, diagnosis of HIV infection can be made in almost 50% of infected infants at birth and in more than 95% of infected infants by 1 to 3 months of age.[12] Unfortunately, identification of HIV-infected infants at early stages of disease in the United States appears to be relatively poor; data from a population-based study in Massachusetts indicate that only 35% to 65% of perinatally infected infants have been identified by the health care system by 3 to 4 years of age.[13]

BENEFITS OF HIV TESTING IN THE PRENATAL AND NEWBORN PERIODS

There are now clear medical benefits for pregnant women to know their HIV serostatus. In addition to the importance HIV testing has for early diagnosis and treatment of women,[14] the availability of a treatment capable of significantly reducing perinatal transmission of HIV clearly provides an important impetus for all pregnant women to know their HIV serostatus during early pregnancy.

Knowledge of HIV serostatus permits infected mothers to be counseled about the risk of HIV transmission through breast-feeding. Because of the risk of HIV transmission via breast milk,[15,16] women in the United States who are known to be HIV-infected are advised not to breast-feed, since safe alternatives to breast milk are available.[17]

While evaluation for HIV infection during pregnancy offers potential preventive as well as therapeutic benefits, when maternal serostatus is

unknown, HIV antibody testing of the newborn remains important for therapeutic reasons. Knowledge of neonatal HIV serostatus permits early evaluation of the infant for HIV infection and immunologic monitoring to evaluate the need for initiation of PCP prophylaxis, antiretroviral, and other therapies.

Human immunodeficiency virus infection in women and children is often accompanied by HIV infection in other family members. Family members should be offered the opportunity to undergo evaluation to determine whether they are HIV-infected and provided appropriate medical care and follow-up if found to be infected.

RISKS OF HIV TESTING IN THE PRENATAL AND NEWBORN PERIODS

Risks of prenatal/perinatal HIV testing include those inherent to the identification of HIV infection in any individual. Detection of HIV infection may be associated with anxiety and depression. Other risks include potential social stigmatization and discrimination. Also, because illicit intravenous drug use is associated with HIV infection and may be used as a basis to remove an infant from the mother's care, women who use illicit drugs may fear HIV testing. It is possible if the benefits of HIV testing are not made known to pregnant women, fear of the potential negative consequences may deter some women from seeking prenatal care, particularly if testing is perceived as involuntary. However, in several settings in which HIV counseling and voluntary testing have been routinely offered to all prenatal patients, no measurable decrease in women seeking prenatal care has been observed.

Human immunodeficiency virus seropositivity in a newborn measures maternally derived HIV IgG antibodies that, while not diagnostic of infection in the infant, provide unequivocal evidence of infection in the mother. Human immunodeficiency virus antibody screening of the newborn indirectly evaluates maternal HIV infection status, and therefore has the same intrinsic risks as prenatal HIV testing.

THE ISSUE OF CONSENT FOR HIV TESTING

A relationship of respect and trust between women and the health care system is critically important to the identification of women who are HIV-infected and their subsequent care and treatment. Therefore, provision of education concerning the benefits and possible risks of HIV testing is an important part of the process of HIV testing.

Documentation that information about HIV infection has been provided and that consent for testing was obtained has generally been accomplished by individual counseling followed by written or oral consent. Alternative, less resource intensive, acceptable options to individualized counseling include routine provision of education about HIV in written or video form or in group settings.

Some states have legal requirements for counseling followed by written consent for HIV testing. Routinely used methods in medical practice to document consent or refusal for medical procedures other than HIV testing include: 1) individualized counseling followed by a signature that affirms consent to testing; 2) provision of education followed by a signature that either explicitly consents to or explicitly refuses testing; or 3) education followed by a signature only to explicitly refuse the test. Each of these methods is an ethically acceptable way to respect the individual's decision whether or not to be tested. Each method, however, has different associated dimensions.

Individualized counseling in conjunction with obtaining a signature on an informed consent form requires significant health care resources. Patient education in written form or group settings followed by a signature of consent or refusal may require less intensive resources. In both of these methods of consent, the provider may directly recommend the test. Routine patient education accompanied by a signature only to reject the test (right of refusal) implies that the test is recommended by the health care professional and therefore will be performed unless the patient signs the form, and may also result in the largest number of women being tested. Although some believe that right of refusal consent is inherently coercive, documentation of appropriate patient education and confidentiality reduce the likelihood of such concern.

Because the results of ACTG 076 indicate that zidovudine has the potential to reduce perinatal transmission of HIV, there is now a compelling reason for universal antepartum HIV education and routine testing with consent. Whichever method of obtaining consent is chosen, it is critically important that appropriate education regarding HIV infection is provided to the individual before a decision regarding testing.

Currently, the percentage of pregnant women being evaluated for HIV infection is regrettably small. Therefore, testing programs for HIV infection should undergo periodic evaluation regarding the proportion of women being tested. Those programs in which a proportionately low number of women consent to receive HIV testing should examine the reasons for poor acceptance. Appropriate program modifications may need to be made to ensure that women understand the benefits of testing and feel comfortable undergoing testing.

Because infant testing provides information important to the well-being of the infant and also information regarding the infection status of the mother, the health care provider is obligated to educate the mother about HIV infection and to obtain consent using one of the methods described above when HIV testing of the infant is contemplated.

The purpose of HIV testing is to engage a woman in continuing care for herself and her baby, not to label a woman as being infected. Compliance with medical care is likely to be greatest when the patient feels she has made an informed judgment regarding HIV testing for herself or her infant. Routine HIV education accompanied by offering HIV testing to all pregnant women appears most likely to achieve this goal. Women need to be given sufficient information in a clear and understandable manner to appreciate the benefits and risks of the proposed HIV test and

the consequences of accepting or rejecting testing for herself and her infant. This process is best performed within the context of a professional relationship between the woman and her health care provider.

CONCLUSION

Human immunodeficiency virus infection continues to spread among women of childbearing age in the United States, and is occurring in rural as well as urban areas. With the increasing heterosexual spread of HIV, previously defined risk behaviors for HIV infection incompletely identify women found to be infected. The predominant risk behavior for HIV infection in many women is unprotected sexual intercourse. Perinatal HIV infection has mirrored the increases in HIV infection in women. With the availability of an intervention to reduce perinatal transmission of HIV, there is clear rationale for universal education and routine HIV testing of all women entering prenatal care. The persisting occurrence of PCP in young infants despite the availability of effective prophylactic regimens indicates that the identification and treatment of HIV infection in infants at an early age remains inadequate. Testing programs for HIV antibody must be confidential, voluntary, and accompanied by cultural and ethnically appropriate information regarding HIV infection. Such programs should be universally available.

RECOMMENDATIONS

1. On the basis of recent advances in therapy to reduce the rate of perinatal HIV transmission and the continued occurrence of life-threatening illness in young infants with unrecognized HIV infection, the AAP recommends documented, routine HIV education, and routine testing with consent, for all pregnant women in the United States. Documented consent for maternal and/or newborn HIV testing may be obtained in a variety of ways, including by right of refusal (documented patient education, with testing to take place unless rejected in writing by the patient). The Academy supports utilization of consent procedures that facilitate rapid incorporation of HIV education and testing into the routine medical care setting.
2. Routine education about HIV infection and testing needs to be a part of a comprehensive program of health care for women, particularly for women of child-bearing age.
3. All testing programs for the detection of HIV infection should periodically evaluate the proportion of women who refuse HIV testing following HIV education. Those programs in which a proportionately low number of women receive HIV testing should examine the reasons for poor acceptance, with appropriate program modifications made as needed.
4. For women who are seen by a health care professional for the first time in labor and who have either not received prenatal care or have previously tested negative, but have not been tested for HIV infection during the current pregnancy, education about HIV infection and maternal HIV testing are recommended during the perinatal period.
5. For newborns whose mother's HIV serostatus was not determined during the recent pregnancy or the postpartum period, the infant's health care provider should educate the mother concerning the potential benefits of HIV testing for her infant and the possible risks and benefits to herself of knowing the child's serostatus and recommend HIV testing for the newborn.
6. In the absence of parental availability for consent to test the newborn for HIV antibody, procedures need to be established to facilitate the rapid evaluation and testing of the infant.
7. The health care provider for the infant needs to be informed of maternal HIV serostatus so that appropriate care and testing of the infant can be accomplished. Similarly, if the infant is found to be seropositive when maternal serostatus is unknown, the health care provider for the child should ensure that information about the serostatus and its significance be provided to the mother and, with her consent, to her health care provider. The mother should receive appropriate referral to adult HIV-related services.
8. Comprehensive, HIV-related medical services should be accessible to all infected mothers, their infants, and other family members.
9. The Academy supports legislation and public policy directed toward eliminating any form of discrimination based on HIV serostatus.

PROVISIONAL COMMITTEE ON PEDIATRIC AIDS, 1994 TO 1995
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AIDS Babies Deserve Help, Now

Hundreds of babies infected with the AIDS virus will continue to go undetected and untreated every year unless Congress or New York State deal with this vexing public health problem. The State Legislature, immobilized by a fierce clash between those who want mandatory testing of all newborns and those who prefer a voluntary approach, has been unable to agree on a solution. Congress, knocked off course when the same fierce clash stopped a Federal survey of infected babies, has yet to take action.

Both bodies have a responsibility to get on with the job. It is simply irresponsible to let newborn babies go untreated while arguing over the mechanics of how to help them.

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The need for a vigorous response is clear. Women are becoming infected with the AIDS virus in rising numbers, and about 7,000 of them give birth each year. Many pass the virus on to their babies, either in the womb or during birth. Some 1,000 to 2,000 babies are infected this way each year, with New York State alone accounting for roughly a quarter of the total. Some of the infected babies are detected through voluntary blood tests on the mothers or their newborns. The rest go undetected and untreated until they become sick, when it is too late to offer them the best shot at a longer life.

Medical science knows quite well how to alleviate this damage. The best solution by far is to identify and treat the expectant mother before her child is born. One of the few bright spots in the battle against AIDS was the discovery last year that treating a pregnant woman with the drug AZT can greatly reduce the chances that she will pass the AIDS virus on to her child, saving most of the babies from infection.

Unfortunately, large numbers of women never come near a clinic for prenatal care and many of those who do come in for such care never get tested for the AIDS virus. So a fallback solution is to identify all infected newborns as early as possible, through blood tests, so that they can be closely monitored and treated. Doctors have no way to cure these infected babies, but they can ward off many of the infections that typically kill them, thus prolonging and improving the quality of their lives.

Although the medical solutions are in hand, they are not in fact being broadly applied. In New York State, for example, clinics try, with widely disparate vigor and success, to get women to agree to be tested during pregnancy or at birth and to allow their babies to be tested. But surveys suggest most of the infected babies are missed. A more vigorous effort is clearly needed.

Unfortunately, the State Legislature may be headed for another stalemate. The Senate has passed a bill to require mandatory testing of all newborns and mount a more aggressive voluntary testing program aimed at pregnant women. The new voluntary approach would make it harder and less likely for women to decline testing. But the Assembly has taken no action yet and has only four days before adjournment. Its leaders have traditionally opposed mandatory testing but seem inclined to accept a more vigorous voluntary effort for both pregnant women and newborns.

Either approach would be better than the status quo. This page has long endorsed mandatory tests for newborns on the ground that the health of the baby is more important than any privacy risk to the mother. But there is virtually no political appetite for imposing mandatory tests on pregnant women, so a strong voluntary approach is the only feasible alternative.

The best solution would be a national policy insuring that all infected babies are identified for monitoring and treatment. Representative Gary Ackerman, Democrat of New York, and Representative Tom Coburn, Republican of Oklahoma, will unveil an amendment this week that would require states, as a condition for receiving certain Federal AIDS funds, to test all newborns whose risk of infection has not been determined through voluntary testing of the expectant mother. That approach would provide a needed incentive for the states to identify and help these neglected babies.

Russia's Rancorous Politics

The unruly state of Russian politics was captured aptly the other day on a television talk show when Vladimir Zhirinovsky, the nationalist leader, tossed a glass of orange juice in the face of a reformist governor after he suggested Mr. Zhirinovsky had syphilis. Then there was the member of the Russian Parliament who turned up in the Duma chamber toting a toy gun to protest Government bargaining with Chechen fighters as a loss of Russian honor. His fellow lawmakers agreed, approving a nonbinding motion of no confidence in the Government of President Boris Yeltsin.

tained period of political stability. So far neither President Yeltsin nor the Parliament has shown the steady leadership to provide it.

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Talking points - Vaccines for Children

The Vaccines for Children program is an important part of the broader Childhood Immunization Initiative. The CII includes five key strategies to improve preschool vaccination rates. These include improving the quality and quantity of vaccination delivery services; reducing vaccine costs; increasing awareness, community participation and partnerships; improving the monitoring of disease and vaccination coverage; and improving vaccines and vaccine use.

Improving preschool immunization rates is one of the Clinton Administration's highest priorities. Since taking office, the Clinton Administration has doubled funding, and guaranteed funds for new vaccines. Legislation to launch a new Childhood Immunization Initiative was introduced soon after President Clinton's inauguration. A specific goal was set for 1996: increasing vaccination levels for two-year-old children to 90 percent for the most critical doses. And a new program to provide free vaccines to millions of poor and uninsured children was instituted.

While child immunization rates have improved since the 1989-1991 measles epidemic, VFC is a key part of the national strategy to reach the one million American children who are not fully vaccinated by age two. A 1993 survey found that 33 percent of pre-school children (average age 27 months) had not received a full series of the three most critical vaccines (MMR, DTP and polio). About 45 percent had not received the HIB vaccine, which protects children against bacterial meningitis; and 84 percent had not been vaccinated against Hepatitis B, which causes liver disease.

As an integral part of the CII, the Vaccines for Children program focuses on making free vaccines more widely available, reducing costs and missed opportunities for immunization. In the past ten years, immunization costs have increased ten-fold: the private cost of a full series of immunizations increased from about $27 in 1983 to $270 in 1994. A Spring 1992 survey by the American Academy of Pediatrics showed that 43 percent of pediatricians had increased their referrals to public clinics for vaccinations in the preceding ten years, primarily because of costs.

Under the VFC program, vaccines will be provided free to children who are enrolled in Medicaid or uninsured, and to native Americans and Alaskan natives. That means that physicians will no longer have to refer uninsured children to public clinics, a common practice that means missed opportunities for immunizations and fragmented care. And parents can choose which provider makes the most sense for their child, because the difference in price between the two settings ($270 and $129) won't be a factor.

This will make a tremendous difference for nine million uninsured American children. While Medicaid recipients can receive free vaccines under current law, working families have not had the same guarantee. Under VFC, more than one million infants and toddlers without insurance will now be guaranteed free vaccines, and their parents will pay only a modest administration fee. And because ten percent of all American children don't have health insurance, VFC will also help millions more older children who need follow-up vaccines at age four and fifteen.

Under VFC, every eligible child will receive vaccinations, even if parents cannot afford to pay the administration fee. Private doctors will continue to serve their regular patients, even if the parent or guardian cannot afford to pay the administration fee. Other needy children will not be charged a fee in public clinics.

In addition, VFC will provide free vaccines to children with limited insurance in rural health clinics and Federally Qualified Health Centers. In these settings, additional children whose insurance plans don't cover vaccinations will continue to be eligible for free vaccines.

Funds for new vaccines will automatically be provided. Under VFC, new childhood vaccines recommended by a federal advisory committee will automatically be purchased by the federal government and provided free to eligible children -- and budget constraints will never again limit or delay federal purchase of new vaccines.

States will be able to save money by ordering vaccines at the lower, government price. Because VFC will lower states' Medicaid costs for vaccines, these savings can be used to keep clinics open longer, or take other measures to increase immunization rates. And more states will be guaranteed the lower CDC price for the vaccines they do purchase.

Child immunization protects children and saves money. For example, every dollar spent on the MMR (measles/mumps/rubella) vaccine saves $21 in potential health care costs. For the DTP (diphtheria/ tetanus/pertussis) vaccine, the cost-benefit ratio is 30 to 1. And for polio, it's 6 to 1.

Questions and Answers on the VFC Program
6/15/95

Q: The GAO has challenged CDC's assertion that the cost of vaccines is a barrier to childhood immunization. Is cost a barrier or not?

A: Cost is a barrier because it contributes to delays in achieving full immunization of preschool children with today's vaccines. The cost of the complete vaccine series has increased ten-fold in the past 12 years. Since parents must pay about $270 in vaccine costs and an additional amount in administration fees for the series, those without adequate insurance may not seek immunizations from their private doctors, but from public health clinics where vaccine is free or available at nominal cost. Having to make extra visits to public clinics can result in delays and missed opportunities for immunization.

Numerous surveys of practitioners and health departments have also documented increased referrals of patients from their primary care providers to public clinics, with cost as the most important reason cited. A 1992 American Academy of Pediatrics study revealed that 55 percent of pediatricians refer some or all or their patients to a public provider for immunizations. A 1992 North Carolina survey showed that 93 percent of physicians referred patients to health departments for immunizations, and states such as New York have showed similar trends.

Q: The GAO has recommended that the VFC program should be targeted to certain population groups and areas referred to as "pockets of need." Doesn't this make sense?

A: We believe, and Congress has agreed, that the proper goal of Federal immunization efforts is to raise immunization levels throughout the nation, and to put in place a sustainable system that will ensure that immunization rates remain high. The GAO conclusion assumes that "general immunization rates" are not now a problem and will not be a problem in the future.

While child immunization rates have improved since the 1989-1991 measles epidemic, VFC is a key part of a national strategy to reach the one million American children under two who are unvaccinated against one or more deadly diseases. A 1993 survey found that 28 percent of pre-school children (average age 27 months) had not received a full series of the three most critical vaccines (MMR, DTP and polio). About 40 percent had not received the HIB vaccine, which protects children against bacterial meningitis; and 84 percent had not been vaccinated against Hepatitis B, which causes liver disease.

Q: Does the Administration oppose folding the Vaccines for Children (VFC) program into a block grant?

A: The Clinton Administration has a very simple goal -- to improve preschool immunization rates. Since taking office, the President has lead an aggressive campaign to reach that goal, and we have made great progress. But we believe that our current investment in children's immunizations must be maintained. Childhood immunizations are one of the most cost-effective public health investments we can make -- they save lives and they save money. To take just one example, for every dollar spent on the measles/mumps/rubella vaccine, we save $21 in health care costs.

We are more than willing to work with Congress to make changes to improve the VFC program. But we are not willing to watch as Congress slashes funding for childhood immunizations in just one more shortsighted attempt to cut the budget.

Q: Is the Administration's position that VFC must remain an entitlement?

A: Our position is clear. We believe that the federal budget should be balanced, but in a way that makes sense. The President has laid out a proposal that retains coverage under Medicaid while reducing spending and giving states more flexibility. Medicaid is a critical health care program; it can certainly be improved,but not by cutting it dramatically to balance the budget. The same applies to VFC. If we can improve the way we are going about our childhood immunization efforts, we're certainly willing to work on it. But we must maintain poor and uninsured children's access to life saving and cost-effective vaccines.

AIDS Babies Deserve Help, Now

Hundreds of babies infected with the AIDS virus will continue to go undetected and untreated every year unless Congress or New York State deal with this vexing public health problem. The State Legislature, immobilized by a fierce clash between those who want mandatory testing of all newborns and those who prefer a voluntary approach, has been unable to agree on a solution. Congress, knocked off course when the same fierce clash stopped a Federal survey of infected babies, has yet to take action.

Both bodies have a responsibility to get on with the job. It is simply irresponsible to let newborn babies go untreated while arguing over the mechanics of how to help them.

•

The need for a vigorous response is clear. Women are becoming infected with the AIDS virus in rising numbers, and about 7,000 of them give birth each year. Many pass the virus on to their babies, either in the womb or during birth. Some 1,000 to 2,000 babies are infected this way each year, with New York State alone accounting for roughly a quarter of the total. Some of the infected babies are detected through voluntary blood tests on the mothers or their newborns. The rest go undetected and untreated until they become sick, when it is too late to offer them the best shot at a longer life.

Medical science knows quite well how to alleviate this damage. The best solution by far is to identify and treat the expectant mother before her child is born. One of the few bright spots in the battle against AIDS was the discovery last year that treating a pregnant woman with the drug AZT can greatly reduce the chances that she will pass the AIDS virus on to her child, saving most of the babies from infection.

Unfortunately, large numbers of women never come near a clinic for prenatal care and many of those who do come in for such care never get tested for the AIDS virus. So a fallback solution is to identify all infected newborns as early as possible, through blood tests, so that they can be closely monitored and treated. Doctors have no way to cure these infected babies, but they can ward off many of the infections that typically kill them, thus prolonging and improving the quality of their lives.

Although the medical solutions are in hand, they are not in fact being broadly applied. In New York State, for example, clinics try, with widely disparate vigor and success, to get women to agree to be tested during pregnancy or at birth and to allow their babies to be tested. But surveys suggest most of the infected babies are missed. A more vigorous effort is clearly needed.

Unfortunately, the State Legislature may be headed for another stalemate. The Senate has passed a bill to require mandatory testing of all newborns and mount a more aggressive voluntary testing program aimed at pregnant women. The new voluntary approach would make it harder and less likely for women to decline testing. But the Assembly has taken no action yet and has only four days before adjournment. Its leaders have traditionally opposed mandatory testing but seem inclined to accept a more vigorous voluntary effort for both pregnant women and newborns.

Either approach would be better than the status quo. This page has long endorsed mandatory tests for newborns on the ground that the health of the baby is more important than any privacy risk to the mother. But there is virtually no political appetite for imposing mandatory tests on pregnant women, so a strong voluntary approach is the only feasible alternative.

The best solution would be a national policy insuring that all infected babies are identified for monitoring and treatment. Representative Gary Ackerman, Democrat of New York, and Representative Tom Coburn, Republican of Oklahoma, will unveil an amendment this week that would require states, as a condition for receiving certain Federal AIDS funds, to test all newborns whose risk of infection has not been determined through voluntary testing of the expectant mother. That approach would provide a needed incentive for the states to identify and help these neglected babies.

Russia's Rancorous Politics

The unruly state of Russian politics was captured aptly the other day on a television talk show when Vladimir Zhirinovsky, the nationalist leader, tossed a glass of orange juice in the face of a reformist governor after he suggested Mr. Zhirinovsky had syphilis. Then there was the member of the Russian Parliament who turned up in the Duma chamber toting a toy gun to protest Government bargaining with Chechen fighters as a loss of Russian honor. His fellow lawmakers agreed, approving a nonbinding motion of no confidence in the Government of President Boris Yeltsin.

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THE NEW YORK [illegible]

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

November 9, 1994

Contact: HHS Press Office
(202) 690-6343

WOMEN AND HIV/AIDS

The rapid growth of HIV/AIDS among women is a major public health problem. In 1992, the total number of reported AIDS cases among women was 6,295. In 1993, that figure jumped to 16,824, and since women represent the fastest growing population with the disease, the number infected may be much higher. As a result of perinatal transmissions, AIDS is the leading cause of death among Hispanic children and the second leading cause of death among African American children. Recent research findings have shown that the human immunodeficiency virus (HIV) is more easily spread from men to women than from women to men.

The Department of Health and Human Services under the Clinton Administration has marshalled its resources to respond to these troubling trends, protecting American women and their children.

The Role of the Department of Health and Human Services

- **The National Institutes of Health** (NIH) have adopted a policy requiring the inclusion of women and minority populations in all AIDS clinical trials involving human subjects.
- **NIH-sponsored clinical trials** provided strong evidence that use of AZT by HIV-positive pregnant women dramatically reduced the rate of HIV transmission from mother to infant.
- **The Food and Drug Administration** expeditiously approved changes in labelling indications for AZT to include treatment of HIV-infected pregnant women.
- **The Public Health Service** published "Recommendations on the Use of Zidovudine to Reduce Perinatal Transmission of HIV" to assist women and their doctors in making decisions about the use of AZT to prevent transmission of HIV.
- The NIH created a **Women's Interagency HIV Study** to identify the nature and rate of HIV disease progression in women.
- The NIH has initiated a major research effort to develop **female-controlled barrier methods** to prevent HIV transmission.

- Funding for **the Ryan White CARE Act**, which provides services to people with HIV/AIDS, has risen 81.9 percent since 1993, providing funding for new services to women and children.

- The Centers for Disease Control and Prevention (CDC) launched a national **AIDS Prevention Marketing Initiative** aimed at young adults (ages 18-25), featuring frank, culturally-sensitive public service announcements promoting both abstinence and consistent and correct use of latex condoms.

- **AIDS Hotlines.** The CDC have established two AIDS hotlines, providing general information and treatment referrals to health care professionals and the general public.

HHS FACT SHEET

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OLDER WOMEN

The Department of Health and Human Services, through a range of comprehensive programs and services, is working to improve the quality of life for America's older women. Women comprise 60 percent of today's population aged 65 and over. By the year 2000, it is expected that there will be five women for every two men over the age of 75. Compared to men, elderly women are three times more likely to be widowed or living alone, spending more years and a larger percentage of their lifetimes disabled, and residing in a nursing home. Elderly women are also two times more likely than men to be living in poverty. Recognizing the evolving roles and concerns of women, the Department has devoted new resources to meeting the needs of women throughout their lifespans.

The Role of the Department of Health and Human Services

- **The Initiative on Older Women.** This multi-million dollar initiative, launched in September 1994 by the Administration on Aging, will increase government partnerships designed to address the needs of older women; improve women's capacity to contribute significantly to society throughout their lives; and establish an Older Women's Policy and Resource Center to educate older women at the grassroots level about issues such as income security, health, housing, domestic violence, and caregiving and the importance of addressing these concerns.

- **The White House Conference on Aging.** The 1995 White House Conference on Aging will address long-term care, nutrition, and other issues related to the health of America's older women.

- **Research on Women's Health and Aging.** The Administration's Fiscal Year 1995 budget request included $1.8 billion for women's health. $375 million was appropriated for research on breast cancer and additional funds will go to osteoporosis research, a disease for which older women are particularly at risk. Grants totalling $1.5 million will also fund research on conditions contributing to the loss of independence among older adults; menopause and health in aging women; and elderly population redistribution across the United States.

- **The National Institutes of Health (NIH) Women's Health Initiative.** This initiative, the largest clinical research study ever conducted, will examine the major causes of death and disability in post-menopausal women: heart disease, breast and colon cancer, and osteoporosis.

- **Medicare.** At age 65, almost all U.S. women become eligible for the Medicare program, and six out of ten current Medicare beneficiaries are women. The department is also working with consumer and provider organizations to distribute information on Medicare's free annual flu shots and lifetime pneumonia vaccinations to help prevent these life-threatening diseases.

- **Elder Abuse Prevention.** The Administration on Aging and the Administration on Children and Families are funding a three-year study of the national incidence of elder abuse. In FY 1994, the Centers for Disease Control and Prevention also devoted $9.1 million to improve data collection on violence against women, identify effective prevention strategies, and explore new ways to increase public awareness. $10.3 million will be dedicated to similar efforts in FY 1995.

- **Elder Nutrition.** Recognizing that eighty-five percent of older individuals have a nutrition-related condition or chronic disease, the Administration on Aging is also continuing to support community nutrition services. In 1993, the Department began a two-year, $2.4 million study to evaluate the federal meals program. Last year, nutrition assistance funds totalled $469 million, and helped provide about 250 million meals for older persons.

- **Mammography Quality Standards Act.** Annually, breast cancer affects 87,500 women over the age of 65, accounting for 48 percent of all diagnosed breast cancers each year. Through implementation of the 1992 Mammography Quality Standards Act, the Food and Drug Administration will ensure high-quality and reliable mammography for all women.

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BREAST CANCER

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. The lifetime risk of developing breast cancer today is one in every eight women, up from one in every 20 women just two decades ago. Despite these numbers, nearly half of women age 50 and older have not had a mammogram in the past two years.

In December 1993, Secretary Donna E. Shalala convened an historic conference to establish a National Action Plan on Breast Cancer, affirming the Administration's commitment to addressing breast cancer as a high priority concern. The conference was attended by 150 representatives from advocacy groups, private industry, academia, and government. Proceedings from this conference will provide a framework for action in three major areas: the delivery of health care, the conduct of research, and the enactment of policy. To further the implementation of the National Action Plan, three coordinating groups are continuing to work on a range of activities and strategies.

The Role of the Department of Health and Human Services

- **Comprehensive Clinical Guidelines.** New guidelines on breast cancer were released on October 19, 1994, clearly outlining the responsibilities of women and their doctors in treating the disease. These guidelines were developed by a panel of private sector experts and were distributed nationwide.

- **The Mammography Quality Standards Act.** Effective October 1, 1994, this Act (implemented by FDA) requires uniform safety certification for the roughly 12,000 mammography facilities nationwide. As we promote mammographies for women at risk, this rigorous law requires facilities to hire capable technicians, use quality film, and employ skilled radiologists to interpret the results.

- **The National Breast and Cervical Cancer Early Detection Program.** This program received $68.7 million in federal grants during 1994. The goal of the program is to reduce breast cancer deaths by 30 percent and cervical cancer deaths by more than 90 percent through increased mammographies and Pap testing. In particular, this program is designed to reach women of racial and ethnic minorities where mortality rates are disproportionately high.

- **Increased Funding for Research.** A total of $375 million was appropriated in FY 1995, more funds than under any previous administration, to further understanding of the complexities of breast cancer. Achievements funded and accomplished by this Administration include:

  - Isolation of BRCA1, a gene believed linked to breast cancer in the 1 of 200 women who have the gene. This discovery should lead to the development of a test, identifying those women at risk for the inherited form of the cancer.

  - A study sponsored by the National Cancer Institute that found women who exercise four hours a week can cut their risk of breast cancer by 50 to 60 percent.

- **Imaging Technology**. The Department is working with other federal agencies, including NASA and the Defense Department, as well as private companies, to adapt high-tech imaging and diagnostic equipment to the task of locating malignant cancer in its earliest stages.

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REPRODUCTIVE HEALTH

Through a series of executive and legislative proposals, the Clinton Administration has helped ensure that women can make their own reproductive health decisions safely, with accurate information and without interference. The Administration continues to emphasize the need for comprehensive family planning services, including education to ensure patient understanding of the consequences of unprotected sexual activity and adequate provision of access to family planning and reproductive health services.

The Role of the Department of Health and Human Services

- **Improved Information and Access.** On his second day in office, President Clinton repealed the "Gag Rule" that restricted abortion counseling at federally funded family planning clinics. Pregnant women can now receive full information about their options at these clinics.

- **Equity and Choice.** In the FY 1994 HHS appropriations bill, the Administration made crucial changes to the so-called Hyde Amendment. These changes, renewed this year, obligate states to pay for abortions for poor women whose pregnancies result from rape or incest, or endanger the life of the mother.

- **Family Planning.** In May 1993, the Food and Drug Administration approved the first barrier contraceptive for women that also offers limited protection against sexually transmitted diseases. Research continues on other woman-controlled barrier methods for preventing transmission of the HIV virus and other sexually transmitted diseases.

- **RU-486.** In keeping with a 1993 Presidential Memorandum, HHS has pursued the testing of RU-486 within the United States. In May 1994, Secretary Donna E. Shalala announced that the French pharmaceutical company Roussel Ucalf would donate its United States patent rights for the drug to the Population Council, a not-for-profit organization. Clinical trials are underway within a number of communities throughout the country.

- **Improved Research.** The Administration has ended a five-year moratorium on federal funding of human fetal tissue transplantation research. Through this research, scientists hope to learn more about the reasons behind miscarriages and birth defects.

- **Population and Development.** As one of the leaders at the Cairo International Conference on Population and Development, the U.S. helped ensure the adoption of a comprehensive program emphasizing: commitment to voluntary family planning as a crucial part of reproductive health care; commitment to gender equity through improved education and development; and achievement of these goals in the context of equitable sustainable development.

Mandatory Testing of Pregnant Women

Pros

- Learning one's HIV status allows people the opportunity to seek early medical interventions and the opportunity to provide referrals to social, legal and psychological services. It also provides and opportunity for personal risk assessment, and education about HIV.

- Recent research has shown that Zidovudine (ZDV) treatment, when administered to HIV-infected women during pregnancy and to their newborns, significantly reduces the rate of perinatal HIV transmission. Knowledge of one's HIV status offers the opportunity to offer ZDV treatment during pregnancy.

- Knowledge of a mother's HIV status would prevent possible HIV transmission through breast feeding.

- Knowledge of a mother's HIV status would allow prophylactic measures to be taken to prevent the onset of opportunistic infections such as *Pneumocystis carinii* pneumonia (PCP) in infants.

Cons

- Mandatory testing of newborns and pregnant women would undermine the establishment of a trusting relationship between each mother and the health care system. This partnership, so critical to the proper care of both infant and mother, is far less likely to occur if it begins with a peremptory or imposing act.

- The most important factor in a baby's care is her mother. Building a relationship through counseling and consent enables health care providers to keep the baby connected to the health care system.

- Compliance with medical care is likely to be greatest when the patient feels she has made an informed judgement regarding HIV testing for herself or her infant.

- The best way to insure care for mothers and infants is to provide comprehensive, supportive health care services, including counseling about HIV and voluntary HIV testing.

- The overwhelming majority of women offered the opportunity to be tested voluntarily will do so if they are assured that their confidentiality will be protected and that care and services will be provided for the babies and themselves.

  - Of over 3,500 women registered for prenatal care at Grady Memorial Hospital in Atlanta, GA, 96 percent chose to be tested after being provided HIV counseling and offered voluntary testing (Lindsey, 1989).

- At the Harlem Hospital in New York City, 95 percent of women at the high-risk pregnancy center voluntarily consented to HIV testing after counseling was offered by hospital health care providers (personal communication).

- There is real concern that mandatory testing for HIV will discourage pregnant women form seeking care. Mandatory testing has been shown to drive people away from the health care system. This would result in a double tragedy--adversely affecting infants of mothers who don't have HIV, and denying the opportunity for HIV prevention to infants of HIV positive mothers.

- The majority of HIV-infected women are from low-income communities of color, and many of them have substance abuse histories. These factors, combined with the very real problems of discrimination, domestic violence, fear of losing their children, create barriers to accessing care that will only be exacerbated by mandatory testing programs.

- Allocating funds for mandatory testing is a poor use of resources. Mandatory testing is expensive and ineffective because it causes many people to avoid the system, thereby increasing costs down the road.

- Resources should be put in providing prenatal care which includes counseling about HIV and offers voluntary testing.

PEDIATRIC AIDS

- The issue of whether HIV testing of pregnant women should be mandatory or voluntary is extremely complicated. However, while there are strong arguments on both sides, everyone has the same goal -- preventing babies from getting HIV infection. The question is how best to do that.

The Pediatric AIDS Foundation Event

- The point of your doing the Pediatric AIDS Foundation's event is that while we are arguing about these issues in Washington, we can save thousands of babies across this country. That's why the Pediatric AIDS Foundation's PA campaign is so important -- it's about getting women to get tested **now**, so that they can get the treatment they need to protect their health and the health of their children. The Pediatric AIDS Foundation believes that the best way to prevent transmission from mother to child is to encourage voluntary counseling and testing.

The CDC Study

- Nat Hentoff and Congressman Ackerman have the facts wrong. They argue that we should disclose to mothers the results of blood tests taken as part of a longrunning CDC study in order to prevent transmission of HIV infection from mother to child.

- "Unblinding" the study (i.e., disclosing the results of the study to the mothers of the newborns tested) amounts to mandatory HIV testing of women. However, it's important to separate the CDC study from the larger issue of mandatory v. voluntary testing.

    - The CDC study tests newborns' blood in order to track HIV infection among women. It has provided valuable statistical information and was ethically acceptable at a time when no treatment could be offered to the infants tested.

    - Now, however, treatment to prevent pneumonia is recommended for infants. Therefore, most experts agree that the study should either be "unblinded" or ended. On May 10, Secretary Shalala and Phil Lee asked the CDC to suspend the study in order to determine whether it should be discontinued .

    - Those who support unblinding the study argue that if we test newborns we can know their HIV status and treat them immediately.

- Dr. Art Amman, the Director of Research of the Pediatric AIDS Foundation, argues that the study should be discontinued and that the $10 million that is spent on it each year should be used to pay for voluntary counseling and testing and for treatment for pregnant women. He argues that continuing the study and disclosing the results can at best temporarily postpone the illness of some infants, while getting women tested and treated early in pregnancy can actually prevent infection.

- We need a full discussion of the merits of both sides of this argument. But it is clear that the CDC study is not the best point of intervention. Simply waiting for babies to be born so that we can test their blood to determine that they *have* contracted the virus from their mother is too little too late.

Voluntary v. Mandatory Testing

- The more difficult issue is whether women should be *required or encouraged* to be tested earlier in pregnancy.

  - Because of the recent NIH study, we know that treatment with AZT during pregnancy can dramatically reduce the risk of transmission from mother to child.

  - This leads some to suggest that we should mandate testing for pregnant women.

    - **PROS.** This would clearly enable every pregnant woman who comes for prenatal care to know her HIV status early enough to get life-saving treatment.

    - **CONS.** However, test results only prevent transmission if a woman gets treatment. AZT treatment during and after pregnancy requires cooperation between the doctor and the patient. There is evidence that mandating testing drives women from getting any prenatal care for fear that they will lose their children, homes and health insurance.

      Again, because test results are meaningless without treatment, mandatory testing also raises a host of issues about how we require it, whether we require treatment as well as testing, and who pays for it (e.g., if a woman finds out she is HIV-positive but her insurance doesn't cover AZT).

Finally, women's groups (including NOW) and some AIDS advocacy groups argue that mandatory testing is an invasion of the privacy of the woman. For obvious reasons, I do not find this argument *at all* convincing. (In fact, I think it hurts.)

- Others believe that the best way to get women to get the treatment they need is through voluntary counseling and testing.

    - **PROS.** Studies in Atlanta, Miami and Harlem show that voluntary testing works. About 95% of women chose to be tested after receiving HIV counseling.

    - **CONS.** Voluntary testing does not guarantee that all women will be tested and treated.

Jean Klein

May 8, 1995
Subject: HIV Survey of ChildBearing Women

Dear Colleague:

Issuance of the proposed PHS Recommendations for HIV counseling and voluntary testing of pregnant women and their infants, and provision of preventative therapy is a high public health priority. These efforts, coupled with forthcoming recommendations for prevention and treatment of opportunistic infections in infants, add new urgency to encouraging all pregnant women to learn their HIV status and access appropriate care for themselves and preventive efforts for their newborns.

In light of these new prevention and treatment opportunities, I am requesting that you suspend the Survey of Childbearing Women until we have completed a consultative process with the States, CDC Advisory Committee of Prevention of HIV Infection and interested parties. It is my hope that we can work together to develop a strategy that takes full advantage of the opportunities to prevent HIV transmission and slow the course of disease progression in these populations as outlined in PHS Recommendations for HIV Counseling and Testing for Pregnant Women.

Within the next few weeks, the Director of the Centers for Disease Control and Prevention will begin a process, assisted by external expert consultants, to consider the advisability and feasibility of developing appropriate surveillance mechanisms in the context of implementing prenatal counseling and testing recommendations and advise CDC and the Public Health Service on a plan to: (1) ensure that all pregnant women are [redacted] counseling and testing and that they and their [redacted] are entered into a continuum of medical and support services; (2) fully evaluate the implementation and effectiveness of the guidelines; (3) continue to monitor trends in HIV infection in women; and (4) assess the advisability and feasibility of developing appropriate surveillance mechanics for these purposes. Participation in this process by public health officials, private providers, [redacted] and ethical experts, providers caring for women and children with HIV disease, and communities affected by HIV would be most helpful to ensuring widespread implementation of the Committee's findings and recommendations.

I am confident that this consultative process can provide a strong foundation for determining how best to achieve these goals. It is my expectation that we will continue to meet the important goals held by CDC and State health departments of preventing the spread of the HIV epidemic and monitoring its movement in the country.

Sincerely:

/S/

Philip R. Lee, M.D.
Assistant Secretary for Health

Statement of Dr. Arthur Ammann
May 22, 1995

At last, there is some good news about AIDS: With appropriate care begun early in pregnancy, an HIV-infected woman can significantly reduce the chance that her baby will be born infected. This is the first time that a drug has been shown to be effective in preventing the transmission of HIV.

It is important that people understand and appreciate this progress, because it comes in the midst of a number of confused policy debates, some of which could do significant damage to efforts to prevent and treat HIV infection. In this debate, the message must not be lost that only routine voluntary prenatal testing with counseling provides the maximum benefit to pregnant women and their infants.

A part of the debate is about the longrunning CDC study on the infection rate in newborns around the Nation. This study gathers infants' blood samples from which all identifying information has been removed. It has provided valuable statistical information over the years and was ethically acceptable during the era in which no treatment could be offered to those infants. Once pneumonia prevention treatment was recommended for infants, however, I believe that the study should have been discontinued as ethically unsound. While it was no one's intent to do so, the removal of identification from the samples had the effect of withholding potential treatment from these babies. For that reason, I believe that either the test results should be given to the parent(s) of the child or that the seroprevalence study must be discontinued.

My first preference is for the study to be discontinued (as the Public Health Service has done) and for the $10 million in funding that it consumes annually to be converted to programs to provide routine, voluntary counseling and testing and AZT treatment to pregnant women. To continue the seroprevalence study in its current form will only count infections in infants. To continue the study with names attached will render the statistics questionable (since some women may decline to participate) and could at best help with temporarily postponing the illness of some infants. This misses the mark. The goal of HIV testing should be to provide treatment for mothers and infants to prevent HIV infection. Newborn testing does not provide optimal health care for either mother or infant.

Embarking on a program to routinely provide voluntary prenatal counseling and testing and treatment can actually prevent pediatric AIDS--saving lives and saving dollars. I support the Public Health Service's suspension of the study; now it must take the next logical step and devote the freed-up funds to preventing pediatric HIV infection through counseling, testing, and treatment of pregnant women.

I believe that voluntary testing programs for pregnant women will actually result in more women being tested for HIV than any mandatory program. As with any disease, the trust and cooperation between physician and patient are essential. The data are clear on voluntary programs: From Harlem to Miami and in France and Italy as well, 93-96% of pregnant women agree to be tested voluntarily.

The dangers of mandatory programs are equally clear: From mandatory HIV testing for marriage licenses to mandatory drug testing in drug treatment programs, people refuse to take part in programs that they are afraid of. We lose what is needed--the long-term relationship between patient and physician.

If we are to succeed in reducing HIV infection among babies, we must educate women and doctors alike to believe in the efficacy of the new treatment and in each other. Without such education and trust, no program can succeed.

I believe that mandatory testing for newborns is a blind alley. We will ourselves into believing that we are doing our best to help the infant when we are not. If we are really interested in preventing HIV infection in infants--in saving their lives--we must put all our efforts into routine, voluntary prenatal testing. If we can succeed in a program to provide routine voluntary testing to pregnant women, we will not need to test their newborns.

It should be obvious also that no testing program will be effective in accomplishing any goal if treatment is not available. The treatment needed during pregnancy to prevent HIV infection is far beyond the personal means of most women with HIV. Only if the Federal government maintains its commitment to making therapies available to women of little or moderate means will our efforts be successful. And only if we provide health care and counseling for women before, during, and after pregnancy will we have a significant impact on this disease.

Finally, let me add that the effort to prevent HIV infection in newborns is only one aspect of HIV prevention. Clearly the most effective way of preventing babies from being infected is to prevent their parents from being infected. Routine voluntary prenatal HIV testing provides an opportunity for counseling and education. We must continue and strengthen our efforts to prevent transmission among adults.

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JACK ANDERSON and MICHAEL BINSTEIN

United Nations Faces a 'China Problem'

UNITED NATIONS

The United Nations, which will celebrate its 50th anniversary in October, could soon be dealt a world-class public relations disaster by one of its most obstinate members.

The People's Republic of China ranks among the worst human rights violators in the world. Yet two months before the anniversary celebration, China will host the United Nations' fourth international conference on women. Already, the specter of holding a women's conference in a country where infanticide is still common has drawn complaints from international women's advocates.

The irony is also not lost on top U.N. officials, some of whom have complained privately for years about the tendency of the United Nations to kowtow to Chinese demands. While U.N. officials often feel no qualms about rebuffing American demands, hardly anybody says no to China.

"I've advised [the secretary general] that he has to get tougher on China, and he believes he's going to have to soon," a close aide to Secretary General Boutros Boutros-Ghali told us.

The current "China problem," as it is called here, came about after China begged U.N. officials to host the event several years ago, thinking it would boost its international prestige and visibility. While international Olympic officials turned down China's request to host the Olympics in 2000, U.N. officials obliged. Today, however, both China and the United Nations privately rue the decision.

Chinese officials have raised international eyebrows by moving to exclude several groups from the conference: Representatives from Tibet and Taiwan, lesbian organizations and others whom the government considers politically unsavory have thus far been denied seats at the table.

Yet the surprising thing is not that these groups are being ostracized by China; it's that U.N. officials thought it appropriate in the first place to let China host a conference aimed at improving human rights for women around the globe. This is a country that once engaged in heinous foot-binding and legal concubinage, and is not yet out of the dark ages when it comes to women's rights.

At the moment, behind-the-scenes bickering centers on the conference site for representatives from non-governmental organizations (NGOs). Traditionally, these groups help official representatives from each country with information and support. Some NGO representatives serve on official delegations as well.

Banning NGO representatives from China would be akin to having denied the Sierra Club a place at the table at the Rio de Janeiro environmental summit in 1992. China agreed to admit the groups, but now has conveniently discovered the central Beijing stadium where they were to meet is structurally unsound. Thus, the NGOs have been shuttled to a tourist area far from the main conference.

"By selecting a site that keeps women and their governments apart, the Chinese government is preventing either meeting from succeeding," complained one letter from the Manila-based Women's Media Circle Foundation to Boutros-Ghali.

Conference planners in New York have told our associate Dale Van Atta that the Chinese are also trying to come up with "red-tape reasons" why a few antiabortion NGO groups cannot attend. The Chinese practice abortion routinely as part of the government's effort to control population growth.

As the conference date draws closer, complaints about China's human rights record will likely become more strident. Yet another recent episode is a telling reminder of China's thin-skinned ways of dealing with dissent.

Ian Williams, respected chief of the U.N. Correspondents Association, was invited to address the General Assembly's Committee on Information May 5. He used the closed-door occasion to chide the world body for refusing to allow a prominent Chinese dissident to address the association and for revoking the credentials of two Taiwanese journalists.

Williams's invective drew quick rebuke from Chinese officials, who protested May 8 that Williams "abused the hospitality of the member states," adding that his actions "constitute a gross interference in the internal affairs" of China. Unfortunately, the concept of free speech has yet to enter the vocabulary of China's U.N. representatives.

Perhaps the embarrassing appeasement of China, as typified by the upcoming women's conference, will help remind world leaders that after 50 years of service, the United Nations has yet to live up to its own lofty ideals.

Nat Hentoff

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After winning a Pulitzer Prize for commentary this year, Jim Dwyer of Newsday was being interviewed on the New York affiliate of National Public Radio. The host, Brian Lehrer, was puzzled—indeed disturbed—that part of Dwyer's prize was due to a series of columns exposing the fact that although New York State—like 44 others—has been testing all newborns for various conditions, it does not disclose an infant's HIV status to either the mother or her doctor. It is a "blind" test.

Dwyer considers this failure to inform—with subsequent illnesses and early death for thousands of children who could have been treated—outrageous. The interviewer, however, said to Dwyer: "You're considered a liberal columnist, but on the HIV-testing of infants, you took the conservative position."

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

MAY 22 1995

To: Kitty Higgins
Secretary to the Cabinet

From: Kevin Thurm

Subject: Current Issues Concerning HIV and Pregnant Women:
1) CDC's HIV Survey in Childbearing Women and
2) Counseling and Testing Guidelines

Background

At the request of Leon Panetta, the following briefly discusses two issues concerning HIV and pregnant women which are receiving media attention: CDC's childbearing women survey and its counseling and testing guidelines. Although related, they should be understood independently.

1) Newborn Screening Survey

The CDC's HIV Survey in Childbearing Women, begun in 1988 during the Reagan Administration and carried on through the Bush Administration, was conducted in 45 states, District of Columbia, Puerto Rico, and the Virgin Islands, at a cost of 10.5 million dollars annually. As a blinded (identity of patient not known to researchers) population-based survey, it monitored the HIV epidemic among childbearing women and their newborn children by testing the blood of the newborns. The survey played an important role in our ability to track the expansion of the epidemic in women and children specifically and heterosexuals indirectly (a fact sheet is attached). This survey was begun and conducted before knowledge of an effective treatment for HIV positive pregnant women.

2) Counseling and Testing Guidelines

Over almost two years, there has been a clinical trial testing the effectiveness of administering AZT to pregnant women to prevent perinatal transmission of HIV (076 drug trials). Successful results were reported in February, 1994, disclosing that by taking AZT during pregnancy and childbirth, asymptomatic HIV positive women could reduce the risk of transmission to their children by as much as two-thirds. In August, 1994, CDC issued a report recommending

that all HIV positive pregnant women be offered treatment with AZT to prevent perinatal transmission. In February of 1995, CDC issued preliminary guidelines for physicians to apply these research findings. The guidelines call for counseling all pregnant women to be tested for HIV and advise doctors to explain the potential benefits and risks of AZT treatment to those women who are HIV positive. These have been praised by medical and public health professionals, including the American College of Obstetrics and Gynecology, the American Academy of Pediatrics, and Dr. Art Ammann of the Pediatrics AIDS Foundation.

The preliminary guidelines are expected to be made final in June.

The Ackerman Critique

Since the results of the AZT drug trials, critics of the childbearing women survey, including Congressman Gary Ackerman (D-NY), have proclaimed this survey unethical, as HIV positive newborns are "going home without vital medical care because mothers are unaware of their child's HIV status." Congressman Ackerman introduced a bill with 220 co-sponsors to mandate the notification of patients of the testing results from the survey. The specter of the Tuskegee study has been raised by Dr. Art Ammann and columnist Nat Hentoff.

Action by HHS

On May 11, 1995, Dr. Phil Lee, Assistant Secretary for Health, asked State Health Directors to suspend the Survey of Childbearing Women until the completion of a consultative process with the states, CDC Advisory Committee of Prevention of HIV Infection, National HIV/AIDS organizations and other interested parties (letter attached). The consultative effort will make recommendations to the CDC and the Public Health Service on strategies to: (1) ensure that all pregnant women are offered HIV counseling and testing and that they and their child are entered into a continuum of medical and support services; (2) fully evaluate the implementation and effectiveness of the Counseling and Testing Guidelines; and (3) continue to monitor trends in HIV infection in women. Finally, the consultative effort will address the ethics debate over blinded surveys and distinguish the purpose of surveys from more systemic efforts to identify and enter individuals into care.

KEY ISSUES

1. Ethical Concerns with Survey:

   Although the CDC Investigational Review Board (IRB) cleared the survey, as have many state IRB's, and the general acceptance of blinded surveillance techniques world wide (WHO/IOM STUDY '94), there is still reason to warrant a thorough evaluation of ethical concerns around blinded surveillance procedures.

2. Civil Liberties Issue vs Public Health Strategy (regarding the survey):

   Many woman's groups and representatives of HIV infected women argue that public concerns with the survey are focused on issues around the infant and not the mother; therefore, the issue becomes an either/or situation: the woman's right to refuse testing vs society's interest in knowing about the infant. Casting the issue in this light ignores the most effective public health strategy we know: voluntary identification of as many HIV positive pregnant women as possible and entering the woman (and eventually the child) into a continuum of medical and support services as defined in the CDC/PHS Counseling and Testing Guidelines.

   We presently believe that voluntary identification of HIV infected women will result in the greatest AZT use during gestation, delivery and postpartum in the newborn. Mandatory testing of women runs the risk of alienating the mother from the health care system and she, in most instances, is the primary care giver for herself and the child.

3. Risk of Mandatory Testing due to Survey and Guidelines:

   The Ackerman bill has rekindled discussions around the need for mandatory testing of pregnant women and their newborn infants. The discussion has focused on the new recommendations from the CDC on AZT use during pregnancy and the use of trimethoprim/sulfamethoxazole (Septra/Bactrim) for prophylaxis of PCP infection in infants born to HIV positive mothers. This has also resulted in a re-hash of issues around universal testing, partner notification and name reporting. The concern is that the Ackerman bill, if it comes to a vote, may precipitate House floor discussions that quickly turn to the larger concerns around mandatory universal testing with name reporting.

   We continue to believe that testing should remain voluntary. (Pros and cons of mandatory testing are attached)

Strategy

The CDC/PHS consultation process will happen within the next 5 weeks. It will consist of two pathways--one looking at monitoring the HIV epidemic (both the mechanics of the survey, need, recommended changes to meet the stated mandates); and a second pathway looking at issues of implementation across PHS agencies, states, and the private sector. The CDC will take the lead on the issues surrounding surveillance, and the office of HIV/AIDS Policy will take the lead on implementation. We will then analyze the recommendations from the consultant meetings and design a joint strategy for immediate implementation. We are confident we will be ready to complete this process and initiate a comprehensive Federal approach by the beginning of the next fiscal year (October '95).

Attachments

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

HIV/AIDS PREVENTION

Background information on...

The HIV Survey in Childbearing Women

The HIV Survey in Childbearing Women is an ongoing, national effort begun in 1988. CDC conducts the survey to track HIV infection in women, to provide information for planning health care resource needs, and to better target services and care to two groups increasingly affected by AIDS-women and children. In fiscal year 1994, the survey cost approximately $10.5 million.

How are the findings used?

This survey provides the most accurate picture of the prevalence of HIV infection among women delivering infants nationwide, and allows CDC to estimate the prevalence of HIV infection in the much larger population of all American women. Because infection in the mother indicates HIV exposure to the infant, the survey is also a basis from which to estimate the number of children born with HIV each year. This information is critical for planning, delivering, and evaluating public health programs designed to prevent HIV infection in all women and in children.

What are the findings?

In 1993 (the most recent year for which complete data are available), an estimated 7,000 HIV-infected women gave birth in the United States, or about 1 in every 625 women giving birth. HIV can be passed from mother to child during pregnancy, labor, and delivery ("perinatal transmission") and by breastfeeding. Although all infants born to infected women initially show a positive HIV antibody test, not all are truly infected. The mother-to-child transmission rate is 15%-30%, which translates to about 1,000-2,000 HIV-infected infants born in America in 1993.

What does an HIV-positive test result mean?

A positive HIV antibody test result reflects infection in the mother, *but not necessarily the infant*, because maternal antibodies to HIV are passed to the baby even when the virus is not. Infants' HIV status must be determined through careful follow up, which includes using specialized diagnostic tests and monitoring for clinical signs and symptoms of HIV infection.

Why are the personal identifiers removed (why is the study blinded)?

Blinded testing is the most accurate way to track HIV prevalence in childbearing women across the country. The survey's public health goal is to elicit much-needed information about *all* American women delivering babies and their infants, not to pinpoint specific cases of HIV infection. It is not a diagnostic tool for individual women or infants. CDC has issued draft guidelines for health care providers to address individual pregnant women's needs.

Would unblinding the survey prevent infants from being infected?

No. The best way to prevent HIV infection in infants is to prevent HIV infection in women. To reduce perinatal HIV transmission, women must be offered HIV counseling and voluntary testing before or early during pregnancy. If a woman is infected with HIV, she should consult with her health care provider and weigh the risks and benefits of taking AZT as early as the 14th week of pregnancy, and certainly ***well before*** the birth of her child. Knowing about HIV infection during pregnancy allows the woman and her health care providers to plan better and to coordinate with pediatric care for the infant.

Identifying infants by name in the current metabolic screening program (unblinding the survey) would be the same as mandatory testing of women, which CDC does not support. It would not accomplish public health or medical goals, and it would not be in accordance with the CDC draft guidelines.

Where is the survey conducted?

CDC is conducting the survey in collaboration with the health departments of 45 states, the District of Columbia, Puerto Rico, and the Virgin Islands. The five states not conducting the survey are Idaho, Nebraska, North Dakota, South Dakota, and Vermont.

How are the data collected?

The survey uses leftover blood from routine newborn metabolic screening. After all personal identifying information is permanently separated from the blood, it is tested for HIV antibody. Limited demographic data, including the month and county of birth, are abstracted from the metabolic screening form, and in some states, the mother's age group and race/ethnicity are also collected. State health departments compile the survey results and periodically transfer the data to CDC.

How is HIV antibody testing performed?

Laboratory testing for the survey is conducted in state public health laboratories using standard enzyme immunoassay (EIA) and Western blot methods specially adapted to dried blood specimens collected on filter paper. All laboratories participate in a special CDC quality assurance program.

How are the data from the survey reported?

State health departments periodically report results from the survey in health department newsletters or press releases. CDC recently published a summary of survey data in the *National HIV Serosurveillance Summary, Results through 1992* (single copies available from the CDC National AIDS Clearinghouse, 1-800-458-5231).

What do CDC's draft guidelines for pregnant women call for?

CDC's draft guidelines call upon medical professionals to counsel all pregnant women about HIV and to offer voluntary testing. The draft guidelines were developed to help women learn before or during pregnancy if they are infected, enabling them to seek and receive the care they need for themselves and for reducing the chances of transmitting HIV to their infants. A notice of the public comment period for the draft guidelines appears in the February 23, 1995, *Federal Register.*

Studies show that when her health care provider talks with a pregnant woman about the test and what it means for her and her baby, most women choose to be tested and then be treated as their doctor recommends. For example, in an inner-city hospital in Atlanta, Georgia, 96% of women chose to be tested after being provided HIV counseling and offered HIV testing as part of prenatal care.

What does the Public Health Service recommend regarding use of AZT in pregnancy?

Based on the findings of ACTG 076, the Public Health Service published recommendations in the *MMWR* (Vol. 43, No. RR-11, August 5, 1994). They are designed to provide a basis for discussion between an HIV-infected pregnant woman and her health care provider about the use of AZT to reduce perinatal HIV transmission. The document provides recommendations regarding the use of AZT to reduce the risk of perinatal HIV transmission for women whose clinical situation meets the entry criteria for ACTG Protocol 076 as well as for HIV-infected pregnant women with differing clinical situations.

HIV-infected women should be informed of the substantial benefit and short-term safety of AZT administered during pregnancy and the neonatal period observed in the ACTG Protocol 076. However, they must also be informed that the long-term risks of AZT therapy to themselves and their children are unknown. A woman's decision to use AZT to reduce the risk of HIV transmission to her infant should be based on a balance of the benefits and potential risks of the regimen to herself and her child.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

MAY 11 1995

Sent to All State Health Officers

Lawrence H. Miike, MD, JD
Director of Health
Hawaii Department of Health
P.O. Box 3378
Honolulu, Hawaii 96801

Dear ~~Dr. Miike~~:

Issuance of the proposed PHS Recommendations for HIV counseling and voluntary testing of pregnant women and their infants, and provision of preventative therapy is a high public health priority. These efforts, coupled with forthcoming recommendations for prevention and treatment of opportunistic infections in infants, add new urgency to encouraging all pregnant women to learn their HIV status and access appropriate care for themselves and preventive efforts for their newborns.

In light of these new prevention and treatment opportunities, I am requesting that you suspend the Survey of Childbearing Women until we have completed a consultative process with the States, CDC Advisory Committee of Prevention of HIV Infection and interested parties. It is my hope that we can work together to develop a strategy that takes full advantage of the opportunities to prevent HIV transmission and slow the course of disease progression in these populations as outlined in PHS Recommendations for HIV Counseling and Testing for Pregnant Women.

Within the next few weeks, the Director of the Centers for Disease Control and Prevention will begin a process, assisted by external expert consultants, to consider the advisability and feasibility of developing appropriate surveillance mechanisms in the context of implementing prenatal counseling and testing recommendations and advise CDC and the Public Health Service on a plan to :(1) ensure that all pregnant women are offered HIV counseling and testing and that they and their child are entered into a continuum of medical and support services; (2) fully evaluate the implementation and effectiveness of the guidelines; (3) continue to monitor trends in HIV infection in women; and (4) assess the advisability and feasibility of developing appropriate surveillance mechanics for these purposes. Participation in this process by public health officials, private providers, medical and ethical experts, providers caring for women and children with HIV disease, and communities affected by HIV would be most helpful to ensuring widespread implementation of the Committee's findings and recommendations.

I am confident that this consultative process can provide a strong foundation for determining how best to achieve these goals. It is my expectation that we will continue to meet the important goals held by CDC and State health departments of preventing the spread of the HIV epidemic and monitoring its movement in the country.

Sincerely,

Philip R. Lee, M.D.
Assistant Secretary for Health

Mandatory Testing of Pregnant Women

Pros

- Learning one's HIV status allows people the opportunity to seek early medical interventions and the opportunity to provide referrals to social, legal and psychological services. It also provides and opportunity for personal risk assessment, and education about HIV.

- Recent research has shown that Zidovudine (ZDV) treatment, when administered to HIV-infected women during pregnancy and to their newborns, significantly reduces the rate of perinatal HIV transmission. Knowledge of one's HIV status offers the opportunity to offer ZDV treatment during pregnancy.

- Knowledge of a mother's HIV status would prevent possible HIV transmission through breast feeding.

- Knowledge of a mother's HIV status would allow prophylactic measures to be taken to prevent the onset of opportuinstic infections such as *Pneumocystis carinii* pneumonia (PCP) in infants.

Cons

- Mandatory testing of newborns and pregnant women would undermine the establishment of a trusting relationship between each mother and the health care system. This partnership, so critical to the proper care of both infant and mother, is far less likely to occur if it begins with a peremptory or imposing act.

- The most important factor in a baby's care is her mother. Building a relationship through counseling and consent enables health care providers to keep the baby connected to the health care system.

- Compliance with medical care is likely to be greatest when the patient feels she has made an informed judgement regarding HIV testing for herself or her infant.

- The best way to insure care for mothers and infants is to provide comprehensive, supportive health care services, including counseling about HIV and voluntary HIV testing.

- The overwhelming majority of women offered the opportunity to be tested voluntarily will do so if they are assured that their confidentiality will be protected and that care and services will be provided for the babies and themselves.

  - Of over 3,500 women registered for prenatal care at Grady Memorial Hospital in Atlanta, GA, 96 percent chose to be tested after being provided HIV counseling and offered voluntary testing (Lindsey, 1989).

- At the Harlem Hospital in New York City, 95 percent of women at the high-risk pregnancy center voluntarily consented to HIV testing after counseling was offered by hospital health care providers (personal communication).

- There is real concern that mandatory testing for HIV will discourage pregnant women form seeking care. Mandatory testing has been shown to drive people away from the health care system. This would result in a double tragedy -adversely affecting infants of mothers who don't have HIV, and denying the opportunity for HIV prevention to infants of HIV positive mothers.

- The majority of HIV-infected women are from low-income communities of color, and many of them have substance abuse histories. These factors, combined with the very real problems of discrimination, domestic violence, fear of losing their children, create barriers to accessing care that will only be exacerbated by mandatory testing programs.

- Allocating funds for mandatory testing is a poor use of resources. Mandatory testing is expensive and ineffective because it causes many people to avoid the system, thereby increasing costs down the road.

- Resources should be put in providing prenatal care which includes counseling about HIV and offers voluntary testing.

METRO MATTERS

Joyce Purnick

N.Y. Times; 5-18-95

When AIDS Testing Collides With Confidentiality

IN an announcement that stunned Washington, the Clinton Administration last week suspended a seven-year program to test newborns anonymously for the AIDS virus. The move, which thwarted legislation to open the test results to mothers, was made by top Administration officials in Washington despite some disagreement at the Centers for Disease Control and Prevention in Atlanta and it even surprised those who support it.

Somehow, skeptics saw the never-subtle signs of politics at work, especially since the testing program had been at the center of a furious battle between those who favor telling mothers the test results so that infants can be treated and those who argue that mandatory testing would stigmatize women and scare many away from health care.

Donna E. Shalala, Secretary of Health and Human Services, says the decision was not political at all. "There really are profound ethical questions involved," she said in a telephone interview this week. "Sometimes you do something for one purpose and it has unintended consequences."

In this case, the Government found itself in possession of sensitive information about thousands of Americans. It knew that 7,000 of the 2.5 million babies tested every year showed evidence of infection by H.I.V., the virus that causes AIDS, in their blood. But their mothers did not know because the tests were "blind." Some critics even drew parallels to the infamous Tuskegee experiments, in which the United States Public Health Service denied treatment for syphilis to more than 400 black men, to study the effects of the disease.

"WE thought there was a serious question about collecting information about which we didn't inform parents," said Ms. Shalala. There would seem to be a simple solution: inform the parents, as Representative Gary Ackerman of Queens proposed in the bill he now has to rewrite, as is already done routinely for a number of diseases, ranging from syphilis to sickle cell anemia.

Nothing involving AIDS is that simple, however. Approximately 75 percent of the infants who test positive do not have the virus that causes AIDS; they temporarily carry their mother's antibodies. But *every mother* whose baby tests positive is infected with the virus. Which means that testing the baby is really testing the mother, and this is where politics and policy intersect.

"That's the horror of the way we treat AIDS in this country," said Assemblywoman Nettie Mayersohn of Queens, who has been pushing a mandatory testing and notification bill for New York State for three years. "You can't tamper with confidentiality laws because there is such strong opposition from AIDS activists." The testing in New York, part of the Federal program, will continue with state funds for now, so her bill is still viable. But while it has support from Gov. George E. Pataki and the State Senate, and the Assemblywoman says it has enough votes to pass in the Assembly, it is still bottled up in committee. Only the Speaker, Sheldon Silver, can free it. And Mr. Silver, subject to the same lobbying pressures so strong in Washington, isn't talking.

> There would seem to be a simple solution: inform the parents. But nothing involving AIDS is simple.

OPPONENTS to mandatory testing and notification include some of the most powerful lobbies in the country — advocates for people with AIDS, gay groups, civil libertarians and women and abortion rights proponents. They contend that mandatory testing programs would violate a woman's right to confidentiality, and would discourage many from seeking medical care. Most instead favor mandatory counseling for pregnant women, aimed at persuading them to take a voluntary AIDS test. "This population is so frightened you may scare people away," said Ms. Shalala.

So far, though, counseling has only rarely proven effective, and the evidence that mandatory testing drives women away from health care is ambiguous. Medical professionals are on both sides of that question, but all seem to agree on one point: that prenatal care is crucial because new studies suggest that taking the drug AZT during pregnancy and in delivery can sharply reduce the transmission of H.I.V. from a mother to her baby.

But what about the women who do not seek prenatal care?

In those cases, doctors can prolong the lives of infants born with the virus — if they know the child is infected. Moreover, the many infants who test positive but are not infected can still contract the virus from their mother's milk. If a mother knows in time that she has the virus, she can avoid breast-feeding.

Ms. Shalala, glossing over some of the finer points of the debate, says her objective is to see to it that all pregnant women in the country get prenatal care and testing, and every bit of information available about their babies. "Why would we withhold information from a mother?" the Secretary asks. "We should tell them." But, under the policy now in effect, only if they want to know.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

May 26, 1995

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY

FROM: Donna E. Shalala

Patricia S. Fleming, National AIDS Policy Director

SUBJECT: HIV TESTING OF PREGNANT WOMEN AND NEWBORN INFANTS

Background

Recent scientific advances in the treatment of infants with HIV infection and in the prevention of perinatal transmission of HIV resulting from the AIDS Clinical Trials Group 076 (ACTG 076) have raised a series of public policy issues. Legislation by Rep. Gary Ackerman (D-NY) to "unblind" an HIV survey of childbearing women has also increased the political tension around these issues. The central policy questions raised by this science are:

- Should a blinded epidemiological survey of HIV in childbearing women be continued, discontinued, or "unblinded"?

- Should the Federal government impose mandatory testing on pregnant women or newborns?

In the last 15 months, the Department of Health and Human Services has responded aggressively to the scientific advances represented by ACTG 076 by issuing additional recommendations regarding HIV testing and treatment of pregnant women and newborn infants. It has also recently suspended the ongoing survey of childbearing women. With the survey suspended, HHS will shortly begin a consultative process with states, affected groups, medical professionals, and ethicists to deal with these issues.

I ACTG 076 Results

In February 1994, researchers funded by the National Institutes of Health (NIH) reported the results of ACTG 076, which found that the use of AZT by an asymptomatic HIV-positive woman during pregnancy, labor, and childbirth and by the newborn for six weeks following birth can reduce the risk of perinatal HIV transmission by as much as 67% (from an average of 25% to 8%). This is the first time we have been able to block transmission of HIV with a drug.

II Testing and Treatment of Pregnant Women

Pre-ACTG 076: As early as December 1985, guidelines issued by the Centers for Disease Control and Prevention (CDC) recommended that at-risk pregnant women and their partners should be counseled about HIV and offered a test. In 1987, CDC advised that at-risk women of child-bearing age should be counseled and voluntarily tested in order to discourage those who are HIV-infected from becoming pregnant.

Post-ACTG 076: Following the release of ACTG 076, CDC consulted with outside experts and developed a new set of guidelines for all pregnant women. The new guidelines recommend that doctors counsel pregnant women to accept voluntary HIV testing. Doctors should offer pregnant women who are HIV-positive treatment with AZT to lower the risk of transmission to their babies. The guidelines also recommend that women who have not received prenatal care or do not know their HIV-status at delivery, should be counseled and offered voluntary testing for themselves and their newborns before leaving the hospital. These draft guidelines, which drew strong support from medical, public health, and ethics groups, will be issued in final form in June.

III Testing and Treatment of Newborns

Since all babies carry their mothers' antibodies at birth, a test of a newborn simply reflects the mother's HIV-status -- not the newborn's own HIV-status. However, recent advances make it possible to effectively treat such babies to prevent certain AIDS-related conditions.

Until recently, CDC recommended that only those HIV-positive newborns with suppressed immune systems be treated with antibiotics to prevent Pneumocystis carinii pneumonia (PCP), a nearly always fatal opportunistic infection for babies with AIDS. In April 1995, CDC greatly expanded those guidelines to recommend treating all babies born to HIV-positive women with antibiotics beginning at 4-to-6 weeks for perinatally-exposed infants and continuing treatment through 12 months for HIV-infected infants.

It is critical to note that neither mandatory testing of newborns nor the unblinding of the CDC survey would prevent even one case of perinatal transmission of HIV, since to block transmission AZT must be administered during pregnancy and childbirth. Focusing on testing newborns would be too little, too late to save infants from HIV and AIDS.

IV CDC Survey of HIV in Childbearing Women

Beginning in 1988, during the Reagan Administration, CDC, in cooperation with state and territorial health departments in 45 states, DC, Puerto Rico, and the Virgin Islands, conducted an epidemiological survey of childbearing women in the U.S. to determine the prevalence of HIV infection in that population. The current cost of the survey is $10.5 million a year.

The survey uses leftover blood taken from approximately 45% of newborns during routine "heel stick" tests for genetic conditions. About 2.5 million babies are tested each year out of a total of 4.5 million babies born in the U.S. No additional blood is taken for this survey. To obtain the most accurate and unbiased scientific data and to conform with scientific and ethical review requirements and informed consent statutes, the results are "blinded," thus the women cannot be informed of the results. In fact, all identifiers are separated from the sample before an HIV test is run.

The CDC survey has been approved by numerous ethical review boards. Anonymous, unlinked testing has been accepted as a standard for monitoring the HIV epidemic by the World Health Organization. It would not be feasible to "unblind" this survey without first obtaining informed, written consent from the mothers. Such a change would fundamentally alter the survey, changing it from a surveillance tool to a testing program. Since some women would refuse testing because of their concern about a record of their infection, such an approach would skew the results and render the survey epidemiologically much less useful for monitoring the epidemic.

The survey has provided useful data on the prevalence of HIV among childbearing women and among women in general. CDC has found that an estimated 7,000 HIV-positive women give birth in the U.S. each year and that an estimated 2,000 of those babies remain HIV-positive themselves. The survey has been used to plan research, prevention, and care programs at the state, local, and federal levels.

However, the results of ACTG 076 and the resulting importance of testing women before or early in pregnancy, as well as the new guidelines for treatment of infants with PCP prophylaxis, dictated that this survey be reexamined. Thus, on May 11, with the concurrence of Secretary Shalala, Dr. Phil Lee, Assistant Secretary for Health, asked State Health Directors to suspend testing under the Survey of Childbearing Women and to join the PHS in a consultative process on the best way to proceed on monitoring the epidemic in women and infants, preventing perinatal transmission, and assuring care for HIV-positive pregnant women and newborns.

CDC and PHS officials currently are finalizing plans for a consultative process that will include Federal, state, and local health officials, medical and public health experts, medical ethicists, and members of affected populations. The process will focus on four issues: Counseling and testing of pregnant women; testing of newborns; treatment of HIV-infected women and infants; and monitoring of HIV in women and children. This process should be underway by July 1.

V The Ackerman Bill

The CDC survey has spurred a great deal of public debate, primarily around legislation by Rep. Gary Ackerman (D-NY) that would require states that conduct HIV testing of newborns to notify the mother or legal guardian of the test results.

The Ackerman bill was first introduced in 1994, shortly after the release of the ACTG 076 findings, but saw no action that year. Congressman Ackerman has reintroduced the bill (H.R.1289), and now has 220 cosponsors (including 160 Democrats) ranging across the political spectrum. Mr. Ackerman has been very successful in gaining support for his bill, in part, due to the fact that he began his efforts before the CDC guidelines on counseling and testing were issued. Therefore, members of Congress who were not comfortable with his approach had nothing to be "for." Many members were approached on the floor before they had a chance to study the bill or consult their staff.

Mr. Ackerman has some misunderstandings about his legislation. While he says it would "save babies," the reality is the testing of newborns comes too late to prevent HIV transmission. It would, however, allow for PCP prophylaxis and warn HIV-infected women not to breast feed.

In reality, the Ackerman bill is a *de facto* proposal for mandatory testing of childbearing women. If it were to become law, the CDC surveillance study would be out of compliance with state statutes regarding informed consent. And it still would not prevent a single case of perinatal transmission of HIV.

Mr. Ackerman has modeled his bill on one by New York State Assemblywoman Nettie Mayersohn. Following a heated debate in 1994, New York agreed to establish guidelines for routine counseling and voluntary testing of pregnant women, much like those recently issued by CDC. Early results show a promising rise in the number of women being tested.

VI Mandatory v Voluntary HIV Testing

Throughout the AIDS epidemic, public health officials have pursued a policy of routine counseling and voluntary testing for HIV. The Federal government and the states have made a small number of exceptions to that policy (military recruits and active duty personnel, some Federal prisoners, Job Corps applicants, immigrants, and blood donors). In all other cases, our goal is to pull people toward testing, not to drive them away from it.

A voluntary approach is critical for HIV-positive pregnant women. The treatment required to prevent HIV transmission requires the woman to take AZT during pregnancy and childbirth, and to administer the drug orally to her child three times a day for six weeks after birth. To ensure success, we need maximum cooperation from the mother.

Evidence suggests that mandatory testing would severely damage the likelihood of cooperation by the mother. Indeed, there is strong evidence that routine counseling and voluntary HIV testing of pregnant women can be highly successful. For example, Atlanta's Grady Memorial Hospital has a 96 percent success rate in getting pregnant women to volunteer for an HIV test. Similar results have been reported at public hospitals in Miami, Los Angeles, and New York. Among the women who have tested HIV-positive, a very high percentage agree to AZT treatment.

Conversely, there are several examples where the use of mandatory testing has had negative effects. They include:

- Efforts to impose mandatory drug testing are reported to have resulted in a sharp decline in the number of people seeking care. For women, the reason most frequently cited was a fear that they would lose custody of their children.

- In 1989, Illinois imposed mandatory HIV testing for marriage license applicants and saw a sharp increase in the number of couples crossing state lines to be married. The state repealed the law in 1991.

The use of routine counseling and voluntary testing has been supported by all of the major professional organizations in the country, including the American Academy of Pediatrics, American College of Obstetrics and Gynecology, the American Nurses Association, the Association of State and Territorial Health Officers, the American Public Health Association, and the Pediatric AIDS Foundation.

VII Additional Actions

In addition to the steps described above, HHS has taken other actions to respond to the results of ACTG 076. They include the following.

- The Food and Drug Administration has changed its labeling instructions for AZT to allow its use in pregnant women and newborns.

- The Health Care Financing Administration has instructed states to include perinatal use of AZT in their Medicaid drug formularies.

- NIH is funding research to follow the women and infants involved in ACTG 076 to determine the long-term effects of AZT treatment during pregnancy and childbirth.

- The Agency for Health Care Policy and Research is developing materials for consumers explaining perinatal transmission and AZT's role in reducing transmission.

VIII Conclusion

HHS's approach of counseling and voluntary testing for all pregnant women is a sound public health approach to preventing perinatal transmission of HIV. It has been demonstrated to be effective in getting women tested and to ensure that they cooperate with the full course of treatment for themselves and their newborns. We believe some thoughtful questions have been raised about continuing the CDC Survey of Childbearing Women. The upcoming consultation should produce several viable alternatives to the suspended survey that will allow us to continue vital surveillance of the epidemic and direct Federal resources where they will do the most good.

THE WASHINGTON POST
FRIDAY, JULY 7, 1995

THE PRESIDENT HAS SEEN
7/8/95

AIDS Virus Test Urged for All Pregnancies

By John Schwartz
Washington Post Staff Writer

All pregnant women should be offered a test to see if they are infected with the virus that causes AIDS, the federal Public Health Service recommends in new guidelines published today.

The guidelines, released by the Centers for Disease Control and Prevention (CDC), call for routine prenatal counseling about the human immunodeficiency virus (HIV) and voluntary testing for the 4 million American women who become pregnant each year.

The Public Health Service developed the guidelines after recent studies showed that treatment of HIV-infected pregnant women with the drug AZT sharply reduced the transmission of the virus to their babies—a finding that CDC Director David Satcher called "an unprecedented breakthrough in HIV prevention" in a statement yesterday. The findings were published late last year in the New England Journal of Medicine.

"We believe this should really be the standard of care for pregnant women in the United States," said James Curran, director of HIV/AIDS prevention for the CDC. "This should be a routine part of prenatal care."

The CDC is encouraging insurers and the federal Medicaid program to cover the cost of the tests.

The new recommendations mark a shift in policy for the Public Health Service, which had previously recommended testing for women at high risk of infection, such as intravenous drug users and prostitutes.

Last year's study found that HIV-infected pregnant women who take AZT (also known as zidovudine) can reduce the chances of transmitting the virus to their babies by approximately two-thirds, from about 25 percent to about 8 percent. For best results, the therapy should begin by the 14th week of pregnancy and continue through labor and delivery; the drug should also be administered to the infant for the first six weeks of life.

The CDC estimates that as many as 2,000 HIV-infected babies are born

See HIV, A8, Col. 1

CC:
Jennifer
Klein

HIV, From A1

each year in the United States, and that 7,000 HIV-infected American women give birth each year.

Through December 1994, the CDC had reported 58,428 cases of AIDS among adult and adolescent women, and the numbers are rising faster among women than men. Women made up only 7 percent of all AIDS cases in 1985 but accounted for 18 percent of all cases by 1994. AIDS is the fourth-leading cause of death among women between the ages of 25 and 44.

According to CDC figures, African American and Hispanic women account for 75 percent of all AIDS cases reported among American women, although they make up only 21 percent of the population of American women.

The guidelines also suggest that women who do not receive prenatal care should be offered HIV testing for themselves or their babies after birth. The long-term effects of AZT therapy on mothers and children are not yet known; the CDC said it is continuing to monitor patients for long-term side effects, but stressed that "a woman should make a personal decision about taking AZT only after she discusses the benefits and potential risks for herself and her child with her health care provider."

The CDC announcement comes at a time when a multimillion-dollar government program that provides testing and treatment for poor HIV-infected people is up for renewal in Congress. Reauthorization of the Ryan White Care Act of 1990, a five-year program funding AIDS treatment, is working its way through the legislative process. A coalition that includes some AIDS organizations and religious groups is pushing to have the legislation include mandatory HIV testing of all newborn babies. Without reauthorization, the program will be abolished in September.

"There is massive bipartisan support for reauthorizing Ryan White," said Mike Collins, spokesman for the House Commerce Committee, which is currently considering the bill.

For several years, the CDC has tested a national sample of newborn infants for HIV. A positive test measures antibodies to the virus in a baby's blood and is evidence that the mother is infected—but not necessarily the baby. The testing was conducted solely to track the progress of the disease within the population and was performed anonymously. In May, the Department of Health and Human Services announced that it would discontinue the blind testing program.

The new recommendations call for women's test results to be kept confidential unless state law prohibits it. Studies have shown that most women who have received HIV counseling choose to be tested for the disease; in one inner-city Atlanta hospital, 96 percent of pregnant women who received counseling asked to be tested.

A prominent AIDS activist said that the new proposals don't go far enough. Shepherd Smith, president of Americans for a Sound AIDS/HIV Policy, said that the CDC "got it backwards" and argued that testing should be mandatory.

The recommendations are being published in today's Morbidity and Mortality Weekly Report. Such recommendations are generally influential in setting the standard for medical practice in the United States.

Chris
This looks good—
BC

DRAFT

7/21/95

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.

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

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
C D C Contact: Melissa Sheppard (404) 639-0956	Consumer Advocacy Groups and Providers	C&T Guidelines for Pregnant Women	Distribution to Providers and Consumers	**Published July 7**
	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 ACTG 076

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
C D C	Health Care Professionals	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	Completed March 1995
	Community Planning Groups	Fact sheet for community planning group co-chairs/CBOs	Epidemiology, risk-behaviors, treatment, prevention info	Completed

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

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

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

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
A H C P R	Consumer	Consumer Guide on ZDV Therapy - development of product	Draft pilot tested in 400 women by Columbia U. As result of pilot, brochure shortened and recirculated for additional review and comment.	September 1995
	Consumer	4 Targeted Pieces	In revision -shorten	September 1995
	Consumer	Consumer Guide on ZDV Therapy	Final Product Distribution	September 1995
(with other PHS Agencies)	Consumer	Video Tapes 10 minutes each	3 of 5 shot	September 1995
	Consumer	PSAs	in progress	September 1995
	Consumer	Audio Tapes	in progress	September 1995

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

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
Contact: Peter Garrett (301) 594-1364 x 173	Consumer/Provider	Distribution Plan	Developing Plan	September 1995

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

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

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

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
H R S A	Providers	Letter to Grantees on results of 076	Completed	June 1994
	Providers	Letter to grantees to offer C&T and offer ACTG 076	Completed	January 1995
	Providers	Program Advisory on ZDV therapy in HRSA programs	Draft released for public comment.	Comments due to HRSA by 8/10
	Providers	Technical Assistance to States and Title I EMSs	Develop. implementation strategies	Ongoing
Contact: Russell Gerber, MD (301) 443-4588	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 ACTG 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 **Contact: Russell Gerber, MD (301) 443-4588**	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	Completed	June 1995
	Grantees (BHRD)	Annul Meeting RWCA Title I and Title II - Plenary and Workshops on 076	Completed	June 1995

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

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
H R S A **Contact: Russell Gerber, MD (301) 443-4588**	Grantees (BHRD)	SPNS Project for Comprehensive Care Services for Women including ACTG 076	Funded	June 1995
	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
	Grantees (BPHC)	Publish Newsletter notifying grantees about 076	Under development	June 1995
	Grantees (MCHB)	WIN-Women's Initiative for HIV Care and Reduction of Perinatal HIV transmission		Funded June, 1995

HHS ACTIVITIES ON COUNSELING AND TESTING OF HIV+ PREGNANT WOMEN AND IMPLEMENTATION OF ACTG 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 Tx recommendation - ACOG input on recs.	Offering Treatment to all HIV+ preg. women	

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

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
N I H Contact: Robert Eisinger, Ph.D. (301) 402-8655 (with other PHS Agencies)	Providers Consumers	Treatment Guidelines	Done	August 1994
	Providers	Publication ACTG 076 results	Done	November 1994
	Providers Consumers	Technical Assist. to medical orgs. and consumer grps.	Ongoing e.g. AAP-3/95 Soc. Clin Trials-8/95	
	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 ACTG 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 ACTG 076

AGENCY	AUDIENCE	MEDIUM/ PRODUCT	CURRENT ACTIVITY	DUE DATE
S A M H S A Contact: Barbara Garcia (301) 443-5305	Providers	Letter to Grantees	Recommendations being developed to ensure referral for counseling and testing for pregnant women	August 1995
	Pregnant/ Postpartum Women	Residential Substance Abuse Treatment Prog.	Ongoing	
	Providers	Implementation Plans	Internal meetings to discuss implementation plans	Ongoing